DOCTORAL THESIS

Exploring the attributes of group-based education for the management of chronic diseases, focusing on type 2 diabetes mellitus

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Exploring the attributes of group-based education for the management of chronic diseases, focusing on type 2 diabetes mellitus.

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Abstract

Background: Previous systematic reviews comparing group-based education programs with individual care have demonstrated promising results in terms of health outcomes for people with type 2 diabetes mellitus (T2DM). However, these are out-dated, with searches failing to account for the last eight years of published literature. Additionally, previous reviews have not investigated whether specific attributes of group-based interventions account for improved patient outcomes. Given the widely acknowledged role of self-management in T2DM, the experiences and motivations of individuals who choose to attend group education programs are largely under-explored. Further, there is evidence that Accredited Practising Dietitians (APDs) in Australia are underutilizing group-based education for people with T2DM; however, the reasons for this are currently unknown.

Aims and Objectives: The overarching aim of this thesis is to assess which attributes of group-based education programs for the management of T2DM contribute to effectiveness. The objectives were to assess the effectiveness of these programs and explore the impact of various program attributes on intervention effectiveness, to identify and compare how group-based education programs are developed in practice, and to obtain the opinions of group facilitators and participants on the attributes that affect the success of group-based education. Additional objectives of this thesis were to develop and assess the feasibility and acceptability of a group-based education program for the management of T2DM, to understand individuals' experiences of these programs, explore their motivation for self-management, and to explore the utilization of group-based education, as well as preferences for practice and training, among APDs.

Methods: A systematic review with meta-analyses and meta-regression was completed to assess whether group-based education programs for the management of T2DM are effective at improving clinical, lifestyle and psychosocial outcomes in adults in both the short (6 months) and long term (greater than 12 months) when compared with usual care, waiting list control, or individual interventions. The primary outcome was glycated haemoglobin (HbA1c) levels, while secondary outcomes were fasting blood glucose (FBG), body weight, body mass index (BMI), waist circumference, systolic and diastolic blood pressure, blood lipid levels, diabetes knowledge, depression scores and physical activity levels. Further, this study investigated the impact of various attributes on intervention effectiveness, and assessed the completeness of reporting of included

studies using the Template for Intervention Description and Replication (TIDieR), which aims to improve the reporting and ultimately the replicability of interventions. In addition, three further studies have been conducted to investigate the feasibility of a group-based education program developed using robust formative evaluation methods (including semi-structured interviews with facilitators and participants of existing chronic disease group programs), and to explore the experiences and motivations of participants in the feasibility study (through additional semi-structured interviews). Finally, an investigation of the utilization of group-based education by APDs was conducted using an online survey.

Results: The results of the systematic review, which included 53 publications describing 47 studies, favoured group-based education when compared to controls for the primary outcome (HbA1c) at six to ten months (MD= 0.31%; 95%CI:-0.48, -0.15; 30 studies, n=4107), 12-14 months (MD= 0.33%; 95%CI:-0.49, -0.17; 27 studies, n= 4384), 18 months (MD= 0.72%; 95%CI:-1.26, -0.18; 3 studies, n=194), and 36-48 months (MD= 0.93%; 95%CI:-1.52, -0.34; 5 studies, n=1436) post-baseline. The results of the pooled analyses also favoured group-based education for some secondary outcome measures including FBG after a year, body weight and waist circumference in the shorter term; triglyceride levels at both short and long term follow up; and diabetes knowledge, depression scores and physical activity in the short term. The analyses found no statistically significant effect for group-based interventions when measuring BMI, blood pressure, total or HDL cholesterol, quality of life or energy intake at short or long term measures. Furthermore, the results indicated that the group-based interventions with greater effects on HbA1c appear to be those that: are conducted in primary care settings; that provide materials to participants; have less than 10 sessions provided either in less than one month, or over seven to 12 months or 13 to 60 months; provide either 8 hours or less or over 31 hours of contact time; and include individuals with HbA1c levels greater than 7%. The assessment of the completeness of reporting of the included studies using the TIDieR checklist suggested that group-based education interventions for T2DM are often incompletely reported.

The results of the feasibility study and qualitative investigation, which used thematic analysis underpinned by self-determination theory (SDT), found that factors such as peer identification, normalisation, and group interactions may substantially influence the effectiveness of group-based education interventions for the management of T2DM and may improve motivation for self-management. Additionally, the results of these studies support the use of patient-centred programs

focusing on group interactions rather than the didactic presentation of content. Lastly, the results of the survey of APDs indicated that they are currently underutilizing group-based education programs for the management of T2DM, with the primary reasons likely to be a lack of training provided to APDs in the area, limited access to facilities suitable for groups, the perceived poor cost effectiveness of these programs, and the lack of evidence-based practice guidelines for the group-based management of persons with T2DM.

Conclusions: The series of studies completed for this thesis have resulted in numerous implications for practice and future research directions. Key implications of the research include: the primary focus of the group facilitator should be on encouraging group interactions and group discussions to allow group participants to benefit from peer identification and normalisation; group-based education interventions for the management of T2DM can be effective at improving health outcomes at any length, session number, number of contact hours, and number of participants per group; group-based education programs which are patient-centred and non-didactic are efficacious; group-based education programs can be effective when facilitated by single disciplines, multidisciplinary teams or health professionals with peer supporters; and group-based education programs for the management of T2DM may benefit from the use of self-determination theory (SDT) as a framework for intervention design to enhance participant motivation. Primarily, future research in the area of group-based education for the management of T2DM should further assess the influence of group interactions on health outcomes. Additionally, researchers working in the area should design and publish their results using the TIDieR checklist in order to improve the completeness of reporting and replicability of interventions. Finally, further research into the Medicare Chronic Disease Management group items should be completed in order to determine whether the rebates provided can result in financially viable group-based education programs; and the development of evidence-based practice guidelines for the group-based management of persons with T2DM by APDs may increase the number of groups being facilitated by dietitians which could improve the health outcomes of individuals with diabetes.

Declaration

This thesis is submitted to Bond University in fulfilment of the requirements of the degree of Doctor of Philosophy (PhD). This thesis represents my own original work towards this research degree and contains no material which has been previously submitted for a degree or diploma at this University or any other institution, except where due acknowledgement is made.

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List of Publications

The following papers have been derived from this thesis:

1. **Odgers-Jewell K,** Ball L, Kelly J, Reidlinger D, Isenring E, Thomas R. The effectiveness of group-based diabetes self-management education for persons with type 2 diabetes mellitus: a systematic review with meta-analyses and meta-regression. *Diabetes Care*. Proposed submission date: August 2016.

2. **Odgers-Jewell K**, Hughes R, Isenring E, Desbrow B, Leveritt M. Group Facilitators' Perceptions of the Attributes that contribute to the Effectiveness of Group-Based Chronic Disease Management Programs. *Nutrition & Dietetics*. 2015; 72 (4): 347-55.

3. **Odgers-Jewell K**, Isenring E, Thomas R, Reidlinger D. Process evaluation of a patient-centred, patient-directed, group-based education program for the management of type 2 diabetes mellitus. *Nutrition & Dietetics*; Accepted with minor revisions: June 2016.

4. **Odgers-Jewell K**, Isenring E, Thomas R, Reidlinger D. Group Participants' Experiences of a Patient-Directed Group-Based Education Program for the Management of Type 2 Diabetes Mellitus. *The Diabetes Educator*; Submitted July 2016.

5. **Odgers-Jewell K,** Reidlinger D, Thomas R, Isenring E. The utilization of group-based education for patients with type 2 diabetes mellitus, and preferences for practice and training, by Australian dietitians: a survey. *Australian Journal of Primary Health*: Proposed submission date: August 2016.

Conference Abstracts

1. **Odgers-Jewell K,** Leveritt M, Hughes R, Desbrow B. An evaluation of the effect of group dynamics on group based lifestyle modification programs for chronic diseases, such as type 2 diabetes. Gold Coast Health and Medical Research Conference, Gold Coast, 2011.
2. **Odgers-Jewell K,** Leveritt M, Hughes R, Desbrow B. Exploring the attributes of successful group programs for chronic disease management: a group facilitator perspective**.** Gold Coast Health and Medical Research Conference, Gold Coast, 2011.
3. **Odgers-Jewell K**, Hughes R, Leveritt M, Desbrow B. Perceptions of group facilitators on the attributes that contribute to the success of group-based chronic disease management programs. International Congress of Dietetics, Sydney, 2012
4. **Odgers-Jewell K,** Hughes R, Leveritt M, Isenring E. Group participants' perceptions of the attributes that contribute to the effectiveness of group based chronic disease management programs. Dietitians Association of Australia National Conference, Brisbane, 2014.
5. **Odgers-Jewell K,** Isenring E, Thomas R, Reidlinger D. The Bond Diabetes Intervention: a qualitative evaluation of a patient-directed, group-based lifestyle modification program for the management of type 2 diabetes mellitus. Gold Coast Health and Medical Research Conference, Gold Coast, 2015.
6. **Odgers-Jewell K,** Isenring E, Hughes R, Thomas R, Reidlinger D. The Bond Diabetes Intervention: piloting of a patient-directed group-based lifestyle modification program for the management of type 2 diabetes mellitus. Dietitians Association of Australia National Conference, Melbourne, 2016.
7. **Odgers-Jewell K,** Isenring E, Thomas R, Reidlinger D. The utilization of group-based education for patients with type 2 diabetes mellitus, and preferences for practice and training, by Australian dietitians: a survey. Dietitians Association of Australia National Conference, Melbourne, 2016.

Definitions:

Chronic disease/s: Chronic diseases can range from mild conditions such as short- or long-sightedness, dental decay and minor hearing loss, to debilitating arthritis and low back pain, and to life-threatening heart disease and cancers. These conditions may never be cured completely, and once present, chronic diseases often persist throughout life, although they are not always the cause of death. Examples of chronic diseases include: cardiovascular conditions, cancers, many mental disorders, diabetes, many respiratory diseases, musculoskeletal diseases, chronic kidney disease and oral diseases.[1]

Cognitive behavioural therapy: The underlying premise of cognitive behavioural therapy is that in order to alter a patient's behaviour, the associated negative emotions must first be identified and replaced with a more positive and realistic belief. [2]

Empowerment: The World Health Organization (WHO) defines patient empowerment as "*the process of enabling people to increase control over, and to improve, their health*".[3]

Group interactions: For the purposes of this research, 'group interactions' refers to the forces operating in groups, mutual trust among group members, the development of linkages or relationships among members, group leadership and decision making, and the extent to which group members perceived the work of the group to benefit them and others.[4, 5] The investigation of group interactions explores what gives rise to the forces in groups, what conditions modify them, and what consequences they have.[4]

Implementation failure: Implementation failure is the incomplete or poor quality implementation of interventions, which has been suggested as a major determinant of disappointing intervention outcomes.[6]

Peer identification: For the purposes of this research, 'peer identification' refers to the linkages or relationships between group members which help patients to feel part of the group and reduce social isolation.[4, 7]

Self-determination theory: Self-determination theory (SDT) is a theoretical framework explaining the motivational dynamics affecting health behaviours.[8] It proposes that humans have three innate psychological needs that are the basis for their self-motivation and personality integration, and are essential for ongoing psychological growth, integrity and wellbeing: competence; relatedness; and autonomy. According to SDT, competence is feeling effective and exercising one's capacities; relatedness is feeling respected, understood and cared for by others; and autonomy is the perception of being in charge of one's own behaviour.[8, 9]

Type 2 diabetes mellitus: Diabetes Mellitus or Type 2 Diabetes is a metabolic disorder of multiple aetiology with chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion or action [10] Type 2 Diabetes is the most common form of diabetes, occurring mostly in people aged 50 years or over, and accounting for 85 to 90% of all cases.[1]

Waiting list control study: A waiting list study design allows for the provision of care (often delayed) to research participants who are seeking help, whilst permitting a non-intervention evaluation, which may provide an ethical benefit.[11]

Abbreviations:

ADA	American Diabetes Association
AIHW	Australian Institute of Health and Welfare
ANZCTR	Australia New Zealand Clinical Trials Registry
APD	Accredited Practising Dietitian
BDI	Bond Diabetes Intervention
BMI	Body Mass Index
BP	Blood Pressure
BGL	Blood Glucose Levels
CBT	Cognitive Behavioural Therapy
CDM	Chronic Disease Management
CG	Control group
CHD	Coronary Heart Disease
CIRS	Chronic Illness Resource Survey
CKD	Chronic Kidney Disease
CVD	Cardiovascular Disease
DAA	Dietitians Association of Australia
DAGDC	Diabetes Australia Guideline Development Consortium
DESMOND	Diabetes Education and Self-Management in Ongoing and Newly Diagnosed
DoHA	Department of Health and Ageing
EPC	Enhanced Primary Care

FBG	Fasting Blood Glucose
GBE	Group-based education
GI	Glycaemic Index
GP	General Practitioner
HbA1c	Glycated Haemoglobin
HDL	High Density Lipoprotein
HTN	Hypertension
IDF	International Diabetes Federation
IG	Intervention group
LDL	Low Density Lipoprotein
MBS	Medicare Benefits Schedule
Mths	Months
NDSS	National Diabetes Services Scheme
NHMRC	National Health and Medical Research Council
PAM	Patient Activation Measure
PhD	Doctor of Philosophy
QOL	Quality of life
RCT	Randomized Controlled Trial
RevMan	Review Manager
ROMEO	Rethink Organization to iMprove Education and Outcomes
SDT	Self-determination theory
SIDEP	Structured Intensive Diabetes Education Program
SMBG	Self-monitoring of blood glucose

SPSS	Statistical Packages for the Social Sciences
T2DM	Type 2 Diabetes Mellitus
TG	Triglycerides
TIDieR	Template for Intervention Description and Replication
WHO	World Health Organization
Yrs	Years

Contributions to Studies

Systematic Review with Meta-Analyses and Meta-Regression (Chapter 3)

Authors	Conception & Design	Study Selection & Risk of Bias Assessment	Data Extraction	Meta-Analyses and Meta-Regression	Drafting of Manuscript	Critical Revision
Kate Odgers-Jewell	80	60	80	80	100	-
Elisabeth Isenring	5	-	-	-	-	15
Dianne Reidlinger	5	-	-	-	-	15
Rae Thomas	10	-	-	20	-	50
Lauren Ball	-	35	-	-	-	10
Jaimon Kelly	-	15	20	-	-	10

Feasibility Study: Intervention Development and Evaluation (Chapter 4)

Authors	Conception & Design	Data Collection	Data Analysis	Drafting of Manuscript	Critical Revision
Kate Odgers-Jewell	70	100	75	100	-
Elisabeth Isenring	-	-	-	-	15
Dianne Reidlinger	-	-	-	-	70
Rae Thomas	-	-	-	-	15
Roger Hughes	20	-	15	-	-
Michael Leveritt	10	-	10	-	-

Qualitative Analysis of Interview Data (Chapter 5)

Authors	Conception & Design	Data Collection	Data Analysis	Drafting of Manuscript	Critical Revision
Kate Odgers-Jewell	70	100	60	100	-
Elisabeth Isenring	-	-	-	-	15
Dianne Reidlinger	30	-	40	-	70
Rae Thomas	-	-	-	-	15

Survey of Australian Accredited Practising Dietitians (Chapter 6)

Authors	Conception & Design	Data Collection	Data Analysis	Drafting of Manuscript	Critical Revision
Kate Odgers-Jewell	60	100	85	100	-
Elisabeth Isenring	20	-	-	-	60
Dianne Reidlinger	20	-	15	-	25
Rae Thomas	-	-	-	-	15

Formative Interviews: Group Facilitators and Group Participants (Appendices)

Authors	Conception & Design	Data Collection	Data Analysis	Drafting of Manuscript	Critical Revision
Kate Odgers-Jewell	60	100	70	100	-
Elisabeth Isenring	-	-	-	-	30
Roger Hughes	20	-	20	-	40
Michael Leveritt	15	-	10	-	20
Ben Desbrow	5	-	-	-	10

Contributions by others to the thesis

- Mr Justin Clark assisted with the search strategy for the systematic review study.
- Mr Alberto Pinto and Miss Astrid Naranjo assisted with the translation of Italian and Spanish language publications included in the systematic review study.
- Miss Gina Cleo completed the telephone interviews with participants for the feasibility and qualitative studies and was compensated as a research assistant.

Chapter 1: Introduction

Preamble

This chapter introduces the topic of chronic disease management by exploring chronic diseases with a focus on type 2 diabetes mellitus (T2DM). An overview of the management of T2DM including group-based education, and the Australian Medicare Chronic Disease Management (CDM) program is provided.

1.1 Chronic Diseases

Chronic diseases are the largest cause of death in the world and are predicted to rise substantially over the next decade.[1, 12, 13] This increase in global prevalence appears due to improvements in health care which have extended life expectancies, an ageing population and the adverse effects of behavioural and other health risk factors.[1, 12, 13] The burden of chronic diseases is rapidly increasing worldwide, and is expected to increase to 57% by 2020.[13] Almost half of the total deaths caused by chronic diseases are attributable to cardiovascular diseases (CVD), however obesity and T2DM are a major concern as they already affect a large proportion of the world's population and have started to appear earlier in life.[13] Additionally, T2DM and obesity are major risk factors for CVD.[1]

Chronic diseases are defined as diseases that are long-lasting and have persistent effects.[1] Examples of chronic diseases include cardiovascular conditions, such as coronary heart disease (CHD) and stroke, cancers, such as lung and colorectal cancer, T2DM, many respiratory, musculoskeletal and oral diseases, chronic kidney disease (CKD), and mental disorders such as depression.[1] Once present, chronic diseases may never be cured, persisting throughout life.[1] Chronic diseases are the leading cause of illness, disability and death in Australia, accounting for 85% of the total burden of disease and 90% of all deaths in 2010- 2011.[1] The 14th Biennial health report of the Australian Institute of Health and Welfare (AIHW), *Australia's Health 2014,* identifies that chronic diseases have been termed 'Australia's biggest health challenge' of today and for the future, for three main reasons: the significant and increasing costs of chronic disease management, that most chronic diseases are preventable, and the multi-factorial nature of many chronic diseases.[1]

The cost burden of chronic disease is substantial, with CVD accounting for the vast majority of these costs because of the sheer number of individuals with CVD.[1] The significant economic burden on the Australian health care system provided by chronic diseases is due to the combined effects of health-care costs and lost productivity from illness and death.[1] In 2005, it was estimated that the cost of chronic disease

management in Australia was $56 billion per annum; 65% of Australia's total health expenditure.[1] Chronic diseases often coexist, share common risk factors, and are increasingly being seen as acting together to influence illness.[1] Estimates of the direct healthcare costs of chronic diseases are conservative, as not all health-care expenditure can be allocated by disease, particularly diseases predominantly managed in primary health care.[1] The AIHW estimate that the current cost of chronic diseases in Australia is in the order of several billions of dollars (the indirect health costs of the four most expensive chronic diseases: CVD, oral health, mental disorders and musculoskeletal disorders; were over $36 billion in 2008-2009), which is one of the key drivers for more efficient and effective ways to prevent, manage and treat chronic disease.[1] It is clear that better management of chronic disease is required to reduce the burden of chronic disease on our population and our health system.

Chronic diseases are largely preventable.[13] They can result from complex causes including a number of different health risk factors.[1] The determinants that contribute to the development of chronic disease include physiological determinants such as high blood cholesterol, excess body weight and high blood pressure (BP), as well as lifestyle behaviours such as physical inactivity, tobacco smoking, alcohol consumption and poor diet.[1] Additionally, the presence of one chronic disease increases the risk of developing another. For example, the presence of T2DM substantially increases the risk of developing CVD or CKD.[1]

Changes in health behaviours can reduce the incidence and impact of chronic diseases.[1] The World Health Organization (WHO) estimates that more than one third of cancers and up to 80% of CVD, stroke and T2DM, can be prevented by eliminating smoking, unhealthy diet, physical inactivity and the harmful use of alcohol.[1] The initial priority of chronic disease management is to prevent the onset and to improve the management of individuals with chronic diseases in order to avoid or reduce the hospitalization of these individuals.[1] Individuals living with a chronic disease are responsible for managing their condition, without the daily involvement of health care providers.[1] Health care providers therefore need to equip individuals with chronic disease with the knowledge,

skills, ability and tools to competently self-manage their condition and in turn reduce their dependence on the health system.[1]

The need to find strategies that address the health needs of a large number of individuals with chronic disease using limited resources and reducing the time burden on health professionals is crucial. This thesis will use T2DM as a case study of chronic disease management.

1.2 Type 2 Diabetes Mellitus

Diabetes is the fastest growing disease nationally and internationally, with one Australian diagnosed every eight minutes.[1] It has been estimated that approximately 1 million Australians aged two years and over have been diagnosed with diabetes, with 85% of these persons diagnosed with T2DM.[1] Alarmingly, this figure is likely to be an underestimate, with experts predicting that one in every four Australians have undiagnosed diabetes.[1] The self-reported rates of diabetes have more than doubled from 1.5% to 4.2% from 1989-1990 to 2011-2012.[1] In 2014, the AIHW reported that approximately 49,800 new cases of T2DM were diagnosed annually in persons aged 10 years and over, with 92% of the newly diagnosed persons aged over 40 years.[1] Diabetes has been recorded as the fifth leading cause of death globally, with approximately 2.9 million deaths attributable to diabetes in 2000.[1]

As a result of the increasing prevalence of T2DM and associated co-morbidities, the financial burden on the Australian health care system is great, and is projected to increase. The AIHW reported the health care expenditure on T2DM for 2004-2005 to be approximately $828 million, with 37.5% attributed to hospital services, 29.1% attributed to out of hospital medical services, 27.8% attributed to pharmaceuticals, and 5.6% attributed to research.[1] In 2008-2009, it was estimated that the costs of diabetes health care were $1.507 billion in Australia, which is equivalent to 2.3% of total health care expenditure.[1] It is estimated that by 2033, the cost of the treatment of diabetes will

increase by 520% to $8 billion, from the $1.3 billion estimated cost of treatment in 2003.[1]

T2DM is characterized by disorders of insulin secretion, insulin action, or both, causing chronic hyperglycaemia with disturbances of protein, fat and carbohydrate metabolism.[10, 14] T2DM is a preventable disease, with a decrease or elimination of risk factors resulting in a decreased risk of developing the disease and its corresponding complications.[15] Preventable risk factors responsible for the development of the disease include overweight and obesity, physical inactivity, poor diet, tobacco smoking, high blood cholesterol, and impaired glucose regulation.[15] There is evidence of a 'clustering' of risk factors in persons newly diagnosed with T2DM, whom often have total cholesterol higher than 5 mmol/l, BP over 130/60 mmHg, are overweight or obese, and do not meet the recommended weekly levels for physical activity.[16] Several dietary practices which are risk factors for unhealthy weight and/or T2DM risk have been highlighted by the WHO Global Report on Diabetes.[17] These unhealthy dietary practices include a high intake of saturated fatty acids, a high total fat intake, inadequate consumption of dietary fibre, and a high intake of sugar-sweetened beverages.[18-20] Furthermore, diets rich in wholegrains, fruits, vegetables, legumes, and nuts; moderate in alcohol consumption; and lower in refined grains, red or processed meats, have been shown to reduce the risk of T2DM and improve glycaemic control and blood lipids in individuals diagnosed with T2DM.[18]

Much of the burden associated with T2DM can be attributed to co-morbidities such as CVD, and complications associated with sub-optimal blood glucose control.[21] If poorly controlled, T2DM can lead to a range of complications including retinopathy, nephropathy, neuropathy, and increased risk of cardiovascular, peripheral vascular and cerebrovascular diseases.[1, 10, 14, 22, 23] Furthermore, diabetes is the leading cause of end stage renal failure, blindness and limb amputation.[14, 24] CVD is the most common complication of T2DM, with individuals with diabetes being two to five times more likely to develop CVD than persons without diabetes.[14, 24] A recent report released by the AIHW found that two-thirds (68%) of people with diabetes had been diagnosed with CVD and/or CKD, and that the presence of co-morbidities increased with age, with

persons aged of 65 years seven times more likely than those aged 45-64 years to have been diagnosed with more than one chronic disease.[25] Diabetes has been strongly associated with premature death from CVD such as myocardial infarction and stroke, as well as increased morbidity.[14, 23] Coronary heart disease was noted to be an associated cause of death for 51% of deaths due to diabetes in Australia. Similarly, hypertensive disease was noted as an associated cause of death for 31% of deaths due to diabetes, and kidney failure was an associated cause of death for 26% of deaths due to diabetes.[1]

The United Kingdom Prospective Diabetes Study (UKPDS), the largest T2DM-focused clinical research study conducted to date, provided evidence that the complications of T2DM can be reduced by obtaining both optimal blood glucose and BP levels.[26] The results of this study indicated that each 1% reduction in HbA1c is associated with a 21% risk reduction for deaths related to diabetes, 21% for any end point related to diabetes, 37% for microvascular complications, and 14% for myocardial infarction.[26] Furthermore, reductions in systolic BP of 10mmHg were associated with a risk reduction of 15% for deaths related to diabetes, 12% for diabetic complications, 13% for microvascular complications and 11% for myocardial infarction.[14, 26]

Persons with complications from T2DM have a lower quality of life (QOL) than those without, and are more likely to develop depression as a result of poor glycaemic control, disrupted sleep, restricted activity, poor mobility, social isolation, physical ill health and increased mortality.[1, 22, 27] Additionally, adults with diabetes are more likely to be unemployed, earn less, be limited in the type and amount of work they can perform, and have more sick days than their colleagues without diabetes.[27, 28] Individuals with diabetes also have a considerably shorter life expectancy than persons without diabetes.[24] Many persons newly diagnosed with diabetes have a poor understanding of their condition and do not realise that it is a serious, permanent and chronic condition.[16] Significant knowledge and skill deficits in 50 to 80% of individuals with T2DM, as well as poor glycaemic control in over 50% of these individuals, have been identified previously.[29, 30] It has been suggested that the complexity of diabetes management along with a shortage of health workers has led to the inadequate management of diabetes worldwide.[31] Further research is required to explore how individuals with T2DM can be

motivated to self-manage their condition more effectively and for an extended period of time.[32]

In summary, T2DM is a preventable and treatable disease, and with effective education and management, the burden of the disease can be greatly reduced. The economic burden of T2DM in Australia is excessive, with these figures estimated to rise immensely due to the increases in overweight and obesity, and the improvements in survival rates in the developed world.[1] The complications arising from T2DM can be debilitating and include a number of physical complications, as well as mental effects such as depression, sleep deprivation, and social isolation.[22, 27, 33] Better management of T2DM in Australia could greatly reduce the economic burden and disease burden whilst improved glycaemic control in individuals with T2DM can reduce complications and relieve some of the pressure placed on our health system.

1.3 Management of Type 2 Diabetes Mellitus

The Australian National Diabetes Strategy 2016-2020 published by the Department of Health in late 2015 recognized the need for the development of a nationally endorsed set of diabetes guidelines, assessed against the clinical practice guidelines criteria agreed by the Australian Health Ministers' Advisory Council.[34] The strategy states seven key goals including:

1. Prevent people developing T2DM,

2. Promote awareness and earlier detection of type 1 diabetes and T2DM,

3. Reduce the occurrence of diabetes-related complications and improve QOL among people with diabetes,

4. Reduce the impact of pre-existing and gestational diabetes in pregnancy,

5. Reduce the impact of diabetes amongst Aboriginal and Torres Strait Islander peoples,

6. Reduce the impact of diabetes among other priority groups, and

7. Strengthen prevention and care through research, evidence and data.[34]

Additionally, this strategy highlights the need to expand consumer engagement and self-management by enhancing access to structured self-management education programs for people with diabetes, and ensuring that peer support programs are available to all persons with diabetes.[34]

T2DM is a complex, long term condition, which requires the utilization of various health services and the attention of the individuals with the condition, their doctors and other health professionals, to manage it.[1] The primary goal of diabetes management is to prevent complications, which can be achieved by maintaining blood glucose levels (BGL) within the normal range (4.0-7.8 mmol/L).[1] The subsequent goal of diabetes management is to identify and treat any complications as early as possible.[1] Lifestyle modification has been increasingly recognized as important in the management of T2DM by reducing risk factors for CVD and other complications, and reducing the massive personal and medical costs imposed by the disease.[24]

People with diabetes make the majority of their health-related decisions without input from formal health services, making them the predominant managers of their condition.[35-38] The majority of the consequences of T2DM solely affect the individual, their families and carers.[35, 36] The diagnosis of T2DM imposes lifelong, multiple daily demands on the individual and their spouse or family.[31, 37] The WHO Report on therapeutic patient education recognised that the adoption of self-management skills by the person with T2DM is necessary to enable them to manage their diabetes.[13] Successful self-management of chronic conditions requires sufficient knowledge of the condition and its treatment, and the performance of self-management activities and skills to maintain adequate psychosocial functioning.[39] Self-management activities and skills include meal planning and adjustment of dietary intake, medication administration, foot care, regular physical activity, regular medical visits, and home glucose monitoring.[37]

People with T2DM require support, education, guidance and empowerment from their health professionals to make the best decisions and lifestyle changes for themselves, and to break down barriers to effective self-management. [35, 36, 38] It is now widely agreed that although knowledge is an essential prerequisite to learning, knowledge alone does not translate into behaviour change.[40] It is therefore necessary for health professionals to move from seeing individuals with T2DM as passive recipients of care to active decision makers, requiring their support and understanding along with their knowledge.[37, 38, 40] It has been repeatedly demonstrated that just providing the correct information is insufficient to change the beliefs and lifestyle of individuals with T2DM, whilst engaging the individuals is more likely to influence change.[16] Information provided to people with diabetes is often complex and can leave them feeling overwhelmed.[41] Adherence to self-management plans can enable individuals with T2DM, reduce mortality and disability, improve QOL and reduce health care costs.[42] It is essential, therefore, to find new ways of educating individuals with diabetes to ensure that their self-management competency, self-efficacy and confidence is increased.[41] Additionally, it is important to consider the necessity for individuals with T2DM to maintain effective self-management behaviours. Previous research has indicated that persons with T2DM were motivated to maintain changes following an education intervention by four key factors: getting support from others, experiencing the positive effects of the changes, fearing complications, and making the changes a habit.[43, 44]

Currently in Australia, most people with diabetes acquire the majority of their education from their GP, physician or diabetes specialist nurse in an individual counseling setting.[45] This method of management often does not give the person with T2DM an adequate understanding or knowledge of their condition, or the ability to self-manage their condition on a day-to-day basis.[45] Individual counseling by physicians, GPs or diabetes nurse specialists has been suggested to result in vertical relationships, characterized by one-way communication, in which care providers act as superiors and people with T2DM as subordinates.[45] Vertical relationships can result in dissatisfaction, individuals' reluctance to entrust themselves to their care providers, and a limited understanding of their disease, which makes initiating behaviour change difficult.[45] A vital aspect of T2DM management is the active involvement of individuals with diabetes in their own care.[45] Additionally, people generally receive T2DM education in

individual counseling when visiting their health care provider for regular checkups and screening, which are usually limited by time, providing very little opportunity for questions or education following the completion of drug prescriptions and laboratory reports.[45]

Patient education is the cornerstone of chronic disease self-management and is essential to achieve improved outcomes for people with chronic diseases.[36, 46] Diabetes patient education is acknowledged as an integral and vital component of successful diabetes care.[40, 45, 46] The main goal of diabetes patient education is to promote and support positive self-management behaviours in order to optimize metabolic control, improve long term diabetes control and QOL, prevent acute and chronic complications, and reduce morbidity and mortality, all while remaining cost efficient.[29, 40] It is clear that brief, practical, ongoing lifestyle interventions which involve the participants and can be integrated into routine care, are essential in the continuing management of T2DM.[24] Effectively educating individual with T2DM to self-manage their condition should have vast impacts on our health system by improving diabetes control and in turn reducing the disease burden.

1.4 Group-based Education for Chronic Disease Management

Group-based education for people with T2DM has the potential to be a more cost effective and efficient intervention than individual education, due to the reduced time and funding required to educate numerous people in one sitting.[36] Group education programs offer many potential advantages over individual visits, with group programs allowing time for the provision of more detailed information, decreasing time demands on health workers' already busy schedules, allowing the easy incorporation of families and carers, and facilitating discussions and support from others facing the same challenges.[37, 47] A previous systematic review which evaluated the effectiveness of individual patient education on metabolic control, diabetes knowledge and psychosocial outcomes, and included six studies published up to April 2007 compared individual face-to-face education to usual care, and found no significant improvements in HbA1c over a 12 to 18 month period.[48] Additionally, research has shown that individuals with

T2DM managed by individual care experience deteriorating metabolic control despite intensive hypoglycaemic intervention and health professionals' adherence to practice guidelines, which may be ameliorated by group education interventions.[49]

Group-based education has been compared with individual education for people with T2DM in numerous studies. The majority of these studies have shown that group-based education has many benefits over individual education in regards to health outcomes. A systematic search identified two previous systematic reviews (Table 1.1) which assessed self-management education studies that were specific for people with T2DM, delivered in groups for a minimum duration of one hour for one session, and with a comparison or control group that received routine treatment or usual care, remained on a waiting list, or received individual education (all individual treatments).[14, 47] These reviews found that group-based education for the management of T2DM, when compared to individual education, had significant effects on clinical, lifestyle and psychosocial outcomes. Group-based education may therefore have the potential to substantially improve the outcomes for people with T2DM and reduce the burden that T2DM places on health care systems worldwide.

Table 1.1: Significant outcomes of systematic reviews comparing group-based versus individual education, waiting list control or usual care for T2DM

Author/s	Number of studies and participants	HbA1c	Fasting blood glucose	Diabetes knowledge	Body weight	Blood pressure	Need for diabetes medication	Self-management skills	Treatment Satisfaction	Empowerment/ Self-efficacy
Deakin, McShane, Cade & Williams; 2005[14]	14 publications describing 11 studies n= 1532 (742 intervention participants)	Reduced at 4-6 mths (3 studies; n= 395; P<0.00001); 12-14 mths (7 studies; n=1044; P<0.00001); and 2 yrs (2 studies; n=333; P<0.00001)	Reduced at 12 mths (4 studies; n=641; P<00001)	Improved at 12-14 mths (3 studies; n=432; P<0.00001)	Reduced at 12-14 mths (5 studies; n=591; P=0.02)	Reduced systolic BP at 4-6 mths (2 studies; n=399; P=0.01)	Reduced at 12-14 mths (5 studies; n=654; P<0.00001)	N/A	N/A	N/A
Steinsbekk, Rygg, Lisulo, Rise & Fretheim; 2012[47]	26 publications describing 21 studies n=2833 (1454 intervention participants)	Reduced at 6 mths (13 studies; n=1883; P=0.0006); 12 mths (11 studies; n=1503; P=0.001); and 2 yrs (3 studies; n=397; P<0.00001)	Reduced at 12 mths (5 studies; n=690; P<0.00001)	Improved at 6 mths (6 studies; n=768; P=0.00001); 12 mths (5 studies; n=955; P<0.00001); and 2 yrs (2 studies; n=355; P=0.03)	Reduced at 12 mths (4 studies; n=492; P=0.021)	N/A	N/A	Improved at 6 mths (4 studies; n=534; P=0.01)	Improved at 6 mths (2 studies; n=390; P<0.00001) and 12 mths (3 studies; n=484; P<0.0001)	Improved after 6 mths (2 studies; n=326; P=0.01)

HbA1c= glycated haemoglobin; n =number; mths= months; yrs= years; N/A= not assessed

Although these systematic reviews were able to establish the effectiveness of group versus individual education, both reviews noted the difficulties in defining the 'active ingredient' of a group-based education program, with a program's effectiveness potentially due to any combination of factors such as the skills of the educator, the theoretical model used, the venue, the rapport between participants and so on.[47] [47]The quality of both reviews was assessed using 'A Measurement Tool to Assess Systematic Reviews' (AMSTAR), a reliable and valid measurement tool for assessing the methodological quality of systematic reviews.[50] The AMSTAR scores were categorized in line with previous research[51, 52] with scores of zero to four classified as 'low quality', five to eight classified as 'moderate quality', and nine to eleven classified as 'high quality' systematic reviews. The Cochrane review[14] was assessed as a high quality review receiving a score of nine out of eleven. This review scored low for publication bias assessment, and the inclusion of conflict of interest for included studies. The most recent review in the area, by Steinsbekk and colleagues[47], was assessed as a moderate quality review, receiving a score of five out of eleven. This review scored low as no protocol was provided, grey literature was not considered, publication bias was not assessed, no list of excluded studies was provided, the conflicts of interest of included studies were not explored, and the scientific quality of the included studies was not used appropriately in formatting conclusions. Furthermore, this review only included studies published up until the second week of 2008.[47] Considering the volume of literature published in the clinical area of T2DM, the lack of reviews in the area over the past eight years, and the moderate quality of the most recent review, updating a systematic review by including further research will provide sufficient data to investigate group versus individual education in greater detail.

The International Diabetes Federation (IDF) 'Global Guideline for Type 2 Diabetes', an evidence-based guideline updated in 2012, provides recommendations for patient education which include:

1. Make patient-centred, structured self-management education an integral part of the care of all people with T2DM: From around the time of diagnosis; on an ongoing basis, based on routine assessment of need; and on request.

2. Use an appropriately trained multidisciplinary team to provide education to groups of people with diabetes, or individually if group work is considered unsuitable. Where desired, include a family member or friend.
3. Include in education teams a health-care professional with specialist training in diabetes and delivery of education for people with diabetes.
4. Ensure that education is accessible to all people with diabetes, taking account of culture, ethnicity, psychosocial, and disability issues. Consider delivering education in the community or at a local diabetes centre, through technology and in different languages. Include education about the potential risk of alternative medicine.
5. Use techniques of active learning (engagement in the process of learning and with content related to personal experience), adapted to personal choices and learning styles.
6. Use modern communication technologies to advance the methods of delivery of diabetes education.
7. Provide ongoing self-management support.[53]

The guideline highlights the preference for group-based education over individual education, recommending that individual education is provided only to persons with T2DM who are not suitable for group-based education.[53] Furthermore, the guideline recommends structured, patient-centred education programs which utilize the techniques of active learning, provide ongoing self-management support, include family or friends, and are facilitated by appropriately trained multi-disciplinary providers. However, the recommendations in this guideline are based on evidence from 2009 and earlier, and primarily based on the conclusions of a systematic review by Norris et al[30] published in 2001[53]. The guideline does note the evidence in the area to be 'patchy' and states that the final recommendations were based on the common principles which emerged from the literature reviewed.[53]

Despite the established benefits of group-based education, health professionals working in the area of T2DM management and wanting to commence group-based education programs may struggle for various reasons including the absence of recent systematic reviews in the area, the lack of evidence-based practice guidelines for the group-based

management of persons with T2DM, the poor reporting of intervention studies, and the inability of previous studies to establish which attributes influence group-based education programs effectiveness. In Australia, evidence-based practice guidelines for the individual management of persons with T2DM[40] have been established, however group-based education guidelines for the management of persons with T2DM have not been developed. Furthermore, no specific group-based education guidelines have been identified internationally for persons diagnosed with T2DM. This lack of guidelines may result in wide variations in the group-based education programs offered to people with T2DM, health professionals having difficulty interpreting the evidence and translating group-based education studies into a practice setting, and could deter health professionals from developing or facilitating group-based education programs. The 'National Evidence Based Guideline for Patient Education in Type 2 Diabetes' developed by Diabetes Australia for the individual management of persons with T2DM, noted the limited evidence available to identify the attributes of successful patient education programs for people with T2DM as many of the group education studies reviewed in the development of these guidelines yielded inconsistent results.[40] These guidelines were published in 2009, and as such, the group-based education research available at the time of development was limited.

One of the difficulties faced by health professionals wanting to educate individuals with chronic disease in a group setting is that published reports often do not contain detailed or adequate descriptions of the interventions used making it difficult to compare intervention studies or assess the attributes affecting the success of the interventions.[24, 29, 30] A meta-analysis published in 2002 by Weingarten and colleagues evaluating the characteristics and effectiveness of 118 chronic disease management programs, has highlighted that a wide variety of interventions are used in chronic illness education programs due to the lack of methodological standards and information on which interventions achieve the greatest benefits.[28] Although substantial research has compared group versus individual education, few of the interventions used have been theory based, and very few provide detailed descriptions of the interventions, making them difficult to assess and replicate.[29, 46] It has been suggested that programs based on theoretical rationale and using cognitive framing have better outcomes than other programs, however the reasons for this are unclear.[35] A report published by Diabetes

Australia in 2009 showed that although there is a vast body of literature relating to education theory, there is no general agreement on the most beneficial theory for group-based education programs.[40]

Group-based interventions have been criticized for focusing predominantly on motivated individuals, people able to attend a series of education classes, and mainly newly diagnosed individuals with diabetes, potentially missing a vast number of people requiring self-management education.[24] Furthermore, diabetes dietary self-management and weight control programs have been found to have high attrition rates and be relatively unsuccessful long term unless they are very intensive and continued for long periods.[24] Previous research has indicated that group-based education programs offered to individuals with T2DM are often didactic, unevaluated, variable in length, content and educational style, and run by poorly trained facilitators.[35] This may be a consequence of the complexity of group-based educational interventions, the inconsistency in design and the poor reporting of published studies. The strengths of group-based education programs for the management of T2DM however, far outweigh the weaknesses in regards to cost efficiency, time efficiency, and significant improvements in health outcomes.

1.5 Funding for Chronic Disease Management in Australia

In Australia, persons with T2DM can access group-based education through some public hospitals and community centres, through Diabetes Australia or state specific services such as Diabetes Queensland which are funded by the National Diabetes Services Scheme (NDSS), or via private practitioners. The NDSS is an initiative of the Australian Government that is administered with the assistance of Diabetes Australia and provides a range of services to persons diagnosed with diabetes, including group-based education programs.[54] The group-based education programs provided through the NDSS and state specific services generally provide only one or two sessions to participants, and the evidence to support their effectiveness is either not available or has been not demonstrated. For example, a number of state specific services such as Diabetes New South Wales (NSW), Victoria, Western Australia (WA), Tasmania, and

the Australia Capital Territory (ACT) utilize the 'Diabetes Education and Self-Management for Ongoing and Newly Diagnosed' (DESMOND) program, a group-based education program originally developed in the United Kingdom which has been found to be ineffective at significantly improving HbA1c when compared to control.[22, 55] Furthermore, Diabetes Queensland utilizes a similar group-based education program, 'Diabetes- What Now?'[56], for which evidence of effectiveness is not available. Both the 'DESMOND' programs and the 'Diabetes- What Now?' programs provide only four to six hours of contact time to participants over one full day or two half days.[56, 57]

The Enhanced Primary Care (EPC) package was launched by the Australian Federal Government in the 1999 budget and aimed to improve the health and QOL of older Australians, people with chronic conditions and those with multidisciplinary care needs.[58] The Medicare Benefits Schedule (MBS) items under the EPC package allowed GPs to undertake or participate in activities that supported the aims of the EPC package, such as health assessments for older Australians, care planning for individuals with chronic and complex conditions, and multidisciplinary case conferencing.[58] The EPC package was removed in 2005 and replaced by the Chronic Disease Management (CDM) items.[59]

In 2004, allied health services were included under Medicare funding, introduced as CDM Medicare items, which aimed to enhance the management of these conditions, and allowed individuals to receive subsidized allied health professional services in private clinics.[60, 61] Under the CDM plan, eligible persons with chronic disease are entitled to five individual visits per calendar year from any of the 13 participating allied health professions: Aboriginal health workers, audiologists, chiropractors, diabetes educators, dietitians, exercise physiologists, mental health workers, occupational therapists, osteopaths, physiotherapists, podiatrists, psychologists, and speech pathologists; who can claim an AU$52.95 rebate per consultation (minimum 20 minutes per consultation). [59, 60, 62] Team care arrangements under the CDM plan require that the GP and at least two other health care professionals must take part in the care of the individual, resulting in allied health professionals only being able to obtain rebates for a maximum of four individual visits per calendar year.[1, 61]

People who have been diagnosed with T2DM in Australia can be referred through a GP management plan for small group services.[59] The introduction of group-based education rebates in 2008, under the CDM items of the MBS have allowed group-based education programs to potentially become a more feasible and financially viable method of T2DM education and management.[59] The addition of rebates for group-based education to the MBS indicates that the Department of Health and Ageing (DoHA) has recognized the capability of group education programs to provide positive health outcomes whilst consuming limited resources, which is essential due to the vast increases in chronic disease prevalence and the increasing time pressures on health professionals.

Only dietitians, diabetes educators or exercise physiologists who are working in private practice and registered with Medicare Australia are eligible to provide group services.[1] Eligible providers are required to complete an individual initial assessment (minimum 45 minutes) of each person before the commencement of the group-based education program, which can be facilitated by one provider or a combination of providers.[1] Group-based education sessions are required to be a minimum of one hour per session and groups are required to have two to 12 participants.[1] The scheduled fee for providers for the required initial consultation is AU$67.90, and eligible persons are able to attend up to eight group meetings per annum for which allied health professionals can claim an AU$16.95 per person rebate for each session.[59]

Table 1.2 provides a comparison of the financial viability and time requirements for individual and group allied health services. When comparing both the financial viability and time requirements for individual and group allied health services using the best case scenario (four individual visits for individual services, and twelve people for group services), the rebates available through Medicare Australia per person for the total number of consultations available are similar (AU$264.75 for individual services and AU$203.50 for group services) as is the total time requirement (1 hour and 40 minutes for individual services and 1 hour and 25 minutes for group services). This equates to an hourly rate of AU$158.85 for individual services and AU$143.65 for group services.

Table 1.2: Financial viability and time requirements of group versus individual allied health services for the Medicare CDM items[59]

	Initial consultation	Subsequent consultations	Total per person	Total rebate available per group	Hourly rate for practitioners
Individual Consultation/s	Rebate: AU$52.95 Time requirement: 20mins	Rebate: AU$52.95 Time requirement: 20mins	Rebate: AU$52.95 x 4 visits= AU$211.80 Time requirement: 20mins x 4 visits= 1hr20mins	N/A	AU$158.85
Group Consultation/s	Rebate: AU$67.90 Time requirement: 45mins	Rebate: AU$16.95 Time requirement: 1hr per sessions (8hrs total)	Rebate: AU$67.90 + AU$16.95 x 8 visits= $203.50 Time requirement: Minimum: 1hr x 8 visits= 8hrs= 40mins per person (12 people) +45mins initial consult= 1hr25mins Median: 1hr x 8 visits= 8hrs= 1hr20mins (6 people) +45mins initial consult=2hr5mins Maximum: 1hr x 8 visits= 8hrs= 4hrs per person (2 people) +45mins initial consult= 4hr45mins	Minimum: AU$203.50 x 2 people= AU$407 Median: AU$203.50 x 6 people= AU$1221 Maximum: AU$203.50 x 12 people= AU$2442	AU$143.65

Mins= minutes; hrs= hours

The likelihood of having a person with chronic disease choose to only go to one allied health practitioner for the maximum number of sessions (four) over the year is questionable, as is having twelve individuals with chronic disease attending a group education program with no attrition. Additionally, it is highly likely that individual consultations will be longer than 20 minutes each. For example, a recent study by Jansen and colleagues noted that the average individual consultation time for an Australian dietitian is 46 minutes for an initial consultation and 28 minutes for a review consultation.[62] In these instances, the hourly rate of earning for a health professional providing individual consultations to persons with chronic disease would be AU$97.75, a much less attractive figure. It is clear therefore, that the group-based Medicare CDM items offer at least equivalent (using the best case scenario) if not more generous time limits and fees (using the more likely scenario).

Despite these lengthier consultations, people with chronic diseases require more than one or two visits each year to establish healthy self-management behaviours as they need ongoing support and regular reviews from their allied health professional.[60] In regards to health outcomes, consistent and continuing contact with the allied health professional, as well as the support provided by other participants in a group-based environment, ensures that group-based education is more beneficial for people with chronic disease than individual care.[14] Additionally, the earning potential for health professionals can be better with group-based education than individual education, particularly once the group program has been developed and the health professional does not need to spend time preparing the sessions with each succession of the group-based education program.

Although the effectiveness of group-based education programs for chronic disease management have been proven, few health professionals are currently implementing these for the management of individuals with T2DM in Australia.[60] An Australian study published in 2013 noted that 2.67 million individual allied health services were provided nationwide under the Medicare CDM items in 2010, with the most utilized allied health services being podiatry, physiotherapy, dietetics, chiropractic and speech pathology.[60] In contrast, only 31,000 allied health group service items were provided in

2010, with 90% of these services being provided by exercise physiologists, and the remaining 10% by diabetes educators and dietitians.[60]

The utilization of group services for T2DM management provided by Accredited Practising Dietitians (APDs), the third most utilized Medicare CDM allied health service, has remained relatively low, comprising less than 2% of total dietetic service provision.[62] The usage of individual dietetic services has increased consistently over recent years, whilst group service item usage has decreased.[62] According to a recent qualitative study conducted in Queensland which utilized semi-structured interviews, dietitians who conduct CDM group education sessions report a lack of access to appropriate facilities and to multidisciplinary providers, along with other factors such as the lack of a common national curriculum for T2DM group education programs.[62]

Evidence-based guidelines for managing individuals with T2DM, the 'National Evidence Based Guideline for Patient Education in Type 2 Diabetes', were developed in 2009 under a funding agreement between DoHA and the Diabetes Australia Guideline Development Consortium (DAGDC) to ensure best practice for health professionals in Australia.[40] Even though the guidelines state that diabetes education should be delivered in groups or individually, there are no specific evidence-based guidelines for the group-based management of people with T2DM.[40] Additionally, in 2006 the Dietitians Association of Australia (DAA) published the 'Evidence Based Practice Guidelines for the Nutritional Management of Type 2 Diabetes Mellitus for Adults'.[63] The purpose of these guidelines is to provide a framework to assist Australian dietitians in the dietetic assessment, intervention, and evaluation of outcomes for medical nutrition therapy for the individual management of adults with T2DM.[63] The guidelines note that the need for further research in the area of group-based education for the management of T2DM is clear, and encourages dietitians conducting group-based education programs to read the literature to determine the most effective structure and program content. The lack of evidence based practice guidelines on how best to educate individuals in a group setting, and the long term benefits of these methods of education, is likely to be a deterrent for busy allied health professionals.

The limited usage of the Medicare CDM group service items are likely due to a number of complex factors, not merely the lack of group-based education guidelines. Cant and Foster propose that service system issues, workforce capacity, awareness among practitioners and practitioner attitudes and preferences are the main factors impeding the uptake of these items.[60] In a recent study, Australian dietitians stated that reasons for the low uptake of the Medicare CDM group education items are that they did not find group services to be cost effective, group education programs were not viable, or they were unaware that the rebates were available (unpublished results).[62] The potential to educate individuals in a cost effective and time efficient manner, to enhance care by providing ongoing support, to improve outcomes and to increase the earnings of allied health professionals over longer periods, is not being explored by a vast number of allied health professionals.

1.6 Conclusions

Chronic diseases are the largest cause of death in the developed world and their prevalence and impact are increasing at a rapid rate.[1, 12] Despite Australia's economically developed status and publicly funded universal health care scheme, Medicare, chronic diseases are also the leading cause of illness, disability and death in Australia.[1] Chronic diseases provide a significant economic burden in Australia due to the combined effects of health-care costs, lost productivity from illness, reliance on social security, and death.[1] Developing strategies that address the health needs of a large number of individuals with chronic disease using limited resources and reducing the time burden on health professionals is critical.

Group-based education for the management of T2DM has been shown to have significant positive effects on clinical, lifestyle and psychosocial outcomes, having the potential to vastly improve the outcomes of people with T2DM and reduce the enormous burden that chronic diseases place on health care systems worldwide. Despite the proven effectiveness and benefits of group-based education for the management of T2DM, the Medicare CDM group service items remain surprisingly underutilized. This is likely to be due to a number of complex factors, which may include the lack of group-

based education guidelines, service system issues, workforce capacity, awareness among practitioners, and practitioner attitudes and preferences.[60] Additionally, the vast majority of group-based education studies T2DM management are poorly reported and do not provide an adequate description of interventions, making it difficult to replicate or compare group-based education studies. Health professionals may also be deterred from group-based education due to the difficulty in establishing which attributes of a group-based education program are essential when developing an effective intervention from the current literature.

This chapter has summarized the literature surrounding group-based education and found that it is an efficient and effective means of managing T2DM, and has the potential to improve health outcomes and reduce the financial and individual burden of T2DM.

Chapter 2: Research Framework

Preamble:

There are currently no evidence-based practice guidelines for the development and facilitation of group-based education programs for the management of T2DM in Australia, and published studies are commonly poorly reported and difficult to replicate. It is challenging therefore, to understand why group-based education programs are effective, and which attributes, such as program length, number of participants, setting, and so on, are crucial to ensure group-education program success. This chapter will describe the rationale and main methodological techniques utilized in this thesis.

2.1 Aims and Objectives

The overarching aim of this thesis is to assess the attributes of group-based education programs for the management of T2DM that contribute to effectiveness.

The objectives of this thesis are to:

1. assess the effectiveness of group-based education programs for the management of T2DM and explore the impact of various program attributes (including program structure, program content, group interactions, group facilitators, program length, number of participants, setting, and the use of learning and psychological theories), on group-based education effectiveness;
2. identify and compare how group-based education programs are developed in practice, and obtain the opinions of group facilitators and group participants on the attributes that affect the success of group-based education programs for the management of chronic disease;
3. develop and assess the feasibility and acceptability of a group-based education program for the management of T2DM;
4. understand individuals' experiences of group-based education for the management of T2DM, and explore their motivation for self-management; and
5. explore the utilization of group-based education, as well as preferences for practice and training, among Australian APDs.

Six key research questions have been developed in order to address the objectives of this thesis. The research questions will be introduced and discussed in the following section.

2.2 Research Questions

Research questions have been developed to direct the studies and guide the collection and analysis of data in this thesis. The research questions are as follows:

1. Is group-based education more effective at improving health outcomes in the management of T2DM than routine treatment, waiting list control, or individual education?

2. Which group-based education program attributes influence the effectiveness of group programs for the management of T2DM?

3. How are group-based education programs for chronic disease management developed and facilitated in practice?

4. Is a group-based education program developed to include the attributes identified as affecting success feasible and acceptable to individuals with T2DM in an authentic setting?

5. What are the motivators of individuals with T2DM in regards to their diabetes self-management and what do individuals with T2DM perceive the impact of group interactions is on their experiences and motivation?

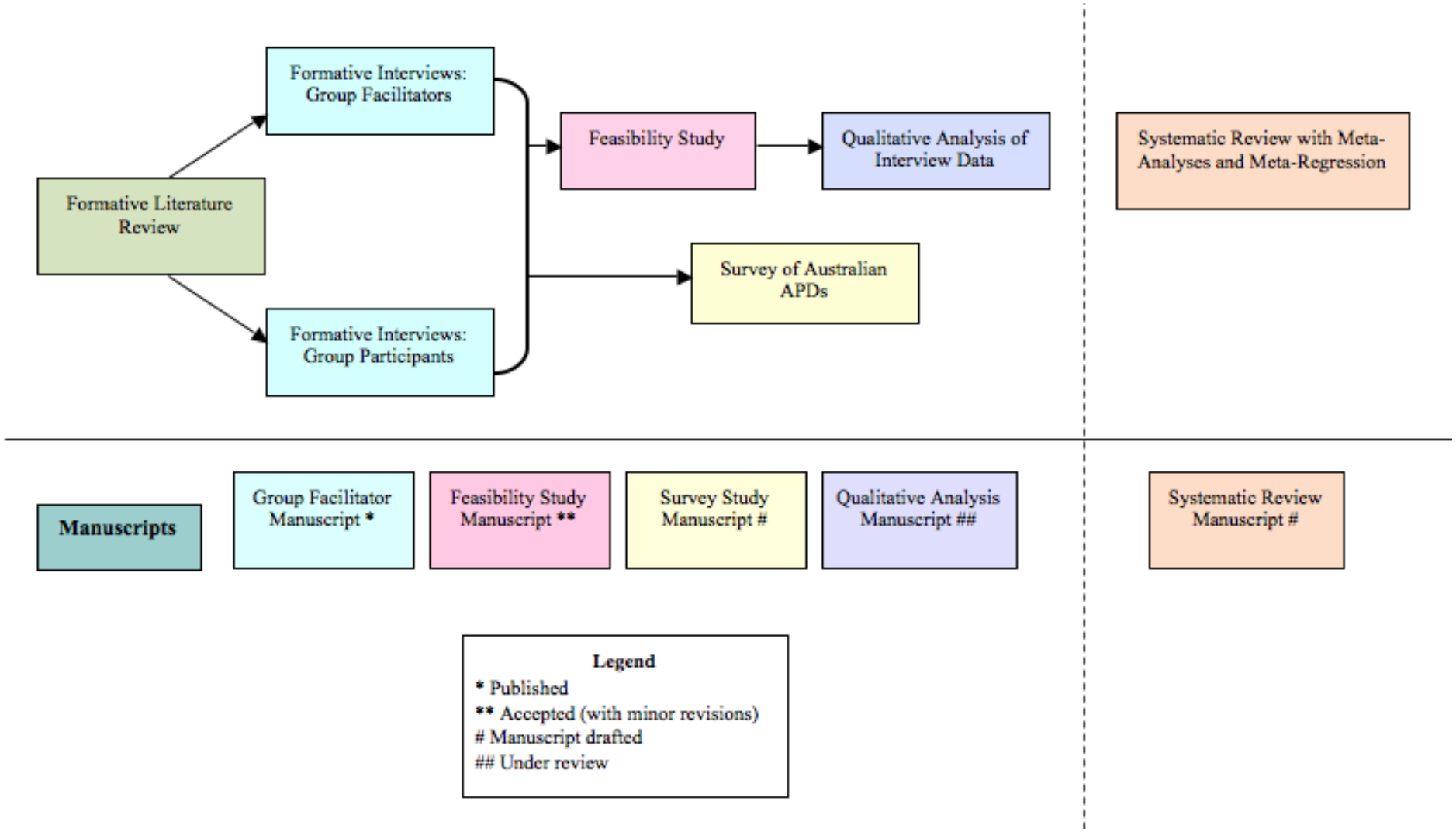
6. Are Australian APDs utilizing group-based education for the management of people with T2DM, and what are their preferences for practice and training?

The approach to these research questions is outlined in Table 2.1 and further explained in the following section. Additionally, the temporal sequence of research is provided in Figure 2.1.

Table 2.1: Research questions and studies through which they will be addressed

Research Question	Systematic Review with Meta-Analyses and Meta-Regression	Formative Interviews: Group Facilitators and Group Participants	Feasibility Study: Intervention Development and Evaluation	Qualitative Analysis of Interview Data	Survey of Australian APDs
1. Is group-based education more effective at improving health outcomes in the management of T2DM than usual care, waiting list control, or individual education?	✕				
2. Which group-based education program attributes influence the effectiveness of group programs for the management of T2DM?	✕	✕			
3. How are group-based education programs for chronic disease management developed and facilitated in practice?		✕	✕		
4. Is a group-based education program developed to include the attributes identified as affecting success feasible and acceptable to individuals with T2DM in an authentic setting?			✕		
5. What are the motivators of individuals with T2DM in regards to their diabetes self-management and what do individuals with T2DM perceive the impact of group interactions is on their experiences and motivation?				✕	
6. Are Australian APDs utilizing group-based education for the management of people with T2DM, and what are their preferences for practice and training?					✕

Figure 2.1: Temporal sequence of research



The research questions will be addressed through six key stages:

1. **Is group-based education more effective at improving health outcomes in the management of T2DM than usual care, waiting list control, or individual education?**

    a. **Systematic Review with Meta-Analyses and Meta-Regression:** A systematic review of the literature with meta-analyses was performed in order to determine whether group-based interventions for the management of T2DM, when compared to usual care, waiting list control, or individual interventions, are effective in improving clinical, lifestyle and psychosocial outcomes in adults.

2. **Which group-based education program attributes influence the effectiveness of group programs for the management of T2DM?**

    a. **Systematic Review with Meta-Analyses and Meta-Regression:** The attributes influencing the effectiveness of the group-based intervention studies explored through subgroup analyses and meta-regression. The subgroup analyses and meta-regression will explore the influence of various study and intervention characteristics on variations in effect size.

    b. **Formative Interviews: Group Facilitators and Group Participants:** Group facilitators' and participants' perceptions and opinions on which attributes influence the effectiveness of group-based education programs for the management of chronic diseases were obtained through two interview studies.

3. **How are group-based education programs for chronic disease management utilized and facilitated in practice?**

    a. **Formative Interviews: Group Facilitators and Group Facilitators:** Group facilitators currently facilitating group-based education programs for the management of chronic diseases were interviewed in order to explore their experiences of developing and facilitating these programs. Group participants who had recently completed group-based education programs

for chronic disease management were interviewed in order to obtain their experiences of these programs in a practice setting.

4. **Is a group-based education program developed to include the attributes identified as affecting success feasible and acceptable to individuals with T2DM in an authentic setting?**
    a. **Feasibility Study: Intervention Development and Evaluation:** A feasibility study which utilized formative research (a preliminary literature review and scoping of group-based interventions, the formative interviews with facilitators of a range of existing CDM group education programs and their participants, and a review of the Medicare group services information pack[20]) to develop a group-based education program for the management of T2DM. The group-based education program was developed, facilitated and evaluated for feasibility and acceptability.

5. **What are the motivators of individuals with T2DM in regards to their diabetes self-management and what do individuals with T2DM perceive the impact of group interactions is on their experiences and motivation?**

    a. **Qualitative Analysis of Interview Data:** A qualitative analysis of interview data to explore the acceptability of the intervention tested in the feasibility study was completed. The study explored participants' motivators in relation to their diabetes management and the impact of group interactions on their experiences and motivation.

6. **Are Australian APDs utilizing group-based education for the management of people with T2DM, and what are their preferences for practice and training?**

    a. **Survey of Australian APDs:** The final study was a survey of Australian APDs, which explored the utilization of group-based education and the barriers to implementing group-based education for the management of T2DM in practice, as well as their preferences for practice and training.

Figure 2.2 provides an overview of the methods used in the studies completed for this thesis, whilst Table 2.2 provides an overview of the research framework, including the proposed publications.

