

Evaluation of a Community-wide Diabetes Prevention Program

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Dedication

To my parents Joaquin Cardona and Luz Salazar de Cardona, who taught me the meaning and benefits of hard work by being constant role models.

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Abbreviations

AUSDRISK	Australian Diabetes Screening Risk Tool
BMI	Body Mass Index
CALD	Culturally and Linguistically Diverse
CBG	Capillary blood glucose (random test)
CI	Confidence interval
DE-PLAN	Diabetes in Europe – Prevention using Lifestyle, Physical Activity and Nutritional interventions
FDPS	Finnish Diabetes Prevention Study
FPG	Fasting plasma glucose
GP	General Practitioner (medical)
HbA1c	Glycated Haemoglobin
IFG	Impaired Fasting Glucose
IGT	Impaired Glucose Tolerance (on the 2-hour OGTT)
IQR	Interquartile range (25% - 75%)
IC	Initial consultation (individual first assessment & coaching)
IS	Individual session (telephone coaching intervention)
LO	Lifestyle Officer

OGTT	Oral glucose tolerance test (2-hour)
RCT	Randomised controlled trial
SD	Standard deviation
SDPP	Sydney Diabetes Prevention Program (focus of this thesis)
USDPP	The U.S. Diabetes Prevention Program
WC	Waist circumference
WHO	World Health Organization

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Author's contribution

As is the nature of collaborative research projects, many investigators and project staff have worked on the study analysed in this thesis. My role in the program was primarily the design of data collection systems, assurance of data integrity, analysis of data and reporting of results.

Below are my specific contributions to each aspect of this evaluation:

Data collection tools and systems

I designed and developed the computer assisted telephone interview (CATI) system for the baseline and 12-month interviews as an Access database to facilitate data entry and enable quality control checks. I trained the CATI interviewers at administering the survey in a standard way and using the database, and undertook ongoing data quality checks. I participated in the design of the equivalent database for the Arabic and Chinese-speaking participants, by guiding the database developers on data specifications, data dictionary and database functionality requirements.

The online lifestyle officers' database containing the clinical, demographic and process information was produced by an external contractor firm. I was instrumental in the design, testing and rollout of the database, guiding the developers on data requirements, variable specifications, data dictionary and functionality. I conducted ongoing data quality control activities and followed-up corrections with database developers and data cleaning activities with data entry staff.

The nutrition information was entered in and exported from the 3-day food record database (*FoodWorks* software). I designed the spreadsheets for the summaries of these extractions.

Background and systematic review

I conceptualised the systematic review scope and questions. I designed the bias assessment tool as an SPSS database and also designed the quality assessment score for use in the critical

analysis of papers reviewed, based on existing critical appraisal tools for other study types. I trained the other colleagues conducting data extraction at using the database codes in a standard way.

I conducted the bias and quality assessment of all studies and three other reviewers independently conducted the second bias and quality assessment of some studies each. Two reviewers including me independently extracted results and assessed the statistical analyses and conclusions. I wrote the research report for the literature search on community-based replications (Chapters 2), wrote the manuscript for the published systematic review (Chapter 3) and incorporated comments from co-authors. I also wrote all searched and summarised literature for all chapters in this thesis.

Impact evaluation design

I produced the study protocol for the process (Chapter 6) and impact evaluation (Chapters 7 and 8) including items to be collected, timelines and responsibilities for different components. Other investigators provided input and other project staff collected the data. I designed the forms for data collection at the 3, 6 and 9-month follow-up and the guide for the focus group discussions with input from the investigators. I wrote the first draft and commented on subsequent versions of the published protocol paper (Chapter 4).

Data analysis and interpretation

I conducted the analysis of data from the systematic review, baseline results (Chapter 5), quantitative aspects of the process evaluation (Chapter 6) and all aspects of the short-term (3 months) and intermediate (12 months) impact evaluation (Chapters 7 & 8). I wrote the research reports and Chapters for all the above.

Economic appraisal design and analysis

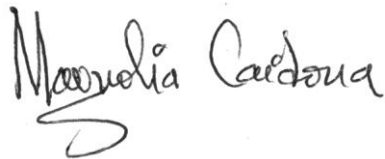
I designed the data collection form and prepared the associated instructions for data collectors on items for documentation of direct program expenses for Divisions. I wrote the protocol and analysis plan for the economic appraisal (Chapter 9), collated, analysed and interpreted the economic data under the guidance of my associate supervisor, Professor Marion Haas.

Statement of authentication

This thesis is submitted to the University of Sydney in fulfilment of the requirement for the degree of Doctor of Philosophy.

The work presented in this thesis is, to the best of my knowledge and belief, original except as acknowledged in the text. I hereby declare that I have not submitted this material, either in full or in part, for a degree at this or any other institution.

Signature:

A handwritten signature in black ink that reads "Magdalena Cardona". The signature is written in a cursive style with a large, sweeping flourish at the end of the name.

Date: 30 August 2011

Abstract

This thesis is an evaluation of the effectiveness of a community-wide diabetes prevention program conducted in three Divisions of General Practice in Sydney, Australia. The aims were to assess whether translation of diabetes prevention programs was feasible in real-life settings and whether results achieved were comparable with those of randomised trials on which this intervention was based. Its primary goals were to assess whether the lifestyle intervention could increase participation in moderate-to-vigorous physical activity to 210 minutes per week, reduce total fat and saturated fat consumption to 30% and 10% of total daily energy intake, increase fibre consumption to 15 g/1,000 kcal/day, and lead to 5% weight loss over one year.

The background section covers the pathophysiology of type 2 diabetes, its risk factors, and the available population screening tools to identify people at risk. The growing morbidity and mortality burden, the economic implications of this public health problem, and the importance and feasibility of preventing or delaying the onset by intervening in the precursor stages are then summarised.

Evidence for preventability is examined through a literature review of lifestyle interventions in research settings comprising highly structured and closely monitored physical activity and dietary programs under controlled conditions. Examples of the effectiveness of translation of randomised controlled trials (RCTs) into less stringent programs in community settings such as workplaces, churches, indigenous communities and whole-of-country initiatives are presented. A systematic review and meta-analysis of effectiveness of the lifestyle approaches in routine clinical practice supplements the evidence for application of prevention principles in real-life settings.

The main chapters of the thesis centre on process and impact evaluation of the semi-structured Sydney-based intervention, which recruited 1,250 participants from the mainstream Australian

public using general practitioner services in the study area, who were followed for 12 months. The intervention's goals aligned with those of the Finnish Diabetes Prevention Program but with less stringent entry criteria and less intensive intervention components delivered by purpose-trained lifestyle officers. The Program included an initial individual assessment and coaching session, three subsequent group sessions in the following three months, then three follow-up coaching calls at three, six and nine months. A final assessment at one year, using the same objective and self-reported measures as in the initial assessment, captured changes in body weight, physical activity and dietary habits.

The process evaluation showed that it is feasible and effective to use targeted screening to identify and recruit high-risk individuals into a free-of-charge program in the general practice setting, however a quarter of participants were lost to follow-up by one year. While minor variations in aspects of the Program were required to meet local need, Program fidelity in delivering components, and self-reported adherence to diet and physical activity was high.

Using a before-after study design, the impact evaluation measured 1-year changes in key Program parameters in relation to baseline. These comprised: measured weight, waist circumference, BMI, and glycaemia measurements; and self-reported dietary intake and structured physical activity, using a 3-day food record and the Physical Activity Scale for the Elderly (PASE) questionnaire, respectively. The main findings at 12 months for the 586 completers as at December 2010 were: a mean weight loss of 2.1 kg; waist circumference reduction of 2.5 cm; no significant change in glycaemia; 3% reduction of fat and saturated fat intake; 16% increase in fibre intake; and mean increase in moderate-to-vigorous physical activity of 13.7 minutes/week. All these changes were smaller than those achieved by the RCTs in research settings, most likely due to the lower intensity and monitoring of the Sydney intervention. Weight loss and waist circumference reductions were similar for participants in

group session and those who received telephone-only coaching. Diabetes incidence was 1% at the end of the first year.

An economic appraisal of the Program implementation completes the evaluation. A cost of A\$400 per kg lost among people achieving the weight goal was estimated on Program completion, but the cost was double for the overall group that included non weight losers. The cost of achieving the physical activity goal and the dietary goals was not feasible or sustainable with resources available in routine clinical settings. The costs per outcome were similar for participants not attending group sessions, who received only telephone coaching. Hence it is worth exploring this less labour-intensive modality if a general practice based Program were to be delivered as routine preventive care.

In sum, the evaluation of this community-wide diabetes prevention program showed that translation of diabetes prevention programs into routine practice, while feasible at less intensive levels than in RCTs, has a somewhat lower effect on diabetes risk reduction and it can still be a financial burden in clinical settings. However, given the potential for population-wide benefit, the effectiveness of alternative delivery modes, number and duration of program components and more targeted patient sub-groups should be investigated.

Chapter 1.

Type 2 Diabetes - Definition, Pathogenesis and Epidemiology

Summary

This chapter defines the clinical characteristics, pathogenesis, natural history, diagnostic criteria, precursors and complications of type 2 diabetes. Estimates of the burden of diabetes in Australia and internationally are summarised to highlight the magnitude of the public health problem.

The chapter also presents evidence of increasing incidence and prevalence of the disease and its precursor stages, and the implications of changing diagnostic thresholds to the overall diabetes epidemic worldwide.

The availability and usefulness of population-based screening tools in various countries is also discussed in setting the scene for the use of a nation-relevant screening tool in the Sydney Diabetes Prevention Program. Consideration is given to both the risk factors that make the condition preventable if detected early, and the indications for screening according to various guidelines.

Finally, the associated appendices show two instruments of interest which are used to detect people at high-risk for developing diabetes at the population level in Finland and Australia.

In sum, this chapter aims to answer the following research questions:

- What is the burden of type 2 diabetes and who is at most risk?
- Is there evidence that early detection is possible?

1.1 What Is Diabetes?

Diabetes mellitus is a metabolic disorder characterised by persistent hyperglycaemia (high blood glucose levels) which can have associated complications such as cardiovascular disease, blindness, renal failure, peripheral vascular insufficiency, peripheral neuropathy, infections and limb amputations.(1)

Diabetes can be asymptomatic (and thus, undiagnosed) for many years even in the presence of complications (2) or have an insidious variety of symptoms reflecting dysfunction of or permanent damage to digestive, circulatory, urinary, or nervous system organs in large proportions of people at the time of diagnosis. (3-6) The disease can also present abruptly with ketoacidosis and coma. In addition to impairing day-to-day living and quality of life, these complications are responsible for substantial reductions in life expectancy of more than 10 years for males and females.(7)

Type 2 diabetes is not a discrete entity but can be considered a stage of a continuum that can take several years from precursor or borderline states to overt disease. These are known as *pre-diabetes* consisting of impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) and will be defined later in this chapter, under the 'diagnostic criteria' subheading. Due to the broad age groups and ethnic populations affected by diabetes, the disease is widely acknowledged as a public health epidemic in the world today, as explained in the next two sections.

1.2 Burden Of Disease in the World And Projections

Type 2 diabetes accounts for 90% of all cases of diabetes worldwide. (8) Estimates of the number of diabetes cases worldwide for all age-groups were 171 million in 2000, 220 million in 2010 and has been predicted to increase to 300 million by 2025 and 366 million in 2030. Of these, 72 million are expected to be people in developed countries and mostly residents of urban areas.(9, 10) The diabetes prevalence projection worldwide from the 1995 figures to 2025 was an increase of 35% for adults aged 20 years and over, with India and China accounting for most of this increase. In 1997, it was estimated that a quarter of the people with diabetes in the US were unaware of their status and by 2001 diabetes was the sixth leading cause of death.(11) Developing countries are expected to experience a 48% increase while in the developed world this increase is estimated to be 27%. (9) The greatest increase in prevalence is expected to occur among people, aged 65 years and over in urban areas and developing countries, based solely on demographic changes, urbanisation and diet changes resulting from both. (10) The number of excess deaths attributable to diabetes worldwide in

adults aged over 40 years in 2000 was estimated at 2.9 million or 5.2% of all-cause mortality. Two thirds of these were estimated to have occurred in developing countries. These estimates place diabetes as the fifth leading cause of death in the world(12) and the data point to diabetes being an important global public health problem. Efforts to prevent diabetes will impact global health, survival and health expenditure.(13, 14)

1.3 Burden of Disease in Australia

Diabetes and its complications account for 8% of the total burden of disease in Australia. (15)

National population-wide biomedical surveys of randomly selected individuals have estimated the prevalence of diabetes among adults to have trebled to 940,000 between 1981 and 1999-2000. In 1999-2000 it was estimated that one in four Australians aged 25 years and older had either diabetes or impaired glucose metabolism, with the prevalence of diabetes for male adults estimated at 8.0% and among females 7.5%. (16) The five-year follow-up AusDiab examination survey in the New South Wales sub-population had a 60.6% response rate and found that among those participating, diabetes prevalence increased from 5.6 to 6.1. This could be an underestimate as survey attendees tended to have lower BMI and were more sedentary at baseline than survey attendees. Of those classified as IFG in the 1999 survey, 19.6% had progressed to diabetes five years later; likewise, of those classified as IGT at baseline 14.0% had progressed to diabetes in 2004. (17) The incidence of diabetes rose from 1.3 to 3.6% between 1989-90 and 2004-05 and hospitalisation rates increased by 35%.(15) Self-reported diabetes in the National Health Survey 2004-05 suggests that a proportion of people are unaware of their diabetes status as the unconfirmed prevalence was 3.6% of all adult Australians. This figure decreased from that estimated in the 1980s when it was estimated that one in two persons with diabetes were unaware of their status. The burden extends to prevalence of a variety of serious complications. In Australia diabetes is the most common cause of attendance to renal dialysis and the most common cause of blindness among people younger than 60 years. (15) Costs associated with direct health care for the disease are reported to be AUD\$907 million or 3% of the recurrent expenditure in the 2004-05 financial year. (15)

Given the above, early identification of individuals at high-risk and early management of the risk factors have important implications for public health policy and practice. A reduction in the number of new cases of type 2 diabetes would decrease morbidity associated with complications, cost of life-long pharmacological treatment, cost of monitoring through periodic laboratory tests, use of outpatient doctor and allied health services, and prevent hospital admissions and premature deaths.(14)

1.4 Pathogenesis

Diabetes causes can be single or multiple. Type 1 diabetes is associated with a genetic predisposition to autoimmune destruction of beta-cells, leading to absolute insulin-dependence.(8) It is the most common chronic disease in children. Patients may be concurrently affected by other autoimmune disorders such as Graves' disease, Hashimoto's thyroiditis and Addison's disease. Environmental factors have also been postulated as a possible cause but the mechanisms are yet to be clarified. (3) Idiopathic forms of type 1 diabetes have also been described in the medical literature, i.e. in the absence of evidence for autoimmunity, there is no identifiable cause.

Type 2 diabetes involves a multiplicity of defects predominantly associated with reduction in beta cells mass, acute insulin response, resistance to insulin action, dysfunction of the pancreatic beta cells and reduced capacity for insulin production over time which precludes compensation for the insulin resistance.(3, 7, 18) In addition to genetic susceptibility, malnutrition during pregnancy and in the first year of life is believed to explain some of the underdevelopment of the beta cells. (18) Several genes linked with genetic susceptibility to the typical disease have been isolated in European, Hispanic and African American populations and this may have implications for customised management as not all patients respond in similar ways to lifestyle or pharmacological treatment.(19, 20)

Single gene defects affecting insulin secretion or action, or the insulin receptor, account for less than 5% of all cases of type 2 diabetes (21) These manifest as atypical clinical presentations such as very early age of onset and severe familial insulin resistance.(21)

Most cases of type 2 diabetes, however, are also associated with environmental causes. Increased rates are observed in communities where transition to 'westernisation' from a traditional lifestyle has taken place and within ethnic groups migrating from developing to developed countries. (22, 23) Abdominal obesity resulting from inadequate physical activity and diet has been consistently identified in prospective and cross-sectional studies as an independent risk factor. (24) Repeat cross-sectional surveys and cohort studies report strong links with low and high birth-weight, physical inactivity, the presence of hypertension or dyslipidaemia, personal history of gestational diabetes or polycystic ovary syndrome.(25-29) Family history of diabetes in one or both parents can also increase the risk by about two-fold, (18, 30) and recent data on sitting time suggests it may be related to impaired glucose metabolism and a diabetes precursor independent of participation in leisure time physical activity.(31)

Other less common causes of diabetes are endocrine diseases, pancreatic fibrosis, pancreatic calculous, drug or chemical-induced pancreatic dysfunction, pancreatic trauma, generalised viral infections, genetic syndromes, pancreatic carcinoma, and surgical removal of the pancreas are beyond the scope of this thesis. (22)

1.5 Natural History of Type 2 Diabetes

Three main defects can be present: insulin resistance, pancreatic beta-cell dysfunction and impaired glucose production by the liver. The hypothesis that insulin resistance (i.e. suboptimal muscle uptake of glucose in response to a given level of insulin) occurs first, followed by damage to beta-cells as a result of chronic exposure to hyperglycaemia is still the subject of debate. This causes insufficient insulin release from affected beta-cells, leading to a decline in insulin levels which in turn triggers an increased glucose production and release by the liver.(32) Other researchers have found that the decline in glucose tolerance over time in people with family history of diabetes is strongly related to the loss of β -cell function. (33)This school proposes early interventions in high-risk individuals to slow the decline in β -cell function.

A simple way to represent the natural history of diabetes is depicted in Figure 1.1 by Ramlo-Halsted and Eldeman. There is growing evidence that that the impaired beta-cells can maintain relatively normal glucose levels while they exhaust insulin reserves in the initial stages.

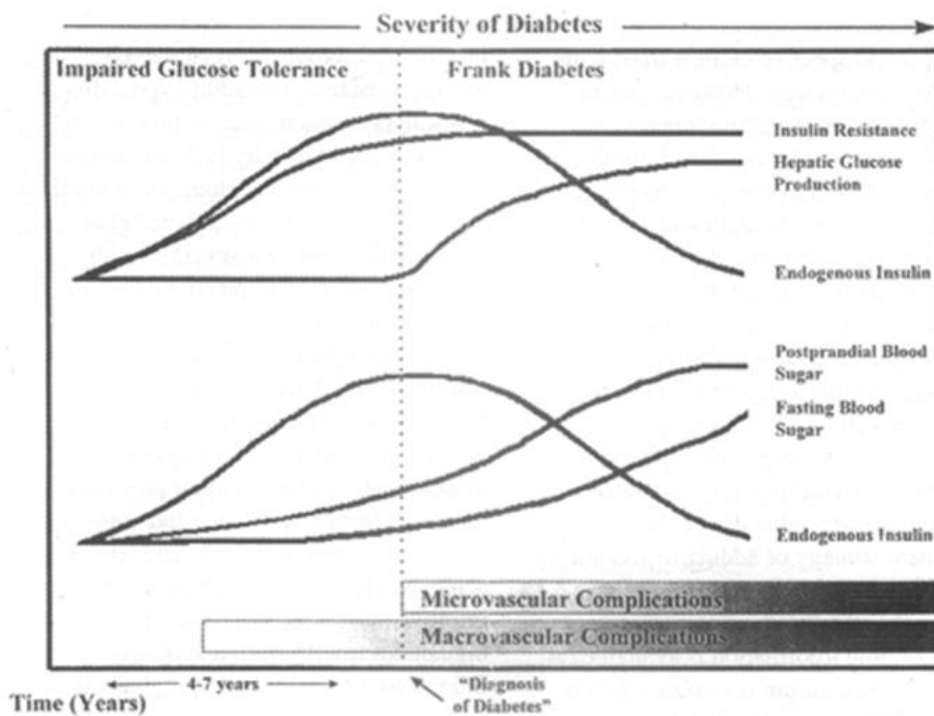
Hyperinsulinaemia is then detected before the pre-diabetes state sets which manifests with mild elevated glucose levels before (IFG) or after meals (IGT). The pre-diabetic stage is thought to last several years. This chronic rise in blood glucose can then become permanent as the beta-cells lose their ability to secrete insulin, the liver releases further glucose, and higher levels of hyperglycaemia can be detected. By the time the disease is diagnosed some of the microvascular (retinopathy, nephropathy, neuropathy) or macrovascular (cardiovascular or cerebrovascular disease) complications will have already developed. (34, 35)

Progression to type 2 diabetes from impaired glucose tolerance (reported variously as six to 10-fold increased risk and as 50% of cases) is widely accepted as part of the natural course of the disease. (18, 22) The annual progression rate is estimated at 5% on average, with some indigenous populations experiencing four times higher rates within 5 years.(21, 36) In some population subgroups, this may be preceded by insulin secretion defects.(18, 36, 37) Impaired fasting glucose is also a recognised risk factor and progression to diabetes from IFG in combination with IGT is estimated to be higher. (38)

The clinical course of these pre-diabetic stages may vary depending on the ethnic make-up of the population, the presence of other cardiovascular risk factors, the severity of the clinical stage and the introduction of lifestyle changes or pharmacological interventions. (18, 21, 39, 40)

An individual can go from impaired fasting glycaemia or IGT back to normoglycaemia or progress to a clinical stage of diabetes that can be either early disease or complicated disease.(3)

Figure 1.1 The natural history of insulin resistance progression from impaired glucose tolerance to overt type 2 diabetes. (Source: Ramlo-Halsted 2000)



IGT hence represents an intermediate stage in the early development of type 2 diabetes(37) with around a third to 40% of these people progressing to full-blown disease within 5 to 10 years.(8, 32) The mechanism by which hyperglycaemia leads to systemic diabetes complications appears to be by inducing enzymatic and receptor disruptions at the cellular level of the blood vessels, smooth muscle cells and white cells. These alterations are believed to generate an inflammatory process that hastens the onset of atherosclerosis.(41)

1.6 Risk Factors and High-Risk Groups

Evidence of a genetic predisposition to impaired glucose regulation has accumulated from population studies in Canada, the US, Indigenous Australia, North Africa, South-East Europe, the Middle East, China, India and the Pacific Islands. (21, 22, 42)

Old age is one of the strongest independent predictors of developing the disease.(43) The onset of disease among people of European descent tends to be after the age of fifty, but among Asian

Indian, Chinese, Pacific Islanders and Aboriginal Australians, recent times have seen cases of type 2 diabetes rise in the second and third decade of life. (30, 42, 44)

A recent systematic review of cohort and case-control studies has confirmed that low level of education and low income are associated with behaviours and risk factors such as obesity which contribute to the incidence of type 2 diabetes in industrialised countries but cast some doubts about this relationship in low-income countries. (45) The prevalence of diabetes in industrialised nations is higher among females than in males but in developing nations there are no significant sex differentials.(9)

More commonly cross-sectional and longitudinal studies in the literature have linked the 'western' diet consisting of excess refined carbohydrates, excess calories from fat and low intake of fibre and unrefined carbohydrates with type 2 diabetes.(21, 22) Other research studies also point towards a protective effect of Mediterranean diets or high-fibre diets but controversy remains.(46, 47) The other risk factor found to be an independent predictor of diabetes development is physical inactivity. Both prospective and cross-sectional studies have found associations between sedentary lifestyle, sitting or low levels of exercise and the incidence of diabetes.

The impact of socio-demographic characteristics and behavioural traits strongly indicate that public health measures have the potential to contain the development or progression of the disease. Human studies have confirmed that caloric dietary restrictions and exercise over at least six months can reverse insulin resistance by reducing fat cell size and preventing deposition of fats in the liver.(48) Chapters 2 and 3 of this thesis will discuss in detail how increased physical activity and healthy eating can delay the onset or prevent the incidence of type 2 diabetes.

1.7 Diagnostic Criteria

It is widely accepted that final diagnosis of diabetes should not be based on a single test (49) and that a single fasting plasma glucose test result with a value in the range of diabetes as per the above definitions should trigger further investigations to confirm diagnosis. (3) Three types

of blood tests are commonly used to confirm the diagnosis: fasting plasma glucose and oral glucose tolerance test are widely recognised and more recently glycated haemoglobin (HbA1c) has been used in some countries. The use of HbA1c for diabetes diagnosis is still controversial and has not been fully adopted in Australia. The decision on which test to use depends on doctor and patient factors, as cost, availability of time and inconvenience to patients are taken into consideration.

Over the past four decades, four changes in the diagnostic parameters defining a case of diabetes and a case of glucose intolerance, reflecting either aetiology or required treatment have occurred. Since the 1980s the World Health Organization (WHO) has disseminated diagnostic guidelines where thresholds have been established for adult populations as seen in Table 1.1. Subsequent enhanced understanding emerged that the thresholds are artificial and the excess risk for cardiovascular disease and microvascular complications start at lower levels of fasting glucose. This led to an agreement in 1997 to introduce 'impaired fasting glycaemia' as an intermediate state and to the lowering of the threshold of fasting glycaemia for the diagnosis of diabetes. While the American Diabetes Association agreed with the IFG concept and the new threshold, they proposed that a fasting glucose test on its own should suffice for diagnosis of both diabetes and IFG, while the WHO emphasises the importance of the additional 2-hour post-glucose load value for diagnosis of all categories of impaired glucose. (50, 51) More recently HbA1c is recognised as an appropriate diagnostic standard in settings where OGTT is impractical due to patient refusal or absence of laboratory facilities to conduct the test. (52)

Table 1.1 Diagnostic criteria for type 2 diabetes over time by the World Health Organization (WHO) and the American Diabetes Association (ADA)

	1985 WHO	1997 ADA	1998 WHO
Normoglycaemia		Fasting plasma glucose: <6.1 mmol/L	Fasting plasma glucose: <6.1 mmol/L 2-h post-glucose: <7.8 mmol/L
T2 Diabetes Diagnosis			
Fasting plasma glucose	≥7.8 mmol/L	≥7.0 mmol/L	≥7.0 mmol/L
2-h Post- glucose load	≥11.1 mmol/L		≥11.1 mmol/L
Pre-diabetic stages			
Impaired fasting* (plasma) glycaemia		Fasting: ≥6.1 & <7.0 mmol/L	Fasting: ≥6.1 & <7.0 mmol/L (2-h post-glucose: <7.8 mmol/L)
Impaired glucose tolerance**			2-h post glucose: ≥7.8 mmol/L but <11.1 (Fasting : <7.0 mmol/L)

* IFG

** IGT

For some time these changes in diagnostic thresholds gave rise to confusion among clinicians and varying estimates of incidence and prevalence have risen in various countries and ethnic groups (49, 50) leading to the identification of many more diabetes and pre-diabetes cases (51) triggering calls and action to halt the epidemic.(22) The most widely known and used definition in clinical practice today comes from the modified WHO 1997-98 classification.

1.8 Screening for Type 2 Diabetes

As this thesis will discuss in detail in later chapters, people at high risk can be managed to slow or stop the onset of disease leading to improved outcomes, quality of life and reduced complication rates, deaths and health care costs. Screening to identify these individuals who have not sought medical attention because they are not symptomatic is an important public health action to initiate diabetes prevention and control.(1) Diabetes is a good candidate disease for screening of asymptomatic populations because it meets several of the principles of effective screening: It is a significant public health problem with substantial burden; it has a detectable preclinical stage; there is evidence that early management generates benefits that outweigh the risks; early treatment results are superior to treatment of late diagnosed disease.(11)

Screening with a blood test could be conducted on entire populations or selectively targeting people at risk. The high cost and inconvenience of taking repeat blood samples on populations

has led many research and clinical groups worldwide to design non-invasive, affordable self-completed instruments for population-wide use. The objective is to identify people at risk so they can be referred for subsequent blood testing and appropriate preventive or management programs. Two of these screening tools will be examined here.

The *Findrisc* (FINish Diabetes Risk SCORE) tool was developed in 1987 as a strategy to minimise invasive and costly tests for population screening. The 7-item risk tool is self-administered and asks questions about age, sex, use of blood pressure medication, history of hyperglycaemia, and history of high blood glucose. This information was supplemented with measured weight, waist circumference and height (Appendix 1.1). The questionnaire was applied to a random sample of 4,746 adults without diabetes aged 25-64 years from the Finnish population register. The postal questionnaire was supplemented with physical examination and confirmatory oral glucose tolerance test at baseline, and measurement of BMI and waist circumference for males and females were added as items on the tool. Diabetes incidence over the ensuing 5 years was ascertained through data linkage with the national drug register to identify new cases of drug-treated diabetes.⁽⁵³⁾ In 1992, a sub-sample of 45-64 year-olds was invited to be re-surveyed and tested for diabetes using the OGTT to ensure coverage of diet-treated diabetes cases who were not identifiable in the register. At this point the risk tool had an extra two questions on level of physical activity under 4 hours per week and daily consumption of fruit or vegetables. The 10-year incidence of diabetes was also estimated using the drug register.

Performance of the Finnish risk score was examined cross-sectionally and prospectively using logistic regression analysis, which generated weights for each individual item. Older age, higher BMI, personal history of high blood glucose or antihypertensive treatment and high waist circumference were the strongest predictors of diabetes development. Four categories of risk from lowest to highest were derived using an additive score of the weighted components: 0-3, 4-8, 9-12 and 13-20. The cut-off point of ≥ 9 was selected as the score with the optimal sensitivity (proportion of individuals in the high-risk quartile of the population in whom the

test is positive) (54) and optimal specificity (the capacity of the test to truly classify the non-high-risk as negative).(55) The positive predictive value (probability of an individual being at high-risk level when the test result yields a high risk score)(1) was 13% in the early version of the tool and only 5% in the second round of testing 5 years later. Positive predictive value is dependent on the prevalence of disease at time of estimation.(56) Yet, the Findrisc accurately predicted >70% of the new cases of drug-treated diabetes. The tool is widely used in Finland today and drives the national screening program.

In Australia, a similar screening tool was developed around 2001 called the *Ausdrisk* (AUStralian type 2 Diabetes RISK assessment) tool. The basis for the choice of risk factors in this instrument was the Ausdiab study cohort of 6,000 adults examined with a questionnaire and glucose blood testing on two occasions (1999-2000 and 2004-2005).(57) The final tool developed to predict the risk of diabetes within 5 years consists of eleven risk factor questions: age, sex, ethnicity/Aboriginal status, country of birth, waist circumference measurement, and dichotomous questions on family history of diabetes, personal history high blood glucose including gestational diabetes, current use of antihypertensive medication, daily intake of fruits and vegetables, smoking status, physical activity levels of 30 minutes/day (For details of the scoring points for each risk factor see Appendix 1.2). Intensity of the physical activity did not change the predictive value of the tool, so only duration was included in the tool.(58) While the waist circumference item was based on objective measurements, the waist circumference item in the tool used for population screening is self-reported.

For confirmation of incident diabetes, the initial tool development study used an OGTT or reporting of treatment with anti-diabetic drugs. As in Finland, similar analysis using logistic regression techniques led to identification of variables that independently predicted diabetes development within five years in the Australian context.(59) A threshold of 12 points in the Ausdrisk score was selected as the one yielding optimal sensitivity (74%), specificity (67.7%) and positive predictive value (12.7%), similar to the findings of the Findrisc. These results were

validated by the authors using data from another cohort study in South Australia. Validation of the Ausdrisk for 10-year prediction of diabetes development was also trialled by others in the women-only Geelong Osteoporosis Study (data from 1994–1997). (60) The predictive value of a score ≥ 12 was 16% but the Ausdrisk published results are designed to estimate five-year risk. When Ausdiab follow-up data for 10 years become available, the sensitivity, specificity and predictive value may change, possibly leading to modifications of the recommended thresholds for waist circumference or total Ausdrisk score.(58) Unlike the Findrisc, the Ausdrisk tool includes ethnicity and sex as part of its contextual adaptation. The tool was approved in 2008 as part of an Australian government initiative to promote a screening and referral procedure for the early identification of people at risk in clinical practice, subsidised by the national public health insurance *Medicare*.

Researchers in other countries such as the US,(61) Thailand,(62) Denmark,(63) India,(64) and Germany(65) have used local risk factor data to develop and validate context-specific non-invasive diabetes risk screening tools. Variations in the type and number of risk factors included in the final questionnaires and predictive thresholds choices have also been derived from multiple or logistic regression analysis. Details of these developments and performance of their tools are beyond the scope of this thesis.

1.9 Preventability of Type 2 Diabetes

Today it is well established that overweight and obesity along with physical inactivity are modifiable risk factors for type 2 diabetes and its cardiovascular complications. (8, 15) As most cases of the diabetes epidemic are arguably associated with these environmental factors, clinicians and public health practitioners alike are aware of the potential for modifiable course through public health interventions promoting improved diet and physical activity. The benefits of early detection include lower rates of cardiovascular events and lower death rates if cases of pre-diabetes or diabetes are detected at lower levels of fasting glycaemia.(2) The first logical step is the early targeted screening with affordable, non-invasive, practical tests. Population screening tools are now known to contribute to relatively accurate identification of people in

the highest quartile of risk for disease development within five years. These tools continue to be refined using locally relevant knowledge for longer-term prediction. At the same time, interventions to slow down the progression of this epidemic are occurring worldwide with mixed, but mostly favourable results as will be discussed in subsequent chapters.

1.10 Conclusions

The growing burden of type 2 diabetes has now placed the disease among one of the leading causes of disability and death worldwide. While some portion of the disease has genetic, endocrine or chemical origin, many of the causal factors are environmental and preventable. The causal pathways are multiple and range from uterine malnutrition to low or high birth-weight, to familial predisposition, environmental exposures to dietary insults and sedentary life style leading to obesity and insulin resistance. The evidence of progression from normoglycaemia and pre-diabetes to established disease is widely documented and both lifestyle and pharmacological approaches are associated with relative success in modifying the natural history of diabetes. This thesis will focus on the evidence of preventability of diabetes accumulated over the past two decades (Chapters 2 and 3), and will feature the process, impact and economic evaluation of a local, contemporary prevention intervention in the real world in Sydney, Australia (Chapters 6, 7, 8 and 9).

Chapter 2.

Primary and Secondary Prevention Interventions in Community Settings

Summary

This chapter highlights how preventable type 2 diabetes is, why diabetes prevention is important and describes the components of 'gold standard' randomised controlled trials (here referred to as *the reference trials*) that constitute the best available level of evidence so far.

The concepts of primary and secondary prevention of diabetes, research translation, replication and implementation research are introduced. Subsequently the design and results from community-based translation studies, based on a literature search conducted to identify translation of diabetes prevention programs in settings such as workplaces, churches and whole communities are examined.

The main purpose of this thesis is to demonstrate the effectiveness of translation efforts in real-life settings. After qualitative and descriptive analysis of these, it becomes apparent that the published evidence supports the feasibility of implementing primary prevention in community-based settings, but provides less evidence that these programs succeed. Given this, it is premature for researchers to determine whether community-based studies can achieve results comparable to the original reference efficacy trials. Possible reasons are related to program design, duration, intensity and the choice of successful indicators to assess effectiveness.

Finally, the discussion section this chapter considers generic barriers and success factors for implementation in the 'real world', based on reported findings.

2.1 Background

2.1.1 The burden of prediabetes and scope for diabetes prevention

A high risk for diabetes comprises single or multiple modifiable and non-modifiable risk factors. Among the non-modifiable are older age, first degree relative(s) with diabetes, age over 40, male sex, personal history of gestational diabetes or polycystic ovary syndrome, and ethnic or racial backgrounds (African-Americans, Hispanic, native Americans, Asian and Pacific Islanders, and Australian Aborigines (66-70)). Many modifiable factors are also well documented and include physical inactivity, obesity, hazardous alcohol consumption, smoking, excess energy intake, low fibre consumption and prediabetes(71) as defined in chapter 1 (impaired glucose tolerance and/or impaired fasting glucose). It is known that the number of risk factors is directly correlated with the level of risk for diabetes incidence .(72)

Prediabetes in particular, can also lead to cardiovascular disease, and reducing obesity and blood lipids is thought to contribute to reversing the pre-diabetic state to normoglycaemia (38); diabetes prevention may also reduce their risk of cardiovascular events.(73) It is estimated that prediabetes affected 14.6% of Australian adults over 25 years of age in 2001 (74) and 22.6% of overweight adults aged 45-74 in the USA in 2000.(75) The prevalence of prediabetes in Europe in 2007 was estimated to be 15% among middle-age adults and up to 30%-40% among the elderly. (73)

As discussed in chapter 1, prediabetes can be reversed through the use of lifestyle and behaviour changes that restore the peripheral tissue insulin sensitivity. The high population prevalence of unhealthy behaviours indicates that there is scope for prevention.

Therefore the research questions to be covered in this chapter are:

- Is there evidence of preventability to justify the establishment of a community-based prevention program?
- Is translation of prevention trials feasible and successful in the community?

As a first step, several diabetes risk assessment tools have been developed and widely tested in countries across Europe, Australia, Asia and America to screen for diabetes risk factors, and to describe appropriate risk thresholds for primary or secondary preventive action.(53, 62, 63, 76-78) After identification of risk levels in individuals and populations, the next step is the planning of primary and secondary prevention strategies as defined below.

2.1.2 Difference between primary and secondary prevention of diabetes

Primary prevention is defined as preventive interventions which target “well” individuals to reduce the development of disease, thus reducing disease incidence and burden long term.(79)

Primary prevention of type 2 diabetes seeks to reduce population risk factors before blood glucose levels become abnormal.(80) In contrast, secondary prevention aims to identify high-risk individuals who are classified as pre-diabetic as their blood glucose is abnormal but not yet high enough to fall into the diabetes category. That is, people with either impaired glucose tolerance or impaired fasting glucose, who will benefit from interventions to delay or reduce diabetes incidence. (81)

An appropriate target for primary prevention are high-risk individuals without hyperglycaemia who are aged 45 years or above, particularly those with BMI of 25 Kg/m² or higher, and younger adults with another risk factor for diabetes(82) excluding pre-diabetic states.(83) To set the context, the components of an ideal primary prevention intervention need to be described.

2.1.3 Components of primary prevention interventions for diabetes

Population-wide primary prevention strategies target people whose glucose level is not yet abnormal but who are considered at risk due to other factors. The most commonly studied components include initiatives to decrease saturated and total fat, increase dietary whole-grain and fibre, and increase moderate physical activity, and to achieve reductions in overweight and obesity. Other components of preventive interventions are strategies to reduce alcohol misuse and reduce tobacco smoking.(7)

An example occurred in Finland with the development of prevention programs after the release of results from the FDPS. Similar lifestyle prevention programs were subsequently made widely available to the wider community beyond the at-risk-groups. The Finnish primary prevention programs are available to populations and are comprised of counselling training of health staff, establishment of weight management clinics in primary healthcare services, and creation of networks that connect different stakeholders.(84)

Another important component is social marketing, through mass-mediated public education campaigns. These aim to increase awareness and influence behaviour change. It is recommended that they are theoretically grounded, convey few but clear messages, encourage family involvement and are intensive and sustained. (85) Further, environmental modifications are an integral component to make the healthy choices to be physically active or access healthy foods easier for target populations. (84, 86-88). Detailed examples of primary prevention initiatives will be discussed later in this chapter, under the “nation-wide initiatives’ section. These primary prevention programs are overarching, and require the involvement of many stakeholders from families to city planners, the food industry, government to healthcare staff, community volunteers and other service providers.(87)

The natural history of diabetes includes progression from glucose dysregulation at a rate of 2% - 5% per year, (89, 90) but longer development periods from normoglycaemic states. Given this, primary prevention is inherently associated with the need for short-term investment followed by long periods before outcomes are realised for those not yet at risk.(83, 91) The low cost-effectiveness ratios of health promotion and disease prevention have long been recognised. Ultimately primary prevention may aim to save lives, not money. (92)

2.2 Secondary Prevention Interventions and their Components

Secondary prevention of diabetes aims to identify people in the pre-diabetic state, to prevent the progression from symptomatic or asymptomatic hyperglycaemia to complete establishment

of disease. As IGT/IFG are considered pre-clinical stages of diabetes,(82) screening for and management of pre-diabetes is classified as secondary prevention. (80) In secondary prevention programs, interventions can be pharmacological or non-pharmacological or a combination.(21) This thesis is concerned with non-pharmacological, lifestyle modification interventions to prevent diabetes.

The clinical effectiveness of lifestyle interventions in preventing or delaying diabetes development in people with proven glucose abnormalities has been established from at least four large randomised trials of structured, intensive interventions conducted over the past two decades in Finland,(93) the USA,(94, 95) China,(97) and India.(98) The replication of these studies in a community setting is the focus of this thesis, thus detailed characterisation of the original efficacy-focused interventions is presented to set the scene for the Sydney Diabetes Prevention Program.

2.2.1 Reference lifestyle modification trials for diabetes prevention

Four secondary prevention trials conducted under closely monitored research conditions and published since 1997 have triggered replication efforts around the world (Table 2.1). They are considered as the 'gold standard' diabetes prevention studies and will be referred to in this thesis as the *reference trials*. Their screening strategies, target groups, intervention modality and outcomes are discussed next.

2.2.1.1 The Finnish Diabetes Prevention Study

Using epidemiological surveys and newspaper advertisements The Finnish Diabetes Prevention Study (93) conducted opportunistic population screening of high-risk groups in five centres, and recruited 3,234 adults aged 40-64 years with IGT, obesity or family history of diabetes. (99) The program goals were to reduce BMI to less than 25 kg/m² or weight loss of 5% of initial body weight, to reduce total fat intake to less than 30% of energy consumed, to reduce saturated fat intake to less than 10% of total energy, to increase fibre consumption to at least 15g/1,000kcal per day, and to increase moderate-intensity physical activity to at least 30 minutes per day. In

the FDPS lifestyle intervention arm, seven individual face-to-face dietary counselling visits were scheduled in the first year, followed by personalised advice every three months thereafter, along with supervised, progressive, and individually tailored resistance training twice a week. Attendance to these sessions varied between 50% and 85% across centres. Participants in the control group were given generic information on healthy diet and exercise at baseline and at subsequent annual visits only. Outcome assessment was objective for weight and diabetes incidence (oral glucose tolerance test), self-report for diet using a 3-day food record, and subjective for assessment of changes in physical activity. The mean duration of follow up was 3.2 years (total duration 6 years between 1993 and 1998).

Key outcomes in the first year were a mean weight loss of $4.2\text{kg}\pm 5.1$ for the lifestyle intervention group and $0.8\text{kg}\pm 3.7$ in the control group; reduction in waist circumference of $4.4\text{cm}\pm 5.2$ and $1.38\text{cm}\pm 4.8$ in the control group; and a 4-year reduction of diabetes risk of 58% in the intervention group.⁽⁹³⁾ Various levels of success in achieving the different program goals were observed, but in all cases, the lifestyle intervention participants had significantly more success: 43% in the intervention group achieved the weight reduction goal vs. 13% in the controls; 47% in the intervention group achieved the fat intake goal vs. 26% in the controls; 26% achieved the saturated fat goal vs. 11% in the controls; 25% achieved the fibre goal vs. 12% in the controls; and 86% achieved the physical activity goal vs. 71% in the controls. The actual values of changes in dietary outcomes were not published. There was a strong inverse correlation between the number of goals achieved and the incidence of diabetes at the end of follow-up, but even small weight reductions had an impact on reducing the incidence. The authors concluded that the intervention delayed or prevented the onset of disease by at least 4 years. The authors subsequently decided to follow-up those who remained free from diabetes yearly for another 3 years without further intervention. ⁽¹⁰⁰⁾ The end result was an absolute difference in diabetes risk between intervention and control of 15%, the same as in the initial 4 year follow-up; and a relative risk reduction of 43% (vs. 58% in the original study). They

concluded that the protective effect of the intervention remained for several years after discontinuation of active counselling.

2.2.1.2 The U.S. Diabetes Prevention Program Outcomes Study

Between 1996 and 1999, the US Diabetes Prevention Program targeted adults with IGT aged 25 years and above including half from ethnic minorities via mass media, mail, telephone, employment or social networks and health systems. Subjects underwent a four-step screening and recruitment process at 27 centres to include exclusively people with IGT. Subjects were randomly allocated to one of three treatment arms: intensive lifestyle intervention, metformin therapy, or placebo. The Program goals were at least 7% weight loss and at least 150 minutes of physical activity per week. The lifestyle arm offered at-risk people an individualised face-to-face 16-lesson program comprising dietary and physical activity modification advice in the first 24 weeks after recruitment, followed by monthly individual sessions and reinforcement behavioural group sessions with case managers for the duration of participation. Attendance to these sessions was not reported but 92.5% of remaining participants had attended a scheduled visit with the previous five months. (101) Outcome assessment of diabetes used an oral glucose tolerance test. Self-reported physical activity was calculated as the product of duration and frequency of activity in hours per week based on the standard Modifiable Activity Questionnaire. This estimate was expressed as the average metabolic equivalents of those activities (METs) per week. The average duration of follow up was 2.8 years.

The outcomes for the lifestyle intervention group were a mean 5.6Kg weight loss in the lifestyle intervention group, significantly higher than the 2.1kg in the metformin group and 0.1 kg in the placebo group. At the end of the curriculum, i.e. first six months, 50% of participants had achieved the weight loss goal and 74% had achieved the physical activity goal. Dietary change at 1 year indicated that the average fat intake had decreased by $6.6\pm 0.2\%$ in the lifestyle intervention group and only by $0.8\pm 0.2\%$ in the other two groups. Reduction in diabetes incidence was 58% in the lifestyle intervention group and 31% in the metformin group as

compared with placebo.(95) The authors concluded that their trial had delayed or prevented diabetes in people at high risk. All participants were invited to continue follow up and 88% did so for a median of 5.7 years. A subsequent follow-up after a decade revealed that people in the lifestyle intervention had partly regained weight whereas the weight loss in the metformin groups had been maintained. (102) The reduction in diabetes incidence after 10 years remained more favourable for the intensive lifestyle intervention group (34%) than for the metformin group (18%) compared to placebo. Improvements in lipid profile and blood pressure were also observed despite reductions in pharmacological treatment by participants. At this stage the authors confirmed that the protective effects of lifestyle or pharmacological diabetes prevention interventions can persist for up to 10 years. A further follow-up report will become available in 2014.

2.2.1.3 The Chinese Diabetes Prevention Program

The Da Qing diabetes prevention program in China, conducted between 1986 and 1992, systematically screened males and females attending 33 urban local health clinics. People aged 25 years and over who had confirmed impaired glucose tolerance were invited to participate in a cluster randomised trial where entire clinics rather than individual subjects were allocated to follow one of four protocols: Diet only intervention, Exercise only intervention, Diet-plus-exercise intervention or control group. The goals of the program were to achieve a gradual weight loss of 0.5 to 1.0kg per month until they reached a BMI of 23kg/m², reduce alcohol and sugar intake, and increase leisure physical activity by at least 1 unit/day. (90)¹ The partial and full lifestyle intervention arms of the study offered initial individualised face-to-face advice on diet and physical activity followed by weekly small group counselling sessions for 1 month, monthly for 3 months then 3-monthly for up to six years. Thorough follow-up occurred at two year intervals and outcome assessment was objective measurement of diabetes incidence and

¹ Types of physical activity were qualitatively described, and units referred to the number of minute equivalents: 30 minutes of mild activity=20 minutes of moderate=10 minutes of strenuous=5 minutes of very strenuous activity.

weight loss. Dietary and physical activity assessment was estimated using non-blinded assessors. The mean follow-up duration was 6 years.

Key outcomes at 6 years in the diet-plus-exercise group revealed a mean weight loss of 1.77 kg among completers who did not develop diabetes, while participants in the exercise-only or diet-only intervention experienced weight gain of between 0.7 to 0.9 kg respectively. Also observed were a reduction in diabetes incidence of 33% in the diet-only group, 47% in the exercise-only group and 38% in the diet-plus-exercise group. This was not directly associated with level of weight loss but incidence rate was higher for people who were overweight at baseline compared with people who were 'lean'. Dietary advice also differed for the interventions depending on the subject's BMI. No significant changes in physical activity or caloric intake were found across intervention groups. Two decades after the first report of this study, multiple sources including medical and death records and family interviews were consulted again to determine diabetes incidence and cardiovascular or all-cause mortality among participants. The combined reduction of diabetes incidence of 51% across lifestyle intervention groups immediately after the intervention remained (43% reduction) 20 years following the initial intervention in this study.(103) Conversely, 93% the people in the control group who had IGT developed diabetes. The authors were reassured that lifestyle intervention using individual and group sessions in Chinese people with IGT had produced long-lasting effects.

Table 2.1 Description of diabetes prevention reference trials by recruitment strategy, study setting and intervention modality (1997-2006)

Author, year, country, duration of intervention	Target group and Inclusion criteria	Recruitment, setting & sample size	# individual sessions	# group sessions and timeframe	# telephone sessions	Mean duration of follow-up	Program delivered by	Study type and methodological issues
Finnish DPS, 2001 (93), 4 years	Overweight or obese adults with IGT	Newspaper advertisement for health screening of both obese patients and first-degree relatives of T2D patients. N=523; with 256 in lifestyle group	7 sessions with nutritionist in first year + 8 sessions over 2 subsequent years + supervised resistance training twice/week	3-6 group meetings	0	2.3 years	Nutritionists	Random assignment to intervention or control, with stratification by centre, sex, and 2-hour OGTT; partly blinded assessment
USA DPP, 2002 (95),	Adults with IGT and IFG, not on glucose altering medications and having no restrictions for exercise	Media, mail & telephone invitation to clients of 27 health centres throughout the country. Oversampling of ethnic minorities. N=3,234; 1,079 on lifestyle arm	16-individual lesson curriculum over 24 weeks + 6 one-to-one reinforcement sessions	6 group sessions in second semester	0	2.8 years	Case managers	Random allocation to either lifestyle, metformin or placebo. Standard measurements and external laboratory outcome assessment
China DPP, 1997 (90), 6 years	Adults with IGT living in an industrial area	Routine screening of people attending 33 occupational health clinics. N=577; 397 in intervention groups	1 initial face-to-face counselling	8 group sessions in the first year and 4 per year in subsequent years	0	6.0 years	Physicians, nurses and technicians	Cluster randomisation of clinics to 1 of 4 protocols did not produce equivalent risk levels in groups. Dietary assessment not blinded.

Author, year, country, duration of intervention	Target group and Inclusion criteria	Recruitment, setting & sample size	# individual sessions	# group sessions and timeframe	# telephone sessions	Mean duration of follow-up	Program delivered by	Study type and methodological issues
India DPP 2006 (104), 2.5 years	Urban Asian Indians with persistent IGT (confirmed on 2 OGTTs)	Middle class population and their families were invited via workplace newsletters. N=531; 395 in intervention groups	5 individual sessions at 6-month intervals	0	~30 or 1 monthly motivational call	3.0 years		Prospective randomised controlled trial

2.2.1.4 *The Indian Diabetes Prevention Programme*

The Indian Diabetes Prevention Programme used workplace announcements and circulars at service organisations to recruit subjects aged 35-55 years from a middle-class group of workers and their families and who had two OGTTs confirming IGT (*persistent IGT*). Of those classified as IGT, 77% returned for the confirmatory second test. Eligible participants (51.8% of those having the second OGTT) were randomly allocated to one of four study arms: lifestyle modification, metformin, lifestyle modification plus metformin, and control group. The intervention protocol comprised face-to-face dietary and physical activity advice followed by monthly telephone contact, six-monthly face-to-face individualised sessions over 2.5 years, with outcomes assessed annually for up to three years. Physical activity goals were increase of physical activity to >30 minutes per day in sedentary people and continuation of routine activities for people working in physical labour or who walked or cycled for >30 minutes/day. Dietary advice was tailored to individual needs but overall recommended avoidance of sugars, reduction of total calories, refined carbohydrates and increase in fibre consumption. Adherence to diet and exercise were assessed by self-report of weekly patterns. Follow-up was conducted between 2001 and 2004, and outcome assessment was mainly laboratory-based for diabetes incidence and insulin resistance. No details were presented on dietary or physical activity outcomes.

Findings indicated a relative risk reduction of around 28% for the lifestyle modification program alone or in combination with Metformin vs. 26.4% reduction for people in the metformin-only group relative to the incidence in the placebo group. These reductions were observed despite weight increases at 2 years in the lifestyle groups and no significant changes in WC measurements throughout the follow-up period.(104) The authors concluded that it was possible to prevent diabetes in the Indian subjects even when they had low baseline BMI and that combining metformin with lifestyle did not confer any additional benefit.

All of the above examples address the secondary prevention of diabetes, and their promising outcomes have inspired researchers around the world to replicate these secondary prevention approaches in various community settings. Replication in this thesis refers to *innovative replication* or replication ‘under new conditions’ where “investigators develop their own design, sampling procedures, measurement techniques and data analysis methods to test and evaluate findings from earlier studies”. (105) In brief, replication of the diabetes prevention trials in this thesis refers to any attempts to conduct the lifestyle intervention in a routine setting, using similar objectives but more affordable or simpler methods to deliver the intervention than the reference trials did.

Implementation of diabetes prevention studies beyond the research setting can be costly and lengthy, and the conduct of RCTs for the purpose of evaluation is not always possible in routine practice due to resource and skill scarcity. Translation research in public health assists in building the evidence that the knowledge acquired from scientific experiments can be put in practice in the real world through replication and dissemination.(106)

2.3 What Is Translation Research And Why Is It Important?

Translation research refers to the investigation of methods used to ensure that new treatments and knowledge actually reach the population for whom they are intended. It can be described as the transfer of results from clinical studies into routine practice.(107) In brief, translation research aims to facilitate broader uptake of efficacious interventions by relevant target groups with the involvement of decision-makers and consumers of health services. It comprises three main types of research: effectiveness research, dissemination research and implementation research as explained below. (108)

Effectiveness research examines whether a treatment or intervention works under real-world conditions after its efficacy has been proven under strictly controlled conditions. (109)

Effectiveness research is therefore a form of initial replication of efficacy studies. Dissemination

research investigates the best approaches to increase uptake of the intervention by the target groups.(110) Implementation research is more concerned with the success factors associated with the process of adaptation of evidence-based interventions in local community settings. This covers the concept of *fidelity*, or whether the original components of the intervention were carried out into the real-world setting.(111)

The role of translation research is important in leading to quality improvement in healthcare. Findings derived from real-world research can lead to innovations in health service provision, including both clinical practice and behavioural programs. (110) The literature contains many examples of long lead-time from discovery to implementation which could have potentially prevented ill-health events and deaths in the areas of communicable diseases, chronic disease care and behavioural interventions.(110) In the case of diabetes prevention, the first published suggestion of effectiveness of primary prevention occurred in the early 1920s (112) but it was only in the mid 1980s when translation research formally started to build the evidence.

Translation research contributes information on the generalisability and external validity of previous studies conducted under research conditions.(105) That is, it validates whether and to what extent results from the reference trials apply in other relevant populations or settings. The importance of translation research is that its results can be used by many players beyond the clinical setting including environmental policy makers, public health administrators, food industry regulators, schools and employers to prioritise funding and research and to change policy and practice.(107, 113) Unfortunately, research activity in the area of reach, implementation and adoption is not often published in the medical literature. (113)

Calls for broader implementation of lifestyle interventions for diabetes prevention in real-world settings continue to appear in the public health arena, (114-121) although there has been recognition that translation of randomised controlled trials is not straightforward. Clinicians and community consumers' perceptions and willingness to change can be challenging, and long-term sustainability is uncertain.(21, 122, 123) The next sections of this chapter deal with the

translation of these ‘gold standard’ reference trials in community settings, their adaptation and their outcomes. For the purpose of this thesis, *community settings* are defined as socio-demographically diverse places where groups of people share an environment, or the same resources and consider themselves as part of that social group, engaging in complementary activities despite not sharing the same socio-demographic profiles. (124-126) So in this chapter it includes urban and rural geographic communities, workplaces, churches and entire nations.

2.4 Translation Efforts

Translation of the reference diabetes prevention trials has occurred in primary and secondary prevention settings, that is, interventions have targeted whole-of-populations and/or exclusively people with prediabetes. This section will present brief descriptions of translational studies in community settings, with particular reference to screening, recruitment requirements, characteristics of recruited subjects, and brief summary of outcomes when available. These experiences range from replication in local areas to adoption in entire nations.

2.4.1 Replication in community-based settings

Following the encouraging results of the reference trials, many attempts have been made to replicate the strategies used in the diabetes prevention efficacy trials in community settings under real-world conditions (84, 88, 114, 116-118, 120, 121, 127-133) Only a few examples (21), mostly recent, have been chosen from a brief literature search to illustrate the topic in detail. This brief search was only undertaken to inform the context of this chapter, i.e. the replication of diabetes prevention programs in community settings. In contrast, Chapter 3 will present a more comprehensive literature review addressing translation of diabetes prevention in routine clinical practice, a topic more directly relevant to this thesis.

The twenty-one community-based studies referred to in this chapter were found through a literature search for articles published between 1998 and 2010 using the search terms “community-based” AND “diabetes prevention” AND (“replication” OR “implementation” OR

“translation” OR “real world”).² Some of the translation efforts found were at the recruitment or design stage, or have not reported results yet. Many of the community-based translations have involved a reduction of the intervention components to less resource-intensive and implementation of more pragmatic versions of those used in the reference trials. These modifications can be grouped in four main areas:

Changes to selection criteria

- include recruitment of people without impaired glucose tolerance but with an otherwise high-risk profile (115, 117, 119, 121)
- allowance for participants to be on prediabetes medication(134)

Changes to delivery mode and intensity

- replacement of face-to-face individual counselling with group-based demonstrations or reinforcement sessions (115, 119, 135-138)
- use of workshop education format (129)
- allowance for home-based or gym-based intervention (119)
- allowance for assisted self-management or individual-based consultation (118)
- flexibility of individually tailored exercise and dietary goals and customisation of working methods to the local context (139)
- briefer intervention duration (117, 118, 120, 134)
- involvement of family members in group demonstration sessions(140-142)
- use of culturally-tailored physical activities (133)
- use of organised community group activities (87)

Changes to follow-up activities

² The PhD candidate conducted the literature search and critical appraisal for this review.

- substitution of the multiple individualised personal follow-ups with patient contact via telephone (134)
- comparatively reduced frequency of follow-up contacts (143)
- shorter follow-up periods (119, 134, 139)

Changes to outcomes measured

- primary endpoints confined mostly to short-term impact on selected risk factors (i.e. behavioural risk factors or improvement of at least one component of metabolic syndrome (119, 137, 141)
- and short-term sustainability of behaviours rather than actual reduction of diabetes incidence (144)

For clarity, the community-based studies are here presented according to the setting in which participants were recruited and/or where the programs were implemented. That is, urban community-based locations (7), indigenous, rural and remote communities (5), confined to either workplaces (3) or churches (2) or delivered at a nation-wide level (4). These illustrate the varying approaches required in diverse community settings for diabetes prevention.

Three of the seven urban community-based studies (Table 2.2) can be considered intensive interventions: one in Australia and two in the US.(115, 138, 141) The two US-based studies more closely replicated the DPP, but their durations were shorter than the original trial. The other programs exhibited greater variation in delivery, as listed above.

Five of the seven studies used before-after study design without a control group (115, 119, 138, 141, 145) and two were randomised interventions with a control group. (121, 129) Recruitment used a combination of strategies, such as advertisements in newspapers (4/7), flyers at workplaces (2/7), and personal invitation through healthcare providers (5/7), church staff (3/7) or community leaders (1/7). Numbers of participants in 5/7 community-based studies tended to be small (31-154 subjects) and two studies were medium sized (~300 participants).(115, 117)

These lifestyle interventions were often (4/7) delivered by a multi-disciplinary team (dietitian, physiotherapist, psychologist, nurse, exercise physiologist or behavioural therapist). In two studies, science graduates or students delivered the lifestyle coaching sessions (115, 134) and in one, the program was delivered by community leaders (129) Five of the seven studies provided group-based intervention only, and two had the major components delivered as individual sessions. (115, 134) Four studies also offered reinforcement or maintenance activities either by phone (134) or face to face. (115, 135, 138) Follow-up periods were mostly (5/7) 1 or 2 years but two studies had short follow-ups of 16 weeks (115) and six months. (120) Attrition rates were generally acceptable, with 3/7 experiencing <20% loss to follow-up, 3/7 losing <30% and 1 losing 43% of participants. The magnitude of attrition was not associated with duration of follow-up but more likely with target population or setting, as the study experiencing the largest losses was of six months duration in a medically underserved community (120) and the one with the best completion rates had 1 year follow-up at a university campus. (134)

Table 2.2 Description of community-based prevention studies by recruitment strategy, study setting and intervention modality (1998-2009)

Author, year, country, duration of intervention	Target group and Inclusion criteria	Recruitment, setting & sample size	# individual sessions	# group sessions and timeframe	# telephone sessions	Duration of follow-up	Program delivered by	Study type and methodological issues
Parikh 2010, USA, 12 months (129)	Overweight members of Spanish or English-speaking community aged 18+, with prediabetes but not on glucose-altering medication	Community leaders championing the study at churches, senior citizen centres, social service agencies and health fairs. Intervention=50 Control=49	0	Eight 1.5-hour sessions over 10 weeks	0	1 year	Lay leaders in their respective organisations	Block randomisation by recruitment site to intervention or delayed intervention in 1 year; 28% lost to follow-up
Matvienko 2009, USA, 12 months (134)	Adults 25-65 years with IGT or diabetes in past 5 years, or high-risk due to obesity, family history of diabetes, personal history of hypertension or Gestational diabetes, dyslipidaemia or sedentary lifestyle	Local advertising via flyers, newsletters and rolling enrolment through local physicians. N=31	24 to 48 meetings in first 6 months and 6 meetings in second six months	0	24 phone calls in second 6 months of maintenance	1 year	Trained students of exercise science at a university campus	Before-after design without a control group; 16% lost to follow-up

Author, year, country, duration of intervention	Target group and Inclusion criteria	Recruitment, setting & sample size	# individual sessions	# group sessions and timeframe	# telephone sessions	Duration of follow-up	Program delivered by	Study type and methodological issues
Amundson 2009, USA, 10 months (115)	Overweight adults aged 18 years and older, with one or more of prediabetes, hypertension, dyslipidemia, history of gestational diabetes	Media advertising, employers, service groups, churches and doctors identified and referred eligible patients to healthcare facilities and YMCA; N=335	16 individual sessions	6 one-hour sessions over 6 months + two supervised group physical activity events	0	16 weeks	Lifestyle coach and health professional with education/science training	Non-randomised before-after study, some centres charged for intervention & 7% were taking weight loss medication. Loss to follow-up 18%
Payne 2008 Victoria, AU, 12months (119)	Adults >35 years, obese, ethnic high-risk, with family history of diabetes, personal history of hypertension or other CVD	Community recruitment through media campaign and promotional materials in disadvantaged localities. N=122 (gym-based=62, home-based=60)	0	1 session per week/ 6 weeks + 1 gym-based supervised resistance training session /week /12 weeks + 34 weeks maintenance program	0	1 year	Dietitian, psychologist, exercise physiologist	Before-after study without a control group but gym-based and home-based interventions compared
Seidel 2008, USA, 12 weeks (120)	Overweight or obese Adults ≥18 years & had 3/5 components of metabolic syndrome & not taking weight loss medication or glucose lowering medication	Recruitment via flyers at workplaces, churches, physicians offices, and newspaper advertisements. N=88	0	12 group sessions of 90 minutes each over 12-14 weeks	0	6 months	Dietitian and exercise specialist	Before-after without a control group. Non-completers were more likely to be older and non-white. Loss to follow-up 43%

Author, year, country, duration of intervention	Target group and Inclusion criteria	Recruitment, setting & sample size	# individual sessions	# group sessions and timeframe	# telephone sessions	Duration of follow-up	Program delivered by	Study type and methodological issues
Laatikainen 2007, AU, 12 months (117)	Patients aged 40-75 years presenting at local doctors with a diabetes risk score of ≥ 12	Primary healthcare practices in semi-rural area. N=311	0	6 structured 90-minute group sessions: first 5 within 3 months and sixth session at 8 months	0	1 year	Nurses, dietitians and physiotherapists	Before-after intervention without a control group; 23.7% lost to follow-up
Wing 1998, USA, 24 months (121)	Overweight and obese adults aged 40-55 years with parental history of diabetes	Community-wide recruitment via newspaper advertisements. N=154		24 meetings in first 6 months and 12 meetings in second 6 months + two 6-week refresher courses in second year	0	2 years	Behavioural therapist and registered dietitian	Random assignment to one of 4 treatment arms (diet, exercise, diet + exercise, control)

The mean weight loss results reported in these seven trials ranged from -2.5kg in urban Australia (117) to -4.1kg in rural Australia, (119) and up to -6.0kg or -7.2kg in urban US. (115, 137, 145) Two other US studies reported that between 37% and 67% of participants achieved weight losses of $\geq 5\%$ of initial body weight. (115, 120, 134) Changes in FPG were reported in four of the seven studies but only in one of them were these changes statistically significant. (119)

In brief, these community-based diabetes prevention programs illustrate the variations in recruitment, staff delivering the instruction, modality of group or individual counselling, telephone or face-to-face follow-up and duration of intervention adopted to meet local needs. Most of these studies included a small sample size but results overall were in the expected direction: weight loss was a consistent contributor to risk reduction.

Other translation examples also found during the search using the terms described above took place in more confined community settings such as remote Indigenous communities, worksites or churches. The summary here is only a selection of examples found, as the focus of this thesis is prevention in broader community-based interventions.

2.4.2 Indigenous rural and remote communities

Studies conducted in rural and remote communities are reviewed separately from other 'community-based' diabetes prevention interventions due to the distinct cultural characteristics and social norms of remote Indigenous communities. Remote communities can be appropriate settings for translation research if good collaboration exists between investigators and the local leaders. Like churches, Indigenous leaders in remote communities can be trained to deliver culturally appropriate health promotion programs. Familiarity with and control of the local environment may be more feasible in these communities if the assistance of influential personalities is obtained. Attribution of Program effects may be less reliant on external influences. Unfortunately, translation of lifestyle interventions in Indigenous or remote settings

are rarely reported, with five examples of studies conducted since 1998 reported here (Table 2.3). (68, 116, 135, 136, 145)

An early pilot among Pima Indians in Arizona used a structured intervention, compared to culturally focused lifestyle intervention. After six and 12 months follow-up, results indicated that despite both groups reporting an increase in hours physical activity, calorie intake had increased along with weight, BMI, OGTT and FPG more in the lifestyle group than in the structured program group. Participation rates in screening were low (31%) and acceptance of randomisation was 73%. The authors concluded that it was feasible to recruit Amerindians to a trial, but difficult to maintain lifestyle changes and recommend that allocating 'treatment' to families rather than individuals could make interventions more effective. (135)

Higher response rates (85%) to screening were seen in a remote Aboriginal Australian community where a culturally appropriate health promotion program offered diet and exercise messages through community meetings. The intervention involved community leaders and health workers in extensive discussion with community members, and education sessions delivered by clinicians and a visiting health educator. (68) The prevalence of diabetes after the intervention remained stable for at least seven years and both cholesterol and IGT showed improvement despite a 3kg weight increase among males and females of all ages. This weight gain was more often observed in people living near the local store than in those residing in communities not adjacent to a store.

A community-led, unstructured lifestyle intervention targeting members of the Ngati rural Maori community in New Zealand recruited participants through a single health facility and delivered the intervention via health workers and community members. Their multifaceted approach consisted of a structured program for high-risk individuals reinforced with community-wide education through media, family involvement, changes to school policies, local nutrition demonstrations and environmental support for physical activity. Outcomes at 2 years after the intervention indicate non-significant increases in mean waist circumference, weight in

men, concurrently with a reduction in the prevalence of insulin resistance and an absolute reduction in diabetes prevalence of 2% for both males and females. Behavioural outcomes appeared to have improved with a 10% increase in reported exercise and 60.3% achieving the physical activity goal. These favourable changes were mostly observed in the more motivated, younger age groups. (116)

Whole of population approaches targeting school children, workplaces and church settings were adopted in a remote Cherokee Indigenous community in USA. While not a replication study, the principles of education on lifestyle choices were implemented over one year in the way of workshops and demonstration sessions by tribal workers, teachers and church members, and community walks under the guidance of nutritionists, dietitians and fitness workers. Maintenance sessions were also offered subsequently to those who wished to remain in the program. The before-after design and overall results of outcomes reported was largely qualitative, but approximately 71% lost some weight, with 10% losing 10 lbs or more. There was reported improvement in healthy eating and walking behaviours and reduction or discontinuation of high blood pressure and diabetes medications.(136) Multivariate analyses were not performed to better determine predictors of success in individuals.

Likewise, in rural India, a 'collective approach' was used to educate children aged 10 years and above and adults on lifestyle choices to achieve the goals of the diabetes prevention program (except for the weight goal, as many community members were underweight). Recruitment included children and adults who agreed to take the survey, and some had confirmatory blood tests. The intervention lasted seven months and was delivered by outside trainers with a science background, who resided in the village for the duration of the intervention.

Improvements in dietary fibre intake and weight loss of 2.2 kg were observed in people with IFG, and reductions in fasting plasma glucose were identified for all.(145) In sum, diabetes prevention programs in Indigenous or remote communities appear feasible; the results are mixed with weight loss and gain, but overall reduction or stabilisation of diabetes incidence.

Community engagement was achieved through consultation with community or leaders before screening and recruitment. Delivery through home visits, family involvement and local workers were features specific to these settings.

Table 2.3 Description of diabetes prevention programs in Indigenous communities by recruitment strategy, study setting and intervention modality (1998-2008)

Author, year, country, duration of intervention	Target group and Inclusion criteria	Recruitment, setting & sample size	# individual sessions	# group sessions and timeframe	# telephone sessions	Duration of follow-up	Program delivered by	Study type and methodological issues
Narayan 1998, (135) USA, 12months	Obese, sedentary, non-pregnant adults without heart disease, not on glucose altering medication	Pima Indians recruited through extensive local advertising and invitation to residents on database	home visits as warranted	1 per week for 1 year	0	1 year	NR	Randomised trial with 2 control groups, one of them was the decliners.
Rowley 2000, (68) Australia, 2 years	Aboriginal residents aged 15 years and above	remote indigenous communities; N=437.Female N=248 males N=189	0	as warranted	0	7 years	clinician and community health educator	Longitudinal study with intermittent education reinforcement and repeat cross-sectional assessments. No validation of diet or physical activity.
Bachar 2006, (136) USA, 1+ years	Whole of population from school age to adults	Indigenous residents of remote mountains. Target group 13,000; actual number of participants NR	Unknown number of workshop demonstrations at workplaces, and school classes	NR	0	At least 1 year, some 1 extra maintenance year	Tribal workers and teachers, plus church members assisted by nutritionists and fitness workers.	Before-after multi-strategy approach for all ages at workplaces, churches and schools. Unclear timeliness of measurements.

Author, year, country, duration of intervention	Target group and Inclusion criteria	Recruitment, setting & sample size	# individual sessions	# group sessions and timeframe	# telephone sessions	Duration of follow-up	Program delivered by	Study type and methodological issues
Balagopal 2008, India (145) 7 months	Population from 10-year-old children to adults screened, those with IFG or diabetes also invited	Indian rural village residents at risk and already diagnosed. N=703	10 face-to-face education sessions					
Coppell 2009,(116) NZ, 24 months	Whole-of-population targeting Ngati Maori people	Sparsely populated rural areas in NZ, recruited 286 through single health facility. N=169 Females and with 67 aged 50 + and 117 males with 63 aged 50+	0	frequent as warranted with the community	0	2 years	Community health workers,, members and local organisations	Interrupted time series prevalence surveys; very small sample size

2.4.3 Workplaces

As diabetes affects many working-age adults, the direct and indirect impact of the disease on productivity can be substantial. Workplaces offer opportunities to identify and intervene on captive sub-populations who share similar age range and socio-economic characteristics, and co-workers who can support each other, with possibly higher program attendance. (118) Two of the community-based replications mentioned earlier had recruited participants through advertising at workplaces.(115, 120) Further, some workplaces have qualified staff, equipment and facilities for health promotion activities. In some countries these settings also facilitate laboratory testing and allow for randomised controlled study designs, thus contributing to better evidence. Three such studies are summarised (Table 2.4).

In Tokyo, a convenience sample of Japanese male workers were recruited through an annual health check-up in an urban clinic and invited to be tested for diabetes risk. All those with borderline glucose levels were invited to be allocated to either a new dietary intervention or a routine dietary advice.(146) The intervention consisted of only one face to face counselling session a month after the health check-up, and a written dietary counselling delivered by post in the second semester of the study. While the study design was a randomised controlled trial, and loss to follow-up was only 10%, outcome assessment did not include weight loss or a dietary measure that enabled comparison with other diabetes prevention programs. A 12-month follow-up fasting plasma glucose change and 2-hour OGTT decrease may be a proxy for diabetes risk reduction but are not sufficient to attribute diabetes prevention in the long-term, as suggested by the article title.

A one-year intervention in a multicultural workplace in USA replicated the US DPP by offering the same number of group and individual sessions delivered by occupational nurses and health promotion staff to co-workers who volunteered after a confirmatory blood test. (147) All physical activity, weight loss and dietary goals were the same as the USA DPP and post-program support was offered on request. Follow-up measurements were taken at 6 months, one and two

years. Improvements were observed at 6 months and 12 months on major outcomes including weight loss of 3.3Kg, but these were not maintained at 2 years. The authors also claim a reduction of 55% in the number of participants that could be classified as having glucose intolerance or diabetes, and on this basis the authors justified offering the program more widely. However, drop-out rate at 2 years was 40% and those completing the program were likely those with highest motivation.

A longer-term study in New Zealand investigated the impact of reduced fat intake on diabetes risk in a population of city workers who were part of a cohort study.(148) The intervention design randomly allocated participants to either a structured education program to achieve a fat-reduced, but otherwise ad-libitum diet, or a usual diet group for 1 year. Annual follow-up assessments occurred for 4 more years. Encouraging results of weight loss of 3.3 Kg and improvements in FPG were reported for the first two years in the intervention group but these only persisted to five years in the most compliant participants. People who did not complete the intervention were more likely to be women, of higher BMI and of Pacific Islander or Maori descent. Overall these three studies illustrate the ease of recruitment but difficulties in retention with a captive audience of workplace volunteers. Attrition rates are high, and results reported are encouraging but possibly reflect outcomes among highly motivated participants.

2.4.4 Churches

As churches expand their role from religion to community programs they are becoming a logical place for education and preventive interventions. However, these groups are heterogeneous in age range and possibly more diverse in lifestyle behaviours as they include entire families; therefore these may be suitable for cluster trials or before-after interventions on entire sub-communities. In theory, church settings constitute good grounds for translation research as there is an existing infrastructure that can be used to deliver sessions, participation can be enhanced via their peer-group, and education can be provided by trained influential

leaders. Likewise, church attendance can increase if the program is timed around religious services. (149) Three of the community-based studies mentioned in the first section under translation efforts used churches as recruitment sources, although the actual interventions were usually delivered at health facilities.(115, 120, 129) Two examples of prevention carried out in church settings are described below (Table 2.4).

A home-visiting screening program was offered to Western Samoan adults in New Zealand; the offer was made at the end of Church services. The diabetes risk reduction program included weekly exercise sessions for the first year and every fortnight for the second year, and eight cooking demonstration sessions.(144) The intervention and control settings were churches located 3 Km apart and headed by the same pastor. Community members trained as aerobic instructor and cooking demonstrator and a nurse educator delivered lifestyle and risk awareness sessions. Blood tests were only performed at the outset to avoid discontinuing participation, and outcomes were not related to diabetes status or clinical parameters, but focused on attendance to sessions, self-reported behavioural changes, and improved knowledge. Despite the absence of weight loss, modest WC reductions in the intervention group, and non-validated changes in physical activity and low-fat meal preparation, the authors concluded that these awareness and behaviour modification programs can reduce diabetes risk. A more recent church-based program in the US screened all 99 African-American adults attending and recruited via church services and the bulletin. This led to enrolment of ten high-risk people participating in a reduced version of the US DPP. This small pilot was modified to a minimum of six group sessions covering nutrition, physical activity and behaviour change.(149). The intervention lasted 7 weeks with six and 12 month follow-up. This before-after study used volunteer medical services for screening and assessment, and free-of-charge church space for the intervention. The authors found good reductions of weight (mean 10.6 lbs) at one year and finger prick sugar levels decreased by an average of 2 mg/dl in the same period.

These two distinct examples illustrate the ends of the spectrum in program standards which are possible in Church settings depending on human and material resources. Both programs used Church services to encourage recruitment. However, the NZ program used local people as instructors, settled for surrogate non-validated measures of risk reduction, and achieved modest results.

Table 2.4 Workplace-based and church-based interventions for diabetes prevention in workplaces and churches. Inclusion criteria, study setting, sample size, and intervention modality (1998-2007)

Author, year, country, duration of intervention	Target group and Inclusion criteria	Setting, recruitment & sample size	# individual	# group sessions and timeframe	# telephone sessions	Duration of follow-up	Program delivered by	Study type and methodological issues	
WORKPLACES									
Watanabe 2003, Japan, 12 months (146)	High-risk men aged 30-75 years, with borderline glucose levels	Annual workplace health checkup in a health examination centre in a city. N=173	1 face-to-face tailored dietary counselling session 1 month after checkup and 1 dietary education session by mail in 2nd semester		0	0	1 year	NR	RCT of new dietary education or usual dietary advice; men only targeted; excluded hypertensive; weight outcome not reported; 10% loss to follow-up
Aldana 2006 (147) 12 months	Pre-diabetic employees of White, Hispanic, and Pacific Islander background	Email invitation via intranet, posted flyers and word of mouth. N=37	4 one-to-one sessions and	a minimum of 16 group sessions required, but 24 offered in first 6 months and a further 6 in the last 6 months		0	2 years	Company registered nurses, health educator & health promotion staff	Before-after study without a control group. Self-selection bias, large loss to follow-up of 40%
Swinburn 2001, NZ, 12 months (148)	Workers aged 40 years and above with IGT or IFG	Workplace cohort study, recalled people with glucose intolerance. N=176 (60 in intervention group)	0	12 group sessions once a month for 1 year		0	5 years	NR	Simple random allocation to fat-reduced diet vs. usual diet; 23% did not complete 1-year intervention and 24% of completers lost to final 5-year assessment

..continued. Table 2.4 Workplace-based and church-based interventions for diabetes prevention in workplaces and churches. Inclusion criteria, study setting, sample size, and intervention modality (1998-2007)

Author, year, country, duration of intervention	Target group and Inclusion criteria	Setting, recruitment & sample size	# individual	# group sessions and timeframe	# telephone sessions	Duration of follow-up	Program delivered by	Study type and methodological issues
CHURCHES								
Simmons 1998, NZ, 24 months (144)	church members at high-risk as determined by blood and behavioural assessment	Recruitment through Western Samoan church services and home visits in urban NZ. N=222 (78 in intervention)	1 for initial assessment	Physical activity: 52 in first year, 26 in second year; dietary advice: 8 group sessions	0	2 years	Nurse educator, aerobics instructor and pastor's wife	Before-after study with a control group; Similar sociodemographic & ethnic make-up of the two groups
Davis-Smith 2007, 7 weeks (149)	Adults 18+ years agreeing to undergo diabetes risk assessment & classified as pre-diabetics	Recruitment through church bulletin and church servie. N=10 out of 150 screened	0	6 sessions over 7 weeks	0	1 year	Volunteer healthcare professionals	Before-after study without a control group; minuscule sample size

RCT= randomised controlled trial

By contrast, the US church study had access to a more generous budget, enabling rigorous implementation of a US DPP replication including clinical and laboratory outcome measures, and subsequently achieved better weight reductions.

Following the description of confined community-based settings, the next section relates to interventions targeting entire populations in developed nations. These have unique characteristics in terms of sample size and multiple approaches, and have often arisen from the success of a pilot project.

2.5 Primary Prevention Examples

Much of the evidence of primary prevention of diabetes comes from observational epidemiological studies where personal choices on diet, physical activity and risky alcohol and smoking habits are measured over long periods of time.(137) The well known MRFIT study, a randomised controlled trial addressing cardiovascular risk factors, provided an opportunity for post-hoc secondary analysis to also examine the favourable influence of the lifestyle intervention on diabetes incidence in a subgroup of participants without impaired glucose tolerance.(138) Likewise, data from cohort studies such as the Nurses Health Study and the Health Professional's Follow-up Study have shown the association between physical activity and reduction in diabetes risk.(141, 150) Large cohort studies have also confirmed the increased risk of diabetes in people reporting high consumption of fat and saturated fat over several years. (66) Observational studies have also shown the role that environmental factors such as availability of infrastructure to enable physical activity play in the development of the disease,(21) and therefore have highlighted possible points for intervention.

Secondary analyses of studies examining prevention of cardiovascular disease have also provided evidence about diabetes prevention in people without hyperglycaemia.(138) Finally, randomised controlled trials have contributed evidence for primary prevention where interventions have been delivered to individuals without IGT.

Four recent examples of implementation of comprehensive primary prevention of diabetes are occurring in Finland, USA, Sweden and Greece and they are summarised below. Large-scale efforts are also being implemented in Australia.

2.5.1 Nation-wide initiatives

Large-scale translation efforts are prevalent in Europe, where at least 25 countries have adopted either guidelines or plans for the prevention and control of diabetes. Greece, Sweden and Finland have proactively published their processes but some are still underway so process and impact results have not been reported yet. Multiple replications of the US DPP have also led to the planning of a nation-wide roll-out through the Young Men Christian Associations (YMCAs) in the US. In Australia the Federal Government has recently encouraged wider dissemination of lifestyle interventions via grants to General Practice networks. While most of these country-wide efforts have not yet published definitive results, description of their strategies is warranted here to compare and contrast the diversity of approaches (Table 2.5). In Finland, following the success of the FDPS, a consortium was formed to implement a nation-wide diabetes prevention program, FIN-D2D.⁽⁸⁴⁾ Part funding was provided by all partners with District hospitals paying for the local expenses of the program, the Ministry of Social Affairs and Health match-funding the implementation process, the Finnish Diabetes Association supporting the salaries of program coordinators, and the National Public Health Institute providing the evaluation costs. ⁽⁸⁴⁾ Five hospital Districts piloted the new prevention model, consisting of three strategies:

The high risk strategy was a health-service based identification of high-risk individuals through opportunistic screening and translation of the FDPS with referral to group-based lifestyle intervention programs embedded in the existing health services.

The population strategy aimed to increase awareness on preventive activities and services offered via media communication and a support network to facilitate the delivery of lifestyle counselling on healthy diet and physical activity.

The early diagnosis and management strategy included large-scale OGTT testing of people at high risk followed by immediate offer of medication and lifestyle guidance.

The results of the impact evaluation have not been published but are due to be released in 2011.

In the US, collaboration with a partner organisation, the YMCA, is expected to lead to more affordable and sustainable delivery of a less intensive prevention program. The YMCA has 2,500 branches within 10,000 disadvantaged residential areas in urban settings and therefore will provide ready access to people at risk. The program has been adapted from 16 face-to-face, individualised sessions delivered over 6 months, to a curriculum of 16 group-based sessions over 4 months without incentives for goal achievement.(140) Physical activity sessions will be delivered by a local YMCA instructor trained in behavioural counselling rather than a specialist lifestyle coach, and the dietary intervention is culturally sensitive and flexible to suit the local context. Self-monitoring tools such as logs and pedometers as well as subsidies for extended membership are also offered. Outside the program participants are encouraged to meet with a partner or as a group at a community location of their choice. This program is still in the planning phase and results will take a few years to emerge.

In Sweden, the Stockholm Diabetes Prevention Program aimed to reduce risk factors in the whole population and decreasing the prevalence of IGT. The strategies went beyond the usual clinical and behavioural approaches and covered environmental modifications, public education, community development, and policy advocacy in the areas of physical inactivity, tobacco use and diet. (86) Funding was obtained from Medical Districts, the County Council and some research institutes. The intervention is delivered by several administrative bodies in the areas of sport/recreation, environmental planning, healthcare, social welfare departments, private food providers and industries, mass media and non-governmental organisations. The evaluation comprises an ecological study examining activity records at each of the recreation venues and population statistics on the incidence of diabetes after 10 years, rather than individual monitoring of physical activity and diet followed by individual assessment.

Table 2.5 Implementation of nation-wide primary prevention of diabetes in developed countries. Study setting, recruitment strategy, size of target group and intervention modality (2002-2007)

Author, year, country, duration of intervention	Target group and Inclusion criteria	Setting, recruitment & sample size	# individual	# group sessions and timeframe	# telephone sessions	Duration of follow-up	Program delivered by	Study type and methodological issues
FIN-D2D Saaristo, 2007, (84)	Findrisc ≥ 15	Primary & occupational healthcare centres, private nutrition or exercise practice, or self-activity groups	1	4 to 8	0	Anytime up to 5 years		Replication study with outcome evaluation throughout 5 years of implementation
Ackermann 2007, USA, 16 weeks (140)	High-risk adults using YMCA services	Recruitment through YMCA facilities	0	16 sessions over 16 weeks	0	ongoing	YMCA fitness instructor	Longitudinal study with ongoing outcome evaluation; possible co-payment may limit access to program and generalisability of results
Andersson 2002, Sweden, ongoing (86)	whole of population	3 Districts in the outskirts of Stockholm, Sweden	0	0	0	10 years	community organisations mass media, government, NGOs,	overarching delivery of activities but evaluation is an ecological study
DE-PLAN Europe 2008, 3 years (142)	High-risk adults, IGT and high Findrisk in 17 European countries	25 sites in 17 countries. N=2633	available depending on demand	All, ongoing	available depending on demand	ongoing	Nurses, dietitians, sports therapists, exercise specialists	Variations in components depending on local need; no control group

The authors acknowledge that the advantage of these wide-ranging strategies is that they can target multiple risk factors and make the program more effective overall. The evaluation of the organised walking campaigns involving volunteers revealed that females engaged in regular physical activity at baseline tended to participate several times a week. The initiative, however, has also found that a third of participants were previously not doing regular exercise, and that finding volunteers to lead walks could be easily recruited.(88)

The European Union has gathered support from service administrators, clinicians and policy-makers from 27 sites in Finland, Austria, Bulgaria, Estonia, France, Germany, Greece, Italy, Lithuania, Norway, Poland, Spain and Turkey to implement replications of diabetes prevention programs.(142) This concerted DE-PLAN effort has adopted a semi-standard approach with a single, low-cost diabetes risk screening tool (The Findrisc), followed by staff training in the delivery of culturally appropriate intervention program in primary care, and recruitment of high-risk individuals into the lifestyle intervention. The flexibility to translate and adapt intervention components seems to be the key to the wide interest expressed. A grant agreement serves as seeding funds for the three-year intervention, and this is supplemented with a commitment to ongoing participant follow-up using either face-to-face, telephone, post, internet, or multimedia to offer booster intervention sessions according to local need.

The overall initiative also comprises process, impact and economic evaluation, following agreed protocols. While screening has covered over a quarter of a million people, recruitment so far has only reached just over 6,000 individuals. When available, results from all participating centres should inform the feasibility, barriers, success factors and effectiveness in large-scale implementation across cultures and budgets. Only the Greek program has published outcomes to date.

The Greece DE_PLAN initiative screened participants via Findrisc questionnaires distributed to patients and their eligible relatives by health staff at workplaces and primary-care centres with a response rate of 50%. The 1-year lifestyle program offered to high-risk individuals included six group sessions on lifestyle by a dietitian, but no formal exercise sessions were provided.

Participation rate was 31%, followed by a 65% completion rate. The program recently reported 1-year weight loss of 1kg (SD 4.7, p=0.022) for 125 completing participants, and very small but statistically significant reductions in FPG and total cholesterol (-0.15+0.69 mmol/l in FPG and -0.37+0.99 mmol/l in cholesterol). The favourable outcomes applied in particular to people with baseline IGT and those with the highest adherence to intervention sessions. (118)

In Australia, the Federal Government has recently encouraged the adoption of locally relevant and flexible diabetes prevention programs through the provision of grants to General Practice networks for formalisation of opportunistic screening of 40-49 year-olds. The strategy comprises patient screening at consultations using Ausdrisk tool, (151) identification of high-risk adults (i.e. Ausdrisk of 15 or higher in the general population or an Ausdrisk score of 12+ among Aboriginal and Torres Strait Islanders), and referral to a local, accredited Lifestyle Modification Program (LMP). These programs are expected to comply with the draft national standards endorsed by the Council of Australian Governments (COAG) using facilitators who have met core competencies to deliver them. The COAG standards accept a minimum of six-months program duration and adoption of a minimum dataset with consistent reporting requirements. (152) Maintenance of an ongoing program is encouraged through service reimbursement for GPs through the MBS items #713 or #717 and for participants on completion of both the intensive phase and full program. To date, several Divisions of General Practice in New South Wales, Victoria and Western Australia have taken up the challenge and lifestyle service providers are registered in every State and Territory. (153)

Variations in approach are observed. In the State of Victoria, Australia, the main components are six face-to-face group sessions, but telephone lifestyle coaching is offered to those unable to attend. (154) A comprehensive example of whole-of-population-level initiative is 'Go for your Life', where community sports for adults and children are coupled with school food services policies, and public advocacy. (155) An evaluation of the effectiveness of another Victorian program, 'The Healthy Life Course' delivering six group sessions to people with proven pre-diabetes used a randomised controlled trial design, with the control group (20% of those

eligible) receiving usual care before being offered the lifestyle intervention. (156) Participation rate in the intervention was around 38% of those eligible and the evaluators concluded that the intervention group achieved improvement in biochemical, anthropometric and cognitive parameters on completion of the program superior to those observed in the group receiving standard care.(155) In Western Australia, a consortium of The Cancer Council, Heart Foundation, Diabetes WA and Health Department have started a free online initiative that can be accessed by people who do not want to or cannot attend group interventions.(157) The Diabetes Prevention Program in NSW is a primary and secondary prevention initiative in three Divisions of General Practice and is the core subject of this thesis. Details of the Program are described in Chapter 4 and results are presented in chapters 5 to 9.

2.6 Discussion

The rigorously designed reference lifestyle trials demonstrated the feasibility of substantial reductions (>28% and up to 68%) in diabetes incidence through structured lifestyle interventions in several countries. Weight loss of over 4 kg appears to be a critical success factor in the European and American studies whereas dietary and physical activity change regardless of weight loss appear to contribute to risk reduction in the Asian studies. The combined diet and physical activity intervention generally showed better results than the individual components or medication intervention. While this is encouraging, real-life interventions are characterised by a reduced ability to deliver intensive interventions.

Efforts to implement large scale primary prevention of diabetes and to replicate smaller scale secondary prevention interventions are occurring in many settings. Secondary prevention replications have been characterised by multiple interpretations according to local context. Two research issues remain problematic: the lack of comprehensive process evaluation, and the lack of publication of impact results to date. Many secondary prevention programs only provide limited evidence using weak research designs.(158) Some evaluations were based on population-level surveys rather than individual follow-up; others used sample sizes that were

too small to detect significant effects . While the seven community-based programs tended to show weight loss, the mean estimates were often not significant. Further, two of the three studies reporting the greatest weight loss used only brief follow-up of four to six months. (118, 120) Changes in FPG levels were unconvincing due to the small effect sizes and confidence intervals including 'no effect'. More detailed evidence from larger studies and longer follow-up periods are required before effectiveness can be confirmed.

As will be discussed in chapter 6, the term 'program fidelity' denotes the level of alignment of the actual delivery of a program and the intended protocol rules.(159) The fidelity of replication of reference trials is not high when whole-of-population approaches are used, as observed in the rural community examples. In the indigenous settings, culturally-relevant initiatives are preferred. In rural areas, low literacy, lack of resources and poor access to healthcare may minimise the potential benefits of interventions. (145) Factors related to the program failure among Pima Indians included low attendance. In the Australian Aboriginal example, lack of change (i.e. no improvement or deterioration) in some prevalence parameters over time could have been due to the different sample composition at baseline and follow-up. No cause-effect can be attributed to the program due to the interrupted time series design not linking individuals from one data collection time point to the next. The reduction in diabetes prevalence in the Ngati Maori setting cannot be attributed to the intervention due to the cross-sectional nature of the data collection at the population level, the absence of a control group, the low response rate to the survey (50%), and the bias in younger, more motivated individuals achieving the expected changes. The rural India program was positive but very short-term, so no conclusions can be drawn about the sustainability of program effects.

The lack of fidelity of community-based intervention is not necessarily a problem. It could be argued that effectiveness within local communities is valuable and worthwhile based on practical applicability. In fact, some have recognised that the conceptual models for diabetes prevention should only be taken as a guide for researchers, as adoption has to suit the local context in each setting if appropriate reach of the target group, generalisability and long-term

sustainability are to be achieved. (111) However, variations in the intervention approaches should not completely disregard the original efficacy studies. A balance between methodological rigour and reinvention in the local context is required, and this is not specific to diabetes translation research.(111, 160)

Evidence of effectiveness from workplace interventions is scarce, sample sizes are small, and samples are biased due to self-selection at recruitment and non-systematic attrition towards the end of the programs. Hence, external validity and generalisability cannot be confidently confirmed.

The evidence generated by translation research in church settings often reports small sample sizes, pre-experimental study designs, and short duration of follow-up. The potential benefits of an expanded church-based program, based on results of the pilot with African-American church members, where weight loss was maintained at 12 months needs to be replicated when implementation occurs at larger scale in multiple church-based settings.

Primary prevention efforts have required partnerships with different community, government and academic sectors and large investments; above all, considerable coordination. In the Finnish nationwide initiative there was a core recommendation on program components but the model allows for adaptation to suit locally relevant needs. This, in theory facilitates uptake by others.

The Fin-D2D, however, identified potential barriers in the process evaluation including low commitment from some service providers, lack of skills for delivery with program fidelity, possible absence of project leadership and heterogeneity of data collections and computer systems that may hinder evaluation efforts. (84)

In the US nation-wide replication through YMCAs, the advantage of having program outlets within a short distance of disadvantaged populations makes it a geographically accessible program.(140)The cost of this adapted program is estimated at about US\$300 per participant, compared with US\$1,400 for the original personalised intervention, which is also encouraging for funding bodies. Yet, the ability for and willingness for co-payment by eligible adults is still

debatable, and if this co-payment is implemented, may limit access to the program and generalisability of results.

The Stockholm prevention program covers all the ideal components from clinical intervention to environmental modifications and involvement of the Media, volunteers, multiple funding bodies and research institutes. It has also conducted several ecological studies to monitor its impact at the population but it does not enable the study of association between program components and their individual impact. Further, the ability for replication and coordination of this program in a less developed setting could be reduced, and its cost might also be prohibitive.

(86) Also in the nation-wide context, the flexibility of the Fin-D2D model also allowed for relevant and comprehensive strategies to cater for local need. The Stockholm DPP and Greece DE-PLAN were also customised, both in terms of approaches and partnerships. The Athens-based program reported low participation rates from high-risk people, with IGT cases and younger people more likely to join. The preliminary results from the Greece DE-PLAN may only reflect effectiveness among the most highly motivated members of the target group. The overall weight loss was only modest by comparison with the FDPS.

Secondary prevention efforts in Australian settings are widespread from urban healthcare settings to indigenous, community-based programs. Evaluators of some of these have identified several problems with recruitment such as the 'pre-diabetes only' barrier, the OGTT barrier, the RCT design barrier and the literacy barrier to follow instructions in group sessions. While no nation-wide primary prevention program is being coordinated as a one strategy, discrete initiatives have been developed over time. The COAG guidelines offer a generic model for primary and secondary prevention with minimum standards to cater for low-resource settings.(152) Examples of these are the Physical Activity Guidelines, the Australian Nutrition Guidelines for Adults and Children, the Australian Guidelines to Reduce Health Risks from Drinking Alcohol, the food labelling regulations as part of the Food Standards, the school canteen guidelines and internet resources for parents and teachers, the diabetes screening MBS items and the Measure-up campaign.(161-165) There is still scope for policies or regulations to

address the problem of affordable city planning to enable access to physical activity venues by the general population and in particular, by disadvantaged groups.

Results of these community programs are mostly forthcoming. The Finnish D2D results may shed some light on effectiveness and process evaluation. In Australia and Stockholm, results from systematic evaluation of outcomes do not appear to be published yet.

2.6.1 Barriers for identification of high-risk people

Two main approaches are used to identify people at high-risk. First is identifying blood glucose levels in the impaired but non-diabetic range and therefore suitable for secondary prevention. Second, is a quantitative risk assessment using a questionnaire that generates a numeric risk score. This is more suitable to identify high-risk populations for primary prevention. A third approach could be analysis of relevant population data. Taking blood specimens from entire adult populations or population subgroups to detect diabetes risk or undiagnosed diabetes may be costly and impractical, and would likely yield high refusal rates. In the Australian Diabetes, Obesity and Lifestyle Study for instance, 44% of eligible people either refused to attend the biomedical exam outright or did not attend the appointment for blood tests after agreeing in principle.(57) Less invasive alternatives such as population-based diabetes risk assessment tools to identify the level of risk are widely used in the first instance,(53, 65, 151) but these need to be followed by confirmatory blood tests in a smaller number of individuals to minimise false positives and false negatives due to poor reliability of the self-reported data (80, 166)

Screening using risk assessment tools can be done systematically or opportunistically. While in 2003 the US Preventive Services Taskforce recommended against population-based screening of adults to identify pre-diabetes states,(167) in 2004 the American Diabetes Association (ADA) developed the opposite recommendation, that there was sufficient evidence to recommend targeted opportunistic screening of adults at risk .(82) The Centres for Disease Control (CDC) also proposed identification of these high-risk people through opportunistic screening in the clinical setting; that is, when patients in the above risk categories consult for an unrelated condition.(168)

The main limitations of screening opportunistically, according to ADA, were the lack of evidence that early identification and treatment would impact significantly on morbidity and mortality in the long term, the absence of a systematic and ongoing screening strategy, and the unconvincing evidence of cost-effectiveness available at the time. Other potential impediments for the success of opportunistic screening according to CDC were the preferential identification of people of privileged socio-economic status, with corresponding chances of missing people at risk who do not access the health system due to lack of insurance coverage. (168)

The secondary prevention efforts based on lifestyle interventions for people with impaired glucose regulation in clinical settings is presented in Chapter 3 as directly relevant to the Sydney Diabetes Prevention Program (Chapter 4), the focus of this thesis.

2.6.2 Barriers for implementation

Overall barriers for implementation and dissemination of diabetes prevention activities can be summarised in three categories: program-related, participant-related and system barriers.

Program-related are those inherent to the program conditions for staff delivering or evaluating the interventions. Application of lifestyle recommendations and demonstrated replication of clinical trial approaches in routine clinical practice often appear to be hindered by lack of resources or reimbursement,(169) lack of practitioners' time or skill, (170) and practical difficulties with recruitment. As will be seen in chapter 6 of this thesis, qualitative observations during the Sydney program experience have shown that comprehensive documentation on the feasibility, effectiveness or cost of replications of lifestyle intervention as part of routine clinical practice can be difficult.

Patient barriers for implementation range from personal or work-related reasons, to the presence of underlying conditions and their associated medications, to lack of readiness for change due to the requirement of adoption of several behavioural changes simultaneously rather than gradually introduction into their lifestyle.(171) Poor patient information retention due to the complexities of the transition between awareness, motivation and action has also been identified.(172) Recruitment into community-based prevention programs can also be

limited by participants' willingness to accept program conditions such as blood tests. In particular, the 2-hour OGTT, and the requirement for a second, confirmatory OGTT.(104) One of the programs in a church used only finger-stick glucose measurements (149) and the other also conducted in a church confined their outcome measures to description of behavioural achievements to avoid drawing blood from participants.(144) Another reason for poor participation was the inability to blind participants to the study arm, which led to discouragement and 'contamination' of information in the control group, whose members started their own exercise program. (144)

From the systems perspective, an important barrier for primary prevention is the difficulty in "selling" the concept to funding bodies as the costs are generated immediately but the benefits are mostly observed long-term and are measured in non-event terms, i.e. number of people not developing the disease.(173) Finally, another system obstacle is the need to enable people's healthy choices once they are ready for a lifestyle change. Environmental modifications to enable physical activity need to supplement education and counselling. This is an important determinant of sustainable behavioural change, in particular for people in financially disadvantaged groups. Overcoming these infrastructural barriers for implementation of primary prevention at the population level requires heightened public awareness, enforcement of associated policies, and political commitment for substantial ongoing funding. Some have gone as far as proposing sustainable funding from government taxes (positive or negative) on the fat components of diet, just as there are taxes on cigarettes and alcohol.(21, 80)

2.6.3 Success factors

By contrast, primary prevention initiatives, i.e. those interventions targeting people with normal blood glucose who have other risk factors for the disease, can be successful if they are associated with a community and policy supports. Community factors known to contribute to sustainability are initiation by and continued involvement of community members, establishment of partnerships with existing community groups, involvement of community members in focus groups to decide on the best times to deliver the interventions, making the

intervention ongoing, and flexibility to cater for different levels of need. On the policy side, legislative support, involvement of industry parties, support for mass education, advocacy from respected members of society, and shared responsibility by government, industry and consumers are identified as predictors of success. (173)

Other factors identified as conducive to success in primary and secondary prevention are the option for participants to achieve the recommended 30 minutes a day of moderate-vigorous physical activity through short bouts or in one long session of 30 minutes/day, and their ability to do home-based rather than clinic-based or gym-based physical activity. (119, 171)

Location and timing of program activities and assessments at a suitable venue also emerged as a success factor in community settings. For instance, to ensure high turnout, church-based interventions made efforts to conduct all activities at the church near church-service times, and workplace interventions conducted testing and delivered interventions in nearby health facilities. Conducting culturally sensitive and appropriate, individualised sessions was a success strategy used in the US DPP and this approach was also reported in the rural India and Pima Indians studies (95, 135, 145) and it is planned in another study of Indians residing in Atlanta. (133)

Nation-wide programs incorporated a multi-strategy approach spanning group-based health service intervention, community-wide education, subsidies for lifestyle products or services and environmental modifications in neighbourhoods.(86)

Studies addressing process of implementation and translation to real-world settings generally do not report a dose-response relationship between attendance at individual or group-based sessions and outcomes. However, reduction in the number of sessions received by participants may have been a factor in the relatively high attendance; unfortunately this can also translate into smaller effects being observed. As the original US DPP established a positive relationship between attendance and outcomes, but prescribing 16 episodes of intervention seems unrealistic, more evaluations are needed in the community-based translation studies to set the minimum and optimum threshold for the number of sessions offered in real world programs.

Finally, it is acknowledged that the identification and recruitment of subjects who generate the biggest impact may have been the clue to why secondary prevention appeared to yield better results than primary prevention examples. Selecting participants more amenable to change could have made the secondary prevention interventions appear more feasible and cost-effective than targeting larger groups with lower absolute risk and less motivation to change. (174)

2.6.4 Lessons learnt

Preventive activities must tackle more than one risk factor simultaneously(175, 176) and a combination of primary and secondary prevention initiatives could be the key to reducing the diabetes 'epidemic'.

Translation of randomised controlled trials into real-world conditions requires practical considerations of the success factors and barriers for implementation learnt from replication studies in churches, workplaces and entire communities. Many program variants have been implemented to make lifestyle interventions available to a broader group of at-risk people who could benefit from them. These are seen as necessary to make these interventions more affordable and sustainable in a 'real-world' environment characterised by financially constrained health systems and competing priorities for both patients and service providers. Possible obstacles that need attention can be classified according to program stages into barriers for identification of risk and implementation barriers.

The positive findings of the review on whole-of-population studies showed many nations were committed to halt the diabetes epidemic in future generations. The World Health Organization recognises, however, that major environmental modifications are essential to facilitate appropriate choices by individuals (177) and this aspect has not been widely adopted by all nation-wide efforts, including Australia. However, it appears that most effects expected from community-based replications will be smaller in magnitude than the achievements reported by the reference trials.

2.7 Conclusions

In summary, community-based studies often reported the conduct of population-wide screening for identification of high-risk groups for intervention. Inclusion criteria were very similar among secondary prevention programs, with some having more relaxed requirements than the original reference trials. The socio-demographic and clinical baseline characteristics of participants in all community-based replications across settings are heterogeneous. That is, they have tried to reach diverse subgroups.

Some programs concentrated on the middle aged, others on any age above 10 years. Selection of target groups recruited in programs also varied from strictly admitting people with IGT, to enabling enrolment of people with one or more of the non-modifiable risk factors: family history, ethnic background, female sex, personal history of gestational diabetes. Other studies allowed any relevant combinations of modifiable risky lifestyle behaviours such as physical inactivity, poor nutrition, smoking and hazardous alcohol consumption. Consequent on program flexibility has been the variation in implementation, and possible dilution of the effectiveness seen in studies with people at lower levels of risk. Pilot studies have tended to be small and under-powered. This has limited the ability to further distinguish sub-groups that might benefit most from diabetes risk reduction programs.

Importantly, there is a need for systematic conduct of evaluations and publication of results to continue building the evidence for effectiveness [or lack of] of diabetes prevention in routine settings. With the current level of heterogeneity of designs, sample sizes and outcome reporting, it is not possible to identify map the most effective intervention components to particular settings.

The next chapter will discuss findings of a systematic review of diabetes prevention interventions in clinical settings, to set the scene for the evaluation of the Sydney Diabetes Prevention Program.

Chapter 3.

Replication Of Diabetes Prevention In Routine Clinical Practice

Summary

This chapter is based on a paper published in a peer-reviewed journal (BMC Public Health, 2010;10:653). The paper argued that the clinical effectiveness of intensive lifestyle interventions in preventing or delaying diabetes development in people at high risk has been established from randomised trials of structured, intensive interventions. However, the challenge is to translate them into routine clinical and community settings. The aim of the paper and this chapter is to review whether lifestyle interventions delivered to high-risk adult patients in routine clinical care are feasible and effective in achieving reductions in risk factors for diabetes. This paper is highly relevant to this thesis as a contribution to current knowledge on feasibility and impact of lifestyle preventive interventions. It justifies the need for further translation studies to supplement the available evidence of effectiveness [or lack of] of lifestyle interventions outside research settings. The Sydney Diabetes Prevention Program is a translation of the lifestyle interventions into routine general practice in Australia, aiming to ascertain whether real-life patients at risk can benefit to the same extent as subjects in the reference trials.

To this end, an extensive search of the peer-reviewed and grey literature was conducted for English-language articles published from January 1990 to August 2009 for the replication in clinical settings. The review included RCTs or before-and-after (with or without a control group) studies of lifestyle interventions with the stated aim of diabetes risk reduction or diabetes prevention conducted in routine clinical settings and delivered by healthcare providers such as family physicians, practice nurses, allied health personnel, or other healthcare staff associated with a health service. Outcomes of interest were weight loss, reduction in waist circumference, improvement of impaired fasting glucose or oral glucose tolerance test results, improvements in fat and fibre intakes, increased level of engagement in physical activity or reduction in diabetes incidence.

Studies of replication in clinical settings yielded 12 suitable for inclusion in the systematic review and four of them were suitable for meta-analysis. A significant positive effect of the interventions on weight was reported by all study types in routine healthcare. The meta-analysis showed that lifestyle interventions achieved weight and waist circumference reductions after one year. Changes in dietary parameters or physical activity were generally not reported by replication in clinical or community settings.

Most studies assessing feasibility were supportive of implementation of lifestyle interventions in routine clinical practice but they appeared to be of limited clinical benefit one year after intervention. Thus, despite convincing evidence from structured intensive trials, this literature review showed that translation into routine practice had less effect on diabetes risk reduction than the intensive trials did.

3.1 Background

As seen in chapter 2, evidence of the efficacy of lifestyle intervention to prevent diabetes under optimal, well-funded randomised controlled trials has built up over the past two decades. By contrast, the feasibility and effectiveness of these interventions (or less intensive adaptations) under 'real-world' conditions does not appear to be widely published. Implementation research investigates the success factors for integration of evidence-based interventions in particular settings and discusses its adaptation to the local context. (108) In routine clinical practice, implementation of evidence-based recommendations is not necessarily associated with a publication of findings, hence achievement of these adaptations as an integral part of routine primary care is not systematically documented. This chapter fills that gap by contributing a synthesis of the methods and findings from a comprehensive search for translations of diabetes prevention in the published and unpublished literature.

The review in this chapter will address two main research questions:

- Can lifestyle interventions (physical activity, nutrition or combination of both) be replicated in primary healthcare? and

- Can the outcomes of large clinical trials on which the intervention is based be replicated in routine clinical practice in real-world healthcare settings?

Hence a systematic review of the literature was conducted and this chapter presents a summary of intervention types and outcomes in the routine clinical context and examines the feasibility of transferring the diabetes prevention research to real-world settings. The review assesses the extent to which outcomes from clinical trials of lifestyle interventions using physical activity and nutrition to lower diabetes risk have been successfully replicated in routine clinical practice. A brief version of this chapter was published in 2010 and is presented in Appendix 3.1.

3.2 Methods

3.2.1 Literature search strategy for clinical practice based replication studies

The search was confined to English language articles published between January 1990 and August 2009. The electronic sources searched included MEDLINE, PubMed, The Cochrane Library, Google Scholar, CINAHL and EMBASE. The search terms used were Diabetes, Pre-diabetes, Type 2 diabetes, Impaired glucose tolerance OR glucose intolerance, Lifestyle intervention OR lifestyle program OR strategy, Physical activity OR Exercise OR Resistance Training, Healthy eating OR diet OR dietary modification OR weight loss, Behavioural modification, AND (Primary health care, General practice, clinical practice, routine clinical care), AND (Prevention, Translation OR Translational research OR translational study OR Replication study).

In addition, internet searches and searches of the grey literature were conducted to identify non-peer-reviewed internal reports from government and health services websites and non-government sources. Supplementary sources consulted included hard copy Australian government publications, unpublished internal reports from key informants for non-indexed publications, and hand searches of reference lists from related articles found whether or not they were eligible for inclusion in this review. All of this was supplemented with hand searches of the reference sections of other systematic reviews. (21, 46, 96, 122, 158, 178-191) Only

studies which investigated at least one of the research questions above, and which were consistent with our inclusion criteria below, were considered in this review (**Figure 3.1**).

Direct email contact was established with authors of reviewed articles where if it was unclear from their papers whether the intervention was conducted in a research or community-based or a routine clinical setting. However, due to resource constraints, no attempt was made to contact the investigators whose papers did not report all measured outcomes.

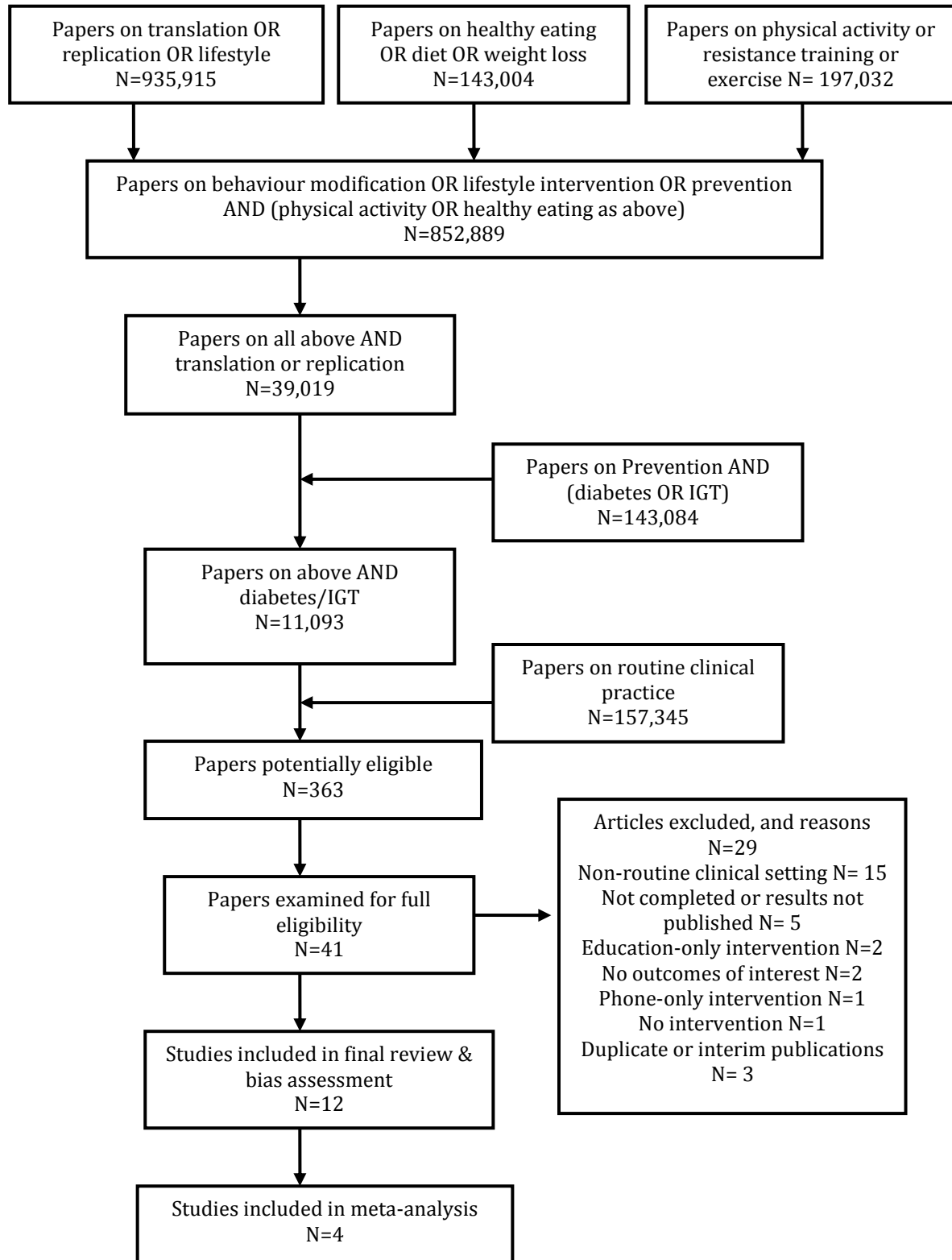
3.2.2 Study selection

The review focused on translational research studies where interventions were based on any of the large reference diabetes prevention RCTs mentioned above. These could be: replication studies in the form of RCTs, before/after evaluations, cohort studies with or without a control group, or interrupted time series analyses, where participants have been exposed to a lifestyle intervention of at least 3 months duration and followed up for at least 3 months. Routine clinical practice was defined as a health service setting providing patient care such as primary health clinics, hospital outpatient clinics or specialist medical centres. After identifying potentially relevant article titles, three reviewers scanned abstracts to ensure that intervention types, target groups and outcomes of interest were covered to confirm eligibility of the publication for inclusion in this review.

3.2.3 Intervention types

Interventions were classified as single (either nutrition or physical activity programs with or without medication), or combined nutrition and/or physical activity programs (structured or unstructured) whether or not they included medication. Structured intervention components were defined as those in which participants received a standard set of sessions with instructions on specific dietary and/or physical activity requirements and goals. In unstructured interventions participants were given generic advice on healthy living without specific goals other than improving diet or physical activity in relation to baseline. The comparison group might be 'no intervention group' or an 'alternative intervention' (single or combined). Prevention programs delivering diabetes education materials only were excluded.

Figure 3.1 Summary of search strategy, selection process and outcomes for systematic review, English language papers published 1990-2009



Likewise, medication-only studies were excluded. Only programs conducted in routine health services, either delivered on-site or in associated facilities, with outcomes measured in healthcare settings by either general medical practitioners, specialist physicians, practice nurses, dieticians, physiotherapists, allied health professionals, community health staff, or research staff attached to the health service, were included in this review.

Interventions either had to be replications or modification of all or some components of the US Diabetes Prevention Program [DPP] (95) or Finnish Diabetes Prevention Study [DPS] (93) as outlined in chapter 2. Alternatively, replications of any other reference trial if they included the reduction of diabetes risk or diabetes incidence explicitly as a goal or objective.

3.2.4 Target group

Participants were adult males or females with any degree of impaired glucose regulation (impaired fasting glucose or impaired glucose tolerance) or with normal glycaemia but at risk of diabetes as determined by risk factors such as obesity or family history. They may have been recruited from the primary or other healthcare patient clientele or from the general population but had to receive the intervention through routine healthcare services. Participants' risk of diabetes may have been determined by a diabetes risk score, either measured or from self-report, and may have had accompanying blood glucose tests to either identify impaired glucose regulation or exclude diabetes before receiving the intervention. Studies including patients with diagnosed diabetes were included in this review only if they were a replication of the reference trials and reported separately on outcomes in participants without diabetes.

3.2.5 Outcomes of interest

Studies were included if they reported at least one of the following main outcome measures of interest:

- Improvement in objectively measured risk factors such as weight loss or waist circumference reduction.
- Metabolic outcomes indicative of diabetes risk reduction (improvement of fasting glucose levels, improved 2-hour post-prandial plasma glucose, or reduction of HbA1c)

- Self-reported or objectively measured behavioural outcomes such as increased physical activity (minutes per day or METS per hour), increased fibre consumption (grams per day or gm per KJ), or reduction of fat intake (% of total energy intake).

The secondary outcome examined was:

Prevention of diabetes (incidence %, or delay in onset or reduction in incidence over a given follow-up time).

3.2.6 Bias assessment

To assess the potential for bias, and given the heterogeneity of studies included in this review, a generalisability and bias assessment tool covering elements of various checklists and resources from the literature was specifically designed for this purpose.

Items examined included among others participant recruitment source, selection criteria, treatment allocation, blindness of outcome assessment, simultaneous collection of data for intervention and control groups, measurement error, subgroup analysis and discussion of study limitations.³ Reference tools used for this design⁴ were STROBE, COCHRANE Collaboration, CLEAR NPT, EQUATOR, PRISMA, TREND and MOOSE.(192-197)

3.2.7 Assessment of study quality

Study quality was assessed and graded on the following binary criteria: (1) evidence of assessment of risk for diabetes at enrolment; (2) explicit eligibility and exclusion criteria; (3) reported participation rate of at least 50% of eligible people; (4) follow-up assessment rates of \geq 65% of program participants by study conclusion or follow-up; (5) evidence of measurable or

³ Tool is available from the PhD candidate on request in the form of an electronic database structure.

⁴ STROBE is an acronym for the Strengthening the Reporting of Observational Studies in Epidemiology, and is a consensus statement recommending better ways of presenting reports of cohort, case-control and cross-sectional studies. CLEAR -NPT is a checklist containing 10 items and 5 sub-items to critically and systematically appraise the quality of reports of non-pharmacological RCTs. EQUATOR is a network working towards Enhancing the Quality And Transparency of health Research; they have issued several statements, guidelines and checklists for reporting RCTs. PRISMA, or Preferred Reporting Items for Systematic reviews and Meta-Analyses provides a 27-item checklist for use by researchers appraising RCTs. TREND, or Transparent Reporting of Evaluations with Nonrandomized Designs, is also a statement promoting guidelines for improved description of design and methods of non randomized trials. MOOSE is a proposal for Meta-Analysis of Observational Studies in Epidemiology that includes recommendations for graphical summaries of study estimates.

explicit outcome assessment; (6) appropriate statistical methods, including adequate control for confounders (in non-RCTs); (7) explicit intervention components; (8) conclusions supported by findings. A single numeric score giving equal weight to each of the above criteria was used to determine quality. The maximum possible score was thus 8, indicating highest quality.⁵

3.2.8 Statistical analysis

The denominator for the effect sizes was the number of subjects in whom the outcome had been assessed. Given the heterogeneity of designs, length of follow-up and outcome measurements of the available studies, pooling of selected results for a meta-analysis was feasible only for four RCTs reporting 12-month follow-up results.(198-201) The remaining eight studies were critically reviewed but not meta-analysed. For the meta-analysis, changes in means, and tests of heterogeneity between trials were calculated using random effects models. When not reported in individual studies, standard deviations of mean differences in outcome measures were calculated from supplied study participant numbers and standard errors or from 95% confidence limits, either of before-and-after means or from before-and-after differences in mean values. Meta-analysis was conducted using NCSS software version 7.1.1.9 (202) on the four main outcomes of interest: changes in weight, fasting plasma glucose, waist circumference and 2-hour OGTT.⁶

Sensitivity analysis by study quality was not deemed necessary as all four studies finally selected for meta-analysis had a quality score of 7 or 8 out of a possible 8 maximum score. The search did not identify unpublished replication studies of diabetes prevention in routine clinical practice. Accordingly, findings are not expected to be significantly affected by publication bias.

⁵ The PhD candidate conducted the bias and quality assessment of all studies and three other reviewers independently conducted the second bias and quality assessment of some studies each. Two reviewers including the candidate independently extracted results and assessed the statistical analyses and conclusions. The candidate wrote the manuscript and incorporated comments from co-authors.

⁶ Meta-analysis was conducted by comparing mean changes in the outcomes of interest at 1 year. Based on results from the reference trials and the heterogeneous patient pools, the effects were assumed to be not equal, hence the random effects model was used. The p values from statistical tests were two-tailed as no *a priori* direction for the effect was assumed. Forest plots were used to display the confidence intervals.

3.3 Results of the Systematic Review

While 363 study titles appeared to be relevant, after careful consideration of the abstract and methods, 89% of them were ineligible for inclusion. This yielded 41 potentially eligible diabetes prevention studies of lifestyle interventions that included various combinations of diet and/or exercise for diabetes risk reduction or diabetes prevention. Of these, 18 studies were excluded because: their replication of lifestyle interventions were conducted in non-routine clinical settings (e.g. in community settings such as homes, public centres, churches, or workplaces),(116, 120, 127, 140, 143, 144, 148, 149) or in a research setting;(121, 198, 203-207) or they did not include at least one of the outcomes of interest.(208, 209) A further 5 were excluded because they were trials underway and/or had not published results to date,(210-213) or they replicated a reference trial for people who already had diabetes.(214) A further 6 studies were excluded because: the study compared results retrospectively with reference trials without conducting an intervention;(174) the intervention was confined to a diabetes education component only;(146, 215) the intervention was telephone-based only and had no replicated components of the reference trials;(216) or they were either duplicates, companion or interim reports of studies already selected.(217-219)

Differences in presentation of results (e.g. monthly weight change without SD,(220) or BMI change instead of weight change,(99) or FPG ranges instead of group means (99)) precluded inclusion of two studies in the meta-analysis. The study with the largest sample size (221) could not be meta-analysed for estimation of the effects of lifestyle, as both the medication and placebo arms received the lifestyle intervention, i.e. the data presented measured the effects of medication as an adjunct to lifestyle intervention.

The final set of 12 studies covered in this review included 7 randomised controlled trials (including one cluster RCT), 3 before-after designs without a control group and two before-after designs with a control group (Table 3.1). The studies were conducted in 8 OECD countries, and had sample sizes ranging from 58 to 3,304 (median 311), with participant ages ranging from 20 to 79 years; six of the studies targeted middle-aged people only. All interventions combined

physical activity and dietary advice, two studies also included medication as part of the intervention, (201, 221) and all were delivered in routine clinical settings, such as specialist services or hospital outpatient clinics (5), general practitioner consulting rooms (5) or community health services (2). Staff delivering the intervention were usually nurses or allied staff (8/12). The target groups were people at high risk, as defined either by the presence of impaired glucose tolerance, severe obesity, metabolic syndrome or some of its components. Eight of these studies also included normoglycaemic patients and two replication studies included both subjects with and without diabetes and pre-diabetes.

Loss-to-follow up rates in the 12 studies varied greatly, from 7% to 57% (median 14%) but were overall 80% or above in the majority (9/12). Two studies lost about one in four or one in five participants (99, 117) and the largest RCT lost about half its participants, mostly those on the placebo arm. (221) Differential withdrawal rates were also observed in a further three studies, where a larger proportion of drop-outs were observed among either: those at highest baseline risk;(220) those from the intensive arm of the intervention;(201) or in those who perceived a poor response to the allocated treatment.(221)

Table 3.1 Classification of eligible secondary prevention studies by design, target population, outcomes and quality score (1990-2009)

Author, year, reference #	Study Design	Total sample size	Target age group	Country & Setting of recruitment	Inclusion criteria: Normal or abnormal GT	Loss to follow-up rate %	Outcome assessment: Measured OR self-reported	Study Quality score ¹
*Barclay, 2008 (222)	RCT	37	50-85	UK: Single general practice	IGT or IFG	19%	Measured weight, WC, FPG, lipids, self-reported exercise, 4-day food diary	7
Greaves, 2008 (223)	RCT	141	18+	UK: 2 GP surgeries	NGT or IGT	18%	Measured weight, WC and self-reported physical activity	7
*Bo, 2007 (199)	RCT	375	45-64	Italy: Family physician GPs	Metabolic Syndrome	11%	Self-reported FFQ & exercise; Measured FPG, insulin, weight, WC, lipids, CRP	8
*Kosaka, 2005 (200)	RCT	458	Adult males 30+	Japan: Hospital outpatient Clinic	IGT	15.9%	Measured FPG, OGTT, HbA1c, measured weight, lipids	7
Torgerson, 2004 (221)	RCT	3,304	30-60	Sweden: Medical centres	NGT & IGT	57% overall; 48% on medication & 66% on placebo	Measured weight, WC, FPG, lipids, serum insulin, fibrinogen	7
*Dyson, 1997 (201)	RCT	227	40-60	UK, France: 5 Hospitals	IFG	11%	FPG, OGTT, HbA1c, lipids, measured weight, max O2 uptake, self-reported 3-day food record & physical activity log	7
Whittemore, 2009 (220)	CLU	58	21+	USA: Primary care practices	NGT & IGT	12%	Self-reported exercise and nutrition Measured weight, WC, insulin resistance, lipids	7
McTigue, 2009 (224)	BAC	166	20-79	USA: Primary care practices	Obese, NGT or diabetic	7%	Measured weight	5
Eriksson, 1991 (99)	BAC	181	47-49	Sweden: Borderline diabetes clinic	NGT & IGT	22.8%	Self-reported exercise, max O2 uptake, FPG, OGTT, lipids, measured weight, skinfold, mortality	7
Pagoto, 2008 (225)	B-A	118	Middle age	USA: Academic medical centre	Metabolic syndrome, NGT or diabetic	17%	Measured weight, BP,	3
Laatikainen, 2007 (117)	B-A	311	40-75	Australia: General practices	NGT & IGT	23.8%	Self-reported FFQ, SF-36, K10; Measured FPG, 2hr PG, WC, weight, lipids	7

Absetz, 2005 & 2009 (219, 226)	B-A	352	50-65	Finland: Primary health care centres	NGT & IGT	9.4%	Self-reported 3-day food diary, physical activity, Measured weight, WC, FPG, lipids	7
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BA= before-after; BAC= Before-after with a control group; BP= Blood pressure; CLU= Cluster-randomised trial; FFQ=Food frequency questionnaire; FPG=Fasting plasma glucose; IGT=Impaired glucose tolerance; NGT=Normal glucose tolerance; PA= Physical activity; OGTT=Oral glucose tolerance test; RCT= Randomised controlled trial; WC=Waist circumference.

*Study used for meta-analyses

1 Higher quality score = higher study quality

3.3.1 Types of lifestyle interventions reported

All studies included a combined lifestyle intervention but two eligible studies included a

medication arm in addition to lifestyle (Table 3.2). All dietary interventions were structured while half the physical activity interventions were unstructured. Unstructured interventions cannot be directly compared as it is difficult to measure intensity of exposure, cut-off points for macronutrients, frequency and quality of eating behaviour; it is also and impossible to attempt to identify which component or behaviour was responsible for the outcome. For the purpose of this thesis, and in the absence of equivalent dietary interventions, we will compare the dietary outcomes bearing in mind this shortcoming of published studies.

In adapting the reference trial approaches from either the US DPP (95) or the Finnish DPS (100) into routine clinical practice, seven of the eligible studies reported adapting their components to cater for limitations in practitioner's time and health service budgets. Modifications required for adaptation to real-life settings were reported in 7 of the 12 studies. These included shorter duration of program; delivery of group sessions instead of individual face-to-face counselling (4/7); reduced number and frequency of individual or group counselling sessions to which participants were exposed (5/7); and mixed group and individual program approaches (1/7). Modifications of interventions during the maintenance phase included intermittent support sessions, more economical versions of the resources given to participants, and multidisciplinary teams, either available on site or hired as an additional service. For interventions delivered in a group-based modality, the maximum number of sessions per program was 16, as per the reference trial (95) (median of 6 sessions), but over a shorter period of time. Among the 5 studies reporting delivery of individual counselling sessions, the median number of individual counselling sessions was 13.5. Detailed descriptions of the contents of the group sessions or the phone counselling contacts were generally not published, so despite the similarity in group-based approach, comparisons also need to be viewed with caution.

Table 3.2 Description of eligible secondary prevention studies by lifestyle components and approaches of each intervention

Author, year [reference]	Physical activity program*		Dietary modification*	Face-to-face Counselling		Phone counselling	Outcome assessment		Duration (months)		Control Intervention	Program Delivered by	Outcomes assessed by
	Struc-tured	Unstruc-tured		No. Indi-vidual sessions	No. Group sessions	No.	Object-ive	Self-report	Inter-vention	Follow-up			
Barclay, 2008 (222)		Y	Y	-	6	-	Y	Y	1	6	Usual management from GP or nurse	Nutritional scientist, psychologist, aerobics instructor	Nutritionist, research assistant
Greaves, 2008 (223)		Y	Y	11		2	Y	Y	6	6	Usual care + information only	Health promotion counsellor	Researcher
Bo, 2007 (199)		Y	Y	1	4	-	Y	Y	12	12	Usual care + general verbal information	GPs, endocrinologists, nutritionists	Physician
Kosaka, 2005 (200)		Y	Y	1	16	-	Y	Y	12	48	Verbal lifestyle advice every 6 months	NR	NR
Torgerson, 2004 (221)		Y	Y	54	-	-	Y	Y	48	48	Same lifestyle advice minus medication	Dieticians	Doctors & other PHC staff
Dyson, 1997 (201)	Y		Y	5	-	-	Y		12	12	Once only, written basic lifestyle advice	Dietician, fitness instructor, physician	NR
Whittemore, 2009 (220)	Y		Y	6	-	5	Y	Y	6	6	20-30 minutes with nurse & 45 minutes with nutritionist	Nurses	Nurses
McTigue, 2009 (224)		Y	Y		12				12	12	No intervention	Nurses	Physicians
Eriksson, 1991 (99)	Y		Y	7	-	-	Y	-	12	60	No specific diabetes prevention intervention or no intervention	Dietician, Nurse, Physiotherapist	Doctor
Pagoto, 2008 (225)	Y		Y		16		Y		4	4	No control group	Dieticians, psychologists, exercise physiologists	Physicians

Author, year [reference]	Physical activity program*		Dietary modif- ication*	Face-to-face Counselling		Phone coun- selling	Outcome assessment		Duration (months)	Control Intervention	Program Delivered by	Outcomes assessed by	
	Struc- tured	Unstruc- tured		No. Indivi- dual sessions	No. Group sessions		No.	Object -ive					Self- report
Laatikainen, 2007 (117)	Y		Y		6	Y	Y		8	12	No control group	Dieticians, Nurses, Physiotherapist	Other PHC
Absetz, 2005, 2009 (226)	Y		Y		6			Y	8	12	No control group	Nurse, dietician, Physiotherapist	Doctor, Nurse

Y=Yes, reported NR=not reported GPs=general practitioners

** Structured= Participants received standard set of sessions with instructions on specific dietary and/or physical activity requirements and goals;*

Unstructured= participants were given generic instructions on improved lifestyle or had flexibility to apply them and no specific goal was set apart from improved diet or physical activity in relation to baseline.

Designs often included a control group, with three studies reporting 'usual care', (199, 222, 223) two studies using the 'do nothing' approach, (99, 224) two providing minimalist verbal or written advice, (200, 201) one reporting a reduced version of the intensive intervention, (220) and one delivering exactly the same lifestyle components with the exclusion of medication.(221) A control group was not present in three of the interventions. (117, 225, 226)

While some interventions were delivered with a core intensive phase and an intermittent approach for the maintenance phase, the median duration of intervention was 32 weeks; follow-up periods also varied from 4 to 60 months with a median follow-up duration of 12 months. Delivery of the modified versions of the reference trial interventions was mostly by nurses, psychologists or allied health staff such as health promotion counsellors, dieticians or exercise physiologists alone (8/12) who provided the training, demonstration, counselling or education sessions. Physicians were mainly involved in assessing participants' eligibility, referral and outcome measurement (7/12). Two studies did not report the professional background of people delivering or assessing the participants.(200, 221)

3.3.2 Type of outcomes reported

Reported measured outcomes of interest were weight (12/12), fasting plasma glucose (9/12) waist circumference (7/12), and 2-hour OGTT (3/12) (Table 3.3). Six studies had follow-up periods enabling the examination of diabetes incidence or incidence reduction, with the remainder confined to reporting risk improvement via behavioural modification or improvement in metabolic or anthropometric parameters. Mean weight loss in the first year of intervention varied considerably and was not associated with study types. The largest weight loss of ≥ 5.2 kg was reported by two before-after studies (224, 225) and one RCT (221). The two before-after studies had the lowest quality score, and the large RCT had a high quality score but the greatest attrition rate of over 50%. A moderate weight loss of around 2.5 kg was reported by two RCTs and one before-after study, (117, 200, 222) all of high quality as defined in the methods for this review. Finally, three RCTs and one before-after studies, all with a quality score of 7, reported the smallest weight losses of either 1.3 kg (223) or ≤ 800 g. (199, 201, 226) Based

on study quality grounds, the mean weight loss in the first year for real-world interventions appears to be about half of that achieved in the intensive reference trials.