Figure 2.2: Overview of the methods used in thesis studies

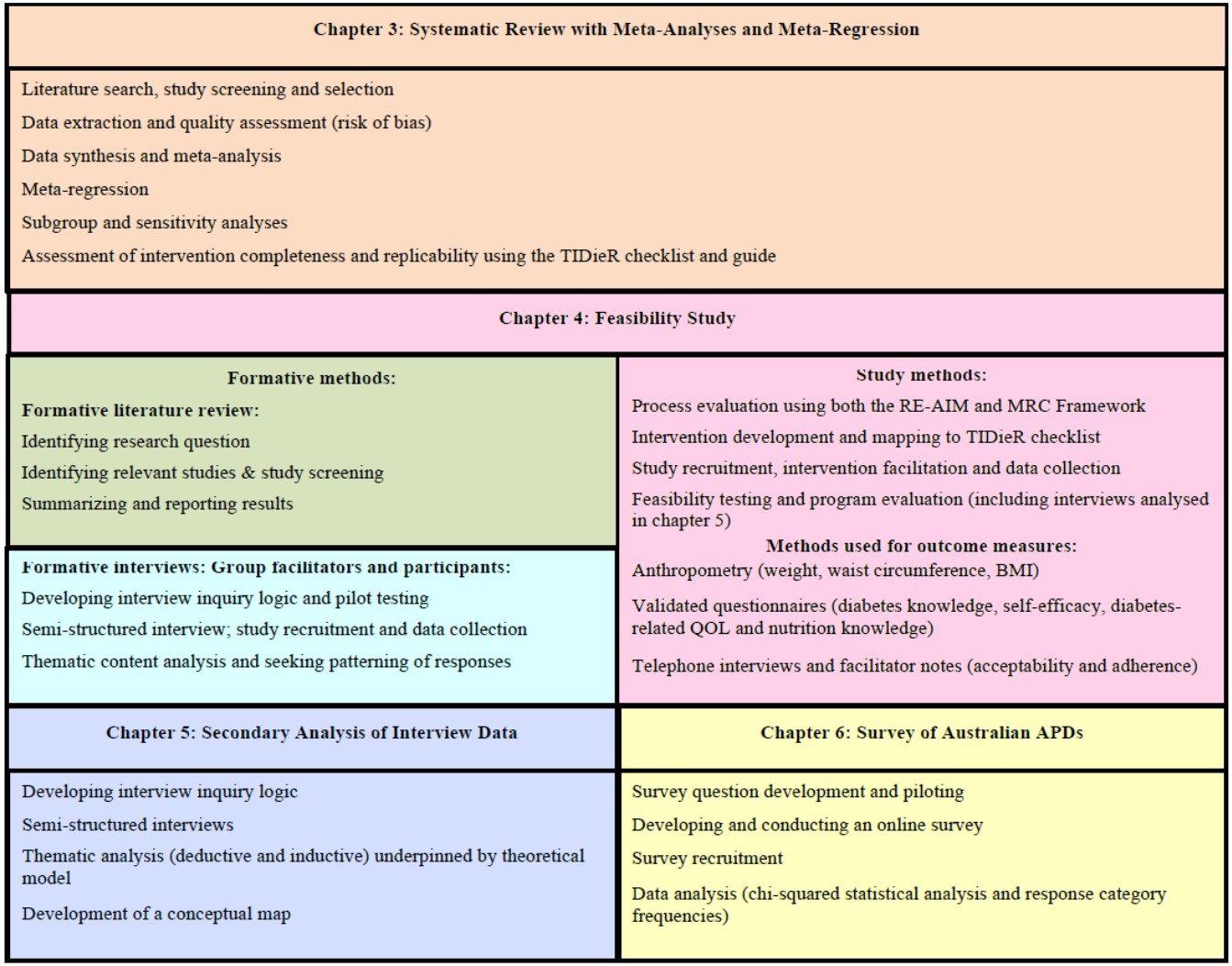


Table 2.2: Overview of the research framework

Study:	Type of Research:	Methods and data expected:	Publications:
Systematic Review with Meta-Analyses and Meta-Regression	Systematic review with meta-analyses and meta-regression	Systematic review of the literature on group-based interventions for the management of T2DM including original studies that reported RCTs, cluster RCTs and CCTs. Included studies were meta-analysed to determine whether group-based interventions are more effective at improving clinical, lifestyle and psychosocial measures when compared to routine treatment, waiting list control or individual interventions. Additionally, studies were assessed for completeness using the TIDieR checklist.[64] A univariate meta-regression and subgroup analyses of the studies was completed to explore the attributes which influence the effectiveness of group-based education programs.	The effectiveness of group-based diabetes self-management education for persons with type 2 diabetes mellitus: a systematic review with meta-analyses and meta-regression. Target Journal: *Diabetes Care* Proposed submission date: August 2016
Formative Interviews: Group Facilitators and Group Participants	Exploratory interview studies	Individual semi-structured interviews with group facilitators running chronic disease groups and group participants who had recently completed a chronic disease group education programs in South East Queensland. Group facilitators' awareness of the theoretical basis of the programs they implement, their experiences of implementation, and their opinions on the attributes contributing to program effectiveness were explored. Group participants' preferences for group education program structure and facilitation, their perceptions of the effect of group interactions on their learning and impression of support, their interest in peer-supported or led programs, and health outcomes were explored. Data were analysed using content analysis of interview transcripts and seeking patterning of responses.	Group Facilitators' Perceptions of the Attributes that contribute to the Effectiveness of Group-Based Chronic Disease Management Programs. Journal: *Nutrition & Dietetics*; *72*(4), 347-355. Published: December 2015
Feasibility Study: Intervention Development and Evaluation	Feasibility study with process evaluation	Intervention development, facilitation and evaluation were completed. Two frameworks, the MRC Framework for Developing and Evaluating Complex Interventions[65] and the RE-AIM framework[66, 67] were utilized. Data to develop the intervention was sourced from a formative literature review, the formative interviews and the Medicare group services information pack.[68] Program evaluation comprised analysis of primary recruitment of participants through general practitioners, baseline and endpoint measures of anthropometry, four validated questionnaires, contemporaneous facilitator notes and telephone interviews with participants.	Process evaluation of a patient-centred, patient-directed, group-based education program for the management of type 2 diabetes mellitus. Target Journal: *Nutrition & Dietetics* Accepted with minor revisions: June 2016

Table 2.2: Overview of the research framework

Study:	Type of Research:	Methods and data expected:	Publications:
Qualitative Analysis of Interview Data	Qualitative study	Individuals with T2DM that completed the intervention study were interviewed using individual semi-structured telephone interviews to explore their motivators in regards to their diabetes management, the acceptability of the intervention, and their perceptions of the effect of group interactions on their experiences and motivators. Interviews were analysed using thematic analysis underpinned by self-determination theory.	Group Participants' Experiences of a Patient-Directed Group-Based Education Program for the Management of Type 2 Diabetes Mellitus. Target Journal: *The Diabetes Educator* Submission date: July 2016
Survey of Australian APDs	Survey study	Australian APDs were surveyed to explore the utilization of group-based education for T2DM management, as well as dietitians' preferences for practice and training. Demographic data was enumerated, whilst data was analysed in SPSS using chi-square testing.	The utilization of group-based education for people with type 2 diabetes mellitus by Australian dietitians: a survey. Target Journal: *Australian Journal of Primary Health* Proposed submission date: August 2016

RCT= randomized controlled trials; CCT= controlled clinical trial; APD= Accredited Practising Dietitian; T2DM= Type 2 diabetes mellitus; MRC= Medical Research Council; RE-AIM= Reach Effectiveness Adoption Implementation Maintenance; SPSS= Statistical Package for the Social Sciences

2.3 Summary

Overall, these investigations will provide an understanding of the attributes of effective group-based education programs for the management of T2DM. Additionally, this PhD research will allow the provision of recommendations for practice, and potentially inform guidelines for the management of individuals with T2DM in a group-based setting. It is assumed that due to the nature of chronic disease management, the program structure could be utilized for various chronic disease programs, not only for T2DM management.

Chapter 3: Systematic Review with Meta-Analyses and Meta-Regression

Preamble

A systematic review with meta-analyses was conducted to determine the effectiveness of group-based education interventions for the management of T2DM. Using HbA1c as a primary outcome, the effectiveness of group-based education programs was compared with routine treatment or usual care, waiting list control, or individual intervention. Additionally, a meta-regression was conducted to explore heterogeneity in effect size based on study design and intervention characteristics. A formative literature review (Appendix D) which informed the Feasibility Study discussed in chapter 4, was completed prior to the completion of the systematic review.

The manuscript for this study titled "The effectiveness of group-based self-management education for persons with type 2 diabetes mellitus: a systematic review with meta-analyses and meta-regression" is currently in draft stage and will be submitted to *Diabetes Care* in August 2016.

The PhD candidate had a principal role in study design, data collection and analysis and wrote the manuscript. Dr Rae Thomas assisted with the study design and data analysis. Dr Lauren Ball assisted with the study selection and risk of bias analysis, and Mr Jaimon Kelly assisted with the study selection and data extraction. Dr Dianne Reidlinger, Prof Elisabeth Isenring, Dr Rae Thomas, Dr Lauren Ball, and Mr Jaimon Kelly have reviewed the manuscript and will comment critically and approve it for submission.

3.1 Abstract

Background:

Patient education for the management of T2DM can be delivered in various forms; most commonly individual education, computer-based education, and group-based education.

Objectives:

This study aimed to determine whether group-based interventions for the management of T2DM compared with routine treatment or usual care, waiting list control, or individual interventions are effective for improving clinical, lifestyle and psychosocial outcomes in adults at both the short (6 months) and long term (greater than 12 months). Further, this study aimed to investigate any variations in effect size based on study design and intervention characteristics, and to assess the completeness of reporting of group-based intervention studies.

Search strategy:

Studies were obtained from computerized searches of several electronic bibliographic databases, including PubMed, the Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, CINAHL, PsycINFO, and ERIC, as well as hand searches of article reference lists and consultation with previous systematic review authors in T2DM.

Selection criteria:

Randomised controlled (RCT), controlled clinical (CCT) and cluster randomised trials evaluating group-based education programs for the management of adults with T2DM were included. Studies were included if they measured glycated haemoglobin (HbA1c), if the groups contained four or more participants, had a minimum of one session lasting for one hour, and if the length of follow up was at least six months or more from baseline.

Data collection and analysis:

Two reviewers independently screened the studies against eligibility criteria and assessed study quality. One reviewer extracted data from each of the included studies, of which a proportion (25%) was checked by a second reviewer. The primary outcome was HbA1c levels, while secondary outcomes were fasting blood glucose (FBG), body

weight, body mass index (BMI), waist circumference, systolic and diastolic blood pressure, blood lipid levels, diabetes knowledge, depression scores and physical activity levels. Meta-analyses were performed when three or more studies reported an outcome at either six to ten, 12 to 14, 18, 24, or 36 to 48 months. A univariate meta-regression examining study designs and intervention characteristics of the included studies was performed to examine heterogeneity.

Results:

Fifty-three publications describing 47 studies were included (N = 8533; n = 4416 (52%) intervention, n = 4117 comparison groups). Of the 47 studies, 40 reported the results of RCTs, four reported the results of CCTs and three reported the results of cluster RCTs. The mean age of participants in the intervention group and control group was 60 years. The proportion of men was lower than the proportion of women (44% intervention group [1917/ 4383], 44% control group [1799/ 4086]). When comparing group-based education to controls, HbA1c reductions were found favouring group-based education at six to ten months post-baseline (MD= 0.31%; 95%CI: -0.48, -0.15; 30 studies, n=4107), 12-14 months (MD= 0.33%; 95%CI: -0.49, -0.17; 27 studies, n=4384), 18 months (MD= 0.72%; 95%CI: -1.26, -0.18; 3 studies, n=194), and 36-48 months (MD= 0.93%; 95%CI: -1.52, -0.34; 5 studies, n=1436) but not at 24 months. Although these reductions did not reach 1%, any reduction in HbA1c has been reported to reduce the risk of T2DM complications.

Similarly, variations in effects were found at different time points for some secondary analyses. Improvements favouring group-based interventions were found for FBG at 12-14 months (MD= 0.68mmol/L; 95%CI: -1.25, -0.11; 8 studies, n=1436); body weight at six to ten months (MD= 1.22kg; 95%CI: -2.22, -0.23; 17 studies, n=2513) and 12-14 months (MD= 1.43kg; 95%CI: -2.09, -0.77; 9 studies, n=1564); waist circumference at six to ten months (MD= 1.19cm; 95%CI: -2.34, -0.05; 5 studies, n=986); triglyceride levels at six to ten months (MD= 0.13mmol/L; 95%CI: -0.24, -0.01; 14 studies, n=2150) and 24 months (MD= 0.32mmol/L; 95%CI: -0.58, -0.06; 3 studies, n=237); diabetes knowledge at six to ten (SMD= 0.61; 95%CI: 0.14, 1.08; 7 studies, n=479) and 12 to 14 months (SMD= 0.58; 95%CI: 0.08, 0.97; 7 studies, n=1291); depression scores at six months (SMD= 0.62; 95%CI: -0.93, -0.31; 3 studies, n=377); and physical activity levels at six months (SMD= 0.23; 95%CI: 0.10, 0.36; 7 studies, n=1097) and 12 to 14 months (SMD= 0.21; 95%CI: 0.06, 0.35; 3 studies, n=862). Pooled analyses found no

statistically significant effect for group-based interventions when measuring BMI, blood pressure, total or HDL cholesterol, quality of life or energy intake. The assessment of the completeness of reporting of the included studies using the TIDieR checklist indicated that group-based education for the management of T2DM are poorly reported and often incomplete.

Conclusions:

The 47 studies included in this systematic review provide evidence supporting the use of group-based education for the management of T2DM to significantly improve HbA1c, FBG, body weight, waist circumference, triglycerides, diabetes knowledge, depression scores, and physical activity levels. There is evidence to suggest that group-based education interventions facilitated by single disciplines, multidisciplinary teams or health professionals with peer supporters, result in improved outcomes in HbA1c when compared to peer-led interventions. Furthermore, the results indicated that the group-based interventions with greater effects on HbA1c appear to be those that: are conducted in primary care settings; provide materials to participants; have less than 10 sessions provided either in less than one month, or over seven to 12 months or 13 to 60 months; provide either 8 hours or less or over 31 hours of contact time; and include individuals with HbA1c levels greater than 7%. The lack of statistical significance in all but one of the subgroup analyses may indicate that other factors such as peer identification, normalisation, and group interactions are the 'active ingredient/s' and as such, substantially influence the effectiveness of group-based education interventions for the management of T2DM. Future group-based intervention studies should design and publish their results using the TIDieR checklist in order to ensure the completeness of reporting and replicability of interventions. Future research in the area should consider the acceptability of these interventions by exploring the perceptions and opinions of group participants.

3.2 Introduction

Diabetes has been identified as an important cause of premature death and disability, and as such was recognized as one of four priority non-communicable diseases (NCDs) targeted by world leaders as part of the 2011 Political Declaration on the Prevention and Control of NCDs.[69] Diabetes prevalence has risen substantially over the past three decades, indiscriminately of country income levels.[17] Affecting approximately 4.7% of the world's adult population in 1980 and increasing substantially to 8.5% in 2014, diabetes mirrors the global increase of overweight and obesity.[17] According to the World Health Organizations (WHO) Global Report on Diabetes the estimated global prevalence of diabetes was 422 million adults in 2014.[17] T2DM accounts for the vast majority (approximately 85%) of diabetes worldwide.[17] Furthermore, a recent review of data from seven countries indicated that between 24 and 62% of people with T2DM are undiagnosed and untreated.[70]

Complications of poorly controlled diabetes include blindness, CKD, CVD, lower limb amputations and several other long term complications, which can substantially impact on the QOL of persons diagnosed with T2DM.[17] Health outcomes can be improved with basic interventions involving education and counseling, medication when required, and regular monitoring and follow-up.[17] The effectiveness of diabetes management depends primarily on a persons' compliance to recommendations and treatment, indicating that patient education is an important component of diabetes management.[17]

Glycated haemoglobin (HbA1c) is a measure that reflects the average plasma glucose levels over a preceding period of eight to 12 weeks, and can be performed with a blood test at any time of day without the need to fast prior to testing.[71] Since the introduction of HbA1c into clinical use in the 1980s it has become the cornerstone of clinical practice for diabetes management, and the preferred test for assessing glycaemic control in people with diabetes.[72] The normal range for HbA1c is less than 6%, with a level ≥6.5% recommended as the cut point for diabetes diagnosis. [73] The UKPDS provided evidence that the complications of T2DM can be reduced by obtaining optimal blood glucose and blood pressure levels, finding that each 1% reduction in HbA1c is associated with a 21% risk reduction for deaths related to diabetes, 21% for any end

point related to diabetes (such as microvascular or macrovascular events, and 'diabetes related death')[74], 37% for microvascular complications, and 14% for myocardial infarctions.[26] Additionally, reductions in systolic blood pressure of 10mmHg were associated with decreases in relative risk of 15% for deaths related to diabetes, 12% for diabetic complications, 13% for microvascular complications and 11% for myocardial infarction.[26].[26] Any reduction in HbA1c and blood pressure has been shown to reduce the risk of diabetic complications.[14]

A Cochrane systematic review (14 publications describing 11 studies published in 2005 with the search concluded in January/ February 2003) assessed the effects of group-based training on clinical, lifestyle and psychosocial outcomes in people with T2DM.[14] The review results favoured group-based education compared with routine treatment, waiting list control or no intervention, finding significant improvements in HbA1c levels, body weight and systolic blood pressure, FBG levels, decreased need for diabetes medication, and increased diabetes knowledge.[14] A subsequent review published in 2012, which built on the original Cochrane review, (26 publications describing 21 studies with the search concluded in January 2008), assessed the effects of group-based diabetes self-management education when compared with routine treatment on the clinical, lifestyle and psychosocial outcomes in individuals with T2DM.[47] The results of this review supported the findings of the Cochrane review also indicating that group-based education programs for the management of T2DM result in significant reductions in HbA1c levels, FBG levels, body weight, and improvements in diabetes knowledge, compared to controls.[47]

The previous reviews had limitations. Firstly, the Cochrane systematic review is out dated and the number of published studies for group-based diabetes interventions has increased substantially since the search was conducted. The original systematic review included only 11 studies and as a result, the researchers were unable to carry out meta-analyses for several of the main outcomes of the review, and heterogeneity of the studies was high.[14] Secondly, there were variations in follow-up analyses. The review conducted by Steinsbekk et al,[47] included more studies (however was limited to RCTs) but only conducted follow-up analyses of the primary outcome up to 12 months from baseline, whilst the Cochrane review assessed follow-up two years or more from

baseline.[14, 47] Finally, both reviews noted that despite statistically significant improvements in clinical and other health outcomes, the exact mechanism or 'active ingredient(s)' of these complex interventions were not able to be identified.[14, 47] The review by Steinsbekk et al[47] relied on the searches and assessments of the previous Cochrane review, only searching five electronic databases from 2003 to the second week of 2008. This may have resulted in the exclusion, or omission, of some studies.

A recent systematic review by Chrvala et al[75] was utilized in the hand searches of previous systematic reviews as part of the search strategy. This review assessed the effect of diabetes self-management education and support methods, providers, duration and contact time on glycaemic control in adults diagnosed with T2DM. The review included individual, group-based, combination and remote interventions for the management of T2DM, with the results suggesting that a combination of individual and group based education was most effective at improving HbA1c (median -0.88%) when compared to controls, and that providing more than 10 hours of contact time were associated with a greater proportion of interventions with significant reductions in HbA1c (70.3% of studies).[75] This review had various limitations including restricting the included studies to English-language publications only, including only RCTs, and including interventions that enrolled individuals with type 1 diabetes and/or T2DM. Furthermore, no meta-analyses were completed, with the review evaluating changes in HbA1c by calculating the percentage of studies that reported a significant difference in HbA1c between the intervention and control groups at one or more follow-up assessments, and by calculating the absolute difference in HbA1c between these groups for a given category of intervention of patient population.[75]

Despite evidence of effectiveness, group-based education interventions are often complex and the characteristics of the interventions often vary greatly, such as in the number of hours, number of sessions, number and characteristics of participants, discipline/s of the group facilitator/s, facilitator training, theoretical framework, and whether family, friends or carers are able to attend.[14, 47] Additionally, published reports of interventions often do not contain detailed or adequate descriptions of the interventions used making it difficult to compare intervention studies, assess the

attributes affecting the success of the interventions, or allow clinicians to implement those interventions found to be effective.[24, 29, 30]

The current systematic review builds upon the two previous reviews[14, 47] by updating the search, including all languages, searching electronic databases from the commencement of records, and including hand searches of reference lists of previous reviews in the area. In concordance with the previous reviews it was hypothesized that:

1. Group-based interventions for T2DM would have greater reductions in HbA1c compared with usual care, waiting list control, or individual interventions at both short (6 months) and long term (more than 12 months) follow-up;
2. Group-based interventions for T2DM would have greater improvements in other clinical, lifestyle and psychosocial measures such as weight, BMI, waist circumference, FBG, blood pressure, lipid profiles, diabetes knowledge, QOL, self-efficacy and empowerment compared with usual care, waiting list control, or individual interventions.
3. Variations in effect sizes could be partially accounted for by study design (i.e. setting, control group, educators) and intervention characteristics (i.e. number of participants, intervention length, number of contact hours).

Finally, included studies were assessed for completeness of reporting using the Template for Intervention Description and Replication (TIDieR)[64], an extension of the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement (item 5) and the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) 2013 statement (item 11), which aims to improve the reporting and ultimately the replicability of interventions.[76]

3.3 Methods

The study was registered with the International Prospective Register of Systematic Reviews PROSPERO (Registration number CRD42015027785).

Data sources and search strategy

A systematic literature search was performed to retrieve publications on group-based education for the management of T2DM in adults. The search was completed in three parts. Firstly, electronic bibliographic databases, including PubMed, the Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, CINAHL, PsycINFO, and ERIC, were searched from commencement of records to the 22nd of September 2015. The search strategy is provided in Appendix A. Key search terms include type 2 diabetes mellitus, patient education, group and group processes. Secondly, hand searches of article reference lists, including the reference lists of the two previous systematic reviews[14, 47] and a recent systematic review by Chrvala et al[75], were completed. Finally, included studies were cross-referenced with the results of an updated search including studies up to May 2012 provided by Professor Steinsbekk (email correspondence).

No language or date restrictions were applied. Abstract only publications and conference proceedings were excluded due to the lack of detail provided. Duplicate articles were removed prior to the initial title and abstract screening.

Inclusion criteria and study selection

Group-based education intervention studies for participants diagnosed with T2DM that reported either randomised controlled trial (RCT), cluster randomised trial or controlled clinical trial (CCT) study designs were included. Participants were required to be aged 18 years and older. Participants could be either medicated or unmedicated. Studies were included if the described intervention met the following criteria: face-to-face, educative group-based interventions (including those with occasional adjunct individual consultations) for people with T2DM; groups that have a minimum of four participants and may include family and friends for support; groups with a minimum of one session lasting for one hour; groups delivered in primary or secondary care compared with a control or comparison group (usual care, waiting list control or individual intervention); and studies that measure HbA1c at both baseline and six months or more from baseline. Studies were excluded if they reported participants were pregnant women diagnosed

with T2DM or gestational diabetes mellitus, adults diagnosed with type 1 diabetes, or children and adolescents. Studies were also excluded if interventions were individual, rather than group-based, provided a substantial number of adjunct individual consultations, included only exercise prescriptions without education, or were web-based, internet-based or telephone-based education programs.

All studies were screened against the eligibility criteria by two independent reviewers using the reference manager software EndNote (Thomson Reuters, USA). Conflicts were resolved by discussion between the two reviewers, and a third party was available for further resolution, however was not required. Studies that met the inclusion criteria, and studies which did not include sufficient information for screening in the title and abstract, were included for further review. Full text versions of all of the included articles were obtained and independently screened. Authors were contacted for missing data up to three times over email, and studies were excluded if the data missing affected the assessment of the studies' ability to meet the inclusion criteria and contact could not be made.

Data extraction and quality assessment

Data extraction was completed by the PhD candidate and a random selection (25%) of the data were rigorously checked by an independent reviewer. No extraction conflicts were found. Data extracted included general information on the study design, trial characteristics, intervention details, participant characteristics, outcome measures, results and information for appraising the risk of bias. Data were also extracted using the TIDieR checklist to assess the completeness and replicability of reporting of each group-based intervention.[64] For the purposes of this study, items 11 and 12 of the TIDieR checklist were combined and item 5 was expanded in order to explore provider training (Table 3.1).

Table 3.1: Template for Intervention Description and Replication (TIDieR) (adapted from reference)[64]

Item number	Item name	Item description
1	Brief name	A name or phrase that describes the intervention
2	Why	Describe any rationale, theory or goal of the elements essential to the intervention
3	What: Materials	Describe any physical or informational materials used in the intervention (including those provided to participants or used in delivery or training of intervention providers) and where to access these
4	What: Procedures	Describe each of the procedures, activities and/or processes used in the intervention including any support activities
5a	Provider/s	Intervention providers and their expertise, and background
5b	Training	Any specific training given to intervention providers
6	How	Describe modes of delivery of the intervention and whether it was provided individually or in a group
7	Where	Describe the type of location/s where the intervention occurred and any necessary infrastructure or relevant features
8	When and How Much	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, their duration and intensity (including the number of participants per group, and the inclusion/ exclusion of family and friends)
9	Tailoring	If the intervention was planned to be personalised or adapted, then describe what, why, when and how
10	Modifications	If the intervention was modified during the course of the study, describe the changes (what, why, when and how)
11	How well: planned	If intervention adherence or fidelity was assessed, describe how and by whom and strategies utilized to maintain fidelity
12	How well: actual	If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.

Study quality was assessed using the Cochrane risk of bias tool[77] by two independent reviewers. Any disagreements were again resolved through discussion. The criteria included minimisation of selection bias, performance bias, detection bias, attrition bias, reporting bias and other bias. Based on these criteria, studies were ranked into three categories:

a. all quality criteria met: low risk of bias;

b. one of more of the quality criteria only partly met: moderate risk of bias;

c. one or more criteria not met: high risk of bias.

This classification was used as the basis for a sensitivity analysis.

Data synthesis and analysis

Descriptive data from included studies were summarized. Data were meta-analysed if the same measurement was used across three or more studies at the same time point. The primary outcome measure was change in HbA1c in group-based education versus control. The secondary outcome measures were changes in FBG, weight, BMI, waist circumference, systolic and diastolic blood pressure, total cholesterol, low density lipoprotein (LDL) cholesterol, high density lipoprotein (HDL) cholesterol, and triglycerides. Additionally, data assessing self-management skills, empowerment, self-efficacy, depression, diabetes knowledge, dietary habits, physical activity levels and quality of life were explored. Studies reporting FBG or lipid profile measures in mg/dl were converted to mmol/L, and studies reporting weight in pounds were converted to kilograms, prior to the meta-analyses. If data were not reported in the required format, authors were contacted up to three times to request the data (n=4). If standard deviations of outcome measures were not provided in published reports they were calculated if possible. Two studies were excluded as the necessary data was unavailable.

Summaries of effect estimates were calculated using a meta-analysis with a random effects model. A random effects model was chosen as it includes consideration of heterogeneity in the effect estimate.[77] Continuous data using the same measures were analysed with a weighted mean difference (WMD) in outcomes between the intervention and control groups, whilst continuous data collected using a variety of measures were assessed using the standard mean difference (SMD). The meta-analyses

were performed using Review Manager (RevMan) version 5.3.[78] For all analyses, the DerSimonian and Laird method provided by RevMan was used. Heterogeneity was assessed using I-squared statistic and reported using the guide provided in the Cochrane Handbook[77]:

1. 0% to 40%: might not be important;
2. 30% to 60%: may represent moderate heterogeneity;
3. 50% to 90%: may represent substantial heterogeneity;
4. 75% to 100%: considerable heterogeneity.

Changes to HbA1c, from baseline to the data collection point closest to the completion of the active intervention was used as the primary outcome for effectiveness of group-based interventions compared with controls, all subgroup comparisons and all sensitivity analyses. Mean differences and confidence intervals (CIs) were calculated in RevMan and standard error for the meta-regression was calculated in Microsoft Excel using the 95% CIs. Subgroup analyses were completed to explore the potential influence of study and intervention characteristics on variations in effect size. Separate analyses for the effect of group-based interventions on HbA1c were performed for the following subgroups:

1. Control group: differences in outcomes for studies where the group-based intervention was compared with usual care, waiting list control, individual intervention, usual care with written information, or a control group that had received group-based education prior to receiving usual care;
2. Delivery setting: studies where the intervention was delivered in primary care compared with other settings;
3. Type of educators: differences in study outcomes for studies with educators from a single discipline, multiple disciplines, and studies facilitated by peer or lay educators, or facilitated by health professionals with peer supporters;
4. Training: whether or not training was provided to the educator/s facilitating the intervention group;
5. Baseline HbA1c levels: outcome differences in studies where the mean baseline HbA1c level of participants in both the intervention and control group were 7%

or more, compared with studies where the mean baselines HbA1c level were less than 7%;

6. Theoretical model: whether or not the use of a theoretical model in the development or facilitation of the intervention was described;
7. Intervention content: differences in studies in which the content was facilitator-directed and studies in which the content was patient-directed;
8. Materials: whether or not materials such as handouts, videos or DVDs and pedometers, were provided to participants in the intervention group;
9. Intervention length: differences in study outcomes where the intervention length was less than one month, one to three months, four to six months, seven to 12 months, or 13 to 60 months;
10. Number of sessions: outcome differences in studies where the total number of sessions provided to the intervention group was five or less, six to ten, 11-20, or 21 or more;
11. Contact time: differences in studies where the total number of hours provided to intervention participants was eight or less, nine to twelve, 13-18, 19-30, or 31 or more;
12. Number of participants: differences in outcomes where the number of participants in each group session was four to ten or 11-20;
13. Family and friends: whether family, friends or carers were included in the group sessions or not.

Sensitivity analyses were conducted to explore the influence of study quality (overall risk of bias and reporting bias), HbA1c baseline differences, attrition, and study publication language on HbA1c outcomes (as measured closest to intervention completion). Overall risk of bias was included in the sensitivity analyses in order to assess whether the risk of bias or quality of the included studies influenced the primary outcome. Reporting bias, or selective outcome reporting was chosen for the sensitivity analysis as studies which did not report the pre-specified outcomes or failed to include the results for an expected outcome, may only be reporting results which support the studies aims or hypothesis.

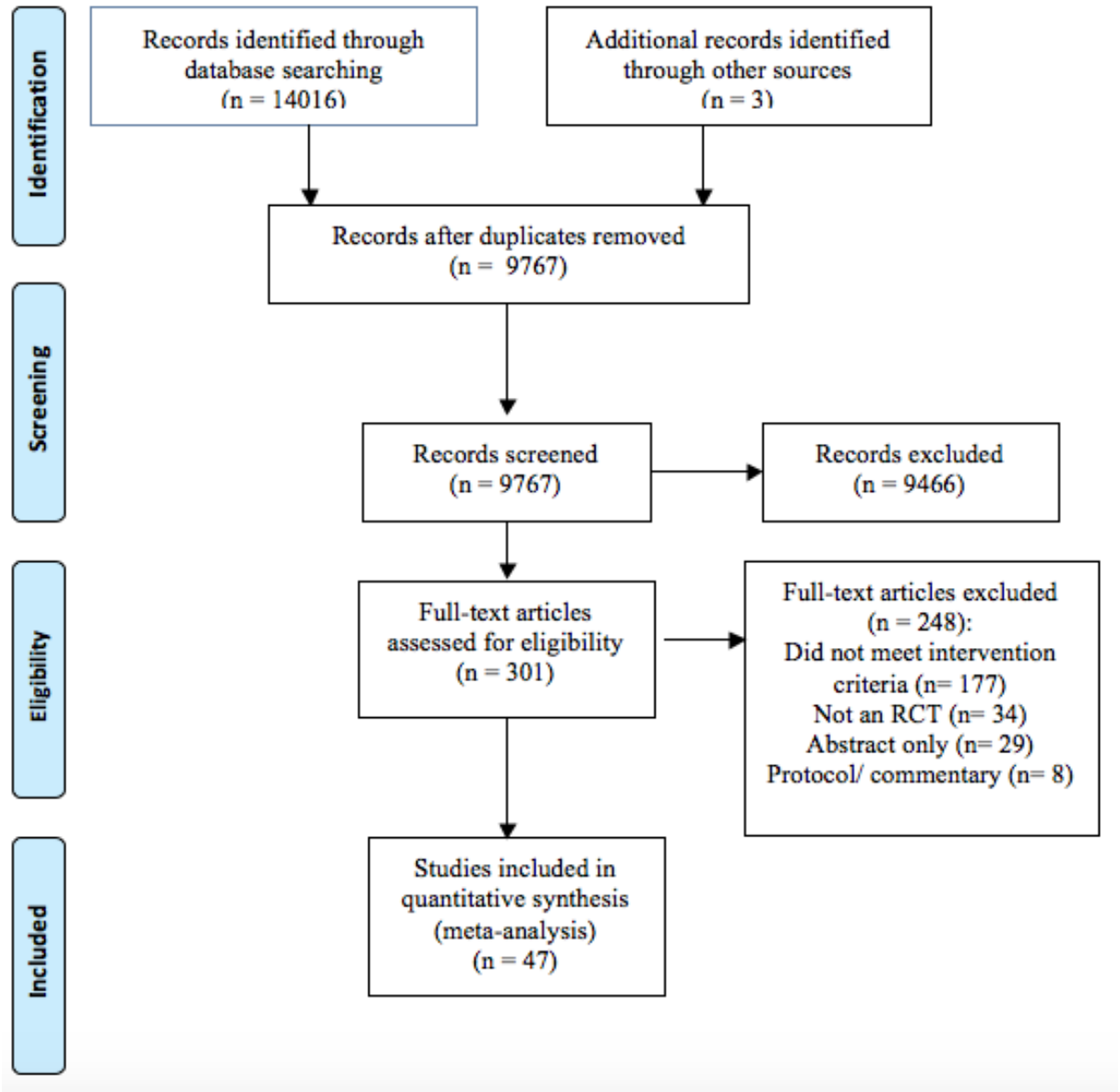
A univariate meta-regression was completed to explore potential associations between the size of effect and varying study and intervention characteristics.[79] Variables were similar to those explored in the subgroup analyses and included theoretical model, educator/s, educator training, materials provided, delivered in primary care, both groups HbA1c <7% at baseline, intervention length, contact time, number of participants, number of sessions, and the inclusion of family and friends. A meta-regression was performed using the Stata statistical software.[80]

3.4 Results

Study selection

The search identified 14016 results, and after de-duplication, 9764 publications were screened against the selection criteria (Figure 3.1). From the literature search, 298 studies were included in the full-text review. Three additional studies, one identified in the consultation with the author of a previous systematic review, and two identified from the reference list from the systematic review by Chrvala et al[75] were also included in full-text review. All three additional studies were excluded after the full-text review however, as they did not meet the selection criteria.

Figure 3.1: Stages of Study Identification



Forty-seven studies reported in 53 publications were included in the systematic review. The reasons for the exclusion of the 248 studies included: the study did not meet the intervention criteria, for example, interventions were not group-based (n=47), follow up was less than six months (n=21), studies did not report HbA1c adequately or at all (n=14), studies included persons diagnosed with type 1 diabetes (n=5), were hospital-based (n=4), contained less than 4 participants per group (6), control groups received group-based education or portion controlled diets (44), and intervention groups received components which may contaminate the effects of the program such as individual home visits, telephone calls or texts, internet-based components, or exercise based interventions (n=36). Additionally, various studies did not meet the predetermined study design criteria such as: not an RCT, CCT or cluster RCT (n=34); were abstract only or conference publications (n=29); or the publication was a protocol or commentary paper (n=8).

Authors of 31 of the 47 included studies (66%) were contacted via email up to three times for missing data. If the lead author did not respond, or the email address was no longer in use, a web search of the authors most recent publications or workplace staff directory was completed to find an updated email address, or the study coauthors were contacted. Of the authors emailed, only five (16%) did not respond. If the authors responded with the missing data, the data was included in the review and the completeness of the relevant TIDieR checklist item was reassessed. Email enquiries resulted in additional data for ten studies. Of these, seven were excluded (e.g. group size did not meet the inclusion criteria, data were not available) and three studies were included and data were extracted.

Study characteristics

Study characteristics are detailed in Table 3.2. Of the 47 studies included in the review, 40 reported the results of RCTs, four reported the results of CCTs and three reported the results of cluster RCTs. The 47 studies were conducted over 14 countries. The majority of the studies were carried out in the United States (18/47, 38%), the United Kingdom (6/47, 13%) and Italy (5/47, 11%). Three studies were carried out in Sweden, two each in Austria, Argentina, Brazil, the Netherlands, and Spain, and one each in South Africa, Korea, Germany, Denmark and Qatar. Forty-two of the studies were published in English, two were published in Spanish[81, 82], two in Italian[83, 84] and one in Dutch[85]. The

47 studies included in the review were published between December 1988 and August 2015. The length of follow up was six to 60 months from baseline.

Table 3.2: Study characteristics of included studies

Author, Year, Country	Study design	Length of follow up in months	Setting	No. of participants at recruitment	No. of participants at follow up	Mean baseline age (SD)	Gender: % Male	Mean baseline HbA1c
Adolfsson 2007, Sweden[38]	RCT	12	Primary care	IG: 42; CG: 46	IG: 42; CG: 46	IG: 62.4 (8.9); CG: 63.7 (9.0)	IG: 57%; CG: 61%	IG: 7.4; CG: 7.1
Brown 2002, USA[86]	RCT	12	Primary care	IG: 128; CG: 128	IG: 115; CG: 115	IG: 54.7 (8.2), CG: 53.3 (8.3)	IG: 40%; CG: 32%	IG: 11.8; CG: 11.8
Cade 2009, UK[87]	RCT	12	Primary care	IG: 122; CG: 127	IG: 86; CG: 108	IG: 65.8 (11), CG: 66.6 (11)	IG: 62%; CG: 58%	IG: 7.3; CG: 7.5
Cheyette 2007, UK[88]	RCT	12	Secondary care	IG: 29; CG: 20	IG: 21; CG: 18	IG: 56.7 (9.7); CG: 58 (10.7)	IG: 48%; CG: 60%	IG: 8.2; CG: 8.2
Clancy 2007, USA[89]	RCT	12	Primary care	IG: 96; CG: 90	IG: 80; CG: 76	IG: 55; CG: 57	IG: 26%; CG: 30%	IG: 9.3; CG: 8.9
Cohen 2011, USA[90]	RCT	6	Primary care	IG: 50; CG: 49	IG: 48; CG: 48	IG: 69.8 (10.7); CG: 67.2 (9.4)	IG: 100%; CG: 96%	IG: 7.8; CG: 8.1
Dalmau Llorca 2003, Spain[81]	RCT	12	Primary care	IG: 33; CG: 35	IG: 35; CG: 38	IG: 64.9 (8.2); CG: 65.6 (8.1)	IG: 64.7%, CG: 35.3%	IG: 7.2; CG: 6.6
Davies 2008[22]/ Khunti 2012, UK[55]	Cluster RCT	12 / 36	Primary care	IG: 437; CG: 387	IG: 404; CG: 345/ IG: 332; CG: 272	IG: 59.4 (11.6), CG: 61.01 (12.1)	IG: 53%; CG: 57%	IG: 8.3; CG: 7.9
Deakin 2006, UK[91]	RCT	14	Primary care	IG: 157; CG: 157	IG: 150; CG: 141	IG: 61.3 (9.7); CG: 61.8 (11)	IG+CG: 52%	IG: 7.7; CG: 7.7
Delahanty 2015, USA[92]	RCT	6	Primary care	IG: 28, CG: 29	IG: 26; CG: 28	IG: 62 (9.6), CG: 61 (11.4)	IG: 61%; CG: 59%	IG: 8.1; CG: 8.3
Domenech 1995, Argentina[93]	CCT	12	Primary care	IG: 40; CG: 39	IG: 40; CG: 39	IG: 52.7 (3.1); CG: 53.1 (1.1)	IG: 55%; CG: 56%	IG: 9; CG: 9

Author, Year, Country	Study design	Length of follow up in months	Setting	No. of participants at recruitment	No. of participants at follow up	Mean baseline age (SD)	Gender: % Male	Mean baseline HbA1c
Edelman 2010, USA[94]	RCT	12.8	Primary care	IG: 133; CG: 106	IG: 122; CG: 89	IG: 63 (9.4); CG: 60.8 (10)	IG: 95.5%; CG: 96.2%	IG: 9.2; CG: 9.2
Forjuoh 2014, USA[95]	RCT	12	Primary care	IG: 101; CG: 95	IG: 86; CG: 73	57.6 (10.9)	IG 46.5%, CG 44.2%	IG: 9.2; CG: 9.0
Gagliardino 2013, Argentina[96]	RCT	42	Primary care	G1: 117; G3: 117; G4: 117	G1: 84; G3: 86; G4: 33	G1 62 (8.4); G3 62.2 (8.4); G4 62.2 (8.4)	G1 32.5%, G3 33.3%, G4 37.6%	IG: 7.7; CG: 7.8
Gallotti 2003, Italy[84]	CCT	36	Primary care	IG: 22; CG: 22	IG: 22; CG: 22	Both groups: 56-73 yrs	IG: 55%; CG: 55%	IG: 6.9; CG: 6.8
Heller 1988, UK[97]	RCT	12	Secondary care	IG: 36; CG: 39	IG: 35; CG: 39	IG 56.5 (95% CI 55-58), CG 56.4 (53-59.9)	IG 55%, CG 41%	IG: 12.3; CG: 12.7
Hornsten 2005 & 2008, Sweden[98, 99]	Cluster RCT	12/ 60	Primary care	IG 44; CG: 60	IG: 40; CG: 59/ IG: 39; CG: 50	IG: 63.6 (9.3); CG: 63.4 (9.1)	IG: 52%; CG: 55%	IG: 5.7; CG: 5.8
Huisman 2009, Netherlands[100]	RCT	6	Secondary care	IG: 53; CG: 38	IG: 21; CG: 12; CG+ manual: 7	IG: 60.07 (6.76); CG: 56.69 (9.88); CG + manual: 56.74 (10.30)	IG: 52%; CG: 46%; CG + manual: 42%	IG: 7.3; CG: 7.2
Kattelmann 2009, USA[101]	RCT	6	Primary care	IG: 57; CG: 57	IG: 51; CG: 53	Unclear	Unclear	IG: 8.9; CG: 8.6
Kronsbein 1988, Germany[102]	CCT	12	Primary care	IG: 50; CG: 49	IG: 50; CG: 49	IG: 65 (9); CG: 63 (8)	IG: 42%; CG: 39%	IG: 7.1; CG: 6.5
Lorig 2009, USA[103]	RCT	12	Primary care	IG: 186; CG: 159	IG: 161; CG: 133	IG: 67.7 (11.9); CG: 65.4 (11.4)	IG: 37.6%, CG: 33.8%	IG: 6.7; CG: 6.7

Author, Year, Country	Study design	Length of follow up in months	Setting	No. of participants at recruitment	No. of participants at follow up	Mean baseline age (SD)	Gender: % Male	Mean baseline HbA1c
Lozano 1999, Spain[82]	RCT	24	Primary care	IG: 120; CG: 123	IG: 115; CG: 119	IG: 63.8; CG: 64.7	IG: 48%, CG: 48%	IG: 6.6; CG: 6.7
McKibbin 2006, USA[104]	RCT	6	Secondary care	IG: 32; CG: 32	IG: 28; CG: 29	53.1 (10.4); CG: 54.8 (8.2)	IG: 68%; CG: 62%	IG: 7.4; CG: 6.7
Miselli 2009, Italy[83]	RCT	24	Primary care	IG: 51; CG: 51	IG: 51; CG: 51	IG: 63.38 (9.68); CG: 63.70 (6.99)	IG: 45.1%; CG: 66.7%	IG: 8.7; CG: 8.8
Mohamed 2013, Qatar[105]	RCT	12	Primary care	IG: 215; CG: 215	IG: 109; CG: 181	IG: 52 (8.9); CG: 55 (10.7)	IG: 37%; CG: 28%	IG: 8.7; CG: 8.6
Muchiri 2015, South Africa[106]	RCT	12	Primary care	IG: 41; CG: 41	IG: 38; CG: 38	IG: 59.4 (6.9), CG: 58.2 (8.0)	IG: 12.2%; CG: 14.6%	IG: 10.8; CG: 11.4
Penckofer 2012, USA[107]	RCT	6	Primary care	IG: 38, CG: 36	IG: 26; CG: 34	IG: 54.8 (8.8), 54 (8.4)	IG: 0%; CG: 0%	IG: 7.8; CG: 7.9
Pennings-Van der Eerden 1991, Netherlands[85]	RCT	6	Primary care	IG: 61; CG: 57	IG: 43; CG: 40	IG: 64.9 (9.77); CG: 63.86 (9.34)	IG: 39.3%; CG: 52.6%	IG: 8.0; CG: 7.7
Philis-Tsimikas 2011, USA[108]	RCT	10	Primary care	IG: 104; CG: 103	IG: 69; CG: 87	IG: 52.2 (9.6); CG: 49.2 (11.8)	IG: 33.7%; CG: 25.2%	IG: 10.5; CG: 10.3
Pieber 1995, Austria[109]	CCT	6	Primary care	IG: 45; CG: 49	IG: 45; CG: 49	IG: 63.9 (8.2); CG: 65.4 (11.2)	IG: 42%; CG: 47%	IG: 8.6; CG: 8.8
Rickheim 2002, USA[110]	RCT	6	Secondary care	IG: 87, CG: 83	IG: 43; CG: 49	IG: 51.6 (9.2); CG: 52.9 (12.8)	IG: 35.6%; CG: 32.5%	IG: 8.9; CG: 8.0
Ridgeway 1999, USA[111]	RCT	12	Primary care	IG: 28; CG: 28	IG: 18; CG: 20	IG: 62; CG: 65	IG: 33%; CG: 25%	IG: 12.3; CG: 12.3
Rosal 2005, USA[112]	RCT	6	Primary care	IG: 15; CG: 10	IG: 14; CG: 9	IG: 62.7 (8.1); CG: 62.4 (9.7)	IG: 20%; CG: 20%	IG: 7.7; CG: 9.3

Author, Year, Country	Study design	Length of follow up in months	Setting	No. of participants at recruitment	No. of participants at follow up	Mean baseline age (SD)	Gender: % Male	Mean baseline HbA1c
Rosal 2011, USA[113]	RCT	12	Primary care	IG: 124; CG: 128	IG: 115; CG: 119	IG: 45-54yrs 32.3%, 55-64yrs 29%; CG: 45-54yrs 27.3%, 55-64yrs 36.7%	IG: 21.8%, CG: 25%	IG: 8.9; CG: 9.1
Sarkadi 2004, Sweden[114]	RCT	24	Primary care	IG: 33; CG: 31	IG: 33; CG: 31	IG: 66.5 (10.7), CG: 66.4 (7.9)	Unclear	IG: 6.5; CG: 6.4
Scain 2009, Brazil[115]	RCT	12	Tertiary care	IG: 52; CG: 52	IG: 52; CG: 52;	IG: 59.3 (8.8); CG: 59.5 (10.2)	IG: 44.2%; CG: 50%	IG: 6.8; CG: 6.7
Smith 2011, UK[116]	Cluster RCT	24	Primary care	IG: 192; CG: 203	IG: 166; CG: 171	IG: 66.1 (11.11); CG: 63.2 (11.04)	IG: 54%; CG: 54%	IG: 7.2; CG: 7.2
Sperl-Hillen 2011/ 2013, USA[117, 118]	RCT	6.8/ 12.8	Primary care	IG: 243; IE: 246; CG: 134	IG: 239; CG: 130; IE: 239/ IG: 227; CG: 124; IE: 239	IG: 61.2 (11.8); CG: 63.3 (11.5); IE: 61.6 (10.9)	IG: 49%; CG: 53.7%; IE: 50.4%	IG: 8.1; CG: 8.0
Toobert, 2003, USA[119]	RCT	6	Primary care	IG: 163; CG: 116	IG: 137; CG: 108	IG: 61.1 (8); CG: 60.7 (7.8)	IG: 0%; CG: 0%	IG: 7.4; CG: 7.4
Toobert 2011A & 2011B, USA[120, 121]	RCT	12/ 24	Primary care	IG: 142; CG: 138	IG: 99; CG: 107/ IG: 97; CG: 93	IG: 55.6 (9.7); CG: 58.7 (10.3)	IG: 0%; CG: 0%	IG: 8.4; CG: 8.2
Torres Hde 2009, Brazil[122]	RCT	6	Secondary care	IG: 54; CG: 50	IG: 31; CG: 26	IG: 61.7 (10.5); CG: 59.4 (10.4);	IG: 24.1%; CG: 26%	IG: 9.3; CG: 9.3
Trento 2001/ 2002/ 2004, Italy[49, 123, 124]	RCT	24/ 48/ 60	Secondary care	IG: 56; CG: 56	IG: 43; CG: 47/ IG: 45; CG: 45/ IG: 42; CG: 42	IG: 63 (Range 37-82); CG: 64 (45-80)	IG: 51%; CG: 64%	IG: 7.4; CG: 7.4

Author, Year, Country	Study design	Length of follow up in months	Setting	No. of participants at recruitment	No. of participants at follow up	Mean baseline age (SD)	Gender: % Male	Mean baseline HbA1c
Trento 2008, Italy[125]	RCT	24	Secondary care	IG: 25; CG: 24	IG: 24; CG: 21	IG: 64.6 (9.3); CG 68.1 (7.1)	IG: 52%; CG: 67%	IG: 7.8; CG: 7.8
Trento 2010, Italy[126]	RCT	48	Secondary care	IG: 421; CG: 394	IG: 315; CG: 266	IG: 69 (8.4); CG: 69.6 (8.4)	IG: 48%; CG: 54%	IG: 8; CG: 8
Vadstrup 2011, Denmark[127]	RCT	6	Secondary care	IG: 70; CG: 73	IG: 61; CG: 60	IG: 58.5 (9), CG: 58 (10.3)	IG: 59%; CG: 60%	IG: 7.9; CG: 7.8
Yoo 2007, Korea[128]	RCT	18	Secondary care	IG: 25; CG: 23	IG: 25; CG: 23	IG: 55.32 (7.56); CG: 55.08 (7.175)	IG: 32%; CG: 34.8%	IG: 8.3; CG: 8.7
Zapotoczky 2001, Austria[129]	RCT	12	Secondary care	IG: 18; CG: 18	IG: 18; CG: 18	IG: 62 (8.2); CG: 53 (11.4)	IG: 44%; CG: 28%	IG: 8.6; CG: 8.0

No.= number; RCT= Randomised controlled trial; CCT= Controlled clinical trial; IG= Intervention group; CG= Control group; SD= standard deviation; HbA1c= glycated haemoglobin

Studies were predominantly conducted in primary care settings (32/47; 68%). Fifteen of the 47 studies (32%) were delivered in secondary or tertiary care settings, for example hospital diabetes centres, tertiary hospitals or board and care homes. Four publications reported on multiple arm studies. For the meta-analyses, the groups that were most similar to the other studies included in the review were included in the analysis, for example, for a three arm intervention study comparing group-based education to a usual care control group and an individual intervention, data were extracted for the usual care control group and group-based education group. For the subgroup analyses however, data was extracted for all groups in order to compare the differences in the various control groups.

A total of 8533 participants were included in the 47 studies with n=4416 (52%) in the intervention group. The mean age of participants in either the intervention group or the control group was approximately 60 years. The mean age was not reported by two of the included studies.[84, 113] The gender of participants was reported for all but one study.[114] The proportion of men was lower than the proportion of women, comprising 44% of participants in the intervention group (1917/ 4383) and 44% of participants in the control group (1799/ 4086). Three of the 47 included studies (6%) recruited only women.[107, 119-121] The known duration of diabetes was reported by 29 of the 47 included studies (62%). The mean duration of diabetes for participants in the intervention group was 8.9 years, whilst the mean duration of diabetes for participants in the control group was 9.4 years. The mean HbA1c level at baseline was 8.3% for both groups and ranged between 5.7% to 12.3% for the intervention group and 5.8% to 12.7% for the control group. The mean HbA1c of 38 (81%) studies for both the intervention and control groups was above 7%.

Intervention characteristics

Intervention characteristics varied and are summarized in Table 3.3. The duration of the interventions evaluated ranged from one day to 60 months (five years). The majority (35/47; 74%) of group-based interventions were compared to routine or usual care control groups, with six of these studies[95, 96, 100, 104-106] providing the control group with written information regarding their diabetes management. Four of the included studies[86,

[102, 109, 114] placed the control group on waiting lists to receive the intervention, and six studies provided the control group with individual education interventions.[81, 91, 92, 117, 118, 122, 127] Two studies[128, 129] provided the control groups with initial group-based diabetes education prior to receiving usual or routine care, and one study[84] only included persons who had taken part in a diabetes health group education course previously.

Materials were provided to the intervention group participants of 40 studies. Examples of these materials were written materials, books, workbooks, log books, food diaries, pedometers, videos, visual aids such as photographs of food, audiotapes or CDs, question cards and recipes. Three of the studies did not provide study participants with any materials or resources, and four of the studies did not state whether they provided materials to participants. The number of participants in each intervention group was reported by all but one study. The smallest groups comprised four to six participants, and largest groups contained up to 20 participants per session. The number of sessions provided to participants in the intervention groups ranged from one to 45 sessions and the contact time provided to intervention participants ranged from three to 200 hours.

The group facilitators/educators varied across the studies, with 20 of the studies utilizing a multi-disciplinary team of educators, 17 of the studies utilizing a single discipline, five studies using peer or lay educators, and five studies utilizing health professionals with peer supports. The health disciplines of facilitators included physicians, nurses, dietitians or nutritionists, psychologists, physiotherapists, pharmacists, diabetes educators, exercise physiologists, occupational therapists, and podiatrists. Included in multidisciplinary teams were also a stress-management instructor[119], and a horticulture officer.[106] Facilitators in five studies were trained peer or lay educators rather than health professionals;[87, 95, 103, 108, 116] four studies used a combination of health professionals and peer or lay educators.[86, 101, 113, 119] Thirty-four of the 47 studies described the training provided to group facilitators or educators, whilst two did not provide specific training to their educators, and 11 did not mention any training.

The use of a theoretical model in the development and facilitation of the group-based

interventions were reported in 23 studies, whilst 24 studies did not mention any theoretical basis for the intervention. The theories commonly utilized included empowerment theory, cognitive behavioural theory, social cognitive theory, social learning theory, adult learning theory, health belief models and motivational interviewing. Twenty-seven studies allowed or invited family, friends or carers of the study participants to attend the intervention program, whilst nine did not allow others to attend and 11 studies did not stipulate whether family, friends or carers were allowed to attend.

Table 3.3: Intervention characteristics of included studies

Author, Year, Country	Intervention duration (mths)	Intervention	Control Group	No. per group	Contact time (hrs)	No. of sessions	Family/ friends included	Theory	Materials (type)	Facilitator/s	Training
Adolfsson 2007, Sweden[38]	7	Empowerment group education	Usual care	5-8	12.5- 15	4-5	No	Empowerment, motivation, learning principles	Yes (document and guidelines for facilitators)	Physicians, diabetes specialist nurses	Yes
Brown 2002, USA[86]	12	Group education program	Waiting list	8	52	26	Yes	Not stated	Yes (videos, lab results)	Bilingual Mexican American nurses, dietitians, community workers	Yes
Cade 2009, UK[87]	1.75	Expert Patient Program (EPP) (adapted for T2DM)	Usual care	12-16	14	7	Yes	Not stated	Yes (written materials plus booklet)	Peer or lay led	Yes
Cheyette 2007, UK[88]	4	Weight No More program	Usual care	8-10	12	8	No	Not stated	Yes (visual teaching aids, food diaries)	Dietitian, physio, diabetes nurse specialist	Not stated
Clancy 2007, USA[89]	12	Group visits	Usual care	14-17	24	12	Yes	Not stated	No	Primary care internal medicine physicians, registered nurses	Yes
Cohen 2011, USA[90]	6	VA MEDIC-E (Veterans Affairs Multidisciplinary Education and Diabetes Intervention for Cardiac Risk Reduction-Extended)	Usual care	4-6	15.5	9	Yes	Not stated	Yes (cardiovascular report card, videos; Powerpoint slides; food log; Pedometers)	Pharmacist led, dietitian, nurse, physical therapist	Not stated

Author, Year, Country	Intervention duration (mths)	Intervention	Control Group	No. per group	Contact time (hrs)	No. of sessions	Family/ friends included	Theory	Materials (type)	Facilitator/s	Training
Dalmau Llorca 2003, Spain[81]	12	Group education	Individual education (3 hrs)	5	3	6	Yes	Not stated	Yes (food photographs, written information; blackboards, transparencies and slides)	Medical resident, nurse	Not stated
Davies 2008[22]/ Khunti 2012, UK[55]	1 day/ 2 half days	Structured group education program	Usual care	8 (range 4 to 16)	6	1 to 2	Yes	Leventhal's common sense theory, dual process theory, social learning theory; Patient empowerment	Yes (patient resources)	Registered dietitians, practice nurses or nurse specialists	Yes
Deakin 2006, UK[91]	1.5	X-PERT program	Individual education (55 mins)	Average 16	12	6	Yes	Patient empowerment, discovery learning	Yes (patient manual)	Diabetes research dietitian	Not stated
Delahanty 2015, USA[92]	4.75	Group lifestyle intervention (GLI) adapted 'Look Ahead'	Individual education (1-5 hrs)	8-10	28.5	19	Not stated	Not stated	Yes (Look AHEAD group materials)	Dietitians	Yes
Domenech 1995, Argentina[93]	1	Group-based structured teaching/ treatment program	Usual care	5-8	6-8	4	Yes	Not stated	Yes (flip-charts, food photographs, question cards, individual log books, patient booklet)	Physicians	Yes

Author, Year, Country	Intervention duration (mths)	Intervention	Control Group	No. per group	Contact time (hrs)	No. of sessions	Family/ friends included	Theory	Materials (type)	Facilitator/s	Training
Edelman 2010, USA[94]	12	Group Medical Clinics	Usual care	7-9	10.5-14	7	Yes	Not stated	No	Primary care general internist, pharmacist, nurse or certified diabetes educator	Yes
Forjuoh 2014, USA[95]	1.5	Intervention: Group program (Stanford CDSMP)	Usual care (with written materials)	7-17	15	6	Yes	Not stated	Yes (companion book, audio relaxation tape)	Stanford-certified CDSMP lay leaders and master trainers	Yes
Gagliardino 2013, Argentina[96]	6	Patient education-Diabetes Structured Education Courses for T2DM	Usual care (with written materials)	6- 10	7.5- 10	5	Yes	Not stated	Yes (Illustrated materials, programme book, questionnaire cards, individual log-book, patient book)	Physicians	Yes (G4 only)
Gallotti 2003, Italy[84]	36	Group program	Usual care	11	54	36	No	Not stated	Yes (manual)	Medical doctors	Yes
Heller 1988, UK[97]	6	Intervention: Group program	Usual care	4-6	7.5	5	Yes	Not stated	Yes (video tape, simple explanatory book)	Diabetes nurses, dietitian	Not stated
Hornsten 2005 & 2008, Sweden[98, 99]	9	Educational intervention (focus on personal understanding of their illness)	Usual care	5-8	20	10	No	Patient-directed, patient-centred, model of chronic illness	No	Diabetes nurses, nurse as moderator	Yes

Author, Year, Country	Intervention duration (mths)	Intervention	Control Group	No. per group	Contact time (hrs)	No. of sessions	Family/ friends included	Theory	Materials (type)	Facilitator/s	Training
Huisman 2009, Netherlands[100]	6	Self-regulation weight reduction intervention	Usual care, or usual care (with written materials)	10-15	16	8	Yes	Self-regulation principles, motivational interviewing	Yes (workbook, pedometer)	Health psychologist	Not stated
Kattelmann 2009, USA[101]	6	The Medicine Nutrition Wheel Nutrition Model education lessons	Usual care	5-9	18-21	6	Yes	Empowerment	Yes (Medicine Wheel Model for Native Nutrition, Powerpoint Presentations, individualized meal plan)	Registered dietitian, tribal member	Yes
Kronsbein 1988, Germany[102]	1	Group structured treatment and teaching program (DTTP)	Waiting list	4-6	6-8	4	Not stated	Not stated	Yes (flip-charts, food photographs, diabetes-related question cards, patients' log-books)	Physicians, physician assistants	Yes
Lorig 2009, USA[103]	1.5	Diabetes self-management program (DSMP)	Usual care	10-15	15	6	Yes	Not stated	Yes (book)	Peer leaders	Yes
Lozano 1999, Spain[82]	24	Health educational workshops	Usual care	12-14	6	4	Yes	Not stated	Yes (handouts, food photographs, self-care devices, insulin pen)	Nurses	No
McKibbin 2006, USA[104]	6	Diabetes Awareness and Rehabilitation Training (DART)	Usual care (with written materials)	32	36	24	Not stated	Social cognitive theory	Yes (handouts, educational materials, pedometers, mnemonic aids, printed materials)	Diabetes educators, dietitians	Not stated

Author, Year, Country	Intervention duration (mths)	Intervention	Control Group	No. per group	Contact time (hrs)	No. of sessions	Family/ friends included	Theory	Materials (type)	Facilitator/s	Training
Miselli 2009, Italy[83]	24	ROMEO	Usual care	6-10	7	7	No	Not stated	Not stated	Doctor, dietitian, nurse	Not stated
Mohamed 2013, Qatar[105]	1	Group-based intervention	Usual care (with written materials)	10-20	12- 16	4	Yes	Empowerment, health belief models	Yes (educational booklet for self-management, pictorial materials, questionnaires)	Physicians	Yes
Muchiri 2015, South Africa[106]	9	Structured nutrition education (NE) program	Usual care (with written materials)	6- 10	25- 29	14	Yes	Social Cognitive Theory, Health Belief Model, Knowledge Attitude Behaviour model	Yes (education materials, diabetes education flip charts, hands on activities, demonstrations, food displays and vegetable gardening)	Sub-district dietitian, final-year nutrition and food science student, experienced dietitian, sub-district horticulture officer	Yes
Penckofer 2012, USA[107]	5.5	Study of Women's Emotions and Evaluation of a Psycho educational (SWEEP) program	Usual care	10-12	10	10	No	Cognitive behavioural theory (CBT)	Yes (progressive muscle relaxation CD, video, workbook, log book)	Nurse	Yes
Pennings-Van der Eerden 1991, Netherlands[85]	1.75	Education program	Usual care	8-10	21-28	7	Yes	Not stated	Yes (written information, audio-visual aids, demonstration materials)	Physicians, dietitians, diabetologist, diabetes nurse	Not stated

Author, Year, Country	Intervention duration (mths)	Intervention	Control Group	No. per group	Contact time (hrs)	No. of sessions	Family/ friends included	Theory	Materials (type)	Facilitator/s	Training
Philis-Tsimikas 2011, USA[108]	10	Project Dulce diabetes self-management classes	Usual care	6-12	32	16	Yes	Not stated	Yes (handouts)	Lay community health workers	Yes
Pieber 1995, Austria[109]	1	Diabetes treatment and teaching program (DTTP)	Waiting list	4-8	6-8	4	No	Not stated	Yes	GP's, office staff	Yes
Rickheim 2002, USA[110]	6	Group intervention	Usual care	4-8	7	4	Yes	Adult learning model, public health nursing model, health belief model, transtheoretical model	Yes	Nurse, dietitian	Yes
Ridgeway 1999, USA[111]	12	Education/ behaviour modification	Usual care	14	10.5	7	Not stated	Not stated	Yes (teaching slides, handouts)	Registered nurse, registered dietitian, diabetes educators, physicians	Not stated
Rosal 2005, USA[112]	2.5	Group based intervention	Usual care	15	25 to 30	10	No	CBT, patient-centred counselling, social cognitive theory	Yes (log book, glucose meter, step counter, large visuals depicting traffic light system, dietary guidelines, soap opera drama)	Diabetes nurse, nutritionist, assistant	Yes

Author, Year, Country	Intervention duration (mths)	Intervention	Control Group	No. per group	Contact time (hrs)	No. of sessions	Family/ friends included	Theory	Materials (type)	Facilitator/s	Training
Rosal 2011, USA[113]	11	The Latinos en Control intervention	Usual care	Up to 15	30	20	Yes	Social cognitive theory	Yes (log book, glucose meter, step counter, visuals of traffic light system, dietary guidelines, soap opera drama)	Nutritionist or health educator, assistant (trained lay individuals)	Yes
Sarkadi 2004, Sweden[114]	12	Experience-based group educational program	Waiting-list	8-10	36	12	Not stated	Not stated	Yes (video, game, booklet)	Pharmacists	Yes
Scain 2009, Brazil[115]	1	Structured group education program based on the Latin American Diabetes Association program for health care providers	Usual care	8-10	8	4	No	Not stated	Yes (brochure, log book, leaflet with anthropometric data and test results, recipes, cooking suggestions)	Nurse educator	No
Smith 2011, UK[116]	24	Peer support meetings	Usual care	10	9- 13.5	9	No	Social support theory	Yes (educational resources; target card, video/ DVD, pedometer, laminated topic sheets)	Trained peer supporters	Yes
Sperl-Hillen 2011/ 2013, USA[117, 118]	1	Group education using the US Diabetes Conversation Map program: IDEA study	Usual care; and individual education (3 hrs)	8-10	8	4	Yes	Patient-centred, non-didactic approach using the US Diabetes Conversation Map	Yes (Conversation Map support materials)	Certified diabetes educators (nurses, dietitians)	Yes

Author, Year, Country	Intervention duration (mths)	Intervention	Control Group	No. per group	Contact time (hrs)	No. of sessions	Family/ friends included	Theory	Materials (type)	Facilitator/s	Training
Toobert, 2003, USA [119]	6	Mediterranean Lifestyle Program (MLP)	Usual care	5-10	116	6	Not stated	Social Cognitive Theory, Goal Systems, Social Ecological Theory	Yes (program materials)	Registered dietitian, exercise physiologist, stress-management instructor, professional, lay support group leaders	Yes
Toobert 2011A & 2011B, USA[120, 121]	12/ 24	Viva Bien! Group education program	Usual care	5-10	164/ 200	36/ 45	Yes	Behaviour change theory	Yes (stress management CDs, recipes, pamphlets)	Physician, dietitian, exercise physiologist, yoga/ meditation instructor, support group leaders	Yes
Torres Hde 2009, Brazil[122]	3	Group meetings	Individual intervention (3 hrs)	Average 13	22	11	Yes	Social learning theory, health belief model	Yes (educational pamphlets, videos)	Nurse-led, doctor, nutritionist, physio, OT	Yes
Trento 2001/ 2002/ 2004, Italy[49, 123, 124]	24/ 48/ 60	Structured education programme	Usual care	9- 10	8 / 15/ 19	8/ 15/ 19	Yes	Systemic education approach	Yes (visual aids, food, graduated containers, flip chart)	Hospital physicians	Not stated
Trento 2008, Italy[125]	24	Group education sessions	Usual care	8-9	4-6.5 hrs	4-6	Yes	Adult learning theory	Yes (operational manual, brochures)	Nurses, dietitian	Yes
Trento 2010, Italy[126]	48	Structured education programme	Usual care	10	14 hours	14	Yes	Systemic education approach	Yes (as per Trento 2001)	Physicians	Yes

Author, Year, Country	Intervention duration (mths)	Intervention	Control Group	No. per group	Contact time (hrs)	No. of sessions	Family/ friends included	Theory	Materials (type)	Facilitator/s	Training
Vadstrup 2011, Denmark[127]	6	Group-based rehabilitation programme	Individual education (6 hrs 45 mins)	8	17 hrs education	9	Not stated	Motivational interviewing; empowerment approach	Not stated	Nurse, physio, podiatrist, dietitian	Yes
Yoo 2007, Korea[128]	13	Comprehensive Lifestyle Modification Program (CLMP)	GBE then usual care	5-8	25 hrs	25	Not stated	Self-efficacy	Not stated	Nurse researchers	Yes
Zapotoczky 2001, Austria[129]	10	Psycho educational group training	GBE then usual care	18	15 hrs	10	Not stated	Learning theory	Not stated	Clinical dietitian	Yes

Physio= physiotherapist; OT= occupational therapist; IDEA= Interactive Dialogue to Educate and Activate; US= United States; T2DM= Type 2 diabetes mellitus; mths= months; hrs= hours; mins= minutes; GBE= group-based education

Study quality

Using the Cochrane risk of bias tool[77], 31 studies were classified as having a moderate risk of bias, four studies were classified as having a low risk of bias and 12 studies were classified as having a high risk of bias. Inter-rater agreement of risk of bias was assessed using Cohen's Kappa in the Statistical Package for the Social Sciences (SPSS version 23). There was moderate agreement[130] between the two independent reviewers' judgements of risk of bias, K= 0.708 (95%CI: 0.54, 0.88).

Table 3.4 provides risk of bias details for each of the included studies and Figure 3.2 illustrates the overall risk of bias. Of the six risk of bias items, allocation concealment (selection bias), blinding of participants and personnel (performance bias), and blinding of outcome assessment (detection bias) were either the least consistently described or were generally poorly conducted in the included studies.

Of the 53 publications describing the 47 included studies, 31 publications (58%) described randomisation methods (e.g. such as random table numbers, random permuted blocks, using a computer random number generator, or coin tossing) and were assessed as low risk. Five publications (9%) described methods of randomisation which were assessed as high risk (e.g. such as allocation by preference of the participant or allocation by availability of the intervention) and 17 publications (32%) did not adequately describe the randomisation process for their study. Allocation concealment was inadequately reported in 46 publications (87%). Of the seven publications which described allocation concealment, only five (9%) reported the use of low risk methods of allocation concealment such as the use of sequentially numbered, opaque, sealed envelopes, whilst two of the publications (4%) noted that they were not able to adequately conceal the allocation of participants and as such were assessed as being of high risk. The blinding of participants and personnel was also poorly described by the majority (33/53; 62%) of publications with only 12 publications (23%) describing adequate blinding of the key study personnel, and eight publications (15%) explaining that neither study participants nor key study personnel were blinded to the allocation of participants. The blinding of participants in a group-based intervention study is difficult due to the nature of the interventions, however the blinding of key study personnel is feasible and can improve study quality. Similarly, the blinding of outcome assessment was poorly described.

Unclear or inadequate descriptions of blinding of outcome assessment or study personnel collecting outcome data were found in 39 publications (74%). Of the 53 publications, ten (19%) described outcome assessment blinding which was assessed as low risk, and four (8%) described outcome assessment blinding which was assessed as high risk. Incomplete data was adequately addressed or explained after email by 43 (81%) of the publications which were therefore assessed as low risk. Seven (13%) publications were assessed as high risk for incomplete outcome data, and only three (6%) of the publications assessed as unclear due to insufficient reporting. All 53 publications provided sufficient information for the reviewers to assess selective outcome reporting and of these publications, 42 (79%) were assessed as low risk and 11 (21%) were assessed as high risk as they generally did not report the study's pre-specified outcomes. The majority of the included publications (46/53; 87%) were assessed as having no other potential threats to validity, seven (13%) of the publications did not adequately describe other potential threats to validity, and two of the publications (4%) were assessed as high risk due to either collecting data only on intervention participants for long term follow up measures[103] or having significant attrition in the control group.[93]

The three cluster RCTs[22, 98, 116] were subject to further assessment in regards to the particular biases that should be considered for cluster RCTs including: (i) recruitment bias; (ii) baseline imbalance; (iii) loss of clusters; (iv) incorrect analysis; and (v) comparability with individually randomized trials.[77] Recruitment bias was not considered to be an issue in any of the cluster RCTs as randomization was completed at a practice level and individuals were recruited to the studies prior to randomization. Two of the studies[98, 116]stated that there were no differences between the intervention and control groups, and baseline differences in HbA1c existed in the third study[22], however these were adjusted for during data analysis. No clusters were lost across the three studies, and each of the studies correctly adjusted for clustering prior to statistical analyses. Finally, contamination or "herd effects" were not considered to be an issue in any of the included cluster RCTs.

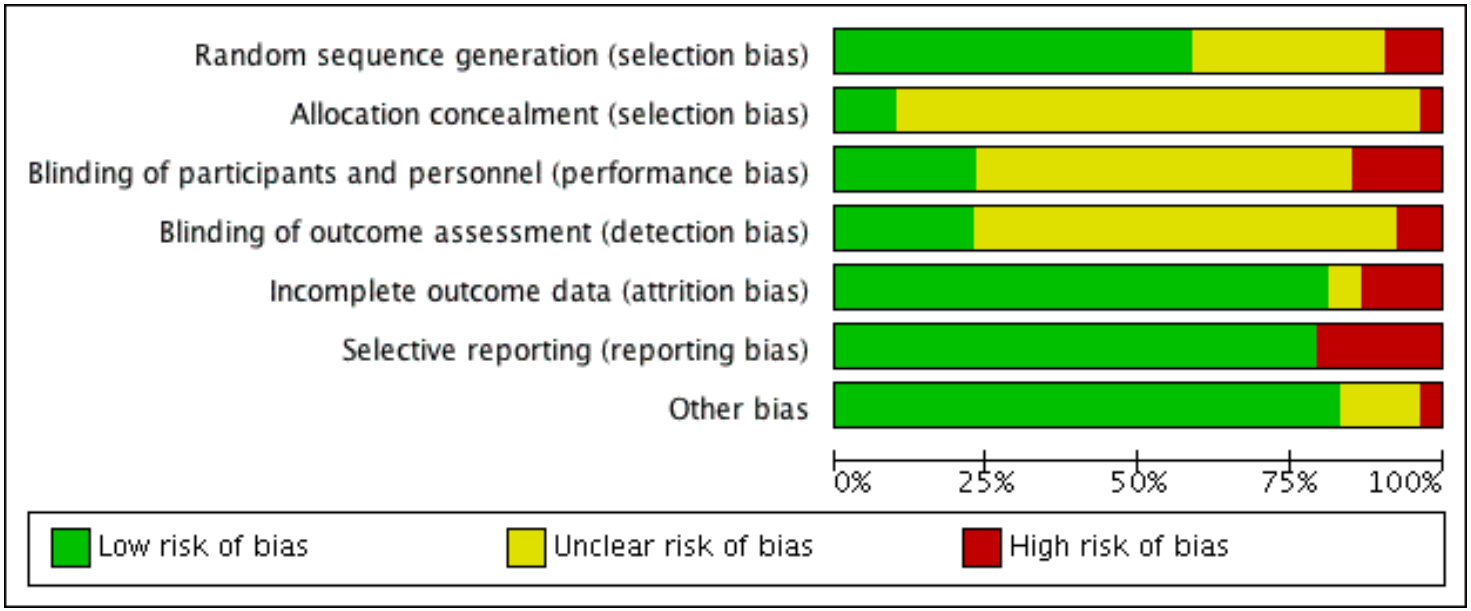
Table 3.4: Risk of bias summary of studies included in systematic review

Author, Year, Country	Overall Risk of Bias	Random Sequence Generation	Allocation Concealment	Blinding	Incomplete Outcome Data	Selection Outcome Reporting	Other potential sources of bias
Adolfsson 2007, Sweden[38]	**Moderate**	Unclear	Unclear	Unclear	Low	Low	Low
Brown 2002, USA[86]	**Moderate**	Unclear	Unclear	Low	Low	Low	Low
Cade 2009, UK[87]	**Moderate**	Unclear	Unclear	Unclear	Low	Low	Low
Cheyette 2007, UK[88]	**Moderate**	Unclear	Unclear	Unclear	High	Low	Low
Clancy 2007, USA[89]	**High**	Low	Unclear	Low	Low	High	Low
Cohen 2011, USA[90]	**Moderate**	Unclear	Unclear	Unclear	Low	Low	Low
Dalmau Llorca 2003, Spain[81]	**Moderate**	Low	Unclear	Unclear	Low	Low	Low
Davies 2008[22]/ Khunti 2012, UK[55]	**High**	Low	Unclear	Unclear	Low	High	Low
Deakin 2006, UK[91]	**Low**	Low	Low	Low	Low	Low	Low
Delahanty 2015, USA[92]	**Moderate**	Unclear	Unclear	High	Low	Low	Low
Domenech 1995, Argentina[93]	**High**	High	Unclear	Unclear	High	High	High
Edelman 2010, USA[94]	**Low**	Low	Low	Low	Low	Low	Low
Forjuoh 2014, USA[95]	**Moderate**	Unclear	Unclear	High	Unclear	High	Unclear
Gagliardino 2013, Argentina[96]	**Moderate**	Unclear	Unclear	High	Low	Low	Low
Gallotti 2003, Italy[84]	**High**	High	Unclear	Unclear	Unclear	High	Unclear
Heller 1988, UK[97]	**Moderate**	Unclear	Unclear	Unclear	Low	Low	Unclear
Hornsten 2005 & 2008, Sweden[98, 99]	**High**	Low	Unclear	Unclear	Low	High	Low
Huisman 2009, Netherlands[100]	**Moderate**	Unclear	Unclear	Unclear	Low	Low	Low
Kattelmann 2009, USA[101]	**High**	Low	Unclear	High	High	High	Low

Author, Year, Country	Overall Risk of Bias	Random Sequence Generation	Allocation Concealment	Blinding	Incomplete Outcome Data	Selection Outcome Reporting	Other potential sources of bias
Kronsbein 1988, Germany[102]	**High**	High	Unclear	Unclear	Low	Low	Low
Lorig 2009, USA[103]	**Moderate**	Low	Unclear	Unclear	High	Low	High
Lozano 1999, Spain[82]	**High**	High	Unclear	Unclear	Low	Low	Unclear
McKibbin 2006, USA[104]	**Moderate**	Unclear	Unclear	Unclear	Low	Low	Low
Miselli 2009, Italy[83]	**Moderate**	Unclear	Unclear	Unclear	Unclear	Low	Unclear
Mohamed 2013, Qatar[105]	**Moderate**	Low	Unclear	Unclear	Low	Low	Low
Muchiri 2015, South Africa[106]	**Low**	Low	Low	Low	Low	Low	Low
Penckofer 2012, USA[107]	**Moderate**	Low	High	High	Low	Low	Low
Pennings-Van der Eerden 1991, Netherlands[85]	**High**	Unclear	Unclear	Unclear	High	High	Unclear
Philis-Tsimikas 2011, USA[108]	**Moderate**	Low	Unclear	Low	Low	Low	Low
Pieber 1995, Austria[109]	**High**	High	Unclear	Unclear	Low	Low	Low
Rickheim 2002, USA[110]	**Moderate**	Low	Unclear	Unclear	Low	Low	Low
Ridgeway 1999, USA[111]	**Moderate**	Unclear	Unclear	Unclear	Low	Low	Low
Rosal 2005, USA[112]	**Moderate**	Unclear	Unclear	Unclear	Low	Low	Low
Rosal 2011, USA[113]	**High**	Low	Unclear	Low	High	Low	Low
Sarkadi 2004, Sweden[114]	**Moderate**	Low	Low	High	High	High	Unclear
Scain 2009, Brazil[115]	**Moderate**	Low	Unclear	Unclear	Low	Low	Low
Smith 2011, UK[116]	**High**	Low	High	High	Low	Low	Low
Sperl-Hillen 2011/ 2013, USA[117, 118]	**Moderate**	Low	Unclear	Unclear	Low	Low	Low
Toobert, 2003, USA[119]	**Moderate**	Unclear	Unclear	Unclear	Low	Low	Low

Author, Year, Country	Overall Risk of Bias	Random Sequence Generation	Allocation Concealment	Blinding	Incomplete Outcome Data	Selection Outcome Reporting	Other potential sources of bias
Toobert 2011A & 2011B, USA[120, 121]	**Low**	Low	Unclear	Low	Low	Low	Low
Torres Hde 2009, Brazil[122]	**Moderate**	Low	Unclear	Unclear	Low	Low	Low
Trento 2001/ 2002/ 2004, Italy[49, 123, 124]	**Moderate**	Low	Unclear	Low	Low	Low	Low
Trento 2008, Italy[125]	**Moderate**	Low	Unclear	Unclear	Low	Low	Low
Trento 2010, Italy[126]	**Moderate**	Low	Unclear	Unclear	Low	Low	Low
Vadstrup 2011, Denmark[127]	**Moderate**	Low	Low	High	Low	Low	Low
Yoo 2007, Korea[128]	**Moderate**	Low	Unclear	Unclear	Low	Low	Low
Zapotoczky 2001, Austria[129]	**Moderate**	Unclear	Unclear	Unclear	Low	Low	Low

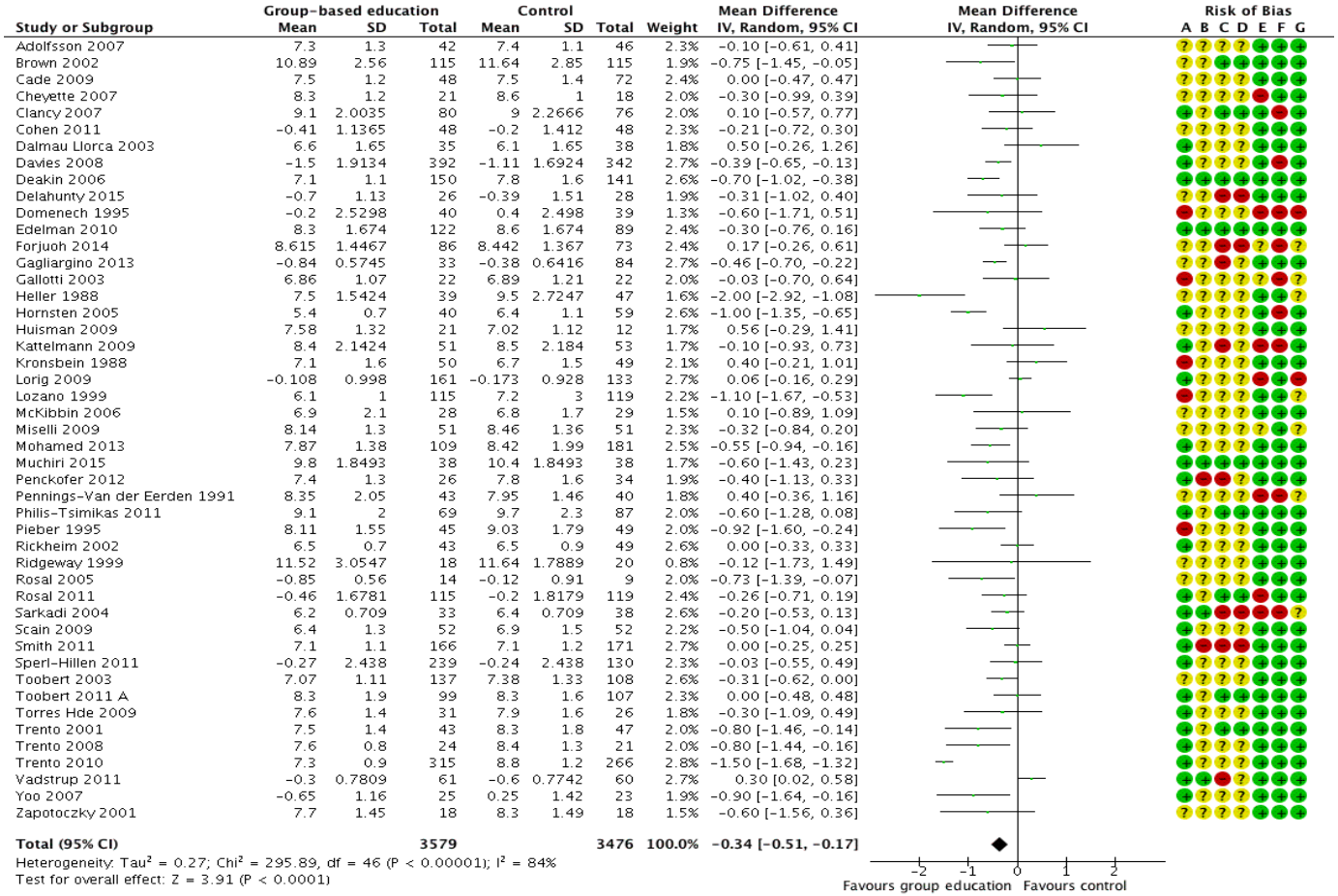
Figure 3.2: Overall Risk of bias for included studies



Overall effects of group-based interventions for HbA1c

A meta-analysis was conducted to assess the effect of group-based education compared with control for all 47 included studies (n=7055) using the measure of HbA1c at the time point closest to the completion of each group-based education intervention (Figure 3.3). Overall, compared with control, group-based intervention was effective in reducing HbA1c by 0.34% (95% CI: -0.51, -0.17; P<0.0001). There was significant heterogeneity between studies (I^2 = 84%). The results of the sensitivity analyses exploring potential reasons for this significant heterogeneity are provided in the section titled 'Sensitivity Analyses'.

Figure 3.3: Effectiveness of group-based interventions compared with controls for T2DM for HbA1c



Study or Subgroup	Group-based education Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Adolfsson 2007	7.3	1.3	42	7.4	1.1	46	2.3%	-0.10 [-0.61, 0.41]
Brown 2002	10.89	2.56	115	11.64	2.85	115	1.9%	-0.75 [-1.45, -0.05]
Cade 2009	7.5	1.2	48	7.5	1.4	72	2.4%	0.00 [-0.47, 0.47]
Cheyette 2007	8.3	1.2	21	8.6	1	18	2.0%	-0.30 [-0.99, 0.39]
Clancy 2007	9.1	2.0035	80	9	2.2666	76	2.0%	0.10 [-0.57, 0.77]
Cohen 2011	-0.41	1.1365	48	-0.2	1.412	48	2.3%	-0.21 [-0.72, 0.30]
Dalmau Llorca 2003	6.6	1.65	35	6.1	1.65	38	1.8%	0.50 [-0.26, 1.26]
Davies 2008	-1.5	1.9134	392	-1.11	1.6924	342	2.7%	-0.39 [-0.65, -0.13]
Deakin 2006	7.1	1.1	150	7.8	1.6	141	2.6%	-0.70 [-1.02, -0.38]
Delahunty 2015	-0.7	1.13	26	-0.39	1.51	28	1.9%	-0.31 [-1.02, 0.40]
Domenech 1995	-0.2	2.5298	40	0.4	2.498	39	1.3%	-0.60 [-1.71, 0.51]
Edelman 2010	8.3	1.674	122	8.6	1.674	89	2.4%	-0.30 [-0.76, 0.16]
Forjuoh 2014	8.615	1.4467	86	8.442	1.367	73	2.4%	0.17 [-0.26, 0.61]
Gagliargino 2013	-0.84	0.5745	33	-0.38	0.6416	84	2.7%	-0.46 [-0.70, -0.22]
Gallotti 2003	6.86	1.07	22	6.89	1.21	22	2.0%	-0.03 [-0.70, 0.64]
Heller 1988	7.5	1.5424	39	9.5	2.7247	47	1.6%	-2.00 [-2.92, -1.08]
Hornsten 2005	5.4	0.7	40	6.4	1.1	59	2.6%	-1.00 [-1.35, -0.65]
Huisman 2009	7.58	1.32	21	7.02	1.12	12	1.7%	0.56 [-0.29, 1.41]
Kattelmann 2009	8.4	2.1424	51	8.5	2.184	53	1.7%	-0.10 [-0.93, 0.73]
Kronsbein 1988	7.1	1.6	50	6.7	1.5	49	2.1%	0.40 [-0.21, 1.01]
Lorig 2009	-0.108	0.998	161	-0.173	0.928	133	2.7%	0.06 [-0.16, 0.29]
Lozano 1999	6.1	1	115	7.2	3	119	2.2%	-1.10 [-1.67, -0.53]
McKibbin 2006	6.9	2.1	28	6.8	1.7	29	1.5%	0.10 [-0.89, 1.09]
Miselli 2009	8.14	1.3	51	8.46	1.36	51	2.3%	-0.32 [-0.84, 0.20]
Mohamed 2013	7.87	1.38	109	8.42	1.99	181	2.5%	-0.55 [-0.94, -0.16]
Muchiri 2015	9.8	1.8493	38	10.4	1.8493	38	1.7%	-0.60 [-1.43, 0.23]
Penckofer 2012	7.4	1.3	26	7.8	1.6	34	1.9%	-0.40 [-1.13, 0.33]
Pennings-Van der Eerden 1991	8.35	2.05	43	7.95	1.46	40	1.8%	0.40 [-0.36, 1.16]
Philis-Tsimikas 2011	9.1	2	69	9.7	2.3	87	2.0%	-0.60 [-1.28, 0.08]
Pieber 1995	8.11	1.55	45	9.03	1.79	49	2.0%	-0.92 [-1.60, -0.24]
Rickheim 2002	6.5	0.7	43	6.5	0.9	49	2.6%	0.00 [-0.33, 0.33]
Ridgeway 1999	11.52	3.0547	18	11.64	1.7889	20	0.8%	-0.12 [-1.73, 1.49]
Rosal 2005	-0.85	0.56	14	-0.12	0.91	9	2.0%	-0.73 [-1.39, -0.07]
Rosal 2011	-0.46	1.6781	115	-0.2	1.8179	119	2.4%	-0.26 [-0.71, 0.19]
Sarkadi 2004	6.2	0.709	33	6.4	0.709	38	2.6%	-0.20 [-0.53, 0.13]
Scain 2009	6.4	1.3	52	6.9	1.5	52	2.2%	-0.50 [-1.04, 0.04]
Smith 2011	7.1	1.1	166	7.1	1.2	171	2.7%	0.00 [-0.25, 0.25]
Sperl-Hillen 2011	-0.27	2.438	239	-0.24	2.438	130	2.3%	-0.03 [-0.55, 0.49]
Toobert 2003	7.07	1.11	137	7.38	1.33	108	2.6%	-0.31 [-0.62, 0.00]
Toobert 2011 A	8.3	1.9	99	8.3	1.6	107	2.3%	0.00 [-0.48, 0.48]
Torres Hde 2009	7.6	1.4	31	7.9	1.6	26	1.8%	-0.30 [-1.09, 0.49]
Trento 2001	7.5	1.4	43	8.3	1.8	47	2.0%	-0.80 [-1.46, -0.14]
Trento 2008	7.6	0.8	24	8.4	1.3	21	2.0%	-0.80 [-1.44, -0.16]
Trento 2010	7.3	0.9	315	8.8	1.2	266	2.8%	-1.50 [-1.68, -1.32]
Vadstrup 2011	-0.3	0.7809	61	-0.6	0.7742	60	2.7%	0.30 [0.02, 0.58]
Yoo 2007	-0.65	1.16	25	0.25	1.42	23	1.9%	-0.90 [-1.64, -0.16]
Zapotoczky 2001	7.7	1.45	18	8.3	1.49	18	1.5%	-0.60 [-1.56, 0.36]
Total (95% CI)			**3579**			**3476**	**100.0%**	**-0.34 [-0.51, -0.17]**

Heterogeneity: Tau² = 0.27; Chi² = 295.89, df = 46 (P < 0.00001); I² = 84%
Test for overall effect: Z = 3.91 (P < 0.0001)

Mean Difference IV, Random, 95% CI

-2 -1 0 1 2

Favours group education Favours control

Risk of Bias A B C D E F G

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Effectiveness of group-based interventions for HbA1c at various time points

A summary of the results of the meta-analyses on the primary outcome measure at various time points is provided in Table 3.5. Using the Cochrane Risk of Bias tool to assess quality of evidence (Table 3.4 and Figure 3.2), there was moderate to low quality evidence that group-based interventions for T2DM were more effective than control groups in reducing HbA1c post-intervention at most time points. Specifically, HbA1c was reduced at six to ten months post-baseline (n=30; MD= 0.31%; 95% CI: -0.48, -0.15; P=0.0002), 12-14 months post-baseline (n=27; MD = 0.33%; 95% CI: -0.49, -0.17; P<0.0001), 18 months (n= 3; MD= 0.72%; 95% CI: -1.26, -0.18; P=0.009), and at 36-48 months (n=5; MD= 0.93%; 95% CI: -1.52, -0.34; P=0.002). HbA1c was measured by two studies[49, 99] at 60 months, which both resulted in significant improvements in HbA1c. Heterogeneity was significant at all time points except at 18 months. In contrast, when eight studies comparing group-based interventions with controls measured HbA1c at 24 months post-baseline there was no significant difference between the groups. This time point also had the highest heterogeneity (I^2= 94%). One study favoured the control group and appeared to be an outlier[121] with a mean difference in HbA1c of 0.60% (95% CI: 0.52, 0.68). The authors of the study noted that contact with intervention participants decreased after six months and HbA1c levels returned to baseline at 12 months follow up. Furthermore, when removing the three studies[82, 84, 116] assessed as high risk as well as the outlier study, heterogeneity decreased substantially (I^2= 0%). However, the outlier study was rated as a low risk of bias and therefore was retained in the meta-analysis.

Table 3.5: Summary of meta-analysis results for HbA1c at various time points

Outcome	Time point (mths)	N studies	N participants (IG/ CG)	Mean Difference (95% CI)	P-value	Heterogeneity (I^2)	Heterogeneity (P-value)
HbA1c (%)	6-10	30	2155/ 1952	-0.31 (-0.48, -0.15)	0.0002	65%	<0.00001
	12-14	27	2233/ 2151	-0.33 (-0.49, -0.17)	<0.0001	64%	<0.00001
	18	3	98/ 96	-0.72 (-1.26, -0.18)	0.009	50%	0.13
	24	8	551/ 555	-0.33 (-0.82, 0.17)	0.20	94%	<0.00001
	36-48	5	747/ 689	-0.93 (-1.52, -0.34)	0.002	93%	<0.00001

N= number; IG= intervention group; CG= control group; CI= confidence interval; HbA1c= glycated haemoglobin; mths= months

Effects of group-based education interventions for secondary outcome measures

A summary of the results of the meta-analyses on the secondary outcome measures assessed using mean difference as the effect measure at various time points is provided in Table 3.6.

Fasting blood glucose

There was variation in effectiveness when comparing group-based interventions with controls for reducing FBG. Group-based education was more effective at reducing FBG compared with controls at 12-14 months post-baseline (n=8; MD=0.68mmol/L; 95% CI: -1.25, -0.11; P=0.02). However, this was not the case for FBG when measured at six to ten (n=10), or 24 months (n=4) post-baseline. The quality of evidence based on risk of bias for this outcome, was low to moderate. All time points were assessed as having significant heterogeneity. The significant heterogeneity at six to 10 months (I^2= 79%) was a result of four outlying studies[84, 85, 101, 127] of which three were classified as having a high risk of bias. The fourth study[127] noted that a major limitation in the study was differences in expertise of the educators facilitating the group-based intervention and individual intervention, which may have resulted in significant improvements in FBG in the individual intervention when compared to the group-based intervention. When removing these four studies, the result was an improvement in FBG favouring the group-based intervention with an unimportant heterogeneity (I^2=15%). The substantial heterogeneity (I^2=65%) at 18 months was due to a high risk study[84] which was not published in English included in the meta-analysis, however the change in heterogeneity when removing this study could not be assessed as the meta-analysis only contained two studies. Finally, the significant heterogeneity (I^2=88%) in the 24 month post-baseline measure was caused by a high risk study which was not published in English (Lozano), which when removed from the meta-analysis resulted in no heterogeneity between studies (I^2=0%).

FBG was assessed by two studies[84, 128] at 18 months and by two studies[123, 126] at 48 months. Of these four studies, two[126, 128] resulted in significant reductions in FBG favouring group-based education, whilst the remaining studies resulted in no significant differences between groups.

Table 3.6: Summary of meta-analysis results of secondary outcomes assessed using mean difference at various time points

Outcome	Time point (mths)	N studies	N participants (IG/ CG)	Mean Difference (95% CI)	P-value	Heterogeneity (I^2)	Heterogeneity (P-value)
FBG (mmol/L)	6-10	10	454/ 461	-0.24 (-0.95, 0.47)	0.51	79%	<0.00001
	12-14	8	496/ 575	-0.68 (-1.25, -0.11)	0.02	55%	0.03
	24	4	204/ 209	-0.10 (-1.60, 1.39)	0.89	88%	<0.0001
Weight (kg)	6-10	17	1341/ 1172	-1.22 (-2.22, -0.23)	0.02	62%	0.0003
	12-14	9	804/ 760	-1.43 (-2.09, -0.77)	<0.0001	0%	0.88
	36-48	4	714/ 605	-0.62 (-1.69, 0.45)	0.25	0%	0.77
BMI (kg/m^2)	6-10	18	1019/ 1016	-0.00 (-0.44, 0.44)	0.99	36%	0.07
	12-14	13	962/ 1082	0.19 (-0.37, 0.75)	0.51	55%	0.009
	24	6	496/ 502	0.80 (-0.93, 2.54)	0.36	89%	<0.00001
Waist circumference (cm)	6-10	5	520/ 466	-1.19 (-2.34, -0.05)	0.04	58%	0.05
	12-14	3	579/ 509	-0.79 (-1.96, 0.38)	0.19	38%	0.20
Systolic BP (mmHg)	6-10	17	1359/ 1218	0.12 (-1.44, 1.67)	0.88	38%	0.05
	12-14	11	1087/ 1083	-0.49 (-1.90, 0.92)	0.49	0%	0.45
	24	4	263/ 265	-0.68 (-5.43, 4.07)	0.78	40%	0.17
	36-48	4	714/ 605	-1.71 (-5.76, 2.34)	0.41	66%	0.03
Diastolic BP (mmHg)	6-10	17	1435/ 1261	-1.77 (-3.73, 0.20)	0.08	92%	<0.00001
	12-14	11	1087/ 1083	-0.80 (-1.71, 0.12)	0.09	0%	0.46
	24	3	97/ 94	1.12 (-1.77, 4)	0.45	17%	0.30
	36-48	4	714/ 605	-1.13 (-2.70, 0.43)	0.16	40%	0.17
Total cholesterol (mmol/L)	6-10	15	1153/ 1117	-0.01 (-0.16, 0.14)	0.87	75%	<0.00001

Outcome	Time point (mths)	N studies	N participants (IG/ CG)	Mean Difference (95% CI)	P-value	Heterogeneity (I^2)	Heterogeneity (P-value)
	12-14	9	891/ 928	0.01 (-0.12, 0.15)	0.84	44%	0.07
	24	3	241/ 243	-0.10 (-0.56, 0.36)	0.67	81%	0.005
	36-48	3	692/ 583	-0.23 (-0.65, 0.18)	0.27	88%	0.0003
HDL cholesterol (mmol/L)	6-10	13	967/ 906	0.16 (-0.09, 0.41)	0.22	99%	<0.00001
	12-14	10	915/ 943	0.02 (-0.02, 0.07)	0.28	74%	<0.0001
	36-48	3	692/ 583	0.04 (-0.10, 0.18)	0.59	94%	<0.00001
LDL cholesterol (mmol/L)	6-10	12	571/ 560	-0.03 (-0.13, 0.07)	0.59	49%	0.03
	12-14	5	333/ 398	0.08 (0.01, 0.15)	0.04	0%	0.44
Triglycerides (mmol/L)	6-10	14	1105/ 1045	-0.13 (-0.24, -0.01)	0.03	4%	0.41
	12-14	11	1045/ 1069	-0.04 (-0.22, 0.14)	0.66	68%	0.0005
	24	3	118/ 119	-0.32 (-0.58, -0.06)	0.01	8%	0.34

N= number; IG= intervention group; CG= control group; CI= confidence interval; FBG= fasting blood glucose; BMI= body mass index; BP= blood pressure; HDL= high density lipoprotein; LDL= low density lipoprotein; mths= months

Anthropometric measures

The anthropometric measures included body weight, BMI and waist circumference. The meta-analyses provided moderate to low quality evidence that group-based education was more effective at reducing body weight compared with controls at both six to ten months (n=17; MD=1.22kg; 95% CI: -2.22, -0.23; P=0.02) and 12-14 months (n=9; MD=1.43kg; 95% CI: -2.09, -0.77; P<0.0001). The meta-analysis at six to ten months had significant heterogeneity (I^2=62%), caused by two outlying studies[100, 110] which had high attrition rates (46-51%) and when removed from the meta-analysis resulted in a moderate heterogeneity (I^2=37%). The meta-analyses at 12-14 and 36-48 months had no heterogeneity between studies (I^2=0%). Despite the statistically significant improvements in body weight at two time points, group-based education was not effective at significantly reducing BMI at any time point. Body weight was additionally assessed by two studies[84, 124] at 24 months post-baseline, with neither of the studies resulting in significant differences between groups.

Group-based education was effective at reducing waist circumference at six to ten months (n=5; MD=1.19cm; 95% CI: -2.34, -0.05; P= 0.04). However, although waist circumference was improved by group-based education at 12 to 14 months, the difference between groups was not significant (n=3; MD=0.79; 95% CI: -1.96, 0.38; P= 0.19). Furthermore, the quality of evidence based on risk of bias for this outcome was moderate to low.

Blood pressure

Both systolic and diastolic BP were measured at five time points (six to ten months, 12 to 14 months, and 24 months post-baseline). When pooled, changes in systolic and diastolic BP were not statistically different between groups for any of these intervals. In the meta-analysis of diastolic blood pressure, at six to ten months, heterogeneity was significant (I^2=92%), however when removing the two studies classified as high risk of bias[22, 84] the reduction in diastolic BP was significant and heterogeneity was moderate (n=17; MD=1.04mmHg; 95% CI: -2.17, 0.08; P=0.05; I^2=37%). At 36 to 48 months (n=4) in the meta-analysis of systolic blood pressure, one study[123] caused the heterogeneity between studies (I^2=66%), and when removed heterogeneity was reduced

to a moderate level (I^2=53%). Additionally, systolic and diastolic BP were assessed by two studies[83, 84] at 18 months, with neither of the studies resulting in significant differences between groups.

Lipid profile

There were no significant differences in total cholesterol between group-based interventions and controls at any time point. Total cholesterol was reduced at six to 10 months (n=15; MD=0.01mmol/L; 95% CI: -0.16, 0.14; P=0.87), 24 months (n=3; MD=0.10mmol/L; 95% CI: -0.56, 0.36; P=0.67), and 36 to 48 months (n=3; MD=0.23mmol/L; 95% CI: -0.65, 0.18; P=0.27), however the improvements were not significant. The heterogeneity between studies was significant at all but one time point (12 to 14 months; n=9). When removing the three high risk studies[22, 85, 101] from the meta-analysis completed at six to ten months, heterogeneity was reduced to a moderate level (I^2=52%). The considerable heterogeneity at 24 months was caused by a non-English language study[83], which when removed, resulted in no heterogeneity (I^2=0%) between studies.

HDL cholesterol was one of four measures included in the meta-analyses in which an increase is desirable. There were no significant differences in HDL cholesterol between groups at six to ten months (n=13; MD=0.16mmol/L; 95% CI: -0.09, 0.41; P=0.22), 12 to 14 months (n=10; MD=0.02mmol/L; 95% CI: -0.02, 0.07; P= 0.28), or 36 to 48 months (n=3; MD=0.04mmol/L; 95% CI: -0.10, 0.18; P=0.59). Heterogeneity was significant at all time points. The heterogeneity at six to ten months was improved to a moderate level (I^2=57%) by removing an outlier[92]. Removing the one high-risk study from 36 to 48 month analysis reduced heterogeneity to an unimportant level (I^2=29%). HDL cholesterol was also measured by two studies[83, 125] at 24 months, with neither study resulting in significant improvements in HDL cholesterol between groups.

There were mixed results for LDL cholesterol when measured at two time points, six to ten months and 12 to 14 months. At six to ten months, the meta-analysis resulted in no significant differences between groups for LDL cholesterol (n=12; MD=0.03mmol/L; 95% CI: -0.13, 0.07; P=0.59). Heterogeneity was significant (I^2 = 49%) due to two high

risk of bias studies[85, 101], which when excluded from the meta-analysis resulted in no heterogeneity (I^2=0%). The studies assessing LDL cholesterol at 12 to 14 months resulted in a significant decrease in LDL favouring the control group (n=5; MD=0.08mmol/L; 95% CI: 0.01, 0.15; P=0.04), with no heterogeneity between studies (I^2=0%). This meta-analysis therefore provides moderate to low quality evidence for an improvement in LDL cholesterol in the control groups when compared to group-based education.

Triglyceride results were also inconsistent. Group-based education was effective at reducing triglycerides at six to 10 months (n=14; MD=0.13mmol/L; 95% CI: -0.24, -0.01; P=0.03), and 24 months (n=3; MD=0.32mmol/L; 95% CI: -0.58, -0.06; P=0.01) with non-significant heterogeneity between studies at both time points (I^2=4 and 8%). At 12 to 14 months, the difference between groups for triglycerides were not significant (n=11; MD=0.04; 95% CI: -0.22, 0.14; P=0.66). The heterogeneity between studies was significant (I^2=68%) and was caused by one outlier[111] which when removed from the meta-analysis, resulted in moderate heterogeneity (I^2=57%). Triglycerides were also measured by two studies[55, 126] at 36 to 48 months, with the study by Trento[126] resulting in significant improvements in triglycerides for the group-based intervention group when compared with the control group. The quality of evidence based on risk of bias for this outcome was considered moderate to low.

Diabetes knowledge, psychosocial measures, and energy intake

Each of these measures used a variety of assessment tools and were therefore assessed using standard mean difference as the effect measure (Table 3.7). Diabetes knowledge was reported by 16 studies [81, 85, 86, 91, 97, 102, 104, 105, 109-113, 122, 124, 126] and was measured using a range of validated questionnaires. The meta-analyses resulted in moderate to low quality evidence for group-based education effectively improving diabetes knowledge at both of two time points: six to ten months (n=7; SMD= 0.61; 95% CI: 0.14, 1.08; P=0.01) and 12 to 14 months (n=7; SMD=0.58; 95% CI: 0.08, 0.97; P=0.02) when compared to controls. Heterogeneity was significant at both time points.

QOL was measured by 11 studies [91, 100, 107, 110, 112, 119, 120, 122, 124-126] using various validated questionnaires. QOL was assessed at six to ten months and resulted in no significant differences between groups (n=5; SMD=0.03; 95% CI: -0.34, 0.29; P=0.86). The heterogeneity was non-significant. QOL was measured by two studies [124, 125] at 24 months and by two studies[123, 126] at 48 months, with all four studies resulting in significant improvements in QOL for the group-based education group when compared to controls.

Depression was assessed in three studies [103, 107, 112] using validated depression scales or questionnaires at six months post-baseline. There was moderate quality evidence of an effect of group-based education on reducing depression scores (SMD=0.62; 95% CI: -0.93, -0.31; P=0.0001) when compared with control groups, with a non-significant heterogeneity between studies.

Table 3.7: Summary of meta-analysis results of secondary outcomes assessed using standard mean difference at various time points

Outcome	Time point (mths)	N studies	N participants (IG/ CG)	Standard Mean Difference (95% CI)	P-value	Heterogeneity (I^2)	Heterogeneity (P-value)
Diabetes knowledge	6-10	7	239/ 240	0.61 (0.14, 1.08)	0.01	83%	<0.00001
	12-14	7	609/ 682	0.58 (0.08, 0.97)	0.02	93%	<0.00001
QOL	6-10	5	135/ 130	-0.03 (-0.34, 0.29)	0.86	34%	0.19
Depression	6	3	201/ 176	-0.62 (-0.93, -0.31)	0.0001	28%	0.25
Self-efficacy	12	3	256/ 272	0.15 (-0.02, 0.33)	0.08	0%	0.92
Energy intake	6	5	182/ 203	-0.11 (-0.44, 0.22)	0.50	58%	0.05
	12	4	389/ 406	-0.21 (-0.58, 0.16)	0.27	84%	0.0003
Physical activity	6	7	619/ 478	0.23 (0.10, 0.36)	0.0006	9%	0.36
	12-14	3	486/ 376	0.21 (0.06, 0.35)	0.005	11%	0.33

N= number; IG= intervention group; CG= control group; CI= confidence interval; QOL= quality of life; mths= months.

Self-efficacy was reported by five studies[38, 103, 113, 116, 120] at three time points (six months, 12 months and 24 months) using validated questionnaires. Group-based education was more effective at improving self-efficacy at 12 months post-baseline (n=3; SMD=0.15; 95% CI= -0.02, 0.33; P=0.08), however these measures were not significant. There was no heterogeneity between the three studies included in the meta-analysis (I^2=0%). Self-efficacy was reported by two studies[103, 120] at six months, and by two studies[116, 121] at 24 months. Of these four studies, only one[103] resulted in significant improvements in self-efficacy favouring group-based education when compared to the control group, whilst three of the studies[116, 120, 121] resulted in no between group differences. Empowerment was measured by two studies[91, 118] also using validated questionnaires, at 12 to 14 months post-baseline with both indicating that group-based education was more effective at improving empowerment than control conditions.

Energy intake was reported by seven studies[87, 91, 101, 104, 106, 112, 113] at two time points (six and 12 months). Meta-analyses at both time points resulted in no significant differences between groups (6 months: n=5; SMD=0.11; 95% CI: -0.44, 0.22; P=0.50; 12 months: n=4; SMD=0.21; 95% CI: -0.58, 0.16; P=0.27). The heterogeneity between studies was 58% and 84% respectively. Nutrition or healthy eating was measured by four studies[100, 103, 113, 117] at two time points (six and 12 months) with two studies[103, 113] resulting in a statistically significant improvement in healthy eating amongst the group-based education participants when compared to the control group (P<0.01), and two studies[100, 117] finding no significant differences between groups. Nutrition or healthy eating and energy intake were measured using food frequency questionnaires, validated healthy eating questionnaires, self-reported three-day food diaries, or 24 hour diet recalls administered by trained professionals.

Physical activity levels were measured by eight studies[91, 100, 103, 104, 110, 112, 117, 120, 131] at two time points, six of which utilized validated physical activity questionnaires, whilst one provided registered pedometers to study participants and one assessed self-reported exercise frequency. Meta-analyses at both time points resulted in moderate to low quality evidence of improvements in physical activity levels favouring the group-based intervention (6 months: n=7; SMD= 0.23; 95% CI: 0.10, 0.36; P=0.0006; 12 months: n=3; SMD= 0.21; 95% CI: 0.06, 0.35; P=0.005) when compared with controls, with

non-significant heterogeneity at both time points.

Other measures including social support, self-monitoring of blood glucose (SMBG), body fat, and fat, protein and carbohydrate intake, were measured by a limited number of studies, and were therefore not included in the meta-analyses. Two studies[86, 116] assessed social support using validated questionnaires at two differing time points (12 and 24 months post-baseline), two studies reported SMBG frequency[91, 112], and two studies measured body fat.[91, 128] No significant differences between groups were found for any of these measures.

Three studies measured fat, protein and carbohydrate intake[87, 101, 106] whilst two studies measured fat and carbohydrate intake[112, 113] and one measured fat intake only.[120] Two[113, 120] of these six studies resulted in significant reductions in the percentage of fat consumed in the intervention group when compared to the control group ($P<0.05$), with the other studies[87, 101, 106, 112] resulting in no significant differences between the intervention and control groups.

Subgroup Analyses

Subgroup analyses were completed for thirteen subgroups using HbA1c, at the point closest to the end of each of the group-based education interventions as the outcome measure. The subgroups included in the analyses were: control group, delivery setting, type of educators, training, baseline HbA1c levels, theoretical model, intervention content, materials, intervention length, number of sessions, contact time, number of participants, and the inclusion or exclusion of family and friends. The results of the subgroup analyses are presented in Table 3.8 and summarized below.

Table 3.8: Subgroup analysis results for primary outcome measure (HbA1c)

Analysis outcome	N studies	N participants (IG/ CG)	Mean Difference (95% CI)	Overall effect: P-value	Heterogeneity	Subgroup differences: P-value
Control group	**47**	**3579/ 3476**	-	-	-	**0.60**
Usual care	28	2414/ 2322	-0.42 (-0.66, -0.18)	0.0007	88%	
Waiting list control	4	243/ 251	-0.34 (-0.85, 0.18)	0.20	70%	
Individual intervention	6	542/ 532	-0.05 (-0.50, 0.40)	0.82	81%	
Usual care with written materials	6	315/ 412	-0.21 (-0.54, 0.12)	0.21	61%	
Group education prior to usual care	3	65/ 63	-0.48 (-1.03, 0.07)	0.09	34%	
Delivery setting	**47**	**3579/ 3476**	-	-	-	**0.38**
Primary care	34	2858/ 2808	-0.28 (-0.41, -0.16)	<0.0001	59%	
Other setting	13	721/ 668	-0.52 (-1.02, -0.01)	0.05	93%	
Type of educators:	**47**	**3579/ 3476**	-	-	-	**0.002**
Peer or lay led	5	530/536	0.02 (-0.12, 0.16)	0.80	0%	
HP led with peer support	5	517/502	-0.27 (-0.48, -0.06)	0.01	0%	
Single discipline	17	1054/ 1080	-0.56 (-0.86, -0.26)	0.0003	86%	
Multidisciplinary	20	1478/ 1358	-0.24 (-0.43, -0.04)	0.02	61%	
Training:	**47**	**3579/ 3476**	-	-	-	**0.82**
Yes	34	2915/ 2814	-0.33 (-0.53, -0.13)	0.001	87%	
No	13	664/ 662	-0.38 (-0.70, -0.05)	0.02	69%	
Baseline HbA1c levels	**47**	**3579/ 3476**	-	-	-	**0.52**
>7% in both groups	38	3043/ 2937	-0.37 (-0.56, -0.17)	0.002	85%	
<7% in both groups	9	536/ 539	-0.24 (-0.60, 0.13)	0.21	82%	
Theoretical model:	**47**	**3579/ 3476**	-	-	-	**0.48**
Yes	24	2227/ 2089	-0.39 (-0.65, -0.12)	0.004	89%	
No	23	1352/ 1387	-0.27 (-0.46, -0.09)	0.003	62%	
Intervention content	**47**	**3579/ 3476**	-	-	-	**0.75**
Facilitator-directed	43	3306/ 3226	-0.34 (-0.52, -0.15)	0.0003	85%	
Patient-directed	4	273/ 250	-0.42 (-0.94, 0.09)	0.11	73%	
Materials	**47**	**3579/ 3476**	-	-	-	**0.90**
Yes	40	3182/ 3100	-0.34 (-0.53, -0.15)	0.0004	85%	
No	7	397/ 376	-0.37 (-0.83, 0.09)	0.12	84%	
Intervention length	**47**	**3579/ 3476**	-	-	-	**0.53**

Analysis outcome	N studies	N participants (IG/ CG)	Mean Difference (95% CI)	Overall effect: P-value	Heterogeneity	Subgroup differences: P-value
<1 mth	6	875/ 790	-0.33 (-0.64, -0.02)	0.04	56%	
1-3 mths	8	585/ 546	-0.20 (-0.50, 0.10)	0.19	71%	
4-6 mths	11	501/ 486	-0.19 (-0.48, 0.10)	0.20	67%	
7-12 mths	13	824/ 850	-0.32 (-0.55, -0.09)	0.007	54%	
13-60 mths	9	794/ 804	-0.66 (-1.14, -0.18)	0.007	93%	
Number of sessions	**47**	**3579/ 3476**	-	-	-	**0.34**
< 5 sessions	13	1223/ 1208	-0.46 (-0.70, -0.23)	<0.0001	68%	
6-10 sessions	21	1360/ 1294	-0.20 (-0.39, -0.01)	0.04	71%	
11-20 sessions	8	707/ 678	-0.48 (-1.04, 0.09)	0.10	92%	
> 21 sessions	5	289/ 296	-0.31 (-0.71, 0.09)	0.13	41%	
Contact time	**47**	**3579/ 3476**	-	-	-	**0.72**
8 or less hrs	13	1168/ 1033	-0.45 (-0.74, -0.17)	0.002	72%	
9-12 hrs	7	536/ 557	-0.35 (-0.59, -0.11)	0.004	55%	
13-18 hrs	10	909/ 909	-0.19 (-0.74, 0.35)	0.48	96%	
19-30 hrs	9	348/ 352	-0.42 (-0.77, -0.08)	0.02	58%	
31 hrs or more	8	618/ 625	-0.25 (-0.42, -0.09)	0.003	0%	
Number of participants	**47**	**3579/ 3476**	-	-	-	**0.40**
4-10	32	2563/ 2426	-0.39 (-0.16, -0.17)	0.0006	87%	
11-20	15	1016/ 1050	-0.25 (-0.48, -0.02)	0.03	64%	
Family and friends	**47**	**3579/ 3476**	-	-	-	**0.70**
Yes	29	2841/ 2700	-0.36 (-0.59, -0.13)	0.002	88%	
No	18	738/ 776	-0.30 (-0.52, -0.08)	0.008	67%	

N= number; HP= health professional; IG= intervention group; CG= control group; CI= confidence interval; HbA1c= glycated haemoglobin; mth/s= month/s; hrs= hours

The subgroup analysis of educators or group facilitators was the only subgroup analysis that resulted in a significant subgroup difference (P= 0.002), with peer or lay led group-based interventions as the least effective resulting in an inability to significantly improve HbA1c (P=0.80). Interventions facilitated by single disciplines (P=0.0003), multidisciplinary teams (P=0.02) or health professionals with peer supporters (P=0.01), were effective at improving HbA1c (Figure 3.4). The types of educators were further analysed to individual disciplines included in the 'single discipline' group, finding that physician-led, dietitian-led and nurse-led group-based education interventions were effective (P<0.00001) at improving HbA1c (Figure 3.5). Heterogeneity for both subgroup analyses was significant (I^2= 79.1% and 89.2% respectively).

Despite the lack of significant differences between subgroups for the other attributes assessed, the analyses indicated that some groups were more likely to be effective at improving HbA1c levels than others. For example, interventions delivered in primary care settings (P<0.0001) may be more effective at improving HbA1c than those delivered in other settings (P=0.05), and group-based interventions which were compared with a usual care control group (P=0.007) were more likely to be effective than those compared with waiting-list controls (P=0.20), individual education (P=0.82), usual care with written materials (P=0.21), or group education prior to usual care (P=0.09). Additionally, interventions which include persons with HbA1c levels above 7% (P=0.002) appear more effective at improving HbA1c than those which include persons with HbA1c levels below 7% (P=0.21), and interventions which are facilitator-directed (P=0.0003), provide materials to participants (P=0.0004), are either less than one month (P=0.04), seven to 12 months (P=0.007) or 13 to 60 months (P=0.007) in length, providing less than five (P<0.0001) or six to ten sessions (P=0.04), over less than eight (P=0.002), nine to 12 (P=0.004), 19 to 30 (P=0.02) or more than 31 (P=0.003) hours appear to be more effective at improving HbA1c than other interventions.

The provision and description of training provided to the educator/s did not significantly impact the effectiveness of the intervention (subgroup differences: P=0.82), with both

groups resulting in significant improvements in HbA1c (Training: P= 0.001; No training: P=0.02). Additionally, studies which reported the use of a theoretical model in the development and/or facilitation of the group-based education intervention were similarly as effective at improving HbA1c with pooled analysis of both groups reaching statistical significance (Yes: P=0.004; No: P=0.003). Furthermore, the number of participants in each intervention group (four to ten participants: P=0.0006; 11-20 participants: P=0.03), and the inclusion or exclusion of family, friends or carers (Yes: P=0.002; No: P=0.008) in the group-based education programs, did not appear to influence the effectiveness of the intervention in regards to changes in HbA1c.

Figure 3.4: Forest plot- Subgroup analysis of the influence of type of educator compared with control on HbA1c

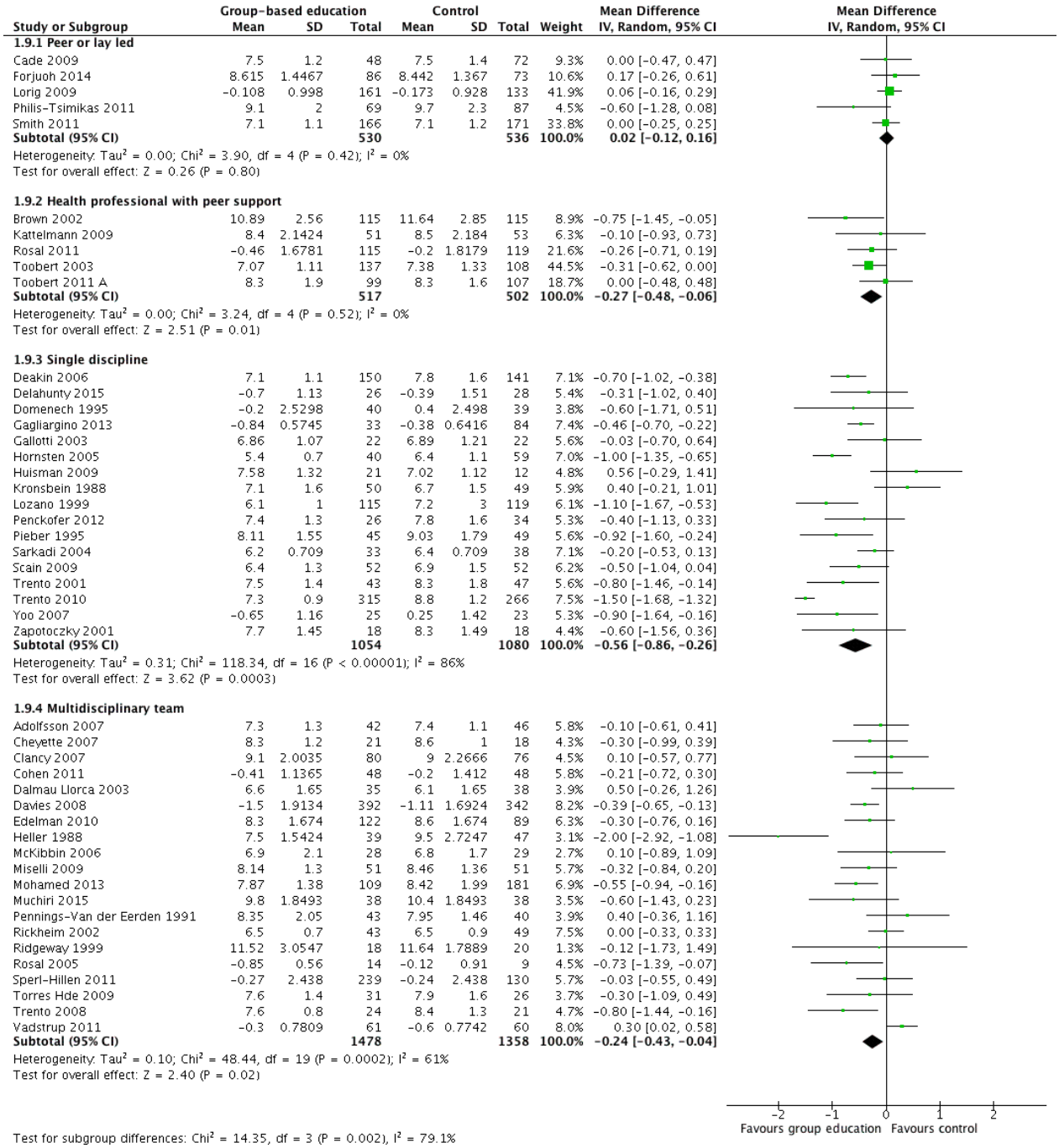
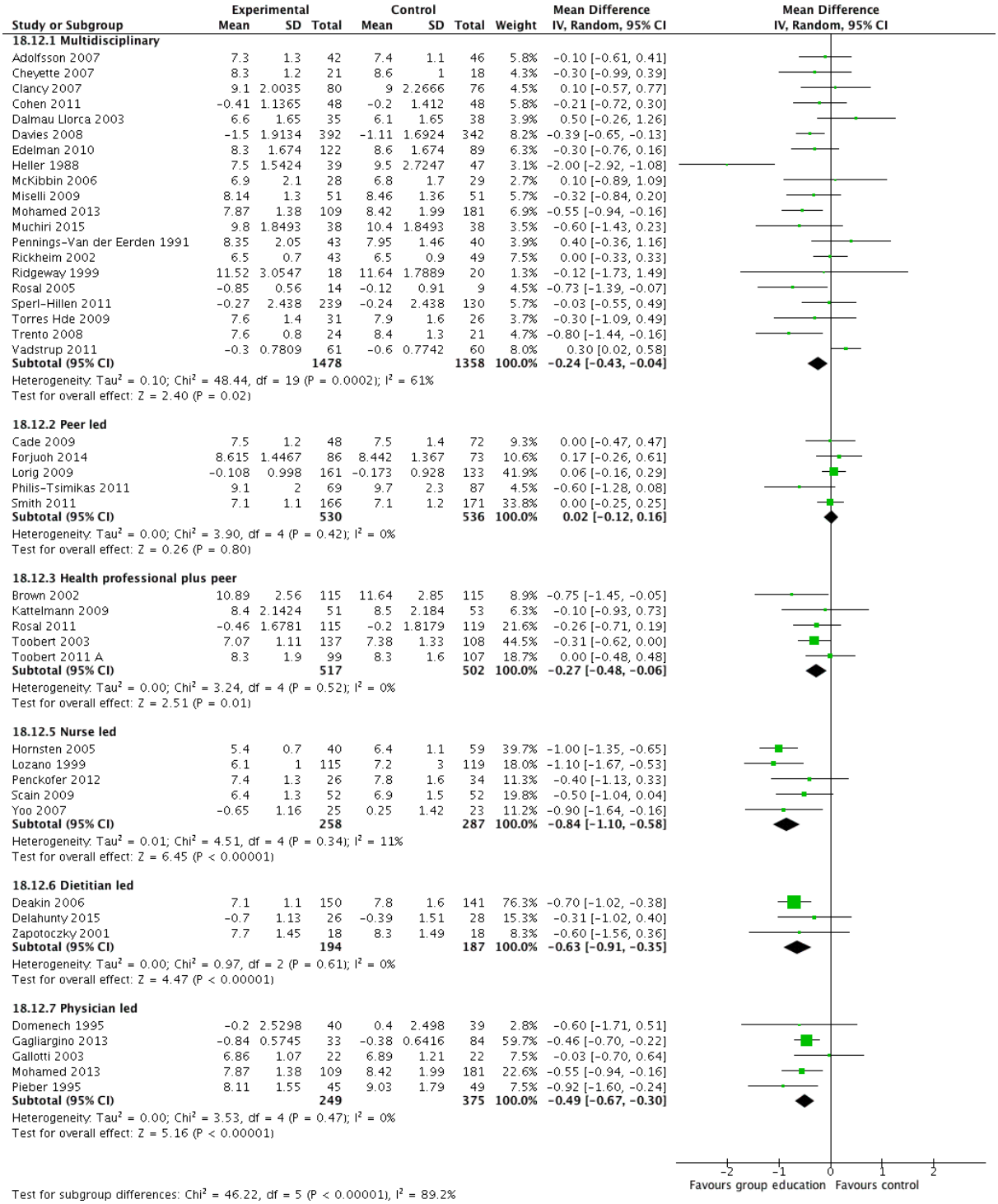


Figure 3.5: Forest plot- Subgroup analysis of the influence of discipline of educator compared with control on HbA1c



Sensitivity Analyses

Sensitivity analyses were performed to explore the influence of study quality and characteristics on post-baseline HbA1c outcomes. Variables included in the analyses were: study ratings for overall risk of bias (low, moderate or high) and reporting bias (low or high risk), studies with baseline differences of HbA1c between groups (≥0.4% difference in baseline measurements between the intervention and control groups), studies with differing attrition (<10% attrition in both groups or >10% attrition in both groups), and studies published in English compared with other languages (Table 3.9). Forest plots for sensitivity analyses are reported in Appendix B.

There were no significant differences in HbA1c outcomes when study quality or characteristics were explored. For example, the overall risk of bias (low, moderate or high) and attrition rate did not significantly impact on the studies' ability to improve HbA1c with all subgroups resulting in significant improvements in HbA1c ($P \leq 0.05$) (Appendix B).

Table 3.9: Sensitivity analysis results for primary outcome measure (HbA1c)

Analysis outcome	N studies	N participants (IG/ CG)	Mean Difference (95% CI)	P-value	Heterogeneity	Subgroup differences: p-value
Overall risk of bias	**47**	**3579/ 3476**	-	-	-	**0.92**
Low	4	409/ 375	-0.40 (-0.75, -0.06)	0.02	52%	
Moderate	31	2011/ 1963	-0.35 (-0.59, -0.12)	0.003	88%	
High	12	1159/ 1138	-0.31 (-0.59, -0.02)	0.03	74%	
Reporting bias	**47**	**3579/ 3476**	-	-	-	**0.38**
Low	38	2792/ 2734	-0.38 (-0.58, -0.18)	0.0002	86%	
High	9	787/ 742	-0.22 (-0.52, 0.08)	0.16	69%	
Baseline differences	**47**	**3579/ 3476**	-	-	-	**0.68**
Yes	10	737/ 695	-0.27 (-0.62, 0.07)	0.12	70%	
No	37	2842/ 2781	-0.36 (-0.55, -0.16)	0.0004	86%	
Dropout	**47**	**3579/ 3476**	-	-	-	**0.09**
<10% attrition	14	1043/ 949	-0.53 (-0.72, -0.34)	<0.00001	41%	
>10% attrition	33	2536/ 2527	-0.27 (-0.49, -0.05)	0.02	88%	
Language of publication	**47**	**3579/ 3476**	-	-	-	**0.48**
English	42	3313/ 3206	-0.36 (-0.55, -0.18)	<0.0001	85%	
Non-English	5	409/ 375	-0.15 (-0.72, 0.42)	0.61	74%	

N= number; IG= intervention group; CG= control group; CI= confidence interval; HbA1c= glycated haemoglobin

Impact of study variables and intervention characteristics on HbA1c

A meta-regression was conducted for 11 study variables or intervention characteristics using the primary outcome measure, HbA1c. Included variables were theoretical model, type of educators, training, materials, delivery setting, baseline HbA1c levels, intervention length, number of sessions, number of participants, contact time, and family and friends. The meta-regression resulted in no statistically significant differences in the assessed variables or intervention characteristics. None of these variables explained significant portions of heterogeneity among the studies (Table 3.10).

Table 3.10: Meta-regression: association between study variables and primary outcome measure (HbA1c) (n=11)

Study variable	Univariate Analyses		
	Coefficient	**95% CI**	**P-value**
Theoretical model (RC: Yes)			
No	-0.0240	-0.43, 0.38	0.91
Type of educators (RC: Multidisciplinary team)			
Nurse only	-0.4849	-1.16, 0.19	0.15
Dietitian only	-0.2418	-1.10, 0.62	0.57
Physician only	-0.1989	-0.88, 0.48	0.56
Psychologist only	0.8659	-0.66, 2.40	0.26
Peer or lay led	0.2516	-0.40, 0.90	0.44
HP led with peer support	-0.4977	-1.17, 0.17	0.14
Pharmacist only	0.1059	-1.18, 1.40	0.87
Training (RC: Yes)			
No	0.0428	-0.42, 0.51	0.85
Materials (RC: Yes)			
No	0.0349	-0.53, 0.60	0.90
Delivery setting (RC: Primary care)			
Other setting	-0.1574	-0.61, 0.30	0.49
Baseline HbA1c levels (RC: >7% in both groups)			
<7% in both groups	0.2164	-0.29, 0.72	0.39
Intervention length (RC: <1 mth)			
1-3 mths	0.1308	-0.61, 0.87	0.72
4-6 mths	0.1181	-0.59, 0.82	0.74
7-12 mths	-0.1945	-0.88, 0.49	0.57
13-60 mths	-0.3246	-1.04, 0.39	0.37
Number of sessions (RC: < 5 sessions)			
6-10 sessions	0.305	-0.16, 0.77	0.20
11-20 sessions	0.0122	-0.58, 0.61	0.97
> 21 sessions	-0.4054	-1.13, 0.32	0.26
Number of participants (RC: 4-10)			
11-20	0.2290	-0.20, 0.66	0.29
Contact time (RC: 8 or less hrs)			
9-12 hrs	0.1286	-0.53, 0.79	0.70
13-18 hrs	0.2705	-0.31, 0.85	0.35
19-30 hrs	0.0715	-0.55, 0.70	0.82
31 hrs or more	-0.1218	-0.75, 0.51	0.70
Family and friends (RC: Yes)			
No	0.1436	-0.27, 0.56	0.49

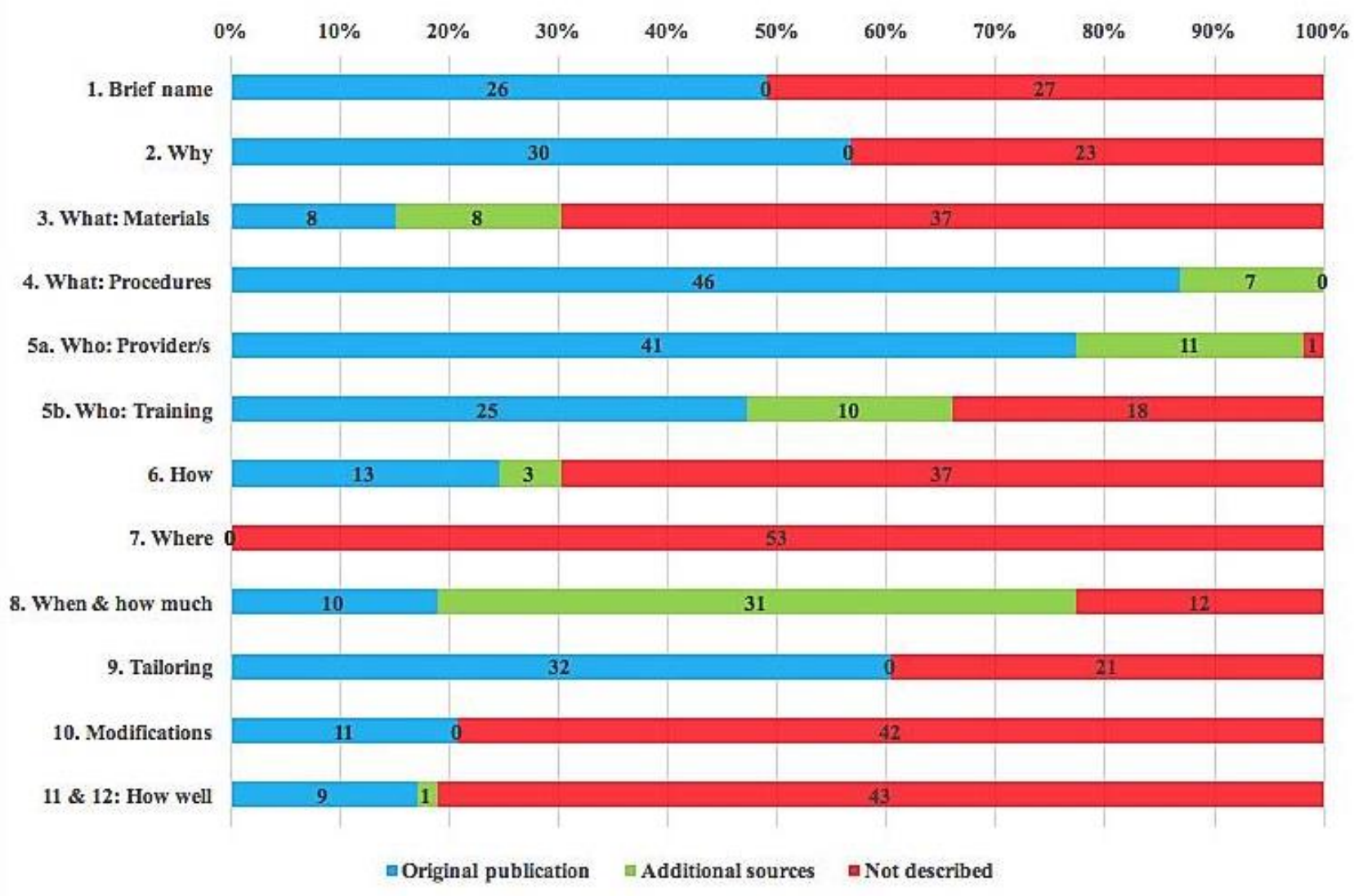
RC: reference category; CI= confidence interval; HbA1c= glycated haemoglobin; mths= months; hrs= hours

TIDieR Checklist

The intervention descriptions included in the 53 publications were assessed for completeness and replicability using the TIDieR checklist.[64] A summary of these results are provided in Figure 3.6, and the details for each study are provided in Appendix C.