Table 3.3 Results of measured outcomes and direction of effect reported at the end of the study: 1 year follow-up or less and 3 years follow-up or more (1990-2009)

Author, year, reference # follow-up time	Reduction in diabetes incidence (% , OR, RR)	Incidence of diabetes	Improvement of FPG or 2h PG in mmol/L	% participants achieving \geq 5% weight loss	Mean weight loss Kg	Mean reduction in WC (cm)
Results at one year or earlier						
McTigue, 2009 (224) 1 year	NR	NR	NR	27% of intervention vs. 6% of controls achieved 7% weight loss	-5.2 Kg intervention vs. +0.2 Kg control	NR
Bo, 2007 (199) 1 year	Adjusted OR=0.23 (0.06-0.85)	1.8% in intervention vs. 7.2% in controls	-0.26 mmol/L FPG intervention vs. +0.07 controls OR for IFG=0.22 (0.13-0.39)	NR	-0.75 Kg in intervention vs. +1.63 Kg in controls	-2.55 cm in intervention vs. +1.96 cm in controls
Laatikainen, 2007 (117) 1 year	23% based on weight loss; 40% based on WC reduction	2.2% of IGT or IFG participants	-0.14 mmol/L	NR	-2.5 Kg	-4.2 cm
Kosaka, 2005 (200) 1 year	NR	NR	NR	NR	-2.5 Kg in intervention vs. -0.39 Kg in control	NR
Absetz, 2005 (226) 1 year	NR	6% of those meeting 4-5 goals vs. 3% of those meeting 3 or fewer goals	+0.1 mmol/L \pm 0.6	12% achieved 5% weight loss	-0.8 Kg \pm 4.5 Kg	-1.6 cm \pm 4.8 cm
Torgerson, 2004 (221) 1 year	NR	NR	NR	72.8% in medication + lifestyle vs. 45.1% in placebo + lifestyle	-10.6 Kg in medication+lifestyle vs. -6.2 Kg in placebo+lifestyle	-9.6 cm in medication+lifestyle vs. -7.0 cm in placebo+lifestyle
Dyson, 1997 (201) 1 year	NR	NR	-0.1 mol/L in intervention vs. -0.2 mmol/L in control	NR	-0.4 Kg in intervention vs. -0.2 Kg in control	NR
Whittemore, 2009 (220) 6 months	NR	N/A	Reported no difference between groups, but no data shown	25% interv vs. 11% control		-0.5 cm intervention vs. -0.1 cm control
Greaves, 2008 (223) 6 months	NR	N/A	NR	23.6% interv vs. 7.2% control	Mean difference 1.3Kg	Mean difference -1.6 cm

Author, year, reference # follow-up time	Reduction in diabetes incidence (% , OR, RR)	Incidence of diabetes	Improvement of FPG or 2h PG in mmol/L	% participants achieving $\geq 5\%$ weight loss	Mean weight loss Kg	Mean reduction in WC (cm)
Barclay, 2008 (222) 6 months	NR	N/A	-0.02 mmol/L FPG intervention vs. +0.25 mmol/L control at 6 months	NR	-2.73 Kg intervention vs. -0.3 Kg control	-6.01 cm intervention vs. -1.18 cm control
Pagoto, 2008 (225) 4 months	NR	N/A	NR	30% achieved 7% weight loss	-5.5 Kg in whole sample and -6.5 Kg in participants without comorbidities at 4 months	NR
(Laatikainen) Kilkkinen, 2007 (217) 3 months	NR	N/A	No change	NR	-2.4 Kg	-3.2 cm
Results at 6,4 or 3 years						
Kosaka, 2005 (200) 4 years	67.4% reduction in intervention group	3% intervention vs. 9.3% in control	53.8% intervention vs. 33.9% in control	NR	-2.2 Kg in intervention vs. -0.39 Kg in control	NR
Torgerson, 2004 (221) 4 years	Total intervention group 37.3%; IGT patients 45%	6.2% in medication + lifestyle vs. 9% in placebo + lifestyle	0.1 mmol/L in medication + lifestyle vs. 0.2 mmol/L in placebo + lifestyle	52.8% vs. 37.3%	-5.8 Kg in medication vs. 3 Kg in placebo	w-6.4 cm in medication + lifestyle vs. -4.4 cm in placebo+ lifestyle
Absetz, 2009 (219) 3 years	NR	12% of those with IGT at baseline vs. 1.2% of those with normal FPG at baseline	0.0 \pm 0.8 mmol/L	NR	-1 Kg \pm 5.6 Kg	+0.1 cm \pm 6.4cm

NR = not reported

The proportion of people losing at least 5% of their body weight within the first year of the intervention was not reported in half of the studies. Two low-quality interventions and two high-quality interventions reported achievement of the weight loss goal to be one in three or one in four. (220, 223-225) These had acceptable follow-up rates of $\geq 80\%$ but small sample sizes of 58-170 participants, and three of them included young people 18 or 20 years and above. This precludes direct comparisons with middle aged adults as their ability to lose weight varies depending on many personal and social factors and the presence of underlying conditions. A before-after study of middle aged people reported one in ten achieving 5% weight loss (226) and the large RCT with considerable attrition rate reported 45% of the lifestyle intervention arm achieving the weight goal. (221)

Waist circumference changes was not reported in four of the studies and it was ≤ 3.2 cm in five interventions. The largest waist circumference reductions of 6.0 cm and 9.6 cm were reported by two high-quality RCTs, having 19% and 57% loss to follow-up respectively. (221, 222) The interpretation of these waist circumference changes is difficult as most interventions led to relatively small WC reductions and the possibility of measurement error in people with big skin folds is known to be high. (227)

Diabetes incidence at the end of the first year was only reported in three of these studies, as their main aim was to reduce the risk. The risk of developing diabetes was around 2% in two interventions (117, 199) and 3-6% in another before-after study. (226). Self-reported outcomes of interest amenable to statistical comparison were limited to mean reduction in fat intake as a percentage of total energy (3/12), and changes in fibre intake (3/12). Reductions of fat intake in two RCTs (199, 201) were relatively small ($\leq 3.5\%$) and so were the reported increases in fibre intake (≤ 1.7 g/day). In general, behavioural changes such as modification in dietary fat and fibre or increase in physical activity were not reported by many studies even though some claimed to have monitored them (Table 3.4). Achievement of the physical activity goal varied greatly from 1.7% to 66% increase in the first year. Yet, the heterogeneity of units reported for changes in physical activity (5/12 studies precluded meta-analyses of the mean change in physical activity.

Table 3.4 Direction and magnitude of self-reported outcomes at end of program of any duration (1990-2009)

Author, year and reference #	Improvement in frequency of physical activity /week		Reduction of fat intake Mean reduction in energy %		Increased fibre intake in g/day	
	% achieved goal	Mean change	% achieved goal	Mean reduction	% achieved goal	Mean increase
Whittemore, 2009 (220)	+17% in interv vs. +1% in controls at 6 months	NR	NR	NR	NR	NR
Bo, 2007 (199)		+4.73 MET-hr intervention vs. in -0.26 MET-hr in controls at 1 yr		-2.64% in intervention vs. -0.02% in controls at 1 yr		+1.7g/day intervention vs. +0.17 g/d in controls at 1 yr
Barclay, 2008 (222)	NR	NR	NR	NR	NR	NR
Greaves, 2008 (223)	37.5% interv vs. 27.5% control	NR	NR	Reported successful reduction of total fat and saturated fat but no data shown	NR	NR
Kosaka, 2005 (200)	NR	NR	NR	NR	NR	NR
Torgerson, 2004 (221)	NR	NR	NR	NR	NR	NR
Dyson, 1997 (201)		+0.17 L/min VO2max in interv vs. -0.03 L/min in controls at 1 yr		-3.5% in intervention vs. -1.4% in control at 1 yr		+0.9g intervention vs. -0.7 in control at 1 yr
Eriksson, 1991 (99)	NR	increase of 17% in IGT and 9% Oxygen uptake at 1 yr	NR	NR	NR	NR
McTigue, 2009 (224)	NR	NR	NR	NR	NR	NR
Pagoto, 2008 (225)	NR	NR	NR	NR	NR	NR
Laatikainen 2007 (117)	NR	NR	NR	NR	NR	NR
Absetz, 2005 (226)	66%	NR	48%	NR	52%	

NR= not reported

3.3.3 Study quality findings

While three out of 12 studies justified their sample sizes on statistical grounds, and not all adjusted for potential confounders, the quality of the study designs and reporting overall was good in 10 of the 12 studies included, based on quality criteria scores of 7 or 8 out of 8. Two studies were considered suboptimal, with quality scores of 3 or 5 out of 8 respectively.(224, 225)

Limited generalisability was identified in five studies, where participants recruited were either self-referred healthy volunteers (201) or a convenience sample of males only,(99, 200) or mostly severely obese middle-age women.(220, 225) Two studies reported higher success rates for participants who had already met the goals at baseline.(220, 226) In two studies (224, 225) the intervention incurred charges and out-of-pocket expenses for each session, which lead to differential exposure to intensity and duration of intervention on the basis of participant's ability to pay. Participation rates, for the 8 studies reporting them, were satisfactory (median 83.5%). However, in one of the studies, where the participation rate was ostensibly 100%, the control group comprised all those people who did not participate due to financial reasons (on whom outcome measures were collected, but possible exposure to other risk reduction regimes was not recorded).(224)

3.3.4 Feasibility of implementation in routine clinical care

Only nine of the 12 studies explored whether translation of these trials into clinical care was feasible. Eight concluded that modification of the original trial approaches for adaptation to real life practice made the lifestyle interventions feasible, affordable or replicable in clinical care settings despite barriers to implementation.(117, 200, 220, 222-226) The other study reported that the transferability of the results from original trials to other settings remains questionable, as the positive effect on outcomes diminishes over time.(199)

3.3.5 Meta-analysis results

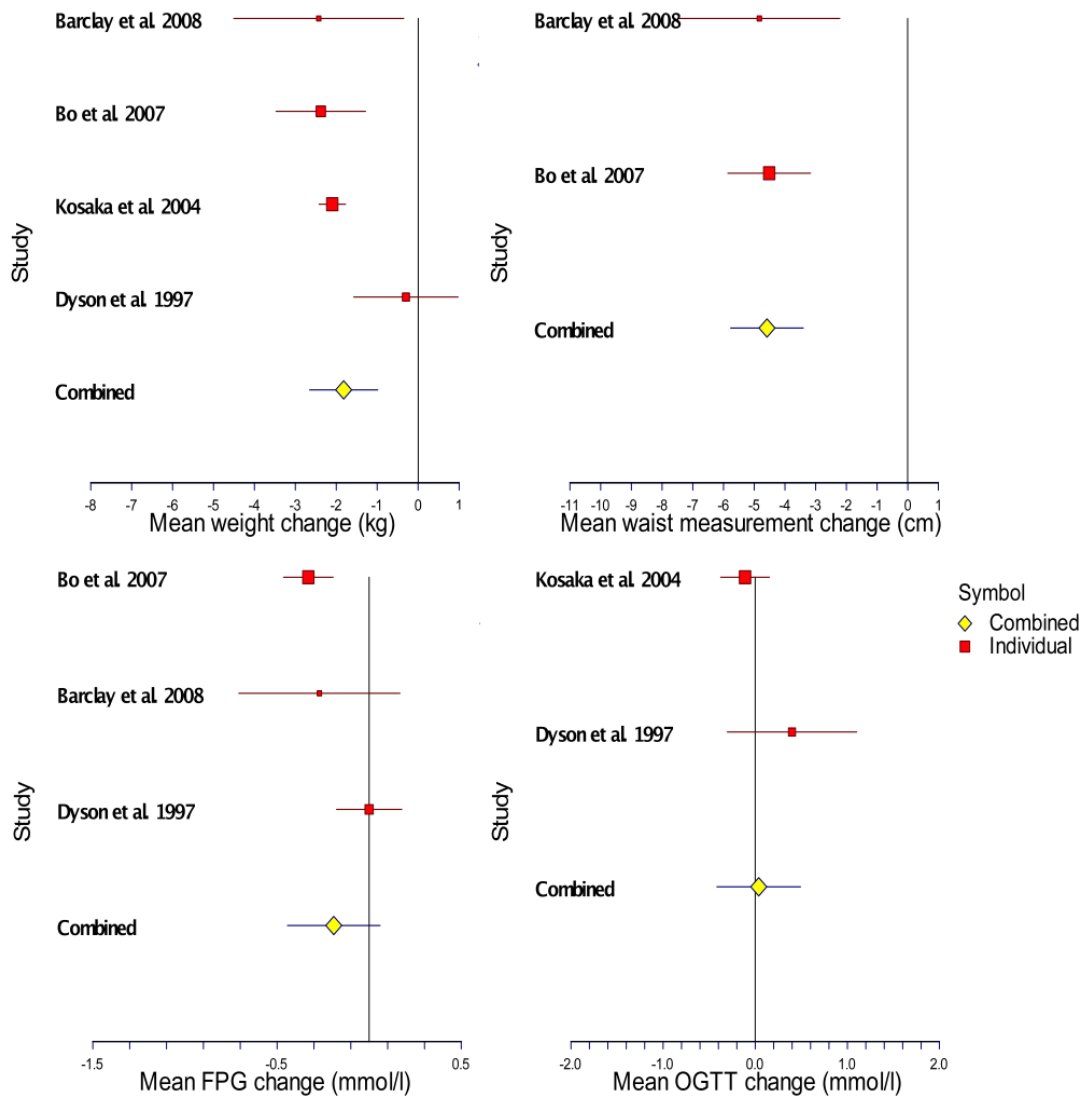
Seven trials which randomised a total of 4,905 participants to lifestyle intervention or control were identified. The shortest follow-up period was 4 months and the longest follow-up period

was six years. Four of these, randomizing a total of 1,129 to intervention or control, reported selected outcomes in comparable units at one year.(199-201, 222) These were (Figure 3.2). I chose not to meta-analyse outcomes at four (221) or six years,(99) as these relate to the maintenance phase of a program rather than the medium term impact and it would be inappropriate to compare them with one-year results.

The systematic review of RCT results at 12-month follow-up shows: mean weight reduction was 1.82Kg greater in treatment than control groups which was statistically significant (95% CI:-2.7 to -0.99Kg), with a range across four studies of -2.4 to -0.3 kg; pooled mean waist measurement reductions in treatment exceeded control groups by 4.6cm, and this was significant (95% CI:-5.8 to -3.4 cm), with the range of -4.8 to 4.5cm across two studies; fasting plasma glucose reduction was 0.19 mmol/l greater in treatment than controls but non-significant (95% CI: -0.44 to +0.06 mmol/l and ranged from 0.0 to -0.33 mmol/l across the three studies; and a non-significant greater increase in 2-hour oral glucose tolerance test result of 0.04 mmol/l (95%CI: -0.49 to +0.42 mmol/l; range across two studies: -0.11 to +0.40 mmol/l). From the above, the interventions so far achieve significant weight and waist measurement reductions at one year but do not significantly change the main metabolic indicators of diabetes risk such as FPG or OGTT.

Four of the 12 studies achieved the greatest weight loss, i.e. 5 Kg or more at 12 months. As only two of these successful studies had optimal quality scores(99, 221) the characteristics of these two studies were further examined to identify common determinants of success in diabetes prevention programs. Common features were RCT design, being based in Sweden, and having long interventions (1 and 4 years) and longer follow-up periods (6 years in Malmo to 4 years in XENDOS). They were not replication studies either, and the frequency of participant contact was amongst the highest, with Malmo providing 12 group sessions and XENDOS providing up to 54 individual counselling sessions.

Figure 3.2 Meta-analyses and pooled estimates of changes in weight, waist measurement, fasting plasma glucose and 2-hour oral glucose tolerance from selected studies at 1 year follow-up



Another common feature was that following initial substantial weight loss, the final outcome after several years of follow-up was only an average of 3 Kg weight loss in both studies. One may conclude that the outcomes of these two studies involve social, cultural and health system characteristics unique to that part of Europe that may not be generalisable.

3.4 Discussion

It is apparent that clinical services are making concerted efforts to translate lifestyle intervention trials into routine practice in several countries, either as pilot studies or as full-scale interventions. All studies included in this review recruited individuals at high-risk of diabetes from IGT, obesity, metabolic syndrome, a combination of these, or based on other standard inclusion criteria. All interventions combined dietary and physical activity and attempted comparisons with previously published outcomes they attempted to match or replicate. The wide range of intervention intensity, duration of follow-up and outcome assessment reflected the availability of service time, staff skills, levels of reimbursement for prevention services, and limited funding and resources for translation research within the health systems.

Results from the lifestyle intervention studies that relied on weight change show promise in achieving some degree of risk reduction. The mean weight reduction excess in intervention subjects over controls of 1.8 kg found here, however, is less than those found in the reference U.S. DPP of the Finnish DPS, which have been of the order of 5.6 Kg and 4.2 Kg respectively.

Results from studies that relied on changes in fasting plasma glucose or 2-hr plasma glucose as a measure of success, were less convincing. However, small changes in FPG after the intervention were also observed in the reference trials (Table 2.1, Chapter 2). Controlled studies meta-analysed here were not successful in showing improved glucose tolerance to a clinically meaningful level that could lead to diabetes prevention.

The independent effects of physical activity and diet and other lifestyle changes in the treatment of pre-diabetes were not examined in many of the studies included in this review. Adjustment for covariates/confounders generally was not conducted or at least not reported in the observational studies examined. It is possible to combine, 'meta-analytically', outcome measures from observational studies but these must be adjusted for confounding, preferably the same confounding variables measured similarly across studies. The meta-analysis excluded all

observational studies and some RCT studies due to the heterogeneity of reported outcome measurements.(228)

The results from RCTs of routine clinical practice presented here would be expected to occur in a real-world non-experimental setting. However, generalisability from the observational studies examined here is limited given the selection bias of some of the intervention and control groups. The participant population expected through routine care services is 'real-life', self-selected even if offered to all those eligible free of charge. The behaviour of people at risk involves refusals, absenteeism from critical measurement time points and self-selection of healthier and/or more motivated patients. In order to achieve results similar to the RCT evidence, these practical issues of non-compliance would need particular attention in a real world setting. The Diabetes-Europe -Prevention using Lifestyle, Physical Activity and Nutritional intervention (DE-PLAN) (142) is developing the structures for a prevention management model which can be implemented into clinical practice. These include 1) the development of an action plan with responsibilities for patients, families, healthcare providers, employees, researchers, etc; 2) the development of a technical handbook for policy-makers on the supporting evidence for prevention and recommendations for program implementation; 3) the development of practice-oriented guidelines covering early detection and standards for quality interventions; and 4) the production of a training curriculum for prevention managers with a focus on nutrition and physical activity but incorporating the social determinants of motivation to participate.(229) Results from this project should shed further light on specific success factors for research translation.

This review also examined the feasibility of implementation of interventions as an integral part of routine clinical care, as this can inform policy on dissemination of diabetes prevention programs or associated subsidies within healthcare systems. To this end, authors' conclusions were sought on whether the given intervention could sustainably be incorporated into usual care provided, for example, without the need for excessive time beyond usual consultation, additional funding or contracting of external staff.

Further, while the outcomes of the two US studies, where participation incurred a fee, probably are the most representative of real life in USA, such market-based rationing of diabetes prevention might not be acceptable in other health systems; such an arrangement certainly will not reach those most in need of such interventions, including low socio-economic groups and people with higher prevalence of risk factors for diabetes.

The national agreement on minimum standards for Australian diabetes prevention programs, (152) and the multiple sites where diabetes prevention is being attempted in Australia as part of clinical practice are encouraging. (117, 153, 154) These programs in Australian general practice, however, are not large scale and not necessarily coordinated nation-wide. More systematic evaluations and publication of those real-world results in Australian settings are also needed to inform future development and delivery of these programs without excessive disruption to routine practice. The Sydney Diabetes Prevention Program, focus of this thesis, has taken into consideration the above evidence and aims to fill some of the gaps through evaluation of process, impact and cost of implementation.

3.4.1 Strengths of this systematic review

From the search it appears that this is the first attempt to comprehensively compile feasibility and effectiveness of translation of diabetes prevention trials specifically for routine clinical settings. The BMC Public Health open access journal accepted this paper for publication in 2010. A purpose-built comprehensive bias assessment and quality scoring system was designed based on individual components of relevance from checklists widely used in quality assessment by others in the literature. This tool with instructions is available electronically for others interested in using it to systematically assess non-randomised controlled studies of real life interventions. The quality criteria allowed for the inclusion of several study types to maximize the chances of identifying relevant diabetes prevention programs. The search was extensive and individual study authors were contacted to either confirm that their study was conducted under routine clinical care or to exclude any translation study conducted in research settings or under simulated clinical care. All authors replied to our queries. Meta-analytic techniques were used

when feasible. The summary of methods used and findings can inform future design and future reporting comprehensiveness of interventions conducted outside research settings.

3.4.2 Limitations

This systematic review was limited to studies published in English language and therefore excluded outcomes from Japanese, Swedish, German, Spanish, French and other European trials which might have contributed to the evidence. (230-234) This review also deliberately excluded studies focusing exclusively on weight loss for prevention of cardiovascular disease. Although not replication trials, some of these studies may have addressed the benefits of weight loss on diabetes risk. The search terms were strict and may have led to exclusion of diabetes prevention in practice which did not use the words “replication” or “translation” but attempted adaptation of components of the reference trials. As the aim of the review was replication in clinical practice, all translation studies conducted in other community settings, such as those discussed in chapter 2, have been deliberately excluded. This could have had an impact on the true estimate of the effectiveness of diabetes prevention in the real world.

Despite the good quality of papers covered in this review, the total number of studies finally included was small; some were exploratory (3 pilots) and many of them had short follow-ups and only modest sample sizes which essentially reflect the financial and time restrictions of real-life interventions in routine clinical practice. We included studies with intervention and follow-up durations of at least 3 months. These are not unusual in routine practice as modifications to duration and intensity of the strict approaches in the reference trials are common in the replication literature. While longer interventions and follow-up times are ideal, in real-world situations longer studies inevitably are affected by sample attrition and attendant generalisability issues. We wanted to include some measurement of short-term impact and avoid attrition bias and selection bias in our assessment of what is being evaluated in routine practice and therefore we allowed for feasibility and pilot studies to be incorporated.

Analyses from before-and-after studies often did not report on adjustment for confounders. More importantly, the reporting of outcomes of interest was either incomplete or disparate in

units of measurement, and thus precluded inclusion of some studies in the meta-analysis, despite the overall good quality of studies included in the broader systematic review. Many weight-loss-only programs and other lifestyle interventions for reduction of cardiovascular disease risk were excluded as they did not specifically mention replication of the diabetes prevention trials. However, we acknowledge that results from these may also be applicable to diabetes risk reduction and, while examples of reviews of these are available in the literature, their focus is beyond the scope of our review.

3.5 Conclusions on Translation Research in Clinical Settings

Published evidence on the effectiveness of diabetes prevention programs in routine clinical settings is limited in numbers, robustness of design, length of follow-up, and availability of reported outcomes. Twelve from 41 potentially relevant studies were included in the review of replication in clinical settings and only four studies were suitable for meta-analysis.

Examination of consistency of findings in routine clinical settings with reference trials using meta-analysis showed that the pooled weight loss in the four RCTs yielded a weight loss of 1.82 Kg at one year (Figure 3.2), compared to the 5.6 Kg loss observed in the lifestyle-only group of the reference DPP trial or the 4.2 Kg reported in the intervention group of the Finnish DPS.

While all studies showed a positive effect on weight loss, only four of the seven studies, 1 RCT and 3 B-A (99, 221, 224, 225) reported weight changes at 1 year of magnitudes comparable to the DPP in the US (around 5 kg, Table 3.5). Excepting the XENical in the Prevention of Diabetes in Obese Subjects [XENDOS] trial,(221) studies reporting proportions achieving a pre-defined weight loss goal of 5% or 7% were less encouraging. Most studies reported half or less of participants than in either the reference DPP trial, where 50% of participants achieved 7% weight loss at 6 months,(95) or in the Finnish DPS where 43% of participants achieved 5% weight loss at 1 year.

The one-year improvements in fasting plasma glucose were similar to the DPP across several studies but were too small to be clinically important; and reductions of diabetes incidence in the two studies reporting them at 12 months follow-up (99, 117) were somewhat less (37% and

23% respectively) than the reductions apparent from the cumulative risk/incidence plots in the Finnish (~70-80%) and DPP (~70%) trials.

The effects of these interventions on fat and fibre intake behaviours at one year were largely unreported and the few studies that reported them did not show substantial improvements. The exception was the Absetz et al. trial which reported half the participants meeting the fibre goal and achieving the total fat intake goal and a third of them achieving the saturated fat goal.(226)

For the five studies in this review measuring waist circumference, all concluded that waist circumference reductions were possible with modified lifestyle interventions, but after 1 year only two achieved reductions of sufficient magnitude that cannot be attributed to measurement error (≥ 4 cm).(227) More consistency is required in the reporting of units of physical activity change and achievement of weight goal (5% or 7%) to enable suitable comparisons.

Despite convincing evidence from structured intensive randomised controlled trials in research settings, this systematic review shows that translation into routine practice has somewhat less of an impact on diabetes risk reduction. Given the heterogeneity and limitations of the studies included in this review, it is also not possible to determine whether the type of clinical setting, the frequency or intensity of interventions, or the modality of the intervention (face-to-face, telephone, written materials, etc) are critical success factors for translation of diabetes prevention programs in routine clinical care. Nor was it possible to assess the separate contributions of individual lifestyle change components to diabetes risk reduction. Accordingly, we cannot yet make specific recommendations on the most effective features of these targeted lifestyle interventions.

Table 3.5 Comparison of selected effect estimates 1 year after the intervention (among studies meta-analysed and not meta-analysed)

Author, year, reference #	Study Type	Effect size for weight ^α	% achieving a) ≥7% or b) ≥ 5% weight loss	% Reduction in diabetes incidence	Effect size for FPG mmol/L	Effect size for 2-hr OGTT mmol/L	Effect for waist circumference (cm)	Effect on fat intake as % of total energy	Effect on fibre intake g/day
Reference Trials									
DPP Research Group, 2002 (95)	RCT	-5.6 Kg	a) 49%	NR [§]	-0.3	NR	NR	-6.6%	NR
Finnish DPS (93)	RCT	-4.2 Kg	b) 43%	NR [§]	-0.1	-0.8	-4.4	-21%	-12%
Meta-Analysed Trials									
Barclay, 2008 (222) ^β	RCT	-2.7 Kg		NR	-0.02	NR	-6.01	NR	NR
Bo, 2007 (199)	RCT	-0.75 Kg		NR	-0.26	NR	-2.55	NR	+1.7
Kosaka, 2005 (200)	RCT	-2.5 Kg		0.5%	NR@1yr	NR	NR	NR	NR
Dyson, 1997 (201)	RCT	-0.5 Kg		NR	-0.1	+0.4	NR	-3.5%	+0.9
Not Meta-Analysed Studies									
Greaves, 2008 (223)	RCT	-0.3 Kg	b) 24%	NR	NR	NR	-1.6	NR	NR
Torgerson, 2004 (221) ^β	RCT	-6.2 Kg		NR	+ 0.2	- 0.4	-7.0	NR	NR
Whittemore, 2009 (220) ^π	ClustRCT	-1.5 Kg	b) 25%	NR	NR	NR	NR	NR	NR
McTigue, 2009 (224)	BAC	- 5.2 Kg	a) 27%	NR	NR	NR	NR	NR	NR
Eriksson, 1991 (99)	BAC	-5.0 Kg		-37%	NR	-1.5	NR	NR	NR
Pagoto, 2008 (225)	B-A	-5.5 Kg	a) 30%	NR	NR	NR	NR	NR	NR
Laatikainen, 2007 (117)	B-A	-2.5 Kg		-23%	- 0.14	- 0.58	-4.2	NR	NR
Absetz, 2005 & 2009 (219, 226)	B-A	-1.0 Kg		NR	+ 0.15	0.0	-1.2 in F +2.3 in M	NR	52% met goal

NR= not reported References to a) or b) indicate comparison to US DPP or Finnish DPS respectively F=females M=Males

α values presented for B-A studies are changes from before to after intervention; values for RCT are differences in change before and after the intervention in the 'lifestyle treatment' group only

§ cumulated diabetes incidence reduction (~58%) reported over 4 and 6 years (US DPP & Finish DPS, respectively)

β values presented as before-after for the lifestyle + placebo group only (excludes effects of medication arm)

π estimates at 6 months

However, based on these findings from routine clinical practice, the trend in the direction of the effects on the four most commonly reported outcomes (weight, FPG, waist circumference and 2-hour OGTT) is positive as expected. The potential effects of a small change could be substantial at population-wide level. The consensus on feasibility of their modification as part of routine care without excessive cost suggest that it is also worth promoting the translation of modified, group-based lifestyle interventions, and conducting more rigorous evaluations in these settings. In conclusion, a significant positive effect of the interventions on weight was reported by all study types in routine healthcare. The meta-analysis showed that lifestyle interventions achieved weight and waist circumference reductions after one year. However, no clear effects on biochemical or clinical parameters were observed, possibly due to short follow-up periods or lack of power of the studies meta-analysed. Studies in non-clinical community settings were usually quasi-experimental and small in participant numbers. Changes in dietary parameters or physical activity were generally not reported by replication in clinical or community settings. Most studies assessing feasibility were supportive of implementation of lifestyle interventions delivered by a variety of clinical health care providers in community settings and routine clinical care.

This literature review suggested that translation into routine practice has a somewhat less effect on diabetes risk reduction. However, those lifestyle interventions for patients at high risk of diabetes had limitations in design, outcome reporting, and heterogeneity in analysis, which preclude the assessment of true clinical benefit one year after intervention. The establishment of a register of translation projects using consistent, measurable outcomes could add more certainty to the effectiveness of routine practice interventions. When more studies with larger sample sizes and data on intermediate end-points become available they could be included in a more comprehensive meta-analysis.

In Chapters 6, 7 and 8 of this thesis, my analysis of The Sydney Diabetes Prevention Program will attempt to close that gap by providing detailed analysis of impact from this larger translation Program using sound methodological design and consistency of outcome

measurement with those reported by others. This will enable more appropriate comparisons with results from reference trials and other translation efforts to answer the questions of feasibility and effectiveness.

Chapter 4.

The Sydney Diabetes Prevention Program Protocol

Summary

The Sydney Diabetes Prevention Program (SDPP) is a translational study delivered through primary health care and with links to the community. This is a collaboration between the Sydney South West Area Health Service, The University of Sydney, three Divisions of General Practice and the Australian Diabetes Council - NSW. The Program plan and materials were endorsed by the University of Sydney's Human Research Ethics Committee.

Males and females aged 50-65 years who attend participating general practitioners in three regions of Sydney were screened for diabetes either opportunistically or via a targeted appointment using the Ausdrisk tool. (151) The screening procedure, inclusion criteria, exclusion criteria and intervention components of the SDPP are described in detail in a peer-reviewed paper (235) Appendix 4.1]. Eligible patients were invited to participate in a 3-month lifestyle modification Program with a 9-month maintenance and support phase. Socio-demographic and behavioural data were collected by computer- assisted telephone interview (CATI) at baseline, and a 3-day non-weighed food diary collected at initial consultation.

Biochemical parameters were tested before enrolment, and waist circumference and weight were measured by lifestyle intervention officers at baseline. The process and impact of this diabetes risk reduction program was evaluated using a pre-post evaluation design. The primary outcomes of the Program impact were weight loss, dietary modifications and increase in physical activity. Secondary outcomes were waist circumference reduction and diabetes incidence. This chapter describes the intervention components and the evaluation plan in detail.⁷ A more comprehensive discussion on the intervention process to date is presented in Chapter 6 along with the protocol for the process evaluation. The short-term impact evaluation is available in Chapter 7. The protocol for the economic evaluation is presented in Chapter 9.

⁷ The evaluation protocol was written in full by the author but its components are presented throughout Chapters 4-9 and their associated appendices.

4.1 Rationale for and Operation of the SDPP

Following the widespread evidence of the effectiveness of structured, intensive lifestyle interventions on reduction of diabetes incidence, and in light of the relative scarcity of evidence of effectiveness in real-world settings (Chapter 2), The NSW Health Department funded this SDPP project as a replication study. The SDPP aimed to translate the goals and replicate the outcomes of the Finnish Diabetes Prevention Study (FDPS) using a more minimalist intervention approach, and determine the extent to which a community-based lifestyle intervention could reach high-risk groups in the target population through screening by general practitioners. Further, the evaluation aimed to assess the feasibility of implementation of a diabetes-risk-reduction intervention program in three different areas of Sydney with differing socio-demographic profiles. Initially there was a formative evaluation to assess the best format for the Program materials and the most efficient to deliver the Program in different areas. Following this, the protocol for the process and impact evaluation were developed. A protocol for the evaluation of implementation costs was also produced.

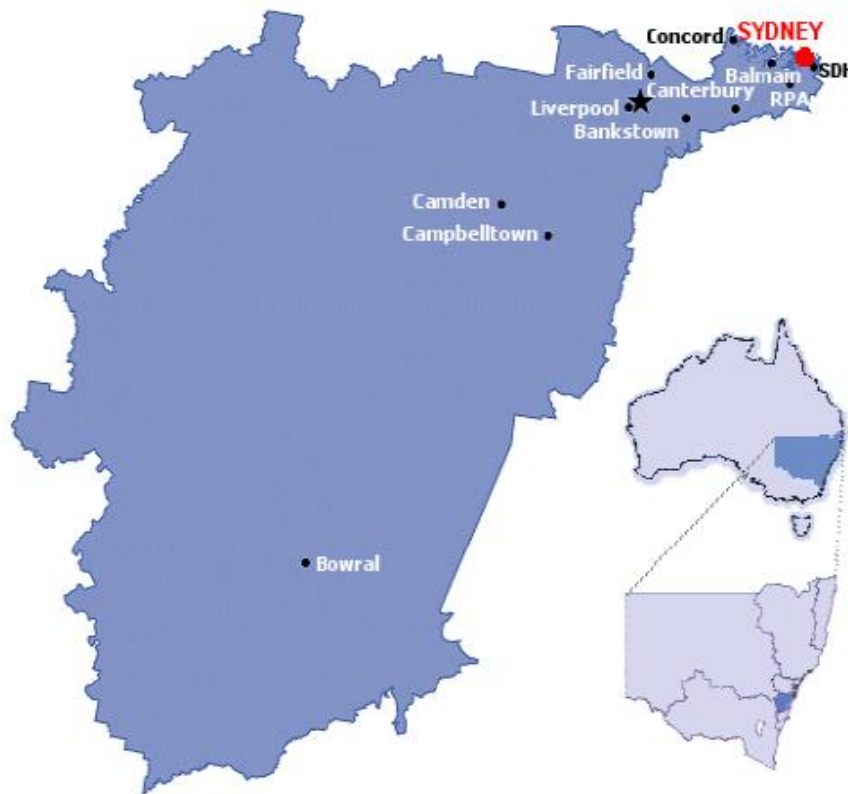
The SDPP was managed by a Steering Committee with representatives from all participating General Practice Divisions, NSW Health Department, BIONE Institute, The University of Sydney evaluators, the health economist partner at the University of Technology Sydney (UTS), and the Australian Council of Diabetes (formerly Diabetes Australia). This group met approximately four times per year. An Evaluation Management Group was also established to carefully plan the evaluation of process, impact and the economic costs of implementation. This group met once per month in the first year and as warranted in the second year.

4.1.1 Target Geographic Areas

The Program was conducted through primary care medical practices within three Divisions of General Practice in different regions of urban and peri-urban Sydney: Southern Highlands, Macarthur and Central Sydney GP Network. All of these were within the catchment area of the Sydney South West Area Health Service (SSWAHS). These areas were selected due to their different geographic locations and the socio-economic make-up of their populations. SSWAHS

covers a land area of 6,380 square Kms, and has a population of 1.3 million residents, with 39% of the population speaking a language other than English at home (Figure 4.1). This makes it the most ethnically diverse Area Health Service in Australia. The Southern Highlands is considered a semi-rural part of the SSWAHS area with a relatively wealthy, mostly Caucasian older population; residents in Macarthur Division are generally younger and socioeconomically disadvantaged; and Central Sydney is an urban Division with a relatively young, multicultural population. It was expected that the three areas would yield diverse high-risk samples to enable evaluation of effectiveness in different real-world settings.

Figure 4.1 Map of the Sydney South West Area Health Service and main localities in the catchment area



This chapter describes the Program protocol, recruitment process and intervention components. Baseline socio-demographic and risk profile of SDPP participants, comparisons of socio-demographic profile with those reported in other similar community-based diabetes prevention programs, and discussion on whether reaching the intended high-risk target group is possible in this setting are covered in Chapter 5.

4.2 Aim and Program Goals

The aim of the Program was to develop, implement and evaluate an evidence-based lifestyle change program to reduce the risk of type 2 diabetes in people aged 50-65 years. There were five primary Program goals adapted from the Finnish Diabetes Prevention Study goals. (93)

The Program goals were set to respond to the following research questions:

- Can the SDPP Increase physical activity to at least 30 minutes per day of moderate to vigorous aerobic and strength training?
- Can the SDPP reduce fat intake to 30% of total daily energy intake?
- Can the SDPP reduce saturated fat to 10% of total fat intake?
- Can the SDPP increase fibre consumption to 15 g per 1,000 kcal (or approximately 30 g per day)?
- Can SDPP participants achieve weight loss of at least 5% within 12 months?

The Program was designed to recruit the majority of participants into a '*mainstream*' cohort, and up to 200 people to be recruited to the culturally and linguistically diverse (CALD) stream: 100 Arabic speaking and 100 Chinese speaking. Goals were the same for the three cohorts but materials and interactions with Program staff were delivered in the relevant languages. This thesis will mainly address the methods and results relevant to the mainstream cohort

4.3 Selection Criteria

Decisions on selection of participating practices and eligible patients took place in 2008, when the inclusion and exclusion criteria were determined by an expert committee as described below.

4.3.1 Inclusion and Exclusion Criteria for Practices

4.3.1.1 Essential Inclusion Criteria

- Medical practices had to be computerised.
- Medical practices had to be able to identify the number of patients on their books aged 50-65 years, who did not have diabetes, and had visited the Practice in the past 6 -12 months.

- Practices had to be willing and able to undertake targeted and/or opportunistic screening of eligible patients.
- Practices had to be willing and able to complete weekly screening and recruitment counts.
- The majority of the practice staff were to be involved in the program (including practice nurses, and receptionists), and available to attend the orientation session.
- Medical practices had digital scales for measuring weight, large tape measures for waist circumference and a stadiometer (or equivalent) for measuring height.
- Medical practices had to have a private room available for measurements to be taken i.e. weight, height, and waist circumference.

These criteria were used to make patient identification, risk assessment, exclusion of people with diabetes, and data extraction possible in a short time and according to a set protocol. The project also required staff ability to track activity for the purpose of the process evaluation, and conduct quality control checks via telephone or email contact. Finally, the equipment and staff skills needed to be standard as far as possible to minimise non-systematic measurement or reporting biases.

4.3.1.2 *Desirable Criteria*

- The Practice had a practice manager.
- The Practice had a practice nurse.
- The Practice could adopt a “whole of practice” approach to the program.
- The Practice had a fax machine.

These desirable criteria would secure a single point of contact with the practice, facilitating communication, filing, document transfer, and speeding up the weekly reports.

4.3.1.3 *Exclusion Criteria*

- The Practice was involved in a program that is in conflict with the SDPP methodology.
- The medical practitioner did not attend the SDPP orientation and training session

The rationale for these exclusion criteria was to prevent any conflict of interest and confusion among patients or staff in relation to the possible management options for people at risk. Further, the program fidelity would not be guaranteed if different doctors were allowed to use different identification, assessment and referral strategies or parameters.

4.3.2 Inclusion and Exclusion Criteria for Participants

Only residents of the Sydney South West Area Health Service (SSWAHS) aged 50-65 years old were invited to be screened to identify their eligibility for the program. The screening process is referred to later in this chapter.

4.3.2.1 Inclusion Criteria

The Program only accepted patients attending selected medical practices whose GP was trained⁸ to participate in the program and

- whose AUSDRISK score was ≥ 15 ⁹ whether or not they were prediabetic
- whose capillary blood glucose (CBG) was < 5.5 mmol/l
- whose Fasting Plasma Glucose (FPG) value was < 7.0 mmol/l and HbA1c was $< 6.5\%$ (note: if available, FPG test results obtained in the last 3 months were also accepted and removed the need for a new blood sample to be drawn).
- whose OGTT was < 11.1 mmol/l (where applicable)¹⁰
- who could read and speak English (only for 'mainstream' cohort participants) and
- who could give informed consent to participate in the program

The Ausdrisk screening was administered at the first contact, before any blood tests were conducted. An Ausdrisk threshold of ≥ 15 was chosen to ensure the highest-risk people were

⁸ GP training was conducted on-site and it included a refresher on diabetes risk assessment, inclusion and exclusion criteria for participants, the use of the Ausdrisk tool, blood test requirements and discussion on standard paperwork to be used for the purpose of referral and evaluation.

⁹ The Ausdrisk score is a sum of points accrued from the presence of risk factors as measured by the Australian Diabetes Risk Screening Tool. A score of < 7 indicates small risk; a score of 7-11 denotes slightly elevated risk; a score of 12-14 indicates moderate risk, and scores of ≥ 15 signal high risk of developing diabetes in the next five years.

¹⁰ pre-diabetes was not a pre-requisite for inclusion in the program as other modifiable risk factors were targeted by the intervention.

recruited as diabetes development was expected to be at least one in seven (or one in three for those with Ausdrisk levels of 20 and above) within five years. As the planned follow-up was only 12-months, any benefit for those at lower risk would take longer to be observed. The threshold for various blood tests was selected for consistency with diabetes diagnostic guidelines in the medical community, as discussed in Chapter 1. Both people in prediabetic or normoglycaemic states were eligible to participate in the preventive intervention.

The language and consent requirement were necessary for practical implementation and ethics approval.

4.3.2.2 *Exclusion Criteria*

The Program was unable to accept patients in the Program if they:

- had been previously diagnosed with diabetes or were newly diagnosed in the course of screening
- had taken Metformin or other glucose lowering medication regularly in the past month
- were taking prescribed weight loss medication (such as an appetite suppressant)
- had undergone gastric bypass or other form of weight loss surgery or
- had a medical condition such as end-stage congestive heart failure, untreated severe aortic stenosis or other structural heart disease, progressive or terminal cancer, multiple sclerosis or a muscle-debilitating disease, severe cognitive impairment or behavioural disturbance, unstable abdominal, thoracic or cerebral aneurysm, unstable coronary artery disease, or malignant arrhythmia.

The above criteria were sensible as pre-diabetics managed with metformin would be contaminating the independent preventive effect of this lifestyle-only intervention. Likewise, people on weight loss medication or post-gastric bypass surgery would artificially inflate the impact of the Program's healthy eating component. Finally, all conditions listed in the exclusion criteria were contraindications for moderate or vigorous physical activity.

Participation in the SDPP was voluntary after written consent and participants were able to withdraw from the program at any point without consequence.¹¹ The date and reasons for withdrawal were documented where possible.

4.4 Screening and Recruitment

Initial risk assessment was conducted using the newly developed 11-question *Australian Diabetes Risk Assessment tool* (Ausdrisk) (151) to assess risk based on age, ethnicity/country of birth, personal history of hypertension or impaired glucose tolerance or gestational diabetes, smoking status, physical inactivity, diet low in fibre, family history of diabetes and current waist circumference (Appendix 4.2). The 5-year risk of developing diabetes was calculated as low (score under 12), intermediate (score of 12-14), or high (score of 15 and above). People who had a risk score of 15 or greater were potentially eligible for referral to the Program and were invited to undertake a comprehensive eligibility assessment.

4.4.1 Assessment of High-Risk Individuals

Those identified as high-risk from the Ausdrisk tool were invited to have a capillary blood glucose (CBG) test. If the CBG test result was <5.5 mmol/l diabetes was considered unlikely and they were immediately eligible to participate in the program. If these people consented to participate in the program they were referred for an FPG and full lipid profile. Those with capillary blood glucose of ≥ 5.5 mmol/l were referred for a fasting plasma glucose (FPG) test and/or HbA1c to exclude diabetes, as well as a full lipid profile. If the FPG was <7.0 mmol/l and HbA1c was <6.5% they were eligible for referral to the program. If the FPG was ≥ 7.0 mmol/l or HbA1c was $\geq 6.5\%$, diabetes was considered likely and therefore these people were ineligible to participate in the program but suitable for referral to a diabetes service.

The World Health Organization (WHO) definition of impaired fasting glucose (fasting plasma glucose of 6.1 to 6.9 mmol/L) and impaired glucose tolerance (2-hour post glucose load of 7.8 to 11 mmol/L) were used to classify abnormal glycaemia. (3) However, people with both pre-

¹¹ A participant information sheet and consent form were given to potential candidates in person after the risk score was confirmed to be high and the study conditions were explained (Appendix 4.3). Written consent was a pre-requisite for enrolment in the Program.

diabetes and normal glycaemia were recruited if they had Ausdrisk scores of 15 or above. The cut-off point for obesity among the mainstream and Arabic participants was 30 kg/m² but cut-off for the Chinese was lower (27.5 kg/m²) selected following the WHO Expert Consultation Group recommendations on appropriate thresholds for Asian populations. (236)

4.4.2 Recruitment Strategies

Divisions of General Practice and the practices within these Divisions were given flexibility to decide on options to recruit participants depending on local circumstances The most commonly encouraged strategies were the following three:

- Opportunistic screening in GP waiting rooms
- Mail out of a letter directly to selected individuals (50 to 65 year-olds) from the practice inviting them to participate in the program
- Use of advertisements and other promotional activities (local newspaper, cinema advertising) encouraging individuals to make an appointment with their GP to discuss their diabetes risk.

4.5 Evaluation Protocol

Before a detailed description of the intervention is presented it is important to explain the types of information documented and highlight the time points where data for the evaluation were collected. This section will summarise the primary and secondary measurements and sections 4.7 and 4.8 will describe the intervention components to be evaluated.

Given the existing evidence from overseas trials on the efficacy of lifestyle modifications in reducing markers of risk for type 2 diabetes, this evaluation assessed the feasibility and effectiveness of a lifestyle modification program in a real-world setting and identified factors associated with good program implementation and delivery. In consultation with the Steering Committee, the Evaluation Management group developed a thorough evaluation plan and data collection systems. The three key elements in the SDPP evaluation were:

- evaluation of the implementation of the SDPP (process evaluation);
- evaluation of the 12-month impact of the SDPP (impact evaluation); and

- evaluation of the 12-month costs and outcomes of the SDPP (economic appraisal).

This evaluation of the SDPP aims to investigate the following aspects:

Process evaluation¹²

- Whether this intervention can be delivered within the primary health care system.
- Whether people at increased risk of type 2 diabetes can be successfully targeted.
- Extent to which the intervention is implemented as intended.

Impact evaluation¹³

- Whether the results of the lifestyle intervention are comparable to those of the trials that inspired them
- Whether it is possible to identify success factors for these programs

Economic appraisal

- Whether the intervention represent value for money

4.6 Research Questions of this Thesis

The following questions will be answered through this thesis:

Process evaluation

- What is the coverage of the Program and did it reach the intended target group?
- What is the fidelity, feasibility and acceptability of the program?

Impact evaluation

- What is the effectiveness of the lifestyle modification program in achieving change in weight, waist circumference, FPG, lipid profile and blood pressure of program participants?
- What is the effectiveness of the lifestyle modification program in increasing total physical activity and decreasing energy intake and fat consumption (total/saturated) and increasing fibre consumption?

¹² Assess implementation of the Program

¹³ Assess the changes in key variables in response to the Program

- What are the predictors of change in participants who changed their lifestyle compared to those who did not change?

Economic appraisal

- What are the costs of planning and implementing a community-based diabetes prevention program and what are the costs per outcome?

These broad questions are further refined into detailed sub-questions in the relevant chapters to document as many aspects as possible of each evaluation.

Chapter 5 addresses the Program reach and Chapters 6 to 9 address the results of the process evaluation, impact evaluation and economic appraisal . This Chapter will deal with the evaluation protocol, activities and measurements used.

4.7 Process, Timing and Role of Lifestyle Officers in Data Collection

Lifestyle officers were involved in data collection from the initial paper-based Ausdrisk tool to the ongoing electronic data entry for initial assessment, follow-up contact and final assessment. They entered data for monitoring of their participants' progress and to enable evaluation by the external team (of which the author was a member).

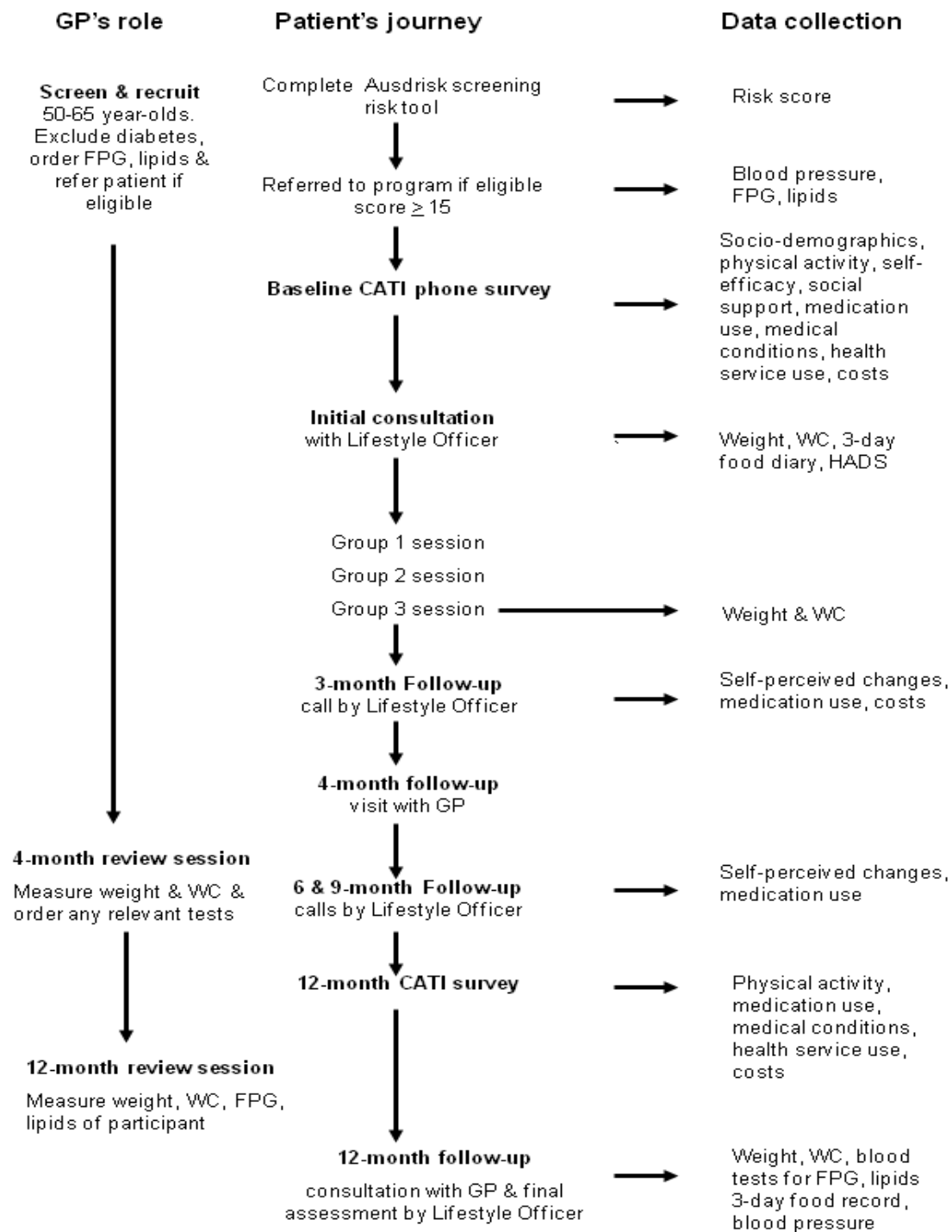
As seen in Figure 4.2, a variety of Program staff collected and entered information from Divisions, participants and clinicians at different points. The clinical and events repository was a centralised, online database used by lifestyle officers during and after contact with participants. In brief, when eligibility was confirmed and patients agreed to take part in the lifestyle intervention, GPs completed the Referral Form (Appendix 4.4). Following this, participants were contacted by a CATI (Computer Assisted Telephone Interview) interviewer to complete a structured questionnaire reporting socio-demographic items, physical activity and health service use. (Appendix 4.5).¹⁴ This occurred approximately two weeks prior to the initial consultation with the lifestyle officer. The interviewers conducted the baseline survey from a CATI facility using standard definitions of intensity for levels of physical activity as

¹⁴ The author trained at least nine interviewers in-house for this purpose, and monitored their initial calls giving feedback until the interviewers built confidence in conducting the telephone surveys unsupervised.

recommended by one of the SDPP expert advisors (Appendix 4.6). Data were entered in a separate database which was later merged for linked analysis.

In addition to personalised assessment and coaching, at the initial consultation weight, height and waist circumference were measured by the lifestyle officer using standard techniques (Appendix 4.7). Participants were then invited to attend three two-hour instruction and demonstration sessions (*The group sessions*) where information was delivered to groups of ten people on average.

Figure 4.2 Patient pathway through SDPP and data collection points: screening, enrolment, attendance at group sessions, contact points and final assessment



CATI= Computer Assisted Telephone Interview

FPG: fasting plasma glucose

GP= General practitioner

HADS=Hospital Anxiety and Depression Scale

WC= waist circumference

All Program goals were covered in each session but each had a different emphasis (Appendix

4.8). Factsheets with a focus on the Program goals were delivered to individual participants at

the end of each session to enable reinforcement of knowledge at home (Appendix 4.9). Weight

and waist circumference was measured again at session 3, which usually took place at week 12 of the Program. Lifestyle officers were also responsible for making the quarterly telephone contacts in order to provide coaching and collect evaluation data via the administration of a standard questionnaires (Appendices 4.10 and 4.11) to document self-reported behaviours and perceived changes to body weight and dietary habits.

Ascertainment of dietary intake (including macronutrient food groups) was based on the 3-day food records delivered by participants at baseline and 12 months (Appendix 4.12). Two weeks before the final 12-month review the CATI interview was administered again to all completing participants. Physical measurements of weight and waist circumference were taken again at the final consultation.

The evaluation design for the culturally and linguistically diverse (CALD) cohorts was developed in consultation with the CALD Working Group. This group comprised of representatives of health promotion, language-specific Division staff, and researchers with expertise in ethnicity and health. The evaluation measures, methods, instruments and processes for the CALD stream were the same as the mainstream program but the tools were translated and the lifestyle officers and survey interviewers spoke the relevant languages.

4.8 Measures and Assessments Used and their Rationale

The specific measurements in this evaluation are referred to here as either primary or secondary outcomes when aligned with the following primary and secondary program goals at 12 months:

4.8.1 Primary Impact Evaluation Measures

- Decrease in weight of at least 5%.
- Achieve a daily total fat intake of not more than 30% of total energy consumption.
- Achieve a daily saturated fat intake of not more than 10% of total energy consumption.
- Achieve a daily fibre intake of at least 15g/1,000kcal.

- Accumulate at least 210 minutes each week (30 minutes per day) of at least moderate intensity purposeful physical activity which includes progressive resistance training (PRT) and aerobic activity.

4.8.2 Secondary Impact Evaluation Measures

Additional evaluation measures were chosen to supplement the evidence on risk reduction and diabetes prevention:

- Fasting Plasma Glucose reduction or OGTT improvement
- Waist circumference reduction
- Lipid profile (total cholesterol/HDL/LDL/triglycerides) improvement
- Blood pressure (diastolic/systolic) improvement
- Change in health related quality of life (improvement)
- Self-efficacy and social support for physical activity and healthy eating
- Changes in medication use (reduction or discontinuation)
- Health service use (reduced number of occasions of service)

The following sections will cover issues of type of measurement, justification for the choice of instrument and summary of their validity or reliability.

4.9 Diabetes Risk and Diabetes Status

Each general practitioner searched in their electronic database using age, family history, weight and FPG blood test in the past three months as screening variables to identify patients who might potentially benefit from the Program. GPs invited some of their potentially eligible patients via a personalised letter to attend screening. At the same time, practice staff approached other potentially eligible middle-aged patients in the waiting room to complete the Ausdrisk tool (further details about the screening process and outcomes are presented in Chapter 6 on Process Evaluation). The Ausdrisk tool is a questionnaire covering eleven risk factors:

- Age group
- Sex

- Ethnicity (different score for certain ethnic groups)
- Region of birth
- Family history of diabetes
- Personal history of high blood sugar (includes IGT/IFG and gestational diabetes)
- Medication for high blood pressure
- Smoking status
- Frequency of fruit or vegetable intake
- Frequency of physical activity per week
- Waist circumference measurement (different score for males/females and high-risk ethnic groups)

Each risk factor [or its absence] was allocated a score and the aggregated possible scores for people in the 50-65 year age group ranged from a minimum of 4 and to a maximum of 38 (Appendix 4.2) The SDPP targeted people with a score of 15 or higher, as a previous Australian a longitudinal biomedical study, the AusDiab follow-up survey, suggests that these people have a probability of at least one in seven (for scores 15-19) and at least one in three (for scores 20+) of developing diabetes within five years. (17, 89) This was the most relevant risk factor instrument found for the Australian context.

4.9.1 Confirmation or Exclusion of Diabetes

Once a risk score of 15 or above was identified, the GP asked further questions on medical history and medication use to determine the presence of contraindications to participate in the Program.¹⁵ Then patients were invited to undergo a random capillary blood glucose (CBG) initially taken to exclude diabetes. This was generally followed by either a FPG or a full 2-hour oral glucose tolerance test (OGTT) after a fasting period of 12 hours. In some cases only a HbA1c test was undertaken due to patient refusal to have a full OGTT. Impaired glucose tolerance was defined using the WHO definition of <7.0 mmol/L on the fasting plasma glucose and ≥ 7.8

¹⁵ Proportions of people screened who scored 15+ are presented in the Baseline Results chapter (Chapter 5).

mmol/L on the 2-hours post glucose load.(3) Diabetes was defined using the most recent diagnostic criteria endorsed by the American Diabetes Association, where fasting plasma glucose values of ≥ 7.0 mmol/L or 2-hour post glucose load values of ≥ 11.0 mmol/L are diagnostic. (237)

4.10 Computer Assisted Telephone Interview (CATI Survey)

Interviews were conducted by trained interviewers at the University of Sydney usually when the participant was at home, at a time of their choice, within two weeks of their initial assessment.¹⁶ The purpose of this interviews was to document both socio-demographic and behavioural risk factors to enable comparative analysis before and after the intervention. Further, data on psychological features that could influence the person's adherence to the Program or withdrawal from it and predict success or failure in achieving the Program goals was collected The various sections of this telephone interview can be viewed in Appendix 4.5 and are described below.

4.10.1 Socio-demographic Factors

Many of the socio-demographic survey questions were selected for consistency with the New South Wales Population Health Survey also administered by telephone to samples of adults from NSW households selected via random digit dialling. (238) These socio-demographic items in the SDPP CATI survey, shown below, use Australian classifications of education, employment and private insurance, thus enabling comparisons with an age-matched sample of the NSW general public.

- Age
- Sex
- Postcode
- Country of birth
- Language spoken at home

¹⁶ The Candidate developed the CATI system as an Access database to facilitate data entry and enable quality control checks.

- Education
- Employment status
- Pension status
- Private health insurance status

4.10.2 Physical Activity Scale for the Elderly (PASE)

PASE is an instrument developed in the United States to collect data on self-reported involvement in a wide range of in physical activities to cater for the routines of elderly people (239) The PASE has been validated and used in a variety of clinical settings and countries over the years.(240, 241)

The instrument (questions 10 to 21 in Appendix 4.5 on baseline CATI survey) contains questions on physical activities in the week prior to the administration of the questionnaire such as:

- Walking out of the house (time and distance)
- Walking upstairs
- Light sports
- Moderate sports
- Strenuous sports
- Resistance Training
- Light and heavy household chores
- Light and heavy gardening
- Household repairs
- Caring for dependents
- Working for pay or as a volunteer
- Classification of job type depending on intensity of physical activity involved

The response options are quantifiable ranges of frequency (frequency ranges in the past seven days) and duration (duration ranges in the past seven days) of structured physical activity and dichotomous responses to unstructured activity. These ranges can be converted into minutes

per week using an algorithm and the test-retest reliability for telephone administration within a 3-7 week interval is acceptable ($r = 0.68$). (239) The PASE questionnaire is considered appropriate for clinical and epidemiological studies and has been used extensively in older individuals (55 years and above) due to its comprehensive coverage of unstructured physical activity including household work, which more closely reflects the routines of older people. PASE has been validated in healthy males and females by concurrently using objectively measured energy expenditure methods such as the *doubly labelled water* (240) and by measuring physiological reactions such as peak oxygen uptake, resting heart rate and blood pressure, percent body fat, and balance. (241) For this SDPP estimation of activity, only frequency and duration of Program-relevant activity (i.e. moderate and vigorous aerobic activity and resistance training) were used to construct 'minutes per week'.

While the SDPP participants are technically not considered to be 'elderly', the PASE instrument was considered appropriate for SDPP as this high-risk group affected by obesity and suffering from underlying chronic conditions was known to be unlikely to be engaged in structured sporting activities and therefore other physical activity questionnaires might not have detected changes in activity after the intervention.

4.11 Three-day Food Record

The non-weighed food record is considered a valid instrument for assessment of macronutrients (i.e. fat, saturated fat and fibre) intake at a population level after the weighed food record and ahead of the food frequency questionnaires. (242, 243) As in other epidemiological studies, the 3-day non-weighed food record was chosen for SDPP with a view to obtaining detailed dietary information without relying on memory,(244) thus enhancing response rates due to relative ease of administration, minimising respondent's burden and reducing project cost. (245) Consideration was also given to the age of participants, their level of literacy and the consistency with the method used in the FDPS reference trial.

The SDPP used a simple template to allow documentation of all foods and beverages consumed by participants on three days of the week including one weekend day (Appendix 4.12). The

templates had accompanying photos of plate and spoon sizes to facilitate estimations of amounts, consistent with the other Australian pilot study on diabetes prevention. (117). The 3-day food records were entered in an Australian version of *FoodWorks* software; that is, the database contained information on the nutritional content of Australian foods to enable calculation of macronutrient intake based on participant self-report. Data were analysed under the supervision of qualified dietetics staff. The individualised reports serve as the evaluation measure of the Program's nutrition goals, as well as being an integral part of lifestyle change in the intervention. Participants received feedback on their dietary intake from their 3-day food diary at their second group or telephone-based session.

4.12 Anthropometric Measurements

Physical measurements were taken at the initial assessment, at the end of the third group session and at final outcome assessment time, one year from enrolment.

Weight, in kilograms, was measured by lifestyle officers using digital scales at the Divisions of General Practice consulting rooms. Officers followed a protocol that included taking heavy clothes and shoes off and placing the scale on a solid, non-carpeted floor (Appendix 4.7). The digital scales were checked for calibration on average twice a year.

Height was measured in centimetres using a standard stadiometer provided by the SDPP intervention team. Lifestyle officers received training in measuring height twice using the Australian Institute of Health and Welfare protocol, relevant to Australia (Appendix 4.7).

Waist Circumference was also measured in centimetres by the lifestyle officer usually twice, once at baseline and once at the end of the Program when the lifestyle officers were more experienced in the measurement procedure (Appendix 4.7).¹⁷

4.13 Lipid Profile

Fasting blood samples were taken at baseline and 12 months for determination of total cholesterol, triglycerides and HDL/LDL. These were taken both to assess diabetes risk and to

¹⁷ Refresher training of lifestyle officers was conducted at the initial stages of implementation to improve reliability of WC measurement in obese people.

observe any changes after the dietary intervention. These purposes were consistent with those of the FDPS.

4.14 Other Risk Factors

Questions on self-reported alcohol consumption refer to usual frequency and intensity of alcohol intake as measured in 'standard drinks as per the National Health and Medical Research Council. (246) These Australian guidelines recommend that adults limit alcohol intake to a maximum of 2 standard drinks per day. Definitions and examples of various types of alcoholic beverages and their equivalent alcohol content for immediate conversion to number of standard drinks were provided by the interviewer at the time of interview. This enabled calculation of total number of drinks and whether the participant exceeded the recommended maximum intake. A single question on smoking allocated participants into one of five possible categories from 'never smoked' to 'current regular smoker' (Appendix 4.5). These categories are also consistent with the NSW Health Survey questions for adults for comparative purposes.

4.15 Morbidity Profile and Associated Treatments

A single-item question on self-assessed health status was asked, using a five-point Likert scale with response options a) excellent b) very good c) good d) fair and e) poor. This question from the SF-36 questionnaire used in the Medical Outcomes Survey(247) has been widely tested for reliability and validity and used in the literature in both cross-sectional and cohort studies across many countries and languages.(35, 248) SDPP chose it for consistency with many national and international studies as well as the NSW health survey. Its response is known to be strongly associated with objective measures of physical health and health service utilisation in several countries. (249) Likewise, the response option 'poor' has also been identified as an independent predictor of mortality after adjustment for socio-economic status and comorbidities in longitudinal studies. (249, 250)

Data on self-reported chronic conditions were collected during the CATI survey using the single question "has a doctor ever told you that you have...[list of chronic conditions including hypertension, asthma, other cardiovascular disease, arthritis or osteoporosis, cancer and high

blood sugar]”. The wording of this question is consistent with the telephone-based NSW Population Health Survey. Self-report is considered reliable as these chronic conditions require some level of confirmatory testing before a definitive diagnosis is made and is therefore unlikely to be associated with recall bias.

Use of general practitioners, specialists, allied health service providers, hospitals or emergency services in the past three months was documented from self-report. The reason for hospital admission or visits to specialists was not explored in the questionnaire. The question wording is consistent with that used in the NSW Health Survey, with the exception of visits to the GP, which has a longer recall period of 12 months in the NSW health survey.

Similarly, use of medications was ascertained with a single question covering prescription medications taken in the three months prior to the interview. Medication name, dose and frequency were self-reported and, where possible, verified against the clinical record. These questions were chosen to provide a full picture of the baseline health status of participants and to explore possible changes to health status during their involvement in the Program.

Comparisons will be possible with equivalent questions in Australian surveys such as the National Health Survey and the AusDiab Survey (Australian Diabetes, Obesity and Lifestyle Study). (16, 251)

4.16 Self-efficacy

The self-efficacy instrument used in SDPP consisted of four questions for each of the separate domains of physical activity and healthy eating. It examined the participants’ confidence about their adherence to good habits when facing special circumstances such as stress, high demands at home, tiredness, lack of time or when experiencing depression. Responses for each question could be classified into one of four categories: not at all confident, a little confident, confident or very confident (Appendix 4.5). These questions were a selection of items from a comprehensive self-efficacy instrument developed, tested for reliability and validated by Sallis et al. (252) in the late 1980s and modified by the SDPP investigators for ease of telephone administration. The

subset was known to have internal consistency from testing conducted in previous surveys by the Prevention Research Collaboration.

SDPP chose to explore the role of self-efficacy in predicting success in the Program because the evidence points towards improved performance or participation in healthy behaviours among those reporting high self-efficacy, whether the confidence is associated with intrapersonal influences such as obesity and past exercise behaviour, or with the local adequacy, safety or cleanliness of the physical environment where exercise takes place. (253-256) Responses were translated into numeric scores where a larger value indicated higher confidence for physical activity or eating. Results were analysed using an overall score with a minimum score 4 and a maximum score of 16. The two domains were also combined for an overall self-efficacy score for each individual (minimum of 8 and maximum of 32).

4.17 Social Support

The SDPP incorporated principles of social cognitive theory in the coaching of participants. This theory hypothesises that factors other than personal aspects such as age, gender and physical inability to exercise can constitute barriers for people's participation in physical activity.

Interactions that have been found to be consistently and positively associated with increased physical activity include interpersonal and environmental factors such as self-efficacy, social support, regular participation in physical activity by friends and family, and satisfaction with their immediate environment to enable safe exercise. (255, 257-259)

The six social support questions used in the SDPP baseline survey enquire about encouragement and support for physical activity or healthy eating received by the participant from family, friends or healthcare providers (Appendix 4.5). Each question uses a four-point Likert scale (never, rarely, sometimes, often) and responses are scored. A minimum of 6 indicates no social support at all and a maximum of 24 indicates strong or frequent support. This concept was included in the baseline SDPP survey as there is evidence that older people who enjoy a high level of social support have an enhanced sense of general well-being and tend to be less sedentary than those who do not have social support for physical activity. (255, 259-

261) The literature contains examples of the separate contributions of family and friends but there is no significant impact on actual physical activity from different sources. Following this, the analysis for SDPP has not been separated by source of support but rather is presented as an overall mean score by various demographic and risk parameters.

4.18 Emotional Health

The SDPP baseline data collection was to cover other potential predictors of both participation in the Program and adherence to healthy behaviours. Anxiety, stress and lower exercise efficacy have previously been identified as determinants of high BMI in the US DPP. (262) In addition to self-efficacy for diet and physical activity, the Sydney DPP used a population screening tool for anxiety and depression.

The Hospital Anxiety and Depression Scale (HADS) consists of seven questions to assess each of the [anxiety and depression] domains and the resulting score for individuals is then categorised as follows: less than 7 is considered normal, 8-10 suggests mild anxiety or depression, 11-14 suggests moderate anxiety or depression, and 15-21 suggests severe anxiety or depression (Appendix 4.13). The HADS was chosen for this program due to its simple format and suitability for self-administration by the general public. The instrument is considered to have good sensitivity to identify mood disorders. (263) The HADS has been tested in various languages and groups of medical patients in hospitals and outpatient settings to screen for mood and anxiety disorders (264) enabling comparisons between SDPP and other published studies. Results will be presented in association with other socio-demographic and risk factors.

4.19 Measurements at the Twelve-month Endpoint Assessment

With the exception of social support and self-efficacy, most of the components of the baseline CATI survey were administered to the participant about two weeks before the final review (Appendix 4.14). A locally relevant module investigating participant satisfaction with the Program was incorporated. At the final review visit, blood pressure, weight and waist circumference were taken again. Repeat lipid profile and glucose test were ordered by the GP before or during the last consultation. While OGTT was encouraged in the Program protocol, the

choice of blood test to exclude diabetes during the first four months or at the end of the Program was left to the discretion of the GP (either FPG, OGTT or HbA1c).

4.20 Intervention Protocol and Components (Impact Evaluation)

After the GP referral was received, including a thorough assessment of eligibility, relevant data were collected at various predetermined time points and Program appointments were booked within a set timeframe (Figure 4.2). The first face-to-face contact between eligible people and Program staff was at the initial consultation, when they formally enrolled and became a 'participant'. The main component of the intervention was the attendance at group sessions within three months of enrolment. However, lifestyle coaching was provided as part of the intervention at the initial assessment, and during each of the follow-up phone calls.

4.21 Initial Consultation

Following their referral to the program, a Lifestyle Officer employed by the relevant Divisions of General Practice undertook an initial consultation and health coaching session with each individual participant. This usually occurred between two and four weeks after the Division had received the referral form. During this consultation the Lifestyle Officer discussed type 2 diabetes with the participant, outlined the program activities and goals, assessed the participant's risk profile and referral form, agreed with participants on initial personal goal/s for the next three months, and took baseline measurements of height, weight and waist circumference. Participants were asked to bring a completed 3-day food diary for nutritional assessment (Appendix 4.12) and a self-administered well-being survey, the Hospital Anxiety and Depression Scale (Appendix 4.13) to this session.

This consultation was designed to assist participants in setting initial short-term diet and physical activity goals. At this point participants were encouraged to attend the three group sessions to support them to achieve their own lifestyle goals.

4.22 Group-based Sessions

These sessions were based on behaviour change principles adapted from the individual counselling of previous Diabetes Prevention Programs where participants were engaged in self-

reflection of their personal reasons for signing up to the lifestyle intervention, requested to commit to the Program conditions and then asked to identify barriers to adherence and propose solutions.(265) Participants took part in the three 2-hour group-based sessions, the core of the intervention. A minimum of 4 and a maximum 15 people were scheduled for each session. The content of the sessions was pre-determined with coverage of the definition of diabetes and explanations of lifestyle changes that may prevent the disease, as well as the Program goals and practical strategies to attain them. Information on how to recognise different types of fats and fibre was provided with practical examples, and demonstrations on structured and unstructured physical activity and how to incorporate it in daily routines. There were also demonstrations of healthy food shopping, label reading, cooking hints through recipe adaptation, and encouragement of the modification of food choices. Discussion also took place about relapse prevention, possible barriers for adherence to the new lifestyle and how to overcome them. More details of the content and structure of the group-based sessions can be found in Appendix 4.8.

Session 1 and Session 2 were held a fortnight apart. Session 3 was held approximately a month after Session 2 to enable participants to reflect on their progress such as self-assessment of weight, waist circumference, physical activity levels and dietary intake, and address any barriers and/or problems encountered in the initial stages of behaviour change. Participants were expected to attend all three sessions within 12 weeks of the initial consultation and before the three-month follow-up call. However, variations were allowed to cater for participants' family or work commitments or time away. The Program also provided participants with other supporting materials, such as a manual, physical activity logs and five Fact Sheets, which contained knowledge and hints to assist them in achieving each of the goals (Appendix 4.9). The first individual session covered the main elements of the entire program to ensure that those participants who did not continue beyond this point, i.e. did not attend further group sessions, still received all the key program messages. The third group session included measurements of weight and waist circumference to assess progress in the early stages.

4.23 Individual Phone Coaching

Participants who were not interested in group activities or were unable to attend group sessions due to distance, time of the sessions, transport difficulties or some other reason were offered three personalised telephone coaching sessions as an alternative. These three coaching phone calls were also delivered at similar intervals as the group sessions by trained lifestyle officers from the Australian Council of Diabetes. The duration of each phone coaching was about half an hour and the contents synthesised those of the equivalent group session. These participants did not attend any demonstrations and were not measured at the third session.

4.23.1 Referral to Community-based Programs – Post intervention Referral

At various times during the three group-based sessions or 3 telephone-based sessions participants received information about a number of community based programs which were considered aligned with the SDPP philosophies and goals, and were encouraged to attend. A comprehensive list which included weight management, healthy eating and physical activity programs and services in the Sydney South West Area Health Service was produced and an extract with geographically relevant services was disseminated to interested participants at the end of the three sessions. This list had been compiled by a SSWAHS team of exercise physiologists and health promotion staff after thorough on-site collection of information on minimal and optimal requirements using a standard assessment tool (Appendix 4.15). More details about this inventory of services is presented in Chapter 6 on the Process Evaluation of the SDPP.

4.24 Three, Six and Nine-month Follow-up Coaching Phone Calls

Three, six and nine months after the initial consultation participants were scheduled to receive a phone call from a lifestyle officer. A health coaching approach was used to assess progress and provide on-going support and feedback. Information on factors such as Program exposure, perceived change, participation in diet or physical activity since Program commencement, monitoring habits and changes in medication are collected during this phone call, as well as economic data on factors such as the amount spent by participants on physical activity and nutrition related items such as gym membership or healthy food items. This information is

collated and used to qualitatively assess the ability of the program to generate and maintain behavioural change (Appendices 4.10 and 4.11).

4.25 Role of the GP and Four-month GP Visit

The role of the GP included identification of own patients at risk, administration of the screening tool, ordering and assessment of blood tests to rule out diabetes at baseline, at four months and at the end of the Program, completion of the referral form (Appendix 4.4), documentation of laboratory profile and anthropometric measurements at 4 months, and final re-assessment. GPs could also be involved in the care of the patient for reasons unrelated to this Program

Participants were encouraged to visit their GP again four months after the initial consultation, to have weight and waist circumference measured and obtain orders for any appropriate blood tests (i.e. FPG or lipid profile). This information was to be used to detect any changes in the participant's profile at this time point. This component of the protocol was not compulsory for evaluation purposes.

4.26 Final Assessment

Twelve months after the initial consultation a final assessment was undertaken separately by the GP and the lifestyle officer. This was the final outcome assessment for the SDPP. Information collected at this time was to be used to detect any changes in the participant's profile over the intervention period. At the follow-up consultation with the lifestyle officer, participants brought another completed 3-day food diary. As part of this consultation, the lifestyle officers reviewed goal achievement, assisted with setting new goals as well as measured blood pressure, weight and waist circumference. To standardise the concepts, messages and procedures relevant to this final review and the initial assessment, instructions were and provided in an *intervention manual* for lifestyle officers (Attachment 4.16).

At this review participants were provided with a referral for FPG, HbA1c and lipids. The results of the blood tests were provided to the participants' GP as well as the lifestyle officer. Following this, an assessment was also conducted by the GP to obtain all the biomedical information collected at baseline (i.e. weight, waist circumference, blood pressure) and confirmation of non-

diabetes status. Within a month of this, and following analysis of their physical activity self-report and food record, participants were provided with written feedback on their progress over the 12-months compared to baseline. At any stage of the program, if a participant had a blood test confirming diabetes, this signalled the end of their participation and they were not required to attend the final assessment at 12 months.

The next Chapter will present the results of the baseline profile of participants overall and by cohort ('mainstream' and Culturally and Linguistically Diverse groups: Arabic and Chinese).

Chapter 5.

Baseline SDPP Survey – Methods and Results

Summary

This chapter describes the methods, variables and measurements used in the SDPP for the purposes of evaluating the Program. It presents baseline survey results of socio-demographic, physical and laboratory parameters, behavioural risk factors and other characteristics of mainstream, Arabic and Chinese participants and their environment. The core measurements in this program are the baseline physical measurements of BMI, weight and waist circumference taken at the initial consultation; levels of physical activity estimated from responses to the CATI survey; and the nutrition profile estimated from the 3-day food record. Secondary variables considered were laboratory profile for blood glucose and lipids. The SDPP succeeded in recruiting high-risk community participants, the appropriate target group for a lifestyle modification program.

Comparisons are presented in this chapter between the profile of mainstream SDPP participants and those of participants in the Arabic and Chinese SDPP cohorts. The emphasis is on baseline estimates of variables measuring the Program goals: Baseline weight, physical activity, and consumption of fat, saturated fat and fibre. Clinical parameters such as blood pressure, lipid profile and glycaemia are also presented for the three cohorts. Self-reported baseline chronic illness and use of health services along with additional correlates of participation in preventive activities such as emotional status, self-efficacy and social support for healthy lifestyle are also discussed.

Finally, the SDPP baseline results, demographic and selected equivalent risk factor data are compared with the NSW Health Survey population in the same age group and with published FDPS, USDPP and other relevant Australian and overseas diabetes prevention programs.

5.1 Background

As described in chapter 2, population screening to identify people at risk of type 2 diabetes is now commonplace and many risk tools have been developed for this purpose. In the SDPP, The Australian Type 2 Diabetes Risk Assessment Tool (*Ausdrisk*) was used to identify potential participants. (151) Details of the screening and intervention protocol are presented in Appendix 4.1, a Study Protocol paper published in a peer-reviewed journal in 2010. (235)

To enable comparisons of the SDPP baseline results with other publications, the SDPP collected selected data items broadly consistent with those used in international and local trials. The reference trials generally reported results of their primary outcomes such as diabetes incidence, weight loss, changes in glucose regulation and lipid profile, blood pressure, and changes in physical activity. (93, 95) The community-based studies referred to in Chapter 2, which usually have shorter durations, tend to report only basic demographic parameters and final changes in weight, waist circumference, and blood glucose. Less often reported are secondary outcomes such as changes in dietary intake, emotional health status or cost-effectiveness. (14, 117, 266)

In the Sydney Diabetes Prevention Program, extensive information was collected from individual participants to build a profile of their baseline socio-demographic profile, health status and health behaviours which could possibly influence their participation in the Program and/or their Program outcomes. These will be used later for comparisons of core parameters at the end of the intervention. Further, information on a range of potential correlates of participation and adherence was also collected at baseline. This entire profile ranging from socio-demographic to behavioural risk factor variables will be the focus of this chapter.

This chapter examines the following research questions at baseline:

1. What was the recruitment rate to the SDPP for the mainstream, Chinese and Arabic cohorts?
2. What were the socio-demographic characteristics of the people screened and recruited in the SDPP?

3. What were the participants' self-reported physical health status by cohort and mental health status by cohort and sex?
4. What was the pattern of reported health service use of participants by cohort?
5. What were the baseline self-reported diabetes risk factors of participants by cohort?
6. What were the baseline self-reported physical activity levels of participants by cohort and sex?
7. What was the level of readiness to change behaviour (prior use of physical activity or healthy eating services, self-efficacy and social support) of participants by cohort?
8. What was the baseline macronutrient profile of participants by cohort and sex?
9. What were the baseline anthropometric and clinical profiles of SDPP participants by cohort and sex?
10. What were the overall correlates of participation in the SDPP and what are the predictors of self-efficacy and social support for the Program?
11. What were the baseline correlates of meeting the Program goals for participants overall?
12. How good was recruitment in SDPP compared to other community DPPs?

5.2 Methods Used and Measurements Reported

As all three cohorts had been recruited at the time of writing this thesis, this chapter summarises the screening and recruitment process and findings at baseline for all three cohorts: mainstream, Arabic and Chinese. Baseline results refer to all three cohorts when available. These comprised data the data items collected between screening time and the time of initial consultation.

Most of the information on demographic characteristics and self-reported health, physical activity and other risk factors was obtained through a computer assisted telephone interview (CATI) survey. Physical activity in minutes/week was estimated from the Physical Activity Scale for the Elderly (PASE) questionnaire. (239) PASE scores were calculated using the standard algorithm to yield a total estimate that incorporates the contributions of structured and unstructured physical activity. In the absence of an Australian norm for PASE, a weighting

system is used for each activity type based on U.S. population norms.(239) The nutrition profile was compiled from the completed three-day food record participants brought to the initial consultation. Trained dieticians entered the information using FoodWorks software, which utilises a comprehensive food selection process that allows for standard nutrient analysis. (267) Emotional health was self-rated using the Hospital Anxiety and Depression Scale (HADS), which participants self-completed before the initial consultation. The HADS scores were derived using the standard scoring system where a score between 0 and 21 is allocated to both scales separately.(268)

In brief, the main outcome measurement presented in this chapter and details of the rationale for choosing the above questionnaires, source of instruments, information on their validity, and explanation on their contents and their usage by others as reported in the literature have been described in chapter 4 and covered the following:

- Screening and recruitment rates
- Ausdrisk scores derived from the *Ausdrisk* screening tool (as per section 4.4 and Appendix 4.2)
- Lipid and glucose profile based on standard laboratory tests (as described in section 4.4.1)
- Anthropometric parameters as measured by the lifestyle officers using calibrated digital scales and metric tape measures (weight measurement protocol in Appendix 4.7)
- Demographic characteristics of participants based on self report and decliners based on the Ausdrisk parameters (section 4.5.5)
- Level of physical activity as measured by the PASE questionnaire (section 4.5.5. and Appendix 4.5)
- Nutrition profile (macronutrients only) as derived from the 3-day food diary (section 4.5.5 and Appendix 4.12)
- Distribution of participants meeting the Program goals at baseline
- Morbidity profile as self-reported in the CATI survey (questions in Appendix 4.5)

- Use of health services and physical activity services self-reported in the CATI survey (questions in Appendix 4.5)
- Emotional health as measured by HADS questionnaire administered at the initial consultation (Appendix 4.13)
- Self-efficacy for physical activity and healthy eating derived from the 8 question-module of the CATI survey (section 4.5.5 and Appendix 4.5)
- Level of social support for physical activity and healthy eating, as derived from the 6 question-module of the CATI survey (section 4.5.5 and Appendix 4.5)

To examine the Program reach of the target group, a descriptive unweighted comparison of the profile of SDPP participants with that of respondents from the NSW Health Statewide Health Survey 2007-2008 was undertaken. This NSW Health Survey is an ongoing telephone survey of adult residents of New South Wales households selected using random digit dialling. It uses computer assisted telephone technology (i.e. CATI) and covers several health modules for various age groups with a consistent core demographics section.(238, 269) This comparator was chosen as the most relevant to the SDPP target group, because the NSW Health Survey sample was extracted from residents in the same population-base, and because some of the NSW Health Survey questions are equivalent to those used in the SDPP CATI survey. The NSW Health Survey results are also readily available, as they are published regularly at various geographic levels including Area Health Service level which has enabled us to conduct comparisons with an age-matched Statewide and SSWAHS sub-group, given that the SSWAHS region covers exactly the same population as the three GP Divisions of SDPP.

5.3 Statistical Analysis

Socio-demographic parameters were compared across cohorts using chi-square statistics. Chi-square statistics were used to compare differences in proportions of risk factors between males and female SDPP participants and across cohorts. Proportions corresponding to various socio-demographic parameters and behavioural risk factors between participants and non-participants were also analysed.

Clinical measurements such as blood glucose, total cholesterol, blood pressure, measured waist circumference, weight and BMI are presented as means and standard deviations. Physical activity data are presented as means, with their respective standard deviation and interquartile ranges.¹⁸

Food categories were selected and total energy and percentages of fat and grams of fibre were calculated. Proportions of participants meeting the goal at baseline were calculated using the chi square statistic to estimate the extent of behavioural change required.

Associations of anxiety and depression with other risk factors were examined separately using binary logistic regression where the outcome was a dichotomous score category with a threshold of >7; i.e. depressed or not, anxious or not. The four response items from the self-efficacy scale (from not confident to confident), and four response items from the social support scale (from never to often) were converted from a scale format (Appendix 4.5) to a numeric format to enable graphical plotting and cohort comparisons of each concept.¹⁹

Unadjusted and bivariate and adjusted analyses are presented in this chapter for selected variables such as baseline self-efficacy and social support. Associations of self-efficacy with other plausible demographic and risk factors were also examined using binary logistic regression analysis. The outcome was dichotomous aggregating the lowest two self-efficacy categories ('not at all confident' and 'a little confident') vs. the higher two categories ('confident' and 'very confident'). Likewise the associations of social support with other plausible socio-demographic and risk factors used dichotomous outcomes in a logistic regression model aggregating 'never and rarely encouraged vs. 'sometimes and often encouraged.

¹⁸ PASE scores are presented also as medians and means in the Appendix.

¹⁹ Each response item in each of the 8 questions of self-efficacy tool was allocated a progressive score (from 1 to 4) and then the scores were added for each scale. For example, not confident=1, a little confident=2, confident=3, very confident=4. Thus, a minimum score would be calculated as 8 and a maximum of 32. Likewise each response item (never =1, rarely=2, sometimes=3 and often=4) in each of the 6 questions of the social support scale was allocated a score, for a minimum total score of 6 and a maximum of 24. Mean scores and standard deviations then facilitated the comparisons across mainstream and the other two cohorts as the higher the score, the higher self-efficacy and higher social support.

In general, measures of central tendency (mean, standard deviation, median, interquartile ranges) were used to illustrate the distribution of continuous variables for each cohort and analysis of variance was used to compare means across the three cohorts: mainstream, Arabic and Chinese participants. This was because the distributions of anthropometric and dietary measures were essentially Normal. Tukey's studentized test was used as the multiple comparison test for pairwise differences between cohorts, and operates on the principle of controlling Type I error (false positive). The Waller-Duncan K-ratio test was used to perform post-hoc identification of the group (s) with unequal mean(s) across the three cohorts.²⁰ T-tests were used to compare mean estimates of continuous variables between males and females within each cohort. Decisions on socio-demographic and risk factors used as covariates in multivariate analysis as potential predictors of goal achievement were based on plausibility and statistical significance.

Unweighted data on equivalent socio-demographic and risk factors were used for comparisons with NSW Health survey participants. In the absence of unit record data beyond the SDPP, descriptive statistics of SDPP participants were used for all other comparisons with participants in other Australian and international prevention programs.

5.4 Results of Screening and Recruitment

Question 1 What was the recruitment rate to the SDPP for the mainstream, Chinese and Arabic cohorts?

5.4.1 Screening and recruitment

The time period of recruitment of mainstream participants into the Sydney Diabetes Prevention Program was September 2008 to July 2010. Macarthur and Southern Highlands Divisions of General Practice commenced recruitment earlier and Central Sydney Division started in February 2009. The Arabic and Chinese cohorts, recruited through the Central Sydney Division were assembled from October 2009. These participants were identified through language-

²⁰ Waller-Duncan k-ratio test is designed specifically for pairwise comparisons based on the studentized range but compares the Type I and Type II error (false negative) rates.

specific GPs using targeted *Ausdrisk* screening in the Central Sydney Division. Recruitment was facilitated by language-specific lifestyle officers. The screening and recruitment requirements were similar to those for the mainstream cohort, i.e. *Ausdrisk* level ≥ 15 and blood test ruling out diabetes.

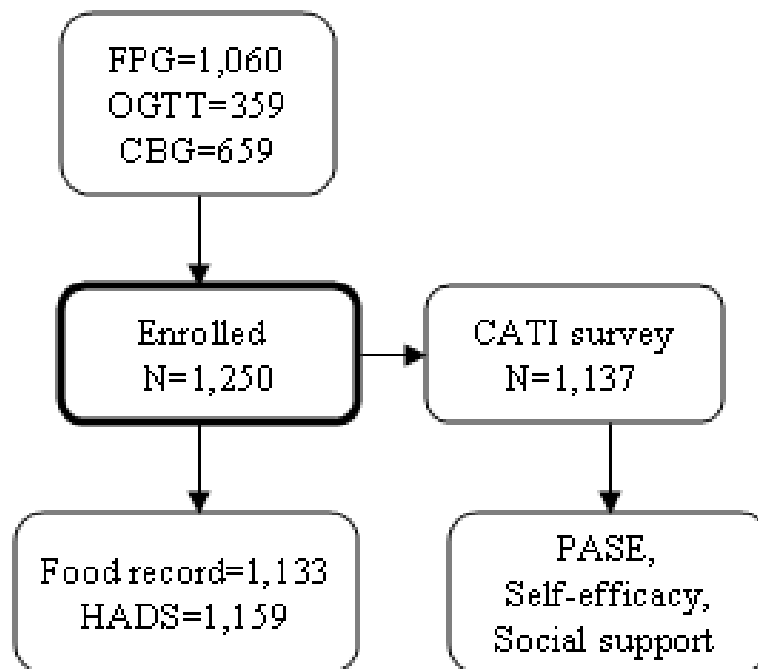
Therefore participants across Divisions are at different stages of the Program and the last enrolled in July 2010 will complete their participation in June 2011.²¹

The sample size for analysis of baseline results was 1,250 mainstream, 84 Arabic and 79 Chinese participants. Screening and recruitment information was available for all participants in the three cohorts. However, participation in the various components and data collection activities of the Program varied from person to person. That is, not all participants agreed to fill in the 3-day food record, or responded to the CATI survey or attended groups or were contactable by telephone every three months. Hence the denominator through the chapter can vary depending on the variable analysed. For instance, 1,137 (91%) of the 1,250 enrolled mainstream participants responded to the baseline socio-demographic and risk factor telephone interview, the CATI survey (Figure 5.1). Likewise, oral glucose tolerance test results were only available for 29% of mainstream participants while a larger proportion (85%) had a single FPG at baseline.

Similar details for the Arabic and Chinese participants are presented in Appendix 5.1, showing participation rates in the CATI survey of 98% and 92%, respectively. The total numbers available for various modules or parameters are specified in each table throughout this chapter. More detailed description of compliance with Program requirements at various time points are presented in Chapter 6 on the Process Evaluation.

²¹ Given the timeframe for completion of the author's PhD candidature, data analysis for the purpose of this thesis will include baseline findings for all 1,413 participants (Chapter 5) and 12-month impact of the 593 completing the Program by December 2010 (Chapter 8).

Figure 5.1 Completeness of different Program requirements and contact points for mainstream participants after the initial consultation (2008-2010).



5.4.2 Screening

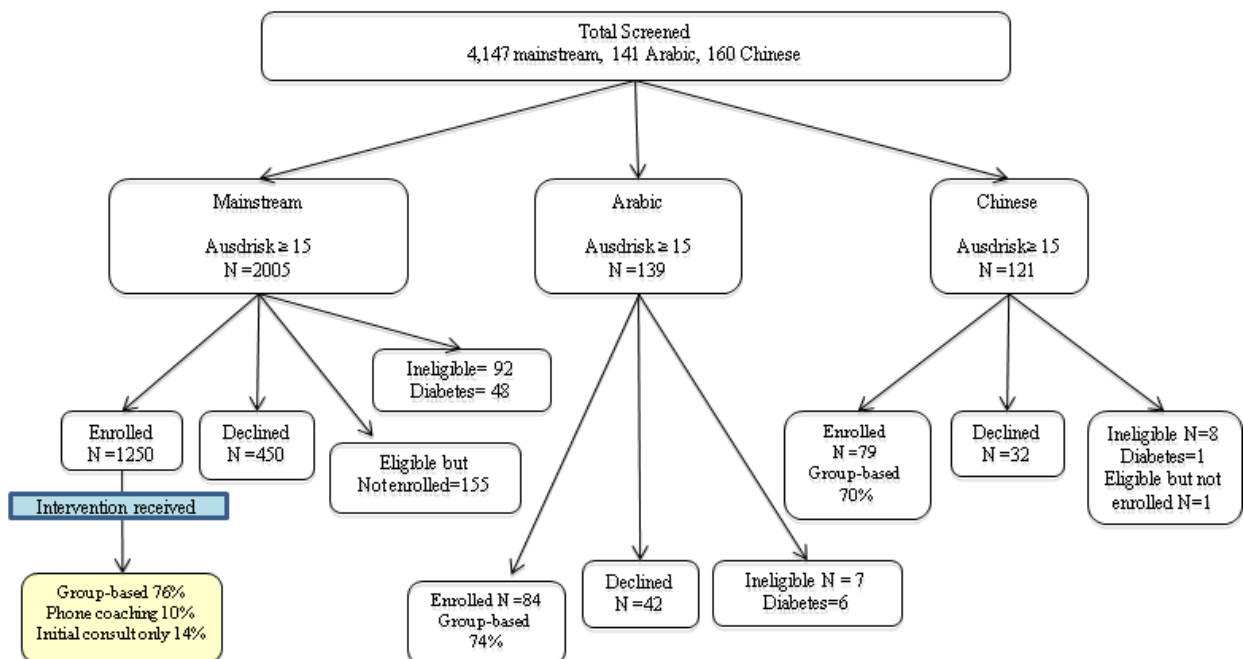
People in the SDPP target group were informed of the Program mostly via the GP rooms, either at the consultation (60.6%), through a letter from their GP (16.9%), by approach at the waiting room (7.8%) or by a call from the Division of General Practice (2.8%). A minority (3.5%) became aware of the Program through the printed or electronic media or were told about the Program by a relative (3.2%), and the remaining 5% were informed through some other (unspecified) means.

Targeted screening of known high-risk patients by participating family doctors yielded at least a 50% chance of finding potential participants with an *Ausdrisk* score of ≥ 15 (one in every two in the mainstream cohort, one in every four in the Chinese cohort and 99% in the Arabic cohort). The actual screening rate is not known because many of the original *Ausdrisk* forms released to doctors did not return filled-in or blank, thus the denominator for the screening rate is uncertain.

5.4.3 Recruitment

Of the 2,265 identified with an *Ausdrisk* of ≥ 15 in the three cohorts, 93% were confirmed eligible after further assessment (2,103). Between September 2008 and July 2010, the SDPP enrolled 1,250 English-speaking, 84 Arabic speaking and 79 Mandarin-speaking (Chinese) participants (Figure 5.2). That is, screening yielded recruitment rates of 67% among the English-speaking (1,250/1,865 eligible), hereby known as "*the mainstream cohort*", 67% of the Arabic (84/126 eligible) and 71% of the eligible Chinese people (79/112).

Figure 5.2 SDPP screening and recruitment process (mainstream, Arabic, & Chinese cohorts)²²



Ineligible people included those who had contraindications for physical activity and those who did not have the blood test to rule out a diagnosis of diabetes.²³ Overall, of those confirmed eligible to participate 67% (or 1,413 of 2,103) commenced participation.

²² Data current as at December 31st, 2010; all enrolments and attendance at group sessions/phone coaching have concluded but follow-up still pending for 30% of enrollees (the complete follow-up is beyond the timeline for this thesis).

²³ Small numbers of people who were deemed eligible did not make the appointment for their initial assessment within the timeframe set for the project and subsequently had to be excluded from participating. These are termed 'eligible but not enrolled' in Figure 5.2.

Question 2 *What were the socio-demographic characteristics of the people screened and recruited in the SDPP?*

5.5 Baseline CATI Data

5.5.1 Baseline Socio-demographic characteristics of participants

The socio-demographic characteristics of mainstream participants (from the CATI survey) indicate they are an English-speaking cohort living in small family structures, have relatively high educational attainment, relatively high rates of private health insurance coverage and are largely still in paid employment (Table 5.1). Mainstream participants were slightly but statistically significantly older than participants in the other two cohorts (t-test = -4.15, $p < 0.001$ compared to Arabic, and t-test=-4.04, $p < 0.0001$ compared to Chinese). The mean age differences between Arabic and Chinese were not significant (t-test= -0.16, $p=0.877$). The mean household size of mainstream participants was significantly smaller than that of both Arabic participants (t-test=7.9, $p=0.001$) and Chinese households (t-test= -6.73, $p < 0.001$). A third of the mainstream participants were born outside Australia and under a third of them were recipients of a pension.

Table 5.1 Baseline socio-demographic characteristics of participants in the three SDPP cohorts who responded to the baseline CATI survey♦

Parameter	Mainstream N=1137 CATI respondents	SDPP Arabic N=82	SDPP Chinese N=73
Age -mean (SD)	58.1y (4.4)**	55.9 (4.7)	56 (4.1)
Household size –mean # people (SD)	2.5pp (1.5)**	4.1 pp(1.9)	5.6 pp(15.2)
Male	37.0	24.0	43.0
Female	63.0	77.0**	57.0
Born outside Australia	32.0	100	100
Education level attained			
university degree	34.5	14.3***	35.4
only primary or no formal education	2.7	25.0***	15.2
Currently employed	59.9	21.4***	50.6
Full-time	40.3	8.3	34.2
Part-time	19.7	13.1	16.5
Retired, home-maker, unemployed	40.0	78.6	49.3
Currently on a pension	30.7	72.6***	30.4
Some form of private health insurance	66.3	22.6***	46.8
Lowest quintiles of disadvantage	20.7**	73.3	53.6

♦ values are percentages unless otherwise specified.

** $p \leq 0.01$ *** $p \leq 0.001$ for comparisons across cohorts

The Arabic cohort comprised significantly higher proportions of females than either the mainstream or the Chinese cohorts ($\chi^2=7.3$, $p=0.007$ for mainstream and $\chi^2=8.6$, $p=0.003$ for Chinese). Arabic participants were significantly less likely than mainstream ($\chi^2=14.4$, $p<0.0001$) or Chinese participants ($\chi^2=9.8$, $p=0.002$) to have a university degree. No statistical differences were found in the likelihood of higher education between mainstream and Chinese participants ($p>0.05$). The Arabic cohort was also more likely to only have primary school or no formal schooling than the mainstream ($\chi^2=97.8$, $p<0.0001$) but were not significantly different from the Chinese cohort at this end of the education spectrum ($\chi^2=2.4$, $p=0.119$). More Chinese than mainstream participants had primary or lesser education ($\chi^2=34.2$, $p<0.001$). Arabic participants were significantly less likely to be employed than the mainstream ($\chi^2=47.6$, $p<0.0001$) or the Chinese ($\chi^2=15.1$, $p<0.0001$). No differences were found in the probability of current employment between Chinese and mainstream participants ($\chi^2=2.6$, $p=0.104$). While the Chinese participants are more likely to report being employed, most of the working participants (69.5% mainstream, 62.2% of Chinese and 91.3% of Arabic) reported performing sedentary jobs in the CATI survey.

The likelihood of being a pension recipient was significantly higher for the Arabic participants than it was for the mainstream ($\chi^2=62.3$, $p<0.0001$) or Chinese participants ($\chi^2=29.1$, $p<0.0001$). Likewise, Arabic participants were significantly less likely to have private health insurance coverage than the mainstream ($\chi^2=60.0$, $p<0.0001$) or the Chinese ($\chi^2=10.6$, $p=0.0011$). Analysis by postcode of residence using the socio-economic index for areas (SEIFA) classification for Australia (270). indicates that one in every five mainstream participants falls in the two lowest quintiles of socio-economic disadvantage.²⁴ It also indicates that almost three quarters of the Arabic and just over half of the Chinese participants were in the two lowest quintiles of economic disadvantage for New South Wales.

²⁴ SEIFA stands for *Socio-Economic Index For Areas* and is a summary measure developed by the Australian Bureau of Statistics. It focuses primarily on disadvantage, and it incorporates Census variables such as low income, low educational attainment, unemployment, and absence of motor vehicles in the household.

With the exception of language spoken at home, similar socio-demographic characteristics were found for the Chinese participants as for the mainstream cohort. The relatively balanced sex distribution in the Chinese cohort was partly explained by the tendency of the Program to enrol couples in this ethnic group as opposed to individuals in the other two cohorts.

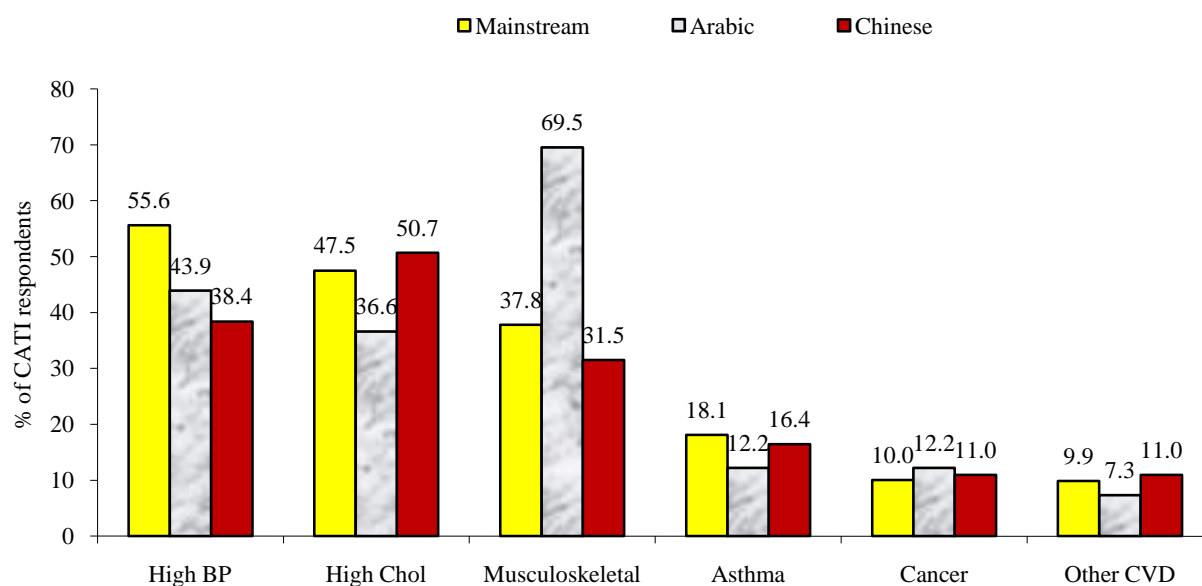
Question 3 What were the participants' self-reported physical health status by cohort and mental health status by cohort and sex?

5.5.2 Baseline Self-reported Morbidity Profile

In the CATI survey, participants in the mainstream cohort reported high levels of underlying chronic conditions (93.3% had been diagnosed with at least one). Only 6.7% of mainstream participants reported being free from chronic conditions such as high blood pressure, other cardiovascular disease, asthma, musculoskeletal ailments (arthritis/osteoporosis), pre-diabetes, or cancer. The mean number of conditions reported was 2.0 (median 2) with the most commonly reported by mainstream participants being hypertension and high cholesterol (Figure 5.3). Of note, one in five of the mainstream participants also reported receiving some treatment for depression or anxiety, although the question on prevalent mental illness was not directly asked, only inferred through the hospital anxiety and depression scale, which is not a diagnostic tool. (263)

Around 14% of the CALD participants reporting no chronic conditions. Arabic CATI respondents reported very high levels of musculoskeletal conditions, almost twice as high as the other two cohorts, but given the absence of validation through medical record reviews, the diagnoses of osteoporosis and arthritis cannot be distinguished from other non-chronic musculoskeletal ailments. These findings confirm that the SDPP participants are a selected high-risk population with multiple co-morbidities.

Figure 5.3 Distribution of self-reported chronic conditions ever diagnosed by a doctor. CATI survey respondents by cohort. N=1292



The psychosocial aspects of the health profile, i.e. mental health, as measured by the HADS questionnaire indicate that two thirds of participants in the mainstream cohort scored within normal ranges for anxiety, but mainstream females had significantly higher mean scores than males (Table 5.2). There were no statistically significant differences in depression scores between mainstream and Chinese cohorts in either males or females, but over half (60.9%) of the Arabic participants, mostly females, were classified in the depressed score categories. Male and female Arabic participants had significantly higher anxiety and depression scores than their counterparts of the same sex from the other two cohorts.

Table 5.2 Differentials in baseline anxiety and depression scores (as measured by HADS). Distribution by sex and cohort among 1249 participants filling the HADS form.

HADS scores	Mainstream N=1,115 Males=416; Females=699		Arabic N=66 Males=16; Females=50		Chinese N=68 Males=30; Females=38	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
Anxiety			*** for F&M			
Males	5.5 (3.9)	5.0 (2.5-8.0)	7.0 (5.8)	5.0 (2.5-10.5)	5.2 (3.6)	4.5 (3.0-8.0)
Females	6.6 (4.2) ♣	6.0 (3.0-9.0)	8.8 (4.2)	8.5 (6.0-11.0)	7.1 (4.8)	6.0 (4.0-10.0)
Depression			*** for M&F			
Males	4.4 (3.3)	4.0 (2.0-6.0)	8.4 (3.9)	7.5 (6.0-10.5)	4.3 (3.3)	4.0 (2.0-7.0)
Females	4.7 (3.6)	4.0 (2.0-7.0)	8.7 (3.6)	8.5 (7.0-11.0)	4.8 (3.0)	4.0 (3.0-6.0)

*** $p \leq 0.001$ for differences across cohorts and within the same sex group (F= females, M= males)

♣ $p \leq 0.001$ for differences between males and females

More details of their distribution of mental health status by socio-demographic and risk factors are presented in Appendix 5.3.

Question 4 *What was the pattern of reported health service use of participants by cohort?*

5.5.3 Use of health services before joining the SDPP

The profile of health service utilisation for those who responded to this item on the baseline CATI survey indicates that the vast majority had seen the GP at least once, and a median of twice just before joining the Program, and small proportions had visited emergency departments or been admitted to hospital for at least one night (Table 5.3).

Table 5.3 Type of healthcare provider and service visited by SDPP participants in the three months before joining the Program (2008-2010). Percentage of CATI respondents using services. N=1292

Health service use and type	Mainstream N=1,137	Arabic N=82	Chinese N=73
Visited a GP in the past 3 months (median 2 visits)	95.9	98.8	98.6
Visited an emergency department in the past 3 months	7.5	6.1	5.5
Stayed at least on night in hospital in the past 3 months	4.2	7.3	1.4
<u>Medical specialists</u> visited at least once			
Cardiologist	3.6	3.7	2.7
Ophthalmologist	2.6	0.0	2.7
Nephrologist	0.7	0.0	0.0
Endocrinologist	0.5	0.0	0.0
Other medical specialist	22.3	8.5	20.5
<u>Allied Health</u> providers visited at least once			
Physiotherapist	2.9	7.3	4.1
Podiatrist/Optometrlist	9.1	4.9	0.0
All other Allied Health	22.3	4.9	0.0
Dietician	0.9	1.2	1.4
Natural therapist	4.7	0.0	0.0
Exercise physiologist	0.4	1.2	0.0

The most commonly visited providers were “other” medical specialists (i.e. non-diabetes or cardiovascular disease related doctors) such as surgeons, gastroenterologists , oncologists and allied health professionals.

This pattern of health service use held for both the mainstream and the CALD cohorts.

Differences across cohorts are not statistically interpretable and could simply indicate random variation as the numbers reported for the CALD cohorts are small.

Question 5 What were the baseline self-reported diabetes risk factors of participants by cohort?

5.5.4 Self-reported risk factors

From the CATI survey, responses indicated that less than half of the mainstream participants reported a family history of diabetes, almost three quarters were regular drinkers, and about one in five mainstream participants were people in the high risk category for alcohol consumption (Table 5.4). Mainstream participants reported the highest levels of alcohol consumption. Only a minority smoked regularly or were on a weight loss program before joining the SDPP. Other than walking, the majority were not engaged in moderate to vigorous physical activity. The mainstream participants were more likely to report the presence of target chronic illnesses than the other two cohorts. Despite the large proportions suffering from chronic disease (93.3%), most of the mainstream participants self-assessed their health as good to excellent.

Differences with the other two cohorts were observed across most variables. Arabic participants were significantly more likely to report family history of diabetes, regular smoking, and no involvement in moderate-to-vigorous physical activity than participants in the other two cohorts.

Table 5.4 Baseline diabetes risk factors among participants in the three SDPP cohorts who responded to the baseline CATI survey (percentage for each parameter). Total N=1,292

Parameter	Mainstream N=1,137 (%)	SDPP Arabic N=82 (%)	SDPP Chinese N=73 (%)
First degree relative with diabetes	45.1	61.0*	49.3
Current regular smoking	8.9	15.9**	5.5
Current regular drinking	73.9**	18.2	30.1
High overall risk (>2 drinks per day) ²⁵			
Males	18.7**	0.0	0.0
Females	5.7*	0.0	0.0
Zero minutes of walking	21.4**	6.1	13.7
Zero minutes of moderate-vigorous activity	72.1	89.0**	71.2
On a weight loss program before joining	7.7**	1.2	0.0
Nil chronic comorbidities ^a	6.7**	14.6	13.7
Self-assessed health (fair or poor)	26.7**	62.2	60.3

* $P < 0.05$ ** $P < 0.01$ *** $P < 0.001$

a cardiovascular disease, diabetes, arthritis/osteoporosis, depression, cancer, other heart disease

Arabic participants reported the lowest levels of regular drinking. Chinese participants reported the lowest rates of regular smoking and no involvement in weight loss programs before joining, but had similar rates of moderate-to-vigorous physical activity and family history of diabetes as mainstream participants (Table 5.4). Two thirds of Arabic and Chinese participants considered their health to be fair or poor while only over a quarter of the mainstream counterparts do so.

The distribution of risk as measured by the *Ausdrisk* tool responses is presented in Appendix 5.2. In brief, increasing age, higher waist circumference and physical inactivity were the most prevalent factors in the mainstream cohort. Being from a high-risk country and being physically inactive were the most common risk factors among the Chinese and Arabic participants.

Question 6 *What were the baseline self-reported physical activity levels of participants by cohort and sex?*

5.5.5 Baseline physical activity from PASE questions

The Physical Activity Scale for the Elderly (PASE) covers questions on structured and unstructured activity, suitable for the SDPP target age group. Structured physical activity, also

²⁵ 162. Australian Government National Health and Medical Research Council. Australian Guidelines to Reduce Health Risks from Drinking Alcohol. 2009 [cited 2010 October 16]; Available from: http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/ds10-alcohol.pdf.

referred to as 'exercise' in the public domain, is a subcategory of physical activity that is planned, repetitive, structured and performed for the purpose of improving or maintaining fitness.(271) The PASE covers a spectrum of activity from light to vigorous intensity and strength or resistance training. Unstructured physical activity, also known as 'incidental' physical activity, is a subcategory of physical activity comprising walking for transport, housework, and the activities of daily living.(272) The PASE covers walking out of the house, gardening, light and heavy household work, caring for others and physical activity in a paid or voluntary job.

Details of the unstructured physical activity findings are summarised in Appendix 5.4 as they are not the focus of the SDPP, where the key Program goal was defined as 210 minutes/week of structured physical activity.

5.5.6 Structured physical activity from PASE

Less than one in five of the mainstream participants were engaged in moderate to vigorous physical activity or resistance training (Table 5.5). Males in the mainstream cohort overall were more engaged in all forms of moderate or vigorous physical activity and strength training than Females . Females tended more to be engaged in light physical activity than males in this cohort. Duration of total activity per week for mainstream males was twice that of women.

About two thirds of participants across all cohorts reported not doing any minutes of moderate or vigorous activity at baseline. Arabic participants reported significantly lower engagement in moderate to vigorous physical activity per week than the other two cohorts, but all three cohorts exhibited high levels of sedentary behaviour. Arabic participants were the least involved in moderate or higher activity than the other two cohorts. Arabic males appeared to be more engaged in strenuous sports than Arabic females but this difference was not statistically significant. Arabic females reported significantly more minutes walking per week than males. There were no other differences between Arabic males and females for any levels of sports intensity. Chinese males reported more engagement in moderate, strenuous and strength training activity than females but these differences are not statistically significant (Table 5.5).

Participants across the three cohorts were minimally involved in strength training activity (about 15 minutes per week).

A third of mainstream participants were asked about the frequency of 'brisk' walking.²⁶ The proportion of mainstream participants reporting brisk walking most of the time or all of the time was 34.6%. When brisk walking was incorporated in the total moderate-vigorous activity for mainstream participants the total number of minutes per week increased from 59.4 to 99.1 (Table 5.5).

²⁶ Question introduced late in the Program evaluation

Table 5.5 Level of engagement of CATI respondents in structured physical activity by cohort and by sex. Percentage of respondents, mean (SD)/median minutes per week (interquartile ranges). N total with complete physical activity data=1,292

PASE domains	Mainstream N=1,137			Arabic N=82			Chinese N=73		
	Males=424; Females=713			Males=18; Females=64			Males=34; Females=43		
STRUCTURED	%	Mean minutes/week (SD)	Median minutes/week (IQR)	%	Mean minutes/week (SD)	Median minutes/week (IQR)	%	Mean minutes/week (SD)	Median minutes/week (IQR)
Light sports	15.6	26.1(88.9)	0 (0 - 0)	19.5	35.7(99.3)	0 (0 - 0)	23.3	37.2(72.1)	0 (0 - 0)
Males	11.9	26.1(87.8)	0 (0 - 0)	22.2	24.2(52.0)	0 (0 - 0)	24.2	41.8(78.9)	0 (0 - 0)
Females	17.7	26.7(89.0)	0 (0 - 0)	18.8	38.9(109.1)	0 (0 - 0)	22.5	33.4(66.89)	0 (0 - 0)
Moderate sport	17.1	29.5(92.8)	0 (0 - 0)	1.2	0.5(5.0)	0 (0 - 0)	9.6	18.1(64.2)	0 (0 - 0)
Males	19.7	43.6(124.2)**	0 (0 - 0)	0.0	0.0	0 (0 - 0)	12.1	23.2(73.9)	0 (0 - 0)
Females	15.4	21.0(65.8)	0 (0 - 0)	1.6	0.7(5.6)	0 (0 - 0)	7.5	13.9(55.6)	0 (0 - 0)
Strenuous sport	8.5	14.73(68.7)	0 (0 - 0)	8.5	11.0(41.6)	0 (0 - 0)	21.9	25.5(58.8)	0 (0 - 0)
Males	12.3	24.2(89.6)*	0 (0 - 0)	16.7	30.05(74.0)	0 (0 - 0)	27.3	31.4(62.1)	0 (0 - 45)
Females	6.3	9.0(51.4)	0 (0 - 0)	6.3	5.6(24.7)	0 (0 - 0)	17.5	20.6(56.3)	0 (0 - 0)
Muscle strength	12.4	15.3(58.5)	0 (0 - 0)	2.4	1.8(12.6)	0 (0 - 0)	6.9	8.6(36.5)	0 (0 - 0)
Males	12.1	16.4(56.4)	0 (0 - 0)	0.0	0.0	0 (0 - 0)	15.2	19.1(52.8)	0 (0 - 0)
Females	12.4	14.6(58.4)	0 (0 - 0)	3.1	2.3(14.2)	0 (0 - 0)	0.0	0.0	0 (0 - 0)
All Moderate-vigorous P.A. (minutes/week)		59.4(148.7)	0 (0-45)		13.4 (43.7) **	0 (0 - 0)		52.2 (100.6)	0 (0 - 45)
Males		84.1(184.9)***	0 (0-105)		30.0 (74.0)	0 (0 - 0)		73.6 (114.6)	0 (0 - 135)
Females		44.5 (119.6)	0 (0-45)		8.7 (29.5)	0 (0 - 0)		34.5 (84.7)	0 (0 - 0)
All moderate-vigorous including brisk walking		99.1 (208.2)	0 (0 -135)		39.5 (99.0) *	0 (0 - 0)		100.7 (179.8)	0 (0 -180)

IQR= interquartile ranges 25%-75%

* $p \leq 0.05$ ** $P \leq 0.01$ *** $P \leq 0.001$ for differences in means across cohorts or between sexes

Some 15.6% of the Arabic reported brisk walking most or all of the time and the corresponding proportion of Chinese participants was 19.1%. When brisk walking was included in the calculations, the mean total moderate-vigorous activity per week almost tripled from 13.4 to 39.5 minutes per week (SD 99) for the Arabic participants, and almost doubled from 52.2 to 100.7 minutes per week (SD 180) for the Chinese participants (Table 5.10). However, the median was still zero minutes per week for both cohorts.

Question 7 What is the level of readiness to change behaviour (prior use of physical activity / healthy eating services, self-efficacy and social support) of participants by cohort?

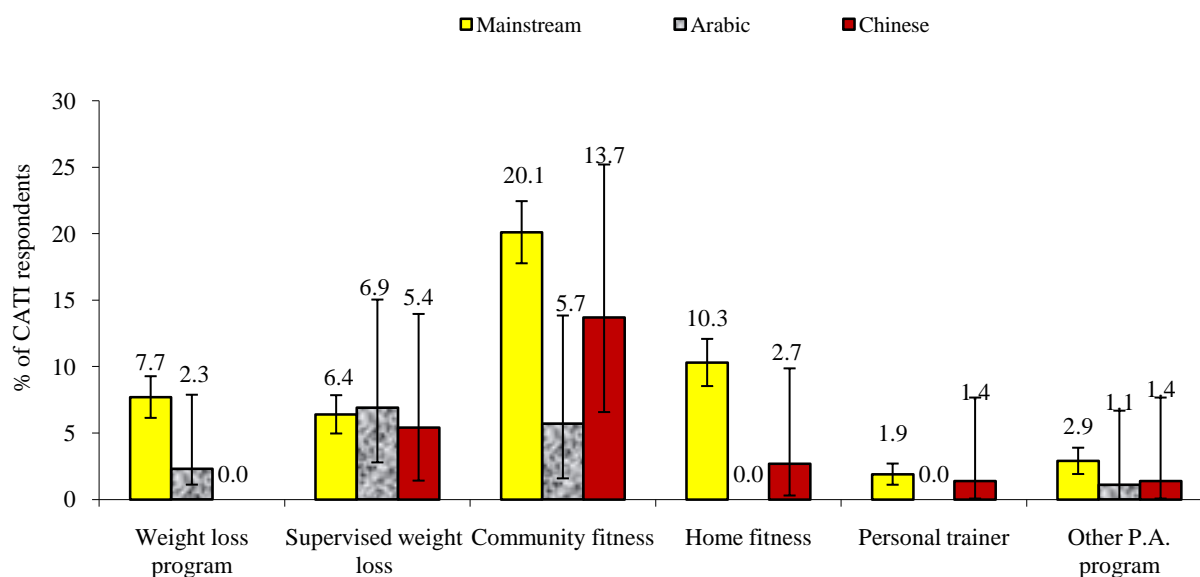
5.6 Participants' Readiness to Join the Program (self-efficacy & social support)

5.6.1 Physical Activity and Weight Loss Services Used Prior to Enrolment

These three aspects of self-efficacy, social support and services used prior to enrolment are used as a proxy for the concept of 'readiness to change'. They are measured to be used as covariates in the analysis of predictors of success in achieving short-term and long term success later in this thesis. The three are used in the multivariate analysis of short-term impact at three months (Chapter 7), and the first two concepts are also tested as potential predictors of achieving the goals in the 12-month impact evaluation (Chapter 8).

About a third of mainstream participants in the CATI survey reported being engaged to various degrees in all types of healthy behaviours before commencing the SDPP (31.4% some regular physical activity, and 6% some form of healthy weight program). The most commonly used services were community fitness venues followed by home fitness and weight loss programs (Figure 5.4).

Figure 5.4 Distribution of participation in physical activity programs or services at baseline by cohort. N=1,292 CATI respondents.



Mainstream participants were over three times more likely to attend some community fitness program than Arabic participants. The distribution of specific healthy lifestyle activities reported by participants before enrolling in the SDPP program indicated that Arabic participants sought weight loss services while Chinese participants sought regular physical activity opportunities.

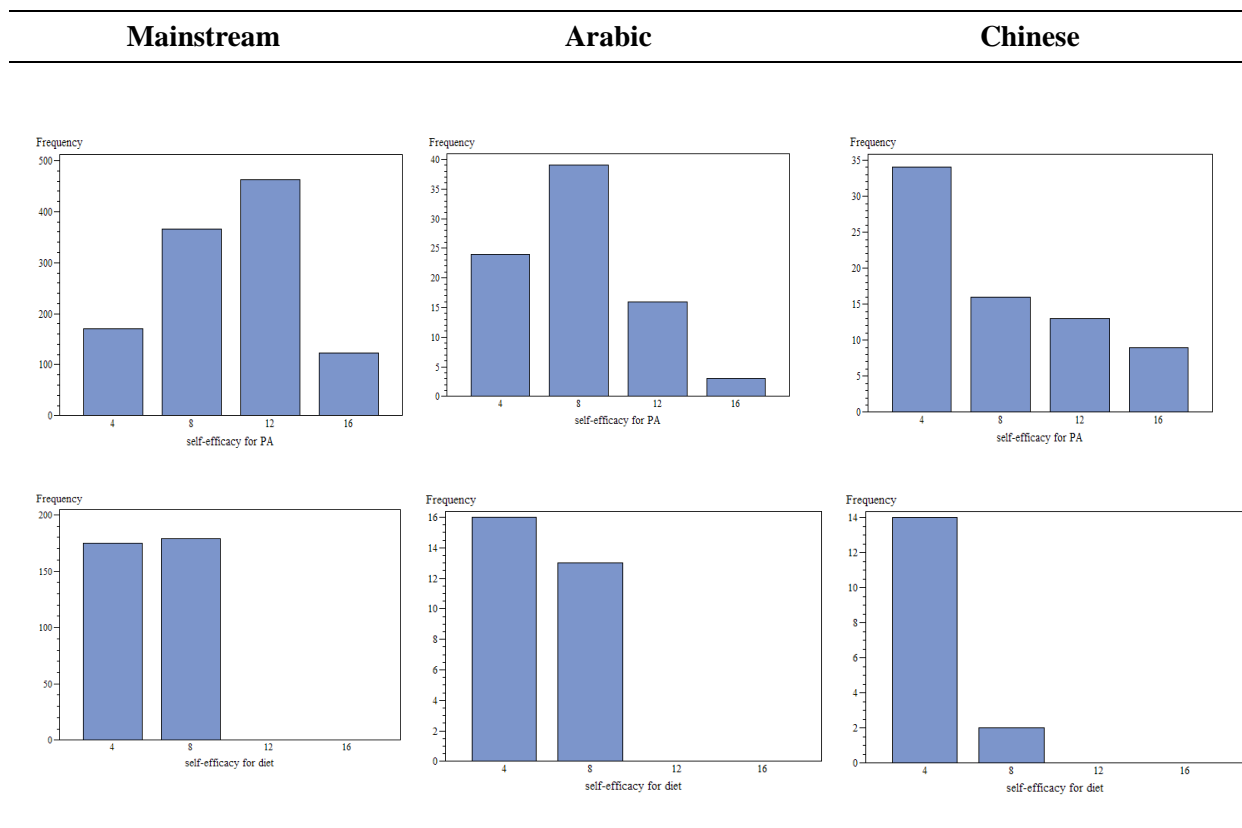
5.6.2 Baseline self-efficacy

Overall self-efficacy for both physical activity and healthy eating showed a non-Normal distribution for all cohorts (Figure 5.5). More than half (53.3%) of mainstream participants scored at the lower end of the confidence scale for physical activity. Four percent of mainstream participants reported no general confidence at all and only 2.2% reported total confidence in achieving their physical activity and healthy eating goals.

The overall distribution of self-efficacy scores for physical activity (Table 5.6) among CATI respondents indicated that the mainstream participants had reasonable levels of baseline self-

efficacy at baseline out of a maximum of 16 (median 10, interquartile ranges 7-12).²⁷ Males in the mainstream cohort scored significantly higher than their female counterparts on self-efficacy for physical activity. For healthy eating, 89.1% of the mainstream participants scored at the lower end of self-efficacy scale, and again, males were significantly more likely to score higher than women. It is apparent that there is far less confidence in adhering to healthy eating than in keeping with physical activity intentions.

Figure 5.5 Distribution of self-efficacy for physical activity (top row) and healthy eating (bottom row) by cohort . Total respondents: Mainstream 1,123, Arabic 82, Chinese 72



The distribution of self-efficacy scores for Arabic and Chinese participants in the CATI survey suggested a different picture, with no differences by sex within cohorts but significantly lower

²⁷ Total number of cases in the self-efficacy module vary from total CATI respondents as score is not calculated if one of the self-efficacy items is missing. For example, if the respondent argues they do not get depressed or are never stressed, then the item does not apply to them.

than mainstream in physical activity self-efficacy scores in both sexes (Table 5.6). Self-efficacy for healthy eating showed that Chinese participants had higher scores than people in the other two cohorts. This is mostly because female Chinese participants have significantly higher scores than their counterparts in the other two cohorts, but there is no difference in self-efficacy for healthy eating among the males across the three cohorts.

Table 5.6 Baseline self-efficacy scores for physical activity and healthy eating by sex (16=high 4=low). Total respondents; Mainstream 1123, Arabic 82, Chinese 72.

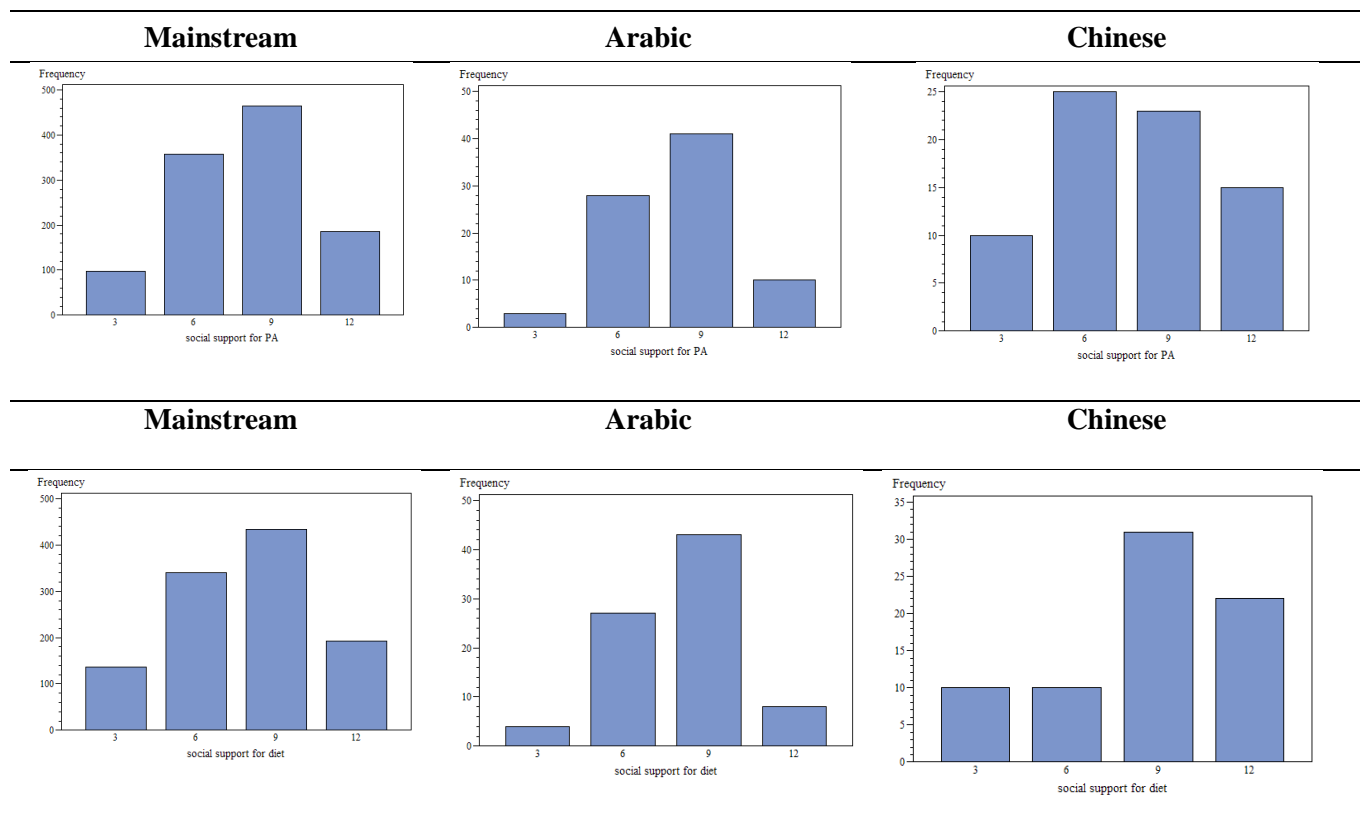
Parameters	Self-efficacy for physical activity				Self-efficacy for healthy eating			
	Mean Scores (SD)				Mean Scores (SD)			
	Mainstream M=422 F=701	Arabic M=18 F=64	Chinese M=32 F=40	p across cohorts	Mainstream M=421 F=696	Arabic M=18 F=64	Chinese M=33 F=39	p across cohorts
Self-efficacy score (overall)	9.5(3.4)	7.4(3.1)	7.5(4.6)	<0.0001	9.1(3.4)	8.6(3.2)	10.1(5)	0.002
Male	10.5(3.2)***	7.6(3.4)	8.5(4.1)	<0.0001	9.8 (3.3)***	9.1(2.9)	9.8(4.6)	0.671
Female	9.0(3.4)	7.3(3.0)	6.9(4.7)	<0.0001	8.7(3.3)	8.5(3.2)	10.7(5.1)	0.002

*** $p < 0.0001$ for sex differentials within cohorts

5.6.3 Baseline social support

The distribution of social support scores for physical activity in the mainstream cohort participating in the CATI survey has a relatively Normal spread similar to that of healthy eating (Figure 5.6). Only 4% of mainstream participants never received any social encouragement for physical activity or healthy eating, and 22% reported it rarely. Six percent of mainstream participants reported receiving social support often, and 68% reported receiving it sometimes. When analysed separately, over a third of mainstream participants never or rarely received encouragement to do physical activity or healthy eating (41.2% and 43.2 % respectively).

Figure 5.6 Distribution of social support scores for physical activity (top row) and healthy eating (bottom row) among SDPP participants by cohort. All participants responding to the self-efficacy section of the baseline CATI survey: Mainstream 1,125, Arabic 82, Chinese 73.



Overall the distribution of social support varied across cohorts, with the Chinese male participants reporting significantly higher support for diet than male participants in the other two cohorts (Table 5.7). However, these differences were not statistically significant in the regression analyses, as explained in section 5.9.2.

No sex differentials were found in the social support scores for physical activity among mainstream males and females, but males had significantly higher scores in social support for healthy eating than females did (Table 5.7).