In summary, 77% (41/53) of publications described the procedures of the intervention and 87% (46/53) of publications described who provided the group-based education intervention. In contrast, fewer than 20% of publications described whether materials were provided and if so, in what form (8/53, 15%), whether the intervention was modified during the course of the study (11/53, 21%), how intervention fidelity was assessed and what proportion of the intervention was delivered as planned (9/53, 17%). None of the publications completely described the type of location where the intervention occurred with any necessary infrastructure or relevant features. When authors were contacted for further information regarding intervention characteristics, the greatest increase in reporting description occurred for information about intervention delivery (i.e. number of times intervention was delivered, schedule, duration).

Figure 3.6: Number and percentage of studies describing each TIDieR checklist item (N=53)



3.5 Discussion

Forty-seven studies of group-based education programs for people with T2DM met the inclusion criteria, were reviewed and data analysed. Meta-analyses demonstrated improvements in the primary outcome measure, HbA1c, at six to ten months, 12-14 months, 18 months, and at 36-48 months, but not at 24 months post intervention favouring group-based education. However, interpretation is cautioned due to the significant heterogeneity in these meta-analyses and low to moderate quality of evidence reported in the trials. Previous research suggests that a 1% reduction in HbA1c is associated with a relative reduction of 21% for deaths related to diabetes, 21% for any end point related to diabetes such as microvascular or macrovascular events, and 'diabetes-related death'[74], 37% for microvascular complications, and 14% for myocardial infarctions.[14] Statistically significant reductions ranged from -0.31% at six to ten months when pooled for 30 studies to -0.93% at 36-48 months when pooled for 5 studies. Although these reductions did not reach 1%, any reduction in HbA1c is a positive and can reduce the risk of T2DM complications.[26, 74]

Results were more variable for statistically significant improvements in secondary outcome measures such as FBG, body weight, waist circumference, triglyceride levels, diabetes knowledge, depression and physical activity levels for a variety of time points including both short and long term. For example, FBG was improved significantly by reducing the average FBG level by 0.68mmol/L at 12-14 months when pooled for eight studies but not at other time points. Previous research suggests that improving FBG in people with T2DM can reduce the development or progression of microvascular complications such as retinopathy, neuropathy and nephropathy, and can improve QOL.[132] Although the data suggest a statistical improvement, we cannot determine if it is clinically meaningful. This may indicate that group-based education programs are not effective at improving various secondary outcome measures when compared to controls, or that further consideration of these measures is required.

Body weight and waist circumference had statistically significant improvements at time points closer to intervention completion than at later times. Pooled average weight loss was 1.2 to 1.4kg at six to ten months and 12 to 14 months for 17 and nine studies

respectively but waist circumference was significantly reduced by 1.2cm at six to ten months only when pooled for five studies. Weight control is recognized as an important component of diabetes care.[132] Any reductions in weight in individuals diagnosed with T2DM can result in improved glycaemic control, insulin sensitivity, BP, lipid profiles, mental health and quality of life,[133-135] with a sustained weight loss of five kilograms associated with a reduction in HbA1c of 0.5 to 1%.[136] Furthermore, in adults with a BMI>35kg/m^2 a weight loss of two to three kilograms may result in clinically significant reductions in systolic blood pressure.[136] Waist circumference is a commonly utilized measure of total body fat, a useful predictor of visceral fat[137], and can be a better predictor of cardiovascular risk[138] than BMI. Despite the statistically significant improvements in body weight and waist circumference, the meta-analyses of BMI did not reach statistical significance. This is likely due to the reductions in both measures not being great enough to influence BMI measures. These results are in line with the previous systematic reviews completed in the area, which both found no statistically significant differences in BMI between groups.[14, 47]

Triglycerides are an independent marker of CVD risk in T2DM[139], and the recommended triglyceride levels for adults are <2mmol/L.[140] Individuals with T2DM commonly have elevated triglyceride levels.[141] Pooled triglyceride levels were reduced significantly at six to ten months for 14 studies and 24 months for 3 studies post intervention by 0.31 and 0.32mmol/L respectively. It is unclear whether reductions in triglyceride levels can influence CVD events in patients with T2DM[141] and what reductions are clinically important. Despite improvements in total cholesterol, statistical significance was not reached at any time point. Furthermore, improvements in HDL cholesterol at any time point did not reach statistical significance but LDL cholesterol improved statistically by 0.08mmol/L at 12 to 14 months for five studies post intervention in favour of the control group. Although it is unlikely to be clinically important. This data is mostly consistent with the review by Steinsbekk and colleagues[47] which also found no statistically significant improvements in any of the blood lipid measures assessed.

Reductions of 10mmHg in systolic BP are associated with decreases in relative risk of 15% for deaths related to diabetes, 12% for diabetic complications, 13% for

microvascular complications and 11% for myocardial infarction.[14] Despite a trend to improvement in the various blood lipid (excepting LDL cholesterol) and BP measures, statistical significance was not reached at most time points. This may be due to the limited number of studies assessing these measures, the lack of intervention focused on reducing blood lipid measures or BP, the inclusion of participants on cholesterol reducing or hypotensive medications, or that included studies were not powered to detect changes in blood lipids or BP, with the majority of interventions aiming to reduce HbA1c instead. Additionally, compliance to the recommendations provided in group-based education interventions was not assessed and may differ between groups. The previous systematic review by Steinsbekk and colleagues[47] similarly found no significant improvements in diastolic or systolic BP between groups.

The meta-analyses indicated that group-based interventions were effective at significantly improving lifestyle or psychosocial measures such as diabetes knowledge, depression scores, and physical activity levels but no statistically significant changes were evident in individual's quality of life, self-efficacy, or energy intake. Improvements in diabetes knowledge is consistent with the Cochrane systematic review and the review by Steinsbekk and colleagues.[14, 47] Successful self-management of T2DM requires sufficient knowledge of the condition and its treatment, and the performance of self-management activities and skills,[39] and it has been clearly established knowledge is an essential prerequisite to learning.[40] Adequate knowledge of diabetes is a key component of diabetes education programs. Significant associations between self-management behaviours and diabetes knowledge have been established in previous studies.[142] Furthermore, although not included in the meta-analysis due to the outcome only being measured by two studies, group-based education appeared to improve patient empowerment. Patient empowerment, in which individuals accept responsibility to manage their own conditions and are encouraged to solve their own problems with information, but not directions, from health professionals, has been shown to be effective, with individuals likely to adjust behaviours and maintain them for long periods of time.[143]

Group-based education was additionally effective in improving depression scores at six months pooled for three studies and physical activity levels at both six months and 12 to

14 months pooled for seven and three studies respectively. Physical activity has been shown to improve both glycaemic control and CVD risk factors in persons with T2DM[144] but it is unclear what changes in physical activity levels are clinically meaningful.

The only significant between group difference when comparing the effect of intervention characteristics on HbA1c outcomes was for the type of group educator. Peer or lay-led group-based interventions were not able to significantly reduce HbA1c levels, whereas interventions facilitated by single disciplines, multidisciplinary teams or health professionals with peer supporters resulted in significant improvements in HbA1c. Furthermore, a subgroup analysis of single educator studies indicated that physician-led, dietitian-led and nurse-led group-based education interventions were equally effective at improving HbA1c levels. The 'Global Guideline for Type 2 Diabetes' published by the IDF states that recommended care for persons diagnosed with T2DM is to use an appropriately trained multi-disciplinary team to provide education to groups of people with diabetes, with limited care suggested as providing education with a smaller team, for example with a physician and diabetes educator, or in very limited situations, an appropriately skilled individual.[53] The results of this review indicate that facilitators from a single discipline providing group-based education to persons with T2DM can be more effective than multidisciplinary teams, a finding also supported by Steinsbekk et al.[47]

Peer support programs can be facilitated in a number of formats: as health professional facilitated interventions with peer coaches or supporters working in an informal, flexible way with participants; as remote peer supporters, providing support via email, telephone or internet; or as peer-led interventions, where peers rather than health professionals are the educators.[37] The benefits of peer support include the establishment of a non-hierarchical, reciprocal relationship with the individual, and the ability to share knowledge, life experience and common illness experience which many health workers would not have.[37] The results of this review support the use of peer supporters working to complement health professionals, rather than replacing the role of health workers.[37] Peer support can enhance and complement other health care services, can provide role

modeling and practical, emotional and ongoing support, and can assist individuals to follow management plans, cope with the stressors of chronic disease, and remain motivated.[31, 145]

Despite the lack of statistically significant differences between subgroups, various subgroup analyses resulted in significant improvements while others did not. For example, studies that provided materials to participants in the intervention group were more likely to improve HbA1c than other intervention studies suggesting the benefits of handouts, books, videos, photographs, or from materials that engage participants in the group-education experience. Additionally, studies where participants had baseline HbA1c levels more than 7% in both the intervention and control group were more likely to improve HbA1c than other intervention studies. The result indicates that it may be easier to improve the HbA1c levels through interventions for those individuals with a higher initial HbA1c level.

Similarly, although there was no statistically significant difference between subgroups, the length, number of sessions and contact time of group-based education programs had different effects on HbA1c. An intervention length of less than one month, between seven to 12 months or between 13 to 60 months had greater improvements than other intervention lengths. Also, providing less than 5 or between six to ten sessions had greater improvements than other session lengths and most contact hours with the exception of between 13 and 18 hours improved HbA1c. Although not directly comparable because we did not reach a pooled reduction of HbA1c of 1%, these results differed from the findings from a previous systematic review by Norris et al which evaluated the efficacy of self-management education on T2DM, and found that the only predictor of a reduction in HbA1c of 1% was contact time with 23.6 hours of contact time.[29] Furthermore, a previous systematic review found that group-based interventions delivered in less than ten months, with more than 12 hours of contact time over six to ten sessions were most efficacious.[47]

Finally, studies in which the content was facilitator-directed resulted in significant improvements in HbA1c, whilst the patient-directed interventions did not significantly improve HbA1c. Although again not significant between groups, these results contradict the findings from previous studies, which support the use of a patient-centred approach, showing that engaging individuals in their health care decisions can enhance their adherence to therapy.[146] Patient-directed interventions, in which participants decide on the content covered in the intervention, have been effective in improving participant knowledge, blood glucose levels, weight, and medication usage, as well as assisting the development of self-management behaviours.[99] The subgroup analysis completed to assess these differences however, was underpowered, with only four studies utilizing a patient-centred approach, compared with 43 studies utilizing a facilitator-directed approach. Furthermore, studies which compared group-based interventions to usual care were effective at improving HbA1c, whilst those which compared to waiting-list controls, individual education, usual care with written materials or group-based education prior to usual care, were not able to significantly improve HbA1c. However, this subgroup analysis did not result in a significant difference between groups, and the analysis was additionally underpowered, with 28 of the studies comparing to usual care controls, and only three to six studies comparing to each of the other control groups.

The univariable meta-regression exploring eleven study variables and intervention characteristics did not result in any statistically significant differences suggesting despite a lengthy list of characteristics and methods the heterogeneity of the studies included in the meta-analyses cannot be explained by these study variables.

The TIDieR checklist findings indicated that group-based education interventions for the management of T2DM are poorly reported and often incomplete. This incomplete reporting of interventions limits the replicability of interventions, increases inefficiencies in research, and limits clinical application. Researchers are spending time developing and piloting new interventions, rather than repeating previous interventions which have been found to be effective and health professionals are not given adequate information about the intervention to implement it. Very few of the 47 studies replicated previous interventions. Additionally, the poor reporting of interventions limits

researchers' ability to explore the differences between interventions, and the effects of intervention variables on outcomes. Possible causes of the poor reporting of interventions include restrictive journal word limits,[147] copyright issues and missing files,[148] however approximately 75% of journals have now progressed to online or hybrid publishing in which authors can publish supplementary information in linked appendices and websites.[64]

Strengths and limitations of the review

This review is a comprehensive up-to-date review of the evidence of the effectiveness of T2DM group-based interventions for improvements in HbA1c, which has not been updated in over eight years. Rather than rely on the searches and assessment completed by the previous systematic review authors, this review searched from the commencement of the records. The review identified seven studies[38, 81, 84, 88, 89, 111, 128] published prior to January 2008 which were not included in the two previous systematic reviews.[14, 47] However, a search of the grey literature in the area was not completed, which may have resulted in publication bias.

Two independent reviewers completed the risk of bias analysis, study selection screening, and checking of data extraction, reducing the potential for bias and error. Contacting the authors of studies with missing information up to three times allowed the inclusion of additional information, which was essential for the subgroup analyses, meta-regression and the evaluation of the TIDieR checklist. This is the first systematic review in the area to complete a meta-regression in order to explore the intervention variables which may contribute to the heterogeneity of the included studies. Furthermore, comprehensive subgroup analyses were completed to explore differences in study and intervention variables. The use of the TIDieR checklist provided rigour to the review and allowed the assessment of group-based intervention completeness and replicability.

The quality of the majority of studies included in the review were assessed as either moderate (31/47 studies) or high risk of bias (12/47 studies). Successfully blinding

participants and assessors to the allocation of participants for group-based education programs is extremely difficult and resulted in many studies being assessed as high risk of bias for this item. Furthermore, the impact of study size on the overall risk of bias was not considered by the reviewers. The addition of a quality assessment may have disseminated any potential bias introduced by sampling variation in smaller studies.[77]

Numerous meta-analyses resulted in high heterogeneity between studies however, this is common in allied health research, particularly in complex interventions, and was comprehensively assessed through sensitivity analyses, subgroup analyses and a univariate meta-regression. Furthermore, the two previous systematic reviews also had issues with high heterogeneity, with the Cochrane review reporting I^2 scores between 0 and 96.4%[14] and review by Steinsbekk et al reporting I^2 scores between 0 and 85.5%[47] for the meta-analyses. Additionally, a random effects model was utilized for the meta-analyses, which considers heterogeneity[77].

Despite the number of studies included in the meta-analyses and meta-regression, it was difficult to identify the intervention or study characteristics that influence the effectiveness of group-based education programs for the management of T2DM.

3.6 Conclusions

The 47 studies included in this systematic review provide evidence supporting the use of group-based education for the management of T2DM to significantly improve HbA1c, FBG, body weight, waist circumference, triglycerides, diabetes knowledge, depression scores, and physical activity levels. But the results are complex with most outcomes improving at time points proximal to the intervention but others improving at more distal time points. Additionally, the results should be interpreted with caution due to the high heterogeneity of a number of the meta-analyses, as well as assessment of the majority of the included studies as moderate or high risk of bias.

There is evidence to suggest that group-based education interventions facilitated by single disciplines, multidisciplinary teams or health professionals with peer supporters, result in improved outcomes in HbA1c when compared with peer-led interventions. Furthermore, to improve HbA1C outcomes for individuals with T2DM, characteristics of group-based interventions with greater effects appear to be those: conducted in primary care settings; facilitator directed; that provide materials to participants; have less than 10 sessions provided either in less than one month, or over seven to 12 months or 13 to 60 months; provide either 8 hours or less or over 31 hours of contact time, include less than 20 participants in each group; and include individuals with HbA1c levels greater than 7%. Subsequent systematic reviews should include subgroup analyses and meta-regression to explore the variables of group-based interventions for the management of T2DM. The lack of statistical significance in all but one of the subgroup analyses may indicate that other factors such as peer identification, normalisation, and group interactions are the 'active ingredient/s' and as such, substantially influence the effectiveness of group-based education interventions for the management of T2DM.

Regardless of these intervention characteristics if future group-based intervention studies do not design and publish their interventions using the TIDieR checklist future research in the area will be restricted. Published studies which do not adequately report the intervention details are at risk of redundancy because they cannot be used to either progress research or improve clinical outcomes. Furthermore, if both researchers and clinicians are unaware of the acceptability of these interventions by participants, there is a danger of creating effective interventions that are not acceptable to participants, and as such not feasible in practice. Future research should explore the perceptions and opinions of group participants to ensure this important intervention characteristic is not forgotten, and should investigate the influence of motivation on self-management behaviours of persons with T2DM.

Chapter 4: Feasibility Study: Intervention Development and Evaluation

Preamble

The following chapter will explore the research question: "Is a group-based education program developed to include the attributes identified as affecting success feasible and acceptable to individuals with T2DM in an authentic setting?" This chapter describes the process evaluation of a feasibility study, which included the development, facilitation, and evaluation of a patient-centred, patient-directed group-based education program for the management of T2DM. To develop the intervention, data were collected from three sources: a formative literature review and scoping of group-based interventions for T2DM management, a formative evaluation based on interviews with facilitators of a range of existing chronic disease management (CDM) group-education programs and their participants, and a review of the Medicare group services information pack, which is evidence-based, available to Australian health-professionals, and likely to influence the development of group-based education programs in practice.

The manuscript presented in this chapter, titled "Process evaluation of a patient-centred, patient-directed, group-based education program for the management of type 2 diabetes mellitus", was accepted with minor revisions by the journal *Nutrition & Dietetics* on the 23rd June 2016. The PhD candidate had a principal role in study design, data collection and analysis and wrote the manuscript. Dr Dianne Reidlinger assisted with the study design and data analysis. Prof Roger Hughes and Dr Michael Leveritt provided early assistance in the study design process. Dr Dianne Reidlinger, Prof Elisabeth Isenring and Dr Rae Thomas commented critically on the manuscript and approved it for submission. Additionally, a manuscript describing one of the formative studies, a study exploring group facilitators' perceptions of the attributes contributing to the effectiveness of group-based chronic disease self-management programs,[149] was published in the journal *Nutrition & Dietetics* in December 2015 (Appendix E). The PhD candidate had a principal role in the study design, data collection and data analysis, and wrote the manuscript. Dr Michael Leveritt, Prof Roger Hughes, and Assoc Prof Ben Desbrow assisted with the data analysis, project design and manuscript editing. Prof Elisabeth Isenring assisted with manuscript editing. All authors participated in the finalisation of the manuscript.

4.1 Abstract

Aim: This study developed and evaluated the feasibility and acceptability of a patient-centred, patient-directed, group-based education program for the management of type 2 diabetes mellitus.

Methods: Two frameworks, the MRC Framework for Developing and Evaluating Complex Interventions and the RE-AIM framework were followed. Data to develop the intervention were sourced from scoping of the literature and formative evaluation. Program evaluation comprised analysis of primary recruitment of participants through general practitioners, baseline and endpoint measures of anthropometry, four validated questionnaires, contemporaneous facilitator notes and telephone interviews with participants.

Results: A total of 16 participants enrolled in the intervention. Post intervention results were obtained from 13 participants with a mean change from baseline in weight of -0.72kg (95%CI -1.44 to -0.01), BMI of -0.25kg/m^2 (95%CI -0.49 to -0.01), and waist circumference of -1.04cm (95%CI -4.52 to 2.44). The group education program was acceptable to participants. The results suggest that recruitment through general practitioners is ineffective and alternative recruitment strategies are required.

Conclusions: This patient-centred, patient-directed, group-based intervention for the management of type 2 diabetes mellitus was both feasible and acceptable to participants. Health professionals should consider the combined use of the MRC and RE-AIM frameworks in the development of interventions to ensure a rigorous design process, and to enable the evaluation of all phases of the intervention, which will support translation to other settings. Further research with larger sample trialling additional alternative recruitment strategies, evaluating further measures of effectiveness, incorporating a control group for comparison and utilizing lengthier follow up periods is required.

4.2 Introduction

Diabetes is the fastest growing disease nationally and internationally.[63] Each year approximately 1 million Australians are diagnosed with diabetes; 85% with T2DM.[1] Patient education, the cornerstone of chronic disease self-management, is essential in achieving improved outcomes and has been acknowledged as an integral and vital component of successful T2DM care.[36, 40, 45, 46] The main goal of diabetes patient education is to promote and support positive self-management behaviours in order to optimize metabolic control, improve quality of life (QOL), prevent acute and chronic complications, and reduce morbidity and mortality.[29, 40]

Group-based education for individuals with T2DM has the potential to be more cost effective and efficient than individual education, due to the reduced time and funding required to educate numerous persons in one session.[36, 97] Group-based education allows time for the provision of more detailed information, decreases time demands on health workers, allows the easy incorporation of families and carers, and facilitates participant discussions and support from others in a similar situation.[37, 47] Research assessing the effectiveness of group-based education compared with usual care for the management of T2DM has found that the benefits in health outcomes include significant improvements in glycaemic control, fasting blood glucose (FBG), diabetes knowledge, self-management skills, self-efficacy, and treatment satisfaction, as well as significant reductions in body weight, systolic blood pressure, and the need for diabetes medication.[14, 47]

Despite the evidence supporting group-based education for the management of T2DM, it is surprisingly difficult to define the ideal content and process by which effective group-based education should be delivered.[150] Group-based education programs can be structured or unstructured, depending on the level of prescription in the content covered and the delivery. Structured programs contain lesson plans with clearly defined content, which can allow programs to be replicated by multiple group facilitators, however are more likely than unstructured programs to utilize a didactic facilitation style, reducing the time for group interactions and discussion.[149] Unstructured or patient-directed programs utilize a non-didactic facilitation style and can allow participants to explore

their own agenda, interests and needs, rather than content that may not interest or assist them in improving their self-management skills or knowledge.[99]

Within Australia, dietitians in particular overwhelmingly favour the provision of individual education services over group-based education. The utilization of group services for T2DM management provided by dietitians has continued to decrease in recent years whilst individual dietetic services have consistently increased.[151] Previous research has proposed that service system issues, workforce capacity, awareness among practitioners and practitioner attitudes and preferences are the main factors impeding the utilization of group-based education by Australian dietitians.[60] A recent study exploring group facilitators' perceptions and experiences of group-based CDM programs found that interventions were being delivered with limited quality control and that facilitators had inadequate knowledge of the evidence base underpinning the programs they were facilitating.[149] An additional surprising finding from this study was that the outcome measures being utilized by facilitators in practice were minimal, with many only collecting an overview of patient satisfaction through surveys, which as a solitary measure, is inadequate in assessing health outcomes or improving the quality of future programs.[149]

The development of a group-based intervention informed by the literature and formative research, followed by feasibility testing and a rigorous process evaluation may result in an intervention that can be easily translated into practice by health professionals interested in delivering group-based education programs and unsure where to start. Additionally, the dissemination of findings from feasibility studies could contribute to health practitioners' knowledge by furthering an understanding of the methodological and practical challenges of developing and implementing intervention studies in a 'real-world' setting, and may highlight outcome measures which are suitable for the evaluation of intervention effectiveness.[152]

The aim of this study was to develop and evaluate a patient-centred, patient-directed, group-based education program for the management of T2DM, using two process

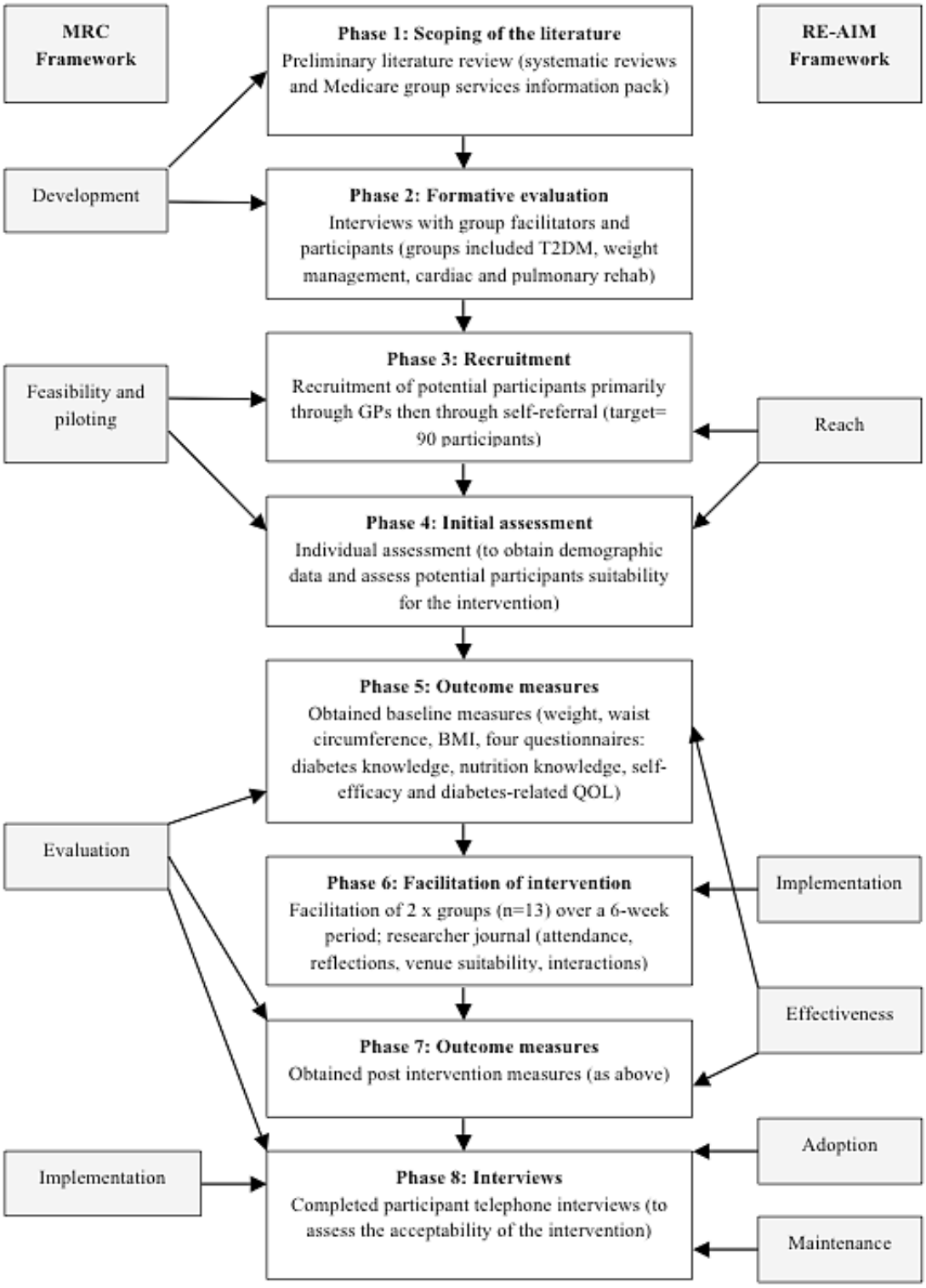
evaluation frameworks, the MRC Framework for Developing and Evaluating Complex Interventions, and the RE-AIM framework.

4.3 Methods

The development and process evaluation of the intervention using the two frameworks occurred over a number of phases (Figure 4.1). However, in brief this involved a scoping of the literature, a formative evaluation, recruitment of participants, initial assessment of participants, obtaining baseline outcome data, the facilitation of the intervention, obtaining follow up outcome data, and the completion of telephone interviews with participants to assess the acceptability of the intervention.

The Medical Research Council (MRC) Framework for Developing and Evaluating Complex Interventions (2008) was used to guide the intervention development and evaluation.[65] The framework incorporates four phases: development, feasibility and piloting, evaluation and implementation, which aim to help researchers to recognise and adopt appropriate measures for the design and evaluation of complex health behaviour change interventions.[65] The RE-AIM framework is an evaluation framework that includes multiple process indicators to evaluate various aspects of an intervention: reach, effectiveness, adoption, implementation and maintenance.[66, 67] The RE-AIM framework not only evaluates the effectiveness or strengths of an intervention, but also the program's translatability, feasibility and limitations, which can potentially be improved upon in future research.[153] Combining both the MRC and RE-AIM frameworks in the process evaluation of the intervention ensure a thorough and rigorous evaluation of all aspects of the program including development, and enables the identification of strengths and limitations.

Figure 4.1: Phases involved in the diabetes group program development and evaluation



To develop the intervention data were collected from three sources: a formative literature review and scoping of group-based interventions for T2DM management (Appendix D), a formative evaluation based on interviews with facilitators of a range of existing CDM group education programs and their participants (Appendix E), and a review of the Medicare group services information pack (Appendix F), which is evidence-based, available to Australian health-professionals, and is likely to influence the development of group-based education programs in practice.[154] Triangulation was achieved by comparing the attributes of effective group-based education interventions with the results obtained from the group facilitator and group participant interviews, and the information provided in the Medicare group services information pack.[154] Triangulation is commonly utilized in health service research as an evaluation method as it enables the integration of methods and approaches to conduct better evaluation studies.[155]

The intervention design, resulting from the systematic development process, was a patient-centred, patient-directed, group-based education program. The program content employed a non-didactic approach, group discussions were encouraged, and the content covered in the group education sessions was decided by group participants in the first session (Table 4.1). Full details of the intervention are described using the TIDieR checklist and guide (Appendix G).[64]

Table 4.1: Content covered in the group education sessions

	Group A	**Group B**
Week 1	Introduction Diagnosis	Introduction Diagnosis
Week 2	Understanding diabetes Medications	Glycaemic index and gluten free food, sugar cravings, reading food labels
Week 3	Diet (GI), hunger pains, best foods, spreads (margarines)	BGL testing and exercise
Week 4	Controlling and checking BGL's, BGL books/ diary	HbA1c, blood testing and medications
Week 5	Feeling overwhelmed and stress	Simple recipes, what to eat
Week 6	Farewell and complete questionnaires	Farewell and complete questionnaires

A recruitment target of 90 participants for the single-arm feasibility study was set. The sample size, although not necessary for a feasibility study, was determined from a practice perspective. The sample size of 90 participants was originally calculated for a two-armed study, in which each intervention group would be composed of 45 participants, allowing for at least 20% attrition, resulting in three groups of 12 participants (per intervention group). General Practitioner (GP) referrals were chosen as the primary recruitment strategy for the feasibility study, based on literature suggesting they are the 'gatekeepers' of primary care, and the initial point of contact for persons who require primary or non-emergency health care.[156] Invitation letters were mailed to all medical centres (n=132) within a 50km radius of the intervention site and each medical centre was telephoned to follow up within two weeks of postage.

Participants were included if they self-reported a diagnosis of T2DM or were referred by their GP as a person diagnosed with T2DM, were 18 years of age or over, had adequate cognitive ability, and had a sufficient understanding of English. Ethical approval was obtained from the Bond University Human Research Ethics Committee (protocol number RO1815), and written informed consent was obtained from each participant prior to the commencement of the intervention, which was provided free of charge.

The PhD candidate, an APD, conducted all of the initial consultations and intervention sessions. Participants attended an initial individual consultation to assess whether they met the inclusion criteria, and to obtain demographic and baseline data. Group-based education sessions were conducted at a local community centre to ensure easy access for group participants. The participants were allocated to one of two groups; both groups were facilitated using the same approach. Group allocation depended on participant availability and to ensure participant numbers were fewer than 12 per group to align with the Medicare CDM group service item guidelines. Groups were facilitated on a weekday morning for two hours for a six-week period.

The group intervention was evaluated using process and participant measures including questionnaires and anthropometric data to assess the feasibility of the intervention, and

semi-structured interviews with group participants to assess the acceptability of the intervention. Additionally, the group facilitator kept a researcher journal throughout the intervention to record reflections and logistics such as participant attendance, suitability of the venue, and peer interactions. The researcher journal enabled researchers to gain further insight into both the feasibility and acceptability of the intervention. For example, participant attendance or study retention and the suitability of the venue were considered as measures of feasibility, whilst peer interactions were considered a measure of acceptability.

Baseline (2-3 weeks prior to commencing the intervention) and endpoint data (taken during the final group session of the program) included weight, waist circumference and height measurements, and four validated questionnaires assessing nutrition knowledge,[157] diabetes self-efficacy,[158] diabetes knowledge[159] and diabetes-related QOL.[160] Only the first two sections (related to dietary recommendations and nutrient sources) from the nutrition knowledge questionnaire[157] were administered, due to the relevance and length of the questionnaire.

Data were assessed for normality and analysed, where appropriate, using the statistical package SPSS (Statistical package for the social sciences, version 23.0). Prior to analysis, each of the data sets was assessed for normality. Normally distributed data was analysed using paired sample t-tests to assess differences in the baseline and endpoint measures of the group participants for the five normally distributed measures. Wilcoxon-signed rank tests were performed on two measures that were not normally distributed.

The adoption, implementation and acceptability of the intervention were measured by the number of face-to-face sessions attended and by individual telephone interviews conducted by an independent research assistant following the completion of the group-based intervention. The interview questions were developed from earlier research (Appendix E).[149] The interviews were audio-recorded, transcribed, checked, anonymised and corrected against the audio files by the PhD candidate. Content was extracted from the interview transcripts by the PhD candidate and confirmed with a PhD

supervisor (DPR) in order to answer the pre-defined set of questions, which explored the acceptability of the intervention. Responses to the demographic questions were categorized and enumerated.

4.4 Results

Three sources were used to develop the intervention. The literature review indicated that patient-centred group education with the following attributes were favoured: participants' involvement in the design, planning, goal setting and decision making process, regular reinforcement after education, individualised content, and non-didactic facilitation by an individual or multidisciplinary team or peer leaders.[14, 47] These were combined with information provided to allied health professionals in the Medicare group services information pack including the need for programs to be: patient-centred, facilitated by a multidisciplinary team, developed according to a plan with achievable and measurable goals and objectives, to incorporate group rules, and to allocate time for individuals to discuss their experiences.[154] Finally, formative interviews with group facilitators and participants from existing CDM group education programs indicated: a preference for a strong focus on group interactions by providing individuals with a non-didactic, interactive, discussion-based program; the importance of group rules set at the commencement of the group-based education sessions; and goal-oriented and patient-centred content.

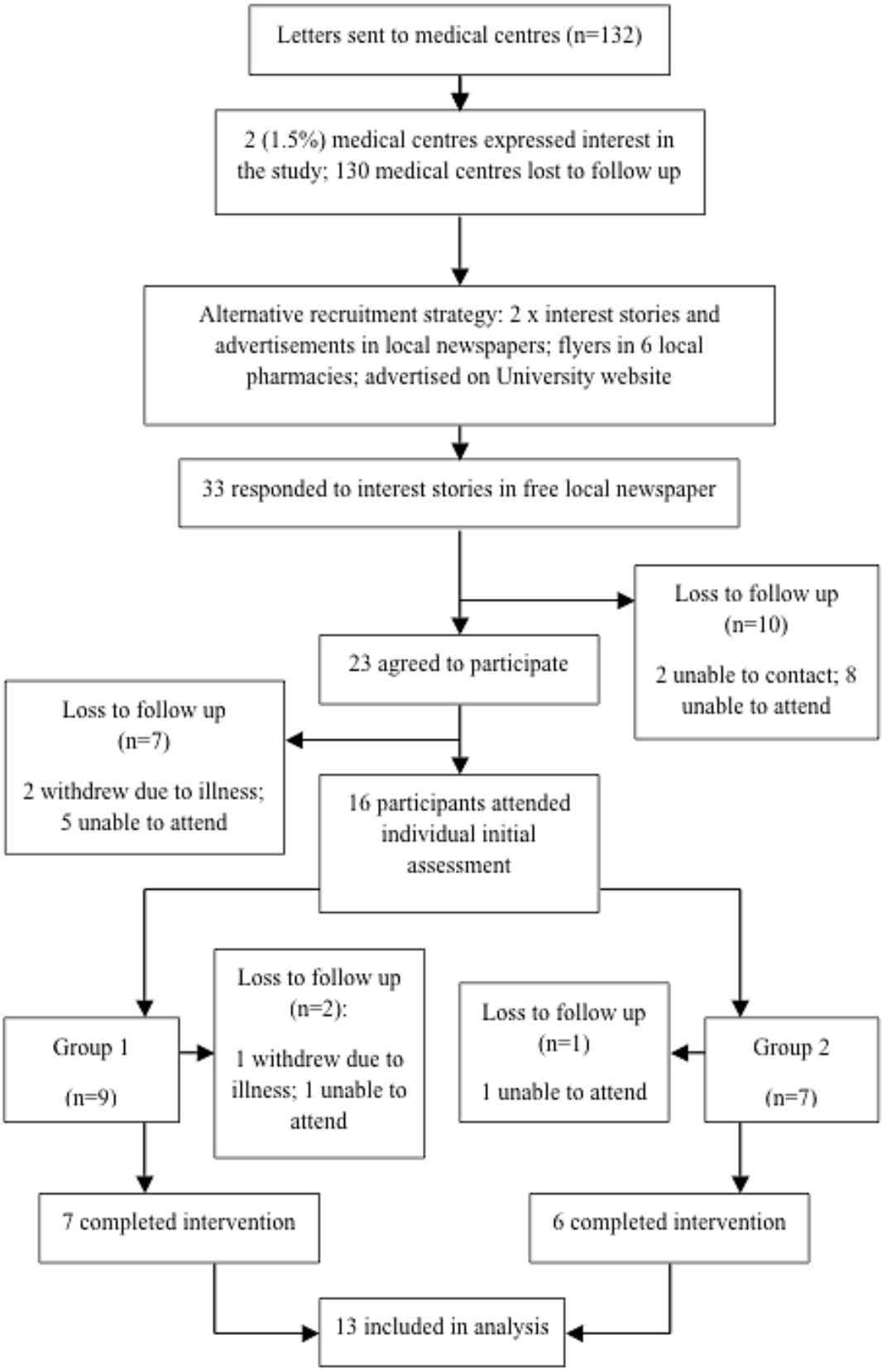
After triangulating these data, the elements used in the development of the final intervention included a non-didactic, patient-centred approach, the incorporation of group rules, and adequate time for group discussions. There was a lack of consensus on the materials or educational content ideally provided to participants of a group-based education program, suggesting that more emphasis should be placed on encouraging group interactions, rather than a sole focus on the content of sessions. There was divergence in the appropriate length and number of sessions, however two-hour sessions were chosen as the literature review and formative interviews indicated that this was an appropriate amount of time to allow group participants to have in depth discussions. Additionally, it was decided that the sessions would run for six weeks -

again to align with the findings of the literature review and formative interviews, and to ensure that the time commitment from individuals was not unreasonable.

Recruitment targets through GPs were not met: only two out of 132 (1.5%) medical centres responded to multiple requests to display recruitment flyers in waiting rooms or consultation rooms. Due to this low response rate, alternative strategies were used including advertisements and stories in two local newspapers, recruitment flyers in six local pharmacies, and an advertisement on the University website. Group participants were all recruited through feature stories in a free local newspaper.

An accurate estimation of the reach of the recruitment strategy was not possible, however it is estimated that the number of persons diagnosed with T2DM within the 50km recruitment radius would be approximately 950 persons.[161] Thirty-three (approximately 3.5% of the estimated area population with T2DM) potential participants made initial contact with the researcher of which a total of 16 participants enrolled in the study. Three participants did not complete the intervention (Figure 4.2).

Figure 4.2: Flowchart of participants for the feasibility study



Demographics of the 13 group participants who attended the program and completed the telephone interviews are presented in Table 4.2. The intervention participants were predominantly Australian; however some participants were born in Europe (United Kingdom, Croatia, France, Poland and Germany).

Table 4.2: Group participant sample attributes summary (n=13)

Attribute	N
Gender:	
Male	7
Female	6
Age:	
55-64 yrs	3
65-74 yrs	5
≥75 yrs	5
Marital Status:	
Married	8
Divorced	2
Separated	1
Widowed	2
Education:	
Primary	1
Secondary	6
Tertiary	6
Employment:	
Casual	1
Self-employed	1
Retired	11
Years since diagnosis:	
<1 yr	2
1-3 yrs	2
4- 6 yrs	4
7-9 yrs	2
≥10 yrs	3
Previous group attendance:	11

The results of the four questionnaires and anthropometric measures are shown in Table 4.3. The results suggest reductions in body weight, BMI, waist circumference, and increased diabetes knowledge, nutrition knowledge, diabetes self-efficacy, and diabetes-related QOL. However, despite two of these outcomes reaching statistical significance, the small sample size of the study was not sufficiently powered to reliably detect significant statistical differences.

Table 4.3: Change in anthropometry and questionnaire outcomes (n=13)

Paired t-tests	**Pre-intervention** Mean (SD)	**Post-intervention** Mean (SD)
Body weight (kg)	87.1 (14.88)	86.4 (14.52)*
BMI (kg/m²)	30.5 (5.3)	30.3 (5.22)*
Waist circumference (cm)	108.7 (16.29)	107.7 (17.44)
Diabetes Knowledge[(a)]	13.38 (4.13)	13.92 (4.19)
Diabetes-related QOL[(a)]	121.5 (47.42)	112.08 (46.63)
Wilcoxon-signed rank tests	**Pre-intervention** Mean (SD)	**Post-intervention** Mean rank (SD)
Nutrition Knowledge[(a)]	44.77 (11.56)	47.54 (7.83)
Diabetes Self-Efficacy[(a)]	60.6 (17.96)	67.15 (12.88)

[(a)] Improved scores post-intervention, ns

* Indicates post intervention measures were assessed as significant (P≤0.05)

The key results of the process evaluation of the intervention study are summarized in Table 4.4.

Table 4.4: Summary table of evaluation results

MRC framework for complex interventions[65]	Key Findings	RE-AIM process evaluation framework[66, 67]
Development phase	**Literature scoping**	**-**
	Two systematic reviews[14, 47]: recommendations were 5 to 16 participants per group; 8 to 52 hours of facilitator-patient contact time over 6 to 12 sessions	
	Medicare group services information pack[154]: recommendations were 2 to 12 participants per group, minimum of 8 x one hour sessions (8 hours of facilitator-patient contact time), individual assessment prior to commencement	
	Formative evaluation	
	Facilitator and participant interviews: recommendations were 5 to 25 participants per group; 10 to 24 hours of contact time over 4 sessions	
Feasibility and piloting	**Recruitment of participants**	**Reach**
	33 potential participants made initial contact with the researcher; a total of 16 participants enrolled (3 dropouts) in the study; 13 completed the study (14.4% of the initial target)	
	Initial assessment	
	100% met the inclusion criteria, were suitable to participate and provided demographic data	
Evaluation	**Baseline measures- anthropometry**	**Effectiveness**
	Mean body weight (±SD) (kg): 87.1 (14.88); Mean BMI (±SD) (kg/m^2): 30.5 (5.3); Mean waist circumference (±SD) (cm): 108.7 (16.29)	
-	**Delivery of intervention**	**Implementation**
	Participants from both groups attended 4 to 6 (67-100% attendance) sessions; those who missed sessions were unable to attend due to other medical appointments, illness or travel plans.	
Evaluation	**Follow up measures- anthropometry**	**Effectiveness**
	Mean body weight (±SD) (kg): 86.4 (14.52); Mean BMI (±SD) (kg/m^2): 30.3 (5.23); Mean waist circumference (±SD) (cm): 107.7 (17.44)	

Implementation[a]	Interviews	Adoption
	Program structure:	
	Aspects liked most: Group interactions and facilitator's relaxed attitude	
	Aspects liked least: Discussions can go off topic	
	Recommended changes: Program could have gone for longer	
	Ideal program length: 6 weeks, for 2 hours per week (as delivered)	
	Group interactions:	
	Helped/ hindered learning: Helped; Peer identification and learning from others' experiences	
	Role of group facilitator: Facilitating the group; Explaining points	
	Patient satisfaction:	
	Recommend program: Yes	

[a] The implementation phase of the MRC framework refers to aspects of maintenance more aligned with the adoption and maintenance phases of the RE-AIM framework

Telephone interviews were used to explore the acceptability of the program, participants' preferences for group program structure and facilitation, and their perceptions of the effect of group interactions. The group-based intervention was acceptable, with all group participants stating that they would recommend the program to friends or family as they found it informative, indicated they enjoyed speaking with other people who had been diagnosed with T2DM, and found the information provided interesting. Participants noted aspects they liked most were: group interactions, the facilitators' relaxed attitude, and the length of the group program. A few participants stated a preference for sessions where they perceived that discussions remained on the agreed topic. Participants frequently reported that other group members helped their learning through peer identification and from others' experiences. Participants from both groups exchanged contact details at the completion of the intervention with the intention to maintain contact beyond the program.

4.5 Discussion

This study reports on the process evaluation of a single-arm patient-centred, patient-directed, group-based education program, and this paper has described its development, feasibility testing and evaluation. Two frameworks were used to capture each phase of the development and evaluation. The triangulation of data from three sources resulted in the development of a non-didactic, patient-centred intervention, which was delivered to participants weekly for a six-week period. The results of the evaluation suggest that the intervention was feasible, and acceptable to the target group. However, the recruitment strategy was inadequate and resulted in an insufficient reach of the target population. As such, the maintenance phase of the RE-AIM framework, or the equivalent implementation phase of the MRC Framework for Developing and Evaluating Complex Interventions, could not be explored.

Group education research has established the ineffectiveness of didactic education techniques when compared to non-didactic patient education.[14, 91] Evidence supports the use of a patient-centred approach, care that is respectful of, and responsive to, individuals' preferences, needs and values, and has shown that engaging individuals in their health care decisions can enhance their adherence to therapy.[146] Within T2DM, patient-centred interventions have been effective in improving knowledge, blood glucose levels, weight, and medication usage, and have been shown to improve

self-management behaviours.[98, 99] A patient-directed approach, in which the content of the group-education program is decided by the participants, reflects participants' own needs and questions, and includes discussions initiated by individuals in the group, has been successfully utilized by various group-based education studies for the management of T2DM.[98, 114] Allowing individuals to direct their own learning through negotiated topics proposed by group members may support self-management.

A key finding and limitation of this feasibility study was the ineffectiveness of recruiting people with T2DM through GPs. The overall poor recruitment rate may have been due to the use of GPs as a primary strategy and the generally low uptake of group education programs by individuals with T2DM. Despite their principal role in the management of persons with T2DM in the primary health care setting, engaging GPs and recruiting participants through GPs was difficult. Barriers to recruitment via GPs in Australia have previously been suggested as time and workload pressures,[162, 163] negative attitudes towards research, concerns about researchers' motives, a lack of interest in the topic of research, and a lack of recognition.[164] Monetary and nonmonetary incentives, endorsement by relevant authorities, and multiple reminder contacts with clinicians may have boosted research response rates.[165] In addition, clinicians may have felt overwhelmed with requests for research participation, desired a greater involvement in the study, or been concerned about the potential lack of effectiveness of a new trial that would not be an ongoing addition to the health care system.[166]

The generally poor uptake of group-based programs for the management of T2DM may have also contributed to the reduced recruitment.[161, 167-169] A recent study found that the three main reasons for non-attendance of group-programs as reported by individuals with T2DM were the lack of information or perceived benefit of the programs, unmet personal preferences such as poor timing or accessibility of group locations, and the shame and stigma of diabetes.[170] Practitioners should consider how health professionals in primary care communicate with persons with T2DM in regards to group-education programs, the optimal timing and location of group programs, and focus on recruitment methods that minimise any health-related stigma around T2DM.[170]

The evaluation found modest improvements in body weight, BMI and waist circumference as well as the quality of life domains, nutrition knowledge, diabetes knowledge and self-efficacy measures.

Despite the improvements in these measures, the results should not be overstated due to the small sample size, short follow-up period and natural fluctuations in weight, BMI and waist circumference which may have occurred over the same time period. Feasibility study results should in general be interpreted cautiously, as effects may be smaller or more variable when a full-scale study is conducted.[65] The effectiveness of feasibility studies should primarily be measured using descriptive statistics, qualitative analysis and basic process evaluation data such as administrative data.[171]

The participant evaluation component of this feasibility study, through interviews with each participant, provided insightful and valuable data from which various conclusions can be drawn. These included satisfaction with the intervention, willingness of participants to recommend the intervention, and the positive evaluations of group interactions. Patient satisfaction has been shown to be clinically relevant, with satisfied individuals being more likely to comply with treatment and to self-manage their condition.[172] The majority of group participants found other group members added to their learning, generally through peer identification and learning from others' experiences. Providing social support to persons with T2DM has been shown to extensively affect behaviour.[173] In particular, group interactions and peer identification may promote self-efficacy, self-esteem, self-perception, awareness, and positive attitudes towards T2DM and reduce disease-related anxiety.[49, 173] The group interactions and discussions encouraged in this study are likely to have had a positive impact on the acceptability and effectiveness of the intervention.

Conducting a feasibility study, which trials components of a randomized controlled trial (RCT), as opposed to a pilot study which trials the operation of all aspects of the developed RCT, allows researchers to assess the design, methodology and feasibility of a larger pilot study, and to identify and prepare for the challenges of evaluating an intervention.[152, 171] Intervention studies are commonly plagued with problems of acceptability, compliance, delivery of the intervention, recruitment and retention, and smaller than expected effect sizes, which could have been predicted, and potentially avoided, through feasibility testing and piloting.[65] Feasibility testing an intervention prior to completing a pilot study additionally allows researchers to assess the acceptability of an intervention and enhances the scientific rigour of the larger study.[152]

Strengths and Limitations

There were a number of strengths of the study. The utilization of two complementary development and process evaluation frameworks enabled a comprehensive evaluation of all aspects of the program, and may provide a useful guide for the development of interventions in future. The intervention was developed based on a scoping of the literature as well as interviews with facilitators and participants from a range of chronic disease management groups (including T2DM, weight management, cardiac and pulmonary rehabilitation), which ensured that elements of good practice common to other chronic diseases were incorporated. The developed intervention reflects facilitator-patient contact time that is suitable for Australian health professionals planning to facilitate group-based education programs through the Medicare CDM group service rebates. The implementation of the intervention in a real-world setting enabled the researchers to explore the feasibility of the program in the context in which diabetes is usually managed. The inclusion of interviews to assess the acceptability of the intervention from the perspective of group participants, and the inclusion of participants from a range of backgrounds and with a range of years since diagnosis, ensured participant evaluation was robust.

There were also several limitations. Recruitment utilizing GPs as a primary recruitment strategy was unsuccessful; however this resulted in key learnings, which may be applied when translating the program to practice. Recruitment to future interventions may be improved through the additional use of specialist clinics, such as diabetes outpatient clinics, which utilize electronic health records enabling the identification and monitoring of participants,[161] involving participants in trial design,[174] using shorter and more informative recruitment flyers,[175] and providing monetary incentives to participants.[176] The potential for sampling bias cannot be ruled out - the sample characteristics of the group participants were dissimilar to the characteristics of participants in the AusDiab study.[177]

4.6 Conclusions

This process evaluation indicated that a patient-centred, patient-directed, group-based intervention for the management of T2DM was both feasible and acceptable to participants. All elements except for participant recruitment through GPs were considered feasible. Additionally, a number of factors were identified as requiring refinement prior to the facilitation of a pilot study, particularly in regards to recruitment issues. Health professionals should consider the use of the RE-AIM and MRC frameworks in the development of group-based interventions to ensure a thorough and complete design, and evaluation of all phases of the intervention. Furthermore, describing an intervention using the TIDieR checklist and guide can improve the completeness of intervention reporting and enable replicability.[64] Further research trialling additional alternative recruitment strategies, evaluating further measures of effectiveness, and utilizing lengthier follow up periods is required.

Chapter 5: Qualitative Analysis of Interview Data

Preamble

Chapter 5 presents a qualitative analysis of interview data obtained from the telephone interviews conducted in the feasibility study (Chapter 4).

The manuscript presented in this chapter titled "Group Participants' Experiences of a Patient-Directed Group-Based Education Program for the Management of Type 2 Diabetes Mellitus" was submitted to *The Diabetes Educator* on the 30th July 2016 and is currently undergoing peer review. The PhD candidate had a principal role in study design, data collection and analysis and wrote the manuscript. Dr Dianne Reidlinger assisted with the study design and data analysis. Dr Dianne Reidlinger, Prof Elisabeth Isenring and Dr Rae Thomas commented critically on the manuscript and approved it for submission.

5.1 Abstract

Purpose: The purpose of this study is to explore the experiences of individuals who participated in a group-based education program, including their motivators in relation to their diabetes management, and the perceived impact of group interactions on participants' experiences and motivation for self-management. Understanding patients' experiences of group-based education for the management of type 2 diabetes mellitus may guide the development and facilitation of these programs.

Methods: Semi-structured interviews were conducted with all individuals who participated in the intervention. Using thematic analysis underpinned by self-determination theory, we developed themes that explored participants' motivators in relation to diabetes management and the impact of group interactions on their experiences and motivation.

Results: The key themes included knowledge, experience, group interactions and motivation. Participants perceived that the group interactions facilitated further learning and increased motivation, achieved through normalisation, peer identification or by talking with, and learning from the experience of others.

Conclusions: The results support the use of patient-centred programs that prioritise group interactions over the didactic presentation of content, which may address relevant psychological needs of type 2 diabetes mellitus patients, and improve patient motivation and health behaviours. Future group-based education programs may benefit from the use of SDT as a framework for intervention design to enhance participant motivation.

5.2 Introduction

People with chronic diseases face many obstacles, including having to rely on a medical system largely designed for acute illness.[178] Chronic diseases pose distinctive challenges to our health care system, with sufferers requiring frequent, ongoing access to health services and medications, and often developing complex multi-morbidities.[179] For the most part, chronic disease patients generally manage their own condition, making up to 99% of their health-related decisions without input from formal health services.[35]

Patient education is the basis of effective chronic disease self-management and is essential to achieving improved outcomes for chronic disease patients.[36, 46] The goals of type 2 diabetes mellitus (T2DM) self-management education are to prevent complications, optimise quality of life and metabolic control, and reduce or prevent reliance on health care systems.[29] Research has shown that diabetes education leads to a range of outcomes including increased knowledge and understanding of diabetes, better self-management, heightened self-determination, enhanced psychological adjustment, and improved clinical outcomes.[180]

Group-based education programs offer many potential advantages over individual education. Group programs allow time for the provision of more detailed information, decrease time demands on health workers' schedules, allow incorporation of families and carers into the education process, facilitate patient discussions and provide support from others facing similar challenges.[37] The benefits of group-based education for the management of T2DM, when compared with individual care alone, include significant benefits for clinical, lifestyle and psychosocial factors potentially substantially improving the outcomes of patients with T2DM.[14, 47] Additionally, research has shown that providing education in a group format rather than individually allows participants to explore their attitudes, and analyse their motives for current behaviours, potentially motivating them to improve their self-management skills and behaviours.[181] Group-based education programs therefore, may be more effective than individual education in empowering and motivating patients to take responsibility for managing their condition.[181]

Self-determination theory (SDT) is a theoretical framework explaining the motivational dynamics affecting health behaviours.[8] It proposes that humans have three innate psychological needs that are the basis for their self-motivation and personality integration, and are essential for ongoing psychological growth, integrity and wellbeing: competence; relatedness; and autonomy. According to SDT, competence is feeling effective and exercising one's capacities; relatedness is feeling respected, understood and cared for by others; and autonomy is the perception of being in charge of one's own behaviour.[8, 9] Meeting these three needs may help to motivate the initiation and long term maintenance of health-promoting behaviours.[8, 182] Unlike other theoretical frameworks, which focus on the quantity of motivation, SDT is more concerned with the type of motivation.[8] The use of SDT as a conceptual framework to study motivational processes has been supported by a recent systematic review.[9]

According to SDT, an individual's motivation and behavioural regulation, or ability to act in accordance with their values, can be categorised as either 'autonomous self-regulation', 'controlled regulation', or 'amotivation'.[8, 9] 'Autonomous' motivation is intrinsic and is based on the reflected endorsement in which people perceive that their behaviour emanates from themselves and find personal meaning from their behavioural consequences.[8, 9] In contrast, 'controlled' motivation is introjected and is externally regulated by pressure to meet demands or obtain rewards,[8, 9] while 'amotivation' refers to a state of lacking any intention to act.[8, 9] The more autonomously motivated individuals are, the more adaptive their behaviour potentially resulting in improvements in health outcomes.[9, 183]

To understand individuals' experiences of group-based education for the management of T2DM, and to guide the development and facilitation of these programs in the future, this research aimed to explore the experiences of individuals who participated in a group-based education program.

The theoretical framework of SDT was used to explore two research questions:

1. What are group participants' motivators in relation to their diabetes management?
2. What impact do participants perceive that group interactions have on their experiences and motivation for self-management?

5.3 Methods

We used qualitative data obtained from semi-structured interviews with the participants of a group-based education program for the management of T2DM to explore their experiences of the program. The intervention is described in detail in Chapter 4. Briefly, the intervention was a patient-centred, patient-directed, group-based education program for the management of T2DM. The intervention was developed using data from a preliminary literature review, a formative evaluation of interviews with the facilitators and participants from a range of chronic disease management group education programs, and a review of the Medicare group services information pack available to Australian health professionals.[68, 149] The program was evaluated using both quantitative measures to assess the effectiveness of the intervention, and qualitative interviews to assess the acceptability of the intervention. The intervention resulted in modest improvements in quantitative outcomes, and was acceptable to participants. After program completion, telephone interviews were conducted with participants by a researcher independent to the program.

Previous content analysis of the interview data formed a process evaluation, which allowed the researchers to explore group participants' preferences for group program structure and facilitation, their satisfaction with the program and their outcomes. The current study was a secondary analysis of the interview transcripts, which allowed the researchers to obtain a deeper understanding of group participants' experiences, motivators, and the effect of the group interactions on their motivation to self-manage their T2DM through the lens of SDT. Secondary analysis of qualitative data explores research questions different from those asked in the primary data analysis. This enables researchers to disentangle data from earlier perspectives and permit new findings to emerge.[184] In this way, secondary analysis can utilize descriptively rich qualitative data sets potentially leading to a deeper understanding of the data.[184]

Data Collection

Ethics approval was obtained from the Bond University Human Research Ethics Committee (protocol number RO1815) and verbal and written consent was obtained from the participants prior to the commencement of the intervention. Additionally, participants provided verbal consent prior to the commencement of the telephone interviews. Thirteen intervention participants agreed to take

part in the telephone interviews, which represented the entire sample of intervention participants who attended the six-week program.

Interview questions (Table 5.1) were developed prior to intervention commencement and were based on a previously developed interview schedule, which focused on participants from a range of chronic disease management programs. The questions were further refined and piloted prior to intervention recruitment. The interviews were conducted by a dietitian external to the study with previous semi-structured interview experience. Prior to data collection, two pilot telephone interviews were undertaken within the research team. The interviews were audio-recorded, transcribed verbatim, checked, anonymised and corrected against the audio files by the PhD candidate (KOJ). No incentives were provided to group participants to take part in the intervention or telephone interviews.

*Table 5.1: Interview Schedule and Inquiry Logic for Semi-Structured Interviews**

Objective:	Question:	Prompts:
To explore patients' motivation and reasons for attending the program	Why did you get involved in the program?	What was it about the program that attracted you to get involved?
To identify patient preferences for group program structure (number of contact hours, facilitator/s)	Can you describe what you liked most about the program?	Was there anything specific that you particularly enjoyed?
	Can you describe what you liked least about the program?	Would you change anything about the program?
	What do you think the ideal program length would be (i.e. number of weeks, number of hours per week)?	Did you feel that six weeks was a good length, or would you like the program to be longer or shorter?
To identify the effect of the group environment on the individuals learning and impression of support	Please describe how the other patients in the group helped or hindered your learning?	Did it help you at all to know that others in the group were in the same situation as you?
	How do you feel the group has contributed to any changes that you have made?	How did others in the group help you to make the changes you have made?
	What was the role of the group facilitator in your discussions within the group?	How did the group facilitator educate the group?
To identify patient outcomes (confidence, self-efficacy, lifestyle changes, attitudes, health and knowledge of T2DM)	Has your knowledge of type 2 diabetes changed since you started the program? How?	In terms of your knowledge, what kind of things do you feel you have learnt?
	How has your diet or exercise changed since you started the program?	Is your diet the same as before you started the program? What has changed?
	How has your blood glucose testing changed since starting the program?	How often were you testing before starting the program? How often do you test now?
	How have your diabetes control and your confidence in managing your diabetes changed since starting the program?	How do you feel you are managing your diabetes since starting the program?
	How have your health and attitudes changed since you started the program?	How is your attitude towards diabetes different since starting the program?
To explore patient satisfaction with the program.	Would you recommend this program to your friends?	Why or why not?

* In line with the semi-structured nature, interview questions and prompts were used as a guide and may have slightly differed between participants.

The themes were analysed using a hybrid deductive and inductive thematic analysis approach based on the pre-selected SDT.[185, 186] An inductive approach directly draws codes, categories, or themes from the data, whilst a deductive approach uses preconceived codes or categories derived from relevant theory, research, or literature.[187, 188] The deductive analysis allowed the use of a predetermined theory to enable an in depth exploration in line with a previously described social phenomenology, whilst the inductive analysis allowed themes to emerge directly from the data.[186]

Specifically, analysis involved the PhD candidate and one supervisor (DPR) completing an initial thematic analysis using an iterative approach including independent analysis followed by frequent discussions until agreement was reached on a final set of codes. The same two researchers (KOJ & DPR) then identified preliminary themes and subthemes. Themes and subthemes were then mapped to the three key needs described in the SDT framework as overarching categories (Competence, Relatedness and Autonomy).[185]

The PhD candidate wrote a summary of the themes and subthemes and identified illustrative quotations. A conceptual map was developed to illustrate the categories, themes and subthemes and their inter-relationships, which was discussed with the PhD supervisor (DPR) to ensure integrity in the final presentation of results. The quotes presented in the results illustrate and exemplify the themes described.

5.4 Results

The characteristics of the participants are presented in Table 5.2. The majority of participants were retired, aged 65 years or older, educated to a secondary school level, married, diagnosed 4 to 6 years ago and had never attended another group education program. Just over half of the participants were male. The intervention participants were predominantly Australian; however some participants were born overseas.

Table 5.2: Characteristics of Participant Sample

Attribute		N= 13
Gender:	Male	7
	Female	6
Age:	55-64 yrs	3
	65-74 yrs	5
	≥75 yrs	5
Marital Status:	Married	8
	Divorced	2
	Separated	1
	Widowed	2
Education level:	Primary	1
	Secondary	6
	Certificate	1
	Diploma	3
	Bachelor	2
Employment status:	Temporary	1
	Self-employed	1
	Retired	11
Years since diagnosis:	≤1 yr	2
	1-3 yrs	2
	4- 6 yrs	4
	7-9 yrs	2
	≥10 yrs	3
Previous group attendance:	No	11
	Yes	2

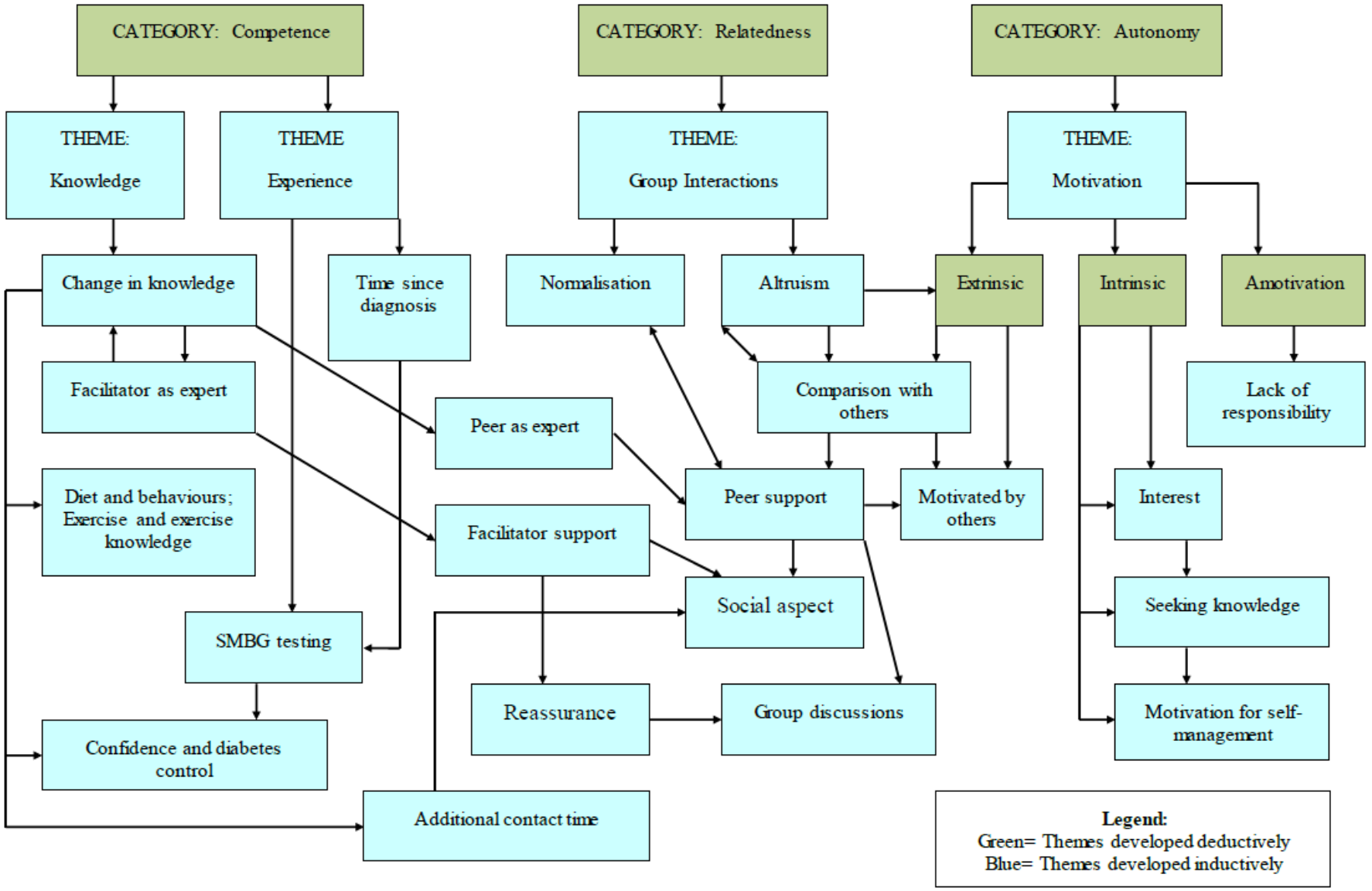
The three needs proposed by SDT - competence, relatedness and autonomy - were used as the overarching categories in this analysis. Additionally, themes and subthemes identified during the process of data analysis reflected the breadth and depth of the concepts brought forward in the interviews (Table 5.3).