Table 5.7 Sex differentials for social support scores within and across cohorts. All participants responding to the social support module of the baseline CATI survey: Mainstream 1,112, Arabic 82, Chinese 73.²⁸

Parameter	Social support Mean Scores (SD)			
	Mainstream M=419 F=693	Arabic M=18 F=64	Chinese M=33 F=40	p across cohorts
Social support score (for P.A.)	8.0(2.5)	7.9(2.2)	7.8(2.8)	0.717
Male	8.1(2.5)	7.2(2.3)	7.8(2.8)	0.265
Female	8.0(2.5)	8.1(2.1)	7.8(2.9)	0.830
Social support score (for diet)	7.9 (2.7)	8.1 (2.1)	8.7 (2.8)	0.031
Male	8.1 (2.6)*	7.5 (2.4)	9.2 (2.4)	0.029
Female	7.8 (2.8)	8.3 (2.0)	8.3 (3.0)	0.149

* $p \leq 0.05$ for sex differentials within cohort P.A.= Physical activity

There were no statistically significant differences in social support for physical activity across the three cohorts or between males and females within the Arabic or Chinese cohorts. Sex differentials in social support for healthy eating within the Arabic or Chinese cohorts were not statistically significant possibly due to the small numbers of males in the sample.

Question 8 *What was the baseline macronutrient profile of participants by cohort and sex?*

5.7 3-day Food Diary Data

5.7.1 Baseline Nutritional Profile

Macronutrient analysis derived from self-completed 3-day food diaries for the week prior to Program enrolment indicates that at baseline mainstream SDPP participants had high fat and saturated fat intake and low fibre intake in relation to the goals of the Program as depicted in black horizontal lines in

Figure 5.7.²⁹

The mean proportion of total energy intake from fat was significantly lower for the Chinese participants than for the mainstream and Arabic participants (

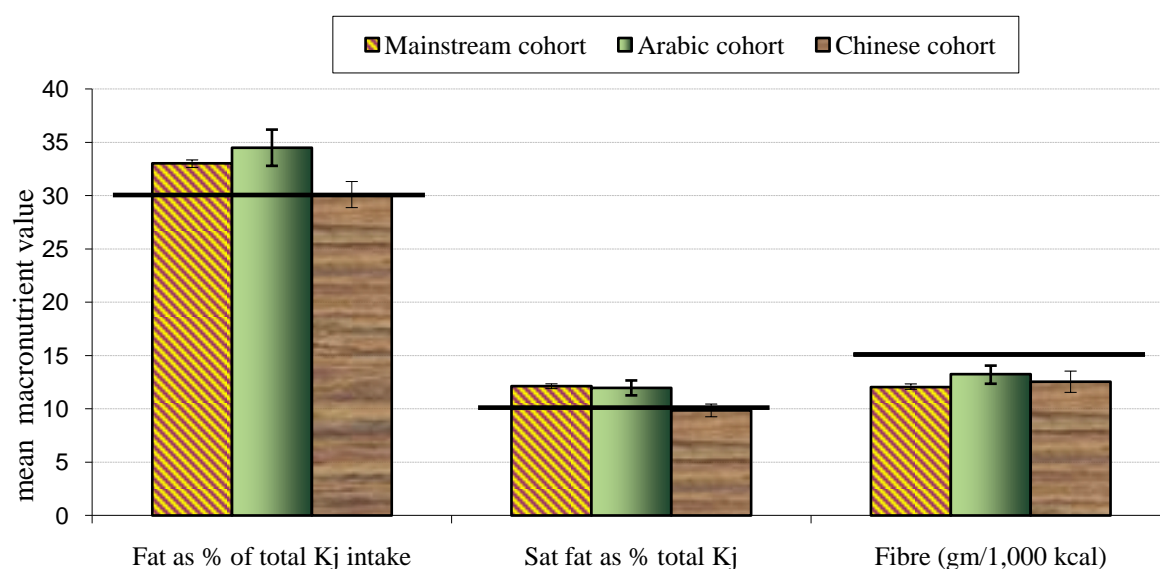
²⁸ N differs from the totals in self-efficacy because scores are not calculated if the respondent argues the item is not applicable to them. For instance, they do not have family to support them, thus the question is not applicable.

²⁹ Goal for total energy from fat: $\leq 30\%$; goal for saturated fat: $\leq 10\%$ total energy intake; goal for fibre: ≥ 15 g/1000kcal/day

Figure 5.7 and Table 5.8).

Likewise, the Chinese participants reported significantly lower levels of saturated fat intake as a percentage of total energy; there was no significant difference between the total or saturated fat intake between the mainstream and the Arabic participants.

Figure 5.7 Mean proportions of macronutrient among SDPP participants from the mainstream, Arabic and Chinese cohorts in relation to Program goals. Participants who delivered the 3-day food record at baseline. Mainstream N=1,133, Arabic=63 Chinese=72



Value of macronutrient is: mean % for fat and saturated fat and mean g/1000 kcal for fibre

The mainstream participants had the lowest fibre intake and there was no statistically significant difference in the estimated fibre intake for Arabic and Chinese.

Males in the mainstream and Chinese cohorts had significantly higher energy intakes than their female counterparts but there were no significant gender differences in total energy intake for Arabic males and females (Table 5.8). Females in the mainstream cohort had significantly higher intake levels of energy from fat than their male counterparts; there were no significant sex

differences in energy intake from fat in the other two cohorts, possibly due to lack of power in the male CALD sample.

Table 5.8 Baseline Nutrition profile (macronutrients) of SDPP participants at baseline by cohort and sex. Completers of 3-day food record: Mainstream=1,133, Arabic 63 and Chinese 72

Macronutrient at baseline	Mainstream Mean (SD) Median (IQR) Male=419 Female=714	p for M vs. A	SDPP Arabic Mean (SD) Median (IQR) Male=14 Female=49	p for A vs. C	SDPP Chinese Mean (SD) Median (IQR) Male=30 Female=42	p for M vs. C
Total energy intake (Kj) (all)	7931Kj (2193) 7623 (6485-9170)	<0.0001	6753Kj (2252) 6187 (5067-8163)	0.0002	8108Kj (1810) 8056 (6625-9408)	0.43
Males	8754 Kj +2375*** /8495 (7225-9961)		6865 Kj (1694) NS 7183 (5090-8481)		8835 Kj (1671)** 9089 (7560-9792)	
Females	7449 Kj (1924) 7262 (6161-8579)		6722 Kj (2401) 6127 (5067-8071)		7589 Kj (1671) 7456 (6307-8384)	
Kj from fat % (all)	33.1 % (6.6) 33.2 (29.0-36.9)	0.07	34.6 % (6.8) 34.7 (30.2-37.5)	<0.0001	30.2 % (5.2) 29.8 (26.1-34.4)	<0.0001
Males	32.0% (6.7)		33.4 % (6.0)		29.1 % (5.4)	
Females	33.7% (6.4)***		34.9 % (7.0) NS		31.0 % (5.0) NS	
Saturated fat as % total energy (all)	12.2% (3.4) 12.0 (9.8-14.3)	0.62	12.0% (2.8) 12.0 (10.1-14.2)	<0.0001	9.9% (2.6) 9.6 (8.3-11.9)	<0.0001
Males	11.9% (3.3) NS		12.8% (3.1) NS		9.9% (2.7) NS	
Females	12.3% (3.5)		11.7% (2.6)		9.8% (2.3)	
Fibre (g/1000kcal) (all)	12.0 g (3.6) 11.6 (9.5-14.1)	0.01	13.3 g (3.2) 12.7 (11.5-15.5)	0.34	12.6 g (4.3) 12.0 (10.1-14.0)	0.03
Males	11.3 (3.4)		13.1 g (3.7)		12.0 g (2.9)	
Females	12.5 (3.7)***		13.3 g (3.1) NS		13.1 g (5.1) NS	

Differences across cohorts: M=mainstream A=Arabic C=Chinese

SD= Standard deviation IQR= interquartile range 25%-75%

*** $p < 0.0001$ ** $p < 0.01$ for male-female differences within cohort

NS=not significant

No statistically significant differences were observed in saturated fat consumption between males and females in any of the cohorts. The fibre intake of mainstream female participants was significantly higher than that of the males. No sex differences in fibre intake were observed in the other two cohorts (Table 5.8).

Overall, the SDPP nutrition profile at baseline showed that mean values for major macronutrients do not meet the program goals and therefore the lifestyle intervention had potential to modify dietary behaviour.

Question9 What were the baseline anthropometric and clinical profiles of SDPP participants by cohort and sex?

5.8 Objective Measurements on Clinical Characteristics

5.8.1 Baseline anthropometry and clinical profile

Baseline physical measurements indicated that the BMI of the majority of the mainstream males and females fell into the obese category ($>30 \text{ kg/m}^2$) and the mean and median waist circumference fell into the high risk category for diabetes both for males and females (Table 5.9). About two thirds (62%) of mainstream participants were classified as obese. The baseline mean and median values for blood glucose, lipids and blood pressure fell within normal ranges for all mainstream participants. However, males had slightly but statistically significantly higher FPG, triglycerides and systolic blood pressure than females. Within those normal ranges females had higher total cholesterol than males. However, these differences may not be clinically important.

From ANOVA, the mean baseline weight was significantly higher for the mainstream participants than for either of the other two cohorts. Males had statistically significantly higher baseline weight than females within and across the three cohorts. However, no significant differences in BMI were found between the mainstream and Arabic participants, and this is explained by differences in height. Seventy percent of the Arabic participants were classified as obese, and Arabic females had significantly higher BMI than their male counterparts. By contrast, BMI in Chinese participants was significantly lower than the other 2 cohorts (only 14% were classified as obese)³⁰ and female Chinese participants expectedly had lower weight than male Chinese participants.

³⁰ Obesity cut off for Arabic and mainstream= 30 Kg/m^2 and for Chinese = 27.5 Kg/m^2 as per WHO expert group. [WHO 2004]

Table 5.9 Baseline clinical profile differentials –Means by sex and cohorts. Data available for 1250 mainstream, 84 Arabic and 79 Chinese participants.⁵

Parameter and sex	SDPP Mainstream Males = 466 Females=784	SDPP Arabic Males =19 Females=65	SDPP Chinese Males = 35 Females=44	P for difference across cohorts
	Mean (SD)	Mean (SD)	Mean (SD)	
Weight at initial consult ³¹ (kg) All (median, IQR¶)	89.7 Kg (17.8) (88.4, 76.9-101)	83.9 (13.3) (84.4, 75.0-93.0)	67.3 (9.9)# (65,61-74)	<0.0001
Males	97.3 (17.8)***	89.1 (10.7)	74.0 (8.4)***	<0.0001
Females	85.2 (16.1)***	82.3 (13.7)	62.0 (7.4)***	<0.0001
BMI at Baseline (units) All (median, IQR¶)	32.4 (5.8) (31.6, 28.3-35.7)	33.0 (6.2) (32.3, 29.5-36.8)	25.1 (2.9)# (24.6, 23.3-26.6)	<0.0001
Males	31.8 (5.3)*	30.7 (4.1)*	25.6 (2.5)	<0.0001
Females	32.8 (6.0)*	33.7 (6.6)*	24.7 (3.1)	<0.0001
Mean WC (cm) (median, IQR¶)	107.1 (13.2) (106.3, 98-115.4)	105.7 (13.5) (105, 96.5-114.3)	88.8 (7.7)# (87.5, 83.4-92.8)	<0.0001
Males	112.0 (13.0)**	106.5 (10.8)	92.5 (6.9)***	<0.0001
Females	104.3 (12.5)**	105.4 (14.3)	85.8 (7.1)***	<0.0001
Fasting Plasma glucose ³² (mmol/L) All (median, IQR¶)	5.3 (0.6) (5.3, 4.9-5.7)	5.2 (0.56) (5.1, 4.7-5.5)	5.3 (0.6) (5.3, 5.0-5.6)	0.086
Males	5.4 (0.7)*	5.3 (0.4)	5.4 (0.7)	0.491
Females	5.3 (0.6)*	5.1 (0.6)	5.3 (0.5)	0.229
Fasting OGTT ³³ (mmol/L) All (median, IQR¶)	5.7 (0.7) (5.6, 5.2-6.0)	5.7 (0.45) (5.7, 5.5-5.8)	5.9 (1.0) (5.7, 5.4-6.1)	0.900
Males	5.8 (0.8)			
Females	5.6 (0.6)			
2-hour Plasma glucose (mmol/L) All (median, IQR¶)	6.7 (2.0) (6.5, 5.2-8.0)	7.1 (2.0) (7.3, 4.8-8.3)	7.0 (1.6) (6.5, 5.9-7.7)	0.855
Males	6.7 (2.0)			
Females	6.7 (1.9)			
Total cholesterol ³⁴ (mmol/L) All (median, IQR¶)	5.3 (1.0) (5.2, 4.6-5.9)	5.5 (1.1) (5.5, 4.8-6.1)	5.4 (1.0) (5.6, 4.6-6.0)	0.282
Males	5.1 (1.0)**	5.3 (0.8)	5.1 (0.9)*	0.934

³¹ 1,236 out of 1,250 mainstream participants had measured weight at initial consult

³² 1,061 out of 1,250 mainstream, 77 out of 84 Arabic and 72 out of 79 Chinese participants had FPG

³³ Only 363 out of 1250 mainstream, 10 out of 84 Arabic and 10 out of 79 Chinese participants had OGTT. No significance testing was attempted for Chinese or Arabic participants due to small numbers.

³⁴ 1182 out of 1250 mainstream, 72 out of 84 Arabic and 78 out of 79 Chinese participants had total cholesterol values documented

Parameter and sex	SDPP Mainstream Males = 466 Females=784	SDPP Arabic Males =19 Females=65	SDPP Chinese Males = 35 Females=44	P for difference across cohorts
	Mean (SD)	Mean (SD)	Mean (SD)	
Females	5.4 (1.0)**	5.5 (1.2)	5.7 (0.9)*	0.277
Triglycerides ³⁵ All (median, IQR¶)	1.6 (0.9) (1.4, 1.0-1.9)	1.7 (0.9) (1.5, 1.1-2.0)	1.6 (1.2) (1.4, 0.0-1.9)	0.594
Males	1.7(0.9)*	2.1 (1.2)	1.8 (1.6)	0.199
Females	1.5 (1.0)*	1.6 (0.8)	1.5 (0.8)	0.924
Systolic blood pressure ³⁶ (mm Hg) All (median, IQR¶)	131 (15) (130, 120-140)	127 (11) (130, 120-135)	125 (12) (127, 116-135)	0.803
Males	132 (14)*	125 (10)	125 (13)	0.139
Females	130 (15)*	128 (11)	125 (11)	0.825
Diastolic blood pressure (mm Hg) All (median, IQR¶)	79 (9) (80, 73-85)	78 (8) (80, 72-83)	76 (8)# (78, 70-80)	0.033
Males	79 (9)	75 (9)	78 (9)	0.180
Females	79 (10)	79 (8)	75 (6)	0.025
Impaired glucose regulation ³⁷				
IFG (% within cohort)	10.1	6.3	11.0	0.886
IGT (% within cohort)	30.0	30.0	20.0	0.202

[§] Not all tests available for all participants for various reasons including participant preference and GP discretion.

¶ Interquartile ranges (presented for whole cohorts only)

denotes the cohort with the significantly different estimate

* $p \leq 0.05$ for sex differentials within cohort

Baseline WC was statistically significantly different for males across the three cohorts, with the mainstream males exhibiting the largest waist circumferences but only the Chinese WCs were significantly different from the other two cohorts. Among females, only the Chinese had a significantly smaller WC than participants in the other two cohorts. There were no statistically significant differences in diabetes risk score, single fasting plasma glucose, fasting OGTT, 2-hour OGTT, total cholesterol, triglycerides, or systolic blood pressure across the three cohorts. Only female Chinese participants had significantly lower diastolic blood pressure than their

³⁵ 1,174 of 1,250 mainstream, 70 out of 84 Arabic and 78 out of 79 Chinese participants had triglycerides results available

³⁶ 51 out of 84 Arabic and 77 out of 79 Chinese participants had recorded blood pressure values

³⁷ As per WHO definition. See section 44.1 in Chapter 4

counterparts in the other two cohorts. Arabic participants appeared to have lower rates of IFG than the other two cohorts and Chinese participants seemed to have lower rates of IGT than their counterparts but these differences were not statistically significant.

Question 10 *What are the overall correlates of participation in the SDPP and what are the predictors of self-efficacy and social support for the Program?*

5.9 Correlates of Participation and Goal Achievement at Baseline

5.9.1 Correlates of participation in the Program

The role of age, sex and socio-economic status have been identified as influencing physical activity engagement in adults. Confounders such as old age and disadvantage (older people and those with chronic disease tend to be less active and poorer people tend to have fewer opportunities to engage in sports), effect modifiers (moderators) such as sex (estimates of the effect vary between males and females) and mediators such as self-efficacy and social support (273) are explored in this thesis. In particular, this Chapter describes the baseline levels and Chapter 8 examines their impact on the Program effects.

Decliners in the SDPP are defined as those people with an *Ausdrisk* score of ≥ 15 who were eligible but declined the invitation to participate.

When compared with mainstream Program participants, the socio-demographic characteristics of mainstream decliners indicate that there was no statistically significant difference in the age-group distribution ($p > 0.05$) but the decliners had a larger proportion of males ($p < 0.0001$).

There was no significant difference in the mean *Ausdrisk* scores of participants and non-participants (Table 5.10).

Table 5.10 Descriptive comparison between mainstream participants and decliners screened during Program implementation (2008-2010)- Demographics and risk score.♦

Parameter	Mainstream participants (N = 1258)	Mainstream decliners (N = 423) ^a
Age distribution (as per risk tool groups)		
50-54years	295 (24%)	99 (23%)
55-64years	866 (69%)	304 (71%)
65 years	89 (7%)	20 (5%)
Sex		
Males	466 (37%)	203 (48%)***
Females	784 (63%)	220 (52%)
Central Sydney N =562 mainstream	M 174 (31%) F 388 (69%)	M 38 (37%) F 64 (63%)
Macarthur N =301 mainstream	M 140 (47%) F 161 (53%)	M 34 (53%) F 30 (47%)
Southern Highlands N =387 mainstream	M 152 (39%) F 233 (61%)	M 82(56%) F 64 (44%)
Ausdrisk score	Median 19 IQR (16-21)	Median 18 IQR (16-20)

♦ Values are percentages unless otherwise specified. Age % is column % within participant /decliner group; MF sex % are row % out of each Division

^a Total number of mainstream decliners was 450 but data were only available for 423 of them

*** $p < 0.0001$

The following section examines those aspects that may improve chances of success at the end of the Program.

5.9.2 Predictors of Readiness to Change Behaviour (social support and self-efficacy)

5.9.2.1 Predictors of social support

The impact of potential predictors of participants reporting being 'sometimes or often' encouraged to do physical activity or eat healthily from family, friends or healthcare providers is shown in Table 5. 11. In the unadjusted bivariate analysis, several factors predicted reporting high social support. Male sex and high BMI and high anxiety scores were significantly associated with high social support. Arabic participants reported high levels of social support but this association was not statistically significant. Conversely, increasing age and being on a pension attracted the least social support, although these negative predictors were not statistically significant.

After controlling for other potential confounders, the most significant predictor of high levels of social support is being a male, followed by having high levels of anxiety. That is, men and

anxious participants (as defined by the HADS) were more likely to receive social support for diet and physical activity than women and non-anxious participants. There was a negative association between age and the likelihood of social support for a healthy lifestyle. That is, the older the participant, the less likely they were to receive social support for physical activity or diet. In contrast, there was a small but statistically significant positive association between BMI and social support, indicating the more obese the person was, the more likely (3% more support for each unit increase in BMI) they were to receive encouragement from others for physical activity and healthy eating.

Table 5. 11 Predictors of moderate to high social support for physical activity and healthy eating combined. Unadjusted and adjusted estimates from logistic regression analysis. All participants responding to the social support module of the baseline CATI survey: Mainstream 1112, Arabic 82, Chinese 73.

Parameters (referent group)	Social support for physical activity and healthy eating combined	
	Predictors of 'Yes' (support scores >12)	
	Unadjusted OR (95%CI)	Adjusted OR (95%CI)
Male sex (Female is referent)	1.28(0.98-1.70)***	1.44 (1.09-1.91) *
Age (continuous)	0.955 (0.93-0.98)*	0.96 (0.93-0.99)*
BMI (continuous)	1.032 (1.01-1.06)*	1.03 (1.01-1.06)*
Arabic stream (mainstream is referent)	1.65 (0.92-3.0)	NS
Chinese stream (mainstream is referent)	1.04 (0.60-1.80)	NS
Depression score (no depression is referent)	1.2 (0.87-1.66)	NS
Anxiety (no anxiety is referent)	1.50 (1.12-2.00)*	1.49 (1.10-2.00)*
On a pension (not on a pension is referent)	0.984 (0.75-1.29)	NS
High self-rated health (low self-rated health is referent)	0.981 (0.744-1.29)	NS

*** $p \leq 0.0001$ ** $p \leq 0.001$ * $p \leq 0.01$ * ≤ 0.05 NS=not significant

Other than age and sex, none of the other socio-demographic variables examined (ethnic cohort, employment status, private insurance coverage, education, pension status, household size) was statistically significantly associated with levels of social support. In the adjusted model, neither self-assessed health status nor depression scores were associated with reporting social support.

5.9.2.2 Overall correlates and predictors of self-efficacy

Logistic regression analysis indicated that self efficacy for physical activity was associated with several demographic and risk factors (correlates). After controlling for other potential correlates, males and people scoring very good to excellent self-reported health were more likely (about twice and four times respectively) to report feeling confident or very confident than the rest of participants (predictors). Conversely, having high BMI, scoring in the depression or anxiety range of HADS, being in the Chinese or Arabic cohort, and being the recipient of a pension, predicted lower self-efficacy for physical activity after controlling for the other variables in the logistic regression model (Table 5.12).

There is also a direct, statistically significant relationship between self-efficacy for healthy eating and being a male and being older, meaning that males have higher self-efficacy for diet and for every increase in years of age there is a 2% increased self-efficacy.

Table 5.12 Correlates and predictors of moderate to high self-efficacy for physical activity and healthy eating. Unadjusted and adjusted estimates from logistic regression analysis. All participants responding to the self-efficacy section of the baseline CATI survey: Mainstream 1125, Arabic 82, Chinese 73.

Parameters (referent group)	Self-efficacy for physical activity Predictors of 'Yes' (efficacy scores >8)		Self-efficacy for healthy eating Predictors of 'Yes' (efficacy scores >8)	
	Unadjusted OR (95%CI)	Adjusted OR (95%CI)	Unadjusted OR (95%CI)	Adjusted OR (95%CI)
	Male sex (female is referent)	2.18 (1.72-2.8)***	1.97 (1.52-2.56)***	1.50 (1.21-1.87)*
Age (continuous)	1.04 (1.02-1.07)**	1.02 (0.99-1.05) ^{NS}	1.06 (1.04-1.09)***	1.10 (1.02-1.09)**
BMI (continuous)	0.96 (0.94-0.98)***	0.97 (0.95-0.99)*	0.96 (0.94-0.98)**	0.96 (0.94-0.98)***
Arabic stream (mainstream)	0.25 (0.15-0.41)***	0.46(0.26-0.81)*	NS	NS
Depression (no depression)	0.42 (0.26-0.69)**	0.36 (0.21-0.63)**	NS	NS
Anxiety (no anxiety)	0.27 (0.12-0.36)***	0.48 (0.33-0.68)***	NS	NS
On a pension (not on a pension)	0.37 (0.29-0.47)***	0.63 (0.47-0.85)*	0.59 (0.44-0.79)**	0.52 (0.40-0.67)***
High self-rated health (low self rated health)	0.57 (0.45-0.72)***	0.71 (0.54-0.929)*	NS	NS

*** $p \leq 0.0001$ ** $p \leq 0.001$ * $p \leq 0.01$ * ≤ 0.05 NS=not significant

There was a negative relationship between BMI and anxiety and self-efficacy for healthy eating. That is, the higher the BMI and the higher the anxiety score, the lower the self-efficacy. These results are adjusted for the other covariates (Table 5.12).

Question 11 *What were the correlates of meeting the Program goals at baseline for participants overall?*

In order to identify the true effect of this lifestyle intervention it is necessary to quantify and characterise the participants who required the least and the most effort to meet the Program goals at 12 months. That is, the Program may assist in maintaining the goals for those who already met them at baseline and it may have the potential to motivate those who do not meet the goals at the outset.

5.9.3 Participants already meeting the goals at baseline

Overall, 10% of mainstream participants reported doing at least 210 minutes of moderate to vigorous activity per week at baseline (Table 5.13). One in every three mainstream participants reported meeting the fat goal, one in every four reported meeting the saturated fat goal, and one in five reported meeting the fibre goal, as measured by the 3-day food record. When brisk walking was incorporated in the calculation of total moderate to vigorous physical activity the proportion of mainstream participants meeting the physical activity goal at baseline increased from 10% to 14.7%. Mainstream males were twice as likely as females to meet the physical activity goal at baseline. Mainstream males are significantly more likely than females to have met the fat goal at baseline, but females were more likely to have met the fibre goal than their male mainstream counterparts. One in every four males and females in the mainstream cohort met the saturated fat goal.

Table 5.13 Overall numbers and proportions of participants meeting the Program goals at baseline by cohort and sex, out of those participating in CATI survey or delivering 3-day food record.

Cohort and sex	Physical activity goal ^y	Fat goal ^a	Saturated fat goal ^b	Fibre goal ^c
	N=1,292 for physical activity ³⁸	N (%)	N(%)	N (%)
	N=1265 for dietary goals³⁹			
Mainstream	113 (10.0)	355 (31.3)	301 (26.6)	209 (18.5)
Males	65 (15.3) ^{***}	157 (37.4) ^{**}	115 (27.4)	65 (15.5)
Females	48(6.8)	198 (27.8)	186 (26.1)	144 (20.2) *
Arabic	1 (1.2) #	14 (23.3)	14 (23.3)	16 (26.7)
Males	1 (1.2)	3 (23.1)	3 (23.1)	3 (23.1)
Females	0.0	11 (23.4)	11 (23.4)	13 (27.7)
Chinese	9 (12.3)	36 (50.0)	40 (55.6)	12 (16.7)
Males	5 (15.2)	19 (59.4)	18 (56.3)	5 (15.6)
Females	4 (10.0)	17 (42.5)	22 (55.0)	7 (17.5)

$p < 0.05$ for differentials across cohorts

* $p < 0.05$ ** $P \leq 0.01$ *** $P \leq 0.001$ for differentials between sexes

y ≥ 210 minutes of moderate-to-vigorous physical activity per week

a $\leq 30\%$ of total daily energy intake b $\leq 10\%$ of total daily energy intake c ≥ 15 g fibre/1,000 kcal per day

Participants from the mainstream and Chinese cohorts were significantly more likely than those from the Arabic cohort to report meeting the physical activity goal at baseline. About one in every five Arabic participants report meeting the dietary goals and the majority did not meet the physical activity goal. No sex differentials were found within the Arabic or Chinese cohorts on any of the Program goals at baseline. When brisk walking was incorporated into total physical activity, the proportions of Arabic and Chinese participants meeting the physical activity goal increased to 6.1% and 20.6% respectively. About half the Chinese participants reported meeting the fat and saturated fat goals at baseline but less than one in five Chinese participants met the fibre goal (Table 5.13).

Exploring bivariate associations between meeting the physical activity Program goal at baseline and other socio-demographic and risk factors yielded no statistically significant associations for age, pension status or employment status among mainstream participants (Table 5.14).

Education and employment appeared to have a strong positive relationship with meeting the

³⁸ N= 1,137 for mainstream, 82 for Arabic and 73 for Chinese for physical activity

³⁹ N= 1,133 for mainstream, 60 for Arabic and 72 for Chinese

physical activity goal but this was not statistically significant, perhaps due to small numbers meeting the PA goal at baseline.

Table 5.14 Correlates of meeting Program goals at baseline for mainstream participants only. Unadjusted odds ratio or probability of meeting the goal at baseline. N=1137 for physical activity and 1133 for dietary goals.

Parameters (referent group)	Physical activity goal OR (95%CI)	Fat goal OR (95%CI)	Saturated fat goal OR (95%CI)	Fibre goal OR (95%CI)
Age in years (continuous)	1.01 (0.97-1.05)	1.02 (0.99-1.05)	1.01 (0.98-1.04)	1.03 (0.99-1.06)
BMI units (continuous)	0.99 (0.95-1.02)	1.00 (0.98-1.02)	0.97 (0.95-0.99)*	0.97 (0.95-0.99)
High Education (low education)	4.26 (0.57-31.9)	0.73 (0.47-1.10)	0.87 (0.56-1.34)	0.91 (0.54-1.55)
Mid Education (low education)	2.95 (0.40-22.02)	0.86 (0.57-1.30)	0.98 (0.62-1.55)	0.95 (0.58-1.56)
On a pension (not on a pension)	0.07 (0.42-1.06)	1.01 (0.76-1.30)	0.80 (0.59-1.09)	1.04 (0.74-1.46)
In the workforce (not in the workforce)	1.28 (0.85-1.92)	0.97 (0.75-1.26)	0.95 (0.72-1.25)	0.98 (0.71-1.34)
Private insurance (not on insurance)	2.01 (1.26-3.22)**	1.28 (0.96-1.71)	1.23 (0.91-1.66)	1.15 (0.81-1.50)

95% CI = 95% confidence intervals of the estimated probability of mainstream participants meeting the goal
 * $p \leq 0.05$ ** $p \leq 0.01$

Mainstream participants on private health insurance were statistically significantly more likely to meet the physical activity goal at baseline. None of the associations between socio-economic variables and meeting the fat goal were statistically significant, although it appeared that high education was negatively associated with meeting the fat goal at baseline.

Fully adjusted analysis of predictors of achieving the goals at the end of the Program will be presented in the 12-month impact evaluation section of this thesis (Chapter 8).

Question 12 *How good was recruitment in SDPP compared to other community DPPs?*

5.10 Discussion

The Sydney Diabetes Prevention Program has been successful at identifying at-risk people through targeted screening by detecting *Ausdrisk* scores of ≥ 15 in at least one in every two adults screened. However, it is acknowledged that the denominator for screening is uncertain as not all forms sent out were accounted for and forms not filled in were not always returned. The Program managed to recruit 67% of those confirmed eligible to participate.

Overall, males and females invited to the mainstream SDPP group seemed equally likely to decline the invitation to participate. While the SDPP was not a randomised trial, it is reassuring that the distribution of both age and Ausdrisk scores among decliners were similar to those of mainstream participants.

5.10.1 Comparisons with the age-matched NSW population

Socio-demographic profile

Compared with an age-matched sample from the New South Wales Health population health survey participants, the socio-demographic and health status profile of the mainstream SDPP group was somewhat different (Appendices 5.5 and 5.6). The mainstream participants are more highly educated (35.9% vs. 25.7% report tertiary education), more likely to be employed (60.4% vs. 52.8%) and to have private health insurance coverage (66.3% vs. 60.4%) than the overall random NSW population survey sample.

The Chinese cohort participants were more likely (37%) than the Arabic (15.9%) and the SSWAHS survey sample (27.2%) to report complete tertiary education.

Examining the aggregated CALD and mainstream SDPP participants (all SDPP in Table A5.5) indicates that the SDPP participants were slightly but significantly more likely to have completed tertiary education than their SSWAHS counterparts (29.6% vs. 27.2%); they were also less likely to be in paid employment (46.5% vs. 53.7%) or be covered by private health insurance (46.9% vs. 55.3%). This conflicting result may have been due to the inclusion of mostly female participants and the high comorbidity rates of the SDPP sample. These findings indicate that the SDPP sample consists of high-risk people, in particular those from non-English speaking background who also appear to be more socially disadvantaged.

Men scored higher self-efficacy for physical activity and healthy eating than women in the mainstream cohort, and overall the mainstream participants reported higher self-efficacy than the Chinese and Arabic cohorts at baseline. Male sex and older age predicted higher levels of self-efficacy whereas having high BMI and anxiety scores predicted less self-efficacy at the outset. Chinese participants reported higher social support for healthy eating than the other

participants but there were no differences in social support for physical activity across cohorts. After controlling for cohort and socio-economic variables, males and participants who were younger, had higher BMI and higher anxiety scores were more likely to report higher social support. The impact of self-efficacy and social support on weight loss outcomes for mainstream participants will be examined in Chapter 8.

Risk factors and morbidity profile

The table in Appendix 5.6 shows that mainstream SDPP participants also had higher body mass index and had more than double the proportion of obese people compared with the other two groups from the NSW Health Survey. Smoking rates were similar for Arabic and mainstream participants and lower for the Chinese sample. Drinking was four times less prevalent in the Arabic sample than among participants in the other two SDPP cohorts.

Rates of self-reported chronic conditions were seven times higher among the SDPP participants than those reported in the same sub-population in the general NSW health survey from where the SDPP participants were recruited (Appendix 5.6). The presence of two chronic conditions in at least 50% of participants and twice the rates of hypertension and high cholesterol among the SDPP participants confirmed that they were a high-risk group, rather than representative of the average middle aged group in the community.

Overall, the baseline risk profile of the Sydney cohorts suggests that this Program has correctly identified high-risk people through targeted screening in clinical practice and community advertising. It has also succeeded in recruiting a sufficiently large sample size of an ethnically diverse group with a clear need for diabetes risk reduction through lifestyle improvement. Only small proportions had achieved the Program goals at baseline, indicating room for change for most SDPP participants.

5.10.2 Comparisons with other studies

Comparisons with other Australian prevalence studies of obesity and diabetes are relevant here to demonstrate that the SDPP sample, recruited through targeted screening in general practice was not expected to be representative of the general population of middle aged adults. For

instance, the prevalence of chronic conditions was higher in SDPP than that found for the general adult population aged 25 years and above surveyed in the Australian Diabetes, Obesity and Lifestyle (AusDiab) Study. The latter is a longitudinal biomedical survey investigating the prevalence of pre-diabetes and incidence of diabetes that used a cluster sampling method to select people in rural and urban areas of six States and one Territory of Australia. (57) The prevalence of obesity in NSW during the 2004 follow-up was 22.3% for 45-54 year-olds and 28.5% for 55-64 year olds, (17) both still well below the estimates for the SDPP participants (61.2% for mainstream and 48.4% overall). Hypertension prevalence was 17.4% in the 45-54 year-old group and 30.7% among the 55-64 year-olds, also much lower than in the SDPP findings (55.6% in mainstream and 47.3% overall). (16) Prevalence of high cholesterol in New South Wales in 2004 was 35.4% for all adults according to the 2004 AusDiab survey, compared with 47.5% in mainstream participants and 44.5% overall. While initial response to AusDiab rate was low, the follow-up survey had participation rates exceeding 70%.

The prevalence of multi-morbidity in SDPP was high, as compared with another random population sample survey in South Australia, the North West Adelaide Health Study conducted in 2000. Fifteen percent of 40-59 year-olds and 39.2% of the 60+ year-olds reported multiple chronic conditions from a list including asthma, diabetes, chronic obstructive pulmonary disease, osteoporosis, arthritis, cardio-vascular disease and mental illness. (274) The presence of chronic conditions may affect the final outcome of the Program and this will be examined in the impact evaluation section of this thesis (Chapter 8).

In ascertaining the feasibility and success of recruitment of high-risk people under real-world conditions, it is worth comparing the samples recruited in this translation program with the reference trials and other replication studies (research question 12). This comparison provides guidance on the differences between recruitment in research settings vs. recruitment in routine practice to inform future replication studies.

The SDPP participants are mostly obese people in their mid to late fifties and predominantly women, not unlike those in the Finnish PDS, the US DPP, and also other urban-based translation

programs in the US, Australia, in Greece. (114, 115, 117-120, 134) The SDPP also had a largely low-income sample, particularly the non-English speaking cohort, similar to other target groups in the USA. (120, 129) In examining the target groups reached by the various programs, substantial differences were observed in the educational and socio-economic level of SDPP participants when compared with the HEED study in Harlem, where the target group was younger and more socially disadvantaged, (129) the Ballarat intervention in Australia where half the participants were highly educated,(119) or in the US studies where participants were predominantly younger women.(121, 129)

As subjects with IGT are a preferred target group for intervention to ascertain the feasibility and effectiveness of the primary prevention of Type II diabetes, (275) the FDPS, the US DPP and the Da Qing trials enrolled only people with IGT. However, SDPP participants were recruited if they met the selection criteria for intervention based on factors that led to high-risk classification according to the *Ausdrisk* screening tool. Other localised and nation-wide studies have also used this approach where IGT or IFG were not the sole requirement to enter the program. (120, 129, 134) In our mainstream cohort the prevalence of IFG was 10.1 % and IGT was 30%. While the IGT levels are consistent with the GGT and Ballarat studies (24.6% and 32% respectively reported IGT), their reported IFG rates among participants were similar in the GGT study (9.5%) but much lower in the Ballarat study (4.9%). Estimates for the general public in Australia indicate that 5.8% of adults have IFG and 10.6% have IGT (74) with the annual progression to diabetes from IFG estimated to be 2.6% and 3.5% from IGT.(89) The high rates of IGT and IFG in the SDPP participants further corroborates their high-risk profile.

Another difference between our Program group and other diabetes prevention programs is that given the high levels of obesity and comorbidities in the SDPP, baseline engagement in physical activity apart from walking was predictably low. For instance only 32% had some level of engagement in moderate to vigorous physical activity (the median was 0 minutes per week with an interquartile range 0-180 minutes in the mainstream cohort), low relative to the Ballarat study, where 29.3% were engaged in at least 150 minutes of physical activity per week, or

compared with Matvienko's study where 53.6% engaged in ≥ 150 minutes of physical activity per week. The US DPP participants were a more physically active group at baseline than those in the SDPP, with an average of 15.5 ± 22.1 MET-hours of physical activity per week (this is equivalent to around 4-5 hours of moderate intensity physical activity per week). The FDPS did not report physical activity measures at baseline. Apart from obesity, underlying chronic conditions in the SDPP participants may have contributed to their sedentary behaviour. In fact, two thirds of the Arabic and Chinese participants reported very high levels of 'poor or fair' self-assessed health compared to a quarter of the mainstream participants.

In terms of anthropometric and laboratory profile at baseline, the mean BMI and WC of mainstream and Arabic SDPP participants seemed comparable to that of FDPS participants, but FDPS participants had higher mean FPG as all its subjects had impaired glucose. The Chinese SDPP participants had lower mean BMI and mean WC than the other 2 SDPP cohorts, but similar BMI to the Da Qing study subjects (25.2 ± 2.9 and 26.3 ± 3.9 respectively) and slightly lower mean FPG than Da Qing subjects (5.3 ± 0.6 and 5.7 ± 0.8 respectively) where all participants had impaired glucose tolerance.

The nutrition profile in the US DPP used face-to-face food frequency questionnaires on usual intake over the past year.(276) Despite these methodological differences, with the exception of fibre, the baseline distribution of total energy intake and macronutrient profile of the mainstream cohort in the Sydney DPP was very similar to that of the overall US DPP. The Da Qing study revealed a relatively low total fat intake (27 ± 9.0) at baseline and the Sydney-based Chinese SDPP participants reported the lowest fat intake of the three SDPP cohorts (28.8% to 30.4% for males and females respectively). Unfortunately the FDPS only reported changes in nutrition parameters rather than actual values at baseline so a direct comparison with SDPP is not possible until completion of follow-up (see Chapter 8 on impact evaluation).

As for the baseline mediators of participation in prevention programs and adherence, the concept of self-efficacy has also been used and validated across cultures(277) and it is regarded as a "well-established construct, based on social-cognitive theory, that has high operative

power". The SDPP found that the mainstream cohort, in particular males and participants with high self-assessed health, had higher levels of self-confidence in overcoming barriers to adhere to physical activity goals. Lower self-efficacy for physical activity was predicted by obesity, low socio-economic status and high depression/anxiety scores. Anxiety was also an independent predictor of low self-efficacy for healthy eating. These findings are consistent with the US DPP where lower exercise efficacy was correlated with higher baseline BMI and anxiety was correlated with less self-confidence for healthy eating. (262) However, the relationships were not straightforward for all ethnic groups (African Americans, Hispanics and whites) in the US DPP. In the SDPP being in the Chinese and Arabic cohorts was associated with low self-efficacy for physical activity but was not associated with lower self-efficacy for healthy eating.

5.11 Conclusions

Target groups for diabetes prevention programs in communities are heterogeneous depending on the setting, level of risk of sub-communities or ethnic groups and the objectives of the Program sponsor. Other studies have used broader age groups, widespread and/or intensive advertising strategies and more confined settings. The SDPP used targeted screening by general practitioner in their rooms and limited external advertising of its recruitment.

The recruited SDPP participants are a high-risk sample with or without prediabetes but with family history of diabetes, personal history of hypertension, mostly obese, who lead a largely sedentary lifestyle and are affected by multiple co-morbidities. These participants were not meant to be representative of the average NSW population in their age group as they were selected from a sample using general practitioner services after targeted screening. This strategy appears to have captured an appropriate target for a lifestyle modification intervention. The inclusion of an Arabic and a Chinese sample with sufficient numbers for analysis has the potential to shed light on the different impact that the Program will have on the goals for diverse individuals at risk. The level of readiness for behaviour change of the enrolees was mixed and there was scope for improvement of their lifestyle as few participants met the Program goals at baseline.

Chapter 6.

Process Evaluation

Summary

This chapter defines process evaluation, and describes the establishment and development of the Sydney Diabetes Prevention Program. The chapter describes its governance, program implementation and the results of program performance against process evaluation objectives. Process evaluation indicators cover program reach, fidelity, and acceptability by Program delivery staff, participants and other Program partners.

Data sources used in the analysis include administrative, clinical databases from enrolment to final follow-up. Questionnaire and self-report data are supplemented with qualitative summaries and documentation from reports of staff working at the Divisions of General Practice, obtained by request of the evaluation team. The discussion concludes that despite the complexities of this real-world translation program the target numbers of participants recruited were achieved, program fidelity was satisfactory, and participant satisfaction was high, but some modifications were required to suit local implementation needs.

6.1 Introduction

6.1.1 Establishment of the SDPP and its evaluation team

This project, to assess the translation of reference Diabetes Prevention Programs into routine community and clinical settings, was initiated in 2007. Funding was provided by the NSW Health Department from July 2007 to September 2011 to cover detailed design, implementation and evaluation. A Steering Committee with representation of stakeholder groups was convened to guide the detailed design and implementation. A team of University of Sydney and external evaluators was appointed⁴⁰ and commenced consultation with stakeholders from the first few

⁴⁰ The PhD candidate contributed to the work in this chapter through database design, data manager, and analyst / statistician in the Evaluation team. All work, for example much of the data collection, that was not carried out directly by the Candidate, is expressed as such in the text.

months of the planning stage to ensure the data collection tools and procedures met the information requirements of the evaluation. This was carried out through regular meetings of the Evaluation Management Group, which had broad partner representation including the evaluators, who continued activities throughout the implementation phase. An executive group was also appointed to give final approval to all major decisions on strategic direction (for details of governance structures and committee composition see Appendix 6.1).

This chapter will discuss the SDPP process evaluation, Chapters 7 and 8 will present results from the impact evaluation and Chapter 9 will deal with the economic appraisal.

6.1.2 What is a process evaluation and why is it important?

A process evaluation is an ongoing or episodic examination of the implementation of a program or service to determine its feasibility and/or sustainability and to improve program quality.

(278, 279)] Process evaluation answers questions on how a specific program operates in terms of what is done, when, by whom, and to whom, (280) and sometimes for quality assurance comparison against a pre-determined standard or benchmark.

The methods used in this level of evaluation are multiple, and may include collection of qualitative and quantitative information (280, 281) to achieve a better understanding of a program's adherence to its intended implementation plan, and to determine the quality and quantity of deliverable program elements. (106) Data for process evaluations should be systematically collected in an ongoing manner (280) or can be retrieved retrospectively if available from existing records or administrative tools. (159, 279, 282)

The process evaluation of a program is important because it represents an ongoing quality assurance exercise whose findings provide an assessment of the strengths and weaknesses of program implementation that can inform subsequent decisions. For example, process evaluation could lead to program re-design, modifications to data collection, reallocation of resources and changes to the delivery of a program to make it more efficient and less costly. Its main goals are to provide better information on the conduct of interventions to maximise their adoption, reach and fidelity and therefore its likely effect. (159, 282)

The term *adoption* is concerned with the number of people, settings, stakeholders and agencies taking up the intervention and can extend to the number of sites that join efforts to replicate or implement program activities. Indicators of adoption can be documented via direct observation, structured interviews or surveys, (282) and may include numbers of people and organisations involved in training, service delivery, and the numbers entering the program and numbers who refused to participate in the intervention. (283)

Program *reach* incorporates the concept of representativeness or adequacy of the target group to be captured by a program. Analysis of the program reach describes similarities and discrepancies of the participants with the base population from where the target group was selected, and expected characteristics of the participants in relation to the original design.(284)

Program reach is assessed qualitatively or quantitatively within the intended target group, (113) and can be reported in terms of demographic profile, accessibility, satisfaction, and barriers for participation.(283)

Program *fidelity* refers to the extent to which the Program was implemented in line with the intended plan. (159) The importance of fidelity lies in the ability to identify variations in protocol adherence resulting from either limited local resources, staff shortages, insufficient training, participant preferences, lack of attention to detail on protocol rules by providers, or external socio-political or environmental imperatives. (220, 279, 282, 285) It may assist program delivery and assist researchers in determining mechanisms for observed program effects [or lack thereof].. Overlooking variations that occur in real life implementation of interventions can lead to both errors in detecting true program effectiveness and missed opportunities to capitalise on success or learn from failures. (278, 286, 287)

6.1.3 Rationale for a Process evaluation of the SDPP

As with any health promotion program, assessment of its implementation is an integral part of its delivery and evaluation. A core piece of work of the evaluation group of the Sydney Diabetes Prevention Program was to undertake a process evaluation. This translational Program was intended as a pilot in three Divisions of General Practice and funded to explore feasibility of

establishment to inform decisions on State-wide dissemination if proven successful. The funding body was interested in assessing whether various groups of partners could partner to deliver this program; how closely the final Program resembled the reference interventions that motivated it; and whether the delivery of intervention varied across sites or by sub-population types.

The aim of the Program was to target 40-65 year old adults in the Sydney South West Area Health Service (SSWAHS). Based on this age range and extrapolating from AusDiab2005 screening experience, (17) it was originally anticipated that up to 15,000 people would need to be screened and that approximately 4,000 of these would have a high risk score (Ausdrisk ≥ 15) of which up to 500 could have previously undiagnosed diabetes. In order to not be confused with the July 2008 launch of the Commonwealth national 40-49 year old lifestyle modification program, the SDPP age range was revised to 50-65 year olds. Based on initial recruitment and referrals to the SDPP, the original sample size was deemed difficult to achieve, and in September 2009 the SDPP Steering Committee revised the enrolment target to 1,250. This number reflects what was considered achievable within the time-frame and still enabled the impact evaluation component to be sufficiently powered to detect changes in major program goals.

The next sections address the findings of the various elements of process evaluation carried out for the SDPP namely Program reach and representativeness, adoption fidelity, and acceptability from both the participant and provider perspectives.

6.2 Objectives of the Process Evaluation

The process evaluation of the SDPP was intended to examine questions related to participation and population reach, program fidelity and data collection quality. The process evaluation elements attempted to answer the following questions (Q):

1. Who was screened for the Program (e.g. age and sex by Division)? [participation]
2. What strategies were used to recruit participants? [formative evaluation – do we know which strategies worked better to recruit participants]

3. Who was recruited to the Program and who declined ?(e.g. age, sex by Division)
[population reach and representativeness]
4. Did the Program recruit the proposed 'target population'? [population reach and representativeness]
5. Were there any groups within the target population not reached by the Program?
[population reach and representativeness]
6. Was the Program delivered and implemented as intended? (e.g. sequence of activities and timeliness)
 - a. Were participants referred to the Program within two weeks of screening?
 - b. Was data collection complete - did participants have requisite blood tests before the initial consultation and provide a baseline food record? [a process measure of data collection]
 - c. Did all enrolled people participate in a baseline CATI survey and attend the initial program consultation within 2 weeks of that survey as hoped for ? [a process evaluation measure of fidelity]
 - d. Did participants attend the group sessions or receive all individual module calls within 12 weeks of the individual consultation? The process evaluation task is how many sessions did participants attend [a measure of fidelity]
 - e. Did all participants have weight and WC measured for short-term progress at group session three? [a process measure of data collection completeness]
 - f. Did all participants attend the 4-month GP visit? [program fidelity]
 - g. Were all contacted by phone at 3, 6, and 9 months from initial consultation? [data collection completeness]
 - h. Did all enrolled people participate in the final CATI survey, attend the 12-month review with a lifestyle officer for final measurements, and deliver final food record?
[data collection completeness]

- i. Did all participants attend a GP visit at 1 year to have a blood test for final outcome assessment?
7. Did Program participants access community-based lifestyle services during the course of the Program? [access and utilisation of services]
8. How satisfied were participants with the Program and their outcomes? [program satisfaction]
9. How did the implementation process compare with other studies? [a review of process evaluation issues in diabetes prevention programs generally]

Following identification of the evaluation questions, the evaluation team proposed the possible data sources, formats, methods and timing of the data collection.

6.3 Methods

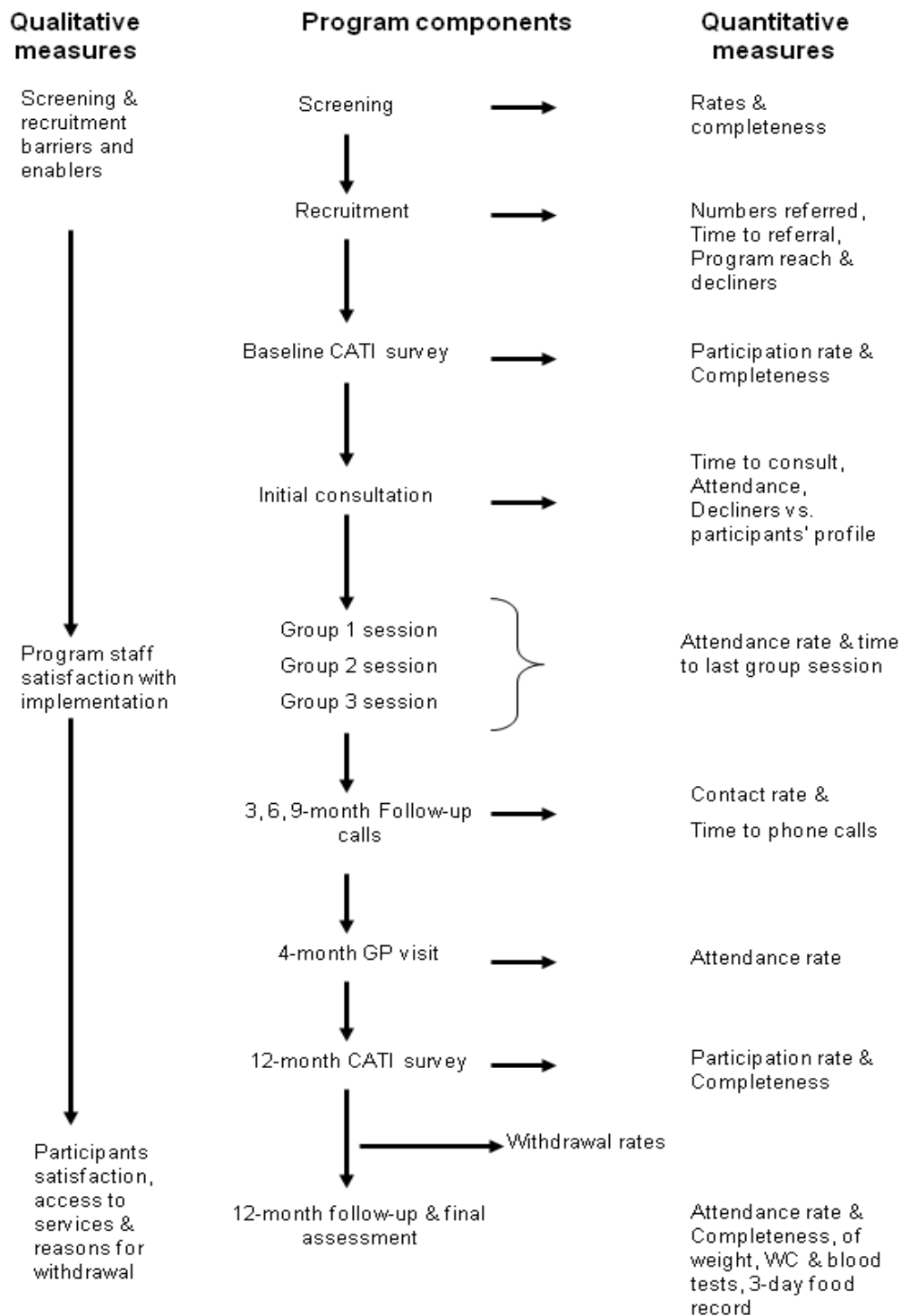
6.3.1 Program Components

The main aspects of this process evaluation (reach, fidelity and acceptability) were examined with a focus on the 1,250 mainstream participants for the main program components using the following corresponding indicators:

- Screening and recruitment – Strategies and reach
- Initial consultation (or enrolment) – Completeness of data collected at baseline
- Group sessions or individual phone module – Attendance by Division
- Follow-up contacts – Completeness of contacts at milestones
- Final review (12 month assessment) – Attendance, completeness of final assessment and Program acceptability

Note that the definition of SDPP “participant” was someone who had attended the initial consultation, signed the consent form and had diabetes excluded after a blood test. Qualitative and quantitative methods were used to document the indicators of implementation (Figure 6.1). Details of data collection measures are described in the next section.

Figure 6.1 SDPP Program components and qualitative and quantitative measures used in the process evaluation (up to December 2010)



6.3.2 Process measures and their data sources

Both periodic and ongoing information was collected to answer the process evaluation questions. For details of the originally proposed process indicators [prior to program commencement] see Appendix 6.2, the Process Evaluation Protocol⁴¹.

6.3.2.1 Participant screening and recruitment (Q1, Q2)

Counts from Divisions and medical practices were made available of the numbers screened and the results of the Ausdrisk screening tool data . Total numbers recruited were emailed weekly by Division staff to the central implementation team and entered into the web-based participants database. Description of strategies used and changes to recruitment plans were discussed at meetings and documented , in a qualitative format, by Divisions on an ongoing basis. Minutes of meetings and Division records were examined to answer the process evaluation questions on screening and recruitment.

6.3.2.2 Recruited participants and target population (Q3, Q4, Q5)

The web-based lifestyle officer database with 1,250 participants, the baseline computer assisted telephone interview (CATI survey) database with 1,137 participants and the decliners database with 423 records were used to describe people recruited into the Program. These data sources were interrogated to produce the information comparing the demographic characteristics of participants and decliners not reached by the Program.

6.3.2.3 Delivery of Initial Consultation (Q6)

After consent was obtained, potential participants were invited to an initial consultation, comprised of a 90 minute face-to-face appointment where objective measurements and qualitative information on physical activity and dietary habits were collected. All anthropometric, psychosocial and dietary data from this initial consultation (which included delivery of the 3-day food record) were entered into the web-based database. Documentation

⁴¹ This process evaluation protocol was developed by the Candidate in 2008 and refined in 2009 in consultation with the investigators.

on whether tests and measurements could not be taken or the food record was not available were extracted from the web-based participants' database.

6.3.2.4 Group attendance, phone coaching and quarterly follow-up (Q6)

Divisions maintained paper records of all group sessions [ranging from no attendance to attendance at all three program sessions]. These data included the number of participants who were invited and the numbers attending, with the attendance date. Weight and waist circumference (WC) measured at the group three session. Follow-up data from the 3, 6 and 9 month follow-up phone calls were also entered on the web-based participants' database. Dates from the individual stream telephone calls on dates delivered and absences were also entered on the web-based database. Information on completeness of these follow-up calls and their associated evaluation questions were obtained from paper records; these were subsequently entered⁴² in the 3-month follow-up database (968 participants of whom 738 had measurements at 3 months); 6-month follow-up database (924 participants); and 9-month follow-up database (714 participants)⁴³.

6.3.2.5 Implementation of the endpoint 12-month review (Q6)

The web-based database had fields to document anthropometric measurements as well as self-reported dietary and physical activity outcomes. Blood test results taken at the 12-month GP visit were also entered with dates. Time to final assessment, completeness of the data items for impact assessment, availability of 12-month food record and CATI survey (outcomes on 586 completers and status data on all 1,250) were estimated from the web-based participants' database and the telephone survey databases. Missing items could be identified from these databases.

⁴² The PhD candidate checked quality and completeness of all baseline, and 3, 6, 9 and 12-month data received and entered all 3-month questionnaires in an SPSS database. The candidate also contributed intellectual input into the design and contents of the baseline and follow-up questionnaires, and built the 3-month, 6-month and 9-month databases with relevant data entry codes made available to trained data entry staff.

⁴³ These were data numbers to December 2010, the date by which data were included in this thesis. These do not reflect absolute final numbers for the SDPP; however, given that most follow up had occurred by then, these are close to final numbers at short term follow up calls.

6.3.2.6 *Participants access to services and satisfaction with Program (Q7, Q8)*

The follow-up calls at 3, 6, and 9 months asked information on whether participants accessed community lifestyle services. For assessment of participant satisfaction with demonstration sessions, a brief written, self administered survey was handed in by lifestyle officers at the end of group session three and collected on the same day. Selected questions on satisfaction with group sessions and Program materials were also asked by the external telephone interviewers on the telephone during the 3-month follow-up, led by lifestyle officers. The 12-month CATI survey also included brief questions on overall satisfaction with the Program asked by external CATI interviewers from the evaluation team.

6.4 Process Evaluation Results

All process evaluation objectives (Questions 1-7) were covered to the extent possible in a real-life setting and wherever the candidate was involved.⁴⁴ Data on stakeholder satisfaction with the Program has been partly covered and conducted by other program staff or external consultants (Appendix 6.3) but its completion by others will occur towards the end of the Program in late 2011.

6.4.1 Program screening and recruitment

Question 1 Who was screened for the Program (e.g. age, sex and Division)?

Overall 4174 people were screened and one in every two (48%) of the total screened had Ausdrisk scores of ≥ 15 making them potentially eligible to be invited to participate in the SDPP (Table 6.1). Of these, a small proportion (2%) were newly diagnosed as diabetic and one in every five eligible people declined the invitation to participate but the reasons are unknown. The ineligible people (5%) were identified as at high risk but reasons for ineligibility despite a risk scores ≥ 15 were mostly unknown (i.e. not documented by GPs or lifestyle officers). A few were documented as related to Program protocol such as being non-English speaking, on

⁴⁴ As the Program is still underway beyond the three-year PhD candidature, this Chapter on process evaluation only covers baseline and follow-up of all available participants until 31 December 2010.

diabetes medication, having history of gastric bypass, or suffering from an illness that precluded physical activity (Table 6.1).

Table 6.1 Screening process and outcomes for eligible and ineligible mainstream participants (July 2008 - December 2010)

Screened and results	N (%)
Number of people completing risk assessment tool	4,174
Have a risk score <15 thus not in the target group for this Program	2,190 (52 %)
People with Ausdrisk score ≥ 15	1,984 (48%)
Numbers and proportions of people who are ineligible and reasons (% of people with scores ≥ 15)	150 (5%) α
Outside the age range	7 (4.7%)
Newly diagnosed with diabetes	48 (32.0)
Contraindication due to illness or treatment	17 (11.3%)
Non-English speaking	13 (8.7%)
Taking medication to prevent diabetes	8 (5.3%)
Lives out of the area	1 (0.7 %)
Recent gastric bypass	1 (0.7 %)
Unknown reason for ineligibility	55 (36.7%)
Have a Ausdrisk score ≥ 15 (key target group) and agreed to participate	1,250 ^s
High risk score 15-19 (1 in 7 will develop diabetes within 5 years)	820 (66%)
Very high risk score 20+ (1 in 3 will develop diabetes within 5 years)	430 (34%)
Self-selected to attend group sessions	950 (76%)
Self-selected to receive phone coaching	119 (10%)
Not attended either group or phone service	181 (14%)
Withdrawn by December 2010	209 (16%)
Unable to contact by December 2010 (past their completion date)	83 (7%)
Not yet completed	372 (30%)
Total completed 12-month review for this thesis by December 2010	586 (47%)

α Percentage out of ineligible people unless otherwise specified
^s 6 people completed Findrisc tool instead of Ausdrisk tool.

The 161 *eligible non participants* (Table 6.1) were people fully assessed and deemed eligible and agreed to participate who never attended the initial consultation. Two main reasons were identified for this: they either made their appointment for initial consultations too late (past the recruitment cut-off date set for the Program) or cancelled and rescheduled too many times.

The result was that 1250 were recruited into the program, a recruitment rate of 68% of those eligible. Of these, three quarters attended at least one-group intervention session, 10% received individual advice, and 14% only had an initial consultation and had not received subsequent intervention components. Of the 1,250 participants who were at high risk (63% female), two thirds were in the high risk category based on the Ausdrisk (scores between 15-19) and the other third had scores in the very high risk range of 20+ (Table 6.1). There were 562 participants from Central Sydney (69% of eligible in that Division), 301 from Macarthur Division (69% of eligible in Macarthur), and 387 from Southern Highlands Division (63% of eligible in that Division).⁴⁵ Comprehensive details of their demographic and clinical profile were discussed in Chapter 5 on baseline results.

6.4.1.1 Screening and recruitment strategies

Question 2 What strategies were used to recruit participants?

Qualitative information provided by each of the General Practice Divisions was audited to examine the strategies used to recruit participants to the SDPP. The Divisions used a mix of strategies that best suited the way they were organised and approached the recruitment tasks. The most frequently reported strategy used was “opportunistic screening at general practices” either by practice staff or by the GP. The second most common strategy was the use of letters sent directly to 50 to 65 year old patients inviting them to participate in the Program. In one Division (Southern Highlands) additional local-level unpaid publicity (i.e. TV, newspaper, radio) was used, encouraging individuals to see their GP to discuss their diabetes risk.

Two main screening strategies were trialled: “opportunistic” and “targeted”:

⁴⁵ Total numbers of people enrolled and attending or not attending group sessions or telephone coaching are final but the numbers of people who complete or withdraw will change as the Program continues. The last participant’s 12-month assessment is scheduled to occur in September 2011.

Opportunistic screening was where patients were approached either by receptionist/practice staff, practice nurse or lifestyle officer to complete the risk tool. The strategy where patients were approached by a lifestyle officer in the waiting room was tried in a number of practices proved to be unsuccessful. There was no systematic method of data collection at the medical practices on the numbers approached using any specific recruitment method.

Targeted screening occurred when patients presented for clinical care, and were in the age range and with a number of risk factors but without diabetes, or could be identified by GPs searching their clinical electronic databases. They were either targeted (highlighted on an appointment list) when they came into the surgery or sent one of two types of letters to the patient's home address: one was an invitation letter with the patient information sheet inviting them to come into the practice for screening, or the alternative was an invitation letter with a brochure and the Ausdrisk tool. In some practices in the Central Sydney Division, letters were followed up with a phone call from Division staff. "Cold calling" was used at Macarthur Division where high risk patients were called by lifestyle officers from the practice and then invited to complete a risk tool at the Division, the GP practice, or to complete partial screening over the phone followed by an appointment with the lifestyle officer. Division staff believe these methods secured the largest number of participants but did not keep clear records, so the denominators are unknown and this part of process evaluation unfortunately cannot be accurately reported⁴⁶.

6.4.1.2 Information sessions with providers to encourage screening and recruitment

In addition to the standard invitations described above, staff in Southern Highlands had the opportunity to undertake local level promotion of the Program via community service announcements on Prime TV. In addition, monthly radio interviews, and articles in the local newspapers were used to promote the Program. Southern Highlands also held two information

⁴⁶ Changes to strategies to enhance recruitment were an ongoing challenge as was staff compliance with record keeping of non-clinical activities. The burden of accounting for items such as invitations and Ausdrisk forms leaving the GP rooms, number of forms returned, description of dates of events, and phone call attempts made was too high. These demands were beyond both the Division's understanding of their role in the Program and capacity to deliver as staff were dedicated to implementing the Program and had little time for meticulous record keeping for the process evaluation.

sessions for GPs and practice staff to promote the Program: A Program launch with the GPs in December 2008 and a “drivers” night (GP champions and practice staff driving the recruitment invited to inspire other participating practices) in July 2009. Macarthur Division also held an evening in February 2009 to launch the Program and 10 GPs attended. Central Sydney held a “drivers” night in November 2009 with only nine people attending (four GPs and five practice staff).

6.4.1.3 Change to the screening and recruitment process

Division staff reported that the recruitment pace was slowed down by many eligible people refusing to have an OGTT before entering the Program. Hence, in September 2009 the Steering Committee approved the modification of the screening process to allow FPG and HbA1c to be used to exclude diabetes instead of FPG and/or OGTT⁴⁷. The cost of this test was covered by the Program since it was not available on the Medicare schedule.⁴⁸ This was communicated by the Divisions to their GPs shortly thereafter. This was taken up differentially across the three Divisions depending on GP preference.

As not many GPs took up the HbA1c option, in February 2010 the process was modified again where GPs could refer patients into the Program before excluding diabetes provided medical clearance to participate in moderate physical activity was granted. The Division were responsible for ensuring the participant had blood tests done before the participant attended the first group session. Southern Highlands and Central Sydney implemented this new procedure in a number of their practices.

⁴⁷ This was a typical example of real time changes in recruitment required in a ‘real life’ translation program. The flexible and changing nature of recruitment occurred because of low numbers of participants in the SDPP in the first year, and the program asking Divisions to adapt and change recruitment strategies to hypothesised locally useful modes to maximize participant numbers [so that the SDPP could achieve N=1250 enrolled]

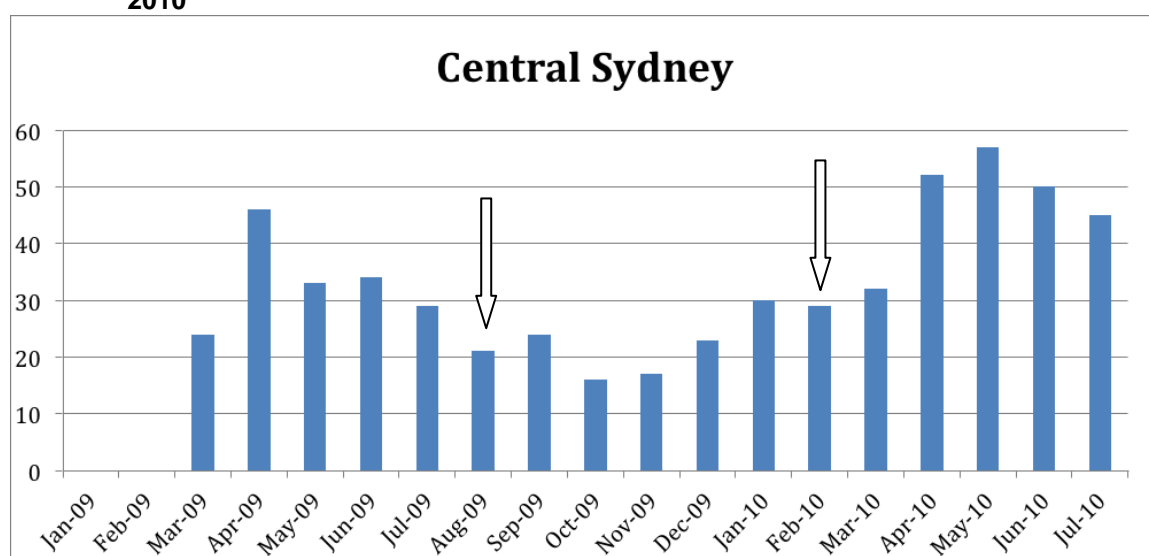
⁴⁸ The Medicare (Australian public health insurance system) benefit covers the cost of fasting plasma glucose or OGTT per 12-month period but not HbA1c testing for diabetes diagnosis.

6.4.1.4 Impact of strategies on recruitment rates across Divisions

The next series of figures shows recruitment over time for each GP Division⁴⁹. Number of initial consultations varied over time reflecting both the number of eligible patients agreeing to participate and the readiness of staff to fit the appointments in their working hours. the Program. Increases in recruitment rates in response to increased activity and changes to the screening and recruitment process were observed in Central Sydney particularly at two points, indicated by the arrows in Figure 6.2.

We were unable to determine the level of impact of each individual recruitment strategy. However, the Central Sydney Program Coordinator attributed this increase to new GPs joining the Program in January-February 2010, along with their Practice managers, and a revitalised screening and referral efforts. Also in 2010, simplification of the screening and referral paperwork to a single double-sided sheet, periodic participant mail outs, the Central Sydney lifestyle officers making more effort to contact GPs and the changed protocol to enable GPs to refer participants without excluding diabetes may have boosted participants recruitment.

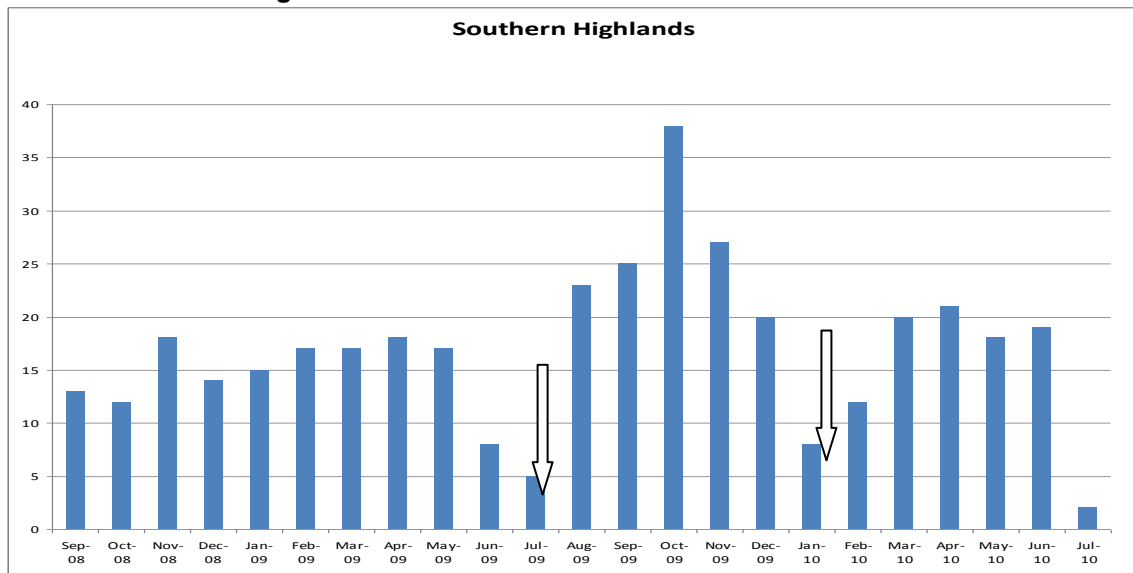
Figure 6.2 Recruitment. Initial consultations by month in Central Sydney GP Network 2009-2010



⁴⁹ While these figures with recruited numbers of participants cannot be causally linked to specific strategies, they do highlight inter-Divisional differences, and show some temporal responses to changes in recruitment strategies

For Southern Highlands Division it is evident from Figure 6.3 that the well-attended (practice staff and GPs) driver’s night with GP champions motivating others, conducted in July 2009 made an impact on recruitment rates.

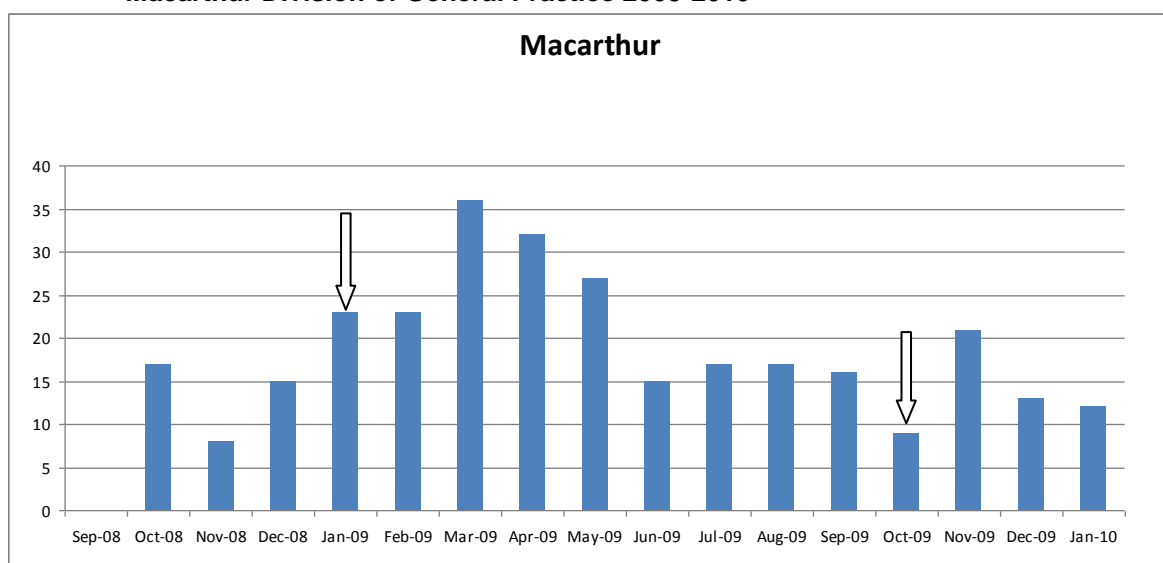
Figure 6.3 Recruitment. Initial consultations by month and change in recruitment strategies Southern Highlands Division 2008-2010



It is also possible that the unpaid local level publicity (Program Coordinator’s radio interview and the newspaper articles) played a role in boosting recruitment pace in early 2010.

In Macarthur Division, there was an initial increase in referrals from January–March 2009, after Divisions and practices had been trained and the holiday season had passed. Lifestyle officers tried a range of strategies throughout the Program but recruitment rates declined after this initial phase remaining steady until the end of the recruitment period. While there was no significant boost to recruitment that could be attributed to a particular activity (Figure 6.4), perhaps the increase in October 2009-January 2010 could be associated with the doubling of the GP incentive payment at that time.

Figure 6.4 Recruitment. Initial consultations by month and change in recruitment strategies. Macarthur Division of General Practice 2008-2010



6.4.2 Program reach

Question 3 *Who was recruited into the Program and who declined? (e.g. age and sex by Division)*

Question 4 *Did the Program recruit the proposed target population?*

As at 31 December 2010, a total of 1250 participants had attended an initial consultation (63% females). Recruitment ended at the end of July 2010. Participation numbers by Division are summarised in Table 6.2, showing selected comparisons with decliners for whom demographic and Ausdrisk information was available. The distribution of age among decliners was similar to that of participants. Overall, two thirds of participants were women in the middle age bracket. Men were more likely to decline in Southern Highlands but not in the other two Divisions. The mean Ausdrisk scores were statistically significantly higher for participants than for decliners but the difference was less than one unit (18.8 vs. 18.3).

To examine the Program reach, a descriptive unweighted comparison of the SDPP participants with participants from the NSW Health Statewide Adult Health surveillance telephone survey⁵⁰ was undertaken (comparisons included SDPP participants against age-matched NSW overall and the regionally matched SSWAHS sub-group of the same age. The comparative profiles were presented in Chapter 5 on baseline results, Appendices 5.2 and 5.3. In brief, with respect to the demographic characteristics, the SDPP sample has similar proportions of non-English speaking participants and people with primary and high school education to the whole of the NSW sample. However, the SSWAHS sample has more non-English speakers, and more with only primary education. The SDPP sample has significantly higher proportions of university graduates, people in paid employment, people covered by private health insurance than both the whole of NSW and SSWAHS samples. No definitive comment can be made about income differences due to the large proportions of refusals in the SDPP data.

⁵⁰ This survey is carried out annually by the NSW Health Department, and is similar to the BRFSS surveillance system in the USA that CDC carries out. In NSW, the data are collected by CATI systems, and report on state-wide and sub-regional estimates and trends in risk factors [annual reports of these data are provided – for example, see <http://www.health.nsw.gov.au/publichealth/surveys/hsa/08summary.asp>. Accessed June 2011]. For these analyses, original raw and weighted Health Survey data were obtained from NSW health, and re-analysed to compare with the SDPP sample demographics and behavioural data. The analyses considered the whole statewide data set, and then regionally matched data from Sydney SW region (SSWAHS), which were NSW health survey responders from the same regions that comprised the SDPP participants.

Table 6.2 Program reach. Comparison of age category, gender and risk score overall and by Division⁵¹: Participants and decliners screened.^α

	Participants (n = 1250)	Decliners (n = 423) ^α	x ² , p value
Age groups ^β			2.13, 0.34
50-54 years	295 (24%)	99 (23%)	
55-64 years	866 (69%)	304 (71%)	
65 years	89 (7%)	20 (5%)	
Sex (overall)			15.4, <0.001
Males	466 (37%)	203(48%)	
Females	784 (63%)	220 (52%)	
Central Sydney	M 174 (31%) F 388 (69%)	M 54 (36%) F 98 (64%)	1.15, 0.28
Macarthur	M 140 (47%) F 161 (53%)	M 37 (55%) F 30 (45%)	1.7, 0.20
Southern Highlands	M 152 (39%) F 235 (61%)	M 112(55%) F 91 (45%)	13.6, 0.0002
Ausdrisk score	Mean 18.8 Median 18.0 IQR (16-21)	Mean 18.3 Median 18.0 IQR (16-20)	T-test 2.43 p 0.02

α Only selected data items are available for decliners in the database.

β Age % is column % within participant/decliner group; MF sex % are row % out of each Division. Age distribution as per risk tool groupings

In terms of diabetes risk factors, SDPP participants had higher body mass index values and have more than twice the proportion of obese people compared with the two NSW Health Survey samples (Chapter 5). Physical activity levels were similar across all groups, with a predominance of sedentary behaviours. The SDPP participants group reported lower levels of

⁵¹ Total numbers of participants per Division: Central Sydney 562, Macarthur 301, Southern Highlands 387; Total numbers of decliners per Division: Central Sydney 152, Macarthur 67, Southern Highlands 203.

smoking than either of the NSW subgroups, possibly resulting from the much higher levels of underlying chronic conditions including high cholesterol and hypertension (Appendix 5.3).

Question 5. Were there any groups within the target population not reached by the Program?

From the comparative findings above, the SDPP has reached obese and sedentary people but also captured larger proportions of people with higher education, in paid employment and in higher income brackets. The SDPP sample also has lower participation of people from non-English speaking background as expected since this was one of the selection criteria for the mainstream prevention Program.

6.4.3 Program fidelity

Question 6. Was the Program delivered and implemented as intended?(sequence of activities as per protocol and timeliness)

6.4.3.1 Timeliness of events (Q 6a- Q 6d)

Time to events is presented to show one indicator of feasibility and fidelity. The original SDPP protocol [See Appendix 6.2] anticipated that participants would:

- a) be referred to the Program within two weeks of screening
- b) have blood tests before the initial consultation and deliver a baseline food record
- c) participate in a baseline CATI survey and attend the initial consultation within 2 weeks of that survey, and
- d) complete attendance at group sessions or receive all individual module calls within 12 weeks of the individual consultation.

The time from invitation to screening was not recorded but timeliness of referral from screening day occurs usually on the same day, and the time taken to attend initial consultation is just over a month, while completion of attendance at groups or completion of individual telephone coaching is still within the first 3 months from initial consultation (Table 6.3).

Timeliness of the 3-month phone call is also within acceptable ranges (about 3 months from first group or telephone coaching).

Table 6.3 Adoption fidelity. Time to commencement of SDPP Program activities for people with complete information on each item.

Indicators on timeliness of events	Result (median & 25%-75% range)
Time from screening to referral. N=1,173	0 days (0-10)
Time from referral to initial consultation. N=1,222	37 days (27-57)
Time from initial consult to completion of groups. N=751	77 days (61-106)
Time from initial consult to completion of individual module. N= 85	92 days (61-137)
Time from individual consultation to 3-m phone call. N=968	98 days (91-112)

6.4.3.2 Participation in and completion of Program activities (Q 6a- Q 6i)

The following sections report on the level of attendance by participants for each of the SDPP program activities, and of the SDPP lifestyle officers in relation to contacting participants.

6.4.3.3 Provision of baseline data and attendance at group or individual session (Q 6b-6d)

At the initial consultation participants were encouraged to attend the groups. If they were not inclined or able to attend the groups they were offered an alternative individual phone based health coaching stream. 119 (10%) participants chose the individual stream – leaving 90% of participants choosing the group based modules. Overall most participants (86%) attended either a group session or had an individual health coaching phone call (Figure 6.2). Two thirds (66%) of participants who chose the groups based modules completed all three group sessions and almost three quarters of the rest (73%) completed all three individual module phone calls (Table 6.4). Varying proportions in each Division (one in ten in Central Sydney and Macarthur, and one in five in Southern Highlands) had neither attended a group nor received a health telephone coaching call after 6 months in the Program. The reasons for people missing out on either intervention modality after the initial consultation were not systematically documented but lifestyle officers reported that some people rescheduled many times and were unable to attend due to personal or family reasons. Southern Highlands had the lowest participation in group sessions and the highest request for phone coaching. Overall completion rates for attending all three groups or three telephone coaching calls was high, at over 70%.

Table 6.4 Adoption fidelity. Outputs and completion of baseline CATI survey, food record, blood test and attendance to intervention (group or individual module).

Indicator (attendance or participation in various activities)	Result
Number and percentage providing any blood test by enrolment (FOG, HbA1c, OGTT, CBG)	1,250 (100%)
Number and percentage providing 3-day e at baseline (% of 1,250 recruited)	1,135 (91%)
Number and percentage participating in baseline CATI survey (% of 1,250 recruited)	1,137 (91%)
Number and percentage of participants recruited attending any group or individual module (% of recruited)	1069 (86%)
Number and percentage receiving group-based intervention	
Attended at least one group (% of total recruited)	950 (76%)
Central Sydney (% recruited within Division)	458 (82%)
Macarthur (% recruited within Division)	237 (79%)
Southern Highlands (% recruited within Division)	255 (66%)
Attended all 3 groups (% of those attending at least 1 group)	695 (73%)
Number and percentage receiving individual module	
Total receiving at least one individual module call (% of recruited)	119 (10%)
Central Sydney (% recruited within Division)	42 (8%)
Macarthur (% recruited within Division)	22 (7%)
Southern Highlands (% recruited within Division)	55 (14%)
All 3 individual module calls (% of those commencing individual module)	84 (71%)
Number and percentage of participants with short-term measurements taken at group three (out of people who attended one group)	78% (741/950)
Central Sydney	80% (365/458)
Macarthur	86% (205/237)
Southern Highlands	67% (171/255)

Indicator (attendance or participation in various activities)	Result
Number and proportion of “individual module” participants receiving all three individual module calls (% of those commencing individual module)	71% (84/119)
Central Sydney	76% (32/42)
Macarthur	77% (17/22)
Southern Highlands	64% (35/55)
Number and percentage of participants missing out on group session and individual module by Division (% of enrolled)	181 (14%)
Central Sydney	11% (62/562)
Macarthur	14% (42/301)
Southern Highlands	20% (78/387)

6.4.3.4 Contact rates at various milestones (Q 6e – Q6i)

Following the Program design it was also anticipated that after the initial intervention participants would

- a) have weight and WC measured for short-term progress at group session three.
- b) attend the 4-month GP visit.
- c) be contactable by phone at 3, 6, and 9 months from initial consultation.
- d) participate in the final CATI survey, attend the 12-month review with a lifestyle officer for final measurements, and deliver final food record
- e) attend a GP visit at 1 year to have a blood test for final outcome assessment.

These process indicators are a combination of *data collection milestones* [relevant only to the evaluation of the program], and contact rates for coaching [relevant to assessing program delivery and reach]. The follow-up telephone contact rate with the lifestyle officer overall and by Division was high at 3, 6, and 9 months (Table 6.5). However, contact rate with the GP at 4

months for the purposes of the SDPP follow-up was below 50%.⁵² This, according to lifestyle officers' view, may have been due to the fact that it was the GP responsibility and therefore the data may be in the medical record. Hence, the visit may have had occurred but not notified to the Program coordinators in the Division and consequently data from the episode of contact were not entered in the database.

⁵² Extract from the protocol: Four months after the initial consultation, participants visit their GP to measure weight and waist circumference and order any appropriate blood tests (i.e. FPG or lipid profile). This information will be used to detect any changes in the participant's profile at this time point.

Table 6.5 Adoption fidelity. Contact rates at different milestones and participation by Division as at 31 December 2010

Indicator (participation in various follow-up activities)	Result
Contact rate of active participants at each follow-up time point (overall) [¶]	
3-months (N & % of eligible to be contacted)	79% (921/1168)
4-m GP visit (N & % eligible for GP visit)	46% (543/1168)
6-months (N & % of eligible to be contacted)	83% (869/1044)
9-months (N & % of eligible to be contacted)	90% (741/826)
12-months(N & % eligible to be contacted)	90% (586/650)
Contact rate of active participants at each follow-up time point (By Division)	
Central Sydney	
3-months (N & % of eligible to be contacted)	83% (445/535)
4-m GP visit (N & % eligible for GP visit)	46% (248/535)
6-months (N & % of eligible to be contacted)	90% (397/443)
9-months (N & % of eligible to be contacted)	95% (284/298)
12-month (N & % of eligible to be contacted-not withdrawn)	105% (206/197) ^α
Macarthur	
3-months (N & % of eligible to be contacted)	86% (232/270)
4-m GP visit (N & % eligible for GP visit)	45% (121/270)
6-months (N & % of eligible to be contacted)	75% (200/265)
9-months (N & % of eligible to be contacted)	82% (210/256)
12-month (N & % of eligible to be contacted-not withdrawn)	83%(191/229)
Southern Highlands	
3-months (N & % of eligible to be contacted)	80% (291/363)
4-m GP visit (N & % eligible for GP visit)	48% (174/363)
6-months (N & % of eligible to be contacted)	81% (272/336)
9-months (N & % of eligible to be contacted)	91% (247/272)
12-month (N & % of eligible to be contacted-not withdrawn)	84%(189/224)

[¶] These timeframes are calculated allowing for 4 weeks past the due date to cater for Division delays in contacting and entering data

^α Some people attended the final review before the due time because they were planning to be away or were unable to meet the scheduled date. Hence the total adds up to >100%

Attendance at the final follow-up assessment by Division was acceptable at around 80% of those due for a 12-month review. In Central Sydney some people attended their 12-month review a little earlier than scheduled.

6.4.3.5 Attendance at final assessment (Q 6h – Q 6i)

These questions were also related to data collection indicators, and separately, to program delivery process indicators. Regarding final outcome assessment, just under 50% of the mainstream participants had completed their 12 months in the Program. Participants generally completed the CATI survey at baseline and 12-months as well as delivering the 3-day food record (participation rates of over 90% in both at baseline and over 75% for both at 12 months).

As of 31 December 2010, 90% of people due for a 12-month review had attended the visit (this does not include withdrawals). The majority of participants attending the final assessment have produced a final blood sample at 12 months but Divisions were making efforts to follow-up with the relevant GPs about the results of 7% for whom there were no data on diabetes status at the end of the Program.

Less than a quarter of enrolled participants had either withdrawn or were lost to follow-up as they were not contactable after multiple efforts following the due date for their final assessment. Withdrawal rates were lower in Central Sydney and Southern Highlands but Macarthur had over a third of participants not completing the Program. This latter Division had staff problems in terms of numbers available and ability for ongoing or timely follow-up. Of the 209 people who withdrew from the Program as at 31 December 2010, 23.4% did so in the first three months of participation, 52.6% between 3 and 11 months, and 24% in the last month of the Program.

While there were some variations in the way each Division promoted the Program locally and devised recruitment strategies, overall there were no major differences in the way the Program was delivered across participating Divisions.

6.4.4 Program acceptability by participants

Question 7 Did Program participants access community-based lifestyle services during the course of the Program?

Question 8 How satisfied were participants with the Program and their outcomes?

Most of the information presented in Table 6.6 below is derived from the ongoing contact with participants via baseline and follow-up telephone calls. No additional face-to-face qualitative evaluation activities have been conducted outside the routine operation of the Program due to a lack of resources. Of the people attending group sessions, most found it easy to travel to the venue, found time to attend the Program events, claimed that they learned new information and were satisfied with the Program materials provided.

Information on satisfaction with groups and Program materials is available from 80% of participants at the time of the 3-month phone call as these questions were introduced late for some participants. Overall respondents contacted at three months agreed that attending sessions posed no problem with transport to the venue or time.

Table 6.6 Participant acceptability. Adherence to Program protocol for completion of milestones at the end of the Program.

Indicator (completion of milestone)	Result
Number and percentage providing follow-up 3-day food record (% of 586 attending 12-m review)	449 (77%)
Number and percentage participating in follow-up CATI survey (% of 586 presenting for 12-m review)	536 (91%)
Number of participants due for 12 review (% of mainstream enrolled)	650 (52%)
Number and proportion of participants completing the whole Program * (% of 650 due for review)	586 (90%)
Attended 12-month review and had blood tests (of 586 completers)	544 (93%)
Attended 12-m review visit but blood test pending (of 586 completers)	42 (7%)
Confirmed missing 12-m outcome information: withdrawals + unable to contact after 365 days (% of those recruited)	
Overall (% of all recruited)	209+83(23%)
Central Sydney (% of recruited within Division)	65+28 (17%)
Macarthur (% of recruited within Division)	72+32 (35%)
Southern Highlands (% of recruited within Division)	72+23 (25%)

They also agreed that the sessions motivated them to change their lifestyle and that the Program materials were useful.⁵³

This was corroborated at the final CATI survey when participants generally expressed satisfaction with the Program (Table 6.7) and agreed that the resources and materials were useful, and the program motivated them to modify their behaviour. In particular, most perceived that at the end of the Program they had improved their fat and fibre intake, but less so their physical activity.

⁵³ At the end of the group three session participants were asked to complete a short questionnaire, designed and analysed by the intervention team. The candidate was not involved in this activity and therefore a brief summary of results is also presented in Appendix 6.3

The reasons for non-attendance at group sessions or individual telephone coaching were not collected systematically but a sub-sample of 242 participants was asked a relevant question on their routine 3-month follow-up call in 2010. The main reported reason for absence from groups was 'chose the individual telephone coaching' (31%), followed by lack of time due to family/personal commitments (10%), illness and injury (7%) and lack of motivation (3%). Reasons related to the Program included dislike of group session experience (3%), lack of interest in groups or telephone coaching (2%), difficulty with transport to the venue (2%), waiting list at Division (1%) and requirement to have a blood test before attending (1%). Forty percent gave no reason for absence to group sessions.

While reasons for withdrawal were unknown in about a third of all cases, the main documented reasons for ceasing participation were not attributed to the Program activities or requirements. These included family or personal commitments making people too busy to commit, health reasons, losing interest or motivation and staying temporarily out of Sydney or moving permanently out of area. A minority claimed reasons related to Program requirements such as the level of English skills required, the need to attend group sessions which they disliked, and perceived lack of usefulness of the Program. A younger male participant died, presumably for reasons unrelated to the Program (had not developed diabetes at the time of death).

Table 6.7 Participant acceptability. Qualitative indicators of Program acceptability by participants interviewed at different time points

Indicator	(%) reporting
Satisfaction with group-based sessions and SDPP materials at 3-months^a	
Found time to attend the venue	89%
Found it easy to travel/park	96%
Learnt new information during sessions	95%
Sessions motivated participant to change	92%
Materials and resources were useful	93%
Overall satisfaction with Program at 12-months^a	
Found group or phone sessions useful or very useful	94%
Believes sessions assisted in improving diet or P.A.	92%
Perceived themselves as eating less/much less fat than 1 year ago	81%
Perceived themselves as eating more fibre than 1 year ago	70%
Perceive themselves as increasing physical activity	33%
Perceived themselves as lost weight from 1 year ago	64%
Number and proportion of Program participants who access community-based services during the course of the Program	
At 3 months (N=920)	8%
At 6 months (N=824)	7%
At 9 months (N=659)	11%
At 12 months (% of 586 completers)	17%
Reasons for not accessing services (% of those contacted at 3, 6, 9 month follow-up)^b	
Prefers to do home-based unstructured activity	17%
Too busy with work or family commitments	19%
Already joined another facility/community service	14%
Costly	7%
Illness or injury	7%
Inconvenient distance/time of facility	5%

Indicator	(%) reporting
Social or family reason	5%
Dislikes gyms	4%
Had not received a provider list at the time of call	3%
Lack of motivation	3%
Time to withdrawal (median days and 25%-75% interquartile range) N=209	193 (91-325)
Reasons for withdrawing from Program any time after commencement (N=209)	
Family or personal social issues	33 (16%)
Too busy with other commitments	32 (15%)
Own health reasons	22 (11%)
Lost interest	18 (9%)
Program not helpful, can't change their risk	13 (6%)
Didn't like groups	8 (3%)
Away from Sydney	5 (2%)
Lacked motivation	5 (2%)
Insufficient English skills	4 (1%)
Moved out of area	3 (1%)
Died	1 (0.4%)
Unknown/unable to be contacted	63 (30%)

^a These findings only apply to participants attending the group sessions (77% of those interviewed at 3-months- N=920)

^β Percentages are averages of the three phone follow-up contact and final CATI. Responses are fairly consistent across 3, 6, 9,12 months

^Ω These data apply to completers who responded to the CATI survey at 12 months

Acceptability and satisfaction by stakeholders is not a core component of this thesis.⁵⁴

Very few participants use the existing community-based services assessed by SSWAHS staff as meeting the guidelines in the initial stages but there was a slow uptake (8% at 3 months and 17% at 12 months). In most cases this was due to personal or family commitments or

⁵⁴ Evaluation of level of stakeholder engagement and Program acceptability by stakeholders was not core responsibility of the candidate and component of this process evaluation are still being collated by others. Some details are presented in Appendix 6.3

preferences for individual, home-based, unstructured activity rather than due to cost or geographic accessibility. At the last call at 12 months, uptake appeared to have increased to at least one in ten participants.

6.5 Discussion

Considering the real-world context in which the SDPP was conducted, a comprehensive process evaluation of a prevention program is feasible but required additional documentation from lifestyle officers, Division staff and intervention and evaluation team staff. The findings from this process evaluation, as summarised below, indicate a reasonable level of enrolment by the target group and a high level of adherence to the Program components by Program staff. These are encouraging and informative findings for future implementation of similar programs in the community as they reassure health planners that its outcomes will reflect the implementation of a Program that occurred largely as initially intended. (284)

6.5.1 Screening and recruitment

The Program reached its target of 1250 mainstream participants despite a complex screening and variable recruitment process according to Divisional setting. The model that was used in the SDPP has proven to be resource intensive at the Division level. There were individual differences in GP perceptions of, and commitment to this Program. Recruitment was reliant on GP referrals, and Divisions spent time and resources addressing these recruitment delays. One in two screened people were potentially eligible and two thirds of these ultimately enrolled in the Program. Changes to financial incentives may have improved the referral process but did not guarantee a constant level of referral over time. Simplification of the screening paperwork for GPs, expansion of the Program to new practices, and allowance for participant referral before the confirmatory blood test seemed to increase recruitment levels in Central Sydney. In Southern Highlands, advertising the Program through local media and conducting a GP driver's night boosted the recruitment pace. In Macarthur, other than doubling of the GP incentive, no particular strategy seemed to affect recruitment rates.

The variability in potential participants' commitment to attend the initial consultation and their [lack of] willingness to undergo an OGTT or an FPG after a CBG test also impacted on the effectiveness of recruitment. Finally, the number of available lifestyle officer per Division determined preparedness for tracking blood tests before any enrolment and for conducting multiple initial consultations cannot be ignored as a potential barrier to uptake of the Program by more participants.

6.5.2 Program reach

The SDPP has reached a large community sample of the intended target group of 50-65 year olds who have behavioural risk factors and underlying chronic conditions. The distribution of Ausdrisk levels of participants and decliners was comparable (median and interquartile ranges) although the mean Ausdrisk was slightly higher for participants (18.8 vs. 18.3), but possibly not clinically important. Similar to other translation programs, the SDPP captured more women (121, 129, 220, 225) than men and those with higher education levels.(119) This could be because men and less educated people either do not visit GPs for routine preventive activities, or choose not to be screened. In rural areas particular (Southern Highlands), men were less likely to enrol in the Program after scoring as high-risk. The implication of this is that they need to be captured through different advertising strategies such as the local Media or through encouragement from peers and relatives.

6.5.3 Program fidelity

Overall the time to Program events and milestones and contact rates were satisfactory across Divisions but uptake of group sessions was lower in Southern Highlands. The impact of population age, distance and local dynamic factors is likely to have been important in recruitment to this SDPP. Participation in CATI surveys and delivery of the laborious food record both at baseline and 12 months exceeded expectations, as compared with other Australian and overseas experiences (see section on comparisons with other studies). There were some minor variations in the timeliness of activities due to local circumstances and patient factors. However, overall participants' exposure to the component of the Program and contact

rate by lifestyle officers at various milestones was high regardless of location. Despite staff changes and shortages, lack of experience in this kind of intervention, and the demands of the formal evaluation, lifestyle officer efforts to adhere to Program conditions were relatively consistent throughout. A future Program that does not require extra documentation for evaluation purposes would be more manageable. SDPP assessments of community-based services was a resource intensive activity but the uptake of community-based services remained low throughout the Program. It only improved slightly as a result of additional promotional activity and reminders during follow-up calls.

The combined loss to follow-up rate so far (~24%) due to withdrawal and inability to contact after 12 months deserves further attention. Lifestyle officers made up to five call attempts and some Divisions sent letters in order to re-capture participants for final assessment or find out the reasons for non-attendance.

6.5.4 Acceptability by participants

At the 3-month call the information was collected by lifestyle officers from the Division, although not necessarily the person who coached them. However, at 12 months, the satisfaction comments were asked by one of the evaluation team members on the telephone. This may have given opportunity for participants to provide different feedback but instead the overall participant satisfaction with Program approaches and materials was confirmed at the end of the Program.

Reasons for participants' withdrawal were mainly personal or family-related rather than associated with Program demands or approaches, while reasons for missing the final assessment are not known. It is possible that they are associated with dissatisfaction with own limited achievement of goals.

Participants did not make much use of fee-for-service community-based services for structured physical activity, nutrition or weight loss. These middle aged people have high obesity rates, suffer complex co-morbidities and largely seem to prefer unstructured, home-based exercise or have poor time availability resulting from family or work responsibilities. Moderate and

vigorous activity habits would be difficult to incorporate and maintain in this population and perhaps different approaches should be explored for physical activity program access in future translation studies.

Question 9. How did the implementation process compare with other studies?

6.5.5 Comparison with other studies

Formal process evaluations of diabetes prevention programs or their translations are scarce in the literature and the methods are not fully described or the process indicators reported do not comprehensively cover the Programs. This is true even for those (226) reporting to have used the RE-AIM Framework for evaluation of reach, adoption and implementation.(113) This section will compare SDPP process indicators with equivalent indicators selectively reported by other community or general practice-based studies.

The SDPP process evaluation results are similar to those of the GGT translation study in Victoria (117) which also recruited a predominantly female sample (73%), reported 76% participant's attendance to at least one group session, and experienced a 23.8% withdrawal rate. Another 2-year translation intervention in urban US reported 15% non-attendance at the first six-monthly assessment and 22% loss to follow-up at 12 months. (121) Whittemore's smaller US primary care-based pilot with a six-month follow-up phase also reported a 22.6% drop-out rate, (220) and a medium size translation study of six month duration in UK reported an 18% loss to follow-up.(223) It appears from the above that in real-world translation studies, one in every five participants fails to complete the program. The SDPP and the small primary care studies in US and UK (220, 223) reported competing life demands and medical issues as the main reasons for this.

By contrast, the Malmo feasibility trial where intervention was offered on a group-based or self-administered, reported an 11% loss to follow-up in the IGT intervention group after six-years. (99) The 'GOAL' implementation trial in Finland, which inspired the GGT protocol, reported a 9% drop-out rate at 12 months, the FDPS reported an 8% withdrawal rate at one year (93). The US DPP reported a 7.5% non-completion rate after and average of 2.8 years of follow-up (95)

and the Chinese DPP achieved a 7% loss to follow-up at six years, with a quarter of these due to participant's death not related to diabetes.(90) The close monitoring and ongoing contact rate observed in clinical trial conditions in the latter three studies, supplemented with availability of staff for closer follow-up may have led to the high completion rates. Further, the culture of population participation in health research may have been contributed to these lower drop-out rates in the three Finnish studies and the Chinese reference trial.

In assessing the reach of these programs, participants in the GGT and Whittemore's trial were mostly middle age women with high levels of obesity and relatively low education. While the GGT do not report on decliner characteristics, their non-completers also had lower educational status as per SDPP. Predominance of female participants in prevention studies is well known. The diabetes reference trials in Finland and US, and several translation studies in Greece and US reported this gender imbalance in participation, some more marked than others. (104, 117, 222, 287-289)

As far as adherence to Program requirements is concerned, in the GGT attendance to all six sessions for completers was 43% while attendance to all 3 sessions in SDPP was 75% for all completers, but it is easier to comply with a smaller number of sessions. A primary-care-based translation study in Finland also found that attendance to all six counselling sessions was only 57% although attendance to the first five was high at 90%. (226) However, their participants had lower education than SDPP and were mostly retired. Another community-based translation study in the US which offered weekly group sessions for the first six months reported attendances of between 57% and 70% in the different lifestyle arms of the intervention. However, attendance fell dramatically to rates of 16% to 37% across groups in the second semester when bi-weekly meetings were offered.(121) The US DPP found an average of 40% attendance at least one lifestyle lesson and 11% attending the full Program.(289) Most studies do not offer a description of the reasons for non-adherence to program activities. The SDPP identified mostly family and personal reasons such as business or ill health rather than program-related reasons for absence from group sessions.

Compliance with evaluation components also varies depending on type and intensity of data collection. For instance, in another, more intensive community-based Australian study in Ballarat, Victoria, (119) the authors reported 68.9% compliance with food frequency and physical activity questionnaires at one year, compared with 77% compliance for food record and 91% for physical activity at one year in SDPP. However, the Ballarat study involved self-administered weekly physical activity questionnaires while the SDPP involved a brief telephone interview administered by a trained interviewer at one year. The Indian DPP also required weekly records of physical activity and diet but compliance with these was not reported.(104) Compliance with clinical measurements at final assessment was 80.3% in the Ballarat study while the SDPP has observed so far a 23% rate of missing data at final assessment, in addition to 7% missing or delayed availability of end-of-study blood tests.

The most relevant and comprehensive evaluation report found was that of a general-practice-based study in South Australia, targeting people with pre-diabetes. (288) The *Go for Your Life* program included an initial individual session and a 'healthy living course' comprising six group sessions on diet, exercise, stress, and motivation for healthy lifestyle choices over six months. This was followed with motivational contacts at between 9 and 12 months. Their aim was also diabetes risk reduction and their goals were aligned with the USDPP on a weight loss of at least 7% and at least 150 minutes of physical activity per week. Dietary goals were the same as per FDPS and Sydney SDPP. *Go for Your Life*, however, used an RCT design (with a wait control group) as opposed to the before-after or repeat measures design of the SDPP.

For the process evaluation, the Ballarat translation study used a combination of quantitative and qualitative methods to collect data from participant and program delivery staff. These ranged from reviews of attendance records to participants/facilitators session evaluation forms centered on acceptability, usefulness and recommendations for improvement. Focus group discussions were also conducted with program providers to gain a better understanding of the recruitment. The SDPP planned focus group discussions (FGDs) with similar objectives but the

workload was too high and the capacity was not there in the early stages of the project. These FGDs will occur towards the end of follow-up, when staff workload is lighter.

As per the SDPP, the *Go for Your Life* recruitment strategies included both opportunistic and GP targeted among known high-risk clients. The latter was more successful in areas where GPs allowed access to client records. The SDPP also found that targeting invitations to known high-risk patients yielded a large pool of Program candidates. Community-wide recruitment strategies and mail-outs proved mostly unsuccessful in both Sydney and South Australia. GP concerns about the referral process was related to the laborious paperwork, similar to concerns expressed in the SDPP.

The blood test barrier, where potential participants were reluctant to comply with the requirement an oral glucose tolerance test to qualify for the program, was identified early in the *Go for Your Life*. This was also a problem with SDPP. Strategies to overcome this in both studies incorporated payment for blood tests (but no transport costs), and allowance for diagnosis of pre-diabetes within three months of commencement of the study. South Australian evaluators also released evidence to participants of the advantages of the 2-hour sample for diagnosis. Evaluators state that despite all these, the barrier remained. In the SDPP most completing participants also chose not to have the final OGTT. In contrast, in the Indian DPP, a completion rate of 95% was observed despite the entry requirement of two OGTTs to confirm IGT and exclude diabetes. (104) Personal motivation due to strong family history, predominance of middle-class participants, and cultural reasons including a higher tendency to comply with doctors orders are possible reasons for this high level of adherence to Program rules in the Indian diabetes prevention program.

The Ballarat participants rated the group sessions favourably (mostly 9 out of 10 ratings for all domains) claiming they motivated them to change their behaviour. This level of satisfaction with groups was not unlike response from SDPP participants. Of note, social desirability of responses remains an issue. Telephone questions on satisfaction with sessions and Program materials administered by telephone interviewers 3 months after the sessions corroborated this

in the SDPP and expressed some dissatisfaction with the length of the participants' manual, although in general the resources were well regarded by most. A small general practice-based feasibility study in the UK offering six group sessions over six months also reported positive qualitative participant assessment about content of the Program overall, motivational effect of the written nutritional feedback and usefulness of the group sessions in making the decision to modify the lifestyle. (222)

Attendance declined in Ballarat towards the last sessions (5th and 6th), with some complaints about the order and contents of the sessions and some concerns were expressed about the complexity of the materials. Likewise, in SDPP, attendance to the last group session (3rd) was lower than for the other two, some people complained of repetitious messages, although most were satisfied and motivated. According to the lifestyle officers, absences to the last sessions in SDPP were possibly due to the fact that follow-up measures were taken and some people preferred not to be confronted at this early stage. Very few people had documented reason for their absence from the last group in SDPP, some stating that ill health and family commitments were the main factors.

Unlike in the SDPP, where GPs tended not to respond to surveys if they did not participate in the program, the *Go for Your Life* Victorian doctors agreed to telephone interviews. They reported that if the recruitment process and workload and activities involved in the Program fitted with their clinical practice, there were more likely to refer participants and less likely to need incentives. The SDPP increased financial incentives in some areas to enhance the numbers enrolled before the end of the recruitment phase.

Community awareness raising occurred in South Australia via letterbox drops, newspaper articles and talks at schools, workplaces and local communities. In Sydney, the SDPP also conducted letterbox drops, local newspaper articles and cinema advertisements in selected areas in the last year of recruitment. While some clinical centres in South Australia considered these activities beneficial to recruitment, in SDPP these activities had no apparent impact on the recruitment rates at that stage of the Program. In 2002 the US DPP reported the need for

variations across clinics in screening and recruitment strategies to suit various age groups, settings and ethnic groups. Stepped screening and stepped consent was recommended. The authors considered ongoing revision of recruitment strategies a valuable exercise for improvement and also recommend that a wide range of approaches could be used either alone or in combination.(290) The Sydney DPP incorporated diverse strategies resulting from continuous assessment of outcomes and reported need at the Division level. SDPP also used a stepped screening and consent strategy to ensure accurate application of selection criteria. Interviews with staff delivering the Program in Whittemore's study revealed that motivational interviewing was the most challenging component of the protocol to follow, and participating nurses requested additional training before building their confidence. (220) The SDPP implementation team also provided periodic updates and ongoing support and refresher training for lifestyle officers. The Program saw lifestyle officer's confidence in personal and telephone coaching grow over time. Finally, overall implementation time took longer than planned in the original protocols both the SDPP and other translation studies. (220) The main reason in the in the US study appeared to be re-scheduling of appointments, staff illness or turnover, and end-of-the-year holidays. In SDPP the main reasons for delays in recruitment and overall study completion were the strict screening and entry requirements, variable rates of referral from GPs and time spent attempting telephone contact with participants.

6.5.6 Strengths of the SDPP process evaluation

A major strength of the SDPP was that the evaluation of this translation Program was planned as an integral part of the conduct of the intervention, as recommended by existing frameworks and authorities in the field. (282, 287, 291). An evaluation team was initially contracted to design, guide and oversee the tasks. This was done with the intention of enhancing the chances of objective assessment, unbiased critical appraisal, and impartial recommendations. The evaluation objectives, questions, methods for gathering evidence, and staff roles were decided in consultation with stakeholders. Agreements on the quality and quantity of indicators to be

documented at various points was reached between the relevant committees and the evaluation team keeping a balance between practicality and methodological rigour. Decisions on ways to document them were discussed from the beginning, and cooperation and skills of program staff were tested in the early stages.

Subsequently, data collected for this process evaluation were largely ongoing and prospective. Evaluation questions were made an integral part of the Program, making the activity more affordable and the data sources available within a few days of the event. This enabled identification of problems and introduction of continuous improvements to suit the local context for recruitment over time.(159) Selected and useful information was collected on non-participants, which allowed for estimation of the level of representativeness of this group among the high-risk people in the target communities.

Another strength of the process evaluation was the wide coverage of implementation elements assessed as recommended in the literature. (281, 286) The breadth of this process evaluation extends from recruitment to withdrawal, from providers and recipients perspective, from within to outside Program issues, from barriers to enablers, and from qualitative to quantitative data items. (279) In general, process evaluations, and in particular, this level of comprehensiveness is unusual in published evaluations conducted in real life settings (159, 286) but fortunately funding this translational Program included a reasonable evaluation budget as it was established as a demonstration project with a view to Statewide implementation.

The targeted screening approach identified larger proportions of eligible people than a population-based screening would have achieved. The Program also largely reached and enrolled people representative of the intended target group. Program fidelity was satisfactory given the many barriers faced in real-world clinical settings. Participant's satisfaction was reflected in high attendance rates at group sessions and high contact rates for telephone coaching and quarterly follow-ups.

6.5.7 Limitations of this process evaluation

Despite the comprehensiveness of the planning and conduct of this process evaluation, some gaps in information remained in the areas of program reach, acceptability and fidelity. For instance, with respect to evaluation data collection, not all data items were available on overall consent for screening and screening rates as denominators were not known. Many of the screening forms sent out were not returned or accounted for by some dis-engaged practices, and some forms were duplicated in very active practices. Also unknown were the reasons for some enrolled GPs not referring any participants to the SDPP after training.

In terms of acceptability, the planned qualitative analysis of stakeholder satisfaction via focus groups was never conducted as the coordination of such large number of people working different hours in different geographic locations made it impractical. Among GPs withdrawing from the Program or refusing to participate, most declined the invitation for an in-depth interview or brief telephone survey to ascertain the reasons.

Program fidelity was a comprehensive but not a complete picture as not all information was available from Division records on the reasons for not attendance at initial consultation by some eligible people. It is known that some made the appointment after the cut-off date for end of recruitment but in other cases it is questionable whether it was due to participant reasons or Division coordination matters. Extent of attendance at the 4-month GP consultation was not always documented in Program files even if the participant presented; some information may exist in the participants medical record but the Program did not have consent to access these. For people who did not attend this mid-Program visit the reasons were not collected at all as there were no reminder systems or fields in the database to document this. Participant's reasons for non-attendance at the final 12-month review were only known in a minority of cases despite repeat attempts by lifestyle officers to contact them and their families. It is not uncommon that some people in a target group are difficult to reach for the purpose of collecting data at various stages. (292)

Another weakness of this process evaluation was some data such as participant's satisfaction with group sessions were collected by program implementation staff immediately after the sessions. This was decided in view of the difficulties in contacting participants by telephone and the staff turnover and shortages to take up additional evaluation follow-up tasks beyond the service implementation. In the end these forms contained likely social desirability biases and were likely to be of limited use. Again, the time and service constraints precluded a complete representation of the process and this is only a reflection of translation to real life settings, as experienced by others. (292) Levels of GP confidence and satisfaction with the Program were assessed by selected staff from the Program implementation team rather than by external auditors due to resource constraints and difficulties with approval to contact GPs. While this is not ideal, the implementation team staff had no direct relationship with the GPs during the Program and did not have the Division of General Practice staff or lifestyle officers present at these interviews. This is believed to have enabled more honest responses from the doctors. In sum, the SDPP staff made numerous efforts to identify and report causes of possible failures in Program implementation and succeeded in covering most aspects. Many cases of missing data were patient-related and others were due to staff shortages at Divisions where competing service delivery priorities resulted in suboptimal record keeping standards or incomplete administrative information. The potential biases in collection of the satisfaction data have been previously acknowledged.

6.6 Conclusions and Research Questions

6.6.1 Screening and recruitment

The Program took longer than expected to reach its quota of participants due to delays in GP referrals; waiting lists for initial consultations at the Divisions due to shortages of lifestyle officers in the initial build up of recruitment; and participant issues such as delays in responding to invitation, having laboratory tests and attending initial consultations and final outcome

assessment; however, participation and retention rates are high once people are deemed eligible.

It is worth exploring the need for, or alternative blood tests required for screening, to overcome the 'blood test barrier' noted in the SDPP to enter the Program. The adoption of the American Diabetes Association recommendation on the use of a single blood test such as the HbA1c to exclude diabetes at the outset and final review may improve participation.

Financial incentives and medical education (CME) points were useful but not sufficient to universally encourage GPs to refer participants to the Program. Further investigation of effective GP incentives other than financial or educational need to be explored to ensure the Program captures the target group in a shorter period. Additional exploration of the feasibility and effectiveness of first phase of screening and recruitment without the intervention of GPs is warranted. Administration of the Ausdrisk tool and referral for a blood test could be done by trained practice staff, such as Practice nurses.

6.6.2 Program reach

The SDPP has largely reached the intended target group: 50-65 year olds from middle socio-economic groups who work, have poor lifestyle habits and suffer from chronic conditions. The SDPP participants had a slightly higher socio-economic profile than the decliners but also higher levels of obesity and co-morbidities that make them an appropriate target for behavioural modification.

To date, however, fewer men and too many participants with higher education levels have also been captured. The sub-groups of at-risk people not reached by this recruitment strategy likely represents those people not visiting GPs for routine preventive activities. To capture the least reached sectors of the target group in future programs, other community-based recruitment activities outside health services need to be explored. Invitation of male partners to join women in the Program could be a start. Recruitment strategies designed to suit the local needs of the target community and those of particular health services are encouraged. A combination of

approaches is essential, and standardized methods may not be necessary as “one size does not fit all”.

6.6.3 Program fidelity

Staff adherence to implementation rules of a lifestyle prevention Program conducted for the community using GP services for identification and referral is feasible. The limited number of sessions (compared with the 16-lesson curriculum of USDPP) and the ease of subsequent telephone contact may be the key to its implementation. Sufficient numbers of trained lifestyle officers would be required to cater for the initial high load of participants so waiting lists for initial assessment and group sessions are circumvented. Minor variations in the timeliness of activities were observed due to local circumstances and patient factors, Division administration and lifestyle officer workloads. However, overall participant’s exposure to the intervention, and contact rate by lifestyle officers were high at most time points.

Attendance of participants at one year follow-up to ensure completion of final assessment may not be amenable to improvement after multiple contact attempts. Additional telephone numbers of relatives or work colleagues would need to be collected from participants in similar programs at the outset. This may ensure ascertainment of true ‘lost to follow-up’ with possible reasons, and minimise the ‘unable to contact’ rate at final assessment time. The 7% of cases who have attended the review but have not provided blood tests may not be able to be tracked to improve the completeness and accuracy of the diabetes incidence estimate.

6.6.4 Acceptability by participants

Most participants attending group sessions found no difficulty in travelling, found time to attend the Program venues, learnt new information and were satisfied with the materials provided. However, after the initial support phase, participants did not make much use of indoor, private fee-for-service community-based services for structured physical activity or weight loss management. These middle aged people have high obesity rates, suffer complex co-morbidities and seem to prefer unstructured, home-based exercise or have poor time availability resulting from family or work responsibilities. Another dimension of acceptability is reflected in the

withdrawal rates. Participants' reasons for withdrawing were mainly personal or family-related rather than associated with Program demands or approaches, while reasons for missing the final assessment were not known. The SDPP did not provide patient incentives to join, other than the free coaching for one year. SDPP participants were offered small financial incentives in the form of cook books and movie tickets for remaining in the program until the end. More enticing incentives for returning to the final outcome assessment may or may not have lead to more complete information on outcomes. Comparisons between outputs or outcomes for patient incentive and non-incentive groups were beyond the scope and budget of the SDPP process evaluation.

In brief, investigation of participant satisfaction is feasible if made as integral part of the running of the Program, i.e. during the routine phone follow-up, given that participants are not easily contactable outside routine Program procedures.

Chapter 7.

Short-Term Impact Evaluation

Summary

This chapter focuses on the short-term (3 months) objective impact of the lifestyle intervention among mainstream participants in the Sydney Diabetes Prevention Program. It presents the results of anthropometric (weight and waist circumference) changes between baseline and the time of the third group session (around three months from baseline) for all mainstream participants who attended the last group session. While these short-term outcomes were not primary Program goals of SDPP, a similar translation intervention, the Greater Green Triangle study conducted in Victoria, Australia, the year before SDPP provided a rare opportunity for a comparator of short-term outcomes. Potential predictors of short-term change are examined via stepwise logistic regression analysis at 3 months using socio-demographic and behavioural risk factors as explanatory variables.

Similarities and differences with other prevention programs reporting short-term outcomes are presented in the form of a critical appraisal of methods and qualitative interpretation rather than statistical meta-analysis. Analyses of self-reported changes in physical activity and diet are presented in the Appendix.

Conclusions are drawn on the short-term impact of the Sydney Diabetes Prevention Program, and possible explanations for the short-term findings from Australia are presented along with suggestions for future research.

7.1 Introduction

As seen in Chapter 2, the impact of intensive lifestyle interventions have been reported generally at one, four, six, ten and twenty years. Few studies have reported the immediate or short-term impact of these interventions, as discussed in Chapter 3. The SDPP examined the short-term impact (at three months) of components of the lifestyle intervention as well as the medium-term impact (12 months) which is described in Chapter 8. This short-term impact was measured to estimate the time when lifestyle changes commence, and the later analysis deals

with the mid-term sustainability of outcomes. This chapter reports on selected primary objective outcomes and secondary self-reported outcomes among mainstream participants at three months.

The public health literature is limited in terms of short-term results from lifestyle interventions. The 3-month outcomes of another Australian study the Greater Green Triangle (GGT) program were considered the most recent and relevant and hence used for comparison. Their cut-off point of weight loss ≥ 2.4 Kg and waist circumference of ≥ 3.2 cm at three months were chosen as a comparative level for defining changes in weight and WC. These were adopted as a benchmark for relevance to the Australian context. Firstly, the GGT used similar methods, materials and group intervention approach. Secondly, the target population was adults (aged 40-75) including the SDPP age group (50-65). Finally, participants in both studies were recruited from similar general practice settings in the Australian context. based on the findings of the other Australian diabetes prevention Program in the Greater Green Triangle. These cut-off points were used as the outcome variable in the bivariate and multivariate analyses.(217) The main focus of this chapter is on analysis of objective, short-term weight changes as they relate to one of the primary outcomes (5% weight loss at 12 months) hence they are the primary research questions.

Results will be presented in response to the following research questions:

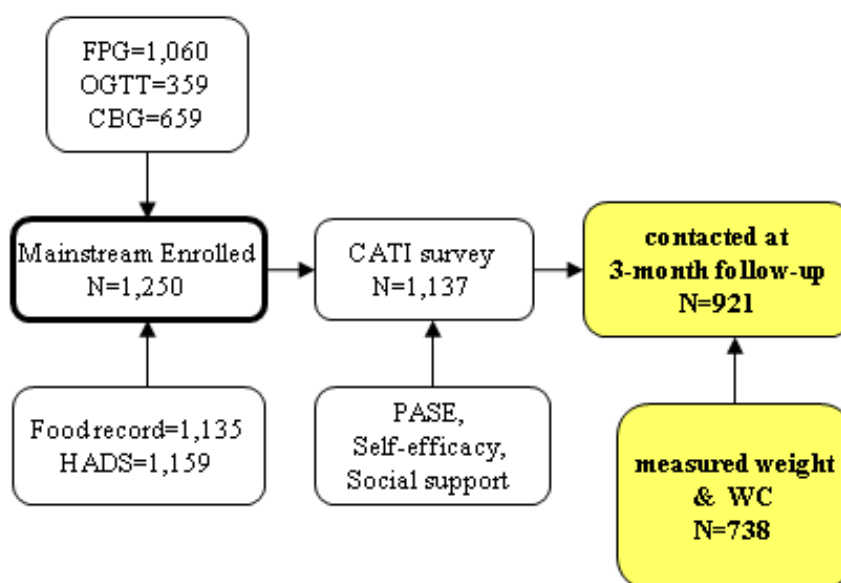
1. Who attended short-term measurement and how different were the non-attendees?
2. What were the objective changes in weight and waist circumference after three months in the SDPP for the whole group and by sex?
3. Were the correlates and potential predictors of achieving weight loss comparable with the results from the Greater Green Triangle Program?
4. Were the correlates and potential predictors of achieving WC reduction comparable with the results from the Greater Green triangle Program?

Note that additional questions were asked at three months on self-rated change in diet and physical activity and the results are presented in Appendix 7.1.

7.2 Methods

Data from 738 participants who attended the third group session (59% of those enrolled and 78% of those choosing group sessions) constitute the focus of this chapter, as no other interim visits for weight or WC measurements were available before their final assessment for participants missing the third group session or for those receiving the telephone coaching (Figure 7.1).

Figure 7.1 Milestones and data sources covered in the short-term impact at 3 months



7.2.1 Data Sources

The online lifestyle officers database was the main sources of information on patient characteristics (age and sex) and anthropometric measurements (objective weight and waist circumference) at baseline and three months and about Divisional information (rurality and lifestyle officer).

The computer-assisted telephone interview databases, conducted by external interviewers, were used to assess:

- more detailed demographic data (pension, income, education, private insurance)
- baseline minutes of aerobic activity and strength training (conversion from the PASE questions on moderate to vigorous activity in the past 7 days)
- Anxiety and depression scores were derived from the Hospital Anxiety and Depression Scale (HADS) (263, 264) handed in by participants at the initial consultation.

For details of the specific baseline data items please refer to the CATI survey questionnaire in Chapter 4, Appendix 4.5. and questions for the HADS instrument can be seen in Appendix 4.13.

7.2.2 Measures

Weight changes were objectively measured using the same digital scales at baseline and three months. These scales were calibrated on-site twice a year. Waist circumference was measured at both time points by a trained lifestyle officer with a purpose-made tape measure which cover a range up to 250 cm.

7.2.3 Statistical analysis

Male and female differentials in mean weight, percentage weight loss and mean WC change were estimated using t-test. Bivariate analysis used chi square for statistical comparisons of proportions.

Predictive models of the characteristics of changes at 3 months were investigated using a manual stepwise regression analysis with all plausible variables incorporated gradually. A cut-off point (threshold) for weight and waist circumference was chosen based on the results of the Greater Green Triangle diabetes prevention program. All models to predict achievement of the weight threshold had at least age, sex and baseline weight in them, as they are well known predictors. Any additional variables such as depression, self-efficacy, number of comorbidities, baseline level of physical activity, and level of education were tested on plausibility grounds based on debate in the literature. (117, 220, 223, 225, 293) These parameters only remained in the model if they were statistically significant at the 0.05 level. All models to predict achievement of the waist circumference threshold had at least age, sex and baseline WC in them, as above. New variables were left in the model if they met statistical criteria ($p < 0.05$). Multivariate analysis used odds ratios estimates and 95% confidence intervals when exploring the associations between potential predictors of achieving the chosen weight threshold for the outcome variable weight loss, as explained below.

Only mainstream participants were included in this analysis as the profile of Arabic and Chinese is very different, the numbers are still small and data for their participation at 3 month follow-

ups had not been fully collected by December 2010. Short-term impact of the CALD cohorts is beyond the scope of this thesis.

7.3 Results

Question 1 Who attended short-term measurement and how different were the non-attendees?

By December 31 2010, of the 1250 mainstream participants enrolled 921 had been contacted by telephone for follow-up (45.1% from Central Sydney, 30.7 from Southern Highlands and 24.2% from Macarthur Division). These data represent initial short-term impact data on around three quarters of the sample. As mentioned in Chapter 6, overall 76% of the 1250 mainstream participants (950) were exposed to at least one group session and 73% of these attended all three sessions. At the third group session lifestyle officers measured participant's weight and waist circumference on 738 participants (see Figure 7.1).

Of the enrolled participants who did not attend the measurement session, most of the reasons are unknown. However, 161 of the non-attendees at session three who were contacted at the three-month telephone follow-up mentioned the following as the main reasons for non-attendance: 8% chose individual sessions, 2% had an illness or injury, 3% had busy schedules with family and work commitments or lacked motivation (1.1%). Others (2%) claimed that the group dynamics were not meeting their needs, and smaller numbers reported that the location or time were inconvenient (0.6%), they were away travelling (0.5%) or were on a waiting list for blood test or Division bookings (0.5%).

Among the people who chose to attend group session intervention modality, there were no statistically significant differences in sex, age, baseline minutes of moderate-vigorous physical activity between the people attending for measurements at 3 months and those missing the measurement session (Table 7.1). Analysis of the baseline anxiety and depression scores for attendees vs. non attendees at this measurement session revealed no significant differences for either anxiety or depression. Likewise, the likelihood of meeting the physical activity goal at baseline was no different for attendees or non-attendees. However, it is important to note that people with either higher baseline BMI, larger baseline waist circumference, or higher baseline

weight were significant less likely to attend these short-term follow-up measurements (Table 7.1).

Table 7.1 Differentials between SDPP participants attending and not attending the third group session for short-term anthropometric measurement. N=733 attendees and 376 absentees.^α

	Attendees ^β N (%)	Absentees N (%)	test, p value
Male	259 (35.1)	207 (40.4)	$\chi^2=0.74$ p=0.39
In the workforce	465 (63.0)	257 (66.0)	$\chi^2=0.925$ p=0.34
On a pension	200 (30.0)	98 (27.8)	$\chi^2=53$ p=0.47
Higher education	258 (38.7)	133 (37.7)	$\chi^2=0.11$ p=0.74
Met physical activity goal at baseline	101 (16.4)	48 (14.7)	$\chi^2=0.46$ p=0.50
Anxious (HADS score ≥ 8)	231 (33.7)	130 (36.9)	$\chi^2=1.05$ p=0.30
Depressed (HADS score ≥ 8)	153 (21.9)	84 (23.3)	$\chi^2=0.27$ p=0.60
Age (mean years, SD)	58.1 (4.3)	57.9 (4.5)	ttest=-0.74, p=0.46
Weekly minutes of moderate activity (mean,SD)	113.1 (95.8)	105.6 (80.1)	ttest=-0.47, 0.64
Baseline weight (mean kg, SD)	88.6 \pm 17.1	91.5 \pm 18.8	ttest=2.56, p=0.01
Baseline WC (mean cm, SD)	106.4 \pm 12.7	108.3 \pm 13.8	ttest=2.3, p=0.021
BMI (mean units, SD)	32.2 (5.5)	33.0 (6.1)	ttest=2.1, p=0.04

^β Figures are N (%) unless otherwise specified

^α N relates to eligible to attend, i.e. those who did not choose telephone coaching. The denominator varies from one parameter to the next depending on data availability for individuals.

Question 2. *What is the objective change in weight and waist circumference after three months in the Program for the whole group and by sex?*

7.3.1 Objectively measured anthropometric changes at third group session

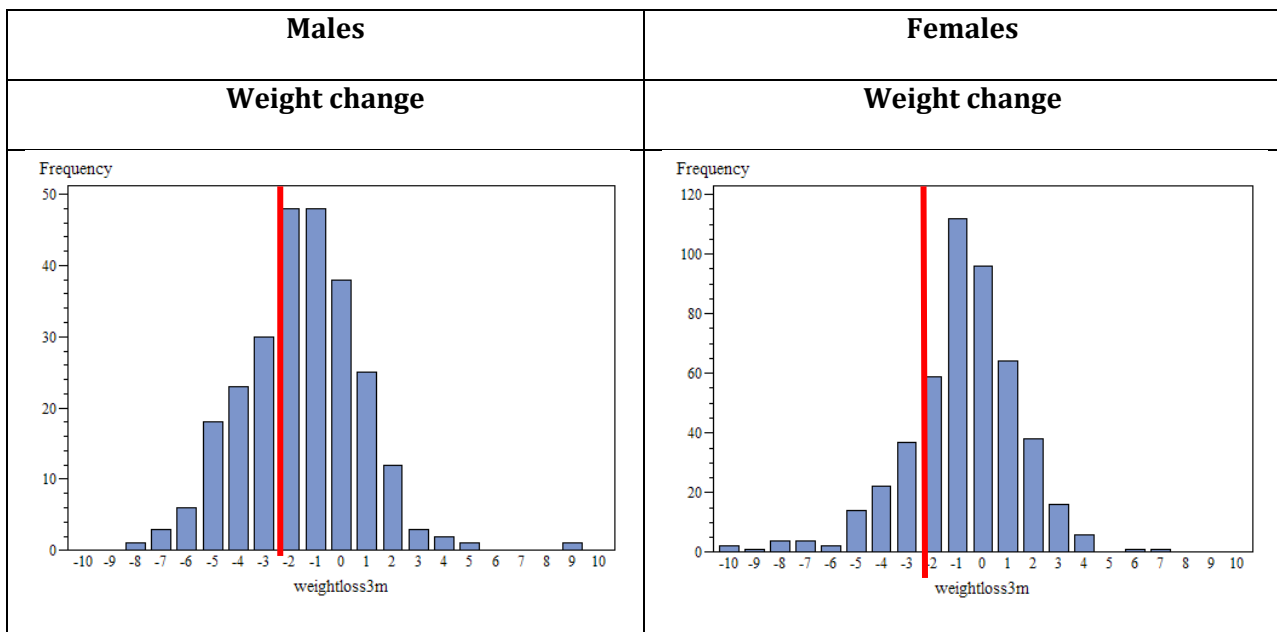
By the third group session both mean weight and mean WC were lower than at baseline, but the mean three-month weight for males was still significantly higher than the mean three-month weight for females (94.8 kg and 83.6 respectively; $p < 0.001$); likewise, mean WC at three months for males was still significantly higher for men than for females (109.4 cm and 102.1 cm respectively; $p < 0.001$).

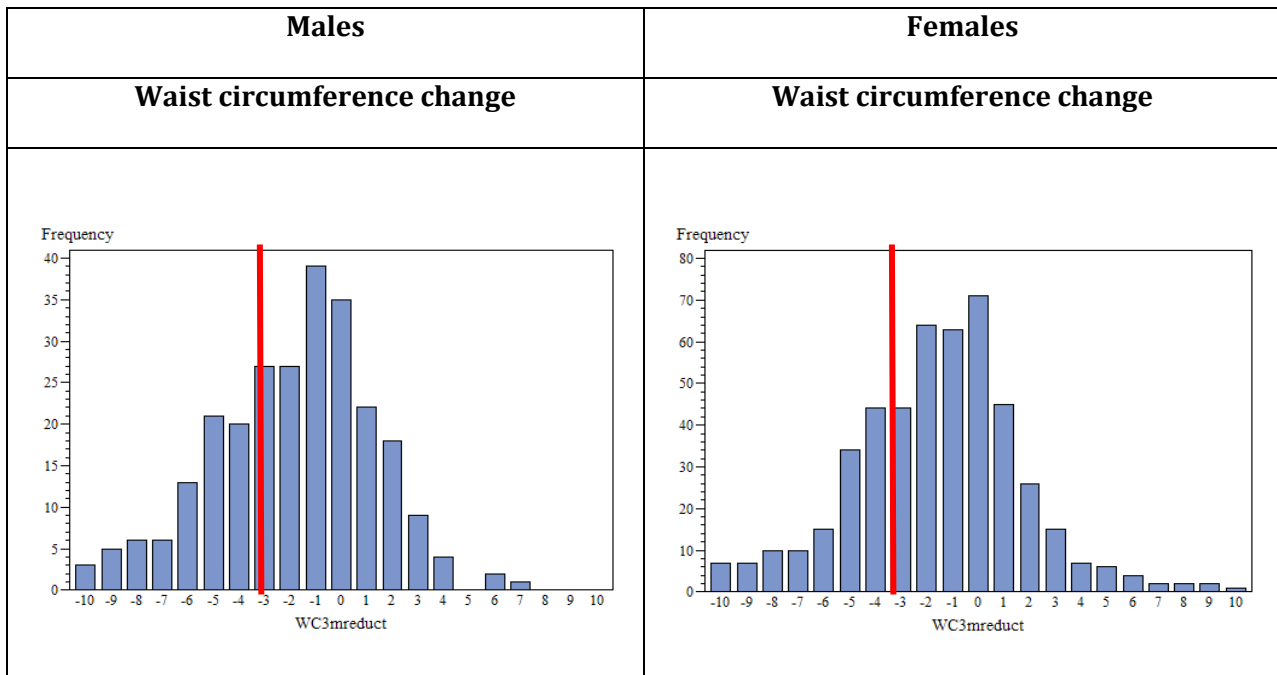
Anthropometric changes based on measurements taken at group-3 session indicate that 51% of those measured at three months lost at least 1 kg in relation to baseline, 17.5% had lost 3 kg or more and three participants lost 10 kg or more of initial body weight. The distribution of weight loss by sex (Figure 7.2) shows that more males than females (68.3% vs. 53.7%) lost at least 1 kg and more women than men (20% vs. 14.7%) experienced no change in weight at three months. Further, more females than males (26.3% vs. 17%) had gained weight at the time of group-3

measurement. The median weight loss for males was -1.5 kg (interquartile range -2.9 to -0.1) while the median for females was -0.7 kg (interquartile range -2.0 to +0.6).

Waist circumference did not change in 13.6% of the males and in 14.8% of the females (Figure 7.1). Up to 38.4% of males and 34.7% of the females experienced reductions of at least 3 cm, with 7% of males and 3% of females achieving a 5-cm reduction. Three males and 7 females lost 10 cm or more of their waist circumference in relation to baseline. One in five males and females (22 and 23% respectively) experienced an increase in WC but only 2% of males and 5% of females had an increase of 4 cm or more. The median WC reduction for both males and females was -1.5 cm, with interquartile ranges of -4.1 to +1 and -3.8 to +0.25 cm respectively (Table 7.2).

Figure 7.2 Distribution of weight and waist circumference change (loss or gain) by sex among mainstream participants attending group-3 session at around 3 months.* N=378, Males=259, Females=479.





** The red vertical line indicates the mean WC reduction and mean weight loss reported by the Greater Green Triangle study.*

The mean weight loss for the cohort by the time participants attended group session #3, was 1.1 kg (see Table 7.2). This corresponds to a mean 1.2% of body weight. At this point 7% of these participants had achieved the 12-month goal of losing at least 5% of their initial weight.

This difference in the higher achievement of weight loss by males when compared with females is confirmed by the t-test (t value=-4.35, p <0.0001 and t value -3.53 p<0.01 respectively).

Within sex differentials in weight loss were also statistically significant. That is, the change in mean weight between baseline and three months was significantly different from zero for both males (paired ttest=11.3, p<0.0001) and females (paired ttest=8.1, p<0.0001). As seen in Table 7.2, the differences in waist circumference reduction between males and females were not statistically significant (ttest=1.1, p=2.69) but the differences between baseline and 3-month WC were significantly different from zero for males (paired ttest=9.8, p<0001) and for females (paired ttest=10.8, p <0001).

Weight loss by BMI levels was not different between the obese and the overweight participants (-1.1 kg, -1.2 kg and 95% CI -0.9 to -1.4 kg for both). The mean weight loss for people within the normal baseline BMI range was slightly lower (-0.7 kg) but the confidence interval overlapped

with those in the overweight and obese categories (95%CI -0.3 to -1.2 kg). There was a slight but statistically significant positive correlation between weight change and WC change ($p < 0.0001$ for Pearson correlation coefficient $r = 0.44$) in particular for males $r = 0.47$ vs. 0.43 for females.

Table 7.2 Mean changes in measured weight and waist circumference overall and by sex at three months.

Outcome (change)	N	Mean	Lower 95% CL for Mean	Upper 95% CL for Mean	P between sexes	p within sex ^α	Median	Interquartile range IQR (25% -75%)
Weight loss 3m (g)	738	-1.1	-1.3	-0.9	***		-0.9	-2.4 to +0.4
Males	259	-1.6	-1.9	-1.3		***	-1.5	-2.9 to -0.1
Females	479	-0.8	-1.0	-0.6		***	-0.7	-2.0 to +0.6
% weight loss 3m (%)	738	-1.2	-1.4	-1.0	*		-1.0	-2.6 to +0.4
Males	259	-1.7	-1.9	-1.4		N/A	-1.6	-3.0 to -0.1
Females	479	-1.0	-1.2	-0.7		N/A	-0.8	-2.4 to +0.7
WC 3months reduction (cm)	737	-1.8	-2.0	-1.5	NS		-1.5	-3.8 to +0.3
Males	258	-1.9	-2.3	-1.5		***	-1.5	-4.1 to +0.1
Females	479	-1.7	-2.0	-1.4		***	-1.5	-3.8 to +0.25

^α Comparison between baseline and 3-months within males and females

N/A= not applicable

* ≤ 0.05

** $P < 0.001$

*** $p < 0.0001$

NS= not significantly different

Question 3. *What are the correlates and potential predictors of achieving weight loss comparable with the results from the Greater Green Triangle Program?*

7.3.2 Bivariate correlates of short-term weight loss

Several sex differences in the changes at three months were observed. Weight loss and waist circumference reduction as continuous variables were highly correlated (correlation coefficient 0.46 for males and 0.43 for females). When the GGT thresholds were applied, males were more likely (33.2%) than females (19.8%) to achieve a weight loss of ≥ 2.4 kg ($p < 0.0001$). However, no difference in the likelihood ($p = 0.25$) of achieving a waist circumference reduction of ≥ 3.2 cm was observed between males (33.7%) and females (29.7%).

Bivariate analysis for weight loss using the GGT threshold found that the most statistically significant predictors of achieving a ≥ 2.4 kg weight loss were being a male and being obese at baseline (Table 7.3). Obese and overweight people were more than twice as likely to lose 2.4 kg

or more at three months (Odds Ratio 2.64 and 2.30). Living in a rural area (Southern Highlands Division) was marginally significantly associated with achieving that level of weight loss. Participants not covered by private health insurance were also more likely to achieve the weight loss threshold. The significant negative association of insurance with weight loss ($p=0.03$) was further investigated. Participants on a pension were less likely (40.5%) than people not receiving a pension (77.7%) to hold private health insurance ($\chi^2=146, p<0.0001$). There was no statistical difference between insurance and the three categories of weight ($\chi^2=2.5, p=0.29$), whereas people in the paid workforce were more likely (75.4%) than people out of the workforce (53.4%) to be private health insurance holders ($\chi^2=57.6, p<0.001$). However, both being in the workforce and having insurance were negatively associated with achievement of the GGT weight loss threshold. As shown in Table 7.3, there appeared to be other positive and negative associations with weight loss but they did not reach statistical significance. Some of them will be explored and controlled for in the multivariate analysis.

Table 7.3 Baseline and three-month correlates of meeting GGT weight reduction levels at three months for mainstream participants. Unadjusted odds ratio or probability of meeting the GGT weight loss threshold. N=738.

Parameters (and referent group)	Weight loss ≥ 2.4 kg OR (95%CI)
Age in years (continuous)	1.01 (0.96 - 1.05)
Male sex (female is referent)	2.0 (1.43 – 2.83) ***
High Education (medium education is referent)	0.94 (0.66-1.34)
Low Education (medium education is referent)	0.46 (0.10 – 2.06)
Low income (medium income is referent)	1.14 (0.77-1.71)
High income (medium income is referent)	0.78 (0.51 – 1.18)
In the workforce (not in the workforce is referent)	0.88 (0.62 -1.24)
On a pension (not on a pension is referent)	0.98 (0.67 - 1.45)
Private insurance (not on insurance is referent)	0.57 (0.4 – 0.83)**
Semiurban (urban is referent)	1.44 (0.97-2.15)
Rural (urban is referent)	1.55 (1.02-2.35) *
Initial weight in Kg (continuous)	1.02 (1.01 – 1.03)***
BMI (continuous)	1.04 (1.01 - 1.07) *
Obese (Normal weight is referent)	2.64 (1.17 – 5.98) *
Overweight (Normal weight is referent)	2.30 (0.98-5.3)
Baseline FPG (continuous)	1.27 (0.96 – 1.67)
Meets P.A. goal at 3M (not meeting PA goal is referent)	1.2 (0.83 – 1.85)
Number of group sessions attended (continuous)	1.47 (0.72 - 2.98)
Most days/week dieting (lower frequency is referent)	1.80 (0.82 – 3.94)
Eating less fat (eating more/same fat is referent)	0.81 (0.51 – 1.30)
Eating more fibre (eating less/same fibre is referent)	0.92 (0.57 – 1.49)
Self-efficacy (low self-efficacy is referent)	0.98 (0.95 – 1.01)
Social support (low/no support is referent)	0.96 (0.92 – 1.00)
Anxious (non-Anxious is referent)	0.91 (0.63 - 1.32)
Depressed (not depressed is referent)	1.16 (0.77 - 1.74)
Good self-assessed health (poor health is referent)	1.02 (0.69 – 1.50)
Money spent on PA products (\$0 is referent)	1.07 (0.77 – 1.50)
Total co-morbidities (continuous)	1.06 (0.90 - 1.25)

* $p < 0.05$

** $p < 0.01$

*** $p < 0.001$

7.3.3 Adjusted predictors of short-term weight loss

Regardless of statistical significance, the base model for predictors of weight loss included age, sex and baseline weight, given the biological plausibility that these factors would influence the outcome. After controlling for age, sex, baseline weight, rural/urban residence and private health insurance status, male sex was the strongest predictor of achieving the GGT threshold (OR 1.85, Table 7.4). That is, males were almost twice as likely as females to achieve the weight loss threshold at three months. Being older was not associated with increased or decreased likelihood of achieving the threshold (OR 1.01, $p=0.537$). People of higher baseline weight were significantly more likely to achieve weight loss threshold (OR 1.02, $p=0.001$).

There was no association between baseline BMI categories and private insurance coverage ($\chi^2 = 2.5$, $p=0.29$). That is, the distribution of baseline obesity and overweight was similar among those covered and those uninsured and likewise for the distribution of BMI categories at 3 months ($\chi^2 = 4.6$, $p=0.09$) among the insured and uninsured. However, at three months, an unexpected finding was that private insurance holders had a significantly reduced odds of losing ≥ 2.4 kg (OR 0.61). The association of insurance with achievement of the threshold weight loss was further examined to investigate whether insurance status was a proxy for some other predictor of weight loss. Insurance was not statistically significantly associated with sex, age, employment, BMI, initial weight, or level of physical activity at three months ($p > 0.10$ for all). However, the bivariate analysis revealed that participants from both the semiurban and rural Divisions of GP were significantly less likely to have private insurance ($\chi^2 = 8.67$, $p=0.013$ & trend test $Z=2.79$, $p=0.005$ with Macarthur at the lowest coverage of 23%, Southern Highlands following close at 29% and Central Sydney 49%); and rural residence was also significantly positively associated with this achieving the GGT threshold for weight loss. The interaction term was not statistically significant in the multivariate analysis.

Table 7.4 Adjusted predictors of achieving the GGT weight loss level for mainstream participants attending the third group session. Odds ratio estimates for participants with weight information at baseline and three months. N=738

Effect (referent group)	Odds ratio	95% Wald Confidence Limits		p
Age (continuous)	1.01	0.97	1.06	0.537
Male Sex (female is referent)	1.85	1.25	2.74	0.002
Baseline weight (continuous)	1.02	1.10	1.03	0.001
Private insurance (no insurance is referent)	0.61	0.41	0.89	0.010
Rural residence (urban is referent)	1.72	1.09	2.72	0.020
Semiurban residence (urban is referent)	1.32	0.84	2.06	0.231

Variables explored which did not achieve statistical significance in the model included:

education level, pension status, income levels, employment status, money spent on physical activity products, minutes of physical activity at baseline or three months, baseline level of fat and fibre intake, perceived change in fat and fibre intake at three months, frequency of healthy diet, money spent on physical activity products, total number of chronic conditions, level of self-efficacy and social support score. While there was a negative association between baseline depression or anxiety as measured by HADS and achievement of the weight threshold at three months, this relationship was not statistically significant. The number of sessions attended was not included as people who did not attend the third sessions did not have the three-month outcome documented.

Separate logistic regression models for each sex were built to examine whether different variables predicted weight loss for males and females.

The association of weight loss with private insurance for males disappeared after adjusting for age ($p=0.077$). At baseline there was no association between age group and private insurance coverage ($\chi^2=5.5$, $p=0.065$). Results indicate that for men, after adjusting for age the only significant predictor of achieving the target weight loss (GGT threshold) was baseline weight (Table 7.5). That is, the higher the baseline weight, the greater the chances of achieving the target weight loss. Age was inversely associated with achieving the GGT weight loss, i.e. the male elderly were less likely than younger male participants to achieve the weight loss but this association was not statistically significant. However, age was left in the model as a customary adjustment decided *a priori*. Pension status, employment status, education or income, rurality,

private insurance, perceived change in physical activity, depression or anxiety showed no significant association with weight loss so they were excluded from the final model for males. For women, the achievement of threshold weight loss is predicted by initial weight and rurality. Females in rural areas were twice as likely to achieve the GGT weight loss threshold as females in urban areas (OR 1.95, p=0.027). The relationship with insurance status disappears after controlling for rurality (p>0.5). Other variables examined in the stepwise regression model for females which did not achieve statistical significance included pension, employment, income, education, minutes of physical activity at three months, self-perceived change in physical activity, and baseline anxiety and depression scores.

Table 7.5 Sex differentials in adjusted predictors of achieving the GGT weight loss level for mainstream participants attending the third group session. Odds ratio estimates for participants with weight information at baseline and three months. N=257 males and 476 females

Effect (referent group)	Males	Females		
	OR & 95% CI p		OR & 95% CI p	
Age (continuous)	0.99 (0.93-1.05)	0.731	1.03 (0.97-1.09)	0.300
Baseline weight (continuous)	1.02 (1.01-1.04)	0.009	1.02 (1.00-1.03)	0.046
Rural residence (Urban is referent)	-	-	1.95 (1.08-3.5)	0.027
Semiurban residence (Urban is referent)	-	-	1.5 (0.80-2.82)	0.211

Question 4 *What are the correlates and potential predictors of achieving WC reduction comparable with the results from the Greater Green triangle Program?*

A brief summary of findings from this analysis on waist circumference reduction follows.

7.3.4 Bivariate correlates of short-term waist circumference reduction

Using the Greater Green Triangle results of -3.2 cm as a threshold reference, bivariate analysis revealed that the most significant predictors of achieving 3.2 cm of WC reduction for SDPP participants were baseline depression (OR 1.67; 95% CI 1.14-2.44; p=0.009); baseline anxiety (OR 1.49; 95% CI 1.07-2.09; p=0.019);⁵⁵ the baseline waist circumference (OR 1.01; 95% CI 1.002-1.027; p=0.026) and not having private health insurance (OR for having insurance 0.67;

⁵⁵ Depression and anxiety were defined as a score from the hospital anxiety and depression scale (HADS) were scores of ≥8 indicate depression or anxiety, and scores of 7 or less indicate no depression or anxiety. Explanation of the instrument scoring system is presented in Chapter 4 and baseline data on HADS scores for SDPP participants is presented in Chapter 5.

95% CI 0.48 to 0.95; $p=0.024$). Bivariate analysis showed that people in rural areas were more likely to be depressed than people in semi-rural areas ($\chi^2=7.0$; $p=0.030$) but no different from participants from urban areas. The mean depression and anxiety scores for males and females at baseline were within normal values (4.4-4.7 and 5.5-6.6 respectively as presented in Chapter 5).

The following variables explored in the bivariate analysis were not associated with achieving the WC threshold: age, sex, income level, employment status, pension status, education, frequency of physical activity, achieving the P.A. goal at three months, frequency of healthy diet, self-perceived increased fibre or reduced fat intake, self-efficacy or social support scores, self-rated health, total number of co-morbidities or spending money on physical activity products at baseline or in the first three months of the program.

7.3.5 Adjusted predictors of short-term waist circumference reduction

Multivariate analysis revealed that the apparent effect of private insurance on WC reduction disappeared after controlling for age, sex, and depression or anxiety. None of the interaction terms insurance*anxiety or insurance*depression or insurance*obesity were significant, but the interaction term insurance*rurality was significant ($p=0.033$). That is, people in rural areas were less likely to be insured. The bivariate analysis had also shown that people in rural areas were more likely to be obese ($\chi^2=11.4$; $p=0.022$). It appears that lack of insurance could be a proxy for rurality, and indirectly a proxy for obesity.

Overall, the strongest predictors of achieving GGT threshold for waist circumference after controlling for age and sex were baseline WC and higher baseline depression scores (Table 7.6). That is, people with central obesity and people with depression (dichotomous if score of 8 or greater) were more likely to achieve 3.2 cm WC loss. Interestingly, this achievement was not associated with having higher level of social support or self-efficacy. Further, neither the interaction term baseline WC*depression score or baseline weight*depression score were statistically significant either.

Table 7.6 Adjusted predictors of achieving the GGT waist circumference reduction for mainstream participants attending the third group session. Odds ratio estimates for participants with waist circumference information at baseline and three months. N=738

Effect (referent group)	Odds ratio	95% Wald Confidence Limits		p
Age (continuous)	0.99	0.95	1.03	0.6316
Male Sex (female is referent)	1.27	0.88	1.84	0.1992
Baseline waist circumference(continuous)	1.01	1.00	1.03	0.0458
Depression (Not depressed is referent) ⁵⁶	1.70	1.13	2.56	0.0109

In an attempt to discern this predictor profile, separate regression analyses by sex were examined.

Results for females indicate that living in the rural Division of General Practice was the only statistically significant predictor of achieving the threshold WC reduction (Table 7.7). This association was not significant for males. Increasing age was not a determinant of success or failure in reducing waist circumference in either males or females.

The association between depression and WC reduction after controlling for the other variables in the model was only significant for males. Two other factors independently predicted achievement of WC reduction of 3.2 cm or more in men: high baseline WC and lack of private health insurance. Stratified analysis of this model for females revealed that the effect of holding insurance disappears in rural areas (OR=2.7; 95% CI 0.64-11.8; p=0.177).

Other variables examined in the multivariate analysis which were not significantly associated with the favourable outcome were: income level, employment status, pension status, education, frequency of physical activity, anxiety scores, level of social support, and level of self-efficacy.

⁵⁶ As measured by HADS, with a threshold of ≥ 8 (see Appendix 4.13 for questionnaire and scoring system).

Table 7.7 Sex differentials in adjusted predictors of achieving the GGT level of waist circumference reduction for mainstream participants attending the third group session. Odds ratio estimates for participants with waist circumference information at baseline and three months. N=258 males and 479 females

Effect (referent group)	Males		Females	
	OR & 95% CI	p	OR & 95% CI	p
Age (continuous)	1.01 (0.95-1.08)	0.746	0.97 (0.93-1.02)	0.272
Baseline waist circumference (continuous)	1.03 (1.01-1.06)	0.007	1.00 (0.98-1.02)	0.847
Private Insurance (not insured is referent)	0.46 (0.25-0.85)	0.012		
Depression (not depressed is referent)	2.26 (1.11-4.6)	0.024		
Rural residence (Urban is referent)			1.76 (1.04-3.0)	0.035
Semiurban residence (Urban is referent)			1.30 (0.72-2.09)	0.449

7.4 Discussion

7.4.1 Main Findings

This short-term evaluation has shown that weight loss of 1.1 kg or 1.2% of body weight, and mean WC reductions of 1.8 cm was achieved overall by the third group session. Males were significantly more likely to lose weight than females but there were no sex differences in the likelihood of reducing waist circumference.

The finding that males and obese people achieved greater weight loss through lifestyle programs is not unexpected. The more obese (males had higher BMI and WC than females at baseline) have greater scope for losing more weight and statistically, regression to the mean may be responsible for this finding in the short term. Females in rural areas (i.e. Southern Highlands Division) were also significantly more likely to achieve this short-term change. Rurality may be reflecting (a proxy for) lifestyle officer experience and performance or connectedness with the participants. These attributes of the lifestyle officers were not measured objectively. Yet, it is known that the lifestyle officers in this Division had much more experience in clinical settings and were also familiar with participants in the area. Rapport between the lifestyle officer and the participants may have influenced commitment to the Program and the short-term weight outcome. This long-term relationship was not present in the other two Divisions, where lifestyle officers were younger and new on the job, hence had no prior rapport with participants.

Based on the multivariate analysis of predictors of weight loss, this short-term evaluation found that baseline weight is the most reliable (statistically stable) predictor of achieving reductions of 2.4 kg or more by three months for both males and females. Selection bias was introduced by the absence at follow-up assessment by people with higher baseline BMI or wider waist circumference. Multivariate analysis revealed that baseline weight and male sex were independent predictors of greater weight loss ; likewise, baseline WC was an independent predictor of WC reduction. This suggests that the overall 3-month weight loss could have been greater if data from people who did not present for measurements (obese and males) had been available. The alternative is also plausible, where these obese people may have avoided this first follow-up measurement session if they thought they had not made substantial (or any) progress with their weight loss.

An interesting finding of this Sydney-based Program, was that socio-economic variables (i.e. employment, income, education or pension) were not significantly associated with expected weight loss but insurance status was negatively associated with weight loss success in the unadjusted model. For females, the insurance effect disappeared after controlling for rurality. This indicates that insurance status could have been a proxy for other correlates of weight loss such as rural residence, which in turn may be a proxy for a Division where it is known that lifestyle officers were experienced and were known to participants through their contact with the health system. The rurality effect was not observed in males. Our bivariate analyses found a significant association of private insurance with Division of General Practice (i.e. rurality) but not with any plausible risk factors or demographic variables. It is possible that some other aspect not measured in this study could have been associated with insurance status and it may be worth exploring further in subsequent research.

Unlike other weight loss programs, in the SDPP depression was positively associated with the ability to achieve the GGT WC reduction of at least 2.4 kg in males but not in females. Studies often report a negative correlation between depression and weight loss particularly for females,

and no correlation in men. (293) The SDPP found no association of depression or anxiety with weight loss in males or females.

Another surprising finding of the SDPP was that neither self-assessed health, number of comorbidities, nor social support or self-efficacy were associated with short-term achievement of weight loss or WC reduction. These outcomes are not consistent with three US-based studies including the USDPP, reporting that self-efficacy is inversely associated with body weight and BMI in males and females and positively associated with adoption of moderate and vigorous physical activity. (253, 262, 293) A possible explanation may be that the length of follow-up was longer (1 year) in the other studies while this association for SDPP is measured at three months after enrolment. The effect of self-efficacy may be observed at the 12-month follow-up. Another possibility is that self-efficacy is a predictor of success in younger people. The mean age in the US DPP was 52.5 years, (262) in the other US weight loss program was 50.2 (293) and in the SDPP was 58 years. The degree of sensitivity to change of the different self-efficacy instruments may have also contributed to the different findings.

Changes in perceived (self-rated change) physical activity and dietary intake at three, six and nine months among any participants contacted quarterly by telephone are considered secondary research questions as the information collected is not objective and was not validated. Selected findings are briefly presented in Appendix 7.1

7.4.2 Comparisons with other studies

References describing expected short-term effects from other studies (115, 120, 217, 220, 222, 223, 225, 290) are not as common as the published diabetes prevention studies which report mid (1 year) to long-term (6, 10, 20 years) results. In addition to the mid-term and long-term results, the USDPP reported interim outcomes immediately after the core phase of the intervention at 16 weeks. These included a mean 6.5 kg weight reduction, an average 6.9% percentage weight loss with 49% of participants achieving 7% weight loss. (95)

The Australian study used as a reference for the three-month impact thresholds in this thesis (≥ 2.4 kg loss and ≥ 3.2 cm reduction in WC) was based on the risk reduction principles of the

Finnish diabetes prevention study and took place in rural clinical practice. A reduced number of group counselling sessions (6 over 8 months) was provided, supplemented with regular self-assessment and opportunities for social networking, but the program goals remained the same as those in the reference trial. Their participation rate among eligible people was around 62% and follow-up measurement rate at three months was 79.7%. Changes reported at this stage were a 2.25 kg weight loss, equivalent to 2.5% percentage weight reduction, and a 1.6 cm reduction in waist circumference. One in five people (19%) achieved 5% weight loss at this early stage. (217) The GGT study in Victoria, Australia, participants were volunteers with a high diabetes -risk score and it used a before-after design without a control group. No information is available on the baseline differentials between those measured at three months and those not measured to assess the extent of bias in these initial results. However, it is known that at baseline non-completers of the GGT Program had a significantly higher waist circumference, significantly higher levels of depression and anxiety and a non-significantly higher BMI than completers. (117)

The Sydney DPP had a 68% participation of eligible subjects and 59% measurement rate at three-month follow-up. This was partly due to the availability of a telephone-based intervention, taken up by 10% of enrolled participants. Participants who were measured at three months achieved a mean 1.1 kg weight loss (median 0.9 kg), 1.2% percentage weight loss (median 1.0%), 1.8 cm reduction in waist circumference and 7% lost five percent of their body weight after an average of 12 weeks. SDPP overall reductions in WC were small, with 34.3% of participants recording 1.5cm or less; it is not possible to ascertain to what extent these small changes in WC from baseline were due to measurement error. Self-reported change in mean minutes of aerobic activity was not significant either over time or between sexes.

The SDPP and the GGT are directly comparable studies. The SDPP is also a before-after study without a control group, and participants are high-risk targeted by the GP in routine practice. Attendance at three-month follow-up in the SDPP was lower than in the GGT and weight loss was also much lower. The people who were significant less likely to attend the 3-month short-

term measurements in the SDPP had either higher baseline BMI, larger baseline waist circumference or higher baseline weight than attendees. There were no differences in the anxiety or depression scores of attendees and non-attendees. As baseline weight was one of the strongest predictors of weight loss at three months, it could be argued that these short-term results could be an underestimate as an additional 183 participants (still active at three months) could have provided data to support the success of the Program.

The few overseas studies reporting short-term results have generally found positive outcomes suggesting lifestyle interventions led to significant weight losses and reduced diabetes risk. However, they have methodological flaws. One study reporting short-term impact in the US implemented a translation of the 16-week USDPP at a Massachusetts hospital-based weight centre. While the goals and components of the education manual remained consistent with the reference trial, protocol modifications were required to adapt them to a real-world, working class setting. These included more modest incentives such as newsletters, access to an electronic library, recipe swapping and pedometers, instead of the USDPP costly package of paid cooking classes, subsidy for exercise class fees, home exercise equipment and liquid meal replacements. (225) They found that outcomes were all less marked than those reported by USDPP, in particular for patient with other underlying diseases. Weight loss was -5.5 Kg (4.5% percentage weight loss) immediately after conclusion of the 4-month intervention, and 30% of the participants achieved the 7% weight loss. Pagoto's study sample consisted of volunteers responding to advertisements and there was no control group. Hence, results cannot be considered comparable. It is also worth mentioning that the Massachusetts participants were slightly younger than those in USDPP (48.7 vs. 50.6 years), had much higher BMI (43.3 vs. 33.9 BMI units), were mostly Caucasian (90.7% vs. 53.8%), and suffered from chronic illness at higher rates (hypertension 52% vs. 30%; depression 35% vs. 10.3%; binge eating disorders 30% vs. 9%). Despite the availability of referral to psychology services to enhance motivation, these baseline differences in co-morbidities, in particular the emotional disorders which are

known to lower weight-loss self-efficacy, (293) could have contributed to the more modest success of the hospital-based weight loss program.

Another US-based lifestyle program reporting short-term outcomes was a cluster randomised design involving four sites where primary care nurses delivered the intervention on a small, convenience sample of eligible at-risk patients. This pilot study adopted the USDPP goals but consisted of a reduced intensity, culturally modified version of the USDPP components.

Modifications included a reduction of the number of face to face sessions from 16 to 6, five telephone-based follow-up sessions and some home-based, self administered program content.

(220) Findings at 6 months indicate that 25% of participants in the lifestyle groups and only 11% of those on standard care achieved 5% weight loss, slightly higher than the 7% achieving 5% weight loss in relation to baseline in the SDPP. Whittemore's study only involved four sites and individual participants were recruited as a convenience sample of eligible at-risk patients. Recruitment centres were selected at random, achieved high attendance at sessions and experienced low attrition at the end of follow-up. However, despite randomisation there were large differences at baseline on age, racial make-up of the subjects, BMI, income and level of physical activity.

In the UK, a study examined whether a simplified intervention delivered on a one-to-one basis by trained health-promotion counsellors was superior to usual care supplemented with 'information only' and could achieve results similar to those in the Finnish and USDPP trials. Total exposure to the active intervention included 11 individual motivational sessions over 6 months, action plans, self-monitoring and follow-up phone calls. The six month outcomes reported included 24% of the intervention group achieving 5% weight loss vs. 7% in the control group. (223) The SDPP's achievement of 5% weight loss at 3 months was equivalent to that of the control group in Graves' study in the UK (7%). A strength of Greaves' evaluation was the pragmatic randomised controlled trial design, with researchers measuring the outcomes and statistician blinded to group allocation. The study, however, was small, had a 57% participation rate, involved only two semi-rural practices and was single-blinded i.e., patients were aware of

their group allocation. Further, baseline characteristics indicated that the control group had higher BMI and WC, and less educated people than the intervention group. So results have to be viewed with caution.

A six-month feasibility study in UK general practice investigated the impact of two diets (low-glycaemic load vs. low-fat) on the reduction of risk factors for diabetes in people with confirmed pre-diabetes. These lifestyle programs were identical in their aerobic exercise advice and group motivational discussion and only differed in the content of their nutritional advice. A 'delayed entry' control group received usual care during the 6 months of the trial. Barclay and colleagues reported a significantly different weight loss favouring the dietary regimes (combined results to achieve statistical significance) over the usual care group. The observed mean weight loss was 2.73 kg in the intervention groups combined vs. 0.3 kg weight loss in the control group at 6 months. Waist circumference reduction was also greater in the combined intervention groups (-6.01 cm) than in the controls (-1.18 cm). (222) The 1.1 kg weight loss and -1.8 cm WC reduction in the SDPP are better than the findings of Barclay's control group. Yet, the numbers in the UK study were extremely small (under 12 in each group) and all drawn from one practice only; and control participants were older and had higher baseline BMI than intervention groups.

Briefly, it appeared that the SDPP estimates for weight loss and WC reduction at three months resemble those in the control groups of the three RCTs reporting short-term results. However, those 3 studies had follow-ups twice as long (6 months) and had design flaws as discussed above. Hence, these UK studies cannot be taken as a reliable reference for short-term impact either.

The modest weight and WC losses among SDPP participants as compared with the GGT participants, and the considerably smaller (7% vs. 19%) proportions achieving 5% weight loss may be due to the less intensive nature of the intervention in Sydney (three sessions over three months vs. six sessions over 8 months in GGT). Some differences between the Sydney DPP and the GGT study could be explained by their broader age distribution which included younger people, and perhaps the level of comorbidities was lower, but this was not reported in the GGT.

However, it is difficult to quantify with certainty whether the differences in short-term impact are real or significant as their analysis did not report stratification, the impact of socio-demographic or dietary factors, nor did it publish multivariate determinants of success. By comparison with the USDPP reference trial, the Australian studies had substantially smaller implementation budgets, delivered reduced number of staff contacts, provided modest incentives to participants, lacked a subsidy for physical activity services and did not offer program-related emotional support services beyond usual care. The US DPP was delivered within a well funded research environment and had sufficient staff to ensure supervised physical activity and frequent counselling to maintain participant's motivation. These may also explain the differences in the magnitude of changes achieved.

7.4.3 Strengths of the short-term impact evaluation

Few studies in the literature report short term impact of lifestyle interventions, and even fewer report multivariate statistical determinants of behaviour change. While not all participants attended short-term measurements exactly at three months, these results shed light on an overall summary of a short term effects in a real-world setting.

The SDPP used both objective and subjective measurements in an attempt to validate self-report. Self-reported weight loss reflected objective weight loss in about half the people succeeding at three months, although weight gain was not associated with self-reported weight gain.

Datasets collected during the course of this intervention provided documentation on many factors to investigate possible determinants of success. Most other studies including the reference trials report on a limited number of variables, mostly those confined to the participant's laboratory profile or physical measurements. In addition to the physical and biochemical factors, the SDPP comprehensively investigated social, emotional and demographic mediators of success.

This real-world program had a relatively high attendance rate at the group intervention and short-term measurements by people who chose groups. This gives an opportunity to compare these short-term findings with those at the 12-month final outcome assessment (See Chapter 8).

7.4.4 Limitations of the short-term impact evaluation

The main limitation of this short-term evaluation is that people who received telephone coaching and people who did not attend the third group session did not have short-term measurements for this analysis. A comparison of the baseline characteristics of these two latter groups indicated that marginally fewer males than females attended the third group session to obtain objective measurements. This could be related to work commitments or Program location. However, male sex was an independent predictor of successful weight loss, so weight loss results presented here could be an underestimate.

There were also systematic biases in that people with higher baseline BMI and higher WC were significantly less likely to present for short-term measurements. The reasons for non-attendance to group 3 among those who chose group sessions are mostly unknown and could be related to lack of weight loss, so mean weight values reported here for the group could be an overestimate. However, their absenteeism from 12-week measurement sessions could have led to an underestimate of the short-term impact as obesity was significantly more prevalent in the group of non-attendees, and baseline weight was an independent predictor of success.

Unfortunately, due to this absenteeism, this analysis could not calculate the existence of a dose-response at this stage of the Program. This information would have been invaluable in estimating the minimum sufficient exposure to intervention that could lead to significant weight loss. The 12-month impact analysis will examine this dose-response (Chapter 8).

Another weakness of this evaluation was that while repeat measurements of participants by the same lifestyle officer minimises inter-observer variability, it could have biased the WC results.

That is because these officers were not blinded to the participants status or intervention modality. However, poor reliability of WC measurement is not unique to SDPP and was addressed by re-training lifestyle officers in the initial stages of the Program. This lack of

blinding did not affect the estimation of weight changes as the same calibrated digital scale was used at every point throughout the Program. Further, changes of less than 4cm in waist circumference may be due to measurement error (227) and therefore the impact analysis reported here needs to be viewed with caution.

The number of participants in the SDPP is a large but nonetheless a convenience sample of eligible subjects in that general practitioners targeted screening and recruitment rather than randomly selecting from their clientele records. This was done to ensure that only high-risk people were targeted by the Program. The SDPP design did not involve a randomised control design because the objective was not to prove efficacy but effectiveness. Instead, a before-after evaluation was conducted, as is often the case in translation research. (99, 117, 224-226)

7.5 Conclusions of The Short-Term Impact Evaluation

After three months in the Program, participants experienced modest weight loss and minimal waist circumference reduction. Males were more likely than females to achieve the weight loss thresholds of the Greater Green Triangle but there were no sex differentials for WC reduction. The major correlates of success in the SDPP at this stage, for males and females, were higher baseline weight and higher waist circumference. Women seemed to be more successful at losing weight in rural areas. Self-efficacy and social support had no impact on the short-term weight or WC change. The differences with the GGT are not necessarily significant but cannot be confirmed without further analysis of their individual participant data. The modest changes achieved in the Australian studies as compared with the US DPP may have been related to a combination of low intensity of the intervention, inability to supervise compliance in routine clinical settings, and restrictions in budget of routine clinical services. Findings in the SDPP about negative associations between private insurance and depression with WC reduction in males warrant further investigation at the final assessment stage.

Chapter 8.

Twelve-Month Preliminary Impact Evaluation

Summary

This chapter presents preliminary results of the impact of the SDPP for the initial 586 participants who completed the 12-month SDPP intervention up to 31 December 2010. A subsection of the chapter also contains comparative findings for people who withdrew from the Program and for people lost to follow-up. Full data collection for the whole sample of n=1,250 will occur by the end of 2011, beyond the timeframe for this thesis.

This analysis has a focus on the changes in weight, waist circumference, physical activity and dietary habits at 12 months follow-up after enrolment in the intervention. The research questions focused on achievement of the Program's primary goals for individuals: sufficient physical activity, weight loss and specific dietary behaviours. Additionally, this chapter explores whether the small number of group-based sessions in SDPP achieved similar results as the complex, more intensive lifestyle interventions provided in the reference trials. Finally, comparisons of the effects of face-to-face and telephone lifestyle coaching are compared. For most analyses, effects are examined by sex and by intervention type: group session vs. individual telephone coaching vs. initial consultation only.

In addition, the research in this chapter examines the demographic, psychosocial and behavioural predictors of success in achieving the physical activity goal, at least two dietary goals and the weight loss goal.

The discussion summarises the differences in effects between this SDPP and the Finnish and USA reference studies, along with two other relevant Australian diabetes prevention Programs, a core question in this evaluation of a translation program. This provides the background for a discussion of the magnitude of change expected in less intensive, real-world diabetes prevention interventions.

8.1 Introduction

Numerous diabetes prevention trials and translational programs in communities or clinical settings have reported risk factor changes and then subsequent changes in diabetes incidence over a follow-up period of 4-6 years (90, 93, 95, 99, 104, 117, 119, 199, 200, 219, 221) A number also report nutrition or physical activity outcomes. (115, 119, 121, 134, 135, 144) Given its shorter follow-up period, The Sydney Diabetes Prevention Program concentrated efforts on measuring risk reductions over one year. The research plan for the SDPP assessed progress towards meeting each of the behavioural program goals. Changes in fasting plasma glucose were also documented in the SDPP but diabetes incidence was a secondary and unlikely outcome at 12 months.

The objective of this 12-month evaluation was to assess whether participants in the SDPP could achieve reductions in selected risk factors for diabetes, comparable to those reported in the reference diabetes prevention trials. These program's primary goals were whether, by the end of the Program, participants were able to :

- lose 5% of their body weight
- achieve 210 minutes of moderate-to-vigorous physical activity per week
- decrease fat consumption to 30% of their total energy intake
- decrease saturated fat consumption to 10% of their total energy intake
- increase fibre consumption to 15 grams per 1,000 kcal per day

Only participants who completed the Program by 31 December 2010 have been included in this analysis. That is, 586 mainstream participants as the remaining mainstream participants and the non-English speaking sub-sample were recruited much later and their Program completion is not expected until the end of 2011, beyond the timeframe of this PhD thesis.⁵⁷

⁵⁷ Role of the author: participation in questionnaire design for the evaluation, database building and field testing, training of data collectors, quality assurance for completeness of all databases, data cleaning for accuracy, extraction, analysis, interpretation and report writing. Data to the end of 2010 are included , given the timeframe for this thesis. Hence, n=586 with 12 months follow up data were included, whereas the whole SDPP anticipates 1250 participants completing by the end of 2011. However, no major differences in risk factor distributions were noted with each wave of enrollees; the one difference is by Division of General practice, with the semi-rural Southern Highlands Division providing more of the

Preliminary results of this impact evaluation are presented in response to the following research questions:

1. How many participants have completed the Program so far, and who were they?
2. What is the demographic and risk factor profile of completers in the program to date, and of those who did not complete the intervention ?
3. What was the impact of the Program on reported physical activity behaviour, overall, by sex and by intervention modality after one year?
4. What was the impact of the Program overall and by sex on measured weight and waist circumference (WC) after one year?
5. Was there a difference in achievement of weight loss or WC reduction by intervention modality?
6. What is the impact of the Program overall and by sex on dietary behaviour at one year?
7. Did changes in dietary behaviour vary by intervention modality?
8. How successful were participants in achieving the Program goals?
9. Was overall program goal achievement influenced by intervention modality?
10. What predicts achievement of goals at one year?

8.2 Measurements Used

In addition to data on the five Program goals as stated above, multiple relevant variables from the CATI survey, the Program's administrative databases, and the clinical databases were explored as potential correlates of goal achievement at 12 months. These include demographics, number of follow-up contacts, attendance at Program activities, baseline self-efficacy, social support, depression and anxiety scores, self-reported health and underlying co-morbidities.

earlier enrollees, and hence more in this thesis [which may show some degree of socio-economic advantage, compared to the demographic profiles of residents of the other two Divisions]. The data in this chapter reflect mainstream completers only, as there were too few Arabic and Chinese stream participants [N<10] completed by December 2010.

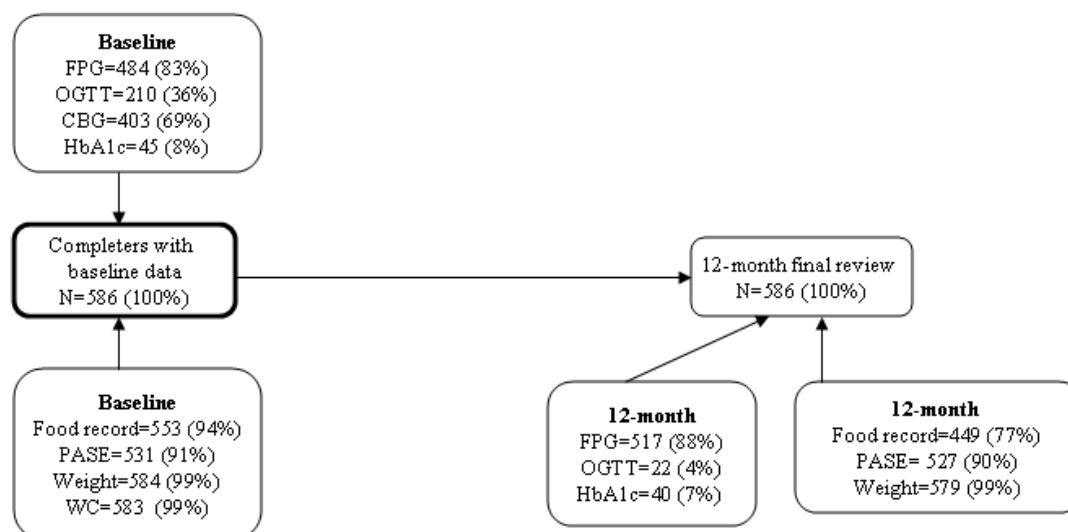
Chapter 4 (The Protocol) describes in detail the instruments used, and Chapter 5 presents the baseline results for these measurements.

8.3 Level of Completeness at End of Program

Only participants who had complete data on a particular parameter both at baseline and 12 months were included in analysis of each goal. The denominators vary from table to table depending on availability of data items from the various sources. Figure 8.1 shows the proportions of people for whom different data items were available at baseline and at the end of the Program (cross-sectional independent data, not matched). Completion of anthropometric measurements was 99% (578/586). Completion of 12-month three-day food records and the CATI questionnaires at baseline and final review was high, with a majority being women, reflecting the distribution of the SDPP participant group.

Denominators were also affected if within particular components the participant refused to answer a particular question in a module or if the question did not apply to them. Finally, completion of some of the Program requirements such as the PASE questionnaire and 3-day records was not consistent at every time point. For instance, of the 586 completers, only 481 (82%) had PASE data at both baseline and final assessment but some of the items were incomplete in 71 cases. Likewise, of the 586 completers only 438 (75%) had dietary information at both time points, but all macronutrients were complete for each case. Completion of blood tests also varied, with 427 (73%) attending FPG testing at both time points.

Figure 8.1 Availability of self-reported and measured data to evaluate the Program impact at one year after commencement. Numbers and proportions (out of all completers) Mainstream completers only, N=586.



For the purpose of this analysis, *completers* are defined as those participants who presented to their 12-month final assessment with the lifestyle officer for anthropometric measurements.⁵⁸ This comprises people who participated in one or more of the following: the 12-month CATI survey (for physical activity comparison), the 12-month food record (for dietary comparison) or the final blood test at the time of final assessment (for diabetes diagnosis).⁵⁹ *Withdrawals* are defined as people who at any stage in the Program notified their lifestyle officer that they were no longer able to attend or interested in continuing participation. These people have no documented final 12 month outcome data. A second group of people without data on their final outcome are the *Unable to contact*, those due for their final assessment and who did not return calls or present for review despite many efforts to reach them. These people did not explicitly state they withdrew but effectively are lost to follow-up and are analysed separately at the beginning of this chapter.

⁵⁸ Ten people were interviewed by telephone as they had moved out of the area but wished to complete the Program follow-up and/or final assessment by post (PASE and food record).

⁵⁹ Some people had the final blood test (either FPG or OGTT or HbA1c) before seeing the lifestyle officer but others did it within days or weeks of that final review. In a minority of cases no blood test result was available at all, so the final estimate of diabetes incidence could not be established in full.

8.4 Subgroups

In addition to age groups and sex, these analyses consider the impact of *intervention modality*.

As mentioned in the study protocol in Chapter 4, the SDPP intended to offer only a 3-session group intervention but a number of participants had difficulty attending group sessions due to the schedule time of the sessions, family commitments or distance from the venue. They were then offered the alternative individual intervention of telephone coaching by lifestyle officers from the Australian Diabetes Council. A third group of people either declined or failed to attend any group sessions or receive any individual telephone coaching. These people received only the coaching at the initial consultation. When the numbers were substantial for statistical comparisons, this chapter incorporates *intervention modality* as one of the analysis subgroups. In other instances, comparisons include “group sessions’ vs. ‘other intervention types’, which aggregates ‘telephone coaching’ and ‘initial consultation only’.

8.5 Statistical Analyses

Univariate analysis was used to present the distribution of continuous and categorical variables for all variables of interest. Results are presented as changes from baseline to 12 months in weight, physical activity and fat/fibre intake. Proportions of people achieving each of the specific Program goals in each sex and intervention modality subgroup were also presented. Measures of central tendency (mean, standard deviation) were used to describe the distribution of changes in continuous variables for each sex and median with interquartile ranges were presented where the distribution was not Normal, as assessed by the Shapiro Wilk test. T-tests were used to compare mean changes between males and females. Analysis of variance was used to compare mean values of change across the three different intervention modalities when relevant or when numbers permitted. Comparisons of more than two proportions used the chi-square test for equality of proportions or as a test for heterogeneity.

Bivariate analyses were conducted to assess the unadjusted associations between plausible predictor variables and the outcomes of selected Program goals. Program outcome variables used were expressed in dichotomous form: 210 minutes of moderate-vigorous physical activity per week (yes/no); weight loss of 5% from baseline (yes/no); and achieving at least two of the

three dietary goals (yes/no). Explanatory variables were derived from previous studies in the literature.(117, 220, 262, 294-296)

Likewise, analyses using binary multiple logistic regression were conducted to examine the individual impact of explanatory variables after controlling for potential confounders. The stepwise approach was initially used whereby explanatory variables were added to the adjusted model if (a) they were biologically plausible and/or (b) they were statistically significantly associated with the outcome of interest in bivariate analysis and/or (c) they were pre-determined components of the base model such as age, sex and intervention modality. Confirmatory testing of this regression analysis was performed using the automated facility from SAS software which uses the backward elimination process whereby all nominated variables are included in the model and every subsequent step excludes a variable if it does not reach statistical significance at the 5% level. The final model for each outcome included the best set of explanatory variables with the highest statistical associations after controlling for other factors for which there is evidence in the literature. Only the final model for each outcome of interest is shown in these results.

When relevant, in estimating the true effect of the Program, analysis were conducted separately for (a) the whole cohort of completers and (b) the subgroup of participants who had not met the goal of interest at baseline. This was meant to enable identification of effect size among participants for whom there was room for improvement.

8.6 Results

Question 1 How many people have completed the Program so far and who were they ?

As at 31 December 2010, 586 people from the mainstream cohort had completed their 12-month follow-up measures. This included 520 people (89% of completers) who finalised their visit with the lifestyle officer and had objective measurements taken and 55 (9%) people who also attended a 12-month review but their blood tests were still pending. Participation rate in the 12-month CATI interview and completion of the 3-day food diary for these completers was high (Figure 8.1). By this date, n=11 participants (2% of completers) had developed diabetes as

confirmed by an FPG or HbA1c at or before completion of the 12-month review. Those diagnosed with diabetes before completion of the Program were excluded from comparisons in this chapter.

Participants were lost to follow-up at different stages and some did not have complete data for final assessment. By 31 December 2010, 209 of the 1,250 mainstream participants enrolled (16.7%) had withdrawn before completing the Program. Of the participants who remained in the Program and were due for final assessment, 86 (8% of remaining 1,041) were unable to be contacted at the end of the Program despite several attempts made after their due date for 12 month review. In addition, of the 586 documented completers, 10 did not have measurements at the final review, mostly (8) because they could not attend the review in person due to illness, family commitments or moving interstate or overseas. They did not present despite rescheduled appointments but did answer questions pertaining to SDPP by telephone (i.e. self-reported weight and waist circumference). One other participant attending the final assessment was too ill to stand to be measured, and another withdrew on the day of final review before measurements were taken. To date, those without anthropometric data for the final follow-up assessment including withdrawals (209), unable to contact (86), and absence of objective measurements despite some form of final review (10) totalled 305 people (24.4% of enrolled participants).

This end-of-program analysis comparing baseline vs. 12-month review is confined to all the primary outcomes for 586 participants who had attended the annual review and for whom either anthropometric measurements or Physical activity data or 3-day food record data were available at both baseline and 12 months (N=586; 62% women). In terms of intervention modality, 522 of the 586 completers (89%) attended at least one group session, 44 (7.5%) received individual telephone coaching and 20 (3.5%) received coaching at the initial consultation only.

Question 2 What was the demographic and risk factor profile of completer and non-completers?

8.7 Demographic Profile of Completers

Of the CATI respondents (N=528) each group was compared with the remaining two groups (completers vs. withdrawals vs. unable to contact) using the χ^2 test. P values are shown as asterisks in Table 8.1 and indicate that the estimate was either significantly lower than the other group or significantly higher than the other group.

Completers were not significantly different from withdrawals in their distributions of age, sex or employment status or in their baseline levels of obesity, physical activity or diet. However, of the CATI respondents, completers were more likely to have university education (34% vs. 24%) and have private health insurance and less likely to be on a pension than the participants who withdrew (Table 8.1). Participants who could not be contacted for final assessment were significantly younger (33% versus 23% aged 50-54 years), and, of the CATI respondents, marginally less likely to be covered by private health insurance (59%) than the completers (68%). Otherwise they had similar socio-demographic and risk factor characteristics to the completers.

Participants who withdrew were significantly older (45% vs. 24% aged 65 yr) and, of CATI respondents, significantly less likely to be employed (50%) than those not contactable (66%) for final assessment. In Macarthur Division females were significantly more likely to withdraw (63%) compared to females not contactable (36%) (conversely for males). Overall there were no statistically significant differences between people unable to be contacted for final assessment and withdrawals in terms of distribution of sex, tertiary education attainment, pension, private insurance coverage, estimated proportions meeting dietary goals at baseline, mean BMI, obesity rates, or total moderate-vigorous physical activity (Table 8.1).

Table 8.1 Comparison of baseline characteristics for SDPP completers and withdrawn participants as at 31 December 2010, within percentage of respondents with information for each section of the CATI questionnaire.

Characteristic	Completers (N = 586)	p diff completers vs. withdrawn	Withdrawals (N = 209)	p diff withdrawn vs. not contactable	Could not be contacted (N=86)	p diff completers vs. not contactable
50-54 years	135 (23%)	NS	55 (26%)	**	28(33%)	**
55-64 years	200 (34%)	NS	61 (29%)	**	37(43%)	**
65 years	251 (43%)	NS	93 (45%)	**	21 (24%)	**
Males	225 (38%)	NS	72 (34%)	NS	37 (43%)	NS
Females	361 (62%)	NS	137 (66%)	NS	49 (57%)	NS
Central Sydney	M 59 (31%)	NS	M 13 (20%)	NS	M 8 (29%)	NS
Division of GP	F 134 (69%)	NS	F 52 (80%)	NS	F 20 (71%)	NS
Macarthur Division of GP	M 89 (46%) F 104 (54%)	NS	M 27 (37%) F 45 (63%)	* *	M 21 (64%) F 12 (36%)	NS
Southern Highlands Division of GP	M 77 (39%) F 123 (61%)	NS	M 32(44%) F 40 (56%)	NS	M 8 (32%) F 17 (68%)	NS
University Education	178 (34%)	*	44 (24%)	NS	25 (35%)	NS
Employed (full or part-time)	320 (61%)	NS	90 (50%)	*	48 (66%)	NS
Pension	157 (30%)	*	72 (40%)	NS	25 (35%)	NS
Has private health insurance	357 (68%)	***	93 (51%)	NS	38 (59%)	*
Met PA goal at baseline [§]	58 (11%)	NS	17 (9%)	NS	4 (5%)	NS
Met ≥ 1 dietary goal at baseline [♦]	139 (25%)	NS	45 (26%)	NS	17 (23%)	NS
Obese (BMI ≥30) ^Ω	344 (60%)	NS	122 (61%)	NS	57 (67%)	NS
Median Baseline BMI – (IQR) ^Ω	31.4 (28-35)	NS	31.6 (29-37)	NS	32.8 (29-37)	NS
Median P.A. – min/week (IQR)	0 (0-45)		0 (0-0)		0 (0-0)	

* $p \leq 0.05$ ** $p \leq 0.01$ *** $p \leq 0.0001$ for χ^2 test for differences between two groups

M= males, F= females NS=not significant

IQR=interquartile range (25% - 75% percentile) P.A. moderate-vigorous Physical activity

§ CATI respondents: completers N= 531 , withdrawals N=181, Unable to contact N=71

♦ BMI measures available for 584 completers, 199 withdrawals and 85 unable to contact

Ω Food record respondents: completers N= 559 , withdrawals N=174, Unable to contact N=74

The following sections present the impact of the Program at 12 months from enrolment for the mainstream SDPP cohort. Indicators follow the Program goals of physical activity, weight loss and dietary recommendations.

Question 3 *What was the impact of the Program on physical activity behaviour overall, by sex and intervention modality after one year?*

8.8 Changes in Moderate-to-vigorous Physical Activity Reported at 12 Months

Estimates of structured physical activity from the PASE questionnaire were calculated in total minutes of moderate to vigorous activity per week which includes aerobic exercise and strength training.⁶⁰ Walking was only included if reported as 'brisk' most of the time. Appendix 8.1 shows sex differentials in PASE scores.⁶¹

At the end of the Program, 286 of the 481 CATI respondents (59.5% of CATI respondents and 48.8% of all completers to date) reported not doing any structured moderate to vigorous physical activity or strength training. There were no differences in the proportions not doing any structured physical activity across group sessions or telephone coaching intervention groups ($\chi^2 = 1.25$, $p = 0.54$).

Analysis of the changes in physical activity at 12 months showed that a large proportion of completers (43.7% of males and 48.5% of females) did not change the total number of minutes reported of engagement in moderate-to-vigorous activity per week (tallest bars in Figure 8.2). The arrows indicate numbers of people experiencing no change, and the bars to the left and right indicate reductions or increases respectively.

⁶⁰ In addition, change in other dimensions of physical activity, including walking minutes alone, and muscle strengthening minutes alone are also shown in Table 8.2, as these indicators are also considered diabetes preventing forms of physical activity [especially if at least moderate intensity walking]; and through different biologic mechanisms, for muscle strength training

⁶¹ Summary of PASE score findings is not core to this thesis; the Program goal for the SDPP is expressed in minutes of moderate-to-vigorous physical activity per week [whereas usual PASE usage would require the PASE score; this was calculated, but shown in Appendix 8.1]

Figure 8.2 Distribution of changes in reported minutes of moderate to vigorous physical activity per week by sex. Program completers as at 31 December 2010. N for males =177, females=292

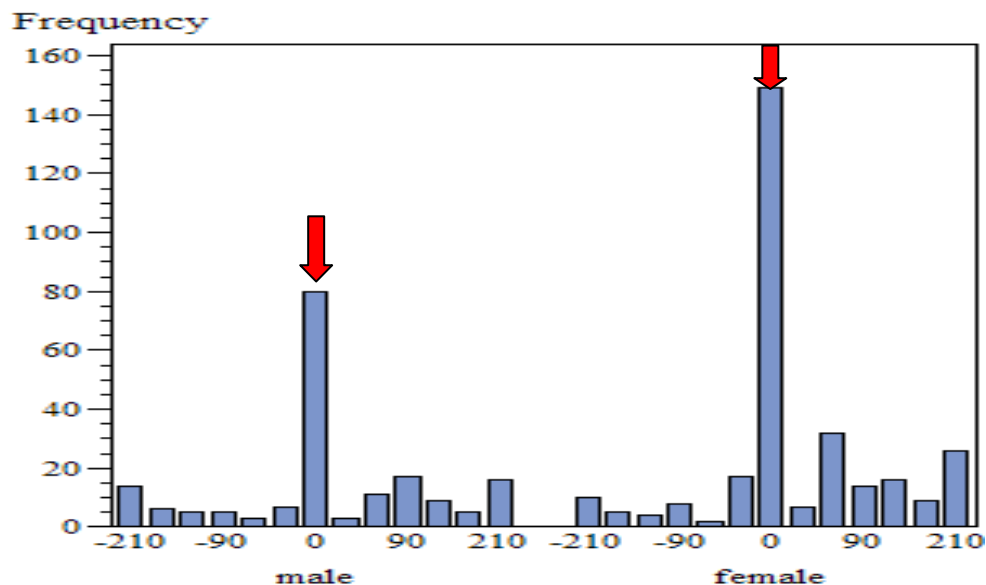


Table 8.2 shows the changes in structured physical activity and walking (unstructured) expressed in minutes per week. A negative sign indicates reduction in the number of minutes of activity in relation to baseline and a positive sign (or no sign) indicates an increase. Closer examination of the PASE sub-components reveals that overall there was very little change in the duration of any of the physical activity components in either males or females. There was a negligible increase in walking, no change in moderate or vigorous activity, and slight but non-significant change in muscle strengthening activity.

types were not statistically significant.

Calculation of means across the three intervention types (group sessions vs. phone coaching vs. initial consult only) also yielded a non-significant difference, due to the small numbers in each of the non-group intervention modalities. When participants in the telephone coaching and ‘initial consultation only’ are aggregated, the mean estimates for total moderate-to-vigorous physical activity including brisk walking indicate a decrease (-8.94 min/week, SD 284.7), while estimates for people attending group sessions increased (74.7 min/week, SD 211.2). This overall difference from baseline was statistically significant ($p=0.04$), and the increase was significantly greater for males than for females ($p\leq 0.001$). Accordingly, from this point on, comparative analysis by intervention type will refer to “Groups” vs. “Phone or IC only” as an aggregated category.

Figure 8.3 Differences in distribution of total moderate-to-vigorous physical activity at baseline and 12 months, with and without brisk walking. Program completers with CATI responses at both time points only (N=481).

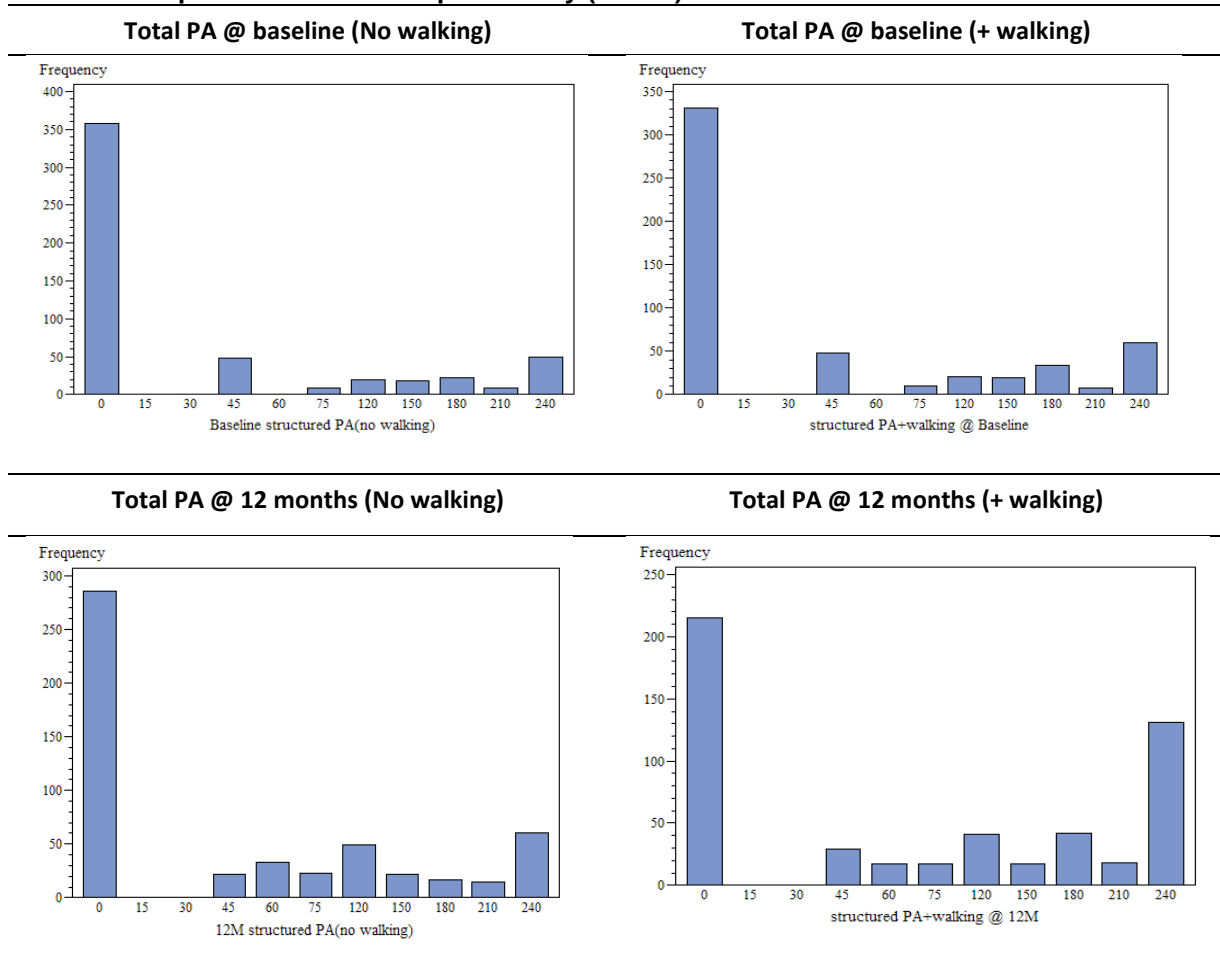


Table 8.3 Change in total minutes of moderate-to-vigorous physical activity/week including brisk walking by intervention modality. Mainstream Program participants completing by 31 December 2010 who participated in the PASE CATI survey at both time points (N=481).

Parameter	Mean (SD), Median (interquartile range) by sex		
	Group sessions M=151 F=277	Phone coaching M= 20 F=16	Initial consult only M=10 F=6
Overall activity	+74.7 (211.2) 0 (0 to 173)	-29.2 (321.1) 0 (-23 to +128)	+36.6 (178.6) 0 (-23 to +143)
Males	+83.0 (208.8)** 45 (0 to 180)	-90.8 (381.9) 0 (-158 to +37.5)	+42 (177.7) 30 (0 to +165)
Females	+70.1 (212.8) 0 (0 to 150)	+47.8 (52.5) 52.5 (0 to +157.5)	+27.5 (195) 0 (-135 to +120)

** $p \leq 0.01$

Of the 323 people who were sedentary at baseline, i.e. did not engage in any moderate or vigorous activity, 6.5% changed their behaviour to achieve the goal at one year and 64.5% remained at zero minutes per week. Of the 49 people who met the physical activity goal at baseline, 44.2% maintained that level of activity, whereas 25.5% decreased to zero minutes per week. More details are presented in Appendix 8.2.

Question 4 *What was the impact of the Program overall and by sex on weight and WC after one year?*

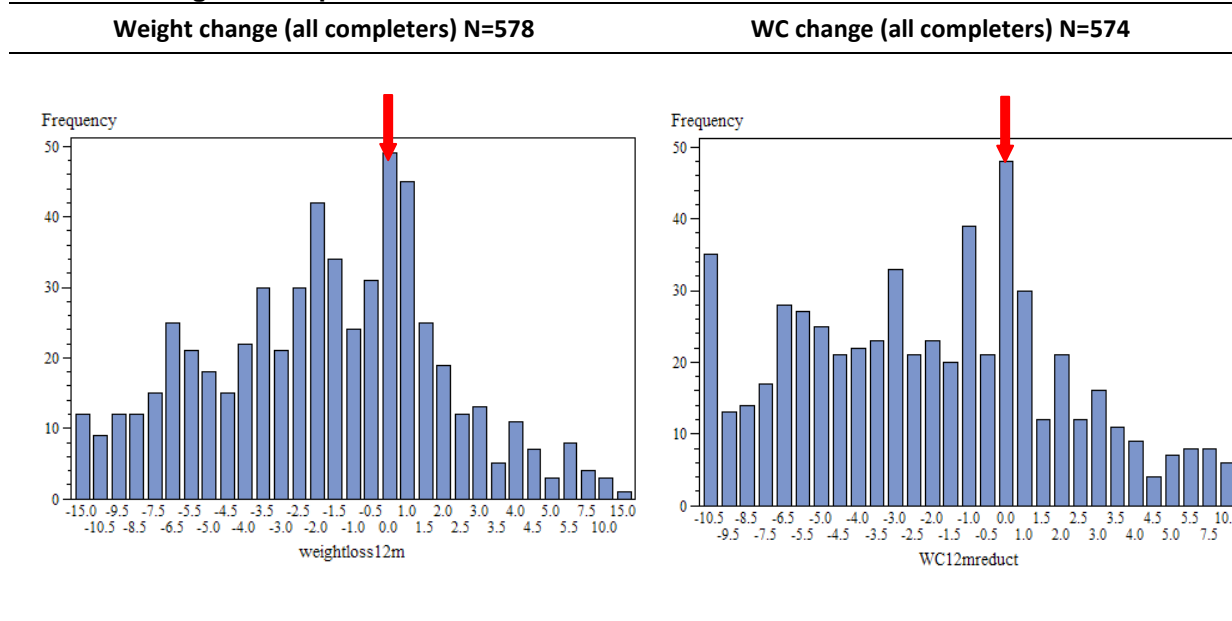
8.9 Anthropometric Changes

As at 31 December 2010, data on objectively measured weight and waist circumference at both baseline and final assessment points were available for 578 and 574 completers respectively (98.6% and 97.9%). Ten who completed the qualitative review of goal achievement by phone and self-reported their weight and WC were excluded from this analysis.

Overall for the mainstream group, 330 (57%) of the completers with information lost at least 1kg by the end of the Program, with 113 (19.6%) losing 5kg or more, and 21 people (1.6%) losing 10kg or more (Figure 8.4). Of those with measured weight, 135 (23%) lost at least 5% of their initial body weight. The figure also shows that 27% of people gained at least 1kg, with 11 participants gaining 5kg or more, and 4 of them (0.7%) gaining at least 10kg.

The distribution of measured WC change showed a total of 196 completers (34% of those with WC measurements) losing 4cm or more of their waist circumference, 6% losing at least 10cm and 69 participants (12%) gaining 3cm or more (Figure 8.4). The arrows indicate numbers of people experiencing no change, and the bars to the left and right indicate loss or gain, respectively.

Figure 8.4 Distribution of weight changes and WC changes after the intervention for all Program completers with relevant measurements at baseline and final assessment.



The observed weight change and WC reductions for the overall group were statistically significant (i.e. 12 month values significantly different from baseline).

Overall, one in every five males (22.2%) and one in four females (25.8%) had lost 5% of initial body weight by the end of the Program. The distribution of these measured anthropometric changes for the mainstream cohort by sex shows most people falling to the left part of the graphs, indicating change in the negative direction (Figure 8.5).

Figure 8.5 Sex differentials in distribution of anthropometric changes at 1 year for all participants with relevant data at baseline and final assessment completing the Program as at 31 December 2010

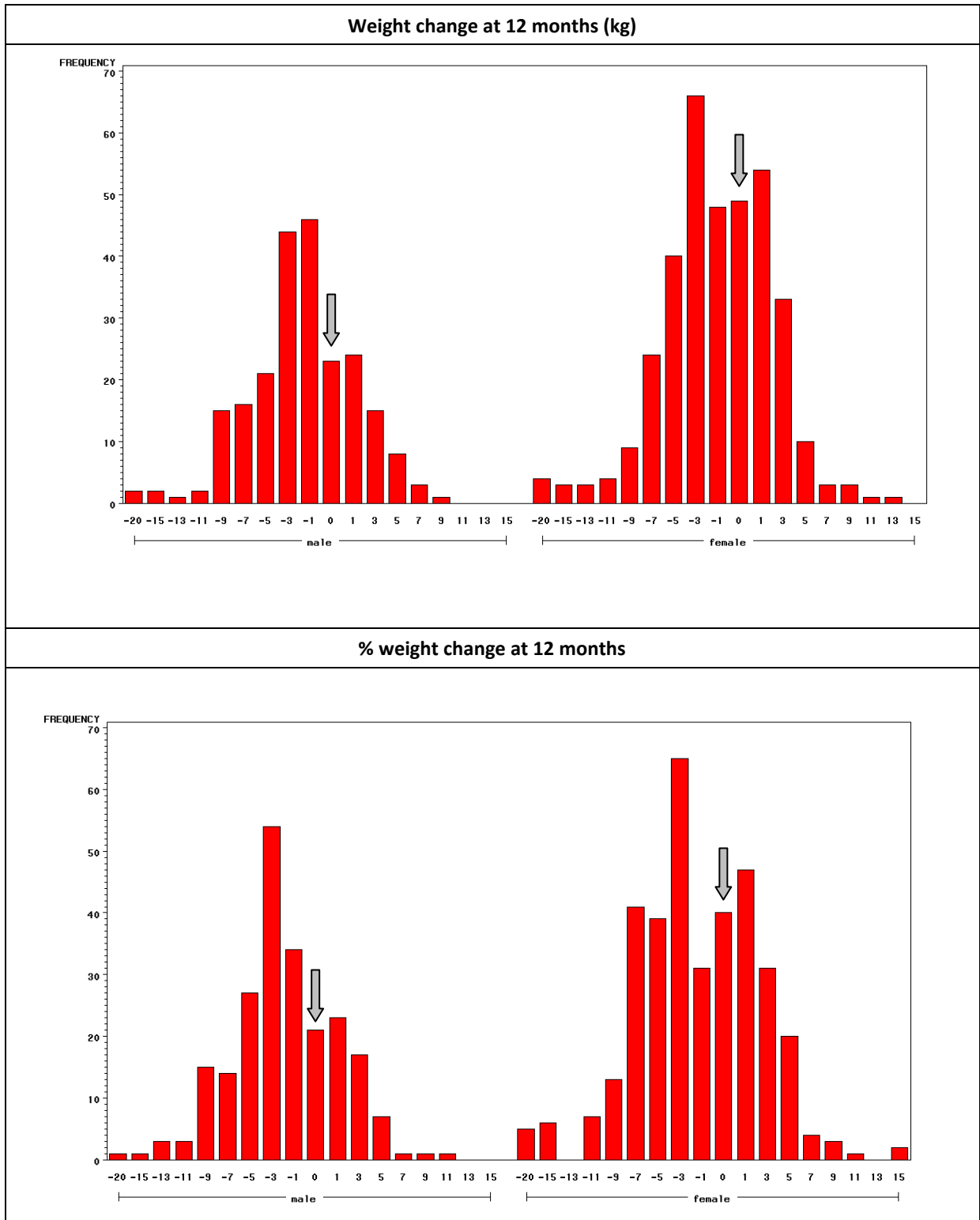


Figure 8.5 ...continued on sex differentials in anthropometric changes at 1 year for all

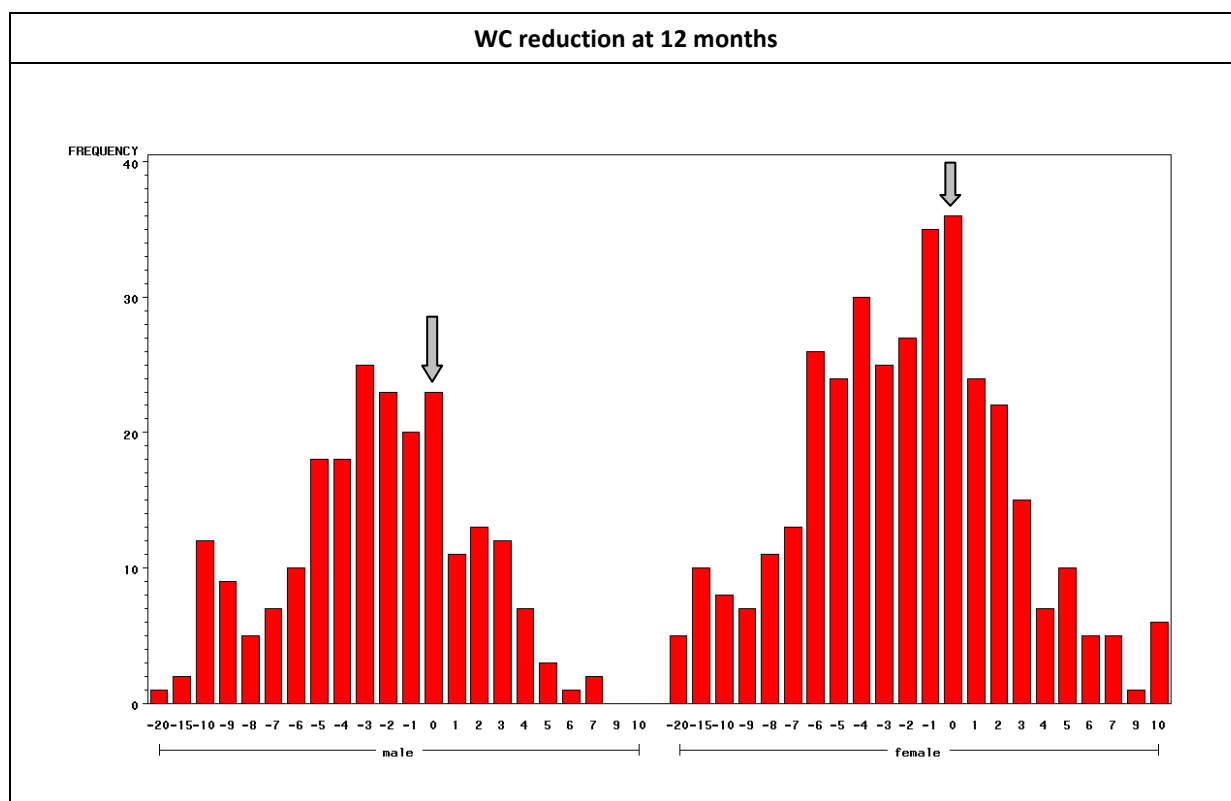


Table 8.4 shows that sex differences in weight loss, percentage weight loss or WC reduction were not statistically significant ($p > 0.05$).

Table 8.4 Sex differentials in anthropometric changes at 1 year for all completers with relevant data as at 31 December 2010.

Outcome (change)	N	Mean (SD)	95% CI for Mean	Median	Interquartile range (25% -75%)
Weight loss12m (kg)	578	-2.1 (4.6)	-2.4 to -1.7	-1.7	-4.1 to +0.6
Males	223	-2.4 (4.5)	-3.0 to -1.8	-1.9	-4.5 to +0.2
Females	355	-1.9 (4.7)	-2.4 to -1.4	-1.5	-3.9 to +0.9
% weight loss12m (%)	578	-2.2 (4.9)	-2.6 to -1.8	-2.1	-4.7 to +0.7
Males	223	-2.4 (4.4)	-3.0 to -1.8	-2.1	-4.5 to +0.2
Females	355	-2.1 (5.2)	-2.7 to -1.6	-1.9	-5.0 to +1.2
WC 12m reduction (cm)	574	-2.5 (5.0)	-2.9 to -2.0	-2.1	-5.0 to +0.5
Males	222	-2.6 (4.4)	-3.2 to -2.1	-2.3	-5.0 to +0.5
Females	352	-2.3 (5.3)	-2.9 to -1.8	-1.8	-5.0 to +0.75

Question 5 *Was there a difference in achievement of weight loss or WC reduction by intervention modality?*

Detailed estimates by various intervention subgroups are shown in Table 8.5. They are expressed as a change in relation to baseline. A negative estimate indicates decrease and a positive estimate indicates increase. There were no statistically significant differences between estimates of weight loss, percentage weight loss or WC reduction for people attending group sessions and people receiving any other form of intervention, either separately (telephone coaching or IC only) or aggregated ($p>0.3$).

Table 8.5 Magnitude of change in anthropometric measurements for all participants attending 12-month review by intervention modality. Total with complete information at baseline and final assessment.

Outcome (change)	N	Mean (SD)	95% CI for Mean	Median	Interquartile range (25% -75%)
All participants					
Weight loss12m (kg)	578	-2.1 (4.6)	-2.4 to -1.7	-1.7	-4.1 to +0.6
% weight loss12m (%)	578	-2.2 (4.9)	-2.6 to -1.8	-2.1	-4.7 to +0.7
WC 12m reduction (cm)	574	-2.5 (5.0)	-2.9 to -2.0	-2.1	-5.0 to +0.5
Those attending groups					
Weight loss12m (kg)	516	-2.0 (4.5)	-2.4 to -1.6	-1.7	-4.2 to +0.7
% weight loss12m (%)	516	-2.2 (4.9)	-2.6 to -1.8	-2.1	-4.7 to +0.7
WC 12m reduction (cm)	513	-2.5 (4.9)	-2.9 to -2.0	-2.2	-5.1 to +0.5
Those on phone module					
Weight loss12m (kg)	43	-2.5 (4.9)	-4.0 to -1.0	-1.8	-4.4 to +0.5
% weight loss12m (%)	43	-2.4 (4.6)	-3.8 to -1.0	-2.2	-4.7 to +0.4
WC 12m reduction (cm)	42	-2.3 (4.8)	-3.8 to -0.8	-1.6	-0.5 to +0.4
Attended initial consult only					
Weight loss12m (kg)	19	-2.7 (5.8)	-5.5 to +0.1	-1.6	-3.3 to +0.7
% weight loss12m (%)	19	-2.6 (6.6)	-5.8 to +0.5	-1.3	-4.1 to +0.8
WC 12m reduction (cm)	19	-2.5 (6.5)	-5.7 to -0.6	-2.9	-3.3 to +1.7
phone coaching and IC only					
Weight loss12m (kg)	62	-2.6 (5.1)	-3.9 to -1.3	-1.8	-3.6 to +0.5
% weight loss12m (%)	62	-2.5 (5.3)	-3.8 to -1.1	-2.1	-4.6 to +0.4
WC 12m reduction (cm)	61	-2.4 (5.3)	-3.7 to -1.0	-2.0	-4.5 to +0.4

IC= initial consultation

CI= confidence interval 12m=at 12 months

On average, it would appear that people receiving only the initial consultation experienced slightly more weight loss than any other groups, but the sample here was very small [n=19], so this comparison produced no statistically significant differences. However, this can further be explained by the presence of two outliers who lost 15kg or more in the IC only group (10% of people in that group) compared with 9 people (2%) who experienced similar weight loss in the “group sessions” arm.⁶² The absence of statistically significant differences by intervention group persisted when all outliers losing ≥ 15 kg in any group were excluded from analysis.⁶³

Achievement rates of the 5% weight loss by the end of the Program were 24.7% for participants attending the group sessions, 22.7% for people receiving the telephone coaching and 20% for those not receiving either intervention following the initial consultation. These between-group differences were not statistically significant ($p=0.86$). Examination of sex differentials within each intervention modality also showed no difference between males and females for changes in either weight, percentage weight or waist circumference (Table 8.6).

⁶² The cases of excessive weight loss were not associated with weight loss surgery. Four people in the Program reported undergoing lap-band surgery. They all attended the ‘group sessions’ intervention and none of them were outliers in terms of weight loss (range -12.6 to +1.5)

⁶³ N=509 group sessions, 41 telephone coaching, 17 IC only; Anova F test=0.33, $p=0.72$.

Table 8.6 Sex differentials in achievement of anthropometric changes by intervention modality for all Program completers as at 31 December 2010.

Outcome(change)	Weight change Mean (SD)	Weight change Median (IQR)	% weight change Mean (SD)	% weight change Median (IQR)	WC change Mean (SD)	WC change Median (IQR)
Those attending groups						
Males (N=188)	-2.3 (4.4)	-1.9 (-4.5 to +0.2)	-2.4 (4.4)	-2.2 (-4.5 to +0.2)	-2.7 (4.4)	-2.2 (-5.2 to 0.0)
Females (N=328)	-1.8 (4.6)	-1.5 (-4.1 to +0.95)	-2.1 (5.1)	-1.8 (-5.0 to +1.2)	2.3 (5.2)	-2.1 (-5.1 to +0.8)
Combined phone coaching and IC only*						
Males (N=35)	-2.5 (5.1)	-1.6 (-4.4 to +0.5)	-2.1 (4.3)	-1.3 (-4.1 to +0.4)	-2.5 (4.4)	-3.0 (-5.0 to +0.4)
Females (N=26)	-2.6 (5.2)	-1.8 (-3.6 to +0.7)	-3.0 (6.3)	-2.3 (-4.7 to +1.0)	-2.2 (6.5)	-1.0 (-4.2 to +1.7)

SD= standard deviation

IQR=interquartile range (25% - 75%)

*Separate statistical comparisons with individual phone coaching and IC only were not performed due to small numbers.

Question 6 *What was the impact of the Program overall and by sex on dietary behaviour at one year?*

8.10 Dietary Changes at 12 Months

Inspection of the overall distribution of fat and saturated fat estimates, as a percentage of total energy intake for the whole cohort, showed a shift to the left after 1 year in the Program (see charts in Figure 8.6), indicating an overall reduction in fat intake for the mainstream SDPP completers. Almost two thirds of all mainstream participants (61.4%) reduced their fat intake as a percentage of total energy by at least 2%, with 8.2% reducing total fat intake by at least 15%. Over half the participants (55.7%) also reduced their saturated fat intake by at least 2% of total energy intake, with 2.5% achieving reductions of at least 10%. Between baseline and 12 months the fibre consumption distribution curve shifted to the right, indicating an increase in fibre consumption overall for the group. Over half of completers (54.3%) increased their fibre consumption by at least 2g per 1,000 kcal, with 4.1% achieving an increase of 10g or more per 1,000 kcal. These changes are all in the expected direction.

Figure 8.6 Comparative distribution of three macronutrients at baseline and 12 months for all completers delivering the 3-day food record at baseline and/or final review. N=438. Top row shows the baseline distribution and bottom row shows the end-of-Program distribution.

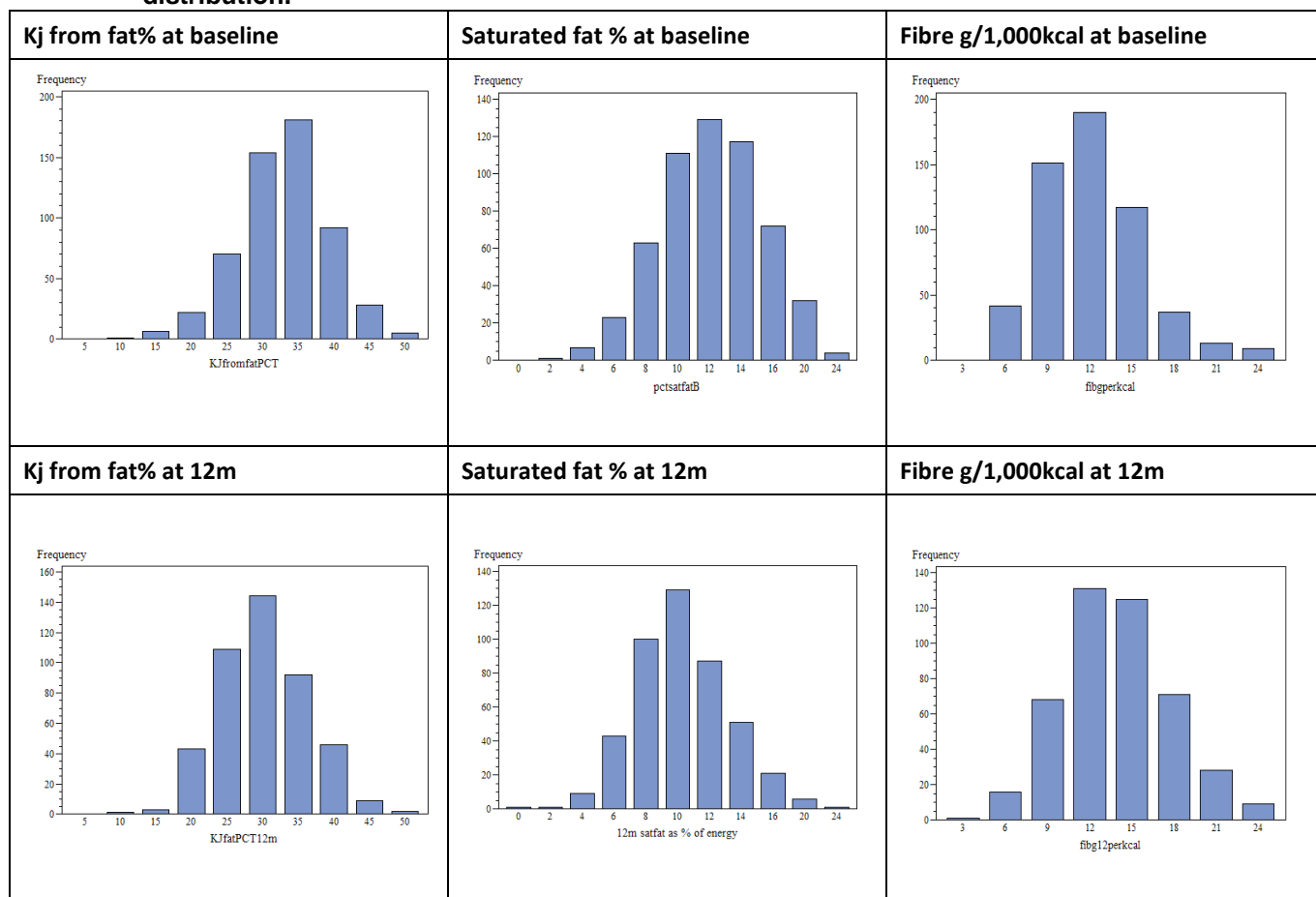
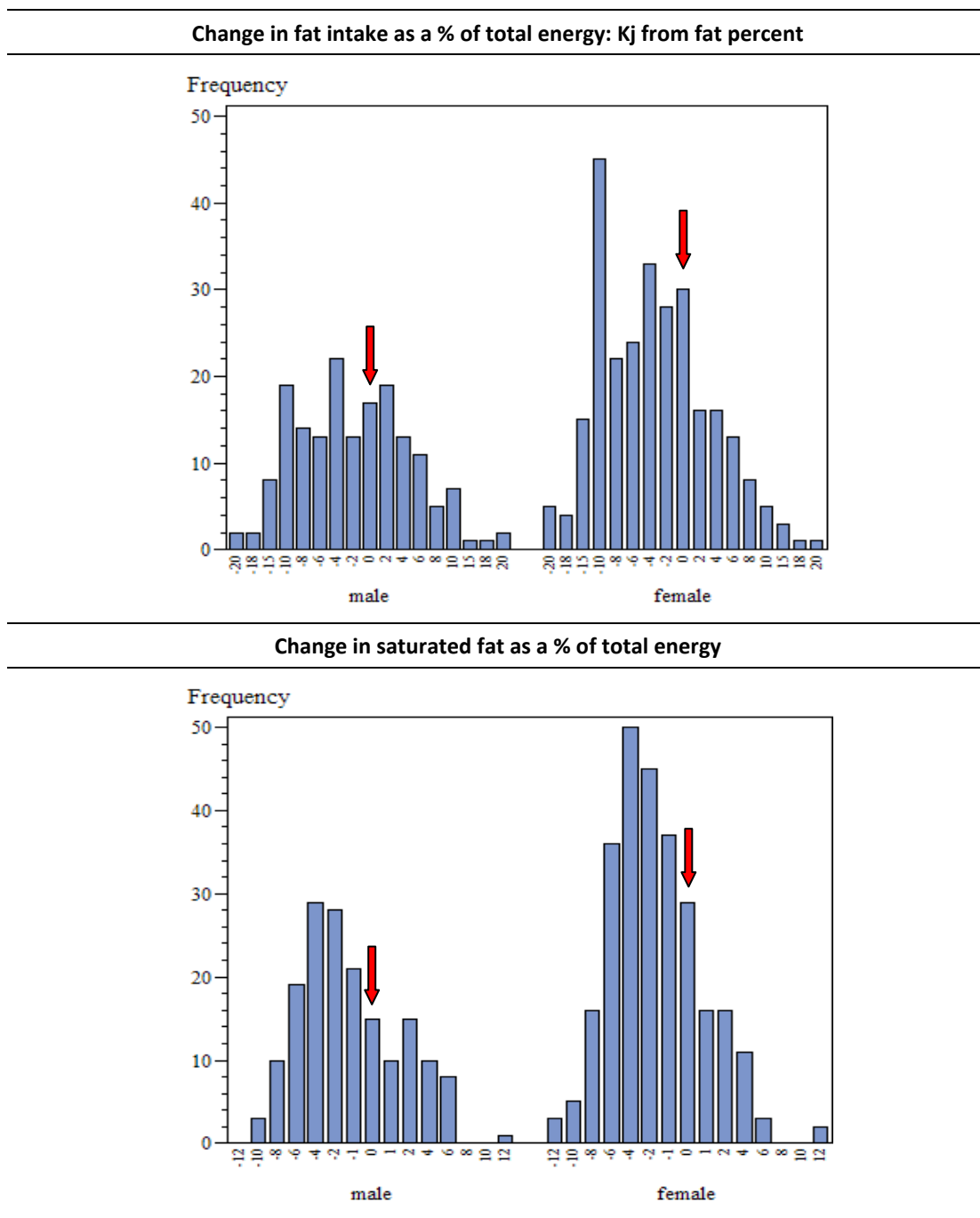


Figure 8.7 suggests that females reduced fats and increased fibre intake more than males did.

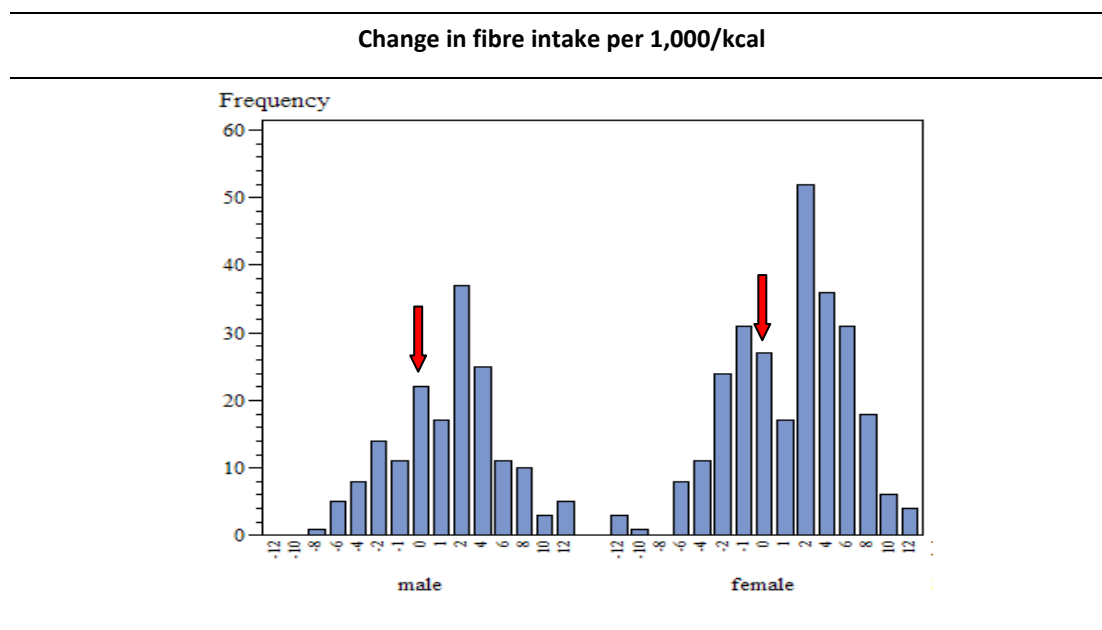
The arrow shows the area of no change, with the bars on the right side of the arrow indicating an increase and the bars on the left side with negative estimates indicating a decrease.

This trend towards reduction of fat intake and increase of fibre intake is confirmed by analysis of the means overall and by sex showing a statistically significant decrease in the proportion of total energy from fat (Table 8.4). This improvement was significantly more marked in females. Overall the energy intake from saturated fat decreased in both sexes but more markedly in females. However, this difference did not reach statistical significance. Fibre consumption after 12 months in the Program suggested a small increase in relation to baseline but there were no significant differences between males and females.

Figure 8.7 Sex differentials in changes in dietary intakes of total fat, saturated fat and fibre from baseline to 12 months for all Program completers with information at both time points as at 31 December 2010. N=438.



...continued. Figure 8.7 Sex differentials in dietary intakes



Question 7 *Did changes in dietary behaviour vary by intervention modality?*

Overall, the 1-year decrease in energy from fat and saturated fat, and the fibre increase were significantly different from zero (95% CIs do not include 0) (Table 8.7). When changes in macronutrients are analysed by intervention type, the favourable changes observed were not significantly different across intervention subgroups for any of the macronutrients (Table 8.7). Females reported significantly higher reductions in both fat and saturated fat intake than males overall, and in the subgroup attending group sessions.

Table 8.7 Mean changes in dietary parameters at 12 months by sex and intervention modality among Program completers who returned the 3-day food record at baseline and final assessment. N=438.

Intervention modality	Kj from fat (%)	Saturated fat as % of total energy intake	Fibre (g/1,000 kcal)
	Mean (SD) Median (IQR)	Mean (SD) Median (IQR)	Mean (SD) Median (IQR)
Overall	-3.0 (7.6)	-2.0 (3.8)	+1.9 (4.2)
Males (N=169)	-1.9 (8.0)	-1.6 (3.8)	+2.0 (4.2)
Females (N=269)	-2.4 (-7.3 to +2.8)	-1.7 (-4.1 to +0.7)	+1.9 (-0.4 to +3.7)
	-3.7 (7.3)*	-2.3 (3.7)	+1.8 (4.2)
	-3.8 (-9.2 to +0.6)	-2.3 (-4.5 to -0.2)	+1.8 (-0.9 to 4.6)
	Mean (SD)	Mean (SD)	Mean (SD)
Those attending groups	-3.1 (7.5)	-2.1 (3.7)	+1.8 (4.3)
Males (N=146)	-1.8 (8.0)	-1.5 (3.7)	+2.0 (1.3)
Females (N=250)	-3.8 (7.1)**	-2.4 (3.6)*	+1.7 (1.2)
Those on phone coaching	-1.8 (9.1)	-1.7 (5.3)	+2.2 (3.3)
Males (N=14)	-2.8 (7.7)	-3.0 (4.8)	+1.4 (3.5)
Females (N=15)	-0.7 (6.1)	-0.5 (5.6)	+2.8 (3.1)
Initial consult only	-3.4 (6.2)	-2.3 (3.2)	+2.5 (3.4)
Males (N=9)	-3.1 (7.3)	-2.1 (3.7)	+2.0 (2.9)
Females (N=4)	-3.9 (3.2)	-2.7 (2.1)	+3.7 (4.6)
Combined phone coaching and IC only	-2.3 (8.2)	-1.9 (4.7)	+2.3 (3.3)
Males (N=23)	-3.0 (7.9)	-2.7 (4.3)	+1.7 (0.3)
Females (N=19)	-1.4 (8.8)	-1.0 (5.1)	+3.0 (1.4)

* $p \leq 0.05$ ** $p \leq 0.01$ for differences between males and females
SD= standard deviation IQR= interquartile ranges

No gender differences were observed for changes to saturated fat or fibre intake.

There were no other significant sex differentials within the other intervention groups, possibly due to small numbers; nor were there statistically significant differences in any of the changes in macronutrients across intervention modalities ($p > 0.6$ for the three macronutrients).

8.11 Program Effects on People not Meeting Dietary Goals at Baseline

Large proportions of participants who did not meet the individual dietary goals at baseline managed to achieve them by the end of the Program. For instance, of the 304 completers who did not meet the fat goal at baseline, 47.3% achieved the goal; of the 332 completers not meeting the saturated fat goal at baseline, 46.4% achieved it; and of the 361 not meeting the fibre intake goal at baseline, 31.1% achieved it. Further, of the 134 people who met the fat goal at baseline, 58.2% maintained this status at the end of the Program; of the 106 completers who

met the saturated fat goal at baseline, 64.2% maintained this status; and of the 77 completers who met the fibre goal at baseline, 68.8% maintained this status.

Question 8 *How successful were participants in achieving the Program goals?*

For the purpose of this thesis, success is defined as achievement of Program goals. The larger the number of goals achieved, the more successful the participant is considered to be.

8.12 Proportions Achieving Program Goals Overall and by Sex

As the SDPP aimed to increase the proportion of participants meeting the Program goals, this section will deal with achievements for individual and combined goals overall and by sex. Note that denominators vary for each goal according to the number of people with complete information at both time points for each item. The goal most achieved was the fat intake goal, and the least likely to be achieved was the physical activity goal. Based on the three-day food record delivered at 12 months, half the completers met the total fat and saturated fat goals and one in every three completers achieved the fibre increase goal (Table 8.8).

One in four completers achieved the 5% weight loss goal at one year and one in ten achieved the physical activity goal. While the numbers are still small, males were more likely than females to meet the physical activity goal at the end of the Program. None of the other sex differentials in achieving goals were statistically significant.

Table 8.8 Indicators of success at one year in relation to primary goals by sex for all completers filling food record at both points and completers participating in the CATI survey at both points.

Indicator of success	Overall mainstream N (%)
% achieved Weight goal of 5% loss N=143/586	143 (24.4)
Males N=88	50 (22.2)
Females N=133	93 (25.8)
% Achieved Physical activity goal of 210 minutes / week N=61/527	61 (11.6)
Males N=200	31 (15.5)*
Females N=327	30 (9.2)
% Met goal of ≤30% total energy from fat N=230/449	230 (51.2)
Males N=172	94 (54.7)
Females N=277	136 (49.1)

Parameters of success	Overall mainstream N (%)
% Met goal of $\leq 10\%$ energy from saturated fat goal N=230/449	230 (51.2)
Males N=172	91 (52.9)
Females N=277	139 (50.2)
% Met goal of ≥ 15 grams of fibre per 1,000 kcal N=173/449	173 (38.5)
Males N=172	56 (32.6)
Females N=277	117 (42.4)

** $P \leq 0.05$ for differences between males and females*

Over three quarters of participants attending the 12-month review (up to 31 December 2010) who had data on all five goals achieved at least one goal, and 57.6% achieved at least two goals (Table 8.9). One in ten completers achieved four goals, one in five did not achieve any goals, and only a negligible number achieved all five Program goals. There was no statistically significant difference by sex in the likelihood of achieving three goals or less ($\chi^2 = 7.8$, $p > 0.17$). However, females were significantly more likely than males to achieve four or more goals ($\chi^2 = 25.3$; $p \leq 0.0001$). The four completers achieving all goals were female (Table 8.9).

Table 8.9 Sex differentials in success as measured by number of goals achieved at one year. Completers with complete information for all goals at 12 months. Total N=410, Males=156, Females=254.

Indicator of success Numbers achieving goals		% of total completing the Program	(%) of completers within sex category♦
% not achieving any goals N=83/410		20.2	
	Males N=29		18.6
	Females N=54		21.3
% Achieved AT LEAST one goal N= 327/410		79.8	
	Males N=127		81.4
	Females N=200		78.7
% Achieved ONLY one goal N= 91/410		22.2	
	Males N=30		19.2
	Females N=61		24.0
% Achieved two goals N=103/410		25.1	
	Males N=47		30.1
	Females N=56		22.1
% achieved three goals N=82/410		20.0	
	Males N=35		22.4
	Females N=47		57.3
% Achieved four goals N=47/410		11.5	
	Males N=15		9.6
	Females N=32		12.6
% achieved all five goals N=4/410		1.0	
	Males N=0		0.0
	Females N=4		1.6

Overall percentages (in bold) indicate percentage of those completing the Program and for whom there was information on all goals. Sex percentages are calculated out of the total male completers or total female completers who had information on all goals.

8.13 True Program Effect on Number of Goals Achieved

A better indication of behaviour change towards goal attainment might be to examine those not meeting the goals at the baseline assessment. Of the 191 completers not meeting goals at baseline (i.e. dietary or physical activity), 26.2% met at least one goal by the end of the Program, 22% met two goals, 15.2% met 3 goals and 11% met 4 goals. That is, the Program encouraged 74% of these participants to attain at least one goal.

Question 9 Was goal achievement influenced by intervention modality?

8.14 Achievement of Goals by Intervention Modality

This section presents goal achievements by individual goal and by number of goals achieved by type of intervention received, i.e. group sessions, telephone coaching or initial consultation only.

No sex comparison across intervention groups are attempted due to small numbers in cells for modalities other than “group sessions”.

Table 8.10 shows that the apparent differences in achievement of the physical activity goal between participants receiving the telephone coaching was only marginally statistically significant ($p=0.05$) but the numbers are small and could reflect random variation. When “other interventions” were combined, the difference in achievement of the physical activity goal was not significantly different from those attending “group sessions”.

Table 8.10 Proportions achieving each of the five Program goals at the end of the Program by intervention modality. Program completers with data on each parameter at baseline and final assessment by 31 December 2010.

Outcome (change)	Met PA goal N (%)	Brisk walking & Met PA goal N (%)	Met weight loss goal N (%)	Met total fat goal N (%)	Met saturated fat goal N (%)	Met fibre goal N (%)
Those attending groups	51 (10.9)	122(26.0)	129 (24.7)	209 (51.5)	207 (51.0)	157 (38.7)
Those on telephone coaching	9 (22.5)*	13 (32.5)	10 (22.7)	13 (43.3)	16 (53.3)	12 (40.0)
Attended initial consult only	1 (5.6)	3 (16.7)	4 (20.0)	8 (61.5)	7 (53.9)	4 (30.8)
Combined phone + IC only	10 (17.2)	16 (27.6)	14 (21.9)	21 (48.8)	23 (53.5)	16 (37.2)

♦ Percentages are calculated within each intervention modality who had the goal documented

* $p=0.05$ for difference between ‘group sessions’ and ‘telephone coaching’

As shown in the second column of Table 8.10, when ‘brisk walking’ was incorporated into the total physical activity measure, the proportion of participants achieving the physical activity goal at 12 months more than doubled (increase to 26.0%) for those attending group sessions, increased to 32.5% for the telephone coaching, and tripled for those attending initial consultation only (16.7%). Yet the differences in achievement of the physical activity goal across intervention groups (whether aggregated or not) were still not statistically significant ($p>0.3$). There were no significant differences in achievement of the weight loss goal, or any of the

dietary goals by intervention modality when 'group sessions' were compared with 'other intervention types' combined ($p>0.5$).

Of note, at baseline slightly larger proportions of participants in the telephone coaching group (17.5%) had met the physical activity goal than those attending the group sessions (10.4%). These differences were not statistically significant at baseline. Examining those participants who had not met the physical activity goal at baseline in both intervention subgroups, the proportions achieving this goal at 12 months also appeared to be higher in the telephone coaching (13.3%) than in the group sessions (7.8%) but this difference was not significantly different ($\chi^2=1.12$, $p=0.29$). No other statistical differences in goal achievements were found at the end of the Program between the participants attending group sessions and those receiving telephone coaching.

8.15 Total Number of Goals Achieved

Comparisons of the number of goals achieved by intervention type (Table 8.11) did not reveal any statistically significant differences ($\chi^2=5.4$, $p=0.35$). Again, most people achieved at least one goal and just over half (56.9% of those attending groups and 63.4% of those on other intervention modalities) achieved at least two goals.

Table 8.11 Number of goals achieved and percentage within intervention received: "group sessions" N=369, for "other interventions" (combined phone coaching and IC only) N=41.

Intervention modality	Met at least one goal N (%)	Met 1 goal only N (%)	Met 2 goals N (%)	Met 3 goals N (%)	Met 4 goals N (%)
Those attending groups	293 (79.4)	83 (22.5)	88 (23.9)	74 (20.1)	45 (12.2)
Combined phone + IC only	34 (82.9)	8 (19.5)	15 (36.6)	8 (19.5)	2 (4.9)

IC only= initial consultation only

People attending group sessions appeared to be almost twice as likely as those in other intervention modalities to achieve four or more goals. However, this difference did not reach statistical significance ($\chi^2=1.1$, $p=0.29$) due to the small numbers achieving 4+ goals. Of the four people achieving all goals, 3 attended group sessions and one received telephone coaching.

Question 10 *What predicted success at 1 year?*

As the correlates of achieving the physical activity goal may be different from the determinants of weight loss or dietary adherence, bivariate analysis and multivariate models are examined separately for physical activity, weight loss and diet (achievement of the dietary goals were analysed as one outcome).

8.16 Correlates of Success (bivariate analysis)

Based on theoretical plausibility, several potential predictors of achieving the relevant Program goal were examined. With the exception of age, sex and the baseline estimate of the outcome measurement in question, only those variables reaching statistical significance remained in the final model. The data in Table 8.12 are presented as unadjusted odds ratios, to examine bivariate associations in these data with goal attainment.

The most highly significant predictor of achieving the physical activity goal of 210 minutes of moderate-to-vigorous activity, was the level of physical activity at baseline, and meeting the P.A. goal at baseline was the strongest. The total minutes of activity/week was also significant, but this was a collinear variable, and the parameter estimate was small. Other statistically significant variables predicting a positive outcome were male sex, having private health insurance, and receiving the telephone coaching calls. It appeared that there was also a dose-response relationship where the chances of achieving the P.A. goal increased with the number of coaching calls.

Table 8.12 Correlates of meeting Program goals at 12 months for mainstream participants only. Unadjusted odds ratios or probability of meeting the goal(s) at the end of the Program. N=527 for physical activity, N=578 for weight loss and N=438 for dietary goals.

Parameter (and referent group)	Physical activity goal OR (95%CI)	5% weight loss OR (95%CI)	Two or more diet goals OR (95%CI)
Age (continuous)	1.00 (0.94 - 1.06)	0.99 (0.99-1.03)	1.02 (0.98 - 1.06)
Male sex (female is referent)	1.82 (1.06 - 3.10) *	0.82 (0.56-1.22)	1.21 (0.83 - 1.78)
High Education (low education is referent)	2.82 (0.81 - 9.78)	3.55 (1.52 – 8.27)**	0.79 (0.40 - 1.57)
Mid Education (low education is referent)	2.00 (0.59 - 6.76)	2.55 (1.12 -5.80) *	0.70 (0.37 - 1.34)
In the workforce (not in the workforce is referent)	1.13 (0.64 - 2.00)	0.92 (0.62-1.37)	1.06 (0.72 - 1.56)
On a pension (not on a pension is referent)	0.72 (0.38 - 1.30)	1.03 (0.68-1.58)	0.76 (0.50 - 1.16)
Private health insurance (not health insurance is referent)	2.51 (1.24 - 5.1)**	0.75 (0.50-1.12)	1.90 (0.72 - 1.66)
BMI (continuous)	0.99 (0.94 - 1.04)	1.02 (0.99 - 1.06)	1.01 (0.97 - 1.04)
Baseline FPG (continuous)	1.37 (0.88 - 2.13)	1.11 (0.82 - 1.50)	0.99 (0.74 - 1.34)
Meets P.A. goal at baseline (not meeting PA goal is referent)	8.91 (4.66 - 17.01)***	N/A	N/A
Total min/P.A.+ brisk walking at baseline (continuous)	1.003 (1.002-1.005)***	N/A	N/A
Meets P.A. goal at 12M (not meeting PA goal is referent)	N/A	1.38 (0.77 - 2.47)	0.72 (0.40 - 1.27)
Total min/P.A.+ brisk walking at 12 months (continuous)	N/A	1.001(1.00-1.002)*	1.001 (1.000-1.002)*
Meets fat goal at 12M (not meet the goal is referent)	1.03 (0.58 - 1.81)	1.92 (1.25 - 2.96)**	N/A
Meet saturated fat goal at 12M (not meet the goal is referent)	0.98 (0.55 - 1.72)	2.02 (1.31 - 3.11) **	N/A
Meet fibre intake goal at 12M (not meet the goal is referent)	0.54 (0.29 - 1.02)	1.70 (1.11 - 2.59)*	N/A
Phone coaching (Groups is referent)	2.38 (1.07 - 5.28)*	0.90 (0.43 - 1.86)	1.22 (0.58 - 2.57)
Initial consultation only (Group sessions is referent)	0.48 (0.06 - 3.70)	0.76 (0.25 - 2.32)	1.25 (0.41 - 3.78)
No. of coaching calls (continuous)	1.36 (1.03 - 1.79)*	0.99 (0.76 - 1.28)	1.04 (0.80 - 1.35)
No. of groups attended (continuous)	0.84 (0.66 - 1.07)	1.06 (0.87 - 1.29)	0.99 (0.81 - 1.20)
Number of follow-up contacts 3,6,9 months (continuous)	1.32 (0.81 - 2.15)	1.54 (1.09 - 2.16) *	1.03 (0.75 - 1.41)
Total interactions with lifestyle officer (continuous)	1.16 (0.86 - 1.56)	1.24 (1.004 - 1.53) *	1.02 (0.83 - 1.24)
Self-efficacy 🎵 (low self-efficacy is referent)	1.47 (0.85 - 2.54)	0.94 (0.63 – 1.40)	1.49 (1.03 - 2.20)*
Social support 🎵 (low/no support is referent)	1.63 (0.82 – 3.25)	0.99 (0.68 - 1.44)	0.96 (0.63 - 1.45)
Anxious (non-Anxious is referent)	0.62 (0.33 - 1.16)	1.24 (0.83 - 1.85)	0.61 (0.41 - 0.93)*
Depressed (not depressed is referent)	0.46 (0.19 - 1.09)	1.18 (0.73 - 1.90)	0.45 (0.26 – 0.76)**
Good self-assessed health (poor health is referent)	1.50 (0.74 - 3.06)	0.62 (0.41 - 0.95)*	1.27 (0.82 – 1.99)
Total co-morbidities (continuous)	1.03 (0.79 - 1.34)	1.11 (0.93 - 1.34)	1.03 (0.86 – 1.23)

OR= Odds ratio estimate 95%

CI = 95% confidence intervals of the estimated probability of meeting the goal

NA= Not applicable

*

$p \leq 0.05$

**

$p \leq 0.001$

🎵

self-efficacy or social support for P.A. if the outcome is the .PA. goal; self-efficacy or social support for diet if the outcome is dietary goals; overall self-efficacy or social support if the outcome is weight loss.

Other variables such as mid to high education, baseline FPG, total number of follow-up contacts, high self-efficacy for physical activity and high social support also showed a positive but not statistically significant association with achieving the P.A. goal at 12 months. Being on a pension, attending initial consultation only, and being depressed or anxious seemed to reduce the likelihood of achieving the P.A. goal, but these associations did not reach statistical significance ($p \geq 0.05$).

Positive unadjusted associations with achieving the 5% weight loss goal were having mid to high education levels, meeting the fat, saturated fat and fibre intake goals at 12 months, and number of contacts with the lifestyle officer, in particular, number of follow-up calls (Table 8.12). There was an apparent negative association between self-assessed health and weight loss. That is, people with better self-rated health were less likely to achieve the weight loss goal. Investigation of a possible explanation, showed no differences in gender, baseline levels of obesity/overweight or social support for diet or physical activity between those self-reporting good-excellent health and those reporting fair-poor health. However, cross-tabulations of self-reported health with age indicate that older people are more likely to report good-excellent health (OR 1.06 $p=0.01$); but older people are also less likely to obtain social support (OR 0.93 $p < 0.001$) and tend to be less likely to achieve the weight loss goal although this latter association is not statistically significant (OR 0.98 $p=0.58$).

This negative association will be examined further in the multiple logistic regression analysis.

Anxiety and depression were not found to be associated with the weight loss outcome in the bivariate analysis.

For associations with achieving at least two of the three dietary goals, bivariate analysis indicates that self-efficacy for healthy eating is positively associated, while depression and anxiety scores are negatively associated. That is, people who are confident about changing their eating habits at baseline were more likely to achieve the dietary goals; and people with higher depression or anxiety scores at baseline were less likely to achieve them. Social support and

number of interactions with the lifestyle officer did not show significant association with the achievement of dietary goals.

The multiple logistic regression models examining predictors of success for the Program goals are presented in the next section. All models include age, sex, and Program modality as a base.

In addition, each model has a relevant baseline value as follows: The physical activity model has a baseline P.A. measure (meeting the P.A. goal); the weight loss model includes the baseline BMI; and the dietary goals model has a baseline dietary measure (meeting either dietary goal).

8.17 Predictors of Achieving the Physical Activity Goal (logistic regression analysis)

After controlling for age, sex and intervention modality, the only parameter significantly associated with achieving the physical activity goal at 12 months was the baseline level of activity. The model showed a significant positive association with either total minutes of activity (with or without including brisk walking) or as proportions of participants meeting the physical activity goal at baseline (Table 8.13). Participants meeting the P.A. goal at baseline were eight times more likely to succeed at the end of the Program.⁶⁴

All the socio-demographic, psychosocial and other risk factors that were examined in the model were not statistically significantly associated with achieving the PA goal. These included: education, pension status, private health insurance status, employment status, total number of group sessions, total number of telephone coaching calls, total number of follow-up quarterly contacts, self-efficacy for physical activity, social support for physical activity, anxiety and depression levels, self-rated health, and number of underlying chronic conditions.

⁶⁴ As only 34 completers who did not meet the P.A. goal at baseline succeeded at 12 months, a separate model could not be built for these to examine predictors of the 'true effect' of the Program.

Table 8.13 Predictors from multiple logistic regression model of achieving the physical activity goal. All Program completers participating in PASE questionnaire at both baseline and final assessment by 31 December 2010 (N=481).

Predictor (referent group)	Odds ratio	95% Wald Confidence Limits		p
Age (continuous)	1.00	0.94	1.07	0.9413
Sex (female is referent)	1.37	0.75	2.51	0.3083
Meet PA goal at baseline (not meeting goal is referent)	8.21	4.21	16.02	<.0001
Telephone coaching (Group session is referent)	1.89	0.75	4.79	0.1793
Initial consultation only (Group sessions is referent)	0.42	0.05	3.53	0.4230

8.18 Predictors of Achieving the Weight Loss Goal (logistic regression analysis)

Table 8.14 presents the independent predictors of achieving five percent weight loss after controlling for possible confounding factors. After controlling for the effects of age, sex, baseline BMI, and intervention type, participants with higher education, those who met the saturated fat goal at 12 months, and those with the largest number of follow-up telephone contacts were more likely to achieve the 5% weight loss goal (Table 8.14). Program completers who had higher education were almost four times more likely to achieve the weight loss goal than those with low education. People who met the saturated fat goal by the end of the Program were twice as likely to lose 5% of their initial body weight as those who did not meet the saturated fat goal. Each additional contact with the lifestyle officer was positively associated with an 82% higher likelihood of losing 5% of body weight. No significant differences in the likelihood of achieving the weight loss goal were found by baseline age, sex, BMI, or intervention type but these variables were left in the final model due to theoretical plausibility of influence on the outcome. Other variables explored in the logistic regression modelling not significantly associated with the weight loss outcome included: employment status, pension status, insurance status, total number of groups attended, total number of telephone coaching calls received, level of moderate-to-vigorous physical activity at 12 months, fibre consumption at 12 months, baseline depression or anxiety, baseline self-efficacy, baseline social support, and total number of chronic co-morbidities. The association between poor self-reported health and achievement of weight loss goal found in the bivariate analysis did not hold in the multivariate analysis. The effect disappeared after adjusting for age, sex and intervention modality.

Table 8.14 Predictors of achieving the 5% weight loss goal. All Program completers as at 31 December 2010. Adjusted odds ratio estimates for completers with weight information at both points. N=578.

Effect (referent group)	Odds ratio	95% Wald Confidence Limits		p
Age (continuous)	0.98	0.93	1.03	0.3953
Sex (female is referent)	1.05	0.66	1.64	0.8706
BMI (continuous)	1.02	0.98	1.06	0.3925
Phone coaching (group sessions is referent)	0.81	0.32	2.01	0.6455
Initial consultation only (group sessions is referent)	0.83	0.21	3.26	0.7913
Mid Education (low education is referent)	2.47	0.91	6.67	0.0754
High Education (low education is referent)	3.83	1.38	10.60	0.0099
Meet saturated fat goal at 12 m (not meeting goal is referent)	2.12	1.36	3.30	0.0010
No. of quarterly follow-up contacts (continuous)	1.82	1.16	2.83	0.0085

8.19 Predictors of Achieving the Dietary Goals (logistic regression analysis)

After adjusting for age, sex and intervention modality, only meeting any of the dietary goals at

baseline predicted achievement of two or more dietary goals at the end of the Program. The

final model is one which includes achievement of the fibre goal at baseline (Table 8.15).

Participants who met the fibre goal at baseline were twice as likely as those not having the

target fibre intake to achieve the dietary goals at the end of the Program. Another important

finding was that a high baseline depression score was significantly associated with more than

50% lower probability of achieving two or more dietary goals. All other demographic,

psychosocial and risk factor variables tested in the model were not significantly associated with

achieving this outcome.

Table 8.15 Predictors from multiple regression modelling of achieving two or more dietary goals. Program completers with dietary information and its correlates at 12 months as at 31 December 2010 (N= 438).

Effect (referent group)	Odds ratio	95% Wald Confidence Limits		p
Age (continuous)	1.01	0.97	1.06	0.5514
Sex (female is referent)	1.16	0.78	1.73	0.4620
Telephone coaching (Groups is referent)	1.20	0.55	2.60	0.6515
Initial consultation only (Groups is referent)	1.31	0.42	4.12	0.6433
Met baseline fibre goal (not meeting goal is referent)	2.15	1.29	3.61	0.0036
Depressed (referent is not depressed)	0.47	0.27	0.82	0.0076

Changes in clinical parameters such as fasting plasma glucose, cholesterol and blood pressure

were very small and not significantly different between males and females or by intervention

modality. Diabetes incidence after enrolment was 1% but complete ascertainment was not available at the time of writing this thesis. As they are secondary outcomes of the Program and outside the scope of this thesis on risk reduction, only a brief summary is presented in Appendix 8.3.

8.20 Discussion

This preliminary 12-month impact evaluation has examined the achievement of the five SDPP program goals and assessed potential determinants of success in their achievement .

Comparisons of the multiple outcomes of the SDPP with other studies will be presented in their relevant sections of this discussion.

8.21 Weight Change

Analysis of the first 586 completing participants indicates that weight loss achievements were encouraging, with an average of just over 2 kg of measured weight loss achieved. On average one-year weight losses were 2.4 kg for males and about 1.9 kg for females, but the median one-year weight loss was slightly lower at 1.9 kg for males and 1.5 kg for females. This is equivalent to about 2% weight loss for both sexes. There were no statistical differences in the likelihood of males or females achieving the weight loss goal. More than half the completers (57%) lost at least 1 kg and about a quarter of completers (24.4%) achieving the expected 5% weight loss goal. This level of weight loss does not tally well with the high compliance ($\geq 94\%$) with dietary recommendations that was self-reported at three, six and nine months; nor does it correlate with the overall reported adherence to physical activity of $\geq 83\%$ and frequency of ≥ 4 days per week in over 70% self-reported by respondents contacted at 3, 6 and 9 months (Chapter 7). This discrepancy is likely to have been due to social desirability of the self-reported telephone responses at 3, 6, 9 months, where participants felt they needed to report good behaviour to their lifestyle officer, (297) and more objective measures could not validate this. These data point to some change in weight, but reinforce the need for objective assessment of change in weight status, here carried out at baseline and 12 months.

When comparing results of the SDPP with one-year results from the Finnish Diabetes Prevention Study,(93) it is clear that the FDPS achieved twice as much weight loss overall (-4.2kg vs. -2.1kg in SDPP), and twice as many participants achieved their weight loss goal (43% achieving 5% weight loss vs. 24.4% in SDPP). The lifestyle intervention group of the US Diabetes Prevention Program (95) also achieved greater weight loss at one year (5.6kg on average) and 50% of participants had already achieved a 7% weight loss in the first six months, which was maintained at one year. The Indian study showed a slight weight increase at 12 months (no estimates reported, only graphic) and a significant weight increase at 24 months.(104) The Indian diabetes prevention program (104) is not directly comparable with Sydney DPP because the target group was younger (25-55 years) and the results are only published at 3 years follow-up.

Other Australian attempts at translation of diabetes prevention programs following the FDPS model or its predecessor, the GOAL study(226) have achieved mixed results. In the Greater Green Triangle (GGT) area between Southern Victoria and South Australia, Laatikainen *et al.*(117) opportunistically screened middle aged patients presenting to local GPs to identify those at high-risk of diabetes. Consenting patients entered a pilot study consisting of six group sessions on lifestyle demonstrations with baseline and final assessments. The follow-up was 12 months and outcomes reported were mostly clinical and laboratory-based rather than behavioural. The mean weight loss at 12 months in the GGT was quite similar (2.5kg) to that observed in SDPP (95% confidence intervals overlap with SDPP). The direction of the weight change at 12 months in SDPP (-2.1 kg overall) was maintained from the weight loss of -1.1 kg overall observed at three months (Appendix 8.4). The general trend for males and females in the Sydney study was for a sustained weight loss until the end of the Program rather than weight regain after the intensive part of the intervention. This encouraging finding is similar to that of participants in the GGT study, where weight loss at three months was 2.2 kg and at 12 months was 2.5 kg. (117, 217), and this suggests an approximate effect size expected for weight loss in Australian diabetes prevention community-based studies.

More recently Payne *et al.* in Ballarat, Victoria (119) conducted a more intensive intervention in disadvantaged communities delivering group sessions once a week for 18 weeks to high-risk people aged 35 years and older. This extensive intervention included gym-based and home-based activity with a maintenance phase of 34 weeks. The mean weight loss at one year for completers (4.07 kg) was twice that of Sydney DPP and similar to the FDPS. Again, this intervention was much more resource and personnel intensive and of longer duration than SDPP,⁶⁵ and less likely to be in a 'generalisable format for scaling up' to whole statewide or national DPPs.

Several community-based programs in the US used before-after designs, and reported larger weight losses in the first year. Matvienko *et al.*'s before-after intervention on 25-65 year-old males and females included 24-48 face-to face individual sessions followed by weekly telephone calls.(134) Findings at 12 months included mean weight loss of 6.0 kg, similar to that achieved by the USDPP. Siedel *et al.*'s short-term study recruited high-risk adults aged 18 years and older for an intervention consisting of 12 group sessions in three months.(120) Over a third of participants lost $\geq 5\%$ of initial body weight in the first six months. These two community-based studies, however, had small sample sizes (31 & 88 respectively), hence results are less generalisable.

The Montana cardiovascular disease and diabetes prevention program also replicated the 16 individual sessions of the USDPP, followed by supervised physical activity and group sessions in mostly white adults over 18 years of age. Two thirds of participants (67%) achieved 5% weight loss or more in the first four months, or a mean 6.7 kg reduction but 7% of participants were taking weight loss medication.(115) A pilot study in a largely Hispanic community setting used a peer-led intervention for pre-diabetics consisting of eight group sessions held over two and a half months.(129) A mean weight loss of 3.3 kg was achieved at the end of the first year. Also in

⁶⁵ although the authors of the Ballarat study in Victoria called it a low-resource intervention by comparison with the reference FDPS, it nonetheless was much higher than SDPP or GGT in resources, staffing and sessions attended.

urban USA, a randomised controlled trial of two years duration delivered an intensive lifestyle intervention to overweight or obese adults.(121) It comprised 24 group meetings in the first 6 months and a further 12 meetings in the second six months and achieved a mean weight loss of 7.4 kg in the first 12 months. Reported weight losses in the Da Qing prevention trial in China were 1.77 kg for people without diabetes and -3.3 kg for those who developed diabetes during the course of the study.(90) However, these findings are not strictly comparable with SDPP as the timeframe was 6-year results and there is no information for the overall group at one year. In conclusion, the weight loss achievements of the three-session SDPP are similar to those found in the six-session GGT and better than the Indian DPP, but less marked than in either the strict, highly-resourced reference trials or some of the other more intensive, but with possibly more selected participants in other community-based interventions.

8.22 Dietary Changes

The SDPP also managed to help improve or maintain levels of fat and saturated fat intakes. Overall the effect of SDPP on dietary behaviour was a reduction of fat by 3% of total energy intake (vs. 21% fat intake reduction in the Finnish DPS) and an increase of fibre by 16% or increase in fibre intake of 1.9g/1,000 kcal (vs. 12% fibre increase from baseline in the FDPS). Both the FDPS and SDPP used 3-day food records. On dietary measures, the Ballarat study reported total and saturated fat changes comparable to SDPP. That is, a reduction of 2.13% and 1.43% in total and saturated fat respectively, much lower than the FDPS but similar to SDPP; and a non-significant reduction in fibre intake vs. an increase in SDPP. The Ballarat study used food frequency questionnaires whereas the SDPP used the measure of 3-day food records (119), and hence SDPP results may be more reliable.

The effect of USDPP on fat intake was a 6.6% reduction as a proportion of total energy intake, twice that of that achieved by the SDPP participants. However, the USDPP measured dietary intake using a food frequency questionnaire, (101, 290) so comparisons with results from a 3-day food record should be viewed with caution. Fibre changes were not reported by the USDPP. Only one other community-based replication study reported fat intake changes. Wing *et al.* used

food frequency questionnaires and 3-day food diaries and found a reduction of 5.3% fat as a proportion of total energy intake, slightly higher than SDPP.(121) Dietary comparisons with the Indian DPP were not possible due to their reporting “% diet adherence” rather than % change in individual macronutrients; and comparisons with the GGT were not possible as no dietary outcomes were reported despite mention of food diaries in the methods. In brief, SDPP achieved similar fibre increases as FDPS but less favourable fat intake reductions than either FDPS, USDPP or its replication study. Comparisons with FDPS and Wing *et al.*'s community replication were appropriate as methods were equivalent across studies. These results in the briefer SDPP were both important and impressive, and indicate the possibility of dietary change, with a lower intensity three-session intervention.

An interesting finding of SDPP was that self-reported adherence to healthy eating as per Program recommendations was high ($\geq 94\%$) at every follow-up contact with the lifestyle officer (see Chapter 7 on short-term changes). Yet measured changes from the 3-day food record at the end of the Program did not corroborate this level of change. Possible explanations are: the small number of days may have included in the food record some food consumption that was not representative of the participants' usual intake; or the social desirability factor as described under the discussion on weight changes.

8.23 Physical Activity Changes

Changes in physical activity one year after the intervention in SDPP were a mean increase of 13.7 reported minutes/week of moderate to vigorous activity, and a mean increase of 65.5 minutes/week when brisk walking was added into the calculation. However, given the large variation around PA measures, as indicated by the median of zero, these changes were not significant.

The USDPP did not report this change in total minutes per week but in MET-hours/week.⁶⁶ A conversion using the equivalence proposed in the literature(298) indicates that the increase at 12 months was around 19.5 minutes per week in the USDPP. This is similar to the mean SDPP achievement of 13.7 minutes per week. Matvienko *et al.*'s before-after study of pre-diabetics measured physical activity using a 7-day log completed the week before the assessment.(134) The level reported at 12 months was 258 minutes. The Finnish study reported that by one year 34% of participants were engaged in more than 4 hours of exercise per week, but this included the whole spectrum of light to vigorous activities in the same questionnaire. Their self-reported physical activity,⁶⁷ was expressed as a shift to a higher category combining intensity and fixed-duration ranges. (93) This limits comparability with the SDPP outcome. Likewise, the Indian DPP reported this outcome as improvement in “% physical activity adherence” from 41.7% to 58.8% which mostly reflected brisk walking patterns rather than minutes of relevant exercise types. (104)

Mean minutes of Physical activity in the Ballarat Australian study increased by over an hour per week but medians were not reported, so there is a doubt about the proportion of people for whom the Program really made a difference. The Australian GGT study did not report physical activity changes.(117) Summarising results for physical activity, small effects were noted, and smaller proportions achieved their program PA goal, compared to diet and weight loss. This could have been due to the measurements used, and certainly has limited comparability with other lifestyle interventions.

⁶⁶ MET stands for Metabolic Equivalent of Task, which reflects the energy consumption of specific physical activities. 1 MET-hr/week is =2.791 minutes of moderate to vigorous activity [Lee IM JAMA 2010]

⁶⁷ “(1) I read, watch TV and work in the household at tasks that don’t strain me physically; (2) I walk, cycle or exercise lightly in other ways at least 4 hours per week; (3) I exercise to maintain my physical condition by running, jogging, skiing, doing gymnastics, swimming, playing ball games, etc for at least 3 hours per week; or (4) I exercise competitively several times a week by running, orienteering, skiing, playing ball games, or engaging in other sports involving heavy exertion.”

8.24 Waist Circumference Changes

Mean waist circumference reduction was -2.5 cm in SDPP and significantly higher in the GGT (-4.17cm with confidence intervals not overlapping with those in SDPP). Curiously, the weight loss was similar in these two programs, and the reasons why this WC difference was observed are not known. The SDPP lifestyle officers had extensive training in the difficult assessment of WC, and differential measurement – observer error might partly explain this observation. The Ballarat study also reported mean WC reductions of 4.7 cm at one year, higher than the SDPP.(119) Mean WC change at 12-months in the Indian DPP lifestyle group was less than 1 cm and not significantly different from baseline. (104) The US community-based study of Hispanics also found a small WC reduction of 1.3 cm despite achieving significant weight loss. The FDPS reported that “*reductions in waist circumference at one year were significantly more among subjects in the lifestyle intervention than in the control group*” but no estimates were published for this milestone. Changes in WC were not reported for the USDPP at any stage. In short, WC reductions in SDPP were in the right direction but less pronounced than in the GGT or Ballarat interventions and the magnitude of difference with the reference trials is unknown. Waist circumference changes may be affected by the ethnic composition of samples, and by rates of obesity, but is even also likely to be significantly influenced by training of those assessing it, namely measurement error. (227)

8.25 Goals Achieved

The SDPP analysis found that one in five participants (22.2%) achieved one goal, one in four (25.1%) achieved two goals, one in five (20%) achieved three goals, one in ten (11.5%) achieved four goals and only 1% achieved all five goals. The corresponding figures in the intervention group of the Finnish DPS were 28.1%, 29.4%, 16%, 10.6% and 10.2%. While similar proportions achieved three and four goals, more participants in the FDPS achieved one or two goals and five goals. The proportions not achieving any goal were 20.2% in SDPP and 5.5% in the FDPS. Neither the US DPP nor the Indian DPP reported success using “number of goals achieved” as a reference. As seen in the multiple logistic regression analysis above, patient-related factors

including education, baseline behaviours, emotional health and contact with Program support can explain some of these differences.

The most challenging goal to achieve in SDPP was the 210 minutes of physical activity per week. The mainstream cohort was very sedentary at baseline and by 12 months \approx 90% of completers had not changed their moderate-to-vigorous physical activity levels to reach the expected goal. This proportion improved if brisk walking was added to the total physical activity estimate, but the overall median number of moderate to vigorous minutes among completers remained at zero after 12 months in the Program. The physical activity goal in the USDPP had a lower cut-off point of 150 minutes/week based on participants' log books, and used different PA questions. Results reported were: 74% achieved the P.A. goal at six months, and 58% at the most recent visit occurring about 2.8 years from enrolment on average.(95) The Montana prevention program also reported 70% of participants achieving the physical activity goal within 12 months(115) and Matvienko *et al.*'s pre-diabetic study in the US also reported 61.5% achieving 150 minutes/week in the first year.(134) In the Sydney DPP 17.6% of the PASE respondents reported doing at least 150 minutes per week at 12 months and this estimate increased to 37% when brisk walking was incorporated in the moderate activity. Yet, the SDPP Program goal was specified at a higher level to achieve 210 minutes per week. The frequency of interaction and close supervision in USDPP and the two other community-based studies could have accounted for the more favourable result in physical activity change. The instruments used to assess changes in physical activity were self-reported P.A. in the past 7 days before assessment, but none of the overseas studies used the PASE, and this measure may have provided more conservative estimates of PA change, compared to other self-report measures used in the other studies, because the PASE was not designed to detect change.

8.26 Predictors of Success for Weight Loss, Physical Activity and Diet

The multiple logistic regression models examined what factors were associated with longitudinal changes in the key program goal risk behaviours. The significant [adjusted] predictors of achieving the weight goal in SDPP were higher education, meeting the saturated

fat goal at 12 months and having the most telephone follow-ups after the intensive phase of the intervention. This suggests that continued support from the lifestyle officers might be needed to address and support complex change such as weight loss.

The strongest predictor of achieving the physical activity goal by the end of the Program was meeting the goal at baseline. This suggests that the Program may have helped people maintain their levels but did not induce many participants to increase their activity to the recommended levels of 210 minutes of moderate-to-vigorous PA. per week. Males were more likely (though not significantly) to achieve the goal than females. This 50-65 year-old group comprises mostly obese people, women, more than half had median to low education levels, were largely busy with two thirds still in employment, and the vast majority (over 90%) had at least one (median of two) chronic condition including anxiety and depression. These factors may have contributed to the poor performance despite episodic encouragement from the lifestyle officers.