Table 5.3: Summary of SDT categories, themes and subthemes developed from the secondary analysis of telephone interview data

Category	Theme	Subtheme
A. Competence	A1: Knowledge	A1-1 Change in knowledge
		A1-2 Facilitator as expert
		A1-3 Diet and behaviours; exercise and exercise knowledge
		A1-4 Confidence and diabetes control
	A2: Experience	A2-1 Time since diagnosis
		A2-2 Peer as expert
		A2-3 Self-monitoring of blood glucose testing improved
B. Relatedness	B1: Group Interactions	B1-1 Normalisation
		B1-2 Altruism
		B1-3 Facilitator support
		B1-4 Comparison with others
		B1-5 Peer support
		B1-6 Social aspect
		B1-7 Reassurance
		B1-8 Group discussions
		B1-9 Additional contact time
C. Autonomy	C1: Motivation	C1-1 Extrinsic
		C1-1-1 Motivated by others
		C2-1 Intrinsic
		C2-1-1 Interest
		C2-1-2 Seeking knowledge
		C2-1-3 Motivation for self-management
		C3-1 Amotivation
		C3-1-1 Lack of responsibility

Themes and subthemes are presented in a conceptual map (Figure 5.1). During the analysis, the researchers perceived these themes and subthemes to often be linked and inter-related, and these interrelationships are represented with arrows in Figure 5.1. Thematic inter-relatedness suggests that enhancing one aspect of an individual's self-determination may enhance other aspects, such as their motivation.

Figure 5.1: Conceptual map of themes developed related to group participants' experiences of the intervention



SDT: Competence

Competence was organized into two themes, Knowledge and Experience. The desire to gain or improve knowledge was a clear motivator for all participants, and appeared the prime motivator to attend the group-based education program.

> *Basically, because I have diabetes, and if I can learn something more about it, or about what I can do for myself, then I've gained.* [Participant 12]

Within this theme, participants spoke of their change in knowledge related to T2DM due to the intervention, with only one of the participants stating that his knowledge remained unchanged. Increased knowledge was described in three main areas, diet, exercise, and self-monitoring of blood glucose (SMBG).

> *You know, I learnt a bit about myself, it's a good reminder of everything, what you should do, what you shouldn't do, what to eat, what not to eat.* [Participant 3]

> *My exercise. That was one of the main things I got from the program actually. Exercise makes such a big difference and … I'm more aware about keeping up the exercise.* [Participant 11]

Improvements in knowledge were generally attributed to either the group facilitators' knowledge, or the knowledge of other participants. Participants perceived to place great value on experiential knowledge.

> *A couple of people were knowledgeable, where they'd been doing it for a very long time, … a lot of it was probably old hat to them, and you know when you've been doing it more than ten years or longer… when someone raised a question, they were able to speak with experience and say well I've had that, I've been doing this for years and years, and this is the best way. There are certain things that [the group facilitator] wouldn't have known probably.* [Participant 9]

Participants described identifying more experienced peers and respecting their opinions and knowledge over others in the group. Participants commonly associated time since diagnosis and experience of T2DM with increased knowledge and self-management skills. At times, participants reported being surprised that experienced participants

lacked knowledge and self-management skills, as they assumed that time since diagnosis was associated with improvements in these areas.

> *But I think that one particular fellow helped, I learnt more I would say off him than I did any of the others around me…. Some of them actually surprised me that, you know like one of the fellows there had been diabetic for a while, and knew next to nothing, I don't think he even knew how to handle his needle properly.* [Participant 11]

A majority of participants claimed to have made changes in their behaviours as a result of the knowledge gained from the group-based intervention, including changes in diet, exercise, SMBG testing, diabetes control and confidence.

> *I am trying to eat healthy, trying to not have too much carbohydrate, and certainly try and cut down on the sugars wherever possible. I'm on a stationary bike, which I'm working on getting more and more on, but it's very hard to get into exercise. I didn't test before the program. I am testing now. I take one first thing in the morning, and then I try and take one two hours after breakfast.* [Participant 4]

The only participant who did not report any physical changes in his behaviours was the most experienced participant. However, he did report being more aware of his diet, exercise and diabetes management.

> *I've really kept on, really just how I have been before actually going on the program, and I think like anything it just makes you more aware.* [Participant 10]

SDT: Relatedness

Relatedness captured participants' experience of group-based education. There was one key theme, Group Interactions. This theme encompassed various subthemes including normalisation, altruism, facilitator support, comparison with others, peer support, social aspects, reassurance, and group discussions. These were often interrelated, and included interactions between other group participants, and with the group facilitator.

A key subtheme, normalisation, captured participants' realisation that other participants had situations similar to their own.

> *So it was an environment among people who all probably had similar experiences, and that was quite good. I didn't feel, like for example, should you tell other people who are non-diabetic or don't know about it, they just think, oh yeah, have a look at other people, you look healthy, what's wrong with you, you are a whinger, you know that is really the problem… you don't want to go somewhere and say oh no I am a diabetic and I feel so bad.* [Participant 8]

Some of the male participants, who had been diagnosed for a number of years, noted that they had never spoken to anyone about their diabetes before coming to the group, but felt comfortable to share their thoughts, concerns and questions within the program.

> *The main thing was I listened to others. I hadn't spoken to anyone else really with it, since I got it, to know how other people think.* [Participant 9]

Normalisation was closely linked to another subtheme, comparison with others. All of the participants described comparing themselves to others in the group, whether negatively or positively. Comparing themselves to others tended to either motivate them to improve or reassure them that they were doing well. Reassurance was also related to Competence. When comparing to those seen as 'doing better' than themselves, participants were either motivated to improve or looked up to these peers as experts. In contrast, when comparing to those seen as 'doing worse' than themselves, participants felt reassured, appeared more confident, or were concerned and wanted to help those they perceived were faring worse. Some participants noted that they were able to obtain some perspective by seeing others who seemed to not be coping, whilst some considered themselves to be different from others because of the specifics of their situation (e.g. one unmedicated participant stated that she was different as she was diet-controlled).

> *Well I think some of them were just, I could have been one of them, but are totally out of it, they have no idea about diet,… in fact I'm terribly worried about one or two of them, I'm sure they didn't even do what I was hoping they'd do. I think it helped because I was not alone as being a total idiot.* [Participant 2]

I feel I'm doing alright, because some people there when I listen to them, were having trouble with certain aspects of trying to diet and getting the right foods and that. [Participant 9]

Peer support was also important to participants. Most participants noted that their peers in the group had provided support to them in various ways. They attributed this to other group members listening to their stories or questions, sharing personal information, having group discussions, and relating with them on a social level.

So it was all fairly simple, and very relaxed, because everybody could talk, everybody could say their thing, and everybody's input to me was important. [Participant 7]

Facilitator support also appeared to motivate some participants. For example, the facilitator taking interest in them in various ways, such as making them feel welcome and comfortable, listening to their stories, answering their questions, demonstrating respect, being open and friendly, and including them in discussions.

[The facilitator] was just a delight, the way she ran it, the way she handled it, made it very easy to want to go back to the next week, you know rather than saying this is a bit of a bore I'll give it a miss… We realised she was making a super effort… and it made it worthwhile to go. I think facilitating the comments of people, making people feel comfortable to discuss anything that they are having a problem with… she was the oil in the whole thing she made it happen quite effortlessly. [Participant 1]

The majority of the participants reported enjoying the social aspect of the group-based intervention, possibly because most of the participants were retired and may have lacked regular social interaction.

Well, I found going there every Thursday, it was great, it was good companionship… the people were happy, I was looking forward to going, it was something to do, you know, of a Thursday, and I sort of missed it for a couple of Thursdays but it's okay now. [Participant 7]

Providing participants with morning tea in each session allowed them to move around the room and have conversations with others in the group, encouraging the social aspect of the program.

> *[The facilitator] is excellent in the fact that she was good how she got the whole group going, you know like she brought a morning tea and the people sat down and have a cup of tea.* [Participant 11]

Some participants reported being reassured during the group-based intervention, mainly from the facilitator, however, at times by peers or by comparison with others.

> *I was aware that I had to do some exercise, so I was already in progress of doing the exercise. So, but it, you know, it just rubber-stamps it that that's what I've got to continue doing.* [Participant 1]

A subtheme related to both Competence and Relatedness was additional contact time. Some participants mentioned that they would have liked the program to go for longer, whilst others were happy with the amount of contact time. Those wanting the program to be extended generally felt that more contact time would allow more time for group discussions and socialising, and believed that this may improve competence.

> *I could have found other things that could have been talked about. Ah, you could probably say maybe 10 [sessions], depending on the sort of period of time, and of course it depends on people's circumstances, what they've got to do.* [Participant 10]

Some participants did realise that others had commitments outside of the program, and that increasing the contact time may make participants less likely to commit to lengthy group programs.

> *I personally would have liked it longer, but other, but I'm retired so I'm one of those that probably hoped it would go all day and all night.* [Participant 9]

An interesting subtheme that emerged was that of altruism (helping others). Many participants reported an altruistic motivation to participate in the program, however some appeared to want to participate in the program in order to improve their own self-esteem.

Now see you're putting me in a spot where I sound big headed… I would feel that the thing we were able to discuss around the table, that I helped people in the group because of my history and what I've done and what I'm still doing, has helped make some of the people in that room a bit more aware of what they should be doing as well. [Participant 10]

I thought… someone's calling for volunteer type things to do with diabetes and I read it,…. and then I thought about it, … and I thought well I should ring and just see if I'm the type of person they're looking for. [Participant 9]

The majority of the participants who discussed helping others were referring to other people with T2DM, however one participant referred to helping his children should they be diagnosed down the track.

Also if say, my sons down the line get diabetes, the information that is gained from it, may help them. [Participant 12]

SDT: Autonomy

In relation to an individual's perceived ability to self-manage their condition the key theme was Motivation. Some participants described various motivators, categorized as either extrinsic or intrinsic. Other participants were categorized as 'amotivated' in accordance with the predetermined SDT category, as they were perceived to lack the intention to self-manage their condition.

Extrinsic factors that motivated participants to learn about and improve their diabetes self-management included comparison with and motivation from others. These were often linked. For example, participants who compared themselves with others and felt that others were better managed than themselves seemed motivated to improve their own management.

I've changed my exercise habits a bit and I'm doing more walking than swimming because I used to get tired easier walking and I heard from some other people how far they walk and I'd shudder because I wasn't doing what some people older than me were doing and there was other people that couldn't walk because they had a physical impairment of one thing or another and I

realised how lazy I was because I don't really have any major impairments to stop me doing anything. [Participant 9]

It was motivating actually, really motivating, because it made me realise that if he's on injections and he keeps as well as he does, and he wasn't real young… and as fit as what he is, it most certainly was motivating that you can you know do that yourself. [Participant 11]

Most of the participants described intrinsic motivators to attend the intervention including being motivated out of interest, knowledge seeking or an internal desire to improve their self-management. Those participants motivated by knowledge seeking or interest usually had some knowledge but felt they needed a refresher, or had minimal knowledge and were not coping well with their diabetes.

Because I would like to go ahead and… keep my health problems under control as I did so far for the past seven years actually. And I did that mainly, well I tried to at least, mainly with diet, my exercise approach is not too successful, I could do much more there, but I think it's a good fresh up. [Participant 8]

A few newly diagnosed participants' interview responses indicated 'amotivation' or described what seemed to be a lack of intention to act or change their self-management behaviours. Some described rationalisations such as sugar cravings, the weather affecting their ability to exercise, looking for miracle cures, unfounded views and a false sense of security.

Well, it made me more aware of what I was eating, which was wrong, so you know I knew I had to do something, and still very hard for me to curb my sugar cravings. I've realised that I could change things dramatically, but you know, I'm always tempted to have a chocolate or cake, those sorts of things. [Participant 6]

To be quite truthful, I still don't think about my diet, I have to pull myself up, you know like… I went for morning tea the other day,… I sat down, I had… sandwiches I had cakes, you name it, and then said to the girl I was with, I'm going to have problems tonight, it's going to be my own fault, and I wasn't even thinking the sugar. [Participant 11]

5.5 Discussion

Using SDT as an analytic framework, qualitative telephone interviews of participants in a T2DM group-based program enabled the exploration of participants' experiences of the program, their motivators in relation to their diabetes management, and the impact of group interactions on their experiences. Three categories (Competence, Relatedness and Autonomy) encompassed the developed themes of Knowledge, Experience, Group Interactions and Motivation.

Knowledge and Experience were two subthemes of Competence. Similar to previous research (where group participants valued the opportunity to gain additional knowledge and report improvements in knowledge),[43] participants highlighted knowledge seeking as a motivator for attending the program. Participants additionally expressed a desire to gain knowledge and improve competence from the intervention to improve their self-management activities, such as meal planning, medication administration, regular physical activity, and home glucose monitoring.[37] Adopting self-management skills is necessary to enable people with T2DM to effectively manage their diabetes,[13] and successful self-management requires sufficient knowledge of the condition and its treatment.[39] Participant self-report suggests that the intervention was successful in improving knowledge and consequently competence, with participants reporting various behaviour changes such as improvements in diet, exercise and exercise knowledge, and SMBG.

Participants attributed their improvements in knowledge to both the facilitator and peers. Peers in a group situation can offer knowledge, practical skills, personal competence, emotional support, and provide encouragement beyond the capacity of many health professionals.[189] Furthermore, participants considered that peers who had been diagnosed for longer than them as more knowledgeable. This insight suggests that it may be helpful to include more experienced peers in group-based education programs to improve the knowledge and competence of newly diagnosed T2DM patients. The WHO has recognized peer-support programs as a valuable and promising approach to diabetes education and management.[37] Previous research has identified the important

role of the facilitator in setting the tone and guiding the direction of groups, which may significantly influence the participant outcomes.[190]

Feelings of relatedness (feeling understood, respected and cared for by others)[8, 9] was experienced through group interactions. Participants expressed that others in the group positively influenced them to learn and achieve changes in various areas of their diabetes management via peer identification, learning from other's experiences, and feeling inspired by role models or motivated by those who were experiencing complications that they wanted to avoid. Group interactions and peer identification have been shown to improve patients' self-esteem, self-perception and self-efficacy, and to promote awareness, empowerment, and positive attitudes towards diabetes.[49] Social support provided by strangers, has been linked to improvements in self-management, psychological functioning and biomedical outcomes,[191] and identified as a clinically relevant factor on the pathway to glycaemic control in T2DM patients.[192] Utilizing a patient-directed approach, in which the content of the program is decided by the participants, therefore reflecting participants' own needs and questions, may encourage group discussions and group interactions. Previous research has indicated that when utilizing a patient-directed approach, participants pay close attention to the information provided, were motivated to make the changes they selected, attrition may have been improved, and participants were able to discuss their experiences, concerns and questions which resulted in lively and relevant sessions.[193]

Autonomy as it relates to SDT, explored the motivators of group participants and interview data were themed to align with extrinsic motivation, intrinsic motivation or 'amotivation'. Extrinsic (external) motivators identified in the data included being motivated by others or motivated by comparing oneself with others. Intrinsic (internal) motivators identified included being motivated by interest, knowledge seeking, or an internal desire to improve self-management behaviours. Intrinsically motivated individuals are more likely to experience improved behaviours and health outcomes.[8] These participants could be considered empowered. Empowerment is a concept used to describe individuals' acceptance of responsibility to manage their own condition and solve their own problems using information, rather than directives, from health professionals.[143] Patient empowerment literature views internal motivation as a more effective motivator for lifestyle change than external motivation, as at times patients are

externally motivated to make changes only to please their health professional, not usually resulting in long term change.[143]

'Amotivation' refers to the state of lacking any intention to act.[8, 9] A few newly diagnosed participants' interview responses indicated 'amotivation' or a perceived lack of intention to act in order to improve their health and self-management. Other research has also reported that some individuals newly diagnosed with T2DM lack the intention to manage their condition,[43, 194] and tend to only take ownership of their diabetes and seek out more specific or detailed information once they have reached a degree of acceptance of their disease.[195] When receiving a diagnosis of diabetes, patients are faced with new challenges and behaviours that are unknown and therefore they may lack the perception of competence or the feeling of being effective in their own management.[9]

Strengths and Limitations

Qualitative interviews were an ideal method to explore patients' experiences and perspectives of the intervention. Qualitative methods can provide rich and diverse data that are not obtainable through quantitative means.[196] Additionally, research has shown that obtaining patients' perspectives on group-based education can reflect patients' real-life experiences and potentially result in data rich in human experience.[181]

Data trustworthiness was achieved by independent analyses of the data by the PhD candidate and one PhD supervisor (KOJ & DPR). Themes and subthemes were discussed until agreement was reached ensuring that the analysis was credible, and that no common themes or subthemes were missed.

Semi-structured interviews, primarily constructed of open-ended questions and probes, allowed group participants to provide in-depth information, which may have been missed using other research methods. However, the use of semi-structured interviews may have influenced participants' responses by prompting them to talk about topics that they may not have discussed otherwise. The interviews were conducted by a third party rather than the group facilitator in order to reduce the potential impacts of a perceived power differential and participants' potential reservations to be honest and

comprehensive in their responses, particularly in relation to the group facilitator.

An additional strength of the study was the inclusion of patients from a range of backgrounds with variations in the years since diagnosis. All intervention participants agreed to take part in the telephone interviews, reducing any potential sampling bias, however the sample size was small due to recruitment difficulties. Although all participants were represented, the limited sample size makes it difficult to ascertain whether theoretical saturation was achieved. Research has shown that theoretical saturation is obtainable using six to twelve participants with interviews as the mode of data collection.[197] For the purpose of the qualitative component of this group-based education study, sample representativeness was not necessary, as the researcher was exploring lived experiences of patients in a real world setting. As with most qualitative research the results of this study should not be generalized beyond this group of participants or beyond the particular intervention.

A potential source of participant bias was that only participants who completed the course were invited to take part in the interviews. Alternate views may have been offered by those who elected not to take part in the intervention or did not complete the whole program. Additionally, it is possible that those who volunteered to participate in the intervention may have been more motivated than the average patient with T2DM, which may have resulted in improved outcomes in comparison to 'amotivated' patients.

5.6 Conclusions

A clear benefit of group-based education for the management of chronic diseases is the impact of relatedness.[185] Unlike individual education, group-based education provides direct opportunities for patients to learn from peers, to be supported by peers, to compare themselves with others in the same situation, to socialise and to feel as though they have helped others. Relatedness seems to have impacted the motivation of individuals in the group, which aligns with the premise of the SDT that relatedness is one of the psychological needs that is the basis of self-motivation.[8, 185] Additionally, the enhanced effectiveness of patient-directed and patient-centred interventions may be considered through the lens of the SDT, which suggests that improving patient

competence by encouraging relatedness and the feeling of autonomy improves patient motivation and health behaviours.[8, 185] Previous research has shown that treating patients as autonomous and equal contributes to patient satisfaction.[45]

In conclusion, the themes generated in the secondary analysis of the qualitative interviews align with SDT, suggesting that group-based education programs that foster group interactions may be addressing relevant psychological needs of T2DM patients and could improve patient motivation. Previous research has shown that meeting the innate needs identified by SDT can motivate patients to initiate and maintain health behaviours over the long term.[8, 182] Group-based education programs appear to provide a critical forum for relatedness.

Practice Implications

This qualitative study is the first to demonstrate the application of the SDT to group-based education for the management of T2DM when viewed from the perspective of the participants themselves. The results support the use of patient-centred, patient-directed programs that prioritise group interactions over the didactic presentation of content, which may address the relevant psychological needs of individuals with T2DM, and improve motivation and health behaviours. Future group-based education programs may benefit from the use of SDT as a framework for intervention design to enhance participant motivation.

Chapter 6: Survey on dietitian use of diabetes group education

Preamble

Group-based education for the management of T2DM in Australia is underutilized. The reasons for this have not been explored in depth, and it is therefore difficult to understand why group-based education programs are less commonly used in Australia than individual education. This chapter will describe a survey study which explored the utilization of group-based education, as well as preferences for practice and training, among Australian Accredited Practising Dietitians (APDs).

The manuscript for this study titled "The utilization of group-based education for patients with type 2 diabetes mellitus by Australian dietitians: a survey" is currently in draft and will be submitted to the *Australian Journal of Primary Health* in August 2016. The PhD candidate had a principal role in study design, data collection and analysis and wrote the manuscript. Dr Dianne Reidlinger and Prof Elisabeth Isenring assisted with the study design and data analysis. Dr Dianne Reidlinger, Prof Elisabeth Isenring and Dr Rae Thomas have commented critically on the manuscript and approve it for submission.

6.1 Abstract

Group-based education for the management of type 2 diabetes mellitus (T2DM) has significant effects on clinical, lifestyle and psychosocial outcomes. Group-based education has the potential to substantially improve the outcomes of individuals with T2DM and reduce the enormous burden that chronic diseases place on health care systems worldwide. Despite this proven effectiveness, the utilization of group services for T2DM by Accredited Practising Dietitians (APDs) is surprisingly low. This study surveyed a sample of 263 Australian APDs to explore the utilization of group-based education for T2DM, as well as dietitians' preferences for practice and training. The results of this study indicated that the utilization of group-based education for the management of T2DM by APDs is limited, with the majority of respondents not currently facilitating (n=130; 58.8%), or having never facilitated (n=49; 38%) group-based education sessions or programs for the management of T2DM. Furthermore, the majority (n=176; 82%) of survey respondents did not currently claim, or had never claimed the Australian Medicare Chronic Disease Management (CDM) group items. The primary reasons reported for not claiming these items were that APDs were not registered as Medicare providers (n=62; 21%) and were therefore not eligible to claim these items, referred individuals with T2DM to publicly funded groups (n=42; 14.5%), unable to access suitable facilities for these programs (n=34; 11.8%), or perceived group programs were not cost effective (n=30; 10.4%). Additionally, the survey found that the majority of APDs either had: only received training during their health professional qualification (n=103; 33%), received informal training from colleagues (n=96; 31%), or had not received training (n=43; 14%) in facilitating group-based education programs. Majority preferences for further training were for either face-to–face or web-based formal training (n=276; 88%) conducted over three to six hours (n=114; 51.6%). Clear, evidence-based practice guidelines for group education for the management of T2DM are needed in order to encourage better utilization of group-based education by Australian dietitians.

6.2 Introduction

Group-based education rebates were introduced in Australia in 2008 under Medicare's Chronic Disease Management (CDM) plans.[59] The introduction of these rebates has allowed group-based education programs to become a more feasible and financially viable method of T2DM education and management.[59] Persons who have been diagnosed with T2DM can be assessed for eligibility to receive up to eight group education sessions per calendar year, which are fully or partially funded through the government Medicare insurance scheme.[59, 68] Only dietitians, diabetes educators or exercise physiologists who are working in private practice and registered with Medicare Australia are permitted to claim the Medicare group service items.[59, 68]

Group-based education programs for the management of individuals with T2DM in Australia are under-utilized with a mere 31,000 allied health group service items claimed in comparison to the 2.67 million individual allied health services provided nationwide under the Medicare CDM items in 2010.[60] Of the health professional groups eligible to provide small group education through the MBS items, exercise physiologists dominate in the number of Medicare group items claimed, providing almost 90% of all group services.[151] Dietitians' usage of group services on the other hand, comprised less than 2% of their Medicare service provision in 2013.[151] In 2010 in Australia, dietitians were the third most utilized Medicare CDM allied health service after podiatry and physiotherapy.[60] The usage of individual dietetic services has increased consistently over recent years, whilst group service item usage has decreased, declining by 46% from 2011 to 2013.[60, 151]

The limited usage of the Medicare CDM group service items is likely due to a number of complex factors, which have not yet been explored in depth. Previous research has proposed that service system issues, lack of workforce capacity, poor awareness amongst practitioners and practitioner attitudes and preferences are the main factors impeding the uptake of these items.[60] In a recent qualitative study based on interviews with twenty-five Australian dietitians, it was suggested that reasons for the low uptake of the Medicare CDM group education items were that dietitians did not find group services to be cost effective, group education programs were not viable, a lack of access

to appropriate facilities and multidisciplinary providers, and the lack of a common national curriculum for T2DM group education programs.[62]

This study aims to explore the utilization of group-based education for T2DM management by Australian APDs, as well as dietitians' preferences for practice and training. The survey was used to investigate three specific research questions:

1. What are the current barriers for practice and the preferences of Australian dietitians in the area of group-based education for T2DM?

2. What are Australian dietitians' perceptions of the need for formal training prior to facilitating group programs, and what training do they receive in practice?

3. Are Australian dietitians uncertain about the evidence base and theoretical development of group programs?

6.3 Methods

A cross-sectional survey of Australian dietitians was undertaken between October 2015 and May 2016. Electronic invitations were sent to all financial members of the Dietitians Association of Australia (DAA) with an additional email invitation sent to the members of the DAA Diabetes, Private Practice and Research Interest Groups. The survey was additionally advertised through the Dietitian Connection newsletters (an online forum in which Australian dietitians can connect), on social media (Facebook, LinkedIn and Twitter), and by email to the researchers' professional contacts. Snowballing techniques were utilized by inviting those who received the recruitment email to forward it on to their own professional networks. According to the DAA annual report for 2015, there are 5042 current financial members and therefore APDs, with 2291 (45%) of these also members of the Diabetes Interest Group.

Dietitians who currently consult with, or who have previously consulted directly with persons diagnosed with T2DM were invited to participate in the study. Participants were included if they were APDs, living in Australia, and had at least 1 year of experience working as a dietitian. Ethical approval was obtained from the Bond University Human

Research Ethics Committee (protocol number RO15456), and DAA and Dietitian Connection approved the circulation of invitations to complete the survey through their newsletters and/or interest groups. The survey was voluntary and anonymous with only non-identifiable data collected. Submission of a completed, or partially completed, survey implied consent to participate, and for all data entered up to the exit point to be included in the study. Participants' data was de-identified by Survey Monkey, except in cases where research participants provided their email address to obtain an executive summary of results. These participants were de-identified manually by the PhD candidate. Participants did not receive any compensation to complete the survey.

The survey development was guided by a previous qualitative study which involved interviews with the facilitators of CDM groups in Australia,[149] as well as recent research which proposed various factors for the poor uptake of group-based education by Australian dietitians.[60, 62, 151] The 32-item questionnaire survey included multiple-choice or Likert scale responses to report demographics, T2DM service provision, group-based education training and provision, reasons for not claiming Medicare group items, as well as information on the awareness of current guidelines in the area, preferences for training and practice, perceived confidence in facilitating and views about group-based education (Appendix A). Additionally, seven of the survey questions provided an opportunity for respondents to enter further information, and a final comments box allowed respondents to provide any additional feedback regarding group-based education for T2DM. Survey questions varied slightly dependent on whether respondents were or were not currently facilitating group-based education programs for individuals with T2DM. Face validity of the online survey was undertaken by piloting the format and content of the survey with five APDs prior to the commencement of data collection, which resulted in minor changes to the wording of some questions. During piloting, the survey took approximately 5 to 10 minutes to complete.

The survey was administered using a web-based interface (SurveyMonkey Inc, Palo Alto, California, USA). Self-reported demographic data of survey respondents was enumerated to describe the sample. Data obtained through the Likert scale statement questions were analysed in SPSS using chi-square testing (goodness of fit or test of independence). Where the expected values of cells were less than five, Fisher's Exact test was applied in place of the chi square test of independence. The free text comment

responses optionally provided by survey respondents were analysed using qualitative content analysis in order to categorise and summarise the responses received.

6.4 Results

Responses were collected from 263 Australian dietitians (representing a response rate of 5% of all APDs and 11.5% of the DAA Diabetes Interest Group membership), of which 202 provided complete data (77% completion rate). Three participants were not currently residing in Australia, and three were not currently APDs and were therefore excluded from answering survey questions. Demographic data was obtained on 221 (84%) participants (Table 6.1). According to the *Australia's Health Workforce Series—Dietitians in Focus* report, the typical dietitian is female (94.6%), aged 34.9 years, with a bachelor (50%) or postgraduate (35%) level of education.[198] Similarly, the typical survey respondent was female (92%), aged 25 to 34 years (51.4%) or 35-44 years (20.3%), and had a bachelor (33.1%) or postgraduate qualification (53%).

Table 6.1: Participants of survey study sample attributes summary (n=221)

Attribute	**N (%)**
Gender:	
Male	20 (8)
Female	231 (92)
Age:	
18-24 yrs	14 (6)
25-34 yrs	129 (51)
35-44 yrs	51 (20)
45-54 yrs	37 (15)
55-64 yrs	16 (6)
65-74 yrs	4 (2)
State:	
QLD	75 (30)
ACT	7 (3)
NT	3 (1)
NSW	65 (26)
WA	16 (6)
TAS	5 (2)
VIC	63 (25)
SA	17 (7)
Geographical area:	
Rural/ Isolated	25 (10)
Regional Centre	69 (28)
Metro/ Large Urban	157 (63)
Highest level of education:	
Diploma/ Advanced Diploma	12 (5)
Bachelor Degree	83 (33)
Honours Degree	26 (10)
Master Degree	101 (40)
Doctoral Degree	6 (2)
Dual Qualification	23 (9)
Years working as a dietitian:	
<1 yr	6 (2)
1-3 yrs	46 (18)
4-6 yrs	48 (19)
7-9 yrs	48 (19)
10-12 yrs	31 (12)
>12 yrs	72 (29)
Years as a group educator:	
No experience	24 (11)
<1 yr	22 (10)
1-3 yrs	43 (20)
4-6 yrs	42 (19)
7-9 yrs	30 (14)
10-12 yrs	20 (9)
>12 yrs	40 (18)
Current area of practice:	
Acute care	38 (17)
Private practice	75 (34)
Community	83 (38)
Industry	1 (1)
Other	23 (11)
Diagnosed with T2DM:	
Yes	0 (0)
No	221 (100)

N= number; yr/s= year/s; T2DM= Type 2 diabetes mellitus

Respondents who were dual qualified had mainly completed additional studies in the area of diabetes education and human movement studies, and were therefore diabetes educators or exercise physiologists as well as dietitians. Those respondents who did not fit into the predefined category for current positions or work areas mainly worked in academia or research.

The number of responses from APDs was compared to the dietetic workforce data obtained from the 2015 DAA annual report.[199] The states or territories with the highest percentage of the overall workforce responses were Queensland (6.6%), Tasmania (6.1%), Northern Territory (5.2%) and the Australian Capital Territory (5%). Conversely, Western Australia (3.7%), New South Wales (4.2%), South Australia (4.8%), and Victoria (4.9%), were the states with the lowest percentage of the overall workforce responses.

The utilization of group-based education by Australian dietitians

Survey participants were asked seven questions regarding their utilization of group-based education for the management of T2DM. The majority of respondents currently facilitating group-based education programs did not claim (n=63; 71%) Medicare CDM items for these programs, and those not currently facilitating group-based education programs had mainly never (n=113; 90%) claimed the items. Responses to these survey questions are summarized in Table 6.2.

Table 6.2: Results of survey questions on the utilization of group-based education by Australian dietitians

Question	**N (%)**
Group: All participants	
Registered as a Medicare Provider:	
Yes	137 (62)
No	84 (38)
Percentage of workload consulting T2DM patients:	
0-25%	73 (33)
25-50%	81 (37)
50-75%	47 (21)
75-100%	20 (9)
Group: Current facilitators	
Currently facilitating GBE programs for T2DM (n=221):	
Yes	91 (41)
No	130 (59)
Claiming of Medicare CDM items for group/s currently facilitating (n=89):	
Yes	26 (29)
No	63 (71)
% of GBE sessions in workplace facilitated by respondents (n=90):	
0-20%	19 (21)
20-40%	18 (20)
40-60%	18 (20)
60-80%	7 (8)
80-95%	10 (11)
100%	18 (20)
Group: Not current facilitators	
Previous facilitation of GBE programs for T2DM (n=129):	
Yes	80 (62)
No	49 (38)
Ever claimed Medicare CDM items for GBE for T2DM (n=125):	
Yes	12 (10)
No	113 (90)

N= number; T2DM= Type 2 diabetes mellitus; CDM= chronic disease management; GBE= group-based education

Current barriers for practice and the preferences of Australian APDs in the area of group-based education for T2DM

Responses to the survey questions on the current barriers for practice for Australian APDs in the area of group-based education for T2DM are summarized in Table 6.3. The primary reasons for not claiming the Medicare CDM items were that survey participants were not Medicare providers and were therefore ineligible to claim these items, that they referred individuals with T2DM to community or hospital-based groups, they were unable to access suitable facilities for these programs, or they perceived that facilitating group programs was not cost effective.

Table 6.3: Results of survey questions on current barriers for practice for group-based education by Australian APDs

Question	N (%)
Reasons for not claiming these items (n=174):*	
Unaware that these items were available	20 (7)
Unaware dietitians were eligible to claim these items	13 (5)
No common national curriculum for T2DM GBE programs	5 (2)
Lack of access to appropriate facilities for GBE	34 (12)
Not confident in knowledge and skills to facilitate GBE	8 (3)
Hiring appropriate facilities is too expensive	11 (4)
Facilitating group programs is not cost effective	30 (10)
Difficult to access multidisciplinary providers	15 (5)
Patient retention is poor in GBE programs	24 (8)
Lack of time needed to run GBE programs	25 (9)
Refer to publicly run (community/ hospital based) groups	42 (15)
Not a Medicare provider	62 (21)

N= number; T2DM= Type 2 diabetes mellitus; GBE= group-based education
*Respondents could select more than one response

Sixty-one participants provided free text reasons for not claiming the Medicare group items, these primarily included: access to public funding by the National Diabetes Services Scheme (NDSS), group-based education not financially viable, claiming the items required excessive paperwork.

The 5-point Likert scale questions regarding preferences for practice, views and perceptions in the area of group-based education, were analyzed according to whether respondents were currently facilitating group-based education programs for the management of T2DM, or not (Table 6.4).

Table 6.4: Comparison of survey question responses representing the preferences for practice, views and perceptions of Australian APDs who were group facilitators vs those who were not currently facilitating groups

Question	Group	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Total responses (N)	χ^2	Fisher's exact	Significance (2-sided)
I would consider myself to be an expert in GBE for T2DM	Current facilitators	0	7	26	46	10	89	47.6	-	P<0.001*
	Not current facilitators	15	44	34	29	2	124			
I would consider GBE for T2DM to be effective	Current facilitators	0	2	14	56	17	89	9.7	9.5	P=0.02*
	Not current facilitators	0	4	32	80	8	124			
I feel that GBE should be multidisciplinary (two or more disciplines)	Current facilitators	5	5	4	33	42	89	13.4	12.9	P=0.008*
	Not current facilitators	0	2	13	58	51	124			
I feel that patient interactions positively affect patient outcomes	Current facilitators	0	2	6	42	39	89	5.3	4.8	P=0.415
	Not current facilitators	1	0	6	67	49	123			
I consider it to be very important to provide patients attending groups with paper-based information	Current facilitators	1	7	10	42	29	89	6.0	5.9	P=0.174
	Not current facilitators	0	4	16	73	31	124			
I feel that GBE is more beneficial to patients than individual education	Current facilitators	2	12	43	24	7	89	13.4	13	P=0.013*
	Not current facilitators	4	30	66	23	1	124			
I prefer to facilitate GBE over individual consultations	Current facilitators	2	13	39	27	8	89	20.6	20.6	P<0.001*
	Not current facilitators	4	42	57	20	1	124			
I feel that the session content is more important than lengthy patient discussions	Current facilitators	10	49	22	6	2	89	47.2	48.7	P<0.001*
	Not current facilitators	1	27	52	40	4	124			

I would feel confident to facilitate an unstructured GBE where the entire content was patient-directed	Current facilitators	2	6	16	47	18	89	14.1	13.9	P=0.007*
	Not current facilitators	0	26	24	60	13	123			

T2DM= Type 2 diabetes mellitus; CDM= chronic disease management; GBE= group-based education

*Indicates measures were assessed as significant (P≤0.05)

Australian dietitians' perceptions of the need for formal training prior to facilitating group programs and what training they receive in practice

Survey respondents were asked about their previous training and their preferences for further training (Table 6.5). Free text comments from 13 respondents suggested no further training was needed, some because they were not planning to facilitate groups, or gave a preference for clinical supervision in the area. Sixty-seven participants had completed training in group-based education which was mainly: Certificate IV in Training and Assessment, training during their diabetes educator course or graduate diploma in diabetes education or DESMOND training.[57]

Table 6.5: Results of survey questions on formal training in the area of group-based education by Australian dietitians'

Question	N (%)
Previous training in delivering GBE for T2DM (n=221):*	
No training	43 (14)
Training during HP qualification only	103 (33)
Informal training from colleagues	96 (31)
Formal training (face-to-face course or workshop)	55 (18)
Formal training (web-based course or workshop)	12 (4)
Training preference to enhance skills in the area (n=221):*	
Informal training from colleagues	39 (12)
Formal training (face-to-face course or workshop)	135 (43)
Formal training (web-based course or workshop)	141 (45)
Preference for time commitment for further training (n=221):	
≤ 2 hours	65 (29)
3-6 hours	114 (52)
7-10 hours	33 (15)
11-20 hours	6 (3)
≥ 20 hours	3 (1)

N= number; T2DM= Type 2 diabetes mellitus
*Respondents could select more than one response

Awareness of the evidence base and theoretical development of group programs

The responses to the two questions on participant's awareness of guidelines for group-based education in the area of T2DM or specifically for dietitians are summarized in table 6.6. Almost 50 survey respondents provided written comments in response to these two questions, which commonly identified the DAA Evidence-based practice

guidelines,[63] the Diabetes Australia National Evidence-Based Guideline,[40] Medicare Australia's Group Allied Health Services Information for Providers[154] or DESMOND.[22, 55]

Table 6.6: Results of survey questions on Australian dietitians' awareness of the evidence base and theoretical development of group programs

Question	**N (%)**
Aware of guidelines for GBE for T2DM (n=221):	
Yes	27 (12)
No	159 (72)
Other	35 (16)
Aware of guidelines specifically for dietitians (n=221):	
Yes	15 (7)
No	192 (87)
Other	14 (6)

N= number; T2DM= Type 2 diabetes mellitus; GBE= group-based education

Finally, those APDs currently facilitating groups were asked to rate whether they understood the theories and rationale behind the group-based education program they were currently facilitating, with the majority (n=77; 86%) agreeing or strongly agreeing with the statement (χ^2=130.409; P<0.001).

6.5 Discussion

This study surveyed a sample of Australian dietitians to explore the utilization of group-based education for T2DM management, as well as barriers to practice, Australian dietitians' preferences for training and practice in the area, prior training, their perceptions of the need for formal training, and their understanding of the theories or rationale behind the programs they facilitate.

The utilization of group-based education for the management of T2DM was limited, with the majority of respondents (n=130; 58.8%) not currently facilitating these groups, and 38% (n=49) of these respondents having never facilitated group-based education programs for the management of T2DM. The majority (n=176; 82%) of APDs who

participated in the survey did not currently claim, or had never claimed the Medicare CDM group items (81000 to 81125). This is in line with previous research, which found that less than 2% of APDs claimed the Medicare CDM group items in 2013.[151]

Research has suggested that the limited use of these items may be due to service system issues, lack of workforce capacity, poor awareness among practitioners, practitioner attitudes and preferences, a lack of cost effectiveness, the perception that group education programs are not viable, a lack of access to appropriate facilities and multidisciplinary providers, and the lack of a common national curriculum for T2DM group education programs.[60, 62, 151] The results indicate that some factors previously suggested by researchers, such as a lack of access to multidisciplinary providers, the lack of a common national curriculum for T2DM group education programs, and APDs being unaware of the Medicare CDM group items, were not commonly reported (range 1.7% to 7% of responses) by survey respondents which could be due to the inclusion of non-facilitators as well as current facilitators.

When comparing the two groups of survey respondents: those currently facilitating group-based education programs for the management of T2DM, and those who were not, the respondents currently facilitating groups were significantly more likely to consider themselves to be experts in the area, to prefer facilitating group-based education programs over individual consultations, and to be more confident than those who were not current group facilitators to facilitate an unstructured group-based education session where the entire content was patient-directed. Furthermore, current group educators were significantly more likely to consider group-based education for T2DM to be effective, to believe that group-based education is more beneficial to persons with T2DM than individual education, and to value lengthy patient discussions over getting through the session content than those who were not current group facilitators. Both groups of respondents indicated that patient interactions positively affect patient outcomes, and that it is very important to provide group participants with paper-based information. It was unclear whether those APDs who were not currently facilitating groups were not doing so due to their preference for facilitating individual consultations or their belief that individual education is more beneficial to persons with T2DM than group-based education. Previous group education research has indicated

that group facilitators perceived that persons diagnosed with T2DM require both individual and group education.[149]

Although current group facilitators were significantly more likely to believe that group-based education programs should utilize a multidisciplinary team, interestingly 11% (n=10) of the current group facilitators disagreed or strongly disagreed that group-based education programs should be facilitated by a multidisciplinary team. A few respondents noted in the free text comments that they had experienced the provision of dietary misinformation by other health professionals, which may explain why APDs preferred group facilitation by a single discipline, rather than a multidisciplinary team. Of those currently facilitating groups, 20% were conducting all of the sessions, indicating that the remaining participants were either facilitating a multidisciplinary group-based education program, or only conducting one or two guest sessions of a program facilitated by a discipline other than dietetics. Previous systematic reviews in the area of group-based education for the management of T2DM indicate that both single discipline and multidisciplinary teams can effectively facilitate these programs.[14, 47] The Global Guidelines for Type 2 Diabetes published in 2014 by the International Diabetes Federation Guideline Development Group recommends that education be provided by a multidisciplinary care team with expertise maintained by ongoing education, however this is not specific to group-based education.[200] This may indicate that a single discipline can effectively facilitate a group-based education, whilst other disciplines in the health care team could provide individual care to person with T2DM. Survey respondents may prefer facilitating more than one or two sessions due to the increased opportunity to build rapport with group participants which may improve group discussions and the perception of facilitator support by group participants.

The training of health professionals in the specialty area of group-based education for the management of T2DM to an advanced level of knowledge and competence, is required in order to deliver effective diabetes education.[201, 202] Previous research has indicated that health professionals facilitating group-based education program for the management of chronic diseases such as T2DM are poorly trained.[149] The results of this survey found that the majority of APDs either had training during their health professional qualification (n=103; 33%), informal training from colleagues (n=96;

31%), or had no training (n=43; 14%) in the area of group-based education for the management of T2DM. Only 22% (n=67) of survey respondents had received formal face-to-face or web-based training which was mainly reported as training during further qualifications such as Certificate IV in Training and Assessment, diabetes educator courses or graduate diplomas in diabetes education, or DESMOND module training. Facilitating group-based education programs without training could lead to APDs to be underprepared, to lack confidence, or could result in reductions in program effectiveness. Dietitians' preferences for training were mainly face-to–face or web-based formal training (n=276; 88%) conducted over three to six hours (n=114; 51.6%). Expert consensus supports the need for specialized training in the area of diabetes education in addition to academic preparation, for health professionals instructing persons with T2DM.[203-206]

Earlier research has suggested that health professionals facilitating group-based education program for the management of chronic diseases lack an understanding of the rationale or theoretical basis of the programs they facilitate.[149] The majority (n=76; 86%) of survey respondents who were currently facilitating groups felt that they understood the theories and rationale behind the group-based program they were facilitating, which differed from previous findings.[149]

There are currently no evidence-based practice guidelines for the development and facilitation of group-based education programs for the management T2DM in Australia. The majority of survey respondents (n=159; 72%) noted that they were not aware of any guidelines for group-based education for the management of T2DM, and almost all (n=192; 86.9%) respondents were not aware of any guidelines in the area for dietitians. Of those respondents who mentioned guidelines, most nominated the DAA's Evidence-based practice guidelines for the nutritional management of T2DM for adults[63], Diabetes Australia's National Evidence Based Guideline for Patient Education in T2DM[40], the Medicare Group Allied Health Services for Patients with T2DM Information for Providers[154] or DESMOND.[22, 55] Of these, the DAA evidence-based practice guidelines are guidelines for the individual management of persons with T2DM,[63] and state that group-based education guidelines have not been included. Additionally, the Diabetes Australia National Evidence Based Guideline for Patient

Education in T2DM[40] state that diabetes education should be delivered in groups or individually, however no specific evidence-based practice guidelines for the group-based management of persons with T2DM are provided.

The Medicare Group Allied Health Services for Patients with T2DM Information for Providers is an information pack[154] which provides some evidence, suggestions or pointers for group-based education for individuals with T2DM, and a possible format for group sessions, however, these are not guidelines. Furthermore, DESMOND or the 'Diabetes Education and Self-Management for Ongoing and Newly Diagnosed' is a group-based education program originally developed in the United Kingdom[22, 55] for which health professionals can be trained on the modules,[207] and is therefore not a guideline. This suggests that respondents are either unclear on the differences between a guideline and group-based education module training, or that in the absence of guidelines they are identifying programs from the literature in an effort to align with evidence-based practice. However, the results of the DESMOND studies demonstrated the program to be relatively ineffective, with no significant improvements in HbA1c when comparing the intervention and control groups.[22, 55] The significant results of the DESMOND studies were reduced body weight and increased levels of smoking cessation, in the intervention group at 12 months follow up, however these were not maintained when reassessed at three years' post-intervention.[22, 55] Practitioners' interest in the DESMOND program may be due to: the limited contact time required with persons in the groups with the program running for either one day or two half days, the availability of training modules and materials eliminating the need for facilitators to develop their own program, or that the program is well-known or recognizable to those in practice.

The results of this study which highlight an underutilized area of practice by dietitians in Australia, a lack of training and evidence-based practice guidelines, and potential workforce development issues, are concerning. It is likely that if less APDs are facilitating group-based education programs, and are not trained, competent or confident in the area, this will in turn affect training opportunities for student dietitians and may result in inadequate training, skills development and confidence in facilitating group-education programs for the future dietetic workforce in Australia. Additionally,

despite the majority of current facilitators reporting that they understand the theories and rationale behind the group-education program they were currently facilitating, previous research has found that many group facilitators do not understand the theoretical underpinnings of their program,[149] which may indicate gaps in facilitator understanding, or that survey respondents felt inclined to respond in a way which favoured the researchers' views of their practice. A lack of understanding of the theoretical basis or rationale behind the group-education program by group facilitators may result in reductions in the quality of programs, could reduce patient engagement and retention, or reduce the effectiveness of programs.

Limitations

The limitations of this study include the potential for sampling bias, the potential for participant bias, and potential issues with survey questions. Comprehensive advertising of the survey through various channels with which Australian dietitians were engaged aimed to reduce the potential for sampling bias. It is likely, however, that participant bias may have existed, with APDs who had an interest in group-based education for the management of T2DM, or alternatively, may have attracted APDs who were dissatisfied with group-based education for the management of T2DM or the Medicare rebates available. The actual knowledge of survey respondents was not assessed, rather, respondents self-reported their knowledge of group-based education for the management of T2DM which may have resulted in an overestimation of their actual knowledge. There is no way of verifying if respondents' perceived knowledge was indicative of their actual knowledge.

The interview questions were piloted and edited prior to the commencement of the study, however there is no guarantee that all questions were understood as intended. Additionally, the interview questions were not tested for validity or repeatability, however the survey was intended to be a descriptive survey exploring the issue of the utilization of group-based education by APDs. The survey took up to ten minutes to complete, which may have dissuaded busy APDs from participating. The rate of attrition was 16% with 221 APDs completed the survey of the 263 who started the survey. Finally, the sample obtained for this survey represented approximately 8.7% of

the DAA's diabetes interest group, and therefore may not be representative of all Australian dietitians working in the area. Although survey studies are an informative and convenient data collection method for researchers, and several studies have found that the validity and reliability of online surveys are comparable to data obtained using traditional methods,[208-212] the results of survey studies are not generalizable.[213] As such, this survey does not provide conclusive evidence, and ongoing scholarship in this area is required.

6.6 Conclusions

APDs are currently underutilizing group-based education programs for the management of T2DM. The results of this survey suggest that primary reasons for the low engagement of APDs in group-based education programs are likely to be a lack of training provided to APDs in the area, limited access to facilities suitable for groups, and poor cost effectiveness of group-based education programs for the management of T2DM. Additionally, the lack of guidelines for the group-based management of persons with T2DM by Australian dietitians is likely to reduce the utilization of these groups. Further research using the Medicare CDM group items should be completed in order to determine whether the rebates provided can result in a financially viable group-based education program for the management of T2DM. The development of evidence-based practice guidelines for the group-based management of individuals with T2DM by Australian dietitians could increase the number of groups being facilitated by dietitians. This may be best achieved through collaboration between Medicare Australia, Diabetes Australia and the Dietitians Association of Australia.

Chapter 7: Study results in relation to thesis objectives, Strengths and Limitations, Implications of the Research

Preamble

The following chapter provides an overview of the results of each of the studies completed in relation to the objectives of this PhD; the strengths and limitations of these studies; and the implications of the research.

The overarching aim of this thesis was to assess the attributes of group-based education programs for the management of T2DM which contribute to effectiveness.

The objectives of this thesis were to:

1. assess the effectiveness of group-based education programs for the management of T2DM and explore the impact of various program attributes;
2. identify and compare how group-based education programs are developed in practice, and obtain the opinions of group facilitators and group participants on the attributes that affect the success of group-based education programs for the management of chronic disease;
3. develop and assess the feasibility and acceptability of a group-based education program for the management of T2DM;
4. understand individuals' experiences of group-based education for the management of T2DM, and explore their motivation for self-management; and
5. explore the utilization of group-based education, as well as preferences for practice and training, among Australian APDs.

7.1 Study results in relation to the thesis objectives

This thesis aimed to identify the attributes of group-based education programs for the management of T2DM that contribute to effectiveness. A comprehensive systematic review, meta-analysis and meta-regression was conducted to pool existing research findings and identify key characteristics of previous interventions that may provide insight into effective group-based education interventions. A feasibility study was undertaken to develop, implement and evaluate a group-based education program that considered the literature as well as the views of participants and facilitators of chronic disease programs. In-depth qualitative analysis of interviews with participants from the feasibility study was conducted in order to explore participant motivators to improve self-management. Finally, dietitians were surveyed to explore their views, experiences and perceived barriers to facilitating group-based education in order to identify areas for practice improvement and further research.

The results of the series of studies completed for this thesis are provided in a format that addresses each of the five thesis objectives.

1. **Assess the effectiveness of group-based education programs for the management of T2DM and explore the impact of various program attributes.**

The results of the systematic review with meta-analyses and meta-regression, which included 53 publications describing 47 studies, favoured group-based education when compared with routine treatment, waiting list control or individual education. The results of the meta-analyses included statistically significant reductions in HbA1c at both short term and long term follow up post-baseline. Secondary outcome measures favouring group-based education included significant improvements in fasting blood glucose after a year; body weight and waist circumference in the shorter term; triglyceride levels at both short and longer term follow up; and diabetes knowledge, depression scores and physical activity in the short term.

The results of the subgroup analyses provided evidence to suggest that group-based education interventions facilitated by single disciplines, multidisciplinary teams or

health professionals with peer supporters, result in improved outcomes in HbA1c when compared to peer-led interventions. Furthermore, the results indicated that to improve HbA1c for individuals with T2DM, the characteristics of group-based interventions with greater effects appear to be those: conducted in primary care settings; facilitator directed; that provide materials to participants; have less than 10 sessions provided either in less than one month, or over seven to 12 months or 13 to 60 months; provide either 8 hours or less or over 31 hours of contact time, include less than 20 participants in each group; and include individuals with HbA1c levels greater than 7%. The lack of statistical significance in all but one of the subgroup analyses may indicate that other factors such as peer identification, normalisation, and group interactions are the 'active ingredient/s' and as such, substantially influence the effectiveness of group-based education interventions for the management of T2DM.

2. **Identify and compare how group-based education programs are developed in practice, and obtain the opinions of group facilitators and group participants on the attributes that affect the success of group-based education programs for the management of chronic disease.**

Group facilitators currently facilitating group-based education programs for CDM were interviewed to explore their experiences of developing and facilitating these programs, and to obtain their perceptions and opinions of the attributes which influence the effectiveness of these programs. Group facilitators consulted in the formative interview studies were uncertain about the evidence base and theoretical development of their programs, very few were offered any formal training prior to facilitating group-education programs, and the assessment measures used by the group facilitators to determine group outcomes were limited. Group facilitator's highlighted group interactions, a non-didactic delivery style, a multidisciplinary team, and using practical activities, as attributes contributing to group program effectiveness.

Group participants who had recently completed group-based education programs for chronic disease management were interviewed in order to obtain their experiences of these programs in a practice setting. Participants expressed satisfaction with the contact time provided and expressed satisfaction with the facilitation of the various group-based

programs. Participants also focused on their interest and their perceived value of group discussions and group interactions. The formative interview studies additionally aimed to explore which attributes are perceived to influence the success of group education programs for chronic disease management, by interviewing group facilitators and participants. Group participants highlighted group interactions, the knowledge provided, and a goal-orientated, patient-centred approach to the program as attributes contributing to group program effectiveness. It appears that group interactions and a patient-centred approach has a positive impact on participant satisfaction and possibly on participant outcomes.

3. **Develop and assess the feasibility and acceptability of a group-based education program for the management of T2DM.**

A feasibility study, developed using a preliminary literature review and scoping of group-based interventions, the formative interviews with facilitators of a range of existing CDM group education programs and their participants, and a review of the Medicare group services information pack,[154] to develop a group-based education program for the management of T2DM, was conducted. The study utilized two process evaluation frameworks, the MRC Framework for Developing and Evaluating Complex Interventions and the RE-AIM framework, to develop and evaluate the intervention. A total of 16 participants enrolled in the intervention and post intervention results were obtained from 13 participants, with modest improvements in weight, BMI and waist circumference from baseline. Importantly, the participants reported satisfaction with the program suggesting it was both feasible to implement and acceptable to participants. However, recruitment through GPs was ineffective and alternative recruitment strategies are required.

4. **Understand individuals' experiences of group-based education for the management of T2DM, and explore their motivation for self-management.**

Qualitative interview data obtained from the feasibility study was analysed further to explore the motivations of participants in the feasibility study. Using thematic analysis underpinned by self-determination theory, themes were developed that explored participants' motivators in relation to diabetes management and the impact of group

interactions on their experiences and motivation. The key themes included knowledge, experience, group interactions and motivation. Participants perceived that the group interactions facilitated further learning and increased motivation, achieved through normalisation, peer identification or by talking with, and learning from the experience of others. Patient-centred programs that prioritise group interactions over the didactic presentation of content, may address the relevant psychological needs of individuals with T2DM, and improve motivation and health behaviours.

5. **Explore the utilization of group-based education, as well as preferences for practice and training, among Australian APDs.**

The final study was a survey of Australian dietitians, which explored the utilization of group-based education and the barriers to implementing group-based education for the management of T2DM in practice, as well as their preferences for practice and training. The results of this study indicated that the utilization of group-based education for the management of T2DM by APDs is limited. The majority of respondents were not currently facilitating group-based education for T2DM management and over a third had never facilitated group-based education sessions or programs for the management of T2DM. Additionally, a vast majority of survey respondents did not currently claim, or had never claimed the Australian Medicare CDM group items. Primary reasons reported for not claiming these items were that APDs were not Medicare providers and were therefore ineligible to claim these items, that they referred individuals with T2DM to publicly funded groups, were unable to access suitable facilities for these programs, or they perceived that facilitating group programs was not cost effective.

Australian dietitians perceived that participant interactions positively affect health outcomes, and that it is very important to provide group participants with paper-based information. Those currently facilitating group-based education programs for the management of T2DM perceived group-based education programs should incorporate a multidisciplinary team, preferred facilitating group-based education programs over individual consultations, valued lengthy participant discussions over getting through the session content, and were more confident than those who were not current group facilitators to facilitate an unstructured group-based education session where the entire

content was patient-directed. The survey found that the majority of APDs had either been trained for facilitating group education during their health professional qualification, informally by colleagues, or had no training. Their preferences for further training were mainly face-to–face or web-based formal training conducted over three to six hours.

An overview of the key objectives of the thesis and findings of each study are provided in Table 7.1 and discussed in the following section.

Table 7.1: Overview of thesis objectives and key findings from each study

Objective	Study and section discussed	Key findings
1. Assess the effectiveness of group-based education programs for the management of T2DM and explore the impact of various program attributes;	Systematic Review with Meta-Analyses and Meta-Regression; Chapter 3	Effectiveness: Significant improvements in HbA1c at six to ten months (MD= 0.31%; 95%CI: -0.48, -0.15; P=0.0002, 30 studies, n=4107), 12-14 months (MD= 0.33%; 95%CI: -0.49, -0.17; P<0.0001, 27 studies, n=4384), 18 months (MD= 0.72%; 95%CI: -1.26, -0.18; P=0.009, 3 studies, n=194) and 36-48 months (MD= 0.93%; 95%CI: -1.52, -0.34; P=0.002, 5 studies, n=1436); fasting blood glucose at 12-14 months (MD= 0.68mmol/L; 95%CI: -0.95, 0.47; P=0.02, 8 studies, n=1436); body weight at six to ten months (MD= 1.22kg; 95%CI: -2.22, -0.23; P=0.02, 17 studies, n=2513) and 12-14 months (MD= 1.43kg; 95%CI: -2.09, -0.77; P<0.0001, 9 studies, n=1564); waist circumference at six to ten months (MD= 1.19cm; 95%CI: -2.34, -0.05; P=0.04, 5 studies, n=986); triglyceride levels at six to ten months (MD= 0.13mmol/L; 95%CI: -0.24, -0.01; P=0.03, 14 studies, n=2150) and 24 months (MD= 0.32mmol/L; 95%CI: -0.58, -0.06; P=0.01, 3 studies, n=237); diabetes knowledge at six to ten months (SMD= 0.61; 95%CI: 0.14, 1.08; P=0.01, 7 studies, n=479) and 12 to 14 months (SMD= 0.58; 95%CI: 0.08, 0.97; P=0.02, 7 studies, n=1291); depression scores at six months (SMD= 0.62; 95%CI: -0.93, -0.31; P=0.0001, 3 studies, n=377); and physical activity levels at six months (SMD= 0.23; 95%CI: 0.10, 0.36; P=0.0006, 7 studies, n=1097) and 12 to 14 months (SMD= 0.21; 95%CI: 0.06, 0.35; P=0.005, 3 studies, n=862) post-baseline. Attributes: Interventions with greater effects on HbA1c appear to be those: facilitated by single disciplines, multidisciplinary teams or health professionals with peer supporters; conducted in primary care settings; that are facilitator-directed; that provide materials to participants; have less than 10 sessions provided either in less than one month, or over seven to 12 months or 13 to 60 months; provide either 8 hours or less, or over 31 hours of contact time; include less than 20 participants in each group; and include individuals with HbA1c levels greater than 7%.

Objective	Study and section discussed	Key findings
2. To identify and compare how group-based education programs are developed in practice, and obtain the opinions of group facilitators and group participants on the attributes that affect the success of group-based education programs for the management of chronic disease	Formative Interviews: Group Facilitators and Group Participants; Appendix E	Group facilitators were uncertain about the evidence-base and theoretical development of their programs, very few were offered any formal training prior to facilitation, and the outcome measures used were limited. Attributes: group interactions, a non-didactic delivery style, a multidisciplinary team, using practical activities, the knowledge provided, and a goal-orientated, patient-centred approach.
3. To develop and assess the feasibility and acceptability of a group-based education program for the management of T2DM	Feasibility Study: Intervention Development and Evaluation; Chapter 4	A patient-centred, patient-directed group-based intervention informed by a preliminary literature review and scoping of group-based interventions, the formative interviews with facilitators of a range of existing CDM group education programs and their participants,[149] and a review of the Medicare group services information pack[154], was developed and evaluated. The results included modest improvements in weight, BMI and waist circumference. The developed intervention was both feasible and acceptable to participants.
4. To understand individuals' experiences of group-based education for the management of T2DM, and explore their motivation for self-management	Qualitative Analysis of Interview Data; Chapter 5	The key themes included knowledge, experience, group interactions and motivation. Participants perceived that the group interactions facilitated further learning and increased motivation, achieved through normalisation, peer identification or by talking with, and learning from the experience of others. The results support the use of patient-centred programs that prioritise group interactions over the didactic presentation of content, which may address the relevant psychological needs of individuals with T2DM, and improve motivation and health behaviours.

Objective	Study and section discussed	Key findings
5. To explore the utilization of group-based education, as well as preferences for practice and training, among Australian APDs.	Survey of Australian APDs; Chapter 6	Utilization: The majority of respondents not currently (58.8%), or never having facilitated (38%) group-based education sessions or programs for T2DM management. The majority (82%) of survey respondents did not currently claim, or had never claimed the Australian Medicare CDM group items. The primary reasons reported for not claiming these items were that APDs were not Medicare providers, referred individuals with T2DM to publicly funded groups, were unable to access suitable facilities for these programs, or they perceived that facilitating group programs was not cost effective. Preferences: Those currently facilitating group-based education programs felt that group-based education programs should incorporate a multidisciplinary team, preferred facilitating group-based education programs over individual consultations, valued lengthy participant discussions over getting through the session content, and were more confident than those who were not current group facilitators to facilitate an unstructured group-based education session where the entire content was patient-directed. The survey found that the majority of APDs either had: no training, only training during their health professional qualification, or informal training from colleagues. Their preferences for further training were mainly face-to–face or web-based formal training conducted over three to six hours.

7.2 Strengths and Limitations

A key strength of this thesis is the completion of a comprehensive, up-to-date systematic review of group-based education studies for the management of T2DM which included various meta-analyses, a meta-regression and an assessment of the completeness of reporting and replicability of studies using the TIDieR checklist and guide.[64] Instead of relying on the searches and assessment completed by the previous systematic review authors, this review searched from the commencement of the records. Additionally, two independent reviewers completed the risk of bias analysis, study selection screening, and checking of data extraction, reducing the potential for bias and error. However, a search of the grey literature in the area was not completed, which may have resulted in publication bias. This is the first systematic review in the area to complete a meta-regression in order to explore the intervention variables which may contribute to the heterogeneity of the included studies. Furthermore, comprehensive subgroup analyses were completed to explore differences in study and intervention variables. Limitations of this study include the quality of the studies included of which the majority were assessed as either moderate (31/47 studies) or high risk of bias (12/47 studies). This highlights the need for high quality studies and improved reporting of group-based interventions for the management of T2DM in the literature. This review assessed the effectiveness of group-based education programs for the management of T2DM at various post-baseline time points, however the maintenance of improvements in health outcomes post-intervention were not assessed. Finally, numerous meta-analyses resulted in high heterogeneity between studies, however, this was assessed further through sensitivity analyses.

The completion of a feasibility study allowed the researchers to test the feasibility and acceptability of the intervention, and the identification of potential issues prior to the consideration of a pilot RCT. The development of the intervention through the triangulation of results from the formative literature review, formative interviews, and the recommendations provided by the Medicare group services information pack,[154] and the description of the study using the TIDieR checklist and guide[64] were strengths of the feasibility study. Furthermore, the utilization of both the MRC and RE-AIM frameworks in the development and evaluation of the intervention added rigour to the study, allowed the comprehensive evaluation of the intervention, and may provide

guidance to researchers on the utilization of a combination of these frameworks in intervention development and evaluation. The study had various limitations which included recruitment difficulties, however this resulted in key learnings, which may be applied when translating the program to practice. Additionally, the potential for sampling bias cannot be ruled out with the sample characteristics of the group participants being dissimilar to the characteristics of participants in the AusDiab study.[177] Further research piloting the intervention using an RCT design using a control group and a larger sample size, and trialling additional recruitment methods, would have been a valuable addition to this thesis. However, the completion of an RCT was outside the scope of this PhD research, and furthermore, time and budgetary constraints did not allow for this.

The qualitative interview study demonstrated a novel hybrid deductive and inductive approach to thematic analysis based on a pre-selected, established psychological theory of motivation, SDT.[185, 186] The inductive approach directly drew codes, categories, or themes from the data, whilst the deductive approach used preconceived codes or categories derived from SDT.[187, 188] Qualitative interviews were an ideal method to explore patients' experiences and perspectives of the intervention. Qualitative methods can provide rich and diverse data that are not obtainable through quantitative means.[196] Additionally, research has shown that obtaining patients' perspectives on group-based education can reflect patients' real-life experiences and potentially result in data rich in human experience.[181] Data trustworthiness was achieved by independent analyses of the data by the PhD candidate and one supervisor (KOJ & DPR) and subsequent discussions of the themes and subthemes until agreement was reached ensuring that the analysis was credible, and that no common themes or subthemes were missed.

Semi-structured interviews, constructed primarily of open-ended questions and probes, allowed group participants to provide in-depth information, which may have been missed using other research methods. However, the use of semi-structured interviews may have influenced participants' responses by prompting them to talk about topics that they may not have discussed otherwise, and the completion of the telephone interviews by a third party may have reduced the potential impacts of a perceived power differential and participants' potential reservations to be honest and comprehensive in

their responses, particularly in relation to the group facilitator. Furthermore, the inclusion of participants from a range of backgrounds with variations in the years since diagnosis, and the inclusion of all of the participants that completed the intervention in the telephone interviews were additional strengths of the study. Limitations of this research include the small sample size due to recruitment difficulties and the potential for participant bias. The small sample size makes it difficult to ascertain whether theoretical saturation was achieved, however research has shown that theoretical saturation is obtainable using six to twelve participants with interviews as the mode of data collection.[197] Furthermore, for the purpose of this study, sample representativeness was not necessary, as the researcher was exploring lived experiences of patients in a real world setting.

The final study in this thesis was a survey of Australian dietitians which explored the utilization and the barriers to implementing group-based education for the management of T2DM in practice, as well as Australian dietitians' preferences for practice and training. Obtaining the views of practicing health professionals can provide a deeper understanding of practical issues affecting the development and facilitation of group-based education programs in the real-world setting. Additionally, obtaining the perceptions and opinions of APDs providing valuable data which could not be obtained from the literature. Previous studies in the area did not comprehensively explore the barriers to implementing group-based education programs or Australian dietitians' preferences for practice and training. The limitations of this study included the potential for sampling bias, the potential for participant bias, and potential issues with survey questions. Although the interview questions were piloted and edited prior to the commencement of the study, there is no assurance that all questions were understood as intended. Additionally, the interview questions were not tested for validity or repeatability, however the survey was intended to be a descriptive survey exploring the issue of the utilization of group-based education by APDs. Finally, the sample obtained for this survey may not be representative of all Australian dietitians working in the area of T2DM management, and as such, the results of the survey are not generalizable.

The incorporation of various research methods, including a systematic review with meta-analyses and meta-regression, formative studies, a feasibility study, a qualitative

investigation and a survey study, which assessed the effectiveness of group-based interventions, explored the attributes which may influence the effectiveness these interventions, investigated the utilization of group-based education for the management of T2DM in practice, and obtained the perceptions and opinions of group facilitators and participants, provided a comprehensive overview of the benefits and barriers to research and practice in the area.

7.3 Implications of the Research

The studies completed for this thesis provide several key findings which are either valuable additions to the current evidence base, or support the findings of previous studies in the area of group-based education for the management of T2DM. The systematic review with meta-analyses and meta-regression provides the highest level evidence, level I, in accordance with the NHMRC evidence hierarchy.[214] The systematic review is a comprehensive update of the evidence, and resulted in numerous key findings which were not identified by the two previous reviews completed in the area, or provided evidence to support some of the findings of the previous reviews (Table 7.2). The results of the meta-analyses which were not previously identified include that group-based education is significantly more effective at improving HbA1c levels at 18 months (MD=0.72%; 95%CI: -1.26, -0.18; P=0.009, 3 studies, n=194) 36 to 48 months (MD=0.93%; 95%CI: -1.52, -0.34; P=0.002, 5 studies, n=1436), reducing triglyceride levels at six to ten months (MD=0.13mmol/L; 95%CI: -0.24, -0.01; P=0.03, 14 studies, n=2150) and 24 months (MD=0.32mmol/L; 95%CI: -0.58, -0.06; P=0.01, 3 studies, n=237), waist circumference at six to ten months (MD= 1.19cm; 95%CI: -2.34, -0.05; P=0.04, 5 studies, n=986) and 12 to 14 months (MD=0.79cm; 95%CI: -1.96, 0.38; P=0.19, 3 studies, n=1088), and physical activity levels were improved at six months (SMD= 0.23; 95%CI: 0.10, 0.36; P=0.0006, 7 studies, n=1097) and 12 to 14 months (SMD= 0.21; 95%CI: 0.06, 0.35; P=0.005, 3 studies, n=862), and depression scores improved at 6 months (SMD= 0.62; 95%CI: -0.93, -0.31; P=0.0001, 3 studies, n=377), when compared to controls. Furthermore, the meta-analyses supported various findings of the previous systematic reviews including that group-based education is more effective at improving HbA1c levels at six and 12 months, FBG at 12 months, body weight at 12 months, and diabetes knowledge at six and 12 months, than controls.

The review by Steinsbekk et al indicated that group-based interventions delivered by a single educator, delivered in less than ten months, with more than 12 hours and between six and ten sessions, appeared to give the best results,[47] whilst the results of the subgroup analyses completed for the Cochrane review indicated that interventions were equally effective when delivered in primary or secondary care by any health professional trained to deliver the program, that there was less evidence for the delivery of programs that were lay or peer led, and no evidence to suggest that larger groups (of 16 to 18 participants) do not reduce the effectiveness of interventions.[14] Furthermore, the Cochrane review was unable to detect whether programs were more successful if participants were able to invite a family member, friend or carer to the program.[14] The subgroup analysis of group-based education providers completed for the systematic review as part of this thesis, resulted in evidence suggesting that group-based education interventions facilitated by single disciplines, multidisciplinary teams or health professionals with peer supporters, result in improved outcomes in HbA1c when compared to peer-led interventions. The findings of the additional subgroup analyses resulted in differences between groups that did not reach statistical significance, however these results indicated that the group-based interventions conducted in primary care settings, that provide materials to participants, offer less than 10 sessions provided either in less than one month, or over seven to 12 months or 13 to 60 months, providing either eight hours or less or over 31 hours of contact time, include less than 20 participants in each group, and include individuals with HbA1c levels greater than 7% may be more efficacious than other group-based education programs.

Both of the previous systematic reviews noted that they were unable to identify the 'active ingredient/s' that influences the effectiveness of these complex interventions. The findings of the current systematic review, which included extensive subgroup analyses and was the first to incorporate a meta-regression, also suggested that other factors such as peer identification, normalisation, and group interactions may be the 'active ingredient/s' and as such, may substantially influence the effectiveness of group-based education interventions for the management of T2DM. A further valuable addition to the literature provided by the systematic review include the assessment of the completeness of reporting of the included studies using the TIDieR checklist which indicated that group-based education for the management of T2DM are poorly reported and often incomplete.

Table 7.2: Key outcomes of systematic review study compared with the outcomes of two previous systematic reviews examining the effectiveness of group-based versus individual self-management education or usual care for T2DM

Author/s	N studies (participants)	HbA1c (%)	FBG (mmol/L)	Body weight (kg)	Blood pressure (mmHg)	Blood lipids (mmol/L)	Diabetes knowledge
Deakin, McShane, Cade & Williams; 2005[14]	14 publications describing 11 studies n= 1532 (742 intervention participants)	Reduced at 4-6 mths* (MD=1.4; P<0.00001, 3 studies; n= 395); 12-14 mths* (MD=0.8; P<0.00001, 7 studies; n=1044); and 24 mths* (MD=1; p<0.00001, 2 studies; n=333)	Reduced at 12 mths* (MD=1.2; P<00001, 4 studies; n=641)	Reduced at 4-6 mths* (MD=2.1; P=0.11, 4 studies, n=566) and 12-14 mths* (MD=1.6; P=0.02, 5 studies; n=591)	Systolic BP reduced at 4-6 mths* (MD=5; P=0.01, 2 studies, n=399)	Total cholesterol reduced at 12-14 mths (MD=0.09; P=0.34, 3 studies, n=552); Triglyceride levels reduced at 4-6 mths (MD=0.24; P=0.09, 3 studies, n=628) and 12-14 mths (MD=0.14; P=0.31, 4 studies, n=652)	Improved at 12-14 mths* (SMD=1.0; P<0.00001, 3 studies; n=432)
Steinsbekk, Rygg, Lisulo, Rise & Fretheim; 2012[47]	26 publications describing 21 studies n=2833 (1454 intervention participants)	Reduced at 6 mths* (MD=0.44; P=0.001, 13 studies; n=1883); 12 mths* (MD=0.46; P=0.001, 11 studies; n=1503); and 24 mths* (MD=0.87; P<0.00001, 3 studies; n=397)	Reduced at 6 mths (MD=0.73; P=0.336, 3 studies, n=401) and 12 mths* (MD=1.26; P<0.00001, 5 studies; n=690)	Reduced at 6 mths (MD=2.08; P=0.239, 3 studies, n=433) and 12 mths* (MD=1.66; P=0.021, 4 studies; n=492)	Systolic BP reduced at 6 mths (MD=0.34; P=0.891, 5 studies, n=814) and 12 mths (MD=2.61; P=0.216, 2 studies, n=327); diastolic BP reduced at 6 mths (MD=0.46; P=0.627, 5 studies, n=814)	Total cholesterol reduced at 6 mths (MD=0.04; P=0.605, 7 studies, n=1161); Triglycerides reduced at 6 mths (MD=0.16; P=0.104, 7 studies, 1161 participants); HDL increased at 6 mths (MD=0.02; P=0.623, 6 studies, n=932) and LDL reduced at 6 mths (MD=0.05; P=0.528, 6 studies, n=932)	Improved at 6 mths* (SMD=0.69; P<0.00001, 6 studies; n=768) and 12 mths* (SMD=0.85; P<0.00001, 5 studies; n=955); and 24 mths* (SMD=1.59; P=0.03, 2 studies; n=355)

Author/s	N studies (participants)	HbA1c (%)	FBG (mmol/L)	Body weight (kg)	Blood pressure (mmHg)	Blood lipids (mmol/L)	Diabetes knowledge
Odgers-Jewell, Ball, Kelly, Reidlinger, Isenring & Thomas (in preparation)	53 publications describing 47 studies n = 8533 (4416 intervention participants)	Reduced at 6-10 mths* (MD= 0.31; P=0.0002, 30 studies, n=4107); 12-14 mths* (MD= 0.33; P<0.0001, 27 studies, n=4384); 18 mths* (MD= 0.72; P=0.009, 3 studies, n=194), 24 mths (MD=0.33; P=0.20, 8 studies, n=1106) and 36-48 mths* (MD= 0.93; P=0.002, 5 studies, n=1436)	Reduced at 6-10 mths (MD=0.24; P=0.51, 10 studies, n=915); 12-14 mths* (MD= 0.68; P=0.02, 8 studies, n=1436) and 24 mths (MD=0.10; P=0.89, 4 studies, n=413)	Reduced at 6-10 mths* (MD= 1.22; P=0.02, 17 studies, n=2513); 12-14 mths* (MD= 1.43; P<0.0001, 9 studies, n=1564) and 36-48 mths (MD=0.62; P-0.25, 4 studies, n=1319)	Systolic BP increased at 6-10 mths (MD=0.12; P=0.88, 17 studies, n=2577); and reduced at 12-14 mths (MD=0.49; P=0.49, 11 studies, n=2170), 24 mths (MD=0.68; P=0.78, 4 studies, n=528) and 36-48 mths (MD=1.71; P=0.41, 4 studies, n=1319); Diastolic BP reduced at 6-10 mths (MD=1.77; P=0.08, 17 studies, n=2696); 12-14 mths (MD=0.80; P=0.09, 11 studies, n=2170) and 36-48 mths (MD=1.31; P=0.16, 4 studies, n=1319); and increased at 24 mths (MD=1.21; P=0.45, 3 studies, n=191)	Total cholesterol reduced at 6-10 mths (MD=0.01; P=0.87, 15 studies, n=2270); 24 mths (MD=0.10; P=0.67, 3 studies, n=484) and 36-48 mths (MD=0.23; P=0.27, 3 studies, n=1275); and increased at 12-14 mths (MD=0.01; P=0.84, 9 studies, n=1819); Triglyceride levels reduced at 6-10 mths* (MD= 0.13; P=0.03, 14 studies, n=2150), 12-14 mths (MD=0.04; P=0.66, 11 studies, n=2114) and 24 mths* (MD= 0.32; P=0.01, 3 studies, n=237); HDL cholesterol increased at 6-10 mths (MD=0.16; P=0.22, 13 studies, n=1873), 12-14 mths (MD=0.02; P=0.28, 10 studies, n=1858) and 36-48 mths (MD=0.04; P=0.59, 3 studies, n=1275); LDL cholesterol reduced at 6-10 mths (MD=0.03; P=0.59, 12 studies, n=1131) and increased at 12-14 mths** (MD=0.08; P=0.04, 5 studies, n=731)	Improved at 6-10 mths* (SMD= 0.61; P=0.01, 7 studies, n=479) and 12- 14 mths* (SMD= 0.58; P=0.02, 7 studies, n=1291)

*Indicates measure reached statistical significance (P<0.05) in favour of group-based education;

**Indicates measure reached statistical significance (P<0.05) in favour of controls;

HbA1c= glycated haemoglobin; BP= blood pressure; FBG= fasting blood glucose; n =number; mths= months; yrs= years; N/A= not assessed.

The formative interview studies which explored the perceptions and opinions of group facilitators and participants of various group-based education programs for CDM, as well as group facilitators' experiences of developing and facilitating these programs, resulted in several findings which support the results of previous studies. Group facilitators highlighted group interactions, a non-didactic delivery style, a multidisciplinary team, and using practical activities, whilst group participants highlighted group interactions, the knowledge provided, and a goal-orientated, patient-centred approach to the program as attributes contributing to group program effectiveness. These findings support the results of previous research which indicate that group interactions, spousal, social or peer support can improve patient behaviour, health and psychological outcomes.[31, 173, 215-218] Additionally, previous research has shown that group interactions and peer identification can improve self-esteem and self-perception, reduce disease-related anxiety, and provoke a feeling of well-being,[49] and ongoing emotional support from peers can improve health and result in the maintenance of behavior change.[31] Knowledge has been established by previous studies as a prerequisite of behaviour change.[39]

A unique finding of the formative interview studies was that group facilitators were uncertain about the evidence base and theoretical development of their programs and very few were offered any formal training prior to facilitating group-education programs. Additionally, these studies found that the assessment measures used by the group facilitators to determine group outcomes were limited.

The feasibility study which utilized two process evaluation frameworks, the MRC Framework for Developing and Evaluating Complex Interventions and the RE-AIM framework, to develop and evaluate a patient-centred, patient-directed intervention, provides a practical example of the utilization of two frameworks in intervention design and evaluation. Health professionals and researchers can utilize the combination of these frameworks to enable the rigorous and comprehensive development and evaluation of intervention studies. Additionally, this study provided an example of the use of the TIDieR checklist[64] in intervention reporting, which has not previously been identified in group-based T2DM education research. The feasibility study supports the findings of previous studies which trialled a patient-directed approach to group-based

education for the management of T2DM, with the results indicated that the intervention was acceptable and resulted in modest improvements in health and psychosocial outcomes.[98, 99, 114]

The qualitative investigation of interview data obtained from the feasibility study utilized a novel hybrid deductive and inductive approach to thematic analysis based on a pre-selected, established psychological theory of motivation, SDT. [185, 186] This practical example may urge qualitative researchers to utilize a hybrid approach to thematic analysis which could strengthen qualitative studies. Furthermore, group-based education research in the area of T2DM has not previously applied SDT in the development, facilitation or evaluation of these programs. This results of this study indicated that using SDT in the development and facilitation of these programs may enhance participants' motivation for self-management. The results of the qualitative investigation supported the findings of previous studies: that knowledge seeking was a motivator for group-education program enrolment and attendance,[43] that group interactions can facilitate further learning and increase motivation,[49, 191] and highlighted the benefits of normalisation, peer identification and peer learning.[189, 191]

The final study, a survey of Australian dietitians, was the first study to date that explored the utilization of group-based education and the barriers to implementing group-based education for the management of T2DM in practice, as well as dietitians' preferences for practice and training. Previous research had suggested reasons for the underutilization of group-based education for the management of T2DM, however, comprehensive research which obtained the perceptions of current practising dietitians in Australia had not been completed. The results of this study both supported and opposed the suggestions by previous researchers. The results indicated that some previously suggested factors, such as a lack of access to multidisciplinary providers, the lack of a common national curriculum for T2DM group education programs, and APDs being unaware of the Medicare CDM group items, were not commonly reported by survey respondents. However, the previously suggested factors supported by the survey study results include service system issues, practitioner attitudes and preferences, a lack of cost effectiveness, the perception that group education programs are not viable, and a

lack of access to appropriate facilities.[60, 62, 151] Additionally, the survey study was the first to obtain Australian dietitians preferences for practice and training.

Recommendations for practice resulting from the completion of this thesis include:

1. Group-based education programs should be recommended for the management of T2DM as they have been shown to be more effective at improving various health outcomes including HbA1c, FBG, body weight, waist circumference, triglyceride levels, diabetes knowledge, depression scores and physical activity levels, than usual care, waiting list control or individual education. Group-based education could act as complementary to individual education, or could replace individual education for persons diagnosed with T2DM assessed as suitable to attend group-based education programs.

2. Group-based education interventions for the management of T2DM can be effective at improving health outcomes at any length, session number, number of contact hours, and number of participants per group as demonstrated by the subgroup analyses and meta-regression. However, despite no statistical differences between subgroups, when data were pooled, this research indicated that the characteristics of group-based interventions with greater improvements for HbA1c levels were those: conducted in primary care settings; that provide materials to participants; have less than 10 sessions provided either in less than one month, or over seven to 12 months or 13 to 60 months; provide either 8 hours or less or over 31 hours of contact time, include less than 20 participants in each group; and include individuals with HbA1c levels greater than 7%. Additionally, interviews with group participants indicated that individuals with T2DM may prefer programs that provide approximately eight hours of contact time over a six-week period.

3. Group-based education programs can be effective when facilitated by single disciplines, multidisciplinary teams or health professionals with peer supporters, however evidence suggests that peer-led interventions are less effective at improving HbA1c outcomes. As such, health professionals wanting to utilize peers in the facilitation of group-based education programs should be

encouraged to include peers as supporters of the program rather than solitary facilitators.

4. Health professionals should be encouraged to develop and facilitate group-based education programs which are patient-centred and non-didactic. Additionally, utilising a patient-directed approach can be effective and could reduce the time required to plan a group-based program.

5. The primary focus of the group facilitator should be to encourage group interactions and group discussions to allow group participants to benefit from peer identification and normalisation.

6. Health professionals should consider the combined use of the MRC and RE-AIM frameworks in the development of interventions to ensure a rigorous design process, and to enable the evaluation of all phases of the intervention, which will facilitate translation to other settings.

7. To enhance motivation for self-management, group-based education programs for the management of T2DM may benefit from the use of a theoretical basis such as SDT as a framework for intervention design.

8. Health professionals who lack experience, training or confidence in developing and/or facilitating group-based education programs should seek further training in the area, consider a mentoring partnership or request clinical supervision with a health professional experienced and trained in the area.

9. Group facilitators should obtain various measures of program and patient evaluation such as clinical, lifestyle and psychosocial as well as measures of acceptability or patient satisfaction.

10. Eligible health professionals in Australia should be encouraged to take advantage of the Medicare CDM group service items in order to provide group-based education programs to persons diagnosed with T2DM in their care.

Chapter 8: Discussion, Future research directions, and Conclusions

Preamble

The following chapter provides a discussion of key findings of the studies completed in order to meet the objectives and research questions of this PhD, including a systematic review with meta-analyses and meta-regression, formative interviews with the facilitators and participants of chronic disease management group-based education programs, a feasibility study, a qualitative analysis of interview data, and a survey of Australian dietitians on the utilization of group-based education programs for the management of T2DM. Additionally, future research directions and conclusions are provided.

8.1 Discussion

This thesis has resulted in several key findings. These include the potential importance and impact of group interactions, peer identification and normalisation in encouraging self-management in persons with T2DM, the potential for peer-supported interventions to improve group participants' health outcomes, and the acceptability of non-didactic, patient-centred and patient-directed interventions. The studies also identified potential barriers to group-based education such as recruitment challenges and adequate descriptions of effective interventions, the benefits of utilizing the TIDieR checklist in reporting interventions to increase usability and provide structure to planning, and the need for evidence-based practice guidelines for the management of persons with T2DM in a group-based setting to support clinicians in knowledge uptake.

Group-based education for T2DM is universally recommended, yet surprisingly the attributes for success have not been identified to date. Despite a robust and comprehensive systematic review with meta-analyses and meta-regression these attributes could not be conclusively identified. This may be due to the lack of consistent features and reporting of interventions used in previous research, which reduces the power of pooled data to produce meaningful recommendations. Based on the current evidence base, it would appear that any type of group-based education program can provide benefits above individual education, waiting list control and usual care regardless of any length, session number, number of contact hours, number of participants per group, and whether they include or exclude family, friends and carers. There is evidence, however that groups facilitated by qualified health professionals are more effective than those that are led by peers only, with single disciplines, multidisciplinary teams and health professional-led interventions with peer support proving effective.

The utilization of peer support was supported by both the systematic review and the formative interviews with group participants, which indicated that group participants valued the qualifications and knowledge of health professionals as well as the understanding, practical knowledge, and real-life experience of a peer diagnosed with diabetes. Peer support has been defined as "support from a person who has experiential

knowledge of a specific behavior or stressor and similar characteristics as the target population".[37] The WHO has recognized peer-support programs as a valuable and promising approach to diabetes education and management.[37] Peer support programs can be facilitated in a variety of formats, including as health professional facilitated programs which allow patients to share their experiences and obtain emotional support from each other, as peer coaches working one on one in an informal, flexible way with persons with T2DM, or as remote peer supporters, providing support via email, telephone or internet.[37]

The benefits of peer support include the establishment of a non-hierarchical, reciprocal relationship with the patient, and the ability to share knowledge, life experience and common illness experience which many health workers do not have.[37] Additionally, peer support is a low cost and flexible means of supplementing formal health care.[37] Peer supporters most often work in a way that is complementary to health workers, rather than replacing the role of health workers.[37] They support them by teaching problem solving skills, communication skills, decision-making skills, helping to access health care resources, providing guidance on planning for the future, understanding the principles of diabetes care, and managing the psychological responses to diabetes.[37] Peer support can enhance and complement other health care services, can provide role modeling and practical, emotional and ongoing support, and can assist patients to follow management plans, cope with the stressors of chronic disease, and remain motivated.[31, 145] Preliminary research suggests that the implementation of a peer coach or peer support person will improve long term health outcomes and enhance individuals ability to cope.[219, 220] Additionally, previous research has suggested that group participants perceive that regular group meetings with peers, or others in the same position as themselves, would increase their motivation to improve their self-management skills and behaviours, supporting the development of ongoing peer support interventions.[221]

A key issue highlighted by this thesis is the overall poor reporting of group-based education interventions in the literature. Recent T2DM education research has highlighted specific problems relating to research in the area which included: that interventions are not described in detail, education themes are not standardised, and the professional background of educators and their training are often unclear.[222] The poor or

incomplete reporting of interventions reduces the replicability of interventions, and may limit research in the area as researchers are spending time developing and piloting new interventions, rather than repeating previous interventions which have demonstrated effectiveness. Additionally, the poor reporting of interventions reduces researchers' ability to comprehensively explore the differences between interventions and the effects of intervention variables on outcomes. Potential reasons for the poor reporting of interventions include restrictive journal word limits,[147] copyright issues, and missing files.[148] However, approximately 75% of journals have now progressed to online or hybrid publishing in which authors can publish supplementary information in linked appendices and websites thereby reducing at least one potential reason.[64] The benefits of improved utilization of the TIDieR checklist,[64] an intervention reporting checklist and guide published in 2014, may include the improved replicability of interventions, enable clinicians to implement effective interventions because of the availability of adequate information and could streamline future research in the area.[64] The TIDieR checklist[64] was utilized in the development and reporting of the feasibility study completed as part of this thesis.

The results of the formative interviews, feasibility study and qualitative investigation provide important findings on effectiveness and acceptability of group-based education programs for the management of T2DM. A key strength of these studies was utilization of group participants, as obtaining the perspectives of individuals diagnosed with diabetes regarding group-based education can potentially result in data which is rich in human experience and reflects their real-life experiences.[181] This is confirmed by the findings of these studies which include the potential importance and impact of group interactions, peer identification and normalisation in encouraging improvements in persons with T2DM participating in group-based education programs, the potential for peer-supported interventions to improve group participants' health outcomes, and the acceptability of non-didactic, patient-centred and patient-directed interventions.

The thesis presents the use of an established psychological theory of motivation, SDT, which provides a unique framework for exploring motivators of group-based education participants. The results of this qualitative investigation are consistent with the findings of the formative interviews, supporting the use of patient-centred programs prioritising

group interactions over the didactic presentation of content. Furthermore, this investigation indicated that a patient-centred approach which focuses on encouraging group interactions may address the relevant psychological needs of individuals with T2DM, potentially improving their motivation and health behaviours. Group interactions or social support have long been established as a protective factor in health, with recognized improvements in health outcomes for various conditions such as depression, cancer, post-myocardial infarctions and strokes.[31] Studies have evaluated the effect of group interactions and spousal or peer support in various health contexts and have found that patients who had perceived support from their peers, spouse or the group generally had better health and psychological outcomes than those who did not.[31, 215-218] Providing social support to individuals with T2DM has been shown to positively affect patient behaviour,[173] and research has shown that group interactions and peer identification can improve self-esteem and self-perception, reduce disease-related anxiety, and provoke a feeling of well-being despite a persons' diagnosis or condition.[49] Ongoing emotional support from peers has been shown to improve health and result in sustained behavior change.[31] Additionally, seeing friends frequently, having a well-functioning social network and perceiving adequate social support from a social network has been associated with high patient activation levels, reduced diabetes related emotional distress and improvements in health-promoting self-management behaviours.[223]

Feelings of relatedness (feeling understood, respected and cared for by others)[8, 9] can be experienced through group interactions. Group interactions and peer identification have been shown to improve participants' self-esteem, self-perception and self-efficacy, and to promote awareness, empowerment, and positive attitudes towards diabetes.[49] Social support provided by strangers, has been linked to improvements in self-management, psychological functioning and biomedical outcomes,[191] and identified as a clinically relevant factor on the pathway to glycaemic control for persons with T2DM.[192] A clear advantage of group-based education for the management of T2DM is the impact of relatedness,[185] which unlike individual education, provides direct opportunities for participants to learn from peers, to be supported by peers, to experience normalisation, to socialise and to perceive that they have assisted others. Relatedness appears to impact the motivation of individuals in the group, which aligns with the premise of the SDT that relatedness is one of the psychological needs that is the basis of self-motivation.[8,

[185] Evidence suggests that meeting the innate needs identified by SDT can motivate individuals to initiate and maintain health behaviours over the long term.[8, 182] Peers in a group situation can offer knowledge, practical skills, personal competence, emotional support, and provide encouragement beyond the capacity of some health professionals.[189] Previous research has indicated that individuals identify with peers as role models[224] and desire to share their experiences with other group participants.[181] Additionally, individuals diagnosed with chronic diseases often use downwards comparison,[225] and have reported perceiving that contact with others in the same situation or considered as being worse off helps to reduce insecurity and enhance self-care.[226] The findings of the qualitative investigation additionally indicated that group participants compared themselves with others and were motivated to improve their own self-care through this peer identification and normalisation.

An interesting finding of the feasibility study and subsequent qualitative investigation was the benefit of including individuals with varying durations of diagnosis, rather than focusing on primarily on newly diagnosed persons. Group-based interventions have been criticized for focusing predominantly on newly diagnosed individuals with diabetes, potentially missing a vast number of people requiring self-management education.[24] The provision of diabetes self-management education which does not focus only on newly diagnosed individuals is supported by the latest joint position statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics, which notes that there are four critical times to provide diabetes education and support: 1. With a new diagnosis of T2DM, 2. Annually for health maintenance and to prevent complications, 3. When new complicating factors influence self-management, and 4. When transitions in care occur.[227] Furthermore, the qualitative study indicated that newly diagnosed participants' interview responses were more likely to indicate 'amotivation' or a perceived lack of intention to act in order to improve their health and self-management, than individuals who had been diagnosed for longer periods of time. Previous research has reported that some individuals newly diagnosed with T2DM lack the intention to manage their condition,[43, 194] and tend to only take ownership of their diabetes or seek knowledge once they have reached a degree of acceptance of their disease.[195] The results suggest that it may be helpful to include more experienced peers in group-based education

programs to improve the knowledge and competence of newly diagnosed T2DM patients and to improve their motivation.

The provision of non-didactic education was supported by the formative interviews, feasibility study and qualitative investigation. Additionally, the superiority of non-didactic compared with didactic education techniques has been established by previous level I and II[214] group education research.[14, 91] Evidence supports the use of a patient-centred approach, care that is respectful of, and responsive to, individuals' preferences, needs and values, and has shown that engaging individuals in their health care decisions can enhance their motivation and adherence to recommendations.[146] Patient-centred interventions focus on eliciting emotions, perceptions and knowledge through active and reflective listening, supporting self-efficacy, exploring the desire to learn or make changes to self-management.[228] Utilizing a patient-centred approach can enable patients to better explore options, choose their own pathway to self-management, and feel empowered by their decisions.[229, 230] Within T2DM management, patient-centred interventions have been effective in improving knowledge, blood glucose levels, weight, and medication usage, and have been shown to improve self-management behaviours.[98, 99]

A patient-directed approach, in which the content of the program is decided by the participants, therefore reflecting participants' own needs and questions, and encouraging discussions initiated by individuals in the group.[98, 114] The intervention developed and evaluated for the feasibility study utilized a patient-directed approach, despite the systematic review indicating that facilitator-directed interventions may be more effective than patient-directed interventions at improving HbA1c. The subgroup analysis comparing patient-directed and facilitator-directed approaches to group-based education for the management of T2DM was underpowered, and did not meet statistical significance. Furthermore, a patient-directed approach to group-based education has been successfully utilized by various group-based education studies for the management of T2DM.[98, 114] Previous research has highlighted that most content of group-based education programs are decided by group facilitators rather than participants, which may result in a focus on the facilitators' perception of what is important, potentially neglecting areas which are important to participants experiences and learning.[226] The

enhanced effectiveness of patient-directed and patient-centred interventions may be considered through the lens of the SDT, which suggests that improving individuals' competence by encouraging relatedness and the feeling of autonomy improves motivation and health behaviours.[9, 185] Additionally, studies have shown that treating individuals as autonomous and equal contributes to patient satisfaction. [45]

Research describing the implementation of an empowerment-based diabetes self-management education program published by Funnell et al in 2005 indicated that health professionals facilitating patient-directed interventions require flexibility, confidence and excellent group facilitation skills to ensure that they are able to respond to questions from participants, misinformation provided by group members, and to ensure that patients have equal opportunities to speak and have questions answered.[193] Facilitating a patient-directed approach may concern health professionals new or inexperienced in the area of group-based education as they may perceive that they are underprepared, feel uncomfortable with discussions of emotional issues, or may be nervous about not being able to answer participants questions.[193] The survey of Australian dietitians supported these findings, indicating that those currently facilitating group-based education programs felt more confident to facilitate patient-directed interventions than those not currently facilitating groups. Finally, the researchers found that a patient-directed approach to group-based education was very rewarding with participants paying close attention to the information provided, being motivated as they had self-selected changes to their own self-management, attendance at group sessions was high, and participants were able to discuss their experiences, concerns and questions which resulted in lively and relevant sessions.[193]

Numerous barriers to the development and facilitation of group-based education programs for the management of T2DM have been identified over the course of this PhD research, including the difficulties of recruiting participants using GP's as the primary recruitment strategy, the high attrition rates of group-education programs, the lack of training of group facilitators, and the lack of evidence-based practice guidelines for the group-based management of individuals with T2DM in Australia. Despite the vital role GP's have in the management of persons with T2DM in the primary health care setting, engaging GPs and recruiting participants through GPs is difficult.

Research suggests that GP's or physician's recommendations to their patients are central factors in the patients' health care decisions.[231] However, a recent survey study found that physician's do not see themselves as responsible for patients lack of interest in diabetes education and generally perceive that educator-delivered diabetes self-management education is effective.[232] Diabetes educators maintain that a key to encouraging patients attendance to diabetes education programs is encouragement by the patients physician.[232]

Barriers to recruitment through GPs identified in previous research include time and workload pressures,[162, 163] negative attitudes towards research, concerns about researchers' motives, a lack of interest in the topic of research, and a lack of recognition.[164] In addition, GPs have may feel overwhelmed with requests for research participation, desiring a greater involvement in the study, or being concerned about the potential lack of effectiveness of a new trial that would not be an ongoing addition to the health care system.[166] Monetary and nonmonetary incentives, endorsement by relevant authorities, and multiple reminder contacts with GPs have been shown to boost research response rates.[165]

Furthermore, group-based programs for the management of T2DM are often hindered with poor uptake by potential participants as well as high attrition rates.[161, 167-169] Recent research indicated that the three key reasons for non-attendance of group-programs as reported by individuals with T2DM were the lack of information or perceived benefit of the programs, unmet personal preferences such as poor timing or accessibility of group locations, and the shame and stigma of diabetes.[170] Health professionals should consider the way in which they communicate with persons with T2DM in regards to group-education programs, the optimal timing and location of group programs, and should focus on recruitment methods that minimise any health-related stigma around T2DM.[170]

The recently published joint position statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics: 'Diabetes Self-Management Education and Support in Type 2 Diabetes' noted that despite the proven benefits and general acceptance of group-based education programs for the management of T2DM, the number of patients that are referred to and

receive education is small.[227] Furthermore, the researchers identified that the low utilization of group-based education programs in the United States had resulted in many of these programs ceasing and highlights the current referral requirements and reimbursement model as key factors limiting practice.[227] Research has additionally indicated that even when group-based education programs are operating at peak service, they are often not financially viable which can encourage facilitators to eliminate programs despite their broader influence on reducing costs and improving health outcomes.[233] These findings may indicate that the poor uptake or utilization of group-based education for T2DM does not only affect individuals diagnosed with T2DM in Australia, but rather that this may be a worldwide issue. Group-based education interventions for the management of T2DM are complex interventions which should be tested using feasibility studies which allow researchers to test the interventions feasibility in practice and assess their acceptability prior to completing full scale studies which may potentially be plagued by poor recruitment, attendance, or other systemic issues.[171] The formative literature review and systematic review indicated that few group-based interventions undergo feasibility or pilot testing prior to the commencement of trials. The dissemination of findings from feasibility studies could contribute to health practitioners' knowledge by furthering an understanding of the methodological and practical challenges of developing and implementing intervention studies in a 'real-world' setting, and may highlight outcome measures which are suitable for the evaluation of intervention effectiveness.[152]

The formative interviews and survey of Australian dietitians highlighted the poor training of health professionals in the area of group-based education for the management of T2DM. Additionally, despite most (72%) of the studies included in the systematic review mentioning the training of group facilitators prior to the facilitation of interventions, the assessment of these studies using the TIDieR checklist[64] found that less than half (47%) of the publications did not adequately describe the training of facilitators, with many authors simply stating that facilitators were trained. Group facilitators establish the tone, guide the group they are facilitating, and can have considerable influence on participant outcomes.[190] Previous research has found that being comfortable in the role of facilitation appears to be the result of an amalgamation of personal and professional experiences, and requires advanced diabetes knowledge, as well as an awareness of, and the ability to manage, various aspects of group

processes.[190] Support from group facilitators can enhance the development of self-management skills in persons with T2DM,[234-236] with several researchers suggesting that support from group facilitators can influence an individuals' motivation to self-manage their condition.[237, 238]

Facilitating group-based education programs without training could lead to health professionals being underprepared, lacking confidence, or reducing program effectiveness. Furthermore, it is likely that if less health professionals are facilitating group-based education programs, and are not trained, competent or confident in the area, this may affect the training opportunities for student dietitians. This may result in inadequate development of facilitations skills and ultimately a prolonged reduction in confidence in facilitating group-education programs within the future dietetic workforce in Australia. The training of health professionals in the specialized area of diabetes education has been identified by the International Diabetes Federation (IDF) as necessary to provide health professionals with the advanced level of knowledge and competence required to effectively facilitate group-based education programs for the management of T2DM.[202] Research has additionally indicated that group facilitators require continuing education to develop and maintain their skills in the area.[190]

Finally, the lack of evidence-based practice guidelines for the group-based management of persons with T2DM by Australian health professionals is likely to reduce the utilization of these groups. Furthermore, this lack of guidelines may result in wide variations in the group-based education programs offered to people with T2DM, health professionals having difficulty interpreting the evidence and translating group-based education studies into a practice setting, and could deter health professionals from developing or facilitating group-based education programs. The development of evidence-based practice guidelines for the group-based management of individuals with T2DM by Australian dietitians could improve the utilization of group-based education in Australia. The results of this series of studies, primarily the systematic review with meta-analyses and meta-regression, could inform the development of evidence-based practice guidelines which may be best achieved through collaboration between Medicare Australia, Diabetes Australia and the Dietitians Association of Australia.

8.2 Future Research Directions

The results of these series of studies provide directions for future research. Future systematic reviews in the area of group-based education for the management of T2DM should assess both the effectiveness and the maintenance of improvements in various measures after the completion of interventions. Additionally, there is currently limited evidence for individual education approaches. Before group-based education is considered superior, an updated systematic review in the area of individual education should be completed. Research in the area of group-based education for the management of chronic diseases such as T2DM should further explore the influence of group interactions through qualitative research or questionnaires on social support networks, on the health outcomes and motivation of individuals with chronic disease. Furthermore, future group-based education intervention studies should explore the benefits of the use of SDT as a framework for intervention design to enhance participant motivation.

Feasibility testing of interventions may additionally improve participant recruitment, reduce attrition, reduce systemic issues and establish the acceptability of interventions prior to the commencement of full-scale studies. The development and evaluation of group-based interventions can be improved with the combined use of the MRC and RE-AIM frameworks to ensure a rigorous design process, and to enable the comprehensive evaluation of the intervention and improve intervention translation. Research in this area should consider the acceptability of these interventions by exploring the perceptions and opinions of group participants, rather than relying solely on intervention outcomes, which may increase patient satisfaction and motivation. Future research should trial alternative recruitment strategies, including the use of specialist clinics, such as diabetes outpatient clinics, which utilize electronic health records enabling the identification and monitoring of participants,[161] should involve participants in trial design,[174] use shorter and more informative recruitment flyers,[175] and provide monetary incentives to participants.[176] Additionally, future research should consider the participants health beliefs, cultural needs, current knowledge, physical limitations, emotional concerns, family support, financial status, medical history, health literacy,

numeracy, and other factors that influence each person's ability to meet the challenges of self-management.[227]

The cost effectiveness of delivering group-based versus individual education to persons with T2DM in a practice setting should be explored in Australia taking into account the Medicare CDM items. The Medicare CDM group items should be reviewed in order to determine whether the rebates provided can result in a financially viable group-based education program for the management of T2DM. Further research into the barriers identified by health professionals to the development and facilitation of group-based education programs for the management of T2DM should be completed. Additionally, the development of evidence-based practice guidelines for the group-based management of individuals with T2DM by Australian dietitians, which may be informed by the results of this research, should be a primary focus of the DAA, Medicare and Diabetes Australia as key stakeholder organizations.

Finally, future group-based intervention studies should design and publish their results using the TIDieR checklist in order to ensure the completeness of reporting and replicability of interventions.

The completion of further research in these areas could greatly improve group-based education programs in practice and would have significant impacts on the management of chronic diseases such as T2DM worldwide.

8.3 Conclusions

The results of the studies completed for this thesis indicate that group-based education programs may be more effective at improving HbA1c, FBG, body weight, waist circumference, triglyceride levels, diabetes knowledge, depression scores and physical activity levels, than usual care, waiting list control or the individual management of persons with T2DM at various time points. The analyses found no statistically significant effect for group-based interventions when measuring BMI, blood pressure, total or HDL cholesterol, QOL or energy intake at short or long term measures. The results of the meta-analyses should be interpreted with caution as the risk of bias of the majority of included studies was moderate or high, many of the meta-analyses resulted in significant heterogeneity. This significant heterogeneity was however explored through sensitivity analyses, subgroup analyses and the meta-regression, and was expected as group-based education interventions are complex interventions.

The length, session number, number of contact hours, number of participants per group, the provision of materials to participants, and the inclusion or exclusion family, friends and carers, did not account for the variations between group-based education studies for the management of T2DM. The 'active ingredient/s' of group-based interventions were not able to be identified despite the completion of rigorous and comprehensive research, which may indicate that other factors such as peer identification, normalisation, and group interactions substantially influence the effectiveness of group-based education interventions for the management of T2DM. Both the formative interviews and the qualitative analysis of interview data studies supported this suggestion, with group participants perceiving that group interactions, normalisation and peer identification facilitated learning and increased motivation. Furthermore, the results of these studies support the use of patient-centred programs, which focus on group interactions rather than the didactic presentation of content.

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Appendices

Appendix A: Search Strategy for PubMed

Pubmed

"Patient Education as Topic"[Mesh] OR "Self Care"[Mesh] OR "Behavior Therapy"[Mesh] OR "Group Processes"[Mesh] OR "Psychotherapy, Group"[Mesh] OR "Self-Help Groups"[Mesh] OR Patient education[tiab] or Self care[tiab] OR Self-care[tiab] OR Self management[tiab] OR Self-management[tiab] OR Behavior therapy[tiab] OR Behaviour therapy[tiab] OR Group process[tiab] OR Group processes[tiab] OR Group psychotherapy[tiab]

AND

"Diabetes Mellitus, Type 2"[Mesh] OR MODY[tiab] OR NIDDM[tiab] OR T2DM[tiab] OR ((non insulin[tiab] OR noninsulin[tiab] OR “Type 2”[tiab] OR “Type II”[tiab] OR Ketosis-Resistant[tiab] OR Ketosis resistant[tiab] OR Maturity-Onset[tiab] OR Maturity onset[tiab] OR Mature-onset[tiab] OR Mature onset[tiab] OR Adult-onset[tiab] OR Adult onset[tiab] OR Slow-onset[tiab] OR Slow onset[tiab] OR Stable[tiab]) AND Diabetes)

AND

Group[tiab] OR Groups[tiab]

NOT

"Diabetes Insipidus"[Mesh] OR Diabetes Insipidus[tiab]

AND

randomized controlled trial[Publication Type] OR controlled clinical trial[Publication Type] OR randomized[Title/Abstract] OR randomised[Title/Abstract] OR placebo[Title/Abstract] OR "drug therapy"[MeSH Terms] OR randomly[Title/Abstract] OR trial[Title/Abstract] OR groups[Title/Abstract]

Appendix B: Sensitivity analysis forest plots

Figure B1: Forest plot- Sensitivity analysis: overall risk of bias

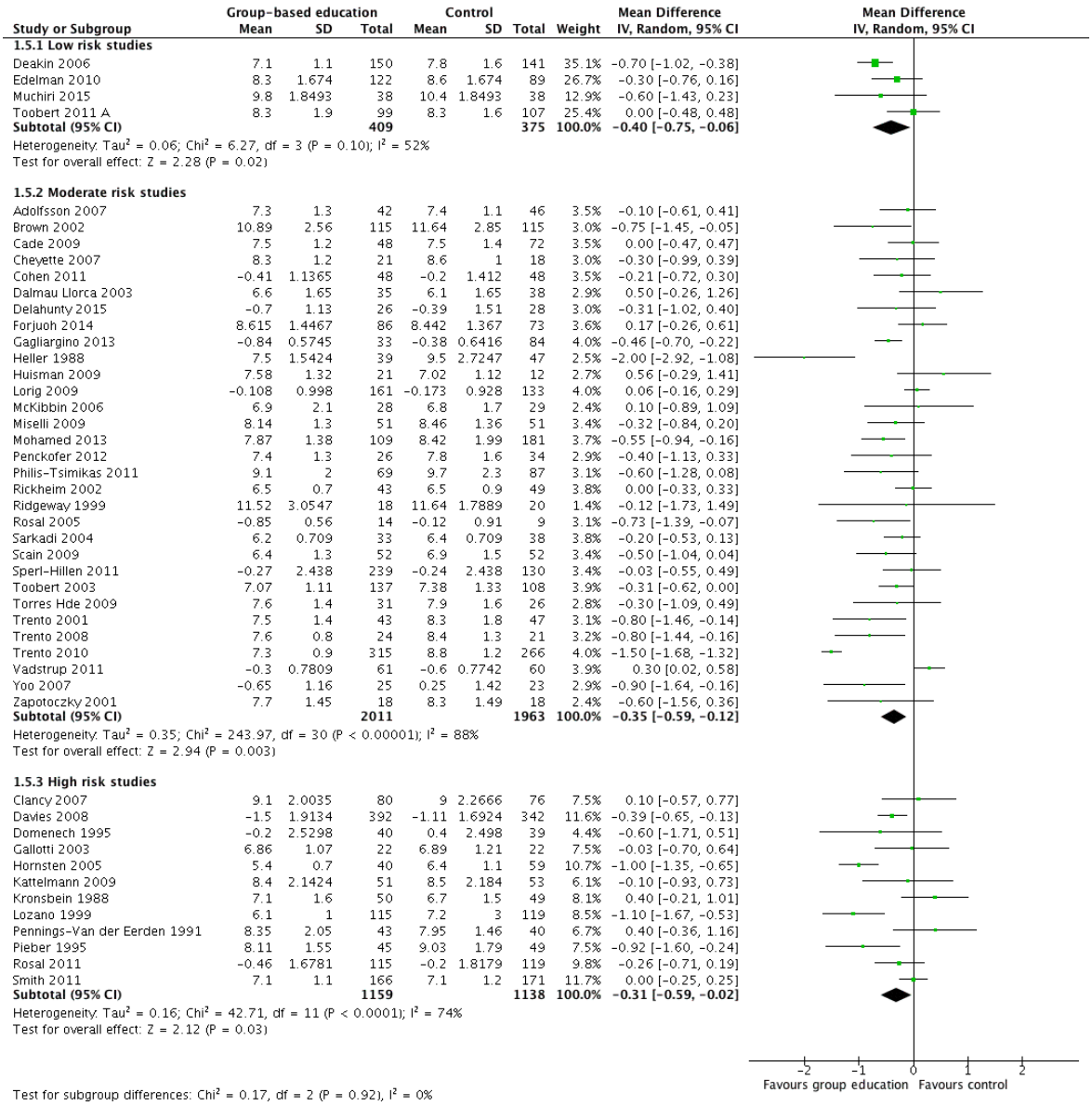


Figure B2: Forest plot- Sensitivity analysis: reporting bias

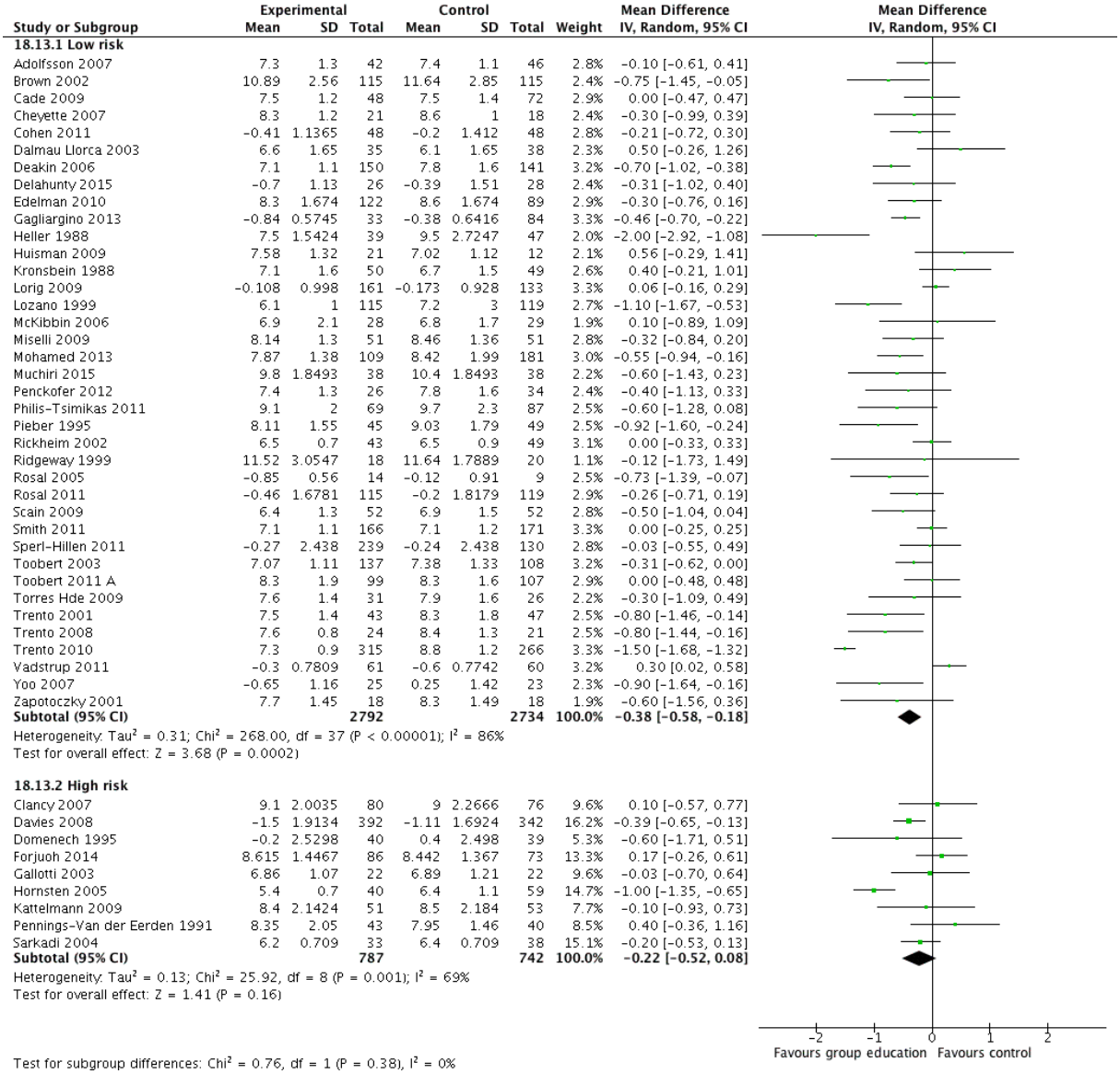


Figure B3: Forest plot- Sensitivity analysis: baseline differences

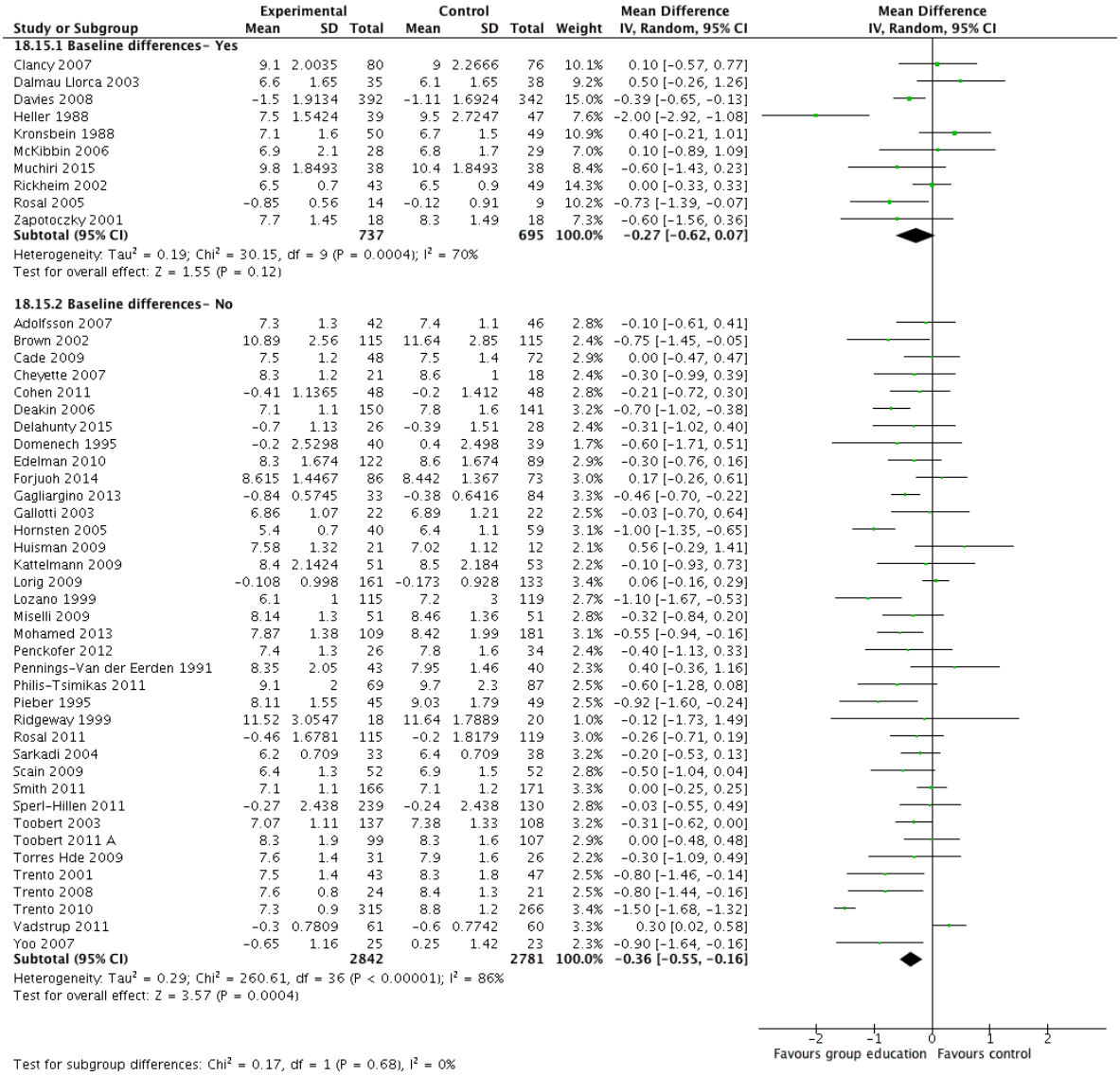


Figure B4: Forest plot- Sensitivity analysis: attrition

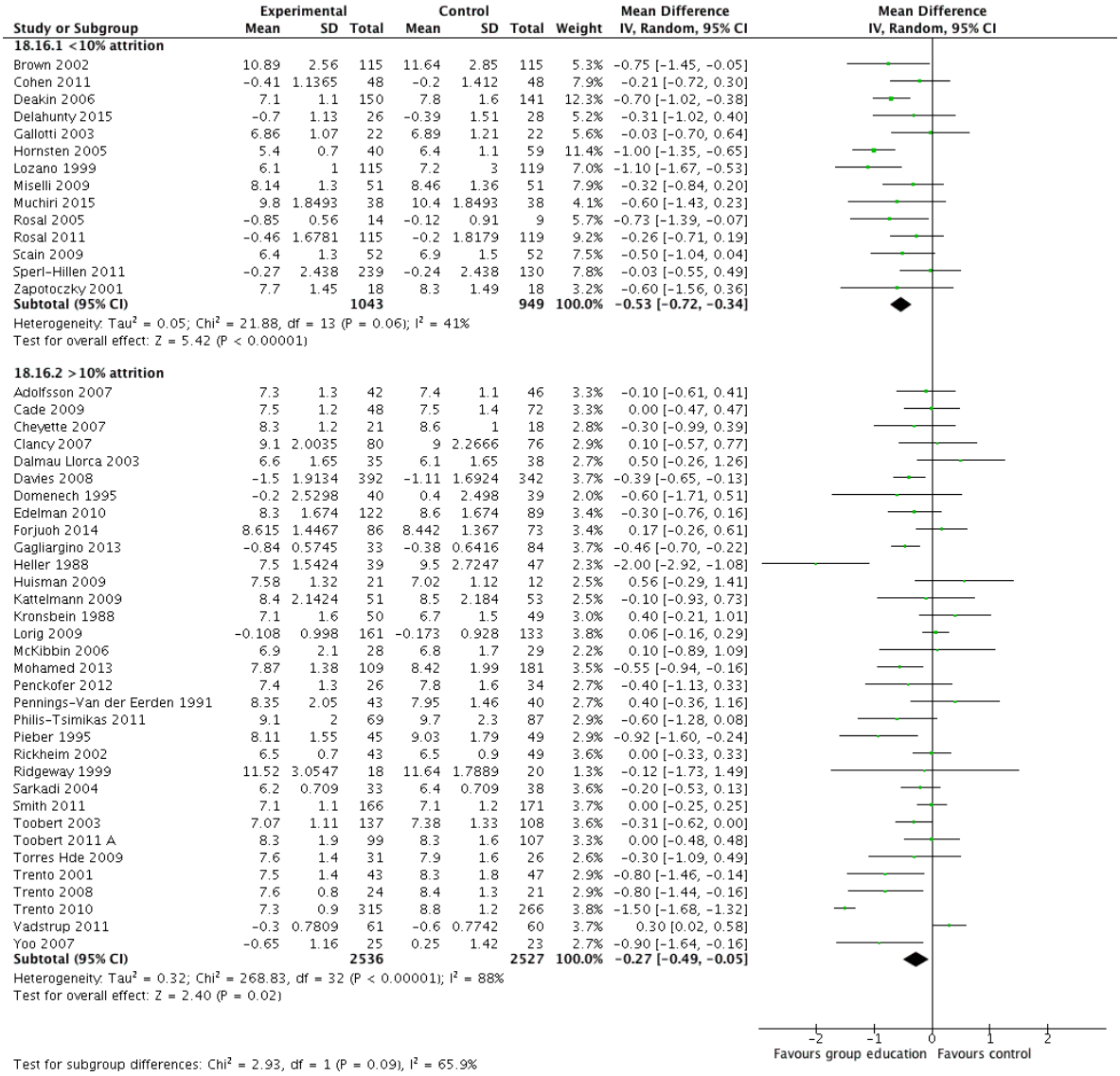
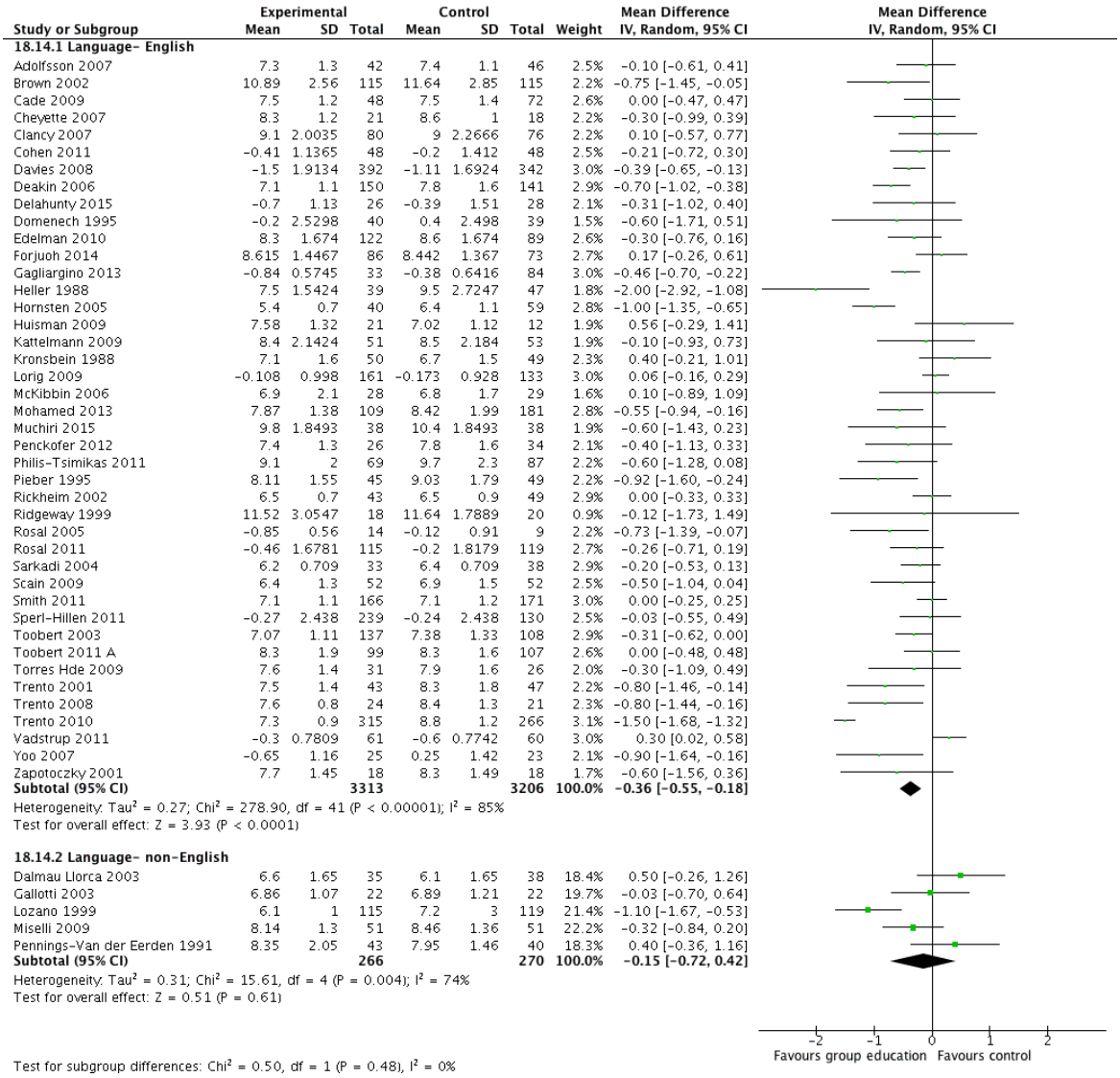


Figure B5: Forest plot- Sensitivity analysis: language of publication



Appendix C: TIDieR checklist results for included publications (N=53)

Author, Year	1. Brief name	2. Why: Rationale/ Theory/ Goal	3. Materials	4. Procedures	5a. Provider/s	5b. Training	6. Program delivery	7. Location/s	8. Contact time/ session description	9. Tailoring	10. Modifications	11 & 12. Adherence
Adolfsson, 2007	No	Yes	No	Yes	Yes	Yes	No	No	No	No	No	Yes
Brown, 2002	Yes	No	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No
Cade, 2009	Yes	No	No	Yes	Yes	Yes	No	No	No	No	No	No
Cheyette, 2007	Yes	No	No	Yes	Yes	No	No	No	Yes	No	No	No
Clancy, 2007	No	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Cohen, 2011	Yes	No	No	Yes	Yes	No	No	No	Yes	Yes	No	No
Dalmau Llorca, 2003	No	No	No	Yes	Yes	No	No	No	No	No	No	No
Davies, 2008	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	No	No	No
Deakin, 2006	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No	No
Delahanty, 2015	Yes	No	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes
Domenech, 1995	No	No	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No
Edelman, 2010	No	No	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No
Forjuoh, 2014	Yes	No	No	Yes	Yes	No	No	No	Yes	No	No	No
Gagliardino,2013	Yes	No	No	Yes	Yes	Yes	No	No	Yes	No	No	No
Gallotti, 2003	No	No	No	Yes	Yes	No	No	No	Yes	No	No	No
Heller, 1988	No	No	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No
Hornsten, 2005	No	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No
Hornsten, 2008	No	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No
Huisman, 2009	No	Yes	No	Yes	Yes	No	No	No	Yes	Yes	No	No
Kattelmann, 2009	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No

Author, Year	1. Brief name	2. Why: Rationale/ Theory/ Goal	3. Materials	4. Procedures	5a. Provider/s	5b. Training	6. Program delivery	7. Location/s	8. Contact time/ session description	9. Tailoring	10. Modifications	11 & 12. Adherence
Khunti, 2012	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes	No	No	No
Kronsbein, 1988	Yes	No	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No
Lorig, 2009	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes
Lozano, 1999	No	No	No	Yes	Yes	No	No	No	Yes	No	No	No
McKibbin, 2006	Yes	Yes	No	Yes	No	No	No	No	No	No	No	No
Miselli, 2009	Yes	No	No	Yes	Yes	No	No	No	Yes	Yes	No	No
Mohamed, 2013	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes
Muchiri, 2015	No	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No
Penckofer, 2012	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes
Pennings-Van der Eerden, 1991	No	No	No	Yes	Yes	No	No	No	Yes	No	No	No
Philis-Tsimikas, 2011	Yes	No	No	Yes	Yes	Yes	No	No	Yes	No	No	Yes
Pieber, 1995	Yes	No	No	Yes	Yes	Yes	No	No	Yes	Yes	No	No
Rickheim, 2002	No	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	No
Ridgeway 1999	No	No	No	Yes	Yes	No	No	No	No	Yes	No	No
Rosal, 2005	No	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes
Rosal, 2011	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes
Sarkadi, 2004	No	No	No	Yes	Yes	Yes	No	No	Yes	Yes	No	No
Scain, 2009	No	No	No	Yes	Yes	Yes	No	No	Yes	No	No	No
Smith, 2011	No	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Sperl-Hillen, 2011	No	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No
Sperl-Hillen, 2013	No	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No

Author, Year	1. Brief name	2. Why: Rationale/ Theory/ Goal	3. Materials	4. Procedures	5a. Provider/s	5b. Training	6. Program delivery	7. Location/s	8. Contact time/ session description	9. Tailoring	10. Modifications	11 & 12. Adherence
Toobert, 2003	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No
Toobert, 2011A	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No
Toobert, 2011B	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No
Torres Hde, 2009	No	Yes	No	Yes	Yes	No	No	No	Yes	No	No	No
Trento, 2001	No	Yes	No	Yes	Yes	No	Yes	No	Yes	Yes	No	No
Trento, 2002	No	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No
Trento, 2004	No	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No
Trento, 2008	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No
Trento, 2010	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No
Vadstrup, 2011	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	Yes	No
Yoo, 2007	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	Yes	No
Zapotoczky, 2001	No	Yes	No	Yes	Yes	No	No	No	No	No	No	No

Key: Text in red indicates the information was obtained from other publications, email responses from the authors or in clinical trials registrations.

Appendix D: Formative Literature Review

Preamble

This appendix provides an analysis of the current group-based education intervention literature. A formative literature review on group-based education interventions for the management of T2DM has been performed in order to explore the effectiveness of group-based education programs as well as the characteristics of studies and interventions in the literature. This appendix is structured in accordance with the National Health and Medical Research Council's (NHMRC) levels of evidence hierarchy, which provides a framework for the appraisal, classification and grading of evidence.[214] Therefore, the appendix will commence with an analysis of the systematic reviews published in this area, then will explore the randomized controlled trials (RCTs), and finally the comparative or case series studies.[214]

Search Strategy

An online literature search was conducted via databases including Web of Science, Pub Med, CINAHL and Science Direct. The literature search was for all English-language papers published between 2000 and 2014 using the following search terms: chronic disease, chronic disease management, type 2 diabetes mellitus, type 2 diabetes, diabetes mellitus, type 2 diabetes education, patient education, self-management, group programs, lifestyle modification programs, group interactions, group-based intervention, self-management education, group-based education and group dynamics.