After controlling for age, sex and intervention modality, the strongest predictor of achieving two or more dietary goals by the end of the Program was meeting the fibre intake goal at baseline. A negative correlation was also found where depressed people were half as likely (OR 0.47) to succeed at achieving their dietary goals than people who scored non-depressed on the HADS scale. The USDPP found that anxiety, emotional eating, perceived stress and binge eating severity were significantly correlated with baseline BMI.(262) The association between obesity and depression has been found to not be reciprocal in a large prospective study; that is, obesity is a risk factor for future depression but the reverse is not necessarily true.(299) The directionality of this relationship remains to be further elucidated, with longer follow-up assessment of both exposure and outcome indicators.

A small number of published studies have reported analysis of predictor of change, as the randomised controlled intervention design does not require adjustment for confounding. The Chinese DPP presented a proportional hazards model for their six-year outcomes, with development of diabetes as the outcome variable. It showed that baseline physical activity did not influence the risk reduction and the intervention type had only modest impact on the

predictive model.⁽⁹⁰⁾ This comparison, however, is not valid for the regression models examined in the Sydney study as the outcome variables in the SDPP analysis were changes in risk factors and not the incidence of disease.

8.27 Effect of Intervention Modality

Comparisons between the two intervention modalities offered in the SDPP, i.e. group sessions and telephone coaching did not yield substantial differences in terms of goal achievement, either individually or in total number of goals achieved. The multiple regression analysis suggested that being in the telephone coaching intervention group increased the odds of achieving the physical activity and dietary goals, whereas for weight loss, group sessions seemed to be more effective. However, people receiving the telephone coaching modality had higher baseline levels of activity and these differences were not statistically significant. The numbers of completers in the telephone coaching arm are still small and this may or may not change these relationships when the entire cohort has completed follow-up, so these data are provisional.⁶⁸ Nonetheless, these findings are interesting, and may not reflect effectiveness differences between intervention modalities, but simply be a marker of propensity to change for those selected into the study. This is a potential issue for the generalisability of the SDPP intervention.

However, it is worth examining studies that have compared different modes of intervention delivery in this area of disease prevention. Studies comparing face-to-face versus telephone lifestyle interventions are uncommon. A U.S. RCT of an intensive weight loss intervention for underserved communities in rural areas compared the 6-month impact of these two interventions with a third intervention consisting of written materials only. (295) Results indicated that weight loss at 6 months was over 9 kg in all three groups, and that weight regain at 1 year was the same for people in telephone and face-to-face interventions (1.2 kg) but higher (3.7 kg) in the control group receiving written education. Participants were females only and

⁶⁸ While the timeframe for this thesis precludes analysis of the complete cohort, quarterly reports produced during the course of the study indicate a very stable set of results with every update. Thus, no substantial changes in findings are expected later.

the interventions were delivered biweekly over the study period. The lack of significant difference in weight loss between intervention modalities is consistent with that of SDPP but the weight loss was greater in the more intensive U.S. counselling study, but again could reflect selection effects into the study. Another small RCT compared three counselling modalities in the US: high frequency face-to-face, high-frequency telephone, and low-frequency face-to-face.(294) The authors reported that the former two methods were equally effective and associated with a mean weight loss at 6 months of 8.9% and 7.7% respectively. People in the low frequency face-to-face counselling and those in a control self-help group experienced significantly less weight loss of 6.4% and 5.2% respectively. While this appears to be a better dose-response relationship than SDPP achieved, the trial had about 70 participants in each arm, all taking appetite suppressants, used block randomisation, had a 30% attrition rate and did not analyse by intention to treat. (300) Hence the evidence of effectiveness from this study [27] is debatable. The reference trials and some of their replication programs in the US have focused on multiple and frequent face-to-face interactions with supplementary telephone follow-up. One immediate explanation for the differences in outcomes between SDPP and the reference interventions is the intensity of the intervention and the frequency of the Finnish and US studies in terms of face-to-face and group contact with participants. With regard to weight loss achievement the Sydney DPP analysis found no dose-response relationship with the number of group sessions or telephone coaching sessions attended, but there was a significant positive association with the number of follow-up contacts after the intensive phase. This may support the hypothesis of improved outcomes following more frequent adviser or 'coach' contact. However, this association did not hold in the SDPP for achievement of either physical activity or dietary goals. In sum, the level of achievement of primary outcomes in the SDPP, and other translation studies at twelve months is not as great as that reported by intensive, structured lifestyle interventions conducted under strict randomised controlled situations. The percentage weight loss achieved was half that of the USDPP and FDPS reference trials. The dietary goal achievements were mixed, with the fibre intake increasing by similar amounts to FDPS but the fat reductions being

substantially lower than those found in FDPS and USDPP. Some of the dietary outcomes found in SDPP are similar to the Ballarat study but the Ballarat weight outcomes were higher, possibly due to the intensity of the intervention overall, and specifically the physical activity component. The number of sessions and weight outcomes of SDPP were similar to those in GGT but the WC reductions were more favourable for the Victorian program. Comparison with other Australian studies need to be interpreted with caution in light of the differences in intervention intensity, but there does appear to be some consistency between GGT and the SDPP, suggesting weight loss effect sizes that may be typical of Australian community-based DPPs.

8.28 Strengths of this Impact Evaluation

This translation Program made efforts to replicate the behaviour change components and goals of the reference trials, but to ground them in a real world context of program delivery. The SDPP collected detailed documentation of changes to all relevant parameters reflecting achievement of the five goals. While data are not equally complete for each indicator, participation rates in all components were high at baseline and final assessment.

Outcomes were partly based on objective measurements such as measured weight, waist circumference at 3 months and 12 months, and FPG or OGTT or HbA1c at baseline and final assessment to exclude known cases of or diagnose new diabetes. For the self-reported behaviours, there was high compliance with the physical activity questionnaire, food diary and the anxiety/depression screening tool.

The evaluation of the Program adds new knowledge on the effectiveness of formal, face-to-face group demonstrations sessions and telephone coaching (and the absence of both, i.e. where the effect of “initial consultation only” could be assessed). This can inform decisions on future design and cost of these community interventions when all participants have completed the Program.

Knowledge gained on the practical application of oral glucose tolerance tests for ascertainment of diabetes status was also informative. It became clear that despite understanding of the conditions of participation and objectives of the Program, most participants were not prepared

to go through an OGTT and instead preferred a single FPG or HbA1c measure, or refused to have a blood test. This is another important consideration for future planning of these interventions.

8.29 Limitations of this Impact Evaluation

This study also was affected by some design weaknesses which are inherent in the practical translation to real world settings. The absence of random selection of the sample led to a less generalisable sample of participants, compared to the underlying populations from which they were drawn. There were imbalances in the distribution of risk factors between the three intervention modalities, e.g. people who were more physically active at baseline chose to receive telephone coaching rather than attend group sessions. While the SDPP did not intend to prove efficacy, interpretation of comparative effectiveness is difficult unless further subgroup analyses are conducted. The size of the SDPP sample of completers as at 31 December 2010 did not enable this completely.

A further limitation of the SDPP is the self-reported nature of the changes in diet and physical activity, especially at the 3, 6, and 9 month intermediate data collection points. The baseline and 12 month collections used established and validated PA and dietary instruments, but these covered four of the five primary outcomes. This is not unlike the reference trials or other translation studies but the design can always be improved by incorporating validation studies in sub-samples of participants. The SDPP used an available validated self-reported measurement of P.A., i.e. the PASE questionnaire.(241) The SDPP also attempted to validate self-report with concurrent use of an accelerometer in a sub-sample of participants. Unfortunately only a small number of participants agreed to be part of an additional study that imposed more laborious participation. The feasibility of validation in routine clinical practice is worth exploring further. The difference in percentage participation in PASE, food record or anthropometric measurements at both baseline and 12 months for all participants may have minimised the chances of calculating change in all parameters for all completers. However, overall participation was very high (82% for PASE, 75% for diet and over 99% at both points for weight) and estimates of the Program goals could be largely calculated for the groups at each

time point. Estimation of the secondary outcomes of risk reduction from decreased FPG, cholesterol and blood pressure were limited by the incompleteness of these data. Few participants had an OGTT on completion, others had FPG and others only HbA1c. Some had different tests at baseline and final assessment times, precluding comparisons. Ten participants had their final interview by telephone and no blood test, so diabetes cannot be ruled out in them.

Short follow-up by telephone led to few follow-up data points and possibly played a role in the attrition rates of 23.6% including proactive withdrawals and unable to contact. This is comparable with loss to follow up in the Greater Green Triangle study,(117) and probably reflects the practical problems of conducting interventions through general practice, where only limited attempts can be made to contact participants due to lack of time and dedicated staff.

A challenge in comparing the SDPP's effectiveness with the reference trials is the lack of reporting of some risk reduction outcomes in those RCTs and the low comparability of some of the measurements used, especially for physical activity, and also for dietary intake. The lack of knowledge about associations between demographic and psychosocial factors in other programs is also limiting. Measuring all potential external confounders and effect modifiers is not practical or feasible. However, this analysis would usefully enhance the ability of both researchers to compare predictive models, and healthcare providers to modify interventions to suit particular subgroups or social circumstances.

8.30 Conclusions on the 12-month Impact Evaluation

Evaluation of the impact of a community-based translation study conducted in a GP setting in Australia is feasible, and produced small but consistent effects on risk factors for diabetes. In particular, the SDPP has had success at achieving half the target weight loss and maintained this for a year. Positive dietary modifications have also occurred, with decreases in fat intake lower than those achieved in the reference trials and fibre increases comparable with the reference trials. This highlights the real-world difficulties in making the translation of reference study effects on healthy lifestyles into real world community settings. There is also room for

improvement in the physical activity patterns of this middle-age SDPP group of high-risk participants. The quarterly qualitative self-report of adherence to diet and physical activity, which consistently indicated high compliance with both, was not corroborated by the more objective measures used at the 12-month assessment; nor did it translate into weight loss outcomes. Global self-report of lifestyle behaviours cannot be considered reliable for surveillance in this population sub-group, and detailed and validated measures are necessary. Most of the apparent improvements occurred in walking rather than in structured aerobic or resistance training, indicating participant preference for this activity. Formal 'brisk walking groups' might be included in future versions of the SDPP.

There does not appear to be a difference in the level of goal achievement according to intervention modality in the SDPP. The apparent effect of group sessions on the weight loss goal and the apparent effect on physical activity of the telephone coaching were not statistically significant. Two small studies in the US point to similar findings of no statistical difference in outcomes following either approach but the evidence is still unclear. One possible explanation in the SDPP is the size of the telephone coaching and "initial consultation only" groups. It remains to be seen if a large sample size with all remaining participants attending the final assessment will confirm or deny this hypothesis. Attending an initial consultation only, not followed by an intensive intervention, appeared to reduce the likelihood of achieving the weight loss and physical activity goals compared to attending group sessions or receiving phone coaching. However, it is too early to tell since the numbers of people in this subgroup were relatively small at the time of writing. Another possible reason for the lack of difference across intervention modality is that the skill of lifestyle officers at the initial consultation and follow-up calls may have sufficed to encourage and maintain participant's commitment to the Program even in the absence of further face-to-face contacts. This hypothesis is supported by the finding from multiple regression analysis that an increased number of quarterly contacts (perhaps a proxy for lifestyle officer's experience or Program intensity) independently predicted achievement of the weight goal. Finally, self-selection of participants more motivated to change

may have occurred at the baseline, and enrolment may itself result in less generalisable samples. The potential cognitive correlates of this, such as detailed measures of intention to change, might be included in further SDPP research.

Being active at baseline correlated with achieving the physical activity goal at the end of the Program. Predictors of 5% weight loss were lower saturated fat intake at baseline, high education and higher number of contacts with the lifestyle officer. Higher fibre consumption at baseline independently predicted meeting two or more dietary goals at one year.

The preliminary findings for 586 completers to December 2010 are likely to be similar for the full sample when followed to the end of 2011. Earlier preliminary impact data from substantially smaller numbers of SDPP completers were consistent with the present findings.

The outcomes of this translation study at 12 months are not dissimilar to other translation studies in Australia, but real-world programs where participant-lifestyle coach interactions do not match the intensity and frequency of the *reference trials* appear to achieve around half the success of the reference trials in terms of key risk reduction indicators.

Chapter 9.

Economic Appraisal of the SDPP

Summary

This chapter describes the resources expended on the planning and implementation of the Sydney Diabetes Prevention Program (SDPP) for baseline and 12-month follow-up to the end of recruitment in July 2010. It also covers the completeness of data for follow-up until the end of December 2010 and discusses the difficulties in conducting real-life economic analyses. In addition to financial spreadsheets from Divisions and central management at the Department of Health, data sources consulted included the online lifestyle officers' database, the baseline and final CATI database and the 3-month follow-up database.

This analysis examines costs and outcomes from the perspectives of the health system and participants, noting that the participants' perspective is limited. As most participants will finish the Program between late 2010 and mid 2011, at the time of writing this chapter, 586 of the 1,250 (47% of enrolled participants or 61% of participants eligible to attend final follow-up) had completed the 12-month assessment. Of these, 579 had complete weight data, 527 had complete physical activity data and 449 complete nutrition data. Comparisons are made with the findings of the reference trials and with selected community-based or general practice-based translation studies that reported relevant indicators.

The complete results in terms of costs and outcomes at 12 months are beyond the scope and timeframe of this thesis because this evaluation covers three years of the Program from inception in 2007 to follow-up in December 2010, and the Program experienced recruitment and follow-up delays beyond the timeframe of this PhD candidature. However, comments on resource implications of a state-wide roll-out will be presented in the discussion and conclusions sections.

9.1 Introduction

The high cost to the health system of managing diabetes and its long-term complications is well established as is the condition's impact on productivity, permanent disability and premature death. (12, 15) A recent estimate from the International Diabetes Federation maintains that in 2010 medical care for diabetes used 11.6% of the world's total health care expenditure. Since there is ample evidence that lifestyle interventions can delay or prevent the onset of diabetes (see Chapters 2 and 3), it is important to discuss the resources required to prevent the disease as well as reduce risk factors before prevention can be confirmed. A number of economic evaluations have been published detailing the comparative cost and effectiveness of diabetes prevention programs. (91, 301-305)

9.2 What Is An Economic Evaluation?

Economic evaluations present comparisons of two or more healthcare interventions in terms of their costs and consequences, (306) whether these are benefits or adverse events. All of the reference trials reporting economic evaluations of diabetes prevention programs have published cost-effectiveness analyses. These are defined as evaluations of alternative interventions where uni-dimensional outcomes compared are expressed in terms of natural units (306) such as new cases of diabetes, or changes in body mass index or death. Lower cost-effectiveness ratios are preferred, as they indicate that more benefits can be generated with that treatment choice.

Economic evaluations can present results from the health system perspective or from the societal (patient and family) perspective. Gains from a health systems perspective if diabetes is prevented or delayed would mean a minimization of the cost of blood glucose monitoring, treatment, nutritional coaching and management of complications, From a societal viewpoint, gains would include lower out of pocket expenses due to reduced medical costs, less time off work, and less impact on the family in terms of expenditure on transport, , time devoted to medical appointments, caring etc. (307)

The importance of economic evaluations is that their results assist public health policy-makers to make informed decisions concerning the efficient allocation of resources to improve population health. (304, 305, 308)

9.3 Cost-Effectiveness of Diabetes Prevention Programs

The cost-effectiveness of diabetes prevention through lifestyle intervention has been well established in industrialised and developing settings. In 1998, an Australian study found that dietary interventions to change behaviour in people with IGT were highly cost-effective at between A\$720 and A\$2,600 per life-year saved.(309) A Canadian study published in 2004 concluded that intensive lifestyle intervention could prevent 117 cases of diabetes over a decade and cost CAN\$749 per life-year gained.(301)

Most published studies have addressed exclusively the health system perspective, but others have also covered a partial patient perspective. Most have also based their calculations on computer simulations.

Studies of the cost-effectiveness of the Diabetes Prevention Program in the US used lifetime simulation models assuming the future progression of disease or non-disease states over 30 years if high-risk people had been exposed to the lifestyle intervention as compared with the hypothetical 'no intervention' group. The authors calculated costs based on real medical and non-medical cost data collected over the three-year intervention. (14) Outcomes examined included the annual cost to the health plan (modified health system perspective) as a function of the annual cost of the lifestyle program, the difference in diabetes incidence and its complications between the groups 'with and without' lifestyle intervention, and the cost per quality-adjusted life year.⁶⁹ Lifestyle intervention was estimated to delay the onset of diabetes by an average of 11 years and the cost per quality-adjusted-life-year (QALY) was US\$1,100. The authors concluded that the lifestyle intervention was cost-effective in all age-groups, and cost-effectiveness was better when implemented in a system resembling routine clinical

⁶⁹ A summary measure of health gain that combines life expectancy and quality of life [Shiell 2002]

practice.(14) Earlier investigation of costs of the US DPP examined the direct implementation costs from screening to final assessment as well as the cost of surveillance of complications and medical care beyond routine care over the three years of the program.(310) The comprehensiveness of this evaluation included also direct non-medical costs or 'out-of-pocket' expenses to participants for attending appointments, cooking special meals and purchasing exercise equipment and societal costs of illness and injury or long-term disability. At the end of the 3-year follow-up in USDPP, the direct medical and other program costs of the lifestyle intervention including screening for IGT were US \$2,919 per participant.

The FDPS has not published a cost per outcome or implementation cost study. However, recently its researchers assessed the cost-effectiveness of prevention of diabetes by using data on the risks of moving from IGT to another state of health from the Finnish DPS and that on the risks of complications based on the UK Prospective Diabetes study applied to a Swedish population. Their results indicate that diabetes prevention through intensive lifestyle intervention prolongs life by 0.18 years and the cost-effectiveness ratio expressed in 2003€ yielded €2,363 per QALY gained.(303)

In their economic analysis, Indian DPP researchers only covered actual, direct medical costs as the non medical and indirect costs were not collected during the intervention. Direct medical costs for the lifestyle arm of the Indian study included salaries for implementation staff, laboratory costs, transport to deliver the program at workplaces and participants' homes, cost of group sessions, and telephone calls related to follow-up or appointment confirmation. (266) The direct costs of screening to identify an eligible subject in India were calculated at A\$116 in 2007. The cost if the lifestyle intervention after 1 year was estimated at \$A85 per participant with the largest component of the expenditure being staff costs. The authors acknowledged that the costs of intervention gradually decreased in the second and third year but were higher in the first year due to the blood tests, screening and multiple phone calls to establish the relationship with the participants. They expected to find different cost-effectiveness ratios given the great variations in the availability and cost of health care in resource-poor countries and

this was confirmed, by comparison with the USDPP results above. The reported number needed to treat to prevent one case of diabetes in India was 6.4.

Generally then, information about implementation and other costs associated with the intermediate outcomes of lifestyle interventions is not necessarily widely published. In this thesis I argue that it is important to estimate both costs and their relationship to intermediate outcomes (ie. behaviour change) because this type of appraisal constitutes the basis for cost-effectiveness analysis in the real world. Further, lifestyle interventions including diet and physical activity have the potential to prevent not only diabetes but other chronic and costly obesity-related conditions such as hypertension and coronary heart disease.(311) For instance, the financial cost of obesity and its associated conditions (diabetes, cardiovascular disease, osteoarthritis and cancer) in Australia was estimated at A\$3.7 billion in 2005. This included costs to the health system, carers, individual productivity, government subsidies and other indirect costs. (312) Data sources consulted covered the costs to patients, their family and friends, all levels of government and other members of society. If a lifestyle modification program such as the SDPP can reduce obesity by even a relatively small amount,, the human and financial gains at a population level are likely to be substantial.

9.4 What the Economic Appraisal of SDPP Will Cover

While information about the cost-effectiveness of preventing diabetes in the context of a clinical trial is readily available, less is known about the resources required to translate these results to the real world. A recent study based on valid population data found that the conduct of these programs in clinical practice is associated with high total costs while the number of diabetes cases prevented could be low. (313) The findings of this study incorporated the level of participation and adherence, which are not usually accounted for in studies assessing costs. Funding from NSW Health was provided to the Sydney Diabetes Prevention Program to cover salaries of lifestyle officers and the administration team, practice incentives, laboratory testing, transport, training and program materials. However, information about the actual resources required to implement the SDPP and their relationship to Program outcomes was not known.

This was of interest to policy makers and planners for the purposes of understanding what would be needed if the SDPP were to be expanded beyond the pilot stage. The evaluation team proposed the following research questions for this economic appraisal of the SDPP:

1. What are the costs to the health system of planning and implementing this community-based program?
2. What are the costs of the group-based lifestyle modification sessions?
3. What are the costs of the individual telephone-based lifestyle program?
4. What is the cost of follow-up and final assessment?
5. What are the costs per outcome and do they differ by intervention modality?
6. What are the costs to individual participants?
7. How feasible is the conduct of an economic appraisal in routine clinical practice?

This chapter will describe the costs reported predominantly from the health service perspective as follows:

- Costs of set up and development of the SDPP, at the levels of both the Program Implementation Team and the Divisions of General Practice
- Costs of discrete program modalities (groups vs. individual telephone module)
- Level of utilisation of health services and medication based on self-report are included in the chapter as a comparison between baseline and the end of the Program
- Limited participants' costs

Costs and outcomes have been compared and are reported as:

- Cost per kilogram of weight lost
- Cost per Program goal attained

9.5 Methods

A variety of methods was used to collect and examine financial data for this appraisal, with a focus on the costs to the health system. Each Division had an existing template for financial reporting and this was modified to enable 6-monthly retrospective expenditure reports. The items collected and their respective sources are described below.

9.6 Health System Perspective

The costs included in this analysis were calculated from the perspective of the NSW Health Department. However, a number of pertinent utilisation and costs issues from the broader health system perspective outside the Program requirements such as GP's time and consultation type, emergency department attendance, hospitalisation, costs of tests and medications were covered by the Australian health insurance scheme (Medicare);(314) [some of these are presented separately in this appraisal as an indication of the cost if these items were to be included in a program budget.

Limited participant costs were collected but they do not constitute the core of this analysis.

They are addressed separately in Appendix 9.1

9.7 Data Sources

The data used to calculate the costs, utilisation and outcomes were obtained from a number of sources.

9.7.1 Costs of planning the Program

The costs associated with set up and development of the SDPP were estimated using summary reports from relevant Division staff. Calculations included salaries of liaison officers, on-costs, recruitment costs, and the costs of transport and catering required during the early phase of the project when participants had not been recruited. These costs were incurred when teams were meeting to discuss practicalities, negotiating screening and recruitment approaches, venues to conduct group sessions, equipment and incentives, designing, refining and pilot testing instruments and Program materials.

The costs associated with time spent on the Program by Central NSW Health advisors and BIONE⁷⁰ Program management staff were self-reported by staff using their records and are reported separately and are excluded from the total implementation calculations to better reflect the local cost at the Division level. This is because it is assumed that if the Program is

⁷⁰ Boden Institute of Obesity, Nutrition and Exercise, University of Sydney

rolled out more widely, these planning and supervision costs will either not apply or be greatly reduced.

The costs associated with screening of participants were estimated using award-based current hourly rates for lifestyle officers multiplied by the estimated time LOs spent in scheduling and conducting screening using the Ausdrisk tool. The costs of blood tests and GP consultations associated with Program participation were considered separately because these were generally covered by Medicare and not by the SDPP. Estimates were made using the published payments used by the Australian insurance scheme for medical services, the Medicare Benefits Scheme. (314)

9.7.2 Costs of implementing the Program

Implementation costs were divided into 'set-up' and 'steady' implementation phases to better reflect the intensity of screening and active recruitment. While screening still occurred in subsequent months, the *early implementation phase* was assumed to be the first three months of involvement at each Division regardless of year of commencement. The early phase occurred in the last quarter of 2008 for Southern Highlands and Macarthur Divisions and in the first quarter of 2009 for Central Sydney. Set up costs were based on records from actual expenses and included: staff salaries, salary on-costs, GP launch/advertising, practice allowance, travel, rent, catering, supplies, administration support, management, it/contractors, maintenance/overheads, & staff/GP training. Numbers of participants enrolled in this phase included the pilot participants from Macarthur and Southern Highlands Divisions.

The 'Steady State' phase comprises the period from the 4th month of implementation until the end of recruitment. Costs associated with this phase include any relevant Division level expenditure incurred from the time of more active participant recruitment into the roll-out Program (i.e. non-pilot) to the time of final assessment at twelve months. They cover follow-up and 12-month review costs of enrolled participants up to the end of recruitment. Screening commenced in July 2008 and ended in June 2010. Recruitment commenced in September 2008

and ended in July 2010 (Appendix 9.2). The specific costs calculated in this chapter are shown below.

9.7.3 Costs of participant recruitment and follow-up, and GP recruitment

Overall, implementation included costs of advertising strategies, GP training, the time lifestyle officers spent inviting, scheduling and conducting initial consultations, salary on-costs, practice staff payments, overheads such as telephone calls for follow-up and appointment schedule, the costs of printing and distributing materials, and GP incentives for each participant referred, plus costs of launching the Program at each Division.

9.7.4 Costs of running groups and individual module

Average estimates of the costs of conducting group sessions were based on the data provided by Divisions which covered lifestyle officer salaries and on-costs, and when relevant also included transport and hire of equipment for the group sessions, rent and catering. The costs of delivering individual phone coaching were based on the price charged by Australian Diabetes Council to cover staff salaries and telephone calls.

The costs associated with the program components in 9.7.2 and 9.7.3 were estimated using the financial summaries from each of the Divisions of General Practice (see Appendix 9.3).

9.7.5 Costs per outcome

Average costs were calculated using the sum of costs in the implementation period for each Division and intervention modality [as per 9.7.3 and 9.7.4 above] for all completing participants divided by the sum of outcomes at the end of the Program (e.g. sum of kg lost by all completers) for each intervention modality (group sessions, phone coaching, neither).

The number needed to treat in order to achieve a goal was estimated by dividing the total cost of the intervention for completers by the number achieving a particular goal (e.g. (cost per participant \$ x number of participants completing 12-month review) /number of participants achieving PA goal)).

9.7.6 Resource use associated with use of health services and medication

Information about the number of emergency department presentations, GP visits, specialist consultations and hospital admissions was collected at baseline and 12 months.

Information regarding utilisation of health services, medication and costs borne directly by participants was obtained by telephone from the CATI surveys conducted within two weeks of enrolment and again within two weeks of the final assessment.

Question 1 *What are the costs to the health system of planning and implementing this community-based program?*

9.8 Results

Participant recruitment commenced in September 2008 for Macarthur and Southern Highlands Divisions and in March 2009 for the Central Sydney GP Network. A total of 1,250 mainstream, 84 Arabic and 79 Chinese non-pilot participants were recruited between September 2008 and July 2010.

9.9 Costs of Planning the Program

9.9.1 Start up & planning phase including screening

During the start-up phase from February to June 2008, the Program Implementation Team spent 100% of their time developing protocols and Program resources, liaising with stakeholders, setting up infrastructure, and managing governance, working groups and committee meetings. Time spent in evaluation activities commenced after June 2008. From July to December 2008 these staff were engaged in designing and testing the online database, recruiting staff, refining program content, training lifestyle officers, and travelling to Divisions to provide ongoing support at the early stages of participant recruitment. Planning for the CALD cohorts commenced in 2009 and included design and translation of Program resources, development of databases and staff hiring and training. For the 18 months from January 2009 to June 2010, less intensive planning took place and the Program implementation team spent 50% of their time in the first 6 months of 2009 and 10% of their time in the financial year July 2009 to June 2010 on planning. Thus planning has been a continuing, although gradually declining

activity until June 2010 when recruitment of all 1,413 participants from the three streams ceased. The cost of planning from 2008 to 2010 covered implementation staff salaries, transport costs and all the items specified above. Overall this cost was equivalent to \$502.72 per participant enrolled.

Program participation required an initial consultation for risk tool screening and health assessment and to obtain a request for a blood test and a second consultation within a few weeks to confirm the absence of diabetes and for the GP to write a referral to the Program; The costs of screening tests before enrolment and the repeat blood test to rule out diabetes at the end of follow-up were covered by the Australian public health insurance system (Medicare).

According to the Program protocol, these included one oral glucose tolerance test (OGTT)⁷¹ at baseline and another at follow-up. Not every potential participant agreed to undergo two OGTT tests and the Program accepted participation based on a single fasting plasma glucose (FPG) test⁷² at both time points if the results were below 5.5 mmol/L (85% of all participants had one FPG test but in 34% of all enrolled, FPG was the only test used for entry into the Program).

For the purposes of estimating the costs of GP consultations, it was assumed that all consultations were standard consultations of more than five minutes but less than 20 minutes duration⁷³. If the general practitioner “bulk-billed” for such consultations the cost of this consultation is fully covered by Medicare (the Australian universal health insurance scheme) and patients do not face any out-of-pocket costs. Although this was not always the case for doctors participating in the SDPP, for the purposes of this exercise, universal bulk-billing has been assumed to occur.

⁷¹ Medicare item number 66542, fee \$19.10 and average cost borne by the government \$15.30

⁷² Medicare item 66500, fee \$9.75 and average cost borne by the government \$7.80

⁷³ Medicare item number 23 for a single Level B consultation, Group A1, fee \$34.90 and full cost borne by the government

Table 9.1 shows the numbers, type and cost per type and number of people attending GP consultations in the course of screening. Large proportions (53%) had a CBG and only 6% did not require a further test. The majority had an FPG and no blood test costs were incurred by the Program for 19 patients who had available FPG or OGTT results from less than three months prior to entry to the Program. However, Medicare only covered the cost of one FPG or one OGTT per year if the results were normal. If results were abnormal, a repeat test at the four-month GP visit was subsidised.

If the prevention program had been responsible for covering these costs, the average cost to the health system for these single and repeat tests on 2005 people with Ausdrisk ≥ 15 would have been \$138,623. As the screening process needed to test 3 people so that two of them could enrol in the program, the cost of enrolling 1250 people would have been A\$126 per person enrolled

Table 9.1 Estimated screening cost to the health system: blood tests and GP consultations

Test type	Cost per item (A\$)	Number of tests required	Cost per person (A\$)	# people undergoing test	Total cost (A\$)
Capillary Blood Glucose only ^β	0.5	1	0.5	86	43.00
CBG + another test ^α	0.5	1	0.5	573	286.50
Fasting Plasma Glucose	9.75	1	9.75	1062	10,354.50
Oral Glucose Tolerance Test	19.1	1	19.1	359	6,856.90
Previous blood test result	0	1	0	19	0
GP (Level B) consultation ^Ω	34.9	2	69.8	1986	138,622.80
GP (Level B) consultation	34.9	1	69.8	19	1,326.20
Overall cost of screening 2005				2005	\$157,489.90
Cost/person to enroll 1,250 participants				1250	\$ 125.99

^β "This SDPP estimate assumed \$50 cost/100 CBG strips to the health system based on the National Diabetes Services Scheme. (315)

^α 659 in total had CBG, of whom 86 had CBG only

^Ω 19 attended only one consultation as they had a recent test result and could be referred after one visit

9.9.2 Implementation phase including recruitment

Between July 2008 and June 2009, the implementation team increased their involvement in training GPs, conducting review days with lifestyle officers, tracking and monitoring progress, and attending Division meetings, spending 40% of their time on these activities. While participant recruitment gradually commenced from September 2008, the intervention team's time commitment to these activities escalated to 70% from July 2009 to June 2010. The discrete

cost of the implementation team during this '*steady state*' was equivalent to \$389.10 per participant enrolled.

Involvement of the two members of the NSW Health Department in providing advice and negotiating with partners continued for 2 hours/week for each staff member. The cost of this technical support during the implementation phase was \$11.95 per participant enrolled during this "steady state".

9.10 Costs of implementing the Program

The implementation phase of the SDPP extended from July 2008 to July 2010. The total costs incurred by each Division as part of implementing the SDPP included the resource use associated with: staff salaries, staff training, equipment, infrastructure, GP payments, delivery of group sessions and phone coaching, consumables and overheads associated with Program advertising and delivery (communication resources, rent for training venues, distribution of materials to GPs and participants, follow-up phone calls and goods and services associated with ongoing delivery of the Program by Divisions e.g. catering, photocopying, etc).

9.10.1 Overall Program costs

The large variation in implementation costs per Division seen in 2008 (Table 9.2) reflects the different stages of preparedness and available infrastructure at Divisions to run the Program. It also reflects the number of GPs trained, the total number of participants enrolled, and the number of staff employed to meet the screening and recruitment targets. The total number of participants enrolled includes participants enrolled in the pilot phase in addition to those enrolled in the definitive Program.

Table 9.2 Recruitment activity and implementation cost per participant enrolled in the early implementation phase and the *Steady State*, September 2008-July 2010 (total definitive participants N=1,413 and 40 pilot participants).

Division	Early implementation phase cost including planning & set-up Sept-Nov 2008 for Macarthur and Southern Highlands, Jan-March 2009 for Central Sydney		Steady state Cost excluding planning & set up January 2009-July 2010	
	Number enrolled	Cost per participant enrolled	Number enrolled	Cost per participant enrolled
Southern Highlands*	39	\$1,203	348	Mean \$1,256 (or \$1,125 excluding GP incentives)
Macarthur*	48	\$1,669	253	Mean \$2,457 (\$2,360 excluding GP incentives 09-10)
CSGPN	73	\$1,484	662	Mean \$1,289(or \$1,136 excluding GP incentives)
Total	190	\$1,123	1263	Overall mean \$1,667 (or \$1,540 excluding GP incentives)

+ cost per month depending on # participants enrolled

* No monthly expenditure provided, just a six-monthly summary provided by the Division for the first three months

Between 2008 and 2010, the cost per participant enrolled varied from month to month due to fluctuations in recruitment activity in Divisions. The cost per participant in the *steady state* is higher than the cost of the *early implementation phase* because it includes cost of attending groups or receiving phone coaching, and cost of follow-ups and final assessment. It is worth noting that these average estimates per participant include all the work associated with inviting and screening a large number of people who may eventually not be enrolled in the Program due to ineligibility or refusal.⁷⁴ The proportion of the total cost associated with staff salaries and GP incentives was on average 45% in Macarthur Division, 61% in Southern Highlands and 67% in Central Sydney over the course of the steady state of the SDPP.

Question 2 *What are the costs of the group-based lifestyle modification sessions?*

9.10.2 Cost per intervention modality

9.10.2.1 Initial consultation

Between September 2008 and July 2010, 1,250 mainstream participants were recruited into the Program, with distribution by Division as follows: 387 in Southern Highlands, 301 in Macarthur,

⁷⁴ Data to 31 July 2010 indicates that 34% (1,413/4,150) of those screened joined the program. This includes mainstream and CALD participants

and 562 in Central Sydney. The initial consultation was usually a 90-minute event with only one lifestyle officer present at a venue that could be co-located at the Division or at rented premises outside the Division building. Hence in some instances, travel costs are incorporated into the costs of the initial consultation. Overall the cost per participant of the initial consultation was \$176 when transport was included (Central Sydney) and \$156 when transport costs were not incorporated (Macarthur and Southern Highlands).

9.10.2.2 Group sessions

Between 2008 and 2010, 2,867 person-sessions were delivered at 595 group sessions in three Divisions (Table 9.3). Divisions of General Practice conducted varying numbers of group sessions for all participants ranging from two to four sessions per month in 2008 increasing to between two and 16 sessions per month in 2009. As most participants completed the Program in 2009 in Southern Highlands and Macarthur Divisions, 0-6 group sessions per month were conducted in 2010 in these two Divisions. In contrast, many of Central Sydney's participants were recruited in late 2009 and early 2010, hence, in this Division, an increase was observed in the number of group sessions per month (from 7 to 25) in the most recent year.

Table 9.3 Number of group sessions conducted and number of people attending by Division of GP, Sep 2008-Oct 2010.

Division	Groups sessions 2008		Group sessions 2009		Group sessions 2010	Person sessions 2008-2010	
	# People attending any number of groups	# groups	# people attending any number of groups	# groups	#	Attending any groups, all years	
Southern Highlands	57	8	418	54*	197	32	672
Macarthur	68	12	563	99	58	13	621
Central Sydney	0	0	491	90	1,083	287	1,574
Total people (column sum)	125	20	1,472	243	1,338	332	2,867

** estimated from online database as Division records available were incomplete*

Although the mean number of participants per group appears larger in Macarthur, the median and interquartile distribution was very similar across Divisions (Table 9.4). Average rates of attendance (i.e. proportion of those booked to attend who actually attended) at group sessions

varied with Central Sydney having the highest overall attendance rates and Southern Highlands conducting more group sessions with three people or fewer per occasion in the first year of the Program, followed by Central Sydney. While a trend was observed in terms of declining attendance rates from the second half of 2009 at Macarthur Division, this did not occur at the other two Divisions. The number of participants attending per session almost doubled in the second half of 2009 at Southern Highlands, and exhibited random variations across sites in Central Sydney.

Table 9.4 Participation rates in group sessions by Division of GP, 2008-2010

Indicator	Distribution within Division 2008-2010		
	SH	Mac	CS
Total recruited (N=1,413)	387	301	725
% Attendance rates at group sessions out of those booked (mean & interquartile range)	60% (range 10%-100%)	73% (range 0%-100%)	83% (range 25%-100%)
Mean/median (IQR) participants /group	6 / 6(5-7)	13/ 7 (4-9)	6 / 6 (4-8)
Completion rates -all 3 groups N (% of all recruited within Division)	159 (41%)	200 (67%)	425 (59%)

SH= Southern Highlands Mac=Macarthur CS=Central Sydney

Between 2008 and 2010, the average proportion attending at least one group session was 84.5% among those choosing groups across the three Divisions; the average completion rate for three group sessions was 55.5% overall, with Southern Highlands having the lowest rate of completion of the group Program. While the reason for lack of attendance to any group session is mostly unknown (question introduced late), the most frequent reasons reported to date are family commitments and illness or injury.

The average minimum cost of a group session including only salaries for two lifestyle officers per session plus catering expenses is estimated at \$249 across all Divisions.⁷⁵ In Southern Highlands, the cost per group session is \$296.60. These costs do not include the cost of producing handouts or materials supplied to participants as specific details on the costs of these items for the group sessions are not available. The average cost per participant of conducting group sessions across Divisions is \$39.75. They are quite similar between Southern Highlands and Macarthur Divisions. Variations in the cost per participant in Central Sydney are due to larger numbers of people attending each scheduled group session in Southern Highlands, and smaller numbers per group session attending in Central Sydney (Table 9.5).

Table 9.5 Cost of running group sessions by Division of GP, 2008-2010.

Division	Number groups run			Average cost per group session in 2008-2010	Total participants	Cost per Group per participant (mean)
	2008	2009	2010			
Southern Highlands	8	54	20	\$296.60	655	\$37.15
Macarthur	12	90	13	\$221.30	689	\$37.40
Central Sydney	0	79	287	\$228.94	1209	\$44.70

The Program catered for each consenting participant to attend the three group sessions offered. However, presentation by individual participants to all or some of the sessions varied even after participants agreed to attend (Table 9.6). The cost of 77% participation in groups for Southern Highlands was \$10,136; the cost of 85% participation in Macarthur was \$9,421; and the cost of 88% participation in groups in Central Sydney was \$18,206. While larger total numbers of people attended groups in Central Sydney, many more sessions were required due to the smaller number of participants attending each session.

⁷⁵ The cost is regardless of whether attendance was 1-10 people or nil participants scheduled as lifestyle officers and catering expenses were already incurred before participants arrived unless the session was cancelled in advance.

Table 9.6 Cost per attendance at group sessions by Division of GP (Mainstream participants only), 2008-2010.

Division	# people who attended the groups in 2009-2010 ^a			Cost for the Division by participant attendance to all or some group sessions		
	1 Group	2 Groups	3 Groups	1 Group	2 Groups	3 Groups
Southern Highlands (chose groups N=330; attended N=255)	33	55	167	\$1,312	\$2,186	\$6,638
Macarthur (chose groups N=279; attended N=237)	12	25	200	\$477	\$994	\$7,950
Central Sydney (chose groups N=519; attended N=458)	40	90	328	\$1,590	\$3,578	\$13,038

^a Distribution of people who did not attend group sessions including those receiving telephone coaching: Central Sydney =104, Macarthur=64, Southern Highlands=132.

Question 3 *What are the costs of the individual telephone-based lifestyle program?*

9.10.3 Individual Module

Individual phone coaching by the Australian Diabetes Council was introduced in 2009. By 30 June 2010, 122 participants had chosen the individual coaching sessions; 119 (98%) actually participated and received between one and three calls each (IS1, IS2, IS3 in Table 9.7). The median duration of one coaching call was 30 minutes (interquartile range 23-36). Table 9.7 shows that participants in Southern Highlands opted for individual phone coaching more often than participants in other Divisions. Overall the rate of completion of the three coaching phone calls was 68% across the Divisions with Macarthur achieving the highest completion rates.

Table 9.7 Participation in phone coaching activity by Division of GP and session number in 2009-2010

Division	N (%) people who chose individual module*	# people who actually received individual module in 2009-2010			Person sessions	% received all 3 calls
		IS1	IS 2	IS 3		
		All				
Southern	57 (14.7)	55	42	37	134	67%
Macarthur	22 (7.3)	22	17	17	56	77%
Central Sydney	43 (5.9)	42	34	29	105	69%
		119	93	83	295	

*Percentage of those enrolled in the respective Division
IS1,2,3= Individual session #1,2,3

The cost of individual phone coaching conducted by the Australian Diabetes Council lifestyle officers per successful contact includes the cost of phone calls and lifestyle officers' time. At a flat rate of \$35 per each successful initial or follow-up contact [IS1, IS2 and IS3], the total cost of this service provided to June 30, 2010 was \$10,325 for 295 phone coaching sessions. The cost of individual module per person [\$35 per session] appears to be similar to the average cost per participant per group session shown in Table 9.5.

Question 4 *What is the cost of follow-up and final assessment?*

9.10.4 Follow-up calls and final assessment

The remaining components of the Program, i.e., follow-up phone calls and final assessment are covered in the overall Division costs. Actual data on discrete cost per individual initial assessment and final session including on-costs and travel expenses are not available. However, an estimate of this cost using only the time (salary, pro-rata on-costs and telephone calls) spent by a lifestyle officer on each of the activities and data entry following the participant contact, suggests that each of the quarterly follow-up calls cost \$71, for a total of \$213 per participant if all three contacts are established. The final 12-month assessment with the lifestyle officer cost \$154 including time spent on scheduling the appointment, preparing paperwork, conducting the final assessment and coaching, entering data and obtaining blood test results from the GP. Finally, all participants were required to attend a follow-up consultation with their GP at 12 months to discuss the results of the follow-up blood test. As at December 2010, 586 participants had completed the final assessment (7 by telephone, 579 presented in person); 295 (24% of enrolled) had not presented for their final assessment either due to withdrawal from the program or were unable to be contacted. The majority of completers (88%) had an FPG, An additional 7% agreed to have HbA1c⁷⁶ (cost covered by the SDPP Program) and only 4% had an OGTT.

⁷⁶ cost of HbA1c as per Medicare Benefits Schedule at the time of the study was \$16.90

Table 9.8 Estimated cost of per participant attending the final assessment by GP and lifestyle officer as per protocol

Component	# people	cost per unit (A\$)	total (A\$)
FPG	517	9.750	5,040.75
OGTT	22	19.10	420.20
HbA1c	40	16.90	676.00
GP (Level B) consultation	579	34.90	20207.1
Plus lifestyle officer cost	579	154.00	89,166
TOTAL for all attendees			\$ 115,510.05
Average cost per participant			\$ 351.12

If the Program had covered the blood tests and GP consultation, in addition to the Lifestyle officer time, the average cost of items pertaining to the final assessment per participant would have been \$351.12.

Question 5 *What are the costs per outcome and do they differ by intervention modality?*

9.11 Cost per Outcome of Interest (12-month completers only) 2010

As of 31 December 2010, 586 people had completed their participation in the Program and 578 had objective weight measurements at both time points. Sixty seven percent of completers (386/586) had lost some weight, with 57% of completers losing at least 1 kg and 4% losing over 10 kg.

The average weight loss for all of these completers (including people who lost, gained and did not change weigh) was 2.1 kg (95%CI -2.4 to -1.6) and total weight loss for the group was 1193.4 kg, with all Divisions achieving similar levels of weight change, i.e. no statistically significant differences across Divisions (Table 9.9).

9.11.1 Cost per kg lost

Of the completers, 92% in Central Sydney, 95% in Macarthur and 83% in Southern Highlands had attended at least one group session (N=411 for the three Divisions). Of the remainder, 31 people had received phone coaching and 14 did not receive either intervention. Costs presented here have catered for these differences.

Note that the average cost per kg lost by Division ((a) in Table 9.9) also includes the costs for participants who had gained weight by the end of the Program. However, when only those

participants losing weight in relation to baseline are included in the appraisal ((b) in Table 9.9), the mean weight loss for this subgroup was higher (95%CI -5kg to -3.7kg) and the cost per kg lost among successful completers was at least 50% lower than the cost per kg lost for the overall completers. This sub-group analysis indicates the best case scenario that could inform future roll-outs of this Program if they are delivered to highly motivated people likely to achieve some weight loss.

The overall cost per kg lost appears to be lowest in Southern Highlands and highest in Macarthur Division but the pattern of lower cost for the subgroup achieving any weight loss remains across Divisions. In general, it also appears that at the end of the Program, the cost per kg lost is higher among those attending group sessions than among people receiving individual phone coaching, particularly in Macarthur. Since the cost per person of sessions and coaching calls is similar, this difference in cost per outcome could reflect the fact that *on average* participants attending group sessions lost less weight per person than participants receiving phone coaching. However, after examining the 95% confidence intervals, it becomes clear that only people attending group sessions experienced significant weight loss (i.e. 95% CI did not include weight gain), whereas the estimates for telephone coaching and non-intervention subgroup show that the 95% CI crosses zero and includes people experiencing weight gain (Appendix 9.4).

Of note, in Macarthur and Southern Highlands the mean weight loss appears to have been greater for people not attending either individual or group sessions. This is an artefact driven by a small number of people in the “non-intervention” subgroup who lost a large number of kg (two outliers in Southern Highlands lost over 15 kg each and one in Macarthur lost 8 kg).

Table 9.9 Cost per kg of weight lost overall and by Division and by intervention type for all completers and for completers losing weight by the end of the Program

Division of General Practice	N completed	a) Mean and (total) weight change in kg for all completers	Cost per kg lost for all completers	N losing any weight	b) Mean and (total) weight loss in kg for weight losers only	Cost per kg lost for weight losers only
Overall	578	-2.1 kg (-1,193.4 kg)	\$807.55	386	-4.2 kg (-1,611.2 kg)	
Attended groups	516	-2.0 (-1,033.8)	\$832.20	341	-4.2 (1,415.2)	\$401.75
Phone coaching	43	-2.5 (-108.9)	\$656.50	32	-4.2 (-134.5)	\$395.60
Initial consul only	19	-2.7 (-50.7)	\$609.95	13	-4.7 (-61.5)	\$344.00
Southern Highlands	198	-2.2 (-443.4kg)	\$560.90	132	-4.4 (-586.6kg)	
Attended groups	161	-2.3 (-376.6)	\$536.95	107	-4.6 (-492.7)	\$272.80
Phone coaching	23	-1.1 (-25.8)	\$1,117.80	15	-3.0 (-44.8)	\$419.80
Initial consultation only	14	-2.9 (-41.0)	\$416.20	10	-4.9 (-49.1)	\$248.4
Macarthur	192	-2.2 (-417.9kg)	\$1,025.10	131	-4.2 (-549.4kg)	
Attended groups	182	-2.1 (-375.6)	\$1,070.50	122	-4.2 (-506.6)	\$591.70
Phone coaching	7	-4.3 (-29.9)	\$574.70	6	-5.1 (-30.4)	\$484.50
Initial consultation only	3	-4.1 (-12.4)	\$585.40	3	-4.1 (-12.4)	\$585.40
Central Sydney	188	-1.8 (-332.1kg)	\$718.02	123	-3.9 (-475.2kg)	
Attended groups	173	-1.6 (-281.6)	\$1,509.45	112	-3.7 (-415.9)	\$347.10
Phone coaching	13	-4.1 (-53.2)	\$312.61	11	-5.4 (-59.3)	\$237.30
Initial consultation only	2	+1.4 (+2.7)	\$921.70	-	-	-

a) Includes weight gainers, losers and people not changing weight

The cost per kg lost appears lower in the “non-intervention” subgroup for the reason stated above.

9.11.2 Cost per goal achieved

There were no differences in the likelihood of achieving the weight loss goal between participants in terms of sex, baseline obesity, employment status, education level attained, pension or foreign status in the bivariate analysis. However, attending any number of face-to-face group sessions and having a higher number of telephone follow-up contacts were associated with significant weight loss.

Analysis of cost per goal achieved is presented overall for Program completers and not by Division as the numbers by Division are still small at this stage (Table 9.10). In summary, four people are required to complete the 12 month lifestyle intervention in order for one person to achieve the weight loss goal. The cost for one person to achieve the weight loss goal is more than \$7,000.

Achieving the goals related to reduced intake of fat and saturated fat costs about \$3000, but it costs about five times more for one person to achieve the physical activity goal. The number needed to complete the intervention is two for one person to achieve either the fat or saturated fat goal.

Table 9.10 Cost per goal achieved for Program completers (N=586)*

Goal	Number (%) of completers achieving Goal	Cost per person for goal achieved	Cost per person achieving goal (if GP incentives excluded)
5% weight loss	112 (24.6%)	\$7,785	\$7,388
<=30% energy from fat intake	272(59.6%)	\$3,205	\$3,042
<=10% saturated fat	270(59.2%)	\$3,229	\$3,065
>=15g fib/1000 Kcal	125(27.4%)	\$6,975	\$6,620
210 min moderate-vigorous/P.A.	52(11.4%)	\$16,767	\$15,913

* *N and % vary depending on data items available among 586 completers*

The cost of achieving the fibre intake goal is more than twice that of achieving the fat-related goals. About one in four people achieve this goal, so the number needed to complete the 12-month intervention is four for one person to achieve the fibre intake goal.

Approximately ten people need to attend the lifestyle Program so that one person can achieve the physical activity goal. This is the most expensive goal to achieve, at a cost of over \$16,000 per person.

If a change in screening and delivery of the Program was considered using exclusively non-medical staff in a non clinical setting, the total cost of the Program could be somewhat reduced (last column of Table 9.10). In either case, the implementation costs presented here do not cover either blood tests required to enter or complete the Program (as they were covered by Medicare) or participant's costs.

The following sections are based on information collected from 449 completing participants who responded to the Baseline CATI survey (92% of participants recruited between 2008 and 2010).⁷⁷

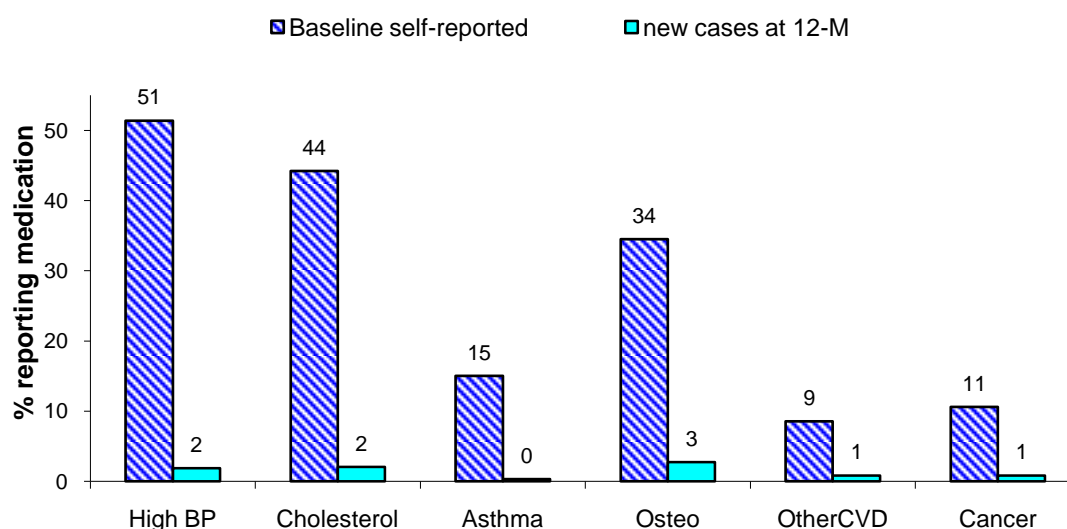
9.12 Chronic conditions

Ninety-five per cent of participants in the baseline CATI survey (N=531) reported at least one of the target underlying conditions (Figure 9.1). The mean and median number of co-morbidities was two and the maximum was six. These findings confirm that the SDPP participants are a selected high-risk population.

At the 12-month contact, 494 CATI participants provided information on newly diagnosed illnesses. Most of these respondents (92%) reported no change in their chronic disease profile compared to baseline status. However, 16 participants reported being newly diagnosed with osteoarthritis or osteoporosis, 12 with high cholesterol, 11 with of high blood pressure, 7 with angina or other cardiovascular diseases, 5 with cancer and 2 newly diagnosed cases of asthma.

⁷⁷ Note that total responses (N=) vary for different CATI survey items

Figure 9.1 Chronic conditions reported at baseline and end of Program by people completing in 2009-2010, CATI participants N=494.



While lifestyle interventions are recommended for long-term benefit, the SDPP is not expected to prevent cardiovascular events in just a few months. Data on time to events have not been collected, and detailed analyses of adverse events other than injuries, are beyond the scope of this thesis.

9.13 Health Service Use Changes at 12 Months

The profile of health service utilisation for Program completers who responded to this item on the baseline CATI survey (N=531) up to December 31, 2010 reflects the high prevalence of chronic conditions in this high-risk group (Table 9.11).

Small increase in the reporting of visits to emergency and hospital overnight stays was observed but this could reflect random variation. Generally, no substantial changes were observed in the frequency of reported visits to most out-of-hospital healthcare providers with the exception of a small reduction in visits to ‘other medical specialists’ and podiatrists/optometrists, and an increase in visits to a physiotherapist. These variations could reflect either the guidelines for care of particular conditions or frequency of subsidised services (i.e. podiatrists and optometrists visits recommended every two years and gastroenterologists every five years) as well as recall bias. An increase in use of physiotherapy services resulting from increased physical activity as a result of participants’ involvement in the SDPP cannot be ruled out.

However, these data are difficult to interpret in relation to the impact of the SDPP as data on reasons for consultation were not collected.

Table 9.11 Types of healthcare providers and services visited SDPP completers answering CATI at baseline and in the last 3 months of the Program (2008-2010; N=586 Program completers)

Health service use and type	Percentage at Baseline*	Percentage at 12 months*
Visited an emergency department in the past 3 months	4.9%	5.5%
Stayed at least on night in hospital in the past 3 months	3.1%	4.4%
<u>Medical specialists</u> visited at least once		
Cardiologist	3.1%	2.0%
Ophthalmologist	2.4%	2.4%
Endocrinologist	1.0%	0.3%
Nephrologist	1.0%	0.7%
Other medical specialist	21.5%	19.8%
<u>Allied Health</u> providers visited at least once		
Podiatrist/Optommetrist	8.4%	5.1%
Physiotherapist	2.4%	6.3%
Dietician	1.0%	0.2%
Natural therapist	3.6%	2.2%
All other Allied Health	19.6%	N/A

For ease of interpretation, percentage is made out of 586 completers although information on health service use is only available for 531 completers at baseline and 522 completers at 12 months.

N/A = at 12 months question not asked specifically about allied health other than Podiatrist/Optommetrist

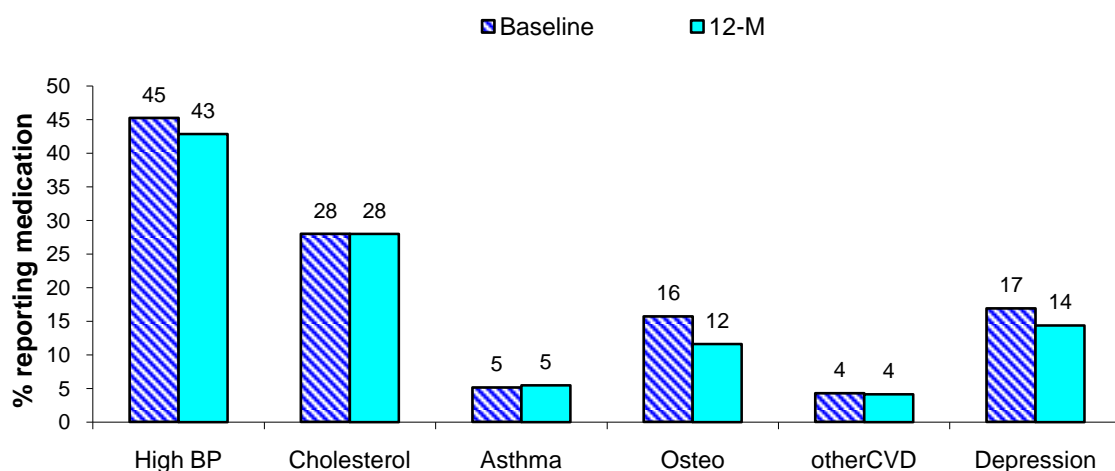
9.14 Prescription Medication Use and Changes

A majority of completers participating in the baseline CATI survey (91%) reported taking prescription medications for the target chronic conditions in the 3 months prior to joining the Program. At 12 months this figure for completers was 83%. The median number of medications at both time points was two and interquartile range one to three. As seen in Figure 9.2, high blood pressure and arthritis/osteoporosis related medications were most often consumed at any point in time.

Overall it appears that at 12 months there are no major differences in reported consumption of medication for chronic disease in relation to the baseline self-report, perhaps with the exception of medications for arthritis and osteoporosis. This could be due to either random variation in clinical practice, respondents' uncertainty about the indication for their medication, or poor recall. It may also reflect some level of inconsistency in the documentation of medications prescribed in the past 3 months between self-reported and clinical records.

Data from the 3-month follow-up calls to 515 completers indicate that 10.1% of completers (N=52) reported changing medication within 3 months of joining the Program: mostly high blood pressure (N=21), cholesterol medication (N=12) and other non-target medications (N=7). The direction of changes in medication is only known for 58% (N=30) of these: 30% of them (N=9) ceased or decreased dose, 50% (N=15) commenced or increased dose, and 20% (N=6) switched brands. While detailed information about the reason for change is not available, such variations in medication use are not uncommon and are most likely the result of modifications made as part of routine clinical care.

Figure 9.2 Indications for self-reported prescription medications among CATI participants - people completing in 2009-2010, N=586.⁷⁸



Question 6 *What are the costs to individual participants?*

9.15 Costs to Participants

The participant perspective of this economic appraisal is confined to expenditure on exercise products or services and the costs of travelling to attend scheduled Program visits or group sessions as asked at baseline CATI survey, at the three-month follow-up call and at the 12-month CATI survey. We did not measure broader societal costs such as gains or losses in productivity resulting from participants' improved ability to work, sacrificed leisure time, time spent participating in the Program, doing exercise outside the group sessions, time spent in

⁷⁸ For ease of interpretation of this graph, the denominator is all completers although medication data in CATI survey was available for 531 completers at baseline and for 488 at 12 months.

obtaining care, indirect costs to employers resulting from absences from usual duties or cost to participants' families resulting from their time volunteering to accompany or care for the participant when using health services.

9.16 Exercise Products and Services

These data will refer to mainstream participants only as none of the CALD participants had reached the 12-month milestone by the end of June 2010. Of the 1,130 mainstream participants who responded to the baseline CATI survey, one in every five participants (22%) reported they had already spent money on exercise products or services before joining the SDPP. The most common expenses were gym membership, shoes and clothes.

The most expensive items at any time point were gym membership and gym equipment for home. Note that this does not account for people who already had gym equipment at home before joining the Program. During the Program there was a general increase in the proportion of people reporting expenditure on exercise products or services.

Among participants completing the Program by December 2010, one in four reported expenditure on these products before joining the Program and this slightly increased to one in three at 3 months but remained at one in four at 12 months. The mean and median amounts spent towards the end of the Program were somewhat smaller than at baseline (Table 9.12). However, this is not unexpected if people had already spent money at previous time points before and during the Program. The amount reported at 12 months also refers to expenditure 'in the past month', as opposed to 'in the past 3 months' asked at baseline.

Table 9.12 Completing participants' expenditure on exercise products or services before joining the program at 3-months and 12 months - CATI respondents only.

Indicator	Before joining the Program N=531*	In first 3 months after joining program N=508**	In last month of program N=529*
Percentage of participants spending any exercise products/services	26.9% (N=143/531)	39.6% (N=201/508)	32% (N=71/529)
Mean \$/median spending on exercise products or services (&Interquartile range for those who spent)	\$157 / \$80 (IQR \$50-\$179)	\$162 / \$80 (IQR \$30-\$228)	\$143 / \$75 (IQR \$45-\$104)

*Completers who were CATI respondents at baseline and 12 months (531/529)

**Only those completers contacted at 3-months with data on this item

9.17 Time Off Due to Illness or Injury

'Injury' was not defined in a standard way, just asked as a generic question. Overall more people took time off work due to illness than as the result of injury. However, the mean reported time away from work due to injury was twice as long as that for illness. At baseline one in four of all completers with CATI data reported having time away from work due to illness and one in twelve took time off due to injury in the 3 months prior to commencement of the Program. Table 9.13 shows that at the end of the Program the proportion reporting days off was smaller than at baseline (one in six took time off due to illness and one in seventeen took time off due to injury).

At the 3-month follow-up call, 6% of those contacted reported an inability to do the recommended physical activity due to illness or injury and less than 1% reported ill health as an impediment to healthy eating at this time point. At the 6 and 9-month follow-up points, 7% and 6% of the completers respectively reported ill health or injury as a reason for not doing exercise in the 3 months prior to this contact.

Table 9.13 Completing participants' time off due to illness or injury in the 3 months prior to joining and in the last 3 months prior the end of the Program (2008-2010)*

Days off usual duties	At Baseline	At 12 months
due to illness	N=133 (25.1%)	N=83 (16.3%)
Mean days / median, IQR and (range) days off due to illness	6.8 d / 2 d IQR 2.5 d (overall range 1-90 d)	6.6 d / 2 d IQR 2-7 d (overall range 1-90 d)
due to injury	N=44 (8.3%)	N=30 (5.9%)
Mean/ median, IQR and (range) due to injury	14 d / 3 d IQR 2-14 (overall range 1-90 d)	11.8 d / 5 d IQR 2-14 (overall range 1-56 d)

α Denominators: N=529 completers participating in CATI at baseline and 510 at 12 months

These changes over time may be due to random variation and no costs have been allocated to these absences from work as no information is available about participants' occupation or

salary. Further, it is not clear that any absences from work were due to the conditions of interest to the Program or injuries related to participation in SDPP.

9.18 Adverse Events

As at December 2010 1% of participants (six completers) contacted at 3 months reported experiencing adverse events as a direct result of participation in the SDPP. These include three people sustaining muscle injuries after commencing resistance training, one who developed angina during moderate P.A. and was told to stop by the GP, one who pulled a hamstring while walking uphill and another reported several injuries since commencing exercise. A further 33 people reported adverse events clearly unrelated to the Program, mostly work or household related injuries.

9.19 Transport Costs

At the end of recruitment, data on the 3-month follow-up were available from 515 of the 586 completers, but cost data based on km travelled was only available for 508.

Median distances between completers' residence and Program venue for initial consultations ranged from 6 to 30 km return. These participants drove on average 11 km one way for the initial visit (Table 12). Based on the NSW Health fuel refund policy 2008-2009⁷⁹ the average cost of return travel per participant for the initial consultation was \$17.00.

Information on distance (km) travelled by completers to any number of group sessions was available for 94% of those contacted at 3 months. Completing participants drove an average of 52.1 km one way to participate in all group sessions combined. Variation in costs per Division is associated with the total number of sessions attended and distance travelled (Table 9.14).

Accounting for the total number of sessions attended, Macarthur participants had to travel the longest total distances to attend initial consultation and group sessions, followed by participants from the Southern Highlands. However, these distances are not negatively correlated with attendance rates as Macarthur participants had the highest rates of completed attendance at

⁷⁹ For a 1.6 to 2.6 cc vehicle, refund was 80.3 cents in 2008 and 74 cents in 2009. We used an average of 77.15 c per Km

group sessions. Central Sydney participants travelled the smallest distances but had rates of completed attendance at three group sessions similar to those in Southern Highlands, where longer distances were required to be travelled in order to participate in the SDPP groups. Only 2.7% (14 people) of completing participants contacted at three months travelled by public transport to the initial consultation at an average cost of \$8.60 per return trip (median \$5.00); and 2% (ten people) used bus or train to attend the group sessions at an average cost of \$13.00 per return trip (median \$5.00).

Table 9.14 Distance to initial consultation and group sessions and cost by Division for completers having cost data at 3-m follow-up (N=418)

Indicator	Overall Distribution and by Division 2008-2010			
	Overall	SH	Mac	CS
Total completers contacted at 3-m	515	176	170	169
Total cost data available	485-508	169-174	156-170	160-164
Total return Km travelled to attend initial consult (mean/ median, IQR)	22.0/ 12 km (6-30 km)	25.5/16.0 km (8-40 km)	31.7 /25 km (10-42.5 km)	8.8 /7 km (4-10 km)
Cost of petrol to attend initial consult (mean/ median)	\$17.0 /\$9.30	\$19.70/\$12.30	\$24.50/\$19.30	\$6.80 /\$5.40
Total Km travelled to all groups attended (mean/ median, IQR)	52.1Km/ 30 km (12-70 km)	50.6/ 30 km (2-72 km)	83.8/ 60 km (27-120 km)	22.6/ 18 km (9-30 km)
N(%) attending 3 sessions	440 (75%)	125(62.5%)	167 (86.5%)	148(76.0%)
Cost of petrol to attend all groups	\$40.20 /\$23.15	\$39.10 /\$23.15	\$64.65 /46.30	\$17.45 /13.90

SH=Southern Highlands Mac=Macarthur CS=Central Sydney

9.20 Summary of Costs of Individual SDPP Elements

The cost of individual Program components is presented in Table 9.15 to provide decision and policy-makers with detailed information about the possible elements that could be considered for adoption or modification to suit local needs (Table 9.15). In summary the adoption of a lifestyle diabetes prevention program can take place at a variable cost depending on its choice of elements. The early implementation phase of training and ongoing support is the most expensive component and could be minimised by reducing the number and type of people involved. Telephone coaching was marginally less expensive per participant than group sessions but this depended on the numbers attending group sessions. The second highest cost was the final assessment by both lifestyle officer and GP with the inclusion of a blood test. This might be minimised by limiting the participation of the GP, perhaps to those with abnormal

results. Numbers needed to treat are largest for physical activity or weight loss and smaller for achievement of dietary goals.

Table 9.15 Estimated costs of individual SDPP elements of the intervention from recruitment to final assessment excluding GP incentives as at December 2010

Program element/activity	Cost per participant (A\$)
One CBG screening blood test	0.50
One FPG test	9.75
One OGTT	19.10
2 GP visits before enrolment	69.80
Average cost of GP visits & blood test	126.00
Early implementation (staff training & support)	1,667.00
Group session	39.75
One phone coaching session	35.00
Final assessment by lifestyle officer (incl. data entry)	154.00
Final GP visit and blood test	197.10
Outcome	Average cost per participant (A\$)
Kg lost among completers	401.75
5% weight loss achieved	7,388.00
Physical activity goal achieved	16,767.00
Fat goal achieved	3,042.00
Saturated fat goal achieved	3,065.00
Fibre goal achieved	6,620.00
Transport to participants (IC and group sessions)	28.60
Physical activity products and services	152.50

IC= initial consultation

Question 7 *How feasible is the conduct of an economic appraisal in routine clinical practice?*

9.21 Feasibility of Measuring Implementation Resource Use and Outcomes in Routine Clinical Practice

As part of a pragmatic appraisal of a project designed to test the extent to which trial results could be translated into a population-based program, the assessment of resource use and costs was intended to be non-disruptive to the routine operations of both general practices and the Divisions of clinical practice. Individual practices were responsible for advising what project-related activity occurred. The Divisions of General Practice had a coordinating officer and dedicated lifestyle officers appointed for this project. All Divisions also employed finance officers, whose role included collecting, managing and reporting finance information in formats and frequencies customised to their local needs for all Division activities. For the purposes of this appraisal, the evaluation team based at the University of Sydney, of which the candidate was the principal analyst, received Division cost data at six-monthly intervals. As a result of the

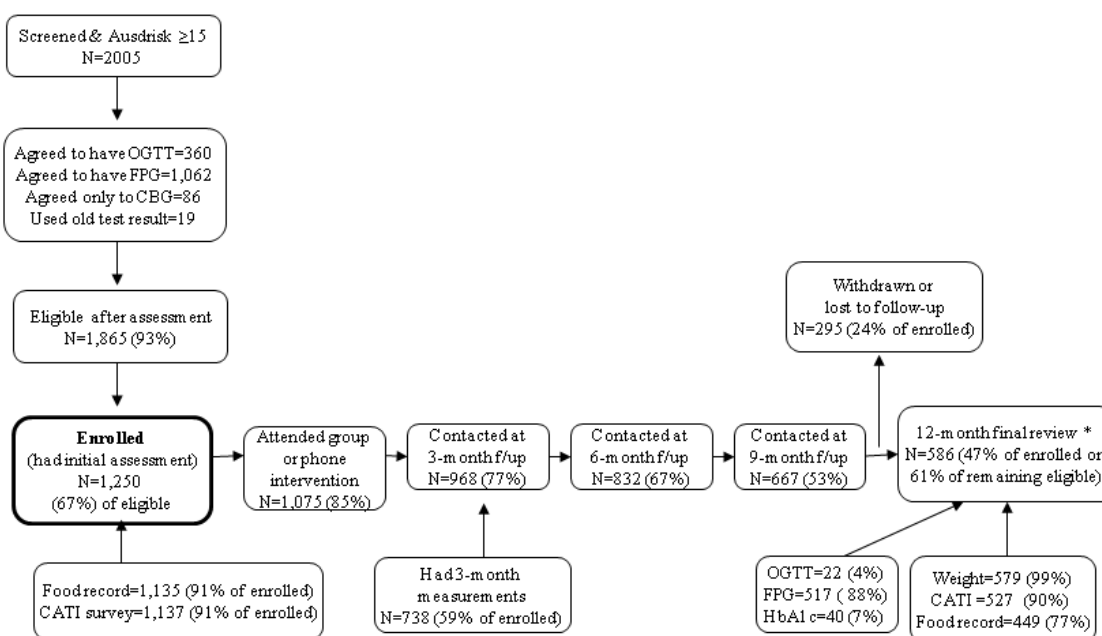
individual nature of each Division's finance data, the six-monthly summaries varied in terms of how SDPP expenditure was categorised, which has made comparisons across Divisions difficult. However, these results are likely to be broadly representative of the actual situation in these three Divisions.

In addition to the limitations of the financial data, the actual completion rates for all activities in the project were not homogeneous over time. Figure 9.3 shows that the pragmatic nature of this Program (i.e. not a research trial) led to variations in availability of data to calculate the resource use associated with the intervention. For example, although every eligible person enrolled had a blood test, of the 659 who had a CBG risk test, 86 declined a subsequent blood test to exclude diabetes diagnosis, although only 5 of those without subsequent entry test had high CBG (≥ 5.5 mmol/L). Likewise, of the 1,062 people who had a FPG (85% of eligible) 451 (42%) did not proceed to an OGTT but none had an FPG of ≥ 7.0 mmol/L. Finally, only 28% of all enrolled participants agreed to have an OGTT, which in the *reference trials* is the entry criterion for a diabetes prevention intervention. The Indian DPP required two OGTTs to confirm IGT before enrolment.(104) As the Sydney DPP was designed to enrol participants in the context of a routine clinical setting, inclusion of participants on the basis of CBG only or FPG only was allowed if either test yielded results of < 5.5 mmol/L, following the screening recommendations in the protocol. (Appendix 9.5)

In summary, based on the outcomes of screening with blood tests for SDPP, the costs of a future program may be estimated assuming the following: 53% of potentially eligible participants would agree to have a CBG test and for 7% this will be the only test required; 85% would agree to have an FPG test and for 34% of those eligible this would be the only test required; 29% would agree to have an OGTT and for 6% of those enrolled this would be the only test required; and 1.5% would not require an additional blood test as a recent result would be available in their clinical record. The distribution of these screening and diagnostic categories may differ for other sub-populations in other Divisions, rural localities or other socio-economic groups.

With regards to the availability of data at subsequent time points, although less than two thirds of participants had information about weight loss/WC reduction recorded at three months, information was available for most completers at 12 months: 99% of Program completers were recorded as having a final weight measurement and blood test to assess the development of diabetes; 90% provided information about physical activity to assess goal achievement; and data on macronutrients to assess fat and fibre changes were available for 77% of completers . The overall contact rate at 3, 6 and 9 months was reasonable but decreased progressively (Figure 9.3).

Figure 9.3 Breakdown of program activities for the estimation of program costs from baseline to final assessment of participants to date (July 2008 to December 2010).



**so far to December 2010*

The cost of such contacts is difficult to estimate as lifestyle officers spent time in multiple attempts to contact participants. One in every four participants withdrew or was lost to follow-up, so their final assessment costs are not included. Overall the completion rates for tests and other data items were high enabling reliable estimation of goal achievement. However, the variations in the type of data available discussed here highlight the practical difficulties in

determining the resource use and costs associated with the implementation of a program in clinical practice.

9.22 Discussion

The use of economic evaluations in healthcare has increased over the past two decades as clinicians and policy-makers become aware of its importance for clinical practice and resource reallocation. Palmer et al. postulate that the cost of establishing and conducting a diabetes prevention program is high in the short-term but justifiable given the long-term benefits it derives. (304) They based their estimates on health economic modelling techniques which incorporated the cost of metformin for prevention, cost of treatment of side effects, the probabilities of transition from IGT to active diabetes as compared with the costs of diabetes treatment once diagnosed, and the annual probabilities of dying after diabetes diagnosis. Their conclusions indicate that delaying the onset of diabetes through lifestyle intervention has the potential to achieve small but clinically important increases in life expectancy associated with cost-savings or minor increases in cost for patients. An Australian study using 1993-94 cost data to estimate the proportion of Type 2 diabetes and health care system costs attributable to overweight and obesity also concluded that a weight loss of 1 kg could potentially save A\$8.5 million in health system costs and a weight loss of 2 kg could lead to reduction of healthcare costs of \$18.1 million. (308)

The economic appraisal of the Sydney DPP aimed to describe the resource use and costs associated with the planning and implementation a prevention program in a real world setting of three Divisions of General Practice with the objective of providing information about the resources that would be required if the Program were to be expanded or rolled out more widely. As per the 2001 Australian study of diabetes costs (308), this information can potentially be used in future to estimate the cost-effectiveness of a population-based program including any potential savings to the health system.

At December 2010, the overall cost per kg lost was around \$400 per participant amongst those achieving any weight loss, but twice as much for the entire group of completers as one third did

not lose any weight. The cost of achieving the 5% weight loss goal was around \$7,000 for this first group of 586 Program completers (61% of those eligible to complete), as only one in four completers achieved the weight loss goal. The cost of achieving the fibre goal was similar, at around \$6,600 per participant, while the cost of achieving the fat and saturated fat goals was about half this, at \$3,000 as one in two participants achieved the dietary fats goal. The Program was not as successful at changing participants' level of physical activity. Only one in ten participants achieved the goal of 210 minutes per week, at a cost of about \$16,000 per person. Many factors including underlying health, family commitments, motivation and financial access to supervised facilities contributed to this relatively poor outcome.

These results are consistent with previous analyses of more preliminary data. Hence, it is not expected that the final outcomes when all remaining participants complete the Program will be different in terms of numbers needed to treat for goal achievement.

A pilot translation of the intensive 16-lesson USDPP into the community via two YMCA outlets in the US reported 76% attendance at one or more group session, similar to the Sydney DPP but mean weight loss at 12 months was around 5.7 kg, much higher than SDPP.(114) In their experience, conducting the Program in group sessions of 8-12 people instead of one-to-one intervention cost ~USD\$240 per participant in the first year and reduced staff costs by 50%. Details of the cost and outcomes study were not published and therefore comparability with SDPP is limited.

In the Sydney DPP, the relatively minor variations in direct Program costs which occurred across GP settings depending on readiness, recruitment strategies, participant motivation to attend, and type of blood test required for entry into the prevention initiative did not appear to have an impact on the overall costs of the SDPP. The cost per kg lost was very similar whether the intervention was delivered face-to-face or by telephone. However, the face-to-face intervention resulted in significantly better weight loss outcomes compared to the telephone coaching, regardless of number of sessions attended. In Chapter 8, results from the 12-month impact evaluation showed that the total number of telephone follow-up contacts with the

lifestyle officer predicted successful weight loss, but only one in four people receiving the prevention program achieved the weight loss goal.

9.23 Costs to the Health System

The average cost per participant of the program implementation team in providing technical support to Divisions through the planning and implementation phases was equivalent to about 49% of the average Divisional cost per participant for delivering the intervention. The Program implementation dilemma is that this central technical support seems essential to maintain performance but at the same time it is relatively expensive.

Despite incomplete attendance at group sessions, conducting these face-to-face sessions appears to be worthwhile as it appears to generate high rates of participation. The likely benefit of offering more than 3 of group sessions is still debatable given the personal difficulties experienced by participants in attending all three sessions.

The costs of telephone and group sessions are similar. Thus, any difference in outcomes is of great interest. If the interventions were equally beneficial, it would be useful to know that the provision of individual telephone coaching is a viable option. As reported in Chapter 8, for those completing the SDPP at December 2010, no statistically significant differences were observed by intervention group. If this is still the case at the end of the Program in December 2011, this suggests that a telephone-based follow-up could be implemented after the initial face-to-face consultation.).

Some potentially important aspects of resource use associated with the SDPP have not been included. No systematic collection was made of the time spent screening people who did not participate. Variations in recruitment may be explained by GPs adopting a targeted screening approach which resulted in their not screening people perceived as 'not at-risk'; or to not referring some eligible people to the program for reasons unknown to the implementation team.

As quality assurance and technical support to Divisions seems integral to the conduct of the Program, less expensive options to provide this service need to be explored. Attempts to

measure a dose-response in terms of weight loss and attendance at group sessions did not yield promising results in this preliminary analysis, as seen in Chapter 8. The total number of contacts with the lifestyle officer (and in particular, the total telephone follow-up calls) seemed to already be positively associated with weight loss (Chapter 8). These results can inform future programs in terms of a minimum recommended number of attendances at sessions.

9.24 Cost to Participants

It is not surprising that large variations in the costs of attending Program activities were observed as individuals were required to travel varying distances and chose to spend different amounts of money on program-related products and services. Twice as many people spent money on exercise or healthy eating products or services after 3 months in the Program than they had at baseline.

Distance does not appear to be a deterrent to attendance at group sessions but rural location does. The SDPP did not document whether poor attendance was associated with personal finances or transport difficulties. More people in the rural Division chose to have individual phone coaching but the reasons for this choice are not known to the evaluators. Individual telephone coaching could be more appropriate as an intervention option for people living a long distance from the venues where group sessions are conducted.

In the US DPP, the time that participants reported as lost from school, work, or usual activities resulting from DPP visits, illness, or injury was measured using the *Interval History Questionnaire*. Their estimates were 21.2 days lost due to morbidity in the three years of the Program.⁽³¹⁰⁾ The SDPP project did not have the resources to explore the direct costs of medical care or indirect non-medical cost to participants resulting from adverse events. The only outputs reported related to this issue are health service utilisation and days away from usual activity. These indicated that service use at 12 months was not significantly different from that at baseline although no validation through record review was attempted. The mean number of days lost due to illness in the one-year Sydney DPP was about a third of that reported in USDPP over three years. While this suggests that the mean number of days lost due to illness

may be equivalent in both programs, it is not possible to extrapolate the SDPP estimate to three years because of the different morbidity profile of participants in Australia and the US.

9.25 Comparisons with Other Studies

Very few of the published studies focussing on diabetes risk reduction have reported comparable information from an economic appraisal as undertaken for the SDPP. More often trials have measured or estimated the cost per outcomes in terms of diabetes cases averted, or quality-adjusted life years (QALYs) with researchers conducting modelling using simulations and requiring many assumptions, as described at the beginning of this chapter.

The US DPP reported in 2003 that in the first year the direct medical cost of the intensive lifestyle intervention was US\$1,399 per participant, with just over half the cost (54% or \$750) of the direct medical cost of the lifestyle intervention attributed to DPP staff time (estimates adjusted to 2000 US dollars). (310) The direct cost of laboratory tests to identify one subject with IGT was USD\$139 and the health system costs for the entire intensive lifestyle intervention at the end of three-year follow-up were \$2,269. An Australian review used Markov modelling based on this trial results and reported the outcome at A\$300 per additional kg lost over and above the mean difference between intervention and control groups. (316)

The Sydney DPP was conducted about a decade later at a mean cost of A\$1,667 per participant for one year including screening and intervention, and cost around A\$832 per kg lost overall (or \$400 per kg lost among participants successfully losing weight). The cost of tests borne by the SDPP was markedly cheaper than those in the US DPP but this comparison is not strictly valid because the SDPP did not include other medical, non-medical costs or societal costs in these estimations. The mean proportion of costs attributable to staff costs across the three Divisions of general practice in SDPP in 2008-2010 was 57.7%, consistent with the US prevention program experience.

In India, the direct costs of screening to identify an eligible subject including repeat OGTTs were calculated at A\$116 in 2007, more expensive than those in Sydney DPP in 2010. This is because the Indian program needed to perform twenty OGTTs to identify one IGT case. However, the

cost of the lifestyle intervention after 1 year in India was estimated at A\$85 per participant with staff costs accounting for a large proportion of the total direct cost. (266) While staff costs may be lower in developing countries, more types of personnel were used for each intervention and the laboratory resources are less widely available. This is an important consideration when planning prevention programs in different settings. Entry criteria also need to be considered carefully; In India the strict criteria confined the target group to IGT cases and required two OGTTs. This led to more costs and made the intervention less applicable to the real world setting. The SDPP entry criteria were more relaxed, including people deemed to be at risk even if they could not be classified as IGT cases, and only required one OGTT to rule out diabetes at the outset if the FPG was abnormal. This made it both less costly and more suitable for delivery in routine clinical care.

Only three studies reporting cost per kg lost were found in the medical literature. The most recent study was an internet-based weight loss program for young adult males in the workforce. Researchers used a provider's perspective and a randomised trial design with a 'usual care' control group. They reported that after six months the cost of the behavioural intervention was US\$49.24 per participant, with an estimated cost of \$25.92 per kg of weight loss.(317) Neither the intervention type nor the target group are comparable to SDPP, but the results of this study are presented here to provide an indication of the costs associated with intermediate outcomes for less intensive weight management interventions.

The second study was a general practice-based health promotion study in Western Australia undertaken in the mid 1990s. The authors examined the clinical and cost outcomes of nutritional counselling delivered to 273 overweight, hypertensive or diabetic patients by doctors and dietitians over one year. Findings from this small randomised trial indicated that nutritional counselling in clinical practice was cost-effective (in 1993/94 Australian dollars) whether a doctor was involved (\$A9.76 per kg lost, mean loss 6.7 kg) or not, and counselling by dietitians alone also led to similar and more affordable weight loss (\$A7.30 per kg lost, with average weight loss of 5.6kg). (318) The authors reported that the weight loss differences were

not statistically significant while the higher cost in the first group were due to costs associated with doctors' time. The WA Program costs included in the appraisal were not comprehensively detailed in the published manuscript and only covered the resource use associated with the direct delivery of a service (i.e. the hourly salary rates for dieticians and reimbursement rates for GPs). Thus it is not possible to directly compare the results of this study with those of the SDPP.

Data from a UK study of nutritional counselling in general practice was used by Australian researchers in a third study which estimated the incremental cost-effectiveness of such counselling.(316) The results indicate that counselling cost A\$88 per person, A\$13 per additional kg lost, and A\$917 for 0.087 QALYs gained per person (i.e. an average of \$10,540 per QALY gained). These estimates were based on a model run for 20 years, whereas the SDPP results refer to costs at the end of the first year of follow-up of a broader intervention with repeat group sessions and follow-up telephone calls.

9.26 Strengths and Limitations of the Methods

This economic appraisal used a combination of a top-down and bottom-up approach to data collection. That is, many actual implementation costs such as GP and practice incentive payments, the costs associated with the time spent by lifestyle officers on various activities training, materials, catering, rent and staff salaries were documented and provided by Division staff and Program providers. This micro-costing exercise is regarded as the most accurate approach to costing and in this case was necessary as prices for some program-specific activities are not readily available. (319) However, , other costs such as screening blood tests, GP consultations, and some transport costs were estimated on the basis of published costs and/or prices from Australian sources applicable in 2009-2010.

Caution should be used in comparing Divisions in terms of resource use. It is not possible to separate the costs of screening from those associated with Program implementation as activities happened concurrently but it is anticipated that data from 2011 will more clearly reflect actual implementation costs when follow-up has ceased. Information from the

participant's perspective is more accurate as unit record data are available at two time points for the majority of participants who agreed to respond to these questions. However, data items could not be as comprehensive as originally planned partly because ethics approval was subject to reduced respondent burden in terms of data collection. Questions on occupation, salary, time spent attending screening, time spent attending at physical activity services and cost of lost income from participation in the Program or cost of time away from usual activities due to injury were not able to be included.

The costs of screening and diagnostic blood tests or GP services were based on administrative data on payments by the Australian national insurance system (Medicare); costs of lifestyle officer time were based on hourly rates and proportion of time spent on each activity.

The economic appraisal presents the costs of Program activities in disaggregated form. This is important to inform decision-makers on what elements of the Program are to be taken on board or whether some activities or elements should be simplified or a hybrid model adopted.

9.27 Conclusions and Recommendations

The interim appraisal of resource use and costs associated with the implementation of the SDPP suggest that it is a relatively expensive Program which may not be feasible to deliver within existing resources in clinical practice. The most affordable costs per outcomes are in relation to changing fat intake, followed by weight loss. The cost of achieving the physical activity goals is high. Given that the SDPP was not an intensive lifestyle intervention, the Program might be less costly or more effective if the goals were set at a more realistic level or confined to dietary and weight loss outcomes.

No major differences in findings are expected when the remainder of participants complete the Program. However, it is important to continue monitoring costs per outcome and total implementation costs until the end of the Program to confirm whether significant changes from these preliminary estimates of 61% of completers are observed.

In particular, investigation of the differences in outcomes between participants attending initial consultation only, one group session and telephone-only follow-up should continue. Distance

did not appear to be a deterrent to attendance at group sessions but rural location did. The individual telephone coaching could be an appropriate intervention option for people living in rural areas. It is worth exploring this further as more data become available. The likely benefit of various numbers of group sessions is yet to be confirmed, and approaches involving fewer face-to-face contacts with lifestyle officers may be more viable in routine clinical care.

Other examples in the literature have shown that the Program could be conducted without the intervention of GPs, using allied health personnel. In rural or remote areas of Australia where services are operated by nurses, this could work well. The SDPP experience indicated that using trained allied health staff to deliver the Program and measure outcomes is feasible. Participants could be recruited through community advertising as per the US DPP or the Southern Highlands experience (Chapter 6 on Process evaluation). Alternatively, if general practitioners are to be involved, a government subsidy for screening and referring 50-65 year olds, similar to the current diabetes screening subsidy for 40-49 year-olds, would make the population-based approach more viable.

Less expensive options for providing quality assurance and technical support to Divisions need to be explored as the cost of providing technical support for setting up the Program and negotiating with Divisions was substantial compared to the cost of delivering the intervention. Finally, collection of detailed and comprehensive health system and patient costs as part of routine program delivery is not feasible in clinical practice in Australia. Therefore a combination of micro-costing and use of reference values from the relevant context may enable continuing evaluation of costs and outcomes.

Chapter 10.

Conclusions on The Evaluation of the SDPP

Summary

This final chapter summarises and reviews the main findings in this thesis from the evaluation of the Sydney Diabetes Prevention Program up to December 2010. Aspects considered include reflections on the translation process, barriers to implementation, success factors, strengths of the design and implementation, the impact of the Program and comparisons of effectiveness of the intervention with other community-based translation programs and the reference trials. The contributions to current knowledge of each chapter of these three evaluations are also covered along with strengths and weaknesses of the translation effort. Considerations are given to modifications required to enable implementation in the real world, justification for the limitations of the Program, and suggestions are made about possible solutions to the practical difficulties. Further areas for research are also outlined.

10.1 Reflections on the Process and Outcomes of SDPP

This research translation of the SDPP process aimed to determine whether the intervention could be delivered within the primary health care system and whether people at increased risk of type 2 diabetes could be successfully targeted. Examination of approaches to recruitment and screening was the first step. Targeted screening in general practice was very effective. Of those screened, there was a one in two chance of identifying a mainstream person eligible for the Program, and almost one in one chance of identifying an Arabic or Chinese person at risk. Personal invitations to join from the GP, supplemented by local media and lifestyle officer invitations also resulted in two thirds of eligible participants enrolling in the Program. In determining the extent to which the intervention was implemented as intended, it was clear that some flexibility to choose alternative methods of blood testing to enter the Program facilitated recruitment of a larger sample size compared with the use of OGTT alone. Time to referral was usually on the same day of the test result or within 10 days. Compliance with the

measurements asked (weight and WC) was also high (99%). Compliance with questionnaires on physical activity and 3-day food record exceeded expectation (around 90%).

The SDPP participants were mostly obese people, predominantly females with comorbidities, not unlike those in the Finnish DPS and the US DPP. Participants were largely sedentary, of mid to low education level and low socioeconomic status, which fitted the expected target group. However, males and participants without private health insurance were under-represented. Median time to initial consultation was just over one month from referral. After the initial assessment and coaching interview, two thirds attended group sessions at least once, 10% chose individual phone coaching, and over 70% received either all three group sessions or all three coaching calls. Fourteen percent did not attend subsequent coaching following initial consultation and instead received quarterly follow-up calls. The above indicates that the people at high risk could be successfully targeted and they demonstrated high levels of acceptability of the intervention. Once in the Program, contact rate was generally high at over 80% for all quarterly follow-ups. Attrition rates were 24%, and the reasons, when known, were mostly associated with personal or family commitments rather than with Program demands.

Over 75% also attended the 3-month measurement session (third group session). The short-term (3-month) evaluation showed weight loss of 1.1 kg or 1.2% of body weight, and mean WC reductions of 1.8 cm. Males were more likely to lose weight than females but there were no sex differences in the likelihood of reducing waist circumference. The correlates of short-term weight loss comparable with the findings of the Greater Green Triangle study were baseline weight, sex (male), and living in a rural area (possibly a proxy for lifestyle officer experience). Conclusion on whether the results of the lifestyle intervention were comparable to those of the trials that inspired them were derived from the impact evaluation questions. At 12 months mean weight loss was larger to 2.1 kg and WC reduction was 2.5 cm. These results were similar to the weight and WC reductions achieved in the more intensive Greater Green Triangle study in Victoria, and generally consistent with modest reductions found in other translation programs under real-life conditions. Of interest was the observation that weight loss continued from 3-

month to the 12-month follow-up suggesting persistence of lifestyle changes among some participants. Meeting the physical activity and dietary goals at baseline correlated with achieving Program goals at final assessment; this suggested that the Program was good at maintaining high-risk people's lifestyle when they were already motivated. The Program also motivated many participants to commence moderate and vigorous physical activity but not sufficiently to achieve the goal of 210 minutes per week. However, self-report of changes in diet and physical activity were greater than the objective risk reduction observed.

Changes in biochemical parameters (glycaemia and lipids) at 1 year were very small but comparable with the reference trials. Yet the confirmed incidence of diabetes in the first year was less than 1% in the SDPP, which is lower than that reported for other studies. The true SDPP estimate could be somewhat higher as the diabetes status of those not presenting for final assessment is unknown and the SDPP was not powered or designed to detect diabetes incidence.

The critical appraisal helped inform whether the intervention represented value for money. The mean cost of the Program was A\$1,667 per participant for one year including screening and intervention, with the cost per kg weight lost overall of A\$832, and A\$400 per kg lost among participants successfully losing weight. Attendance at group sessions led to increased likelihood of increasing physical activity but no difference in weight loss or dietary outcomes was observed between group sessions and telephone coaching or initial consultation only. Four people were required to complete the 12-month lifestyle intervention in order for one person to achieve the 5% weight loss goal; 10 people were required to complete the Program for one person to achieve the physical activity goal of 210 minutes per week; two people needed to complete the Program for one person to achieve either the fat or saturated fat goal (<30% and <10% of total energy intake respectively).

As the SDPP target group is not completely representative of the general middle-aged population, the findings of this study are applicable only to adults aged 50-65 years at high-risk for diabetes. This Program has generalisable features that can be applied in other routine

clinical settings: proactive identification by the GP of people at risk for diabetes from electronic records; targeted invitation via letter from the medical practice supplemented by local media advertising; screening using a standard validated 10-item questionnaire; ability to join a program after a simple CBG or after a single FPG if normal. Referral and enrolment within a month; ability to receive group sessions or individual coaching during the intensive phase; telephone follow-up to minimise attrition and cost; ability to complete the Program after assessment by a lifestyle officer. Further, the Program showed the feasibility of delivering three-session lifestyle programs via general practice in New South Wales.

Aspects that did not work as well as expected were the need for GP incentives to increase referrals, restricted access to blood test results delaying people's enrolment, waiting lists to attend the group sessions due to staff shortages or venue limitations, the multiple goals each participant was expected to meet simultaneously, the type of physical activity expected of this obese target group affected by co-morbidities, the number needed to treat to achieve the physical activity goal, and the cost of guidance and supervision of staff delivering the intervention. The most common limitation reported by other translation examples was the 'blood barrier' or requirement for a single or repeat OGTT.

10.2 What this Thesis Contributes to Current Knowledge

The Sydney Diabetes Prevention Program has attempted to test the transition from efficacy trials to translation research by attempting to replicate the principles and goals of large randomised controlled trials which delivered intensive interventions in Finland and the US. Implementation through a practical adaptation of its components has made it feasible for routine clinical practice in Australia.

The SDPP is one of the largest translation studies in routine practice in Australia, and a comprehensive evaluation of a translation study in routine clinical settings. The sample was community-based, recruited through a combination of targeted and opportunistic screening, and broadly representative of middle age Australians at risk of diabetes presenting to general practice. The paragraphs below summarise findings, implications for clinical practice and

population health, and proposed strategic approaches for future implementation of similar programs.

This thesis was mainly concerned with the assessment of feasibility, program fidelity, impact and cost per outcome. Note that the thesis only assessed follow-up to December 2010, when approximately 24% had been lost to follow-up, and around 62% of the remaining participants had completed the 12-month assessment. However, the Program effects and the problems noted with translation are likely to be very similar in the full sample. The unique features of the SDPP comprised a comprehensive process evaluation, objective measurement of the intervention effects on known parameters comparable with other interventions, and a pragmatic economic appraisal on cost-per-outcome and cost-per-goal achieved, not available in the published academic literature or the grey literature. The importance of this evaluation is: it provides new and detailed documentation on how far the adaptation of strategies, activities and timelines need to go for the program to be feasible to implement under real-world conditions of service provision and budget constraints, its conclusions on how realistic it is to embed these prevention interventions in the routine practice given the limited staff time, and it indicates how effective lifestyle interventions are on people at high-risk with comorbidities. In addition it highlights the number of people needed to be offered a lifestyle program in non-research conditions for one participant to achieve specific goals.

By comparison with reference trials, replication and adaptation in the SDPP protocol included a reduced number of contacts with lifestyle officers, face-to-face group demonstration sessions instead of individual coaching sessions, shorter duration of the intensive phase, and a maintenance phase comprising three quarterly coaching follow-up phone calls instead of personalised visits for the remainder of the 12-month Program. Self-efficacy skill building and minimal telephone support were central to the delivery of the SDPP as participants were encouraged to engage in either gym-based or home-based regular aerobic and resistance training but were not offered a supervised curriculum outside the three group demonstration sessions. The SDPP approach covered a face-to-face assessment, group-sessions and three

telephone follow-up/coaching calls for behavioural reinforcement. The Program used coaching goal setting, self-monitoring, identification of barriers to adherence, skill building in problem solving and participant's engagement in putting in place their own practical individualised solutions, including using social support. (265)

Details of the burden of diabetes in Australia and worldwide were presented in **Chapter 1**. The rationale for this Program and evaluation was the well established awareness that the incidence and prevalence of type 2 diabetes are growing and leading to significant disability and increased health expenditure despite its causal factors being largely environmental and preventable.

The literature review in **Chapter 2** identified many instances of whole-of-community, workplace or church-based and nation-wide replication attempts delivering lifestyle interventions to diverse at-risk subgroups over the past 20 years. Some were confined to people with IGT and others broadened entry criteria to other modifiable and non-modifiable risk factors. Success factors for lifestyle interventions in community settings included assessment at an accessible location, delivery at suitable times, catering for different levels of need and cultural sensitivities, flexibility for participants to adhere to physical activity through home-based and gym-based options, and absence of participant co-payment. At the nation-wide level, success in implementation was associated with mass education, government, industry and academic engagement, and legislative support. Implementation barriers were common across programs, including personal or work-related commitments, the need for blood tests, patient co-morbidities and poly-pharmacy, and provider factors such as limited time or skill.

The more extensive and systematic review and meta-analyses of interventions in routine clinical care presented in **Chapter 3** provided additional information on feasibility and success factors for risk reduction. In general, translation efforts in clinical practice used the same ambitious goals as the reference trials despite multiple adaptations required of the intervention itself. Most were conducted at small scale, in limited numbers of centres, with small numbers of patients or with short follow-up periods, and reported their outcomes in different ways. All studies reported positive effects in terms of weight loss and waist circumference reductions to

various extents, but no substantial effect on biochemical parameters. Feasibility was associated with involvement of a range of health professionals delivering the intervention.

Chapter 4 introduced the study protocol with inclusion and exclusion criteria for practices and participants, the timelines for activities and all the instruments used for this translation research. Screening and measurement protocols, process and impact evaluation, the rationale for choice of measurement tools and, when available, information on their validity and appropriateness for use at the population level were examined. This is important for any potential Statewide roll-out of this SDPP Program or for replication of similar diabetes prevention programs in other settings. The details here supplement an abridged version of the study protocol published in an open access journal.(235)

The profile of participants from the mainstream and Arabic and Chinese cohorts were described in **Chapter 5**. Screening in general practice enabled SDPP to successfully identify high-risk 50-65 year-olds suitable as a target group for a lifestyle modification. It shows that it is possible to recruit two thirds of those identified as eligible to participate. Program participants had high levels of obesity and chronic comorbidities and were on multiple medications. Like in other non-Australian translation studies, most participants were women, from low income groups, and their nutrition profile revealed high fat consumption. Differences between the SDPP group and other community-based studies included lower prevalence of IGT and much lower baseline engagement in physical activity. A feature of the SDPP was the measurement of anxiety, depression, self-efficacy and social support as possible influences on participation or goal achievement. Males had higher self- efficacy scores for physical activity and healthy eating than females. Few translation studies have reported as many outcomes measured as the SDPP, particularly nutritional or physical activity changes.

The methods and results of the process evaluation were described in detail in **Chapter 6**. The protocol for this component of the thesis was also provided as reference for future replication by others. This contributes to filling multiple gaps in the published and grey literature on the domains of adoption, program reach and fidelity of implementation. Process evaluations of

other studies are uncommon and are often confined to a single aspect, usually acceptability. The blood test barrier for recruitment was commonly mentioned by others, and targeted screening proved appropriate in two other Australian diabetes prevention programs (Greater Green Triangle and Go For Your Life). The SDPP loss to follow-up rate of ~24% is lower than the 37% reported for Go For your Life and comparable to other translation studies but higher than in the reference trials. By contrast, adherence to Program components and follow-up contact rates among those remaining were much higher in the SDPP than in other translation and reference trials, possibly due to the reduced number of sessions and the short follow-up in SDPP. The success factors were: the high identification rate using targeted screening through invitation from the medical practice; entry criteria allowing a variety of blood test options for those unwilling to have an OGTT; high attendance rate at group sessions; flexibility of an alternative telephone coaching; and high post intervention contact rate for follow-up at 3, 6, and 9 months. Among the lessons learnt from this process were the need for additional human resources to cater for the load of completing initial assessment and conduct of the intensive phase (group sessions) shortly after identification of eligible people, the need for different strategies to capture at-risk males outside the general practice setting, and the need for alternative exercise modalities for this age-group since the use of local community lifestyle services by participants was low due to social constraints and preference for home-based activity.

To achieve dissemination of this kind of programs, proposed solutions to the implementation barriers include reconsideration of the target group, the type of staff and the Program goal, as described below. This process must involve wider community advertising and rely on non-GP personnel to screen potential participants and deliver the Program in close connection with the clinical setting to identify eligible people, follow-up and assess outcomes. Programs need not be reliant on GPs as gate-keepers. Targeted invitation to Ausdrisk screening by practice nurses to particular age groups, worksites or other Area Health Services could be attempted. Enabling authorisation of CBG testing and subsequent FPG or OGTT request by practice nurses or lifestyle

officers would reduce the unnecessary cost of multiple blood tests and expedite enrolment and exposure to the intensive phase of the intervention.

Chapter 7 presented the short-term (3-month) impact of the Program on behavioural risk factors using both objective and self-reported measures. Attendance at this intermediate measurement session was relatively high. Comparative analysis with baseline revealed that modest reductions in weight and waist circumferences are possible within a few weeks of enrolment. Higher baseline weight and rural residence were independent predictors of change in the expected direction. The latter suggests that the skill of the lifestyle officer may be a moderator of success. Few other studies report short-term outcomes; however, regardless of approaches used and biases introduced in the methods, they were consistent with the SDPP finding that lifestyle interventions led to weight loss of various magnitudes, often less marked than the US DPP. The SDPP also achieved a smaller mean weight loss and WC reductions than the other Australian prevention program in general practice used as a reference (Greater Green Triangle). This was possibly due to the lower intensity of the Sydney Program compared with the other two Australian studies and the younger target population in the Greater Green Triangle study.

In **Chapter 8** this preliminary 12-month impact evaluation of the SDPP confirmed the feasibility of evaluating the impact of a community-based translation programs in a GP setting in Australia. It also showed that after 1 year, the weight loss effects of the Program were sustained, although they were less than those reported by the reference trials run under strict conditions of implementation and supervision. This was most likely due to the higher intensity and the higher frequency of interactions in the reference trials compared with what is feasible in real life programs. One of the novel aspect of this chapter is the analysis of the correlates of goal achievement. The fat-related goals were most commonly achieved and the strongest predictors of achieving two or more dietary goals was meeting the fibre goal at baseline. The physical activity goal was the hardest to achieve and the biggest predictor was doing a sufficient level of activity for health benefit (210 minutes per week) at baseline. Predictors of 5% weight loss

were higher education, meeting the saturated fat goals at baseline, and having the most telephone follow-up calls in the maintenance phase, regardless of intervention modality. The other new aspect this chapter contributes is the extent of outcome differences between three intervention modalities: group sessions, telephone coaching, and counselling at the initial session only. The assessment of weight loss and dietary goals revealed no significant differences between group sessions and the other two modalities. The physical activity goal, however, was more likely to be achieved for people attending group sessions, particularly for males. This is informative for process and impact evaluation. Individuals with depression had a decreased likelihood of achieving dietary goals but this did not predict achievement of the weight or physical activity goals. The issue of self-selection of motivated individuals into the program, and targeted screening strategies is acknowledged as potentially limiting the generalisability of the SDPP sample.

The findings of this evaluation indicate that there is no significant difference in achievement of weight loss or dietary goals by intervention modality (Chapter 8). Other studies in Australia and the Netherlands have shown the feasibility and effectiveness of telephone counselling for weight loss in hard to reach obese in rural areas or worksites. (320, 321) Hence offering telephone coaching as the first choice after initial assessment and the group session as the alternative would minimise the hurdles of venue hire, equipment purchase, bookings for several people on the same day, and reduce the shame factor and the need for travel that discouraged some participants from attending groups. However, frequent telephone follow-up should be maintained as it was demonstrated in the SDPP to increased likelihood of achievement of the weight loss goal at 1 year. Further, an open invitation for a whole-of-family attendance to demonstration sessions as attempted successfully in minority groups in other studies targeting at-risk individuals of similar age groups in communities (Chapter 2),(134, 140, 143) may result in improved motivation for those who have cultural concerns or enjoy appropriate levels of social support.

In **Chapter 9** the preliminary economic appraisal of the Program indicates that the physical activity component of diabetes prevention programs in general practice is more costly for than the dietary components. More at-risk participants achieve the fat and fibre goals than achieve the physical activity goal. These results are consistent with previous analyses of more preliminary data and it is not expected that the estimates of final outcomes will change when all remaining participants complete the Program. The cost of technical support to Divisions was considerable given the level of guidance required for staff delivering the Program on an ongoing basis. This cost would be reduced if the requirements for evaluation and data collection are minimised. Incentives for GPs were observed to increase the overall Program cost and consequently options for conducting programs without GP intervention are canvassed. Analysis of participants' costs showed that the Program encouraged many participants to spend money on physical activity and nutrition products and services. The cost of attending varied depending on distance to the Program facility but distance did not influence attendance rates significantly. Comparisons of costs with other studies were difficult to interpret due to the inclusion of partial direct costs in Australia as Medicare covers some consultation and testing and because the SDPP did not include indirect medical costs or societal costs. Further, comparisons of cost per kg lost with other studies were not possible due to either a lack of detail on the calculations by others or variations in methods including long-term simulations. After considering these limitations, the economic appraisal still concluded that it is not feasible to deliver this kind of comprehensive program within existing resources in general practice, as implementation costs are relatively high. In particular, the involvement of GPs and achievement of the physical activity goal are costly components and variations should be reconsidered including a focus on dietary goals and weight loss goals and screening/recruitment by nurses rather than doctors. Likewise, the conduct of detailed cost studies in general practice is not a viable option unless context-specific reference values are available, as bottom-up approaches are time-consuming and require certain skill level not always available in routine clinical care. The SDPP evaluation

has informed cost requirement in the initial [intensive] and steady stages, and documented the lessons learnt to facilitate replication in other similar Australian settings.

10.3 Strengths of SDPP Translation Effort

This Program had similarities with other community-based translation efforts: the SDPP used goals consistent with the reference trials, planned reduced number of interactions with lifestyle officers, delivered small group sessions rather than face-to-face individualised visits, and measured a variety of intermediate outcomes given the short follow-up period. Conversely, the unique features mentioned below make the SDPP a valuable reference study in the translation literature.

10.3.1 Methods

From the methods perspective, the large sample size has exceeded that of other translation efforts and even that of the reference FDPS, Chinese and Indian DPPs. This gave opportunity for sub-group analysis and to explore multivariate predictors of success which is rare in published studies. The recruitment of an Arabic and a Chinese cohort and delivery of language-specific Program sessions and follow-up calls in a predominantly English-speaking setting is only the second attempt in Australia after the *Go For Your Life* program in Victoria.(288) The SDPP also made efforts to document short-term (3-month) and intermediate (12-month) impacts, which is important to characterise individuals likely to withdraw or succeed. Weight and WC outcomes were objectively measured at baseline, 3 months and 12 months. The high compliance with PASE, 3-day food record and blood test at final assessment facilitated evaluation of Program goals in most participants.

10.3.2 Screening

Targeted and opportunistic screening by the participant's own general practitioner was possible using a validated, widely endorsed, easy to self-administer screening tool (the Ausdrisk tool) for first-stage identification of risk. This led to at least a one in two chance of identification of potentially eligible mainstream and Chinese participants, and a one in one chance of

identifying high-risk eligible Arabic participants. This was less time-consuming and less resource-intensive than screening the whole adult-population or whole GP clientele.

10.3.3 Intervention Fidelity

The intervention itself delivered as coaching and demonstration sessions by purpose-trained, dedicated lifestyle officers in a stand-alone facility associated with Divisions of General Practice was another strength of the SDPP. Consequently routine clinical health services were not disrupted and despite this communication between diagnostic and preventive services was maintained. Importantly, the use of language-specific doctors, CATI interviewers and lifestyle officers facilitated recruitment of minority groups who would otherwise have missed the opportunity of being identified as high-risk individuals, and invited into the prevention Program. The overall fidelity of the Program was high, with lifestyle officers largely adhering to time intervals and procedures over the course of the Program despite the many local variations in participants needs, distances, resources available, and staff shortages.

10.3.4 Translation Partners and Documentation

The SDPP's multidisciplinary effort involved the government, non-government, academic and private medical sectors and incorporated an exhaustive process and impact evaluation and an economic appraisal. These involved planning, training and investment in data collection from the outset and enlisted the cooperation of lifestyle officers in data quality control. While this was time consuming and may not be required in future translation programs, it has enabled a thorough evaluation to inform future implementation strategies and resource allocation. Finally, detailed documentation on the SDPP translation effort will contribute to filling the knowledge gap. Many translation efforts are occurring in developed nations and in Divisions of General Practice across Australia without any published data on process, outputs or complete impact. This study is the second diabetes prevention program reporting detailed methods and results on a process evaluation in Australia, along with the *Go for Your Life* project in Victoria.

10.4 Limitations of SDPP Design and Implementation

Several features of this translation study, including design and implementation weaknesses, deserve attention as there is potential for improvement in future replications.

10.4.1 Methods

As this evaluation did not include a multifactorial RCT, it is not possible to determine which of the Program components contributed more or less to the relative success of the intervention. The *Go For Your Life* program used an RCT design but the impact of diet and physical components were not explored separately. Findings on the independent effects of specific program components could have informed whether a diet-only version of the intervention would have yielded the same effects as the one combining physical activity with healthy eating in a real-life setting. However, the RCT evidence for lifestyle interventions emerging over the past two decades already indicates the need for a holistic approach.

Another methodological limitation of this Program include the absence of validation for self-reported physical activity, such as the 2-km walking test used to determine the physical fitness index in the FDPS. Fitness tests and accelerometers provide a relatively non-intrusive, objective measure giving more credibility to self-report on aerobic activity if the level of agreement is high. However, the disadvantages include high cost, requirement of specialised staff to interpret the data and lack of sensitivity to static activity such as resistance training. The SDPP attempted to validate using accelerometers in a convenience sub-sample of 100 participants but this proved impractical since the SDPP was a routine service offered in clinical practice and not a research project. In addition, the response rate was too low.

10.4.2 Measurements

The SDPP used the Physical Activity Scale for the Elderly (PASE) questionnaire recording activity undertaken in the past 7 days. While this instrument takes into account unstructured activity likely to be carried out by older adults, the PASE algorithm bases calculations of physical activity on averages from broad categories, not on exact estimates of minutes per day. This means that it is not sensitive enough to detect small differences or changes after the

intervention and this could be a problem in detecting achievement of the physical activity goal at the end of intervention. However, the PASE is recognised as an appropriate tool for older adults as it reflects their engagement in unstructured activity and it minimises the recall bias introduced by questionnaires focused on 'usual activity' over longer time periods.

The energy and macronutrient intake was self-reported on the basis of a 3-day food diary. While this may introduce measurement error and social desirability bias, it is superior to 'usual intake' summaries or food frequency questionnaires, and more amenable to implementation than a weighed food record. It was the only practical and feasible means of directly assessing in real-world settings and it was preferred for its comparability with the food-frequency-questionnaire method used in some of the reference trials.

10.4.3 Reach

Suboptimal reach of men was one of the drawbacks but this is prevalent in most published translation programs as discussed in Chapter 5. Men are less likely to consult GPs or preventive services and may also have been less inclined to agree to give a blood sample or attend demonstration sessions which may involve cooking instructions or food shopping skills. However, the age-sex profile of decliners did not differ from that of participants.

10.4.4 Attendance and attrition rates

A fifth of confirmed eligible people in the SDPP did not attend the initial consultation, mostly due to lack of time, family commitments and to some extent, the waiting lists for commencement at Divisions, rather than due to Program demands or complexities of the enrolment process. Employing larger numbers of allied staff at the outset may have assisted in catering for the demand.

Attrition rates were higher than those in the reference trials but similar to other translation programs. Unlike in the highly funded trials where considerable time and resources are spent on ensuring follow-up is as complete as possible to demonstrate effectiveness, in real-world interventions, preventive efforts are associated with losses to follow-up. This is because limited staff and resources only allow for minimal follow-up attempts by telephone or electronic means,

and participants are not research subjects with contracts but volunteer participants with other life events affecting their ability to complete programs.

In summary, the SDPP adopted as many evaluation measurements as practicable in real-world situations without jeopardising providers' cooperation or participants' continued involvement in and enthusiasm for the Program.

10.5 Challenges of Diabetes Translation in Sydney and recommendations on future implementation

Many modifications attempted in real-world conditions appear to make the translation of diabetes prevention through lifestyle intervention feasible, affordable and successful. While this is partly true, identified barriers for implementation and evaluation of the SDPP were also encountered by other translational diabetes prevention projects.

An initial hurdle was the recruitment strategy, which followed the FDPS model of opportunistic screening through health services. However, as time passed and insufficient numbers of potential participants were identified, the screening strategy was extended to involve GPs in sending personalised letters to their middle age patients without diabetes whose electronic medical record suggested a high-risk score. In addition, the US DPP approach of direct telephone contact with patients and advertising the screening service through local media and local cinemas was adopted.

Implementation of blood test requirements to exclude diabetes prior to enrolment also required some modification. Due to some participants' unwillingness to undergo a time-consuming OGTT blood test before enrolment, the Program had to allow some participants to only have FPG or HbA1c before commencement as difficulties in obtaining two blood samples led to low participation rate at the outset. The use of HbA1c instead of an OGTT led to increased recruitment rates in the weeks following relaxation of the entry criteria.

A system issue identified not unique to the SDPP or Australia but to real-life health services in general, was that no funding existed to provide customised individual coaching through case managers in the Australian health system. The heavy workloads of GPs, limited coaching skills

and low availability of nurse practitioners in GP rooms, prevented routine provision of lifestyle coaching by these professionals at sufficient intensity to maintain patient motivation and sustain behavioural changes. The SDPP required paid, dedicated lifestyle officers with nutrition, exercise physiology, psychology and nursing backgrounds to deliver face-to-face and telephone-based ongoing support necessary for participants to remain in the Program and adhere to recommendations.

The major challenges were the achievement of goals particularly 5% weight loss in 12 months and desired maintenance of increases in physical activity to 210 minutes of moderate or vigorous levels. The findings from the *reference trials* reflect the intensity of the intervention and the frequency of monitoring and counselling in a well-resourced research environment catering for a relatively homogeneous, motivated target group. Real life translations involve understaffed and underfunded services offering more flexible patient entry criteria, allowing for more chronically ill, more obese, busier, less educated and less motivated individuals to commence. This, not surprisingly, led to relatively higher withdrawal rates. More importantly, less intensive interventions covering limited number of demonstration sessions, limited number of follow-up contacts and allowing for self-monitored, unsupervised, home-based physical activity and diet necessarily resulted in smaller effect sizes. This was a consistent finding of adaptation of these trials in various community-based and clinical settings where resources precluded exact replication. The implications of smaller weight loss on diabetes prevention may not be concerning, as found by the Indian and Chinese DPPs. Lower attainment of physical activity, diet and WC changes are likely to lead to less substantial impact on diabetes incidence in the long term.

Further consideration of a more suitable type of physical activity and weight management may be warranted for this high-risk group rather than moderate or vigorous exercise or strength training. It might be worth exploring the impact of provision of free-of-charge power walking group leaders as occurred in European nation-wide programs. (86, 118, 139, 140, 142) These

are now common in Australia, sponsored by the National Heart Foundation.⁸⁰ A preliminary self-reported evaluation survey of the 3-year pilot walking groups achieved 41% response rate. Results showed participation predominantly (81%) by women, with 43% aged over 65 years, and 36% from lower income families and retention rate at 3 years of about 70%. Neither the cost-effectiveness nor the health impact of these walking groups in Australia have been published to date.

While the SDPP evaluation has shown that offering lifestyle intervention is feasible in routine care, investigation on the possible impact and cost of further modifications to certain aspects of the intervention is still warranted before a wider roll-out can be recommended. Changes may include less stringent program goals or a staged delivery. These are not necessarily based on findings of this evaluation but on feedback received during its implementation and may identify further success factors. For instance, the Program could be offered only to at-risk people who can be categorised as motivated to make the change (based on a suitable questionnaire) and to people who show readiness to persist with healthy habits. A different program intensity should be considered, such as 150 minutes per week of moderate to vigorous physical activity such as in the FDPS instead of 210 minutes/week. Alternatively a staged introduction to the Program with a preparatory phase is likely to be required for sedentary people who have not passed the contemplation stage and may not effectively take up physical activity advice. The obese and chronically ill should be encouraged to focus on brisk walking or resistance training rather than aerobic sports, and compliance encouraged through availability of free local volunteer-led brisk walking groups as part of the intervention, as successfully delivered in nation-wide European programs and not yet evaluated in Australia. On the other hand the Program could focus on dietary change which was achieved by many more people in the SDPP, and it seemed to generate better cost per outcome ratios. The threshold for reduction of fat as a proportion of

⁸⁰ www.heartfoundation.org.au/.../Ms%20Michelle%20Wilson.pdf

total calorie intake can be reduced to make it less onerous on people. Studies have demonstrated that a less stringent threshold can also achieve good results. Weight loss may only be overemphasised for the obese, as the Indian and Chinese DPPs demonstrated that diabetes prevention is possible despite minimal weight loss if other risk factors are addressed.(90, 104) People classified as depressed by the HADS at baseline will require more intensive counselling at the outset and/or increased number of reinforcement follow-up calls as depression correlates with reduced ability to achieve the dietary goals. The physical activity component could be delayed for a later phase after healthy eating motivation has set in and some level of weight loss has occurred.

10.6 Implications for Routine Clinical Practice

The evaluation confirmed the feasibility of implementation of prevention Programs in the Australian community using a clinical setting as a screening and recruitment vehicle but having additional staff types to deliver the intervention, rather than relying on existing clinical staff to deliver coaching during their limited consultation time. This evaluation also highlighted the need to consider the provision of a venue associated with or outside the clinical location to deliver the intervention and monitor outcomes.

From the evidence to date, community-based programs are expected to include less motivated participants, time-poor staff, and low-intensity intervention modalities. Hence, they are anticipated to be less efficacious but still worthwhile. The 12-month analysis confirmed that less intensive interventions generate smaller effect size on high-risk, less ready sub-populations.

What do these results mean in the context of other translational efforts? Less intensive and less ambitious but well structured interventions including telephone-based behavioural coaching and involvement of allied health staff are more likely to be implemented and could further assist in recruiting hard to reach groups such as males and people in rural areas. Wider dissemination to other areas has the potential to have an additive effect of containing the rapid progression of pre-diabetes at the population level. As more impact evaluation results emerge from other

translation experiences, the evidence will build up to inform decisions on whether subsidy should also be recommended for routine preventative care for at-risk populations in the 50-65 year age groups, just like the 40-49 currently subsidised by Medicare in Australia.

10.7 Implications for Population Health

The Sydney Diabetes Prevention Program brought together lessons in its replication of the FDPS and overall the Program reached a reasonably sized group with the intended high-risk profile. The effect size found for weight loss and waist circumference was about half that achieved by participants in the intensive, structured, closely monitored reference trials. Yet in the absence of global consensus on specific guidelines for practical implementation of behaviour modification programs in the real world, it is worth pursuing small or large-scale local lifestyle interventions in these settings. The SDPP's modest effect would translate into considerable risk reduction and public health benefit if extrapolated to all people with pre-diabetes in primary care or to entire populations with high prevalence of risk factors. However, using a standard prevention approach for all at-risk adults may not be appropriate. Motivating asymptomatic people or chronically ill people to engage in and maintain high levels of physical activity remains a great challenge. Mass media campaigns and standard GP prescriptions for exercise need reconsideration as strategies to achieve levels that result in health benefit. Achieving sustained adoption of healthy lifestyle requires a more targeted approach which may include coaching on specific types of exercise for people in different demographic and morbidity profiles. This needs further investigation at the patient and population level. Alternatively, as the cost of an individual achieving Program goals may be too high to apply to the overall population at risk in routine clinical settings, the Program could be more efficiently administered if targeted to highly motivated individuals and limited to pursuing the goals that generate the best and less costly results. This may contribute to risk reduction but its impact on diabetes prevention at a population level may be even smaller.

10.8 Possible areas for future research

A qualitative review of options for improved access to community-based lifestyle services for middle-age at-risk people of limited financial resources could be conducted to improve uptake of regular physical activity. Alternatively, a consultation with current and former participants could be undertaken on preferred options for moderate-vigorous physical activity in this group of obese, busy people suffering multiple comorbidities. Investigation of the effectiveness of subsidies for home gym equipment could provide valuable information on a more acceptable transition phase for sedentary people who are unfamiliar with or have reservations about using private physical activity facilities or Programs but are motivated to make sustainable behaviour changes.

Other areas identified for future research following this Program could focus on: impact of modification to goals or gradual implementation of goals; alternative less expensive ways to maintain healthy behaviours among those who already meet the goals at baseline; specific types of moderate physical activity that lead to sustained engagement among people in particular demographic and morbidity sub-groups; the cost-effectiveness of targeted screening compared with opportunistic screening; the effectiveness of *initial consultation only* followed exclusively by telephone support on a larger sample than that available for the SDPP telephone coaching group; the degree of benefit of this lifestyle intervention for people who are at high risk for diabetes but are not obese (e.g. the Chinese cohort); and the long-term impact of involvement in the Program several years after the end of the active phase (i.e. a cohort study of SDPP completers with a control group not exposed to lifestyle intervention).

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Appendix 1.1 The Findrisc tool



TYPE 2 DIABETES RISK ASSESSMENT FORM

Circle the right alternative and add up your points.

1. Age

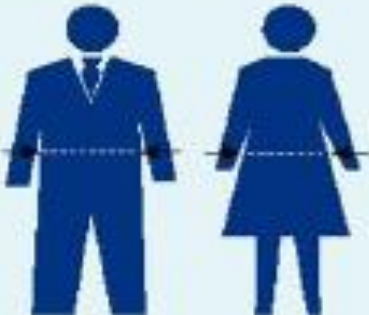
0 p. Under 45 years
 2 p. 45–54 years
 3 p. 55–64 years
 4 p. Over 64 years

2. Body-mass index
 (See reverse of form)

0 p. Lower than 25 kg/m²
 1 p. 25–30 kg/m²
 3 p. Higher than 30 kg/m²

3. Waist circumference measured below the ribs (usually at the level of the navel)

	MEN		WOMEN
0 p.	Less than 94 cm		Less than 80 cm
3 p.	94–102 cm		80–88 cm
4 p.	More than 102 cm		More than 88 cm



4. Do you usually have daily at least 30 minutes of physical activity at work and/or during leisure time (including normal daily activity)?

0 p. Yes
 2 p. No

5. How often do you eat vegetables, fruit or berries?

0 p. Every day
 1 p. Not every day

6. Have you ever taken antihypertensive medication regularly?

0 p. No
 2 p. Yes

7. Have you ever been found to have high blood glucose (eg in a health examination, during an illness, during pregnancy)?

0 p. No
 5 p. Yes

8. Have any of the members of your immediate family or other relatives been diagnosed with diabetes (type 1 or type 2)?

0 p. No
 3 p. Yes: grandparent, aunt, uncle or first cousin (but no own parent, brother, sister or child)
 5 p. Yes: parent, brother, sister or own child

Total Risk Score

The risk of developing type 2 diabetes within 10 years is

Lower than 7	Low: estimated 1 in 100 will develop disease
7–11	Slightly elevated: estimated 1 in 25 will develop disease
12–14	Moderate: estimated 1 in 6 will develop disease
15–20	High: estimated 1 in 3 will develop disease
Higher than 20	Very high: estimated 1 in 2 will develop disease

Please turn over

Appendix 1.2 The AusDrisk tool

The Australian Type 2 Diabetes Risk Assessment Tool (NOSDRISK)

- | | | | |
|---|------------------|----------|--|
| 1. Your age group? | | | |
| Under 35 years | 0 points | | |
| 35 – 44 years | 2 points | | |
| 45 – 54 years | 4 points | | |
| 55 – 64 years | 6 points | | |
| 65 years or over | 8 points | | |
| 2. Your gender? | | | |
| Female | 0 points | | |
| Male | 3 points | | |
| 3. Ethnicity/Country of birth: | | | |
| 3a. Are you of Aboriginal, Torres Strait Islander, Pacific Islander or Maori descent? | | | |
| No | 0 points | | |
| Yes | 2 points | | |
| 3b. Where were you born? | | | |
| Asia (including the Indian sub-continent), Middle East, North Africa, Southern Europe | 2 points | | |
| Other | 0 points | | |
| 4. Have either of your parents, or any of your brothers or sisters been diagnosed with diabetes (type 1 or type 2)? | | | |
| No | 0 points | | |
| Yes | 3 points | | |
| 5. Have you ever been found to have high blood glucose (sugar) (for example, in a health examination, during an illness, during pregnancy)? | | | |
| No | 0 points | | |
| Yes | 6 points | | |
| 6. Are you currently taking medication for high blood pressure? | | | |
| No | 0 points | | |
| Yes | 2 points | | |
| 7. Do you currently smoke cigarettes or any other tobacco products on a daily basis? | | | |
| No | 0 points | | |
| Yes | 2 points | | |
| 8. How often do you eat vegetables or fruit? | | | |
| Everyday | 0 points | | |
| Not everyday | 1 point | | |
| 9. On average, would you say you do at least 2.5 hours of physical activity per week (for example, 30 minutes a day on 5 or more days a week)? | | | |
| Yes | 0 points | | |
| No | 2 points | | |
| 10. Your waist measurement taken below the ribs (usually at the level of the navel)? | | | |
| For those of Asian or Aboriginal or Torres Strait Islander descent: | | | |
| Men | Women | | |
| Less than 90 cm | Less than 80 cm | 0 points | |
| 90 – 100 cm | 80 – 90 cm | 4 points | |
| More than 100 cm | More than 90 cm | 7 points | |
| For all others: | | | |
| Men | Women | | |
| Less than 102 cm | Less than 88 cm | 0 points | |
| 102 – 110 cm | 88 – 100 cm | 4 points | |
| More than 110 cm | More than 100 cm | 7 points | |

Add up your score

Your risk of developing type 2 diabetes within 5 years*:

5 or less: Low risk

Approximately one person in every 100 will develop diabetes.

6–14: Intermediate risk

For scores of 6–8, approximately one person in every 50 will develop diabetes.

For scores of 9–14, approximately one person in every 20 will develop diabetes.

15 or more: High risk

For scores of 15–19, approximately one person in every seven will develop diabetes.

For scores of 20 and above, approximately one person in every three will develop diabetes.

If you scored 15 or more points, it is important that you discuss your score with your doctor.

*The overall score may overestimate the risk of diabetes in those aged less than 25 years and underestimate the risk of diabetes in people of Aboriginal and Torres Strait Islander descent. The Australian Type 2 Diabetes Risk Assessment Tool was originally developed by the International Diabetes Institute on behalf of the Australian, State and Territory Governments as part of the COAG Diabetes reducing the risk of type 2 diabetes initiative.

Appendix 3.1 Systematic Review (peer-reviewed) paper

Cardona-Morell et al. *BMC Public Health* 2010, **10**:653
<http://www.biomedcentral.com/1471-2458/10/653>



RESEARCH ARTICLE

Open Access

Reduction of diabetes risk in routine clinical practice: are physical activity and nutrition interventions feasible and are the outcomes from reference trials replicable? A systematic review and meta-analysis

Magnolia Cardona-Morell¹, Lucie Rychetnik, Stephen L. Morrell, Paola T. Espinel, Adrian Bauman

Abstract

Background: The clinical effectiveness of intensive lifestyle interventions in preventing or delaying diabetes in people at high risk has been established from randomised trials of structured, intensive interventions conducted in several countries over the past two decades. The challenge is to translate them into routine clinical settings. The objective of this review is to determine whether lifestyle interventions delivered to high-risk adult patients in routine clinical care settings are feasible and effective in achieving reductions in risk factors for diabetes.

Methods: Data sources: MEDLINE (PubMed), EMBASE, CINAHL, The Cochrane Library, Google Scholar, and grey literature were searched for English-language articles published from January 1990 to August 2009. The reference lists of all articles collected were checked to ensure that no relevant suitable studies were missed. Study selection: We included RCTs, before/after evaluations, cohort studies with or without a control group and interrupted time series analyses of lifestyle interventions with the stated aim of diabetes risk reduction or diabetes prevention, conducted in routine clinical settings and delivered by healthcare providers such as family physicians, practice nurses, allied health personnel, or other healthcare staff associated with a health service. Outcomes of interest were weight loss, reduction in waist circumference, improvement of impaired fasting glucose or oral glucose tolerance test (OGTT) results, improvements in fat and fibre intakes, increased level of engagement in physical activity and reduction in diabetes incidence.

Results: Twelve from 41 potentially relevant studies were included in the review. Four studies were suitable for meta-analysis. A significant positive effect of the interventions on weight was reported by all study types. The meta-analysis showed that lifestyle interventions achieved weight and waist circumference reductions after one year. However, no clear effects on biochemical or clinical parameters were observed, possibly due to short follow-up periods or lack of power of the studies meta-analysed. Changes in dietary parameters or physical activity were generally not reported. Most studies assessing feasibility were supportive of implementation of lifestyle interventions in routine clinical care.

Conclusion: Lifestyle interventions for patients at high risk of diabetes, delivered by a variety of healthcare providers in routine clinical settings, are feasible but appear to be of limited clinical benefit one year after intervention. Despite convincing evidence from structured intensive trials, this systematic review showed that translation into routine practice has less effect on diabetes risk reduction.

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Background

The clinical effectiveness of intensive lifestyle interventions in preventing or delaying development of diabetes in people at high risk has been established from randomised controlled trials of structured, intensive interventions conducted over the past two decades in the USA [1,2], China [3], Finland [4,5], and India [6]. These interventions, promoting healthy eating and moderate physical activity, have shown that sustained weight loss of 3.5 kg or more can be achieved with lifestyle interventions, and that onset rates of diabetes can be reduced by as much as 58% in the first few years. A protective effect of the lifestyle intervention of about 43% has also been shown 20 years following the initial intervention in a Chinese study [7]; and a 34% reduction in diabetes incidence was shown to persist 10 years following an intervention in the USA [8]. There is also evidence, from a large cohort study, that even without a formal intervention, diabetes risk was lowered in people whose lifestyle change was consistent with at least three of the goals of the Finnish Diabetes Prevention program [9]. The study's authors estimated that a further 20% reduction in the incidence of diabetes after 4.6 years of follow-up would occur if a further goal were met.

Calls for broader implementation of lifestyle interventions for diabetes prevention in clinical settings are not uncommon in the literature [10-17], although there has been recognition that translation or replication of randomised controlled trials is not straightforward, and long-term sustainability is uncertain [18,19]. Application of lifestyle recommendations and demonstrated replication of clinical trial approaches in routine clinical practice often are hindered by lack of resources or reimbursement [20], lack of practitioners' time or skill [21,22], practical difficulties with recruitment, measurement error, and poor patient retention due to the complexities of the transition between awareness, motivation and action [18,23,24]. Little systematic information exists on the feasibility or effectiveness of replications of these interventions (or less intensive and more generalisable settings for lifestyle intervention), and on achievement of expected associated benefits as part of routine clinical practice.

To our knowledge, no compilations of trials or reviews of replication studies as part of preventive care in routine clinical practice appear to have been reported. Accordingly, this review presents a summary of outcomes from the routine clinical context and examines the feasibility of transferring the diabetes prevention research to real-world settings. In short, the review assesses the extent that outcomes from clinical trials of lifestyle interventions into physical activity and nutrition

to lower diabetes risk have been replicated in routine clinical practice.

Methods

Search strategy

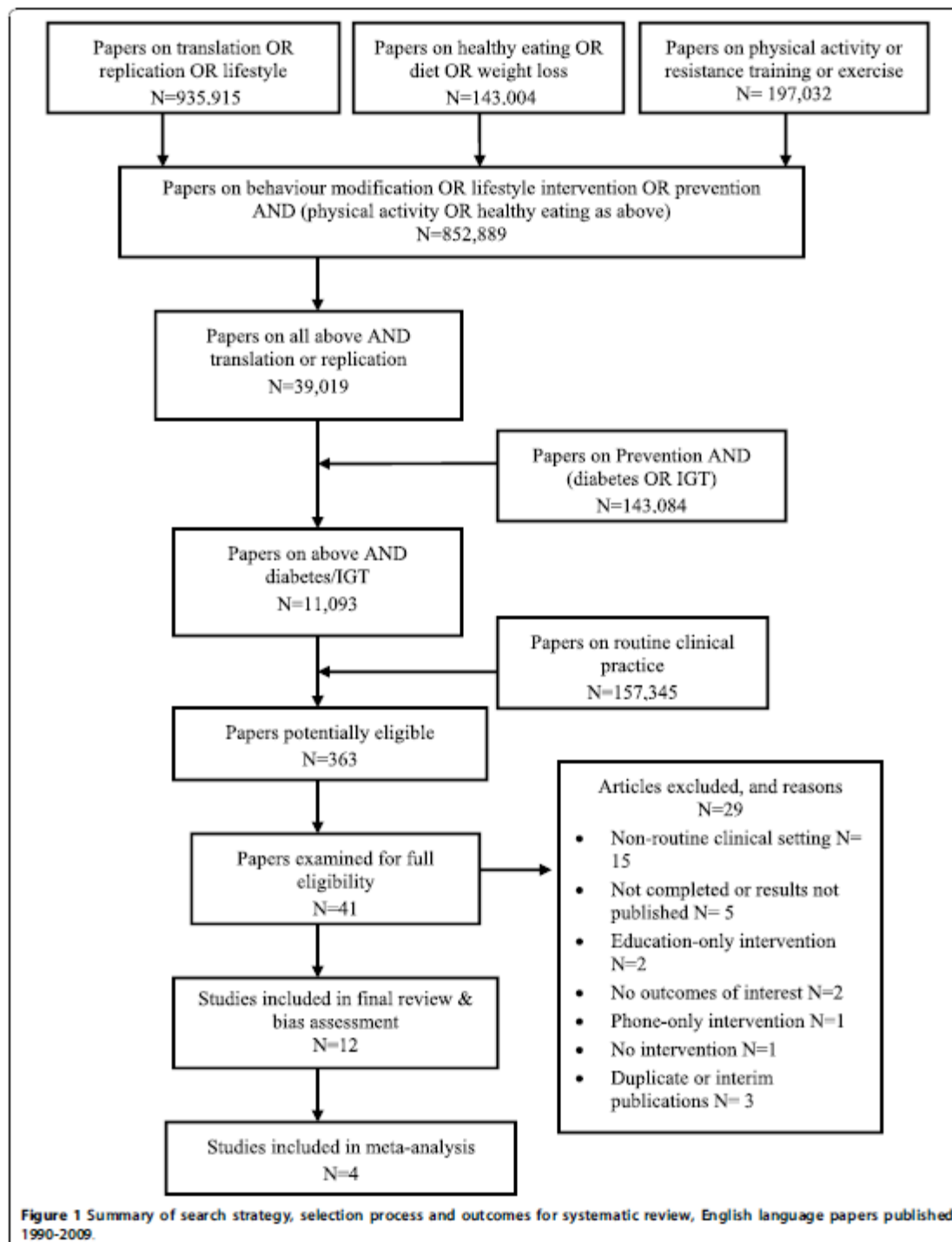
The search was confined to English language articles published between January 1990 and August 2009. Three authors (MC-M, LR, AB) separately interrogated different data sources using the same search terms (see appendix). This was supplemented with hand searches of the reference sections of other systematic reviews [2,18,19,25-40]. Only studies which investigated at least one of our research questions above, and which were consistent with our inclusion criteria below, were considered in this review (Figure 1).

Study selection

The review focused on translational research studies where interventions were based on any of the large reference diabetes prevention RCTs mentioned above. These could be: replication studies in the form of RCTs, before/after evaluations, cohort studies with or without a control group, or interrupted time series analyses, where participants have been exposed to a lifestyle intervention of at least 3 months duration and followed up for at least 3 months. Routine clinical practice was defined as a health service setting providing patient care such as primary health clinics, hospital outpatient clinics or specialist medical centres.

Intervention types

Interventions were classified as single (either nutrition or physical activity programs with or without medication), or combined nutrition and/or physical activity programs (structured or unstructured) whether or not they included medication. Structured intervention components were defined as those in which participants received a standard set of sessions with instructions on specific dietary and/or physical activity requirements and goals. In unstructured interventions participants were given generic advice on healthy living without specific goals other than improving diet or physical activity in relation to baseline. The comparison group might be 'no intervention group' or an 'alternative intervention' (single or combined). Prevention programs delivering diabetes education materials only were excluded. Likewise, medication-only studies were excluded. Only programs conducted in routine health services, delivered on-site or in associated facilities, with outcomes measured in healthcare settings by general medical practitioners, specialist physicians, practice nurses, dietitians, physiotherapists, allied health professionals, community health staff, or research staff attached to the health



service, were included in this review. Interventions either had to be replications or modification of all or some components of the US Diabetes Prevention Program [DPP] [1] or Finnish Diabetes Prevention Study [DPS] [5] or any other reference trial, or had to include the reduction of diabetes risk or diabetes incidence explicitly as a goal or objective.

Target group

Participants were adult men or women with any degree of impaired glucose regulation (impaired fasting glucose or impaired glucose tolerance) or with normal glycaemia but at risk of diabetes as determined by risk factors such as obesity or family history. They may have been recruited from the primary or other healthcare patient clientele or from the general population but had to receive the intervention through routine healthcare services. Participants' risk of diabetes may have been determined by a diabetes risk score, either measured or from self-report, and may have had accompanying blood glucose tests to either identify impaired glucose regulation or exclude diabetes before receiving the intervention. Studies including patients with diagnosed diabetes were included in this review only if they were a replication of the reference trials and whose outcomes were reported separately from participants without diabetes.

Outcomes of interest

Studies were included if they reported at least one of the following main outcome measures of interest:

- Improvement in objectively measured risk factors such as weight loss or waist circumference reduction.
- Metabolic outcomes indicative of diabetes risk reduction (improvement of fasting glucose levels, improved 2-hour post-prandial plasma glucose, or reduction of HbA1c)
- Self-reported or objectively measured behavioural outcomes such as increased physical activity (minutes per day or METS per hour), increased fibre consumption (grams per day or gm per KJ), or reduction of fat intake (% of total energy intake).

The secondary outcome examined was:

- Prevention of diabetes (incidence %, or delay in onset or reduction in incidence over a given follow-up time).

Bias assessment

To assess the potential for bias, and given the heterogeneity of studies included in this review, a generalisability

and bias assessment tool covering elements of various checklists and resources from the literature was specifically designed. Items examined included participant recruitment source, selection criteria, treatment allocation, blindness of outcome assessment, simultaneous collection of data for intervention and control groups, measurement error, subgroup analysis and discussion of study limitations (tool available from the authors on request). Reference tools used for this design were STROBE, COCHRANE Collaboration, CLEAR NPT, EQUATOR, PRISMA, TREND and MOOSE [41-46]. One of the authors (MC-M) conducted the bias and quality assessment of all studies and three other authors (LR, SM & PTE) independently conducted the second bias and quality assessment of some of the studies. Two of the authors (MC-M & SM) independently extracted results and assessed the appropriateness of statistical analyses and conclusions.

Assessment of study quality

Study quality was assessed and graded on the following criteria: (1) evidence of assessment of risk for diabetes at enrolment; (2) explicit eligibility and exclusion criteria; (3) reported participation rate of at least 50% of eligible people; (4) follow-up assessment rates of $\geq 65\%$ of program participants by study conclusion or follow-up; (5) evidence of measurable or explicit outcome assessment; (6) appropriate statistical methods, including adequate control for confounders (in non-RCTs); (7) explicit intervention components; (8) conclusions supported by findings. A numeric score giving equal weight to each of the above criteria was used to determine quality. The maximum possible score was thus 8, indicating highest quality.

Statistical analysis

The denominator for the effect sizes was the number of subjects in whom the outcome had been assessed. Study results were categorised as positive (statistically significant difference observed), negative (no difference or statistically significant negative effect), or inconclusive (showed no difference but lacked sufficient power to detect a difference). Given the heterogeneity of designs, length of follow-up and outcome measurements of the available studies, pooling of selected results for a meta-analysis was feasible only for four RCTs reporting 12-month follow-up results [47-50]. The remaining eight studies were critically reviewed but not meta-analysed. Changes in means, and tests of heterogeneity between trials were calculated using random effects models. When not reported in individual studies, standard deviations of mean differences in outcome measures were calculated from supplied study participant numbers and standard errors or from 95% confidence

limits, either of before-and-after means or from before-and-after differences in mean values. Meta-analysis was conducted using NCSS software version 7.1.1.9 [51] on the four main outcomes of interest: changes in weight, fasting plasma glucose, waist circumference and 2-hour OGTT.

Sensitivity analysis by study quality was not deemed necessary as all four studies finally selected for meta-analysis had a quality score of 7 or 8 out of the possible 8 maximum score. Our search did not identify unpublished replication studies of diabetes prevention in routine clinical practice. Accordingly, we expected findings not to be significantly affected by publication bias.

Results

Our searches identified 41 potentially eligible diabetes prevention studies of lifestyle interventions in clinical practice that included various combinations of diet and/or exercise for diabetes risk reduction or diabetes prevention. Of these, 18 studies were excluded because: their replications of lifestyle interventions were conducted in non-routine clinical settings (e.g. in community settings such as homes, public centres, churches, or workplaces) [52-59], or in a research setting [47,60-65]; or they did not include at least one of the outcomes of interest [66,67]. A further 5 were excluded because they were trials underway and/or had not published results to date [16,68-70]; or they replicated a reference trial for people who already had diabetes [71]. A further 6 studies were excluded because: the study compared results retrospectively with reference trials without conducting an intervention [9]; the intervention was confined to a diabetes education component only [72,73]; the intervention was telephone-based only and had not replicated components of the reference trials [74]; or they were either duplicates, companion or interim reports, of studies already selected [75-77].

Differences in presentation of results (e.g. monthly weight change without SD [78], or BMI change instead of weight change [79], or FPG ranges instead of group means [79]) precluded inclusion of two studies in the meta-analysis. One study, with the largest sample size [80], could not be meta-analysed to estimate the effects of a lifestyle intervention, as both the medication and placebo arms received the lifestyle intervention, i.e. the study measured the effects of medication as an adjunct to lifestyle intervention.

The final set of 12 studies covered in this review included 7 randomised controlled trials (including one cluster RCT), 3 before-after designs without a control group and two before-after designs with a control group (Table 1). The studies were conducted in 8 OECD countries, and had sample sizes ranging from 58 to 3,304 (median 311), with participant ages ranging from 20 to

79 years; six of the studies targeted middle-aged people only. All interventions combined physical activity and dietary advice, two studies also included medication as part of the intervention [50,80], and all were delivered in routine clinical settings, such as specialist services or hospital outpatient clinics (5), general practitioner consulting rooms (5) or community health services (2). Staff delivering the intervention were usually nurses or allied health staff (8/12). The target groups were people at high risk, defined either by the presence of impaired glucose tolerance, severe obesity, or metabolic syndrome or some of its components. Eight of these studies also included normoglycaemic patients and two replication studies included both subjects with and without diabetes and pre-diabetes.

Types of lifestyle interventions reported

All studies included a combined lifestyle intervention but two eligible studies included a medication arm in addition to lifestyle. Seven studies attempted replication of the reference trial approaches from either the U.S DPP [1] or the Finnish DPS [81] with adaptation to routine clinical practice, mostly to cater for limitations in practitioner's time and health service budgets [14,48,49,78,82-84]. Modifications included: shorter duration of program (2/7); delivery of group sessions instead of individual face-to-face counselling (4/7); reduced number and frequency of individual or group counselling sessions to which participants were exposed (5/7); and mixed group and individual program approaches (1/7).

Modifications of interventions during the maintenance phase included intermittent support sessions, more economical versions of the resources given to participants, and multidisciplinary teams, either available on site or hired as an additional service. For interventions delivered in a group-based modality, the maximum number of sessions per program was 16, as per the reference trial [1] (median of 6 sessions), but over a shorter period of time. Among the 5 studies reporting delivery of individual counselling sessions, the median number of individual counselling sessions was 13.5.

All dietary interventions were structured and half the physical activity interventions were unstructured (Table 2). While some interventions were delivered with a core intensive phase and an intermittent approach for the maintenance phase, the median duration of intervention was 32 weeks; follow-up periods also varied from 4 to 60 months with a median follow-up duration of 12 months. Delivery of the modified versions of the reference trial interventions was mostly by nurses, psychologists or allied health staff such as health promotion counsellors, dietitians or exercise physiologists alone (8/12) who provided the training, demonstration,

Table 1 Classification of eligible studies by design, target population, outcomes and quality score (1990-2009)

Author, year, reference #	Study Design	Total sample size	Target age group	Country & Setting of recruitment	Inclusion criteria: Normal or abnormal GT	Loss to follow-up rate %	Outcome assessment: Measured OR self-reported	Study Quality score ¹
*Bailey, 2008 [87]	RCT	37	50-85	UK: Single general practice	IGT or IFG	19%	Measured weight, WC, FPG, lipids, self-reported exercise, 4-day food diary	7
Greaves, 2008 [86]	RCT	141	18+	UK: 2 GP surgeries	NGT or IGT	18%	Measured weight, WC and self-reported physical activity	7
*Bo, 2007 [48]	RCT	375	45-64	Italy: Family physician GPs	Metabolic Syndrome	11%	Self-reported FFQ & exercise; Measured FPG, insulin, weight, WC, lipids, CRP	8
*Kosaka, 2005 [49]	RCT	458	Adult males 30+	Japan: Hospital outpatient Clinic	IGT	15.9%	Measured FPG, OGTT, HbA1c, measured weight, lipids	7
Torgerson, 2004 [80]	RCT	3,304	30-60	Sweden: Medical centres	NGT & IGT	57% overall; 48% on medication & 66% on placebo	Measured weight, WC, FPG, lipids, serum insulin, fibrinogen	7
*Dyson, 1997 [50]	RCT	227	40-60	UK, France: 5 Hospitals	IFG	11%	FPG, OGTT, HbA1c, lipids, measured weight, max O2 uptake, self-reported 3-day food record & physical activity log	7
Whittemore, 2009 [78]	CLU	58	21+	USA: Primary care practices	NGT & IGT	12%	Self-reported exercise and nutrition Measured weight, WC, insulin resistance, lipids	7
McTigue, 2009 [84]	BAC	166	20-79	USA: Primary care practices	Obese, NGT or diabetic	7%	Measured weight	5
Eriksson, 1991 [79]	BAC	181	47-49	Sweden: Borderline diabetes clinic	NGT & IGT	22.8%	Self-reported exercise, max O2 uptake, FPG, OGTT, lipids, measured weight, skinfold, mortality	7
Pagoto, 2008 [14]	B-A	118	Middle age	USA: Academic medical center	Metabolic syndrome, NGT or diabetic	17%	Measured weight, BP,	3
Laatikainen, 2007 [83]	B-A	311	40-75	Australia: General practices	NGT & IGT	23.8%	Self-reported FFQ, SF-36, K10; Measured FPG, 2 hr PG, WC, weight, lipids	7
Absetz, 2005 & 2009 [77,82]	B-A	352	50-65	Finland: Primary health care centres	NGT & IGT	94%	Self-reported 3-day food diary, physical activity, Measured weight, WC, FPG, lipids	7

BA = before-after; BAC = Before-after with a control group; BP = Blood pressure; CLU = Cluster-randomised trial; FFQ = Food frequency questionnaire; FPG = Fasting plasma glucose; IGT = Impaired glucose tolerance; NGT = Normal glucose tolerance; PA = Physical activity; OGTT = Oral glucose tolerance test; RCT = Randomised controlled trial; WC = Waist circumference.

*Study used for meta-analyses.

¹ Higher quality score = higher study quality.

counselling or education sessions. Physicians were mainly involved in assessing participant eligibility, referral and outcome measurement (7/12). Two studies did not report the professional background of people delivering the intervention or assessing the participants [49,80].

Type of outcomes reported

Reported measured outcomes of interest were weight (12/12), fasting plasma glucose (9/12) waist

circumference (7/12), and 2-hour OGTT (3/12) (Table 3). Six studies had follow-up periods enabling the examination of diabetes incidence or incidence reduction, with the remainder confined to reporting risk improvement via behavioural modification or improvement in metabolic or anthropometric parameters. Self-reported dietary and physical activity outcomes of interest amenable to statistical comparison were not often reported and were confined to mean reduction in fat intake as a percentage of total energy (3/12), and changes in fibre

Table 2 Description of studies by lifestyle components and modality of each intervention

Author, year [reference]	Physical activity program*		Dietary modification*	Face-to-face Counselling		Phone counselling	Outcome assessment		Duration (months)		Control Intervention	Program delivered by	Outcomes assessed by
	Structured	Unstructured		No. Individual sessions	No. Group sessions		No.	Objective	Self-report	Inter-vention			
Barclay, 2008 [87]		Y	Y	-	6	-	Y	Y	1	6	Usual management from GP or nurse	Nutritional scientist, psychologist, aerobics instructor	Nutritionist, research assistant
Greaves, 2008 [86]		Y	Y	11		2	Y	Y	6	6	Usual care + information only	Health promotion counsellor	Researcher
Bq, 2007 [48]		Y	Y	1	4	-	Y	Y	12	12	Usual care + general verbal information	GPs, endocrinologists, nutritionists	Physician
Kosaka, 2005 [49]		Y	Y	1	16	-	Y	Y	12	48	Verbal lifestyle advice every 6 months	NR	NR
Torgerson, 2004 [80]		Y	Y	54	-	-	Y	Y	48	48	Same lifestyle advice minus medication	Dieticians	Doctors & other PHC staff
Dyson, 1997 [50]	Y		Y	5	-	-	Y		12	12	Once only, written basic lifestyle advice	Dietician, fitness instructor, physician	NR
Whittemore, 2009 [78]	Y		Y	6	-	5	Y	Y	6	6	20-30 minutes with nurse & 45 minutes with nutritionist	Nurses	Nurses
McTigue, 2009 [84]		Y	Y		12				12	12	No intervention	Nurses	Physicians
Eriksson, 1991 [79]	Y		Y	7	-	-	Y	-	12	60	No specific diabetes prevention intervention or no intervention	Dietician, Nurse, Physiotherapist	Doctor
Pagoto, 2008 [14]	Y		Y		16		Y		4	4	No control group	Dieticians, psychologists, exercise physiologists	Physicians
Laatikainen, 2007 [83]	Y		Y		6	Y	Y		8	12	No control group	Dieticians, Nurses, Physiotherapist	Other PHC
Absetz, 2005, 2009 [82]	Y		Y		6			Y	8	12	No control group	Nurse, dietician, Physiotherapist	Doctor, Nurse

Y = Yes, reported NR = not reported GPs = general practitioners.

* Structured = Participants received standard set of sessions with instructions on specific dietary and/or physical activity requirements and goals;

Unstructured = participants were given generic instructions on improved lifestyle or had flexibility to apply them and no specific goal was set apart from improved diet or physical activity in relation to baseline.

Table 3 Results of measured outcomes and direction of effect reported at the end of the study: 1 year follow-up or less, and 3-years or more (1990-2009)

Author, year, reference # follow-up time	Reduction in diabetes incidence (% OR, RR)	Incidence of diabetes	Improvement of FPG or 2 h PG in mmol/L	% participants achieving \geq 5% weight loss	Mean weight loss Kg	Mean reduction in WC (cm)
Results at one year or earlier						
McTigue, 2009 [84] 1 year	NR	NR	NR	27% of intervention vs. 6% of controls achieved 7% weight loss	-5.2 Kg intervention vs. +0.2 Kg control	NR
Bo, 2007 [48] 1 year	Adjusted OR = 0.23 (0.06-0.85)	1.8% in intervention vs. 7.2% in controls	-0.26 mmol/L FPG intervention vs. +0.07 controls OR for IFG = 0.22 (0.13-0.39)		-0.75 Kg in intervention vs. +1.63 Kg in controls	-2.55 cm in intervention vs. +1.96 cm in controls
Laatikainen, 2007 [83] 1 year	23% based on weight loss; 40% based on WC reduction	2.2% of IGT or IFG participants	-0.14 mmol/L	NR	-2.5 Kg	-4.2 cm
Kosaka, 2005 [49] 1 year	NR	NR	NR	NR	-2.5 Kg in intervention vs. -0.39 Kg in control	NR
Absetz, 2005 [82] 1 year	NR	6% of those meeting 4-5 goals vs. 3% of those meeting 3 or fewer goals	+0.1 mmol/L \pm 0.6	12% achieved 5% weight loss	-0.8 Kg \pm 4.5 Kg	-1.6 cm \pm 4.8 cm
Torgerson, 2004 [80] 1 year	NR	NR	NR	72.8% in medication + lifestyle vs. 45.1% in placebo + lifestyle	-10.6 Kg in medication +lifestyle vs. -6.2 Kg in placebo+ lifestyle	-9.6 cm in medication +lifestyle vs. -7.0 cm in placebo+ lifestyle
Dyson, 1997 [50] 1 year	NR	NR	-0.1 mol/L in intervention vs. -0.2 mmol/L in control	NR	-0.4 Kg in intervention vs. -0.2 Kg in control	NR
Whittemore, 2009 [78] 6 months	NR	N/A	Reported no difference between groups, but no data shown	25% interv vs. 11% control		-0.5 cm intervention vs. -0.1 cm control
Greaves, 2008 [86] 6 months	NR	N/A	NR	23.6% interv vs. 7.2% control	Mean difference 1.3 Kg	Mean difference -1.6 cm
Barclay, 2008 [87] 6 months	NR	N/A	-0.02 mmol/L FPG intervention vs. +0.25 mmol/L control at 6 months		-2.73 Kg intervention vs. -0.3 Kg control	-6.01 cm intervention vs. -1.18 cm control
Pagoto, 2008 [14] 4 months	NR	N/A	NR	30% achieved 7% weight loss	-5.5 Kg in whole sample and -6.5 Kg in participants without comorbidities at 4 months	NR
(Laatikainen) Kiviköinen, 2007 [75] 3 months	NR	N/A	No change	NR	-2.4 Kg	-3.2 cm
Results at 6, 4 or 3 years						
Etiksson, 1991 [79] 6 years	RR = 0.37 (0.20-0.68)	10% prevalence in intervention vs. 28.6% prevalence in controls	52.2% normalized 2 hr OGTT in intervention vs. 35.7% normalized in IGT non-intervention controls	NR	-3.3 Kg vs. +0.2 Kg	NR

Table 3 Results of measured outcomes and direction of effect reported at the end of the study: 1 year follow-up or less, and 3-years or more (1990-2009) (Continued)

Kosaka, 2005 [49] 4 years	67.4% reduction in intervention group	3% intervention vs. 9.3% in control	53.8% intervention vs. 33.9% in control	NR	-2.2 Kg in intervention vs. -0.39 Kg in control	NR
Torgerson, 2004 [80] 4 years	Total intervention group 37.3%; IGT patients 45%	6.2% in medication + lifestyle vs. 9% in placebo + lifestyle	0.1 mmol/L in medication + lifestyle vs. 0.2 mmol/L in placebo + lifestyle	52.8% vs. 37.3%	-5.8 Kg in medication vs. 3 Kg in placebo	w-6.4 cm in medication + lifestyle vs. -4.4 cm in placebo+lifestyle
Absetz, 2009 [77] 3 years	NR	1.2% of those with IGT at baseline vs. 1.2% of those with normal FPG at baseline	0.0 ± 0.8 mmol/L	NR	-1 Kg ± 5.6 Kg	+0.1 cm ± 6.4 cm

NR = not reported N/A = not applicable.

intake (3/12). These are summarised in Table 4. Due to the heterogeneity of units used for measuring and

Table 4 Direction and magnitude of self-reported outcomes at end of program of any duration (1990-2009)

Author, year and reference #	Improvement in frequency of physical activity/week		Reduction of fat intake Mean reduction in energy %		Increased fibre intake in g/day	
	% achieved goal	Mean change	% achieved goal	Mean reduction	% achieved goal	Mean increase
Whitmore, 2009 [78]	+17% in interv vs. +1% in controls at 6 months	NR	NR	NR	NR	NR
Bo, 2007 [48]		+473 MET-hr intervention vs. in -0.26 MET-hr in controls at 1 yr		-2.64% in intervention vs. -0.02% in controls at 1 yr		+1.7 g/day intervention vs. +0.17 g/d in controls at 1 yr
Barclay, 2008 [87]	NR	NR	NR	NR	NR	NR
Greaves, 2008 [86]	37.5% interv vs. 27.5% control	NR	NR	Reported successful reduction of total fat and saturated fat but no data shown	NR	NR
Kosaka, 2005 [49]	NR	NR	NR	NR	NR	NR
Torgerson, 2004 [80]	NR	NR	NR	NR	NR	NR
Dyson, 1997 [50]		+0.17 L/min VO ₂ max in interv vs. -0.03 L/min in controls at 1 yr		-3.5% in intervention vs. -1.4% in control at 1 yr		+0.9 g/day intervention vs. -0.7 g/day in control at 1 yr
Eriksson, 1991 [79]	NR	increase of 17% in IGT and 9% Oxygen uptake at 1 yr	NR	NR	NR	NR
McTigue, 2009 [84]	NR	NR	NR	NR	NR	NR
Pagoto, 2008 [14]	NR	NR	NR	NR	NR	NR
Laatikainen 2007 [83]	NR	NR	NR	NR	NR	NR
Absetz, 2005 [82]	66%	NR	48%	NR	5.2%	

NR = not reported.

reporting changes in physical activity, it was not possible to meta-analyse these outcomes.

Study quality findings

While three of the 12 studies justified their sample sizes on statistical grounds, and not all adjusted for potential confounders, the quality of study design and reporting overall was good in 10 of the 12 studies included, based on quality criteria scores of 7 or 8 out of 8 (Table 1). Two studies were considered suboptimal, with quality scores of 3 or 5 out of 8 respectively [14,84].

Limited generalisability was identified in five studies, where participants recruited were either self-referred healthy volunteers [50] or a convenience sample of males only [49,79], or mostly severely obese middle-age women [14,78]. Two studies reported higher success rates for participants who had already met the goals at baseline [78,82]. In two studies [14,84] the intervention incurred charges and out-of-pocket expenses for each session, which lead to differential exposure to intensity and duration of intervention on the basis of participant's ability to pay. Participation rates for the 8 studies reporting them were satisfactory (median 83.5%). However, in one of the studies, where the participation rate was ostensibly 100%, the control group comprised all those people who did not participate due to financial reasons (on whom outcome measures were collected, but possible exposure to other risk reduction regimes was not recorded) [84].

Loss-to-follow up rates in the 12 studies varied greatly, from 5% to 57% (median 14%). Differential withdrawal rates were reported in a further three studies, where a larger proportion of drop-outs were observed: in participants at highest baseline risk [78]; in those from the intensive arm of the intervention [50]; or in subjects who perceived a poor response to the allocated treatment [80].

Consistency of findings with reference trials

The meta-analysis showed that the pooled weight loss in the intervention group from the four RCTs yielded a weight loss of 1.82 Kg at one year (Figure 2), less than the 5.6 Kg loss observed in the lifestyle-only group of the reference DPP trial or the 4.2 Kg reported in the intervention group of the Finnish DPS. While all studies showed a positive effect on weight loss, only four of the seven studies, 1 RCT and 3 B-A studies [14,79,80,84] reported weight changes at 1 year similar in magnitude to the DPP in the US (around 5 Kg, Table 5). Excepting the XENical in the Prevention of Diabetes in Obese Subjects [XENDOS] trial [80], studies reporting proportions achieving a pre-defined weight loss goal of 5% or 7% were less encouraging. Most studies reported half or less of participants than in the US reference DPP trial,

where 50% of participants achieved 7% weight loss at 6 months [1], or in the Finnish DPS where 43% of participants achieved 5% weight loss at 1 year.

The one-year improvements in fasting plasma glucose were similar to the DPP across several studies but were too small to be clinically important; and reductions of diabetes incidence in the two studies reporting them at 12 months follow-up [79,83] were somewhat less (37% and 23% respectively) than the reductions apparent from the cumulative risk/incidence plots in the Finnish (~70-80%) and DPP (~70%) trials. For the five studies in this review measuring waist circumference, all concluded that waist circumference reductions were possible with modified lifestyle interventions, but after 1 year only two achieved reductions of sufficient magnitude that cannot be attributed to measurement error (≥ 4 cm) [85]. Decreases in fat consumption and increases in fibre consumption resulting from interventions generally were not reported, and the few studies that did showed no substantial improvements. The exception was the Absetz *et al.* trial which reported half the participants meeting the fibre goal and achieving the total fat intake goal and a third achieving the saturated fat goal [82].

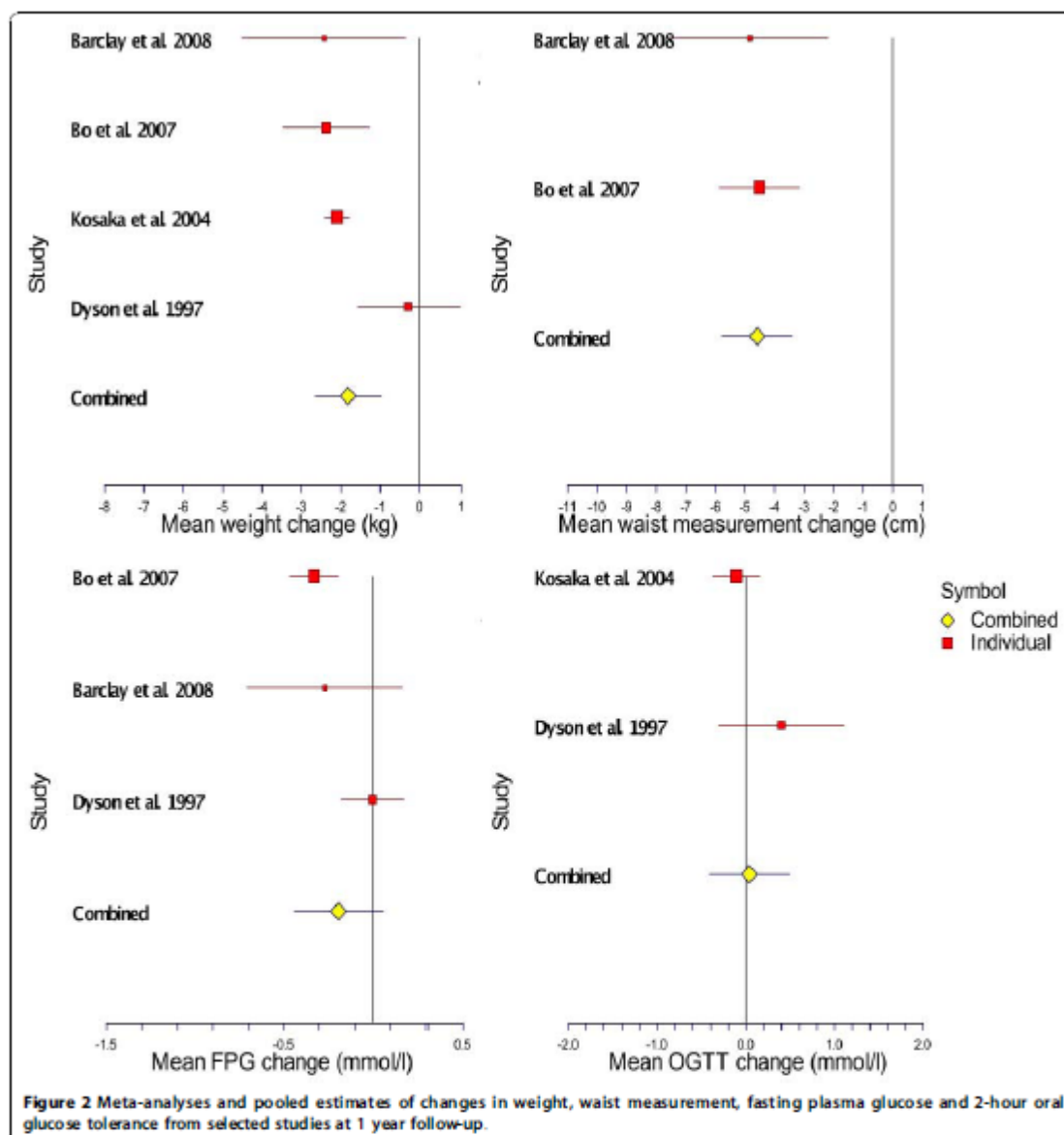
Feasibility of implementation in routine clinical care

Nine of the 12 studies explored whether translation of the reference trials into clinical care was feasible. Eight concluded that modification of the original trial approaches for adaptation to real life practice made the lifestyle interventions feasible, affordable or replicable in clinical care settings despite barriers to implementation [14,49,78,82-84,86,87]. The remaining study reported that the transferability of the results from original trials to other settings remains questionable, as the positive effect on outcomes diminishes over time [48].

Meta-analysis results

Seven trials which randomised a total of 4,905 participants to lifestyle intervention or control were identified. The shortest follow-up period was 4 months and the longest follow-up period was six years. Four of these, randomising a total of 1,129 to intervention or control, reported selected outcomes in comparable units at one year [48-50,87]. These were meta-analysed, although not all outcomes of interest were available from all these studies (Figure 2). We chose not to meta-analyse outcomes at four [80] or six years [79], as these relate to the maintenance phase of a program rather than the medium term impact and it would be inappropriate to compare them with one-year results.

The systematic review of RCT results at 12-month follow-up showed: mean weight reduction was 1.82 Kg greater in treatment than control groups which was statistically significant (95% CI: -2.7 to -0.99 Kg); pooled



mean waist measurement reductions in treatment exceeded control groups by 4.6 cm, and this was also significant (95% CI: -5.8 to -3.4 cm); fasting plasma glucose reduction was 0.19 mmol/l greater in treatment than controls but non-significant (95% CI: -0.44 to +0.06 mmol/l); and a non-significant greater increase in 2-hour oral glucose tolerance test result of 0.04 mmol/l (95%CI: -0.49 to +0.42 mmol/l). From the above, it is apparent that the interventions can achieve significant

weight and waist measurement reductions at one year but do not significantly change the main metabolic indicators of diabetes risk such as FPG or OGTT.

Four of the 12 studies achieved the greatest weight loss, i.e. 5 Kg or more at 12 months. As only two of these successful studies had optimal quality scores [79,80], we further examined the characteristics of these studies to identify common determinants of success in diabetes prevention programs. Common features were

Table 5 Comparison of selected effect estimates 1 year after the intervention (among studies meta-analysed and not meta-analysed)

Author, year, reference #	Study Type	Effect size for weight*	% achieving a) ≥ 7% or b) ≥ 5% weight loss	% Reduction in diabetes incidence	Effect size for FPG mmol/L	Effect size for 2-hr OGTT mmol/L	Effect for waist circumference (cm)	Effect on fat intake as % of total energy	Effect on fibre intake g/day
Reference Trials									
DPP Research Group, 2002 [1]	RCT	-5.6 Kg	a) 49%	NR [§]	-0.3	NR	NR	-6.6%	NR
Finnish DPS [5]	RCT	-4.2 Kg	b) 43%	NR [§]	-0.1	-0.8	-4.4	-2.1%	-1.2%
Meta-Analysed Trials									
Barclay, 2008 [87]**	RCT	-2.7 Kg		NR	-0.02	NR	-6.01	NR	NR
Bo, 2007 [48]	RCT	-0.75 Kg		NR	-0.26	NR	-2.55	NR	+1.7
Kosaka, 2005 [49]	RCT	-2.5 Kg		0.5%	NR@1 yr	NR	NR	NR	NR
Dyson, 1997 [50]	RCT	-0.5 Kg		NR	-0.1	+0.4	NR	-3.5%	+0.9
Studies Not Meta-Analysed									
Greaves, 2008 [86]	RCT	-0.3 Kg	b) 24%	NR	NR	NR	-1.6	NR	NR
Torgerson, 2004 [80]**	RCT	-6.2 Kg		NR	+ 0.2	- 0.4	-7.0	NR	NR
Whittemore, 2009 [78]***	ClustRCT	-1.5 Kg	b) 25%	NR	NR	NR	NR	NR	NR
McTigue, 2009 [84]	BAC	- 5.2 Kg	a) 27%	NR	NR	NR	NR	NR	NR
Eriksson, 1991 [79]	BAC	-5.0 Kg		-37%	NR	-1.5	NR	NR	NR
Pagoto, 2008 [14]	B-A	-5.5 Kg	a) 30%	NR	NR	NR	NR	NR	NR
Laatikainen, 2007 [83]	B-A	-2.5 Kg		-23%	- 0.14	- 0.58	-4.2	NR	NR
Absetz, 2005 & 2009 [77,82]	B-A	-1.0 Kg		NR	+ 0.15	0.0	-1.2 in F +2.3 in M	NR	52% met goal

NR = not reported

References to a) or b) indicate comparison to US DPP or Finnish DPS respectively.

* values presented for B-A studies are changes from before to after intervention; values for RCT are differences in change before and after the intervention in the lifestyle treatment* group only.

§ cumulated diabetes incidence reduction (~58%) reported over 4 and 6 years (US DPP & Finnish DPS, respectively).

** values presented as before-after for the lifestyle + placebo group only (excludes effects of medication arm).

*** estimates at 6 months.

RCT design, being based in Sweden, and having long interventions (1 and 4 years) and longer follow-up periods (6 years in Malmo, 4 years in XENDOS). They were not replication studies, and the frequency of participant

contact was amongst the highest, with Malmo providing 12 group sessions and XENDOS providing up to 54 individual counselling sessions. Another common feature was that following initial substantial weight loss,

the final outcome after several years of follow-up was only an average of 3 Kg weight loss in both studies. We may conclude that the outcomes of these two studies involve social, cultural and health system characteristics unique to that part of Europe that may not be generalisable.

Discussion

It is apparent that clinical services are making concerted efforts to translate lifestyle intervention trials into routine practice in several countries, whether as pilot studies or as full-scale interventions. All studies included in this review recruited individuals at high-risk of diabetes from IGT, obesity, metabolic syndrome, a combination of these, or based on other standard inclusion criteria. All interventions combined dietary and physical activity and attempted replication of previously published studies. The wide range of intervention intensities, durations of follow-up and outcome assessments reflected the availability of service time, staff skills, levels of reimbursement for prevention services, and limited funding and resources for translation research within the health systems.

Results from the lifestyle intervention studies that relied on weight change show promise in achieving some degree of risk reduction. The weight reduction in intervention subjects exceeded controls by 1.8 kg, which was less than that found in the reference U.S. DPP (5.6 Kg) or the Finnish DPS (4.2 Kg). Results from studies that relied on changes in fasting plasma glucose or 2-hr plasma glucose as a measure of success, were less convincing. However, similarly small changes in FPG after the intervention were also observed in the reference trials (Table 5). Controlled studies meta-analysed here were not successful in showing improved glucose tolerance to a clinically meaningful level that could lead to diabetes prevention.

The independent effects of physical activity and diet and other lifestyle changes in the treatment of pre-diabetes were not examined in many of the studies included in this review. Adjustment for covariates/confounders generally was not conducted or at least not reported in those observational studies we examined. It is possible to combine, 'meta-analytically', outcome measures from observational studies but these must be adjusted for confounding, preferably the same confounding variables measured similarly across studies. We excluded from the meta-analysis all observational studies and some RCT studies due to the heterogeneity of reported outcome measurements [88].

The results from RCTs of routine clinical practice presented here would be expected to occur in a real-world non-experimental setting. However, generalisability from the observational studies examined here is limited given

the selection bias of some of the intervention and control groups. The participant population expected through routine care services is 'real-life', self-selected even if programs are offered to all those eligible free of charge. The behaviour of people at risk involves refusals, absenteeism from critical measurement time points and self-selection of healthier and/or more motivated patients. In order to achieve results similar to the RCT evidence, these practical issues of non-compliance would need particular attention in a real world setting. The Diabetes in Europe - Prevention using Lifestyle, Physical Activity and Nutritional intervention (DEPLAN) [89] is developing the structures for a prevention management model which can be implemented in routine clinical practice settings. Results from this project should shed further light on specific success factors for research translation.

This review also examined the feasibility of implementation of interventions as an integral part of routine clinical care, as this can inform policy on dissemination of diabetes prevention programs or associated subsidies within healthcare systems. To this end, we examined authors' conclusions on whether the given intervention could sustainably be incorporated into usual care provided, for example, without the need for excessive time beyond usual consultation, additional funding or contracting of external staff.

Finally, while the outcomes of the two US studies, where participation incurred a fee, probably are the most representative of real life in USA, such market-based rationing of diabetes prevention might not be acceptable in other health systems, and certainly would not reach those most in need of such interventions, including low socio-economic groups and people with higher prevalence of risk factors for diabetes.

Strengths of this review

To our knowledge, this is the first attempt to comprehensively compile feasibility and effectiveness of translation of diabetes prevention trials specifically for routine clinical settings.

We used a purpose-built comprehensive quality scoring system based on individual components of relevance from checklists widely used by others in quality assessment of the literature. Our quality criteria allowed for the inclusion of several study types to maximise the chances of identifying and assessing relevant diabetes prevention programs. The search was extensive and individual study authors were contacted to either confirm that their study was conducted under routine clinical care or to exclude any translation study conducted in research settings or under simulated clinical care. Meta-analytic techniques were used when feasible.

Limitations

Despite the good quality of papers covered in this review, the total number of studies finally included was small; some were exploratory (3 pilots) and many of them had short follow-ups and only modest sample sizes which essentially reflect the financial and time restrictions of real-life interventions in routine clinical practice. We included studies with intervention and follow-up durations of at least 3 months. These are not unusual in routine practice, as modifications to duration and intensity of the strict approaches in the reference trials are common in the replication literature. While longer interventions and follow-up times are ideal, in real-world situations longer studies inevitably are affected by sample attrition and attendant generalisability issues. We wanted to include some measurement of short-term impact and avoid attrition bias and selection bias in our assessment of what is being evaluated in routine practice and therefore we allowed for feasibility and pilot studies to be incorporated.

Analyses from before-and-after studies often did not report on adjustment for confounders. More importantly, the reporting of outcomes of interest was often incomplete or in disparate units of measurement precluding inclusion in the meta-analysis. However, the overall good quality of these studies enabled their inclusion in the broader systematic review.

Many weight-loss-only programs and other lifestyle interventions for reduction of cardiovascular disease risk were excluded as they did not specifically mention replication of the diabetes prevention trials. However, we acknowledge that results from these may also be applicable to diabetes risk reduction, and while examples of reviews of these are available in the literature, their focus is beyond the scope of our review.

Conclusions

Despite convincing evidence from structured intensive randomised controlled trials in research settings, this systematic review shows that translation into routine practice has somewhat less of an impact on diabetes risk reduction. Given the heterogeneity and limitations of the studies included in this review, it is also not possible to determine conclusively whether the type of clinical setting, the frequency or intensity of interventions, or the modality of the intervention (face-to-face, telephone, written materials, etc) are critical success factors for translation of diabetes prevention programs in routine clinical care. Nor was it possible to assess the separate contributions of individual lifestyle change components to diabetes risk reduction. Accordingly, we cannot yet make specific recommendations on the most effective features of these targeted lifestyle interventions.

However, based on our findings, the direction of the effects on the four most commonly reported outcomes

(weight, FPG, waist circumference and 2-hour OGTT) are encouraging; and the consensus on feasibility of their modification as part of routine care without excessive cost suggest that it is still worth promoting the translation of modified, group-based lifestyle interventions, and conducting more rigorous evaluations in these settings. The establishment of a register of translation projects using consistent, measurable outcomes would add more certainty to the effectiveness of routine practice interventions, and when more studies with larger sample sizes and data on intermediate end-points become available they could be included in a more comprehensive meta-analysis.

Appendix - Description of the search strategy

Electronic sources searched

- Articles were identified through searches in MEDLINE, PubMed, The Cochrane Library, Google Scholar, CINAHL and EMBASE.
- Internet searches and searches of the grey literature were conducted to identify non peer-reviewed internal reports from government and health services websites and non-government sources.

Supplementary sources

- Hand searches of reference lists from related articles found whether or not they were eligible for inclusion in this review
- Hard copy Australian government publications and unpublished internal reports from key informants for non-indexed publications.
- Authors of reviewed articles were contacted by MC-M if it was unclear from their papers whether the intervention was conducted in a research or community-based or a routine clinical setting. However, due to resource constraints, no attempt was made to contact the investigators whose papers did not report all measured outcomes.

Search terms

Diabetes, Pre-diabetes, Type 2 diabetes, Impaired glucose tolerance OR glucose intolerance, Lifestyle intervention OR lifestyle program OR strategy, Physical activity OR Exercise OR Resistance Training, Healthy eating OR diet OR dietary modification OR weight loss, Behavioural modification, AND (Primary health care, General practi\$, clinical practice, routine clinical care), AND (Prevent\$. Ti, ab, Translating OR Translation OR Translat\$. Ti, ab., Translation research OR translational study OR Replication study).

Authors' contributions

MC-M, conceived the study, designed the quality and bias assessment tools, conducted database searches and quality assessments, wrote the first draft

of the manuscript and incorporated changes suggested by others. MC-M coordinated database searches by LR and AB; LR, SM and PTE conducted bias assessments; AB and LR assisted in the design of the study; MC-M and SM performed the statistical analyses. SM, AB and LR helped to comment on and refined the manuscript. All authors have read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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The Sydney Diabetes Prevention Program: A community-based translational study

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Abstract

Background: Type 2 diabetes is a major public health problem in Australia with prevalence increasing in parallel with increasing obesity. Prevention is an essential component of strategies to reduce the diabetes burden. There is strong and consistent evidence from randomised controlled trials that type 2 diabetes can be prevented or delayed through lifestyle modification which improves diet, increases physical activity and achieves weight loss in at risk people. The current challenge is to translate this evidence into routine community settings, determine feasible and effective ways of delivering the intervention and providing on-going support to sustain successful behavioural changes.

Methods/Design: The Sydney Diabetes Prevention Program (SDPP) is a translational study which will be conducted in 1,550 participants aged 50-65 years (including 100 indigenous people aged 18 years and older) at high risk of future development of diabetes. Participants will be identified through a screening and recruitment program delivered through primary care and will be offered a community-based lifestyle modification intervention. The intervention comprises an initial individual session and three group sessions based on behaviour change principles and focuses on five goals: 5% weight loss, 210 min/week physical activity (aerobic and strength training exercise), limit dietary fat and saturated fat to less than 30% and 10% of energy intake respectively, and at least 15 g/1000 kcal dietary fibre. This is followed by 3-monthly contact with participants to review progress and offer ongoing lifestyle advice for 12 months. The effectiveness and costs of the program on diabetes-related risk factors will be evaluated. Main outcomes include changes in weight, physical activity, and dietary changes (fat, saturated fat and fibre intake). Secondary outcomes include changes in waist circumference, fasting plasma glucose, blood pressure, lipids, quality of life, psychological well being, medication use and health service utilization.

Discussion: This translational study will ascertain the reach, feasibility, effectiveness and cost-effectiveness of a lifestyle modification program delivered in a community setting through primary health care. If demonstrated to be effective, it will result in recommendations for policy change and practical methods for a wider community program for preventing or delaying the onset of type 2 diabetes in high risk people.

Background

The number of people developing type 2 diabetes is rising dramatically worldwide with 439 million cases projected by 2030 [1]. This trend is mirrored in Australia where the prevalence of diabetes has more than doubled between 1981 and 2000 [2]. Currently in Australia there are over 1 million people with type 2 diabetes and approximately 8 per 1,000 people aged 25 years and older develop diabetes each year [3]. The annual health care costs in Australia of

type 2 diabetes have been estimated at \$2.2 billion AUD [4].

The increasing prevalence of diabetes, the increase in modifiable risk factors for the disease (obesity, sedentary behaviour and poor nutritional choices), as well as the severe and costly complications which can be difficult to prevent and treat, mean that prevention is an important strategy for reducing the burden of diabetes.

There is strong and consistent evidence from randomised controlled trials that type 2 diabetes can be prevented or delayed through lifestyle modification interventions which aim to improve diet, increase physical activity and reduce weight in people at high risk of

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developing the disease. The Finnish [5] and US [6] studies achieved a 58% reduction in diabetes incidence through lifestyle modification while the Chinese Da Qing study [7] achieved a 40% reduction in type 2 diabetes. Both the Finnish [8] and Chinese studies [9] showed long-term persistence of reduced diabetes risk over 7 and 20 years respectively. Similar benefits have been shown in the Japanese [10] and Indian [11] diabetes prevention trials, suggesting the generalisability of these findings.

Diabetes prevention programs recognise the importance of a theoretically-grounded behavioural intervention as a core component of the lifestyle modification, although no single behavioural theory has dominated. The behavioural programs have focused on encouraging physical activity and dietary changes and included various components such as initial assessment, individualised goal setting, individual counseling, on-going support, regular assessment and feedback and monitoring of behaviours and outcomes throughout the study.

Small community-based programs have reported some success in modifying surrogate markers for diabetes through lifestyle intervention. The Greater Green Triangle Diabetes Prevention Project in Australia [12] and the Good Ageing in Lahti Region Lifestyle Implementation Trial in Finland [13] confirmed that short-term lifestyle modification programs can reduce risk factors for diabetes in primary care settings.

The current challenge is to translate this evidence into cost-effective large scale community-wide programs. There is increasing acknowledgement that the best way to do this is through studies which have an explicit focus on generalisation and feasibility and which report information on contextual variables such as representativeness, reach, implementation and adaptation, costs and other outcomes important to policy makers [14]. Thus the current study employs a design which will not only provide data on intervention effectiveness, but also will examine contextual factors through process evaluation central to what has been called by some the 'science of delivery' [15].

The overall aim of this study is to assess the effectiveness of a community-based lifestyle modification program on modifiable risk factors for type 2 diabetes. Additional aims include assessing the feasibility of delivering the program in a primary health care setting; identifying determinants of the interventions which are associated with and predict a beneficial outcome; and the costs and cost-effectiveness of the program.

Methods/Design

The SDPP is a translational study based on the active arm of international randomised controlled trials demonstrating the effectiveness of lifestyle modification interven-

tions in reducing the incidence or delaying the onset of type 2 diabetes in high risk individuals.

Setting

Communities in three Divisions of General Practice, one in metropolitan Sydney, one in a semi-rural area and the other in a rural area of NSW, Australia.

Ethics

Ethics approval to conduct this trial has been granted by the Research Ethics Review Committee of the Sydney South West Area Health Service - Eastern Zone (ID Number X08-0053). Written informed consent is obtained by all participants prior to enrolment.

Participants and recruitment

The Divisions of General Practice have recruited over 75 practices and 150 general practitioners (GPs) to participate in the study. This was done through expression of interest by letter and fax, information sessions and site visits. The main pre-requisite for inclusion was the practice having a computerised patient record system.

People aged 50-65 years (18 years and older in the indigenous subgroup) without known diabetes attending study general practices are approached to participate. A variety of methods are used to identify potential participants including opportunistic recruitment when the person attends the general practitioner for a routine consultation, using the practice's computer database to identify people in the target age range and sending a letter suggesting they attend for risk assessment, and local media advertising of the program.

Risk is assessed using the AUSDRISK tool, a questionnaire developed in Australia [16]. The questions focus on demographic and diabetes risk factors and include an objective assessment of waist circumference performed by trained research staff. The maximum AUSDRISK score is 38 and a score of ≥ 15 is considered high risk. A score of 15-19 is associated with a 1 in 7 chance and a score of ≥ 20 with a 1 in 3 chance of developing diabetes over the next 5 years [16]. A score of ≥ 12 is considered high risk in the indigenous subgroup.

A person with a risk score of ≥ 15 is required to undergo investigations to exclude prevalent diabetes. This initially involves measurement of capillary blood glucose in the general practitioner's surgery, followed by measurement of fasting plasma glucose and possibly an oral glucose tolerance test.

Study exclusion criteria include new or previously diagnosed diabetes, taking a hypoglycaemic medication in the past month, use of prescribed weight loss medication or a medical contraindication to participation in a physical activity program. Participants enter the study after written consent is obtained, eligibility criteria have been met and clearance is received from their general practitioner.

The study plans to recruit 1,550 high risk people into the lifestyle intervention program. Among these 100 will be Arabic-speaking, 100 will be Chinese-speaking and 100 will be indigenous people.

Intervention - Lifestyle Modification Program

The five aims of the lifestyle modifications are:

1. At least 30 min/day of moderate to vigorous intensity physical activity, including aerobic exercise 3 or more days/week plus strength training at least twice/week (210 min/week total structured exercise)
2. Reduction in the intake of energy from total fat to less than 30%
3. Reduction in the intake of energy from saturated fat to less than 10%
4. Fibre intake of at least 15 g/1000 kcal
5. Achievement of a 5% reduction in body weight at 12 months.

In addition to the 210 min/week structured exercise goal, participants are encouraged to increase incidental physical activity in ways which would enhance both cardiovascular and musculoskeletal fitness.

These five goals are entirely concordant with the Finnish DPS (5), which was one of the most successful diabetes prevention trials. The physical activity goal, which has been modified slightly from the Finnish DPS is based on a review of the physical activity prescriptions utilised in relation to outcomes achieved in all of the successful trials of diabetes prevention (5,6,7,10,11), considerations of cost and feasibility in this translational setting, as well as other literature regarding modality, volume, and intensity of exercise required to improve metabolic risk and body composition in similar cohorts. Both the Finnish DPS and the US DPP included resistance training (strength training) in their supervised exercise sessions and is explicitly specified within the physical activity goal of the SDPP. Resistance training is an anabolic form of exercise, differing substantially from aerobic exercise in its ability to induce muscle hypertrophy and associated metabolic and functional changes [17,18]. It improves insulin sensitivity, glucose homeostasis, blood pressure, dyslipidaemia, markers of inflammation and catabolism, and visceral obesity, thus addressing the key metabolic abnormalities in adults at high risk of type 2 diabetes [19,20]. Importantly, resistance training (but not aerobic exercise) attenuates or prevents the loss of lean tissue (muscle and bone) accompanying weight loss diets such as those prescribed in this study [21].

The behavioural components are based on stages of change [22] and social cognitive theories [23]. The intervention is delivered by dedicated program lifestyle officers from a variety of health backgrounds including dietetics, nursing, psychology and exercise physiology. The lifestyle officers undergo specific training in health

coaching, group program delivery and standardized data collection used for evaluation. The health coaching approach incorporates principles from self-management, removing psychological blocks to change and confidence [24].

An overview of the program and the evaluation plan is shown in Figure 1.

High risk individuals agreeing to participate in the lifestyle modification program complete an initial computer-assisted telephone interview (CATI) survey. This survey includes socio-economic and demographic information, physical activity habits, quality of life, and self-efficacy, as well as recent health service utilisation and current medication use. Participants are then scheduled to attend an individual consultation with a lifestyle officer. At this consultation, the lifestyle officers measure height, weight and waist circumference using calibrated stadiometers, scales and tape measures, following a standardized anthropometric protocol as specified by the International Society for the Advancement of Kinanthropometry (ISAK) [25]. The individual consultation includes a general discussion about diabetes risk and prevention, an overview of the program, and uses motivational interviewing techniques to assist participants to set goals and develop tools to self-

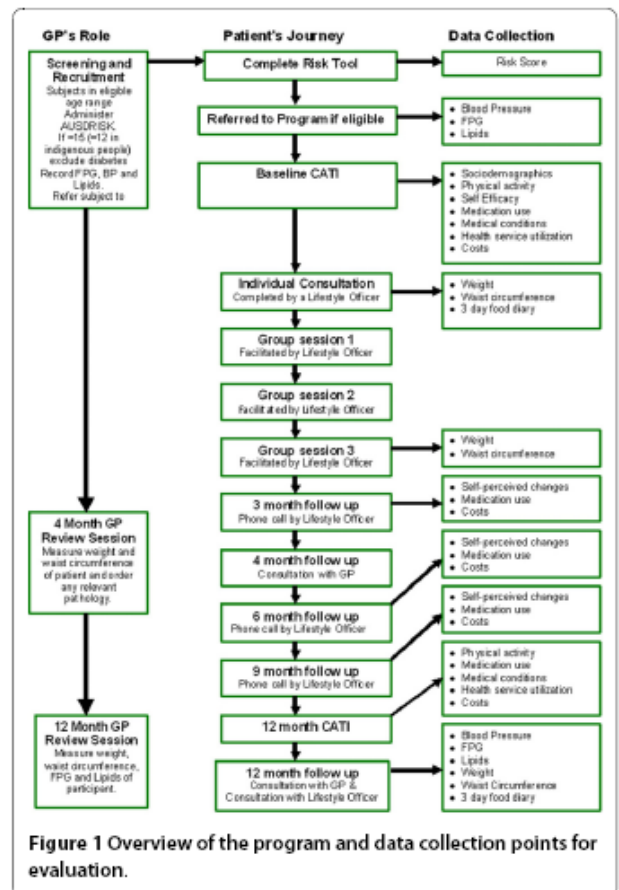


Figure 1 Overview of the program and data collection points for evaluation.

monitor. Following this session, arrangements are made for participants to attend three two-hour group programs held over a six to eight week period. Lifestyle officers conduct these group sessions of approximately 10 people, which cover theoretical, behavioural and practical aspects of diet and physical activity. The overall program motto is: "Eat better and move more". Those who are not able to or do not want to attend a group program are offered the option of three individual health coaching sessions by telephone, covering the same material. The intervention delivered to indigenous participants will be slightly modified to take account of cultural issues.

Follow up telephone calls are made by the lifestyle officers to each participant at 3, 6 and 9 months to enquire about progress, assist with behaviour change and offer participants additional support as required.

In addition, participants are provided with details of local community-based lifestyle programs which have been evaluated by the research staff and found to be consistent with the goals of the SDPP. Participants have the option of enrolling in such programs as one way to assist in achieving the SDPP physical activity and dietary goals.

At 12 months the CATI survey is repeated and participants undergo an individual assessment with the lifestyle officer and their general practitioner.

Outcome measures and evaluation plan

The evaluation plan has three components:

1. Impact evaluation measures changes at 12 months in the key outcomes known to be associated with reduced diabetes incidence: weight loss; increase in moderate to vigorous physical activity (including both aerobic and strengthening activities); increase in dietary fibre consumption; decrease in fat consumption and decrease in saturated fat intake. Program and participant factors which predict these outcomes are assessed.

2. Process evaluation measures program reach, fidelity, satisfaction and knowledge of program delivery by staff, satisfaction of consumers, and identifies facilitators and barriers associated with program implementation and delivery.

3. Economic evaluation involves health system and individual perspectives and estimates implementation costs, costs per outcome and cost-effectiveness.

Impact Evaluation

Outcomes are assessed at baseline and 12 months by research staff, using a combination of in-person assessment and CATI questionnaires. Physical activity is assessed using the Physical Activity Scale for the Elderly (PASE), which has established reliability and validity [26]. Dietary intake (including total fat, saturated fat and fibre) is assessed by a self-completed 3-day non-weighed food record, which is analysed using Foodworks [27].

Weight, height, waist circumference and blood pressure are measured using standard methods. Blood is collected for measurement of fasting plasma glucose and lipids. Additional questions on socio-demographic characteristics, concomitant diseases and medications, smoking, alcohol, social support, self-efficacy for lifestyle change, and quality of life are asked at the baseline and 12 month CATI surveys.

Analyses of these data will determine whether the program goals are achieved by individuals, by the group as a whole and differentially by sub-groups (e.g. GP Division and gender). In addition, these data will be used to model the projected impact of the program beyond the 12-month intervention period.

Process Evaluation

This is a central component of the evaluation of this translational study in order to assess whether the program is implemented as planned, achieves population reach and whether it is feasible in the primary care field setting. Details of the process evaluation components are shown in Table 1.

Economic Evaluation

The economic evaluation will adopt a health system perspective by measuring costs at Area Health Service, Government and general practice levels. It will also use a limited societal perspective by measuring direct costs to participants. In addition, the estimated costs of a state-wide rollout of the SDPP will be reported. The base cost year will be 2008. No discounting will be applied as this is a 12-month program including intervention and follow-up.

The economic evaluation will compare the cost of program implementation with its intermediate outcomes. The results of the study will be used to build a model of future costs and effects beyond the study period using Australian population and risk factor data [28-32]. Information to be collected about resource use will include program expenses (e.g. cost of screening and delivering the intervention), individual level and health system expenditure data. These will include direct health-related costs (visits to health professionals, hospitalisation, medication use etc) and direct non-health costs (gym subscription, exercise equipment, etc.) relevant to diabetes prevention, and indirect costs (e.g. sick days). This information will allow estimation of the cost per estimated case of diabetes prevented and cost per outcome (e.g. cost per kg weight loss; cost per change in additional time of physical activity, etc). Modelling will project these calculations beyond the study period using lives saved, life-years saved and quality-adjusted life-years (QALYs) gained to calculate the benefits associated with this program.

Table 1: Process evaluation components in the Sydney Diabetes Prevention Program

Evaluation Component	Data source and format	Timeframe
Screening, participation and recruitment rates	Administrative documentation from Divisions of General Practice	Ongoing during recruitment
Program fidelity, program completion, intervention completed	Participants' database	Ongoing
Assessment of practice staff awareness and engagement with program	Telephone administered questionnaires to selected doctors and practice staff	Ongoing
Barriers to recruitment, and program delivery	In-depth-interviews and focus groups with practice staff	Ongoing
Challenges in program delivery and patient maintenance in program.	Focus group with lifestyle officers	Ongoing
Participants' barriers to attendance at group sessions	From participants via the Lifestyle Officers	Three months after group sessions completed
Number and type of organisations participating, perceived level of collaboration, barriers and success factors for community-based programs/services for physical activity and weight management	In-depth-interviews and focus groups with key stakeholders	Towards the end of the Program, when 12 month follow up data available

Statistical methods

Analysis at 12 months will determine the extent that program goals were achieved, through overall and sub-group analysis. Primary outcomes which will be reported include weight loss (and 5% weight loss goal achievement), physical activity levels (in minutes per week of overall intentional activity, and sessions per week of strength training) and PASE scores, dietary measures (total energy/day, estimated fibre intake (gm/1,000 kcal), total fat intake (gm/day), fat as a proportion of total energy intake and saturated fat as a proportion of daily energy intake), and proportions of the cohort achieving 1,2,3,4, or all 5 goals. Logistic regression analysis will be used to examine factors associated with the achievement of program goals. Separate models will examine predictors of 5% weight loss, achievement of 210 min/day of physical activity, and achievement of dietary goals.

Missing data due to either refusal to respond to selected questions or withdrawal from the program before the endpoint will be dealt with by imputing values for the discrepant self-reports using data from "similar" participants or using last observation carried forward (LOCF) techniques when appropriate.

A minimal sample size of 1,000 completed participants with baseline and 12 month data will provide 90% power to detect small differences in primary outcomes effects at the 5% level of confidence for the whole group. Specifically, we will be able to detect:

- 5% weight loss
- increase of 2.5 g of fibre/1,000 kcal
- 3.4% reduction of fat intake as a percentage of total energy

- 2.7% reduction of saturated fat intake as a percentage of total fat intake
- 11.7 min/wk of increased physical activity.

Discussion

Lifestyle modification has been shown to effectively reduce the risk of incident diabetes in randomised controlled trials. The main challenge is to translate this evidence into a routine community-wide setting and provide a feasible, effective and cost-effective intervention. The current study is designed to address these presently unanswered public health and policy-relevant questions.

The information gathered in this study will be of direct relevance to the design, implementation and affordability of community-wide diabetes prevention programs throughout Australia and other countries with a well-developed health care system. The key questions which can be addressed by the SDPP relate to the delivery, effects, costs and structure of community-based lifestyle modification programs, including key barriers and facilitators and key determinants of process and impact outcomes. Importantly, the study should provide a better understanding of the interplay of these factors in real-world settings in metropolitan, regional and rural settings across populations of differing socioeconomic status and ethnic background and by doing so increase the generalisability of the findings. Answers to these issues are of direct relevance to future local, national, and international evidence-based policy and practice with regard to prevention of diabetes and lifestyle-related chronic diseases. The study will also provide an understanding of the preferences of participants for lifestyle-related strategies

and programs, which will also be relevant to the design of future strategies and programs.

List of abbreviations used

AUD: Australian Dollar; BP: blood pressure; CATI: Computer-assisted telephone interview; DPP: Diabetes Prevention Program; DPS: Diabetes Prevention Study; FPG: fasting plasma glucose; GPs: General Practitioners; PASE: Physical Activity Scale for the Elderly; QALY: Quality Adjusted Life Year; SDPP: Sydney Diabetes Prevention Program.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

SC conceived of the study, and participated in its design, evaluation and implementation. PV participated in finalising the protocol and is responsible for the implementation of the study. MC-M participated in the design of the study evaluation and is performing the statistical analyses. MFS participated in the study design, its implementation and evaluation. LF participated in the design and implementation of the study evaluation. AM participated in the design, evaluation and implementation of the study. MH participated in the design and the general and economic evaluation of the study. AB participated in the study design and implementation and conceived and oversees the study evaluation. All authors made substantial contributions to the conception, design and writing of the manuscript and had the opportunity to critically review the manuscript during its development and all approved the final manuscript.

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Appendix 4.2 Ausdrisk Tool

10.8.1 *Live Life Well* Diabetes Prevention Program

TYPE 2 DIABETES RISK TEST

Name: _____ ID _____

Date of Birth: _____

Please circle your answers. Your risk of developing type 2 diabetes within the next 10 years is determined by adding up all your points.

Points

1. Age

(0) Less than 45 years

(2) 45 – 54 years

(3) 55 – 64 years

(4) More than 64 years

2. Physical Activity

Do you do every day, either in your leisure time or in your work, some kind of physical activity for at least 30 minutes (for example moderate or brisk walking to work)?

(0) Yes

(2) No

3. Diet

How often do you eat vegetables or fruit?

(0) Every day

(1) Less than every day

4. Medication

Have you ever regularly used medication for high blood pressure?

(0) No

(3) Yes

5. Previous high blood sugar

Have you ever been diagnosed as having high blood sugar (for example in health checks, during illness, during pregnancy)?

(0) No

(2) Yes

6. Family history

Has someone in your immediate family or other relatives got diabetes (type 1 or type 2)?

(0) No

(3) Yes – grandparent, uncle, aunt, 1st cousin

(5) Yes – parent, brother, sister, own child

Please ask the Study Nurse/Research Officer to help you complete the following questions.

7. Body Mass Index (Your body mass index is weight divided by height squared)

Weight (kg) _____

Height (m) _____

Body mass Index _____

(0) Less than 25kg/m²

(1) 25-30kg/m²

(2) Higher than 30kg/m²

Waist Circumference

Measurement (cm) _____

MEN

(0) Less than 94cm

(3) 94-102cm

(4) More than 102cm

WOMEN

Less than 80cm

80-88cm

More than 88cm

Total Risk Score: _____

Score Explanation

Less than 7: SMALL RISK: approximately one in one hundred develops type 2 diabetes

7 – 11: SLIGHTLY ELEVATED RISK: approximately one in twenty five develops type 2 diabetes

12-14: MODERATE RISK: approximately one in six develops type 2 diabetes

15 –20: HIGH RISK: approximately one in three develops type 2 diabetes

More than 20: VERY HIGH RISK: approximately one in two develops type 2 diabetes

Find internet PDF version at:

[http://www.health.gov.au/internet/main/publishing.nsf/content/C73A9D4A2E9C684ACA2574730002A31B/\\$File/Risk_Assessment_Tool.pdf](http://www.health.gov.au/internet/main/publishing.nsf/content/C73A9D4A2E9C684ACA2574730002A31B/$File/Risk_Assessment_Tool.pdf)

Appendix 4.3 Participant Consent Form

GP Division Logo

Live Life Well Diabetes Prevention Program PARTICIPANT CONSENT FORM

I,[name]

of[address]

have discussed the Live Life Well Diabetes Prevention Program with

.....

I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

I consent to the information on this Referral Form being sent to the Division.

I consent to additional health information being sent from my GP's computer to the Division's secure database.

I freely choose to participate in this study and understand that I can withdraw at any time.

I also understand that the research study is strictly confidential.

I hereby agree to participate in this research study.

NAME:

SIGNATURE:

DATE:

NAME OF WITNESS:

.....

SIGNATURE OF WITNESS:

.....

Appendix 4.4 GP referral form

GP Division Logo

SDPP Referral Form

Patient Details

Name:

Gender: M / F

DOB:

Address:

Phone: (H)

(mob)

GP Name (or Stamp)

Medical Contraindications Checklist:

Please check all boxes below that apply to the patient at this time. If any boxes in this column are checked, patient is ineligible for the SDPP and please do **not** refer them.

- a. End-stage congestive heart failure
- b. Severe cognitive impairment or behavioral disturbance
- c. Unstable abdominal, thoracic or cerebral aneurysm
- d. Untreated severe aortic stenosis or other structural heart disease
- e. Progressive or terminal cancer
- f. Type 1 or Type 2 Diabetes

g. Malignant arrhythmia, type: _____

Clinical Information:

Blood Pressure: _____

Fasting Plasma Glucose (FPG) value: _____ **Cholesterol:** _____

Medications: _____

Comments: _____

GP Exercise Consent:

- I have read the GP information sheet and understand what the SDPP involves for the referred patient.
- I have completed the Medical Screening Details above and have completed any further investigation that I felt was necessary.
- I agree that the patient listed above is suitable to participate in the SDPP.

GP Signature: _____ Date: _____

Appendix 4.5 Baseline CATI Survey

Please ensure the patient consent is completed

The following questions are for statistical purposes

Q1 How old are you today? _____(years)		Q2 Are you male or female?		<input type="radio"/> Male	<input type="radio"/> Female	
Q3 What is your postcode?						
Q4 Which country were you born in?		<input type="radio"/> Australia	<input type="radio"/> Other (please state) _____		<input type="radio"/> Refused to answer	
Q5 What language do you usually speak at home?		<input type="radio"/> English	<input type="radio"/> Other (please state) _____			
Q6 What is the highest level of education you have completed?	<input type="radio"/> No formal schooling	<input type="radio"/> Primary school	<input type="radio"/> Secondary education (secondary school/technical school yr 7-10)	<input type="radio"/> Vocational training (TAFE/VET)	<input type="radio"/> Higher School Certificate (HSC/VCE) or higher levels of technical school	<input type="radio"/> University education
Q7 Are you presently employed?		<input type="radio"/> Yes, full time	<input type="radio"/> Yes, part time	<input type="radio"/> No, unemployed	<input type="radio"/> No, retired	
Q8 Do you currently receive a pension, allowance or benefit?				<input type="radio"/> Refused	<input type="radio"/> Yes	<input type="radio"/> No
Q9 Are you currently covered by private health insurance?		<input type="radio"/> Yes, hospital only		<input type="radio"/> Yes, hospital + extras	<input type="radio"/> No	

The following questions are about your physical activity each week

Q10 Over the past 7 days, how often did you participate in sitting activities such as reading, watching TV or doing handcrafts?				
<input type="radio"/> never	<input type="radio"/> Seldom (1-2 days)	<input type="radio"/> Sometimes (3-4 days)	<input type="radio"/> Often (5-7 days)	
Q10a What were these activities?				
Q10b On average, how many hours per day did you engage in these sitting activities on these days?				
<input type="radio"/> less than 1 hour		<input type="radio"/> 1 but less than 2 hours	<input type="radio"/> 2-4 hours	<input type="radio"/> more than 4 hours
Q11 Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example for fun or exercise, walking to work, walking the dog etc?				
<input type="radio"/> never	<input type="radio"/> Seldom (1-2 days)	<input type="radio"/> Sometimes (3-4 days)	<input type="radio"/> Often (5-7 days)	
Q11a On average, how many hours per day did you spend walking on these days?				
<input type="radio"/> less than 1 hour		<input type="radio"/> 1 but less than 2 hours	<input type="radio"/> 2-4 hours	<input type="radio"/> more than 4 hours
Q12b What was the total distance (kms) that you walked in the past 7 days?				
<input type="radio"/> less than 1 km		<input type="radio"/> 1 but less than 2 kms	<input type="radio"/> 2-4 kms	<input type="radio"/> more than 4 kms
And how much of the time would you say that walking was BRISK walking?				
<input type="radio"/> None of the time	<input type="radio"/> 1/4 of the time	<input type="radio"/> half of the time	<input type="radio"/> 3/4 of the time	<input type="radio"/> All of the time
Q13 How many flights of stairs did you climb up in the past 7 days? (one flight = 10 steps) Total number of steps climbed in the past week _____, or flights of steps _____.				
Q14 Over the past 7 days, how often did you engage in light sport or recreational activities such as 'light' cycling on an exercise bike, lawn bowls, bowling, water aerobics, golf with a cart, yoga, tai chi, fishing from a boat or pier or other similar activities?				
<input type="radio"/> Never	<input type="radio"/> Seldom (1-2 days)	<input type="radio"/> Sometimes (3-4 days)	<input type="radio"/> Often (5-7 days)	
Q14a What were these activities?				
Q14b On average, how many hours per day did you engage in these light sport or recreational activities on these days?				
<input type="radio"/> less than 1 hour		<input type="radio"/> 1 but less than 2 hours	<input type="radio"/> 2-4 hours	<input type="radio"/> more than 4 hours
Q15 Over the past 7 days, how often did you engage in moderate sport or recreational activities such as doubles tennis, ballroom dancing, golf without a cart, softball or other similar activities?				
<input type="radio"/> Never	<input type="radio"/> Seldom (1-2 days)	<input type="radio"/> Sometimes (3-4 days)	<input type="radio"/> Often (5-7 days)	
Q16a What were these activities?				
Q16b On average, how many hours per day did you engage in these moderate sport or recreational activities on these days?				

	<input type="radio"/> less than 1 hour	<input type="radio"/> 1 but less than 2 hours	<input type="radio"/> 2 – 4 hours	<input type="radio"/> more than 4 hours	
Q16 Over the past 7 days, how often did you engage in strenuous sport or recreational activities such as jogging, swimming, cycling, singles tennis, aerobic dance or other similar activities?					
<input type="radio"/> Never	<input type="radio"/> Seldom (1-2 days)	<input type="radio"/> Sometimes (3-4 days)	<input type="radio"/> Often (5-7 days)		
	Q16a What were these activities? _____				
	Q16b On average, how many hours per day did you engage in these strenuous sport or recreational activities on these days?				
	<input type="radio"/> less than 1 hour	<input type="radio"/> 1 but less than 2 hours	<input type="radio"/> 2–4 hours	<input type="radio"/> more than 4 hours	
Q17 Over the past 7 days, how often did you exercise specifically to increase muscle strength and endurance such as lifting weights or push-ups etc?					
<input type="radio"/> Never	<input type="radio"/> Seldom (1-2 days)	<input type="radio"/> Sometimes (3-4 days)	<input type="radio"/> Often (5-7 days)		
	Q17a What were these activities? _____				
	Q17b On average, how many hours per day did you engage in exercise to increase muscle strength/endurance on these days?				
	<input type="radio"/> less than 1 hour	<input type="radio"/> 1 but less than 2 hours	<input type="radio"/> 2–4 hours	<input type="radio"/> more than 4 hours	
Q18 During the past 7 days, have you done any light housework such as dusting or washing dishes?				<input type="radio"/> No	<input type="radio"/> Yes
Q19 During the past 7 days, have you done any heavy housework or chores such as vacuuming, scrubbing floors, washing windows?				<input type="radio"/> No	<input type="radio"/> Yes
Q20 During the past 7 days, did you engage in any of the following activities?					
a Home repairs like painting, wallpapering, electrical etc				<input type="radio"/> No	<input type="radio"/> Yes
b Lawn work or yard care including snow or leaf removal, wood chopping etc				<input type="radio"/> No	<input type="radio"/> Yes
c Outdoor gardening				<input type="radio"/> No	<input type="radio"/> Yes
d Caring for another person such as a dependent child, dependent spouse or another adult				<input type="radio"/> No	<input type="radio"/> Yes
Q21 During the past 7 days did you work for pay or as a volunteer?					
a How many hours per week did you work for pay and/or as a volunteer? _____ hours				<input type="radio"/> No	<input type="radio"/> Yes
b Which of the following categories best describes the amount of physical activity required on your job and /or volunteer work?					
<input type="radio"/> Mainly sitting with light arm movements (eg. Office work, watch maker, seated assembly line worker, bus driver etc)					
<input type="radio"/> Sitting or standing with some walking (eg. Cashier, general office worker, security officer, light tool and machinery worker)					
<input type="radio"/> Walking with some handling of materials generally weighing less than 50 pounds (eg. Mailman, waitress, construction worker, heavy tool and machinery worker)					
<input type="radio"/> Walking and heavy manual work often requiring handling of materials weighing over 50 pounds (eg. Farm or general labourer).					

Q22 In the past three months have you participated in any weight loss programs such as weight watchers, Lite n' easy, Jenny Craig or other similar programs?

Yes No Can't remember

Q23 In the past three months have you attended any services to improve your eating habits such as a dietician, nutritionist or medical specialist?

Yes No Can't remember

Q24 In the past three months have you participated in any regular programs to increase your physical activity such as being a member of a gym, swimming at a pool, attending Tai chi, aerobics, or yoga classes?

Yes No Can't remember

Q24a If yes, what sort of regular activity was that? *Tick as many as relevant*

- Community fitness centre / group
- Personal trainer/coach
- Training by myself at home or in the neighbourhood
- Internet support program
- Other

These questions will provide a measurement of alcohol intake and smoking status

Q25 How often do you drink alcohol?	<input type="checkbox"/> _____ number of days per week	<input type="checkbox"/> Less than once per week	<input type="checkbox"/> I don't drink alcohol (skip to Q 25)		
Alcoholic drinks are measured in terms of a "standard drink". A standard drink is equal to 1 middy of full-strength beer, 1 schooner of light beer, 1 small glass of wine or 1 pub-sized nip of spirits.					
Q26 On a day when you drink, how many standard drinks do you usually have? _____ number of drinks					
Q27 Which of the following best describes your smoking status?	<input type="checkbox"/> I smoke daily	<input type="checkbox"/> I smoke occasionally	<input type="checkbox"/> I don't smoke now but I used to	<input type="checkbox"/> I've tried it a few times but never smoked regularly	<input type="checkbox"/> I've never smoked

These questions measure physical activity and healthy eating self-efficacy

a. are tired?	<input type="checkbox"/> Not at all	<input type="checkbox"/> A little confident	<input type="checkbox"/> Confident	<input type="checkbox"/> Very confident
b. are stressed?	<input type="checkbox"/> Not at all	<input type="checkbox"/> A little confident	<input type="checkbox"/> Confident	<input type="checkbox"/> Very confident
c. have a lot of other demands at home?	<input type="checkbox"/> Not at all	<input type="checkbox"/> A little confident	<input type="checkbox"/> Confident	<input type="checkbox"/> Very confident
d. feel depressed?	<input type="checkbox"/> Not at all	<input type="checkbox"/> A little confident	<input type="checkbox"/> Confident	<input type="checkbox"/> Very confident
Q29 How confident are you that you can eat a healthy diet when you:				
a. are in a hurry?	<input type="checkbox"/> Not at all	<input type="checkbox"/> A little confident	<input type="checkbox"/> Confident	<input type="checkbox"/> Very confident
b. feel stressed?	<input type="checkbox"/> Not at all	<input type="checkbox"/> A little confident	<input type="checkbox"/> Confident	<input type="checkbox"/> Very confident
c. have a lot of other demands at home?	<input type="checkbox"/> Not at all	<input type="checkbox"/> A little confident	<input type="checkbox"/> Confident	<input type="checkbox"/> Very confident
d. feel depressed?	<input type="checkbox"/> Not at all	<input type="checkbox"/> A little confident	<input type="checkbox"/> Confident	<input type="checkbox"/> Very confident

These questions measure social support for physically activity and healthy eating

Q30 How often do the following people encourage you to be physically active?				
a. How often do your friends encourage you to be physically active?	Never	Rarely	Sometimes	Often
b. How often does your family encourage you to be physically active?	Never	Rarely	Sometimes	Often
c. How often does your doctor or other health professional (e.g. physiotherapist, nurse etc) encourage you to be physically active?	Never	Rarely	Sometimes	Often
Q31 How often do the following people encourage you to eat a healthy diet?				
a. How often do your friends encourage you to eat a healthy diet?	Never	Rarely	Sometimes	Often
b. How often does your family encourage you to eat a healthy diet?	Never	Rarely	Sometimes	Often

c. How often does your doctor or other health professional (e.g. physiotherapist, nurse etc) encourage you to eat a healthy diet?	Never	Rarely	Sometimes	Often
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These questions measure health related quality of life

Q32 In general, would you say your health is:	<input type="radio"/> Excellent	<input type="radio"/> Very good	<input type="radio"/> Good	<input type="radio"/> Fair	<input type="radio"/> Poor
Q33 The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?					
a First, moderate activities such as moving a table, pushing a vacuum cleaner, bowling or playing golf.	<input type="radio"/> Limited a lot	<input type="radio"/> Limited a little	<input type="radio"/> Not limited at all		
b Climbing several flights of stairs.	<input type="radio"/> Limited a lot	<input type="radio"/> Limited a little	<input type="radio"/> Not limited at all		
Q34 During the past four weeks, have you accomplished less than you would like as a result of your physical health?	<input type="radio"/> No			<input type="radio"/> Yes	
Q35 During the past four weeks, were you limited in the kind of work or other regular activities you do as a result of your physical health?	<input type="radio"/> No			<input type="radio"/> Yes	
Q36 During the past four weeks, have you accomplished less than you would like to as a result of any emotional problems, such as feeling depressed or anxious?	<input type="radio"/> No			<input type="radio"/> Yes	
Q37 During the past four weeks, did you not do work or other regular activities as carefully as usual as a result of any emotional problems such as feeling depressed or anxious?	<input type="radio"/> No			<input type="radio"/> Yes	
Q38 During the past four weeks how much did pain interfere with your normal work including both work outside the home and housework?	<input type="radio"/> Not at all	<input type="radio"/> Slightly	<input type="radio"/> Moderately	<input type="radio"/> Quite a bit	<input type="radio"/> Extremely
Q39 These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.					
a. How much time during the past 4 weeks have you felt calm and peaceful?					
<input type="radio"/> All of the time	<input type="radio"/> Most of the time	<input type="radio"/> A good bit of the time	<input type="radio"/> Some of the time	<input type="radio"/> None of the time	
b. How much of the time during the past 4 weeks did you have a lot of energy?					
<input type="radio"/> All of the time	<input type="radio"/> Most of the time	<input type="radio"/> A good bit of the time	<input type="radio"/> Some of the time	<input type="radio"/> None of the time	
c. How much time during the past 4 weeks have you felt down?					
<input type="radio"/> All of the time	<input type="radio"/> Most of the time	<input type="radio"/> A good bit of the time	<input type="radio"/> Some of the time	<input type="radio"/> None of the time	
d. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities like visiting with friends, relatives etc?					
<input type="radio"/> All of the time	<input type="radio"/> Most of the time	<input type="radio"/> Some of the time	<input type="radio"/> A little of the time	<input type="radio"/> None of the time	

These questions measure relevant illnesses and injury

Q39 Has a doctor EVER told you that you have:	
a. Asthma or emphysema	<input type="radio"/> Yes <input type="radio"/> Your age when condition was first found ____ years
b. Cancer	<input type="radio"/> Yes <input type="radio"/> Your age when condition was first found ____ years
c. Heart attack or angina or other heart disease	<input type="radio"/> Yes <input type="radio"/> Your age when condition was first found ____ years
d. High blood pressure	<input type="radio"/> Yes <input type="radio"/> Your age when condition was first found ____ years
e. High blood cholesterol	<input type="radio"/> Yes <input type="radio"/> Your age when condition was first found ____ years
f. Diabetes or high blood sugar	<input type="radio"/> Yes <input type="radio"/> Your age when condition was first found ____ years
g. Osteoarthritis, osteoporosis or low bone	<input type="radio"/> Yes <input type="radio"/> Your age when condition was first found ____ years

density		years		
g. None of these	<input type="radio"/>			
h. Has anyone in your immediate family or other relatives got diabetes (type 1 or type 2)	<input type="radio"/> No	<input type="radio"/> Yes, grandparent, uncle, 1 st cousin	<input type="radio"/> Yes, parent, sibling, own child	<input type="radio"/> Don't know

Q40 In the past 3 months how many days have you taken off work due to illness?	<input type="radio"/> Nil	
Q41 In the past 3 months how many days have you taken off work due to serious injury?	<input type="radio"/> Nil	

These questions measure relevant medications

Q42 Have you taken any prescription medications for any reason in the last 3 months?	<input type="radio"/> Yes	<input type="radio"/> No (go to Q43)		
Q42a If yes, please state the name, strength and dose of the prescription medications have you taken in the last three months.				
1. high blood pressure medication	name	strength	Daily dose	cost
2. Diabetes/ high blood sugar medication				
3. Depression medication				
4. weight loss medication				
5. asthma/COPD medication				
6. arthritis/osteoporosis medication				

These questions are related to the economic analysis

Q43 Have you had any admissions to a hospital emergency department in the last 3 months? (e.g. accident, emergency, casualty)	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> can't remember
Q43a If yes, how many emergency department visits have you made in the last three months? _____			
Q44 Have you stayed overnight in a hospital in the last 3 months?	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> can't remember
Q44a If yes, how many nights have you spent in a hospital in the last three months? _____			
Q45 Have you seen a general practitioner at a surgery in the last 3 months?	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> can't remember
Q45a If yes, how many visits to a GP have you made in the last three months? _____			
Q46 Have you seen any medical specialists or health care professionals apart from your GP, or following referral from your GP in the last 3 months?	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> can't remember
Q46a If yes, what medical specialists or other health care professionals have you seen and how many times have you seen them in the last 3 months? (SEE LIST BELOW)			

Health Professional	Number of visits in the past 3 months
<input type="radio"/> Allied Health Other (optometrist, podiatrist)	
<input type="radio"/> Cardiologist	
<input type="radio"/> Diabetes Specialist / Endocrinologist	
<input type="radio"/> Dietician	
<input type="radio"/> Exercise Physiologist	
<input type="radio"/> Eye specialist /Ophthalmologist	
<input type="radio"/> Kidney specialist / Nephrologist	
<input type="radio"/> Natural Therapist	
<input type="radio"/> Other Medical specialty (surgeon, ENT, gastroenterologist)	
<input type="radio"/> Physiotherapist	
<input type="radio"/> Psychologist / Psychiatrist	

Q47 In the past month, have you spent any money on exercise-related products or services (such walking/running shoes, gym membership, exercise classes/equipment)? <input type="radio"/> No <input type="radio"/> Yes					
Q47a. If yes, how much have you spent on exercise-related products or services in the past month					
Product/service			Amount spent (\$)		
<input type="radio"/> walking or running shoes					
<input type="radio"/> gym membership or personal trainer					
<input type="radio"/> gym equipment for use at home					
<input type="radio"/> sports/exercise clothing					
<input type="radio"/> other					
Q 48 In the past week, approximately how much did your household spend on food?					
<input type="radio"/> Less than \$50	<input type="radio"/> \$50- \$100	<input type="radio"/> \$101-150	<input type="radio"/> \$151-\$200	<input type="radio"/> More than \$200	<input type="radio"/> can't tell / unsure

Q49 Including you, how many people live in the household? _____

Q50 What is your annual household income (before tax is taken out)?	<input type="radio"/> up to \$20, 000	<input type="radio"/> >\$20, 000 - \$40, 000	<input type="radio"/> >\$40, 000 - \$80, 000	<input type="radio"/> >\$80, 000 – \$80, 000
	<input type="radio"/> >\$80, 000 – \$100,000	<input type="radio"/> >\$100, 000- \$120,000	<input type="radio"/> > \$120,000	<input type="radio"/> don't know or don't want to answer

And just to conclude, we are interested in learning how you became aware of the Live Life Well program. Can you tell me how you found out about it?

- | | |
|--|--|
| <input type="radio"/> GP told me during consult or after blood test | <input type="radio"/> I read it in the local newspaper |
| <input type="radio"/> I received an invitation letter from my GP | <input type="radio"/> I heard about it on the radio |
| <input type="radio"/> I was approached by staff in the waiting room | <input type="radio"/> I saw it on TV |
| <input type="radio"/> A Division staff member rang me and asked me | <input type="radio"/> From the NSW Health/Division website |
| <input type="radio"/> From an advertisement/MP communication in my letterbox | |
| <input type="radio"/> A relative or friend told me | |
| <input type="radio"/> I saw an announcement at the cinema | |
| <input type="radio"/> Other | |

Have you received the 3-day food record? Do you need any help filling it in? Please don't forget to bring it to your initial consultation with the lifestyle officer. Do you have any questions for us? This concludes the interview. Thank you your participation. Good luck with the Program. Bye.

Interviewer's name _____

Appendix 4.6 CATI Interviewers manual with definitions of physical activity levels



TELEPHONE INTERVIEWER'S QUICK REFERENCE GUIDE FOR THE BASELINE AND 12 MONTH QUESTIONNAIRE – paper version

This reference will point you to queries (and their answers) you might have when conducting the telephone interview for the Live Life Well Diabetes Prevention Program.

In most cases, the questions and answers on the database screen are self-explanatory. However, in some instances, further instructions are needed. See below for general and specific recommendations.

IN GENERAL:

- Record the PIT number as allocated on the paper list.
- Have a calculator handy. You will probably need it to add up hours/minutes of physical activity, dollars spent on exercise products, dollars spent on food, and aggregated household income for all family members.
- Record the start time as soon as the participant comes to the phone and record the finish time as soon as you say 'goodbye'. This would include time spent on any clarifications even after the end of the questions.
- Never ask "are you male or female", just record the relevant answer judging by the participant's name, or ask the project staff before making the call.
- Clearly state your name during the introduction.
- If the respondent says it's not a good time, make sure you immediately arrange for a day/time that suits the participant.
- If you notice the respondent has a foreign accent or is poorly educated, make sure you read the multiple choice questions slowly enough (without sounding patronizing).
- While you are interviewing, make sure you let the respondent know every time you are moving to a different section of the survey or to a new set of questions so the transition is not too abrupt.
- It is standard practice to read out all response options for the Physical Activity module (PASE), the 'social support and self-efficacy' module and the SF-12 module. This is the standard way of administering those modules, even if some respondents think it's boring or repetitive. You might want to clarify that all interviewers are doing the same. If the respondents jump in with their responses, let them and record the answer.
- The exception is, **do not read out** the 'not applicable' or "don't/know" or "refused to answer" or "can't remember" or "can't tell/unsure" options of any set of questions.
- If the respondent expresses his/her preference not to answer, say 'that's ok' and move on to the next question. Do not insist on obtaining an answer to any particular question.

It is better to secure a partially complete questionnaire than to lose the participant altogether.

SPECIFICS:

Question on ‘currently on paid employment’:

If the respondent says they are not currently working, then ask ‘would you describe yourself as unemployed, home-maker or retired?’ If they (or you) need clarification on the meaning of terms, here they are:

- An ‘unemployed’ person is defined as someone who is physically able to work but is currently out of the workforce and looking for a job or thinking about getting a job.
- A ‘retired’ person is defined as someone who has no prospects of going back to work either because s/he chose to retire or because s/he became too ill to return to work.

Question on ‘Physical activity each week

Beware that respondents may tend to over-report their level of physical activity; this may be because they honestly believe their type of exercise is vigorous or moderate but in reality it could be only light at best. Please become familiar with the list of exercises and categories of intensity (see appendix) so you can be as accurate as possible when you enter the data.

Question on how many flights of stairs did you climb up?

The average is 10 but you need to ask how many steps per flight (some are only 2 or 5!). Record the number of flights. For the next question on total number of steps, multiply number of flights by number of steps per flight and enter that total in the box. **Do not include steps walked down.**

Question on ‘what sort of REGULAR physical activity do you do?:

Let the respondent volunteer the information and tick as many boxes as applicable. If they cannot come up with an answer then start reading out the response options. If they cannot nominate anything, then go back to the previous questions and tick ‘No’.

Question on ‘Do you drink any alcohol?:

If respondent drinks once per week or more, the next two questions on frequency and quantity should always be asked. If the respondent says, maybe twice a year or a rare occurrence, ask how many standard drinks. If they say 1 tick ‘No’ on ‘do you drink any alcohol’ and skip the next 2 questions.

Question on self-efficacy (how confident are you...):

There are 4 questions on physical activity and 4 questions on healthy diet. As the wording is very similar for both sets, make sure you stress out those key words so the participant does not think you are repeating a question. Read out four of the five response options. Do NOT read out ‘not applicable’ (N/A tick box). Try to get a response fitting either of those four response options as much as possible. This will help us calculate a ‘self-efficacy score’. Only tick the N/A box if the participant says “I never get depressed” or “I am never stressed” or “I don’t have demands at home because I live alone”, in which case, the question really does not apply to them.

Question on relatives with diabetes

We are most interested in **first degree relatives** with diabetes. So, if the respondent has a sister and uncle with diabetes, tick the ‘parent, sibling or own child’ box. If the respondent

has only a grandparent, uncle or cousin, then tick that box.

Question on ‘has a doctor told you that you have any of the following conditions’:

Read out slowly each of the diseases listed. If the respondent says, ‘No’ to the first disease on the list, then read out the next disease and so on.

If the respondent says ‘Yes’ to any of the diseases then ask the question: ‘how old were you when you were **first** diagnosed?’ and type in the age.

If a participant has more than one heart attack, ask for and only record the age when the first heart attack was diagnosed. If the participant has more than one type of cancer, record the age when each cancer was diagnosed.

Important: The field for ‘**diabetes or high blood sugar**’ is to identify participants who have had diabetes during pregnancy in the past but are not diabetics today, and for people who have impaired glucose tolerance (IGT or pre-diabetes). However, if the respondent has been diagnosed with diabetes (outside pregnancy) you need to tell the Program staff so they can follow up with the recruitment staff. This participant should not be part of the Program.

Question on prescription medications the participant is taking or has taken in the past 3 months. Tell the participant to feel free to check their medications boxes so you can get accurate information on name, strength and dose. Start with medications for those illnesses mentioned before, which you recorded in the previous section (illness & injury).

You can read out the broad categories of medications with a focus on the 6 priority categories of SDPP i.e. high blood pressure medication, other cardiovascular diseases, cholesterol medication, arthritis, asthma and depression medications. Record the name of the medication, the strength and the dose they are taking each day (e.g. Isoptin ® or the generic name Verapamil, tablets of 40mg, two tablets per day). Then multiply the number of daily tablets taken by 7 to enter a total for the week. E.g. in the case of Isoptin above you enter 14. A number of people will tell you they only take the tablet once or twice per week. Record this number (1 or 2) directly. If the medication is a nebulizer or a puffer, specify this when you write the medication name and ask for how many doses the participant has per week and write the number of puffer doses per week under ‘tablets per week’.

Do your best to allocate the medication to the right category. As this takes time you may need to do this after the interview has completed until you are familiar with the categories.

Do not be shy to ask for the spelling of any medication. The participant knows you are not a doctor.

Question on specialists or other health professionals seen in the past 3 months. If respondent says ‘No’ then tick ‘no’ and skip the question on “what medical specialists”. If respondent says ‘yes’ then ask them “what medical specialists.. etc” and tick the appropriate professional (doctor or allied health) from the list. If the respondent cannot name the specialty, help them by reading out the list. It is important to record the number of visits for each relevant specialist or allied health category.

However, please note that the “other” categories are for occupations not necessarily related to

diabetes prevention or control. For example, if the participant says “breast cancer surgeon” then you tick “other medical specialist”. If the participant has visited more than one of those ‘irrelevant’ specialists just record the total number of visits.

Question on "Have you ever had any form of weight loss surgery such as bariatric surgery, lap band surgery, sleeve gastrectomy, gastric banding surgery, or gastric or intestinal bypass surgery?"

Please read out all the descriptions of surgery. Please record the first 3 letters of the month and the year as 4 digits. E.g. Jan 2001.

Question on “have you spent any money on exercise-related products or services such as walking or running shoes, gym membership, or equipment for use at home, or casual fees for exercise classes, aerobics, yoga or admission to a swimming pool? Read out all options on that question.

If respondent says “No” to all, then tick ‘no’ and skip the question on ‘how much money did you spend...’ and move on to the next question on ‘how much money was spent on food’.

If respondent says ‘Yes’ to any exercise product or service, then go to the list under ‘If yes, how much money did you spend...’. Then let the respondent tell you what items there were or read out each item from the list and tick those relevant to the respondent. Remember to enter in whole dollars (no cents) the money spent on EACH item. If respondent spent \$ on more than one type of shoes or more than one type of equipment, just add up the total cost and enter it under the relevant category.

If the participant takes medication that is not related to conditions relevant to this program, record as ‘Other medications’.

Question on income “what is your HOUSEHOLD income before tax is taken out?” Wait for the respondent to give you the exact figure and then choose a category from the list. If the respondent hesitates or says he prefers not to tell, you can say “this is only for statistical purposes. Would you be happier giving me a range? For example 0-\$20K, \$20-40K, etc?” Often people are more prepared to give information on a range. If the respondent definitely refuses, just click on ‘refused’, gracefully say “that’s ok” and thank them for their time during the interview.

If the respondent asks “why are you asking these [economic] questions?” you can say something like: "We are asking **everyone** about what medication they are taking, numbers of visits to health services and how much money they spend on exercise and diet. This is because we want to find out if there is any relationship between the amount of money spent on exercise and food and their amount of medication they take or the number of times they use health services.”

If the respondent asks questions about the point of the program and why it is important, use the following key messages:

- This is more than just an exercise program - its a lifestyle program; It is not just about information, is about demonstrations on how to get more active and eat better
- It is approved by your Doctor
- It's about small manageable changes/steps (not a life overhaul like The Biggest Loser)
- It has been designed by experts and run by a range of trained health professionals
- It has been successful for other people at risk of diabetes, just like you.

Question on 'learning how you became aware of the Live Life Well Diabetes Prevention Program'

Please ask the question without prompting for the answers. Let the respondent tell you and then tick as many boxes as applicable.

Do not forget to record 'finished time' as this is important to keep track of costs.

CAUTION

- **Do not ring another participant until you have checked for completeness and recorded all medications under the correct category.**
- A maximum of five (5) attempts to contact each participant should be made at different times of the day and on different days of the week depending on the nominated time by participant.
- If you must leave messages on answering machines do not mention the word 'diabetes', just say your name, you are calling from the 'Live Life Well Program' and say you or a colleague will ring back. Advise the Program Manager when all attempts have been exhausted and you have been unable to contact the participant.

Expert recommendations on classification of activity levels

Light Physical Activity

Golf with a cart

Lawn bowls

Cricket

Water aerobics/ aquarobics

Pilates

Oelyptical machine

Playing with kids in the yard

Splashing around the pool

Gardening

Calisthenics, yoga, gentle exercise

Body weight exercise such as stretching, sit ups or push-ups without weight lifting,

Moderate Physical Activity (question respondents if they report more than 1 hour per day)

Walking on a treadmill

Walking machine

Shadow Boxing

Dancing

Pool walking

Bushwalking (unless specified as 'high-grade')

Swimming (if not laps or if specified as 'gentle')

Slow/gentle cycling

Brisk walking (only if it makes the person puff and it's done deliberately for fitness)

Vigorous/Strenuous Physical Activity (question respondents if they report more than 1 hour per day)

Cycling machine (if fast or against resistance)

Swimming **laps** (unless specified as 'gentle swimming')

Running on treadmill

Horse riding (machine)

High-grade bushwalking

Fast jogging

Resistance/Strength (question respondents if they report more than 1 hour per day)

Only include weight lifting with free weights or machines. Pushups only included here if other resistance training is mentioned as well.

A single notation of “push ups” or “sit ups” goes into light exercise

Implausible if they report muscle strengthening exercise 5-7 days per week (older age group)

Question respondents if they report more than one hour of resistance training per day

Examples of unstructured physical activity that should not be classified under either moderate, vigorous or muscle strengthening activity

Lifting boxes at work

Walking to and from work (this goes under ‘walking outside the house for any reason’)

Gardening (goes under gardening question even if it’s considered moderate by respondent)

_____END OF CATI INTERVIEWERS MANUAL_____

Appendix 4.7 Measurement Protocols for height, weight, WC and blood pressure

Height Measurement Protocol for the Live Life Well Diabetes Prevention Program

Guide for Lifestyle Officers

This protocol will assist lifestyle officers in ensuring precision of the height measurement of participants of all ages in the Diabetes Prevention Program. Self-reported height is not reliable as adults tend to 'shrink' with age and their last reported measurement could differ from the truth by several centimetres for people over the age of 60 years. This protocol is recommended to use in population surveys and health care settings.⁸¹

Equipment requirements

The measurement of height requires a vertical metric rule, a horizontal headboard, and a flat, even surface on which the participant stands. The recommended type of device for measuring height is a wall-mounted system where the horizontal arm is securely affixed and remains at a 90° angle (stadiometer, which may be fixed or portable). The graduations on the metric rule should be at 0.1 cm intervals, and the metric rule should have the capacity to measure up to at least 210 cm. Measurement intervals and labels should be clearly readable under all conditions of use of the instrument. All stadiometers should be the same type across participating Divisions of General Practice (SDPP recommends model WS-220S). Any differences in equipment should be reported.

Using the stadiometer for adults who can stand⁸²

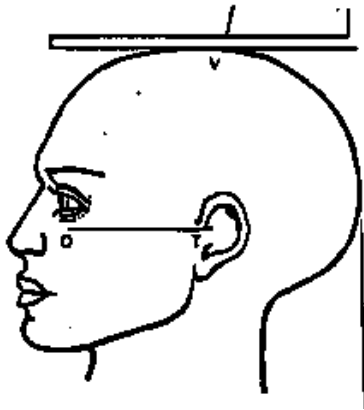
- It is essential that the participant be measured without shoes (either barefoot or wearing thin socks is acceptable) and wearing minimum clothing so that the positioning of the body can be seen by the lifestyle officer.
- The participant should stand with weight distributed evenly on both feet, heels close together, and the head positioned so that the line of vision is at right angles to the body. The arms should hang freely by the sides.
- The head, back, buttocks and heels should be positioned vertically so that the buttocks and the heels are in contact with the vertical board or wall.
- For those being measured against a wall or wall mounted unit, the back of the head should not touch the wall or the unit if this takes the head out of position.
- To ensure correct position for the head is best to place the head in the Frankfort horizontal plane (Norton et al. 1996, see figure). The Frankfort Plane is an imaginary line going from the lower border of the bony socket containing the eye and the upper border of the hole in the ear. The movable headboard should be parallel to this line.

⁸¹ The measurement protocol described here is adapted from the one recommended by the International Society for the Advancement of Kinanthropometry (ISAK) as described by Norton et al. (1996), and the World Health Organization (WHO Expert Committee 1995), which was adapted from Lohman et al. (1988). A complete protocol published in the AIHW's Metadata Online Registry can be found at:

<http://meteor.aihw.gov.au/content/index.phtml/itemId/270361> Accessed 2nd September 2008.

⁸² People who are unable to stand are ineligible to participate in the Diabetes Prevention Program

- Place the headboard over the crown of the head, with the headboard forming a right angle to the scale. The headboard should touch the scalp, with sufficient pressure to compress the hair as much as possible.
- To obtain a consistent measure, the participant is asked to inhale deeply and stretch to their fullest height.
- Frankfort horizontal plane for measuring body height ⁸³



10.8.2 Recording the measurement

The measurement is recorded in centimetres to the nearest 0.1 cm.

While you become familiar with the procedure, take a repeat measurement. You can do this on the first ten or fifteen participants that you measure. After the two measurements are taken, calculate the height as the average of the two observations: this will be the participant's measured height to be recorded on the form (see example AB in the table below).

If the two measurements disagree by more than 0.5 cm, then take a third measurement. If a third measurement is taken, then calculate the height using the average of the two closest measurements (see example CD in the table below).

It may be necessary to round the average value to the nearest 0.1 cm. If so, rounding should be to the nearest even digit, to reduce systematic over reporting (Armitage & Berry 1994). For example, an average value of 172.25 cm would be rounded to 172.2 cm, while an average value of 172.35 cm would be rounded to 172.4 cm.

Participant	Height1	Height2	Height3	Average	final measure to be recorded
AB	165	165.5		$= (165 + 165.5) / 2 = 165.25$	165.2
CD	171.3	173.5	172.2	$= (171.3 + 172.2) / 2 = 171.75$	171.8

All raw measurements should be recorded on the data collection form (or database, whichever applies). If only an average value is entered into the database then the data collection forms should be retained for quality control.

Anything that may affect or interfere with the measurement should be noted on the data collection form (e.g. physical problems such as scoliosis of the spine) or in the participants database (whichever applies).

After you are confident that you can accurately measure height, only one measurement is required to be taken and entered.

⁸³ Figure taken from the Anthropometry section of the NIH's operation's manual 2007. Available at: http://www.nhlbi.nih.gov/resources/deca/ mesa/Forms/MESA_E1_Anthropometry_MOP.pdf

Quality control measures

Before measuring height, all equipment, whether fixed or portable should be checked prior to each session to ensure that both the headboard and floor (or footboard) are at 90 angle to the floor and the stadiometer is mounted perpendicular to the floor. With some types of portable stadiometer it is necessary to check the correct alignment of the headboard, during each measurement, by means of a spirit level.

Extreme values of measured height should be checked during data collection by the lifestyle officer. However, individuals should not be excluded on the basis of true biological difference (ie. too tall or too short people). Unusually high or low levels of the measured height will be checked by the statistician after data entry.

Last digit preference, and preference or avoidance of certain values, will be analysed in the total sample and by observer, survey site and over time over the survey period.

Weight Measurement protocol for the Live Life Well Diabetes Prevention Program

Guide for Lifestyle Officers

This protocol will assist lifestyle officers in accurately recording participants' weight at all relevant stages of the Program. It is based on internationally accepted standards.⁸⁴

Equipment requirements

A digital scale is recommended for all Divisions of General Practice to ensure accuracy, minimise the need for double measurements, and consistency with follow-up measurements at baseline and final assessment. The SDPP recommends Wedderburn model TI-HD 351, which has capacity for 200Kg, platform size over a foot wide, large and easy to read display, reading in Kg and pounds and a memory to recall weight for up to 5 people.

Measurement technique

The scale should be on a firm, level surface (not on a carpet, for example).

Check to make sure that the scale's reading panel displays zero when no weight is on the scale. Heavy jewellery should be removed and pockets emptied. Light indoor clothing can be worn, excluding shoes, belts, and jumpers. Any variations from light indoor clothing (e.g. heavy clothing, such as kaftans or coats worn because of cultural practices) should be noted on the data collection form.

Instruct the participant to stand in the middle of the platform of the balance scale, with head erect and eyes looking straight ahead and the body weight evenly distributed between both feet. If the participant is too obese to stand securely on the scale's platform when looking straight ahead, he/she may stand sideways on the scale to take the weight measurement; facing to the side rather than the front will provide the participant a wider base and more stability (if the scale has a rectangular platform).

If the participant has had one limb amputated, record this on the data collection form and weigh them as they are. If they are wearing an artificial limb, record this on the data collection form but do not ask them to remove it. Similarly, if they are not wearing the limb, record this but do

⁸⁴ The measurement protocol described here is that recommended by the WHO Expert Committee (1995) and published as part of the AIHW Metadata Online Registry.
<http://meteor.aihw.gov.au/content/index.phtml/itemId/270208>. Accessed 2 September, 2008.

not ask them to put it on. Any anomalies of this sort should be (entered in the database comments section) reported to the statistician via the Division Coordinator.

If a participant is frail or unsteady, measure his/her weight while participant is lightly steadied by you or an assistant. Perhaps reconsider their eligibility for the Program.

If a participant is unable to stand on the scale for a weight measurement, do not attempt a weight measurement. Reconsider participant's eligibility or make a note on the record that there was a modification in protocol for weight measurement and notify the Division Coordinator.

Recording the measurement

Record the results, to the nearest 0.1 Kg, in the form/database (as applicable).

It may be necessary to round the mean value to the nearest 0.1 kg. If so, rounding should be to the nearest even digit to reduce systematic over reporting (Armitage and Berry 1994). For example, a mean value of 72.25 kg would be rounded to 72.2 kg, while a mean value of 72.35 kg would be rounded to 72.4 kg.

If the participant weighs over 200Kg refer him/her to a facility (shopping centre machine or nearby gym) where weight can be accurately measured and ask participant to record it).

Quality control

Precision error should be no more than 0.1kg. Check that the batteries are not low so scales maintain accuracy at every day of use.

If practical, check calibration by using one or more objects of known weight in the range to be measured. It is recommended that the scale be calibrated at the extremes and in the mid range of the expected weight of the population being studied (e.g. approximately 80-150 Kg). If required, the scale must be calibrated by the manufacturer or by the appropriate institution personnel.

Follow manufacturers' guidelines with regard to the transportation of the scales.

No repeat measurements or inter-observer agreement will be conducted as digital scales do not leave room for interpretation of the weight measurement.

Adjustments for non-standard clothing (i.e. other than light indoor clothing) should only be made in the data checking/cleaning stage prior to data analysis.

The statistician will also check for extreme values at the upper end of the distribution of measured weight after data entry.

Waist circumference measurement protocol for the Prevent Diabetes Live Life Well Program

Guide for Lifestyle Officers

The tape measurement

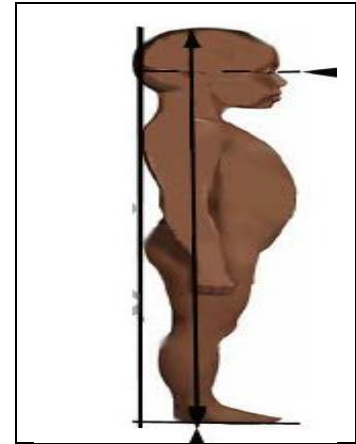
The measurement of waist circumference requires a narrow (7 mm wide), flexible, inelastic tape measure, of adequate length. The graduations on the tape measure should be at 0.1 cm intervals and the tape should have the capacity to measure up to 200 cm. Measurement intervals and labels should be clearly readable under all conditions of use of the tape measure.

Measurement technique

1. The participant should remove any belts and heavy outer clothing. Tight clothing, including the belt, should be loosened and the pockets emptied. Measurement of waist circumference should be taken over at most one layer of light clothing. Ideally the measure is made directly over the skin, so participant should be asked to lift their shirt or blouse after removing their belt. If this is not possible, for example due to cultural reasons, the alternative is to measure

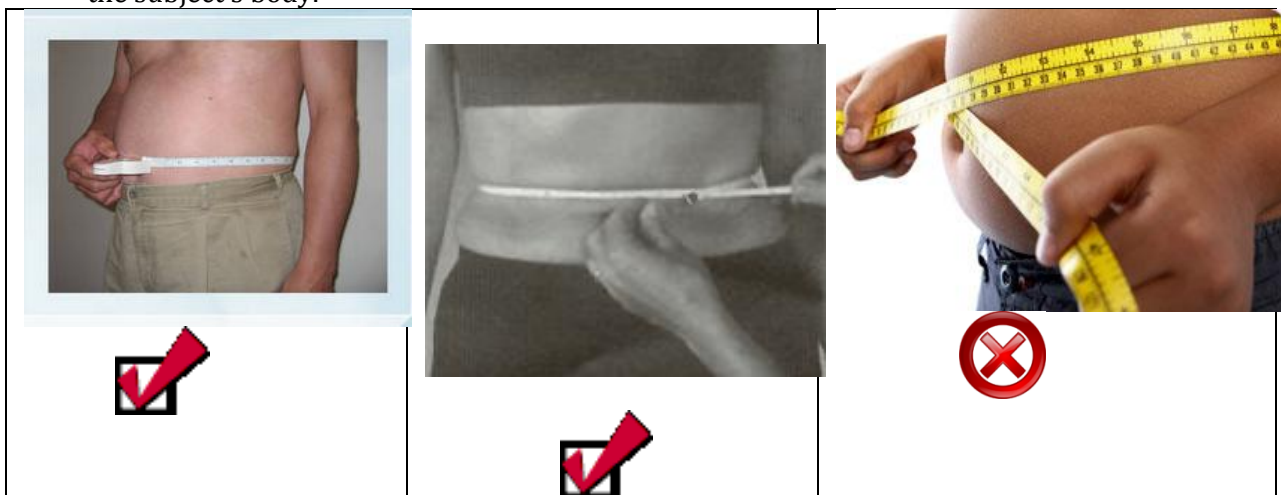
the circumference on the subject without heavy outer garments and record this fact in the data collection form.

2. Posture can affect waist circumference. The participant should stand with his/her weight evenly distributed on both feet, and feet separated about 25-30 cm. Arms should hang loosely at the sides. The measurement is taken midway between the lower margin of the last rib and the top of the hip bone, along the mid-axillary line (an imaginary perpendicular line that runs through the side of the body between two points as shown in the graph).

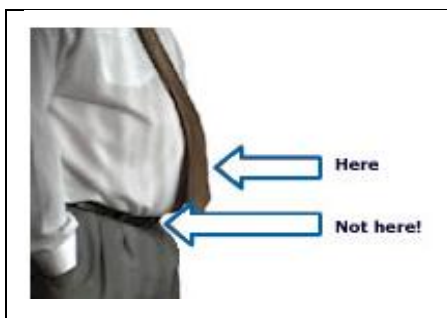


Each landmark should be palpated (touched), and the midpoint determined with the tape measure and if possible marked.

3. Once the midway is determined, the inelastic tape is placed around the body starting at the marked midway, then bringing it all the way around. The measuring tape should be held firmly, ensuring it is in a horizontal position. – this usually falls about 5 cm (2 inches) above the belly button. The tape must be snug, but without compressing underlying soft tissues. The tape should be loose enough to allow the observer to place one finger between the tape and the subject's body.



In practice it may be difficult (or inappropriate) with very overweight patients to accurately identify those bony landmarks. In this case palpation is not recommended but the tape must be leveled with the participant's navel.



4. The lifestyle officer should stand at the side of the participant in order to have a clear view of the back and the front of the participant's body. Placing a mirror at the back of the participant would help to ensure that the tape is horizontal.

5. Participants should be asked to breathe normally; the reading of the measurement should be taken at the end of normal expiration. This will prevent subjects from contracting their abdominal muscles or from holding their breath.

Quality control of the waist measurement

- The measurement should be recorded at the end of a normal expiration to the nearest 0.1 cm. Lifestyle officers should take a repeat measurement and record this repeat measurement to the nearest 0.1 cm.
- If the two measurements disagree by more than 1 cm, a third measurement should be taken.
- All raw measurements should be recorded on the data collection form.
- The statistician will calculate the mean WC after the consultation.

Measurement Protocol for resting Blood Pressure

Guide for Lifestyle Officers

Source: AIHW's Metadata Online Registry. Accessed 17 July, 2009- Available at:

<http://meteor.aihw.gov.au/content/index.phtml/itemId/270072>

The diastolic blood pressure is one component of a routine blood pressure measurement (i.e. systolic/diastolic) and reflects the minimum pressure to which the arteries are exposed.

The patient should be relaxed and seated, preferably for several minutes, (at least 5 minutes). Ideally, patients should not take caffeine-containing beverages or smoke for two hours before blood pressure is measured.

Ideally, patients should not exercise within half an hour of the measurement being taken (National Nutrition Survey User's Guide).

Use a mercury sphygmomanometer. All other sphygmomanometers should be calibrated regularly against mercury sphygmomanometers to ensure accuracy.

Bladder length should be at least 80%, and width at least 40% of the circumference of the mid-upper arm. If the velcro on the cuff is not totally attached, the cuff is probably too small.

Wrap cuff snugly around upper arm, with the centre of the bladder of the cuff positioned over the brachial artery and the lower border of the cuff about 2 cm above the bend of the elbow.

Ensure cuff is at heart level, whatever the position of the patient.

Palpate the radial pulse of the arm in which the blood pressure is being measured.

Inflate cuff to the pressure at which the radial pulse disappears and note this value. Deflate cuff, wait 30 seconds, and then inflate cuff to 30 mm Hg above the pressure at which the radial pulse disappeared.

Deflate the cuff at a rate of 2-3 mm Hg/beat (2-3 mm Hg/sec) or less.

Recording the diastolic pressure use phase V Korotkoff (disappearance of sound). Use phase IV Korotkoff (muffling of sound) only if sound continues towards zero but does not cease. Wait 30 seconds before repeating the procedure in the same arm. Average the readings.

If the first two readings differ by more than 4 mmHg diastolic or if initial readings are high, take several readings after five minutes of quiet rest.

Person—blood pressure (diastolic) (measured), millimetres of mercury NN[N]

Identifying and definitional attributes

Metadata item type: [i](#) Data Element
Short name: [i](#) Blood pressure—diastolic (measured)
METeOR identifier: [i](#) 270072
Registration status: [i](#) Health, Standard 01/03/2005
Definition: [i](#) The person's diastolic [blood pressure](#), measured in millimetres of mercury (mmHg).
Data Element Concept: [i](#) [Person—blood pressure \(diastolic\)](#)

Value domain attributes

Representational attributes

Representation class: [i](#) Total
Data type: [i](#) Number
Format: [i](#) NN[N]
Maximum character length: [i](#) 3

Supplementary values: i	Value	Meaning
	999	Not stated/inadequately described

Unit of measure: [i](#) Millimetre of mercury (mmHg)

Data element attributes

Collection and usage attributes

Guide for use: [i](#) The diastolic pressure is recorded as phase V Korotkoff (disappearance of sound) however phase IV Korotkoff (muffling of sound) is used if the sound continues towards zero but does not cease.
If Blood pressure - diastolic is not collected or not able to be collected, code 999.

Collection methods: [i](#)

Comments: [i](#) The pressure head is the height difference a pressure can raise a fluid's equilibrium level above the surface subjected to pressure. (Blood pressure is usually measured as a head of Mercury, and this is the unit of measure nominated for this metadata item.)
The current (2002) definition of hypertension is based on the level of blood pressure above which treatment is recommended, and this depends on the presence of other risk factors, e.g. age, diabetes etc. (NHF 1999 Guide to Management of Hypertension).

Source and reference attributes

Submitting organisation: [i](#) Cardiovascular Data Working Group
National Diabetes Data Working Group

Origin: [i](#) The National Heart Foundation Blood Pressure Advisory Committee's 'Guidelines for the Management of Hypertension - 1999' which are largely based on World Health Organization Recommendations. (Guidelines Subcommittee of the WHO-ISH: 1999 WHO-ISH guidelines for management of hypertension. J Hypertension 1999; 17:151-83).
Australian Bureau of Statistics 1998. National Nutrition Survey User's Guide 1995. Cat. No. 4801.0. Canberra: ABS. (p. 20).
National Diabetes Outcomes Quality Review Initiative (NDOQRIN) data dictionary.

Reference documents: [i](#) 'Guidelines for the Management of Hypertension - 1999' largely based

on World Health Organization Recommendations. (Guidelines Subcommittee of the WHO) *J Hypertension* 1999; 17: 151-83.).

Diabetes Control and Complications Trial: DCCT *New England Journal of Medicine*, 329(14), September 30, 1993.

UKPDS 38 Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UK Prospective Diabetes Study Group. *British Medical Journal* (1998); 317: 703-713.

Appendix 4.8 Structure & Contents of Group-based sessions

Group session 1 (Week 3) – Welcome and pa/exercise and nutrition role in type 2 diabetes

Goal	Session content, materials, resources
General	
Welcome to group, introduction via ice-breaker	<ul style="list-style-type: none"> • Introduce each person and get them to tell the group one thing they would like to get out of being part of this exciting program. • Write these up and state that we are going to try and cover everything people want to know at some point during the next three sessions. This will make them feel like they are receiving the information they want.
Recap of the SDPP project	<ul style="list-style-type: none"> • Expand on and reiterate information about SDPP and generate enthusiasm. • Recap what is the SDPP and what will be involved. • Let the participants know what they will get out of the program. Potential points presenter could use to generate enthusiasm include: <ul style="list-style-type: none"> • Learning how to eat well and be more active for free. • Improved quality of life (improved energy levels, reduced fatigue, better sleep patterns etc.). • Involvement in a worthwhile project. • Learn mind matters behind eating and activity behaviours. • Learn coping strategies. • Steer you on the path to good health forever. • Learn information you can also pass onto your family to keep them healthy. • Above all, hopefully it will help prevent you from getting T2DM, a large issue in our community. • Any other points of benefit.
Establish expectations and format	<ul style="list-style-type: none"> • Reiterate group format, timeline and what they will learn each week (briefly). •
T2DM and effects of lifestyle on prevention	<ul style="list-style-type: none"> • What is T2DM? • Who is at risk/what are the risk factors? • How prevalent diabetes? • How is it related to lifestyle? • How can I prevent myself from getting T2DM? • Other benefits of leading a healthier lifestyle (aside from losing weight and preventing T2DM), like increased energy levels, reduced risk of CVD, reduced stress levels, improved sleep patterns and increased productivity. • Show a slide with the health benefits of just 5-10% weight decrease (↓ blood pressure, ↓ total cholesterol,

Goal	Session content, materials, resources
	triglycerides and LDL cholesterol).
Nutrition Component	
What constitutes a healthy diet?	<p>ENERGY BALANCE</p> <ul style="list-style-type: none"> • Use energy balance slides and clearly show how much energy we need daily (approximations for males and females). • Explain too much energy causes weight gain. Talk about decreased energy consumption and increasing energy expenditure. • Keep referring back to the daily energy needs (approximations) throughout sessions to put caloric content of foods and energy expenditure via physical activity into perspective. <p>FOOD GROUPS</p> <ul style="list-style-type: none"> • A slide on each food group (breads & cereals, dairy, lean meat, fruits & vegetables). For each group state why we need it, how much we need each day (number of serves and what is a serve) and healthiest options in each group eg. Whole grains in breads and cereals section. • Use the Australian Guide to Healthy Eating (AGTHE) plate (give out AGTHE pamphlets) – emphasise the need for each group each day for good health. Speak about everyday vs sometimes foods via AGTHE plate diagram (sometimes foods in the far corner, NOT on the everyday plate). • PLATE ACTIVITY: Give participants an empty paper plate and tell them to think about dinner. Hypothetically they have a steak, pasta salad and vegetables. Ask them to draw on their plate how much of the plate would be taken up by the meat, pasta and vegetables if we allowed them to put these 3 foods on their plate with no restrictions. Then show them the ¼ protein (steak), ¼ carbohydrate (pasta) and ½ vegetables plate recommendation slide. • AGTHE ACTIVITY: Get participants to do a quick 24 hour food recall (or use one day out of the three day food record). Give participants a handout which has a plate separated into different sections according to how many serves per day of each food group are recommended eg. 2 spaces for fruit, 5 spaces for vegetables, 3 spaces for dairy, 2 spaces for lean meat, 4-9 spaces for breads and cereals. Spaces for extras and drinks are to the side of the plate. Ask participants to colour in one space for each serve in their food recall (while referring to the AGTHE pamphlet). It will soon become obvious to participants which food groups are lacking and where they are over consuming.

Goal	Session content, materials, resources
	<p>FIBRE</p> <ul style="list-style-type: none"> • Slide for special emphasis on fibre. Explain that eating by the dietary guidelines will ensure adequate fibre consumption (30g-40g per day). • Slide on importance of fibre for bowel health, satiety and bowel cancer prevention. • Slide on how to get enough fibre each day. Include the following daily to ensure adequate fibre: Serve of high fibre cereal + 3 slices grain/wholemeal bread+ 2 serves fruit + 5 serves of vegetables + small can of baked beans. <p>ALCOHOL</p> <ul style="list-style-type: none"> • Slides on alcohol and what happens in the body including the fact that small amounts can be protective against heart disease by ↑ HDL cholesterol levels, thinning blood (aspirin like affect) and providing antioxidants. Also highlight the fact that consumption above recommended levels is detrimental to health, ↑ risk of certain cancers, cirrhosis of the liver and ↑ risk of stroke. Make special reference to weight gain. Alcohol contains empty kilojoules and can easily contribute to weight gain. Show examples of how many kJ are in different alcoholic drinks and refer this back to daily energy needs, the group will soon see how adding 3-4 beers or wines to their daily meal plan can easily add too much excess energy. • Slide to show alcohol recommendations. A standard drink is 100ml wine, 30ml spirits, middy of beer or a schooner of light beer. Aim for a maximum of 1-2 per day with 2 alcohol free days per week. <p>GLYCAEMIC INDEX</p> <ul style="list-style-type: none"> • Glycaemic Index is also an important part of a healthy diet. • Only applies to carbohydrate foods – breads, cereals, rice, pasta, fruit, milk, yoghurt, potato, corn and legumes. • The GI is a system of ranking foods according to their effect on blood glucose levels. • Show slides with visual representation of low vs high GI food with time on the x axis and blood sugar on y axis.

Goal	Session content, materials, resources
	<ul style="list-style-type: none"> • Benefits of eating low GI foods include: Increase satiety (fullness) and preventing blood sugar highs and lows which can spike appetite. • Give participants a list of low, moderate and high GI choices. Ask them to look at the foods they normally eat and their GI rating. If they are eating high GI options, try and substitute with a lower GI option eg. swap white bread for grain bread and swap white potato for sweet potato. • Slide on using common sense with the GI as some foods that are low GI as high in fat (and often high in saturated fat). For example chocolate and chips have a low GI but this does not mean they are healthy foods.
Different types of fat	<ul style="list-style-type: none"> • What are the different types of fat – separate into saturated and unsaturated. • Saturated = animal fats, palm and coconut oils. • Unsaturated = plant oils and nuts (excluding palm or coconut oils), fish and seafood. • Give handout with examples of which foods contain which types of fats. • Role of fat in the body – fat soluble vitamin transport and regulation of body processes. • Undesirable affects of bad fats – increased LDL cholesterol • Desirable effects of good fats – lower LDL cholesterol, omega 3’s can increases HDL cholesterol and reduce blood pressure. • Energy density considerations (fat vs protein vs carbohydrate vs alcohol kJ per gram for each macronutrient). • Use the National Heart Foundation fat cube slides to emphasize different food choices and their fat content. • Give participants handout of ‘Tips to reduce fat’ including how to choose low fat foods and how to lower amount of fat in cooking.
Weight loss and coping mechanisms	<ul style="list-style-type: none"> • Show group a slide outlining the dieting cycle (uncomfortable with shape, restrict food intake, feel deprived, rebel against the ‘diet’, overeat and binge, guilt sets in, emotional eating, increase in weight) . Ask them if they are familiar with this and can they identify being through these stages. • Emphasise that it is NOT about dieting, we want changes that can be sustained for a lifetime. It is about lifestyle change through healthy eating, physical activity and a positive frame of mind.
Nutrition goals over the 12 months	<ul style="list-style-type: none"> • To eat according to the guidelines for good health (as above). Increase fruit & vegetables to 2 & 5 as well as increasing legumes and wholegrain cereals (to achieve total daily fibre intake of 15g/1000Kcal – conveyed to participants in serves of food format). • Reduce fat consumption to 30% or less (possibly not mention this as this is confusing for people. Convey this as low fat eating and less energy dense food choices). • Reduction in saturated fat intake to 30% or less of total fat of total energy intake (again, by teaching participants to swap saturated fats for unsaturated fats hopefully this will achieve this outcome).

Goal	Session content, materials, resources
Self monitoring weight, waist and BMI	<ul style="list-style-type: none"> • Link in with previous section by way of using ‘so how are you going to measure how you are going?’ • Show slides with examples of how to do this – weight, waist (demonstrate on willing participant) and BMI (show how to calculate on slides). • Emphasise that scales are not the only measure of success and often not the best measure. Waist circumferences, how clothes fit, blood pressure, blood lipids, sleep patterns, increased productivity and increased energy levels can provide excellent success measures.
Physical Activity Component	
Why bother?	<ul style="list-style-type: none"> • Outline benefits of activity for good health and T2DM prevention (reduces BP, increases HDL cholesterol, lowers risk of CVD, lowers stress levels, improves energy, weight loss and maintenance etc.). Also ask participants to list benefits they feel they achieve through being involved in regular exercise, so this has more relevance to them.
Structured vs unstructured activity	<ul style="list-style-type: none"> • Explanation of structured vs unstructured activity and the role of both in weight reduction, diabetes prevention and good health. • Structured activity = physical activity that is planned, structured and involves repetitive body movements done to maintain or improve physical fitness. • Unstructured activity = any activity that involves significant movement of the body or limbs (incidental). • ACTIVITY: Put up a slide with a list of activities and ask them to put these in two groups. Presenter will write these on the white board as the group yells out what category they classify them in.
Aerobic vs resistance	<ul style="list-style-type: none"> • Explanation of aerobic vs resistance training exercises and benefits of each in weight loss and diabetes prevention. • Aerobic = exercise using large muscle groups that lasts at least 10 minutes and is rhythmic and repetitive eg. walking, swimming, cycling, rowing. • Resistance = the use of weights or other resistive forces to provide muscular conditioning and strength. Eg. lifting weights, sits ups, push ups, theraband exercises. • ACTIVITY: Give another list of activities and ask them if they are aerobic or resistance exercises. Ask them to yell out which activities are ‘Aerobic’ or ‘Resistance’ and presenter will put an ‘A’ or ‘R’ next to their answers. Let them know if they have them correct or not. • Emphasise the need to have BOTH as part of an effective exercise program. Especially the need to incorporate resistance training. • Talk about safety in regards to all activity including warming up properly, using correct technique, cooling down and stretching.
Incorporating physical activity in everyday life	<ul style="list-style-type: none"> • Ask group for examples of what they could do to increase the amount they move each day? • Show a slide with some additional examples like parking further away from work/shops, taking the

Goal	Session content, materials, resources
	<p>stairs, limiting use of labour saving devices.</p> <ul style="list-style-type: none"> • Write the groups suggestions on the white board and ask them to choose 2 to commit to and start implementing before next session (homework).
Physical activity in adverse events and management	<ul style="list-style-type: none"> • What to do in times of high stress, illness or injury and when to contact your GP for help. • Try and keep a routine. Even if the amount of physical activity you do is greatly reduced, keeping up the habit is the important part. • Schedule your activity in your diary so it does not get last priority. • If you have an illness, injury, feel lethargic or just do not feel right consult your doctor before continuing.
Setting personal physical activity goals – incidental, recreational, supervised	<ul style="list-style-type: none"> • Spell out goals of the DPP in terms of time, type and frequency. Explain that they might not be able to go out and do these tomorrow but progress towards these in coming weeks. • The best results will be achieved by reaching the DPP goals of: • 30 minutes of planned (structured) activity daily at a moderate intensity (incorporating aerobic and resistance training activities) plus incidental activity. • What is moderate intensity? Explain that moderate activity is activity that causes slight but noticeable increases in breathing and heart rate. You should still be able to talk but not sing. • How each individual works towards these goals is individual and activities will be dependent on what types of activities you enjoy, what facilities you have access too etc. This is why personal goal setting is so important.
How to review diaries and set SMART goals to achieve the 210 mins/week with intent. Emphasis on progression and intensity.	<ul style="list-style-type: none"> • Explain what a SMART goal is. A SMART goal is specific, measureable, achievable, realistic and time bound. • Show a slide with a few examples of goals which are not SMART and ask the group to help reform these into SMART goals eg. 'I just want to lose a bit of weight' could be made SMART by saying 'I want to lose 5% of my body weight in the next 12 months' • 'I want to get fitter' can be made SMART by saying 'I will complete 30 minutes of swimming twice a week, 30 minutes of walking twice a week and 30 minutes of resistance training three times a week at 60% of my maximum heart rate'. • Show slides on progressing physical fitness. Explain that if participants do the same exercise at the same intensity for the same amount of time week after week they will not see changes. Start small and work up. • Show examples of how to progress frequency, intensity, time and type using two example weekly programs. • ACTIVITY: Get participants to set themselves some SMART short and long term goals and write these on a goal sheet they can put on the fridge. • Explain that these short and long term goals can then be used to review diaries and check they are on

Goal	Session content, materials, resources
	track to achieving their goals.
Barriers and enablers to change	<ul style="list-style-type: none"> • Slide on 'What are your biggest exercise excuses?' • Ask the group to let the presenter know what they see as barriers to them participating in regular physical activity and discuss these. Major thing to come up will most likely be 'lack of time'. • Use slides to put time management into perspective. For example: A week contains 168 hours. If we sleep for 56 hours a week and work for 40 hours a week, that leaves 72 hours to fit the rest of our lives in. Dedicating 3 ½ hours in a week to exercise is an achievable aim. • Talk about time management in detail. • HOMEWORK: Show group a slide of a contextual diary, a day by day diary including all activities with times allocated to each necessary task (eg. 7am-8am drive to work, 8am-4pm work, 4pm-4.30pm exercise, 5pm-6pm make and eat dinner, 6pm-6.30pm make school lunches for following day, 6.30pm-8pm TV time, 8pm put kids to bed, 10pm bedtime). Tell the group the idea of planning out their time is to realize where they waste time and where they utilise their time effectively and hopefully they will be able to juggle things around to fit in physical activity. Ask them to do this for homework for next session (give template).
Reminder to complete diaries and bring next week	<ul style="list-style-type: none"> • Remind that they not only have to remember these for next week they also have the following homework: • To action their 2 incidental activity commitments and start working on physical activity goals. • Do their contextual diaries to fit in exercise (set aside 30 mins daily but can work up to this). • Bring food labels of things they usually eat so we can check out how healthy they are in food label reading next session (if they want too, presenter will have a lot of labels anyway).

Session 2 (Week 5) – Diabetes and diet further detail

Goal	Session content, materials, resources
General	
Welcome and ice breaker	<ul style="list-style-type: none"> • Ice breaker can be discussing what they did in regards to actioning their incidental activity goals and quick chat about how they went with contextual diary. Ask if they have now found time they did not know they had?.
Q&A about T2DM and relation to PA/diet	<ul style="list-style-type: none"> • Review what they learnt last session – possibly a quick quiz to test knowledge retention. •
Recap role of food choices in T2DM prevention	<ul style="list-style-type: none"> • Recap different food groups and how many serves are needed each day. Also revisit saturated vs unsaturated fat and its role in T2DM. Ask group if anyone has made any changes to the types of spreads, oils, foods they are having?
Nutrition Component	
Adapting recipes	<ul style="list-style-type: none"> • Healthier cooking methods – show slides of same meal cooked differently and differing energy and fat contents (eg. Poached vs scrambled vs fried eggs or grilled vs barbecued vs fried chicken). • How to modify recipes – practical tips to decrease fat, decrease sugar and increase fibre. • Low fat cooking tips: removing fat from meat before cooking, using low fat cooking options like grilling, using spray oil or non stick pans, modifying recipes with lower fat ingredients etc. Give handout with low fat cooking tips. • ACTIVITY: Give two recipes and ask participants to decide how they could make recipes healthier through a variety of modifying cooking methods and ingredients (this can be done in pairs or groups). Discuss these and provide extra suggestions if group has not exhausted all possible modifications. • List of alternatives ‘swap this for this’ handout. Eg swap regular pastry to filo pastry and sour cream for low fat natural yoghurt.
Reading food labels	<ul style="list-style-type: none"> • Ask participants what they usually look for on a label – write these up. • Explain what they should look for and what the numbers should actually be – take through an example food label handout specifying the following: <ul style="list-style-type: none"> • Total fat <10g/100g for solids and <3g/100ml for liquids. • Saturated fat <3g per 100g. • Sugars <25g per 100g (except if high in fruit). • Dietary fibre >3g per serve. • Sodium <400mg/100g. • ACTIVITY: Get participants to examine different packages and ascertain what is healthy and what is ‘not so

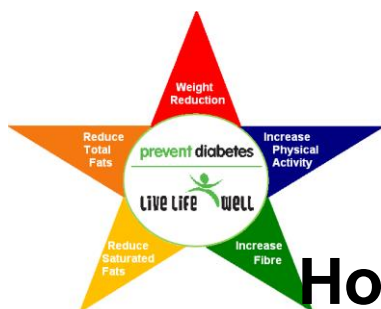
	<p>healthy'. Go through cereals, snacks, breads, dairy etc.</p> <ul style="list-style-type: none"> • ACTIVITY: 'Educational' guessing game – Have 4-5 products from each category and ask them to rate which has the most/least of a particular nutrient. Eg. Drinks: Juice, soft drink, diet soft drink, plain mineral water and flavoured milk – which has the most and which has the least sugar per 100g. Then line them up in order from most to least sugar.
Healthier eating out and take away choices	<ul style="list-style-type: none"> • Ask participants how many times they eat out or get take away for breakfast, lunch and dinner each week. • Talk briefly about changes in eating out/take away habits over time (give some Australian statistics). • Mention problems with eating out regularly including high fat, sugar and salt foods, little idea of how food is prepared, large serve sizes and cost. • Show slides of different take away meals and fat and energy content. For example a deep fried fish and chip meal vs a fresh seafood meal and a tomato based pasta vs creamy pasta. • Make these numbers relevant by reminding participants of average energy needs per day eg. 'A take away Indian Curry with rice has over 3000kJ – this is nearly half of an average female's daily energy intake and that's before you count any drinks or the rest of the day's meals!' • Top picks for eating out and take away. • Give healthy eating out and take away guide with nutritional information so that participants can make informed choices. • Quick healthy meal ideas/recipes handout. Because people are time poor, give recipe example of healthy meals they can have made and on the table in under 30 minutes.
Setting personal goals with reference to diaries	<ul style="list-style-type: none"> • Get all participants to look at where they are at individually and work on improving this in small steps. Let participants find the solutions and presenter positively reinforces this and checks how realistic the goals are.
Physical Activity component	
Recap PA/exercise – structured vs unstructured etc and T2DM prevention.	<ul style="list-style-type: none"> • Use 3-4 quick questions. What have people been doing? How are they feeling?
How to measure PA intensity	<ul style="list-style-type: none"> • Talk about the importance of intensity and how to measure this. • Show and explain Rate of Perceived Exertion Scale. • Show and explain how to work out and use working heart rate. • ACTIVITY: Get participants to do 1-2 minutes sit to stand. Get them to take pulse rate at start and end and state RPE.
Exercise demonstration	<ul style="list-style-type: none"> • Any injuries/illnesses of recent development? (Give 2-3 minutes while you organize for demonstration and ask people to approach you individually if they need to discuss any illnesses/concerns they may have). • DEMONSTRATION: Focus on activities that they can do at home with no/minimal equipment and focus on major muscle group, multi joint resistance training activities. Can either run this as a circuit or

	<p>everyone doing each activity at the same time.</p> <ul style="list-style-type: none"> • Give example exercise sheet to take home so they can do this in lounge room/garage/backyard.
Reminder to keep physical activity/exercise log and record pedometer readings (if have one) for next week	<ul style="list-style-type: none"> • HOMEWORK: Shopping or cooking: • Option 1 - go to the shops and look in each section. Report on 2 healthier items you have tried which you normally do not try. Try and bring the package (or just remember the name) and report back to the group on how it was. • Option 2 - try modifying a recipe and write it out on paper and bring it in. The best ones I will type up and bring for you all next week so you can collect a bank of healthy recipes/meal ideas.

Session 3 (Week 7) – Recap, on-going support available and useful contacts (long-term behavioural strategies)

Goal	Session content, materials, resources
General	
Welcome and ice breaker	<ul style="list-style-type: none"> • Use shopping examples and/or recipe modification homework from last week as the ice breaker. Has anyone tried anything new? Made a healthy recipe that is worth sharing?
Review of T2DM, nutrition, exercise & DPP	<ul style="list-style-type: none"> • Recap from previous two sessions very briefly.
Review exercise diary and food log	<ul style="list-style-type: none"> • Participants will self analyse how they have been going. Facilitator to help with this. Are people filling these out? Are they finding them useful?
Food awareness activity, weight loss and coping	<ul style="list-style-type: none"> • Talk to group and show slides about food awareness, feeling of guilt, the last supper theory and non hungry eating. • ACTIVITY: Food awareness activity using an indulgent food eg. Snack size (15g) chocolates. Focusing on the sensation of the food rather than quickly eating it (often happens when experiencing feeling of guilt). Link this back to moderation.
Exercise demonstrations	<ul style="list-style-type: none"> • DEMONSTRATION: More aerobic based exercise circuit. Ensure all exercises are still using minimal equipment and can be done at home. • Give example exercise sheet to take home so they can do this in lounge room/garage/backyard.
Review stages of change & social cognitive theory to build and strengthen motivation &	<ul style="list-style-type: none"> • GROUP DISCUSSION: what motivates you and how do you stay motivated? • Importance of finding your real reason to change (something that has real meaning) eg. to be fit enough to go bike riding with your children on the weekends.

self efficacy	
Identification of barriers to change	<ul style="list-style-type: none"> • Revisit barriers to change. What barriers have participants come up against over the past 7 weeks? Discuss how to overcome these, again, trying to get participants to solve their own problems and positively reinforcing this. • ACTIVITY: On a sheet ask participants to list their barriers in one column and list strategies to overcome/deal with these in the opposite column.
Relapse prevention	<ul style="list-style-type: none"> • Revisit the stages of change model and reiterate that relapse is a normal part of the change process, however what you learn from each relapse is the most important aspect. Ask people to think about and identify where they are at right now in terms of the stages of change cycle. Mark this on their session handouts. Is this different to when they first came along to these group sessions?. If so mark this on their handouts. Commend progressions forward.
Reminder of 3, 6 and 12-month GP follow-up booster visits and to expect a 'phone call at 4 months	<ul style="list-style-type: none"> • Present a slide with a timeline and have this as a handout so that participants know what to expect over the coming months, explaining what is involved at each of these time points.
Other supports/useful contacts	<ul style="list-style-type: none"> • Present a slide and give participants a handout with helpful websites, approved exercise providers or groups in the community and resources that might help them.



How can I prevent Type 2 Diabetes?

Type 2 diabetes is serious...

Type 2 diabetes is a serious chronic disease that develops over time. The gradual development of pre-diabetes (the precursor to type 2 diabetes) can mean that symptoms are not noticed and this can prevent early diagnosis. Because of this it is especially important to be aware of your risk factors and take action now to reduce your risk before it is too late.

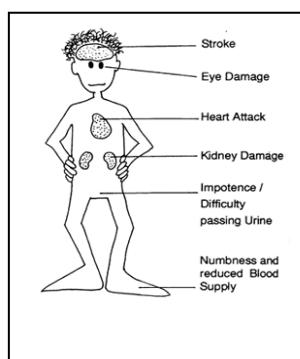
What is type 2 diabetes?

People who have type 2 diabetes have higher blood glucose levels than normal, because the body does not produce enough insulin or cannot use the insulin it does produce properly. Insulin is a hormone made by the body to control blood sugar levels.

Why should I be concerned?

People with diabetes are at higher risk of:

- Heart attack
- Stroke
- Kidney failure
- Blindness
- Amputation



In New South Wales, one in four adults over the age of 25 has type 2 diabetes or is at high risk of developing it.



Around 500 people develop type 2 diabetes every week. It is estimated that for every person known to have type 2 diabetes there is another who has it without knowing.

...But it can be *prevented!*

The good news is that studies have shown that nearly 60% of cases of type 2 diabetes can be prevented through the simple lifestyle choices of *Eating Better and Moving More*.

You can significantly reduce your risk of developing type 2 diabetes by reaching and maintaining a healthy weight, being physically active and following a healthy eating plan -see the five goals below.

What are the symptoms of type 2 diabetes?

Type 2 diabetes usually develops gradually, so you may not notice any symptoms. In fact, some people may have had type 2 diabetes for some years without symptoms and may not know they have it until the diabetic complications set in.

When symptoms do occur, they may include:

- Frequent urination
- Increased thirst
- Blurred vision
- Skin infections
- Slow healing
- Tingling and numbness in the feet
- Tiredness

What are my risk factors?

What I CAN'T Change	Risk Score	What I CAN Change	Risk Score
<input type="checkbox"/> Age	_____	<input type="checkbox"/> High blood pressure	_____
<input type="checkbox"/> Gender	_____	<input type="checkbox"/> Smoking	_____
<input type="checkbox"/> Country of birth	_____	<input type="checkbox"/> Lack of fruit/veg in diet	_____
<input type="checkbox"/> Ethnicity	_____	<input type="checkbox"/> Lack of physical activity	_____
<input type="checkbox"/> Parent/sibling with diabetes	_____	<input type="checkbox"/> Overweight around the waist	_____
<input type="checkbox"/> High blood glucose in past	_____		_____

What is my risk score?

What does this mean?

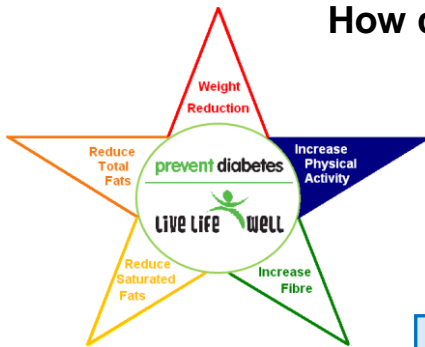
What can I do to reduce my risk?

The goals of the **Prevent Diabetes *Live Life Well*** program are to:

1. **Increase physical activity to at least 30 minutes per day of at least moderate intensity, including aerobic exercise and resistance training.**
2. **Decrease daily total fat content in diet.**
3. **Decrease daily overall saturated fat content in diet.**
4. **Increase daily fibre intake by eating more fruit, vegetables, legumes and wholegrain foods.**
5. **Achieve a moderate weight reduction of 5% of body weight.**

By following these program goals you can **reduce your risk of developing type 2 diabetes by up to 60%.**

How can I reduce my risk of developing type 2 diabetes?



Increase Physical Activity (*Move More*)

Recommended goal: To increase my physical activity to at least 30 minutes per day of at least

Why is physical activity important for reducing my risk?

Regular moderate-to-vigorous physical activity (aerobic exercise and resistance training) will help you to prevent type 2 diabetes. Regular physical activity helps the body to use insulin more effectively, which in turn regulates glucose levels in the blood.

Resistance training, in particular, is important as it changes the way muscles store and use glucose and fat. Exercise uses the glucose in the muscles as energy, preventing blood glucose levels from becoming too high. Increased muscle means decreased glucose floating around in the blood causing damage.

What is aerobic exercise and resistance training?

Moderate intensity aerobic physical activity should increase your breathing and heart rate, e.g., brisk walking where you can talk but not sing. If you're not breathing faster than usual, it's not intense enough. However, if you are out of breath and unable to talk then it is too intense.





Resistance training, or strength training is any activity that makes muscles contract, usually against a resistance, e.g., lifting dumbbells (or heavy items in the house or yard), using machine weights or using your own body weight (e.g., push-ups or squats, standing on one leg).

How much is enough?

It is recommended that you build up to at least 30 minutes on all days of the week, for a total of at least 210 minutes of intentional activity. It is essential to start slowly and gradually increase the length of time of each session. Don't push yourself or expect too much, it takes time to build up fitness.

If you can't do a full 30 minutes you can break this up into smaller bouts of activity over the day. Also look for ways to increase the amount and intensity of physical activity in all activities you do throughout the day. Note, if you're trying to lose weight many studies suggest that 60 minutes of activity per day is needed. Remember 30 minutes is only 2% of your day, and even 60 minutes is only 4% of your day.

What are the benefits of physical activity?

- Improves the body's response to insulin, which can lower blood glucose levels
- Lowers blood pressure, improves cholesterol, reduces the risk of heart disease / stroke
- Improves muscle strength and endurance
- Controls weight
- Reduces stress and tension
- Increases energy levels
- Improves walking and balance
- May reduce the risk of many cancers
- Improves sleep
- Promotes psychological well-being
- Helps build and maintain healthy bones
- Prevents and helps arthritis
- Improves memory



General guidelines:

A positive attitude towards physical activity is important. Think of any movement as an opportunity to improve your health, not as an inconvenience. Increases in daily activity can come from small changes made throughout the day, for example:

- Park further away or get off the bus a stop or two early and walk to your destination.
- Take the stairs instead of the lift or escalator.
- Stand instead of sitting.
- Squat instead of bending over to pick something up.

How do I get started?

- Start with no or light weights and as you improve lift heavier weights.
- Do some form of resistance training two to three times a week and include exercises that target most of the large muscle groups including arms, legs and trunk.
- Have a day's break in between to allow your muscles to recover.
- Aim to do each exercise 8 – 12 times (repetitions) and perform 1 – 3 lots (sets) of each exercise.

Two ways to increase your metabolism and improve your strength:

1. Increase the resistance (e.g., lift a heavier weight; take stairs 2 at a time).
2. Use less muscle to accomplish a standard task (e.g., stand on one leg instead of two; rise from a chair without using your arms to assist you, etc.).

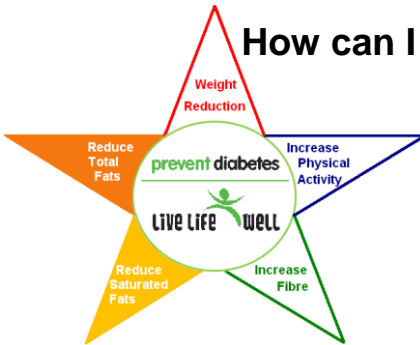
Both of these strategies can be used in either structured weight lifting sessions or incorporated as effective strengthening activities into everyday life.

Warning: Always consult a doctor before beginning a new exercise program and please stop and see your doctor if you experience any unusual symptoms during exercise.

The goals of the **Prevent Diabetes Live Life Well** program are to:

1. **Increase physical activity to at least 30 minutes per day of at least moderate intensity, including aerobic exercise and resistance training.**
2. **Decrease daily total fat content in diet.**
3. **Decrease daily saturated fat content in diet.**
4. **Increase daily fibre intake by eating more fruit, vegetables, legumes and wholegrain foods.**
5. **Achieve a moderate weight reduction of 5% of body weight.**

How can I reduce my risk of developing type 2 diabetes?



Decrease Dietary Fats

Recommended goal: To decrease the daily total fat and

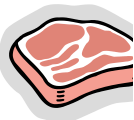



Why is decreasing dietary fat important for reducing my risk?





Fats are the most ‘energy dense’ food as they have more kilojoules (calories) per gram than other foods. A diet high in fat will cause you to put on weight and make it more difficult to manage blood glucose levels. Excess body fat, particularly abdominal fat, stops insulin from working properly, so reducing dietary fat will help control weight and therefore blood glucose levels.

Reducing the amount of fat in your diet will also reduce your risk of heart disease. Saturated fat raises your LDL (“bad”) cholesterol level which is one of the main risk factors for heart disease.

We do need to consume some fat for good health. However, the type of fat you choose is very important.

What are the three major types of dietary fat?

Saturated fats <i>LIMIT these</i>	Mono-unsaturated fats <i>Include small amounts</i>	Poly-unsaturated fats <i>Include small amounts</i>
Fatty meats 	Canola oil 	Fish and seafood 
Full cream milk	Olive oil	Sunflower oil
Full fat cheese	Avocado	Soybean oil
Butter & cream 	Olives	Corn oil

Take-aways	Mono margarines	Poly margarines
Cakes	Most nuts	Some nuts (e.g., walnuts)
Biscuits		
Chocolate		
Palm oil		
Coconut oil		

Tips for reducing overall fat, in particular saturated fat include:

- Choose reduced or low fat dairy products.
- Choose lean meats and trim visible fat before cooking.
- Use unsaturated margarines or avocado instead of butter.
- Limit pastries, cakes, puddings, chocolate and savoury packet snacks.
- Limit the use of processed deli meats and take-aways.
- Use unsaturated spray oils in cooking.
- Have a small handful of plain nuts as a snack instead of chips, biscuits etc.

How much fat am I eating?

Answer the following questions to assess your fat eating habits. Add up the numbers beside each response you have selected and write down your score.

<p>1. When eating cheese, how often do you choose reduced fat cheese in preference to regular cheese?</p> <p>1.....Never</p> <p>2.....Rarely</p> <p>3.....Occasionally</p> <p>4.....Usually</p> <p>5.....Always</p> <p>9.....I don't eat cheese</p>	<p>5. How many days a week do you eat processed meats (e.g., bacon, salami, ham)?</p> <p>1.....4 or more days</p> <p>2.....2 or 3 days</p> <p>3.....Once a week</p> <p>4.....Less than once a week</p> <p>5.....Never</p> <p>6. How often do you trim all</p>	<p>9. How often do you choose low-fat milk in preference to whole milk?</p> <p>1.....Never</p> <p>2.....Rarely</p> <p>3.....Occasionally</p> <p>4.....Usually</p> <p>5.....Always</p> <p>9.....I don't drink milk</p> <p>10. How many days a week do</p>
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<p>2. How many days a week do you eat fried food with batter or breadcrumb coating?</p> <p>1.....4 or more days 2.....2 or 3 days 3.....Once a week 4.....Less than once a week 5.....Never</p>	<p>the visible fat off the meat you eat?</p> <p>1.....Never 2.....Rarely 3.....Occasionally 4.....Usually 5.....Always 9.....I don't eat meat</p>	<p>you eat take-away food such as fried or BBQ chicken, fish and chips, Chinese, pizza or hamburger?</p> <p>1.....6 or more days 2.....3-5 days 3.....1-2 days 4.....Less than 1 day 5.....Never</p>
<p>3. How often do you eat fried or roasted vegetables?</p> <p>1.....Always 2.....Usually 3.....Occasionally 4.....Rarely 5.....Never</p>	<p>7. When eating bread (such as toast, sandwich or a snack), how often do you spread butter or margarine on it?</p> <p>1..... Always 2.....Usually 3.....Occasionally 4.....Rarely 5.....Never</p>	<p>11. How often do you (or the person who cooks for you) use fat when cooking (e.g., butter, margarine, oil, lard)?</p> <p>1.....Always 2.....Usually 3.....Occasionally 4.....Rarely 5.....Never</p>
<p>4. How often do you (or the person who cooks for you) remove the skin from chicken before it is cooked?</p> <p>1.....Never 2.....Rarely 3.....Occasionally 4.....Usually 5.....Always 9.....I don't eat chicken</p>	<p>8. How many days a week do you eat fried potato (e.g., hot chips or potato crisps)?</p> <p>1.....6 or more days 2.....3-5 days 3.....1-2 days 4.....Less than 1 day 5.....Never</p>	<p>12. How many days a week do you eat high fat cheeses (e.g., cheddar or cream cheese)?</p> <p>1.....6 or more days 2.....3-5 days 3.....1-2 days 4.....Less than 1 day 5.....Never</p>

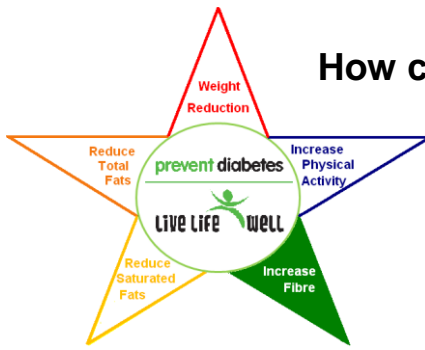
My score is: _____

Circle the number on the scale that is closest to your score to see how you rate

High fat eating habits	Low fat eating habits
13 17 21 25 29 33 37 41 45 49 53 57 61 65 69 73 77 81	

The goals of the **Prevent Diabetes *Live Life Well*** program are to:

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2. **Decrease daily total fat content in diet.**
3. **Decrease daily saturated fat content in diet.**
4. **Increase daily fibre intake by eating more fruit, vegetables, legumes and wholegrain foods.**
5. **Achieve a moderate weight reduction of 5% of body weight.**



How can I reduce my risk of developing type 2 diabetes?

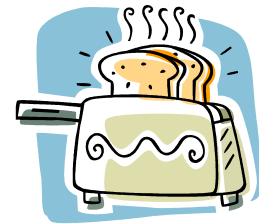
Increase Dietary Fibre

Recommended goal: To increase my daily fibre intake by eating more fruit, vegetables, legumes and

Why is eating more fibre important for reducing my risk?

Eating a diet high in fibre will reduce your risk of developing type 2 diabetes by:

- Helping to control your appetite which assists in weight loss
- Stabilising glucose levels in the blood by slowing down absorption from the small intestine and preventing sudden peaks in glucose levels



Other health benefits of increased fibre intake:

- A healthy digestive system
- Helps lower blood cholesterol levels (soluble fibre)
- Increased vitamin and mineral intake, as foods high in fibre are often high in vitamins and minerals too

What are high fibre foods?



High fibre foods include:

- Fruit
- Vegetables
- Legumes (e.g., dried peas, beans, and lentils)
- Wholegrain foods (e.g., wholegrain breads and cereals)

The term 'wholegrain' simply means that the entire grain of wheat, oat or rice is used in making the food. There are 2 main types of dietary fibre:

1. *Soluble fibre* is found in fruit, oats and some vegetables.
2. *Insoluble fibre* is found in wholegrain foods and vegetables.

Why go for 2 fruit & 5 veg?

Eating 2 pieces of fruit and 5 serves of vegetables every day can help protect against heart disease, constipation, some cancers and can help you in reaching and maintaining a healthy weight. It also helps reduce blood pressure and blood cholesterol levels. Most importantly, fruit and vegetables promote good blood glucose control.

How much fibre is enough?

Most people don't eat enough fibre. It is recommended that adults eat approximately 30-40g of fibre daily. An example of what you would need to include daily to reach this target:

- | | |
|--|---|
| <ul style="list-style-type: none"> • A bowl of high fibre cereal • 3 slices grain bread • 2 pieces of fruit | <ul style="list-style-type: none"> • 2 cups vegetables • Small can of baked beans |
|--|---|

Am I eating enough fibre?

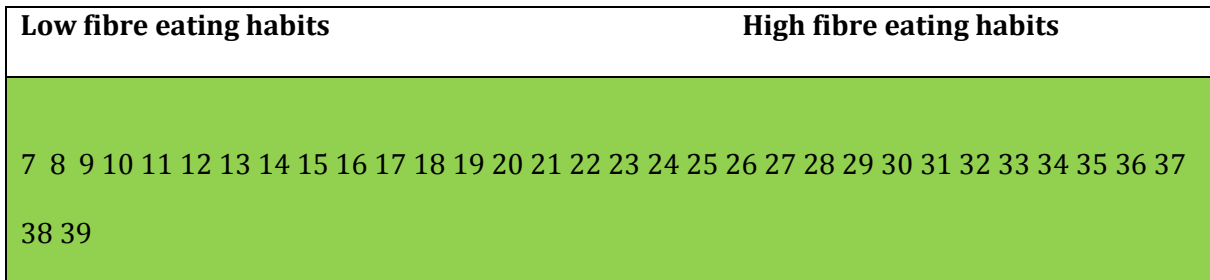
Answer the following questions to assess your fibre eating habits. Add the numbers beside the response you have selected for each question.

<p>6. How many days a week do you eat a high fibre breakfast cereal (e.g., Weetbix, All-Bran, untoasted muesli, porridge)?</p> <p>1.....Never</p> <p>2.....Less than 1 day</p> <p>3.....1-2 days</p> <p>4.....3-5 days</p> <p>5.....6 or more days</p>	<p>4. How many servings of vegetables do you eat in a typical day (1 serve is equal to one small potato or ½ cup of cooked vegetables or 1 cup of salad)</p> <p>1.....None</p> <p>2.....Less than 1 serve</p> <p>3.....1 or 2 serves</p>	<p>6. How many days a week do you eat a high fibre breakfast cereal (e.g., Weetbix, All-Bran, untoasted muesli, porridge)?</p> <p>1.....Never</p> <p>2.....Less than 1 day</p> <p>3.....1-2 days</p> <p>4.....3-5 days</p> <p>5.....6 or more days</p>
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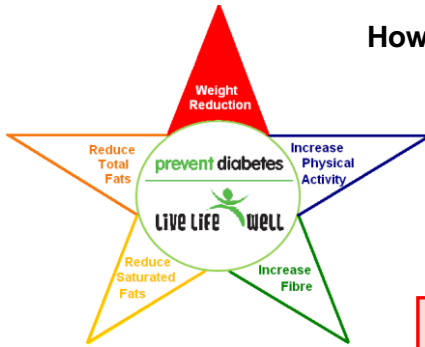
<p>7. How often do you choose wholemeal spaghetti or pasta in preference to regular spaghetti or pasta?</p> <p>1.....Never 2.....Rarely 3.....Occasionally 4.....Usually 5.....Always 9.....I don't eat pasta</p>	<p>4.....3 or 4 serves 5.....5 or more serves</p> <p>5. How many days a week do you eat legumes (e.g., baked beans, three bean mix, lentils, split peas, dried beans)?</p> <p>1.....Never 2.....Less than once /week 3.....Once a week 4.....2 or 3 days 5.....4 or more days</p>	<p>7. How often do you choose wholemeal spaghetti or pasta in preference to regular spaghetti or pasta?</p> <p>1.....Never 2.....Rarely 3.....Occasionally 4.....Usually 5.....Always 9.....I don't eat pasta</p>
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My score is: _____

Circle the number on the scale that is closest to your score to see how you rate



How can I reduce my risk of developing type 2 diabetes?



Manage your weight

Recommended goal: To achieve a moderate weight reduction of 5% over the next 12 months.

Why is maintaining a healthy weight important for reducing my risk of developing type 2 diabetes?

In Australia, nearly half of all women and two thirds of all men are overweight. Being overweight is an important risk factor for developing type 2 diabetes. Reducing your weight has a direct impact on insulin sensitivity (i.e., how well your insulin works). Fat cells are more resistant to insulin than muscle cells, so being overweight makes it harder for insulin to move glucose from your blood into your cells where you need it as energy.

Studies have shown that losing just 5% of your total body weight
CAN make a difference to preventing diabetes!!

Other benefits of weight loss:

Decreased blood pressure

Decreased cholesterol levels

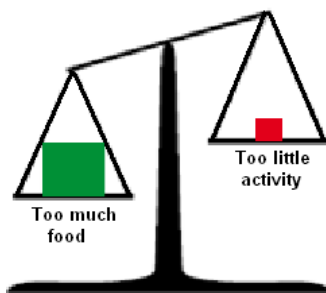
Decreased arthritic pain

Improvements in mobility

Decreased stress levels and increased self-confidence

The most effective way to reduce your weight is to make long-term changes to how you eat and move that fit into your lifestyle. Eating Better and Moving More is the first step to managing your weight and reducing your risk.

The energy balance



the energy equation:

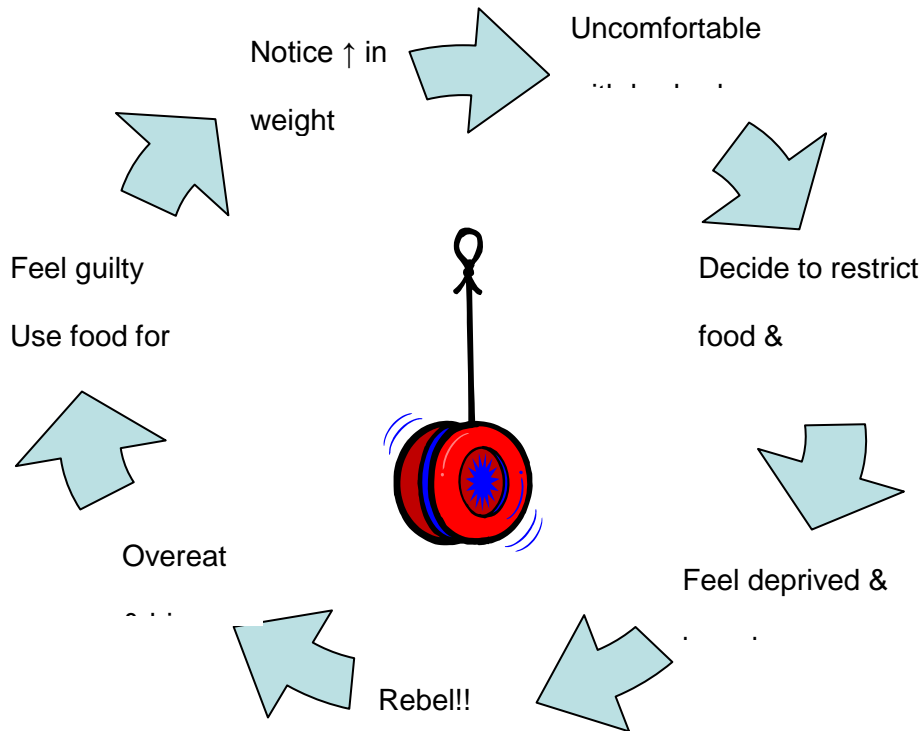
food and drink) vs ENERGY OUT (activity)

in and less energy out = weight gain

Less energy in and more energy out = weight loss

Avoid fad diets and yo-yo dieting:

Both fad diets and yo-yo dieting may have a negative effect on your health and in the long-term actually increase your weight. Fad diets may give you short-term results but they are extremely difficult to maintain and deprive you of essential nutrients.



Does the above diet cycle look familiar to you??

There is no quick and easy way to lose weight. It is better to make small and achievable changes to your eating habits and physical activity patterns that are easily incorporated into your lifestyle and easily maintained over time. If you lose weight gradually (up to 0.5kg per week) you have a much better chance of maintaining that weight loss.

Implementing goals 1 – 4 below is a great way to help you lose weight and prevent type 2 diabetes!

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2. **Decrease daily total fat content in diet.**
3. **Decrease daily saturated fat content in diet.**
4. **Increase daily fibre intake by eating more fruit, vegetables, legumes and wholegrain foods.**
5. **Achieve a moderate weight reduction of 5% of body weight**

Appendix 4.10 3-month follow-up phone questionnaire

Name of participant: _____ ID# _____

Date of interview: _____ Name of Lifestyle Officer: _____

Hi <participant>

It's <name of LO> from the Prevent Diabetes *Live Life Well* program. Do you have a few minutes to talk with me about how you are going with reducing your risk of type 2 diabetes and the goals you set during the sessions?

1. Have you been doing any physical activity/exercise since your last <i>Live Life Well</i> session (group or individual)?	<input type="checkbox"/> No	<input type="checkbox"/> Yes (go to Q1b)
<p>1a. What has stopped you from doing physical activity/exercise?</p> <p><i>Or pre-coded answers?</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> health reason <input type="checkbox"/> family/work commitments (no time) <input type="checkbox"/> Lack of motivation (nobody to exercise with, depression) <input type="checkbox"/> No facilities in the neighbourhood / safety issues <input type="checkbox"/> Other _____ 		
<p>If yes,</p> <p>1b. What <u>physical activity/ exercise</u> have you been doing ? (tick all that apply – may do home-based AND join a</p>		

gym)

- A facility or service suggested at our groups (list of providers)

Facility/service/program name: _____

- Another facility in the community
- Started home-based exercise (e.g. your own routine)
- Continued with existing membership or home-based routine
- Unstructured** (walking more, gardening, more incidental activity)
- Strength training
- _____

1c. On average, how often do you exercise? (include the combined frequency of all of the above) (*Let respondent tell you the answer and tick the box that most closely reflects the answer*)

- Rarely (once per week/fortnight or less)
- 2 -3 times per week
- 4 - 5 times per week
- About every day

1d. On average how much time do you spent in moderate or strength training each week?

_____ moderate aerobic activity (hours and/or minutes)

_____ strength training (hours and/or minutes)

<p>2. Have you been doing any programs/activities for weight loss or healthy eating since the last <i>Live Life Well</i> session (group or individual)?</p>	<input type="checkbox"/> No	<input type="checkbox"/> Yes (go to Q2 b)
<p>2a. What has stopped you from doing programs/activities for weight loss or healthy eating? <i>Or pre-coded answers?</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Health reason <input type="checkbox"/> Family/work commitments (eg no time for healthy cooking or shopping) <input type="checkbox"/> Lack of motivation (eg stressed, depressed) <input type="checkbox"/> No family support (eg rest of family don't want healthy eating) <input type="checkbox"/> No programs/activities in the neighbourhood <input type="checkbox"/> Other _____ 		
<p>2b. If yes, what type of <u>healthy eating/weight loss</u> activities/programs have you been doing (<i>tick as many as applicable</i>)</p> <ul style="list-style-type: none"> <input type="checkbox"/> A healthy eating/weight loss facility or program suggested by <i>Live Life Well</i>. Facility/service/program name: _____ <input type="checkbox"/> Another facility in the community <input type="checkbox"/> Following LLW recommended guidelines <input type="checkbox"/> Home-based nutrition (your own nutrition choices, not LLW-based) <input type="checkbox"/> Other _____ <p>2c. On average, how often do you follow the healthy eating/ weight loss program(s)? Include all instructions from either community-based program or facility or home-based healthy eating/ weight loss. (<i>Let respondent tell you the answer and tick the box that most closely reflects the answer</i>)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Rarely (once per week/fortnight or less) <input type="checkbox"/> 2 - 3 times per week <input type="checkbox"/> 4 - 5 times per week <input type="checkbox"/> About every day 		

3. Since the initial consultation would you say you have:

3a. Changed your level of aerobic physical activity?	<input type="checkbox"/> No change/about the same	<input type="checkbox"/> Yes, doing more	<input type="checkbox"/> Yes, doing less
3b. Changed your level of strength training?	<input type="checkbox"/> No change/about the same	<input type="checkbox"/> Yes, doing more	<input type="checkbox"/> Yes, doing less
3c. Changed the amount of fat you eat daily?	<input type="checkbox"/> No change/about the same	<input type="checkbox"/> Yes, increased	<input type="checkbox"/> Yes, decreased
3d. Changed the amount of fibre you eat daily?	<input type="checkbox"/> No change/about the same	<input type="checkbox"/> Yes, increased	<input type="checkbox"/> Yes, decreased
3e. Changed your weight?	<input type="checkbox"/> No change/about the same	<input type="checkbox"/> Yes, put on weight	<input type="checkbox"/> Yes, lost weight

4. Now I would like to ask you about how you are monitoring your diet, physical activity and weight.

(Do NOT read the answers, just tick the appropriate box)

4a How often do you weigh yourself? _____

4b How often do you measure your waist circumference? _____

4c. How do you keep track of your aerobic physical activity and/or strength training?	<input type="checkbox"/> I don't monitor	<input type="checkbox"/> I just remember in my head	<input type="checkbox"/> Keep a log or notes of exercise I do	<input type="checkbox"/> Use a pedometer	<input type="checkbox"/> Other (please state):
4d. How do you keep track of your diet or healthy eating ?	<input type="checkbox"/> I don't monitor	<input type="checkbox"/> I just remember in my head	<input type="checkbox"/> Keep a log or notes of food I eat	<input type="checkbox"/> Other (please state):	

4e. How do you keep track of your weight loss ?	<input type="checkbox"/> I don't monitor	<input type="checkbox"/> I just remember in my head	<input type="checkbox"/> Keep a log or check and record weight	<input type="checkbox"/> Other (please state):
--	--	---	--	--

The following questions are for the evaluation and economic analysis of the *Prevent Diabetes Live Life Well* program.

Q5. In general, please tell me if you agree or disagree with the following statements about the *Live Life Well* sessions you attended (*Do NOT read out 'undecided'*)

a. You found it easy to find time to attend the sessions	0 Agree	0 Disagree	0 Undecided
b. You found it easy to travel to the sessions	0 Agree	0 Disagree	0 Undecided
c. You learned new information or refreshed your skills about decreasing your risk of developing diabetes in the sessions	0 Agree	0 Disagree	0 Undecided
d. The demonstrations during session motivated you to change your eating habits or increase your physical activity levels	0 Agree	0 Disagree	0 Undecided
e. You thought the materials and resources given to you were useful	0 Agree	0 Disagree	0 Undecided

As part of your *Prevent Diabetes Live Life Well* sessions you would have received a list of physical activity healthy eating facilities/providers/services consistent with the messages of the program.

6a. Have you used of the facilities/services/programs in this list? Yes No

6b. Which facilities/services/programs from this list have you used?

NB: this can include a specific class

6c. If no, what has prevented you from using one of the facilities/services/programs on the list?

6d. Are you likely to use this list in the future? Yes No

7. Since I saw you the initial consultation have you changed any medications? Which ones? (*write dose and frequency*)

8. In the past **3 months** (or since I last saw you) has a doctor told you that you have diabetes? (confirmed after a blood test). Yes No

9a. How much did a visit to the Lifestyle Officer or group session normally cost you? (return travel)

Charges	Lifestyle Officer	Group Program
Bus/train/taxi	\$	\$
Parking/tolls	\$	\$

9b. If you normally travelled by private car to visit the lifestyle officer or attend the group sessions, how many kilometers did you travel **one way**?

Number of kilometres (one-way) to Lifestyle Officer? _____

Number of kilometres (one-way) to group sessions? _____

(Lifestyle Officer use only) write down # of group sessions attended by participant _____

9c. (if participant chose groups instead of phone counselling): And just remind me, did you attend the 3rd group session where you had weight and waist circumference measurements taken?

Yes, go to Q.10

No, go to Q 9d.

9d. If not, Could you tell me what prevented you from attending? (DO NOT READ OUT ANSWERS, just tick as many as the participant mentions)

Participant had an Illness or injury

No time, too busy with work or family commitments

Forgot to attend on the day

Waiting list at the Division

Went to 1 or 2 sessions but stopped because didn't like it (groups sessions didn't appeal/didn't help)

Transport difficulties (doesn't drive, no public transport, lives too far away)

Declined invitation to attend groups or individual phone counselling

Received individual counselling by Diabetes Australia

Other _____

10. Since beginning the *Live Life Well* program, how much money have you spent on physical activity-related products, fees or services?

Product/service	Amount spent (\$)
<input type="checkbox"/> Nil	
<input type="checkbox"/> walking or running shoes	
<input type="checkbox"/> gym membership or personal trainer	
<input type="checkbox"/> gym equipment for use at home	
<input type="checkbox"/> exercise clothing	
<input type="checkbox"/> casual fee for pool, yoga/tai chi or aerobic lesson	
<input type="checkbox"/> other (specify) _____	

11. In the past week, approximately how much money did your **household** spend on food? This includes supermarket food as well as money spent going out to dinner or buying take-away food.

<input type="checkbox"/> Less than \$50	<input type="checkbox"/> \$50-\$100	<input type="checkbox"/> \$101-150	<input type="checkbox"/> \$151-\$200	<input type="checkbox"/> > \$200	<input type="checkbox"/> can't tell / unsure
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Appendix 4.11 Six and nine-month follow-up forms

Name of participant: _____ ID# _____

Date of interview: _____ Name of Lifestyle Officer: _____

Hi <participant>

It's <name of LO> from the Prevent Diabetes *Live Life Well* program. Do you have a few minutes to talk with me about how you are going with reducing your risk of type 2 diabetes and the goals you set during the sessions?

1. Have you been doing any physical activity/exercise since we last spoke on the phone?	<input type="checkbox"/> No	<input type="checkbox"/> Yes (go to Q1b)
<p>If no,</p> <p>1a. What has stopped you from doing physical activity/exercise?</p> <p><i>Or pre-coded answers?</i></p> <p><input type="checkbox"/> health reason</p> <p><input type="checkbox"/> family/work commitments (no time)</p> <p><input type="checkbox"/> Lack of motivation (nobody to exercise with, depression)</p> <p><input type="checkbox"/> No facilities in the neighbourhood / safety issues</p> <p><input type="checkbox"/> Other _____</p>		

If yes,

1b. What physical activity/ exercise have you been doing ? (*tick all that apply – may do home-based AND join a gym*)

A facility or service suggested at our groups (list of providers)

Facility/service/program name: _____

Another facility in the community

Started home-based exercise (e.g. your own routine)

Continued with existing membership or home-based routine

Unstructured (walking more, gardening, more incidental activity)

Strength training

1c. On average, how often do you exercise? (include the combined frequency of all of the above) (*Let respondent tell you the answer and tick the box that most closely reflects the answer*)

Rarely (once per week/fortnight or less)

2 -3 times per week

4 - 5 times per week

About every day

1d. On average how much time do you spent in moderate or strength training each week?

_____ moderate aerobic activity (hours and/or minutes)

_____ strength training (hours and/or minutes)

2. Have you been doing any programs/activities for weight loss or healthy eating since we last spoke on the phone?

No

Yes

(go to Q2 b)

If no,

2a. What has stopped you from doing programs/activities for weight loss or healthy eating?

Or pre-coded answers?

- Health reason
- Family/work commitments (eg no time for healthy cooking or shopping)
- Lack of motivation (eg stressed, depressed)
- No family support (eg rest of family don't want healthy eating)
- No programs/activities in the neighbourhood
- Other _____

If yes,

2b. What type of healthy eating/weight loss activities/programs have you been doing (*tick as many as applicable*)

- A healthy eating/weight loss facility or program suggested by *Live Life Well*.
Facility/service/program name: _____
- Another facility in the community
- Following LLW recommended guidelines**
- Home-based nutrition (your own nutrition choices, not LLW-based)
- Other _____

2c. On average, how often do you follow the healthy eating/ weight loss program(s)? Include all instructions from either community-based program or facility or home-based healthy eating/ weight loss. (*Let respondent tell you the answer and tick the box that most closely reflects the answer*)

- Rarely (once per week/fortnight or less)
- 2 - 3 times per week
- 4 - 5 times per week
- About every day

3. Since we last spoke on the phone would you say you have:

3a. Changed your level of aerobic physical activity or exercise?	<input type="checkbox"/> No change/about the same	<input type="checkbox"/> Yes, doing more	<input type="checkbox"/> Yes, doing less
3b. Changed your level of strength training?	<input type="checkbox"/> No change/about the same	<input type="checkbox"/> Yes, doing more	<input type="checkbox"/> Yes, doing less
3c. Changed the amount of fat you eat daily?	<input type="checkbox"/> No change/about the same	<input type="checkbox"/> Yes, increased	<input type="checkbox"/> Yes, decreased
3d. Changed the amount of fibre you eat daily?	<input type="checkbox"/> No change/about the same	<input type="checkbox"/> Yes, increased	<input type="checkbox"/> Yes, decreased
3e. Changed your weight?	<input type="checkbox"/> No change/about the same	<input type="checkbox"/> Yes, put on weight	<input type="checkbox"/> Yes, lost weight

4. Since we last spoke on the phone how have you been monitoring your diet, physical activity and weight.

(Do NOT read the answers, just tick the appropriate box)

4a How often do you weigh yourself? _____

4b How often do you measure your waist circumference? _____

4c. How do you keep track of your aerobic physical activity and/or strength training ?	<input type="checkbox"/> I don't monitor	<input type="checkbox"/> I just remember in my head	<input type="checkbox"/> Keep a log or notes of exercise I do	<input type="checkbox"/> Use a pedometer	<input type="checkbox"/> Other (please state):
4d. How do you keep	<input type="checkbox"/> I don't	<input type="checkbox"/> I just	<input type="checkbox"/> Keep a log	<input type="checkbox"/> Other (please state):	

track of your diet or healthy eating?	monitor	remember in my head	or notes of food I eat	
4e. How do you keep track of your weight loss?	<input type="checkbox"/> I don't monitor	<input type="checkbox"/> I just remember in my head	<input type="checkbox"/> Keep a log or check and record weight	<input type="checkbox"/> Other (please state):

The following questions are for the evaluation and economic analysis of the *Prevent Diabetes Live Life Well* program.

As part of your *Prevent Diabetes Live Life Well* sessions you would have received a list of physical activity healthy eating facilities/providers/services consistent with the messages of the program.

5a. Have you used of the facilities/services/programs in this list? Yes No

5b. Which facilities/services/programs from this list have you used?

NB: this can include a specific class

5c. If no, what has prevented you from using one of the facilities/services/programs on the list?

5d. Are you likely to use this list in the future? Yes No

6. Since we last spoke have you changed any medications?

Which ones? (*write dose and frequency*)

7. In the past **3 months** (or since I last saw you) has a doctor told you that you have diabetes?

(confirmed after a blood test).

Yes

No

Appendix 4.12 3-day Food Record



This food diary will help you estimate your daily food and drink intake over three days.

Please fill in this food diary on **3 separate days, including 2 weekdays and 1 weekend day**. The days do not need to be in a row but do need to be within the same week.

Recording all food items is the best way of knowing a person's food intake. At times you may find the process tedious and may want to eat differently during the recording period.

However, it is important to remember that the reason for the diary is to find out what you would *usually* eat which will be looked at by a qualified dietician who will then give you some feedback on your diet.

How should you fill-in your food diary?

The purpose of the food diary is for you to write down **everything** you eat and drink on **each of the 3 days**. The instructions below will help you fill out your 3-day food diary.

1. Start a new sheet for each new day.
2. Use a new line for each food & drink e.g. for a sandwich, list the bread and each filling on a separate line. For **each** food and drink please write:
 - a. the time you consumed the food or drink. Each entry should be made at the time you consumed the food or drink, not at the end of the day;
 - b. the type of meal or snack using the following codes:
B=breakfast, L=lunch, T=tea/evening meal, AT=afternoon tea, MT: morning tea, S=supper;
 - c. a detailed description of the food or drink, including brand names where possible e.g. 'Pura whole milk', not just 'milk';
 - d. the amount you ate or drank, referring to the **handout of measures** as a guide when necessary;
 - e. how the food was cooked e.g. frying, boiling, and what was used for cooking e.g. butter, vegetable oil, water;
 - f. where the food and drink was consumed e.g. at home, restaurant or other location.
3. Remember:
 - a. If you are eating a meal, write the separate food and drinks eaten in that meal separately

e.g. list the amount of fish & list the amount of hot chips.

- b. If you eat or drink a whole package of an item e.g. yoghurt, write the weight that is listed on
the package.
 - c. If you are eating meat, write whether or not it was lean, and whether or not the fat was
trimmed before cooking.
 - d. Write down any nutritional claims that are on the packaging of the food or drink e.g. 97% fat free.
 - e. Write down the name and amount of accompanying items such as sauces, mustards.
4. If there is something you think is important, please write this down in the comment line e.g. I was sick on this day so did not eat much. You do not have to write any comments if you do want to.

Please take your completed 3-day diary to your individual session with your lifestyle officer.

Sample - DAY 1 DATE: 7 / 8 / 08

Time	Meal type (e.g. lunch)	Description of food/drink item (be specific, include brand names. One item per line)	Amount eaten or drunk (see handout of measures)	Cooking method (e.g. frying, boiling)	Location (e.g. home, café, KFC)	Additional comments
6:30am	B	Porridge	1 medium bowl	Boiled	Home	
		Brown sugar	1 teaspoon		Home	
		No fat shape milk	1 large glass		Home	
		Banana	1 medium		Home	
10:00	MT	Vanilla Cream biscuits (Arnotts)	2 biscuits		cafe	
		Earl grey tea	1 mug		Café	
		Full cream milk	Half a cup		Café	
12:50	L	Maryland chicken in satay sauce (without skin)	1 piece	Stir fried at home	Work	
		Noodles in soy sauce	Half a small plate	Stir fried at home	Work	

		Mixed vegetables (carrot, peas, zucchini)	1 medium serve	Boiled at home	Work	
4:00pm	AT	'Logicol' yoghurt 98% fat free (strawberry flavour)	1 tub x 200gm		Work	
7:45	D	Rice paper rolls with vegetables (spinach, mushrooms, olives, carrot, mint leaves)	4 medium size rolls	boiled	Home	
		Tuna salad with mayo (tuna in olive oil-drained the oil)	1 small serve (1 tuna tin x 50g)	Mixed with 1 Tbs of Kraft light mayo	Home	
		Home-made lemon juice with 1 teaspoon of white refined sugar	1 large glass		Home	
		XXX beer	1 can of 375mls			

If yes, in what way (e.g. party, felt sick) _____

Time	Meal type (e.g. lunch)	Description of food/drink item (be specific, include brand names. One item per line)	Amount eaten or drunk (see handout of measures)	Cooking method (e.g. frying, boiling)	Location (e.g. home, café, KFC)	Additional comments

DAY 1

DATE: / /

Name: _____ ID# _____

DAY 1 Continued

Time	Meal type (e.g. lunch)	Description of food/drink item (be specific, include brand names. One item per line)	Amount eaten or drunk (see handout of measures)	Cooking method (e.g. frying, boiling)	Location (e.g. home, café, KFC)	Additional comments

Was intake unusual in any way? no yes If yes, in what way (e.g. party, felt sick)

Name: _____ ID# _____

Time	Meal type (e.g. lunch)	Description of food/drink item (be specific, include brand names. One item per line)	Amount eaten or drunk (see handout of measures)	Cooking method (e.g. frying, boiling)	Location (e.g. home, café, KFC)	Additional comments

Name: _____ ID# _____

DAY 2

DATE: / /

DAY 2 Continued

Time	Meal type (e.g. lunch)	Description of food/drink item (be specific, include brand names. One item per line)	Amount eaten or drunk (see handout of measures)	Cooking method (e.g. frying, boiling)	Location (e.g. home, café, KFC)	Additional comments

Was intake unusual in any way? no yes If yes, in what way (e.g. party, felt sick)

Name: _____ ID# _____

Time	Meal type (e.g. lunch)	Description of food/drink item (be specific, include brand names. One item per line)	Amount eaten or drunk (see handout of measures)	Cooking method (e.g. frying, boiling)	Location (e.g. home, café, KFC)	Additional comments

DAY 3

DATE: / /

Name: _____

ID# _____

Appendix 4.13 HADS form and scoring template

Emotions play an important part in health and wellbeing. Read each item below and tick the box next to the response which is closest to how you have been feeling in the past week. Don't take too long; your immediate response to each item will probably be more accurate than a long, thought out response.

A I feel tense or 'wound up'

- 3 Most of the time
 2 A lot of the time
 1 From time to time, occasionally
 0 Not at all

I get a sort of frightened feeling as if something awful is going to happen

- 3 Very definitely and quite badly
 2 Yes but not too badly
 1 A little but it doesn't worry me
 0 Not at all

A Worrying thoughts go through my mind

- 3 A great deal of the time
 2 A lot of the time
 1 Not too often
 0 Very little

A I can sit at ease and feel relaxed

- 0 Definitely
 1 Usually
 2 Not often
 3 Not at all

I get a sort of frightened feeling like butterflies in my stomach

- 0 Not at all
 1 Occasionally
 2 Quite often
 3 Very often

A I feel restless as if I have been on the move

- 3 Very much indeed
 2 Quite a lot
 1 Not very much
 0 Not at all

A I get sudden feelings of panic

- 3 Very often indeed
 2 Quite often
 1 Not very often
 0 Not at all

D I enjoy a good book or radio or television program

- 0 Often
 1 Sometimes
 2 Not often
 3 Very seldom

D I still enjoy the things I used to enjoy

- 0 Definitely as much
 1 Not quite as much
 2 Only a little
 3 Hardly at all

D I can laugh and see the funny side of things

- 0 As much as I always could
 1 Not quite as much now
 2 Definitely not so much now
 3 Not at all

D I feel cheerful

- 3 Never
 2 Not often
 1 Sometimes
 0 Most of the time

D I have lost interest in my appearance

- 3 Definitely
 2 I don't take as much care as I should
 1 I may not take quite as much care
 0 I take just as much care as ever

D I feel as if I am slowed down

- 3 Nearly all the time
 2 Very often
 1 Sometimes
 0 Not at all

D I look forward with enjoyment to things

- 0 As much as I ever did
 1 Rather less than I used to
 2 Definitely less than I used to
 3 Hardly at all

Appendix 4.14 Twelve-month CATI Survey

Sydney Diabetes Prevention Program 12-month-follow up

Participant Name: _____ ID: _____ Date: _____

Good morning/afternoon. My name is _____. I am calling from the Prevent Diabetes Live Life Well program. You were advised before your final consultation as part of our program that you would be receiving a follow-up telephone survey and this will take about 15mins. Is now a good time for us to speak? Good. I will be asking you for information so we can see how far you've come since you've started the Program and all answers that you give us will be treated confidentially.

T

The first few questions is to evaluate what people thought of the program overall.

1. How useful did you find the <i>Prevent Diabetes</i> sessions?	Not at all useful	A little useful	Useful	Very useful	N/A
2. How helpful were the <i>Prevent Diabetes</i> sessions in assisting you to eat better and move more?	Not at all helpful	A little helpful	Helpful	Very helpful	N/A
3. Compared to 12-months ago how would you rate the amount of fat you eat?	Much more fat	More fat	About the same amount	Less fat	Much less fat
4. Compared to 12-months ago how would you rate the amount of fibre you eat?	Much more fibre	More fibre	About the same amount	Less fibre	Much less fibre
5. Compared to 12 months ago how would you rate your physical activity levels each week?	Much more active	More active	About the same level	Less active	Much less active
6. Compared to 12-months ago do you weigh	Much more	More	About the same	Less	Much less
7. Compared to 12-months ago is your waist circumference measurement	Much more	More	About the same	Less	Much less

8. Did you receive a list of physical activity and healthy eating facilities, services or programs from a Lifestyle Officer from the *Prevent Diabetes Live Life Well Program*?
 Yes No Can't remember

9. Have you used any of the facilities, services or programs on this list?
 Yes No Can't remember

10. If yes, which facilities, services or programs have you used?

11. If no, what prevented you from using the facilities, services or programs on this list?

12. Apart from those you have already mentioned, in the past three months have you participated in any weight loss programs such as, Lite n' easy, Jenny Craig, Get Healthy Line or similar programs?
 Yes No Can't remember

13. Apart from those already mentioned, in the past three months have you attended any services to improve your eating habits such as a dietician, nutritionist or doctor?
 Yes No Can't remember

14. Apart from those already mentioned In the past three months have you participated in any regular programs to increase your physical activity such as being a member of a gym, swimming at a pool, attending Tai chi, aerobics, or yoga classes?
 Yes No Can't remember

If yes, what sort of regular activity was that? Tick as many as relevant

- Community fitness centre / group
- Personal trainer/coach
- Training by myself at home or in the neighbourhood
- Internet support program

These questions are about alcohol intake and smoking status

Q15 How often do you drink alcohol?	<input type="radio"/> _____ number of days per week	<input type="radio"/> Less than once per week	<input type="radio"/> I don't drink alcohol
Alcoholic drinks are measured in terms of a "standard drink". A standard drink is equal to 1 middy of full-strength beer, 1 schooner of light beer, 1 small glass of wine or 1 pub-sized nip of spirits.			
Q16 On a day when you drink, how many standard drinks do you usually have? _____ number of drinks			
Q17 Which of the following best describes your smoking status?			
<input type="radio"/> I smoke daily <input type="radio"/> I smoke occasionally <input type="radio"/> I don't smoke now but I used to <input type="radio"/> I've tried it a few times but never smoked regularly <input type="radio"/> I've never smoked			

These questions measure health related quality of life

Q18 In general, would you say your health is:	<input type="radio"/> Excellent	<input type="radio"/> Very good	<input type="radio"/> Good	<input type="radio"/> Fair	<input type="radio"/> Poor
Q19 The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?					
First, moderate activities such as moving a table, pushing a vacuum cleaner, bowling or playing golf.					
	<input type="radio"/> Limited a lot	<input type="radio"/> Limited a little	<input type="radio"/> Not limited at all		
Q20 Climbing several flights of stairs.	<input type="radio"/> Limited a lot	<input type="radio"/> Limited a little	<input type="radio"/> Not limited at all		
Q21 During the past four weeks, have you accomplished less than you would like as a result of your physical health?				<input type="radio"/> Yes	<input type="radio"/> No
Q22 During the past four weeks, were you limited in the kind of work or other regular activities you do as a result of your physical health?				<input type="radio"/> Yes	<input type="radio"/> No
Q23 During the past four weeks, have you accomplished less than you would like to as a result of any emotional problems, such as feeling depressed or anxious?				<input type="radio"/> Yes	<input type="radio"/> No
Q24 During the past four weeks, did you not do work or other regular activities as carefully as usual as a result of any emotional problems such as feeling depressed or anxious?				<input type="radio"/> Yes	<input type="radio"/> No
Q25 During the past four weeks how much did pain interfere with your normal work including both work outside the home and housework?	<input type="radio"/> Not at all	<input type="radio"/> Slightly	<input type="radio"/> Moderately	<input type="radio"/> Quite a bit	<input type="radio"/> Extremely
Q26 These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.					
a. How much time during the past 4 weeks have you felt calm and peaceful?					
<input type="radio"/> All of the time <input type="radio"/> Most of the time <input type="radio"/> A good bit of the time <input type="radio"/> Some of the time <input type="radio"/> None of the time					
b. How much of the time during the past 4 weeks did you have a lot of energy?					
<input type="radio"/> All of the time <input type="radio"/> Most of the time <input type="radio"/> A good bit of the time <input type="radio"/> Some of the time <input type="radio"/> None of the time					
c. How much time during the past 4 weeks have you felt down?					
<input type="radio"/> All of the time <input type="radio"/> Most of the time <input type="radio"/> A good bit of the time <input type="radio"/> Some of the time <input type="radio"/> None of the time					
d. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities like visiting with friends, relatives etc?					
<input type="radio"/> All of the time <input type="radio"/> Most of the time <input type="radio"/> Some of the time <input type="radio"/> A little of the time <input type="radio"/> None of the time					

These questions are about illnesses and injuries you may have recently had.

Q27 Since you began the Prevent Diabetes Live Life Well program, has a doctor told you that you have Diabetes?

- Yes If yes, go to Q28
 No Go to Q28 too

Q28 Are you taking any medication to treat / prevent diabetes? (INTERVIEWR: ask whichever is relevant)

- Yes If yes, go to Q29
 No If no, go to Q31

Q29 What medication/s are you taking for diabetes? (list brand name only- no dose required)

Q30 What test did you have to find out if you have diabetes or not?

- Finger prick test (random Capillary blood glucose)
 Fasting plasma glucose test
 Random plasma glucose test
 Oral Glucose tolerance test
 HbA1c
 Urine test/dipstick
 Blood test Unknown
 No test at all

Q31 Do you mind if we check with your GP about this?

- Yes, I mind, do not contact my GP No, don't mind, feel free to contact my GP

Q32 Since you began the Prevent Diabetes Live Life Well program, has a doctor told you that you have any of the following		
a. Asthma or emphysema	<input type="radio"/> No	<input type="radio"/> Yes
b. Cancer	<input type="radio"/> No	<input type="radio"/> Yes
c. Heart attack or angina or other heart disease	<input type="radio"/> No	<input type="radio"/> Yes
d. High blood pressure	<input type="radio"/> No	<input type="radio"/> Yes
e. High Cholesterol	<input type="radio"/> No	<input type="radio"/> Yes
f. Osteoarthritis, osteoporosis or low bone density	<input type="radio"/> No	<input type="radio"/> Yes
Q 33 In the past 3 months how many days have you taken off work due to illness?		
Q 34 In the past 3 months how many days have you taken off work due to serious injury?		

These questions measure relevant medications

Q35 Have you taken any prescription medications for any reason in the last 3 months?	<input type="radio"/> Yes	<input type="radio"/> No (go to Q37)
Q36b. Please state the name, strength and dose of the prescription medications have you taken in the last three months.		

The following questions are about your physical activity each week

Q37 Over the past 7 days, how often did you sit down to do activities like watch tv, read, use the computer or do handcrafts?		
<input type="radio"/> never	<input type="radio"/> Seldom (1-2 days)	<input type="radio"/> Sometimes (3-4 days) <input type="radio"/> Often (5-7 days)
Q 37a What were these activities?		
Q37b On average, how many hours per day did you do these sitting activities <u>on these days</u> ?		
<input type="radio"/> less than 1 hour	<input type="radio"/> 1-2 hours	<input type="radio"/> 2-4 hours <input type="radio"/> more than 4 hours
Q 38 Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example for fun or exercise, walking to work, walking the dog etc?		
<input type="radio"/> never	<input type="radio"/> Seldom (1-2 days)	<input type="radio"/> Sometimes (3-4 days) <input type="radio"/> Often (5-7 days)
Q38a On average, how many hours per day did you spend walking <u>on these days</u> ?		
<input type="radio"/> less than 1 hour	<input type="radio"/> 1-2 hours	<input type="radio"/> 2-4 hours <input type="radio"/> more than 4 hours
Q38b What was the total distance (kms) that you walked in the past 7 days?		
<input type="radio"/> less than 1 km	<input type="radio"/> 1 but less than 2 kms	<input type="radio"/> 2-4 kms <input type="radio"/> more than 4 kms
Q 39 And how much of the time would you say that walking was BRISK walking?		
<input type="radio"/> None	<input type="radio"/> 1/4 of the time	<input type="radio"/> half of the time <input type="radio"/> 3/4 of the time <input type="radio"/> All of the time
Q40 How many flights of stairs did you climb up in the past 7 days? (one flight = 10 steps)		
Total number of steps climbed in the past week _____, or flights of steps _____.		
Q41 Over the past 7 days, how often did you do light sport or recreational activities such as 'light' cycling on an exercise bike, lawn bowls, bowling, water aerobics, golf with a cart, yoga, tai chi, fishing from a boat or pier or other similar activities?		
<input type="radio"/> Never	<input type="radio"/> Seldom (1-2 days)	<input type="radio"/> Sometimes (3-4 days) <input type="radio"/> Often (5-7 days)
Q 41a What were these activities?		
Q 41b On average, how many hours per day did you do these light sport or recreational activities <u>on these days</u> ?		
<input type="radio"/> less than 1 hour	<input type="radio"/> 1-2 hours	<input type="radio"/> 2-4 hours <input type="radio"/> more than 4 hours
Q42 Over the past 7 days, how often did you do moderate sport or recreational activities such as doubles tennis, ballroom dancing, golf without a cart, softball or other similar activities?		
<input type="radio"/> Never	<input type="radio"/> Seldom (1-2 days)	<input type="radio"/> Sometimes (3-4 days) <input type="radio"/> Often (5-7 days)
Q42a What were these activities?		
Q42b On average, how many hours per day did you do these moderate sport or recreational activities <u>on these days</u> ?		
<input type="radio"/> Less than 1 hour	<input type="radio"/> 1 but less than 2 hours	<input type="radio"/> 2-4 hours <input type="radio"/> more than 4 hours
Q43 Over the past 7 days, how often did you do strenuous sport or recreational activities such as jogging, swimming, cycling, singles tennis, aerobic dance or other similar activities?		
<input type="radio"/> Never	<input type="radio"/> Seldom (1-2 days)	<input type="radio"/> Sometimes (3-4 days) <input type="radio"/> Often (5-7 days)
Q43a What were these activities?		
Q43b On average, how many hours per day did you do these strenuous sport or recreational activities <u>on these days</u> ?		
<input type="radio"/> Less than 1 hour	<input type="radio"/> 1 but less than 2 hours	<input type="radio"/> 2-4 hours <input type="radio"/> more than 4 hours
Q44 Over the past 7 days, how often did you exercise specifically to increase muscle strength and endurance such as lifting weights or push-ups etc?		
<input type="radio"/> Never	<input type="radio"/> Seldom (1-2 days)	<input type="radio"/> Sometimes (3-4 days) <input type="radio"/> Often (5-7 days)
Q44a What were these activities?		
Q44b On average, how many hours per day did you do these exercises to increase muscle strength//endurance?		
<input type="radio"/> less than 1 hour	<input type="radio"/> 1 but less than 2 hours	<input type="radio"/> 2-4 hours <input type="radio"/> more than 4 hours
Q45a During the past 7 days, have you done any light housework such as dusting or washing dishes?		
<input type="radio"/> Yes	<input type="radio"/> No	
Q45b During the past 7 days, have you done any heavy housework or chores such as vacuuming, scrubbing floors, washing windows?		
<input type="radio"/> Yes	<input type="radio"/> No	
Q46 During the past 7 days, did you engage in any of the following activities?		
a Home repairs like painting, wallpapering, electrical etc	<input type="radio"/> Yes	<input type="radio"/> No
b Lawn work or yard care including leaf removal etc	<input type="radio"/> Yes	<input type="radio"/> No
c Outdoor gardening	<input type="radio"/> Yes	<input type="radio"/> No
d Caring for another person such as a dependent child, dependent spouse or another adult	<input type="radio"/> Yes	<input type="radio"/> No
Q47 During the past 7 days did you work for pay or as a volunteer?		
<input type="radio"/> Yes	<input type="radio"/> No	
Q47a How many hours per week did you work for pay and/or as a volunteer? _____ hours		
Q47 b Which of the following categories best describes the amount of physical activity required on your job/volunteer work?		

- Mainly sitting with light arm movements (eg. Office work, watch maker, seated assembly line worker, bus driver etc)
- Sitting or standing with some walking (eg. Cashier, general office worker, security officer, light tool and machinery worker)
- Walking with some handling of materials generally weighing less than 25kg/50 pounds (eg. Mailman, waitress, construction worker, heavy tool and machinery worker)
- Walking and heavy manual work often requiring handling of materials weighing over 25kg/50 pounds (eg. Farm or general labourer).

These questions are related to use of health services and expenses on physical activity

Q48 Have you had any admissions to a hospital emergency department in the last 3 months? (e.g. accident, emergency, casualty)	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> can't remember
Q48a If yes, how many emergency department visits have you made in the last three months?			
Q49 Have you stayed overnight in a hospital in the last 3 months?	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> can't remember
Q49a If yes, how many nights have you spent in a hospital in the last three months? _____			
Q 50 Have you seen a general practitioner at a surgery in the last 3 months?	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> can't remember
Q 50a If yes, how many visits to a GP have you made in the last three months? _____			
Q51 Have you seen any medical specialists or health care professionals apart from your GP, or following referral from your GP in the last 3 months?	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> can't remember
Q51a If yes, what medical specialists or other health care professionals have you seen and how many times have you seen them in the last 3 months? (e.g. physiotherapy, osteopath, acupuncture, homeopath, chiropractor, surgeon/specialist)			
Q52 Have you ever had any form of weight loss surgery such as gastric by-pass or lap band surgery? <input type="radio"/> No <input type="radio"/> Yes			
Q52a If yes, what month and year? Month _____ / year _____ (first 3 letters) (4 digits)			
Q53 In the past month, have you spent any money on exercise-related products or services (such walking/running shoes, gym membership, exercise classes/equipment)? <input type="radio"/> No <input type="radio"/> Yes			
Q53a. If yes, how much have you spent on exercise-related products or services in the past month			
Product/service	Amount spent (\$)		
<input type="radio"/> walking or running shoes			
<input type="radio"/> gym membership or personal trainer			
<input type="radio"/> gym equipment for use at home			
<input type="radio"/> sports/exercise clothing			
<input type="radio"/> other			
Q 54 in the past week, approximately how much did your household spend on food?			
<input type="radio"/> Less than \$50 <input type="radio"/> \$50- \$100 <input type="radio"/> \$101-150 <input type="radio"/> \$151-\$200 <input type="radio"/> More than \$200 <input type="radio"/> can't tell / unsure			

I understand that you have made an appointment to see your Lifestyle Officer in the next few days [mention date of 12-month review if known]. If you have not done so, please ring to make the appointment. This will be your last consultation as part of this program. You will be measured again to see the results after 1 year of participation. Do you have any questions for me? Well, this concludes the interview. Thank you very much for your time and responses. We hope you got something positive out of the program. OK, Good bye.

Interviewer name: _____
 Interviewer: Mark participant's ethnicity A= Arabic C=Chinese

††	Facility currently registered with Fitness Australia	<i>Expiry date:</i>
††	Toilets, Change rooms, Lockers and Showers	
††	Temperature regulation: †A/C	†Fans †Heating
	†Natural air flow	†Other list:

Information:					
Parking available:	†	Free	†	Cost	Cost:
Walk:	†	1 block	†	2 blocks	† 3 blocks and more
Public Transport accessible:					
†	Bus		†	Train	
	Routes:			Lines:	
	Walk distance:			Walk distance:	
Wheelchair accessible?	†	Yes	†	No	
	<i>If no, how many flights of stairs need to access facility?</i>				
	†	1 flights	†	2 flights	† 3 or more flights
Child Care facilities:	†Yes	†No	<i>Cost of child care?</i>		
Other facilities:					
†	Squash courts	†	Basketball courts	†	Tennis courts
†	Ovals	†	Hockey court	†	Other, list:
<hr/>					
<i>Statistics</i>					
†	Commercial	†	Non- for profit		

Gym Providers

(Place where people can go to exercise independently and use a gym facility under supervision but not in a class setting, they may provide a personal program occasionally as part of their membership)

Provider Name:					
Program Category:					
†	Class Aerobic	†	Class Resistance	†	Class Aerobic/ Resistance
†	Nutrition	†	Gym	†	Pool
				†	Individual training
<hr/>					
Essential:					
Screening clients					
Y/N					
††	Any written screening tool (Reference ACSM)				
Y/N					
††	Identify coronary artery disease (CAD) risk factors (i.e. Family history, cigarette smoking, hypertension, dyslipidemia (cholesterol), impaired fasting glucose, obesity (BMI or waist circumference M>102cm, F>88cm, sedentary lifestyle)				

- †† Signs or symptoms of cardiovascular, pulmonary or metabolic disease (i.e. pain or discomfort in chest, neck, jaw, arms or other areas that may result from ischemia, shortness of breath at rest or mild exertion, dizziness or loss of consciousness, orthopnea or paroxysmal nocturnal dyspnea, ankle edema, palpitations or tachycardia (unpleasant awareness of the forceful or rapid beating heart), intermittent claudication (pain in muscle when doing exercise), known heart murmur, unusual fatigue or shortness of breath with normal activities)
- †† Assess risk for exercising (low risk- men<45yrs,W<55yrs not asymptomatic and only meet one risk factor; mod risk – men>45yrs, W>55yrs have two or more risk factors; high risk- one or more signs and symptoms)
- †† List any reason not to exercise

Y/N

- †† Client details gained
- †† Clients emergency contact details collected
- †† GP consent if moderate to vigorous exercise training for moderate to high risk clients

Gym Floor

Y/N

- †† Monitoring/ reporting system in place for exercise-related adverse events
- †† Trained staff available on premises to provide assistance e.g. poor exercise technique, use of equipment
- †† Routine checks of equipment for faults
- †† Gym balls checked daily to ensure inflation and only in accordance with the manufacture

Desirable

Y/N

- †† Supervision of the gym floor at all times
- †† Fitness assessment available
- †† Personalised program available
- †† Instruction cards (written or diagrams) on equipment provided
- †† Evidence of compliance with NSW Fitness Code of Practice

(The Fitness Industry Code of Practice has been established to set standards of Service, Safety and Fair Trading within the Fitness Industry. Fitness businesses are required to adhere to the Code when they become members of their Industry Association. This is voluntary in NSW.)

- †† Records kept regarding client progression
- †† Range of membership options

Instructors/ Supervisors

†Person with Certificate 4 or Tertiary Education (ie. exercise science, physio, exercise rehab, sport science, physical education degree and student with own insurance) available during operation hours

†Person with current First Aid and CPR certificate available during operation hours

Information

Hours of Operation/ Days:

Waiting list: † Yes † No *Waiting period prior to start:*

Medical check (i.e. GP certificate): † Preferred † Not required † Essential

↑ Free weights (DB, BB, ankle weights)	↑ Weight Machines
↑ Hydraulic Machines	↑ Resistance Bands
Medicine balls	
↑ Metal apparatus for body weight ex (inc. chin-up, knee up, dips, abs, back ext), ↑ Potable resistance apparatus (not weights or bands)	
↑ Weight Racks (inc. squat & chest)	
↑ Benches	↑ Boxes (wooden)
Exercise Mats	
Balance:	
↑ Swiss balls	↑ Balance boards (inc. BOSU)
Stretching:	
↑ Stretching Bands (i.e. Yoga band)	↑ Yoga boxes & cylinders
Other:	
↑ Sport Equipment (inc. all types of balls)	↑ Trampolines
↑ Boxing equipment (pads, gloves, bags, etc)	↑ Vibration plate

<u>Information Provided by</u>		
1. Name:	Position:	Date:
2. Name:	Position:	Date:
3. Name:	Position:	Date:

<u>Assessed by</u>		
Name:		
Signature:		Date:
<hr/>		
Recommended	↑ Yes	↑ No
<hr/>		
Other Notes/ Recommendations:		

Swimming Pools

(Place where go to swim not under instruction and you pay to access their facility e.g. Doesn't include swimming squad)

Provider Name:					
Program Category:					
↑ Class Aerobic	↑ Class Resistance	↑ Class Aerobic/ Resistance			
↑ Nutrition	↑ Gym	↑ Pool	↑ Individual training		
<hr/>					

Essential:

Y/N

↑ ↑ Person with current First Aid and CPR Certificate during hours of operation

Desirable:

↑ ↑ Supervision of swimmers at all times

↑ ↑ Lifeguards are have current Pool Lifeguard qualification from Royal Life

↑ ↑ Keep to swimmer ratio 1:100 and 1:50 (wave pool) *RSL Guidelines for Safe Pool Operations*

Information

Heated Pool ↑ Yes ↑ No

Hydrotherapy Pool ↑ Yes ↑ No

Lap swimming Available ↑ Yes ↑ No *No. of lanes available:*

Other paper work needed:

Hours of Operation/ Days:

Waiting list: ↑ Yes ↑ No *Waiting period prior to start:*

Medical check (i.e. GP certificate): ↑ Preferred ↑ Not required ↑ Essential

Other paper work needed:

Cost

Member Only Pool: ↑ Yes ↑ No

Casual Swimming: ↑ Yes ↑ No

Joining Fee:

Membership annually:

Ability to suspend membership for specific times, illness, holidays ↑ Yes ↑ No

If yes, please specify conditions:

Monthly:

No. Sessions:

Casually:

Fees reimbursed if quit ↑ Yes ↑ No ↑ By individual case

Fees reimbursed if facility closes ↑ Yes ↑ No

Additional costs:

1. Equipment Hire

2. Other

Pensioner discount ↑ Yes ↑ No Student discount ↑ Yes ↑ No

Healthcare card discount ↑ Yes ↑ No

Other

Cater for:

Gender ↑ Male ↑ Female

Single only ↑ Yes ↑ No

If No, do you have specific single gender only times ↑ Yes ↑ No

If Yes, please specify:

Do you cater for a specific community language group? ↑ Yes ↑ No

If Yes, please specify:

Do you cater specifically for Aboriginal and Torres Strait Islander Community?

↑ Yes ↑ No
If yes, please specify:

Information Provided by

1. Name: _____ Position: _____ Date: _____

2. Name: _____ Position: _____ Date: _____

3. Name: _____ Position: _____ Date: _____

Assessed by

Name: _____
 Signature: _____ Date: _____

Recommended ↑ Yes ↑ No

Other Notes/ Recommendations:

Specific Class Providers

(Class runs on a regular schedule, person instructing the class, don't include personal training or group personal training that operate irregularly, people from the public able to access the classes)

Class Name:

Provider Name:

Program Category:

↑ Class Aerobic ↑ Class Resistance ↑ Class Aerobic/ Resistance
 ↑ Nutrition ↑ Gym ↑ Pool ↑ Individual training

Essential:

Y/N

↑↑ Routine checks of equipment for faults

If use of gym balls are all gym balls checked prior to class to ensure inflation and only used in accordance with manufacture ↑ Yes ↑ No

If equipment used suitable for aerobic/resistance training ↑ Yes ↑ No

↑↑ Instructor participant ratio does not exceed (1:30 aqua class as RSL Guidelines of safe Pool Operations) ↑ Not Applicable

†† Assess participants ability, injuries, mobility each class (maybe just a visual assessment of each individual)

Screening clients

Y/N

†† Par Q OR any written screening tool
(Reference ACSM)

Y/N

†† Identify coronary artery disease (CAD) risk factors (i.e. Family history, cigarette smoking, hypertension, dyslipidemia (cholesterol), impaired fasting glucose, obesity (BMI or waist circumference M>102cm, F>88cm, sedentary lifestyle)

†† Signs or symptoms of cardiovascular, pulmonary or metabolic disease (i.e. pain or discomfort in chest, neck, jaw, arms or other areas that may result from ischemia, shortness of breath at rest or mild exertion, dizziness or loss of consciousness, orthopnea or paroxysmal nocturnal dyspnea, ankle edema, palpitations or tachycardia (unpleasant awareness of the forceful or rapid beating heart), intermittent claudication (pain in muscle when doing exercise), known heart murmur, unusual fatigue or shortness of breath with normal activities)

†† Assess risk for exercising (low risk- men<45yrs, W<55yrs not asymptomatic and only meet one risk factor; mod risk – men>45yrs, W>55yrs have two or more risk factors; high risk- one or more signs and symptoms)

†† List any reason not to exercise

Y/N

†† Client details gained

†† Clients emergency contact details collected

†† GP consent if moderate to vigorous exercise training for moderate to high risk clients

Class content

Y/N

†† 50% session consists of aerobic or resistance training (e.g. 30min+ /1h class)

†† List of clients participating in the class

†† 3 participates exercising moderately

†† Warm up of at least 5 mins

†† Cool down that includes stretching for at least 5 mins

†† Alternative exercise if participant can't do that particular exercise or that exercise contraindicated to their condition

Desirable:

Y/N

†† Provide at least 2 modifications for each exercise (inc. modifications to make the exercise harder or easier)

†† Individual prescription within the exercise class (own program specific to condition)

†† Consultation including discussion with participant or fitness assessment prior to starting the class

†† Assessment procedures (i.e. medical history, physical examination, body composition)

†† Records kept regarding client progression

Instructors/ Supervisors

Instructor name 1: ↑ Tertiary (rehab, ex phs, pe, physio) ↑ Current Cert 4
 ↑ Current Cert 3 ↑
 ↑ Current first aid ↑ Current CPR
 ↑ Professional Indemnity Insurance
 ↑ Public Liability Insurance

If Cert 3 is a Cert 4 or equivalent available Yes ↑ No ↑

Instructor name 2: ↑ Tertiary (rehab, ex phs, physio) ↑ Current Cert 4
 ↑ Current Cert 3
 ↑ Current first aid ↑ Current CPR
 ↑ Professional Indemnity Insurance
 ↑ Public Liability Insurance

If Cert 3 is a Cert 4 or equivalent available Yes ↑ No ↑

Instructor name 3: ↑ Tertiary (rehab, ex phs, physio) ↑ Current Cert 4
 ↑ Current Cert 3
 ↑ Current first aid ↑ Current CPR
 ↑ Professional Indemnity Insurance
 ↑ Public Liability Insurance

If Cert 3 is a Cert 4 or equivalent available Yes ↑ No ↑

Equipment AVAILABLE FOR USE IN THE particular class (please tick)

LAND BASED

Aerobic:

↑ Treadmills ↑ Upright Bikes ↑ Semi-Recumbent Bikes
 ↑ Steppers ↑ Elliptical Trainer ↑ Rowing Machine
 ↑ Spinning Bikes ↑ Reeboks Steps

Resistance:

↑ Free weights (DB, BB, ankle weights) ↑ Weight Machines
 ↑ Hydraulic Machines ↑ Resistance Bands ↑
 Medicine balls
 ↑ Metal apparatus for body weight ex (inc. chin-up, knee up, dips, abs, back ext), ↑
 Potable resistance apparatus (not weights or bands)
 ↑ Weight Racks (inc. squat & chest)
 ↑ Benches ↑ Boxes (wooden) ↑
 Exercise Mats

Balance:

↑ Swiss balls ↑ Balance boards (inc. BOSCU)

Stretching:

↑ Stretching Bands (i.e. Yoga band) ↑ Yoga boxes & cylinders

Other:

↑ Sport Equipment (inc. all types of balls) ↑ Trampolines
 ↑ Boxing equipment (pads, gloves, bags, etc) ↑ Vibration plate

AQUA BASED

Swimming:

↑ Kickboards ↑ Goggles ↑ Flippers
↑ Rubber Bands ↑ Hand paddles ↑ Buoy
↑ Snorkel

Other:

↑ Noodles ↑ Water belts ↑ Balls
↑ Magic mats ↑ Nose clips ↑ Boogy Boards

Information

Class information

Skill required to do class:

↑ Low (none) ↑ Med (at least once before) ↑ High (more than once)

Skill determined by: Low don't need any skill do the class, moderate better have completed the class once or have some coordination, or something like it, High have to have completed the skill more than once.

Difficulty of class (i.e. intensity):

↑ Low (no impact) ↑ Med (impact and no impact) ↑ High (impact)

Bring Own Equipment ↑ Yes ↑ No

If yes, what equipment?

Max number per class:

Time of session/ Timetable: ↑ See provider

List:

Waiting list: ↑ Yes ↑ No *Waiting period prior to start:*

Medical check (i.e. GP certificate): ↑ Preferred ↑ Not required ↑
Essential

Other paper work needed:

Cost

Joining Fee:

Membership annually:

Ability to suspend membership for specific times, illness, holidays ↑ Yes ↑ No

If yes, please specify conditions:

Monthly:

No. Sessions:

Casually:

Fees reimbursed if quit ↑ Yes ↑ No ↑ By individual case

Fees reimbursed if facility closes ↑ Yes ↑ No

Additional costs:

1.

2.

Pensioner discount ↑ Yes ↑ No Student discount ↑ Yes ↑ No

Healthcare card discount ↑ Yes ↑ No

Other

Cater for:

Gender↑ Male ↑ Female

Single only ↑ Yes ↑ No

If No, do you have specific single gender only times ↑ Yes ↑ No

If Yes, please specify:

Do you cater for a specific community language group? ↑ Yes ↑ No

If Yes, please specify:

Do you cater specifically for Aboriginal and Torres Strait Islander Community?

↑ Yes ↑ No

If yes, please specify:

Statistics

Number of staff members (trained staff only):

Number of AEP:

Number of Cert 4:

How long they have been operating:

% membership 40-65yrs:

% membership >65yrs:

Information Provided by

1. Name: Position: Date:

2. Name: Position: Date:

3. Name: Position: Date:

Assessed by

Name:

Signature: Date:

Recommended ↑ Yes ↑ No

Other Notes/ Recommendations:

Individual Training (AEP, PT)

(May include both individual consultations and group personal training)

Provider Name:

Program Category:

↑	Class Aerobic	↑	Class Resistance	↑	Class Aerobic/ Resistance		
↑	Nutrition	↑	Gym	↑	Pool	↑	Individual training

Essential:

Y/N

↑↑ Routine checks of equipment for faults

If use of gym balls are all gym balls checked prior to class to ensure inflation and only used in accordance with manufacture ↑ Yes ↑ No

If equipment used suitable for aerobic/resistance training ↑ Yes ↑ No

Screening clients

Y/N

↑↑ Par Q OR any written screening tool

(Reference ACSM)

Y/N

↑↑ Identify coronary artery disease (CAD) risk factors (i.e. Family history, cigarette smoking, hypertension, dyslipidemia (cholesterol), impaired fasting glucose, obesity (BMI or waist circumference M>102cm, F>88cm, sedentary lifestyle)

↑↑ Signs or symptoms of cardiovascular, pulmonary or metabolic disease (i.e. pain or discomfort in chest, neck, jaw, arms or other areas that may result from ischemia, shortness of breath at rest or mild exertion, dizziness or loss of consciousness, orthopnea or paroxysmal nocturnal dyspnea, ankle edema, palpitations or tachycardia (unpleasant awareness of the forceful or rapid beating heart), intermittent claudication (pain in muscle when doing exercise), known heart murmur, unusual fatigue or shortness of breath with normal activities)

↑↑ Assess risk for exercising (low risk- men<45yrs, W<55yrs not asymptomatic and only meet one risk factor; mod risk – men>45yrs, W>55yrs have two or more risk factors; high risk- one or more signs and symptoms)

↑↑ List any reason not to exercise

Y/N

↑↑ Client details gained

↑↑ Clients emergency contact details collected

↑↑ GP consent if moderate to vigorous exercise training for moderate to high risk clients

Class content

Y/N

↑↑ 50% session consists of aerobic or resistance training (eg 30min/ 1hr session)

↑↑ List of clients participating in the class

↑↑ Warm up of at least 5 mins

↑↑ Cool down that includes stretching for at least 5 mins

↑↑ Progressive exercises as the participants improve in future classes

↑↑ Provide alternative exercise if participant can't do that particular class or that exercise contraindicated to their conditioned

↑↑ Assess participants ability, injuries, mobility each class

Desirable:

Y/N

- ↑↑ Provide at least 2 modifications for each exercise
- ↑↑ Provides individual prescription within the exercise class (own program specific to condition)
- ↑↑ Consultation including discussion with participant or fitness assessment prior to starting the class
- ↑↑ Records kept regarding client progression

Instructors/ Supervisors

- Instructor name 1: ↑ Tertiary (rehab, ex phs, physio) ↑ Current Cert 4
↑ Current first aid ↑ Current CPR
↑ Professional Indemnity Insurance
↑ Public Liability Insurance
- Instructor name 2: ↑ Tertiary (rehab, ex phs, physio) ↑ Current Cert 4
↑ Current first aid ↑ Current CPR
↑ Professional Indemnity Insurance
↑ Public Liability Insurance
- Instructor name 3: ↑ Tertiary (rehab, ex phs, physio) ↑ Current Cert 4
↑ Current first aid ↑ Current CPR
↑ Professional Indemnity Insurance
↑ Public Liability Insurance

Information

Hours of Operation/ Days:

Waiting list: ↑ Yes ↑ No *Waiting period prior to start:*

Medical check (i.e. GP certificate): ↑ Preferred ↑ Not required ↑
Essential

Other paper work needed:

Cost

Joining Fee:

Membership annually:

Ability to suspend membership for specific times, illness, holidays ↑ Yes ↑ No

If yes, please specify conditions:

Monthly:

No. Sessions:

Casually:

Fees reimbursed if quit ↑ Yes ↑ No ↑ By individual case

Fees reimbursed if facility closes ↑ Yes ↑ No

Additional costs:

1. Fitness Assessment:

2. Personalised Program:

3. Personal Training:

4. Other:

Pensioner discount ↑ Yes ↑ No Student discount ↑ Yes ↑
No

Healthcare card discount ↑ Yes ↑ No
 Medicare ↑ Yes ↑ No
 Health Funds Rebated ↑ Yes ↑ No

If yes, please list:

Other

Cater for:

Gender ↑ Male ↑ Female

Single only ↑ Yes ↑ No

If No, do you have specific single gender only times ↑ Yes ↑ No

If Yes, please specify:

Do you cater for a specific community language group? ↑ Yes ↑ No

If Yes, please specify:

Do you cater specifically for Aboriginal and Torres Strait Islander Community?

↑ Yes ↑ No

If yes, please specify:

Statistics

Number of staff members (trained staff only):

Number of AEP:

Number of Cert 4:

How long they have been operating:

% membership 40-65yrs:

% membership >65yrs:

Information Provided by

1. Name: Position: Date:
2. Name: Position: Date:
3. Name: Position: Date:

Assessed by

Name:

Signature: Date:

Recommended ↑ Yes ↑ No

Other Notes/ Recommendations:

Walking Class (LOW RISK ACTIVITY)

Class Name:

Provider Name:

Program Category:

↑ Class Aerobic ↑ Class Resistance ↑ Class Aerobic/ Resistance
↑ Nutrition ↑ Gym ↑ Pool ↑ Individual training

Essential:

Screening clients

Y/N

†† Par Q OR any written screening tool

(Reference ACSM)

Y/N

- †† Identify coronary artery disease (CAD) risk factors (i.e. Family history, cigarette smoking, hypertension, dyslipidemia (cholesterol), impaired fasting glucose, obesity (BMI or waist circumference M>102cm, F>88cm, sedentary lifestyle)
- †† Signs or symptoms of cardiovascular, pulmonary or metabolic disease (i.e. pain or discomfort in chest, neck, jaw, arms or other areas that may result from ischemia, shortness of breath at rest or mild exertion, dizziness or loss of consciousness, orthopnea or paroxysmal nocturnal dyspnea, ankle edema, palpitations or tachycardia (unpleasant awareness of the forceful or rapid beating heart), intermittent claudication (pain in muscle when doing exercise), known heart murmur, unusual fatigue or shortness of breath with normal activities)
- †† Assess risk for exercising (low risk- men<45yrs, W<55yrs not asymptomatic and only meet one risk factor; mod risk – men>45yrs, W>55yrs have two or more risk factors; high risk- one or more signs and symptoms)
- †† List any reason not to exercise

Y/N

- †† Client details gained
- †† Clients emergency contact details collected
- †† GP consent if moderate to vigorous exercise training for moderate to high risk clients

Class content

Y/N

- †† List of clients participating in the class
- †† Warm up of at least 5 mins
- †† Cool down that includes stretching for at least 5 mins
- †† Progressive exercises as the participants improves in future classes
- †† Assess participants ability, injuries, mobility each class

Desirable:

Y/N

Healthcare card discount ↑ Yes ↑ No

Other

Cater for:

Gender ↑ Male ↑ Female

Single only ↑ Yes ↑ No

If No, do you have specific single gender only times ↑ Yes ↑ No

If Yes, please specify:

Do you cater for a specific community language group? ↑ Yes ↑ No

If Yes, please specify:

Do you cater specifically for Aboriginal and Torres Strait Islander Community?

↑ Yes ↑ No

If yes, please specify:

Statistics

Number of staff members (trained staff only):

Number of AEP:

Number of Cert 4:

How long they have been operating:

% membership 40-65yrs:

% membership >65yrs:

Information Provided by

1. Name: Position: Date:

2. Name: Position: Date:

3. Name: Position: Date:

Assessed by

Name:

Signature:

Date:

Recommended ↑ Yes ↑ No

Other Notes/ Recommendations:

Nutrition (Inc. Individual Consultations, Group Education and Support Groups)

Provider Name:

Program Category:

↑ Class Aerobic ↑ Class Resistance ↑ Class Aerobic/ Resistance
↑ Nutrition ↑ Gym ↑ Pool ↑ Individual training

Essential:

Screening

Y/N

- ↑↑ Pre-screening tool

 - ↑↑ Nutrition assessment undertaken prior to class or on initial consultation
- Y/N
- ↑↑ Client details
 - ↑↑ Medical History
 - ↑↑ Allergies
 - ↑↑ Family History
 - ↑↑ Health Complications
 - ↑↑ Weight Height, BMI
-

Class content

Y/N

- ↑↑ Complies with DAV Criteria for selecting a weight management service (Reference DAV)
- Y/N
- ↑↑ Recommends a weight loss of no more than 1kg per week
 - ↑↑ Encourages body fat loss and improved health, not just weight loss (using measurements such as waist circumference, improved blood glucose control, improved blood pressure, etc)
 - ↑↑ Recommends regular physical activity (and not use of passive exercise equipment)
 - ↑↑ Doesn't recommend an energy intake below 5000kJ/1200kcal per day
 - ↑↑ Does not punish weight gain
 - ↑↑ Does not claim to be effortless
 - ↑↑ Does not suggest you can eat as many kilojoules as you like and still lose weight
 - ↑↑ Program doesn't eliminate major food groups
 - ↑↑ Based on healthy eating plan including all major food groups (breads and cereals, fruit and vegetables, meat and meat alternatives, dairy and dairy alternatives)
 - ↑↑ Does not recommend a strict meal plan with no substitutions or variations allowed
 - ↑↑ Does not involve buying meal replacements, powders or supplements not proven to be safe or necessary for effective long-term weight management
-

Y/N

- ↑↑ **Uses Australian Guide to Healthy Eating (*Department of Health & Ageing*)**
 1. Choose foods from each of the five food groups every day.
 - Bread, cereals, rice, pasta, noodles
 - Vegetables, legumes
 - Fruit
 - Milk, yoghurt, cheese
 - Meat, fish, poultry, eggs, nuts, legumes

↑ Professional Indemnity Insurance
↑ Public Liability Insurance

Information

Individual consultations

Hours of Operation/ Days:

Waiting list: ↑ Yes ↑ No *Waiting period prior to start:*

Medical check (i.e. GP certificate): ↑ Preferred ↑ Not required ↑ Essential

Other paper work needed:

Cost

Joining Fee: ↑ Yes ↑ No *If yes, how much?*

Membership annually:

Ability to suspend membership for specific times, illness, holidays ↑ Yes ↑ No

If yes, please specify conditions:

Monthly:

No. Sessions:

Casually:

Non Attendance Fee ↑ Yes ↑ No

Fees reimbursed if quit ↑ Yes ↑ No ↑ By individual case

Fees reimbursed if facility closes ↑ Yes ↑ No

Additional costs:

1.

2.

Pensioner discount ↑ Yes ↑ No Student discount ↑ Yes ↑ No

Healthcare card discount ↑ Yes ↑ No

Other

Cater for:

Gender ↑ Male ↑ Female

Single only ↑ Yes ↑ No

If No, do you have specific single gender only times ↑ Yes ↑ No

If Yes, please specify:

Do you cater for a specific community language group? ↑ Yes ↑ No

If Yes, please specify:

Do you cater specifically for Aboriginal and Torres Strait Islander Community?

↑ Yes ↑ No

If yes, please specify:

Group Classes available

1. **Class Name:**

Specific Description:

↑ Educational ↑ Support Group ↑ Exercise/Nutrition

Time limited program ↑ Yes ↑ No *If yes, how long?*

Max number per class:
Time of session/ Timetable: ↑ See provider
List:
Waiting list: ↑ Yes ↑ No *Waiting period prior to start:*

Medical check (i.e. GP certificate): ↑ Preferred ↑ Not required ↑ Essential
Other paper work needed:

2. Class Name:
Specific Description:
↑ Educational ↑ Support Group ↑ Exercise/Nutrition
Time limited program ↑ Yes ↑ No *If yes, how long?*

Max number per class:
Time of session/ Timetable: ↑ See provider
List:
Waiting list: ↑ Yes ↑ No *Waiting period prior to start:*

Medical check (i.e. GP certificate): ↑ Preferred ↑ Not required ↑ Essential
Other paper work needed:

Cost
Joining Fee ↑ Yes ↑ No *If yes, how much?*
Membership annually:
Ability to suspend membership for specific times, illness, holidays ↑ Yes ↑ No
If yes, please specify conditions:
Monthly:
Joining Fee ↑ Yes ↑ No *If yes, how much?*
No. Sessions:
1. 2.
Casually:

Non Attendance Fee ↑ Yes ↑ No
Fees reimbursed if quit ↑ Yes ↑ No ↑ By individual case
Fees reimbursed if facility closes ↑ Yes ↑ No
Additional costs:
1.
2.
Pensioner discount ↑ Yes ↑ No Student discount ↑ Yes ↑ No
Healthcare card discount ↑ Yes ↑ No

Other
Cater for:
Gender ↑ Male ↑ Female
Single only ↑ Yes ↑ No
If No, do you have specific single gender only times ↑ Yes ↑ No
If Yes, please specify:
Do you cater for a specific community language group? ↑ Yes ↑ No
If Yes, please specify:



The *Live Life Well* Diabetes Prevention Program

Southern Highlands Division of General Practice



Intervention Manual for the Program Coordinator and Lifestyle Officers

6 August 2008

Acknowledgements

The *Live Life Well* Diabetes Prevention Program in the Southern Highlands Division of General Practice is part of the Sydney Diabetes Prevention Program.

The Sydney Diabetes Prevention Program is a collaboration between:

- Sydney South West Area Health Service (SSWAHS);
- Institute of Obesity, Nutrition and Exercise, University of Sydney;
- Central Sydney General Practice Network;
- Macarthur Division of General Practice;
- Southern Highlands Division of General Practice; and
- Diabetes Australia- NSW.

The principal staff involved in the Sydney Diabetes Prevention Program are:

- Professor Stephen Colagiuri, Professor of Metabolic Health, University of Sydney
- Professor Ian Caterson, Boden Professor of Human Nutrition, University of Sydney
- Professor Maria Fiatarone Singh, John Sutton Chair of Exercise and Sport Science, University of Sydney
- Professor Adrian Bauman, Professor of Public Health, University of Sydney
- Associate Professor Chris Rissel, Director, Health Promotion, SSWAHS
- Professor Nicholas Zwar, University of NSW
- Ms Mandy Williams, Deputy Director Health Promotion, SSWAHS
- Dr Michael Moore, CEO, Central Sydney General Practice Network
- Mr Rene Pennock, CEO, Macarthur Division of General Practice
- Mr Warwick Ruscoe, CEO Southern Highlands Division of General Practice
- Mr Andrew Milat, Manager Strategic Research and Development Branch, NSW Department of Health
- Ms Blythe O'Hara, Manager Telephone Lifestyle Advisory Service, NSW Department of Health
- Mr Philip Vita, Director, Sydney Diabetes Prevention Program, SSWAHS
- Ms Louise Farrell, Evaluation Manager, Sydney Diabetes Prevention Program, SSWAHS
- Ms Magnolia Cardona, Statistician/Data Manager, Sydney Diabetes Prevention Program, SSWAHS
- Ms Jacky Hony, Project Officer and Macarthur Division of General Practice Divisional Liaison Officer, Sydney Diabetes Prevention Program, SSWAHS
- Ms Kellie Nallaiah, Project Officer and Southern Highlands Division of General Practice Divisional Liaison Officer, Sydney Diabetes Prevention Program, SSWAHS
- Ms Rona McNiven, Evaluation Project Officer, University of Sydney

The staff in Southern Highlands are:

Program Coordinator: Jill Snow
Lifestyle Officer: Cheryl Jones
Lifestyle Officer: Gail Forlonge

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For more information call 1300 796 341 or visit www.livelifewell.nsw.gov.au

1. Intervention Overview

A *Live Life Well* Lifestyle Officer employed by the Southern Highlands of Division of General Practice will contact each person you have referred by telephone.

This phone call will be to organise a suitable time for participants to come in for an initial assessment and counselling session. Ideally, this should occur between 2 and 4 weeks after the Division has received the referral form.

The Initial assessments and counselling session will be held at Bowral Specialist Centre, 6B Mona Rd, Bowral. Group-based sessions will be held at Resilience, Enthusiasm, Opportunity (REO), Unit 6, 44-48 Bowral Rd, Bowral.

Once a date and time has been confirmed with the participant a confirmation letter and information pack will be sent to the participant. This pack will contain more detailed information about the *Program* and a 3-day food record to be completed to bring to the initial assessment and counselling session.

The participant will also be contacted by telephone by a staff member of the *Live Live Well* Diabetes *Prevention* Program evaluation team to complete a baseline questionnaire that should take between 15-20 minutes to enable the *Program* to be evaluated.

Initial assessment

At the initial assessment and counselling session the Lifestyle Officer will go through the participants risk profile and referral form information including medication use, discuss diabetes and take additional measures of weight and waist circumference. The participant will be provided with tools to self-monitor weight, physical activity and dietary intake. A review of the 3-day food record will be conducted with appropriate tailored feedback on healthy eating strategies. In addition, the session will assist participants to set some personalised short-term goals.

At the initial assessment and counselling session participants will be encouraged to attend the three group sessions to support and encourage them to achieve their lifestyle goals.

After completion of the initial assessment and counselling session the Division will send a letter to the referring GP advising them of the outcomes of the session.

Three group-based sessions

Groups of 8-15 people will be scheduled. Participants will be given the choice to attend day (within business hours), evening/night (after hours), or Saturday group sessions (where there is a demand). Each group session will run for 2 hours. Session 1 and Session 2 will be held a fortnight apart. Session 3 will be approximately a month after Session 2 to enable people to report back on their success (ie self-assess weight, waist circumference, physical activity levels and dietary intake), as well as addressing barriers and problems encountered.

This is an appropriate time to review strategies put in place to achieve their lifestyle goals from previous sessions.

After the completion of the three group sessions a letter will be sent by the Division to the referring GP advising them of the attendance record of the participant, progress towards achieving their lifestyle goals and any barriers they may have encountered.'

Three months follow up phone calls

Three months after the initial assessment a follow up phone call will be made to the participant using a health coaching approach to provide on-going support and feedback.

After completion of the three month follow up phone call session a letter will be sent by the Division to the referring GP advising them of the outcomes of the session.

Four months GP visit to review progress

At four months it is recommended that you schedule an appointment with your patient to review their progress against their lifestyle goals, measure weight and waist circumference and order any appropriate blood tests (i.e. FPG or lipid profile).

Six months follow up phone call

Six months after the initial assessment a follow up phone call will be made to the participant using a health coaching approach to provide on-going support and feedback.

After the completion of the six month follow up phone call session a letter will be sent by the Division to the referring GP advising them of the outcomes of the session.

Nine months follow up phone call

Nine months after the initial assessment a follow up phone call will be made to the participant using a health coaching approach to provide on-going support and feedback.

After the completion of the nine month follow up phone call session a letter will be sent by the Division to the referring GP advising them of the outcomes of the session.

12 month follow up (Program evaluation)

Twelve months after the initial assessment a final assessment needs to occur. This will have to be conducted by the GP as it will be necessary to obtain all the biomedical information collected at baseline (i.e. weight, waist circumference, blood pressure, FPG and full lipid profile). The evaluation team will also conduct a follow up telephone survey and also 3-day food record will be collected. These are the outcome measures used to enable the **Program** to be evaluated.

After the completion of the twelve-month follow up a letter will be sent by the Division to the referring GP advising them of the outcomes of the session.

A letter will also be sent to the participant providing them with their individual results compared to baseline and thanking them for their participation.

After the entire **Program** is finished a letter will be sent to all GPs and participants providing them with a summary of the final evaluation report (After 30 June 2010).

2. Program Coordinator and Lifestyle Officer Roles and Responsibilities

1. Decide which roles and responsibilities should be delegated to the Lifestyle Officers and delegate accordingly.
2. Identify and recruit General Practices using practice selection criteria.
3. Obtain all relevant information to complete the General Practice Details form.
4. Schedule a training session at each participating General Practice for SDPP to attend.
5. Ensure PC and LOs have all Training manuals and appropriate papers (contact SDPP for these).
6. Set up Referral Form on Medical Director if requested.
7. Collect all Risk Tools, Referral Forms, and Screening and Recruitment Record sheets.
Note: some forms will be collected personally, some mailed and some faxed to the Program Coordinator. How these forms get to the Program Coordinator will be Practice specific.
8. Maintain accurate and up to date records of participant details in Participant Database.
9. Monitor the Screening and Recruitment process and Intervention process on a weekly basis.
10. Update the SDPP Divisional Officer Kellie Nallaiah on a weekly basis.
11. After receiving a Referral Form check for missing data and contact the GP/Practice to obtain missing data if necessary.
12. Pass the Referral Form onto LO to progress (see section 3 *Initial phone call from Lifestyle Officer to participant*).
13. Conduct individual assessments and provide feedback to GP.
14. Conduct groups sessions and provide feedback to GP.

15. Conduct follow up phone calls with participant at 3/6/9 months and provide feedback to GP.
16. Send reminders to participant prior to individual and each group session.
17. Send reminders to participant to make 4 and 12 month GP appointment or remind General Practice to do this.
18. Attend Divisional Liaison Group meetings.

3. Initial phone call from Lifestyle Officer to participant

1. Within one week after receiving a LLW Referral form with no missing data, contact participant and introduce self.
2. Explain their name has been given to them by Dr _____ via a Referral Form.
3. Ask the participant what they know about the program. Relay information from the following script accordingly:

As part of the Program, we are offering you the opportunity to attend a 90-minute initial assessment and counselling session and three 2-hour group sessions. These are being run by qualified Divisional staff. Successful completion of these activities will empower you with the knowledge and skills to lead a healthier lifestyle. The aim is to help you achieve and maintain a healthy weight, be physically active and follow a balanced healthy eating plan. Follow up phone calls and regular check ups your GP are also part of the **Program**. The **Program** will last for one year and is free for eligible participants.

The main goals of the **Program** are to:

- Increase physical activity
- Reduce fat intake
- Increase fibre
- Reduce weight by 5%

Achieving these goals will prevent or delay the onset of type 2 diabetes.

4. The first step is to come in for an individual assessment and counselling session. This involves a 90 minute one-on-one session with a Lifestyle Officer conducted at Bowral Specialist Centre on Mona Rd, Bowral. This session will involve discussing weight, physical activity and dietary intake and formulating some personal goals.

5. Schedule an individual assessment and counselling session (date and time) between 2 and 4 weeks away. Mention that on the day prior to the initial assessment they will be sent a reminder- ask how they would like to be reminded (email/SMS/phone). Emphasise that the appointment they make is like any other- 24 hours notice of cancellation would be appreciated.

6. Explain an Introductory pack will be posted to them containing
 - a. a confirmation letter including their appointment date, time and location
 - b. a 3 day food record- explain the purpose/importance of the 3 day food record and that it needs to be brought to the initial assessment
 - c. HADS
7. Post the above mentioned pack to the participant.
8. Explain that we would like them to complete a lifestyle survey. Explain the purpose of the lifestyle survey is to enable the Program to be evaluated and that a member of the evaluation team will contact the participant prior to their initial assessment to conduct the survey over the phone. Emphasise that the survey is completely confidential. It should take approximately 15 to 20 minutes to complete. Ask the participant when the best time to contact them is (days and time).
9. Contact the SDPP Divisional Officer Kellie Nallaiah with the days and time that the participant nominated to complete the Lifestyle survey.

Kellie Nallaiah will contact the Program Evaluation Team (PET).

The PET will call the participant and conduct the Lifestyle survey over the phone. PET will let Kellie Nallaiah know when it has been completed or if the participant has declined to complete the survey.

Kellie Nallaiah will contact the LO and let them know it has been completed.

4. Decliners

If the potential participant declines or fails to attend an individual assessment send a standard letter from the Division to:

1. the participant thanking them for their interest with standard information about physical activity and nutrition, some key websites and encouraging them to discuss this with their GP; and
2. the participant's GP advising them of the patients outcome

5. Initial Assessment

1. Contact participant (email/SMS/phone) on the day before their scheduled individual assessment to remind them about the time, date and place. Remind them to complete and bring their 3 day food record and HADS.

2. Prior to the participant arriving review the following data from the Referral form and Risk Test
 - Risk of diabetes (risk score)
 - BMI
 - WC
 - Blood pressure
 - Lipids
 - Medication use
 - Pre-existing conditions
 - Fruit and veg self reported (every day or less than every day)
 - Physical activity (30 minutes a day)

3. Content of Individual Assessment and Counselling Session (Week 1)

Handouts: LLW SDPP 3-day food diary and physical activity/exercise log book, and tape measure

- Establish relevance to participant of personal risk (refer to mailed food and activity logs)
- Goals of the SDPP project in its entirety including differentiation between confidentiality as opposed to anonymity
- Goals of the intervention and the translation of these into behavioural strategies, self-monitoring and goal setting.
- 3-day food diary reviewed or 24-hour food diary taken for those participants who have not brought a completed diary
- Discussion about current physical activity levels
- Specific directions given about diet and activity level changes needed
- Measurement of height, weight, BMI and waist circumference
- Explanation of how to reduce personal risk through lifestyle modifications
- Explain how to use the pedometer (when provided)
- Ascertain interest in addressing high risk status
- Establish expectations and describe the outline content/format of intervention component (the group sessions)
- Assess for risk of drop out (smoker, BMI > 35, low self-efficacy, depressive symptoms)
- Identification of any pre-existing conditions or use of medications that may preclude group participation including basic fitness and strength test
- Alcohol reduction and smoking cessation advice if needed
- Referral to a group session (*additional module provided by Diabetes Australia, NSW offered to those declining group sessions – participant manual offered along with list of recommended community-based programs, advise of SDPP follow-up calls and need to maintain GP screening for diabetes*)
- Discussion about any relevant personal barriers

- Reminded to complete 3-day food diary and physical activity/exercise log book and bring to first group session if not available at the initial assessment
 - Reminder to wear suitable clothing and footwear at the group sessions
4. Send a letter back to the participant's GP confirming that their patient has attended an individual assessment and is therefore considered to be part of the LLW program. Also include what was discussed at the individual assessment.

6. Groups Sessions

1. On day/week prior to each Group session contact participant (email/SMS/ph) to remind them about the time and location.
2. Content as per attachment in the Program protocol
3. Send feedback to GP regarding the attendance record of the participant, progress towards achieving their lifestyle goals and any barriers they may have encountered.

7. Follow up phone calls

Three month follow up phone call

1. Send a letter to the participant 14 days prior to remind them they will be receiving a phone call.
2. Three months after the initial assessment call the participant and provide on-going support and feedback using a health coaching approach.

Enquire about

- what community based programs they have joined
 - overall health
 - any questions re injury or medical refer to GP
3. After completion of the three month follow up phone call session send a letter to the referring GP advising them of the outcomes of the session.
 4. Enter SDPP outcomes of the session on the database

Six month follow up phone call

Content similar to 3 months as per Program protocol

Nine month follow up phone call

Content similar to 3 months as per Program protocol

Follow up appointments with GP

Four month follow up appointment with GP

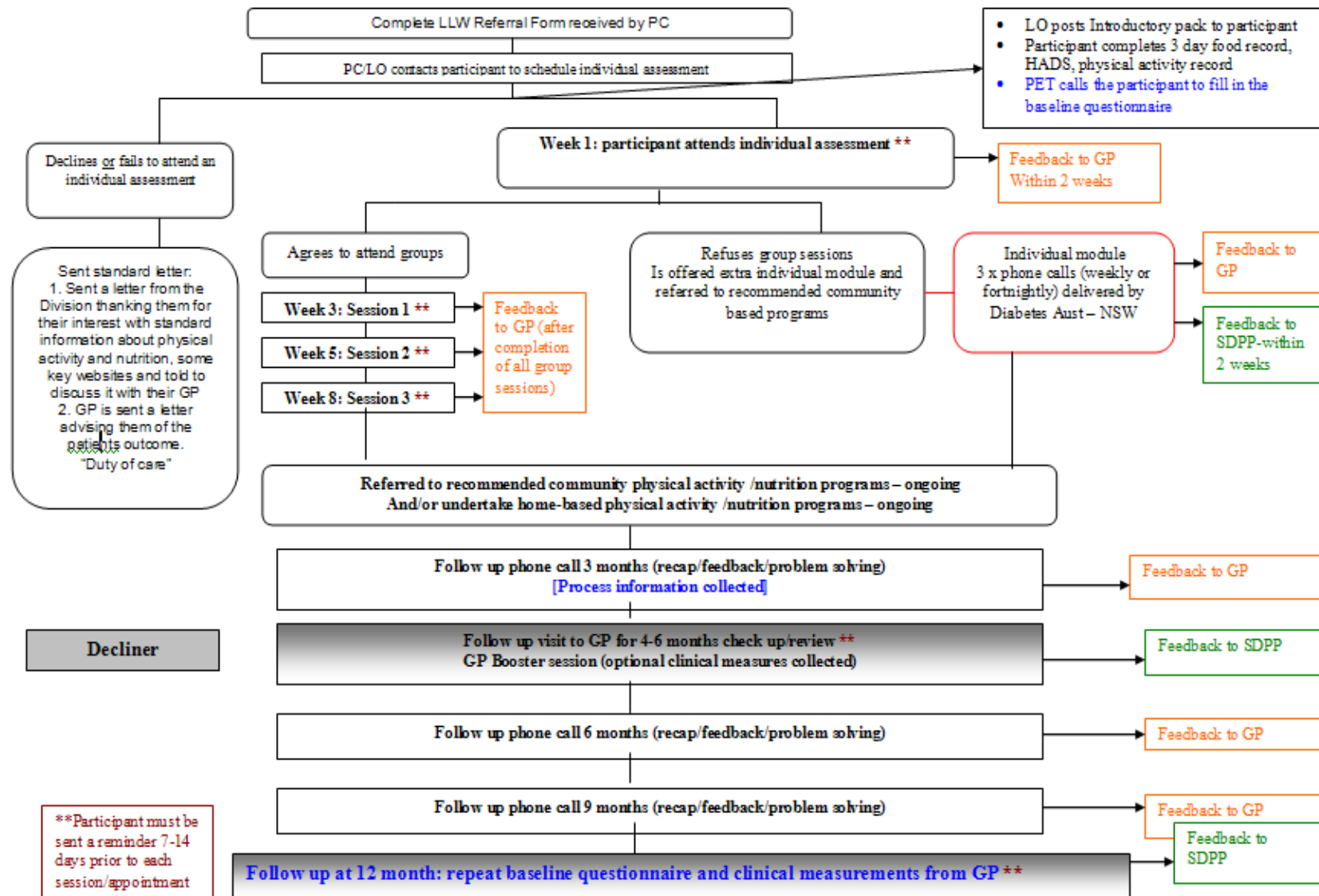
1. Contact the participant to remind them to make an appointment for the 4 months follow up appointment with their GP. Ensure information from this appointment is fed back to SDPP by entering test results on the online database.

Twelve month follow up appointment with GP

1. During the 9-month follow-up call to participant remind them to make an appointment for the 12 months follow up appointment with their GP. Ensure information from this appointment is fed back to SDPP in a letter at the end of the Program.

9. Flowchart of Intervention Process

The following page shows the steps from referral to end of participation and the role of the lifestyle officer at every point in time. Note that feedback needs to be provided to the referring GP soon after each event.



10. Appendices to Lifestyle Officers Manual

Appendix 1: Feedback letters

1. Decliner: Letter sent from Division to decliner

Date _____

Dear _____,

Re: *Live Life Well* Diabetes Prevention Program

Thank you for your interest in the *Live Life Well* Diabetes Prevention Program. This new prevention program aims to help participants reach and maintain a healthy weight, be physically active and follow a healthy eating plan. The outcome of these lifestyle changes is a significant reduction in the risk of developing type 2 diabetes.

You can take simple measures to help prevent the onset of type 2 diabetes such as aiming to eat 5 serves of vegetables and 2 serves of fruit every day, limiting take away foods, choosing low fat dairy products and lean meat. Eating smaller servings can also assist in managing your weight.

Incorporating 30 minutes of moderate intensity physical activity on most days of the week is another way to reduce your risk of developing type 2 diabetes. Moderate intensity exercise causes a slight increase in breathing and heart rate and may cause light sweating.

For more information on nutrition and physical activity please have a look at the following websites.

<Insert useful websites here>

The LLW Diabetes Prevention Program website: www.livelifewell.nsw.gov.au

Diabetes Australia- NSW: www.diabetesnsw.org.au

This letter confirms that you have declined to participate in the *Live Life Well* Diabetes Prevention Program and your GP has been notified of this. You are encouraged to discuss your type 2 diabetes risk with your GP.

Yours Sincerely,

1a. Letter sent from Division to GP

Date_____

Dear Dr _____,

Re: *Live Life Well* Diabetes Prevention Program

Thank you for referring your patient _____ to the *Live Life Well* Diabetes Prevention Program. This new prevention program aims to help participants reach and maintain a healthy weight, be physically active and follow a healthy eating plan. The outcome of these lifestyle changes is a significant reduction in the risk of developing type 2 diabetes.

Your patient has declined to participate in the Program. We have sent your patient a letter confirming that they are not part of the Program and some information on how to prevent type 2 diabetes including some useful websites. In addition, your patient was encouraged to discuss their type 2 diabetes risk with you.

Thank you again for your referral.

Yours Sincerely

2. Individual assessment: Letter sent from Division to GP

Date_____

Dear Dr _____,

Re: *Live Life Well* Diabetes Prevention Program

Thank you for referring your patient _____ to the *Live Life Well* Diabetes Prevention Program. This new prevention program aims to help participants reach and maintain a healthy weight, be physically active and follow a healthy eating plan. The outcome of these lifestyle changes is a significant reduction in the risk of developing type 2 diabetes.

This letter confirms that _____ is a participant in the Program.

Your patient has attended an individual assessment and counselling session with a Program Lifestyle Officer (name) _____ on (date)_____ at the Bowral Specialist Centre, 6B Mona Rd, Bowral.

Your patient was given a brief overview about diabetes and the causes and consequences of this disease. Their individual risk and current lifestyle habits were discussed. The following issues were identified (e.g. too much fat in diet, no physical activity etc etc):_____

Your patient currently (e.g. eats the recommended amount of fruit and vegetables every day etc etc):

How the Program can help your patient reduce their risk of developing type 2 diabetes was discussed and your patient is (e.g. highly) _____ motivated to adhere to the Program and reduce their risk.

Ways to successfully change behaviour was discussed.

The following goals were set for the next month: _____

The following long term goals (12 months?) were set:

Potential barriers to achieving goals were identified and discussed: _____

Your patient has agreed to attend three 2 hour group based sessions. After completion of the three group sessions you will receive a letter regarding your patient's attendance record, progress towards achieving their lifestyle goals and any barriers they may have encountered.

[Or

Your patient has declined to attend the three group based sessions however he/she agreed to receive an alternative module. This alternative module involves three phone calls delivered fortnightly.

These calls will use a health coaching approach to provide on-going support and feedback. You will receive a letter regarding the outcomes of these ph calls after their completion.]

Yours Sincerely,

3. Diabetes Australia module: Letter sent from Diabetes Australia to GP

Date _____

Dear Dr _____,

Re: *Live Life Well* Diabetes Prevention Program

Thank you for referring your patient _____ to the *Live Life Well* Diabetes Prevention Program. This new prevention program aims to help participants reach and maintain a healthy weight, be physically active and follow a healthy eating plan. The outcome of these lifestyle changes is a significant reduction in the risk of developing type 2 diabetes.

As you are aware, your patient declined to attend the three group based sessions which are part of the mainstream Program. An alternative module was provided which involved three phone calls delivered fortnightly (?). Content?

The outcomes of these phone calls were ??

Yours Sincerely,

4. Group sessions: Letter sent from Division to GP

Date_____

Dear Dr _____,

Re: *Live Life Well* Diabetes Prevention Program

Thank you for referring your patient _____ to the *Live Life Well* Diabetes Prevention Program. This new prevention program aims to help participants reach and maintain a healthy weight, be physically active and follow a healthy eating plan. The outcome of these lifestyle changes is a significant reduction in the risk of developing type 2 diabetes.

Following their initial assessment your patient has attended XX out of the scheduled three 2 hour group based sessions on (insert dates here).

Patient X has achieved/progressed on their goals of _____.

He/she has had difficulty with _____.

The group sessions are followed up with a 3, 6, and 9 month phone call. After each (or all??) phone call has been conducted you will receive a letter regarding the content of the phone calls including your patient's progress towards achieving their lifestyle goals and any barriers they may have encountered.

Yours Sincerely,

5. Phone calls: Letter sent from Division to GP following three month phone call

Letter sent from Division to GP following six month phone call

Letter sent from Division to GP following nine month phone call

Date _____

Dear Dr _____,

Re: *Live Life Well* Diabetes Prevention Program

Thank you for referring your patient _____ to the *Live Life Well* Diabetes Prevention Program. This new prevention program aims to help participants reach and maintain a healthy weight, be physically active and follow a healthy eating plan. The outcome of these lifestyle changes is a significant reduction in the risk of developing type 2 diabetes.

Your patient has attended an initial assessment and XX out of the scheduled three 2 hour group based sessions.

XX was discussed during the 3/6/9 month phone calls.

Patient X has achieved/progressed on their goals of _____.

He/she has had difficulty with _____.

Yours Sincerely,

6. Follow up appointment with GP:

Letter sent from GP to Division following four month follow up appointment with GP

Weight:

Waist circumference:

Optional clinical measures:

Letter sent from GP to Division following twelve month follow up appointment with GP

Weight:

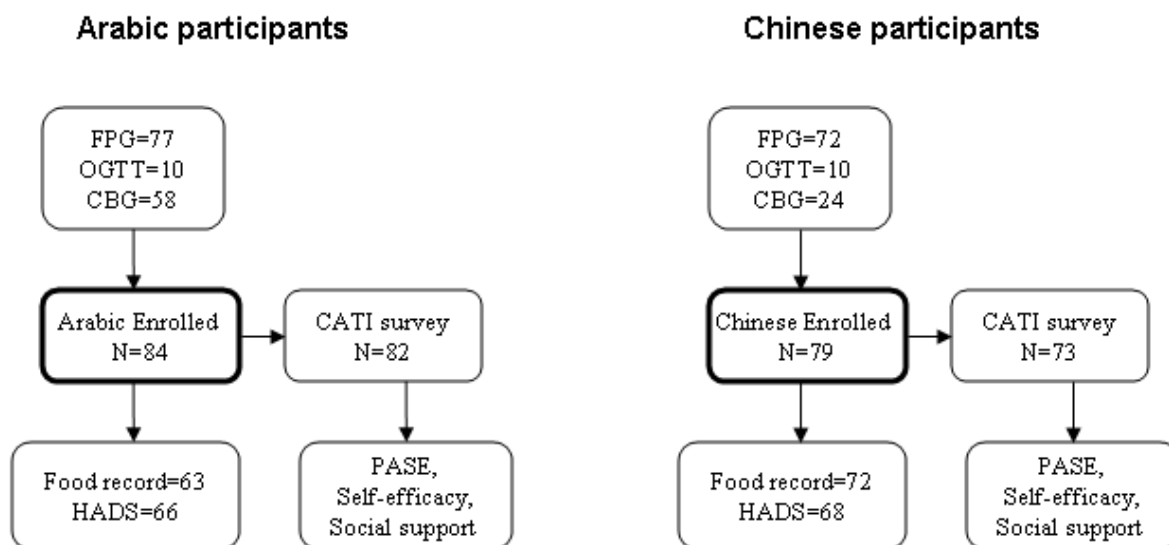
Waist circumference:

Clinical measures: blood pressure, lipids- HDL, LDL, TG, FPG

_____END of Lifestyle Officers Intervention Manual _____

Appendix 5.1 Completeness of program enrolment requirements for the Arabic and Chinese cohorts

Figure A5.1. Completeness of CATI survey, 3-day food record and blood tests by CALD cohort



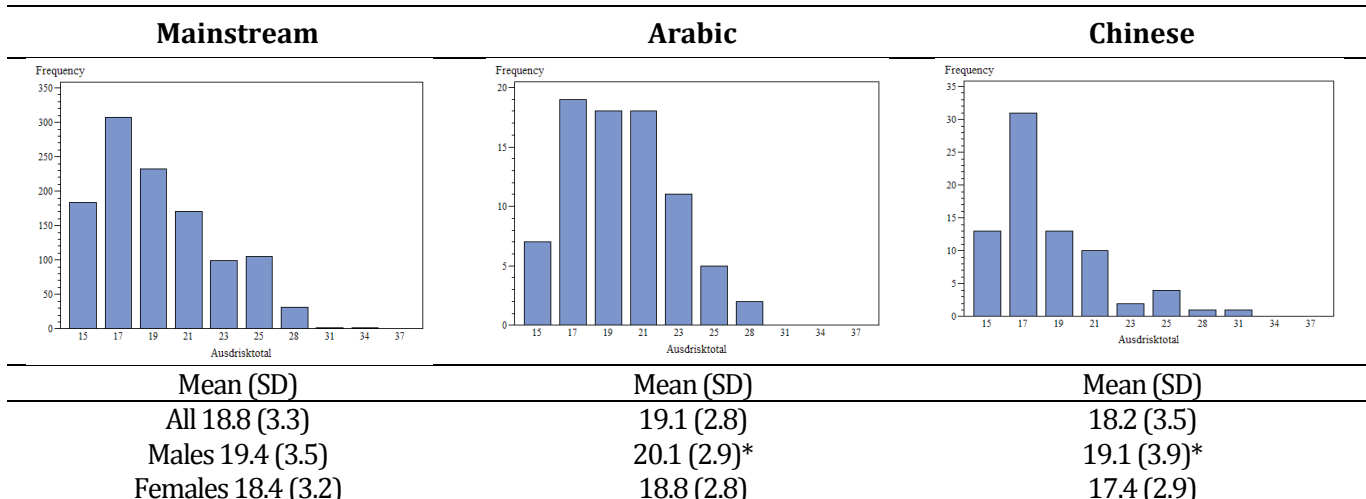
Participation rates in CATI survey were high at over 90% in both cohorts and relatively high for 3-day food record at 75% for Arabic and over 90% for Chinese participants.

Appendix 5.2 Prevalence of items (risk) on Ausdrisk by cohort at baseline

Distribution of self-reported risk factors from the screening tool by Ausdrisk levels in the mainstream cohort was: 66% high risk (Ausdrisk 15-19 or 1 in 7 a chance of developing diabetes in the next 5 years); and 34% very high risk (Ausdrisk 20 or above, with 1 in 3 odds of disease over the same period) as seen in Figure A5.2.

In the mainstream cohort, baseline values consistent with impaired fasting glucose (IFG) were 10.1% of those undergoing a fasting plasma glucose test; values consistent with impaired glucose tolerance (IGT) were 30% of those undergoing an OGTT. From the self-reported history of high blood sugar, 43% of the mainstream participants fell into the category of impaired glucose regulation during illness or pregnancy. Closer examination of the eleven Ausdrisk items is important to assess what components of the risk assessment tool are responsible for the classification of 'high-risk' among SDPP participants. In general, the individual risk factors that contribute the most to the total Ausdrisk score are increasing age (up to 8 points), waist circumference (up to 7 points), and personal history of high blood sugar (up to 6 points). High scores can be due to ethnicity, family history, age or sex (non-modifiable risk factors) or to large waist circumference, physical inactivity and poor diet (modifiable).

Figure A 5.2 Distribution of Ausdrisk scores: Total score and mean (SD) for each cohort. N total=1413



* $p < 0.01$ between males and females

For the mainstream participants, the distribution of individual components and their contribution of the Ausdrisk to the final risk score indicates that being of middle age, doing less than the recommended 2.5 hours of physical activity per week and having a 'high-risk' waist circumference were the most prevalent risk factors (Table A5.2a) Compared with the other two cohort, in the mainstream group there were significantly more older people, and higher proportions with personal history of hypertension and glucose impairment.

Among non-English speaking participants who had a FPG test for enrolment in SDPP,⁸⁵ the prevalence of IFG was 6.3% in the Arabic-speaking cohort and 11% in the Chinese. [1] Of those having an OGTT in the Arabic and Chinese cohorts, 30% and 20%, respectively, were classified as having IGT. From the Ausdrisk

⁸⁵ Potential participants were asked to fast for at least 8 hours and had a fasting plasma glucose or an oral glucose tolerance test to rule out diagnosis of diabetes before commencing the intervention. Diagnostic levels were consistent with the WHO classification of either diabetes, IGT, IFG or normoglycaemia. [WHO 1999]

self-report of personal history of high blood sugar, 14.3% of Arabic and 26.6% of Chinese participants fell into the impaired glucose regulation category.

In the SDPP, the prevalence of the Ausdrisk components making up the final score among the Arabic participants shows that being born in a high-risk country, being physically inactive, having family history of diabetes, having a 'high risk' waist circumference were the most common risk factors (Table A5.2) The Arabic cohort reported the strongest family history of diabetes, the highest smoking and physical inactivity rates, the lowest rates of daily vegetable and fruit consumption, and the highest proportions of 'high risk' waist circumference of the three cohorts.

Table A5.2 Distribution of risk score components from the Ausdrisk tool among participants by cohort. Number and proportion of participants within each screening tool domain. Total completing Ausdrisk: 1250 mainstream, 84 Arabic, 79 Chinese.

Ausdrisk component	Mainstream Males = 459 Females=791 N (%)	Arabic Males =18 Females=66 N (%)	Chinese Males = 34 Females=45 N (%)	P for difference across cohorts
Age group				<0.0001
50-54years	291 (23.3)	40 (47.6)	31 (39.2)	
55-64years	880 (70.4)	43 (51.2)	47 (59.5)	
65 years	79(6.3)	1 (1.2)	1 (1.3)	
Male	459 (36.7)	18 (21.0)	34 (43.0)	0.0040
High risk ethnicity¶	43 (3.4)	0.0	0.0	-
Born in high-risk countryΩ	162 (13.0)	82 (97.6)	77 (97.5)	<0.0001
Family history of diabetes	576 (46.1)	53 (63.1)	39 (49.4)	0.0096
Personal history of high blood sugar	542 (43.4)	12 (14.3)	21 (26.6)	<0.0001
On medication for hypertension	619 (49.5)	31 (36.9)	26 (32.9)	0.0019
Current smoker	135 (10.8)	24 (28.6)	6 (7.6)	<0.0001
No daily Vegetable and fruit intake	242 (19.4)	35 (41.7)	9 (11.4)	<0.0001
Do less than 2.5 hours of P.A./week†	657 (52.6)	63 (75.0)	52 (65.8)	<0.0001
WC high risk§	652 (52.2)	51 (60.7)	14 (17.7)	<0.0001
WC medium risk§	438 (35.1)	29 (34.5)	52 (65.8)	<0.0001

¶ Aboriginal, Torres Strait Islander, Pacific Islander or Maori

Ω Asia including India & China, or Northern Africa, Middle East or Southern Europe

† P.A. = Physical activity

§ WC high risk=7 points and medium risk=4 points

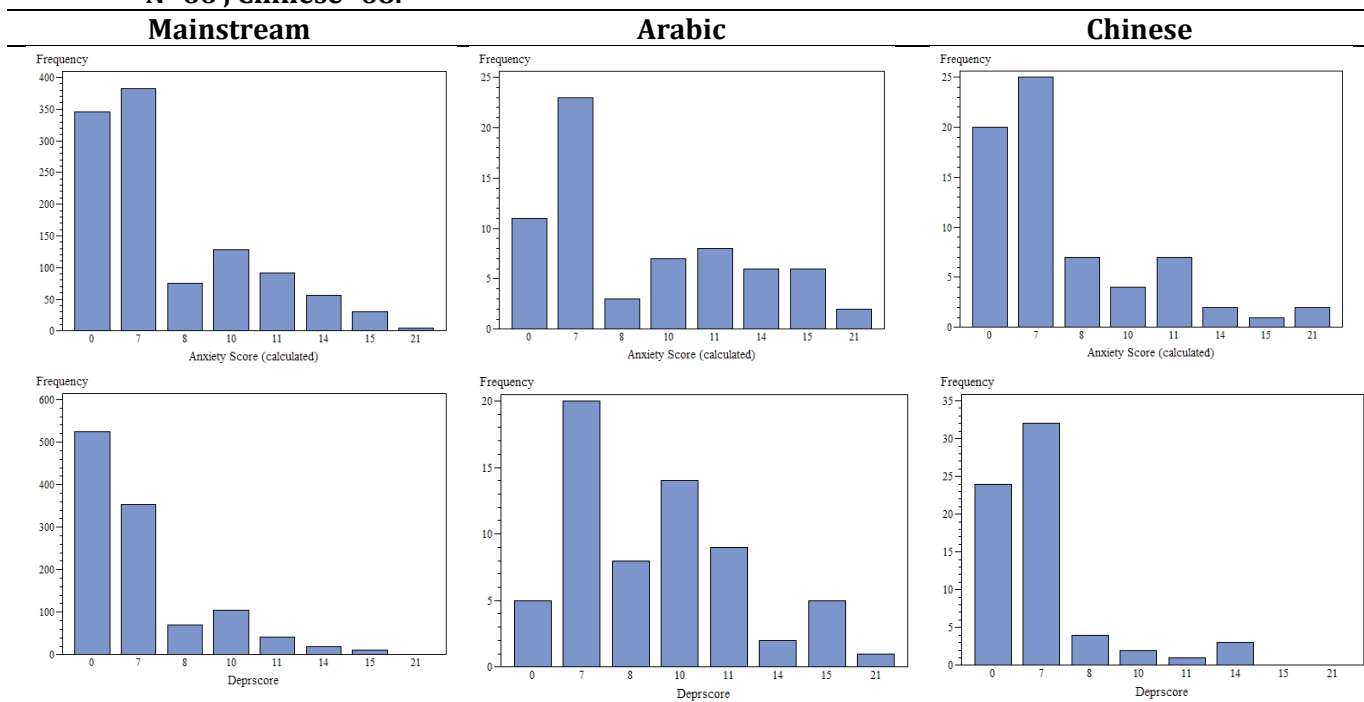
The Ausdrisk profile for the Chinese participants shows that being born in a high-risk country, being physically inactive, having a 'medium risk' waist circumference and being a male were the most prevalent components of the overall risk score. The obesity prevalence among the Chinese is notably very low even after using the lower BMI cut-off point of 27.5 Kg/m² as per WHO recommendation for Asian populations. [2] The prevalence of history of high blood glucose [3] was similar across the 3 groups and physical inactivity was the norm across cohorts.

Appendix 5.3 Mental health: distribution of HADS scores by sex across three cohorts

The distribution of anxiety scores among the mainstream participants is skewed, as expected, with most people (65.4%) scoring within the normal ranges (0-7). However, 31.4% fell into the mild to moderate anxiety levels and 2.8% scored at a level consistent with severe anxiety (15-21) as measured by the HADS (Figure A5.3). The mean anxiety score for females in the mainstream cohort were significantly higher than the scores for males but still mostly within normal ranges (**Error! Reference source not found.**). The depression scores for mainstream participants also fell mostly (78.2%) within normal ranges (0-7), and only 1% of the remaining 22% scored as 'severely depressed' (scores of 15-21).

The distribution among Arabic participants showed 48.5% reporting some level of anxiety (scores ≥ 8) and 12.2% reporting severe anxiety. Anxiety scores among Arabic females were significantly higher than for women in the other two cohorts (Table A5.3). Depression scores among Arabic participants were very different from the mainstream and Chinese participants. They showed 60.9% of Arabic participants scoring as depressed, with 9.4% scoring as 'severely depressed' according to HADS (Table A5.3). It is worth remembering that 70% of the Arabic participants are female.

Figure A5.3 Distribution of baseline anxiety (top row) and depression (bottom row) scores by cohort for those participants completing the HADS form. Mainstream N=1,123 , Arabic N=66 , Chinese=68.



In examining distribution of anxiety scores and selected socio-demographic factors, one in three of mainstream participants scored within the anxiety range Table A5.3. There were no statistically significant differences in depression scores between mainstream males and females.

Table A5.3 Distribution of HADS scores indicating baseline anxiety or depression by selected parameters. Participants completing HADS form only; N=1252: 1122 mainstream, 64 Arabic and 66 Chinese[¶]

	Any level of anxiety (score >7) N (% within cohort)			Any level of depression (score >7) N (% within cohort)		
	Mainstream N=1122	Arabic N=64	Chinese N=66	Mainstream N=1122	Arabic N=64	Chinese N=66
Overall prevalence	386 (34%)	32 (48%)	23 (34%)	245 (22%)	39 (61%)	10 (15%)
Sex						
Males	111 (10%)	5 (8%)	9 (13%)	78 (7%)	8 (13%)	4 (6%)
Females	275 (25%)***	27 (41%)	14 (21%)	167 (15%)*	31 (48%)	6 (9%)
Age group						
50-54	103 (9%)**	16(24%)	10 (15%)	71 (6%)*	23 (36%)*	4 (6%)
55-59	146 (13%)	5 (7%)	6 (9%)	89 (8%)	4 (6%)	1 (2%)
60-65	137 (12%)	11 (17%)	7 (10%)	85 (8%)	12 (19%)	5 (8%)
Education						
Primary school	11 (1%)	6 (9%)	3 (5%)	6 (0.5%)	7 (11%)	2 (3%)
Middle educ ⁸⁶	219 (22%)**	21 (32%)	12 (19%)	148 (15%)**	25 (40%)	6 (10%)
University	110 (11%)	4 (6%)	7 (11%)	59 (6%)	6 (10%)	1 (2%)
BMI						
Obese	241 (22%)	28 (42%)*	0 (0%)	164 (15%)*	31 (48%)	0 (0%)
Not obese	145 (13%)	4 (6%)	23 (34%)	81 (7%)	8 (13%)	10 (15%)

[¶] Note that totals in the table caption refer to those completing HADS questionnaire but N and % in the table refer to respondents out of all in their cohort completing HADS who scored high enough on HADS to classify as having anxiety or depression.

* $p \leq 0.05$ ** $p \leq 0.01$ *** $p \leq 0.001$ for differences within and across cohorts

Females, people with mid level education and older people in the mainstream cohort were significantly more likely to score in the anxiety range than their counterparts. Obese people appeared to be more likely to be anxious but the difference with the non-obese was not significant.

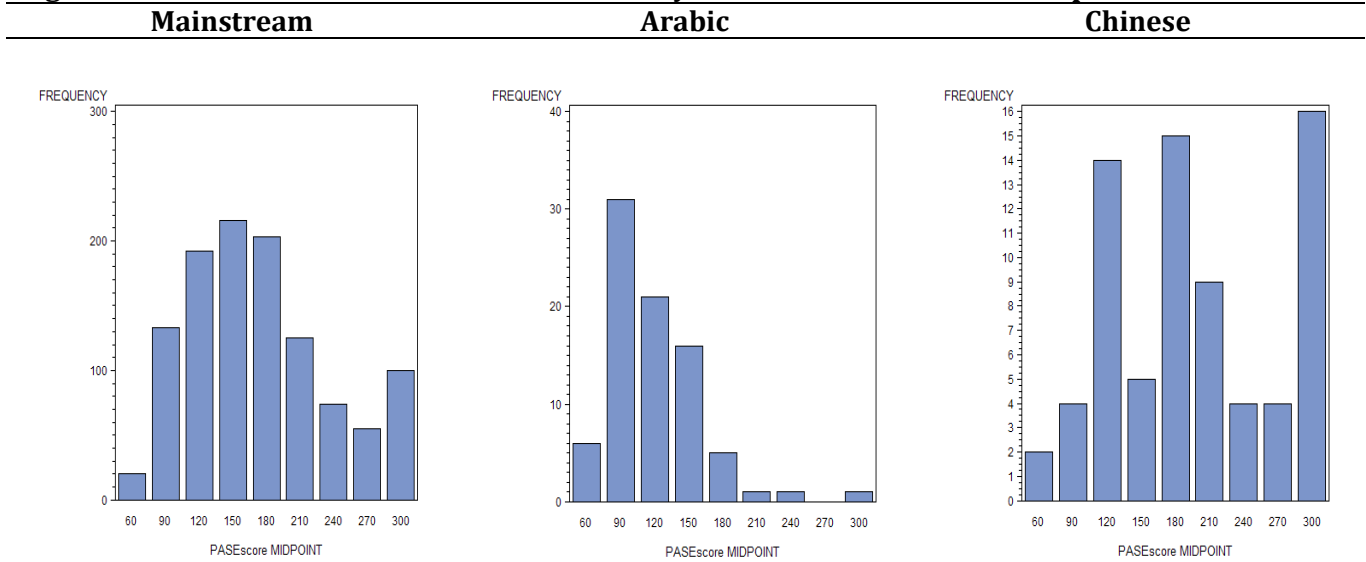
One in five mainstream participants scored as depressed as measured by the HADS. Older people, females, people with middle education and the obese were significantly more likely to score in the depressed range. One in every two Arabic participants scored within the anxiety range, with the obese being seven times more likely to be anxious. Almost two thirds of Arabic participants scored as depressed, with younger people significantly more likely to be in this category than the older age groups. Arabic obese females were more likely to score in the depressed and anxious range than Arabic males but the differentials were only statistically significant for anxiety. Chinese participants had similar overall prevalence of anxiety to the mainstream cohort but there were no differences by sex, age group or obesity levels within the cohort. Self-reported depression as measured by HADS was much lower among the Chinese and differences by sex, age or obesity levels could not be estimated due to small numbers.

⁸⁶ Includes people with incomplete and complete high school and TAFE/certificates

Appendix 5.4 Distribution of PASE scores at baseline

Out of the 1,250 mainstream participants, 1,137 participated in the CATI survey but complete data on the self-reported PASE questionnaire were available from 1,118. The distribution of PASE scores among the mainstream participants is relatively Normal (Figure A5.4). The distribution of PASE scores for the Arabic is skewed to the right, with fewer people on the lower end of the range. The distribution (median and interquartile range) of PASE scores for the Chinese more closely resembles that of the mainstream cohort but Chinese participants report higher levels of physical activity that make their PASE scores more widely spread, with larger proportions in the upper scores (Figure A5.4).

Figure A5.4 Distribution of overall PASE scores by cohort for baseline CATI respondents. N=1273.



The mean PASE scores of all three cohorts are significantly different from one another (Table A5.4a). Among mainstream, mean PASE score is significantly higher than that for the Arabic participants ($t_{test} = -11.86, p < 0.0001$) and significantly lower than that for the Chinese ($t_{test} = 2.62, p < 0.01$). The PASE score for Arabic participants was also significantly lower than that for the Chinese ($t_{test} = -7.8, p < 0.0001$).

Table A5.4.a PASE scores by cohort and by sex. Mean (SD)/median (interquartile ranges) for CATI respondents with complete PASE information. N total=1273.

PASE score	Mainstream N=1,118 Males=422; Females=689	Arabic N=82 Males=18; Females=64	Chinese N=73 Males=32; Females=41			
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
All	176.8(69.6)###	164.6 (125-211)	119.7(39.3)	118.1 (94-136)###	202.8(83.1)##	188.4 (129-277)
Males	197.3 (80.4)***	184.4(138-241)	120.6(53.7)**	122.4(75-140)	238.8(85.5)	212.2 (177-303)
Females	164.1 (58.7)	150.8 (122-195)	119.4 (34.8)	117.9 (97-135)	174.8 (70.3)	166.7 (118-215)
##	<i>p</i> ≤0.01 for differentials across cohorts					
**	<i>p</i> ≤0.01 *** <i>p</i> ≤0.001 for differentials between sexes within a cohort					

Within the mainstream cohort, the mean PASE score was significantly higher for males (ttest=7.35, *p* <0.0001); among the Arabic, there was no difference in mean PASE scores by sex (ttest=0.08, *p*=0.93); and among Chinese participants, males had significantly higher PASE scores than females (ttest=3.5, *p*=0.0008).

Unstructured physical activity from PASE

The major source of physical activity for this age group in the mainstream cohort seems to be walking and household work whether light or heavy type rather than structured physical activity (Table A5.4.b), with more than two thirds of the mainstream participants reported walking regularly and household chores. Males in the mainstream cohort were significantly more likely than females to work for pay or as a volunteer and be involved in lawn work and repairs (Table A5.4.b). Mainstream females reported significantly more involvement in light and heavy household work and caring for a dependent than their male counterparts. The mainstream participants were significantly less likely than the other two cohorts to report physical activity of caring for others, and females across the three cohorts were significantly more involved than the men.

Working people in all three cohorts performed mostly sedentary jobs but Chinese participants were more likely to report work involving heavy manual duties than the other two cohorts (*p*<0.01). On average, both males and females in the Chinese cohort are engaged in walking significantly more minutes per week than participants in the other two cohorts (Table A5.4.b) although the Arabic participants report larger proportions walking. Sex differentials within cohorts were only significant among the Arabic participants. Arabic women report significantly more involvement in walking than their counterparts in the other two cohorts (Table A5.4c. For the Arabic and Chinese participants, within-cohort sex differentials in proportions walking are not statistically significant, possibly due to small numbers). Males and females within the mainstream and Chinese cohorts seem to be equally engaged in light household work and gardening, while larger proportions of Arabic women report involvement in these activities than do men. The Arabic were significantly less likely to report engagement in paid or volunteer work lawn work and gardening than the other two cohorts. For the mainstream and Chinese, engagement in household work, lawn work and gardening were significantly higher than for the Arabic. Overall females reported significantly more engagement in household work and caring for a dependent across the three cohorts while men were more often involved in lawn work and repairs, with the exception of the Arabic males.

Table 5.4.b Percentage of CATI respondent participants engaged in various types of unstructured physical activity by cohort and sex. N total=1,273 CATI respondents with complete responses to PASE questions.

Unstructured Activity type	Mainstream N=1,118	Arabic N=82	Chinese N=73	p for difference across cohorts
Walking outside	78.4	93.9	86.3	0.0002
Males	79.1	100	87.9	0.1689
Females	78.2	92.2	85.0	0.0026
Work for pay/volunteer	52.1	25.6	60.3	<0.0001
Males	58.1**	47.6**	78.8**	0.0307
Females	46.7	19.7	46.3	<0.0001
Light housework	91.5	85.4	98.6	0.0064
Males	81.8	50.0	94.1	0.0005
Females	97.1***	95.5***	93.0	0.2757
Heavy housework	68.7	64.6	86.3	0.0033
Males	57.3	27.3	88.2	<0.0001
Females	76.7***	75.8***	76.7	0.3895
Lawn work	43.5	13.4	50.7	<0.0001
Males	59.4***	31.8**	58.8	0.0734
Females	31.7	9.1	39.5	0.0002
Gardening	55.0	4.9	41.1	<0.0001
Males	55.0	9.1	47.1	0.0002
Females	48.7	6.1	32.6	<0.0001
Caring for Other	26.1	36.6	35.6	0.0172
Males	19.1	19.1	24.2	0.7598
Females	32.2***	42.4	46.3**	0.0156
Repairs	16.0	0.0	15.1	0.0002
Males	28.5***	0.0	32.4***	0.0235
Females	7.0	0.0	0.0	0.0156

** $p \leq 0.01$

*** $P \leq 0.001$ for sex differences within cohorts

Table 5.4.c Estimates of walking duration in minutes per week by sex and cohort among CATI respondents at baseline (PASE questions). N=1273.

	Mainstream		Arabic		Chinese	
	Mean minutes/week k (SD)	Median minutes/week k (IQR)	Mean minutes/week k (SD)	Median minutes/week k (IQR)	Mean minutes/week k (SD)	Median minutes/week k (IQR)
Walking	208.3(290.0)	135 (45-180)	176.0(165.1)	120 (45-180)	309.5(366.0)*	180 (45-540)
g					*	
Males	241.7 (332.2)**	180 (45-180)	119.2(73.2)	105 (45-180)	317.7(418.5)	180 (45-270)
Females	188.1(259.5)	105 (45-180)	192.0(180)*	135 (45-315)	302.6 (321.7)	180 (105-540)

** $p \leq 0.01$ * $p \leq 0.05$ for differences within and across cohorts

Appendix 5.5 Comparison of socio-demographic characteristics of SDPP cohort with a NSW sample

Table A 5.5 Socio-demographic profile of the 50-65 year-old participants in the NSW Health population telephone surveys (N=7,836 in 2007-08) and the SDPP participants (N=1292 in 2008-2010).

Parameter	SDPP CATI respondents (2008-2010)				NSW Health Surveys (2007-2008)			
	Mainstream N=1,137	P for diff mainstream vs. all NSW	Arabic N=82	Chinese N=73	All SDPP	Whole of NSW	SSWAHS N=890	P for diff all SDPP vs. SSWAHS
Speak language other than English at home	7.2%	0.41	92.7%	98.6%	66.2%	7.9%	18.7%	0.37
Education level								
Primary school	2.2%	0.42	20.7%	6.9%	9.9%	2.6%	5.3%	0.22
Incomplete secondary /yr 7-10	30.9%	0.05	32.9%	17.8%	27.2%	33.8%	30.2%	0.05
HSC complete /year 12	12.8%	<0.0001	24.4%	32.9%	23.4%	13.6%	15.1%	0.31
TAFE certificate/diploma	18.2%	<0.0001	6.1%	5.5%	9.9%	23.2%	19.9%	0.61
University degree or higher	35.9%	<0.0001	15.9%	37.0%	29.6%	25.7%	27.2%	<0.0001
Employment								
In paid employment	60.4%	<0.0001	25.3%	53.9%	46.5%	52.8%	53.7%	<0.0001
Unemployed or unpaid job	39.6%	<0.0001	74.7%	46.1%	53.5%	47.2%	46.3%	<0.0001
Covered by private health insurance	66.3%	<0.001	26.4%	48.0%	46.9%	60.4%	55.3%	<0.0001
Household Income range								
Up to \$20,000	14.9%	<0.0001	31.7%	6.3%	17.6%	20.6%	22.1%	<0.0001
>\$20,000-60,000	24.6%	<0.0001	11.0%	50.0%	28.5%	35.6%	31.4%	<0.0001
>\$60,000-80,000	11.2%	0.22	1.2%	6.3%	6.2%	10.0%	10.0	<0.0001
>\$80,000	28.9%	<0.0001	2.4%	18.7%	16.7%	19.9%	20.7%	<0.0001
Refused /Don't know	20.4%	<0.0001	53.7%	18.7%	30.9%	14.0%	15.8%	<0.0001

Comparisons of the mainstream cohort with an age-matched *whole of NSW* survey sample (p testing the difference in the third column of Table A5.5) suggest that the proportions speaking a language other than English at home were similar for mainstream participants and the whole of NSW sample.

The statistical comparisons also reveal that the SDPP mainstream participants are significantly less likely to hold a TAFE certificate but more likely to hold a university degree and to be in paid employment than the age-matched NSW population. Mainstream SDPP participants are also more likely to report being in paid employment and being covered by private health insurance. Of those responding the income question (SDPP were also more likely to decline answering this question), larger proportions reported being in the higher income brackets than their NSW counterparts.

For the aggregated SDPP sample including Arabic and Chinese sample, the proportions speaking a language other than English at home were not statistically significantly different from the SSWAHS (last column in Table A5.5). Non-English language was a reason for recruiting these two cohorts separately from the mainstream. Compared with the overall SDPP and CALD participants, the differences in education with SSWAHS were only significantly different for tertiary education. SSWAHS had smaller proportions of people completing tertiary education than the SDPP sample participants of all three cohorts.

SDPP participants including the CALD groups were less likely to be in paid employment or be covered by private health insurance than their SSWAHS counterparts.

Comparisons with the SSWAHS survey sub-sample (last column in Table A5.5) suggests that the whole of SDPP CALD and mainstream aggregated sample is significantly more likely to refuse to answer the income question and among those responding they are less likely to report being in the higher income brackets. Further, due to the impact of the Arabic sample, the overall SDPP is also significantly less likely to be covered by private health insurance or be in paid employment as the SSWAHS counterparts.

Appendix 5.6 Comparison of selected risk factors and morbidity profile of SDPP participants with the 2008 NSW Health Survey sample

Table A 5.6 Comparison between SDPP participants and the 50-65 year-old participants in the NSW Health population telephone surveys (2008). N= mainstream 1,137, Arabic 82, Chinese 73.

Parameter							NSW Health Surveys (2007-2008)		
	SDPP mainstream	P for difference mainstream vs. NSW	SDPP Arabic respondent s	SDPP Chinese respondent s	All SDPP subjects	P for difference SDPP vs. SSWAHS	Whole of NSW N=4,735	SSWAHS N=890	
% obese**	61.2%	<0.0001	70.2%	13.9%	48.4%	<0.0001	26.7%	28.2%	
Males	56.2%	<0.0001	57.9%	17.1%	43.7%	<0.0001	25.6%	27.3%	
Females	64.6%	<0.0001	73.9%	11.4%	50.0%	<0.0001	27.5%	28.9%	
Current regular smoker	8.9%	<0.0001	15.9%	5.5%	10.1%	<0.0001	14.5%	18.1%	
Regular drinker ⁸⁷	73.9	<0.0001	18.2%	30.1%	40.7%	<0.0001	80.3%	75.5%	
No chronic conditions	6.7%	<0.0001	14.6%	13.7%	11.7%	<0.0001	51.7%	46.2%	
Suffers from asthma	18.1%	0.36	12.2%	16.4%	15.6%	0.84	19.3%	18.0%	
Suffers from hypertension	55.6%	<0.0001	40.2%	38.4%	44.7%	<0.0001	24.4%	20.3%	
Has high cholesterol	47.5%	<0.0001	35.4%	50.7%	44.5%	<0.0001	23.0%	26.4%	
Self-assessed health good to excellent	73.3%	0.19	37.8%	39.7%	50.3%	0.15	71.3%	66.2%	

⁸⁷ Defined as someone who drinks alcohol more than one day per week

...continued - Table A 5.6 comparisons of selected risk factors between SDPP participants and NSW Health Survey participants

Parameter	NSW Health Surveys (2007-2008)				
	SDPP mainstream	SDPP Arabic respondent s	SDPP Chinese respondent s	Whole of NSW N=4,735	SSWAHS N=890
Body mass index					
Males (median-IQR)	30.9 (28.2-34.8)	30.8 (27.7-34.1)	25.0 (23.8-26.9)	26.8 (24.4-29.9)	27.4 (24.6-30.3)
Females (median-IQR)	32.0 (28.4-36.3)	32.9 (29.8-37.9)	24.4 (22.5-25.6)	25.8 (22.8-30.1)	26.2 (23.1-30.2)
Minutes walking last week					
Males (median-IQR)	180 min (45-180)	105 min (45-180)	180 min (45-270)	120 min (30-240)	120 min (20-240)
Females (median-IQR)	105min (45-180)	135min (45-315)	180 min (105-540)	120 min (40-240)	120 min (30-210)
Moderate/vigorous PA/week					
Males (median-IQR)	0 min (0-105)	0 min (0-0)	0 min (0-135)	0 min (0-180)	0 min (0- 140)
Females (median-IQR)	0 min (0-45)	0 min (0-0)	0 min (0-0)	0 min (0-90)	0 min (0-20)

* *paid or unpaid*

** *% within each sex who are obese; NSW survey data for 2008 only due to large numbers missing BMI in 2007*

Comparison of the morbidity and risk factor profile of mainstream SDPP cohort with the overall NSW Health survey sample (3rd column in Table A5.6) shows that the SDPP participants have more than twice the rate of obesity estimated for the overall NSW population. The difference is significant for both sexes, males in particular. Mainstream SDPP participants are also significantly less likely to be regular smokers or drinkers, possibly as a consequence of their underlying comorbidities. The NSW population sample is significantly healthier sub-population, with half the surveyed people in the NSW group reporting absence of comorbidities, while the corresponding figure for SDPP was significantly lower (~72%). NSW age-matched residents also reported half the hypertension and high cholesterol rates of those reported by the mainstream SDPP. No statistically significant differences in the prevalence of asthma or self-assessed health were observed.

Comparing all SDPP participants including the two CALD cohorts with the SSWAHS telephone survey respondents (7th column in Table A5.6) shows that SDPP participants reported twice the rates of obesity, hypertension and high cholesterol as the SSWAHS residents overall. SSWAHS residents reported almost twice the smoking rates of the SDPP counterparts. Rates of regular alcohol drinking in the overall SDPP-CALD participants were about half of those in SSWAHS. The proportions of SSWAHS reporting no chronic conditions was significantly lower than the proportion in SSWAHS.

However, the NSW Health sample, the SSWAHS sample and the three SDPP cohorts are largely sedentary, reporting less than 30 minutes per day of walking and very low engagement in moderate or vigorous physical activity (median of zero minutes for all groups).

References

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Appendix 6.1 SDPP evaluation governance and committee representations

SDPP Evaluation Management Group

The role of the EMG is to guide and oversee the development and ongoing data collection and analysis to ensure the evaluation is rigorous and high quality. Further the EMG will lead the interpretation and analysis of the results of the SDPP evaluation. To support this function, the SDPP Research Committee (RC) has been formed as a sub-committee of the Steering Committee. The RC reports to the Steering and Executive Committees. Initially this group will meet on a regular basis (every 4-6 weeks). Once the project is in the ongoing implementation phase, the frequency of meetings will be reviewed.

Composition: Representatives from Sydney South West Area Health Service, University of Sydney evaluators, New South Wales Health headquarters, Centre for Health Program Evaluation, University of New South Wales.

SDPP Steering Committee

The Steering Committee has the role of providing strategic advice and guidance related to operational, implementation and evaluation aspects of the program. This Committee has a broad representation of all program stakeholders. All relevant documentation related to the evaluation of the SDPP will be tabled with the Steering Committee for review, discussion and subsequent endorsement. Once evaluation documentation has been endorsed by the Steering Committee, it will be tabled with the Executive Group for final approval.

The Steering Committee meets quarterly and its composition includes representatives from Sydney South West Area Health Service, University of Sydney evaluators, New South Wales Health headquarters, Centre for Health Program Evaluation, Macarthur Division of General Practice, Southern Highlands Division of General Practice, Central Sydney GP Network, Australian Diabetes Council, University of New South Wales and Boden Institute of Obesity Nutrition and Exercise.

SDPP Executive Group

The Executive Group will provide final approval for the evaluation plan and other documents related to the ongoing evaluation including reporting as well as the analysis and interpretation of data. This group will monitor the progress of the evaluation throughout the course of the program.

The Executive Group meets as required and has evaluation team representation.

Appendix 6.2 Process Evaluation Protocol

Purpose of the process evaluation

The process evaluation of the SDPP will assess:

- the reach of the program into the primary health care setting;
- the reach of the program into the community-setting;
- the reach of the program into the target population group;
- the acceptance of the program within the primary health care setting;
- the extent to which the program was delivered through the primary health care system; and

Specifically, the process evaluation will address the following questions.

1. Did the program engage with all potential stakeholders e.g. AHS, DGPs, general practice?
2. Who was screened for the program?
3. Who was recruited to the program?
4. What was the program reach (did the program recruit the target population)?
5. Were there any groups within the target population not reached by the program?
6. How well was the program delivered and implemented?
7. Was the program delivered as intended?
8. Did program participants access community-based programs during the course of the program?

To assess the acceptability and fidelity of the program the evaluation will measure the level of engagement of key stakeholders; project acceptance with all stakeholder groups; rates of participant recruitment and the representativeness of people who participate in the program. This includes identifying those populations least reached by this intervention. Further, quality of program delivery in different settings will be measured. Descriptive statistics will be used to compare characteristics of participants and non-participants should minimum demographic data are available on the latter group.

Evaluation of program screening and recruitment of participants

Monitoring and tracking screening and recruitment processes and progress is an important part of not only the process evaluation but also quality assurance of the overall program.

Data collection tools, methods and procedures

Participating practices will monitor screening and recruitment rates within their own Practice. During the screening and recruitment phase they will provide the relevant DGP with a list of the number of people, in their practice, who have:

- a. been sent a letter inviting them to complete a type 2 diabetes risk assessment; and/or
- b. been approached opportunistically to complete a type 2 diabetes risk assessment; and
- c. completed a type 2 diabetes risk test;
- d. a risk score ≥ 15 ; and
- e. been referred to the program.

The Program Coordinator (or LO as delegated) will provide the Program Implementation Team (PIT) with a weekly or monthly (as convenient) list of total numbers within their Division of people (stratified by sex) who have:

- a. received a letter inviting them to complete a type 2 diabetes risk assessment;
- b. been approached opportunistically to complete a type 2 diabetes risk assessment;
- c. completed a type 2 diabetes risk assessment; and
- d. been referred to the program.

The form in which this data will be provided to the PET can be found in attachment P1. Initially completed forms will be provided to the respective Division Coordinators each week, but this may become less frequent towards the end of screening and recruitment.

In addition, the Divisions will routinely provide the PIT with the original copies of each individual type 2 diabetes risk assessment (regardless of the risk score) which includes the respondent's date of birth, sex and a unique ID.

Completed referral forms will be forwarded on a regular basis to the PIT. Referral forms will have clinical lab results & medications and when applicable medical reasons for why patient did not participate or were not referred to the program.

Data from the risk assessment and referral forms will be entered into the participant database which is used by the LOs to manage their participants. The participant database is also used by the PIT and PET to monitor program activity and progress as well as access key clinical (CBG, FPG, HbA1c), anthropometric (BP, weight, height, waist) and socio-demographic data on each participant. All data is de-identified for the purposes of evaluation.

Analysis of program screening and recruitment

The aim of this analysis will be to examine the rates of screening and patient recruitment in general practice and ascertain interest in participation in the program in the target group. This analysis is also designed to determine the extent to which the program reaches the target population. Specific analysis that may be undertaken include:

- Overall consent rates for risk score screening. The number of people completing a risk assessment over number of patients sent invitation letters and opportunistically approached to be screened.
- The proportion of those people who completed a risk score who fell into one of the following categories.
 - At risk of type 2 diabetes; risk score ≥ 15 (AUSDRISC) (key target group).
 - Have undiagnosed or likely type 2 diabetes (ineligible to participate in the program).
 - Have other metabolic and/or cardiovascular risk factors. or are ineligible for other health reasons
 - Have a risk score < 15 and therefore not in the target group for this program.
- Overall consent rates for participation: The number and proportion of high-risk individuals who met eligibility criteria and also gave consent to participate in the Program (based on referral forms).
- Comparison of the profile of SDPP participants with the SSW population.
- The number and proportion of individuals who refused to participate in the group-based program and were offered individual lifestyle module via telephone.
 - Frequency distribution of reasons for refusal and program drop-outs.

Evaluation of information and training sessions

As part of the implementation of the SDPP, a manual has been produced to support and guide Practices in screening and recruitment. Additionally each participating Practice will receive a face-to-face information and training visit from either the PIT or relevant Division. Assessing GP and practice staff satisfaction with these sessions and knowledge acquired will be an important part of ongoing quality assurance as well as the process evaluation.

LOs and other relevant SDPP team members will also take part in training sessions to support the delivery of the intervention i.e. individual consultation, group-based sessions and follow-up

phone calls. Assessing satisfaction with this training and knowledge acquired will also be an important part of the ongoing quality assurance as well as the process evaluation.

Data collection tools, methods and procedures

Following their participation in training or information sessions, a randomly selected sample of GPs in Southern Highlands and Macarthur and other staff from each practice will be asked to respond to a 'satisfaction and knowledge questionnaire'. This will be administered either over the telephone or by email ideally within a week of training to minimise recall bias. The purpose of this will be to assess provider satisfaction with the training on the three aspects of screening, recruitment and referral, and associated materials, as well as ascertain short-term impact of the training session by assessing basic knowledge. Results will assist in identifying areas for future improvement.

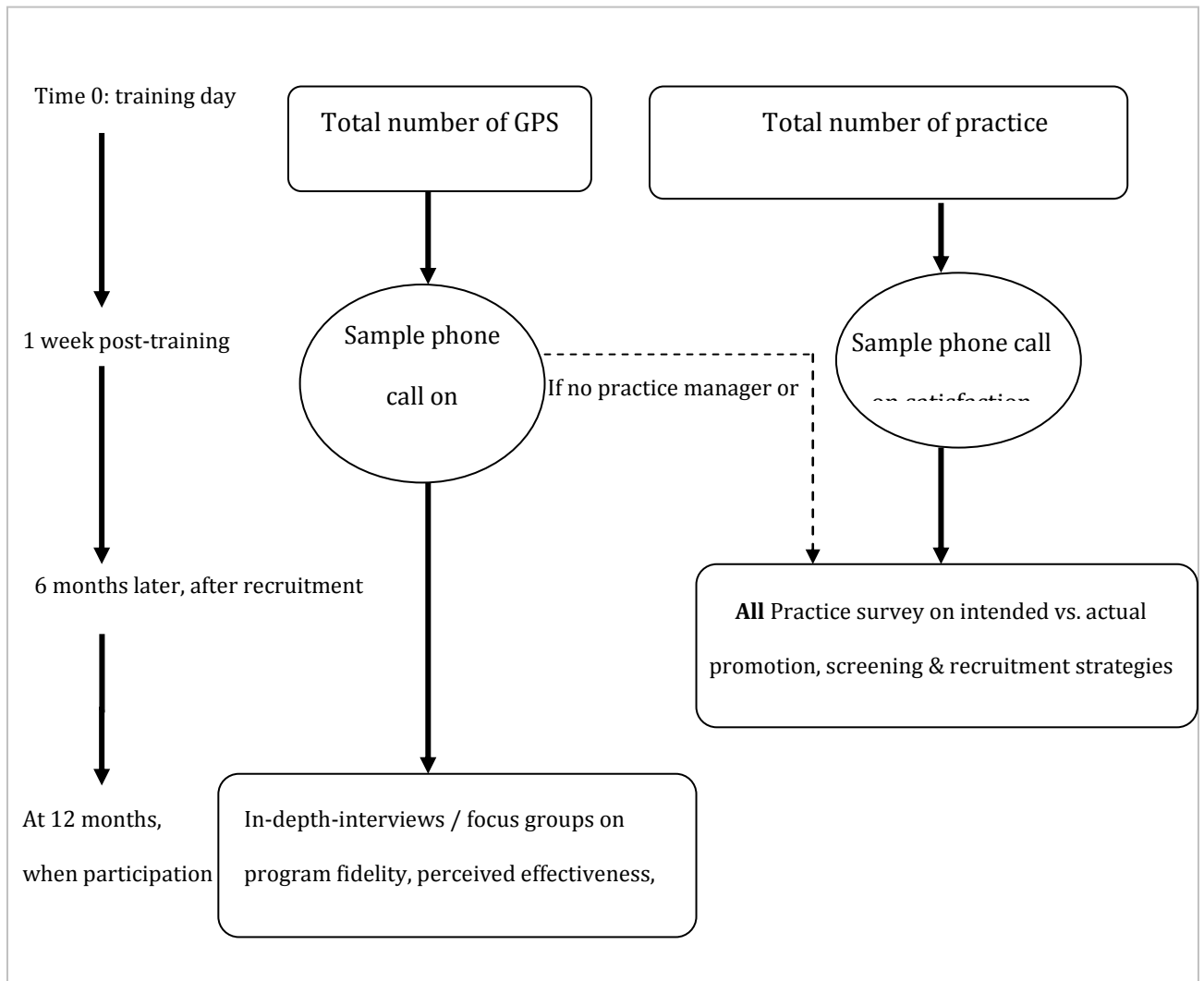
These brief telephone surveys will be conducted by the PET or other SDPP staff not involved in the training, at intervals specified in the Figure below. The specific details of the questions to be included are shown in attachment P2. Some questions will be relevant to GPs and some to other practice staff, according to their role in the program and depending on the screening and recruitment approach in each medical practice.

In Central Sydney General Practice Network all GPs trained in the program will have an opportunity to respond to the questionnaire regarding their satisfaction with the training. In this Division the survey will be administered using an on-line computer-based survey which can be completed at a time convenient to the GP. The link for the on-line survey will be provided to the Division by the PET. The Program Coordinator will email all GPs who have received training, providing them with this link. Should a GP request a written copy of the survey or wish to complete the survey over the telephone, this will be arranged.

At approximately six-months following program commencement or after recruitment in each practice has been completed, an additional survey may be emailed to all practices to explore any discrepancies between strategies planned for recruitment and strategies actually implemented. Alternately, the relevant Division Liaison Officer (from the PIT) will gather this information from each of the participating DGPs and provide to the PET. A possible data collection form can be found in attachment P3.

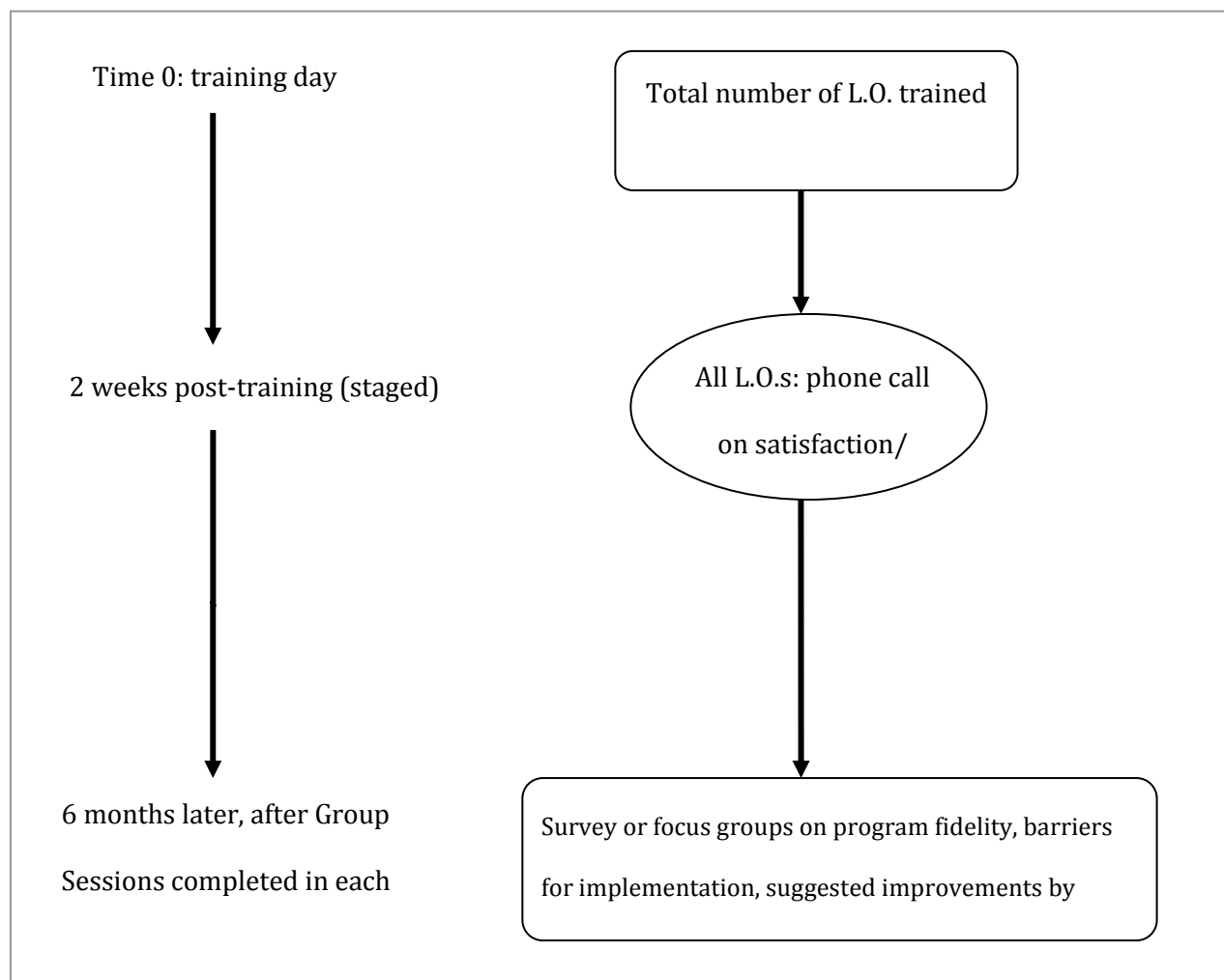
In addition, at the conclusion of the program, a random sample of participating GPs, stratified by Division and practice type, **may** be invited to participate in either in-depth interviews or focus group discussions to investigate barriers to fidelity in program implementation, perception of the program effectiveness, and perceived usefulness of the SDPP in improving patient's risk factors and health outcomes (see focus group guide at attachment P4).

Figure P1. Evaluation of training and implementation for GPs and practice staff



To assess LOs satisfaction with training, confidence in program delivery and perceived usefulness of components of program materials, focus groups to discuss barriers may be conducted the majority of aspects of the program have been delivered. The facilitator’s guide for focus group discussions targeting LOs can be seen at attachment P5.

Figure P2. Evaluation of lifestyle officer's involvement



Analysis of training sessions evaluation for SDPP staff

Analysis of data from qualitative information from GPs, practice staff and LOs on the implementation and information sessions will report:

- The number of practice staff attending information and training sessions;
- GP satisfaction with information and training sessions;
- GP satisfaction with the resources provided to support the program;
- GP understanding and knowledge of and confidence in the various stages of the program;
- GP perceived barriers and success factors;
- LO satisfaction with training provided to support the delivery of the program;
- LO satisfaction with resources provided to support the delivery of the program and basic knowledge acquired; and
- LO perceived barriers for program fidelity and implementation.

Evaluation of program reach (staff & participant-related)

Data collection tools, methods and procedures

The participating Divisions recruit practices and general practitioners to the SDPP. It is anticipated that across each Division there will be some differences in the methods and processes used to recruit practices and general practitioners to the program. Participating Divisions will document number of practices and individual general practitioners who participate in the program as well as tracking the number of practices and GPs who subsequently withdraw from the program. This information will be gathered prospectively as recruitment is being undertaken in each Division. The questions that will be used to gather this information can be found in attachment P6.

The LOs will track whether individual participants opt for the group-based or telephone-based sessions. This information will be entered into the participant database and accessed by the PET for evaluation purposes.

Analysis of program reach

These analyses will examine the program reach and identify possible explanations for non-participation and rationale for why participants take part in the group-based sessions or take up the option of telephone-based sessions when it is offered to them.

The following analyses may be conducted to assess program reach and delivery.

- Number of Practices and general practitioners recruited to the program (and as a proportion of total Practices and general practitioners within the Division).
- Reasons why Practices and general practitioners decide not to participate or are not considered suited to recruitment to the program.
- Practice staff participation rates by type (practice managers, receptionists, practice nurses,) per Division.
- General cross-tabulations of demographic profile of program participants: age, sex, socio-economic position (education, employment, income, private health insurance, pension, distribution of diabetes risk levels (quartiles), number of co-morbidities and mental health score (SF-12).
- Participants' demographic profile by Division of General Practice (metro, rural, semi-urban) Comparison with non-participants by age, sex, GP Division and risk score.
- Distribution of attendance to various community-based services (including those newly established) by participants at various time points.
- Reasons for attendance and non-attendance of SDPP-assessed programs/services.

Evaluation of program delivery (participants)

Data collection tools, methods and procedures

Following the group-based sessions or telephone-based sessions participants will complete a program evaluation form (attachment 7). This will gather information on participants' satisfaction with the group-sessions or telephone based-sessions as appropriate and provide written feedback on the program.

Additional process data will be gathered as part of the routine 3-, 6- and 9-month follow-up calls (See appendices in Chapter 4). A survey has been developed to be completed by LOs as part of or after the phone call has taken place.

Analysis of program delivery at 3-months

The aim of analyses of program delivery will be to:

- determine participant satisfaction with the group-sessions or telephone sessions;
- determine the proportion of participants' accessing programs and services on the community-providers list;
- ascertain participant's preferences for type of community-based programs, satisfaction with their chosen programs;
- determine level of program fidelity and quality both overall and by Division.

Univariate analyses at 3-months

The following analyses might be undertaken as part of the univariate analysis at 3-months.

- The number and proportion of people indicating they had been referred to SDPP approved community providers of physical activity, weight management or healthy eating programs or facilities.
- The proportion of participants who access, use or join these facilities and programs.
- The number and proportion of participants who are satisfied with their chosen community based programs and reasons for their satisfaction or dissatisfaction.
- The number and proportion of participants who access other community providers of physical activity, weight management or healthy eating programs.
- The number and proportion of participants who are satisfied with these 'other' venues and reasons for their satisfaction or dissatisfaction.
- The number and proportion of participants who do not access any community providers of physical activity, weight management or healthy eating programs.
- The number and proportion of participants who take up a combination of home-based and community-based options.
- The number and proportion participants who use pedometers and weights (dumbbells & ankle weights) regularly.
- The number and proportion of participants who choose to take up the 3 telephone-based sessions instead of the 3 group-based sessions.
- Overall drop-out rate for each intervention modality at three months.

Bivariate analyses at 3-months

The following analyses might be undertaken as part of the bivariate analysis at 3-months.

- The number of group-based sessions delivered in each of the Divisions of General Practice. (This will be different in each Division as the number of program participants will vary across the Divisions).
- Number and proportion of participants attending 3 group-based sessions and perceived quality of program delivery of group sessions at different sites by Divisions of General Practice.
- The number of participants in each Division who opt for the telephone-based sessions.
- Number and proportion of 'individual module' participants receiving 3 phone calls.
- The quality of program delivery of the group-based and telephone-based sessions.

Data Analyses at 6 and 9-months

The aim of analysis at this stage is to determine the level of adherence with the program several months after the group-based or individual telephone sessions have ceased. This is an aspect of implementation of maintenance of lifestyle behavioural changes.

The following might be undertaken as part of the 6 and 9-months analyses.

- The number and proportion of participants still accessing community providers of physical activity, healthy diet and weight loss programs and facilities at 6-months and 9-months.

- The number and proportion of participants who receive 6 and 9-month follow-up phone calls from lifestyle officers. Lifestyle officers will note reasons (when available) for non-contact with participants e.g. repeated no answer, asked not to call.
- The number and proportion of participants who adhere to program requirements (diet and physical activity).

Evaluation of overall SDPP program delivery at 12-months

While these analyses are exploratory and mainly descriptive, the information will enable the evaluation to ascertain stakeholder engagement, program adherence, difference in program delivery between DGP as well as enablers and barriers to successful program implementation.

Data collection tools, methods and procedures

In the latter stages of the evaluation after completion of all participation, selected process indicators on satisfaction with the collaboration may be documented from in-depth interviews or focus groups with key stakeholders in the program. This may include: Division Coordinators, Lifestyle Officers and other key Division stakeholders, practice staff and GPs and AHS staff (see focus group guide at attachment P8).

In addition, selected data items may also be gathered from DGP and SSWAHS records, such as updates of the list of community providers consistent with the goals of the SDPP, establishment of community-based programs where there was an identified and participant's access to the facilities on the list as well as other programs and facilities. Further, information on which community-based programs/services are used by participants throughout the SDPP will be documented at the follow-up phone calls with the LOs as well as the 12-month CATI.

Data Analyses of overall program delivery at 12 months

Data from the in-depth interviews or focus groups will allow for thematic interpretation which involves text analysis techniques to extract, order, code, reduce in matrices or diagrams, summarise and integrate the key salient points from the transcripts of the groups.

The following qualitative analyses might be undertaken as part of the assessment of overall program delivery.

Stakeholder engagement

- The number of organisations participating in SDPP (& no. of people from each)
- The type and characteristics of the organisations participating in SDPP
- Perceived level of usefulness of the collaboration
- Barriers and success factors for establishment of community-based programs/services for physical activity and weight management

Program delivery

- Factors which enabled and/or facilitated the implementation of the SDPP as intended in the participating DGPs.
- Barriers to implementation of the SDPP as intended in the participating DGPs.
- Differences in delivery of the program between the participating DGPs.
- Satisfaction with program among participating DGPs.
- Numbers of community-based Programs/services accredited as meeting our SDPP criteria.
- Number and proportion of participants attending at least one community-based Programs/services by the end of the intervention

Attachments for Process Evaluation can be seen in the following pages.

Attachment P1- Practice screening and recruitment record

Live Life Well Sydney Diabetes Prevention Program (insert logo)

Practice screening & recruitment record

This form is for recording the screening and recruitment of participants to the *Live Life Well Sydney Diabetes Prevention Project*. This form will help you monitor and track screening and recruitment in your Practice.

Completed forms will need to be sent to the XXX Division of General Practice each week.

Instructions:

1. Fill in your contact details (in case we need to contact you for clarification or additional information)
2. Fill out the dates/time period that this form relates to
3. On each day of the week, please record the **number of males** and the **number of females** in the Practice who have:
 - a) been mailed a letter inviting them to participate in the project;
 - b) completed a Diabetes Risk Score Tool; and
 - c) been referred to the program.
4. Write down any additional comments you feel are relevant in the lines at the bottom of the form
5. Fax this form at the end of **each week** to XXX at XXX Division of General Practice on XXX.

Name of person completing this form: _____ Contact number: _____

Email: _____ Position: _____

Surgery name: **(pre-filled out)** Surgery address: **(pre-filled out)**

Time period: from __/__/20__ to __/__/20__

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
	male female	Male female	Male female	Male female	Male female	Male female	male female
a) No. people sent invite letter							
b) No. people completed risk tool							
c) No. people referred to program							

Comments _____

Attachment P2 – GP Training evaluation

Division name _____

Participant ID (from random list) _____

Role GP Other staff

Following the training visit from the Sydney Diabetes Prevention Program team, we, the evaluation team, would like to find out your views on the quality of the training you received and your perceived level of confidence to implement the program in your practice. The information you give us will be treated confidentially and analysed anonymously. Results will be used to improve the training in the future. The first few questions are about the materials used during training.

1 On a scale of 1-5 (1 being poor and 5 being excellent) please rate the following aspects of the *Screening and Recruitment Manual for Practices*.

	Rating
Description of the screening and recruitment process for the SDPP	
Clarity of instructions provided about the screening and recruitment process.	
Clarity of instructions about the recruitment tally sheet	

2	If you did <u>not</u> find some aspects of the training Manual clear or useful (rating of 3 or less above) ,please specify why

3 What aspect of the information session did you think most important and Why?

4 Was there any information that you thought important but was not covered in the training or in the materials?

5 Having completed the instruction on all the processes involved,

5a	How would you rate your overall understanding of the <u>purpose</u> of the Sydney Diabetes Prevention Program?						
<input type="checkbox"/>	Excellent	<input type="checkbox"/>	Very good	<input type="checkbox"/>	Good	<input type="checkbox"/>	Fair/Poor
5b	How confident are about your understanding of <u>your role</u> in the program						
<input type="checkbox"/>	Very confident	<input type="checkbox"/>	Somewhat confident	<input type="checkbox"/>	Not confident at all	<input type="checkbox"/>	Undecided
5c	How confident are you that your practice will screen and recruit the numbers of patients expected to be referred to the program?						
<input type="checkbox"/>	Very confident	<input type="checkbox"/>	Somewhat confident	<input type="checkbox"/>	Not confident at all	<input type="checkbox"/>	Undecided

5d Can you remember the 5 goals of the program? Or some of them?	Correct Answer (explicit)	Correct answer (broad)	Incorrect Answer or cannot remember
Increase physical activity to at least 30 minutes per day of purposeful activity			
Reduce fat intake to 30% of total energy intake			
Reduce saturated fat to 10% of total fat intake			
Increase fibre consumption to 15g per 1,000kcal (approx. 30g per day)			
Reduce weight by 5%			

(FOR ALL)

6. Can you remember what happens to participants after the referral is completed?

- Initial consultation with lifestyle officer
 - Attendance to Group Sessions where instruction and demonstration are given
 - Participants have to join structured physical activity program or do regular exercise on their own
 - Participants have to follow a nutrition/weight loss program or follow their own diet
 - Participants have to see the GP at 4 months and 12 months
 - Lifestyle officers ring the participant three/several times during the year
-

(FOR GPS ONLY)

7 How confident do you feel about:

a. identifying and inviting potentially eligible participants?

- Very confident Somewhat confident Not confident at all Undecided Not applicable
-

b. using the AUSDRisk screening tool as the basis for referrals?

- Very confident Somewhat confident Not confident at all Undecided Not applicable
-

c. the referral process and paperwork to be completed?

- Very confident Somewhat confident Not confident at all Undecided Not applicable
-

d. activities to be conducted during the 4-month and 12 month follow-up visits to GP?

- Very confident Somewhat confident Not confident at all Undecided Not applicable
-

7e. Can you remember the exclusion criteria for participation in the SDPP?

<input type="checkbox"/> Currently taking prescribed weight loss medication
<input type="checkbox"/> Currently taking Metformin
<input type="checkbox"/> End-stage congestive heart failure
<input type="checkbox"/> Malignant arrhythmias
<input type="checkbox"/> Pregnancy
<input type="checkbox"/> Progressive or terminal cancer
<input type="checkbox"/> Severe cognitive impairment or behavioural disturbance
<input type="checkbox"/> Unstable abdominal, thoracic or cerebral aneurysm
<input type="checkbox"/> Untreated severe aortic stenosis or other structural heart disease
<input type="checkbox"/> Unstable Coronary artery disease
<input type="checkbox"/> Type 1 or type 2 diabetes
<input type="checkbox"/> Participants don't speak or read English
<input type="checkbox"/> Other
<input type="checkbox"/> Can't remember any

(FOR OTHER PRACTICE STAFF ONLY)

8 After this training Program, how confident do you feel about applying the knowledge in your practice in relation to?

a. Invitations and how they are conducted

- Very confident Somewhat confident Not confident at all Undecided Not applicable

b. Using the AUSDRisk screening tool as the basis for setting GP appointment

- Very confident Somewhat confident Not confident at all Undecided Not applicable

(FOR ALL)

9 What additional support do you anticipate might be required by your practice?

Thank you very much for your participation in this survey.

Attachment P3 – Practice record of screening

As you know, each practice was allowed to use one or more strategies to promote and implement the program. We are interested in finding out how your practice conducted promotion of the program, screening and recruitment. Initially your practice may have intended some strategies but the actual strategies used may have changed through the implementation of the program. Could you tell us about :

Opportunistic screening:

Strategy	Which was intended in your practice?	What actually happened?
Lifestyle Officer approaches patient in the waiting room and completes	<input type="checkbox"/> 1	<input type="checkbox"/> 1
The receptionist/Practice Manager/Practice Nurse hands out the	<input type="checkbox"/> 2	<input type="checkbox"/> 2
The GP administers the entire AUSDRISK tool.	<input type="checkbox"/> 3	<input type="checkbox"/> 3

Targeted recruitment Perform database search for patients 50 to 65 years old who do not have diabetes. Letter sent directly to patient from the Practice inviting them to participate in the program.

Strategy	What was intended in your practice?	What actually happened?
Send letters to patients with upcoming appointments inviting them to fill in AUSDRISK tool at their appointment with their GP.	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Send letters to patients inviting them to make an appointment with their GP.	<input type="checkbox"/> 2	<input type="checkbox"/> 2
Send letters to patients inviting them to make an appointment with the LO. Include which days SDPP recruitment is occurring and advise the patient to	<input type="checkbox"/> 3	<input type="checkbox"/> 3

Finally, we need an indication of the type of practice where the Program was undertaken. Would you please let us know the characteristics of you practice:

Solo or group practice

1 Group

2 Solo

Total number of participating doctors and other staff (practice manager, receptionist)

1 GPs

2 Other staff

Number of days of patient contact (1 to 7)

Number of days per week

Total hours per week of patient contact (eg. 20

Number of hours per week

Receptionist/practice manager

Attachment P4 GP focus group discussion guide

GP's perceived barriers to implementation of SDPP components

OVERALL QUESTIONS TO ANSWER IN FOCUS GROUP DISCUSSION:

Reminder to moderator:

The purpose of this focus group is to determine the following:

1. What are the main doctor issues in implementing the SDPP on a routine basis?
2. What are the barriers and obstacles to initiating and completing documentation of patient participation from the general practice perspective?
3. What level of support did GPs receive from practice staff and from Division staff for adherence to SDPP requirements and how did this level of support impact participation/performance?
4. How did this group overcome the barriers and obstacles encountered in different Divisions of General Practice?
5. What is the GP perception about the usefulness of the SDPP for patient's risk and health outcomes?
6. What are the suggestions for improvement if the program is rolled-out Statewide?

Notes for moderator:

Part 1: Introduction (approx. 10 minutes)

Insert here objectives of the sessions, ground rules and brief individual introductions

Part 2: Discussion questions for each of the main topics specified above (approx 1 hour and 15 minutes)

Insert here all specific questions of interest to cover the objectives

Part 3: Question and Answer (approx. 15 minutes)

Invite participants to answer any questions that they may have about the current status and future of the SDPP. These questions will be answered by the experts in the room.

Part 4: Conclusions

Insert here summary and acknowledgement to participants for their contributions

Lifestyle Officers perceived implementation barriers and enablers

OVERALL QUESTIONS TO ANSWER IN THE FOCUS GROUP DISCUSSION:

Reminder to moderator:

The purpose of this focus group is to determine the following:

1. What was the perceived level of usefulness of training and associated materials?
2. What was the level of lifestyle officer satisfaction at different stages of the SDPP implementation?
3. What was the Lifestyle Officers perception of usefulness of the Program and whether the doctors collaborated and the participants found it possible to follow the Program?
4. What was the overall level of confidence in Program delivery by individual lifestyle officers and what changes were necessary?
5. What were the most significant difficulties in ensuring program adherence and how did lifestyle officers overcome these barriers?
6. What were the perceived enablers to successful implementation of the initial consultations, group sessions and participants' follow-up?
7. What are some practical recommendations to give other Area Health Services if this Program is rolled-out Statewide?

This audience will include: Lifestyle Officers from all Divisions of General Practice.

Part 1: Introduction (approx. 5 minutes)

- Welcome participants and introduce yourself.
- Explain the general purpose of the discussion and the process
- Mention the issue of confidentiality of information provided.
- Inform the group that information discussed is going to be analysed as a whole and that participants' names will not be used in any analysis of the discussion.

The focus group facilitator will explain:

This group is convened to generate a comprehensive summary of Lifestyle Officers' satisfaction with training, perceived usefulness of program materials, confidence in program delivery, and barriers for implementation. The information gathered from this discussion will inform the Statewide roll-out of the Program.

We will cover the topics of Training, Interaction with Participants, Program Coordination, and what can be done better during the implementation phase.

I encourage you to be as honest as possible so the lessons learnt can be applied in practice to other Area Health Services if this Program is rolled-out Statewide.

Notes for moderator: GROUND RULES

- *There will be a note-taker and a facilitator but no recording equipment.*
- *Needless to say, this discussion will be conducted in the most friendly and respectful environment, so feel free to share your experiences.*
- *There are no right or wrong answers*
- *3-5 minutes will be allocated to obtain responses from each question. While not everyone has to respond to every question, it's ideal if at least one view from each Division is presented, and any relevant contributions that address the questions are welcome.*
- *All discussions and opinions will be on a volunteer basis but if someone has been too quiet, the moderator may specifically address a question to her/him so all views are incorporated.*
- *Be prepared for the moderator to interrupt to assure that all the topics can be covered in the time allocated.*
- *Confidentiality of responses will be preserved by not attributing comments to any particular individuals in the report.*

Part 2: Discussion questions for each of the main topics specified above (approx 1 hour)

Let's get started!

TRAINING

Q1. [5 min] What training methods worked best in your opinion? (**Probe:** Did classroom-type instruction facilitate your understanding? Did demonstrations help you skill-up? Was supervised observation useful?)

Q2. [3 min] From your experience, what training methods did NOT work well? (**Probe:** Were there areas covered in the training that you felt were not of much help?)

Q3. [3 min] How did you find the Program Manual, measurement protocols and any other associated materials you received. Did you consult them much at all? Did they facilitate your work? Or were they redundant after you had received the practical training? (**Probe:** How could these be enhanced, reduced or modified in any way?)

INTERACTION WITH PARTICIPANTS

Q4 [3min] Think about your experience conducting qualifying interviews, initial consultations and follow-up phone calls up to now. What advice would you give a new staff member about to conduct his or her first patient assessment and follow-up and their first group session? (**Probe:** What do you consider to be a good interview/ consultation and a good group session?)

Note for moderator: *Make up a separate list on butchers paper for initial assessment and group session*

Q5. [3 min] Are there any particular interviewer skills (learned or inherent) or personal qualities that you believe contribute to more effective interviews or lead to greater cooperation from patients?

Q6. [5 min] Try to recall an interview or patient contact that you considered bad or unsuccessful or at least 'not so good'. Now describe the things that should be avoided or things that should be done to prevent this from happening to other lifestyle officers.

Q7. [3 min] In general, considering your patient clientele, is i) delivering group sessions and ii) interviewing patients about their progress, something you do with relative ease, or do you find either of these activities rather challenging?

Q8. [5 min] In what areas do you think you/ or other lifestyle officers could use more training or practice? **Probe**

- communication skills?
- cultural/age sensitivity?
- dealing with difficult patients?
- measurement of height and waist circumference?
- increased knowledge of diabetes prevention issues?

PROGRAM COORDINATION

Q9. [5 min] What do you think about the way the SDPP process has been handled by medical practitioners in your Division? (**Probe:** Focus on the practice level and the way doctors have reached their patients and tried to recruit them, documented the referrals, facilitated access to FPG or OGTT and recorded 4-month follow-up visits).

Q10. [5 min] Now think of the administrative role in your Division. How do you think the coordinating role was managed? (**Probe:** how do you feel communication and supervision went? Were Division Liaison meetings useful and necessary? What sort of things could have been managed better? How?)

PROGRAM BENEFITS AND ROOM FOR IMPROVEMENT

Q11. [10 min]

Now I want to explore your views on the benefits and potential negative impacts you think this Program has had for your local population. As you can see on the sheet of paper on the wall, there's a line with positive things on one end and not so positive things on the other. I'd like you all to take a minute and think about some real (not theoretical) things that have happened to your participants (we'll do the same later about things that happened to you) during the course of the Program. As you think of ideas, tell them to me and I will write them down and then we will prioritise them in terms of level of impact on your participants' ability to adhere to the Program well (from greater impact to lesser impact).

Then we will move to some harms or negative effects of the Program [if any] as you have heard from your participants. After we have listed them, we will also prioritise these from greatest impact to lowest impact on their ability to adhere to the Program and what the participant, you or someone in your Division assisted in finding a solution.

Program benefits and Barriers (table on Program participants)

Positive	Negative	What was done to overcome problem

Q12. [10 min]

Now we will do a similar exercise but this time the focus is YOU as a Lifestyle Officer. Please list the positive experiences of delivering a community-based Program and how these had an impact on your ability or confidence to deliver the Program as expected of you. Then list the most significant barriers you have encountered in delivering the Program as planned and tell me what you or your Division did to overcome these problems.

Program benefits and Barriers (table on Lifestyle Officers)

Positive	Negative	What was done to overcome problem

Part 3: Question and Answer (approx. 5 minutes)

Invite participants to answer any questions that they may have about the current status and future of the SDPP. These questions will be answered by the most appropriate person in the room.

Part 4: Conclusions (approx 5 minutes)

Produce here a verbal summary of how the FGD process went, outline the recommendations proposed and acknowledge participants for their contributions.

Celebrate the conclusion of the activity with a morning tea or a physical activity game.

Attachment P6 Tracking recruited practices and GPs

As part of the overall evaluation of the *Prevent Diabetes Live Life Well* Program, a detailed process evaluation is being undertaken. One important part of the process evaluation is documenting how Practices and general practitioners (GPs) are recruited to the program and the uptake of the program across participating Divisions. This information will be particularly useful in informing any future implementation and roll-out of *Prevent Diabetes Live Life Well* across NSW.

Please use the following form to describe and outline how your Division recruited Practices and individual general practitioners to the *Prevent Diabetes, Live Life Well* Program.

Division: _____ Name of person completing this form: _____

1. How many Practices are there in your Division?
2. How many general practitioners are there in your Division?
3. Please describe the specific methods and processes your Division used to recruit Practices and general practitioners to participate in the program.
4. How many Practices did your Division invite to take part in the program?
5. How many general practitioners did your Division invite to take part in the program?
6. How many Practices in **total** has your Division recruited to the program?
7. How many general practitioners in **total** has your Division recruited to the program?
8. How many practices declined to participate in the program?
9. How many general practitioners declined to participate in the program?

If possible, please identify the given be Practices and/or general practitioners for declining to participate in the program. e.g no time, lack of capacity

Attachment P7 Group sessions evaluation Questions

a) self-administered questionnaire (not included in analysis)
 b) selectee questions administered by the lifestyle officer at the 3-month follow-up phone call
 The following questions are for the evaluation of the *Prevent Diabetes Live Life Well* program.
 Q5. In general, please tell me if you agree or disagree with the following statements about the *Live Life Well* sessions you attended (*Do NOT read out 'undecided'*)

a. You found it easy to find time to attend the sessions	0 Agree	0 Disagree	0 Undecided
b. You found it easy to travel to the sessions	0 Agree	0 Disagree	0 Undecided
c. You learned new information or refreshed your skills about decreasing your risk of developing diabetes in the sessions	0 Agree	0 Disagree	0 Undecided
d. The demonstrations during session motivated you to change your eating habits or increase your physical activity levels	0 Agree	0 Disagree	0 Undecided
e. You thought the materials and resources given to you were useful	0 Agree	0 Disagree	0 Undecided

As part of your *Prevent Diabetes Live Life Well* sessions you would have received a list of physical activity healthy eating facilities/providers/services consistent with the messages of the program.

6a. Have you used of the facilities/services/programs in this list? Yes No

6b. Which facilities/services/programs from this list have you used?

NB: this can include a specific class

6c. If no, what has prevented you from using one of the facilities/services/programs on the list?

6d. Are you likely to use this list in the future? Yes No

Stakeholders perceived benefits and barriers to collaboration in SDPP

OVERALL QUESTIONS TO ANSWER IN FOCUS GROUP DISCUSSION:

Reminder to moderator:

The purpose of this focus group is to determine the following:

1. What was the level of stakeholder engagement at different stages of the process?
2. What was the perceived level of usefulness of the collaboration from various perspectives?
3. What were the difficulties in program adherence and the main differences in program delivery between Divisions of General Practice? (clinical or non clinical)
4. What were the perceived enablers to successful implementation of the process (focus on managerial/operational, not the clinical perspective)?
5. Which were the most significant barriers and success factors for establishment of community-based programs/services for physical activity and weight management in Divisions and outside the Divisions?
6. How did this group overcome the barriers and obstacles encountered in different Divisions?
7. What are the suggestions for improvement if the program is rolled-out Statewide?

Notes for moderator: This audience will include: Division Coordinators, Lifestyle Officers and other key Division stakeholders, SSWAHS staff and members of the Steering Committee

Part 1: Introduction (approx. 10 minutes)

Insert here objectives of the sessions, ground rules and brief individual introductions

Part 2: Discussion questions for each of the main topics specified above (approx 1 hour and 15 minutes)

Insert here all specific questions of interest to cover the objectives

Part 3: Question and Answer (approx. 15 minutes)

Invite participants to answer any questions that they may have about the current status and future of the SDPP. These questions will be answered by the experts in the room.

Part 4: Conclusions (10 minutes)

Insert here summary and acknowledgement to participants for their contributions.

-----END OF PROCESS EVALUATION PROTOCOL -----

Appendix 6.3 Process evaluation components undertaken by others

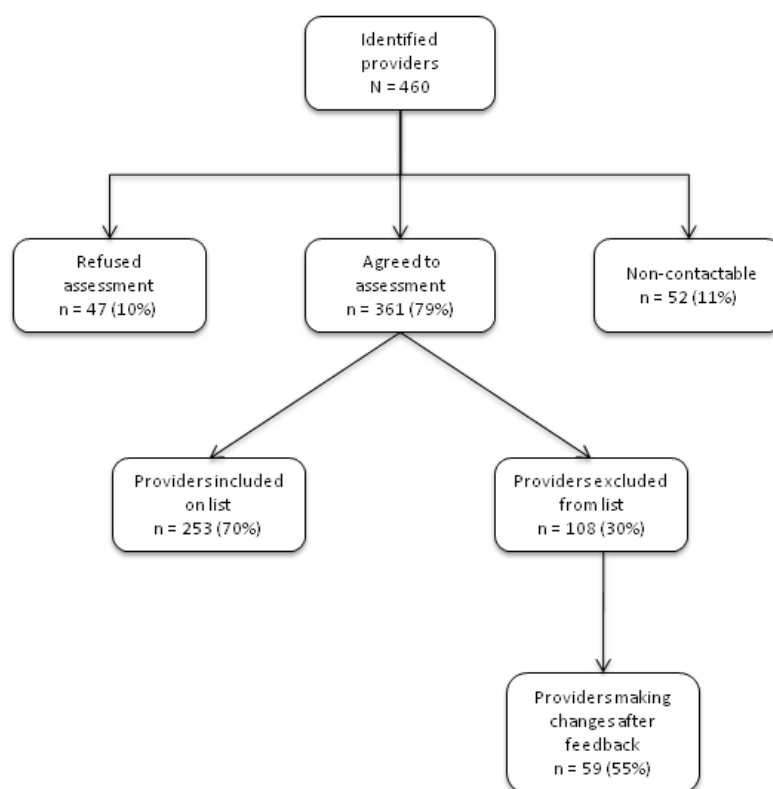
Three sub-components of the process evaluation were planned or carried out by other Program staff. They are outside the scope of this thesis as the candidate did not participate in their design or conduct

Inventory of community-based services

The SSWAHS Health Promotion Unit undertook to identify all existing nutrition and physical activity providers in each of the Divisions. Site visits were undertaken jointly by an exercise physiologist and a nutritionist using a “minimum standards” tool to assess quality and appropriateness of the venue and whether the business practices met the requirements of the SDPP. The aim was to compile a user friendly providers’ list that included the location and type of services offered for those wishing to formally and regularly exercise following their initial consultation. Updates on the process were given by the Unit staff verbally and in writing at meetings of the Steering Committee.

Guidelines for assessment of community-based lifestyle services addressing exercise prescription, dietary advice, professional qualifications and compliance with legislative requirements were developed by local expert consensus (For details of assessment criteria for inclusion on list recommended to SDPP participants see Appendix 4.15). Overall 460 community providers were identified in the three Divisions and each one was invited to participate in the assessment. Most consented and were visited to determine consistency with the goals of the Program. A total of 361 community providers were assessed using these guidelines.

Figure A 6.3 Audit of existing weight management/healthy eating and physical activity Programs in three participating Divisions of General practice (2008-2010)



It was also anticipated that new community-based Programs (weight management, healthy eating and physical activity) would be established within the participating Divisions after the Program commenced, and they would fulfil the assessment criteria. However, due to resource constraints and the availability of multiple services in all areas, this did not occur for this mainstream cohort.

As shown in Figure A6.3, the majority (70%) of providers met all guidelines. Those not meeting guidelines were excluded from the list. Fifty-nine providers (55%) of those initially not meeting the guidelines subsequently made appropriate changes to meet the minimum standards after receiving feedback. A list containing the details of the services meeting the guidelines was produced by the SSWAHS Health Promotion Service and locally relevant sections were either offered to participants at group session three or posted to those choosing the individual telephone coaching.

Program involvement and acceptability by providers and Program partners

Stakeholder groups participating in SDPP fall into four categories: university, government, NGO and professional organisations. Nine main stakeholders are engaged in the design and implementation as follows: three Divisions of General Practice (Southern Highlands, Macarthur and Central Sydney), Sydney Southwest Area Health Service, the Australian Diabetes Council, NSW Department of Health, The University of New South Wales and The University of Sydney. Their engagement consisted of attendance to planning and progress meetings, budget management, staff recruitment, negotiation with Division managers and high level technical input into the protocol and practicalities of implementation. There is cross-representation in committees as specified below:

- Principal Investigators include stakeholders from USYD/BIONE, SSWAHS, and UNSW
- Executive Group: USYD/BIONE, SSWAHS, New South Wales Health, CSGPN
- Steering Committee: USYD/BIONE, SSWAHS, New South Wales Health, CHERE, DA-NSW, CSGPN, MDGP, SHDGP, UNSW.
- Research Committee: USYD/BIONE, SSWAHS, New South Wales Health, SHDGP
- Divisional Liaison Group: USYD/BIONE, SSWAHS, DA-NSW, CSGPN, MDGP, SHDGP, New South Wales Health

The implementation team was based at the Divisions, and engaged lifestyle officers from various health professions to deliver the intervention and document data for the evaluation. Each Division also appointed a coordinator and negotiated progress with a liaison officer representing the funding body, NSW Health.

In addition, the Prevention Research Collaboration at the University of Sydney (where the author was affiliated) were the main drivers of the evaluation. This team worked in conjunction with the Centre for Health Economics Research and Evaluation, University of Technology Sydney, the SSWAHS Health Promotion Service and the NSW Department of Health.

Stakeholders engagement and satisfaction

No formal information has been routinely collected on the satisfaction levels of other stakeholders involved such as practice staff, Division coordinators, Division CEOs or Area Health Service staff, University collaborators, Australian Diabetes Council counsellors, NSW Health Department representatives from head office or Health Promotion Service in SSWAHS. Due to limited resources to date, neither focus groups nor in-depth interviews had been conducted with other stakeholders to examine their level of engagement or satisfaction with involvement in the Program.

Brief surveys on satisfaction with training were conducted at the onset, shortly after training in a convenience sample of participating GPs.⁸⁸ Selected in-depth telephone interviews on barriers and enablers for implementation were conducted after 2 years of Program commencement with another convenience sample of high and low referring GPs. The candidate decided to keep this component also outside the evaluation as its quality and representativeness were unacceptable.

General Practitioners

GP eligibility and recruitment

Divisions routinely collected information on potential eligibility and recruitment of general practitioners who were to implement the Program. Table A6.3 shows that overall a third of potentially eligible GPs were trained and recruited into the Program but in Southern Highlands the majority of GPs invited joined the Program whereas in Macarthur and Central Sydney only about a fifth agreed to participate. We were unable to ascertain the reasons why some practices and GPs decided not to participate, despite our efforts to investigate due to refusal of non-participating GPs to be contacted.

Overall two thirds of trained GPs subsequently referred participants, with Macarthur Division having the lowest referral rates. Once recruited, most GPs remained in the Program and referred on average 14 participants each, but there was variability across the Divisions (Central Sydney=9 per GP, Southern Highlands=17 per GP, Macarthur =15 per GP) and this is mostly due to the large number of GPs involved in Central Sydney. The highest number of participants referred by one GP in each Division is as follows: Southern Highlands (109); Macarthur (119); Central Sydney (50).

Table A6.3. General practitioners flow from recruitment to participation in referrals (2008-2010)

Indicator	Southern Highlands	Macarthur	Central Sydney	Total
Number of potential GPs ^π	67	208	692	967
Number of GPs invited to participate	67	208	423	698
Number of practices recruited	16	29	38	83
Number of GPs recruited and trained (% of GPs who were invited)	58 (87%)	49 (24%)	115 (27%)	222 (32%)
Number of GPs who referred one or more participants (% of GPs trained)	38 (66%)	28 (57%)	90 (78%)	156 (70%)
Number of GPs withdrawn or left (% of GPs recruited)	7 (12%)	12 (24%)	18 (16%)	37 (17%)
Number of GPs still participating (% of GPs recruited)	51 (88%)	36 (73%)	97 (84%)	184 (83%)

^π from eligible practices in the Division

The original target was to recruit up to 150 GPs from at least 25 practices. This target was surpassed and overall the Program recruited and trained 222 GPs from 83 practices for the mainstream cohort only. Additional invitations to GPs were necessary because the number of participants referred from each GP was lower than predicted

The following sections address the level of Program acceptance reported by selected stakeholder groups.

GP Satisfaction with training, knowledge and support throughout the Program

During the GP training sessions, randomly selected GPs were asked if they were willing to receive a follow-up phone call post training. In all, 21 trained GPs indicated they would be willing to receive a follow-up phone call and complete the 5–10 min survey.

⁸⁸ The candidate did not participate in their design or sampling strategy.

In the end 12 GPs were successfully contacted⁸⁹ to examine the following indicators:

- GP satisfaction with training received
- GP satisfaction with the resources provided to support the Program
- GP understanding and knowledge of and confidence in the various stages of the Program

Below is a summary of findings from these surveys and interviews:

- All GPs indicated that the quality of the description of the screening and recruitment process and tally sheet was good to excellent and all could identify at least one event that happened to their patients once referred to the Program.
- Approximately half of the contacted GPs rated their overall understanding of the Program as very good, felt very confident about their understanding of their role in the Program, somewhat confident at their ability to screen and recruit the number of patients required in 3 months, and very confident at their ability to identify potentially eligible participants.
- Approximately half of the interviewed GPs reported being very confident in using the Ausdrisk tool as the basis for referring patients to the Program, somewhat confident in understanding the referral process and the paper work required, and somewhat confident in understanding the activities that needed to occur at the 4 and 12-month follow-up visits.
- Most of the GPs could identify at least one of the Program's exclusion criteria, the most often identified being "diagnosed diabetes".

While there appears to be some indication of GP confidence and knowledge from these phone interviews, the small numbers of participants in this survey and self-selection bias preclude any certainty about inferences from GP satisfaction with their training, understanding of and confidence in implementing the Program.

GP perceived barriers and enablers to recruitment

The assessment of GP perceived barriers and enablers was undertaken via in-depth semi-structured interviews in 2010 with a convenience sample of 23 GPs (13 high and 10 low referrers) who were willing to answer questions by the Division Liaison Officers and the Program Director. Out of those invited, the proportion of GPs who participated varied (46% from Central Sydney, 58% from Macarthur and 77% from Southern Highlands). Therefore this sample maybe biased due to self-inclusion/ exclusion by the GPs and caution should be made in their interpretation.

Overall, GPs said they had many competing priorities and were time poor. However, all agreed that they had a role in diabetes prevention but that it was not the highest priority. The barriers were: the lack of time; the complex screening and recruitment process, (paperwork and getting patients to get blood tests (OGTT) to exclude diabetes); and also lack of patient motivation. The enablers were: support from Divisions, engagement of practice staff, use of HbA1c to exclude diabetes, financial incentives, electronic support tools.

Lifestyle Officers

Lifestyle officers' satisfaction with Program implementation including barriers, enablers and suggestions for improvement were obtained via an anonymous web-based survey. Most lifestyle officers participated.⁹⁰

⁸⁹ The remainder either refused or were never available to be interviewed

Lifestyle officers recruitment and satisfaction

Nineteen lifestyle officers (LOs) were recruited and trained. Professional backgrounds of the LOs are as follows: GP overseas-trained doctor (1), nurses (2) diabetes educators (3), dieticians (6), exercise physiologists (6), dietician/ exercise physiologist (1), and psychologist (1). Four have subsequently left the Program to take up other roles and one is currently on maternity leave. No exit interviews to gather their views on Program experience have been conducted to date. Their training to implement the SDPP comprised a 2-day health coaching course delivered by Health Coaching Australia and two additional days in specific Program content and also standardised waist circumference training. On-the-job training was given on the use of the online database but no formal training was provided in data quality control, systematic event documentation or standard administration of telephone questionnaires.

While regular meetings are held with lifestyle officers to raise implementation and evaluation issues, no performance assessment or exit interview or ongoing documentation of their satisfaction with training and support or their confidence in Program delivery took place to date.

An anonymous internet-based survey was offered for current and former lifestyle officers to gather their views on the Program and their barriers for implementation. Response rate to this survey was 72%. In brief, results indicate that the majority of the LOs believe the Program was likely to achieve its objective of reducing diabetes risk, and the Program was delivered as intended and as well as it could have been. Most felt confident delivering the intervention and agreed that the practice staff, Health Promotion Unit staff and University of Sydney intervention team were well engaged and supported the Program. However, half the responding LOs perceived GPs to not be very engaged or supportive of the Program, a third are undecided about whether many participants will reach their behaviour change goals, a quarter do not believe the Program reached the people at risk who need it the most and half are undecided about this. Three quarters think the evaluation and data collection tasks hindered the delivery of the Program, and over half were unsure or did not believe that the Program would be easy to replicate and deliver in other Divisions of General Practice in Australia.

Lifestyle Officers perceived barriers

The main barriers identified by LOs for screening and recruitment were the perceived lack of commitment of GPs and staff requirements for completing enrolment paperwork. The next most reported barriers were the lengthy protocol and the screening restrictions. Smaller numbers of LOs responded to the question on barriers for delivering the Program. Among other issues, time spent completing the paperwork, time attempting to contact participants, too much focus on referrals or data collection rather than delivering the Program, and participants' dislike of forms and phone calls.

Lifestyle Officers suggestions for improvement

While there were few respondents to this question, proposals ranged from simplifying the manual and the recruitment process, to offering participants free exercise classes or pedometers and better marketing of the Program in the community. Specific suggestions for particular Program components included more focus content of the Group sessions (either physical activity or nutrition but not both in each individual session), delivery by a relevant

⁹⁰ The candidate was not involved in either production or analysis of lifestyle officer survey.

tertiary-trained staff, more flexibility in the conduct of sessions and timelines for attendance, shorter duration of the sessions and larger number of sessions, with an additional group convening half-way through the Program or after 9 months. Regarding the follow-up phone calls, some suggested to make calls optional for the successful participants and incorporate face-to-face follow-up at 3 or 6 months instead of the phone call. The content of the call was proposed to be more coaching-oriented than evaluation-driven. To improve the final assessment, a few LOs suggested less time devoted to documenting the outcomes for research purposes and more time used in planning for the future, with the option of a group session at the end.

Other aspects of participant satisfaction

A brief questionnaire designed by the intervention team was handed to attendees at the last group session, enquiring about satisfaction with session content and facilitator skills. The biases introduced in these responses are acknowledged by the candidate, who played no role in this activity. In brief, there were 799 responses (response rate 84% of those attending groups). Most (94%) rated the Program very good or excellent and 98% would recommend it to others. One in 5 participants wanted more group sessions, and 92% thought the length of the sessions (2 hours) was good.

Interim conclusions on engagement and acceptability by stakeholders

- The Program has exceeded its target of number of practices and GPs involved in the Program. While this could be an advantage in terms of the breadth of participants reached, it can also constitute a costly barrier for administration, technical support, quality control and standardisation of data.
- It is feasible to involve a multidisciplinary team in the planning and implementation of lifestyle interventions in clinical practice, but success is reliant on financial incentives and ongoing administrative support for GPs from Divisions, and periodic technical assistance for lifestyle officers.
- Lifestyle officers participating in SDPP come from a wide range of professional backgrounds and have received standard training in lifestyle advice and ongoing technical support.
- The opinions of GPs on satisfaction in this report are derived from a self-selected, small group of enthusiastic practitioners and do not necessarily reflect the whole picture of GP satisfaction. None of the withdrawing GPs were willing to be interviewed.
- GP workloads and patient's lack of perceived risk and motivation were the main barriers to screening and referral and to a lesser extent, the strict Program selection criteria and its paperwork requirements.
- The Program was seen as a one-stop shop for risk management and both financial incentives and ongoing technical /administrative support by Divisions were appreciated by the general practitioners surveyed.

Recommendations

- a) A qualitative assessment satisfaction levels among stakeholders other than doctors and lifestyle officers should be undertaken. Further knowledge of the perceived usefulness of Division coordinators and practice staff in the planning and oversight of this process and discussions on identification of barriers and enablers would be useful to inform lessons learnt before Statewide rollout of this Program proceeds.

- b)** Program implementation maintaining the financial incentive and excluding the strict requirements of a parallel evaluation may enhance GP involvement in screening and recruitment
- c)** Strategies need to be explored to assist GPs in improving patient's perceived level of risk and motivation to engage in lifestyle interventions.

Appendix 7.1 Comparative self-reported changes at 3, 6, and 9 months

Research questions

The objective changes at three months are supplemented with comparisons of self-perceived changes in physical activity and diet reported every at three months based on data from the three month follow-up call to participants. Analysis describes the answers to the following secondary research questions (based on self-perceived changes at 3, 6, 9 months)

1. What is the extent of self-reported behavioural changes, i.e. physical activity and healthy eating at three months ?
2. What behavioural changes are observed based on self-reported lifestyle at 6 and 9 months?
3. What are the changes reported by the cohort who had data at every milestone?

Methods

Comparisons of self-reported changes in physical activity and dietary behaviour were made between baseline and three months, three months and six months, and between six and nine months. Results are presented first for anyone with data at two consecutive milestone; and subsequently for participants with data at all three milestones.

Data sources

- baseline participation on healthy eating and regular physical activity (frequency and intensity) were obtained from the CATI survey
- Data on qualitative self-perceived changes in lifestyle for the 3, 6 and 9 months milestones were collected by lifestyle officers when contacting their participants at the quarterly telephone call.

Questions from the 3-month follow-up telephone interview included:

- engagement in physical activity in the previous three months (self-reported, unstructured type, frequency and intensity)
- adherence to a healthy diet in the previous three months (unstructured question on type, frequency and intensity)
- reasons for lack of participation in physical activity or non-adherence to diet (open ended subsequently recoded)
- self-perceived changes in aerobic activity, strength training and fat/fibre consumption (structured increased, decreased or remained the same)

Data items on perceived changes are presented in the follow-up questionnaires for 3 months, in Appendix 4.10

It is important to note that the baseline questions on physical activity had a different format to the subsequent telephone follow-up at three months, but estimated in the same units (minutes per week). The questions used to estimate physical activity at baseline were structured, based on the validated PASE instrument and covered each type of physical activity, duration, intensity and frequency as shown below for moderate physical activity:

*Q 16 Over the past 7 days, how often did you engage in **moderate** sport or recreational activities such as doubles tennis, ballroom dancing, golf without a cart, softball or other similar activities?*

O Never O Seldom (1-2 days) O Sometimes (3-4 days) O Often (5-7 days)

Q 16a What were these activities?

Q 16b On average, how many hours per day did you engage in these moderate sport or recreational activities on these days?

O less than 1 hour O 1 but less than 2 hours O 2 – 4 hours O more than 4 hours

These ranges were converted to minutes per week of each activity using the PASE algorithm as explained in Chapter 5 on baseline results, and then added for a total number of minutes per week. The complete PASE questionnaire can be seen in Appendix 4.5, Chapter 4.

The lifestyle officer took detailed notes on activity described by the participant and entered them into the database. The PhD candidate consulted the project's physical activity expert to decide whether the physical activity described fell into the moderate or vigorous category⁹¹ according to the standard activity levels recommended by (Appendix 4.6).

In contrast, at three months, the estimated total moderate to vigorous activity per week was asked qualitatively of the patient using own descriptions of activity types and their own estimated minutes per week from the following questions:

Ia. Have you been doing any physical activity/exercise since we last spoke on the phone?

No Yes

Ib. What physical activity/ exercise have you been doing ?

A facility or service suggested at our groups (list of providers)

Facility/service/program name: _____

Another facility in the community

Started home-based exercise (e.g. your own routine)

Continued with existing membership or home-based routine

Unstructured (walking more, gardening, more incidental activity)

Strength training

Ic. On average, how often do you exercise? (include the combined frequency of all of the above) (Let respondent tell you the answer and tick the box that most closely reflects the answer)

Rarely (once per week/fortnight or less)

2 -3 times per week

4 - 5 times per week

About every day

Id. On average how much time do you spent in moderate or strength training each week?

_____ moderate aerobic activity (hours and/or minutes)

_____ strength training (hours and/or minutes)

The adoption of an alternate version of the physical activity question at three months, by contrast with the structured PASE at baseline, was due to an ethics committee requirement for a briefer questionnaire at follow-up.

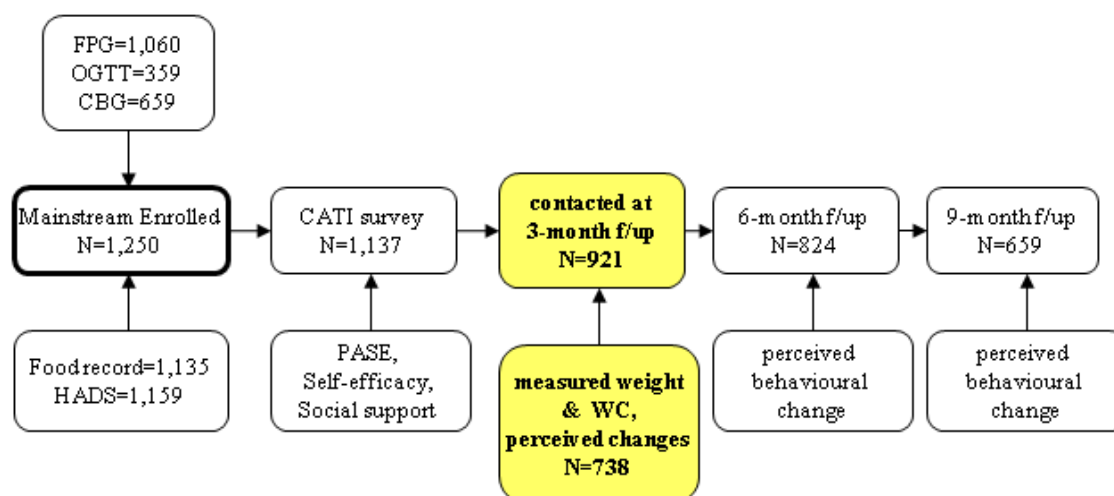
⁹¹ For example, if the participant reported 'moderate-vigorous activity' of one hour and the description was 'playing with the kids in the yard', the activity was assumed to be *light* instead of *moderate*. If the activity reported was dancing or brisk walking, it was classified under moderate. If the activity reported was 'swimming laps' or 'fast jogging' then the activity was classified as *vigorous*.

A similar issue on potential differential measurement occurred for dietary habits, although no attempt to measure fat or fibre was made at follow-up other than qualitative perception of increase or decrease in relation to baseline. At baseline nutrient intake was calculated from the unweighed 3-day food record (Appendix 4.12). At follow-up there was a semi-structured question on whether the participant perceived an increase, decrease or no change in their consumption of fat and fibre since the last contact with the lifestyle officer, approximately three months before.

Results

In analysing changes in self-reported behaviours among mainstream participants note that by the end of December 2010, 52.7% of enrolled participants had been contacted at 9 months, and larger proportions at earlier milestones (Figure A7.1). Data on perceived behavioural changes was available at three, six and nine months.

figure A7.1 Mainstream participants contacted at various milestones and type of data available for the 3, 6 and 9-month comparisons.



Variable data for the various milestones by Division were available as shown in Table A7.1: All baseline, three quarters of 3-month contacted, two thirds of enrolled contacted at 6 months and just over half of the enrolled who were contacted at 9 months. The differences in the proportions contacted at each milestone are due partly to the timeframe of recruitment, where Central Sydney commenced over six months later, and had a final recruitment boost in mid 2010. This led to smaller numbers of people in the late follow-up of this analysis.

Question 1. What is the extent of self-reported behavioural changes, i.e. physical activity and healthy eating at three months ?

Question 2. What behavioural changes are observed based on self-reported lifestyle at 6 and 9 months?

Self-reported changes in physical activity at 3, 6 and 9 months

Table A7.1 Number and proportion (Division %) of participants with follow-up self-reported data at different time points.

Milestone	Total	Southern Highlands	Macarthur	Central
Baseline enrolled	1,250	387	301	562
3-month follow-up	921 (74%)	283 (73%)	223 (74%)	414 (74%)
6-month follow-up	824 (66%)	262 (68%)	193 (64%)	369 (66%)
9-month follow-up	659 (53%)	225 (58%)	187 (62%)	247 (44%)

Unmatched Samples

Table A7.2 shows a comparison of self-perceived behavioural changes reported to the lifestyle officer (LO) at the milestone follow-up times. The question was standard about total minutes of moderate-to-vigorous activity at 3, 6, and 9 months. However, as mentioned above, the baseline calculation for total physical activity was based on the PASE questionnaire. Note that the samples are unmatched, i.e. includes the cross-section of any participant contacted at each time point. Overall, several months after joining the program most participants reported still adhering to some form of physical activity program. This suggests maintenance of the behavioural change. Over two thirds report doing physical activity at least four days per week. The data show that most people still report maintaining some physical activity over time, but 1 in 3 report home-based exercise and 1 in two report unstructured activity and only 1 in five report strength training. Rates of logging physical activity or using a pedometer are very low at each follow-up period.

Table A7.2 Self-reported physical activity behaviours at each of the follow-up phone calls for active mainstream participants up to December 31, 2010.

	3 months* N=921	6 months* N=824	9 months* N=659
Physical Activity			
Still doing physical activity	86%	83%	85%
PA \geq 4 days/week	72%	71%	71%
Started home based, own routine	35%	16%	14%
Unstructured (more walking and gardening)	47%	41%	40%
Strength training	26%	23%	23%
Continued existing routine (home-based or gym)	19%	43%	47%
Reports increased aerobic PA since last LO contact	68%	39%	38%
Reports increased strength training since last time ©	40%	22%	21%
Logs physical activity	14%	12%	11%
Uses pedometer	2%	3%	1%

* Percentages indicate % of total participants contacted at this time point or % of those asked the question (selected questions on strength training and frequency of weight/WC checks were introduced late)

© Only around 81% asked the question (introduced late)

For those reporting inactivity, in descending order of frequency, the three main reasons for people not doing physical activity at three, six and nine months were health-related issues, family/work commitments and lack of motivation.

Table A7.3 compares the group's self-reported minutes of moderate to vigorous activity at various stages of the program for the subset of participants who were asked relevant questions.⁹² This information had been collected from only 81% (average) of the participants by December 2010 as the question was introduced late. It appears that overall self-reported engagement in aerobic activity did not change from 3 to 6 months (overlapping 95% confidence intervals around the mean number of minutes/week).

⁹² The questions not originally quantified in minutes/week but were introduced late when it became apparent that self-perceived intensity and duration were inconsistent with the definitions by the experts. Hence the first sub-group of participants were not asked the question.

Table A7.3 Self-reported overall minutes of physical activity types by sex at various milestones for those who remain active. Mainstream participants until 31 December 2010.

Stage in the program (# of people asked the number of minutes/)	Aerobic activity Median (Interquartile range) ^β Mean (95%CI)	Strength Training Median (Interquartile range) ^β /mean	N (% of respondents) ^α doing zero minutes of	
			Moderate- vigorous aerobic	Moderate – vigorous resistance training
At 3 months (N=781/920) mean -Males (N=284) mean-Females (497)	60 min(0-180)/ 95 min (88-102) 101 (89-114) 97 (88-105)	0 min(0-40)/ 24 min	302/781 (38.7%)	470/781 (60.2%)
At 6 months (N=684/824) Males Females	90 min(0-210)/ 108 min (100-116) 111 (97-125) 111 (102-121)	0 min(0-45)/ 26 min	230/694 (33.1%)	419/684 (61.3%)
At 9 months (N=561/659) Males Females	105 min(0-210)/ 116 min (107-125) 120 (104-136) 116 (106-125)	0 min(0-45)/ 27 min	166/561 (29.6%)	352/561 (62.84%)

α Note that denominators for aerobic and strength training vary according to number of participants engaged in each activity

β Note that following expert advice within the Program team, minutes of self-reported P.A. were re-coded if the qualitative description given by the participant on the notes did not correspond to the level of intensity claimed. For instance, splashing with the children in the pool is not considered moderate physical activity.

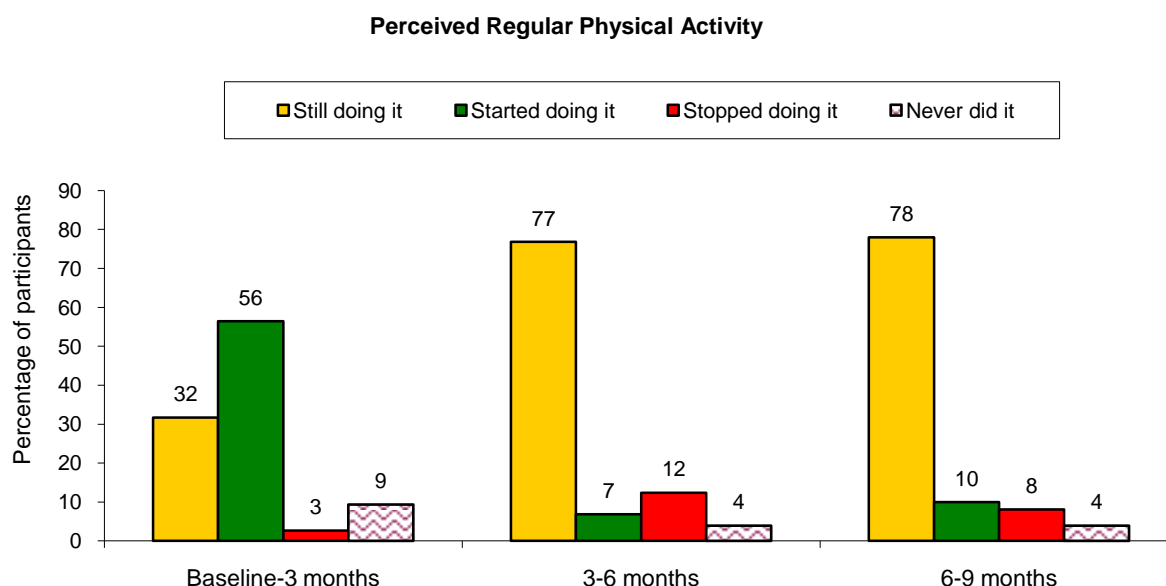
There were no differences by sex in the level of engagement in aerobic activity at any of the three follow-ups (see 95% confidence intervals in table). Strength training routines have not improved for the whole group at any contact time following the initial consultation (median 0 minutes throughout from baseline).

From the self-reported information, at baseline 10% of mainstream participants met the physical activity goal of 210 minutes per week of moderate to vigorous exercise (Chapter 5). This increased to 27.5% of contacted participants at three months, 33.5% at 6 months and 35.3% at 9 months.

A comparison of self-perceived changes in physical activity among those people contacted at the 3-month, 6-month and 9-month follow-up phone calls in this period can be seen in Figure A7.2. These questions asked about self-reported physical activity maintenance. Note that the denominators vary for each time point as not all enrolled participants were reached at 3, 6 or 9 month follow up milestones. A later section of this appendix will show the results for matched data. The total number of people who had comparative physical activity data for two consecutive milestones were as follows: baseline to 3 months 852, three-month to six-month 640, and six-month to nine-month 432 people.

The self-perceived physical activity graph (Figure A7.2) shows that the program has been successful at encouraging people to start regular physical activity, particularly in the first three months (56% started doing physical activity), but also at later follow-up dates. SDPP has largely helped maintain perceived levels of activity (over 75%) into the 6th and 9th month of participation. The weekly frequency of physical activity has not been incorporated in this qualitative estimate. Chapter 8 on the 12-month impact evaluation discusses whether these qualitative increases in physical activity remain at the end of the Program.

Figure A7.2 Proportions of participants contacted at follow-up who report changes in physical activity at three milestones.



Perceived changes in healthy eating behaviour at 3, 6, and 9 months

Almost all participants report adhering to a healthy eating scheme at all time contacts and a majority (>80%) report adhering to dietary guidelines at least four days a week (Table A7.4). Of the people reporting adherence to healthy eating at three months (N=355), 63% had lost at least 500 g, and 29.2% met the GGT weight loss threshold (≥ 2.4 Kg). However, there was no statistically significant difference with the proportion of those not following a diet and also achieving the GGT threshold ($\chi^2=0.26$, $p=0.61$).

Table A7.4 Self-reported eating behaviours at each of the follow-up phone calls for active mainstream participants up to December 31, 2010.

	3 months* N=921	6 months* N=824	9 months* N=659
Healthy eating			
Still doing healthy eating	95%	94%	96%
Diet ≥ 4 days/week	90%	92%	90%
Follows the recommended LLW guidelines	89%	90%	91%
Follows his/her own home-based healthy choices	11%	7%	6%
Uses another weight loss program in the community	2%	2%	1%
Decreased fat consumption since last LO contact	80%	54%	43%
Increased fibre consumption from last LO contact	79%	54%	47%
Keeps a log of eating patterns	12%	9%	6%
Keeps a log of weight changes	23%	19%	12%
Checks own weight at least once per month**	51%	56%	56%
Checks own WC at least once per month**	12%	17%	14%
Perceives weight loss since last LO contact	63%	53%	41%

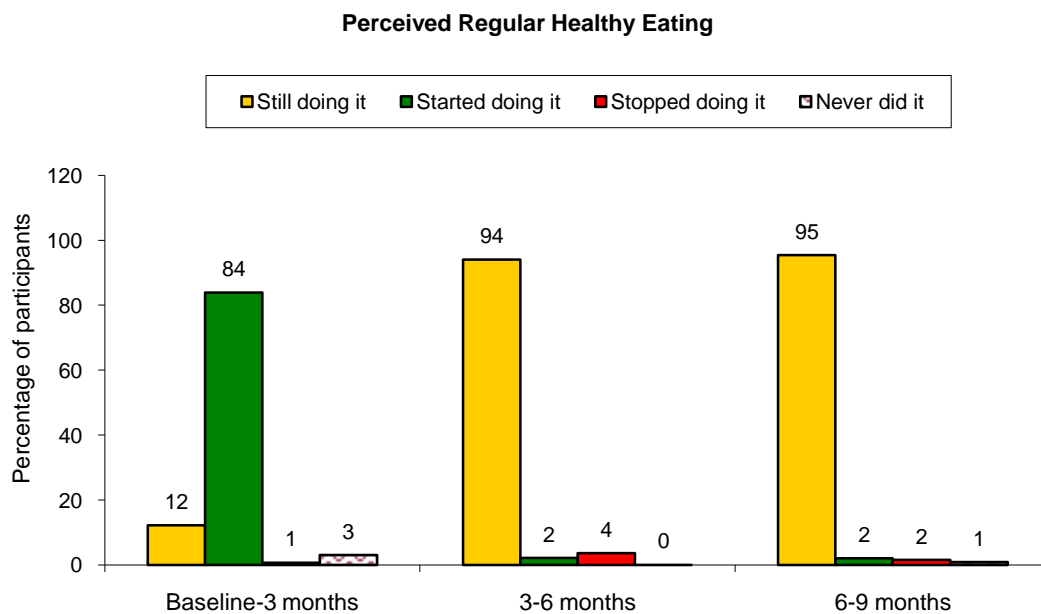
* Percentages indicate % of total mainstream participants contacted at this time point or % of those asked the question (selected questions on strength training and frequency of weight/WC checks were introduced late)

** Only 54% the respondents were asked this item (question introduced recently)

For people reporting not following healthy eating recommendations the main reasons were lack of motivation and family/work commitments. Although self-perceived dietary changes were also high, logging eating patterns were lower, but around half measured their weight monthly. Far greater numbers reported that they monitored their weight, compared to measuring their waistline. Three quarters (76.4%) of participants contacted at 3 months never check their waist circumference and about a quarter never check their weight (26.6%). The comparison between perceived weight changes and measured changes revealed great variation. For instance, 43% of those who lost weight perceived losing weight, and only 4.2% of those gaining weight perceived weight gain. A quarter (26%) of the people experiencing no weight change correctly reported being of the same weight at three months, but 43% of those gaining weight reported perceiving weight loss.

A comparison of self-perceived eating behaviours among those people contacted at the 3-month, 6-month and 9-month follow-up phone calls in this period is illustrated in Figure A7.3. Note that the denominators vary for each time point as not all enrolled participants were reached at 3, 6 or 9 month follow up milestones (data for a matched sample is presented later in this appendix). The total number of mainstream participants who had comparative self-reported dietary data for two consecutive milestones were as follows: baseline to 3 months 852, three-month to six-month 640, and six-month to nine-month 546 people. The frequency of dieting has not been incorporated in this calculation and can be different at each time point even among those who maintained healthy eating patterns.

Figure A7.3 Proportions of any participants contacted at follow-up (cross-sectional prevalence) who report changes in healthy eating at three milestones.



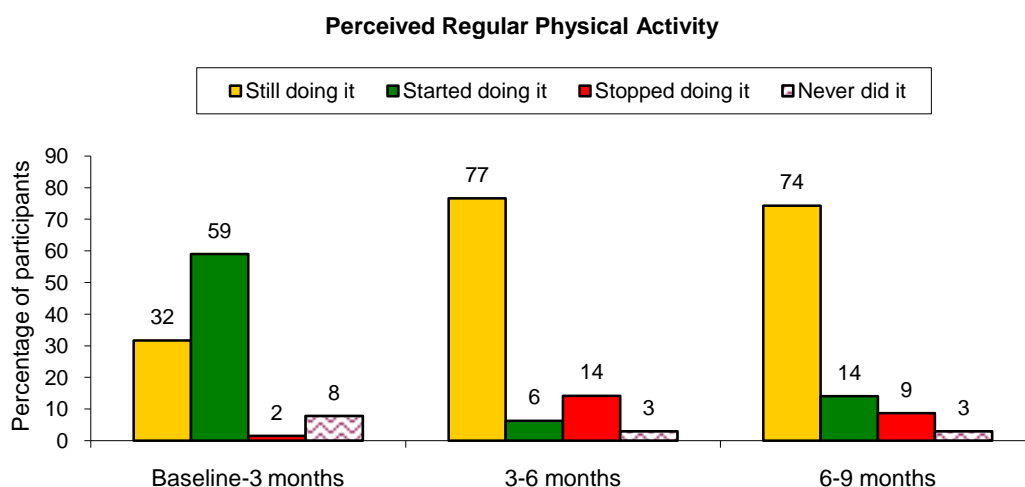
The distribution over time suggests that for healthy eating habits, the self-perceived success rate was high both for starting within the first three months and maintaining the good perceived dietary habits well into the 6th and 9th month after enrolment.

Matched data

A smaller sample of 206 participants had data at every follow-up time (3 and 6 and 9 months) after participating in the baseline CATI survey, so baseline self-reported physical activity and dietary data were available for comparisons. When this comparative analysis is conducted on people who had self-perceived data recorded at every follow-up, a similar finding as the unmatched data emerges (Figure A7.4), of three quarters of participants adhering to regular physical activity. Most people who

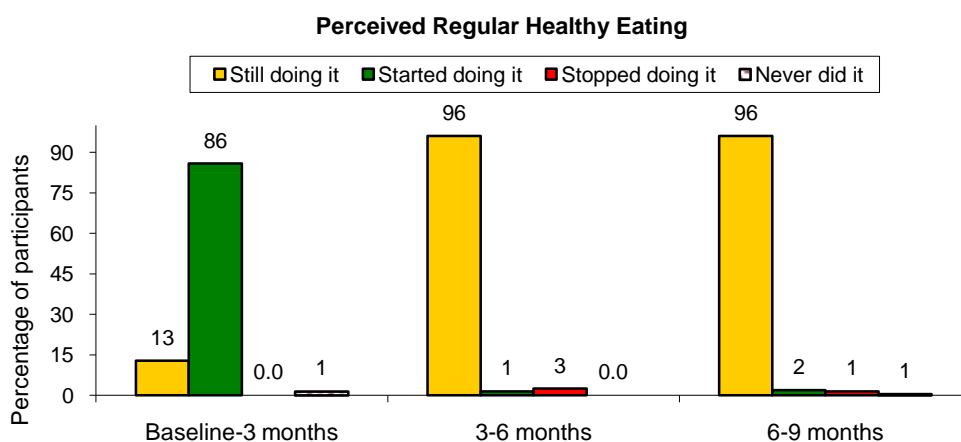
commenced engagement in physical activity did so within the first three months and large proportions continued doing it at subsequent follow-ups.

Figure A7.4 Distribution of self-reported engagement in physical activity as proportion of participants contacted at all consecutive follow-ups (cohort prevalence). N=206.



Likewise for healthy eating, the cohort with data at all follow-ups reports very high level of adherence to the SDPP guidelines from the first three months and this level is maintained up to 9 months (Figure A7.5)

Figure A7.5 Distribution of healthy eating reports as a proportion of participants contacted at all consecutive follow-ups (cohort prevalence). N=206.



Based on self-report, the Program has had a “maintenance” effect for physical activity and even more pronounced for healthy eating at 3, 6, and 9 months post-enrolment.

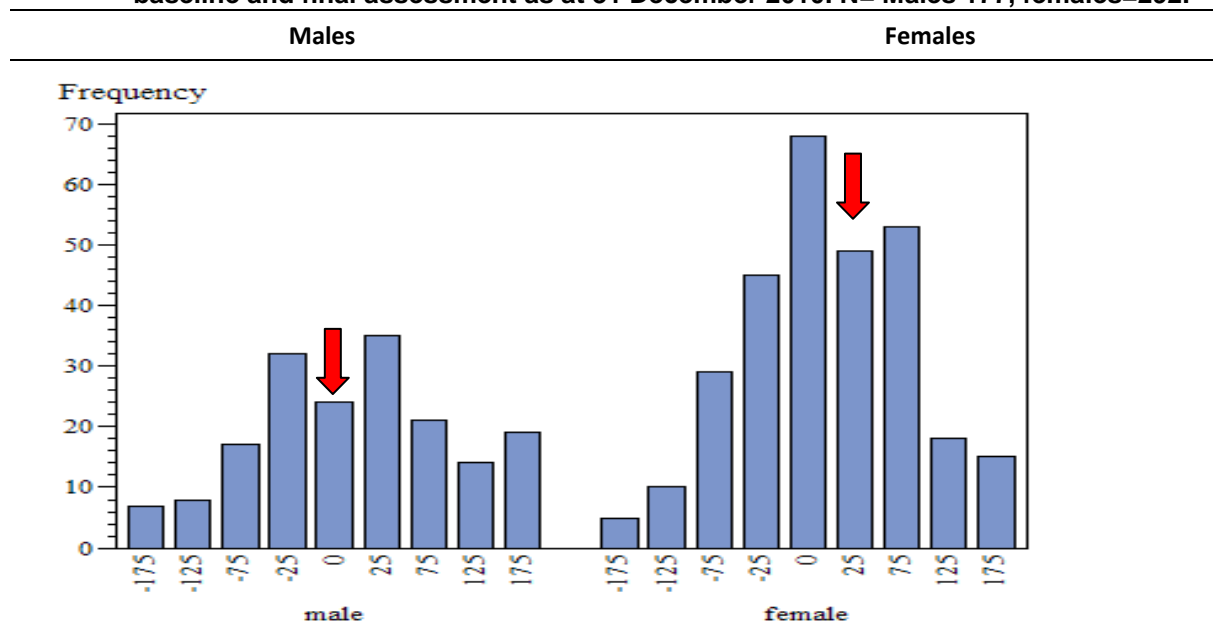
The limitations of self-perceived change in lifestyle behaviours are acknowledged. The physical activity estimates are based on self-report by the participant on both PASE and follow-up phone call. It is expected that any bias associated with socially acceptable responses would have affected both estimates. Further, using the difference in total minutes of physical activity calculated in different ways between baseline and three months may have introduced other artefacts or bias which cannot be identified unless a validation study occurs. Perceived increase in physical activity was not associated with more weight loss at 3 months but both measured and self-perceived weight loss predicted WC reduction. These findings suggest that perceptions of behaviour change may be related to achievement of diabetes prevention goals.

Appendix 8.1 Estimates of physical activity at baseline using PASE scores

PASE scores

Among completers the distribution of CATI respondents to the PASE questionnaire by intervention type was high for all: 82% for group sessions and individual phone coaching, and 80% among those not receiving either. The PASE score, an overall measure of structured and unstructured physical activity (see Chapter 4), is presented as a score where a higher number indicates higher level of physical activity. Change in PASE score was calculated for those with data at baseline and final assessment. By the end of participation, females appeared to have not changed and instead reduced their PASE score more than males (Figure A0.). For females, 23.3% of completers had not changed from baseline, 30.5% had decreased and 46.2% had increased. For males the PASE score had not changed in relation to baseline for 13.6% of completers, decreased in 36.1% and increased in 50.3%. The differences in mean change (+20.2 for males and +17.6 for females) were not statistically significant ($p=0.75$).

Figure A0.1a Distribution of changes in PASE scores by sex. Program completers with data at baseline and final assessment as at 31 December 2010. N= Males 177, females=292.



Appendix 8.2 Impact for people at various baseline levels of physical activity

Estimated changes in physical activity by duration category

Analysis of the Program achievements for all participants according to magnitude of change in physical activity indicates modest change in behaviour after one year in the Program (Table A8.2a). Among the participants attending groups and those receiving any other intervention less than a quarter (23.5% and 22.6% respectively) increased their total moderate-to-vigorous activity by more than one hour per week and the difference between the subgroups was not statistically significant ($x^2 = 0.7$, $p = 0.785$). Just under three quarters did not change their baseline physical activity levels despite the counselling in groups or individually. It is worth remembering that 67.5% of the completers were not doing any moderate-to-vigorous exercise at baseline and that 54.3% of completers are not engaged at this level of activity by the end of the Program.

Table A8.2a Categories of overall change at 12 months in moderate-to-vigorous physical activity in relation to baseline for completers with PASE information at both times (N=481).

Magnitude of change in P.A. (minutes/week)	Group sessions N=522 N (%)	Phone coaching or IC only N=64 N (%)
Increased by ≥ 210	26 (5.0)	2 (3.1)
Increased by 150-209	18 (3.5)	4 (6.3)
Increased by 91-149	53 (10.1)	5 (7.8)
Increased by 61-90	3 (0.5)	1 (1.6)
Increased by 30-60	40 (7.7)	3 (4.7)
Increased by < 30	8 (1.5)	2 (3.1)
No change or decreased	374 (71.7)	47 (73.4)

PA= Physical activity IC= initial consultation

Changes in people not meeting the physical activity goal at baseline

To assess the true magnitude of the Program effect, an analysis of change in physical activity excluding 159 people already were engaged in moderate-to-vigorous physical activity for at least 210 minutes at baseline is warranted. Of the people who were sedentary at baseline, many showed improvement as 35.5% of those doing zero minutes of moderate-to-vigorous exercise who attended group sessions started moving more, with 25% increasing to more than one hour per week (Table A8.2b).

Table A8.2b Magnitude of change for completers doing no moderate-to-vigorous activity at baseline and who responded to CATI survey at 12 months (N=323). Percentage within intervention type.

Started doing structured P.A. (min/week)*	Group sessions N=293 N (%)	Phone coaching or IC only N=30 N (%)
Changed from 0 to ≥ 210	19 (6.5)	2 (6.7)
Changed from 0 to 150-209	12 (4.1)	2 (6.7)
Changed from 0 to 61-149	42 (14.3)	3 (10.0)
Changed from 0 to 30-60	31 (10.6)	2 (6.7)
Changed from 0 to < 30	--	--
Remained at zero	189 (64.5)	21 (70.0)

* Either or all of moderate/vigorous/resistance training

For the 'other interventions' group the corresponding values are 30% started moving more and 23.4% increased activity to more than one hour per week. While the increase is an average, the

median change is still zero and the difference between means in intervention subgroups is not statistically significant ($\chi^2 = 0.43$, $p = 0.51$).

A similar pattern was observed for those participants who were not completely sedentary but did not meet the moderate/vigorous physical activity goal at baseline (N=104). Almost two thirds remained at the same level or decreased their duration in both the 'group sessions' arm and in the 'other interventions' arm (Table A8.2c). Four percent of those attending group sessions achieved the P.A. goal but none of those on any other intervention did.

Table A8.2c Magnitude of change for completers who were somewhat active at baseline (>1 minute but <210 minutes) and responded to baseline and follow-up CATI survey (N=104). Percentage within intervention type.

Continued doing P.A. (minutes/week)*	Group sessions N=91 N (%)	Phone coaching or IC only N=14 N(%)
Increased by >=210	4 (4.4)	--
Increased by 150-209	5 (5.5)	2 (14.3)
Increased by 61-149	12 (13.2)	1 (7.9)
Increased by 30-60	8 (8.8)	1 (7.1)
Increased to <30	7 (7.7)	2 (14.3)
No change or decreased	55 (60.4)	8 (57.1)

* Either or all of moderate/vigorous/resistance training

Finally, when the non-sedentary group of 58 people (10% of completers) who already met the P.A. goal at baseline is examined (Table A8.2d), 51 of them participated in the final PASE survey. Just under half of them in both intervention type subgroups have maintained their adequate level of moderate/vigorous activity (210 minutes/week) and about 1 in 10 maintained over 150 minutes of activity per week by the end of the Program. The other 40% decreased their level including a quarter in both subgroups who reported zero moderate/vigorous P.A. at the end of the Program. Of note, the PASE questionnaire reflects P.A. in the past week and this is affected by weather and temporary illness.

Table A8.2d Magnitude of change in moderate-to-vigorous physical activity for those completers meeting the goal at baseline and who responded to the PASE module at 12 months (N=44). Percentage within intervention type.

Maintenance of P.A. (minutes/week)*	Group sessions N=49 N (%)	Phone coaching or IC only N=9 N (%)
Maintained >=210	19 (44.2)	4 (50.0)
Decreased to 150-209	4 (9.3)	1 (12.5)
Decreased to 61-149	-	--
Decreased to 30-60	9 (20.9)	1 (12.5)
Decreased to 1 to <30	-	--
Decreased to zero	11 (25.5)	2 (25.0)

* Either or all of moderate/vigorous/resistance training

No statistical comparisons across groups were attempted for the above estimates in Tables 8.4-8.7 due to the small numbers of people in each cell.

Appendix 8.3 Changes in clinical parameters at one year

One-year changes in fasting plasma glucose (reduction of ≤ 0.01 mmol/L) and total cholesterol (reduction of 0.3 mmol/L or less) were small for both males and females in any SDPP intervention group (Table A8.3a). By comparison, FPG reduction in the GGT was slightly higher (-0.14 mmol/L) but cholesterol reduction was similar (-0.29 mmol/L). In the Finnish DPS the reported FPG change was an increase of 0.1 mmol/L while total cholesterol decreased only by -0.11 mmol/L. The magnitude of FPG change in USDPP at one year was somewhat higher at around -0.25 mmol/L (based on the published graph) in the lifestyle intervention group but this reduction was not sustained at 1.5 years.⁽⁹⁵⁾ No cholesterol changes were reported for the USDPP. In sum, FPG and cholesterol changes in SDPP were more favourable than for the FDPS but FPG reduction was smaller than that in USDPP. The clinical importance of this difference is not known.

Changes in The apparent increase in systolic blood pressure of 2.4 mmHg for people attending groups or initial consultation only, and apparent decrease of 5.4 mmHg among those receiving individual phone coaching was not statistically significant ($p > 0.5$). This was possibly due to small numbers in the phone coaching subgroup. Changes in these parameters by sex were not observed either ($p > 0.5$) so no statistical comparisons between males and females were attempted for the intervention subgroups. Medians and interquartile ranges not presented as distributions of change estimates for all the above parameters have a Normal distribution.

Table A8.3a Estimates of clinical and laboratory changes by sex and intervention modality for Program completers as at 31 December 2010. Totals for participants having relevant measurements at baseline and final assessment.

Outcome (change)	FPG change N=427§ M=159 F=268 Mean (SD)	Cholesterol change N=504 M=195 F=309 Mean (SD)	Systolic blood pressure N=458 M=177 F=281 Mean (SD)	Diastolic blood pressure N=455 M=175 F=280 Mean (SD)
Overall	-0.007 (0.7)	-0.23 (0.9)	+2.3 (18.3)	+0.7 (9.9)
Males (N=159)	-0.001 (0.7)	-0.3 (0.9)	+1.6 (18.3)	+1.3 (9.6)
Females (N=268)	-0.01 (0.7)	-0.2 (0.9)	+2.7 (18.4)	+0.4 (10.0)
Those attending groups	-0.008 (0.6)	-0.2 (0.9)	+2.7 (17.8)	+0.9 (9.6)
Those on phone coaching	-0.007 (0.6)	-0.005 (0.8)	-5.4 (22.5)	-1.6 (13.8)
Attending IC only	+0.002 (1.0)	-0.3 (1.1)	+6.5 (22.0)	-0.4 (8.8)

§ Not every completer had FPG at 12 months. Some had HbA1c, others OGTT and for others the participant refused to have a final blood test or the GP had not produced a blood result at the time of writing this chapter.

The observed incidence of diabetes among SDPP Program participants is still low at 1% of mainstream people enrolled in the program (13/1250) and 2% of completers to date (11/586). This is similar to the 0.99% one-year incidence reported for the lifestyle intervention group in the FDPS but the latter had only a 7.9% loss to follow-up at one year whereas SDPP experienced over 23% missing final assessment, so the complete picture of diabetes incidence among SDPP enrollees is not known. The diabetes incidence rate found in SDPP is consistent with the expected for the annual incidence in a high-risk population without an intervention such as that of NSW AusDiab cohort in 2004 which included people with IGT, IFG and normoglycaemia. (17) As per the FDPS findings, diabetes did not develop among SDPP participants who achieved four or five goals. The SDPP estimate for one-year diabetes incidence is substantially lower than that found in the other studies. The 12-month diabetes incidence in the lifestyle intervention group of the USDPP was around 5% and just over 10% in the lifestyle intervention arm of the Indian DPP.⁽¹⁰⁴⁾ The Australian GGT study reported one-year incidence of 2.2% only for those with

IGT at baseline but not for the entire group of participants.(117) The Da Qing study in China found a cumulative diabetes incidence of 44.6% in the 'exercise plus diet' intervention group vs. 65.9% in the control group but did not report 12-month diabetes incidence.(90) The SDPP findings cannot be compared with those of the other reference trial in China, because the risk reduction outcomes in the Chinese DPP were only available for 6-year and 20-year follow-up and were presented only for obesity and glucose/diabetes subgroup levels rather than overall. A possible explanation for the lower diabetes incidence in SDPP relative to the USDPP is that the inclusion criteria in the Sydney Program extended to people at risk with and without IGT, whereas the USDPP study recruited exclusively people with IGT, who have a higher annual rate of conversion to diabetes. Another tentative reason for the lower incidence in SDPP is that the Sydney study has had incomplete outcome assessment for almost one in every four participants so far. Thus diabetes cannot be ruled out in those lost to follow-up. The current report of 1% for SDPP could be an underestimate.

Appendix 8.4 Weight changes between three-month and twelve-month follow-up

As discussed in Chapter 7 on the short-term impact evaluation, 78% of the completers (458) had attended the third Group session at approximately three months from enrolment. Based on measured weight at this session, the weight loss measured at three months for males was significantly greater than that for females ($p \leq 0.01$; more details in Chapter 7). At 12 months sex differentials in weight loss were not statistically significant. While there appear to be a trend for the mean weight loss to be larger at 12 months than the weight loss found at three months, statistically there was no difference between the first and second time points either between sexes or overall (see confidence intervals in table App 8.1).

Figure A8.1 Weight change over time by sex for completers with weight data at 3 months and 12 months (N=171 males and 287 females).

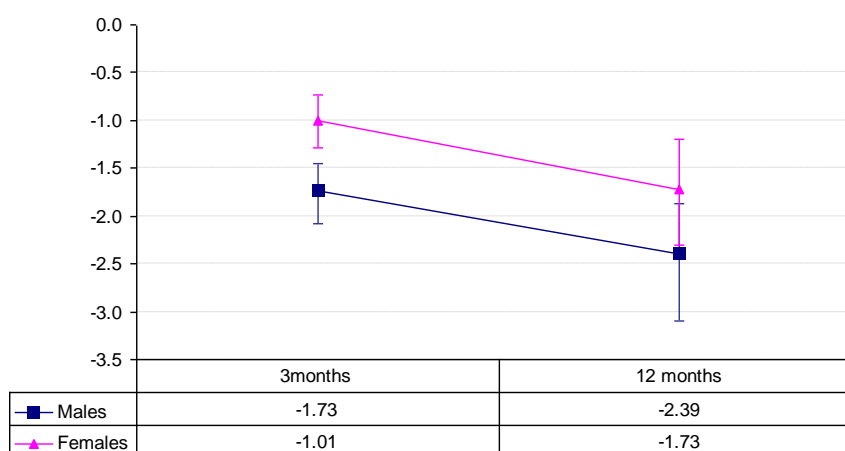


Table A8.1 Weight loss differentials (3-months & 12-months) by sex. N= 225males and 361 females.

Sex	Time point	N	Mean	Lower 95% CL for Mean	Upper 95% CL for Mean
Male	Weight loss 3m	171	-1.73	-2.08	-1.398
	weight loss 12m	223	-2.37	-2.968	-1.78
Female	Weight loss 3m	287	-1.01	-1.288	-0.73
	weight loss 12m	355	-1.87	-2.368	-1.39

Appendix 9.1 Participants costs

Out of pocket expenses were investigated in a limited way from the SDPP participants. Questions were included in the baseline CATI, 3-month follow-up call and 12-month CATI to estimate detailed participant costs. These costs include expenditure associated with the purchase of clothing, equipment, nutritious food, community-based programs co-payments and additional transport costs. Every contacted participant was expected to be asked the relevant questions at each milestone.

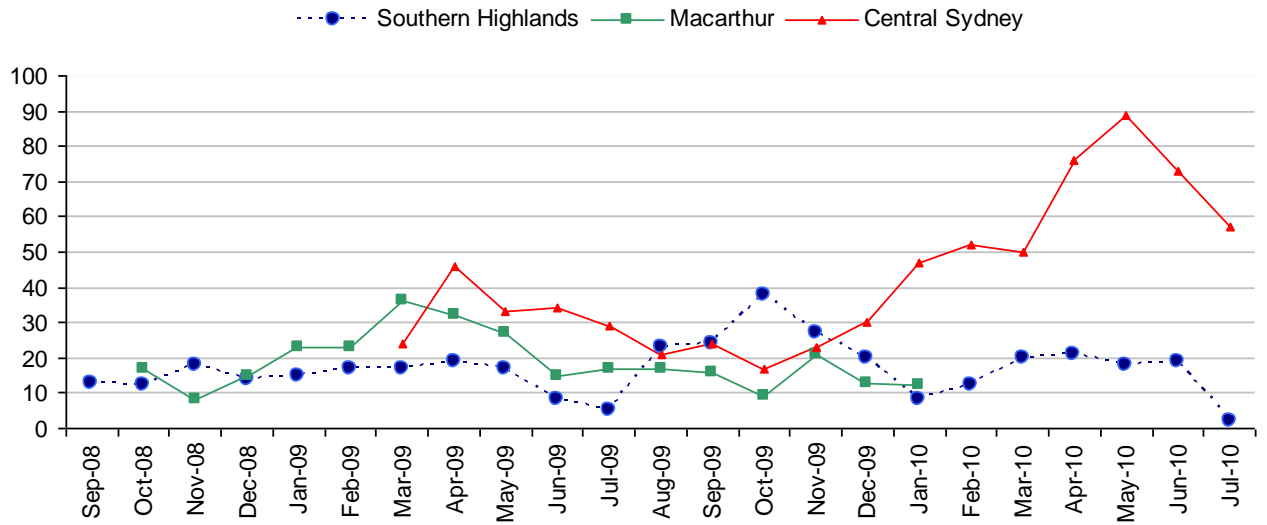
In addition, detailed questions on use of prescription medications were asked at baseline and in the final CATI, and costs based on PBS listing. A single question on whether there had been a reduction or increase in prescription medication was asked at each quarterly follow-up call. This information was meant to assist calculation of changes in costs to the participant and/or the health system if substantial variations in medication use are detected. This was not the case, so information has not been used for the economic appraisal, only for the purpose of descriptive statistics.

At baseline and 12-month CATI times, this information was mostly complete (92% and 91% respectively) but at the 3-month follow-up the completion of these items varied depending on call duration due to participant's availability and cooperation or the lifestyle officers' competing responsibilities. On average 11% of these data are missing for the 3-month contact, 16% for the 6-month contact, and 13% for the 9-month follow-up. However, this does not reflect the cost of lifestyle officer time in attempting to contact participants (a maximum of 3 attempts per participant).

There is no comparability of costing estimates for participants and the health system perspective. Participants were asked to give an estimate using recall for the past three months for physical activity products or services, but no validation of self-report was attempted. Nor there was a comparison with market value for the items reported.

Likewise, the SDPP did not attempt to cost days off due to illness or injury, or time spent away from work in attending Program activities because information on the occupation of participants was not collected and there are no reference values for all subpopulations in Australia.

Appendix 9.2 Monthly recruitment figures by Division from 2008 to 2010



Recruitment in Southern Highlands and Macarthur Division was very slow in the early implementation phase as staff were being trained, screening strategies were being discussed, materials were not fully developed, and a pilot Program was being conducted. In Central Sydney the implementation phase was associated with a larger number of lifestyle officers and all materials fully developed, so recruitment numbers in the early implementation phase were higher. The noticeable increase in numbers joining in Central Sydney in 2010 was due to imminent closure of recruitment. Many strategies were put in place to ensure target quota was achieved (see process evaluation).

Appendix 9.3 Template for the collection of health system costs

A template was proposed to collect monthly information on the operational costs of the Program and technical assistance to undertake the data collection was offered to relevant Division staff. The aim was to collect data files on a monthly or quarterly basis. Each Division, however, had an existing reporting template for financial data for other operations and programs or did not document expenditure on a monthly basis. Each Division provided a modified version of the template in the form of 6-monthly retrospective expenditure reports. Such variability in the amount of detail provided has limited our ability to analyse and compare costs and utilisation data. Thus the SDPP is only able to estimate an average cost per participant.

DATA COLLECTION GUIDE FOR THE ECONOMIC EVALUATION OF SDPP For Division Coordinators and Area Health Service Staff July 2008

Purpose of this guide

This document is designed to assist the Divisions of General Practice and Area Health Service staff in documenting information that will be used as part of the economic evaluation of the Live Life Well Diabetes Prevention Program.

Why are we collecting economic data?

The most important reason to collect economic data is to provide information about the financial resources that would have to be committed if introducing the same program in other Area Health Services or rolling-out a State-wide program.

Therefore, important economic information includes documenting what resources were used for planning, organising and implementing the program. While the economic appraisal of this program will not be exhaustive, it will take a practical view and will collect generic and some specific cost data for the components of the program.

How will we go about documenting Program-related costs?

The program related costs relevant to this economic appraisal are: staffing; equipment; consumables; and overheads.

The following page has a worked example to help you keep track of your organisation's status in relation to relevant costs of the Live Life Well Sydney Diabetes Prevention Program. An electronic spreadsheet is also attached for your convenience. This can be used as the basis of your documentation. Feel free to add other data e.g. staff, equipment to meet your needs and reflect program spending.

How often will economic data need to be collected, documented or reported?

It will be easier for Division Coordinators to use the electronic form for documenting expenses on an ongoing basis from the beginning of the Program. You can then have a compilation for each month, which in turn, can be translated into total costs at the end of the Program.

There is no need to transfer this information every month, but just keep the records up to date and deliver them once, at the end of the agreed data collection period (possibly end of 2009).

Should you need any clarifications on how to fill in the form, feel free to consult with the evaluation team (mcardona@med.usyd.edu.au) at any time.

Division of General Practice: _____
 Name of person completing this form: _____ Position: _____
 Contact number: _____ Email: _____

STAFF	position name/level	annual salary for F/T equivalent	start date	basis of employment	Proportion of time used in SDPP Program	salary costs this period (\$ one month)	on-costs 15%	Total salary cost
	Lifestyle officer 1	50,100	01-07-08	0.8 FTE (4 days per week)	80%	3,340	501	\$ 3,841
	Lifestyle officer 2	50,100	02-07-08	0.5 FTE (2.5 days per week)	50%	2,087	313	\$2,400
	Division Coordinator	48,500	15-07-08	0.6 FTE (3 days per week)	60%	2,425	363	\$2,788
	Exercise physiologist 1	57,500	01-07-08	0.2 FTE (1 day per week)	20%	958	143	\$ 1,102
	Nutritionist	69,000	01-07-08	0.1 (half a day per week)	10%	\$ 575	86	\$ 661
EQUIPMENT	item	date of purchase	whole dollars spent	one-off or ongoing	Proportion of usage spent on the program	Total cost of Program-related equipment THIS MONTH		
	small car	02-05-08	22,500	one off	80%	\$ 18,000		
	12 wedderburn scales	13-06-08	2,340	one off	100%	\$ 2,340		
	stadiometer	29-05-08	310	one off	100%	\$ 310		
	12 tape measures	13-06-08	36	one off	100%	\$ 36		
CONSUM-ABLES	item description	month of expenditure	whole dollars spent	one-off or ongoing	Proportion of usage spent on the program	Total cost of Program-related consumables THIS MONTH		
	recruitment costs	July	730	one off	100%	\$ 730		
	Advertising Program	July	1,200	one off	50%	\$ 600		
	paper	July	145	ongoing	100%	\$ 145		
	printing costs	July	620	ongoing	100%	\$ 620		
	travel costs	July	921	ongoing	100%	\$ 921		
OVERHEADS	item description	month of expenditure	whole dollars spent	one-off or ongoing	Proportion of usage spent on the program	Total cost of Program related overheads THIS MONTH		
	Room rental (initial assessment)	July	246	ongoing	100%	\$ 246		
	electricity	July	111	ongoing	50%	\$ 55		
	telephone	July	88	ongoing	40%	\$ 35		
	fax	July	20	ongoing	100%	\$ 20		

Appendix 9.4 Weight loss by intervention type and by Division of GP

Division & intervention	Estimate mean weight loss (kg)*	95% Confidence interval (kg)
Attending groups		
Macarthur	-1.7	(-2.4 to -1.1)
Southern Highlands	-2.4	(-3.2 to -3.7)
Central Sydney	-1.7	(-2.5 to -1.0)
Phone coaching		
Macarthur	-4.6	(-12 to +2.7)
Southern Highlands	-1.3	(-3.2 to +0.7)
Central Sydney	-3.4	(-9.1 to +2.3)
Neither		
Macarthur	-4.1	(-13.4 to +5.1)
Southern Highlands	-4.2	(-10.1 to +1.7)
Central Sydney	+1.4	(-6.9 to +9.6)

* Negative sign indicates weight loss and positive sign indicates weight gain

Appendix 9.5 Screening pathway and entry criteria for SDPP

Prevent Diabetes *Live Life Well* Screening Pathway