Inclusion Criteria

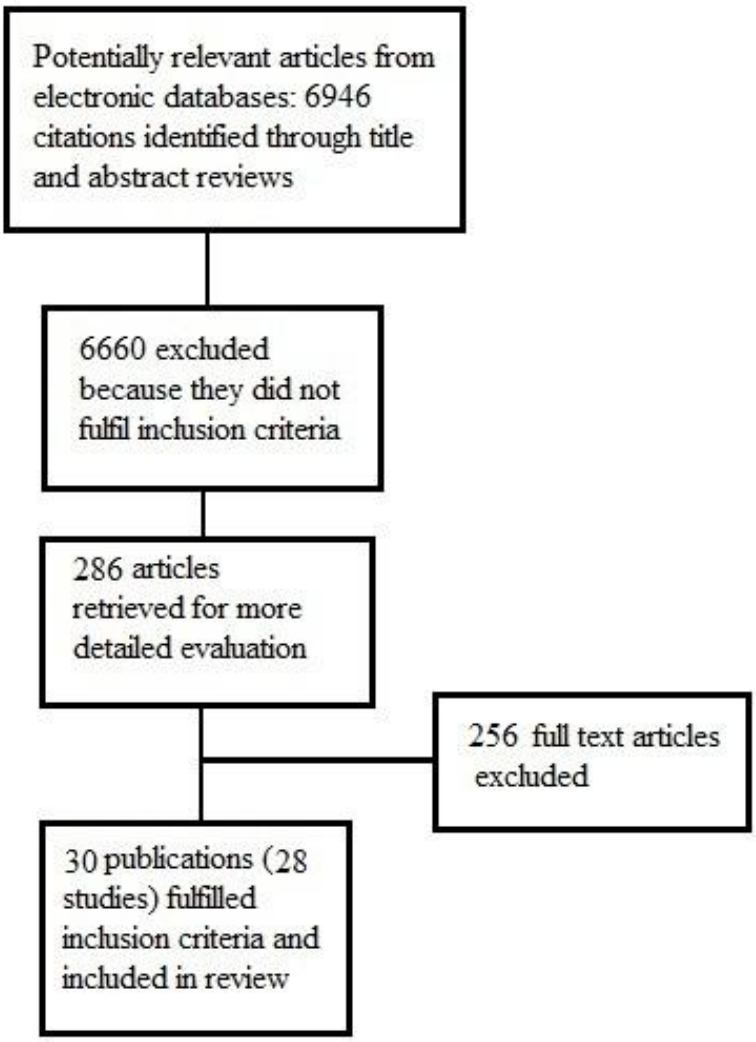
Studies included in the formative literature review were those which provided care to a group of individuals who had been diagnosed with T2DM. Studies were included if the study participants were over eighteen years of age, participants had been diagnosed with T2DM, if the participants were offered a minimum of three contact hours and one group-based session, and if the number of participants in each group was four or more. Abstract-only papers were excluded due to the limited amount of information and methodological detail provided. Additionally, studies that were not published in English were excluded. All published guidelines relating to the education and management of T2DM patients were also included in the review, as were systematic reviews of the current literature, if relevant to the search terms and meeting the inclusion criteria.

Study Identification

The stages of study identification are shown in figure D1. Electronic searches identified 6946 citations. Title and abstract screening was completed by the PhD candidate. Of the 6946 publications, 6660 were excluded, as they did not fulfill the inclusion criteria. Full text screening was completed for the remaining 286 publications. Finally, 30 publications describing 28 studies were included in the formative literature review. The reasons for the exclusion of the 256 studies included being foreign language papers, lacking a control group, including individuals that had not been diagnosed with T2DM or individuals with type 1 diabetes, poor reporting of pre-specified outcomes, or using individual care rather only than group-based interventions.

Two systematic reviews were included in this study which reviewed group-based interventions published between 1988 and 2007. Following the search and study selection, the included studies were reviewed in order to explore the effectiveness of group-based education programs versus usual care or individual interventions, as well as the characteristics of studies and interventions in the literature.

Figure D1: Stages of study identification



Systematic Reviews of Group-Based Education Interventions

Introduction

Two systematic reviews have been assessed for the purpose of this formative literature review. Systematic reviews provide the highest level evidence (level I), making the results more reliable than studies providing lower level evidence. The two systematic reviews discussed in this section include a Cochrane Review published by Deakin and colleagues in 2009, and a systematic review by Steinsbekk and colleagues published in 2012.[14, 47] The systematic reviews are summarized in Table D1 and discussed in the following section.

Results

A Cochrane Review published in 2005 by Deakin et al assessed 14 publications describing 11 studies, which involved a total of 1532 participants published between 1988 and 2002.[14] The objective of this review was to assess the effects of group-based, patient-centred training on clinical, lifestyle and psychosocial outcomes in people with T2DM.[14] The included studies were either RCTs or controlled clinical trials which compared group-based education programs for adults with T2DM with routine treatment, waiting list control or no intervention.[14] The researchers only included studies with a follow up of at least 6 months, and interventions which consisted of at least one group education session, with a minimum of six participants.[14] Of the 11 studies included in this systematic review, six have been included in this formative literature review, with the remaining five having been excluded as they did not meet the predefined date restriction (2000-2014).

Table D1: An overview of two systematic reviews assessing the effectiveness of group-based interventions for the management of T2DM

Author/s	**N: studies and participants**	**Outcome Measures**	**Results**
Deakin, McShane, Cade & Williams; 2009[14]	14 publications describing 11 studies n= 1532 (742 intervention participants)	HbA1c; reduction in diabetes medication; FBG; BP; diabetes knowledge; mortality; body weight; total cholesterol; and TG	HbA1c: Reduced at 4-6 mths (3 studies; 395 participants; p<0.001); 12-14 mths (7 studies; 1044 participants; p<0.001); and 2 yrs (2 studies; 333 participants; p<0.001); FBG: Reduced at 12 mths (4 studies; 641 participants; p<0.001); Diabetes knowledge: Improved at 12-14 mths (3 studies; 432 participants; p<0.001); Body weight: Reduced at 12-14 mths (5 studies; 591 participants; p=0.02); BP: Reduced systolic BP at 4-6 mths (2 studies; 399 participants; p=0.01); Need for diabetes medications: Reduced at 12-14 mths (5 studies; 654 participants; p<0.001)
Steinsbekk, Rygg, Lisulo, Rise & Fretheim; 2012[47]	26 publications describing 21 studies n=2833 (1454 intervention participants)	HbA1c; FBG; diabetes knowledge; self-management skills; QOL; self-efficacy/ empowerment; weight; BMI; BP; total cholesterol; LDL; HDL; TG; treatment satisfaction; and death.	HbA1c: Reduced at 6 mths (13 studies; 1883 participants; p=0.0006); 12 mths (11 studies; 1503 participants; p=0.001); and 2 yrs (3 studies; 397 participants; p<0.001); FBG: Reduced at 12 mths (5 studies; 690 participants; p<0.001); Diabetes knowledge: Improved at 6 mths (6 studies; 768 participants; p=0.00001); 12 mths (5 studies; 955 participants; p<0.001); and 2 yrs (2 studies; 355 participants; p=0.03); Body weight: Reduced at 12 mths (4 studies; 492 participants; p=0.012); Self-management skills: Improved at 6 mths (4 studies; 534 participants; p=0.01); Treatment satisfaction: Improved at 6 mths (2 studies; 390 participants; p<0.001) and 12 mths (3 studies; 484 participants; p<0.001); Empowerment/ self-efficacy: Improved after 6 mths (2 studies; 326 participants; p=0.01)

N= number; HbA1c= glycated haemoglobin; BP= blood pressure; FBG= fasting blood glucose; LDL= low density lipoprotein; HDL= high density lipoprotein; TG= triglycerides

The results of this Cochrane review indicated that group-based education programs for the management of T2DM result in significant reductions in HbA1c, body weight and systolic blood pressure, FBG levels, the need for diabetes medication, and improvements in diabetes knowledge.[14] The reductions in HbA1c resulting from the group-based education programs are associated with an approximate reduction in relative risk of 16.8% to 29.4% in diabetes complications and deaths related to diabetes, a reduction of 11.2% to 19.6% in myocardial infarction risk, and a reduction of 29.6% to 51.8% in microvascular complication risk.[14] The reductions in systolic blood pressure in the group education program participants equates to a reduction in relative risk of diabetes complications of 6%, a reduction in deaths related to diabetes of 7.5%, a reduction of risk of myocardial infarction of 5.5% and a reduction in relative risk of microvascular complications of 6.5%.[14]

In 2012, a team of Norwegian researchers, Steinsbekk and colleagues, published a systematic review with meta-analysis assessing group-based diabetes self-management education compared to routine treatment for people with T2DM.[47] The review examined 21 RCTs, published across 26 manuscripts between 1988 and 2007, involving a total of 2833 participants who were mainly women (60%), had a median baseline age of 60 years and diabetes duration of 8 months.[47] The Cochrane review included 7 of the RCTs reviewed by Steinsbekk et al. Of the 21 interventions included in this systematic review, 17 have been included in this formative literature review, whilst three of the other interventions were published outside of the exclusion period, and one was a Spanish language paper.

The group-based education programs reviewed varied in design, with follow-up periods between six months and five years, contact time between six and 96 hours, and the number of participants in each group between five and 40.[47] The majority of the studies had a length of follow up of 12 months (11/26), were run from a primary care setting (21/26), were run by health professionals (24/26), assessed HbA1c at some time point (24/26), and used a control group that received routine care only (16/26). [47]

This systematic review supported the findings of the Cochrane review, that group-based education programs for the management of T2DM result in significant reductions in

HbA1c, FBG levels, body weight, and improvements in diabetes knowledge. Additionally, review established that group-education programs result in significant improvements in self-management skills, treatment satisfaction, and self-efficacy or empowerment.[47] These results are clinically significant, with the reductions in HbA1c associated with an approximate reduction in relative risk of 9.2% to 18.3% in diabetes complications and deaths related to diabetes, a reduction of 6.2% to 12.2% in myocardial infarction risk, and a reduction in relative risk of microvascular complications of 16.3% to 32.2%.[47]

Discussion

The results of these systematic reviews demonstrate that group-based diabetes education for adults with T2DM result in clinically and statistically significant improvements in various health outcomes, including HbA1c, FBG levels, body weight, systolic blood pressure, diabetes knowledge, self-management skills, treatment satisfaction, self-efficacy or empowerment and the need for diabetes medications.[14, 47]

Key learning's from the Cochrane review include:

- There is no evidence to suggest that programs delivered by a physician, dietitian or nurse are more effective than programs delivered by other trained health professionals;
- Programs based on therapeutic patient education using the principles of empowerment, participation and adult learning have been proven effective; and
- The number of participants and contact time offered to these participants does not appear to impact on the interventions effectiveness.[14]

Key learning's from the systematic review by Steinsbekk et al include:

- Interventions delivered by a single educator tend to be more successful as long as the clinical, pedagogical and personal qualities of the person are of the highest standards;

- Having a theoretical model underpinning the program is not needed to achieve better results;
- Participants should be included in the planning, carrying out and evaluation of the program;
- Programs should be delivered in less than ten months; and
- Programs should provide more than twelve contact hours over 6 to 10 sessions.[47]

The key learning's from the two systematic reviews are very different, and at times conflicting. This may be an indication that the inclusion of a greater number of RCTs, which have additionally been published more recently, has enabled Steinsbekk et al to more clearly establish which aspects of group-based education programs are required to improve their effectiveness. Despite the substantial number of RCTs in large patient groups assessed by these systematic reviews, it still remains difficult to conclude which attributes are essential to improve the effectiveness of group-based education programs for the management of T2DM. Both reviews noted that although they were able to show that group-based education programs result in clinical and statistically significant health outcomes, the exact mechanism and 'active ingredients' of these complex interventions could not be identified.[14, 47]

Limitations of the reviews

The studies included in the Cochrane were assessed as being either moderate or poor quality studies, whilst the studies included in the systematic review by Steinsbekk and colleagues were mainly assessed as moderate quality.[14, 47] Both of the systematic reviews highlighted the fact that it was very difficult, and in some cases impossible, to carry out meta-analyses on several of the outcomes due to the high heterogeneity of the studies.[14, 47] Additionally, these reviews highlighted the poor reporting of group-based intervention studies, for example only ten studies included in Steinsbekk et al's systematic review reported the use of a theoretical model and only ten studies reported the number of participants in each group.[47] This poor reporting of group-based interventions will hopefully be improved with the introduction of the TIDieR checklist, an intervention reporting checklist and guide published in 2014.[64] The limited descriptions of interventions in published studies make the comparison and replication of the studies to be near impossible.[24]

Unfortunately, the only program attributes explored in these systematic reviews were the type of intervention, contact time, program facilitators, number of participants, and theoretical basis for the program, ignoring potentially essential attributes such as the delivery of the program, training of group facilitators, and the group interactions. Obtaining a thorough overview of all of the attributes which affect the success of group-based education programs could greatly benefit health professionals working in the area of CDM by informing the development and facilitation of group-based education programs that have more potential to be effective than a group-based education program which has not been informed by the literature.

Randomized Controlled Trials

Introduction

The 25 group-based RCT interventions, described over 27 publications identified for this formative literature review are summarized in Table D2. Of the 25 RCTs, only two did not result in statistically significant changes between the intervention and control groups, with the remaining 24 RCTs reaching significance for a range of outcome measures. This indicates that group-based education programs are effective in the management of T2DM. The primary outcome measure for the majority of the RCTs was HbA1c, which was significantly improved in more than half (13/25) of the studies. Other primary outcomes included diabetes knowledge, which was significantly improved in seven of the studies, body weight or BMI, which was significantly improved in five of the studies, and various psychosocial measures such as QOL, depression scores, treatment satisfaction, health beliefs, self-efficacy and social support, which were significantly improved in 11 of the studies.

Table D2: Summary of 25 RCTs of group-based education interventions for the management of T2DM

Research Paper	Intervention	Population	Outcome measures	Improvements favouring group education
Adolfsson, E., et al; 2007.[38]	Empowerment group education, 4- 5 sessions of 2.5 hrs each including one follow up session within 7 months.	88 participants with T2DM, receiving oral or anti-diabetes treatment, < 75 years of age, HbA1c of 6.5%- 10%, diabetes duration >1 yr, able to participate in a group, understood Swedish, not previously educated.	Diabetes knowledge, self-efficacy, satisfaction with daily life, HbA1c, and BMI.	1 yr follow up: level of confidence in diabetes knowledge was significantly improved in the IG. HbA1c was maintained in the IG despite the progressive nature of the disease.
Baradaran, et al; 2006.[239]	Group education vs. routine care. Intervention group received three 2.5 hr sessions, one dietitian led (1 hr), and one podiatrist led (1.5 hrs) within three months.	101 participants with T2DM; mainly South Asian people- split into ethnic and white groups; over 30 years of age. 44 IG participants and 57 CG (36 ethnic and 21 white).	Knowledge, attitudes and practice of diabetes.	No significant differences in any of the outcome measures between the IG and CG.
Barrera, MB., et al; 2006.[217]	Comprehensive lifestyle intervention: 6 month duration- commenced with 3 day retreat- taught all program components; then wkly meetings of 1 hr each of PA, stress management, a Mediterranean diet potluck, and support groups.	279 participants: 116 randomized to usual physician care (UC) and 163 to the Mediterranean Lifestyle Program (MLP). Post-menopausal women diagnosed for ≥6 months with T2DM, living independently, had a telephone, able to read English, not developmentally disabled, and lived within 30 miles of the site.	Social support measures; Dietary fat, PA, HbA1c.	Social support measures: Social Network Index improved $p<0.01$ as did the Chronic Illness Resource Survey $p<0.001$. Caloric expenditure $p<0.01$; % calories from fat $p< 0.01$; and HbA1c $p< 0.01$.

Research Paper	Intervention	Population	Outcome measures	Improvements favouring group education
Brown, S., et al; 2002.[86]	3 months of 2 hr wkly instructional sessions, 6 months of biweekly and 3 months of monthly 2 hour support group sessions. Goal: promote behaviour changes through problem solving and food preparation demonstrations.	256 (128 per group) T2DM patients between the ages of 35 and 70 years, all diagnosed after 35 years of age.	HbA1c, BMI, FBG, cholesterol, TG, diabetes knowledge and diabetes-related health.	IG had significantly lower levels of HbA1c and FBG at 6 and 12 months and higher diabetes knowledge scores.
Clancy, D, et al. 2007.[89]	2 hr monthly group sessions for 12 months. Content was patient-guided but physician-directed to cover the core curriculum.	186 African-American patients with poorly controlled T2DM (HbA1c>8%); aged over 18 years.	HbA1c, BP, lipid profiles, and quality of care measures.	Significant improvements in ADA process of care indicators (p<0.001); higher screening rates for cancers of the breast (p=0.006) and cervix (p=0.019).
Cooper, H, Booth, K & Gill, G; 2008.[173]	"Look after yourself" (LAY) program: theoretically constructed with a focus on systems of motivation. Sessions were delivered weekly for 8 weeks and were 2 hours each.	89 T2DM patients between the ages of 21 and 75 years, all diagnosed with T2DM for ≥1 yr. IG had 53 participants, and wait-list CG had 79 participants.	HbA1c, BMI, drug treatment, diabetes-specific questionnaires; and focus groups to discuss group perceptions of the educational process.	The intervention group was associated with benefits in HbA1c levels (p=0.005), illness attitudes (p=0.04), and perceived treatment effectiveness (p=0.03) at 6 months. At 12 months only illness attitudes (p=0.01) and self-monitoring (p=0.002) showed benefit.
Davies, MJ., et al; 2008.[22] & Khunti, K., et al; 2012.[55]	Based on a series of psychological theories of learning: Leventhal's common sense theory, the dual process theory, and social learning theory. Philosophy of patient empowerment. 6 hours of education.	824 participants. T2DM patients, referred within 2 weeks of diagnosis, and attended a structured group education program within 12 weeks of diagnosis.	HbA1c, weight, blood pressure, blood lipid levels, waist circumference, lifestyle questions (smoking, PA), QOL, and illness perceptions.	IG improved TG levels (P= 0.008), wt loss at 4+12 months (P= 0.024 and 0.027), reduced CVD risk (P <0.002); reduction in smoking status at 8+12 months (P= 0.033), increase in PA sig at 4 months (P= 0.046), improved illness belief scores (P< 0.001), improved depression scores (P= 0.032). The significant benefits for IG across four out of five health beliefs sustained at 3 yrs (p<0.01).

Research Paper	Intervention	Population	Outcome measures	Improvements favouring group education
Deakin, TA., Cade, JE., Williams, R., Greenwood, DC; 2006[91]	X-PERT programme: 6 x 2 hour group sessions of self-management education (based on theories or empowerment and discovery learning).	314 participants. Adults with T2DM.	HbA1c, lipid profile, BP, body weight (BMI), body fat, waist circumference, medication, diabetes knowledge, nutritional intake, self-care activities, treatment satisfaction, perceived frequency of hypoglycaemia and hyperglycaemia, QOL and empowerment score.	IG showed significant improvements in HbA1c ($p< 0.001$), body weight ($p< 0.001$), BMI ($p< 0.001$), waist circumference ($p< 0.001$), total cholesterol ($p= 0.01$), self-empowerment ($p= 0.04$), diabetes knowledge ($p< 0.001$), PA levels, foot care, fruit and vegetable intake ($p= 0.008$), enjoyment of food ($p= 0.004$), psychosocial adjustment ($p= 0.03$), readiness to change ($p= 0.04$), goal setting ($p= 0.03$), and treatment satisfaction ($p= 0.04$).
Holtrop, J, et al; 2002.[240]	Intervention: 6 wkly sessions (1.5hrs each) facilitated by lay health advisors.	Females with T2DM (HbA1c>7% in past 6 mths), aged over 40 years and with a BMI>27.3. IG= 67 participants; CG= 65 participants.	HbA1c, BMI, Dietary habits, Beliefs and stages of change at 6 mths.	Significant improvements in confidence to eat a low-fat diet ($p=0.05$); their opinion about the importance of eating three meals per day ($p=0.03$); the belief that good diabetes control is due to one's own efforts ($p=0.04$); fruits eaten per week ($p=0.02$); and confidence that they could eat three meals a day ($p=0.04$).
Hornsten, A., et al; 2005;[98] & Hornsten, A., et al; 2008.[99]	Ten 2 hour sessions (5 to 8 per group), over a 9 month period. Focus on patient's own needs and questions, focused on their understand of their illness.	102 patients diagnosed with T2DM during the previous 2 years, Swedish speaking and between the ages of 40 and 80 years.	HbA1c, total cholesterol, HDL, LDL, TG, BP, BMI, and questionnaires on well-being and treatment satisfaction.	HbA1c was significantly lower at 12 months ($p<0.001$), and 5 yrs ($p<0.0001$); TG's significantly lower ($p=0.002$), and HDL higher ($p=0.029$) at 12 months.
Ko, S., Song, K., et al; 2007.[241]	CBT approach, intensive inpatient program (6 hours daily/ 5 days during to inpatients). Group education provided annually (3hr session) for 4 yrs.	547 participants (219 intervention). People with T2DM who were admitted with symptoms related to glycaemic control and had no experience of previous systematic diabetes education.	BP, BMI, FBG, dietary habits, PA, and the frequency of SMBG.	Mean HbA1c was significantly lower in the IG at 6 mths ($p<0.0001$), 3 yrs ($p=0.004$) and 4 yrs ($p<0.0001$) follow up. Better diet ($p<0.001$), PA ($p=0.004$), SMBG ($p<0.001$); and reduced frequency of hospitalization ($p<0.05$) .

Research Paper	Intervention	Population	Outcome measures	Improvements favouring group education
Lorig, K, Ritter, P., et al; 2009.[103]	Peer led groups; 10 to 15 participants (incl family and friends); 6 wk program of 2.5 hour wkly sessions. Non-didactic delivery with an emphasis on action planning and problem solving.	345 participants. T2DM patients over 18 years of age.	HbA1c, health status, health behaviours, health care utilization, and self-efficacy.	Sig improvements in depression scores, symptoms of hypoglycaemia, communication with physicians, healthy eating and reading food labels (P<0.01) at 6 mths. Improvements in patient activation, self-efficacy, depression scores, communication with physicians, healthy eating, patient activation and self-efficacy (P<0.01) at 12 mths.
Lujan, J, Ostwald, S & Ortiz, M; 2007.[242]	2 hr sessions for 8 wks plus biweekly phone calls (by community lay workers); Culturally specific participative classes (available in English and Spanish), interactive and involved small groups.	149 participants (75 intervention group and 74 control group); Mexican-Americans aged over 40 yrs; diagnosed with T2DM for at least 1yr, taking or having taken hypoglycaemic agents within the past 6 mths.	HbA1c, diabetes knowledge, and diabetes health beliefs at 6 mths.	HbA1c improved significantly (p<0.001); diabetes knowledge improved significantly (p<0.02); diabetes health belief score improved significantly (p<0.01).
Mayer-Davis, E, et al. 2004.[243]	Two interventions: Intense: 1 hr weekly sessions for four mths plus monthly for 6 mths (3 group and 1 individual); or reimbursable: condensed version of the intense intervention in which key elements were delivered over four 1 hr sessions (3 group and 1 individual) over 12 mths (both facilitated by nutritionist).	152 participants (56 in control group; 47 in reimbursable-lifestyle intervention; and 49 in intensive-lifestyle intervention); T2DM patients living in rural communities with a clinical diagnosis of diabetes, a BMI of 25 or greater during the previous calendar year.	Weight loss, BMI, HbA1c, lipid profile, and BP.	Weight loss in the intensive group (vs. usual care group) at 6 mths (p<0.01) and 12 mths (p<0.05); improvements in HbA1c in each group (p<0.05); no significant between group differences.

Research Paper	Intervention	Population	Outcome measures	Improvements favouring group education
McKibbin, C, et al.; 2010.[131]	Diabetes Awareness and Rehabilitation training; groups of 6 to 8 run by a diabetes-trained mental health professional; 24 weekly 90 min sessions for 6 mths.	64 patients with diagnosed schizophrenia or schizoaffective disorder and provider-confirmed diagnosis of diabetes mellitus; aged 40 or over.	HbA1c, BMI, waist circumference, diabetes knowledge, psychiatric symptom severity, depressive symptom severity and cognitive functioning.	Significant improvements in BMI ($p<0.01$); waist circumference ($p<0.05$); and diabetes knowledge ($p<0.01$) at 12 mths.
Rickheim, PL., Weaver, T, et al; 2002.[110]	Individual and group sessions: consisted of 5 (individual) to 7 (group) hrs of education. Initial visit was 3 hrs for group; 2 hrs for individual; with a 2 hr follow up and 1 hr follow up 2 weeks later. 3 month and 6 month follow-ups were 1 hour for both.	Patients aged 30 to 80- with T2DM (newly diagnosed, or previously diagnosed with no history of prior systematic diabetes education). 87 in IG and 83 individual group.	HbA1c, BMI, weight, attitudes, mental health related QOL, patient satisfaction, and medication regime.	Similar improvements in knowledge, BMI, health related QOL, attitudes, and other indicators in both groups. HbA1c decreased in the whole study population ($p <0.01$) - however by more in the group setting (2.5 +/- 1.8% whilst individual was 1.7 +/- 1.9%).
Rosal, M, et al.; 2005.[112]	Initial 1 hr individual session followed by 10 weekly 2.5-3hr group sessions and two 15 min individual sessions occurring immediately prior to group sessions. Patient-centred.	25 participants (15 intervention and 10 control participants); Hispanic persons, diagnosed with T2DM, aged ≥18 yrs, having a home phone, having their doctors consent to participate and being able to provide informed consent in English and Spanish.	HbA1c, lipid profile, BP, height, weight, waist and hip circumference, 24-hr diet recall, PA questionnaire, 24-hr recall of SMBG, diabetes knowledge, diabetes related QOL, insulin management self-efficacy scale and depression scale.	Significant improvements in HbA1c at 3 mths ($p=0.02$) and 6 mths ($p=0.005$) and depressive symptoms at 3 mths ($p=0.02$).

Research Paper	Intervention	Population	Outcome measures	Improvements favouring group education
Rygg, L., et al; 2012.[47]	Group education (diabetes self-management education). Education lasted for 15 hours over three sessions with 1-2 weeks between sessions.	146 participants with a doctor confirmed T2DM diagnosis, were older than 18 years, had been to a GP in the previous 3 years, and were between the ages of 40 and 75.	HbA1c and patient activation.	Diabetes knowledge and some self-management skills improved significantly p=0.004) at 12 mths.
Sarkadi, A & Rosenqvist; 2004.[114]	Pharmacist-led, yearlong intervention (monthly meetings over 12 mths); led by pharmacist assisted by diabetes nurse specialists for the two first meetings; goal of the program was to reinforce the participants experiences and use them as a basis for the acquisition of practical skills.	64 participants (33 in intervention group; 31 in control group); T2DM patients, treated with insulin for only 2 yrs or less. Wait-list control (2 yrs then offered intervention).	HbA1c at 6, 12 and 24 mths.	Significant improvements in HbA1c at 6 mths (p=0.05) and 24 mths (p=0.023).
Thomas, P., et al; 2006.[27]	*Know Your Health* program: culturally sensitive health education practices for self-management; designed for populations with low functional health literacy. 3 hrs for DM patients (conducted by trained facilitators).	239 patients (with uncontrolled T2DM or HTN or both) – 18 years or over, English speaking, not pregnant or lactating, and cognitively aware. 124 in intervention group, 115 in control group.	HbA1c; BP; Morisky Score; Readiness to Change Questionnaire, Patient Satisfaction Questionnaire	Diastolic BP decreased significantly P= 0.04. 83.3% of patients in the intervention group were very satisfied with the program.
Trento, M., Passera, P., et al; 2004.[49]	Three monthly group sessions based on a systemic education approach; positive group dynamics induced.	Patients with non-insulin dependent T2DM (112 in total) randomized into individual or group care.	Knowledge of diabetes; Problem solving ability; QOL; Body weight; BMI; FBG; HbA1c; Creatinine; Total cholesterol; HDL cholesterol; TG.	HbA1c stable in the group care patients but increased in the control (p <0.001); diabetes knowledge (P <0.001); problem solving ability (p <0.001); QOL improved in group care, but worsened in control group (p <0.001).

Research Paper	Intervention	Population	Outcome measures	Improvements favouring group education
Trento, M., Gamba, S., et al; 2010.[126]	The Rethink Organization to iMprove Education and Outcomes (ROMEO) trial: Group care and individual visits were every 3 months (by the same operators). Seven 1-hour sessions were held over 2 years and repeated (plus individual consults at least yearly).	815 patients with non-insulin-treated T2DM of >1 year known duration, aged <80 years were randomized to either the intervention group or individual care.	Body weight, fasting glycaemia, BP and HbA1c were measured every 3 months. Creatinine, total and HDL cholesterol, TG, health behaviours, QOL, knowledge of diabetes.	HbA1c, total cholesterol, LDL cholesterol, TG, systolic and diastolic BP, BMI, serum creatinine and higher HDL cholesterol ($p<0.001$ for all); Health behaviours, QOL, and knowledge of diabetes ($p<0.001$ for all).
Trouilloud, D. & Regnier, J; 2013.[244]	Therapeutic patient education (TPE): consisting of a three-day program including eight group sessions, each lasting 2-3 hours; groups of 5-8 patients.	Patients with physician-confirmed type 2 diabetes, aged between 20 and 80 years, and able to speak and read French; 120 participants.	HbA1c, diabetes self-management behaviours, perceived confidence in diabetes self-management.	HbA1c ($p<0.001$); PA ($p<0.001$); adherence to dietary recommendations ($P<0.001$); perceived confidence towards PA ($p<0.05$); perceived confidence towards dietary recommendations ($p<0.001$).
Wattana, C, et al.; 2007.[245]	Intervention group received a 120 min small group education class, four small group discussions (90 mins), two individual home visits from the research (45 mins) and patient education manual.	147 patients (75 intervention; 72 control); >35 yrs, diagnosed with T2DM for >6 mths, FPG <140mg for at least 2 visits, Asian participants with oral hypoglycaemic agent treatment.	HbA1c, lipid profiles, CHD risk and QOL at 6 mths.	Significant improvements in HbA1c ($p<0.05$); CHD risk ($p<0.05$) and QOL ($p<0.001$).
Zapotoczky, H, et al.; 2001.[129]	1.5 hrs monthly for 10 mths; dietitian delivered.	36 participants (18 intervention and 18 control patients); overweight T2DM patients.	HbA1c, weight, blood pressure, cholesterol and TG.	Significant reduction in body weight ($p<0.05$); and HbA1c ($p<0.000$) at 12 mths.

T2DM= type 2 diabetes; HbA1c= glycated haemoglobin; FBG= fasting blood glucose; FPG= fasting plasma glucose; BMI= body mass index; TG= triglycerides; QOL= quality of life; PA= physical activity; BP= blood pressure; HTN= hypertension; SMBG= self-monitoring of blood glucose; HDL= high density lipoprotein cholesterol; LDL= low density lipoprotein cholesterol; CHD= coronary heart disease; QOL= quality of life; mths= months; hr= hour; min/s= minutes; IG= intervention group; CG= control group

Of the 27 publications analysed in this section, nine (Barrera, 2006; Cooper, 2008; Davies, 2008; Khunti, 2012; Ko, 2007; Lorig, 2009; Rygg, 2012; Thomas, 2006; and Trouilloud, 2013) were not included in the Cochane review or the systematic review by Steinsbekk et al.[14, 47] The reasons for the exclusion of these studies are because they were either published after the reviews, the intervention group received individual appointments in addition to the group-based program, or the length of follow-up was too short. These nine RCTs will be reviewed and discussed in this section.

Results

Barrera et al published a study in 2009 evaluating the effects of social support and social-ecological resources as mediators in lifestyle change for postmenopausal women diagnosed with T2DM (n=279).[217] The intervention group participants were provided with a comprehensive six month Mediterranean Lifestyle Program which included dietary, PA, and stress management education, as well as emphasized cohesion among participants and the importance of social resources.[217] The intervention commenced with a three day retreat where the participants were taught all of the components of the program, after which they attended weekly meetings of an hour each of PA, led by an exercise physiologist, stress management, such as yoga, progressive deep relaxation, meditation and receptive imagery, a Mediterranean diet education session run by a dietitian, and support groups led by a professional and a peer leader.[217]

The results of the study included significant improvements in HbA1c ($p<0.01$), % of calories consumed from fat ($p<0.01$), exercise ($P<0.01$), the social network index and chronic illness resource survey ($p<0.05$) at six months post-baseline.[217] The researchers found that the social support and socio-ecological resources provided had a significant effect on PA change, fat consumption change and change in HbA1c, with 23.1% of total effect attributed to PA change, 12.7% of total effect attributed to fat consumption change, and 25.1% of total effect attributed to HbA1c change.[217] This research indicates that there may be a significant health benefit to providing and encouraging social support and social-ecological resources in T2DM group-based education interventions. It is difficult, however, to speculate whether this effect may be seen in groups utilizing a

less intensive approach, which may be necessary, as taking participants away on a three day retreat and having them commit to six months' of weekly sessions, may not be feasible in a real world setting.

A randomized controlled wait-list designed study conducted in the United Kingdom by Cooper, Booth and Gill, published in 2008, assessed the effect of a structured, empowerment-based educational system, the "Look After Yourself" or LAY program for persons (n=89) who had been diagnosed with T2DM for at least one year.[246] The program was theoretically constructed on the premise that knowledge acquisition alone does not necessarily promote self-directed action, and instead focused on systems of motivation and the teaching of practical, physical, conceptual, emotional, social and personal skills.[246] A variety of teaching methods were used, including group discussion, role-playing, goal-setting, relaxation and skills practice.[246] The program was delivered by experienced and qualified diabetes specialist nurses trained in the LAY program in two hour weekly sessions for eight weeks.[246]

The significant outcomes in the intervention group included improvements in HbA1c levels ($p=0.005$), illness attitudes ($p=0.04$), and perceived treatment effectiveness ($p=0.03$) when compared to the control group at 6 months.[246] At 12 months, only the illness attitudes ($p=0.01$) and self-monitoring practice ($p=0.002$) showed benefit.[246] The disappointing results of this study, in regards to glycaemic control at 12 months post-intervention, may be due to the small number of participants or the lack of reinforcement provided to intervention group participants following the eight-week program.

A study investigating the long term effects of a structured intensive diabetes education program (SIDEP) for individuals with T2DM conducted by Ko et al in South Korea and published in 2007 (n=547) concluded that a well-designed, intensive patient education program is necessary for persons with T2DM.[241] The research compared an intervention group, who completed an intensive inpatient program, with a control group, who received conventional glycaemic control without intensive education.[241] The patient

education program as designed using a cognitive-behavioural therapy (CBT) approach and consisted of six hours of education for five days during the patients hospital stay.[65] The program aimed to improve the knowledge, skills and attitudes which would encourage, promote and support self-management skills, resulting in improved long term behaviour.[241] In addition to the intensive education offered to the intervention group, participants were followed up at regular three monthly intervals in the outpatient clinic after discharge for over four years.[241] Furthermore, a three hour group education session was provided annually to intervention participants which included a review of self-management along with the presentation of new topics such as obesity, dyslipidemia, and the use of glucose- lowering agents.[241]

The outcomes of the SIDEP program included significantly reduced HbA1c in the intervention group at six months ($p<0.0001$; -2.3% vs. -1.3%), three years ($p=0.004$; -1.6% vs. -0.8%) and four years follow up ($p<0.0001$; -1.5% vs. 0.5%).[241] The 1% reduction in HbA1c at four years post–baseline equates to a reduction in relative risk of 21% for deaths related to diabetes, 37% for microvascular complications and 14% for myocardial infarction.[26] This impressive improvement in HbA1c may be contributed to the consistent long term follow up and annual reinforcement provided to the participants, the length of the program, or the CBT approach, however it is difficult to conclude which of these attributes had the greatest impact on the interventions success. Other significant improvements in the intervention group were significantly better diets ($p<0.001$), PA levels ($p=0.004$), self-monitoring of blood glucose (SMBG) ($p<0.001$), and frequency of hospitalization ($p<0.05$).[241] The results of this study were particularly interesting, as the group-based education program was intensive and offered to hospital inpatients. The success of the implementation of an intensive, group-based education program in this authentic setting is very promising for future program development.

A recent French study by Trouilloud and Regneir aimed to confirm and extend knowledge about the effects of therapeutic patient education among adults with T2DM ($n=120$).[244] The intervention consisted of a three-day program including eight group sessions which were interactive, patient-centred and consisted of both educational and problem-solving activities on diet, PA and medication.[244] The results of the study were a

significant decrease in HbA1c ($p<0.001$), a significant increase in PA ($p<0.001$), significant changes in adherence to dietary recommendations ($p<0.001$), a significant increase in perceived confidence towards PA ($p<0.05$), a significant increase in perceived confidence towards dietary recommendations ($p<0.001$) improved in the intervention group. [244] The results of this study indicate that therapeutic patient education can significantly improve the competence, self-management behaviours and glycaemic control in adults with T2DM in the short term.

A RCT utilizing a wait-list control group was completed in Norway by Rygg et al in 2012 (n=146).[247] The intervention was facilitated across two hospitals, and sessions were held either weekly or fortnightly lasting a total of 15 hours over three sessions.[247] There were no differences in HbA1c at 12 months, however the control group had an increase in HbA1c of 0.3% points during follow-up.[247] Diabetes knowledge and some self-management skills improved significantly in the intervention group compared to the control group, however the intervention group also showed a trend for poorer QOL.[247] Those initially in the highest quartile for HbA1c had significant improvements in HbA1c and patient activation, and a trend for better outcome at 12 months, which may be an indication that individuals with poor diabetes control are more likely to experience a positive outcome from group education.[247] Additionally, the limited contact time with participants in the intervention group (15 hours over three to six weeks) may have impacted health outcomes.

The Diabetes Education and Self-Management in Ongoing and Newly Diagnosed (DESMOND) study, completed in the UK and published by Davies et al in 2006, was an education program for persons newly diagnosed with T2DM, based on an empowerment philosophy and a series of psychological theories; Leventhal's common sense theory, the Social Learning Theory, the dual process theory, and a discovery learning process.[22, 35] The program consisted of six hours of education, delivered either in one day or as two half day equivalents and was piloted on a large sample group (n=824), allowing generalisability of the program due to the sample group being representative of persons newly diagnosed T2DM in the developed world.[22]

Participants in the DESMOND program were followed up at four, eight and 12 months, with the results indicating a significant reduction in weight at four and 12 months ($p=0.024$ and $p=0.027$), a significant improvement in TG levels at eight months ($p=0.008$), a significant reduction in CVD risk at 12 months ($p<0.002$), a significant improvement in PA levels at four months ($p=0.046$), and smoking cessation at eight months and 12 months ($p=0.033$).[22] Additionally, the four illness belief scores were significantly improved ($p<0.001$) in the intervention group, as were the patients' understanding of their illness and its seriousness.[22] Depression scores in the intervention group were significantly better at 12 months follow up ($p=0.032$), however QOL scores did not differ between the intervention and control groups.[22]

An interesting outcome of the DESMOND study was that the participants who reported a greater perception of responsibility for the course of their diabetes lost more weight.[22] The reduction in mean HbA1c was greater in the intervention group than the control group (1.49% vs. -1.21% at 12 months), however this did not reach statistical significance.[22] This non-significant change in HbA1c may support the hypothesis that the length of the educational intervention is closely linked to the reduction in HbA1c, as the DESMOND program, with only six hours of contact time over one to two sessions, is the shortest of the interventions reviewed.

After completing six hours of structured education, DESMOND participants were more likely to understand their condition, to agree that T2DM is a chronic illness and a serious condition, and understand that they can affect its course.[35] This study showed that individuals newly diagnosed with T2DM were willing and open to attending an education program, and that a program based on psychological theories and empowerment philosophy can provide education on the serious nature of diabetes without having a negative impact on the persons emotional well-being.[35] The DESMOND program has shown that a group-based education program focused on behaviour change, with a patient-centred approach, can successfully instigate some

effective lifestyle changes in persons with T2DM which are sustainable over 12 months from diagnosis.[22]

In 2012, a three year follow-up study on the DESMOND trial was published by Khunti et al.[55] Of the 824 participants included in the original trial, 731 were eligible for follow-up and biomedical data was collected from 73% and questionnaire data from 62% of these participants.[55] HbA1c levels had decreased in both groups, however these levels did not differ significantly between the groups.[55] The groups did not differ for other biomedical and lifestyle outcomes, and drug use, however the significant benefits in the intervention group across four out of five health beliefs seen at 12 months were sustained at three years ($p<0.01$).[55] The results of this study support the integration of ongoing education and support for participants following a group-based intervention, however, the optimal interval and contact time has not yet been evaluated.[55]

The *Know Your Health* program is a group education program for individuals diagnosed with T2DM and/ or hypertension (HTN) (n=239) which consists of a one hour group education session for patients with hypertension, and a three hour group education session for persons with T2DM.[27] The program was piloted in a large employer group in the United States and participants in the intervention group were provided with a three hour education session for those with T2DM which covered culturally sensitive health education practices for self-management, and communication strategies and techniques for those with low functional health literacy.[27] In addition to the education session, participants were provided with diet and exercise regimes, and encouraged to enroll in onsite fitness centres.[27]

The outcomes of the *Know Your Health* program were a high program satisfaction level (83.3%), and a significant improvement in diastolic blood pressure ($p=0.04$).[27] At six months, significantly more participants in the intervention group than in the control group were at goal ($p=0.046$).[27] The program also noted improvements in systolic blood pressure, HbA1c, compliance behavior, and readiness to change, however none of these measures reached statistical significance.[27] The insignificant improvement in HbA1c

may have been due to the limited number of individuals with T2DM in the program, the short program time, the didactic teaching style, or the limited content covered.

In 2009, Lorig completed a community-based peer-led diabetes self-management program, with a focus on English-speaking adults (n=345) with T2DM.[103] The intervention groups consisted of 10 to 15 participants including participants family and friends, and were run by two peer leaders.[103] The program ran for six weeks and consisted of weekly two and a half hour sessions.[103] The peer leaders utilized a non-didactic delivery with an emphasis on action planning and problem solving.[103] The results of the program were significant improvements in the intervention group for depression scores, symptoms of hypoglycaemia, communication with physicians, health eating and reading food labels ($p<0.01$), and significant improvements in patient activation and self-efficacy at six months post intervention.[103] At 12 months post intervention, participants showed significant improvements in depression scores, communication with physicians, healthy eating, patient activation and self-efficacy ($p<0.01$).[103] Unfortunately, there were no improvements in HbA1c when compared to the control group.[103] This may be due to the fact that most of the participants either did not have an elevated, or had only slightly elevated, HbA1c levels (<7%), prior to commencing the program.[103] Additionally, the relatively limited number of contact hours provided to participants in the intervention group may have reduced the efficacy of the program.

Discussion

The nine RCTs reviewed and discussed in this section resulted in a range of statistically significant outcomes including reductions in HbA1c, reductions in body weight, increases in PA levels, improvements in diabetes knowledge and self-management skills, improvements in depression scores and self-efficacy, reductions in TG and CVD risk, and improvements in SMBG. Some of these studies were more effective than others, however each of the studies resulted in significant improvements in one or more outcome measures.

The RCTs completed by Barrera et al, Cooper, Booth and Gill, Ko, and Trouilloud & Reigner, all resulted in significant improvements in HbA1c. These results are clinically significant, as any reduction in HbA1c has been shown to reduce the risk of diabetic complications, with each 1% reduction in HbA1c associated with reductions in the relative risk of 21% for deaths related to diabetes, 21% for any end point related to diabetes, 37% for microvascular complications, and 14% for myocardial infarctions.[14]

Only one of the RCTs (Davies et al) resulted in significant reductions in body weight.[22] Previous studies have confirmed the benefits of modest weight loss on glycaemic control, with reductions of just 2 to 5 % of body weight resulting in clinically significant improvements in glycaemic control in overweight or obese persons with T2DM[248] Additionally, weight losses of 5- 10% of initial weight in this group have been found to significantly reduce CVD risk factors, with greater weight losses associated with greater improvements in risk factors such as blood pressure and lipids.[248]

Diabetes knowledge was improved significantly in one of the RCTs by Rygg et al.[247] Adequate knowledge of diabetes is a key component of diabetes education programs with the potential benefits of diabetes knowledge including a sense of empowerment and improved QOL.[142] Additionally, significant associations between self-management behaviours and diabetes knowledge have been established in previous studies.[142] This indicates that other outcome measures may be improved at a later stage, as the improvement in diabetes knowledge should translate to behaviour changes, which will influence health. Finally, one of the RCTs, by Lorig et al, resulted in significant improvements in self-efficacy.[103] Perceived self-efficacy can be thought of as a person's confidence regarding a behaviour and describes the belief a person has about his or her personal capabilities to accomplish a task.[249] Self-efficacy is a strong predictor of adherence to diabetes related goals, and efficacy beliefs affect what people will try, motivating them to choose skills with which they believe they will be successful at.[249]

Despite the variability in significant results, it is clear from the review of these nine RCTs that group-based interventions are more effective in improving a range of

outcome measures than individual interventions in the management of T2DM. These RCTs provide high-level evidence (level II evidence), which should inform practice in the area. The heterogeneity of these intervention studies, however, makes it difficult to compare the interventions and assess which attributes are important in predicting effectiveness.

Comparative or Case Series Studies

Introduction

The following section reviews three comparative studies. Table D3 summarizes these intervention studies and their results. None of these studies were included in the Cochrane review by Deakin et al or the systematic review by Steinsbekk et al, as they are not RCTs.[14, 47] The studies explored in this section provide lower level evidence (level III-2) than the systematic reviews and RCTs discussed in the previous sections; however, the methods used for these group-based interventions are novel and interesting. Furthermore, analyzing these studies has provided valuable information.

Table D3: A summary of comparative or case study interventions assessing group-based interventions for the management of T2DM

Author/s	Intervention	Population	Outcome measures	Improvements favouring group education
Forlani, G., Lorusso, C., et al; 2009.[250]	Three groups: sole prescriptive diet, diet with an additional short-course elementary nutrition education (4 group sessions) or an intensive CBT (12- 15 group sessions). Prescriptive diet: 500kcal/day deficit and increase PA to >30 mins, 5 days/wk. The short course group attended four weekly 90 min sessions. The CBT group (12- 15 sessions of 120 minutes each) extended the information given in the first group.	822 patients diagnosed with T2DM.	Weight loss, weight loss maintenance, metabolic control, and secondary failure to insulin use.	Both structured programs produced a greater weight loss than diet alone- with the CBT program producing significantly higher weight loss than the other two groups (CBT= 5.3% wt loss; ENE= 1.5% wt loss; DIET= 0.6% wt loss). Both groups favoured metabolic control.
Kulzer, B., et al.; 2007.[251]	Three intervention groups: group A (didactic-oriented intervention; four sessions 90 mins each); group B (self-management/ empowerment approach; 12 lessons 90 mins each); group C (same context as group B but the 6 sessions were individual and 6 group- based).	181 T2DM patients aged 40-65 year, no insulin, stimulated C-peptide >0.8nmol/l, BMI > 26.7kg/m², no acute psychiatric illness and able to read and speak German.	HbA1c, weight, diabetes knowledge, psychological determinants of eating, anxiety symptoms, psychological strain, self-care behaviour, and medication usage.	HbA1c: significant improvement in group B, initial significant improvement in group C at t1; HbA1c significantly lower in group B compared with group A; FBG fell significantly in all three groups, in group A it rose thereafter; BMI in group B and C improved significantly.
Lorig, K. & Gonzalez, V; 2000.[252]	Group based program: 2 hrs wkly for 6 wks (10-15 participants/ group), run by 19 trained peer educators.	149 participants. T2DM patients, able to attend the course at the site near their home; courses were held in community centres, clinics and churches.	Health behaviours (diet, exercise, relaxation, foot examination, communication with providers, glucose monitoring), self-efficacy, health status (self-reported health, role function, fatigue, physical discomfort, health distress, and health care utilization).	All studied behaviours improved (except for feet examining) significantly ($p<0.05$); self-efficacy improved ($p<0.001$).

T2DM= type 2 diabetes mellitus; CBT= cognitive behavioural therapy; BMI= body mass index; PA= physical activity; HbA1c= glycated haemoglobin; FBG= fasting blood glucose; wks= weeks; wkly= weekly; mins= minutes

Results

The first study reviewed in this section was a prospective cohort study conducted by Forlani et al in Italy in 2009 which measured the effectiveness of moderate and high intensity interventions on weight loss, metabolic control and insulin use in persons with T2DM (n=822).[250] The researchers divided the subjects into three groups, a sole prescriptive diet group, a diet group with an additional short course on elementary nutrition education, and an intensive CBT group.[250] Subjects in the first two groups were advised to comply with a 500k/cal per day calorie deficit and encouraged to increase their PA to reach a goal of at least thirty minutes, five days per week; with those in the diet plus additional short course also receiving a short counseling group on PA, lifestyle changes and aspects of nutrition conducted for ninety minutes once weekly for four weeks.[250] The final group, the CBT group received 12 to 15 sessions of two hours each which extended the information given to the previous group by adding calorie counting, monitoring of daily food intake, and behavioural strategies for stimulus control and the development of a regular pattern of eating.[250]

The intervention participants were followed up 48 months post-intervention.[250] Both of the group education programs resulted in greater weight loss than the diet prescription alone, with the CBT program resulting in a significantly higher weight loss than the other two groups ($p<0.001$; at 4 yrs follow up: CBT= 5.3% weight loss; ENE= 1.5% weight loss; DIET= 0.6% weight loss).[250] Additionally, both group programs favoured metabolic control and delayed the use of insulin, the CBT program more so than the short group program.[250] The favourable results for the CBT program may have been due to its theoretical basis, the increased content provided to the participants, or the increased contact time. The intervention by Forlani et al, in which the only significant improvement was in weight lost by the CBT program group, provided no reinforcement for participants and focused on weight control rather than other important factors in the treatment of T2DM, such as reducing HbA1c.

The second comparative study was a randomized, prospective trial conducted by Kulzer et al in Germany which evaluated the efficacy of three educational programs; a didactic-

oriented training program, a self-management-oriented program, and an individualized approach, for persons with T2DM (n=181).[251] The didactic group-based education program focused on the acquisition of knowledge, skills and information regarding diabetes treatment, and ran for four sessions of 90 minutes each.[251] The self-management-oriented program was based on an empowerment and self-management approach with a focus on the emotional, cognitive and motivational processes of behaviour change.[251] The content of this program was delivered over 12, 90 minute sessions, and the goal of the program was to promote lifestyle modifications in daily life, particularly in regards to eating and exercise behaviours.[251] The final program, the individual education program, consisted of the same content as the second program delivered over 12 sessions, the first six being individual consultations, and the last six delivered in a group setting.[251]

The results were in favour of the self-management-oriented group intervention, which was more effective than the other two groups, with significant improvements in BMI, FBG, psychological and behavioural measures.[251] When comparing the individual education program to the self-management-oriented program, no significant differences were found, which may indicate that providing a mix of individual and group-based education may be less beneficial than providing group-based education exclusively.[251] HbA1c was significantly improved in the self-management-oriented program at both three and 15 months (reduction of 0.7%), and was significantly lower in this group than in the didactic-oriented training program (P=0.017).[251] There was no change in HbA1c in the didactic-oriented training program, whilst the individual care program showed a significant improvement in HbA1c at three months, which was not sustained at 15 months follow up (7.8% at baseline, 7.1% at 3 months follow up, and 7.6% at 15 months follow up).[251] HbA1c was significantly lower in the self-management-oriented group when compared to the didactic-oriented program (P=0.017).[251]

FBG improved in all three of the groups from baseline to three months, however it rose again in the didactic-oriented group and was significantly higher at 15 months than at baseline or three months (P<0.001).[251] In the self-management-oriented program, FBG was significantly improved at 15 months when compared to baseline and three months

(P<0.001); whilst in the individual care group, FBG was significantly higher at 15 months, than at three months, and similar to baseline (P<0.001).[251] BMI was reduced significantly in the didactic-oriented group at three months, however this returned back to baseline at 15 months follow up (P<0.001).[251] In the self-management-oriented program and the individual care program, BMI was reduced significantly at both three and 15 months when compared to baseline (P<0.001 for both).[251] Knowledge improved equally in all groups, which further strengthens the argument that knowledge alone does not instigate behaviour change or lifestyle modification.[251] Determinants of eating were improved significantly in the self-management-oriented program and the individual care program when compared to the didactic-oriented program (P<0.001).[251] There was a significantly reduced treatment effect for trait anxiety in the self-management-oriented group when compared to the didactic-oriented group (P<0.001), and no advantage of the individualized approach when compared to the group approach.[251]

This study results showed that although outcome measures in the individual care program were improved, sometimes more than in the group programs, the deterioration over time was much greater in the individual care group than in the group program.[251] The researchers noted that the group effects may help in the maintenance of behaviour and attitude changes, and that there seems to be no benefit of an individualized approach when compared to the more cost effective group education programs.[251] This research was particularly interesting as it compared a non-didactic approach to group education, to a didactic approach and a more individualized approach. It is one of the only group-based research studies reviewed which used education groups who were taught the same content delivered in different ways, as opposed to using a control group who receive only usual care against an education intervention group. Reasons for the success of the self-management-oriented program may be the length of the program, although the individual care approach used the same program length and had less impressive outcomes, the non-didactic, self-management and empowerment based approach, or the group processes.

The third study reviewed was a definition and case study published in 2000, by Lorig and Gonzalez, who ran a community-based, peer-led diabetes self-management program

for Spanish-speaking people (n=149) in California.[252] The program was group-based and was delivered to groups of 10 to 15 participants by trained peer educators for two hour weekly sessions, over a six week period.[252] The program was designed to enhance self-efficacy using strategies such as skills mastery, modeling using peer educators, reinterpretation of symptoms, and social persuasion.[252] The results of the program were significant improvements in health behaviours, such as diet, exercise, relaxation, communication with health providers, and glucose monitoring ($p<0.05$), as well as significantly improved self-efficacy ($p<0.001$).[252] Unfortunately, no physiological measures, such as HbA1c, weight, BMI, or waist circumference, were obtained for the purposes of this study. The results of this study show that educated peer-leaders can successfully facilitate group-based education programs for individuals with T2DM, which could potentially reduce the workload of health professionals.

Discussion

The three comparative studies reviewed in this section resulted in some significant improvements in HbA1c, fasting blood glucose, body weight, self-efficacy and health behaviours. Improvements in HbA1c, FBG and body weight have been shown in past research to be clinically significant in improving patient outcomes such as deaths related to diabetes, microvascular complications, and the risk of myocardial infarction.[26] Additionally, improvements in diabetes knowledge and self-efficacy can result in changes in self-management behaviours and motivation, which are likely to positively affect patients health and well-being.[142, 249]

The results of these comparative studies support the results of the previous sections, that group-based interventions are more effective than individual interventions for the management of T2DM.

Conclusions:

The results of the two systematic reviews assessed for this formative literature review indicate that group-based education is more efficacious in the management of T2DM resulting in significant improvements in glycaemic control, diabetes knowledge, body weight, self-management skills, systolic BP and the need for diabetes medications over time periods ranging from four months to two years.[14, 47] Additionally, the assessment of the 25 group-based RCTs, and three comparative or case control studies indicate that group-based education is more effective in significantly reducing HbA1c, diabetes knowledge, body weight or BMI, BP, blood lipids, self-efficacy, FBG, QOL, depression scores, and CHD risk, in patients with T2DM, than individual care.

Thirteen of the RCTs resulted in significant improvements in HbA1c at time periods ranging from six months to five years, which can result in clinically significant reductions in diabetes related complications. The systematic reviews, RCTs and comparative or case control studies also highlight the poor reporting of many group-based intervention studies, making the replication and comparison of these intervention studies very difficult.[24] This would be improved with the greater application of the TIDieR checklist, an intervention reporting checklist and guide published in 2014.[64]

It is difficult to establish the attributes of a successful group education from the currently available literature, as there are huge variations in the aspects of each program tested and often limited explanations are given in regards to the methods, theoretical basis and content of these programs. The attributes contributing to the success of group education programs have not been specifically explored, with important information such as the group interactions, facilitator training and the theoretical basis of the interventions often being ignored in previous research. Further research is required to assess which group processes are responsible for the beneficial effects of group-based education when compared to individual education.[251]

Appendix E: Formative Evaluation

This appendix provides an overview of two formative interview studies conducted with group facilitators currently facilitating group-based education programs for the management of chronic diseases, and group participants who had recently completed group-based education programs for CDM. The interviews aimed to explore group facilitators experiences of developing and facilitating these programs, group participants' experiences of these programs in a practice setting, and the facilitators and participants perceptions of the attributes contributing to the effectiveness of group-based chronic disease self-management education programs.

A manuscript describing the first of the formative interview studies was published in *Nutrition & Dietetics* in 2015 and is provided in this section. Additionally, an overview of the group participant interview study is available in this appendix.

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Nutrition & Dietetics

ORIGINAL RESEARCH

Group facilitators' perceptions of the attributes that contribute to the effectiveness of group-based chronic disease self-management education programs

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Abstract

Aim: This qualitative study aimed to explore group facilitators' perceptions of the attributes contributing to the effectiveness of group-based chronic disease self-management education programs.

Methods: Fourteen group facilitators across a range of disciplines (dietitians, nurses, exercise physiologists, social workers and physiotherapists) individually participated in semistructured interviews, which explored facilitators' awareness of the theoretical basis of the programs they implement, their experiences of implementation and their opinions on the attributes contributing to program effectiveness. The interviews were audio-recorded, transcribed verbatim and analysed using thematic content analysis and seeking patterning of responses.

Results: Group facilitators were uncertain about the evidence base and theoretical development of their programs, and very few were offered any formal training prior to facilitating group education programs. Additionally, the outcome measures used by the group facilitators were limited. Group interactions, a non-didactic delivery style, a multidisciplinary team, and using practical activities, were highlighted as attributes contributing to group program effectiveness.

Conclusions: The present study suggests that group facilitators had limited training and were unaware of the rationale for their programs, which may limit quality control. Health professionals should have an understanding of the basis of their program and be adequately trained prior to facilitating group education programs for chronic disease management. Group facilitators should additionally ensure a focus on the collection of suitable outcome measures to allow the quality improvement of programs in order to improve patient outcomes.

Key words: chronic diseases, group education, group interactions.

Introduction

Chronic diseases, such as type 2 diabetes, kidney disease, heart disease and respiratory disease, are estimated to be responsible for around 80% of the total burden of disease in Australia, and the prevalence of chronic diseases is rising.[1] Chronic diseases provide particular challenges to our health-care system, with sufferers requiring constant access to health services and medications, resulting in high health-care expenditure over extended periods of time.[1] In 2005, it was estimated that the cost of chronic disease management in Australia was $56 billion per annum; 65% of Australia's total health expenditure.[2] This cost burden provides a strong imperative to develop health services that treat, manage and prevent chronic diseases and their comorbidities in a time and cost-effective manner.

Patient education is the cornerstone of chronic disease self-management and is essential in achieving improved outcomes for chronic disease patients.[3,4] Patients require support, education, guidance and empowerment from their health professional to make the best decisions and lifestyle changes for themselves, and to break down barriers to effective self-management.[5–7] Patients with chronic disease make most of their health-related decisions without input from formal health services, making them the predominant managers of their condition.[3,6–8] The goals of self-management

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education are to optimise quality of life, prevent acute and chronic complications, reduce or prevent reliance on healthcare resources, and optimise metabolic control, all while remaining cost-efficient.[9]

Group-based education programs can be more efficient and cost-effective for the education of chronic disease patients, when compared to individual counselling or usual care.[10–15] Group-based education can also be more successful at improving a number of patient health outcomes, such as glycated haemoglobin, body weight, waist circumference, blood pressure and cholesterol.[10–14,16–19] Group education programs offer many potential advantages over individual visits, with group programs allowing time for the provision of more detailed information, decreasing time demands on health workers, allowing the easy incorporation of families and carers, and facilitating patient support from others facing the same challenges.[6]

It is difficult to determine which attributes of group education programs account for the significant benefits of group versus individual education for chronic disease management. The descriptive logistical attributes (e.g. number of sessions, contact hours, group size) of successful chronic disease group education programs vary considerably (number of sessions = 6–12 sessions, contact time = 12–52 hours, and group size = 5–16 persons).[10–13,18–22] This indicates that program logistics may have less influence on the effectiveness of chronic disease group education programs than other attributes such as group interactions and social support. Understanding the specific attributes that directly influence the success of group-based education programs would greatly benefit health professionals working in the area of chronic disease management by informing the development and facilitation of more successful, efficient and cost-effective group education programs.

The present study aimed to explore health practitioners' training and awareness of the theoretical and programmatic basis of group-based chronic disease self-management education programs they implement in practice, and their opinions of the attributes contributing to program effectiveness. Additionally, the study aimed to explore their experiences of program implementation and the outcome measures used to evaluate chronic disease group education programs.

Methods

Group facilitators were recruited using a mix of purposive and snowball sampling. Health professionals from eight public and private hospitals, six community centres, three private practices and four non-government disease support agencies in the South East Queensland region were contacted directly via email and invited to take part in the research. These facilities were selected following Internet searches for group-based chronic disease self-management education programs in South East Queensland and discussions with others in the area. The health professionals contacted were asked to forward the original email to other health professionals currently facilitating chronic disease group education programs. Nine health professionals were approached originally for the purposive sampling, and an additional 27 health professionals were contacted through snowball sampling.[23] There was no specific relationship between the study participants and the authors.

It is difficult to estimate the total number of health professionals running group-based education programs for chronic disease management in the South East Queensland region; however, the latest Medicare item report indicates that 1593 claims were received for initial consultations relating to allied health group services for chronic disease management in Queensland for the period from June 2012 to July 2013.[24] This figure does not however take into account group-based chronic disease education programs run in public or private hospitals in the region, nor does it determine the number of patients actually attending all of the group-based education sessions.

Group facilitators were included if they were 18 years of age or over, were qualified health professionals and had experience facilitating a group education program for any chronic disease or condition. Facilitators were included if their group sessions consisted of two or more participants, were specific for persons with a chronic disease or condition and ran for a minimum of one session lasting one hour. The chronic disease or condition groups included in the present study were type 2 diabetes, heart failure, hypertension, coronary heart disease, chronic kidney disease and chronic obstructive pulmonary disease. The researchers ceased recruitment once data saturation was met, which was defined as there being no new information introduced by the group facilitators in the interviews for at least three interviews.

Expedited ethics approval was obtained from Griffith University's Human Research Ethics Committee, and Multi-site Low Risk Ethics approval was obtained from Queensland Health's Human Research Ethics Committee. Verbal and written informed consent was obtained from each facilitator prior to the commencement of the interviews. All of the interviews were conducted in person at the participants' workplace, by the first author, and were recorded using a digital recorder. Participants and their responses were de-identified by the interviewer prior to analysis.

This qualitative study employed a semi-structured interview method to explore the perceptions and opinions of the group facilitators' on the attributes that contribute to the success of group-based education programs for chronic disease self-management. An exploratory, qualitative study design was chosen due to the broad nature of the topic and the current lack of information on the subject area. Semi-structured interviews, primarily constructed of open-ended questions and probes, allowed facilitators to provide in-depth information, which may have been missed using other research methods.[23]

The interview questions were designed to reflect an inquiry logic, based on the assumptions about the type of information the questions will provide (refer to Table 1). The interviews were designed to contain a limited number of specific questions to ensure that they were succinct, yet provided comprehensive responses. All of the interviews

Table 1 Interview inquiry logic exploring group facilitators' awareness of the theoretical basis of the programs they implement, their experiences of implementation and their opinions on the attributes contributing to program effectiveness

Key inquiry questions:	*Logic:*
Describe the program to me in your own words.	To identify the program structure of a cross section of chronic disease education groups
What training did you receive before facilitating the program?	Identify the training provided to group facilitators
How was the program developed (was it evidence based)? Describe any learning and or behavioural theories used in the development of the program.	To identify how group-based lifestyle modification programs are developed and whether they are based on evidence, and behavioural or learning theories
What aspects of the program do you find most effective and why?	To identify the perceptions of group facilitators regarding the most effective program structure or activities
What outcome measures are used to assess the success of the program (individual outcomes and program outcomes)?	To identify the methods used to review the outcomes of group-based lifestyle modification programs
What are your (or managements) reasons for educating patients in a group setting rather than an individual setting?	To identify reasons for educating patients in a group setting rather than an individual setting
How do you feel the interactions within the group affect the patient outcomes?	To identify the effect of group interactions on a group-based lifestyle modification program

were conducted in person by the first author. Interview lengths were variable (between 11 and 32 minutes); however, even the shortest interview produced eight pages of transcripts and included in-depth discussions.

The interviews used a number of closed-ended demographic questions as well as open-ended questions and probes to explore how chronic disease group education programs are developed, the reasons for educating patients in a group setting, the facilitators' perceptions and opinions on the impact of various program attributes on the effectiveness of the programs, the training provided to group facilitators and the outcome measures used for evaluation. Group facilitators were not told how to define 'effectiveness'; however, the majority referred to patient satisfaction and patient retention when discussing effectiveness, rather than quantifiable outcome measures.

The interviews were transcribed verbatim by the first author. The transcribed text was read several times and discussed by the research team. Data analysis was completed manually and independently by three of the authors (authors 1, 2 and 5) who systematically coded the data using inductive coding, a process by which codes are created to explain the data regardless of the previous theory.[23] The coded data were then analysed using thematic content analysis, with analytical themes derived on the basis of the analysis, and seeking patterning of responses.[23] The data obtained from these interviews were grouped and the similarities and differences between the groups were assessed. The researchers then met and compared their analysis and verified themes via researcher triangulation to confirm that the analysis was completed objectively and that no common themes were missed. The research was of a descriptive nature, and an interpretive approach was used in the data analysis.[25] The coding and analysis additionally included attention to interview themes that offered differing or deviant responses when compared with the most common themes (fair dealing).[26] Responses to the demographic questions were sorted into categories and enumerated.

Results

Of the 36 health professionals invited to participate in the study, 14 accepted, 9 were no longer working in the area, 7 did not respond, 2 declined and 4 were not able to be interviewed due to the time-consuming ethics applications required by their workplaces. The 14 group facilitators interviewed were employed by five community centres (8/14), two public hospitals (5/14) and one private practice (1/14), and facilitated 10 chronic disease-based group education programs. The attributes of the 14 group facilitators interviewed in the present study are presented in Table 2. The typical facilitator from this sample was female (86%), 25–34 years of age (64%) and was a dietitian (43%) or nurse (29%).

The responses to the various questions relating to the development of the group education programs facilitated revealed much uncertainty. The majority (57%) of the participants noted that they were unsure as to why the group program was developed, how it was developed, who developed the program and whether or not a theoretical background was utilised in the development of the program. Most (57%) of the group facilitators reported that their group education program was based on evidence; however, none of the facilitators were able to report which evidence the programs were based upon. Additionally, the responses revealed that very few (21%) of the group facilitators were offered any formal group education training by their employer or workplace, with most employers assuming that adequate group education training and experience was obtained during the facilitators university education.

When asked about the ideal group education program length, session length and number of participants, group facilitators generally referred back to the program they were facilitating and reported that this program or session length

Table 2 Group facilitator sample attributes summary (n = 14)

	n	*Percentage*
Sex		
Female	12	86
Age (years)		
18–24	1	7
25–34	9	64
≥35–44	4	28
Profession		
Dietitian	6	43
Nurse	4	29
Other (social worker/exercise physiologist/dual qualified)	4	29
Education level		
Diploma/Advance Diploma	1	7
Bachelor	7	50
Masters	6	43
Years in the field		
<1	1	7
1–3	3	21
3–5	3	21
≥5	7	50
Years as group facilitator:		
<1	1	7
1–3	5	36
3–5	5	36
≥5	3	21
Number of times facilitated?		
1–5	3	22
6–10	2	14
>10	9	54
Have the condition?		
No	12	86
Program type		
Type 2 Diabetes Education/Prevention	8	57
Healthy Eating and Lifestyle Program	4	29
Cardiac/Pulmonary Rehabilitation	2	14
Number of sessions		
One	1	7
Four	6	43
Seven	1	7
Eight	5	36
Nine	1	7
Length of sessions (hours)		
1.5–1.75	2	14
2	5	36
2.5	5	36
3	2	14
Number of settings		
One	12	86
One plus supermarket tour	2	14

and number of participants was ideal. Most (43%) of the facilitators were involved in programs that were four weeks in length.

Almost all (93%) of the group education programs used patient satisfaction surveys for the evaluation of their group education program rather than biomarkers of risk or definitive health-related events. Validated tools such as the intuitive eating scale or the diabetes management self-efficacy scale were occasionally (29%) used in the assessment of patients; however, these were not used as repeat measures, and group facilitators did not appear to be analysing the results of these measures. Few (21%) of the group facilitators reported obtaining initial anthropometrical measures; however, they noted that no follow-up data were obtained.

Group facilitators generally reported that the reasons for educating patients in a group setting were time efficiency (57%), cost-effectiveness (29%) and patient benefits such as normalisation and support (64%). Despite these results, however, some (36%) of the group facilitators felt that group education alone was not enough for the comprehensive education of chronic disease patients. Most (57%) of the other group facilitators felt that group education was an adequate means of educating chronic disease patients, and that group education promoted patients' autonomy, helped them to take responsibility for their health and taught them the necessary skills to implement lifestyle changes.

Most (57%) of the interviewed facilitators felt that increasing the practical or hands-on activities and increasing the group interactions greatly improved group education programs. Examples of the practical activities included supermarket tours, activities utilising food models, label reading activities, food preparation, exercise sessions and goal setting. Most (57%) of the group facilitators encouraged the use of non-didactic discussion-based education techniques using a number of different media, such as PowerPoint presentations, videos, discussion-based activities and hard copies of reading materials, to improve the delivery of group education programs. The majority (64%) of the group facilitators referred to improving the enjoyment of participants and themselves and reducing participant attrition as the main goals when discussing improving their group education program. The improvement in measures of patients' health, anthropometric and biochemical outcomes was much less likely (14%) to be mentioned as the focus of any proposed changes to the group education programs.

The majority (64%) of group facilitators reported that the group interactions and use of a multidisciplinary team were the aspects that had the greatest positive impact on the effectiveness of group education programs in terms of patient satisfaction and program enjoyment. Facilitators reported that group interactions assisted with the normalisation of group participants, helping them to feel less alone and to understand that there were other people going through the same experiences, and that group participants offered significant support to each other. All but one of the programs (93%) utilised a multidisciplinary team, of which the team ranged from two to eight health disciplines, including dietitians, exercise physiologists, physiotherapists, nurses, occupational therapists, social workers, diabetes educators, podiatrists, pharmacists and psychologists. The reported benefits of having a multidisciplinary team presenting to the participants were the broad range of topics and areas covered, and the range of expert knowledge and advice

Table 3 Summary of key response themes relating to group program development, program structure, outcome measures, the reasons for educating patients in a group setting and group interactions

Area:	*Sub-area*	*Common response themes*	*Example quote*
Program development:	Training	No training offered; assumed knowledge	'Not a great deal! No particular group training as such.' (Participant 1)
	Development	Unsure	'I didn't develop this program so I'm not sure what it was based on.' (Participant 1)
	Evidence base	Yes—unsure which evidence	'It would be evidence based, yeah definitely. It references articles and things in it.' (Participant 4)
	Theoretical base	Unsure or not used	'I'm pretty sure they have, in the psychology bit definitely. Sorry, I don't know, I just picked it up and ran with it.' (Participant 6)
	Why developed	Unsure	'I couldn't tell you, it is a state-wide program and it's being run at several major hospitals.' (Participant 10)
Program structure:	Effective aspects	Group interactions	'The group dynamic is really effective for patients normalising how they feel. They're around other people that are going through the exact same experiences as themselves and after the program, their mood is increased.' (Participant 5)
	Recommended changes	Increase practical activities and group interactions	'We could probably do some more hands on food preparation perhaps; it might be a good idea. In the experience I've had, it's something people find enjoyable as well.' (Participant 10)
	Ideal delivery	Interactive; discussion-based delivery	'I think a combination of presenting the information, but allowing questions and interaction within the group.' (Participant 9)
	Ideal program length	Four weekly sessions	'I think four weeks is the maximum, because any longer and it starts to be a bit too hard for people to commit to and the people that work can't take any longer off.' (Participant 8)
	Ideal participant number	Uncertainty (range: 5–25 participants)	'Maybe you can tell me, because I know there is literature out there about it, but I can't find it!' (Participant 1)
Outcome measures:	Program and individual	Patient satisfaction surveys	'At the moment there's nothing. I just have the survey, that was something I just introduced this year, and in terms of health outcomes there's nothing assessed.' (Participant 1)
Group education:	Why group not individual	More beneficial to patients; time efficiency	'I think with anything delivered as a group you've got all those added components of group support, hearing others stories, not feeling so isolated, being able to ask questions or hear others questions and then hearing the answers that are then going to be supportive of you.' (Participant 12)
	Is group more beneficial	Yes; need a combination of group and individual	'There are definitely benefits, because they share experiences, and from that point of view it's a benefit, but if you could see a patient more regularly on an individual basis, I would say that that's more beneficial in terms of resource utilization.' (Participant 2)
Group interactions:	Effect on outcomes	Positive—provides support and normalisation	'Ah, I think it's brilliant, because they realise that they're not the only ones.' (Participant 3)
	Positives	Participants helping and supporting each other	'They all just problem solve each other, like they all come up with things, and things that I would never have even thought to come up with about certain situations.' (Participant 3)
	Negatives	Opinionated participants being disruptive	'I guess there are always the people that are very strongly opinionated and can try to take over, and sometimes that can be quite negative.' (Participant 8)
	Combating negatives	Group rules; gently challenging opinions	'The other thing we do at the beginning of each session is that we talk about the rules of the group, and respecting what we say is confidential, not talking when someone else is talking, so the basic, normal respect and group dynamics and respecting each other.' (Participant 7)
	Aspects which improve interactions	Group discussion	'I think open discussion is probably really good for improving the group dynamic, but you just have to have a tight control on bringing it back around when you feel that there's been enough.' (Participant 4)
	Aspects which diminish interactions	Presenting in a lecture style	'I think if people are too dependent on the power point presentation—if they do just talk to the audience, rather than engaging the audience—then it's a different kind of presentation—it's really a lecture.' (Participant 12)

offered to participants to assist their understanding of the condition.

The main negative (57%) reported with regard to group interactions were dominant or difficult participants who disrupt the group, provide incorrect information or takeover the group; however, most group facilitators noted that they had established various ways of dealing with negative interactions in the group sessions. The majority (71%) of group facilitators placed great importance on a non-didactic or discussion-based delivery of education as opposed to lecture style delivery, which reportedly significantly decreased group interactions. Poor group interactions were generally (86%) combated by establishing group rules at the beginning of the sessions, gently challenging difficult individuals or saving questions for the end of the session or for an individual consultation. A summary of the key response themes is provided in table 3.

Discussion

Group facilitators' perceptions and opinions regarding the attributes that appear to contribute to the success of group education programs for chronic disease management were group interactions, a non-didactic, interactive delivery style, a multidisciplinary team approach and using practical, hands-on activities. Group facilitators were uncertain about the theoretical and programmatic basis of their group education program, and very few of the group facilitators reported being offered any formal training prior to facilitating their group education program. The outcome measures that facilitators used to evaluate the majority of the group programs were limited. These factors may have a significant impact on the implementation and evaluation of group education programs for chronic disease management.

Group facilitators perceived that group interactions had a significant influence on the success of group education programs, which may be an indication that greater emphasis should be placed on encouraging group interactions rather than concentrating on the logistical aspects of group education programs. The majority of the facilitators interviewed discussed the benefits of the normalisation, social support and reduced feelings of isolation provided by positive group interactions. Social support has been long established as a protective factor in health, with improved health outcomes for conditions such as depression, cancer, post-myocardial infarctions and strokes.[27] Group interactions and peer identification can improve self-esteem and self-perception, reduce disease-related anxiety and provoke a feeling of well-being in spite of the patients' disease or condition.[28] Additionally, recent group education research has suggested that group interactions are more important than program logistics, such as content, in affecting improvements in patient outcomes and coping skills.[29,30] It is therefore important for group facilitators to ensure that a strong focus is placed on group interactions by facilitating social support, discussions, group activities and positive interactions instead of presenting in a didactic style, which reduces patient interaction.

Most of the facilitators felt that a non-didactic, interactive or discussion-based approach was the ideal form of program delivery as it allowed the development of a social dynamic and improved patient support and interaction. This is consistent with previous research which has shown that educational interventions involving patient collaboration, when compared to didactic education techniques, have shown improvements not only in patients' subjective reports but also in physiological measures such as weight, lipid profiles and glycaemic control.[31] Additionally, approaches to group education, which are both interactive and patient centred, have been shown to be effective.[17,32] The perceptions of the group facilitators interviewed for the present study, coupled with the evidence from the literature, indicate that non-didactic, discussion-based delivery should be incorporated into group education programs for chronic disease management.

A multidisciplinary team approach was also recommended by the group facilitators interviewed as it allowed for the presentation of a broad range of topics from a range of health experts. Group facilitators did not specify which disciplines they felt needed to be involved in the programs, instead focusing on the benefits they perceived from utilising a multidisciplinary team approach, such as the range of professional knowledge provided, an increased variety in presenters and improvements in patient understanding. Numerous group education intervention studies have highlighted the link between intervention success and the use of a multidisciplinary team of health professionals.[10,12,20,33] This indicates a successful translation of research into the practice setting.

Group facilitators expressed various opinions with regard to the overall duration of group education programs, which included the need for flexibility for working participants, the difficulties in getting participants to commit to lengthy programs and the need for longer programs to ensure that patients were required to make a serious commitment and make the most of the education on offer. Type 2 diabetes group education studies have highlighted the link between contact time and intervention success, finding that increased contact time results in better patient outcomes with research showing that every hour of contact resulted in a decrease in HbA1c of 0.04%.[7,9,13,27] It is challenging however to develop a program that is lengthy enough to affect health outcomes while being short enough to encourage patients to commit to the program and encourage low attrition rates.

Group facilitators were unable to suggest the most effective session length or number of sessions, and generally referred to the program they were facilitating, reporting that this was ideal. This may be due to familiarity bias and a lack of knowledge or insight into the area of group education. Alternatively, group facilitators may have found that their program and session length was ideal for the material covered and that the time taken allowed them to meet their program objectives. Additionally, this may reflect the divergent nature of the conditions discussed in these group education programs. As an example, when reviewing the literature on group education programs for type 2 diabetes, it was discovered that the range of contact hours were 12–52 hours, while the type 2 diabetes-based group interventions

facilitated by the participants of the present study usually provided 2–12 hours of contact time (most commonly 10–12 hours).[10–13,20] This may be an indication that the group education programs used for the present study are not adequate in length.

There is clearly some uncertainty in both the literature and the perceptions and opinions of the group facilitators interviewed with regard to group size. For example, previous group education research completed in the area of type 2 diabetes showed significant improvements in HbA1c, with each having a different group size (16, 5–8, 5–10 and 6–11).[10–13] This suggests that running a group education program with any more than 4 and any less than 16 participants may be both feasible and effective. The results of the present study show no apparent link between the number of participants and the success of the interventions. It may be assumed however that to improve the efficiency and cost-effectiveness of group education programs, the number of participants in each group should be maximised.

The outcome measures used by group facilitators were limited, with most using only patient satisfaction surveys. Evaluating participant satisfaction with health services can be clinically relevant as satisfied patients are generally more likely to comply with treatment and to self-manage their condition.[34] However, using patient satisfaction as a solitary outcome measure is inadequate as satisfaction can be an unreliable measure of patient health outcomes, particularly because patients generally have no or limited clinical expertise, and are often readily influenced by non-medical factors.[34] Additionally, there are very few published reports on the reliability of satisfaction surveys.[34] Without quantifiable outcome measures, it is difficult to assess whether group education programs are effectively improving patients' health outcomes. Medicare Australia suggests numerous repeatable outcome measures in the Medicare group services information pack, including self-management behaviour measures such as physical activity, diet, and medication changes, knowledge and skills, psychological measures such as self-efficacy, empowerment, coping, quality of life and stress, and biochemical measures such as fasting glucose or glycosylated haemoglobin levels.[35]

The perceptions and opinions were sought for the present study from a sample of group facilitators in order to provide a deeper understanding of current practice in chronic disease management. Obtaining opinions and practical insights from those currently in the field of group education was a valuable addition to the knowledge obtained from the literature. The sampling method and subsequent sample obtained for the present study is not representative of all group facilitators in Australia. The sample obtained however was expected to be competent in the development and facilitation of group education programs for chronic disease management and was adequate to meet the objectives of the present study.

An unexpected result of the present study was that group facilitators had limited knowledge of the group program development, and the theoretical or evidence base on which their program may have been designed. Various intervention studies have highlighted the need for the inclusion of learning or psychological theories in the development of group education programs for chronic disease management.[4,5,36–38] The group facilitators' limited knowledge may be a result of the lack of training provided by their employers, time restrictions or the difficult task of interpreting the current evidence and translating it into practice. The translation of research-based interventions into practice contexts is a critical and poorly understood aspect of health-care research. The majority of our understanding of group education research is based on randomised controlled trials. Despite clinical and health research continually generating new findings, which may assist in the effective and efficient care of patients, the translation of these findings into practice can be slow and unpredictable.[38] Additionally, clinical practice resources are often limited when compared to experimental settings, which can make the implementation of successful lifestyle interventions challenging.[40]

Another difficulty with extrapolating evidence from efficacy studies to practical applications is that it assumes that the intervention assessed will be implemented as planned by extensively trained and highly skilled experts in the field.[41] Implementation failure, incomplete or poor quality intervention implementation has previously been suggested as a major determinant of disappointing intervention outcomes.[42] Successful implementation of lifestyle interventions into practice settings is challenging for various reasons, and the evaluation of intervention implementation in the literature is limited.[40] It is critically important for health professionals to understand how programs run in our current health system. Without the provision of facilitator training, it was difficult to assess, from the current study, whether the group education programs had been poorly designed or whether experimentally successful programs were being disseminated without quality control and therefore risked implementation failure.

The results of the present study are potentially alarming, indicating that chronic disease group education programs are being disseminated with limited quality control and group facilitators have limited knowledge of the program development and theoretical or evidence base. It is difficult to establish whether this is a result of group programs being poorly implemented, the difficulty of translating evidence into practice, time management issues or the lack of training provided to group facilitators. The present study highlights the need for the provision of suitable group education training to facilitators to ensure that group education programs for chronic disease management are run as effectively as possible. Additionally, group facilitators should ensure the collection of suitable outcome measures to allow the quality improvement of programs, in turn, improving patient outcomes.

The limitations of the present study include the potential for sampling bias, the relatively small area from which facilitators were recruited, the potential for participant bias and potential issues with the interview questions and prompts. Group facilitators based in the South East Queensland region may have been missed if the details of their group education program were not easily found online, or if they were not

invited to participate in the research through snowball sampling, potentially resulting in sampling bias. The decision to complete all of the interviews in person forced the study to be based specifically in the South East Queensland region, which reduced travel costs and study completion time. It is likely that participant bias existed, as group facilitators who volunteered to participate in the study may have seen the interviews as an opportunity to vent, or express their dissatisfaction about poor experiences. Alternatively, the sample of health professionals obtained for the present study may have felt confident in their skills and ability as a group facilitator and may have used the interviews as an opportunity to put across their personal opinions. The interview questions were piloted using three group facilitators from the target participant group; however, this does not guarantee that the participants understood or responded to all questions clearly. It may have been beneficial to add further, more specific prompts, to the questions regarding outcome measures and group interactions and to allow participants the opportunity to view the questions prior to their interview.

Active group facilitators agree that chronic disease management group education programs should incorporate a multidisciplinary team, utilise a non-didactic delivery style and focus on using practical activities to support and encourage positive group interactions. Group facilitators' limited knowledge of the theoretical basis of their group education programs, their lack of training and the lack of clinical outcome measures is concerning and requires further examination to elucidate the reasons.

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Conflict of interest

The authors have no conflicts of interest to declare.

Authorship

KO-J undertook this project as part of her Doctor of Philosophy. She had a principal role in study design, data collection and analysis and took a lead role in drafting this manuscript. ML, RH and BD assisted with the data analysis, project design and manuscript editing. EI assisted with the manuscript editing. All authors participated in finalisation of the manuscript.

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Formative Interviews: Group Participants

Introduction

Persons with chronic diseases face many obstacles, including having to rely on a medical system largely designed for acute illness.[178] Chronic diseases pose distinctive challenges to our health care system, with sufferers requiring frequent, continuous access to health services and medications, and often developing complex multi-morbidities.[179, 253] Patient education is the basis of effective chronic disease self-management and is essential in achieving improved outcomes for chronic disease patients.[36, 46] Chronic disease patients are the predominant managers of their condition, making up to 99% of their health-related decisions without input from formal health services.[35-38] The goals of self-management education are to optimize QOL, prevent acute and chronic complications, reduce hospitalization, and optimize metabolic control, all while remaining cost efficient.[29]

This study aimed to explore participants' preferences for group program structure and facilitation, their perceptions of the effect of group interactions on their learning and impression of support, their interest in peer-supported or led programs, and patient outcomes, such as health, knowledge of their condition, lifestyle changes, and attitudes. The perceptions and opinions of group participants were sought for this study as a valuable addition to the knowledge obtained from the literature, and ensured that the information provided was representative of our current health care system and could be translated for practical applications. Actively involving individuals in the chronic disease care process has additionally been shown to improve patient outcomes. [45] Obtaining patients' perspectives on group-based education can potentially result in data which is rich in human experience and reflects the real-life experiences of individuals diagnosed with chronic disease.[181]

Group education programs offer many potential advantages to persons with chronic disease over individual visits, such as allowing time for the provision of more detailed

information, allowing the integration of families and carers, and facilitating support from others facing the same challenges.[37] Various studies have compared group versus individual education for CDM, however very few have explored the attributes contributing to the effectiveness of group education programs. Understanding the specific attributes that directly influence the success of group-based education programs would greatly benefit health professionals working in the area of CDM by informing the development and facilitation of more successful, efficient and cost effective group education programs.

Methods

The perceptions and opinions of this important group, persons with chronic disease, were sought for this study as a valuable addition to the knowledge obtained from the literature, and ensured that the information provided was representative of our current health care system and could be translated for practical applications.

Sampling

Group participants were contacted through group facilitators who were recruited for the previous study using a mix of purposive and snowball sampling.[254] All of the group facilitators were asked to either provide the group participants with information on the study, or to allow the researcher to attend a group education session to explain the study to participants who may have been interested in taking part. The group participants were provided with an invitation letter and participant information sheet and consent form via email. The participants were required to return the consent form with their contact details to the researcher in person, or by mail or fax. The researcher then contacted the participants to arrange an interview time and place.

Nine group facilitators were approached initially for the purposive sampling, one of whom took part in the study. From these nine facilitators, an additional 27 facilitators were contacted through snowball sampling. Of these 36 health professionals contacted, 14 participated in the study. 20 group participants consented to participate in the study, however four of these participants did not respond to the researcher after initial contact

was made. The 16 group participants interviewed were from nine chronic disease based group education programs. There was no relationship between the study participants and the authors.

Inclusion Criteria

Participants of group education programs were included if the group education program consisted of two or more participants, were specific for persons with a chronic disease or condition, and ran for a minimum of one session lasting one hour. The chronic disease or condition groups included in this study were any group-based lifestyle modification program for:

- Type diabetes mellitus,
- heart failure,
- coronary heart disease,
- chronic kidney disease,
- chronic obstructive pulmonary disease,
- arthritis and osteoarthritis.

Group participants were included in the study if they were 18 years of age or over, had been diagnosed with a chronic disease or condition, had taken part, or were taking part, in a group-based lifestyle modification program, had adequate cognitive ability, and had a sufficient understanding of English. The researchers ceased the recruitment once saturation was met, which was defined as there being no new information introduced by the group participants in the interviews for at least three interviews.

Ethical Considerations

Ethics approval was obtained from the Griffith University Human Research Ethics Committee (GU Protocol number PBH/04/11/HREC). Additionally a multisite low risk

ethics approval was obtained from Queensland Health (QH Protocol number HREC/11/QGC/55). Verbal and written consent was obtained from each participant prior to the commencement of the interviews. The interviews were recorded using a digital recorder upon gaining consent. Participants and their responses were de-identified by the interviewer prior to analysis. All of the interviews were conducted in person by the PhD candidate in the same location that the group education programs were run from, to ensure participants were not inconvenienced. Additionally, closed-ended demographic questions were completed by the group facilitators prior to the commencement of the interviews.

Data Collection

This study employed a semi-structured interview method to explore the perceptions and opinions of the group participants on the attributes that contribute to the effectiveness of group-based lifestyle modification programs for chronic disease self-management. An exploratory study design was chosen due to the broad nature of the topic and the current lack of information on the subject area, and semi-structured interviews, primarily constructed of open-ended questions and probes, allowed participants to provide in-depth information, which may have been missed using other research methods.[254]

The interview questions were designed to reflect an inquiry logic that makes clear the assumptions about the type of information the questions will provide. The development of the interview questions was informed by the results of the group intervention analysis and the exploration of the attributes of successful interventions. The interviews were designed to contain a limited number of specific questions to ensure that they were succinct, yet provided comprehensive responses. The final interview questions were piloted using two group participants from the target audience. After the completion of each pilot interview, a consultation with the participant, researcher and research supervisors took place and some minor changes to the interview questions were made. The data from the pilot interviews was not included in the overall analysis. The inquiry logic including the interview questions and probes for group participants, is provided in Table E1.

Data Analysis

The interviews were transcribed verbatim by the PhD candidate. The transcribed text was read several times and discussed by the research team. Data analysis was completed manually and independently by the PhD candidate and two supervisors who systematically coded using inductive coding to label the data without the consideration of previous theory.[255] The data were analysed using content analysis, with analytical themes derived on the basis of the analysis, and seeking patterning of responses.[254] The data obtained from the interviews was then grouped and the similarities and differences between the groups were explored. The researchers met and compared their analysis and verified themes via researcher triangulation to confirm that the analysis was completed objectively and that no common themes were missed. The research was of a descriptive nature, and an interpretive approach was used in the data analysis.[255] The coding and analysis additionally included attention to interview themes that offered differing or deviant responses when compared with the most common themes (fair dealing).[256] Responses to the demographic questions were categorized and enumerated.

Table E1: Interview inquiry logic exploring group participants' preferences for group program structure and facilitation, their perceptions of the effect of group interactions, their interest in peer supported or led programs, and their outcomes

Objective:	**Question:**
To identify patient preferences for group program structure (number of contact hours, facilitator/s, location/s, referrals, program content)	**Describe the program to me in your own words.** Describe what you liked most about the program? Describe what you liked least about the program? **How did you get involved in the program, and why?** **Which group educator did you enjoy the most and why?** **How do you feel the program could have been improved?**
To identify the effect of the group interactions on the individuals learning and impression of support	**Describe how the others in the group helped or hindered your learning outcomes?**
To identify patients interest in peer supported or led programs	**How do you think the program would have been different if it was run by someone who had your condition?**
To identify patient outcomes (lifestyle changes, attitudes, health and knowledge of their condition)	**How has your health changed since you started the program?** How has your knowledge of your condition changed since you started the program? How have your everyday behaviours, health and attitudes changed since you started the program?

Results

The attributes of the 16 group participants from the nine chronic disease group education programs included in this study are presented in Table E2. The typical participant from this sample was male (56%), 55 to 65 years of age (44%), was married (63%), had completed secondary school (44%), was retired (44%), earned less than or equal to $30,000 per annum (50%), was newly diagnosed (less than one year since diagnosis) (50%), and had not previously attended a group education program (81%). Of the group participants' interviewed, almost half participated in healthy eating and lifestyle modification programs (44%), whilst the majority of the others participated in type 2 diabetes education or prevention programs (44%).

The group participants interviewed for this study were asked various questions relating to the structure of the group education program they attended, as well as their thoughts on the strengths and weaknesses of the program, and any suggested changes. The responses to these questions revealed that the majority of group participants felt that the program strengths were the knowledge provided (56%), the approach to the program (31%), and the group interactions (27%). Group participants did not recognise any program weaknesses, and the majority did not suggest any changes (56%). Some participants (31%) suggested increasing the program length to allow more discussion time and to further improve group interactions.

Table E2: Group participant sample attributes summary (n=16)

		N	Percentage
Sex:	Male	9	56%
Age:	35- 44 yrs	2	12%
	45-54 yrs	3	19%
	55-65 yrs	7	44%
	65-74 yrs	3	19%
	≥75 yrs	1	6%
Marital Status:	Married	10	63%
	Divorced	4	25%
	Never Married	2	12%
Education level:	Primary	2	12%
	Secondary	7	44%
	Certificate	5	31%
	Bachelor	2	12%
Employment status:	Full time	2	12%
	Self-employed/ Homemaker	2	12%
	Retired	7	44%
	Disabled/ Ill	5	31%
Current household income:	≤$30,000	9	56%
	$30,000- $50,000	2	12%
	$50,000- $75,000	2	12%
	$100,000- $125,000	3	19%
Years since diagnosis:	≤1 yr	8	50%
	3-5 yrs	3	19%
	7- 10 yrs	2	12%
	≥10 yrs	3	19%
Previous group attendance:	No	13	81%
Program type:	Type 2 Diabetes Education or Prevention	7	44%
	Healthy Eating & Lifestyle Program	7	44%
	Cardiac/ Pulmonary Rehabilitation	2	12%

Group participants were additionally asked how they came to be enrolled in the program and which of the group facilitators they enjoyed most and why. Most (81%) of the participants had been referred by their general practitioner or specialist. Half (50%) of participants enjoyed all of the group facilitators and could not single one out as being the best. The reason most commonly provided for the appreciation of group facilitators was that they provided good information.

Group participants were asked how the others in the group helped or hindered their learning. Almost all (88%) of the participants reported that the others in the group helped their learning by sharing ideas, supporting each other, and allowing others to learn from their experiences. Additionally, most (88%) of group participants reported feeling normalised by the group education experience and their interactions with peers. When asked whether they thought that the program would have been different if it were peer led, responses were mixed. Most (81%) felt that having a peer led program would be beneficial as the group facilitator would have a better understanding, practical knowledge and real life experience than a group facilitator without the condition; whilst others (25%) believed that the group facilitator would need to be as well educated as a health professional in the field to facilitate the programs effectively.

The interviewed participants reported various health improvements when asked how their health had improved since starting the program. These included weight loss (44%), feeling healthier or better (38%), having improved awareness in regards to their health (31%), improvements in diet (31%), increased exercise levels (25%), and improved blood glucose control (25%). The majority (94%) of group participants reported great improvements in knowledge especially in regards to diet (50%), which they related directly to the education provided in the group program. Additionally, participants' attitudes (25%), diet (44%) and awareness of their health and choices (44%) were most often improved following the completion of the program. A summary of the key response themes provided by the group participants interviewed for this study are available in Table E3.

Table E3: Summary of key response themes: Participant Interview Study

Area	Sub-area	Common themes	Example Quote
Program structure	Aspects liked most	Knowledge base; goal orientated, patient-centred approach; group interactions	"The approach for this program was entirely different, they never told me you have to do this or you have to do that, or you can only eat this or that." (Participant 3)
	Aspects liked least	Nothing (like everything)	"I don't think I had any negative feelings at all. I suppose I was a bit apprehensive when I first came here, I didn't know what to expect, but the person running it made us all relax." (Participant 1)
	Referral pathway	Most participants were referred by their doctor or specialist	"I was referred initially by the doctor, the doctor then sent a fax to the QE2 hospital, the QE2 then instigated everything and I ended up here." (Participant 2)
	Favourite group educator and why	All were good; only had one; dietitian- because they provided good information	"I enjoyed them all. All of them had their own special qualities and they all had really good input." (Participant 7)
	Recommended changes	None, increase program length, allow more discussions/ group interaction	"I think the sessions could go a little longer actually. I think for really good interaction between the people and understanding what everybody is doing and what they are trying to get through, you need more time to do that." (Participant 1)
Group interactions	Helped or hindered learning	Helped; peer identification; sharing ideas; support; learning from others	"They helped by just simply making remarks, and then the more they talk the more you realize 'yeah I'm going through that, I'm not mad after all'. It's listening to other people talk, and you can relate a lot better with a group session. If you were one off you would probably be questioning your own feelings." (Participant 15)
Peer led programs	Difference if peer led	Programs would be better as facilitators would provide more understanding, experience and practical knowledge; No- they need the education and knowledge background	"I think it would have been a lot more beneficial actually. Because you could see someone who had actually gone through, and knew the problems that you were going through, and had dealt with some of the same issues themselves and could guide you." (Participant 13)

Health outcomes	Health changes	Decreased weight; feeling better/ healthier; more aware of good choices/ health/ exercise; improved diet; increased exercise, improved BGL's	"In the ten weeks, I've lost near on 20 kilo's. My diabetes has changed dramatically. I've seen a doctor and I've had two tablets completely taken away. I feel a lot better, I can walk more, and I'm not using my walking stick." (Participant 3)
	Knowledge	Improved; especially in regards to diet	"My diet has changed quite a bit, because I am more aware of a lot of things. I know things that I didn't know before, specifically the portions." (Participant 4)
	Behaviours, health and attitudes	Improved attitudes; diet and awareness	"Definitely making better conscious choices – as to what I am putting in my mouth and thinking about it more." (Participant 7)

Discussion

Group participants' perceptions and opinions of the attributes which appear to contribute to the success of group education programs for the management of chronic diseases, are the group interactions, the knowledge provided, and a goal-orientated, patient-centred approach. Group participants were generally satisfied with the program structure and facilitation; however some suggested lengthening session times to allow more time for group interactions and discussion.

Group participants' perceived that group interactions had a significant influence on the success of group education programs, which may be an indication that more emphasis should be placed on encouraging group interactions, rather than concentrating on the structural aspects of group education programs. The majority of group participants indicated that the others in the group helped their learning by providing peer identification, as is often experienced in group education settings, and by sharing ideas, providing support to each other, and allowing others to learn from their experiences. It is important for group facilitators to ensure a strong focus on group interactions by facilitating social support, discussions and positive interactions.

Social support has long been established as a protective factor in health for various conditions such as depression, cancer and CVD, with research showing that individuals who had perceived support from their peers, spouse or the group, generally had better health and psychological outcomes than those who did not.[31, 215-218] There is potential for social support to improve outcomes for all participants in a group- based lifestyle modification program as individuals diagnosed with chronic disease can provide each other with peer support, understanding, shared experiences, and assistance to overcome challenges to improve their health. Research has shown that group interactions and peer identification can improve self-esteem and self-perception, reduce disease-related anxiety, and provoke a feeling of well-being.[49] Additionally, recent group education research has suggested that effective group interactions and processes are a reliable predictor of improved patient outcomes and coping skills.[257, 258]

The majority of group participants felt that the knowledge provided by group facilitators was a very important aspect of the group education program, indicating that future programs should maintain a focus on knowledge provision rather than focusing on group interactions alone. The importance of patient knowledge in achieving better health outcomes for individuals with chronic disease has been highlighted by various studies.[36, 46, 179] Various group education studies have shown significant improvements in patient knowledge when comparing individual and group education programs.[38, 49, 86, 91] Additionally, evidence strongly suggests that a knowledgeable person with chronic disease achieves better health outcomes.[179] It is now widely agreed that although knowledge is an essential prerequisite to learning; knowledge alone does not translate into behaviour change.[40] The findings of this study, coupled with the evidence, indicate that it is essential for health professionals to ensure that group education programs for the management of chronic diseases ensure adequate course content and knowledge provision to group participants.

Evidence supports the use of a patient-centred approach, and research has shown that engaging individuals in their health care decisions can enhance their adherence to therapy.[146] Additionally, patient-centred interventions have been effective in improving patient knowledge, blood glucose levels, weight, and medication usage, as well as assisting the development of self-management behaviours.[99] A patient-centred approach is defined as an approach to "providing care that is respectful of and responsive to individuals' preferences, needs, and values and ensuring that patient values guide all clinical decisions".[146] Recent chronic disease group education research has shown an association between patient satisfaction and course content.[257] The perceptions of the group participants interviewed for this study and the results from the literature indicate that educating persons with chronic disease in a group setting using a patient-centred approach would be efficacious.

The WHO recently recognized peer-support programs as a valuable and promising approach to diabetes education and management.[3] Peers can offer knowledge, expertise, emotional support, and provide encouragement beyond the capacity of many health professionals.[189] Allowing peers to facilitate chronic disease group education programs can result in reduced healthcare costs and relieve some of the pressure placed on health professionals.[189] Research has shown that peer led, face-to-face self-management education programs for persons with T2DM can produce short-term improvements in self-efficacy, cognitive symptom management, and self-rated health, however it is clear that long term, ongoing support is required in order to maintain these improvements.[189] Most group participants felt that a peer led program would benefit individuals with chronic disease as they believed that the group facilitator would have a better understanding, more practical knowledge and real life experience than a group facilitator without the condition. Other group participants felt that group facilitators should be qualified health professionals to effectively facilitate a group education program. The inclusion of peer educators or supporters to group education programs for CDM may be a valuable addition to future programs.

The interviewed participants self-reported various health improvements resulting from the chronic disease group education program they took part in. These included improvements in biometric measures such as weight and blood glucose control, as well as improvements in knowledge, attitudes and behaviour, such as healthier food choices and increased exercise levels. Research has shown that group-based education programs can be successful at improving a number of patient health outcomes, such as HbA1c, body weight, waist circumference, blood pressure and cholesterol.[22, 91, 98, 241, 251, 259-262]

The sample obtained for this study is not representative of all group participants in Queensland; however the sample was adequate to meet the objective of this study, which was to explore individuals' with chronic disease perceptions of the attributes that contribute to the effectiveness of group-based CDM programs. For the purpose of this interview study, sample representativeness was not necessary, as the researchers were

exploring lived experiences of individuals diagnosed with chronic disease in a real world setting. A strength of the study was the inclusion of persons from a range of backgrounds and various chronic disease group education programs. It is possible that participant bias existed, as those who volunteered to participate may have seen the interviews as an opportunity to vent, or express their dissatisfaction. Alternatively, the sample obtained for this study may have felt extremely satisfied with their group education experience and may have volunteered because of this.

It is difficult to determine which attributes of group education programs account for the significant benefits of group compared to individual education for CDM. The descriptive program attributes (e.g. number of sessions, contact hours, group size) of successful chronic disease group education programs vary considerably (number of sessions= 6- 12 sessions, contact time= 8- 52 hours, and group size= 5- 16 persons).[86, 91, 98, 179, 241, 251, 261-263] This indicates that program logistics may have less influence on the effectiveness of chronic disease group education programs than other attributes, such as group interactions and social support.

Conclusion

The participants in this study reported that they felt that the group interactions and a patient-centred approach were the attributes that had the greatest impact on the changes they experienced after the course. This may indicate that group interactions and a patient-centred approach may have a greater impact on patient satisfaction and outcomes than other program attributes. Further research into the impact of group interactions on group education programs is clearly required. Future CDM group education programs should utilize a patient-centred approach, be goal-oriented, and focus on supporting and encouraging positive group interactions.

Conclusions of formative interview studies

In conclusion, according to the group facilitators and group participants of group-based chronic diseases management programs, the attributes contributing to the success of group education programs are:

- A strong focus on developing and encouraging group interactions;
- A patient-centred, goal-oriented approach;
- A non-didactic, or interaction and discussion based education style which also incorporates practical activities;
- A multi-disciplinary team;
- Establishing group rules at the commencement of the program;
- Providing a good knowledge base to group participants;
- Providing 10 to 24 hours of facilitator-patient contact time ideally over four weekly sessions and to groups or 5 to 25 participants; and
- Possibly including peer supporters to assist the group facilitator and provide support to the group participants.

Appendix F: Medicare Group services information pack

Medicare Group Items for People with type 2 diabetes

From 1 May 2007, new Medicare items will be available for group services for people with type 2 diabetes provided by Credentialled Diabetes Educators (CDEs) and/or Accredited Exercise Physiologists (AEPs) and/or Accredited Practising Dietitians (APDs) who are registered providers with Medicare Australia.

More detailed information about these new items (81100 to 81125) can be found on the Department of Health and Ageing (DoHA) website at: www.health.gov.au/epc. This site provides a range of material:

- Allied health group services under Medicare for patients with type 2 diabetes – Information for allied health professionals
- Allied health group services under Medicare for patients with type 2 diabetes – Information for GPs
- Referral form for Allied Health Group Services under Medicare for patients with type 2 diabetes
- MBS Item Descriptors (items 81100 to 81125)
- MBS Explanatory Notes (items 81100 to 81125)

This booklet has been prepared by representatives from the Australian Diabetes Educators Association (ADEA), the Australian Association for Exercise and Sports Science (AAESS) and the Dietitians Association of Australia (DAA), to complement the material produced by DoHA and assist CDEs, AEPs and APDs to develop and provide best practice group services.

The multidisciplinary approach: what does it mean?

A collaborative, multidisciplinary approach to delivery of these group services is encouraged. Multidisciplinary practice is a team approach to the provision of healthcare, involving all relevant medical and allied health disciplines. In the case of the Medicare group items, this would involve general practitioners (GPs), CDEs, AEPs and APDs working together to deliver services aimed at improving the health of people with type 2 diabetes.

As well as delivering benefits to patients, collaboration can also provide benefits for allied health professionals. Such benefits include sharing the management of program administration such as coordinating engagement with local GPs, sharing of educational resources and program evaluation, professional development, access to venues and reinforcing positive group dynamics.

Working with GPs and engaging with the local Division/s of General Practice to promote services and seek their input on preferred referral and feedback practices, will also enhance collaboration and produce better patient outcomes. Divisions of General Practice may assist with local referral directories, website links and newsletter promotions.

ADEA, AAESS and DAA have all significantly enhanced their websites to facilitate the easy identification and location of Medicare registered providers and the services they provide. Ensuring you are listed on these websites and that your details are current will promote your services and enable GPs to refer to your programs.

The evidence for group interventions

A recent Cochrane review[1] on literature up until 2003 has concluded that group-based, patient-centred training results in effective clinical, lifestyle and psychosocial outcomes for people with type 2 diabetes. Benefits to group participants included reductions in glycosylated haemoglobin (HbA_{1c}), fasting blood glucose, body weight and systolic blood pressure, improved diabetes knowledge and reduced need for diabetes medications. Recent literature[2] supports these findings and indicates patients may also benefit from groups by improving blood lipids[3, 4] and locus of control[5], reducing anxiety/distress[3, 6, 7], increasing knowledge[3, 4, 8, 9] and satisfaction in knowledge[10], improving quality of life[3] and feelings of well-being[11] and by eliciting positive changes in health care behaviours (exercise, diet and other self-management strategies)[3, 10, 12-14].

Most interventions reviewed were multidisciplinary and achieved positive outcomes for participants.

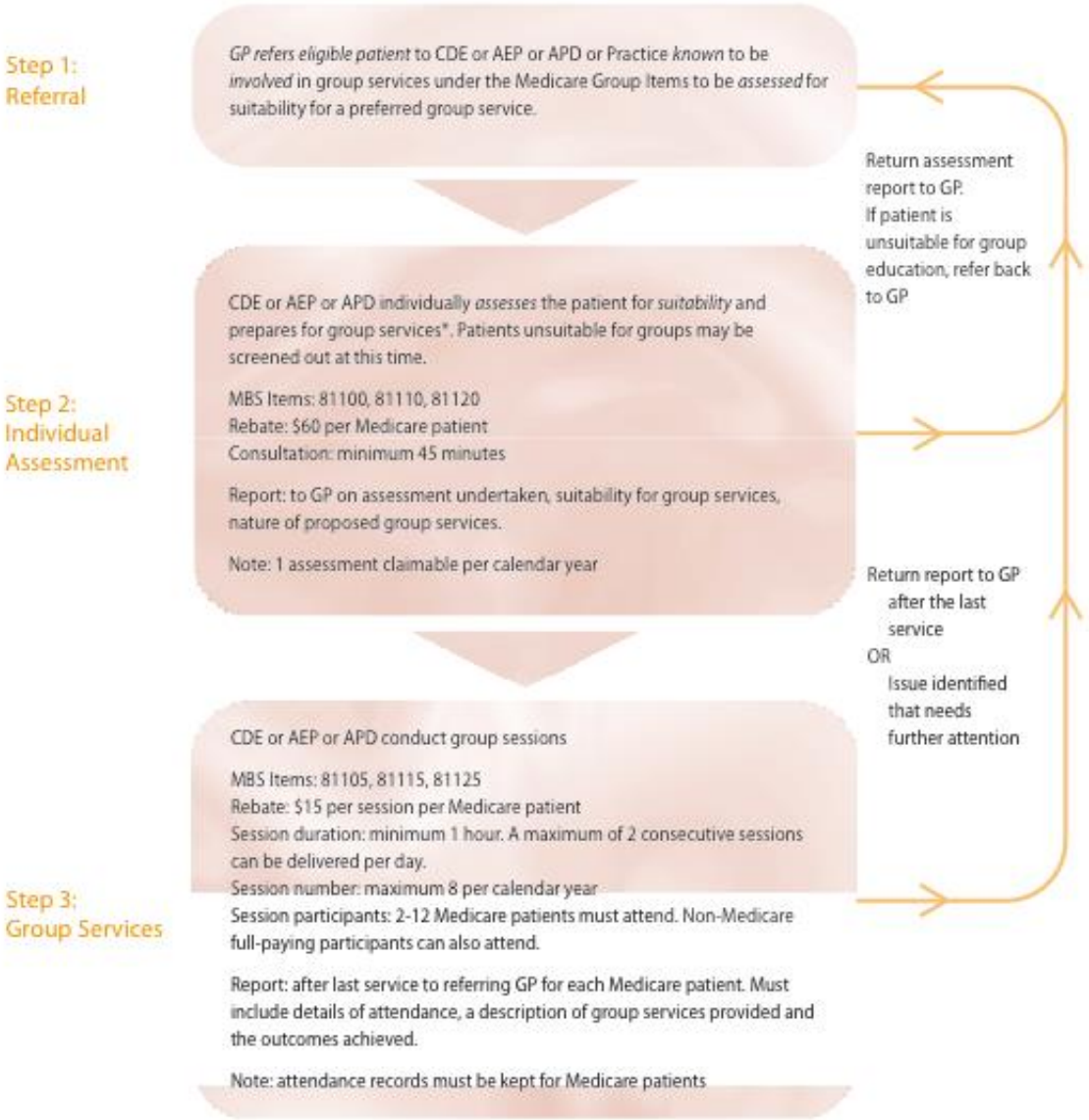
Group practice pointers

The resources provided on the DoHA website (see above) provide detail on the requirements for the group services. Figure 1 summarises these requirements in flow chart format.

Allied health professionals may also find the following group practice pointers helpful:

- Information and education needs of individuals vary[15]. Evidence and current practice suggest that adult groups may often be mixed for age and gender, however disease stage (e.g. newly diagnosed) and cultural, language and other specific needs may be targeted[2]. Group education should be learner-centred[15] and each individual assessed for available and appropriate group interventions.
- The literature[2] and current practice suggest that groups of ten or less participants work well. The success of larger groups is not precluded by these findings.
- Multidisciplinary practice is strongly encouraged but it is recognised that all 3 disciplines may not be available to provide group services. For certain group services a single discipline approach may be appropriate. Dual/multi qualified practitioners appropriately registered with Medicare Australia may deliver sessions under all disciplines in which they are credentialled/ or accredited.
- There is no set length of session that appears best. Sessions of 1-3 hours were common in reviewed literature[2].
- There is no set number of sessions or standard content type that appears to be best. The number of sessions may vary according to the content and goals of each program.
- Group programs should be developed according to a plan with achievable and measurable goals and objectives. Evaluation of the success of group sessions can be measured against key indicators of success using process and impact indicators at the group and individual level.

Figure 1- Flow Chart: Summary of Group Service Process



Phone Medicare Australia for claim enquiries on 132 150

*The CDE or AEP or APD carrying out the assessment would ideally be part of the group delivery team, however, this is not an essential requirement.

Eligibility

To be eligible for allied health group services, a patient must:

- have type 2 diabetes;
- have a relevant care plan in place; and
- be referred by their GP to the eligible allied health professional for assessment for group services.

In some cases, a patient may not be suitable for any *of your* group services but these patients should still be assessed as eligible for group services. These patients can be directed to an appropriate group program elsewhere. These aspects of patient suitability should be included in the assessment report to the GP.

Individual Assessment

All prospective clients must be assessed before commencing a group program. This includes taking a comprehensive patient history, identifying individual goals and preparing the patient for an appropriate group program. The assessment will also determine the patient's suitability for group services.

The assessment

- must be conducted by a CDE or AEP or APD (registered with Medicare Australia) as an entry point to any allied health group services available; and
- can only be conducted once per calendar year for each patient.

A generic assessment checklist is provided (Figure 2). This assessment checklist should provide the basis for the assessment conducted by any one of the three disciplines. Additional discipline specific assessment should be undertaken as required and as relevant to the type of group program requested.

As the assessment is generic in nature a CDE or AEP or APD can then direct patients to any type or combination of group services. For example, a person newly diagnosed with type 2 diabetes may not be appropriate for inclusion into a group program targeting participants with longstanding diabetes but may be suitable for another program being offered in the local area. Similarly, patients with limited spoken English and/or specific cultural needs may not suit your program/s but may be suitable for another group service where these particular needs are met.

Exclusions

Items 81100 to 81125 do not apply for services that are provided by any other Commonwealth or State funded services except where an exemption under sub-section 19(2) of the *Health Insurance Act 1973* has been granted. These items also can not be provided to a person who is an admitted patient of a hospital.

Figure 2: Assessment checklist and outcomes

CLIENT DETAILS

- Name
- Date of birth
- Contact details
- Next of kin and contact details
- Occupation
- Social / family
- Identifies as Aboriginal or Torres Strait Islander YES/NO

CORE ASSESSMENT

Diabetes History

- Year of diabetes diagnosis
- Family history of diabetes/CVD
- Complications/co-morbidities
- Recent hypoglycaemic episodes (frequency/severity)
- Review of BGL log book
- Any change in medical history since GP referral

Previous diabetes care/education

- Diabetes educator/diabetes education program
- Dietitian
- Exercise physiologist
- Other

Biomedical

- Glycosylated haemoglobin
- Lipid profile
- BP

Anthropometry

- Weight, height, BMI
- Waist circumference

Current activity level

- Current activity
- Contraindications to physical activity
- Mobility issues

Smoking status

Alcohol Intake

PATIENT ELIGIBILITY AND REFERRAL PARTICULARS

- Confirm that the person has been diagnosed with type 2 diabetes.
- Confirm patient is eligible for Medicare rebates for the group intervention.
- Confirm that the patient has a relevant care plan in place under Medicare
- Not exceeded eight group interventions in calendar year
- Check that patient understands that the referral involves participation in a group program.

Medications

- Prescribed (type, dose)
- Over the counter

Current Self Care

- Self blood glucose monitoring (frequency / self efficacy)
- Carries ID
- Carries 'hypo' treatment (if applicable)
- NDSS registration

Relevant Special needs

- Vision
- Hearing
- Physical
- Cognitive
- Literacy
- English as a second language
- Need for interpreter
- Any current signs / symptoms of hyperglycaemia

Readiness to change and ability to participate

- Previous experience in group programs
- Stage of change specific to proposed intervention
- Willingness / capacity to participate in group program as specified (eg, capacity to participate in exercise program, willingness to discuss eating issues in nutrition program or confidence to manage feelings in a group setting with regard to their diabetes)

OUTCOMES OF THE ASSESSMENT

- Discuss outcomes of assessment and suitability for specified group program with patient
- Check the patient understands the focus, content, timeframe, costs and billing arrangements for the group program
- Make arrangements for enrolment in specified group program or discuss alternative intervention in conjunction with referring medical practitioner

Possible Format for Group Services

Practitioners may develop a sequential program with sessions building on different aspects of diabetes management, or stand alone sessions that may be "cherry picked" according to patient needs. An example of the content of an eight week sequential program delivered by all three professionals working in their scope of practice might include:

1. Program introduction and overview, professional introduction, participant introduction, group guidelines for success, overview of type 2 diabetes (CDE or AEP or APD).
2. Introductory nutritional principles for type 2 diabetes, including glycaemic index, glycaemic load, fats, protein, carbohydrates, portion sizes & food labelling (APD).
3. Hypoglycaemia and hyperglycaemia, blood test results, blood glucose monitoring (CDE).
4. Physical activity overview, physical activity guidelines for people with type 2 diabetes and strategies to overcome barriers to participation (AEP).
5. Associated healthcare issues for people with type 2 diabetes - foot care, kidney function, eye tests, vascular function etc (CDE).
6. Nutrition guidelines for weight management and optimal cardiovascular function (APD).
7. Exercise strategies for weight management and optimal cardiovascular function (AEP).
8. Review of core program components, Q&A, evaluation & participant feedback (CDE or AEP or APD).

Possible Program Variations

While the evidence supports a multidisciplinary team approach this may not always be possible (for example in rural and remote locations). Group sessions will still be available under the group item for patients who are assessed as suitable whether one or a combination of the three eligible professions deliver the group program.

A practitioner who is dual qualified may deliver separate discipline-specific group sessions and have the claims lodged under the relevant items for the discipline. For example a dual qualified AEP/APD can run a physical activity-specific group session and a separate nutrition-specific group session with the sessions being claimed under MBS items 81115 and 81125 respectively.

Groups may also be designed for Indigenous, culturally and linguistically diverse (CALD) communities and other groups with specific needs. Groups may target specific aspects of diabetes management or different stages of the diabetes continuum (for example weight loss, managing cardiovascular disease, interpreting self monitoring of blood glucose, insulin therapy in type 2 diabetes). Suitable patients may also access a group program that includes people without diabetes providing the program is delivered by an eligible provider and includes topics to assist with the management of their diabetes.

Examples of such programs include general weight loss programs, healthy heart programs and general physical activity programs. There must be at least 2 Medicare-funded patients in any of these groups for the new Medicare items to apply.

Tips for conducting successful group programs

Engaging with your local GP Division/s

- Advertising groups sessions through the Division via newsletters.
- Using flyers to target local GPs
- Posters in GP surgeries
- Offering flexible session times for varying clientele
- Ensuring your practice and group services are listed on your Association website
- Offering an information session at a GP continuing education event or meeting
- Liaison with practice nurses/practice managers

Maximising group attendance

- Offering flexible session times for varying clientele
- Reminder letters or telephone calls
- Encouraging support (within group/bring a partner)
- Social engagement: incorporating educational outing (supermarket tours, walks)
- Giving participants "homework" for the next session
- Allow opportunities to make-up or "cherry pick" sessions within a suite of potential sessions

Maintaining group dynamics

- Establishing group / program 'rules'
- Time allocated at commencement of each session for participants to share experiences in achieving goals set the previous week, barriers encountered and group problem solving

Program Evaluation

Evaluation is an essential process to assist with quality assurance within your group practice.

Process Evaluation
This is related to the program activities (quality and implementation) and reach (of target group and within target group)[15].

Possible indicators of success include;

- Referrals to the program
- Requests for further consultation
- Feedback from participants and GP
- Satisfaction of participants and GP
- Attendance/dropouts
- Audience involvement/participation

Impact Evaluation
This is related to the immediate effects of the program[16].
Possible indicators of success include;

Change in pre-/post-testing of

- self-management behaviours: physical activity, diet, medications achieving set goals, problem solving
- knowledge and skills
- self-efficacy, empowerment, coping, quality of life, stress
- Fasting glucose, glycosylated haemoglobin levels

Reporting

The CDE or AEP or APD must provide a report to the referring GP after the assessment *and* after the last group service in the program.

The assessment report needs to include the following:

- an outline of the assessment undertaken
- whether the patient is suitable for group services
- the nature of the group services proposed

At the completion of the group program a written report for *each Medicare* patient is required which includes the following:

- attendance record
- a description of the group services provided for the patient
- outcomes achieved

Useful Resources, References and Links

- Department of Health and Ageing: www.health.gov.au/epc
- Medicare Australia: http://www.medicareaustralia.gov.au/providers/
- Australian General Practice Network (AGPN) www.agpn.cam.au
- Australian Diabetes Educators Association: http://www.adea.com.au
- Australian Association for Exercise and Sports Science: http://www.aaess.com.au
- Dietitians Association of Australia: http://www.daa.asn.au
- Diabetes Australia: http://www.diabetesaustralia.com.au/

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Appendix G: Intervention study design using the TIDieR checklist and guide

1	**Brief name**	The Bond Diabetes Intervention (ANZCTR registration: Trial ID: ACTRN12614000572662)
2	**Why**	Rationale or theory: Patient-centred care, non-didactic approach, patient-directed intervention Goal: To evaluate the feasibility and acceptability of the Bond Diabetes Intervention using two process evaluation frameworks (MRC Framework for Developing and Evaluating Complex Interventions and RE-AIM)
3	**What:** Materials	Participants were provided with freely available handouts from the Diabetes Queensland website[1] and the Australian Government Department of Health Eat for Health website[2]; and simple recipes were given to the participants of group 2 only at the request of group members
4	Procedures	Participants were phoned by the group facilitator a week before the commencement of the program to remind them of the commencement date and location. The first session commenced with an introduction by the facilitator, followed by introductions by each of the participants who also explained when they were diagnosed with T2DM. A brainstorming process was used whereby suggested topics were transcribed onto a whiteboard, and then assigned to the sessions to guide content. The topics chosen varied slightly between groups: Group 1 (n= 7) selected understanding diabetes, medications, diet and glycaemic index, hunger pains, margarines and spreads, controlling and checking blood glucose levels (BGLs), BGL diaries, and feeling overwhelmed or stressed; Group 2 (n= 6) selected glycaemic index, gluten free food, sugar cravings, reading food labels, BGL testing, exercise, HbA1c levels, medications, simple recipes, and what to eat. Group rules, informed by previously published 'responsibilities of the group', were established at the first session and discussed to ensure that all participants were aware of expectations.[2] These rules included: 1. Come to every session, 2. Ask anything you want, 3. Maintain confidentiality, and 4. Give new activities at least a 2-week trial.[3] A short break was taken in the middle of each session for morning tea, which was provided, in order to allow the participants to become better acquainted in a relaxed environment.

		The final session included a summary of the topics and farewell.
5	**Who provided**	Provider: Accredited Practising Dietitian (KOJ); Training: Informal group education training (online) and formal training during University degree (Master of Nutrition and Dietetics with Honours) and professional placements across Individual Case Management.
6	**How**	Face-to-face, group-based, non-didactic delivery using a discussion based, patient-centred and patient-directed approach.
7	**Where**	Local community centre (Robina Community Centre)
8	**When and How Much**	12 hours: 6 weeks of sessions (2 hours each); Group 1: Thursday mornings 9-11am; Group 2: Friday mornings 9:30-11:30am.
9	**Tailoring**	Personalization: The intervention was personalized in that participants received the first session as an individual session in which the topics for the sessions were brainstormed, and group sessions were patient-directed.
10	**Modifications**	Nil modifications to the intervention were made, apart from the tailoring of content to each group's needs.
11	**How well:** Planned	Intervention adherence and fidelity was assessed by the group facilitator (KOJ) who kept a researcher journal throughout the intervention to record reflections and logistics. A three armed, randomized study comparing the effectiveness of the patient-directed intervention, to a structured intervention and a wait-list control group was planned.
12	Actual	The recruitment target was not met resulting in an amendment of the planned study to a single armed feasibility study with no randomization.

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Appendix H: Survey of Australian Dietitians

1. Background:

The aim of this survey is to explore the utilization of group-based education for patients with type 2 diabetes mellitus (T2DM) by Australian Accredited Practising Dietitians (APDs). Additionally, we are interested in the preferences for practice and the training provided to Australian dietitians prior to the commencement of group-based education programs for the management of T2DM.

Is this you?

This survey is aimed specifically towards APDs who currently consult directly with patients and/or clients (i.e. acute care, private practice) or previously consulted directly with patients and/or clients. Therefore, clinicians who are not currently APDs or work in roles that do not meet these criteria are unfortunately ineligible for this survey. Additionally, only APDs who have worked in the field for at least one year and are currently living in Australia will be included in this survey.

Please read the following:

To help guide your responses to this survey, please use the following classification when thinking about the term "group-based education for the management of type 2 diabetes mellitus":

- Face-to-face education of patients of clients in a group of two or more.
- Programs which run for a minimum of 1 hour and 1 session.
- Programs which are specific for patients who have been diagnosed with type 2 diabetes mellitus.

For the sake of the study, "group-based education for the management of type 2 diabetes mellitus" DOES NOT include:

- Individual consultations
- Group-education programs which include patients who have not been diagnosed with type 2 diabetes mellitus unless they are support persons attending with a family member, spouse or friends (who has been previously diagnosed with type 2 diabetes mellitus).

Ethics information:

The study is voluntary and anonymous. We will collect non-identifiable data only and demographic data will be pooled. We anticipate this survey will take approximately 7-10

minutes to complete. It is up to you to decide whether or not to take part in the survey, and once you have started the survey you do not have to complete it. Submission of a completed or partially completed survey implies consent to participate, and for data entered, or all data entered up to the exit point, to be included in the study. As participation is anonymous it will not be possible for us to withdraw your data once you have submitted the completed survey. This research protocol (RO15456) has been approved by the Bond University Human Research Ethics Committee. If you have any questions regarding this project, please contact the principal investigator, Professor Liz Isenring (lisenrin@bond.edu.au). Should you have any complaints concerning the manner in which this research is being conducted please make contact with: Bond University Human Research Ethics Committee, c/o Bond University Office of Research Services. Bond University, Gold Coast, 4229; Tel: +61 7 5595 4194; Fax: +61 7 5595 1120; Email: buherc@bond.edu.au

Please click the 'Yes' button below if you give your consent to participate in this study.

2. Do you currently reside in Australia?

- Yes
- No

3. Are you currently an Accredited Practising Dietitian (APD)?

- Yes
- No

Answering 'no' to either of the above questions will exclude the participant from the study (they will be thanked for their time and told that they unfortunately do not meet the inclusion criteria for the study).

Demographic Questions (all participants):

1. **Are you:**
   - Male
   - Female

2. **How old are you?**
   - 18 to 24 years
   - 25 to 34 years
   - 35 to 44 years
   - 45 to 54 years
   - 55 to 64 years
   - 65 to 74 years

3. In which state do you mostly practice:

- QLD
- ACT
- NT
- NSW
- WA
- TAS
- VIC
- SA

7. What is your geographical area:

- Rural or isolated
- Regional Centre
- Metro or large urban (>100,000 people)

8. What is the highest level of education you have completed?

- Diploma/ Advanced Diploma
- Bachelor Degree
- Honours degree
- Masters degree
- Doctoral degree
- Dual qualification (please specify)

9. Number of years working as a dietitian:

- < 1 year
- 1- 3 years
- 4- 6 years
- 7- 9 years
- 10- 12 years
- > 12 years

10. Number of years experience as a group educator:

- No experience
- < 1 year
- 1- 3 years
- 4- 6 years
- 7- 9 years
- 10- 12 years
- > 12 years

11. Are you currently registered as a Medicare provider?

- Yes
- No

12. Which of the following best describes your current job area (i.e. greatest time spent in your current position):

- Acute care
- Private practice
- Community
- Industry
- Other ….. (please specify)

13. Approximately how much of your workload is spent consulting with patients with type 2 diabetes mellitus?

- 0-25%
- 25-50%
- 50-75%
- 75-100%

14. Are you aware of any guidelines for group-based education in the area of T2DM?

- Yes
- No
- If yes, please name the guidelines

15. Are you aware of any guidelines developed specifically for dietitians for group-based education in the area of T2DM?

- Yes
- No
- If yes, please name the guidelines

16. What training have you undertaken in delivering group-based education for the management of type 2 diabetes mellitus? (tick as many as apply)

- No training
- Training during health professional qualification only
- Informal training from colleagues
- Formal training (face-to-face course or workshop)
- Formal training (web-based course or workshop)
- Other (please specify)

17. If the following training was available to you, which would you prefer to attend in order to further enhance your skills in the area of group-based education for type 2 diabetes mellitus:

- Informal training from colleagues
- Formal training (face-to-face workshop or course)
- Formal training (web-based course or workshop)
- Other (please specify)

18. What time commitment do you feel would be appropriate and necessary for the training offered (as per the above question):

- ≤ 2 hours
- 3-6 hours
- 7-10 hours
- 11-20 hours
- ≥ 20 hours

19. Have you been diagnosed with Type 2 Diabetes Mellitus?:

- Yes
- No

20. Do you facilitate group-based education programs for T2DM as part of your current role?

- Yes
- No

Survey Questions (APDs currently facilitating groups for T2DM):

1. **Of all the group education sessions provided in your workplace for T2DM, what proportion do you facilitate yourself (please work out an approximate percentage):**

- 0-20%
- 20-40%
- 40-60%
- 60-80%
- 80-95%
- 100%

Please describe how much you agree or disagree with the following statements regarding group-based education for the management of type 2 diabetes mellitus:

Strongly disagree Disagree Neutral Agree Strongly agree

1. **I would consider myself to be an expert in group-based education for T2DM**
2. **The program that I currently facilitate is effective**
3. **The program that I currently facilitate is multidisciplinary (two or more disciplines)**
4. **I feel that patient interactions positively effect patient outcomes**
5. **I consider it to be very important to provide patients attending groups with paper-based information (worksheets/ handouts)**
6. **I feel that group-based education is more beneficial to patients than individual education**
7. **I prefer to facilitate group-based programs over individual consultations**
8. **I understand the theories and rationale behind the group-based education program I am currently facilitating**
9. **I consider getting through the session content more important than allowing patients to have lengthy discussions**
10. **I would feel confident to facilitate an unstructured group-based education session where the entire content is directed by the patients on the day.**

11. **Do you claim Medicare Chronic Disease Management group items (81100 to 81125) for the group you are currently facilitating?**

- o Yes
- o No

Survey Questions (APDs NOT currently facilitating groups for T2DM):

1. Have you previously facilitated group-based education programs for T2DM as part of your current or former roles?

- o Yes
- o No

Please describe how much you agree or disagree with the following statements regarding group-based education for the management of type 2 diabetes mellitus:

Strongly disagree Disagree Neutral Agree Strongly agree

1. **I would consider myself to be an expert in group-based education for T2DM**
2. **I consider group-based programs for T2DM to be effective**
3. **I feel that group-based programs need to be multidisciplinary**
4. **I feel that patient interactions positively effect patient outcomes**
5. **I consider it to be very important to provide patients attending groups with paper-based information (worksheets/ handouts)**
6. **I feel that group-based education is more beneficial to patients than individual education**
7. **I prefer to facilitate group-based programs over individual consultations**
8. **I feel that the session content is more important than lengthy patient discussions**
9. **I would feel confident to facilitate an unstructured group-based session where the entire content is directed by the patients on the day**

10. **Have you ever claimed Medicare Chronic Disease Management group items (81100 to 81125) for group-based T2DM education?**

- o Yes
- o No

What are the reasons you have not claimed these items before: (tick as many as apply)

- o I was unaware that these items were available
- o I was unaware that dietitians were eligible to claim these items
- o There is no common national curriculum for T2DM group education programs
- o I do not have access to appropriate facilities for group programs
- o I do not feel confident in my knowledge and skills to facilitate group programs
- o Hiring appropriate facilities is too expensive
- o Facilitating group programs is not cost effective
- o It is difficult to access multidisciplinary providers
- o Patient retention is poor in group programs
- o I do not have the time needed to run group programs
- o I refer my T2DM to publicly run (community or hospital based) groups
- o I am not a Medicare provider
- o Other (please specify)

You have completed our survey.

We sincerely thank you for your input!

Please feel free to provide any additional feedback regarding group-based education for T2DM in the comments box below:

The results of this survey will be submitted to a peer review journal for publication.
We will also be compiling an executive summary of results once the survey is closed. If you would like to see executive summary please provide your email address below and we will email them to you.

Email address: