THE EFFECTIVENESS OF AN EDUCATION PROGRAMME IN IMPROVING DIETARY COMPLIANCE AND OTHER OUTCOMES IN INSULIN-DEPENDENT DIABETICS

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PREFACE

The studies for this thesis were carried out from 1977 to 1982 in the Department of Social and Preventive Medicine at the Commonwealth Institute of Health within the University of Sydney, under the supervision of Professor Charles B. Kerr. The planning and implementation of the randomised controlled trial were conducted under the supervision of Professor Walter O. Spitzer, former director of the Clinical Epidemiology and Evaluation Unit of the Royal North Shore Hospital of Sydney. Field work for both studies was carried out at that hospital in collaboration with the Diabetes Education and Assessment Programme, under the direction of Dr. Martyn J. Sulway.

The design and format of the education programme were devised by the entire D.E.A.P. team and co-ordinated by Ms. Hilary Tupling, Psychologist.

The selection of outcomes for the programme's evaluation and the design of the measurements were primarily my own, although team members contributed greatly to their development. All team members participated in data collection and processing.

The Data Analysis was carried out through the Faculties of Medicine and Mathematics at the University of Newcastle, under the supervision of Professor Stephen R. Leeder and Associate Professor Annette J. Dobson. Mrs. Dianne O'Connell was the data analyst who did the computing for both studies.

Many others contributed to the work reported in this thesis and they are acknowledged in the last section of this thesis.

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CHAPTER 1

SECTION

1.1 Diet Therapy for Insulin-Dependent Diabetics

The treatment for Type I or insulin-dependent diabetes mellitus comprises a therapeutic diet and daily insulin-injections. The aims of treatment are to prevent or minimise the development of micro- and macro-vascular complications of diabetes through improved daily metabolic control of blood glucose and serum lipids (Porte and Halter 1981). Many factors influence the achievement of these treatment goals but diet is thought to play a major role (Friedman 1980).

Medical opinion differs about optimal diet therapy, and consequently there is no standardised dietary regimen prescribed for insulin-dependent diabetics (Wood 1980). However, there is a general consensus that prescribed diets should promote the achievement and maintenance of an ideal body weight, a nutritionally adequate diet, the restriction of refined sugar, and the distribution of food intake throughout the day and between days (American Diabetes Association 1979). Areas of controversy concern the composition of the diet, the need for restricting various kinds of carbohydrate foods and the need for close regulation and constancy of food habits, (West 1980, Taft 1982).

1.2 Non-compliance with diabetic diet regimens.

The term "compliance" within the context of health care refers to "the extent to which a person's behaviour (in terms of taking medication, following diets or executing life-style changes) coincides with medical or health advice" (Haynes et al 1979). The term "adherence" has also been used to describe this behavioural phenomenon and is used interchangeably with "compliance" throughout this thesis.

Complex, self-administered treatment regimens lasting over a life-time such as the diabetic diet bring with them the potential for patient

non-compliance. The problem of low compliance with diabetic diet regimens has been widely documented (Watts 1980) and constitutes a major problem in the effective treatment of diabetes since "no treatment can be effective if it is not applied" (Dunbar and Stunkard 1979). Thus, much of the morbidity and mortality associated with the poor control of diabetes is thought to be preventable through improved patient compliance with prescribed diabetic diets (West 1973).

Currently very little is known about effective strategies to improve dietary compliance. There has been considerable speculation about the causes of non-compliance with diabetic diets, yet very little research has been conducted into its determinants. The development and implementation of patient education programmes for people with diabetes has been widespread in recent years (Report of the National Commission on Diabetes 1976). While published reports of evaluations indicate that such programmes improve the diabetes-related knowledge of programme participants, few have rigorously evaluated their effects on compliance and other relevant patient outcomes (Watts 1980, Graber et al 1977).

1.3 The Diabetes Education and Assessment Programme.

An education programme for adult, insulin-dependent diabetics and their families was established in 1974 at The Royal North Shore Hospital of Sydney, the primary aim of which was to improve compliance with diet and other self-care regimens. Many of the strategies incorporated into the education programme were selected on the basis of their documented effectiveness in other health and educational settings (Neufeld 1976) and they are described in Chapter 3.

The programme provided dietary recommendations for each participant with a focus on the maintenance of achievement of ideal

weight and a low-fat, moderate carbohydrate diet. The regimen is also described further in Chapter 3.

1.4 The Aims of Study

The primary aim of the studies reported in this thesis was to document the effectiveness of the education programme in improving compliance with the recommended dietary regimen. The programme's impact on other outcomes including metabolic control of diabetes knowledge about diabetes, health beliefs and feelings about living with the disorder were also of interest.

A second aim was to identify factors which were associated with and potentially predictive of dietary compliance.

1.5 The Studies

Two studies were carried out between 1978 and 1981. The first of these as a "before and after" design termed the "pre/post study" in which dietary compliance and other outcomes were assessed in a group of 140 insulin-dependent diabetics before and six months after participation in the education programme.

A more rigorous evaluation, a randomised controlled trial, was carried out from 1980 to 1981, in which the changes in compliance and other variables were observed before and three months after the programme and these were compared with changes during a "control" phase three months prior to the programme. The study design and its rationale is given in Chapter Three.

Potential determinants of compliance were measured prior to the education programme in both studies and analysed for their associations with and ability to predict subsequent dietary compliance.

1.6 The Format of the Thesis.

In Chapter Two, an overview of literature is presented concerning the types of dietary regimens typically recommended to diabetics and the rationale for these, the extent of compliance and non-compliance with them, potential determinants of compliance and reports of the effectiveness of diabetes education programmes. Literature concerning methodological issues in the study of dietary compliance is discussed in some detail as the basis for research methods used in the studies of this thesis.

The education programme, the dietary regimen and the research methods are described in Chapter Three. Chapters Four and Five present the results of the pre/post study and the randomised controlled trial. The results, their interpretation and implications for diabetes education programmes, are discussed in Chapter Six and the conclusions are summarised in Chapter Seven.

The Appendices include detailed descriptions of the education programme, the dietary regimen (including patient hand-outs), the research instruments and the procedures for assessments and data processing.

Acknowledgements of the the many individuals and organisations who contributed to the completion of these studies are given in the last section of this thesis.

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CHAPTER 2

LITERATURE REVIEW

INTRODUCTION

The extensive literature on compliance with medications, appointment-keeping and other health behaviours has been reviewed most recently by Haynes et al (1979). However, few studies of dietary compliance were included in their review and were intended to be a "morsel, not a feast" (ibid). Reviews of the major studies of dietary compliance were conducted by Glanz (1980) and Dunbar and Stunkard (1979) but they included only a small portion of the research into compliance with diabetic diets.

This review summarises the evidence concerning -

(a) the role of diet in the management of insulin-dependent diabetics and how diet therapy is practised (Section 1), (b) the identification of the extent of compliance and non-compliance with the diabetic diet (Section 2), (c) factors related to, and determinants of dietary compliance (Section 4), (d) the effectiveness of educational strategies to enhance dietary compliance (Section 5).

The studies reviewed are summarised in Tables 2.1, 2.4 and 2.5. Methodological issues in the study of dietary compliance are reviewed in Section 2. The quality of evidence presented in the original research reports of dietary compliance and evaluations of diabetic education was evaluated using a scoring system adapted from Haynes et al (1979) (Appendix 2.1). The scores for methods are presented in Table 2.2. Methods of measuring dietary compliance and comments about their use are given in Table 2.3.

SECTION 2.1

DIABETIC DIET REGIMENS

There is no standard dietary regimen prescribed for insulin-dependent diabetics (Wood, 1980, Taft 1982, Truswell et al 1975). Controversy exists amongst the medical and dietetic professions over the importance of diet in the management of diabetes as well as the priorities and emphases of the regimens (West 1973). This uncertainty has generated a variety of dietary regimens which differ considerably in their nutritional composition and in the dietary behaviours expected of diabetics (Truswell et al 1975). The rationale for some of these recommendations is often not supported by empirical evidence (Wood 1980).

In the study of compliance, it is useful to consider the types of regimens with which diabetics are expected to comply, the rationale for these, and in the form in which they are prescribed and presented to diabetics. Thus, this section summarises the literature concerning

(a) the therapeutic aims of dietary and other treatments in diabetes (b) dietary and other factors affecting the achievement of those aims (c) and current practices and problems in prescribing dietary regimens.

The references reviewed include several recent reviews concerning the principles of diet therapy for diabetics, original research reports, textbooks of diabetic management and policy statements of the American Diabetes Association (1979) and Australian Diabetes Society (unpublished). Since the subjects of study in this thesis were adult insulin-dependent diabetics, literature concerning

children or non-insulin-dependent diabetics was excluded. The survey of dietary management practices by Truswell and colleagues is the only original research in this area and so was summarised in detail (Truswell et al 1975, Thomas et al 1974).

A. THERAPEUTIC GOALS OF TREATMENT

The aims of medical and dietary management of diabetes mellitus are both short and long-term.

In the short-term, there is general agreement amongst the medical profession that treatment should aim at the maintenance of blood glucose levels within a physiologically normal range, to prevent the symptoms of hyper- and hypoglycaemia (Porte and Halter 1981).

In the long-term, treatment is aimed at prevention of the degenerative complications including retinopathy, neuropathy, nephropathy and early death from atherosclerotic heart disease (Porte and Halter 1981). Recent clinical and experimental data suggest that optimal control of blood glucose is likely to prevent the development of the complications (Reaven et al 1979). The achievement of optimal blood glucose control has been endorsed by the American Diabetes Society as their official policy (Cahill et al 1976). Considerable controversy remains over the importance of serum lipid regulation in the prevention of atherosclerosis in diabetics, but the majority of evidence favours the maintenance of lower levels of serum cholesterol and triglycerides (Reaven et al 1979, Friedman 1980).

B. DIETARY AND OTHER FACTORS WHICH AFFECT THE ACHIEVEMENT OF TREATMENT GOALS.

1. Type of Diabetes

The type of treatment prescribed for diabetics and its probabi-

lity of success in achieving the treatment goals depends to some extent on the type of diabetes (Reaven et al 1979, West 1973). Recently, it has been acknowledged that diabetes mellitus is a heterogeneous group of diseases with a common symptom: hyperglycaemia (Porte and Halter 1981, West 1979, Reaven et al 1979, Friedman 1980). The National Diabetes Data Group (1979) have devised an updated classification system for five types of diabetes based on the level of elevation of blood glucose, proneness to develop ketosis, body weight status and association with other diseases and conditions. The two most common types are insulin-dependent diabetes mellitus (IDDM, Type I) and non-insulin dependent diabetes (NIDDM, Type II).

The majority of individuals with Type II diabetes tend to be obese, not prone to ketosis and have only modest fasting hyperglycaemia. Those with Type I diabetes are more frequently lean, have severe fasting hyperglycaemia, wide excursions of blood glucose and are prone to develop ketoacidosis (West 1979). However, within the Type I class there are variations, since some diabetics who require insulin to maintain a normal blood glucose are not ketosis-prone. It has been suggested that they be referred to as "partially" insulin dependent (ibid.). Accordingly, the appropriate dietary and medical treatment priorities will vary with the type of diabetes. Too often this has not been recognised (West 1973).

2. Drug Therapy

Individuals with Type I diabetes require insulin therapy as well as dietary measures to achieve and maintain a normal blood glucose and to prevent ketosis (Reaven et al 1979). Thus, although diet is traditionally regarded as the "cornerstone" of treatment for all diabetics, it is insufficient in Type I diabetes to achieve metabolic regulation. Drug therapy is also required (Arky 1978).

The extent to which insulin therapy is appropriate for an individual will determine, to a large extent the achievement of good diabetic control. Factors such as the pattern and degree of elevation of blood glucose throughout the day, body weight, production of endogenous insulin and presence of insulin-resistance determine the appropriate type, dosage and schedule of insulin therapy (Tattersall 1979).

In view of individual variations in insulin requirements, the potential for inappropriate or ineffective insulin prescriptions is great and may seriously affect results of studies to determine the effectiveness of various dietary regimens. Indeed, Reaven et al (1979) suggested that the observed reductions in insulin requirements in some dietary trials may have been due to inappropriate insulin therapy initially.

3. Dietary Factors

Dietary factors which have been linked either positively or negatively with the achievement of the therapeutic goals include -

> (a) obesity, (b) composition of the diet with respect to carbohydrate and fat in particular, (c) the type and form of dietary carbohydrate and fibre and (d) the distribution of energy and nutrients throughout the day and the constancy of intake between days.

The evidence concerning the effects of these factors on the short-term achievement of metabolic regulation of diabetes is summarised below.

a) Obesity

The only aspect of dietary management of diabetes about which there are no dissenting reports is the beneficial effect of weight reduction in obese diabetics (West 1980, Porte and Halter 1981, Friedman 1980, Mann 1980). It has been widely documented that obesity is accompanied by insulin-resistance and a reduction in insulin-receptor sites which leads to impaired glucose tolerance and poor metabolic regulation (Reaven et al 1979).

The beneficial effects of weight reduction have been clearly demonstrated in Type II diabetes (Reaven et al 1979). Significant reductions in the degree of hyperglycaemia, oral anti-diabetic therapy, and insulin resistance have been observed in a number of studies. Although similar benefits can be expected with obese insulin-dependent diabetics, this has not been well studied (ibid.).

(b) Composition

A point of major disagreement amongst health professionals caring for diabetics has been the composition of the diet (West 1980). Traditionally, low-carbohydrate, high-fat regimens have been advocated by the majority of health practitioners but in the past decade, the trend in dietary management has been towards liberalising the carbohydrate content of the diet (ibid.). Currently, the weight of evidence is in favour of the high carbohydrate diet. However, consensus regarding the optimum composition of the diet for diabetics is lacking. Some diabetologists and academic nutritionists advocate high-carbohydrate diets, believing that good control is achievable at a range of levels of carbohydrate (West 1980, Friedman 1980, Davidson et al 1979, Wahlqvist 1980). Others dispute this, wanting more con-

vincing evidence for the safety of the high carbohydrate regimen (Reaven et al 1980, Turtle 1976, Wood 1980). The American Diabetes Association stated in their 1979 policy statement that "carbohydrate should account for 50 to 60% of total energy intake" while the Australian Diabetes Society says, more conservatively, "at least 40% of the energy intake should be obtained from carbohydrate" (unpublished).

High carbohydrate diets are advocated from epidemiological and clinical studies. Diabetes and cardiovascular disease are uncommon in countries which consume low-fat, high-starch diets (Friedman 1980, West 1980). Recent clinical studies of both insulin-dependent and non insulin-dependent diabetics have demonstated that blood glucose levels and insulin requirements are reduced on diets of approximately 60% carbohydrate, particularly when the diets are high in fibre (Anderson and Ward 1979, Simpson et al 1979, Simpson et al 1981). Other investigators have observed beneficial changes for some subjects but not for others (Weinsier et al 1974, Kiehm et al 1974, Brunzell et al 1974).

Reaven et al (1979) have criticised the conclusions of some of these studies because several confounding variables may have caused the observed improvements in metabolic control, for example weight loss, the use of liquid formulae and the fibre content of the diet. For individuals with the most severe fasting hyperglycaemia, diabetes control appeared to worsen on the high-carbohydrate diet when insulin therapy was not altered.

The effect of a high-carbohydrate diet on serum lipids of insulin-dependent diabetics is uncertain. Few studies have been done and the confounding effects of intakes of total fat, polyunsaturated

fat and fibre are substantial. Only two such studies of insulin-dependent diabetics were reviewed by Reaven et al (1979) and these reported conflicting results. A significant increase in serum triglycerides was observed in one study with no change in serum cholesterol on a diet in which carbohydrate constituted 85% of energy. Another study observed a significant decrease in serum cholesterol and no change in serum triglycerides on a 60% carbohydrate diet, the differences in results being attributable to the difference in carbohydrate or fat levels, or to the use of formula vs "real food" diets.

Since that review, studies by Anderson et al (1979), Simpson et al (1979), and Simpson et al (1981) have observed no significant rise in serum triglycerides of insulin-dependent diabetics during trials of high-carbohydrate, high-fibre regimens. Whether this effect is due to the fibre content of the diet remains uncertain (Anderson 1980, Manhire et al 1981).

(c) Regularity, Constancy and Distribution of Food Energy and Nutrient Intake

The maintenance of regular and constant eating habits has been a basic principle of diet therapy for insulin-dependent diabetic since the advent of insulin (Wood and Bierman 1972). The adequate distribution of energy and nutrient intake throughout the day and their contancy between days is emphasised in most textbooks of nutritional and diabetes management (West 1977, West 1980, Porte and Halter 1981, Friedman 1980, Davidson et al 1979), and in summaries of diabetes management procedures published in medical journals (Wahlqvist 1981, Tattersall 1979, Chisholm 1976, Turtle 1976, Arky 1978).

The policy of the American Diabetes Association in regard to insulin-dependent diabetics states: "day to day constancy in amounts

and distribution of carbohydrates, fat and protein, should be a major goal" and "the need for maintenance of a regular eating pattern should be strongly emphasised" (American Diabetes Association 1979). Similarly, the Australian Diabetes Society advises "carbohydrate should be distributed throughout the day in relation to the mode of action of insulin or hyperglycaemic agents and in relation to the individual's lifestyle". The rationale for this aspect of treatment is that wide fluctuations in blood glucose may occur when nutrient or energy intake is irregular and when disproportionate amounts are consumed at one time of the day thereby increasing the risk of hypoglycaemia. However, there is disagreement as to whether such recommendations apply to energy intake or carbohydrate intake, or both (West 1980). Thus some dietary systems used to teach the diabetic regimen, particularly in the U.K. and Australia, emphasise the constancy of carbohydrate intake whilst the system used widely in the United States aims to distribute and regulate total energy intake (Truswell et al 1975).

Experimental evidence in support of the efficacy of a constant and regular intake of either energy or carbohydrate in preventing hypo- and hyperglycaemia is meagre. Most of the evidence has been obtained from clinical experience. Clinical research does not provide evidence for the need for such careful regulation of eating habits. Knowles et al (1965) found that diabetic children on unmeasured diets (followed in a prospective study for over 10 years) fared no worse in terms of the degenerative complications or diabetic control than "reported in other studies of subjects on a diet in which foods were carefully measured". However, the conclusions from this study are limited by the lack of a comparison group and of an accurate measurement of the variability in nutrient intake. A recent study by Henry

et al (1981) showed that diabetics assigned to a carefully measured diet had no less variation in their daily carbohydrate intakes than those on unmeasured diets and Dorchy et al (1977) found that wide variations in daily carbohydrate and energy intake were observed to have no deleterious effect on glycaemic control. However, the results of these studies could not be considered definitive since the samples were very small, the studies were not rigorous trials and the frequency of hypoglycaemia likely to result from erratic food intake was not reported.

(d) Types of Foods and Beverages

Certain types of foods and forms are typically restricted or encouraged within dietary regimens for insulin-dependent diabetics. These include dietary sources of (i) refined sugar, (ii) alcohol and (iii) fibre. Recently, attention has also been given to types of complex carbohydrate foods and the physical forms of foods (liquid, whole, ground).

(i) Sugars (mono- and disaccharides)

Insulin-dependent diabetics are usually advised to restrict their intakes of foods containing refined sugar, glucose or honey (Wood, 1980). On some regimens, fructose (in the form of fruit or refined) and lactose (in milk products) are also limited (Davidson et al 1979). However, no specific limits with respect to quantity have been recommended. For example, West (1980) suggests that diabetics "eat less sugar" and Davidson et al (1979) advise health practitioners that sugar containing foods "should be kept to a minimum".

The rationale for the restriction of sugar-containing foods is their glucogenic effect and their tendency to increase body weight

(Friedman 1980). They have also been reported to produce a lack of satiety and a tendency to hypoglycaemia following meals (Ardvidsson Lenner 1976). However, the glycaemic effect of carbohydrate foods has not been carefully studied until recently. It now appears that other factors such as the physical form of the food (e.g. liquid, ground or whole), the fibre content of the food and whether it is consumed in a mixed meal or singly, may be more influential on post-prandial glucose rise than type of sugar (Crapo et al 1976, Jenkins et al 1981, Collier and O'Dea 1982). Further research is needed to identify the impact of "intact" foods on diabetic control (Wahlqvist 1980). Although Mann (1980) considers that "the restriction of quickly absorbed carbohydrates ... remain an important aspect of all diabetic diets", Wood (1980) commented that "the value of restricting the intake of all simple sugars is unproven".

(ii) Fibre

Insulin-dependent diabetics are often encouraged to increase dietary fibre, particularly that from natural foods such as whole grains, cereals and breads, fruits and vegetables (American Diabetes Association 1979, Wahlqvist 1980, Davidson et al 1979, Reaven et al 1979, Friedman 1980, Taft 1982).

Diets and foods high in fibre reduce serum lipids and the post-prandial rise in blood glucose which occurs in diabetics following a high carbohydrate meal (Wahlqvist 1980, Reaven et al 1979). As mentioned previously improved diabetic control on high carbohydrate regimens may be is due to the carbohydrate or fibre content of the diet (ibid.).

The long-term acceptability of high fibre diets has been questioned since many of the test diets have included large quantities

of substances not normally consumed i.e. guar gum, pectin and leguminous fibre (Jenkins et al 1976, Simpson et al 1981).

(iii) Alcohol

The official policies of the American and Australian Diabetes Societies state that modest alcohol consumption in amounts permitted by the physician is compatible with good diabetic control provided their energy content and potential hypoglycaemic effect is considered. Definitions of "moderate" alcohol consumption are conspicuously absent from the literature on diabetes management and the policy tends to be to tailor the recommendation to the individual. Such policies appear to reflect the opinions of diabetes physicians and nutrition practitioners in Australia and the United States (Wahlqvist 1980, Taft 1982, Chisholm 1976, West 1979, Friedman 1980) and the United Kingdom, (Davidson et al 1979).

Empirical evidence suggests that modest alcohol consumption is not detrimental to glycaemic or serum lipid control in most diabetics. McDonald (1980), in a review of the literature on the effects of alcohol consumption by diabetics concluded that "although there are contraindictations to its use by certain people, alcohol in moderation does not appear to compromise carbohydrate homeostasis in most individuals and...if earlier studies are confirmed, could possibly have some beneficial side effects".

Concerns about alcohol intake by diabetics are that their concentrated energy content will lead to the development of obesity (West 1979) and thereby contribute to poor metabolic control. Moreover, excessive alcohol consumption has been observed to result in severe hypoglycaemia in some diabetics (Arky 1978). As well, the lack of

nutrient content of alcoholic beverages may increase an individual's risk of nutrient deficiencies, particularly thiamine (Davidson et al 1979).

C. CURRENT PRACTICES AND PROBLEMS IN PRESCRIBING DIABETIC DIET REGIMENS.

These are the general principles underlying the diabetic diet regimens and their rationale. How are these theories applied in practice? The differences of opinion amongst medical and dietetic practitioners about several aspects of dietary management are reflected in the wide variety of prescribed dietary regimens. The form in which the regimen is presented to patients, what it contains, what it means in terms of dietary behaviours expected at meal-times, the terminology used to describe the various regimens and who prescribes and communicates the regimen to patients, are all aspects of the dietary regimen important in the study of compliance (Thomas et al 1974, Truswell et al 1975, West 1973).

Diet Sheets or Plans

Prescribed dietary regimens are usually presented to the diabetic in the form of a diet sheet or plan and these form "the lines of communication we (health practitioners) rely on most" (Thomas et al 1974). As such, their content and format are crucial to the diabetic's understanding of the dietary regimen.

In the United States, a printed, standardised system for prescribing diabetic diets has been widely used over the past two decades (American Diabetes and Dietetic Associations 1976). The system is based on an "exchange" concept in which quantities of food with relatively equivalent energy and nutrient content can be substituted for one another, to allow flexibility in food selection while

promoting a controlled energy and nutrient intake. On this system, a diabetic is prescribed a specified number of "exchanges" of bread, fruit, meat, fat and vegetables at each meal and snack. Quantities are described in household measures and weights. Guidelines for health professionals have been published which describe how to use these exchange lists in prescribing diets at different energy levels, consistent with the stated policy of the American Diabetes Association (Bierman et al 1971). The extent to which health professionals use the "exchange" system and the guidelines (in preference to other forms of dietary regimens) to prescribe diets is uncertain.

In a survey of "diet sheets" used in Great Britain, Thomas et al (1974) discovered at least five types used by major diabetic and medical clinics. Over half of them used a system in which a fixed menu was prescribed for each meal. A carbohydrate portion "exchange" system was an alternative used by 22% clinics. On this regimen, only a specific number of carbohydrate portions are prescribed for each meal and snack and the selection of foods is made by the diabetics themselves from an exchange list, and such foods are weighed or measured to obtain exactly one exchange. In Australia, two commonly used systems are the total "exchange" system similar to that used in the United States, and the carbohydrate "exchange" system (Hosking 1976), although the extent of use of these systems has not been surveyed. A number of problems with these systems and diet sheets which are likely to cause non-compliance with the dietary regimen were identified by Thomas et al (1974) and Truswell et al (1975).

Considerable discrepancies between the stated dietary policy of the clinic and the diet sheets were noted in their survey. For example, they found that a number of clinics who claimed to recommend

high carbohydrate diets issued diet sheets in which carbohydrate comprised only 32 - 40% of energy.

Many of the diet sheets were inaccurate, impractical, unrealistic, unnecessarily rigid and unattractively presented. Major errors of fact were detected in a number e.g. "stewed fruit should be cooked with sugar". Monotonous and unrealistic prescriptions were also made e.g. "jelly, junket or stewed fruit" were often prescribed "twice daily". Typed or duplicated diet sheets looked unattractive, and were awkward in size compared with printed diet sheets and booklets. These authors recommended that flexible regimens, accompanied by adequate explanation, presented accurately and attractively and consistent with the stated policies of the clinic, were likely to enhance adherence.

Within the carbohydrate exchange system, there is no standardisation of portion sizes; some hospitals and clinics list food quantities each containing 10 grams of carbohydrate whereas others use the 15 gram standard portions (Hosking 1976, Thomas et al 1974). A newly diagnosed diabetic initially prescribed a "25 portion" diet on a 10-gram system may later attend a diabetic clinic in which the basic diet prescription is the same but he is recommended to have 17 portions (of the 15 gram size).

TERMINOLOGY

Common terms used by physicians to distinguish different basic approaches to diet include "free diet", "strict diet", "rigid diet", "low energy diet", "high (or low) carbohydrate diet", "unmeasured diet" (West 1973, Truswell et al 1975). What is meant by strict vs a free approach varies between physicians (Truswell et al 1975). Such

terms are unlikely to be useful in describing a particular dietary regimen and may be misleading to patients (West 1973).

Who Prescribes the Regimen?

It is traditional that the physician prescribes the type of diet and/or the energy content of the diet and the dietitian translates this into a dietary regimen or food plan for the patient.

However, imprecise terminology referred to in the previous section can result in discrepancies between what the doctor prescribes and what the dietition translates to the patient (West 1973). Both physicians and dietitians have been found on occasions to have a poor understanding of diet prescriptions for diabetics (Etzwiler 1967) and they are frequently unaware of the differences in diet therapy for IDDM and NIDDM (West 1973). The issue of inadequate knowledge of diabetes management procedures is discussed further in the section on "Determinants of Compliance".

SUMMARY

Although there is agreement about the importance of weight reduction for the obese diabetic, there is disagreement about the composition, and the need for close regulation of nutrient intake throughout the day, which foods should be eliminated, restricted or encouraged in the diets of insulin-dependent diabetics and what limits if any, should be imposed on their quantities.

In practice, dietary regimens are communicated to the patients primarily by diet sheets, many of which are inconsistent with the stated dietary policy of the clinic or centre and allow patients little flexibility in food choice. Such regimens are infrequently

tailored to the lifestyles of individual diabetics. Inappropriate dietary regimens may be prescribed for diabetics as a result of inadequate knowledge and skills of diet therapy, or poor communication between doctors and dietitians.

SECTION 2.2

DIETARY COMPLIANCE AND NON-COMPLIANCE WITH DIABETIC DIET REGIMENS

Considered from the point of view of the individual patient with insulin-dependent diabetes, the implementation of a diabetic diet regimen involves substantial behavioural change in the routines of daily life (Tupling 1981, Hoover 1980, Hinkle 1962, Kaufman 1964). Within the context of many other daily self-care tasks such as insulin injections, urine testing, and/or home blood glucose monitoring, the potential for patient non-compliance with the dietary regimen is considerable (Sulway et al 1978). Therefore, it is not surprising that the results of many investigations have shown that a minority of patients comply with the entire regimen or aspects of it.

The problem of non-compliance with diabetic diets has been widely studied, covering approximately a 30-year period and several countries. Reviews by West (1973), Glanz (1980), Dunbar and Stunkard (1979) and Watts (1980) have summarised the findings of some of the classic studies of dietary compliance in diabetes. However, no comprehensive review could be located. Therefore, included in this review are all published studies over the past 30 years in which the assessment of dietary compliance formed a part of the investigation. Studies which claimed to assess dietary behaviour, skill or performance but were, in actual fact, assessments of dietary or diabetes-related knowledge were excluded from the review. Also excluded were the numerous studies of compliance with other aspects of diabetes self-care (injection, urinalysis procedures and home blood glucose monitoring). The remaining references were not screened for the quality of research methods used. However, each study was assigned a score for various aspects of the methods used and these are given in Table 2.2.

Forty-three studies were located which assessed compliance with diabetic diet regimens and the results of these together with a summary of the definitions and measurements of compliance are given in Table 2.1. The table has been arranged in a similar format to that used by Haynes et al (1979) to allow comparison with their summaries of compliance rates to other types of health and medical regimens.

In general, low rates of compliance characterised the results of these studies. The percentages of the study samples who were compliant with aspects of the diabetic diet ranged from 2 to 90% but the majority were less than 50%. Similar ranges in compliance rates to other kinds of diets were observed by Glanz (1980) in her overview of the literature on compliance with a number of dietary regimens. The percentages of "excellent" compliers with diets prescribed to reduce the risk of cardiovascular diseases ranged from 20% to 76%. Compliance with weight reduction regimens was lower: success rates of less than 20% (for sustained weight loss) were commonly seen (ibid.). She concluded that non-compliance with dietary regimens is just as frequent (and perhaps more so) as with medication regimens when compared with rates observed by Haynes et al (1979).

TABLE 2.1

COMPLIANCE WITH DIABETIC DIET REGIMENS

AUTHOR	YEAR	SAMPLE(1,2,3)	MEASURE	DEFINITION	COMPLIANCE	
Dahlberg et al (Sweden)	1947	5,207 IDD+NIDD (responders to National survey (34% response)	self-rating mailed questionnaire	followed strict diet followed not carefully did not adhere	35.7% 53.5% 10.8%	
				Weight change during past year:	IDD	NIDD
				decrease	46.7%	46.7%
				increase or constant	53.3%	27.7%
Tunbridge (U.K.)	1949	94 IDD+ NIDD Clinic Attenders (91% response)	7-day food record (measured	"accurate" (within 10% of prescribed calories	16%	
				"fair" (nr)	44%	
				"hopeless"	34%	
Gabriele & Marble (U.S.A.)	1949	83 IDD juveniles (boys) attending camp (72% response)	self-rating (self-administered questionnaire)	followed diet did not follow	39% 61%	
Kelding et al (U.S.A.)	1952	451 IDD attending clinic	self-rating (interview)	excellent: (weighed food 80% of time)	2.4%	
				good: (weight initially)	11.1%	
				fair: (rarely indulged in discretions)	20.4%	
				poor: (no weighing or measuring)	66.1%	
Goodman et al (U.S.A.)	1953	33 of first overweight diabetics to attend "group therapy" (Rx-nr)	weight	average weight loss: no. who lost weight: range of weight lost:	14.2 pounds 30 (90% "success") 0-50 pounds	

TABLE 2.1 (continued)

AUTHOR	YEAR	SAMPLE(1,2,3)	MEASURE	DEFINITION	COMPLIANCE	
Jacobi (U.S.A.)	1954	120 IDD juveniles at summer camp	self-report (interview)	energy intake:	Male	Female
				as prescribed	19%	38%
				1 1/2-3 times	52%	29%
				less than prescribed:	0%	3%
				free diet	29%	33%
					(50% of "free" diet subjects had adequate diet)	
Dobson et al (U.S.A.)	1958	224 IDD Clinic Attenders	weight	(Metropolitan life tables)	Male	Female
				normal (range for height)	18%	31%
				o'weight (above range)	74%	54%
				u'weight (below range)	5%	10%
				unknown	3%	4%
Stone (U.S.A.)	1961	160 IDD Clinic Attenders	diet history 24 hour recall	good: follows diet six days per week	Before 21%	After# 53%
				fair: ≥ half the time	17%	11%
				poor: LT 50% of time	62%	34%
Bowen et al (U.S.A.)	1961	51 (23 experimental) (28 controls) (50% response)	weight	within normal range "for height & bone structure	weight: no difference in proportion overweight before or after for both groups	
				weight loss if o'weight	Experimental/Control (ns)	
				loss 4.6-20 pounds	45%	20%
				0 or small change	40%	56%
				gain 4.6-40 pounds	15%	24%

TABLE 2.1 (continued)

AUTHOR	YEAR	SAMPLE(1,2,3)	MEASURE	DEFINITION	COMPLIANCE	
Bowen et al (continued)			clinician rating	"poor diet control"	Before	After
				experimental	30.4%	4.3%
				control group	39.2%	53.6%
Sterky (Sweden)	1962	165 IDD school children 155 non-diabetics (compliance assessed on n=26)	24 hour recall	deviation from prescribed calories		
				< 50% below	0	
				50-25% below	4%	
				25-10% below	15%	
				± 10%	15%	
				10-25% above	35%	
				25-50% above	27%	
				≥ 50% above	4%	
Etzwiler & Sines (U.S.A.)	1962	72 IDD juveniles attending summer camp	parents' report (mailed questionnaire)	"on strict diet	74%	
				has "difficulty" with diet	41%	
				carried sugar for "hypos"	50%	
Knowles et al (U.S.A.)	1965	67 IDD - primarily juvenile (62% response)	self-report (home interview - average intake at each meal)	3 meals per day plus bedtime feeding	72%	

TABLE 2.1 (continued)

AUTHOR	YEAR	SAMPLE(1,2,3)	MEASURE	DEFINITION	COMPLIANCE
Williams et al (U.S.A.)	1967	60 IDD, attending clinics or private practices (80% co-operation)	24-hour recall	"food intake"	
				adequate (protein, vegetables & fruit exchanges)	11.9%
				partial	55.9%
				inadequate	32.2%
				"meals & spacing" score	
				0 (good) 3 meals per day plus bedtime feeding	16%
				1	10%
				2	20%
				3 (poor)	53.3%
		17 IDD+NIDD clinic attenders	7-day record	No. of patient days on which adequate (scored as above):	
			24 hour recall food frequency (only 7-day record results reported)	GE half-time	25%
				LT half-time	75%
					high daily variation in calorie and nutrient intakes observed
Bolt & Miller (U.S.A.)	1967	22 IDD	self-report 1 weeks' recall of sweet foods (home interview)	Sugar Restriction	
				follows diet completely	92%
				follows other aspects of diet	18%
Bloom (U.K.)	1967	111 IDD	nr	weighed food and adhered strictly	15%
				generally adhered	54%
				unable to follow	31%

TABLE 2.1 (continued)

AUTHOR	YEAR	SAMPLE(1,2,3)	MEASURE	DEFINITION	COMPLIANCE
Holland (U.S.A.)	1968	1,957 IDD+NIDD randomly selected from National Health Survey population (82% response)	Self-rating Weight status (interview at home)	Normal or underweight	28.7%
				Overweight	67.5%
				Unknown	3.8%
				Follows diet	53%
				Did not follow	25%
				Not given	22%
Tunbridge & Wetherill (U.K.)	1970	63 IDD+NIDD attending clinic (59% response)	7-day food record weighed	Calories within 10% of prescribed:	
				satisfactory	30%
				tolerable (nr)	38%
				hopeless (nr)	32%
Singleton (U.S.A.)	1971	16 diabetics (Rx-nr) clinic attenders	Self-rating (interview)	Follows diet "all the time"	19%
				Used exchange lists	44%
Wharton et al (Australia)	1972	55 IDD clinic attenders 55 age matched non-diabetics	Recall of food intake for 7 days	Calories prescribed:	(diabetics only) 19-29 yrs / GE 30 yrs
				good (within 10%)	27% / 4%
				fair (11-20%	20% / 24%
				poor (GT 20%)	53% / 72%
					Energy & carbohydrate intakes significantly lower in diabetics than non-diabetics
Baird (U.K.)	1972	93 untreated diabetics 183 non-diabetic siblings	Diet history Weighed food records Weight	Calories, composition tested for significance of differences between siblings and diabetics Obesity >110% of ideal	Calorie intake significantly higher for diabetics than non-diabetic siblings. Composition not sig. different
			(Histories underestimated)	Proportion of sample obese (>110% of ideal)	Diabetics / Non-diabetics: 55% / 35%

TABLE 2.1 (continued)

AUTHOR	YEAR	SAMPLE(1,2,3)	MEASURE	DEFINITION	COMPLIANCE
Weinsier et al (U.S.A.)	1974	19 (83% follow-up)	Body weight 3-day food records (measured) Serial measures 10 x over 40 weeks	Within close range of prescribed high carbohydrate diet: (% of energy) Carbohydrate 60% Fat 45% Protein 15% Cholesterol 300-400 Vege/animal fat 0.5-1.0	x ± S.D. 56 ± 3 28 ± 2 16 ± 1 242 ± 56 0.6 ± 0.2 (similar close agreement for low carbohydrate diet - see reference)
Goodner & Ogilvie (U.S.A.)	1974	174 IDD+NIDD clinic attenders varying weight status)	Weight measured 5 x over 5 years	"stable" body weight co-efficient of variation slope (regression)	Mean body weight stable over 5 years
Tagliacozzo et al (U.S.A.)	1974	190 (total) sub-group of 78 overweight patients with chronic disease attending clinic	Weight	Weight loss Stable/gain	Experi-mental: 34% Control Group: 52% (ns) 66% 48% (ns)
Salzer (U.S.A)	1975	30 NIDD (38% response)	Self-rating (interview)	On special diet Ate good diet Less than 3 meals per day	66% 30% 7% (rates reported before education only)

TABLE 2.1 (continued)

AUTHOR	YEAR	SAMPLE(1,2,3)	MEASURE	DEFINITION	COMPLIANCE
Hadden et al (U.K.)	1975	57 NIDD (60% of eligible study subjects)	Clinician rating weight	Dietitian rating:	
				Good	65%
				Fair	17.5%
				Poor	17.5%
			Biochemical measures	Weight loss	Significant mean weight loss for the group over 6 months
Davies et al (U.K.)	1975	8 hospitalised patients on carbohydrate-restricted	7-day food records (measured by staff)	Deviation from carbohydrate prescribed	
				Within 20%	37%
				21-50%	24%
				GT 50%	37%
Arvidsson Lenner (Sweden)	1976	53 women from population study with abnormal GTT (93% response)	Body weight	(4)Body mass index GT 1.1	Before n = 23 / After n = 18 (ns)
			Diet history		
			24 hour recall	Reduced sucrose consumption	2 sub-groups reduced consumption
			3 day diet record	No. of main meals & snacks	No change
			Clinician prediction	Changed intake of selected food groups	Some change
			Self-rating	Overall - "counselling"	
				successful	42%
				some change	33%
Dorchy et al (Belgium)	1977	8 IDD juveniles	10-day food records	Composition	Group mean
				Protein (12-15%)	12.7%
				Fat (30-35%)	41.6% "too high"
				Carbohydrate (50-55%)	45.7% "too low"
					High spontaneous variation between days in all nutrients.

TABLE 2.1 (continued)

AUTHOR	YEAR	SAMPLE(1,2,3)	MEASURE	DEFINITION	COMPLIANCE
Chambers & Beaven (New Zealand)	1977	192 diabetics - (Rx-nr) Attending clinic New (experimental) = 96 Old (controls) = 96 Complete data (after 3 years) New: 36 (37.5%) Old: 55 (57%)	Weight		Women(a)
				GT 110% "ideal" = overweight	Before / After (8 years)
				Statistically significant weight loss for group	Before: n = 20 / After: n = 11
				"new"	144% / 128.2%*
					Before: n = 30 / After: n = 20
				"old"	121% / 119.7%
Ludvigsson (Sweden)	1977	58 IDD juveniles	24-hour recall	(Criteria nr)	
				Good	20.7%
				Acceptable	60.3%
				Poor	19.0%
Wysocki et al (Poland)	1978	170 IDD attending clinic	Self-rating (home interview)	Adhered to diet	40%
				Restricted sugar	54%
Baxter & Cunningham (U.S.A.)	1979	193 diabetics and hypertensives attending clinic	Self-rating mailed questionnaire	Total compliance (all regimens)	26.4%
				(criteria nr)	
				High	27.5%
				Moderate	32.6%
				Low	11.4%
				Non-compliance	2.1%
				Compliance with low fat diet	
				Total	40.2%
				Partial	42.5%
				Non-compliance	17.3%

(a) A similar table was constructed for men, significant decrease in the first year for both groups - thereafter no change.

TABLE 2.1 (continued)

AUTHOR	YEAR	SAMPLE[1,2,3]	MEASURE	DEFINITION	COMPLIANCE
Baxter & Cunningham (continued)				Lose Weight	
				Total	45.2%
				Partial	43.8%
				Non-compliance	11.0%
					n = 20
Glanz (U.S.A.)	1979	20 patients of nine dietitians on a variety of dietary regimens (included 3 diabetics)	Self-rating (five questionss asked in different sequences)	"Trouble sticking to diet?"	12 (60%)
				"How much of diet do you follow? - All	5 (25%)
				Most"	12 (60%)
				"How much of the time?" All	5 (25%)
				Most"	10 (50%)
				"Overall compliance"	6 (30%)
				"How well do you follow?"	6 (30%)
Alogna (U.S.A.)	1980	50 NIDD clinic attenders	Weight	Weight loss of 20-50 lbs. in 1 year and loss of 10% of initial weight each year	50% (N.B. sample intentionally selected 1/2 compliant)
Bloom Cerkoney & Hart (U.S.A.)	1980	30 IDD Clinic attenders	Self-report (4) (home interview)	Knows name of diet Uses exchange lists Skips means only occasionally Eats undesirable foods more than once per week (incomplete description of criteria for scoring)	Group mean score for diet 65%

TABLE 2.1 (continued)

AUTHOR	YEAR	SAMPLE[1,2,3]	MEASURE	DEFINITION	COMPLIANCE	
Kirkham & Wood (Australia)	1980	80 IDD+NIDD	Diet history weight	Number of features of diet appropriate (criteria nr)	IDD n = 61	NIDD# n = 19
				Energy	42%	57%
				Eliminate refined CHO	79%	80%
				CHO GT 40% of energy	42%	33%
				Adequate nutrients	90%	89%
				CHO distributed throughout day	79%	94%
				CHO constant each day	63%	71%
				[4] TOTAL		
				Excellent	28%	27%
				Good	28%	47%
				Fair	38%	16%
				Poor	6%	5%
				Overweight (GT 110% ideal)	36%	53%
Boulton et al (Australia)	1980	14 IDD juveniles (participating in insulin trial, compared with age-matched non-diabetics)	4-day food record	Nutrient intake tested for significance of differences between non-diabetics and diabetics	Not significantly different from non-diabetics	
Belmonte et al (Canada)	1981	198 IDD juveniles (attending camp)	Urine tests, weight	Prolonged "faked" urine urine tests weight loss	6%	
Henry et al (Canada)	1981	16 IDD well-controlled regular attenders of diabetic clinic	7 1-day food records over six weeks (measured and estimated)	- carbohydrate within 20 g of prescribed	44%	
				- low co-efficient of variation (cv) on conventional diet vs unrestricted diet	Conventional diet (range) cv = 7-24%	Unrestricted diet # (range) cv = 8-22%

TABLE 2.1 (continued)

AUTHOR	YEAR	SAMPLE(1,2,3)	MEASURE	DEFINITION	COMPLIANCE	
Streja et al (Canada)	1981	66 NIDD Attending diabetics education centre (80% response)	Weight Biochemistry	Tested for statistical significance of weight loss for the group	Statistically significant weight loss at short-term follow-up, but weight gain at long-term follow-up	
Webb et al (Australia)	1982	108 IDD attended education programme (78% follow-up)	4-day food record (weighed) weight	Composition (% of energy)	Before	After
				Carbohydrate GE, 45%	13.9%	38.9%*
				Fat LE 30%	9.3%	21.3%*
				(4)Carbohydrate spacing	32.1%	31.2%(ns)
				(4)Carbohydrate variation	29.3%	34.0%(ns)
				Weight		
				O'weight & lost (>5% ideal)		8%
				O'weight & maintained		19%
				Ideal & maintained		63%
				Ideal & gained		9%
Hopper (U.S.A.)	1981	159 IDD, NIDD	Clinician rating Weight	Practitioners consider "compliant)	LT 10%	
				Body mass index (criteria not specified) obese	Males 20%	Females 60%
Broussard et al (U.S.A.)	1982	90 NIDD - American Indians attending clinic	Self-rating	Compliant with diet order	14%	

Key:

(1) unless otherwise specified, samples are adults
(2) study sample numbers are those for which complete data were available
(3) IDD - insulin dependent diabetics, NIDD - non insulin dependent diabetics
(4) for scoring scheme for compliance definition - see original reference
nr = not reported; ns = not statistically significant; * = statistically significant; # = no statistical analysis

SECTION 2.3

METHODOLOGICAL ISSUES IN THE STUDY OF COMPLIANCE WITH DIABETIC DIET REGIMENS

Reviewers of investigations of compliance with medical and dietary regimens have found that reported rates of compliance and non-compliance vary widely, even within studies of the same regimen (Haynes et al 1979, Glanz 1980, Dunbar and Stunkard 1979). The observed variation in compliance rates has been attributed largely by these authors to differences in the research methods used.

A number of methodological problems may bias the results of compliance research including -

(a) the selection of methods inappropriate for the purpose of the study, (b) inadequate operational definitions of compliance, (c) inappropriate, invalid and/or unreliable measures of compliance, (d) inappropriate study designs, (e) lack of careful sampling, and (f) inadequate or inappropriate data analysis (Haynes et al 1979).

This section of the review summarises literature concerning advantages and disadvantages of various methods used to study compliance, particularly as applied to dietary compliance. Critical comments about the studies of compliance with the diabetic diet regimen are presented in the context of each of the methodological problems listed above.

A. THE PURPOSES OF COMPLIANCE RESEARCH

The questions to be answered by a compliance investigation and the purposes for which the results are to be used will dictate the selection of appropriate research methods and the interpretation of the results. Sackett (1979) has attributed much of the inadequate methodology used in compliance research to a lack of clear statements of purpose by the authors.

Four types of questions concerning compliance behaviour have been studied in the literature on medication compliance (Haynes et al 1979). They include the identification of -

> (a) the extent of compliance and non-compliance with a regimen, (b) the efficacy or effectiveness of a new therapy (whether a therapy can work if individuals comply with it and whether it does work in the world), (c) determinants of compliance, and (d) the effectiveness of a compliance-improving strategy.

The primary objective of most studies of compliance with diabetic diet regimens was to describe the extent of the problem of non-compliance (Dahlberg et al 1947, Tunbridge 1949, Jacobi 1954, Dobson et al 1958, Etzwiler and Sines 1962, Sterky 1962, Williams et al 1967, Bolt and Miller 1967, Holland 1968, Tunbridge and Wetherill 1970, Singleton 1971, Wharton et al 1972, Davies et al 1975, Ludvigsson 1977, Baxter and Cunningham 1979, Kirkham and Wood 1980, Boulton et al 1980, and Belmonte et al 1981).

Less often studied was the effectiveness of a compliance-improving strategy (Bowen et al 1961, Tagliacozzo et al 1974, Stone 1961, Arvidsson Lenner 1976, Chambers and Beaven 1977, Goodman et al 1953, Salzer 1975) or the efficacy or effectiveness of diet therapy on

diabetic control (Gabriele and Marble 1949, Keiding et al 1952, Knowles et al 1965, Bloom 1967, Weinsier et al 1974, Goodner and Ogilvie 1974, Dorchy et al 1977, Henry et al 1981, Hadden et al 1975, Streja et al 1981).

Factors related to dietary compliance were only of secondary interest in the major surveys of compliance as reflected by simple analyses of relationships between routinely collected data about patient demographic details and dietary compliance. Only four studies stated as one of their major objectives the study of factors related to compliance (Wysocki et al 1978, Bloom Cerkoney and Hart 1980, Alogna 1980, Broussard et al 1982).

Implicit in the objectives of some of the compliance surveys was the evaluation of effectiveness of a clinic or educational intervention (Kirkham and Wood 1980, Williams et al 1967, Tunbridge and Wetherill 1970, Wharton et al 1972, Baxter and Cunningham 1979, Hopper 1981, Bloom Cerkoney and Hart 1980). However, this was rarely explicitly stated.

B. OPERATIONAL DEFINITIONS OF DIETARY COMPLIANCE

The assessment of dietary compliance is a two-step process; it involves the measurement of food intake or other indicators of compliance and the comparison of collected data with a set of criteria used to define compliance to a particular regimen (Mojonnier and Hall 1968). These criteria are usually referred to as the "definition" of compliance (Gordis 1979 and Dunbar and Stunkard 1979). An operational definition of compliance should specify what an individual must do, to what degree, to be considered compliant (or non-compliant) with the recommended regimen (Gordis 1979).

Dunbar and Stunkard (1979) commented that "the adherence literature, if assesssed only by its ability to define the problem, is in a fairly primitive state." Several problems have been identified with the way compliance has been operationally defined in studies of both medication and dietary regimens. They include: inadequate reporting of compliance definitions, the lack of standardised "regimen-specific" definitions, the lack of biologic rationale for definitions and inappropriate methods for quantifying compliance (Sackett 1979, Gordis 1979, Dunbar and Stunkard 1979, Glanz 1980, Mojonnier and Hall 1968).

Inadequate Reporting of Definitions

Sackett (1979) has emphasised the need for descriptions of therapeutic regimens and compliance definitions to be "precise, unambiguous, appropriate for the purpose of the study and reported in such detail as to be replicable by the reader." In their original and revised reviews of the extensive literature on compliance with therapeutic regimens, Sackett and Haynes (1976) and Haynes et al (1979) found that "a substantial number of investigators failed to provide a proper definition of the object of their research". Similarly, Dunbar and Stunkard (1979) commented that often "reports give the percentage of compliers and non-compliers in a particular sample but fail to disclose the criteria used to define compliance."

The operational definitions of compliance with the diabetic diet regimens in the studies reviewed were frequently vague. For example, Stone (1961) considered subjects who "followed their diets at least 6 days per week" to be compliant, but no criteria were given as to how he defined "following a diet". Other authors specified the behaviours necessary for compliance e.g. "adequate meal spacing", "consults exchange lists", "appropriate energy supply" but failed to give the

TABLE 2.2

(a) SCORES FOR RESEARCH METHODS USED IN STUDIES OF COMPLIANCE WITH DIABETIC DIET REGIMENS AND DIABETES EDUCATION

AUTHOR	YEAR	PURPOSE(S) OF STUDY	REGIMEN DESCRIPTION	COMPLIANCE DEFINITION	COMPLIANCE MEASURE(S)	EDUCATIONAL STRATEGY DESCRIPTION	DESIGN	SAMPLE	DATA ANALYSIS AND REPORTING
Arvidsson Lenner	1976	3	1	1	1+1(A)	1	3+1(A)	2+1(A)+1(B) & (C)	1
Ainslie	1981	3	N/A	N/A	N/A	1	3(C)	2+1(B)	1
Alogna	1980	1	0	2	2	N/A	1	0	1
Baird	1972	0,2	0	1	0,2	N/A	1	0	1+1(B)
Baxter & Cunningham	1979	0,1	0	1	1	N/A	1	0+1(B)	1
Belmonte et al	1981	0,1	0	1	0+1(B)	N/A	1	0+1(C)	1
Bloom	1967	0,2	0	0	0	N/A	1	0	1+1(B)+1(C)
Bloom-Cerkoney & Hart	1980	1	0	1	1	1	1	1	1
Bolt & Miller	1967	0	0	1	1	N/A	1	1	1
Boulton et al	1980	0	0	0	2+1(B)	N/A	1	0	0+1(A)
Bowen et al	1961	3	1	2,0	2,0	2	3(C)	0+1(B)	2
Brock	1978	3	0	0	0	1	3(C)	0	1
Brouhard et al	1978	3	N/A	N/A	N/A	1	3	0	0
Broussard et al	1982	0,1	0	0	0	N/A	1	0+1(C)	1
Chambers & Beaven	1977	3	1	2	2	1	3(C)	0	0
Chandalia & Bagrodia	1979	3	0	0	0	2	3	1	1
Dahlberg et al	1947	0,2	0	1	1	N/A	1	2+1(B)	2
Davidson et al	1976	3	nr	nr	nr	2	nr	nr	0
Davies et al	1975	0	2	1	2	N/A	1	0	1+1(A)
Dobson et al	1958	0	1	1	2	N/A	1	1	1
Dorchy et al	1977	2	2	0	2+(1)	N/A	1	0	1+1(A)
Etzwiler & Robb	1972	3	N/A	N/A	N/A	1	3	2	1
Etzwiler & Sines	1962	0	0	1	1	N/A	1	1	1
Flint	1976	3	N/A	N/A	N/A	1	3	2+1(A)	0+1(A)

Table 2.2 (continued)

AUTHOR	YEAR	PURPOSE(S) OF STUDY	REGIMEN DESCRIPTION	COMPLIANCE DEFINITION	COMPLIANCE MEASURE(S)	EDUCATIONAL STRATEGY DESCRIPTION	DESIGN	SAMPLE	DATA ANALYSIS AND REPORTING
Gabriele & Marble	1949	0	1	1	1+1(B)	N/A	1	0+1(B)	1
Glanz	1979	1	1	2	1	N/A	1	1	2
Goodman et al	1953	3	2	1	2	1	3	0	0
Goodner & Ogilvie	1974	3	0	0	2	0	3	0+1(B)	1
Hadden et al	1975	3,2	2	1	0,2	1	3	0+1(B)	1+1(B)
Hassell & Medved	1975	3	N/A	N/A	N/A	2	4	0	2
Henry et al	1981	2	2	2	2	N/A	1	0	2+1(A)
Holland	1968	0,1	1	1	1	N/A	1	3+1(B)	1
Hopper	1981	1	0	1,0	2,0	N/A	1	0	1
Howe-Davies et al	1980	3	0	0	2+1(B)	1	3	2	1
Jacobi	1954	0	1	1	1	N/A	1	0+1(B)	2+1(C)
Kelding et al	1952	0,2	0	1	1	N/A	1	0	1+1(C)
Kirkham & Wood	1980	0,1	1	1	0+1(A)	N/A	1	0+1(C)	2
Knowles et al	1965	2	2	1	0	N/A	1	1	0+1(C)
Ludvigsson	1977	1	0	0	1	N/A	1	0	1+1(B)
McDonald & Kaufman*	1963	3	N/A	N/A	N/A	1	3	2+1(B)	0
MacMurray & McArthur	1978	3	1	N/A	N/A	1	1	0+1(B)	1
Meadows	1965	3	1	N/A	N/A	1	1	0	0
Miller	1972	3	N/A	N/A	N/A	1	3	2	1
Moffitt et al	1979	3	N/A	N/A	N/A	0	3(C)	2	0
Noviks et al	1976	3	1	2	2	2	3	0	1
Origer	1974	3	0	1	2	2	3	0+1	0+1
Reynolds	1978	3	1	N/A	N/A	2	3	0	1+1(A)
Runyan	1975	3	N/A	N/A	N/A	2	3(C)	2	2

* other reports of same study: (Skift 1965, Spiegel 1967)

Table 2.2 (continued)

AUTHOR	YEAR	PURPOSE(S) OF STUDY	REGIMEN DESCRIPTION	COMPLIANCE DEFINITION	COMPLIANCE MEASURE(S)	EDUCATIONAL STRATEGY DESCRIPTION	DESIGN	SAMPLE	DATA ANALYSIS AND REPORTING
Runyan	1980	3	0	0	2+1(B)	1	3	2+1(B)	0
Salzer	1975	3	0	1	1	2	3	0	0
Schnatz et al	1981	3	N/A	N/A	N/A	1	3	0+1	0
Singleton	1971	3	0	1	0	N/A	1	0	1
Spaulding & Spaulding	1976	3	N/A	N/A	N/A	2	2	2+1(A)	1+1(A)
Sterky	1962	0	1	2	2,0	N/A	1	2	2
Stone	1961	3	0	1	1	0	3	0+1(B)	0+1
Streja et al	1981	2,3	2	1	2+1(B)	1	3	0+1(B)	1+1(B)
Tagliacozzo et al	1974	3	0	0	3(diet)	1	4	1+1(A)	2
Tani & Hankin	1971	3	N/A	N/A	N/A	2	3(C)	1+1(C)	0+1(A)
Tunbridge*	1949	0,1	2	0	2	N/A	1	0	1
Tunbridge & Wetherill	1970	0,1	0	2	2+1(B)	N/A	1	2	2+1(B)+1(C)
Weinsier et al	1974	2,3	2	1	2+1(A)	1	3	1	1
Wharton et al	1972	0,1	0	2	0	N/A	1	0	0
Whitehouse et al	1979		N/A	N/A	N/A	1	1	0+1(C)	0
Wysocki et al	1978	1,0	0	1	1	N/A	1	0+1(B)	2
Williams et al	1967[1]	0	0	2	0+1(A)	N/A	1	0+1(C)	2+1(C)
		0	1	1	2	N/A	1	0	2
Young et al	1969	3	N/A	N/A	N/A	1	3(C)	3	2

N/A not applicable
nr not reported
* other report of same study (Tunbridge 1953)
(a) see Appendix 2.1 for criteria for assigning scores

criteria for adequacy or appropriateness. (Kirkham and Wood 1980, Bloom Cerkoney and Hart 1980). In studies where individuals were asked to assess their own compliance, the definition of compliance was left to the subject and it is uncertain how notions of "following a diet" vary between individual diabetics. For some, the avoidance of sweet foods most of the time may suffice, whilst for others, compliance may mean strict adherence to the prescribed menu, the weighing of food or the avoidance of specific foods such as bread, gravy etc. Whether any of these notions of compliance correspond to the prescribed regimen is also uncertain since diabetics frequently misunderstand the dietary regimen and its rationale (Etzwiler 1963, West 1973, Watts 1980). The frequency of scores of "0" or "1" assigned for no or vague definitions by far exceeded those assigned a 2 for precise, replicable definitions (Table 2.2).

Lack of Standardised Definitions

Clearly, there is no standard working definition which can be applied to all regimens with all patients (Dunbar and Stunkard 1979). However, even between studies of compliance with the same regimen there is a lack of standard criteria against which compliance is assessed. This constitutes a major problem in the interpretation and comparison of compliance rates observed in studies of the same regimen and highlights an area for further development in dietary compliance research (Glanz 1980). The difficulties in achieving such standardisation are not to be under-estimated, particularly in regimens for conditions such as diabetes where the dietetic advice varies widely between programmes and practitioners.

In studies of compliance with diabetic diets, some investigators compared individual intakes with the prescribed levels of energy

(Tunbridge 1949, 1970, Jacobi 1954) or carbohydrate (Wharton et al 1972, Davies et al 1975, Henry et al 1981, Weinsier et al 1974). Others focused on dietary behaviours thought to be important in achieving these nutritional goals such as weighing food (Keiding et al 1952, Bloom 1967) regularity of meals (Arvidsson Lenner 1976, Knowles et al 1965, Watkins et al 1967, Williams et al 1967, Kirkham and Wood 1980, Wysocki et al 1978) avoidance of sugar or sweets (Bolt and Miller 1967, Arvidsson Lenner 1976) use of food exchange lists (Bloom Cerkoney and Hart 1980) and carrying sugar for hypoglycemic reactions (Etzwiler and Sines 1962). Several others used weight loss or weight status to define compliance (Goodman et al 1953, Dobson et al 1958, Bowen et al 1961, Weinsier et al 1974, Goodner and Ogilvie 1974, Hadden et al 1975, Chambers and Beaven 1977).

The degree of compliance required to be classified as a complier or a non-complier varied considerably between studies. For example, Tunbridge and Wetherill (1970) defined "satisfactory" compliance as less than 10% deviation from the prescribed calories, whereas Jacobi 1954 defined it as "within 50% of prescribed." Similarly, definitions of compliance with weight recommendations were not uniform. Bowen et al (1961) defined compliance as a loss of 4.6 to 20 pounds whilst Arvidsson Lenner (1974) required the achievement of ideal weight for her subjects to be considered compliant.

As a consequence of the arbitrary nature of these criteria for defining compliance, considerable variation in the compliance rates and the success rates of compliance-improving strategies is not surprising. Clearly more "lenient" definitions result in higher success rates!

In most studies, compliance tended to be defined too narrowly i.e. limited to only one aspect of the dietary regimen despite the

wide range of recommended dietary behaviours for most diabetics. It is unfortunate that opportunities were often missed to assess a variety of aspects of dietary compliance from the collected data on food intake. Investigations in which compliance was defined more comprehensively were limited to only a few (Williams et al 1967, Baxter and Cunningham 1979, Kirkham and Wood 1980, Bloom Cerkoney and Hart 1980).

The aspects of the regimen used to define compliance partly determine the compliance rates since some aspects of the regimen will be easier to comply with than others. In Table 2.1, reported compliance rates were higher when the avoidance or restriction of sugar was used as the definition of compliance than when other definitions were used.

Uncertainty about the clinical importance of various dietary behaviours used to define compliance

The selection of goals for use in defining compliance should be made on the basis of clinical rationale i.e. those thought to be the most important for the achievement of the treatment goal (Gordis 1979). However the clinical consequences of various aspects of non-compliance with dietary regimens are largely unknown.

Moreover, the validity of the assumption that the achievement of behavioural goals will lead to the achievement of the nutritional goals of diabetic regimens has not been tested. Does weighing food, consulting the diet sheet, or adhering to the prescribed menu plan automatically lead to the consumption of the prescribed energy or carbohydrate intake? Alternatively, can the nutritional goals be achieved without such behaviour? Truswell et al (1975) (discussed in Section 2.1 of this review) suggested that, in some cases, adherence

to the diet "sheet" results in non-compliance with the stated nutritional goals! Also, does adherence to the prescribed energy level lead to the desired weight? This issue is discussed further under "outcome measures" of compliance.

Such knowledge gaps raise doubts about the validity of inferences concerning nutrient goal achievement from other indicators of dietary behaviour. Recently, the validity of compliance estimates from food groups in comparison with ratings based on nutrient intakes has been studied in low-fat dietary regimens (Guthrie and Scheer 1981, Anderson et al 1979, Remmell et al 1980). Such studies are needed in diabetic regimens.

Lack of Biologic Rationale for Assigning Individuals to Compliance Categories

For most types of compliance research "the classification of individual patients as compliers or non-compliers is essential" (Gordis 1979). In particular, studies of determinants of compliance will usually require such classification.

Preferably, the cut-off point which distinguishes compliers from non-compliers should be based on biologic rationale (ibid.), that is, compliers should be more likely to achieve the treatment goal. Frequently, however there is no sound biologic or clinical rationale for such cut-off points and so they are set arbitrarily. For example, it is uncertain whether a weight loss of five kilograms in an overweight diabetic improves their metabolic control (Reaven et al 1979). Similarly, there is little evidence about how far an individual may deviate from the prescribed fat, energy or carbohydrate intake (e.g. 10%, 20% or 30%) and still achieve a clinically significant reduction in serum cholesterol or blood glucose.

Methods of Quantifying Compliance

Dunbar and Stunkard (1979) described three general approaches which have been used to quantify compliance with medication and dietary regimens. They include:

(a) Calculation of percentage of medication (or nutrients or meals) consumed out of the total number or amount prescribed (e.g. the percentage of prescribed energy or carbohydrate, or percentage of recommended weight loss),

(b) Classification of individuals into compliance categories e.g. "fully", "somewhat" or "non-compliant" on the basis of some criteria e.g. the patient's report, alteration in eating behaviour or the clinician's subjective rating.

(c) Assignment of an index or score based on multiple behaviours that is, several aspects of one drug or diet regimen, or compliance to a number of regimens such as diet, medications and appointment-keeping.

For most purposes of compliance research, method (a) is the most desirable because it generates continuous data from which the compliance level of individuals can be described. (Glanz 1980, Gordis 1979, Dunbar and Stunkard 1979). Individuals may later be assigned to compliance categories from continuous data. The advantages of defining compliance on a continuum as compared with a "categorical definition" are that the entire compliance distribution of a group can be described (Sackett 1979) and it is more sensitive in detecting change in compliance or associations with other factors.

Compliance "scores" have been used commonly in the assessment of

dietary compliance to summarise multiple behaviours into one index (Glanz 1980). Occasionally treatment outcomes have been combined with measures of dietary compliance to form an index of compliance (Dunbar and Stunkard 1979). A major disadvantage of these combined scores is the loss of detail in describing compliance (Marston 1970). In studies where compliance rates are reported separately for different aspects of a regimen, there tends to be a wide variation in observed rates (ibid.), while combined scores are less variable and may mask compliance rates to components of a regimen.

Several investigators used combined scores or ratings to summarise compliance rates with a variety of aspects of the dietary regimen (Williams et al 1967, Baxter and Cunningham 1979, Bloom Cerkoney and Hart 1980, Kirkham and Wood 1980) or to combine compliance ratings with aspects of outcome such as achievement of acceptable blood glucose levels, absence of hypoglycaemic episodes or the complications of diabetes (Keiding et al 1952, Gabriele and Marble 1949, Stone 1961).

The results were often difficult to interpret due to incomplete reporting of the scoring systems. The tendency to combine definitions of outcome with behaviours aimed at the achievement of outcomes has been discouraged primarily because outcomes are influenced by factors other than dietary compliance (Dunbar and Stunkard 1979, Glanz 1980). This issue is discussed further under measures of compliance, Section 2.3C. Combined scores for several components of the diabetic diet regimen inadequately describe compliance because rates tend to vary between various aspects of the dietary regimen. For example, Kirkham and Wood (1980) found that 42% of their sample were compliant with energy recommendations while 90% had an adequate nutrient intake. However, only 28% received a combined rating of "excellent". Further

research is needed to identify the relation between compliance with various aspects of one diabetic regimen, particularly to justify the use of combined ratings or scores for compliance with the regimen.

Another question in quantifying dietary compliance which has not been adequately answered is how to define compliance so that it is "fair" to all individuals (Glanz 1980). Clearly, those who deviate the most from dietary or weight goals have a greater potential for change than those who deviate only slightly. Small changes in the latter group may be just as difficult to achieve and as clinically significant as larger absolute changes in those who deviate considerably from the dietary goals.

This problem, in relation to defining compliance with weight reduction diets has been discussed by Feinstein (1959) who reviewed the various criteria used to define "success" at weight reduction. He noted that some criteria, based on a fixed amount of change e.g. a 20 pound weight loss were biased in favour of the grossly overweight because, he claimed, greater weight losses were more easily achieved in this group than in the mildly overweight. Although definitions which were relative to the degree of overweight were less biased, Feinstein found that they still did not adequately standardise for degree of overweight. Thus, he proposed a formula for use in defining weight compliance. However, due to its complexity, Glanz (1980) could find no reports which had used this index since its publication in 1959.

Does Compliance Imply Change?

A conceptual problem related to the classification of compliers and non-compliers and which has not been addressed in the literature is the extent to which compliance with a dietary regimen implies change from current eating habits.

Compliance with a medication regimen always necessitates a change in behaviour from that prior to the prescription of tablets or other medication. However, everyone eats, consuming diets which deviate variably from a special regimen. At the start of diet therapy, some individuals may already meet the prescribed dietary goals and thus require maintenance of current dietary habits. Such a group was identified by Arvidsson Lenner (1976) in a study of effectiveness of dietary counselling for women with abnormal glucose tolerance.

Whether these individuals should be defined as "compliers" and indeed whether they are the same kind of compliers as those who alter their dietary behaviour is uncertain.

C. MEASUREMENTS OF DIETARY COMPLIANCE

Characteristics of a "good" measurement of dietary compliance

Although there is no one perfect method of measuring compliance (Dunbar and Stunkard 1979), certain characteristics identify a "good" measurement or test of dietary compliance. It must be appropriate for the purpose of the study and for the operational definition of compliance, valid, reliable, sensitive and specific, feasible and ethical (Young 1978, Marr 1971, Sackett 1979, Gordis 1979, Mojonnier and Hall 1968).

Among the recommendations of highest priority generated from the U.S. National Institutes of Health/Nutrition-Behavioural Research conference in 1975 was "more rigorous research to develop techniques and instruments capable of measuring actual compliance with dietary regimens" (Becker 1975). Interest in the development of measurements of dietary compliance has been stimulated by a lack of knowledge about their validity, their expensive use of resources (Mojonnier and Hall 1968), and their lack of application for clinical counselling and management (Remmell et al 1982).

Currently there are several methods available for the assessment of compliance (Dunbar and Stunkard 1979, Young 1978, Young and Trulson 1960). The methods include -

(a) direct observation, (b) self-ratings of dietary compliance, (c) clinician ratings of compliance, (d) outcome measures, and (e) self-reports of dietary intake.

Information about the characteristics of each of these measurements and their disadvantages is presented in the following discussion, as summarised from the reviews of dietary compliance by Dunbar and Stunkard (1979), and of dietary methodology by Marr (1971), Burk and Pao (1976), Young (1978), Young and Trulson (1960) and Margetts (1981).

The types of studies and stituations for which each measurement is appropriate and the problems with its use are summarised in Table 2.3.

In the discussion of measurements the terms validity, reliability, sensitivity and specificity have been used as defined below.

Validity

Validity, in relation to measures of dietary intake usually refers to the extent to which a measurement reflects the "true" picture of the aspects of dietary intake which an investigator wishes to describe (Young 1978). However the "true" dietary intake probably cannot be measured (ibid.), because "a reference method that yields absolutely true results does not exist" (Burk and Pao 1976). Thus, the content validity of dietary methods has not been extensively evaluated. However, the concurrent validity has been widely investigated for some measurements of compliance, i.e. the extent to which a measurement reflects the same picture as another measure thought to be valid. The "gold standard" of dietary methods (i.e. that gives the most accurate quantitative information about food and nutrient intake) is the weighed food record (Marr 1971, Burk and Pao 1976). Biochemical tests have also been used to establish concurrent validity of measures of dietary compliance, although they are generally considered to be no more valid than dietary measurements (Young 1978, Dunbar and Stunkard 1979).

Reliability

Reliability describes the reproducibility or repeatability of a compliance measurement i.e. the extent to which it yields the same or similar estimates at least twice under the same conditions (Burk and Pao 1976, Marr 1971).

Sensitivity and Specificity

Similar to the characteristics of a diagnostic test, the sensitivity and specificity of a compliance measurement refer to its ability to distinguish accurately between compliers and non-compliers. A

measurement's sensitivity is its ability to detect non-compliers accurately while specificity is its ability to correctly identify compliers (Sackett 1979).

The determination of sensitivity and specificity, like validity, require comparison with a "gold-standard". The lack of such a gold standard has limited the evaluation of measurements of dietary compliance. However, a few studies have used either food records or biochemical measurements, which approximate gold standards, to assess the sensitivity or specificity of other measurements of compliance.

Evaluation of existing Measures

1. Direct Observation

Because individuals are likely to alter their eating behaviour when they are aware of being observed (Young 1978), researchers of dietary behaviour have tended to use unobtrusive observation techniques i.e. with subjects either unaware of being observed, or of the purpose of observation. Using direct and unobtrusive observations, Caron and Roth (1971) detected deviations from the prescribed diet of hospitalised ulcer patients at the noon meal by an elaborate coding scheme on identification cards used to obtain meals in the dining hall. Coates et al (1981) noted changes in eating behaviour of school children during the lunch period, from direct observations of food and drink consumption before and after an education programme.

However, where direct observation is possible, dietary intakes differ from "usual" eating behaviour, since free choice of food is limited by reactivity to the observation. Hence, this method of compliance assessment may lack content validity, i.e. reflection of usual or habitual eating behaviour.

Unobtrusive observation also poses an ethical dilemma. "Informed consent" with the compliance measurement may alter the variable of prime concern since, as patients know their compliance is under investigation, they will comply" (Jonsen 1979).

2. Self-ratings of Compliance

A commonly used technique in the study of compliance with medication regimens (and to a lesser extent with dietary compliance) is the self-report or self-rating (Gordis 1979, Dunbar and Stunkard 1979). Individual subjects may be interviewed or complete a self-administered questionnaire. Examples of questions which have been used to assess dietary compliance include: "Do you follow your diet?", "How well (or closely, strictly) do you follow your diet?" or "How difficult is it for you to follow your diet?"

This technique differs from the self-report of food intake in that the subject is required not only to recall his food intake but also to recall the regimen, to assess his usual eating behaviour according to his own definition of "following a diet" and report his assessment accurately. Occasionally, subjects may be asked to report on specific aspects of the dietary regimen, e.g. "How often do you weigh your food, eat sweets, go off your diet?" etc. Included in this category of measurements are self-reported body weight and weight change, e.g. "What do you weigh?" "Have you gained, lost or maintained your weight in the past few months?" or "Do you weigh more, less or the same as you did one year ago?"

The self-report of compliance has been used to assess compliance with a healthy diet (Haefner and Kirscht 1970), a regimen for hypertensive patients (Kirscht and Rosenstock 1977) and a variety of

TABLE 2.3

METHODS OF ASSESSING DIETARY COMPLIANCE

Method	Appropriate in what circumstances and for what kinds of compliance studies	Disadvantages and Problems
1. Direct observation (unobtrusive)	- Institutionalized individuals - When only a "snapshot" sample of compliance behaviour is of interest - When operational definition of compliance is focused on eating behaviour rather than quantitative measure of nutrient intake	- Usually impossible with free living subjects - Institutionalised subjects do not have free choice (lacks content validity) - Questionable ethics
2. Self-Ratings of Compliance	- Simple regimens (i.e. avoids sweets) - In combination with other methods - Large-scale surveys of compliance - When subject co-operation is likely to be very low - When resources are extremely limited - When specificity more important than sensitivity (detecting only the non-compliers) e.g. clinical counselling or management.	- Subject has to assess his own compliance - may not co-incide with investigator's views of compliance - Subject may not report accurately particularly if no other check on compliance - Qualitative vs quantitative - thus not useful in describing degree of deviation from prescribed regimen or change in compliance - Unreliable - answers vary depending on the question asked and the order - Insensitive - detects only approximately 50% of the non-compliers - Inappropriate for studies of determinants, trials of efficacy of diet therapy or compliance - improving strategies

TABLE 2.3 (continued)

Method	Appropriate in what circumstances and for what kinds of compliance studies	Disadvantages and Problems
3. Physician or Clinician Ratings of Compliance	- In combination with other methods i.e. food intake measurements - When specificity more important than sensitivity e.g. clinical management or counselling - When only a qualitative, categorical description of compliance is required	- Insensitive (detects only half of the non-compliers) - Reproducibility and inter-rater reliability unknown - Needs validation in each setting - Usually does not provide quantitative data
4. Biochemical or outcome measures	- In combination with other measures - To verify dietary methods or to assess the relationship between compliance and treatment outcome - Weight may be a more valid measure of compliance with weight-reduction diets due to difficulties in estimation of energy intake	- Not a direct measure of dietary compliance - Confounding variables may influence biochemical or other outcomes despite compliance - Not recommended as a substitute for dietary compliance measures
5. Self-Reports of Food Intake		
A. Recall of past intake	- Quantitative and qualitative estimates of compliance	- Not valid or reliable for compliance estimates for individuals
(1) 24 hour recall	- Useful in describing compliance level of a group (e.g. mean nutrient intake) in studies of compliance - improving strategies and surveys of compliance	- Population error introduced from subject's memory, estimation skill, daily and seasonal variation in food intake, interviewer skill

TABLE 2.3 (continued)

Method	Appropriate in what circumstances and for what kinds of studies	Disadvantages and Problems
5. Self-Reports of Food Intake (continued)		
(ii) food frequency	- Qualitative estimates of compliance with consumption of food types	- Probably not valid nor reliable for quantitative estimates of nutrient intake (see above)
(iii) diet history	- Measure of past compliance - Qualitative description, large groups	- Not useful in assessing compliance of individuals - Not a measure of current compliance (see comments for other recall methods)
5.B. Prospective Record of Daily Intake		
(i) Quantities Weighed (7 days or reliable number)	- For compliance studies of small samples - For precise quantitative estimation of the compliance level of individuals - For detecting change in compliance of individuals and groups (i.e. therapeutic trials and programme evaluations)	- Usually limited to small samples - High subject co-operation may reduce response rates and thereby bias compliance results - May lack content validity (individuals may alter what they eat) - May not be reliable due to seasonal variation in food intake - Expensive to collect and process - Needs pre-testing on study population to determine how many and which days of the week give reliable estimates for nutrients of interst
(ii) Quantities Recorded in household measures or estimated	- As above, although not as accurate	

dietary regimens (Glanz 1979). It has also been used extensively in the study of compliance with the diabetic diet regimen (Dahlberg et al 1947, Gabriele and Marble 1949, Keiding et al 1952, Bolt and Miller 1967, Holland 1968, Singleton 1971, Salzer 1975, Wysocki et al 1978, Baxter and Cunningham 1979, Bloom Cerkoney and Hart 1980. One study used the parent's report of how strictly their children adhered to a diabetic diet (Etzwiler and Sines 1962).

The advantages of this technique are its simplicity, low cost and applicability in large-scale mail or interview surveys. However, in reviews of the literature on medication compliance, Gordis (1979) concluded that patient interviews lack validity when self-reports of compliance are compared with pill counts and urine tests. In the cited investigations, compliance tended to be over-estimated and non-compliance under-estimated. Dunbar and Stunkard (1979) drew similar conclusions in their review; "clinicians should not expect to achieve a reliable and objective assessment from the interview."

Because dietary regimens are usually more complex, it might be expected that the validity and reliability of self-ratings of dietary compliance would be even less than for medication regimens. However, very limited research has been done to assess this.

The concurrent validity of self-ratings of compliance was studied by Hyman et al (1982) who compared the subjects' self-ratings of compliance to a modified fat diet with various measures of serum lipids. They observed statistically significant correlations between these, although the correlation coefficients were quite small ($r = 0.17$ to 0.27) and the significance levels were not adjusted to account for a large number of comparisons (80) between all measures of compliance and of serum lipids. Also the extent to which these

results are generalisable is questionable (as the authors themselves acknowledge) since the sample was a select group of volunteers.

The validity of self- reports of weight also appears limited since under-reporting of body weight has been observed in several studies, (Charney et al 1976, Biro 1978) particularly by over weight women (Pirie et al 1981).

The report of a study by Glanz (1979) suggests that the self-ratings of compliance are not reliable. Her results showed that patients' responses to questions about compliance with various dietary regimens varied considerably within individuals, depending on the types of questions asked and their order. No other studies of reliability or validity of the self-rating of dietary compliance could be located.

Sackett (1979) has argued in favour of the use of the self-rating to detect non-compliance with medication regimens particularly in the clinical setting because it has been shown to be specific i.e. individuals do not report themselves to be non-compliant when they are compliant. However, the sensitivity of the self-rating is low; only half of the non-compliers are usually detected by this means (ibid.). Thus, on the available evidence, its use in the research setting appears to be limited.

3. Clinician Ratings

A technique sometimes used to assess medication or dietary compliance is the judgement of the clinician (physician or nutritionist) (Dunbar and Stunkard 1979). Ratings may be based on general impressions from an interview or from knowledge about the clinical condition or self-reported food intake (e.g. food records or

24-hour recall). Such ratings are usually made without knowledge of the nutrient calculations of dietary intakes and without an objective set of criteria. It is this which distinguishes the clinician rating from measures of self-reports of food intake.

Although clinician ratings have been used widely in assessing compliance with other dietary regimens (Mojonnier and Hall 1968, Hyman et al 1982, Remmell et al 1980) only four studies reported their use in measuring compliance with the diabetic diet (Bowen et al 1961, Hadden et al 1975, Arvidsson Lenner 1976, Hopper 1981).

Like the self-rating, clinician ratings of compliance are simple to do and inexpensive (Mojonnier and Hall 1968). However, clinician ratings have not been found to be valid in assessing compliance with medication regimens. Gordis (1979) concluded from his review that "physicians appear to estimate compliance no better than chance". Similar results have been obtained for nutritionists. While several investigators have shown that nutritionists' ratings correlate with the compliance of their patients (Mojonnier and Hall 1968, Hyman et al 1982, Arvidsson Lenner 1976), only one half of the non-compliers were identified as such. Thus, this measurement appears to lack sensitivity. In all these studies, compliance ratings were made by nutritionists and interviewers who had prior knowledge of the patients' food and nutrient intake i.e. from food records and/or 24-hour recall data (Dunbar and Stunkard 1979).

4. Measures of Outcome

Biochemical or other physical indicators have been used in place of, or in addition to, behavioural measures to assess dietary and medication compliance, the rationale being that if compliance is high,

health or biochemical outcomes will be achieved (Dunbar and Stunkard 1979). Biochemical and biological indicators have been frequently used to derive estimates of compliance with fat-controlled diets, weight reduction diets (Glanz 1980) and diets for hemodialysis patients (Blackburn 1977).

Frequently, measures of blood glucose control, e.g. fasting blood glucose, random blood glucose, or incidence of ketoacidosis, have been made in studies of dietary compliance with diabetic diets. However, these are rarely used as the only measurement of compliance such as they were in the studies by Chandalia and Bagrodia (1979).

Biochemical tests are regarded as the most valid measurements of compliance with medication regimens, against which other methods have been compared to establish their validity (Haynes et al 1979). However the relationship between dietary compliance and treatment outcome or biochemical end-points is not direct and other factors may override the effect of dietary compliance (Dunbar and Stunkard 1979). Glanz (1980) commented that "in view of possible confounding factors in nutrient absorption and utilisation, measures of food intake should actually yield a more "direct" measure of eating behaviour".

Serum lipids, as measurements of compliance, may lack validity "due to the multiplicity of factors that affect serum lipids, variations in patients' responses to diet and other technical measurement problems" (Hyman et al 1982). Similar factors limit the utility of measurements of blood glucose control as valid indicators of dietary compliance (Williams et al 1967).

Compliance with weight reduction diets is most commonly measured using an index of outcome rather than adherence; weight or weight

change (Feinstein 1959, Stunkard and McLaren-Hume 1959, Glanz 1980). Because of the ease of the measurement and its accuracy, body weight may be preferable to estimates of energy intake in assessing compliance with weight reduction diets (Lansky and Brownell 1982). However, some doubt about the validity of body weight as a measurement of adherence to diet has been raised by several authors. The assumption that adherence to a standard weight-reduction diet will result in weight loss has been challenged by Garrow (1978). Evidence that some individuals require more substantial energy deficits than expected to achieve weight loss was obtained when he observed the failure of some hospitalised patients to reduce weight on 1200 and 800 calorie regimens (under strictly supervised conditions).

Other factors, apart from dietary compliance, may contribute to substantial weight loss. Glanz (1980) cited evidence from one study in which subjects took laxatives, diuretics and vigorous exercise to achieve weight loss prior to attending a weekly behaviour modification programme. In diabetics, particularly those requiring insulin, it is well-recognised that rapid weight loss may occur during periods of poor blood glucose control irrespective of dietary intakes (Porte and Halter 1981).

In summary, Gordis (1979) and Dunbar and Stunkard (1979) caution against the use of outcome variables as substitutes for the measurement of compliance (a process variable) on the basis that they are two distinct phenomena. However, biochemical and other outcome measures may be useful to establish confidence in dietary measurement methods or to clarify relationships between compliance and treatment outcome (Sackett 1979).

5. Self-Reports of Food Intake

Methods used to measure the food intake of individuals (as distinguished from methods appropriate for the measurement of food consumption of households and populations) are based on two general types of measures:

(a) an estimation from an individual's recall of past intake, or

(b) prospective records of foods and beverages consumed in a specific time interval

with numerous variations on these two basic themes (Margetts 1981, Young 1978, Burk and Pao 1976, Marr 1971).

(a) Recall Methods

Commonly used techniques in the dietary literature are the 24-hour recall, the food frequency questionnaire (usually one week or one month) and the diet history ("usual" eating over a period of months or years). Subjects may be asked to estimate quantities consumed or the frequency of consuming "average serves". Either of these procedures may be interviewer- or self-administered. If an interviewer is used, quantities may be estimated with or without food models.

The 24-hour recall has been used to assess the average compliance of a group of individuals with fat modified diets, either singly (Poddell et al 1978) or in combination with other measures (Mojonnier and Hall 1968, and Remmell 1980). It has also been used to assess the compliance level of individuals with diabetic diets as a single measure (Ludvigsson 1977, Williams et al 1967) or in addition to other measures (Watkins et al 1967, Arvidsson Lenner 1976).

The food frequency questionnaire and diet history interview have been used to assess compliance levels of groups and individuals with cholesterol-lowering diets (Leren 1966, Fleischman 1967, Stern et al 1976, Gotto et al 1977) and with diabetic diets (Jacobi 1954, Stone 1961, Knowles et al 1965, Bolt and Miller 1967, Wharton et al 1972, Arvidsson Lenner 1976, Kirkham and Wood 1980).

Burk and Pao (1976) commented that the recall methods are "much less likely to change consumption behaviour" than other dietary methods. In addition, the data may be more representative of a population because subject co-operation rates are usually higher than with record methods (Marr 1971). However, the validity and reliability of the 24-hour recall is limited by the subject's memory, ability to estimate portion sizes accurately and the fluctuations in daily and seasonal dietary intakes (Garn et al 1978, Burk and Pao 1976, Young et al 1952 and Marr 1971). Errors of both under and over-estimation have been frequently observed when recall methods have been compared with weighed or measured prospective records (Margetts 1981).

The validity and reliability of the 24-hour recall is also influenced considerably by the interviewer's skill (Marr 1971, Young and Trulson 1960, Young et al 1952).

Marr (1971) concluded in her review that "a 24-hour period has been shown to be of very limited value in identifying intakes of individuals even at the extremes of the distribution; this cannot be stressed too strongly". However, for summarising group averages, this method has shown close agreement with group data from seven-day weighed records (Marr 1971 and Burk and Pao 1976). Thus, 24-hour recalls would be appropriate only for quantitative or qualitative measurements for large groups.

The validity and reliability of other recall methods are also limited by their dependence on the subject's memory, estimation skill interviewer technique and within-individual variation in food intake. Opinions vary about the ability of the diet history to provide accurate quantitative data about the nutrient intake of individuals. Huenemann and Turner (1942) concluded that diet histories "had little quantitative value". However, others have concluded that food records and diet histories are measuring different aspects of dietary intakes and no conclusions may be drawn about which method is more valid (Becker et al 1960). With regard to the food frequency method, Burk and Pao (1976) concluded that this method has little value in describing quantitative nutrient intake of individuals.

(b) Prospective Food Records

Prospective food records involve the recording of all foods and beverages consumed over a stated period of time. Food recording procedures may be subdivided into those which require the food quantities to be recorded by weight or household measures or simply by menu (no quantities).

Numerous procedures for weighing food have been used but the most common requires that the subject weigh his individual serves of prepared food and the plate waste.

The records are usually kept by the subjects themselves, although supervised recording has been used (Margetts 1981). Records are commonly kept for three to seven days, although the time periods used in dietary research have ranged from one day to several months (Young et al 1952).

Prospective continuous food records kept by the subjects themselves (either weighed or measured) for three, four, seven or fourteen

days, have been used to assess compliance with cholesterol-lowering diets (Mojonnier and Hall 1968, Shorey et al 1976, Witschi et al 1978, Tillotson et al 1981), with weight reduction diets (Lansky and Brownell 1982, Romanczyk et al 1974) and with diabetic diet regimens (Tunbridge 1949, Williams et al 1967, Tunbridge and Wetherill 1970, Weinsier et al 1974, Davies et al 1975, Ardvidsson Lenner 1976, Dorchy et al 1977, Boulton et al 1980 and by ourselves, Webb et al 1982). Intermittent food records over a number of weeks or months were used in one study of compliance with a low fat diet (cited in the review by Dunbar and Stunkard 1979) and with a diabetic diet (Henry et al 1981).

Weighed records are useful not only for quantifying dietary intakes of individuals and groups but also for qualitative descriptions of dietary intakes of selected food groups or meal and snack patterns. Dunbar and Stunkard (1979) commented that one advantage of food records over other methods is that they generate continuous data about behaviour that may help the researcher and clinician to detect patterns of non-compliance and "to identify origins of the patient's problems with the regimen".

However, food records may lack content validity and may not reflect habitual compliance. Attempts to check the validity of food records with biochemical measurements such as serum lipids or urinary nitrogen have generally shown that whilst means for the group agree closely, there is considerable variation for individuals (Brown 1968, Hyman et al 1982, Briones et al 1973, Johnstone et al 1981, Isaksson 1980). It is uncertain whether the discrepancies are due to invalid dietary methods on individual biologic variation (Liu et al 1978).

Young and Trulson (1960) commented that the issue of how many and which days of the week provide a reliable estimate of nutrient

intake for groups and for individuals has been the subject of much investigation and remains a subject for "debate, active interest and investigation". For group comparisons (of average energy and nutrient intake) Young (1978) and Marr (1971) cited evidence from several studies that less than a seven day record (one to four days) gives sufficiently reliable estimates of some nutrients for individuals. However, the days of the week chosen for record-keeping may influence the reliability and validity since several investigators have observed a day-of-week effect for nutrient or energy intakes with weekends tending to be different (Burk and Pao 1976).

Significant differences in the energy and nutrient intake of groups have been found between winter and summer months, although the differences are not consistently in the same direction (Marr 1971). Thus, it is recommended that the influence of days of the week and the season on the estimates of dietary intake be assessed by pre-testing the method on the study population of interest (Young and Trulson 1960).

Due to the amount of effort required of subjects, seven-day weighed records are usually considered feasible only with small and highly co-operative samples (Burk and Pao 1976, Young and Trulson 1960). Marr (1971) reviewed the co-operation rates with weighed seven-day food record procedures used in several studies with different sample characteristics. The percentages of reliable records of the total samples (including those ineligible and unable to co-operate) ranged from 32% to 79% and the majority fell between 60% and 79%. Co-operation rates from five studies using seven-day estimated or measured records were similar to those for weighed records but records of less than seven days may yield higher response rates (ibid.).

Summary of Methods used to measure compliance with diabetic diets

In view of the number of factors which can influence the validity and reliability of dietary compliance measurements, complete reporting of the methods is crucial to the interpretation of the results. However, only a minority of studies provided adequate descriptions of the methods (Williams et al 1967, Tunbridge and Wetherill 1970, Sterky 1962). In studies where self-ratings were used, the actual questions asked of diabetics were infrequently reported. Those which used self-reports of food intake by recall frequently failed to describe the method adequately, who interviewed, whether food models were used to assist subjects with portion estimations etc. (Jacobi 1954, Stone 1961, Knowles et al 1965, Bolt and Miller 1967, Wharton et al 1972, Wysocki et al 1978). Several studies reported using a "diet history" but did not describe which of the various components of the classic "Burke diet history" (1947) were used (Stone 1961, Arvidsson Lenner 1976). Studies which used prospective records generally failed to report whether quantities were recorded in weights, household measures or estimated.

The validity and reliability of many of the results of these compliance investigations are jeopardized by the use of inappropriate measurements for the purpose of the study and/or for the operational definitions of compliance. For example, several studies which aimed to document compliance rates or factors related to compliance, or the effectiveness of an intervention, used dietary recall methods to estimate the habitual intakes of nutrients or food groups of individuals and for classification them into compliance categories (Stone 1961, Jacobi 1954, Williams et al 1967, Bolt and Miller 1967, Wharton et al 1972, Kirkham and Wood 1980.

In view of the previously reported lack of sensitivity of the self-rating as a measure of compliance, percentages of non-compliers could be double those observed in studies which used this technique!

Clearly, much more information is needed about the validity and reliability of methods of measuring compliance with diabetic diets. It is unfortunate that, in studies which used multiple measures of compliance, the results from only one measurement were reported and no comparison was made between the methods. The impression from the majority of the literature on compliance with diabetic diets is that insufficient attention was given to defining the object of research and the selection or development of appropriate methods to measure it.

D. Study Designs

In their original review of the literature, Sackett and Haynes (1976) described the use of four types of study designs in compliance research; the randomised trial, the quasi-experimental (before-after), the analytic (case-comparison or cohort) and the descriptive study (cross-sectional or survey).

The study designs and the types of compliance research for which they are appropriate are briefly summarised here. A randomised trial is the only true experimental design comprising the random assignment of a sample to either an experimental treatment or a control group who are followed forward in time to determine the effects of the experimental manoeuvre on some outcome of interest, e.g. compliance. Such designs are appropriate for all aspects of compliance research and are particularly important in studies of the effectiveness of compliance-improving strategies.

Because randomised trials are the most expensive form of research, "sub-experimental" designs are fequently employed - par-

ticularly to identify causes or predictors of compliance and to describe or document the effects of a compliance-improving programme. One such design is the "before and after" approach in which the effects of an experimental strategy are described only in the experimental group. Although a control group may be used for the comparison of effects, subjects are not randomly drawn from the study population, thus the data obtained are subject to biases which result from the potential lack of comparability of the control group.

Another sub-experimental approach is the cohort study. Two groups, alike in all respects except one (e.g. started diet therapy) are followed over time to identify the occurrence of some outcome event. The cohort design has been recommended for the documentation of compliance rates and the identification of predictors or causal factors in compliance (Haynes et al 1979). However, its use is relatively rare in compliance research because of the difficulty in "tracking down" members of a cohort (ibid.).

Although regarded as less rigorous than other sub-experimental designs, the case-control study may be used for similar purposes in compliance research. It is a retrospective approach which involves the identification of two groups (e.g. compliers and non-compliers) and a search back in time to discover differences in exposure or causal factors, e.g. exposure to an education programme or differences in doctor-patient interactions.

Non-experimental research designs (i.e. surveys or cross-sectional studies at a point in time) have been used frequently to determine the magnitude of compliance and non-compliance in a study sample and to assess differences between compliers and non-compliers in characteristics of interest (Haynes et al 1979).

Sources of Bias

All of these designs are subject to bias, the most vulnerable to which is the survey. The "prevalence" of non-compliance measured at a single point in time will probably misrepresent the true compliance rates because compliance is time-dependent (ibid.). Survey results which document the co-existence of selected characteristics with high or low compliance do not suggest a causal relationship, and thus may lead to erroneous conclusions about determinants of compliance (Taylor et al 1979).

Thirty-five potential biases in the use of case-control studies have been described by Sackett (1979) the most important of which is the misrepresentation of a cohort i.e. those not studied because they have dropped out of therapy, were misdiagnosed in the first place, were cured, died, moved or for other reasons were untraceable. A similar weakness (which applies to all designs) is the "non-respondent bias" of the identified cases. Another difficulty with case control studies is the potential "recall bias" i.e. diffrences in recall of cases and controls due to differences in questioning procedures. Although cohort studies are considered less vulnerable to bias than case-control, problems such as non-response or overambitious detection in one group can lead to inaccurate results. Case-control and cohort studies are analytic, not experimental, and are therefore inappropriate for the determination of the effects of programmes and strategies designed to improve compliance.

Designs used to study compliance with diabetic diets

The cross-sectional survey was, by far, the most common design in the reviewed studies (Table 2.2). It was used to describe the extent of compliance and non-compliance and to identify relationships between compliance and other measured factors. The lack of use of the cohort design limits the validity of the observed compliance rates as discussed previously. No prospective designs were employed to assess determinants of compliance. Thus, significant associations could have been coincidental and/or important determinants of compliance may have been undetected. Of the several studies which evaluated the effects of an intervention on dietary compliance, only one of these was a randomised controlled trial (Tagliacozzo et al 1974)! The remainder used "before and after" designs, some of which included a control group (non-randomly assigned) for comparison of results. Although the results from these studies are more indicative of the effects of a clinic or programme, than cross-sectional studies or those without a control group, their validity is limited by the lack of randomly selected control groups.

E. Sampling

The extent to which the results from compliance research can be generalised to compliance in the community is dependent upon the similarity between the study sample and the population of potential compliers. Sackett (1979) suggested that careless sampling is the most common weakness of compliance investigations. He discussed two major sources of sampling bias which are commonly introduced. The first is the lack of sampling from an entire "inception cohort" discussed previously. The exclusion of those who drop-out of treatment, or otherwise remain unidentified "may invalidate conclusions

about the magnitude of compliance, its determinants and the effectiveness of strategies for its improvement."

Secondly, samples of patients for compliance research tend to be drawn from locations where they are conveniently identified, e.g. clinics and health centres. Such samples may be self-selected with respect to diagnosis, the clinical stage of disease or treatment and compliance behaviour. The need for careful definition of the study population and the use of random sampling procedures was emphasised as a priority in future compliance research.

The size of the sample affects the ability to detect statistical associations between compliance and another variable, or a difference between compliance rates between an experimental and control group. The sample size required will depend on the error of the compliance measurement and the magnitude of the difference one wishes to detect. In their review Haynes et al (1979) used the criterion of a sample size of 50 per comparison group as a basis for which to recognise or disregard results of compliance investigations. The rationale was that a sample of this size was required to detect a difference of 25% on some factor between two groups (compliers and non-compliers or experimental and control) with 80% confidence.

In the majority of investigations of compliance with diabetic diets, highly select samples of diabetics who were attending clinics or summer camps were studied. Only two investigations attempted to obtain representative samples of diabetics in the general population through careful sampling techniques, but the final samples were not without problems (Dahlberg et al 1947, Holland 1968). Taking advantage of a rare opportunity to identify the population of diabetics in Sweden by way of special food ration cards, Dahlberg and colleagues

(1947) attempted a survey of the entire diabetic population of 15,000. Whilst a substantial number of individuals (5,207) returned completed questionnaires, this represented only 36% of the original study population. In the U.S. National Health Interview Survey, considerable care was taken to obtain a large and representative sample of the American population through stratified random sampling procedures (Holland 1968, McDonald 1968). However, the sample obtained was somewhat biased, as the authors acknowledged, due to the exclusion of diabetics who were hospitalised at the time of the home survey.

Although random sampling procedures were used to obtain study samples in three investigations, the study populations from which they were drawn were limited to single clinics or camps and were therefore unlikley to acurately represent compliance in the entire population of diabetics. Inadequate descriptions of sampling techniques and demographic profiles of study samples were common (as shown by a score of "0" for sampling in over 60% of reports listed in Table 2.2). Subject attrition rates at various stages of the selection and measurement process were adequately documented in only a few reports and it was not uncommon to find only the final sample number reported. Unfortunately, the most carefully conducted studies and those using the most precise methods to measure dietary compliance, tended to utilise such small sample sizes that the results are not generalisable (Williams et al 1967, Tunbridge and Wetherill 1970, Weinsier et al 1974, Henry et al 1981, Davies et al 1975).

F. Data Analysis and Reporting

Very little has been written about methods of statistical analysis for use in compliance research. Statistical issues which may influence the interpretation of results of therapeutic trials were

discussed in the review by Haynes et al (1979). Yet, no critique was made of the statistical methods used or the adequacy of reporting in the compliance studies reviewed.

Several problems were identified with data analysis and reporting procedures which could have led to errors in results and/or conclusions drawn of studies of compliance in diabetics. Thus, basic guidelines were devised for scoring this aspect of research methodology (Appendix 2.1). As shown in Table 2.2, very few studies obtained a score of "2" for appropriate and complete analysis and reporting of data.

It was not uncommon to find studies of educational interventions or factors related to compliance with no statistical analysis! Hence, the observed effectiveness of some intervention strategies (Stone 1961, Davidson et al 1976, Salzer 1975, Origer 1974, McDonald and Kaufman 1963) or factors associated with dietary compliance (Holland 1968, Broussard et al 1982, Tunbridge and Wetherill 1970) could have been due to chance!

Inappropriate statistical analyses were applied to data in several studies. In those which used a matched pair design, the matching did not appear to be used in the analysis (Chambers and Beaven 1977, Wharton et al 1972). Similarly, changes in control groups were analysed separately in some studies and no statistical comparison was made between the two groups (Ainslie 1981, Chambers and Beaven 1977). Changes in compliance were analysed by sub-groups in the study by Arvidsson Lenner (1976) but no statistical comparison in changes in the whole group were made. Thus, the observed "success" of diet counselling may not have been statistically significant for the group as a whole. In "before and after" studies, paired com-

parisons are a more appropriate (and conservative) (Winer 1971) yet, paired t tests or repeated measures analyses of variance were rarely used.

The probability of type I errors are increased with the number of statistical tests carried out (Miller 1966). One method of dealing with this is to adjust the critical alpha levels for the number of statistical comparisons. In studies of factors related to compliance, numerous statistical comparisons have been made without adjustment of the significance level. Thus, some observed "significant" associations may have been due to chance (Alogna 1980, Wysocki et al 1978).

Finally, the lack of complete analysis and reporting was a major limitation in many reports. Frequently, the significance levels were given but the statistics were not reported. Several outcomes or potential determinants of compliance were often measured but the results of these were not mentioned.

In many studies where treatment outcomes such as blood glucose or lipids were assessed, their relation to compliance was not statistically analysed.

Clearly, there is a need for more sophisticated and thorough statistical procedures to be applied in studies of compliance with diabetes self-care regimens and in the evaluation of effectiveness of diabetes education.

Section 2.4

DETERMINANTS OF COMPLIANCE WITH DIABETIC DIET REGIMENS

In practical terms, research into factors related to dietary compliance aims to provide a rational basis on which to plan and modify strategies designed to improve it. However, while poor compliance with diabetic diet regimens has been the subject of much speculation, little systematic empirical investigation has been reported.

Some studies have documented the co-existence of patient factors such as poor knowledge in situations of poor compliance but have not examined the relationship between compliance and such factors. A number of authors have proposed hypotheses for the failure of dietetic advice to positively influence compliance but few of these hypotheses have been tested (Beaser 1956, Etzwiler, 1968, Hinkle 1962, Kaufman 1964, Ohlson 1968, West 1973, Williams et al 1967, Wilson 1965). Similarly, existing knowledge of determinants of compliance to other dietary regimens is relatively meagre as evidenced by the reviews by Glanz (1980) and Dunbar and Stunkard (1979). In contrast, a large body of knowledge now exists with respect to factors related to medication compliance (Sackett and Haynes 1976 and Haynes et al 1979).

To help identify gaps in our understanding of factors determining compliance with dietary regimens in diabetes, the results of the few published studies are summarised in Table 2.4. Determinants of compliance with other diet and medication regimens were also reviewed for their promise as variables for future investigations in compliance with diabetic diets. Significant determinants as observed in the reviews by Glanz (1980), Haynes et al (1979) and Dunbar and Stunkard (1979) are summarised in the following discussion.

Evidence about factors related to other dependent variables such as health knowledge or control of diabetes was not included. The framework for considering factors related to dietary compliance was similar to that used by Sackett and Haynes (1979). Factors were grouped under the major headings of features of -

(a) the regimen, (b) the disease, (c) the patient, (d) the clinician and interactions between patient and clinician.

Characteristics of the educational process or intervention are also determinants of compliance (Haynes 1976). Evidence concerning the effects of various interventions on compliance is considered separately in Section 2.5. The patients' family has been found to influence compliance with medication regimens Becker and Green (1974). Limited investigation has been made of the influence of the family on self-management of diabetic children, but has not been studied in relation to compliance with the diabetic diet in adults (Anderson and Auslander 1980, Wishner and O'Brien 1978). Thus, although family characteristics are no doubt of major importance in compliance with a dietary regimen they are not discussed in this review. Similarly, features of the setting of care have not been studied with respect to their effect on dietary compliance and so were excluded from the review.

A. Characteristics of the Regimen

Watts (1980) stated that the most relevant findings to emerge from general compliance research of Sackett and Haynes (1976) was that "complicated regimens, persisting over a long period of time and requiring substantial degrees of behavioural change are associated with particularly poor treatment compliance." Thus compliance with

diabetic regimens (involving life-time and multiple regimens) is likely to be lower than for single regimens or those for short-term illness. Moreover, compliance with the dietary regimen is likely to be poorer than with medication or urine testing regimens because of the complex and restrictive nature of the diet as well as the major lifestyle and habit changes often required (Glanz 1980). Indeed, in the diabetes literature, factors most commonly hypothesised as responsible for poor dietary compliance have focused on characteristics of the regimen and include its complexity, cost, presentation, the lack of tailoring a standardised diet to the individual, the uncertain efficacy or effectiveness and the "life-time" nature of the diet.

Complexity and degree of behaviour change required

Haynes (1976) from his review of "determinants" of compliance said: "one of the few features of the regimen about which there are no dissenting reports concerns the degree of behavioural change the regimen requires of the patient". Compliance with regimens administered by health personnel and requiring little active co-operation by the patient (such as medications given to hospitalised patients) is easily achieved whilst compliance with regimens which require patients to "alter old behaviours such as diet" is much more difficult. Still more challenging is compliance requiring the breaking of personal (and possibly addictive) habits such as smoking, drinking, drug abuse or over-eating (Haynes et al 1979).

Compliance with multiple regimens tends to be lower than for single regimens, the number of daily medications prescribed has a strong negative association with compliance and combining one or more treatments or three or more life changes may lead to high rates of non-compliance (Haynes 1976). Haynes concluded that the "data suggest

TABLE 2.4

THE RELATIONSHIP BETWEEN SELECTED FACTORS AND COMPLIANCE WITH DIABETIC DIETS (AND OTHER SELF-CARE REGIMENS)[a]

FACTOR	AUTHOR(S)	YEAR	ASSOCIATION WITH COMPLIANCE[b]		
			Positive	Negative	No Association
Characteristics of the Regimen					
Number of recommendations	Baxter & Cunningham	'79		Inconclusive	
Degree of change required	Webb et al	This report			
Diet for Insulin-dependent vs Non-insulin dependent diabetics	Kirkham & Wood	'80			x
	Tunbridge & Wetherill	'70	x	*x	
Effectiveness of diet (to improve indices of diabetic control	Dahlberg et al	'47			x
	Bloom	'67			x
	Watkins et al	'67			x
	Tunbridge & Wetherill	'70			x
	Wharton et al	'72			x
	Ludvigsson	'77			x
	Knowles et al	'65			x
	Keiding et al	'52 (combined)	x		
	Streja et al	'81			x
	Hadden et al	'75	x		
	Webb et al	This report	*x (diet composition)		x (other aspects of diet

TABLE 2.4 (continued)

FACTOR	AUTHOR(S)	YEAR	ASSOCIATION WITH COMPLIANCE(b) Positive	Negative	No Association
Characteristics of the Disease					
Duration	Dahlberg et al	'47	x		
	Keiding et al	'52	x (combined)		
	Hulka et al	'75	*x (medications		
	Watkins et al	'67	x (injections)		x (other aspects of diet)
	Tunbridge & Wetherill	'70		x	
	Wharton et al	'72			x
	Holland	'68			x
	Bloom	'67			x
Symptoms	Dahlberg et al	'47		x	
Severity -					
Metabolic control	See "Effectiveness of Regimen"	xxx			xxxxxxxxx
	Kirkham & Wood	'80			x
Type of treatment	Tunbridge & Wetherill	'70	x		
IDD vs NIDD	Keiding et al	'52			x
Insulin-dose					

TABLE 2.4 (continued)

FACTOR	AUTHOR(S)	YEAR	ASSOCIATION WITH COMPLIANCE(b) Positive	Negative	No Association
Characteristics of The Patient					
Knowledge of diabetes and the regimen	Ludvigsson	'77			x
	Stone	'61	x (overall mgt)		
	Watkins et al	'67	x (overall mgt)		
	Holland	'68	x		
	Wysocki et al	'78	*x (all except diet)		x
	Tagliacozzo & Ima	'70	*x (appt keeping)		
	Tagliacozzo et al	'74			x (appt keeping)
	Webb et al	This report			x
Ability to recall recommendations	Hulka et al	'75			x (medi-cations)
Health Beliefs	Tagliacozzo et al	'74			x (appt keeping)
	Bloom Cerkoney & Hart	'80	*x (combined hb scores & combined compliance score)		x (diet)
	Webb et al	This report			x
	Alogna	'80	*x (weight & per-ceived severity)		
Other Attitudes					
Self-assessed "good" health	Linn et al	'80			x

TABLE 2.4 (continued)

FACTOR	AUTHOR(S)	YEAR	ASSOCIATION WITH COMPLIANCE(b) Positive	Negative	No Association
Positive attitude towards urine testing	Ludvigsson	'77	x (urine testing)		x (diet)
Positive attitude towards clinic	Tagliacozzo et al	'74	*x (appt keeping)		
Locus of control	Alogna	'80			x
	Lowery & Du Cette	'76			x (combined regimens)
Characteristics of the Clinician and the Clinician/Patient Interaction					
Communication scores for doctors	Hulka et al	'75			x (medication)
Dietitian's effectiveness (orientation to social influence)	Glanz	'79			x

(a) Unless otherwise specified, association is with dietary compliance

(b) Unless indicated with a *, positive and negative associations between factors and compliance were not analysed statistically

* Statistically significant associated at p LT.05

that individuals can cope only with a limited number of changes or intrusions in their lives at any given time".

Although a number of authors have emphasised the need to simplify and tailor the diabetic diet regimen, (Wilson 1965, Hinkle 1962, Kaufman 1966, West 1973, Chandalia and Bagrodia 1979), the effects of such modifications have not been evaluated. The following reports provide only indirect evidence for the importance of this factor in compliance with a diabetic regimen.

Baxter and Cunningham (1979) investigated the relationship between the number of recommendations in the medical regimens (medications and diet) of 262 patients attending outpatient clinics for a variety of chronic disorders including diabetes. Patients were categorised into one of five compliance levels and either high (greater than nine) or low (less than nine) number of recommendations. They found that the proportion of totally compliant patients was signficantly higher for patients whose regimens contained fewer recommendations. However, the relationship was reversed for the next level of compliance, i.e. a greater proportion of patients with a high number of recommendations were highly compliant. Thus the data are inconclusive. Unfortunately, data for diabetics are not reported separately.

The dietary regimen prescribed for insulin-dependent diabetics tends to be more complex than that for diabetics treated by oral hypoglycemics or diet alone. The former group, in addition to avoiding sugar and controlling weight, require much greater daily regulation of their energy and nutrient intakes. Thus it would be expected that dietary compliance rates of insulin-requiring diabetics might be lower than for other diabetics. However, their compliance rates have not been consistently lower (Kirkham and Wood 1980) or

higher (Tunbridge and Wetherill 1970) than for non-insulin dependent diabetics.

Some evidence concerning the effect of major life-style changes required by a dietary regimen was reviewed by Glanz (1980). In the National Diet-Heart study, men who frequently ate in restaurants were less likely to comply with a low-fat diet and the provision of low-fat but familiar food was thought to enhance adherence to the diet (Brown 1968). Also, gradual and incremental changes appeared to be more effective in improving compliance with weight reduction diets (Mahoney 1975).

Cost

In the review by Haynes (1979) the evidence concerning cost of a regimen as a determinant of compliance is conflicting. Out of eight studies which investigated cost as a factor, four found a negative association, two found a positive association while the remaining two found no association.

The cost of a diabetic diet with its emphasis on fresh fruits, vegetables and animal protein foods is often mentioned in the literature as a major barrier to compliance, particularly in low-income diabetics. Dobson et al (1958) reported that social service interviews with 180 diabetics attending a clinic revealed that over half of the patients had less than the minimum amount of money to purchase a diabetic diet. In surveys by Hopper (1981) and Broussard et al (1982), a common reason given by low-income diabetics for non-compliance to diet was the inability to pay for it. Lugvigsson (1977) observed that in his study in Sweden, some families had obvious difficulties in purchasing the prescribed diet.

Three studies compared the cost of a diabetic diet to a normal diet and the results were conflicting. Tunbridge (1949) and Tunbridge and Wetherill (1970) compared the cost of an average diabetic diet prescribed in their clinic to that of a normal diet and to the average cost of the actual diets consumed by the subjects of their survey. Both studies reported the average weekly cost of the "ideal" diabetic diet to be higher than a normal diet and for the actual diabetic diet consumed to be even higher than the "ideal" diabetic diet. Wharton et al (1972) also compared the average weekly cost of the food consumed by Australian diabetics and non-diabetics and found no significant difference. However, when both groups were divided by age (under 30 and over 30) the average cost for diabetic diets for those over 30 was less (by approximately one dollar) than for their non-diabetic counterparts, as calculated from their one week's recall of food intake. The authors attributed the difference in cost to the alcohol consumed by the non-diabetics over age 30 although the mean energy difference of 400 calories between these two groups was due to differences in all macro-nutrients.

No attempt was made in any of these studies to relate the cost of the diet to the level of adherence, thus no conclusions can be drawn as to the role of cost of the diet as a determinant of dietary compliance, although it is likely to be a contributing factor. The recent trend to prescribe a higher carbohydrate and low animal protein and fat diets may have reduced its cost.

Side Effects

The impact of side effects of medication regimens on compliance is apparently not substantial (Haynes 1976). Nonetheless, side effects have been associated in some reports of studies of compliance

with drug regimens. However, the study of side effects is complicated by the fact that the symptoms and complaints experienced during treatment may not be due to the medication or diet but to the disease itself or other factors (Dunbar and Stunkard 1979). These authors commented that well-controlled studies have documented that patients on inactive placebos frequently complain of symptoms that would be attributed to the medication, were they taking it.

The impact of side effects of the dietary regimen on dietary compliance has not been studied. However, anecdotal evidence suggests that alarming, unpleasant and unexpected side effects or symptoms may result from close adherence to the diabetic diet regimen, including excessive hunger or overfull or bloated sensation, unwanted weight gain or loss, increased hypoglycemic reactions or increased frequency of hyperglycemia (Bloom 1967, Broussard et al 1982). Whether these undesirable effects are attributable to adherence to the diet is uncertain, but if they are perceived so by the patients, compliance may be affected.

Effectiveness of the Regimen

Becker et al (1978) stated "To date, research on patients' compliance has focused mainly upon health problems for which recommended regimens of considerable and consistent effectiveness have been developed. Less often studied, however, are conditions for which the prescribed ameliorative medications have a relatively lower probability of continuing success."

Diabetes is such a condition. The uncertainties about the most efficacious diet therapy have been described in Section 2.1. The effectiveness of the dietary regimen is also questionable since in the

majority of studies of free-living diabetics, dietary compliance does not appear to be related to diabetic control as measured by blood glucose levels, and/or presence of complications (Dahlberg et al 1947, Bloom 1967, Watkins et al 1967, Tunbridge and Wetherill 1970, Wharton et al 1972, Ludvigsson 1977, Knowles et al 1965, Streja et al 1981) (Table 2.4). However, given the difficulties in reliable measurement of both these variables, it is impossible to be sure that compliance is not related in some way to diabetic control.

The lack of certain effectiveness of the dietary regimen might be expected to reduce compliance by diminishing the belief (or faith) in the regimen of both the health practitioner and patient and by the lack of observable improvement (and reinforcement) in the patients' control (Watts 1980). However, the patients' and health professionals' perceptions of effectiveness in relation to dietary compliance have not been studied.

B. CHARACTERISTICS OF THE DISEASE

Characteristics of the disease which have been cited in the general compliance literature as determinants include its duration, severity, experience of symptoms, degree and kind of physical and social disablement. Haynes et al (1979) commented, however, that less than half the reports which examined these variables in relation to compliance found any significant association. For dietary compliance, Glanz (1980) reported some evidence to suggest that it is higher amongst patients with more severe nutritional and physical disorders. She reported that Seaton and Rose (1965) observed a significantly lower drop-out rate from a weight reduction clinic for diabetics than for others; insulin-dependent diabetics recalled more of their self-care regimens that those treated by diet alone (Hulka et al 1975);

drop-out rates from a weight reduction group were lower amongst more severely obese patients (Garb and Stunkard 1974) and ulcer patients with complications were more compliant with their diets (Caron and Roth 1971). By contrast, longer duration of disease has been related to poorer dietary compliance for ulcer patients (Caron and Roth 1968) and for those on hemodialysis (Blackburn 1977).

The evidence from studies which have examined the relationship of compliance to disease characteristics of diabetes is presented below and suggests that they are not particularly important determinants of dietary compliance.

Duration of Diabetes

The relationship between the time since diagnosis of diabetes and level of compliance with diabetic self-care regimens has been examined in a number of studies and the results have been conflicting. Dahlberg et al (1947) found that diabetics who had been diagnosed for a shorter time reported themselves to be more compliant with diet. In contrast, Tunbridge and Wetherill (1970) found that a shorter duration of diabetes was significantly associated with poor dietary compliance in their sample. Watkins et al (1967) and Hulka et al (1975) observed that those who had diabetes longer made more errors in insulin dosage, but there was no relationship between duration of disease and other aspects of management. Several others have found no significant relationship between duration of diabetes and compliance with diabetic diet (Wharton et al 1972, Holland 1968 and Bloom 1967).

It should be noted that all of the studies reviewed here were cross-sectional surveys mostly drawing on conveniently obtained samples. Thus the design and samples are inappropriate for the deter-

mination of the effect of factors such as duration of disease on compliance (Sackett 1976).

Severity

Objectively assessed seriousness of diabetes is an uncertain determinant of compliance. The seriousness of diabetes is often defined by the type and amount of medication required and/or by blood glucose levels. Diabetics requiring insulin injections in large doses are generally thought to have more "severe" diabetes than those controlled by low doses of insulin, oral hypoglycemics or diet alone. Keiding et al (1952) observed no relationship between level of insulin-dosage and a combined rating for self management and control. The relationship between compliance and severity of disease as judged by insulin-dependence or blood glucose levels is not at all clear. Kirkham and Wood (1980) observed a trend for insulin-requiring diabetics to have slightly poorer dietary compliance scores (although not statistically significant). Tunbridge and Wetherill (1970) found dietary compliance to be poorer amongst diabetics treated by oral hypoglycemics than by injected insulin. As discussed previously, the level of compliance with diabetic diet regimens has not been found to be related to level of blood glucose.

Complications of Diabetes

Wharton et al (1972) reported a "trend" for diabetics with the vascular complications of diabetes to adhere more closely to their diets, although this relationship was not statistically significant. In contrast, Keiding et al (1952) found that diabetics with poorer management and dietary control, had the highest incidence of retinopathy, calcification and nephropathy.

Symptoms

Blackburn (1977) suggested that one factor which may affect dietary compliance in chronic hemodialysis patients is that the complications which result from non-compliance occur slowly and are unobservable. Thus, "the potential for developing complaints such as heart disease can be denied by a patient, even as it is occurring" (ibid.).

A similar situation exists in diabetics. They may have an extended period of asymptomatic hyperglycemia, whilst developing neuropathy, cardiovascular disease and retinopathy (Porte and Halter 1981). Whether the symptoms of hyper- or hypoglycemia affects compliance is uncertain.

Some evidence to suggest that the patient's feeling unwell affects compliance was reported by Dahlberg et al (1947). In his population survey in Sweden, diabetics who reported adhering carefully to a strict diet were more likely to feel unwell and to perceive themselves as having a poorer working capacity than those on a normal diet (with or without sugar restriction). It is possible, though, that diabetics who felt unwell, or perceived their working capacity as reduced were stimulated to adhere to a stricter diet in order to improve their condition, or as the authors concluded, close adherence produced the symptoms.

C. FEATURES OF THE PATIENT

Demographic characteristics of patients such as age, sex, socio-economic status, education, marital status, race and religion have been found repeatedly to have weak or no associations with compliance to a wide variety of therapeutic regimens (Haynes 1976, Marston 1970,

Glanz 1980, Dunbar and Stunkard 1979). Where associations have been found, they have rarely been predictive of compliance (Marston 1970).

Glanz (1980) noted that the examination of demographic variables in relation to dietary compliance has been limited since studies have tended to focus on one sex, age or socio-economic category such as obese women, young coronary-prone males or low-income black patients. The same criticism tends to apply to studies of dietary compliance in diabetics.

Becker (1976) has aruged that the identification of demographic determinants of compliance is useless since these are "unalterable and enduring characteristics". On the other hand, awareness of demographic determinants may help to identify individuals at high risk for non-compliance and stimulate the development of educational approaches tailored to the needs of special groups.

Sex

Part of the traditional sex-role behaviour of women is to obtain and prepare the family's food (Schafer 1978). Women tend to be more knowledgeable about food and nutrition, more health conscious and may influence more directly the food eaten in the home (ibid.). It might be expected therefore, that women would be more compliant than men to dietary regimens. However, this has not been supported by research (Glanz 1980). In fact, in several studies, men have been found to be more successful at weight reduction than women (Stunkard and McLaren-Hume 1959). Most evidence suggests that women are no more or less compliant with the diabetic diet regimen than men (Keiding et al 1952, Wharton et al 1972, Dahlberg et al 1947, Bloom Cerkoney and Hart 1980, Tunbridge and Wetherill 1970).

Positive associations between sex and dietary compliance have, however, been observed by several authors. Belmonte et al (1981) found that 12 children of 96 were "cheating" on urine tests in order to obtain more food, and the majority of these were girls. Hopper (1981) found that a much greater proportion of women than men (60% vs 20%) were obese in a sample of 159 low-income clinic patients. Kirkham and Wood (1980) observed in their sample of 80 that significantly more women were overweight than men (50% vs 26%). However, the lack of description of sampling procedures in these studies limits the generalisability of these results to their samples. In contrast, Chambers and Beaven (1977) conducted an audit of weight reduction in a diabetic clinic and found that, after a three year follow-up, women had lost significantly more weight than men. However, the men were not comparable to the women in other respects as they were significantly less overweight initially and their drop-out rate was higher (50% for women and 60% for men).

Age

Studies which have sampled from a wide age range of diabetics have generally found no significant association between age and dietary compliance with the diabetic diet (Bloom 1967, Watkins et al 1967 and Holland 1968). However, Tunbridge and Wetherill (1970), whose sample of 63 ranged in age from 15 to 81 (with a mean age of 56) found a tendency for diabetics under 40 to be more compliant and for those over 60 to be less compliant with a diabetic diet. In contrast, Dahlberg et al (1947) observed that diabetics who were very young or over age 50 tended to adhere better to diets than others. Wharton et al (1972) also found younger diabetics (under 30) to be more compliant than older ones. Ludvigsson (1977) found in a study of juvenile

diabetics aged 6 to 17, that those over 12 had significantly "poorer" food habits than the younger ones. From the conflicting evidence reported here, no conclusions can be drawn about the effect of age on dietary compliance.

Socio-economic status

Low socio-economic status, associated with poor education, low income and low status occupations, is frequently mentioned in compliance investigations as a contributor to poor dietary compliance. Moreover, health practitioners often tend to regard diabetics in this class as lacking intelligence, self-control and character (Hopper 1981). However, no study could be located which systematically evaluated the relationship between socio-economic status and dietary compliance in diabetes. Bloom Cerkoney and Hart (1980) mention, in passing, that no association was found in their study but no details were given as to the socio-economic status of their sample of 30, or how it was determined. A number of workers have found that the incidence of obesity increases with declining socio-economic status (Goldblatt et al 1965).

Intelligence

Health practitioners frequently cite level of intelligence of their patients as an important consideration in compliance expectations and further that educational strategies need to be tailored for the intelligence levels of patients (Welborn 1976, Tunbridge 1953). However, in the review by Sackett and Haynes (1976) none of the five studies which examined this variable found any association between intelligence and compliance levels.

Borkman (1976) investigated the relationship between staff estimates of intelligence of their hemodialysis patients and their

compliance with dietary regimens. They found no substantial evidence that estimates of intelligence levels were directly useful in explaining compliance, although patient understanding was related to level of compliance. They caution health practitioners against the use of estimates of patient intelligence as a criterion for selecting patients for treatment or in their management.

Knowledge about diabetes and self-care

Inadequate knowledge of diabetes management by diabetic patients and their families has been widely documented (Etzwiler and Sines 1962, Collier and Etzwiler 1971, Stulb 1968, Beaser 1956, Holland 1968, Simon and Stewart 1976 and Miller 1978). Moreover, several investigations have found the level of patient knowledge to be related to level of compliance with dietary and other regimens. Stone (1961) observed that, of 126 diabetics with unsatisfactory management (to several self-care regimens), 83 had poor knowledge. He did not, however, report the number of patients with adequate management who had poor knowledge. Watkins et al (1967) also observed a relationship between knowledge and overall management (including diet). Diabetics who had a "good knowledge" had acceptable management practices in significantly more aspects of diabetic care than those who had poor knowledge. Unfortunately, the relationship between knowledge level and dietary management was not examined separately. In the U.S. National Health Survey, Holland and co-workers (1968) found that diabetics who reported following their diets were more likely to give correct answers to questions about diet than those who reported not following a diet. Wysocki et al (1978) noted that whilst knowledge was not significantly related to dietary compliance, it was related directly to other aspects of diabetic self-care. Tagliacozzo and Ima

(1970) found in one study that compliance with appointment-keeping at a clinic was higher amongst patients (with a variety of chronic illnesses) who had greater knowledge about their illness. However, in a subsequent study of diabetics, knowledge was not significantly related to appointment-keeping (Tagliacozzo et al 1974).

The co-existence of inadequate knowledge with low compliance or adequate knowledge with high compliance observed in these studies does not suggest a causal relationship. Thus, these studies do not provide evidence to support the notion that increasing patient knowledge about diabetes will increase compliance. Indeed, it has been repeatedly demonstrated in the general compliance literature and in diabetes-related studies that knowledge can be increased with no concurrent improvement in self-care or health status (Haynes 1976, Graber et al 1977, Watts 1980).

Recall of Recommendations

There is some evidence that diabetic patients cannot consciously recall self-care recommendations but whether this affects compliance is uncertain. Hulka et al (1975) studied 242 diabetics to determine the effect of patient recall of information given by the physician on medication compliance. Watts (180) summarised these results in his review by stating that at least one third of the information could not be recalled by patients two weeks later but there was no significant correlation between patient recall of information and compliance with the prescribed medication or metabolic control.

Page et al (1981) conducted a study of patient recall of self-care recommmendations in 24 juvenile diabetics immediately after a follow-up visit to a paediatric outpatient clinit. Subjects ranged in

age from 2 to 21 years and some were accompanied by their parents. Respondents included parents if they were present, they found that subjects recalled on average only two recommendations out of the seven given. As well, they recalled recommendations which had not apparently been made, which may have reflected their recall of previous instruction. The authors did not relate recall of self-care recommendations to subsequent compliance with them, nor did they assess the effect of the number of recommendations on recall. Thus, they provided little evidence to support their conclusion that the number of recommendations should be kept to a minimum.

Lawrence and Cheely (1980) studied the recall of self-care information and demonstration of injection and urinalysis skills of 30 adult diabetics at irregular intervals (three to 17 months) following their clinic visits at which they had mastered correct knowledge and skills. They found that approximately one third of these patients who previously made no errors, had error rates of 10% or more at follow-up (a rate which they considered to be unacceptable). Due to the irregular intervals at which follow-up assessment occurred, no conclusions could be drawn about the effect of fixed periods of time on deterioration of knowledge and skills.

Health Beliefs

The health belief model (HBM), a theoretical model based on social-psychological theory was originally formulated by Rosenstock (1966) and colleagues in an attempt to explain preventive health behaviour of well individuals (e.g. participation in screening and immunisation programmes). The model was based on the hypothesis that behaviour undertaken to prevent ill-health was a function of an individual's perception of his or her susceptibility to illness, the

severity of it as well as the benefits and costs of the recommended health action. A behavioural cue or stimulus for appropriate action also formed a model component (ibid.).

The model was later reformulated its application in explaining health actions (or compliance with health recommendations) of acutely and chronically ill individuals (Becker 1976).

Health Beliefs and Chronic Diseases

The relevance of health beliefs to studies of compliance in patients with chronic illness has been discussed by Kasl (1974) and Becker et al (1978).

Chronic diseases such as hypertension, diabetes, renal failure, asthma and cardio-vascular disease pose some unique and difficult challenges for their sufferers and health care providers. In contrast to regimens for acute illness or prevention of illness, self-care regimens for chronic diseases usually -

> (a) place the burden of self-care with the patient and family rather than the doctor, (b) are long-term, often life-time, (c) are multiple, e.g. diet, drugs, exercise, appointment-keeping, (d) are not cures but "control" measures, (e) may be of uncertain or variable efficacy.

Thus, health beliefs of primary interest in chronically ill patients are those which relate to the perceived disabling effects of disease, the interference of the various regimens with individual and family life, and the perceived efficacy of the regimens to control disease. Due to the continuing dependency on doctors, characteristics of the doctor-patient relationship may also be a key determinant of compliance in chronic disorders.

The health belief model has recently been applied to the study of factors affecting compliance with a variety of dietary regimens in chronically ill and well individuals and found to be "somewhat successful" in explaining compliance (Glanz 1980). However, the HBM may be only partially adequate to explain dietary compliance and should not be the entire focus of research to identify determinants (ibid.).

Health Beliefs of Diabetics

In his review of the literature of behavioural issues in diabetes, Watts (1980) pointed out that whilst health beliefs have been demonstrated to be of importance in compliance in a wide variety of health and disease situations "currently, very little is known about the health beliefs of diabetics and their association with self-care". Ludvigsson et al (1980) discussed the potential relevance of health beliefs to compliance in juvenile diabetics and recommended further research to determine their importance.

However, only two studies could be located which examined the relationship between health belief model dimensions and dietary compliance in diabetics and conflicting results were obtained. Bloom Cerkoney and Hart (1980) assessed self-reported compliance to diet, urine testing and medication regimens in 30 diabetics. The following five health beliefs were also assessed: perceived susceptibility, severity, benefits, barriers and cues for compliance. When individual and combined belief and compliance scores were compared in correlation analyses, the total compliance score was significantly correlated with the total HBM score ($r = .50$) with perceived severity ($r = .42$) and with cues to action ($r = 0.4$). However, none of the individual health beliefs, nor the total belief score was related to dietary compliance

or urine testing compliance. Although the above correlations were statistically significant, the authors stated that "the correlations of the magnitude found in this study indicate that health belief motivators could only account for approxiately 25% of the variation in the compliance sample. A much higher correlation ... would be necessary to use these motivators as reliable clinical predictors". These findings suggest that health beliefs contribute to some aspects of compliance behaviour in diabetes, although not to diet. Their lack of relationship with diet may be due to unreliable assessments (self reports) of dietary compliance. Alternatively, other health belief dimensions not evaluated in this study such as perceived efficacy of the regimens, faith in doctors and satisfaction with care were more relevant to dietary compliance. In another study of health beliefs in diabetics, Alogna (1980) found that compliers with weight reduction diets were significantly more likely to perceive their diabetes as a severe illness than non-compliers. Apparently, other health beliefs were not measured.

Other Studies of Attitudes in Diabetics

In several studies of diabetics, attitudes have been assessed which bear some resemblance to selected HBM dimensions. As such, they are of interest in this review. Linn et al (1980) studied the relationship between patients' self-assessment of health and their compliance with the medication regimen in 75 diabetic males and 75 matched non-diabetics (on other oral medications). They found no significant difference between the compliance level of diabetics who assessed their health as poor or as good. Similar results were obtained for the non-diabetic group. A major difficulty in interpreting these results is that they were not reported separately

for diabetics on oral hypoglycemics, injected insulin and diet alone. Moreover, pill counts which they report as their measurement of compliance could not have been used with the latter two groups, yet no information was provided as to how compliance in these diabetics was, in fact, assessed.

Ludvigsson (1977) studied the attitudes of 58 juvenile diabetics aged 6 to 17 towards their treatment regimens including diet, urine testing, insulin injections, physical exercise, visits to the clinic. The majority of these diabetics (93%) reported positive attitudes towards their treatment regimens, but the relationship between attitudes and compliance was not investigated. The positive attitudes of these children towards their self-care tasks is surprising, given the poor compliance rates reported in another section of the same study, only 20% of the sample were considered to be compliant with diet. The discrepancy between attitudes towards the regimens and compliance with them (not discussed by the author) may have been due to unreliable assessments of attitude, i.e. these children may have reported attitudes to "please" the investigators rather than their true feelings. Alternatively, children who were non-compliant may not have felt negatively towards aspects of self-care which they did not attempt to follow.

Tagliacozzo et al (1974) assessed the impact of nurse intervention on: patients' definition of the seriousness of their illness, self-judgement of compliance, scepticism of medical care, attitudes towards the clinic and understanding of physicians' orders. They observed no statistically significant differences in these attitudes after intervention or between the experimental and control groups. With the exception of attitudes toward the clinic, the relationship

between these attitudes and appointment-keeping compliance were not investigated. Those who had more favourable attitudes to the clinic were more likely to be compliant.

Predictive Ability of Health Beliefs

Disagreement has arisen as to the clinical utility of measuring health beliefs and similar attitudes. Dunbar and Stunkard (1979) presented their opposing points of view. Dunbar argued that the evidence from research to date indicated that health beliefs are of little use in explaining or predicting compliance because she claims that the correlations frequently obtained between health beliefs and compliance have been too low (0.3 to 0.4) to account for a substantial portion of the variance between patients in compliance behaviour. Moreover, the doctor-patient relationship components of the model have correlated best with compliance while attitudinal variables have contributed little. Finally, there is some evidence that attitude change follows behaviour change rather than causing it. Stunkard, on the other hand, contended that while the model has these deficiencies, it provides a useful theory for drawing together and interpreting research results in the vast field of health behaviour.

Reservations about the usefulness of the HBM are shared by others. Taylor et al (1979) have questioned the validity of several major conclusions which have been drawn from research on the health belief model namely that health beliefs -

> (a) cause or determine health behaviour, (b) may be useful to clinicians in predicting the subsequent compliance of their patients, and (c) may improve compliance if strategies are directed at changing beliefs.

However, they pointed out that most studies have used cross-sectional designs (i.e. measured health beliefs and compliance at a single point in time), thus no conclusions may be drawn from these about cause and effect. The authors summarised the current dilemma about health beliefs by saying -

> "It is thus unclear whether (1) Health beliefs of an appropriate sort cause people to behave in a compliant fashion, or (2) Compliant behaviour causes people to hold certain health beliefs, or (3) Unknown factors cause high compliance and appropriate health beliefs."

To establish such a relationship, evidence is required in which compliance is measured some time after the measurement of health beliefs. To address the question, Taylor and colleagues (1979) carried out an experiment on hypertensive steelworkers, in which pre-treatment health beliefs were measured, compliance-improving strategies were then applied and subsequent compliance and health beliefs were assessed six months later. They observed that, in general, health beliefs were not predictive of subsequent compliance behaviour, although beliefs measured six months after initiation of therapy related to compliance assessed at that time. They concluded that an initial enquiry into patients' health beliefs was not helpful in identifying problems of non-compliance in their setting.

Motivation

Motivation in relation to compliance has been defined by Becker and Maiman (1975) as the "push" factor towards some health action. Lack of motivation is frequently cited as a major problem in individuals who fail to comply with dietary advice, particularly weight loss

regimens (Glanz 1980, Gifft et al 1972 and Berman 1975). Of great interest to health professionals is what motivates patients to "stay on" or "go off" their diets and how to motivate them to stay on the diet. It is widely accepted that motivations other than "good health" are significant factors in dietary compliance. Berman (1975) provided evidence for this in a study of 487 dieters attending weight loss groups. Subjects gave as their reasons for wanting to lose weight (in order of most frequent choice), personal appearance, health, family opinon, sex appeal, pending event, and the opinion of friends. Health, as a motivator became stronger as age increased while for younger people, sex appeal and the opinions of others was far more important. Self-reported motivations for "going off" the diet were complex. Undeserved gains or losses, and conversely deserved gains and losses caused dieters to "give up". Those who had the most weight to lose were also discouraged by clothes becoming too small and by ridicule or compliments from others about their weight. These positive and negative motivations and self-defeating behaviour practices were not, as the author acknowledges, studied in relation to the success of these women at weight reduction.

The level of motivation to comply with or deviate from the diabetic diet is no doubt important but empirical evidence of this is difficult to obtain due to uncertainties about how to define and measure motivation. Consequently, there has been little formal research attempting to relate patients' level of motivation to dietary compliance (Ohlson 1968). An individual's intention to comply is most commonly used to estimate level of motivation and has been related in a number of studies to drug and appointment-keeping compliance (Becker and Maiman 1975).

Arvidson Lenner (1976) sought to identify the importance of motivation in dietary adherence of women with abnormal glucose tolerance tests. She investigated the relationship between her initial assessment of the subjects' likelihood of adherence (based on subjective assessment of motivation) and their own assessment one year later of how well they had adhered. She expected motivation to be high since the women were informed that clinical diabetes could probably be prevented through dietary control. The basis on which she formed her estimates of motivation was not reported. However, she did state that eight out of 25 overweight women were "unwilling to reduce". Her predictions of compliance were accurate in approximately two-thirds of cases. Although suggestive of motivation as a determinant of compliance in this sample, the conclusions which can be drawn are limited due to lack of description of methods, the criteria used to assess motivation, and the inadequate validation of self-reports of compliance in relation to actual adherence.

Psychological, Emotional and Personality Characteristics

Haynes et al (1979) listed 43 psychological characteristics of patients which have been investigated in relation to compliance behaviour. They can be grouped into the following general categories -

(a) self-esteem, self-image or self-worth, (b) locus of control, (c) psychological states, e.g. anxiety, depression, fear, (d) psychological gain from the "sick role", (e) coping mechanisms, (f) personality "type", (g) adjustment (response) to illness, (h) motivation.

Understanding of the role of these factors in compliance is limited by a lack of repeated investigations on the same psychological

or personality characteristics, differences in the methodologies used and the lack of a unifying theory (such as the HBM) which draws together factors within the psyche of an individual which may influence compliance.

Few psychological or personality characteristics have been systematically investigated in relation to dietary compliance. Most research into the psychological aspects of dieting has concentrated on obese individuals, in an attempt to identify psychological causes and/or effects of over-eating, but little evidence has been revealed which distinguishes personality or emotional characteristics of those who are likely to be successful at weight reduction (Glanz 1979).

Psychological and emotional characteristics and states are likely contributors to eating behaviour and the probability of changing it. Gifft et al (1972) described the following ways in which changes in eating behaviour may be difficult to effect due to the strong emotional meaning and uses of food. Familiarity with food may stimulate feelings of emotional security and, for some individuals, unfamiliar foods or eating patterns may arouse the oppostite-extreme insecurity. Foods also have a strong association with memory of events. To the extent that these memories are pleasant, associated foods or eating behaviours are likely to continue through life. Unpleasant memories associated with certain foods tend to have the opposite, but powerful effect. Food and eating behaviour tend to be used at times by both children and adults as an emotional weapon or a crutch. Eating (or refusing to eat) may be used to rebel against, hurt or arouse anger in another or it may be a coping device used to deal with unpleasant emotions or psychological states such as anxiety, tension or frustration. The authors commented that such emotional

meanings are so deeply embedded that they are often resistant to change. Thus, nutritionists' efforts to motivate change are likely to be more successful when these fundamental meanings are not challenged.

Despite extensive study of the psychological and emotional aspects of diabetes, there has been almost no inquiry into how these relate to self-care behaviour of the diabetic. Results of the limited studies which have investigated personality and psychological characteristics related to dietary compliance or compliance in chronic disease are reported below.

Locus of Control.

Lane and Evans (1979) suggested that personality and emotional factors may influence patient outcomes of diabetic education programmes in that patients who are "independent, and oriented towards self-control and self-mastery could be expected to respond better to teaching programmes which usually advocate controlled, responsible behaviour". Such individual characterisitics have been described by Rotter (1966) in a concept he called "locus of control". Individuals who are internally oriented feel that their behaviour directly influences an outcome, e.g. health, whereas those who are externally controlled tend to feel that "fate" or other factors determine an outcome and that their behaviour has no such influence. Thus, it has been predicted that "internally" controlled people tend to comply more closely with their self-care regimens, believing that such action favourably influences health.

Research findings, however, have been conflicting. Haynes et al (1979) reported five investigations which examined locus of control in relation to a range of compliance behaviours. Two studies reported a

positive association between compliance and "internal" control, whilst one reported a negative association and two others found no association.

The results of this factor in predicting success with weight reduction are not impressive. Rodin et al (1977) found no association in their sample of 267 obese patients, whilst they report that "weak and non-significant differences" were observed in studies by others.

Lowery and Du Cette (1976) examined the effect of locus of control on diabetic knowledge and indices of disease control. Disease control was assessed from patient records by a composite score for each incidence of elevated fasting blood glucose, infection, hyperglycemic or hypoglycemic episodes, weight gain or missed appointments. Thus, measures of compliance were included in the score for disease control, and were not analysed or reported separately. As predicted, "internals" had a greater knowledge of diabetes, however, as the duration of diabetes increased, the difference in knowledge between internals and externals disappeared. Contradictory to expected results, they reported that "internals" experienced more problems with disease control that externals. Alogna (1980) found no significant association between compliance with weight reduction in diabetics and locus of control.

Self-Esteem

Self-esteem refers to an individual's attitude or regard for himself in social, academic, family and personal domains (Hauser et al 1979). Low self-esteem has not been widely investigated in relation to compliance. Haynes et al (1979) reported the results of only three studies, two of which found no association. Rodin et al (1977)

hypothesised that self-esteem (positive or negative self-regard) would be related to weight loss since obesity is so highly stigmatised in western society. However, no association was observed in their study between success at weight reduction and level of self-esteem.

Low self-esteem amongst diabetic patients has been a frequent clinical observation and noted in some empirical investigations. Studies have by and large, focussed on adolescence, a period in the life cycle when the impact of having a chronic illness is likely to negatively influence self-esteem, body image and self-regard. However, Hauser et al (1979) commented that from their research results and those of others who have compared diabetics with non-diabetics, diabetic children are not characterised by lower self-esteem than non-diabetic children.

D. FEATURES OF THE CLINICIAN AND CLINICIAN-PATIENT INTERACTION

Although it is generally agreed that the nature of the interaction between clinicians and patients is an important determinant of compliance, remarkably little is known about the kinds of interactions which enhance compliance or non-compliance, the crucial components of the interactions and how they can be measured (Hulka 1979). Dunbar and Stunkard (1979) summarised the research findings regarding the effect of clinician characteristics on patient compliance with medication regimens. High compliance is fostered by seeing the same clinician at each visit, private vs clinic practice, and a clinician who demonstrates warmth, empathy, interest and genuine concern, and believes in the efficacy of the medication prescribed.

Very few aspects of the patient-clinician interaction have been examined in relation to dietary compliance or to other diabetic regimens. Relevant publications are summarised below.

Communication Between Doctors and Dietitians.

Glanz (1980) suggested that a confounding problem of research in the area of patient-clinician interactions and dietary compliance is the source of dietary advice. Almost invariably, patients receive such advice from both doctor and dietitian and there is some evidence that the professional relationship between them may contribute to patient non-compliance. Several studies which documented a lack of communication between doctors and dietitians, the provision of contradicting diet advice, discrepant evaluations by doctors and dietitians of patients' problems, and a failure of physicians to detect communication problems with patients. Problems between doctors and dietitians are exacerbated by the division of responsibility in dietary care. Physicians generally prescribe diets, whilst dietitians instruct and counsel patients. As a result, Glanz (1980) commented that dietitians perceive themselves as having low status and they question their own effectiveness.

Lack of Professional Knowledge and Conflicting Views about Dietary Management

West (1973) placed the responsibility for the poor dietary compliance of diabetics with physicians and dietitians who, he claimed, underestimate the barriers to successful diet therapy. He attributed the health professionals' failure to provide effective diet therapy to such factors as confusion about dietary goals, failure to relate dietary advice to the type of diabetes, uncertainties about the efficacy of diet, inappropriate or indefinite diet prescriptions and disagreements about importance or nature of diet therapy.

The health professionals' lack of knowledge about diabetes has been documented by Etzwiler (1967) and Stern (1970). These knowledge

tests focussed on aspects of medical and general diabetes management and were administered to nurses and dietitians. Although it is no doubt important, physicians' knowledge of diabetes management and in particular diet therapy has not been assessed. Physicians receive little formal training in nutrition or diet therapy and yet they frequently prescribe and instruct patients on the diabetic diet (West 1973).

The lack of standardisation and apparent conflict between health professionals in dietary advice is likely to affect compliance by creating confusion in the patient and a lack of confidence in the regimen or in the source of dietary advice, (Lane and Evans 1979), particularly in mobile patients who may consult a number of health professionals.

Communications between Patient and Clinician

Hulka et al (1975) studied the relationship between doctor-patient communication and the various outcomes in diabetics. Outcomes included compliance, diabetic control and patient satisfaction with medical care. Communication was operationally defined as "the proportion of information about the regimens communicated to the patient of the total amount the physicians wanted to communicate". The investigators found no significant correlation between the overall communication score and any of the outcome variables, i.e. compliance, diabetic control or patient satisfaction. However, some specific communication items related to behavioural outcomes, e.g. those who were correctly informed about how to test urine and knew the name of their insulin or oral hypoglycemic drug were more likely to test urine correctly and to possess the correct insulin or drug. Doctor-patient communication was better with insulin-dependent diabetics than for

diabetics controlled on oral medication or diet alone. The authors concluded from this and subsequent analyses of their data that patient outcomes cannot be predicted from process variables such as communication, although they acknowledge that they may not have included all relevant process and outcome variables (Romm and Hulka 1979).

Glanz (1979) studied the relationship between dietitians' attitudes and counselling performance on the health beliefs, satisfaction and compliance level of 20 of their patients (on a variety of dietary regimens). She found that the patients counselled by dietitians with high interest in communication had significantly higher health belief scores, but there were no significant differences in patients' compliance levels, satisfaction, or the reliability of dietitians' predictions of compliance. Although the results of this pilot study are interesting, they do not provide evidence for the importance of dietitians' effectiveness on patient compliance. The validity of the results could have been affected by numerous methodological limitations of the study which the author herself acknowledged including: the small sample size, the lack of randomised procedures to assign patients to various therapists, the lack of consistent results from the various questions to assess compliance and the unknown validity and reliability of the procedures used to measure interest in communication. She concluded that a larger study with more refined measurements and improved methodology was needed.

SUMMARY OF DETERMINANTS

From the evidence presented in this review, it is clear that the important determinants of compliance with the diabetic diet remain unidentified. As such, intervention programs attempting to alter compliance must base their strategies primarily on "hunches", rather

than on empirical evidence, that the modification of certain predisposing or co-existing factors will improve compliance.

Currently, a great deal of effort is being invested by a group in the development of tools to diagnose the educational needs of diabetics and to select appropriate strategies suited to the individual (Davis et al 1981). While such an instrument is needed, its development seems premature since we are uncertain about the characteristics of compliers and non-compliers.

Implied in the word "determinants" is a causal relationship, i.e. when modified, such factors also modify dietary compliance. Past research has been primarily cross-sectional and directed at describing the co-existence of certain factors with high or low levels of compliance (e.g. knowledge, attitudes). The modification of these when examined prospectively, has proved to be of little use in predicting compliance. Consequently, future investigations of dietary compliance need to employ experimental designs, to determine the effects of various interventions on carefully selected factors and on compliance.

Promising variables for future research in diabetes (derived from determinants of compliance to other diets and other health care behaviours) include -

(a) characteristics of the regimen (its complexity, efficacy, cost and the extent of change required); (b) the influence of the family and significant others; (c) the patient's motivation to comply or deviate from the diet, stress levels and coping styles; (d) the dynamics of the dietitian-doctor-patient interaction and their influence on patient compliance; (e) and finally, the setting in which diabetic management and education are provided.

Demographic variables (e.g. age and socio-economic status) while they should not constitute the major focus of any study of determinants of compliance, need to be documented for they may be useful in predicting favourable or unfavourable responses to particular types of educational strategies and programmes.

The consistent lack of an observed relationship between dietary compliance and metabolic control of diabetes is disturbing and constitutes a major problem facing compliance researchers and health personnel attempting to improve compliance with dietary advice. The lack of an immediate pay-off to the diabetic for high compliance (in the form of improved control and health) seriously jeopardises continued adherence to diet. It may be that a direct relationship exists but simply cannot be detected by current methods of measurement. However, it is more likely that the relationship is a complex one. The evidence from various clinical trials indicates that dietary factors are important in diabetic control, while that from surveys of free-living, heterogeneous groups of diabetics suggests that intervening factors, e.g. insulin and stress, play a major role in determining metabolic control. Future dietary compliance studies may need to occur in settings where comprehensive care i.e. medical, psychological and dietary treatment can be provided to maximise the likelihood of the diet's effectiveness. At the very least, compliance investigators need to use the best methods available for defining and measuring dietary variables and metabolic control and to report the relationship between the two.

It also appears that determinants of various kinds of dietary behaviours contained within the diabetic regimen may differ. Factors affecting success at weight reduction do not yield results consistent

with factors associated with the avoidance of sugar, or the regularity of meals and snacks. Thus, complete reporting of factors associated with each kind of dietary behaviour is essential to our understanding.

Finally, it must be re-emphasised that the highest priority for future studies of compliance determinants is the use of reliable and comparable measurements of compliance (and of factors) in a variety of settings on larger, more representative samples.

SECTION 2.5

THE EFFECTIVENESS OF DIABETES EDUCATION IN IMPROVING DIETARY COMPLIANCE AND RELATED PROGRAMME OUTCOMES

A substantial increase in the provision of diabetes education services has occurred in the last decade. A survey by the American Hospitals Association showed that the number of hospitals in the U.S. providing diabetes education services increased from 15% in 1972 to 46.4% in 1975 (Redman 1977).

In 1975, the National Commission on Diabetes convened a working party on Diabetes Education to review the problems of existing programmes and to formulate a plan for future development of these services. One of the recommendations was to "evaluate the effects of education on diabetic patient behaviour and self-management."

Rational future development of diabetic education strategies to improve compliance to self-care regimens depends on our ability to learn from past successes and failures rather than to devise or discard educational programmes purely on the basis of fashion. Much has been written recently about the development of education programmes and strategies, yet their effects have been infrequently evaluated. To date, the results of published evaluations has not been summarised or comprehensively reviewed, although Williams (1979) compiled abstracts and commentaries of recent innovations in diabetes education and Watts (1980) and Graber et al (1977) have discussed some implications of the results of selected evaluations. Consequently, there is a need to summarise the results of evaluations of diabetic education particularly in relation to dietary compliance and to identify unanswered questions concerning the techniques currently in use.

This section reviews reports published over the past two decades which describe an evaluation of a health education strategy or programme designed for people with diabetes. Unevaluated educational strategies, descriptive or theoretical articles were excluded from this review. Reports of medical interventions which did not contain a major education component were also excluded.

Of primary interest were strategies which aimed to alter compliance to the diabetic diet. However, studies which tested the effects of education on other outcomes (e.g. knowledge, attitudes and health) are included in the table because of their importance, relevance and possible associations with dietary behaviour.

Original articles of evaluated educational interventions for diabetics published between 1950 and 1981 are summarised in Table 2.5. Thirty-seven reports were located.

Studies were grouped according to type of education programme or strategy. The classification procedures used are described in the next Section. Information presented in Table 2.5 about each study includes

(a) the number of subjects for which there was pre- and post-test data (including the control group if one was used), (b) the number of sessions or patient contacts involved in the assessment and educational process (often extrapolated from vague descriptions), (c) the stated length of time after the education programme to follow-up assessment, (d) the drop-out rate from the education programme (if given) or the percentage of study subjects with initial but incomplete or no follow-up data.

Finally, the observed changes in the study group are presented in terms of positive or negative change. Surprisingly, change in a negative direction was not reported in any of the investigations of the outcomes reviewed! The statistical significance, if determined, of the changes was noted. Dashes in the table indicate that the study did not evaluate a particular outcome. The quality of evidence presented here varies considerably, as reflected by the methods scores for all aspects of the research methodology (Table 2.2).

CLASSIFICATION OF EDUCATIONAL STRATEGIES AND PROGRAMMES USED IN DIABETES EDUCATION

Compliance-improving strategies have been broadly grouped into educational, behavioural or a combination of these two (Haynes 1976). Educational methods are usually distinguished from behavioural ones by their emphasis on the transfer of information for purposes of improving patient knowledge, attitudes or behaviour. They include such techniques as programmed learning, classes/lectures or audio-visual programmes. Behavioural methods such as self-monitoring, contracting and tailoring the regimen, tend to focus more directly on the target behaviour than on attitudes or knowledge change (Dunbar et al 1979). Green (1979) has discouraged the distinction between behavioural and educational strategies because they both rely on techniques regarded as educational.

Glanz (1980) devised a scheme for classifying strategies used in dietetic practice into five major groupings: instructional, motivational, behavioural, educational diagnosis and assessments. Although the desirability of using a similar classification scheme in this review is appreciated, it was not warranted, or possible, due to the insufficient reporting of essential features of intervention proce-

dures in the majority of reports. Hence the following rough groupings were devised for strategies used in diabetes education literature, (not all of which are intended to be compliance improving) -

> (a) individual diet counselling, (b) programmed learning and other audio-visual programmes, (c) lectures, demonstrations and classes, (d) education in conjunction with diabetic stabilisation (medical intervention), (e) multi-faceted (e.g. small group, feedback, frequent follow-up), (f) unspecified strategies, when no description of the intervention was included.

EFFECTS OF DIABETES EDUCATION STRATEGIES

Dietary Compliance

Only five studies were found which evaluated the effects of a strategy or programme on improving compliance with aspects of the diabetic diet regimen other than weight reduction. Four of these report positive effects although the lack of control groups makes it impossible to conclude with certainty that the observed improvements were a direct result of the programme or strategy.

In a group of 160 diabetics, Stone (1961) reported that only 21% initially had good "control" but this increased to 52% after counselling. The contribution of diet to the improved percentage with "good control" or management was not reported although the author states that poor control was largely due to dietary non-adherence.

Arvidsson Lenner (1976) found that only 15% of a group of 53 women with positive glucose tolerance tests had adequate dietary habits prior to counselling, whereas one year after dietary counselling, 57% were adhering to the recommendations (judged by self-

TABLE 2.5

EFFECTS OF DIABETES EDUCATION ON COMPLIANCE AND OTHER PATIENT OUTCOMES

EDUCATIONAL STRATEGY	YEAR	n[1]	NO. OF[2] SESSIONS	FOLLOW-UP PERIOD	DROP[2] OUT	COMPLIANCE DIET	COMPLIANCE WEIGHT	COMPLIANCE OTHER	DIABETIC CONTROL	HOSPITAL ADMISSIONS	KNOWLEDGE	ATTITUDES/ SATISFACTION
INDIVIDUAL COUNSELLING +												
CLINIC SERVICES												
Arvidsson Lenner	1976	53	(varied) 1-31	1 year	7%	*+	*+	--	--	--	--	(5) nr
Chambers & Beaven	1977	82	4+ (varied)	3 years	52%	--	*+	--	--	--	--	--
Chandalia & Bagrodia	1976	43	1	1 month	nr	--	--	--	*+	--	*+	--
Goodner & Ogilvie	1974	174	GT 5	5 years	53%	--	0	--	0	--	--	--
Hadden et al	1975	57	6	6 months	43%	+	+	--	+	--	--	--
Stone	1961	160	4+	2 years	10%	+	--	+	+	--	nr	(4,5)
Streja et al	1981	66	1 hr+2 follow-up	2 months & 31 mths	20%	--	+* short term 0 long term	+*	--	--	--	
PROGRAMMED INSTRUCTION												
Brock	1978	8	(varied)	3 days	0	--	--	--	--	--	*+	--
Etzwiler & Robb	1972	66	nr	3 months	27%	--	--	--	0	--	*+	--
McDonald & Kaufman	1963	106	nr	nr	42%	--	--	--	--	--	+	+
Meadows	1965	131	1-6	nr	nr	--	--	--	--	--	--	+
Tani & Hankin	1971	26	2	nr	nr	--	--	--	--	--	+	+
Young et al	1969	78 (exp.) 103 (cont.)	(varied GT 2)	1 month	68% exp 28% cont.	--	--	--	--	--	*+	inconclusive

TABLE 2.5 (continued)

EDUCATIONAL STRATEGY	YEAR	n[1]	NO. OF[2] SESSIONS	FOLLOW-UP PERIOD	DROP[2] OUT	COMPLIANCE DIET	COMPLIANCE WEIGHT	COMPLIANCE OTHER	DIABETIC CONTROL	HOSPITAL ADMISSIONS	KNOWLEDGE	ATTITUDES/ SATISFACTION
AUDIOVISUAL (PRIMARILY)												
Hassell & Medved	1975	19 (exp.) 22 (cont.)	1	nr	10%	--	--	--	--	--	*+	(4)
Origer	1974	9	nr	1-6 mths	10%	--	+	--	+	--	--	--
CLASSES/LECTURES DEMONSTRATION												
Ainslie	1981	461 juveniles	1 week	6.2 yrs (6 mths-22 years)	8%	--	--	--	*(growth) 0 (24 hour) urine glucose	-- --	-- *+	-- 0(5)
Bloom Cerkoney & Hart	1980	30	nr	6-12 mths	nr	△ nr	--	△ nr	--	--	--	△ nr
Bowen et al	1961	28 (exp.) 23 (cont.)	5	6 months	26%	+	0		0			
Reynolds	1978	71	2	18 months	33%	--	--	--	*+	--	--	+
Salzer	1975	30	3	1 year	64%	--	--	+	--	--	+	--
Schnatz et al	1976	36	(varied)	3 months	54%	--	--	--	--	Inconcl.	+ then loss after 3 mths	--
Tagliacozzo et al	1974	64 (exp.) 61 (cont.)	4	nr	54% (exp.) 56% (cont.)	--	0 (compliance[c] referrals, lab tests, medications)	0	--	--	0	0[5]
Whitehouse et al	1979	178	nr	6-8 weeks	51%	--	--	--	--	Inconcl.	nr	--[5]

TABLE 2.5 (continued)

EDUCATIONAL STRATEGY	YEAR	n[1]	NO. OF[2] SESSIONS	FOLLOW-UP PERIOD	DROP OUT[2]	COMPLIANCE			DIABETIC CONTROL	HOSPITAL ADMISSIONS	KNOWLEDGE	ATTITUDES/ SATISFACTION
						DIET	WEIGHT	OTHER				
EDUCATION & MEDICAL INTERVENTION (DAY-CARE/STABILISATION)												
Davidson et al	1976	1500	1 day	12 months	nr	--	+	+ (Appt. keeping)	+	+	--	+
Flint	1980	92	nr	12 months	nr	--	--	--	--	+	--	--
Howe-Davies et al	1980	71	(varied)	6 months	20%	--	0	--	+	--	--	--
Miller	1972	2680 hosp. adms.	nr	2 years	nr	--	--	--	--	+	--	--
Moffitt	1979	(Bed days)	1 week	2 years	nr	--	--	--	--	+	--	--
Noviks et al	1976	100	1 week	2-5 weeks	nr	--	--	--	*+	--	--	--
Runyan	1975	797 (exp.) 410 (cont.)	nr	2 years	nr	--	--	--	*+	+	--	--
Spaulding & Spaulding	1976	24	1 week	2-5 weeks	nr	--	--	--	0	--	--	--
MULTI-FACETED e.g. small group, feedback, tailoring, group therapy												
Goodman et al	1953	33	35-52 wks	9-18 mths	nr	--	+	--	--	--	--	--
Webb et al	1982	140	8	6-12 mths	23%	*+	0	--	0	--	*+	*+(5)
Weinsier et al	1974	19	15	40 weeks	4%	+	0	--	0	--	--	+

TABLE 2.5 (continued)

EDUCATIONAL STRATEGY	YEAR	n[1]	NO. OF[2] SESSIONS	FOLLOW-UP PERIOD	DROP[2] OUT	COMPLIANCE DIET	COMPLIANCE WEIGHT	COMPLIANCE OTHER	DIABETIC CONTROL	HOSPITAL ADMISSIONS	KNOWLEDGE	ATTITUDES/ SATISFACTION
UNSPECIFIED EDUCATIONAL INTERVENTION												
Brouhard et al	1978	59	nr	5 years	nr	--	--	--	--	+	--	--
MacMurray & McArthur	1978	54	nr	3 months-3.5 years	45%	--	--	--	--	--	--	+

Key:

(1) n refers to the numbers of subjects for whom there were complete data, i.e. before and after
(2) includes follow-up sessions for re-assessment
(3) drop-out rates include the percentage of eligible study stubjects excluded due to incomplete data, the attrition of study subjects and programme drop-outs
(4) not systematically investigated
(5) attitudes other than patient satisfaction
nr not reported
\+ improvement reported
* statistically significant. N.B. improvements not marked with a * indicate no statistical analysis was done
0 no effect or change (compared with a control group if one was used)
Δ nr change not reported
— not evaluated

report 24-hour recall, food history, food record and weight). Statistically and clinically significant decreases in the consumption of sucrose, potatoes and high fat foods were noted for 33 women who reported they had followed or tried to follow the diet, while no such decrease was found in the seven who reported not following the diet. No improvement was seen in the frequency of meals or snacks and the recommended frequency was not reported. Diet counselling was regarded as successful in those who were motivated and reported "trying to" or following the diet closely. It is likely that this group were, in general, more highly motivated to adhere to the recommendations since they were informed of the possible decreased risk of developing diabetes if dietary advice was followed. Thus the effects of this variety of diet counselling cannot be generalised to the diabetic population.

Weinsier et al (1974) reported mean nutrient intakes (calculated from three-day food records) of a group of 19 diabetics to be within 5% of the recommended diets during and after participation in a 40-week, multi-faceted education programme. They attributed their success to a number of factors: e.g. frequent follow-ups (10 visits), small-group process, feedback of results and family involvement. It would have been interesting to compare these results with baseline nutrient intakes and with a control group who received equal attention and contact with health professionals. The generalisability of these results to other diabetes education settings is also limited by the "therapeutic trial" nature of this study. In this setting, high compliance was expected only for the duration of the trial, whereas in most instances, compliance is required for a life-time.

Thirteen studies were located which evaluated the impact of an education strategy or programme for diabetics on compliance with

weight recommendations, only two of which were controlled studies. Neither of these showed any programme effect on weight when compared with weight changes in a control group (Tagliacozzo et al 1974, Bowen et al 1961). Seven of the remainder reported positive effects and four, no effect. One of the seven (Weinsier et al 1974) defined compliance as weight maintenance, since study subjects were all near to ideal weight. However, compliance to weight reduction recommendations has been repeatedly demonstrated to be a most difficult programme goal to achieve so the methods used in studies with positive results were examined in detail.

Individual counselling was reported to be successful in improving weight compliance in four of the five investigations. Ardvisson Lenner (1976) found that 17 of 25 overwieght women with abnormal GTT's reduced weight after participation in dietary counselling. Ten of these women who sought extra counselling (three to thirty-one visits) reduced weight by a mean of 7.1 kg - a clinically and statistically significant decrease. Data on the magnitude of weight loss of the other seven women or the mean loss over the entire group of 25 overweight women, were not reported. The short-term success of this intervention may have been due to client motivation to prevent the onset of diabetes (as judged by their willingness to seek extra help) and/or the reinforcement from the frequency of contact with a health professional. From this study, no conclusions can be drawn about whether the success of this approach was attributable to the counselling process or about its success in the long-term.

Goodman et al (1953) obtained successful results in a group of 33 established diabetics who participated in a version of "group therapy" weekly over nine to twelve months. Thirty patients lost an

average of 14.2 pounds, and anecdotally, maintained the loss over one and a half years. The initial degree of adiposity of this group was not reported so it is difficult to judge whether this was a substantial clinical improvement. Origer (1974) reported in a pilot evaluation of nine patients who participated in his education programme (audio-visual) that seven had lost an average of 6.5 pounds, one to six months afterwards. Further reports of a full evaluation could not be located.

Impressive weight changes were reported by Davidson et al (1976) in diabetics who attended a comprehensive day-care and one-day education programme. He reported that 80% of overweight diabetics reduced weight by at least 20 pounds. Unfortunately, details of the number studied, methods of the evaluation or a description of the particular intervention(s) used with overweight clients could not be located in this or other publications (Graber et al 1977, Isaf and Alogna 1977).

A major reduction in the percentage of ideal weight was noted by Chambers and Beaven (1977) in a group of women who were new patients attending a re-organised diabetic clinic, when compared with a matched group of "old" patients. However, the new patients were substantially more overweight initially (144% vs 121% of ideal weight) and they had a higher drop-out rate (45% vs 33%). Although the improvement in weight noted only after three years (but not after one or two years), could have been a result of the programme, it may also have been due to the higher drop-out rate in the new patients. No significant weight reduction was observed for men.

The long-term maintenance of weight loss is notoriously difficult to achieve (Wilson 1979). Yet, few of the evaluations reviewed here assessed weight changes over periods longer than six months after

intervention. One report of short- and long-term follow-up (2 years) by Streja et al (1981) showed significant weight loss at one 2-month follow-up, but weight was re-gained (approaching baseline weights) at the 2-year follow-up.

The results of diabetes education methods to improve dietary and weight compliance are conflicting. Strategies which use frequent patient contact have yielded the best results, but no conclusions can be drawn confidently due to lack of control groups. Watts (1980) noted that although promising results have been frequently reported using behavioural strategies to treat obesity, such strategies have yet to be applied and evaluated in treating obese diabetics. The limited available evidence suggests that compliance to other aspects of the diabetic diet regimen can be improved by educational and/or behavioural interventions. The majority of reports reviewed here can only be considered descriptive evaluations i.e documentation of the changes which occurred after an intervention. Clearly, much more extensive study, using more rigorous methodology and careful reporting, is required to confirm their beneficial effects.

B. Knowledge

Approximately 50% of the studies assessed the impact of education and knowledge, the majority of which report improvements after exposure to education (Table 2.5). When these knowledge gains were compared with those of control groups, four found statistically significant advantages for the experimental groups (Young et al 1969, Brock 1978, Hassell & Medved 1975, Bowen et al 1961) whilst two found improvements for both groups but no differences in mean scores at follow-up between the two groups (Tani and Hankin 1971, Tagliacozzo et al 1974). Since knowledge was not assessed in most studies which utilised multi-

faceted, behavioural or stabilisation procedures, no comparison can be made in knowledge improvements between educational methods.

C. Diabetic Control

Approximately one-third of these studies assessed the impact of education or other strategies on the diabetic control of participants as measured by blood glucose levels or frequency of hypoglycaemia and the results were conflicting. The data presented suggested change in a positive direction for seven of the studies, no change for three, and two did not present results, although they claimed a positive effect. Only three of these studies compared changes in diabetic control between experimental and control groups, two of which demonstrated improvements but no statistical advantage of education and/or stabilization (Bowen et al 1961, Spaulding and Spaulding 1974, Runyan 1975).

Programmes which combine medical and educational strategies might be expected to have a greater impact on biochemical measures and health than those without a medical component. Unfortunately, several such programmes have not reported their effects on the metabolic control of participants, and hence benefits can only be inferred from the reported decrease in hospitalization due to diabetes (Miller 1972, Moffitt et al 1979, Flint 1980, Davidson et al 1976).

Some evidence that stabilisation strategies may be more effective than educational ones comes from the observed improvements in diabetes control in several studies (Runyan 1975, Noviks et al 1976, Howe-Davies et al 1980 and anecdotally from Davidson et al 1976). However, it is unclear whether most of these observed improvements were due to the educational and medical intervention or whether they would have occurred whatever the intervention.

In general, the variation in results obtained in these investigations are most likely due to differing study designs, study samples, diabetes control status before the education programme, type of diabetes, and the methods of measurement and classifications used. Thus, the results cannot be ascribed to the type of educational strategy.

D. Hospital Admissions

Of the eight education programmes which investigated their effects on hospital admissions, six reported positive results whilst two were inconclusive. In several cases, the education programme was an adjunct to a stabilisation programme. The experimental manoeuvres included both a policy change to stabilise diabetics out of hospitals and an educational intervention. Thus, the observed effects could have been primarily due to the policy change rather than to the medical or the educational interventions although it is impossible to say.

E. Attitudes/Beliefs

Frequently documented programme aims in diabetes education are to improve the diabetic's adjustment to and acceptance of the disorder, to foster attitudes and beliefs which will promote better self-care and to improve the quality of his or her life. However, very little research has been done on the effects of a strategy or programme to alter such attitudes, beliefs and perceptions. Only two of the studies in this review examined the change in attitudes or beliefs of diabetics after participation in a programme. Bowen et al (1961) studied the diabetic's acceptance of diabetes from responses to an interview before and after classes about diabetes. They found no effect when attitude changes were compared to a control group, although some improvement was noted in both groups. Similar findings

were obtained by Tagliacozzo et al (1974) who found that attendance at classes produced no change in self perceptions of the seriousness of their condition, the scepticism towards medical treatment, or self-evaluation of compliance when these were compared with attitudes of a control group.

Although the studies by Bloom Cerkoney and Hart (1980) and by Alogna (1980) reported on health beliefs of patients after they attended classes or counselling, no comparative measures were obtained beforehand.

F. Patient Satisfaction

Patient satisfaction with the education programme or strategy was evaluated in ten studies, all of which report high levels of satisfaction. Thus, patients are highly satisfied with any method of education they receive, the extra attention, or alternatively they consistently supply complimentary responses when asked if they liked the programme.

Inadequate Descriptions of Education Interventions

Detailed descriptions of the "precise experimental manoeuvre" are required for adequate implementation, interpretation and replication of trial of compliance-improving strategies (Sackett 1979). Such a detailed description should specify "who will do what to which patients, for what reasons, where, how often, with what expenditure of time and effort, with what feed-back to whom."

The lack of detail in the descriptions of educational interventions used in the majority of studies reviewed in Table 2.5 would not enable readers either to reproduce them or, in some cases to even

determine what strategy was actually being evaluated. For example, many of the combined medical and educational interventions described their stabilisation procedures but failed to describe essential components of their educational strategies (Moffitt et al 1979, Miller 1972, Flint 1980). Similarly, those who evaluated the effects of an individual counselling strategy frequently did not describe how the counselling process differed from conventional approaches (Stone 1961, Arvidsson Lenner 1976, Chambers and Beaven 1977). Strategies used in classes, lectures and demonstrations appeared to vary considerably between studies (e.g. small group process vs conventional classroom approaches, or a combination of these) but it was often impossible to tell which process predominated.

Many of the reports tended to describe the audio-visual or written materials used but neglected to furnish such details about the number of patient contacts, who carried out the education, in what setting and what was actually done at each contact by health professionals and patients.

Understandably, the space available in many journals limits the descriptions of educational interventions to short mechanistic summaries. However, crucial elements in the intervention process should be included in future reports supplemented by full descriptions in appendices or published elsewhere.

The Limited Spectrum of Outcomes Evaluated

Lane and Evans (1979) provided an extensive list of possible outcomes or indicators of programme impact which can and should be measured to determine the effects of diabetes education. They include physiology, behaviour, knowledge, adaptation and use of health ser-

vices. Although most educational programmes and strategies discussed in the studies in this review appeared to aim for far more than knowledge gains in their patients, knowledge was the most commonly (and sometimes the only) evaluated outcome probably because it was the easiest to measure. Patient satisfaction was measured in about one half of the studies while the health and diabetic control of patients was measured in less than one third. With the exception of two studies, Tagliacozzo et al (1974) and Bowen et al (1961) no attempts were reported to assess effects of a programme on health beliefs, quality of life or adaptation to disease.

Although metabolic control of diabetes or other health status indicators should not be viewed as the only outcomes of interest in diabetes education, they underly the intermediate aims of improved knowledge, attitudes and compliance with self-care regimens. Thus, they should be included in every evaluation of diabetes education.

The lack of evidence about educational impact on a wide spectrum of patient outcomes is one of the greatest deficiencies in the published literature to date.

Summary

In summary, very little can be concluded from the results reviewed here regarding the effectiveness of the educational methods in current use for diabetics. The interpretation and comparability of results is considerably limited by the lack of rigorous evaluation methods, the inadequate reporting of the educational process and the insufficient measures of programme outcome. Currently, the expenditure of resources on the education of diabetic patients is considerable, yet from the existing evaluation studies, it is uncertain

which of them, if any, are effective in improving dietary or other self-management behaviour, health and quality of life.

CHAPTER 3

METHODS

SECTION

3.1 DESCRIPTION OF THE EDUCATION PROGRAMME

The Diabetes Education and Assessment Programme (D.E.A.P.) was established at the Royal North Shore Hospital of Sydney in 1974. The major continuing activity of the centre is an education programme for adult insulin-dependent diabetics and their families. The goal of the education programme is to promote the physical and psychological well-being of programme attenders. The specific objectives are to help diabetics to:-

(a) comply with their recommended self-care regimens, including diet, insulin injection methods, appropriate treatment of hypoglycaemic reactions, self-monitoring of diabetic control, foot care and appropriate use of professional resources; and

(b) develop or expand their skills and those of family members for coping with the restrictions of the regimens without sacrificing enjoyment or quality of life.

The education team comprises a diabetes physician, clinical psychologist, nutritionist, and nurse educator, with secretarial and clerical support. The programme is held in a relaxed, informal setting in a renovated cottage within the hospital grounds.

Diabetics are encouraged to bring with them a family member or close friend for support and mutual learning. Henceforth in this thesis, they are referred to as "family members".

The education programme consists of six sessions held on four evenings and two full days over a period of five weeks. A general programme timetable showing the topics covered at each session is given in Appendix 3.1. The development of the philosophy, structure

and content of the education programme have been documented in detail by Tupling (1981). The educational process is non-didactic and is based on group learning and problem-solving. Information about diabetes and diet are presented within the context of problem-solving so that didactic teaching, unrelated to the needs of the group, is minimised. A variety of educational group exercises have been devised for use at each session and some examples of these are given in Appendix 3.2 (ibid.).

The assessments are used a focus for the educational process. At initial sessions, diabetics and their accompanying family members are assessed on their knowledge, diet, weight, biochemical status, etc. The results are returned to programme participants at subsequent sessions as the basic data upon which recommendations for change are built. For example, biochemistry results and a computerised analysis of each individuals' food record are provided together with recommendations for change.

Participants are encouraged to discuss their reactions to the results of their assessments, their perceptions of susceptibility to health risks and difficulties with implementing the recommendations for change in their home, work or social environments. Following such discussion, simulated problems and exercises relevant to the needs of each group are used as opportunities for generating new solutions and for practice in implementing the recommendations.

In the final sessions, diabetics and their family members are assisted to formulate contracts for achievable, measureable goals. These form the basis for a follow-up education session held soon after the last session of the programme.

Throughout the assessments and the programme, the participation of family members is encouraged as a means of ongoing support to the diabetic and to stimulate relevant dietary behaviour changes in the entire family.

The terms of reference of the programme's establishment limited the intervention to education and dietary manipulation. The D.E.A.P. team has no authority to manipulate insulin dosage or to intervene clinically with programme attenders.

3.2 DESCRIPTION OF DIETARY REGIMEN

The education programme team recommends that diabetics and their family members achieve and maintain ideal body weight from a balanced diet in which energy from fat, sugar and alcohol are limited to 30%, 5% and 5% respectively and complex carbohydrate (all carbohydrate except sucrose, glucose and honey) constitutes at least 45% of energy. Diabetics are also encouraged to space their complex carbohydrate evenly throughout three meals periods during the day (three major meals plus three between-meal snacks) and to vary it minimally from day to day.

In view of the lack of certainty about an optimal diet for diabetics, these dietary goals were thought to be the "best bet" in assisting insulin-dependent diabetics to achieve and/or maintain good control of blood glucose and serum lipids. At the time these evaluation studies commenced, the dietary recommendations were consistent with the dietary policy of American Diabetes and Dietetic Associations (Bierman et al 1971).

Individual dietary recommendations are given to programme participants in the form of a computer print-out "Dietade", based on an

analysis of his or her four-day food record (Tupling and Webb, 1979). An example of the computer print-out is shown in Appendix 3.3. Procedures used for keeping food records and the processing of these data are described in Section 3.7 of this chapter.

The Dietade programme produces for each participant a three page print-out containing five sections:

1. a weight assessment (actual weight, ideal weight, percentage of ideal weight and weight recommendation);

2. a summary of the daily intake and four-day average of energy, protein, fat, complex carbohydrate, sugar and alcohol, and the recommended intake for a "balanced" diet;

3. the composition of the four-day intake, that is, the percentage contribution of each of the energy-containing nutrients to the total energy intake, compared with the recommended composition;

4. a listing a vitamins and minerals found to be less than two thirds of the Recommended Dietary Allowances for Australians (1975) average over the four days) or a message to indicate that intakes of selected vitamin and minerals appeared to meet standards on those four days; and

5. the complex carbohydrate intake at each meal and snack over the four days and the recommended intake in grams and in carbohydrate "portions" (the amount of food containing 15 grams of carbohydrate). This section appears only for diabetics.

Each section includes an assessment of current intake, a listing of health risks associated with each dietary problem for diabetics and non-diabetics, and recommendations for change, if necessary.

Within the Dietade programme, the dietary recommendations are calculated as follows:

1. Energy: if the client is overweight (more than 110% of ideal weight) the recommendation is a 25% reduction of current energy intake (after energy from alcohol has been deducted). Clients who are at their ideal weight are recommended to continue with current energy intake.

2. Energy-containing nutrients: (protein, fat, complex carbohydrate, sugar and alcohol): The recommendations are calculated as percentages of the recommended energy level, i.e., 15%, 30%, 45%, 5%, 5% respectively. They are then converted to grams by dividing by the relevant number of calories per gram, i.e., 4, for protein, complex carbohydrate and sugar, 9 for fat and 7 for alcohol.

3. Carbohydrate Spacing: The recommended spacing is derived by allocating 25% of the total daily recommended complex carbohydrate to each of the three major meals and 8% to each of the three between-meal snacks, achieving an even distribution over three major meal periods. The carbohydrate "portion" recommendation is also calculated by dividing the recommended grams by 15 (there are 15 grams of carbohydrate in a carbohydrate portion). A small amount of flexibility ($\pm$ two portions) is suggested in this pattern to allow for variation in insulin action and personal preference in eating patterns.

4. Carbohydrate Variation: The recommended daily variation for all diabetics is 0 except for intentional variation for strenuous exercises or hypoglycaemic reactions.

Specific diet sheets or food plans are not given to clients. However, food composition tables and a carbohydrate "portion" counting manual (Appendix 3.4) are supplied with the computer dietary assessment. The manual is based on the "carbohydrate exchange" system (described in Chapter 2) in which any of the foods in the quantities listed in the "amber pages" may be exchanged to obtain the recommended number of carbohydrate portions at each meal and snack. Although "fat" exchanges are not counted, the use of high-fat foods is discouraged within the manual, the computer print-out and the education programme. Food composition tables assist participants to increase their awareness of the nutritional composition of foods, with a focus on the fat content.

In educational sessions, participants are encouraged to acquire sufficient knowledge of food composition and skill in selecting food to suit personal preference and to achieve the recommended dietary goals. Practice in measuring and estimating carbohydrate "portions" in individual foods and mixed meals is provided at meals served at the Centre during the education sessions, and as homework. The preparation of high-carbohydrate, low-fat meals is encouraged by providing recipes and an opportunity to prepare them at a cooking session on one day of the programme.

3.3 OBJECTIVES AND RESEARCH QUESTIONS

OBJECTIVE 1

To determine the success of the Diabetes Education and Assessment Programme for insulin-dependent diabetics in improving:

(a) compliance with the dietary regimen

(b) knowledge of the rationale for and procedures of diabetes self-management

(c) selected biochemical indicators of metabolic control of diabetes and blood lipids

(d) health beliefs

(e) quality of diabetic life (randomised controlled trial only).

Related Study Questions

1. For adult insulin-dependent diabetics who attend an education programme, what is the direction and magnitude of change in these variables:

(a) six months after an education programme compared with measurements made immediately prior to education? (Pre/Post Study).

(b) three months after the education programme as compared with a three month control period prior to education? (Randomised Controlled Trial).

2. What is the effect of the assessments themselves on modifying dietary compliance and other outcomes (as reflected by the comparison between measures of compliance and other outcomes) made three months apart with no intervening education?

OBJECTIVE 2

To identify patterns of dietary compliance in individuals.

Related Study Questions

Do individuals who comply with one type of dietary recommendation comply with other dietary recommendations?

OBJECTIVE 3

To identify predictors of compliance with the recommended dietary regimen.

Related Study Questions

Can compliance with dietary recommendations after an education programme be predicted from initial measurements of diet, diabetic history, biochemistry, demographic or psycho-social characterics?

OBJECTIVE 4

To identify the relationship between compliance with the dietary recommendations and the achievement of acceptable levels of blood glucose and serum lipids.

Related Study Questions

Are individuals who comply with the dietary recommendations more likely to achieve acceptable metabolic control of diabetes and blood lipids than non-compilers?

OBJECTIVE 5

To determine the validity of a four-day food record in accurately reflecting compliance with a diabetic diet regimen.

Related Study Questions

What is the correlation between protein intake as calculated from a four-day dietary record and as predicted from a 24-hour urinary urea excretion (during the record keeping period)?

3.4 STUDY DESIGNS

Two studies were conducted over four years to answer the research questions outlined in Section 3.3. The first of these (1978 to 1980) was a simple pre-post study with no control group and the second (1980 to 1981) was a randomised controlled trial. These designs, their rationale and the general strategies used are described below:

A. Pre-Post Study

The pre/post study was carried out to describe the changes which occurred in dietary compliance and other programme outcomes over a six-month period following the education programme. The aims were also to identify which, if any, of the variables measured at the base-line assessment were predictive of dietary compliance and whether dietary compliance was associated with achievement of acceptable metabolic control of diabetes.

We were aware initially, of two fundamental limitations in this simple "quasi-experimental" design. First, without a control group (diabetics who did not participate in the experimental education programme) any observed changes in compliance between pre-and post-assessments would not be directly attributable to the education programme. Secondly, the study period of six months would be insufficient to identify the long-term effects of the programme. However, the study design and follow-up period were necessary compromises made because of practical contraints.

In a pilot study carried out by the D.E.A.P. team during 1976 to 1977, the feasibility of obtaining a comparable control group was explored but found to be impossible for several reasons (D.E.A.P. Report to the Northern Metropolitan Region of the Health Commission of N.S.W. 1978). The self-selection of diabetics who volunteered for the study and the exceedingly low response rates (52% to six-month follow-up assessment procedures suggested that a useful control group was unobtainable at this stage. Also considered was the randomisation of programme enrolments into an experimental education group and a minimal education group. However, the D.E.A.P. team were unwilling to provide the minimal intervention because of the low referral rate from medical practitioners early in the programme's history and the pressure from referral sources to provide the full education programme to all patients.

A follow-up period of at least a year was considered desirable for this study. However, due to the low accrual rate of patients during the early years of the programme's establishment, the study would have had to extend over at least three years to acquire sufficient numbers of subjects, (that is 100-150). Unfortunately, the funds available for programme evaluation limited the study period to two years.

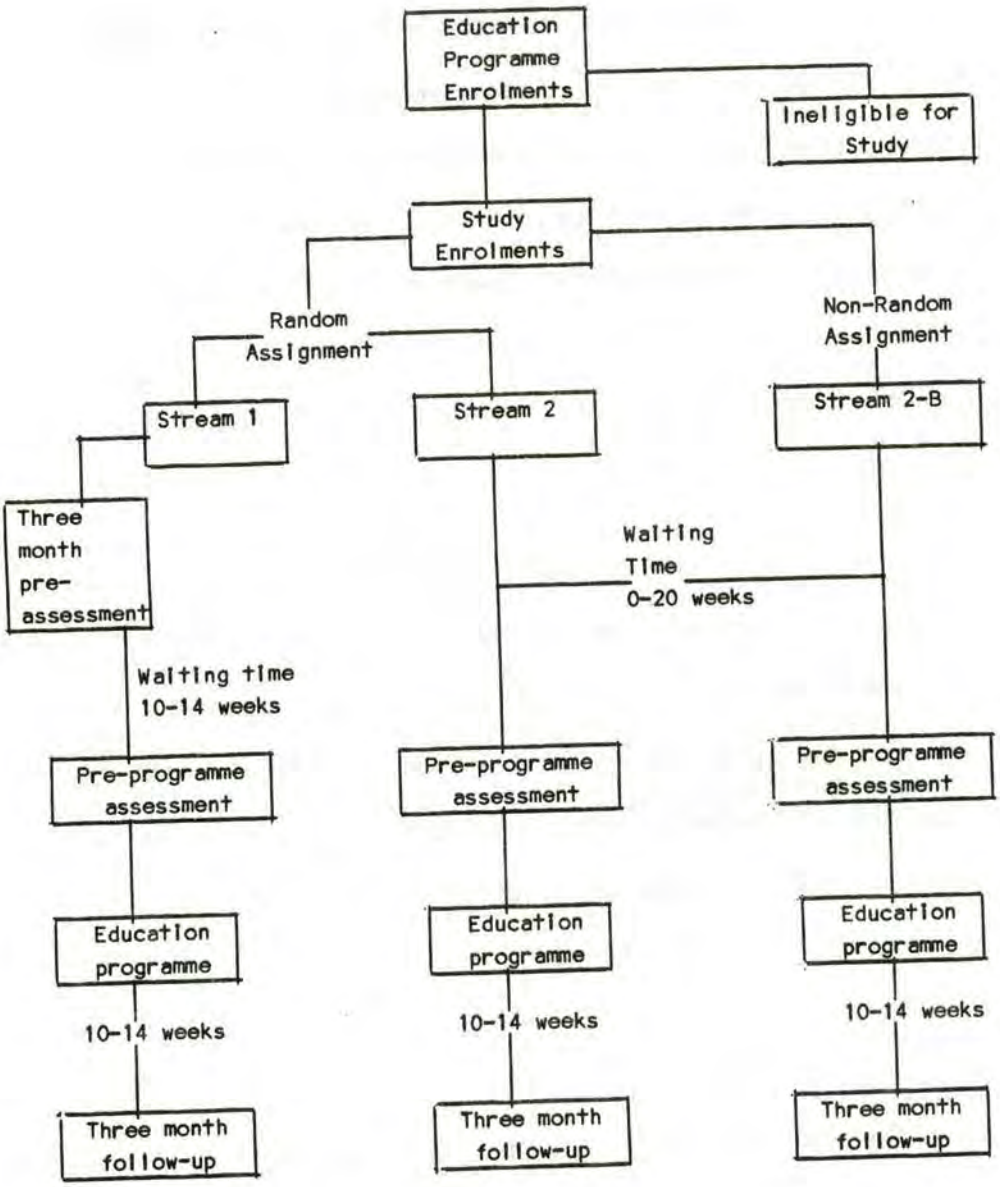
B. Randomised Controlled Trial

This study was initated in April 1980 when further funds and a waiting list of patients made possible a more rigorous evaluation. The design of the randomised controlled trial is shown in Figure 3.1. Essentially, all individuals who enrolled in the education programme from July 1980 to July 1981 and met the eligibility criteria for inclusion in the study were randomly assigned to one of two streams:

FIGURE 3.1

DESIGN OF A RANDOMISED CONTROLLED TRIAL
TO EVALUATE A DIABETES EDUCATION PROGRAMME

1980 - 1981



those who received the education programme as soon as space was available (Stream 2) and those who underwent a three month "waiting" period (Stream 1), that is, they were assessed before and after the waiting period during which the D.E.A.P. offered no education. Due to the extensive waiting list at the commencement of the study, Stream 2 subjects often waited as long as Stream 1 for the education programme. A third group, Stream 2-B underwent all study procedures although were not randomly assigned because of the timing of their bookings into the education programme. Reasons for their inclusion in the study were to prevent wastage of useful data on study subjects and to identify differences between this group and the others (if sufficient numbers were acquired).

To determine the effects of time on dietary compliance, two post-education assessements, one at three months and one six months after education, were planned for Stream 2 subjects. As with the pre/post study, the time period over which patients were followed after education was shorter than desirable but it was the longest practical period in which to acquire sufficient numbers of subjects in each group and complete the study in the remaining 1½ years of available funding. However, due to the poor response rate (53%) to six month follow-up assessments after attempting to obtain data on five consecutive education groups, the six month follow-up assessment was abandoned. Thus, the final design was a controlled trial in which Stream 1 acted as their own control for the effects of education and assessments. Changes in Streams 1 and 2 following the education programme were compared to clarify further the effects of additional pre-programme assessment procedures (administered only to Stream 1 subjects).

Alternative designs were reconsidered including the use of a control group from a pool of subjects from outside the Northern Metropolitan region or the provision of a minimal intervention to D.E.A.P. clients as an alternative to the experimental education programme. However, these designs were dismissed for reasons similar to those given before, which were that no comparable population of diabetics were accessible for study and the D.E.A.P. were unwilling to provide less than the full intervention to any patients referred to the Centre.

3.5 THE SAMPLE

A. The Study Population

The study population of interest in these studies comprised adult, insulin-dependent diabetics who enrolled in the D.E.A.P. The programme primarily serves the Northern Metropolitan Region of Sydney which has an estimated 8,000 insulin-dependent diabetics. Within the Region there are several district hospitals (greater than 200 beds) and a large regional referral hospital (greater than 800 beds). The D.E.A.P. is located at the latter of these (Royal North Shore Hospital) which is also a teaching hospital.

Until 1980, the D.E.A.P. was the major diabetes education programme in Sydney; it was the only centre with full-time medical and allied health personnel and therefore has provided education for diabetics residing anywhere in Sydney or nearby country areas.

Diabetics are referred to the centre from a variety of sources including the private practice of the team's endocrinologist and from other medical practitioners in the community, the Region's hospitals (outpatient clinics and discharged inpatients), the Diabetic

Association of New South Wales, from media publicity and from previous participants in the programme.

B. Criteria for Subject Inclusion and Exclusion

During the evaluations (1978-1981) all insulin-dependent diabetics who enrolled in the education programme were considered eligible for participation in the studies with the following exceptions: 1. those who had been first diagnosed as diabetic less than eight weeks from the projected time of attendance at the education programme; 2. non-English speaking; 3. illiterate; 4. under 18 years; 5. blind; 6. previously attended the D.E.A.P.; 7. unwilling to participate in the study.

The rationale for these criteria was as follows. Newly diagnosed individuals were generally excluded from the programme as well as the studies because their receptivity to learning was thought to be reduced due to their psychological reactions to diagnosis. Adolescents and children were not usually included in the programme for adults and therefore, the occasional exception was excluded from the study. Individuals who were unable to read and write fluently were disadvantaged in the written assessments and parts of the educational intervention. Assessments of diabetics who were attending the education programme for a second (or third) time were likely to be influenced by their prior attendance and so they were excluded. Those unwilling to participate in any assessments would not provide any data. However, refusal to participate in the study was considered an individual's right following the explanation of the purpose and requirements of the study.

C. Sample Size

Sample size was determined largely by the D.E.A.P. enrolment rate and the time period over which funds were available for evaluation. During the pre/post study, the accrual rate of subjects was approximately eight or nine adult insulin-dependent diabetics per month for ten months of the year. Thus, in a two-year study period, 180 enrolments were expected.

At the start of the randomised controlled trial, client enrolments had increased to approximately 12 to 14 per month so that during the 12 to 13 months planned for study, (July 1980 to July 1981), approximately 150 subjects were expected (75 per Stream).

D. Procedures for Sampling and Random Assignment

All insulin-dependent diabetics who enrolled in the programme during the study periods and met the eligibility criteria were included in the studies.

In the randomised controlled trial, random assignment procedures were as follows:-

1. Immediately following enquiries about the programme, a brochure and an application form (Appendices 3.5, 3.6) were mailed to interested diabetics. The application form requested basic information about potential participants so that study eligibility could be determined.

2. Those wishing to enrol returned a completed application form and their eligibility for the study was determined by the D.E.A.P. secretary.

3. The names of eligible study subjects were recorded adjacent to consecutive numbers from 1 to 160, in the random assignment book. At the end of each day, the D.E.A.P. clerk (who had no acquaintance with newly enrolled study subjects) randomly assigned subjects to one of the two streams, using random numbers. From the tables of Rohlf and Sokal (1969), the last three digits of numbers in every other column were used to select 80 random numbers. Subjects assigned to Stream 1 were those whose consecutive programme booking number corresponded to one of the selected random numbers.

4. Individuals assigned to Stream 1 were booked by the D.E.A.P. Secretary into a programme which was at least 10 weeks from the date of booking to allow for attendance at the three month pre-assessment. Stream 2 subjects were booked into the next available programme. Each education programme included approximately equal numbers of subjects from both streams, to minimise the confounding effect of seasonal variation on outcomes.

5. A letter of welcome (Appendix 3.7), a schedule of appointments (Appendix 3.8), a map of R.N.S.H. and a health and treatment details questionnaire (Appendix 3.9) were mailed to study subjects and non-study clients. Telephone reminders were made to all programme participants the week before their first appointment at the Centre.

6. If an individual cancelled his programme booking and re-enrolled later in the study period, he retained the original stream assignment. Occasionally, a subject assigned to Stream 1 had to attend the programme sooner than originally booked (due to anticipations of moving away from the area, extended work commit-

ments, or holidays overseas) precluding his participation in three month pre-assessment procedures. These late re-allocations to study groups were included in Stream 2-B. Also included in this group were clients who were referred for "urgent" education, and those who attended the first two programmes during the "dress rehearsal" phase of the study.

7. At the first appointment, the nature of the study, the assessments and the commitment to attend the follow-up assessment was explained by me to all study subjects. Individuals were encouraged to participate because the results of assessment procedures were to be used to tailor the education programme to their needs, but programme participants were informed that they were free to choose not to participate in the study without sacrificing the opportunity to attend the education programme. Those who chose not to participate were thus excluded from the study.

3.6 VARIABLES OF INTEREST

A. Programme Outcomes

Four general outcomes of interest were evaluated in the pre/post study. These were dietary compliance, knowledge of diabetes management, health beliefs and achievement of biochemical goals. For the randomised controlled trial, quality of diabetic life was also evaluated. These provided a cross-section of cognitive, attitudinal, behavioural and short-term health outcomes by which the education programme could be evaluated.

The aspects of the dietary regimen of primary interest in these studies were those thought to be most influential in promoting optimal

glycaemic control and in reducing the risk of atherosclerosis. They were: the percentage of energy contributed by complex carbohydrate, spacing of complex carbohydrate throughout the day, complex carbohydrate variation between days, and, energy intake as reflected by relative body weight. These aspects of dietary compliance were termed "carbohydrate composition", "carbohydrate spacing", "carbohydrate variation" and "weight" compliance.

Compliance with other aspects of diabetic self-care regimens such as injection techniques and foot care were not evaluated in this study, although they were included as important components of the education programme. Several other health outcomes could have been evaluated such as diabetes-related hospitalisations, or the development of clinical complications. However, such a detailed evaluation of the impact of a programme on comprehensive health status would have required a long-term follow-up period. Also, because the education programme team did not have the responsibility for the clinical management or manipulation of insulin dosage of programme participants, our expectations of the programme's impact on health status were limited. In such circumstances, it was uncertain whether a more rigorous evaluation of health outcomes would have been warranted.

Biochemical measurements were selected as those likely to give the most reliable indicators of short-term metabolic control of diabetes and risk of coronary heart disease. These were fasting blood glucose, glycosylated haemoglobin, fasting serum triglycerides and cholesterol.

B. Factors Related to Dietary Compliance

Several variables were selected for initial measurement and analysis of predictors of dietary compliance. Most of these were either features of the patient, the disease, or the referral source. They included -

1. demographic characteristics (age, sex, social class, area of residence);

2. health and diabetes treatment details (insulin dose, number of daily injections, duration of diagnosed disease, presence of clinical complications, previous dietary advice or attendance at an education programme);

3. family member attendance at the programme and their dietary intakes;

4. referral source;

5. health beliefs (also an outcome variable);

6. presence of current psychological dysfunction;

7. knowledge of diabetes management (also an outcome variable), and

8. initial dietary and biochemical status.

C. 24-Hour Urinary Urea Determinations to Check Validity of Dietary Records (Randomised Controlled Trial)

There was a need to estimate the validity of the dietary survey methods used (weighed food records), since conclusions about the effectiveness of the education programme depended primarily on these. As discussed in Chapter 2, there is no "gold standard" against which

the food record data could be compared. However, as previously reviewed, several studies have used 24-hour urinary nitrogen determinations to estimate the validity of dietary survey methods, by relating them to protein intake. The results obtained have also been applied to estimates of the validity of recorded and calculated values of fat, carbohydrate and energy (Isaksson 1980) although the assumption of generalisability has not been tested.

Because of the practical difficulties in obtaining nitrogen analyses, urea was used as the urinary constituent to check the recorded protein intakes. Few laboratories do nitrogen analyses routinely and are therefore not equipped with automated techniques. Kjeldahl nitrogen analysis (bench technique) requires special apparatus not commonly found in routine laboratories and is time-consuming and therefore expensive. Moreover, we found no laboratory in Sydney willing to undertake such analyses for the number of subjects in this study. As an alternative, urinary urea was considered because it also reflects dietary protein intake (Simmons 1976) and is routinely measured at the Royal North Shore Hospital.

No publications were found reporting the use of urinary urea to cross-check the results of dietary methods, although urinary urea nitrogen and its ratio to creatinine have been used in related studies. In one investigation, Johnstone et al (1981) used several biochemical methods to check the validity of the dietary records of pregnant women. One of these measures was the ratio of the urinary urea nitrogen to creatinine (from single urine specimens). The investigators found an "acceptable degree of correlation" ($r = .60$) of this index with nitrogen intake calculated from food records. A similar correlation was observed between 24-hour urinary nitrogen and food

record nitrogen which suggested that both biochemical measurements correlate relatively well with dietary practice.

Obviously, the potential for non-compliance with the collection of 24 hours of urine is high, particularly in studies requiring subject co-operation with other measurement procedures. Although none of the studies of the validity of dietary methods reported a check on the adequacy of urine collection, such a check is routinely used in clinical research via the creatinine content of 24-hour urine collections (Harper 1971). Creatinine excretion per 24 hours has been considered useful as a biochemical check because it can be predicted for an individual of a known age, and weight. However, its reliability has been questioned by Edwards et al (1969) who observed considerable daily variation in the creatinine excretion of patients in a hospital ward. Nonetheless, it was measured in this study as an attempt to check the adequacy of the 24-hour urine collections.

3.7 ASSESSMENT INSTRUMENTS AND PROCEDURES

All information was collected from study subjects at the D.E.A.P. cottage. An outline of the measurements made for diabetics and their family members at each of the assessments in both studies is given in Table 3.1. The dates of assessment for each intervention group in the randomised controlled trial are shown in Appendix 3.10. Prior to the start of the RCT, criteria for discontinuation of the study were devised in the event that the schedule was not met (Appendix 3.11).

Due to the large number of assessment procedures, they were carried out over two or more sessions (including the first sessions of the education programme) to minimise test fatigue. However, care was taken to assure that assesssments occurred before the relevant section

TABLE 3.1

RANDOMISED CONTROLLED TRIAL

MEASUREMENTS MADE FOR DIABETICS
AND THEIR FAMILY MEMBERS AT EACH ASSESSMENT

	*D **F	D F	D F
A. MEASUREMENTS OF OUTCOMES	3 MONTH PRE-ASSESSMENT (Stream 1 only)	IMMEDIATE PRE-ASSESSMENT	3 MONTH POST-EDUCATION ASSESSMENT(a)
1. DIETARY COMPLIANCE			
(a) 4-day Food Record	X	X X	X X
(b) Weight/height	X	X	X
2. QUALITY OF DIABETIC LIFE(b) QUESTIONNAIRE	X	X	X
3. BIOCHEMISTRY(c) (Blood sample)			
(a) Haemoglobin A_1	X	X	X
(b) Serum Cholesterol	X	X X	X X
(c) Serum Triglycerides	X	X X	X X
(d) Fasting Blood Glucose	X	X	X
4. HEALTH BELIEFS (Interview Questionnaire)	X	X	X
5. KNOWLEDGE (Questionnaire)	X	X X	X X
6. ATTENDANCE AND PARTICIPATION IN ASSESSMENTS	X	X X	X X
B. DESCRIPTIVE MEASUREMENTS			
1. Demographic, Diabetic History and Treatment Details (Questionnaire)	X	X	
2. Current Psychological Dysfunction (G.H.Q.)	X	X X	X X
3. 24-Hour Urinary(b) Urea and Creatinine	X	X	X

* Diabetic
** Family Member

(a) 6-month post assessment in the pre/post study.

(b) Not measured in the pre/post study.

(c) 24-hour urinary glucose measurement was made in addition to other biochemical assessments in the pre/post study but was discontinued due to its inferiority as a measure of diabetic control.

of the education programme was presented, e.g. food records were submitted before any dietary information was presented.

The schedule of assessment procedures used for the randomised controlled trial is given in Appendix 3.12. The schedule used in the pre/post study was similar except that three month pre-assessments were not done and subjects attended a revision session at the six month follow-up. Training for food record and urine collection procedures occurred during the first evening of the programme, whilst most individual testing procedures including questionnaires, interviews, anthropometric measurements and clinical assessments occurred during a one-hour appointment one week later. Fasting blood samples were collected on two early morning appointments (7.00 a.m.) before breakfast. All team members and a research assistant were involved in the assessment procedures.

Measuring instruments and assessment procedures were similar for both studies excepting that for the randomised trial, knowledge and health belief questionnaires were updated and revised; the health belief questionnaire was interviewer-administered to improve completeness of data; the procedure for subject recording of food weights was altered slightly (to remove the necessity for arithmetic by study subjects); and the clinical assessment for diabetic complications, the quality of diabetic life questionnaire and 24-hour urinary urea determination were added to the list of assessments.

The assessment procedures and instruments are described in detail below.

A. Four-Day Weighed Food Records

1. Training of Subjects

Subjects were trained to weigh and record food intake at the first session of the education programme (Stream 1 subjects were trained for record-keeping at the three month pre-assessment during their first early morning appointment). The nutritionist explained that the purpose and benefits of record keeping were twofold: (a) a "unique opportunity" for subjects to obtain a computerised dietary assessment, and (b) valuable information about the eating habits of people with diabetes and their families to be used in the improvement of diet lists and educational services.

A demonstation of record-keeping procedures was provided by the psychologist, nutritionist and nursing sister which was followed by a practical session in which the diabetics and their family members practised weighing and recording food samples. For this exercise, pre-weighed containers, aliquots of food and food recording forms were issued to subjects to practise (a) the graduated weighing procedure described in the instructions; (b) estimating and describing accurately any meal they might eat out; (c) recording this information correctly.

D.E.A.P. team members checked each subject's practise forms and corrected errors.

2. Food Record Forms and Written Instructions

Packets of food record forms, sufficient for four days (48 forms), written instructions and an example food record (Appendices 3.13 and 3.14) were issued to each subject together with a set of Salter Scales (one kilogram capacity in five-gram graduations) and a plastic plate. Metric measuring cups and spoons were also provided for use in recording liquids and when weighing proved too difficult.

3. Days of Record Keeping

Subjects were usually trained on a Monday, asked to practise on Tuesday, to begin formal recording on Wednesday morning on arising and to record all food and drink until Sunday morning (if food was eaten during the Saturday night, this was to be included). They returned the records on the following Monday or Tuesday.

4. Collection and Checking Procedures

When subjects returned food records, they were checked by either the coder or nutritionist for the following details - (a) all four days recorded; (b) all meals on each day recorded or noted that meal was not eaten; (c) graduated weighing procedure followed including scale readings for container; (d) suspicious weights or scale readings limited to one or two; (e) possibly omitted items, e.g. spread on bread, milk on cereal, beverages with meals, dressing on salad; (f) complete descriptions and quantities of estimated foods; (g) correct procedure followed for recording recipes for mixed foods.

If, in the nutritionist's judgement, a food record was grossly inaccurate or incomplete the subject was asked to keep another one. Those who refused were documented as such and their food records were excluded from analyses.

5. Rationale for Four Days (Wednesday to Saturday)

The selection of a four-day record-keeping period was based primarily on practical considerations. Although a seven-day record would have been desirable, the need to obtain high subject co-operation with numerous assessment procedures and to minimise time and expense in coding and processing food records (to allow for their routine use in the education sessions on diet) contributed to the compromise of four days. The selection of days of the week (Wednesday through Saturday) was also based primarily on logistics. Because the programme schedule was such that food record instruction always occurred on Monday and records were to be returned one week later, Wednesday through Saturday was the only practical four consecutive day period (which included one weekend day). It was thought that three week days plus one weekend day (as consecutive days) would provide the most reliable estimate of nutrient intake because in several studies, nutrient intakes at weekends have been shown to be different from other days of the week.

To determine the reliability of using four days instead of seven days to estimate dietary composition, spacing and variation compliance, a reliability study was carried out in 1977. Seventeen insulin-dependent diabetics known by the D.E.A.P. team and who were thought to represent a cross section of diabetics who enrol in the education programme kept food records for seven

days. The seven-day estimates of selected dietary components were compared with those from four days (Wednesday through Saturday) to determine the error introduced by reducing the record-keeping period. The results are given in Appendix 3.15.

B. Anthropometric Measures

All anthropometric measures were made by the nutritionist or nursing sister and recorded on a standard form (Appendix 3.16).

1. Body weight - was measured on a beam balance scale and recorded to the nearest tenth of a kilogram. Two measurements were made (a week apart at the three-month pre- and post-assessments, and on two consecutive days at the education programme) and the mean of two measurements were taken as the observation. Subjects were weighed before breakfast and subjects wore light indoor clothing and no shoes.

2. Heights - were measured using a metal tape which had a moveable headpiece and was fixed to a wall. All subjects removed shoes for the measurements.

3. Skinfold thicknesses - were measured in private with top clothing removed. Subjects were measured on the left side at four sites (triceps, biceps, subscapular and suprailiac) using Harpenden calipers according to procedures described by Jellife (1966). Skinfolds were measured twice, five minutes apart and the mean of two was used as the measurement. The reliability of the skinfold measurements were checked by comparing the results obtained by the two nutritionists on 20 individuals. The results indicated that the measurements were unreliable between nutritionists; only 30% of the measurements differed by less than one millimeter.

Thus, skinfold measurements were not used in the data analysis of these studies.

C. Biochemistry

1. Blood - Venesections were performed by the nursing sister, pathology technician/research assistant or the endocrinologist. Samples were collected on fasting diabetics and their relatives between 7.00 and 8.00 a.m. (instructions for fasting were given in the schedule of appointments. Two blood samples were collected one week apart for lipid and blood glucose analyses at the three month pre-assessment and the follow-up assessments. They were collected on consecutive days at the assessment early in the education programme (the pre-programme assessment). From diabetics, approximately ten mls of blood were collected at each assessment, and from family members, five mls.

The nursing sister or pathology technician then processed the samples and sent them to the appropriate laboratory for analyses. Three mls were placed into "Sequestrene" tubes and sent to the Royal North Shore Hospital, Department of Nuclear Medicine for Hb A_1 determinations (ion exchange chromotography, adapted to mini-columns by Quik-Sep). Two mls of whole blood were placed in tubes with fluoride oxidase and immediately tested for glucose on a Beckman Glucose Analyser by the D.E.A.P. nursing sister. Prior to each batch of glucose determinations and at several points throughout, the machine was calibrated according to the manufacturer's standard glucose solution.

The remaining five mls of whole blood were then spun in a centrifuge to obtain approximately two mls of serum. The serum was

immediately frozen and sent within a week by courier to the Lipid Research Laboratory, St. Vincent's Hospital, Sydney where serum cholesterol and triglycerides were determined by an autoanalyser. (Technicon R method N-28). For family members, blood was processed and sent for serum lipid analyses only.

All samples were sent with pathology sheets and were marked with the subject's name, number and identified as A or B for first and second sample collected. Results were returned to clients on a standard form (Appendix 3.17). The interassay coefficients of variation for glucose, haemoglobin A_1, serum cholesterol and triglyceride determinations were 0.02, 0.03, 0.04 and 0.06, respectively.

2. 24-hour Urine Collection

At the food record training sessions, subjects were asked to collect all of their urine for a 24-hour period of the third day (Friday) of the record-keeping period. Either the nursing sister or the pathology technician gave oral and written instructions as in Appendix 3.18. Subjects were told to collect all urine from Friday at 8.00 a.m. to Saturday at 8.00 a.m. They were specifically instructed to discard the first urine passed on the first day of collection.

A subject was allowed to collect the urine on another day during the record keeping period if inconvenient on the Friday. Five, 500 ml plastic bottles with preservative were issued to each subject. Subjects were asked to refrigerate the collection on Saturday and Sunday and return it to the Centre on Monday or Tuesday.

Returned collections were processed by the pathology technician or nursing sister; volumes were measured and recorded and a ten ml sample was frozen and sent to the Northern Region Biochemical Service, Royal North Shore Hospital for 24-hour urea and creatinine determinations (routinely done on autoanalyser). Duplicates were kept frozen so that they could later be checked for the reproducibility of laboratory results.

D. Clinical Assessment for Presence of Diabetic Complications

The D.E.A.P. team's endocrinologist conducted the clinical examination for complications of diabetes. These examinations were done at the time of the assessment appointment (one week after the commencement of the education programme) and took approximately ten minutes. Retinae were examined with an opthalmoscope only because a thorough ophthalmological examination was not possible. To detect symptoms of peripheral neuropathy, subjects were questioned, examined for pedal pulses, ankle jerk reflexes, and light touch sensation in their lower limbs. Evidence for the presence of vascular and retinal complications was also sought by history and medical reports, when available.

If the D.E.A.P. endocrinologist was unable to keep appointments for the clinical examination for complications due to other hospital responsibilities, he obtained the relevant clinical information from their medical records, where available. The results of the examination were summarised in letters to the diabetics and their medical practitioners.

E. Questionnaires

1. Demographic details

Demographic, health, and treatment details were obtained from subjects via the application form (Appendix 3.6) and a self-administered questionnaire (Appendix 3.9) which was mailed out when they enrolled in the programme. These were returned at the first education session or at the three month pre-programme appointment (for Stream 1).

2. Knowledge

The knowledge questionnaire about diabetes management was completed by diabetics and their family members before and after the education programme. In both studies, a multiple choice format was used (Appendices 3.19 and 3.20). The majority of questions were selected from the questionnaire of Etzwiler (1967) and adapted for Australian conditions and terminology. The questionnaire used in the pre/post study was updated, revised and shortened for use in the randomised controlled trial, although the content and format were similar. The pre/post questionnaire took approximately 35 minutes to complete compared with 25 minutes for the one used in the randomised controlled trial.

3. GHQ

Current psychological dysfunction was measured on a 30-item standardised questionnnaire devised by Goldberg (1972) referred to as the General Health Questionnaire (GHQ) (Appendix 3.21). The G.H.Q. was administered to diabetics and their family members before and after the education programme.

4. QDL

Quality of diabetic life (Q.D.L.) was measured before and after education on a 19 item self-administered questionnaire devised by the D.E.A.P. team (Appendices 3.22, 3.23). The questionnaire was intended to measure whether subjects felt better, the same, or worse after the programme about various aspects of living and coping with diabetes. No published questionnaire for diabetics which measured a variety of feelings about living with diabetes could be located. In order to obtain some estimate of the reliability of Q.D.L. questionnaire items, subjects were given a similar questionnaire before the programme. Time taken to complete the Q.D.L. questionnaire was approximately ten minutes.

5. Health Beliefs

Health Beliefs were measured at each assessment using a self-administered questionnaire (pre/post study - Appendix 3.24) or a structured interview (randomised controlled trial - Appendix 3.25). Questions were selected from questionnaires used in previous health belief research (Sackett et al 1976, Becker et al 1977) and adapted for use with diabetes and the diabetic diet regimen. In the pre/post study, general questions were asked together with several specific ones to determine which performed best in discriminating between subjects. For example, responses to "how much would you say your diet interferes with your daily life?" was compared with "how much do the following aspects of the dietary regimen interfere with your life?" Some open-ended questions also included in the pre/post study questionnaire were not included in the data analysis. Questions which did not discriminate well in the pre/post study were excluded from the

analysis and from the questionnaire used in the randomised controlled trial.

To improve the completeness of data from the health belief questionnaire for the randomised controlled trial, two experienced interviewers were employed to administer the structured questionnaire. Initial training in the use of this schedule and relevant coding procedures was given. The introduction to the interview was standarised so that all subjects were informed of their rights to refuse to answer and were assured of the confidentiality of their answers from the D.E.A.P. team and others. The interview took 15 to 20 minutes to complete.

E. Questionnaire Administration

With the exception of the demographic, health and treatment details (mailed questionnaire, Appendix 3.9), all questionnaires were administered at the D.E.A.P. Centre during assessment appointments. To minimise questionnaire fatigue or the effects of completing similar questionnaires in succession, measurements were divided between the subjects' two assessment appointments. Generally, the knowledge questionnaire, the GHQ and the QDL questionnaire were administered the first week and the health belief questionnaire, at the second appointment. At the assessments immediately prior to the education programme, all questionnaires (except knowledge) had to be administered during the same assessment apppointment.

Storage of Collected Data

The majority of information collected from study subjects at each assessment was stored in individual patient records at the D.E.A.P. Cottage. Confidential questionnaires (health beliefs, quality of

diabetic life), the results of which were not to be shared with the D.E.A.P. team, were stored separately at the Clinical Epidemiology Unit of the hospital. The D.E.A.P. clerk was responsible for the numbering, dating, filing, and storing of all assessment forms in patient files.

3.8 METHODS OF DATA PREPARATION

Due to the large quantity of collected data and the need for expedient nutrient analyses of food records (for use in the education programme) a computer was used to analyse the data in these studies.

Computerised nutrient analyses of the food records were obtained throughout the study period by the psychologist and nutritionists at the D.E.A.P. (Ms. Hilary Tupling, Ms. Jane Atkinson and myself) using the Cyber computer at the C.S.I.R.O. Division of Computing Research at the University of Sydney.

The Data Analysis for these studies was done Computer Centre in the Department of Mathematics of the University of Newcastle by Mrs. Dianne O'Connell, a Ph.D. student in the Faculty of Mathematics.

Data were coded and prepared for analysis according to the procedures described below. Except where indicated, procedures for processing data were similar in the pre/post study and the randomised controlled trial.

Standard 80-column computer coding forms were used as the "data summary sheets" for both studies (Four cards per subject in the pre/post study and nine cards in the randomised controlled trial). These were termed "data summary sheets".

A. DIETARY DATA

1. Food Records - Coding Procedures

When completed food records were returned and checked with subjects, they were immediately coded by the D.E.A.P. clerk, secretary, the project research assistant or the nurse using standardised coding procedures for dietary research in New South Wales. An (unpublished) food coding manual was developed for this purpose jointly by nutritionists at the D.E.A.P. and the Commonwealth Institute of Health (University of Sydney) and revised in conjunction with the Human Nutrition Unit (University of Sydney) prior to the commencement of these studies. Food record coding procedures were devised for use with S.P.E.A.D.D., a computer dietary analysis package developed by Zed, Heywood and Hain (1977).

The steps in coding are described in detail in the coding manual but are briefly summarised below:

(a) Each food recording sheet (Appendix 3.13) was assigned a subject number, day of study, day of week and calendar day.

(b) Recorded foods and beverages were assigned a meal or snack code (from 1 to 8) from information recorded in "meal and time" column.

(c) Foods and beverages were assigned food item codes using the Australian Tables of Food Composition Codes (Heywood, Hain and Zed, 1978). Recorded food or beverage items which were not listed in the Australian Food Tables were

assigned the code of a food item with a similar energy and macro-nutrient content. Such item codes for commonly consumed foods were listed in the food coding manual. However, occasionally nutritionists were required to make judgements about item codes for unusual foods and such decisions were recorded in the manual for consistent coding throughout the study period. Mixed foods such as spaghetti sauce or apple pie were coded according to their individual components as recorded by subjects on recipe sheets.

(d) The weight of each food or beverage consumed was coded in grams in the pre/post study as determined from subjects' calculations (subtraction of plate weight and waste from the weight of the serve). For the randomised trial, food weights (in grams) were calculated by coders by subtracting the scale reading recorded for the plate or container from the scale reading for the food plus container. Weights were corrected for left-overs. For mixed dishes and recipes, weights of component food items were determined by - (i) calculating the proportion of the weight of the total recipe contributed by each ingredient, and (ii) multiplying these ingredient factors by the weight of the recorded serve of the mixed dish.

The weights of food and beverage items which had been estimated or recorded in household measures were obtained from the food coding manual in the first instance or from U.S.D.A. Handbook No. 456 (1975). A working party of nutritionists described approximately 150 food items

(including fruits and vegetables, and commercially prepared foods) in linear dimensions, household measures and gram weights to allow for easy conversion of estimates and measures to weights. The average time spent coding a four-day food record was one hour but varied between 40 minutes and two hours depending on the number of mixed dishes recorded.

(e) All coded food records were checked by D.E.A.P. nutritionists for errors in meal, item or weight codes and coders were given a list of errors made in coding each batch of food records (Appendix 3.26). As well, a sample of three or four records in each batch of records collected over the study period were re-coded by nutritionists to determine error rates in coding. If the error rate (that is, number of errors divided by number of coded items) were greater than 10%, it would have been necessary to re-code all records. However, coding error rates were below 10% in all batches. Thus, careful checking of each record was considered sufficient. The average time to check a four-day record was 25 minutes.

(f) Computer cards were punched by a keypunch operator who was under contract with the Northern Metropolitan Region of the Health Commission of New South Wales.

2. Computer Dietary Analysis

Punched cards provided the input data for S.P.E.A.D.D. (Heywood, Hain and Zed, 1977) which provided estimates of energy and 17 nutrients for each subject for each meal and snack consumed over

the four day recording period. Because values for added sugar (sucrose, glucose or honey) were not available on the Nutrient Data Bank (from the Australian Tables of Food Composition) a "select" option on the S.P.E.A.D.D. programme was used to select out foods which contained added sugar and to then calculate the approximate amount of sugar in each meal and snack. Selected foods were grouped into four categories according to the approximate percentage of their total carbohydrate contributed by sugar, that is, 25%, 50%, 75%, and 100%. Values for added sucrose, glucose and honey content of foods were obtained from food manufacturers' information. A listing of each food item included in the four groups is contained in the food coding manual.

The output from S.P.E.A.D.D. together with information about the subject's body weight and sex formed the input data for the dietary assessment package "Dietade" (Tupling and Webb, 1979) described earlier in this chapter. A copy of the Dietade print-out and the food record forms was filed in the patient's file and other copies were given to the patient, his doctor and his dietitian. The print-outs from the three month pre-assessment for Stream 1 were withheld from subjects until after they had completed the second food record (at the assessment immediately prior to the programme). Occasionally, coding errors were detected after subjects were given a copy of their computer outputs. These coding errors were corrected and records were re-analysed in the next batch of computed records.

3. Coding Dietary Data for Final Data Analysis

At the completion of the study period, selected information from file copies of Dietade print-outs were coded onto data summary sheets by the D.E.A.P. clerk, research assistant and myself. Information coded for all diabetics and their accompanying family members were as follows:-

(a) intake of protein, fat, complex carbohydrate, sugar and alcohol (in grams) for each of the four days

(b) the percentage of energy contributed by the energy-containing nutrients (average over four days)

(c) complex carbohydrate values for each of the three meal periods over four days (12 values, diabetics only)

(d) the recommended complex carbohydrate values for each of the three meal periods (diabetics only)

4. Definitions of Dietary Compliance

Scores for carbohydrate spacing and variation were calculated for each diabetic subject from meal period values for complex carbohydrate. A detailed explanation of the formulae used to calculate the scores (devised by Professor A.J. Dobson) is given in Appendix 3.27. Essentially, scores were derived from analyses of variance in which the factors were logarithms of the actual and recommended amounts of carbohydrate consumed at a particular meal period. The sums of squares of deviations between actual and recommended amounts at each meal period formed the "raw scores" for spacing and variation. For variation, the "recommended" value was zero since zero variation was considered optimal.

Since these statistics have very skewed distributions, the square roots of raw scores was taken to achieve more symmetric distributions.

The advantages of generating spacing and variation scores by analyses of variance are that the scores are continuous, they are standardised across subjects according to the "recommended" intake and the random or residual deviations from recommended level (not due to habit or pattern of intake at a particular meal period or day) is used as the score. This makes biological sense if, as discussed in Chapter 2, regularity of eating is an important factor in regulating blood glucose of diabetics.

Other methods of quantifying compliance with spacing and variation were considered, including: (1) actual intake as a percentage of recommended intake (averaged over 12 meal periods) and (2) number or proportion of meal periods within close range of recommended. However, the main disadvantage of the first method is that unlike the analysis of variance it does not account for the source of the deviation from recommended spacing or variation, that is, meal period and day. The latter method sacrifices precision thereby limiting the opportunity to detect differences between groups or assessments. It also requires that limits for which there is no sound biologic rationale, be set around the recommended value. Carbohydrate variation compliance could have been expressed as standard deviations or coefficients of variation in carbohydrate intake derived from daily totals or meal period values over the four day record keeping period. However, such estimates from only four observations are unstable and therefore insensitive to differences between groups and

assessments. Moreover, the residual variation (not attributable to habitual variation by meal period and day) could not be separated from the simple coefficients of variation.

5. Classification into Compliance Categories

For the analysis of differences in characteristics between compliers and non-compliers, individuals were classified into one of four compliance groups, that is, those who -

(a) met dietary and weight goals before and after the education programme (complier, complier, CC),

(b) did not meet the goals initially but were compliant at follow-up (non-complier, complier:NC);

(c) met the goals before but did not afterwards (complier,non-complier:CN); or

(d) did not meet goals before or after the programme (non-complier, non-complier;NN).

The dietary goals of the programme were used as the classification criteria, that is, greater than or equal to 45% complex carbohydrate, spacing and variation scores of less than 0.07 and 0.03, respectively.

The rationale for the use of a definition of compliance based on both pre- and post- dietary measures is that some individuals who were compliant after the programme were "good guys" initially and were therefore likely to be different in other respects from those compliers at follow-up who made considerable behavioural change to achieve their "compliant" status.

Similarly, non-compliers after the programme were a mixture of "bad guys" (those who were initially non-compliant) and of "back-sliders" (who became non-compliant). These "types" of compliers and non-compliers required some distinction in the analysis of predictors of dietary compliance behaviour.

To check the utility of these definitions when applied to our data, pre- and post-assessment values (on the continuous scale) of dietary measures and weight were plotted, and the numbers in each of the four compliance groups was calculated. For all except carbohydrate composition compliance, there were sufficient numbers in each of the four groups. However, for carbohydrate compliance, there were very few individuals in the CN group. Since their initial and final values were similar to the CC group, they were included in this group for the analysis of factors associated with compliance.

B. WEIGHT AND HEIGHT

1. Coding

Body weights of diabetics and family members measured at each assessment were coded on the data summary sheets to the nearest tenth of a kilogram. Also coded were "ideal" body weight determinations as follows:

2. Determination of ideal weight

Metropolitan Life Assurance Tables (1959) were used and midpoint of medium frame for the subject's height was taken as his ideal weight.

3. Determination of Relative Body Weight (percentage of ideal weight)

For each diabetic and family member, the percentage of ideal weight at each assessment was calculated as follows:

$$\text{relative weight} = \frac{\text{actual weight}}{\text{ideal weight}} \times 100$$

4. Classification Criteria for Assignment to Weight Categories

Diabetics and family members were classified into one of four weight categories at each assessment on the basis of their percentage of ideal weight as follows:

Less than 90%	underweight
90-110%	ideal weight
111-120%	slightly overweight
Greater than 120%	overweight

5. Classification Criteria for Assignment to Weight Compliance Categories

For assignment to one of the four weight compliance categories, the difference in percentage of ideal weight between pre- and post-assessments was calculated. Individuals were assigned as follows -

Initial Weight Category	Weight Change	Compliance Group
Overweight, Slightly overweight	Loss of greater than or equal to 5 % of ideal	NC
Overweight, Slightly overweight	No loss or a gain of greater than or equal to 5% of ideal	NN

Ideal weight	Gain of greater than or equal to 5% of ideal.	CN
Underweight	Exceeded 110% of ideal at follow-up	
Ideal weight, Underweight	Did not gain 5% of ideal. Did not exceed 110% of ideal at follow-up	CC

The criterion of change, i.e. at least 5% of ideal weight was arbitrary but appeared clinically appropriate in seeking better diabetic control. Many overweight individuals could not have been expected to achieve their ideal weight within the short post-programme study periods so goal achievement was not used to define compliance with weight goals. Rather, change in the desired direction was considered to be compliant behaviour. Diabetics who were significantly underweight (less than 90% of ideal) were allowed to gain greater than 5% of ideal weight, so long as they did not exceed 110% of ideal at the end of the study period (a physiologically unlikely possibility).

C. BIOCHEMICAL MEASURES

1. Coding

Laboratory results for all blood tests were received within a week and recorded immediately in the subject's file and on standard forms. The results were given back to the patient at sessions five or six and sent to his or her doctor with the computer dietary analysis print-out.

Laboratory slips for urinary urea and creatinine results were immediately filed and were not given to study subjects.

All biochemical results were later coded on the data summary sheets for final data analysis. Where available, two results

were coded for serum lipids and blood glucose and the mean of two results was calculated by computer and used as the value for final data analysis.

2. Definitions of "elevated" and "acceptable"

For analysis of the associations between dietary compliance and achievement of biochemical goals, individuals were classified into one of two categories, those at or above and those below the upper limit of acceptable clinical values. The cut-off points used were determined by the D.E.A.P. endocrinologist as follows - Serum cholesterol 6.5mmol/l, serum triglycerides 2.0 mmol/l, glycosylated haemoglobin 9.0%, and fasting blood glucose 10.0mmol/l.

3. Comparison of Measured Creatinine with Predicted Creatinine

To check the adequacy of the 24-hour urine collections, measured creatinine per 24 hours was compared with predicted creatinine excretion per 24 hours. Predicted creatinine was derived from the following formula (Cockcroft and Gault 1976):

$$\text{Predicted Creatinine (mmols/kg/24 hrs)} = (28 - (.02 \times \text{age})) \times \text{weight}$$

(x .0085 for conversion to mgs/kg/24 hours)

Measured creatinine was then converted to a percentage of predicted as follows:

$$\frac{\text{Measured creatinine}}{\text{predicted creatinine}} \times 100$$

For individuals who were more than 110% of ideal weight, their ideal weight was substituted in the equation because creatinine excretion is dependent on lean body mass (ibid.).

For the correlation analyses between 24-hour urea values and recorded protein intake, urea values were converted to "estimated protein intake" (in grams) using the following formula:

Estimated Protein = 24-hour urinary urea (mmol/l) x .175 + 20 grams*

*(for faecal and skin losses)

D. CLINICAL EXAMINATION FOR PRESENCE OF COMPLICATIONS (Randomised Controlled Trial only)

Individuals were classified into one of two categories:presence or absence diabetic complications. Those who had any evidence of retinal damage, nephropathy or peripheral neuropathy (in the clinical judgement of the endocrinologist) were coded as "complications present". All others (with no evidence of retinopathy, neuropathy or nephropathy) were coded as "complications absent".

E. QUESTIONNAIRES

1. Knowledge was scored by the D.E.A.P. clerk from standard answer keys. The number of correct responses out of the total possible number (51 in the pre/post study and 42 in the randomised controlled trial) was used as the score. Scores were recorded on the data summary sheets for diabetics and family members at each assessment.

2. Demographic, Diabetic History and Treatment Details were coded onto the data summary sheets from the application form and the health and treatment details questionnaire according to coding procedures given in Appendix 3.28. All of these variables were categorical with the exceptions of age, duration of diabetes and dose of insulin. For some variables, e.g. geographic area of

residence, there were zero frequencies in some cells and so the categories were combined for statistical analyses. Categories used in the analyses are shown in the tables of Chapter 4 and 5.

3. General Health Questionnaire (GHQ) was scored accoding to procedures described by Tennant (1977). Circled responses in the two right-hand columns were counted as one point and scores of five or greater were considered "positive" suggesting "current psychological dysfunction". Those with scores of less than five were considered negative and coded as such on data summary sheets.

4. Quality of Diabetic Life (Randomised Controlled Trial only).

Responses to each of the 19 questions were assigned codes from one to five from "much less than before" (1) to "much more than before" (5) and individual scores for each item were entered on data summary sheets.

For some questionnaire items, e.g. "feeling confident about diabetes", the desired response was "much more than before" whereas, for other items, e.g. "feeling confused about my diet", the desired response was in the opposite direction, that is "much less than before". Therefore, selected items, i.e. 3, 4, 5, 6, 9, 10, 11, 13, were re-coded on the computer so that the desired end of the response scale was coded as a 5. Thus comparable "scores" were obtained for each item.

For the data analysis, the scores for individual items were analysed separately and as a total "average" score (over all items for each subject). This procedure was used in preference to adding scores for all items together so that changes in desired and undesired directions could be identified.

In an attempt to reduce the number of items, a factor analysis was done on the pre- and on the post-questionnaires on the two streams separately and together. However, no sensible groupings of items were obtained from these analyses and the factors and groupings were highly unstable (i.e. they varied considerably between groups and assessments). Thus, all 19 items were analysed separately.

5. Health Beliefs

Scoring

In the pre/post study, scores were calculated by hand according to procedures outlined in Appendix 3.29. For the randomised trial, responses were coded on the pre-coded interview schedule (Appendix 3.25) and scores for individual health belief dimensions were calculated on the computer according to procedures described in Appendix 3.30.

Factor analyses on the first and follow-up interviews were used to derive six health belief dimensions or factors for the randomised controlled trial. The factors, together with their individual component questionnaire items are also shown in Appendix 3.30.

In the pre/post study the possible score for perceived susceptibility to complications was greater for males because "impotence" was included as a question sub-item. As well, in both studies, the number of scored responses varied because some individuals responded "have now" or "don't know" to various conditions. Thus, to obtain comparable scores across subjects, scores for this and all other questions were divided by the total

number of items actually answered (excluding "don't know", "have now" and "not applicable" responses).

3.9 METHODS USED FOR STATISTICAL ANALYSES

Initially, the data were checked to identify coding or punching errors by checking all values lying outside the expected range of values. The distributions of all continuous variables were also checked for symmetry. In the pre/post study, spacing and variation scores were skewed so they were transformed by taking square roots. For the randomised controlled trial, highly skewed distributions were observed for serum triglycerides, alcohol intake, sugar intake, spacing and variation scores and health beliefs. Logarithms (to base ten) were used to obtain a more symmetric distribution for serum triglycerides (Sokal and Rohlf 1969). For other variables, neither logarithms nor square roots improved the symmetry sufficiently so they were transformed to binary variables (ibid.). The cut-off points used for classification for the dietary variables were the dietary goals (i.e. less than or equal to 5% energy for sugar and alcohol and spacing and variation scores of less than .07 and .03 respectively). For health beliefs the median scores were used as the cut-off point.

In both studies, the probability of making a type I error (detecting significant associations by chance alone) was high due to the large number of statistical tests. To minimize the likelihood of this occurrence, adjustments were made to the critical alpha levels required to be considered statistically significant. The Bonferroni method was used for these adjustments which involved dividing the critical probability values which are generally regarded as indicative of statistical significance (i.e. .05, .01 and .001) by the number of comparisons in a "family" of comparisons (Miller 1966).

Thus, the significance levels for results of comparisons (i) between returns and non-returns; (ii) between Streams 1 and 2 in the randomised controlled trial; and, (iii) between factors and compliance, were adjusted for the number of variables measured at the baseline assessment. Similarly, the critical significance levels for the repeated measures tests of the effects of assessments and the education programme were adjusted for the number of outcome variables i.e. 20. Although the actual number of comparisons for the RCT was twice the number of outcome variables (for two Streams), each Stream was regarded as a separate "family" of comparisons (ibid.).

1. Baseline Similarities and Differences Between "Returns" and "Non-Returns"(Both Studies).

Prior to the substantive analysis of data, all measurements made at the initial assessment were analysed for differences between diabetic subjects who returned for their follow-up assessments and those who did not. The terms "returns" and "non-returns" were used for these two groups to distinguish them from progrmame "drop-outs". Programme drop-outs were those who missed more than one education session. Since drop-outs were not asked to return for follow-up assessments, they were included in the "non-returns" for the analyses of initial differences. Returns and non-returns were compared on all variables measured at the first assessment using between-group t tests. Chi square tests were used for the analyses involving categorical variables. Pearson Chi square values were reported for contingency tables with more than four cells and Yates' corrected chi square values were given for two by two tables.

Due to the large number of comparisons between baseline measures

for "returns" and "non-returns" (28 variables in the pre/post study and 34 in the randomised controlled trial), the critical significance levels were adjusted for the number of variables.

2. Baseline Similarities and Differences Between Streams (Randomised Controlled Trial)

To determine whether Streams 1 and 2 were similar in important respects, they were compared on all measures made at their first assessment. Thus for Stream 1, values from their three month pre-assessment were compared with information collected immediatey prior to the education progrmame for Stream 2. As for the previous analysis, differences on continuous variables were determined by between-group t tests and comparisons for categorical variables were made by chi square tests. Stream 2-B subjects were excluded from the data analysis due to the small numbers in this group.

In the programme for comparison of groups means (P7D) the Levene's test of equal variances is applied (B.M.D.P. Manual 1977). If a statistically significant difference (p less than .05) in variances between returns and non-returns or between streams was observed, the Welch's statistic, probability level and degrees of freedom was reported. Welch's statistic is more robust than the F ratio under inequality of variances. (Brown and Forsyth 1974).

3. The Effects of Assessment (alone) on Outcome Variables (Randomised Controlled Trial)

To determine effects of the assessments themselves on dietary compliance and other programme outcomes of interest, measurements made three months prior to the programme on Stream 1 were compared with the same measurements made immediately prior to education, using paired t tests for continuous variables and McNemar's tests of symmetry for categorical variables. McNemar's test is used (in preference to a chi square test of independence) to test for change in a categorical variable when the contingency table is based on measures of the same subjects at two points in time (Siegel 1956). The formula for its calculation is given in the B.M.D.P. Manual (1977). Changes in health beliefs, spacing and variation compliance were determined by testing the differences in the proportions of the sample above and below the pooled median (scores at both assessments). Probability values to reach statistical significance were adjusted for comparisons of 20 outcome variables. Stream 1 subjects who attended the three month pre-assessment but did not return for the assessment immediately before the programme were excluded from this analysis.

4. The Effects of Education on Outcome Variables (Both Studies)

In the pre/post study, all outcome variables measured on those who returned for the six month follow-up assessment were compared with similar measurements made at entry to the programme. Paired t tests were used exclusively since all outcome variables for this study were measured on a continuous scale.

In the randomised controlled trial, a two-factor repeated measures analysis of variance (P2V) was used to determine the

effects of the programme on continuous outcome variables for Streams 1 and 2 (B.M.D.P. Manual, 1977). The two factors were Stream and assessment. This analysis was used (instead of paired t tests) so that simultaneous comparisons could be made to test for (a) the effects of the programme; (b) differences between Streams before or after the programme; and (c) differences between Streams in direction and magnitude of change (interaction) (Winer 1971).

The two groups were compared on measurements made immediately prior to the programme and those made three months afterwards. The effect of the programme on categorical outcome variables was determined by use of McNemar's tests of symmetry. For this analysis, the cut-off points for health beliefs, spacing and variation scores were the grand medians, that is, the medians derived from pooling the scores for both streams before and after the programme. Adjustments were made in critical p values for 20 comparisons.

5. Dietary Compliance Rates Before and After the Education Programme (Both Studies)

The previous analyses addressed the question of the direction and magnitude of change in dietary variables for the group as a whole. Also of interest was the proportion of the study sample who met the criteria for each type of dietary compliance before and after the programme. Although "compliance" was somewhat of a misnomer when used to describe dietary behaviour before the programme, it was used to distinguish between those who met dietary goals from those who did not. These proportions and the statistical significance of the differences (before and after the

programme) were determined in both studies using McNemar's tests. For the randomised controlled trial the proportions of compliers and non-compliers in Streams 1 and 2 were compared for each type of dietary compliance at both assessments and since they were not significantly different, the two groups were combined for further analysis of factors associated with compliance. The proportions of the sample who were compliant before and after the programme were calculated on the basis of "returns" only since there were no follow-up data on non-returns. However, differences in initial dietary variables between returns and non-returns were checked in the analysis described earlier.

6. Associations Between Four Types of Dietary Compliance (Both Studies)

To determine whether individuals who were compliant with one aspect of the dietary regimen were also compliant with others, the compliance classifications of individuals were compared for each of the four types of dietary compliance and chi square tests were used to assess the significance of associations. This analysis was done in two ways. First, the associations between compliance behaviour based on post-programme data were used. Because some of the compliers at follow-up met the dietary goals at entry to the programme, the analysis was repeated to test the associations between types of dietary compliance for the four compliance groups CC, CN, NC and NN. The critical significance levels were adjusted for six comparisons.

7. Predictors of Dietary Compliance (Both Studies)

The purpose of this analysis was to identify which, if any, of the variables measured at pre-programme assessment were associated with and/or predictive of subsequent dietary compliance. Thus, all variables (including initial dietary variables) measured at the pre-programme assessment were included in the analysis. With the exception of demographic information, the three month pre-assessment measures for Stream 1 were not used in the analysis of predictors because the time periods for prediction would not have been comparable for the two groups. Moreover, values at the pre-programme assessment were not significantly different from three month pre-assessment values.

In the pre/post study, associations between baseline measures and the four types of compliance were first analysed using only the six month follow-up data for classification of individuals into two categories. The analysis was then repeated testing associations between baseline measures and compliance defined in terms of both assesssments (CC, CN, NC, NN). For the second analysis, weight compliance was eliminated because the majority of subjects were in the CC category and too few were in the NC group.

For the randomised controlled trial, the analysis of factors was done using only the definition of compliance based on pre- and post-measures because it described compliance groups more accurately and the results obtained from the two analyses in the pre/post study were similar.

In both studies, the analysis of predictors was done in two stages. First, significant associations between baseline measures

and compliance were determined from one-way analyses of variance for continuous data and chi square tests for categorical data. Second, all variables were tested in discriminant analyses for their ability to predict the various types of dietary compliance. Discriminant analyses were used because differences between three or four groups were being tested. Only variables for which differences in compliance groups yielded large F values (that is greater than 4.0) entered the discriminant function (P7M, B.M.D.P. Manual, 1977). On the basis of the prediction equations generated from these analyses, the percentage of subjects correctly classified into compliance groups was determined using jacknifed classification procedures (ibid.). Thus, to classify each subject, four discriminant functions were calculated (excluding the data for that subject) and he was then assigned to the compliance category corresponding to the largest Z value.

8. Associations Between Dietary Compliance and Biochemical Measures of Glycaemic Control and Serum Lipids (Both Studies)

For this analysis, individuals were first classified into two categories (above acceptable, at or below cut-off point) for the four biochemical measures made at the post-programme assessment i.e. serum cholesterol and triglyceride, blood glucose and glycosylated haemoglobin).

Four by two contingency tables were then constructed according to the four compliance groups (three groups for carbohydrate compliance) and the two levels of biochemical measurement. Associations were tested by chi square tests and significance levels were adjusted for 16 comparisons. Compliance with weight recommendations was included in this analysis despite the small numbers in the NC and CN groups.

9. Four-Day Weighed Food Records (Randomised Controlled Trial)

For each stream, the percentage of subjects attending the first assessment who kept apparently reliable and accurate food records at each assessment was thereafter calculated. The percentage co-operation could have been calculated using as a denominator either the total number of subjects who were initially enrolled in the study or the number who attended each assessment. However, the former method would have provided an overly conservative estimate of co-operation because individuals who did not keep their first appointment with the D.E.A.P. team were unlikely to be aware of the requirement for food record-keeping. On the other hand, co-operation would be overestimated if calculated from the number who attended each assessment since non-attendance may have been due to unwillingness to keep food records. Percentages of those who submitted doubtful or incomplete food records were calculated separately from those who refused or declined to participate in record-keeping.

To check the concurrent validity of the food records, correlation analyses were used to determine the relationship between protein intake calculated from food records and that estimated from 24-hour urinary urea values. The average protein intake calculated from two days of the food record, Thursday and Friday, were correlated with estimated protein intake calculated from urea values obtained from 24-hour urine collected on Friday to Saturday. For individuals who collected urine on Saturday, protein intake was calculated from food records on Friday and Saturday. Correlations between food record values and urinary urea values were examined at each assessment, for each stream separately and for the two groups combined.

CHAPTER 4

RESULTS - PRE/POST STUDY

SECTION

CHAPTER 4

SECTION 4.1 - INTRODUCTION

The results of the pre/post study describing the direction and magnitude of changes in the programme outcomes for the study group were published in the Australian and New Zealand Journal of Medicine in April 1982. An off-print of that article is included in this chapter as the presentation of results for the study questions pertaining to the evaluation of the programme.

Results concerning compliance rates, associations between the various types of compliance behaviour, and predictors of dietary compliance and the relationship between compliance and the achievement of biochemical goals are presented in full in the second half of this chapter.

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Evaluation of a Diabetes Education Programme

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Abstract: Evaluation of a diabetes education programme. K. L. Webb, A. J. Dobson, H. E. Tupling, G. W. Harris, D. L. O'Connell, J. Atkinson, M. J. Sulway and S. R. Leeder, *Aust. N.Z. J. Med.*, 1982, **12,** pp. 153–160.

An education programme was evaluated for 140 insulin-dependent diabetics and their family members from 1978 to 1980. Dietary, biochemical and other assessments were made before and 6 months after the programme.

As a group, the diabetics were initially in good metabolic control and this was maintained, or improved, over the study period.

The programme recommended a diet in which complex carbohydrate constituted at least 45% of energy intake and fat was limited to 30%. The diabetics and their family members significantly increased their consumption of complex carbohydrate and decreased fat intake. On this regimen, diabetics did not gain weight and their relatives lost weight.

There were also improvements in knowledge of the disorder and in perceptions of susceptibility to complications and barriers to compliance.

Key Words: Diabetes education—Evaluation of health education—compliance—Diabetic diet.

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Introduction

Education programmes to improve compliance with self-management regimens in chronic disorders such as diabetes mellitus can be planned and modified rationally only if they are properly evaluated. At the Royal North Shore Hospital of Sydney, Australia, a Diabetes Education Centre was established in 1974. One of the services implemented at the Centre in 1975 was an education programme to improve compliance of adult insulin-dependent diabetes to their self care procedures. This programme was evaluated between January 1978 and July 1980. The evaluation sought to:

(i) assess the nature and magnitude of changes in dietary behaviour after participation in the education programme; and
(ii) compare the characteristics of individuals who complied with the dietary recommendations and those who did not.

This paper presents our findings for the first of these evaluation objectives.

Materials and Methods

Education Programme

The goal of the education programme is to promote the physical and psychological well-being of adult, insulin-dependent diabetics and their families.[1] The specific objectives are to help them to:

(a) comply with recommended self-care regimens including diet, insulin injection methods, treatment of hypoglycaemia, self-monitoring of diabetic control, foot care and the use of professional resources; and

(b) develop or expand their skills for coping with the restrictions of the regimens without sacrificing quality of life.

The education programme encourages diabetics and their families to achieve ideal body weight from a balanced diet in which calories from fat, sugar and alcohol are limited to 30%, 5% and 5% respectively and complex carbohydrate (all carbohydrate except sucrose, glucose or honey) constitutes at least 45%. Diabetics are also recommended to space their complex carbohydrate consumption throughout the day and to vary it minimally from day to day.

The education programme* consists of six group sessions held on four evenings and two full days over five weeks (30 hours). Follow-up sessions are held one month and, as nearly as possible, six months later. A team comprising a diabetes physician, clinical psychologist, nutritionist, nurse educator, secretary and clerk, work with groups of 8–12 diabetics who are asked to bring with them a family member or close friend, henceforth referred to as a family member. The programme is held in a non-institutional atmosphere in a cottage within the hospital precinct. The education process is non-didactic and is based on group learning in a relaxed, informal setting.

At initial sessions diabetics and their family members are assessed on their knowledge, current diet, weight and biochemical status as measured by questionnaires, a four-day self-kept food record, blood tests, etc. The results are used in subsequent sessions as the basic data upon which recommendations for change are built. For example, a computerised analysis of each participant's food record is provided together with recommendations for change, and if any significant dietary problem is identified, a list of associated health risks is included.[2] Specific diet sheets or food plans are not given. However, food composition tables[3] and a carbohydrate portion counting manual[4] are supplied. With these, participants are encouraged to acquire sufficient knowledge of food composition and skill in selecting food to suit their personal preference and to achieve the recommended dietary goals.

Participants are encouraged to discuss their reactions to the results of their assessments, their perceptions of susceptibility to health risks and difficulties with implementing the recommendations for change in their home, work or social environments. Following such discussion, simulated problems and exercises relevant to the needs of each group allow for practise. Information about diabetes is provided within the context of problem-solving so that didactic teaching, unrelated to the needs of the group, is minimised. In final sessions, diabetics and family members are assisted to formulate contracts for achievable, measurable goals. These form the basis for the one-month and six-month follow-up review sessions.

Throughout the assessments and the programme, the participation of family members is encouraged as a means of ongoing support to the diabetic and to encourage relevant dietary behaviour changes in the entire family.

Due to the terms of reference of the programme's establishment, it is entirely focused upon aspects of diabetes other than the manipulation of insulin dosage.

The Study Population

The sample frame comprised 183 insulin dependent diabetics who enrolled in the education programme between 1 January 1978 and 31 December 1979. Of these, 36 persons were excluded because they were under 18 years of age and seven others were excluded because they spoke little English, could not read, had been diagnosed as diabetic only during the last 8 weeks or were unwilling to participate in the study. Data were collected from all 140 remaining subjects at the commencement of the study. Follow-up data were obtained six months later, or as soon after six months as possible, for 108 (77% of the sample); these individuals are referred to in the following text as "returns". Diabetics were lost to follow-up due to illness, hospitalisation, migration or inability or unwillingness to participate in further assessment; they are referred to as "non-returns". Only four diabetics dropped out during the five-week education programme; they have been included in the "non-returns".

Measurements

Initially, demographic characteristics and diabetic treatment details were obtained. Also, the following information was collected before and, where possible, six months after the programme:

(a) Food and drink intake, recorded by weight over four days—Wednesday through Saturday. Records were coded and analysed for individual nutrients and their average contribution to total calories, using packaged computer analyses. Summary scores were obtained for carbohydrate intake in relation to quantity, spacing by meals and day-to-day variation from analyses of variance. Scores were expressed as the sums of squares of differences between actual and recommended amounts and should have been near zero.
(b) Weight and height measured and expressed as a percentage of ideal weight.[5]
(c) Knowledge about diabetes, assessed by a 51 item, multiple choice questionnaire, adapted from Etzwiler.[6]
(d) Blood collected on two consecutive mornings for the following analyses; fasting plasma glucose (glucose oxidase method using Beckman Glucose Analyser), glycosylated haemoglobin (ion exchange chromatography adapted to mini-columns by Quik-Sep), serum cholesterol and triglycerides by Autoanalyser (Technicon® Method N-28). The interassay coefficients of variation for these analyses are, respectively, 0·02, 0·03, 0·04 and 0·06. For the blood glucose and glycosylated haemoglobin tests, results above 10·0 and 9·0, respectively were considered to be elevated.
(e) Current psychological dysfunction assessed using the 30 item general health questionnaire (GHQ).[7]
(f) Twenty-four hour urine glucose analyses on two consecutive days during the 4-day food record period.
(g) Health beliefs, measured by a 21 item self-administered questionnaire adapted from Sacket *et al.*[8] and Becker *et al.*[9] Standardised scores were calculated for each health belief factor.

Items (a), (b), (c) and (e) were also collected from family members attending the programme. Knowledge, glycosylated haemoglobin and the health belief questionnaire were introduced as evaluation measurements during the second year of the study (1979). The urine glucose measurement was discontinued in January 1979 because of its wide within-individual daily variation and its inferiority to glycosylated haemoglobin as a measure of diabetic control.

Compliance to other aspects of diabetic self-management, including insulin medication and urinalysis were not evaluated in this study.

*A manual giving a detailed account of the procedures and timetables used in the programme is available from the authors.

Analysis
To compare characteristics of the returns and non-returns, between group *t*-tests were used for the continuous variables and chi-square tests for the categorical variables. To compare measures before and after the programme, individual differences were analysed using single sample *t*-tests.

Results

The study subjects cannot be considered a random sample of all diabetics; their desire to participate in an education programme, their attendance at the programme and their subsequent willingness to undertake the follow-up assessments mark them out. Also, compared to the general Sydney population, a higher proportion of the study group came from the upper two social classes[10, 11] characteristic of the northern metropolitan region of Sydney where most of the group resided. Excluding the "retired—not known" data, the distribution (with Sydney population norms in brackets) was as follows: Class A, 6·2% (4·0%); Class B, 33·0% (19·1%); Class C, 48·0% (56·6%); Class D, 11·8% (20·4%). On the other hand, group means for biochemical measures indicated that, at entry to the programme, the group did not have a predominance of poorly controlled diabetes or elevated serum lipids. Group values for per cent contribution of major nutrients to total energy are given in Table 1 and these show a substantial deviation from the goals recommended by most dietitians in Australia. Diabetics were consuming excessive amounts of fat* and insufficient complex carbohydrate. As well, carbohydrate intakes tended to be erratic throughout days and between days as indicated by the mean scores for carbohydrate spacing and variation (which should have been near zero). Although the group mean for weight indicated that these diabetics were not particularly obese, 31% of them were greater than 110% of ideal weight.

At entry to the programme, diabetics had blood glucose and glycosylated haemoglobin values which were considered to be only slightly above the desirable range while mean serum cholesterol and triglycerides were well within the normal range (Table 2). The mean of the initial knowledge scores for diabetics was 32·7 out of 51, i.e. 64% of the possible correct responses.

Initially, family members were consuming diets which deviated considerably from the programme's recommendations for an optimal diet (as discussed in the methods section) and the Australian Dietary Guidelines.[12] The proportions of energy contributed by fat, sugar and alcohol exceeded the recommendations whilst complex carbohydrate intake was deficient (Table 4). As a group, they were more overweight than diabetics. Like their diabetic

*This represents total fat. Values for type of fatty acids were not available on the computer data bank used to analyse our dietary data.

TABLE 1
Changes in dietary compliance in 108 diabetics—means before and after an education programme and mean differences

	Before	After	Mean difference ± standard error	Significance level
I. Per cent of "Ideal" weight ($n = 108$)	105·03	104·93	−0·10 ± 0·57	n.s.
II. Dietary balance (per cent of calories) ($n = 108$)				
Protein	16·21	16·02	−0·19 ± 0·23	n.s.
Fat	40·91	36·57	−4·33 ± 0·76	$p < 0·001$
Complex carbohydrate	36·87	41·92	5·05 ± 0·76	$p < 0·001$
Sugar	3·56	3·81	0·25 ± 0·32	n.s.
Alcohol	3·61	3·43	−0·19 ± 0·37	n.s.
III. Carbohydrate compliance* ($n = 106$)				
Quantity†	0·892	0·723	0·169 ± 0·067	$p < 0·02$
Spacing†	0·451	0·415	0·036 ± 0·034	n.s.
Variation†	0·266	0·269	−0·003 ± 0·021	n.s.

*Two diabetics were omitted from this analysis having completed only 3 days of the food record.
†Sums of squares of differences between the logarithms of the actual and recommended amounts.

TABLE 2

Comparison of biochemical status for diabetics—means before and after an education programme and mean differences

	n	Before	After	Mean difference ± standard error	Significance level
Fasting blood glucose (mmol/*l*)	95*	10·39	9·57	−0·81 ± 0·45	$p < 0·1$
24-hour urine glucose (mmol/24 hours)	34†	73·82	70·55	−3·26 ± 18·26	n.s.
Haemoglobin A_1C (%)	48‡	9·01	8·61	−0·40 ± 0·25	n.s.
Serum cholesterol (mmol/*l*)	95*	5·24	5·06	−0·18 ± 0·09	$p < 0·1$
Serum triglycerides (mmol/*l*)	95*	1·76	2·02	0·26 ± 0·07	$p < 0·001$

*13 diabetics did not have fasting blood tests.
†Measurement discontinued after 12 months due to its unreliability.
‡Measurement initiated in March 1979.

TABLE 3

Comparison of knowledge and health belief scores for diabetics—means before and after an education programme and mean differences

	*n**	Before	After	Mean difference ± standard error	Significance level
I. Knowledge score	62	32·74	39·96	7·22 ± 0·68	$p < 0·001$
II. Health beliefs					
(i) perceived susceptibility to complications of diabetes	53†	0·278	0·336	0·058 ± 0·016	$p < 0·001$
(ii) concern about complications	53	0·478	0·528	0·050 ± 0·026	n.s.
(iii) perceived susceptibility to other health problems	53	0·168	0·165	−0·003 ± 0·013	n.s.
(iv) concern about other health problems	53	0·230	0·249	0·019 ± 0·020	n.s.
(v) perceived interference of lifestyle by diabetes	57	0·215	0·184	−0·031 ± 0·018	n.s.
(vi) perceived barriers to dietary compliance	57	0·261	0·219	−0·042 ± 0·017	$p < 0·05$
(vii) perceived efficacy of diet to improve health	57	0·646	0·754	0·109 ± 0·129	$p < 0·001$

*The questionnaires for knowledge and health beliefs were introduced in November 1978.
†Four diabetics failed to complete part of the health belief questionnaire.

relatives, the mean initial score for family members was low, i.e. 54% of the possible correct responses.

Analyses of differences between baseline measures for the diabetic returns and non-returns showed that those not returning tended to be younger and somewhat more likely to reside outside Sydney. They had significantly poorer scores for measures of carbohydrate compliance (quantity, spacing and variation), they perceived themselves as more susceptible to the complications of diabetes and had a higher mean score for barriers to dietary compliance. In other respects (sex, duration of diabetes, social class, referral source, hospitalisation during the last year, previous dietary advice or previous involvement in an educational programme) the two groups were similar. There was also no difference found in level of knowledge about diabetes, biochemical markers or in weight status between the two groups.

Comparing the diabetics before and after the education programme, dietary composition improved significantly due to an increase in complex carbohydrate consumption and a decrease in fat intake, as shown in Table 1. However, little change in carbohydrate spacing or variation, or per cent of ideal weight was noted among the diabetics. There were slight but not significant reductions in blood glucose, glycosylated haemoglobin and serum cholesterol (Table 2). A statistically significant increase in serum triglycerides was observed at the follow-up assessment. This was an unexpected finding, in view of the reduction in fat intake. We investigated whether this rise was related to changes in weight, blood glucose or intakes of alcohol, carbohydrate or fat. Although we found no evidence of any such associations, our inability to assess change in the polyunsaturated fatty acid ratio in the diet leaves the clinical assessment incomplete. In view of this unexpected result, particular attention was paid to details of collection, storage and transport of the samples, and discussions were held with the Director of the Lipid Research Laboratories at St. Vincent's Hospital about methodology and quality control. While no evidence of change in technique was apparent and while quality control sera appeared to give reproducible results throughout the period, there was an upward drift in the pre-intervention triglyceride values during the study period (Fig. 1). The median of pre-intervention triglycerides measured after 1978 was significantly higher than that of measures made during 1978 ($\chi^2 = 23 \cdot 24\ p < 0 \cdot 001$). After January, 1979, the upward drift appeared to stabilise and thereafter, no significant difference was found between pre-intervention and post-intervention triglyceride values ($\chi_1^2 = 0{:}0,\ p = 1 \cdot 0$), using the median test.

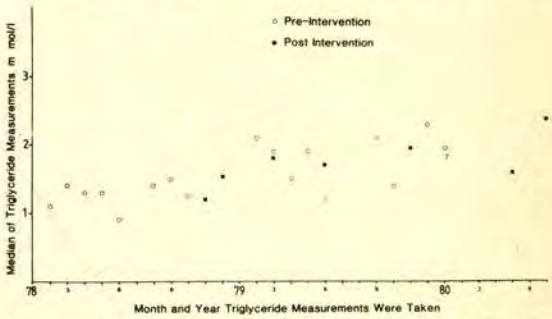

FIGURE 1. Fasting Serum Triglyceride measurements on 140 Diabetics before and after an Education Programme.

LEGEND Median values of each batch of triglyceride measurements shown against date of determination. Circles represent medians of pre-intervention sera, squares, post-intervention sera.

A comparison of the knowledge and health belief scores for diabetics before and after the programme is shown in Table 3. A considerable improvement in knowledge and slight but statistically significant changes in three of the seven health beliefs occurred. Perceived susceptibility to the complications of diabetes increased as did perceived efficacy of the dietary regimen, while the score for perceived barriers to dietary compliance decreased.

The family members who attended the programme made significant improvements in diet, weight and knowledge (Table 4). They substantially reduced fat and sugar intake and increased complex carbohydrate consumption. Their increase in knowledge was even greater than those of their diabetic relatives. While no change was found in the weight of diabetics, a significant decrease was observed in the per cent ideal weight of family members. Of the 66 family members who returned for the six-month follow-up, only 40 (61%) completed four-day food

TABLE 4
Changes in dietary balance, weight and knowledge for 40 family members of diabetics—means before and after an education programme and mean differences

	n	Before	After	Mean difference ± standard error	Significance level
I. Per cent "Ideal" weight	40	110·53	107·88	−2·65±0·96	$p<0·01$
II. Dietary balance (per cent of calories)	40				
Protein		14·27	15·50	1·23±0·48	$p<0·02$
Fat		39·50	35·72	−3·78±1·12	$p<0·001$
Complex carbohydrate		33·40	39·20	5·70±1·30	$p<0·001$
Sugar		9·15	6·95	−2·20±0·85	$p<0·01$
Alcohol		4·38	4·12	0·25±0·57	n.s.
III. Knowledge score	29*	27·44	38·51	11·06±0·98	$p<0·001$

*Initial scores were not available for 11 family members who returned for follow-up because the knowledge questionnaire was introduced later in 1978.

records so the impressive changes noted may represent unusually high compliance in this group.

Discussion

After attending the education programme, adult insulin-dependent diabetics showed significant improvements in knowledge, dietary composition and health beliefs. As well, family members made large improvements in knowledge, fat and carbohydrate intake, and weight status. No significant changes were observed in the diabetic group in measures of glucose control, weight, serum cholesterol, or carbohydrate spacing or variation, although mean values indicated that the group was near ideal weight, in reasonable diabetic control and had a relatively low serum cholesterol before and after the programme. Serum triglyceride increased significantly after the programme, although the increase appeared to be a general rise in measured values over time, rather than an outcome of the programme.

While significant changes for the group did not occur in weight or glucose control, it is helpful to consider the proportion of the group who made clinically important changes in these parameters. At the six-month follow-up assessment, over half (52%) of the diabetics were considered to have complied with the programme's weight recommendations, including overweight diabetics who reduced weight by at least 5% of "ideal" and slim diabetics who maintained their weight within the "ideal" range. Of the 58 diabetics who were initially recommended to reduce weight, 16 (36%) complied with these recommendations.

Two-thirds of the diabetics had acceptable blood glucose values (below 10·0 mmol/*l*) at the follow-up assessment. For the subgroup on whom glycosylated haemoglobins were available, two-thirds were considered to be in good control (values less than 9%) before, as well as after, the programme. While the changes in biochemical measurements were in the desired direction and may have been a clinically significant improvement, they were not statistically significant.

The reduction in fat and increase in complex carbohydrate intake is encouraging in light of the current debate about high carbohydrate diets for diabetics.[13] Simpson *et al.*[14] have recently demonstrated the efficacy of a diet containing 60% carbohydrate in improving diabetic control but have questioned the long-term acceptability of such a diet. Our programme's recommendation of at least 45% complex carbohydrate is likely to be a substantial departure from the composition of the average Australian diet[15], yet the results indicate that these goals are achievable both by diabetics and non-diabetics. Thus, the educational strategies used in this programme may have a wider application, for example, in promoting the new Dietary Goals for Australians[12] to the general community.

It is difficult to assess the validity of the self-kept records. Some individuals may have under or over reported food and drink intakes.

Estimates of sugar and alcohol intake may be particularly suspect because sources of these are easy to identify, but it is harder to "fudge" food records to indicate that the goals of 30% fat, 45% complex carbohydrate and 12% protein are being met. Positive changes in these variables remind us of the validity of our evidence of dietary compliance. Nevertheless, in our ongoing evaluations, we are comparing protein consumption estimated from food records with that calculated from 24 hour urinary urea.[16]

The relationship between health beliefs and compliance behaviour has been well documented in previous studies.[17] However, little research has been carried out to evaluate the effects of an educational programme which seeks to modify these beliefs. As far as we know, this is one of the first investigations documenting simultaneous changes in both health beliefs and behaviour.

The increases in perceived susceptibility to the complications of diabetes and perceived efficacy of the dietary regimen are consistent with the programme's emphasis on personal vulnerability to ill-health and the dietary regimen as a method of prevention. The reduction in perceived barriers to dietary compliance may have been due to increased patient satisfaction with the flexibility in food selection offered by the recommended dietary regimen or from learning to cope with the restrictions of the diet. Alternatively, it is possible that the changes in health belief scores reflected an increase in knowledge of complications of diabetes and a desire to please the team by giving complimentary responses, although the likelihood of this explanation is difficult to assess.

The potential value of the changes in health beliefs observed in this study is that they may contribute to changes in behaviour or that changes in beliefs and behaviour may act to reinforce one another. We will address the question of dietary compliance behaviour of these diabetics in relation to health beliefs, sociodemographic characteristics and health status in another paper.

While the programme was successful in achieving some goals in the areas of knowledge, attitudes and dietary behaviour, considerable revision may be required to achieve biochemical and weight goals. For example, the failure of the programme to assist the majority of overweight diabetics to reduce weight or to improve the biochemical status of those with initially high glucose values, indicates important areas for further development. However, because insulin dosage and medical management was not under control of the team, our expectations with regard to biochemical outcomes were limited.

It is unfortunate that the upward trend in the pre-intervention triglyceride values during the initial phases of the study makes any reliable conclusions about this parameter impossible. Secular variation in the population statistics, unidentifiable variation in laboratory or collection methods must all be considered possible. Further study will be needed to enable any conclusions to be drawn about the impact of the education programme on triglycerides.

So far, we have evaluated our programme using a "before and after" approach with no control group. It is possible that by simply contacting and assessing clients and providing no educational intervention, we might have achieved successes of the same order. To investigate this further, we are conducting a randomised trial which compares changes in outcome measures at 3 months after contacting the centre and undertaking the initial assessments (including keeping food records) with those which occur 3 months after participation in the full programme.

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Serum Myoglobin, Creatine Kinase and Creatine Kinase-MB as Mutually Supportive Indices of Myocardial Infarction and Infarct Size*

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Abstract: Serum myoglobin, creatine kinase and creatine kinase-MB as mutually supportive indices of myocardial infarction and infarct size*. R. N. Johnson, W. F. Lubbe, C. J. Mercer, N. L. Sammel and R. M. Norris, *Aust. N.Z. J. Med.*, 1982, **12**, pp. 160–165.

A comparison was made between the appearance of serum myoglobin and creatine kinase in 22 patients with acute myocardial infarction who were admitted to a coronary-care unit within four hours of onset of chest pain. The MB isoenzyme of creatine kinase was measured in 12 patients. The more rapid appearance and disappearance of myoglobin relative to creatine kinase and creatine kinase-MB was confirmed, as was the correspondence between their respective peak values. A significant correlation was also obtained between the area under the myoglobin time-course and the respective peak levels. Whereas creatine kinase activity declined exponentially from a single peak, myoglobin appeared in multiple episodes inadequately represented by a single peak value and having no clear clinical correlation. The role of myoglobin as a diagnostic aid in myocardial infarction is probably limited to its ability to support creatine kinase and creatine kinase-MB as indices of infarct size.

Key Words: Myoglobin—Creatine kinase—Myocardial infarction.

A raised concentration of myoglobin in serum[1–5] and urine [6] has been found to be associated with myocardial infarction. It seems probable that the serum value is the more informative in view of the finding that only a small proportion of the serum myoglobin content is detectable in urine.[3–5] Serum myoglobin concentration is frequently elevated before a rise in the activity of creatine kinase (CK) can be detected[4, 7, 8] and is

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SECTION 4.3

PRE/POST STUDY

RESULTS OF RESEARCH QUESTIONS CONCERNING

DIETARY COMPLIANCE OF DIABETICS

A. Compliance Rates Before and After an Education Programme

Contingency Tables 4.5A through 4.5E show the percentage of the "returns" who met the programme's dietary and weight goals at entry to the programme and six months afterwards. A statistically significant improvement was observed over the study period in the proportions of subjects who met the goals for carbohydrate and fat composition (Tables 4.5A and 4.5B). Initially, only 14% of these subjects had intakes of at least 45% complex carbohydrate but at follow-up, nearly 40% had reached this goal. Less than 10% met the goal for fat composition at the baseline assessment, but 21% did so after the programme. Although many subjects did not achieve these goals, a considerable proportion of subjects made substantial changes in the desired direction for carbohydrate and fat intakes over the study period. A reduction of greater than 10% in total energy from fat was made by 20% of subjects, although they did not reach the goal. An increase of similar magnitude in complex carbohydrate intake was made by 30% of those who did not achieve the goal. Changes in an undesired direction occurred for less than 5% of subjects in carbohydrate and fat composition.

Approximately one-third of subjects met the goals for carbohydrate spacing and variation both before and after the education programme (Table 4.5C and 4.5D). No significant changes occurred in the proportion of subjects who met these goals after education, although some change was observed in both desired and

and undesired directions for a small percentage of the sample.

For weight compliance, nearly three-quarters of the subjects were within the ideal range (less than 110% of ideal) initially and remained so during the study period (Table 4.5E). Twenty-eight percent were either slightly or very overweight at the initial assessment and no change in the proportion of the sample classified as overweight occurred at the six month follow-up. However, nine of the 30 overweight subjects (i.e. 30% of the overweight group or 7% of the total sample) lost at least 5% of ideal weight, even though they did not achieve their ideal weight. A few underweight subjects were within the ideal range at the six month follow-up; most of them had experienced weight losses prior to the programme due to periods of poorly controlled diabetes. Undesired weight gains occurred during the study period for 9% of subjects who were initially within the ideal range. None of the overweight subjects had gained weight (in amounts equivalent to at least 5% of their ideal) at the six month follow-up.

For the analysis of associations between compliance and other variables, individuals were classified into one of the four compliance groups depending on whether or not they met the criteria for each type of dietary compliance before and after the education programme. The numbers of the sample classified into each compliance group, that is, 1) compliers-compliers (CC); 2) compliers-non-compliers (CN); 3) non-compliers-compliers (NC); 4) non-compliers-non-compliers (NN), are given in Table 4.6 and are depicted in figures 4.2a through to 4.2e for each of the types of compliance.

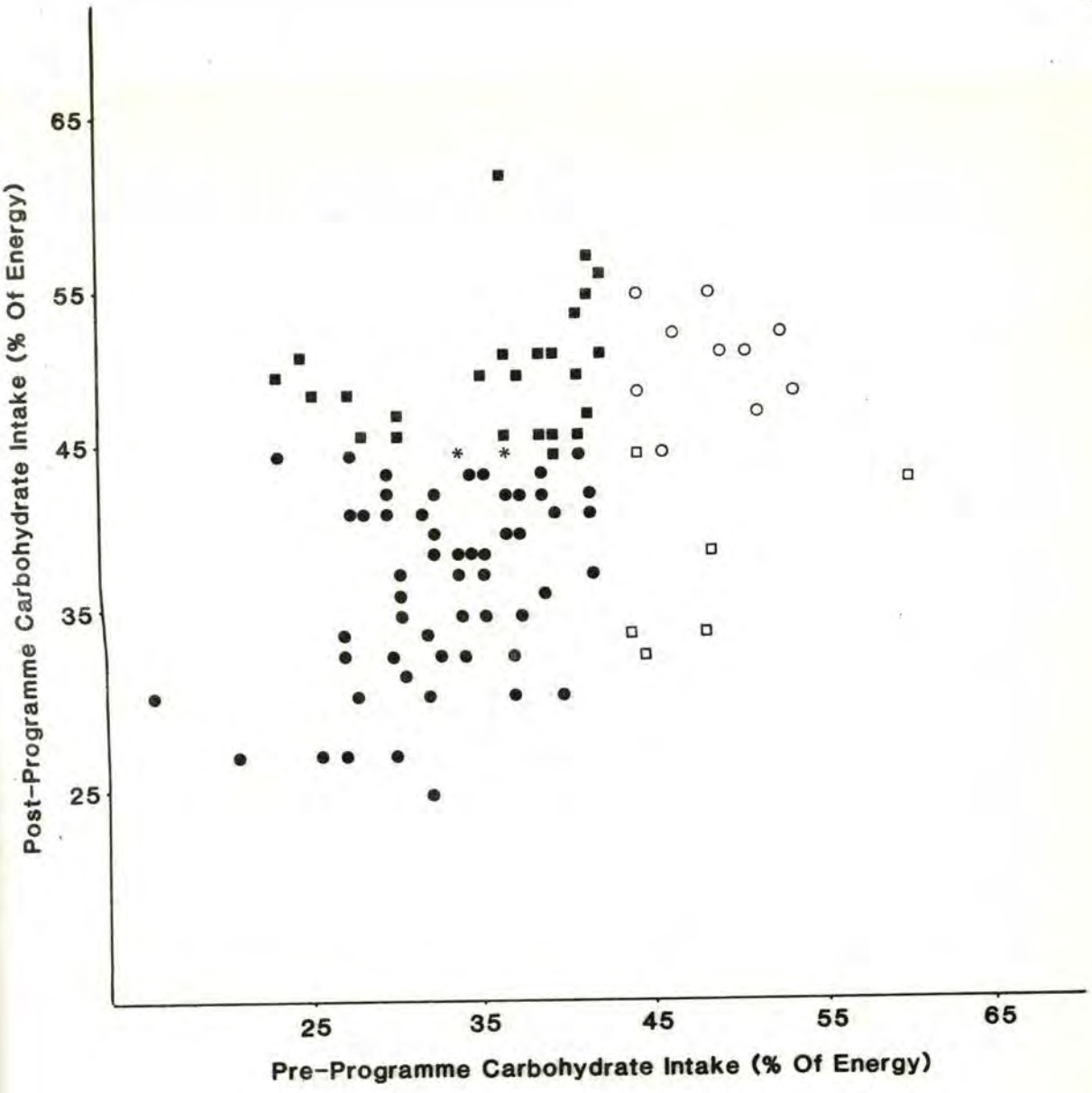
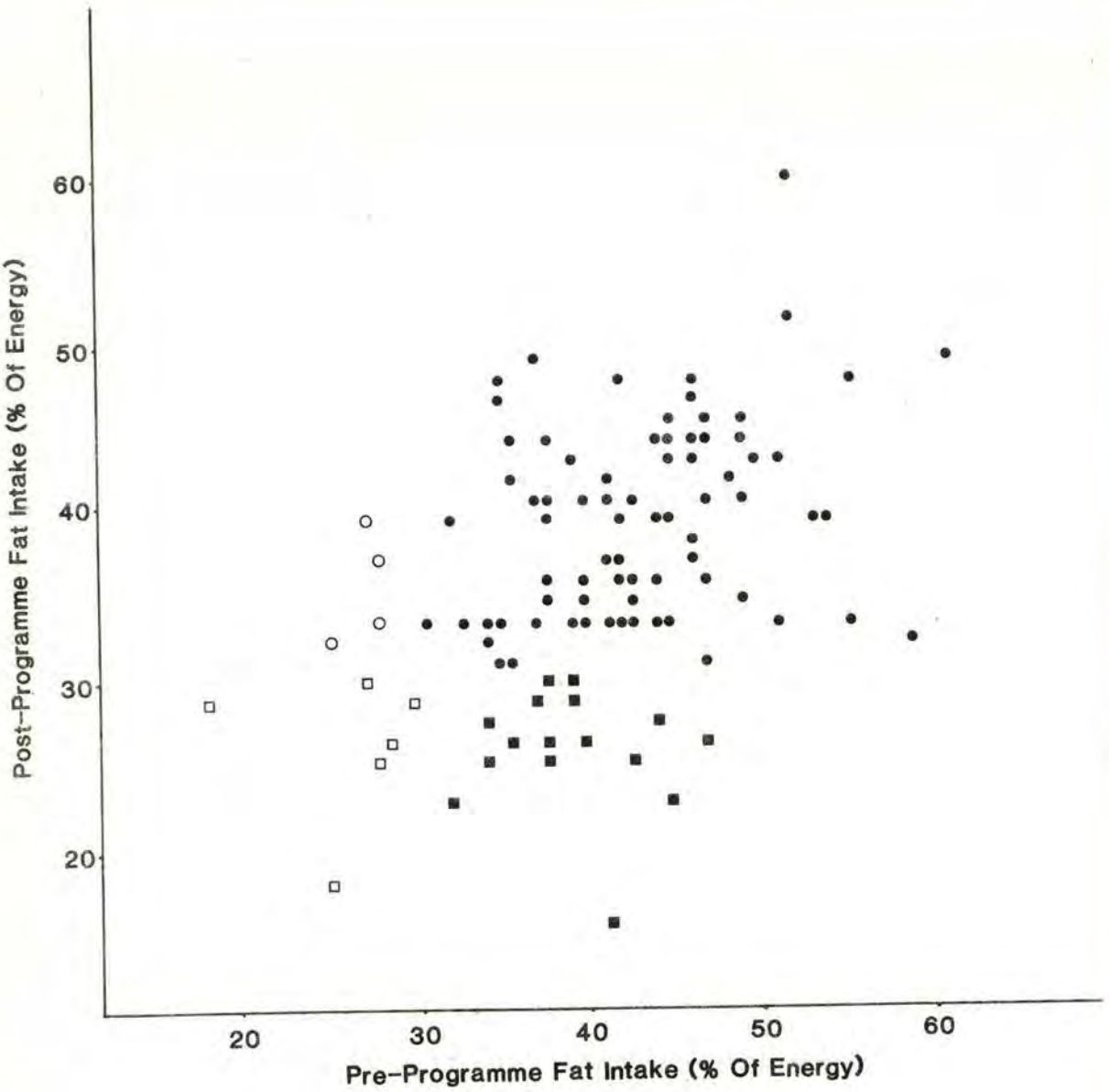


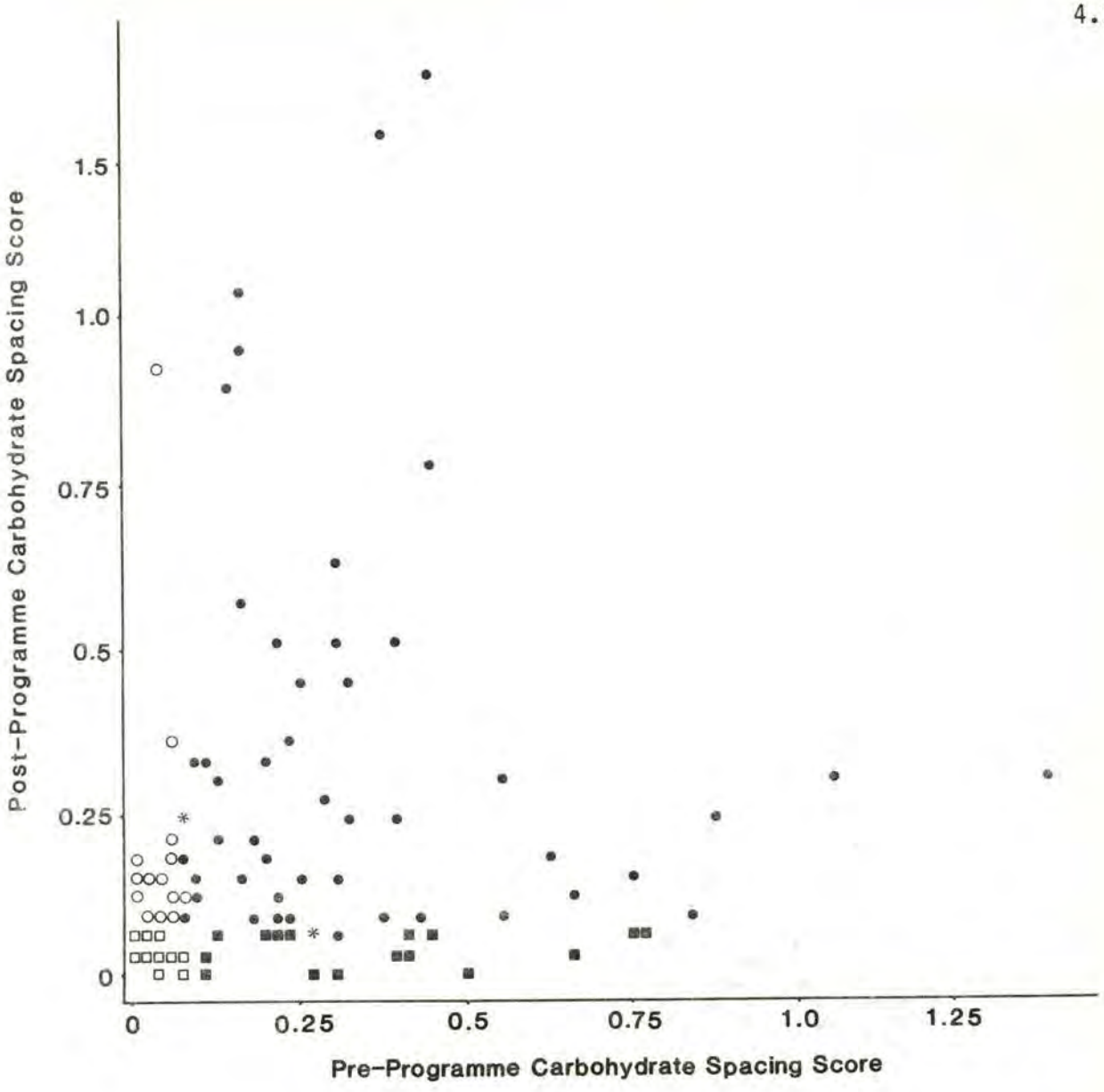
FIGURE 4.2.a Compliance with recommendations for complex carbohydrate intake (greater than or equal to 45% of energy) assessed before and six months after an education programme for insulin-dependent diabetics. (pre/post study)



LEGEND:

- ● Non-Compliers Before And After The Programme
- ■ Non-Compliers Before And Compliers Afterwards
- ○ Compliers Before And Afterwards
- □ Compliers Before And Non-Compliers Afterwards

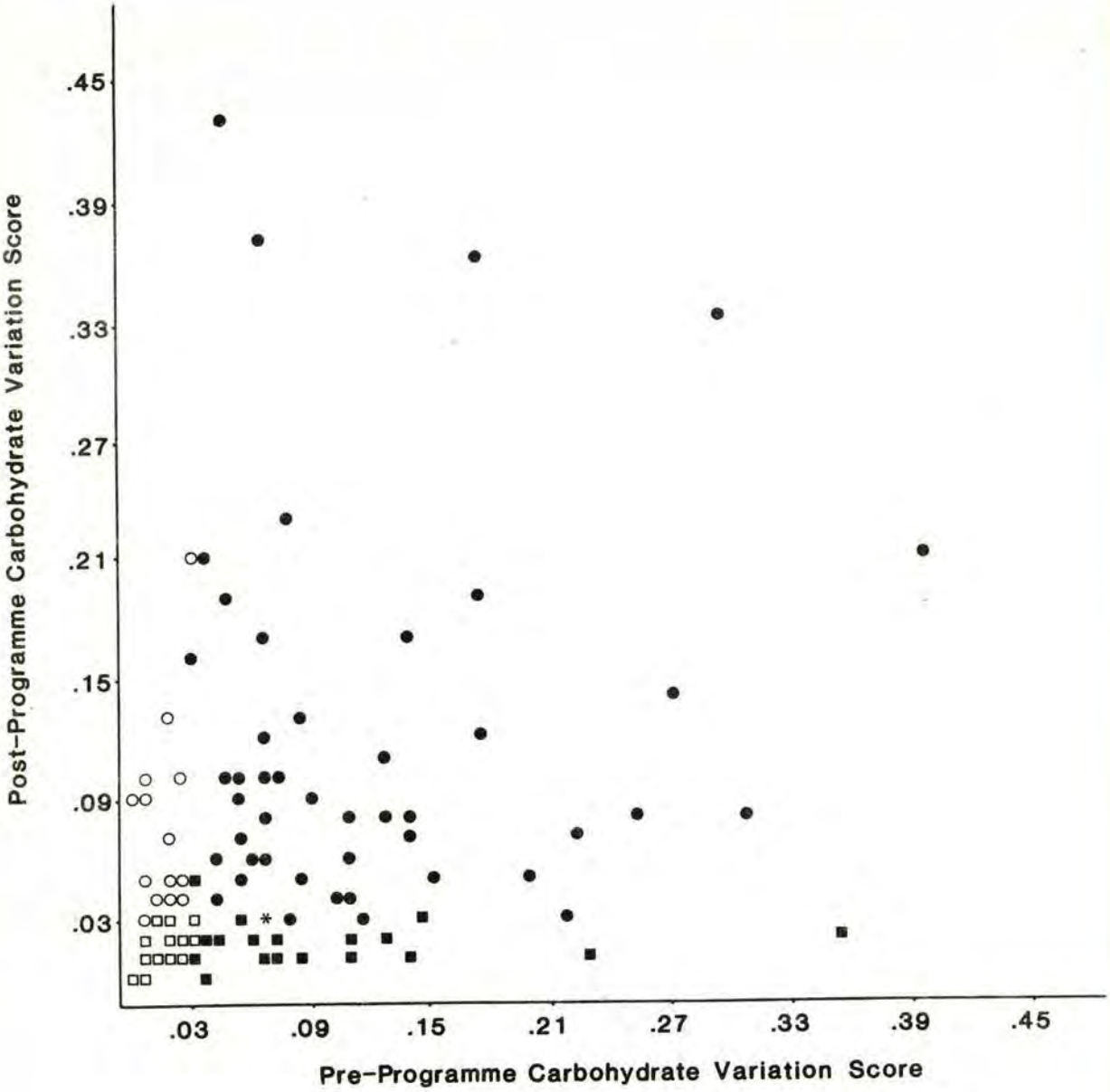
FIGURE 4.2.b Compliance with recommendations for fat intake (less than or equal to 30% of energy) assessed before and six months after an education programme for insulin-dependent diabetics. (pre/post study)



LEGEND:

- ● Non-Compliers Before And After The Programme
- ■ Non-Compliers Before And Compliers Afterwards
- ○ Compliers Before And Afterwards
- □ Compliers Before And Non-Compliers Afterwards

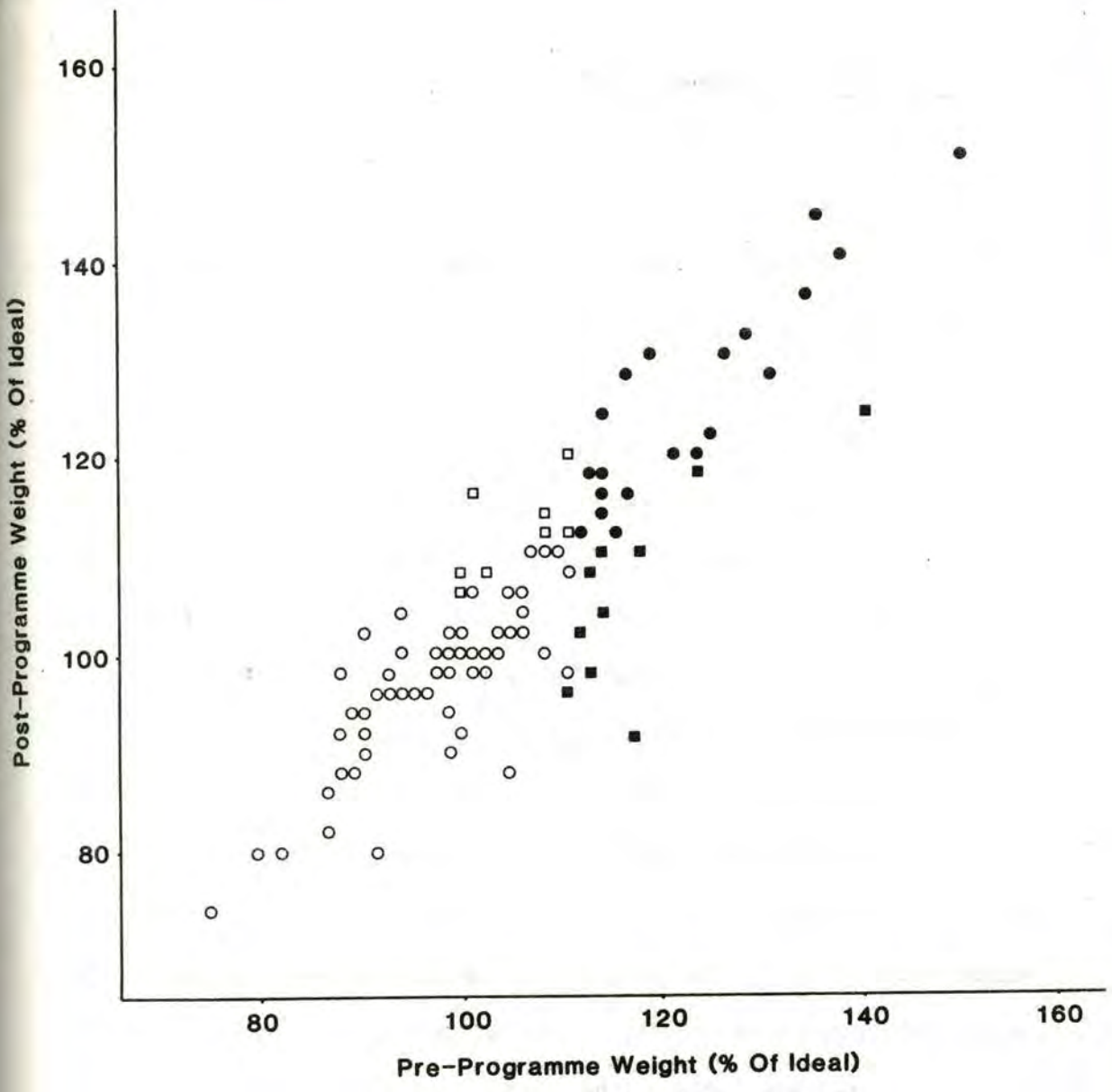
FIGURE 4.2.c Compliance with recommendations for carbohydrate spacing (scores less than .07) assessed before and six months after an education programme for insulin-dependent diabetics. (pre/post study)



LEGEND:

- ● Non-Compliers Before And After The Programme
- ■ Non-Compliers Before And Compliers Afterwards
- ○ Compliers Before And Afterwards
- □ Compliers Before And Non-Compliers Afterwards

FIGURE 4.2.d Compliance with recommendations for carbohydrate variation (scores less than .03) assessed before and six months after an education programme for insulin-dependent diabetics. (pre/post study)



LEGEND:

- ● Non-Compliers Before And After The Programme
- ■ Non-Compliers Before And Compliers Afterwards
- ○ Compliers Before And Afterwards
- □ Compliers Before And Non-Compliers Afterwards

FIGURE 4.2.e Compliance with recommendations for weight, assessed before and six months after an education programme for insulin-dependent diabetics. (pre/post study)

B. Associations Between Four Types of Dietary Compliance

As shown in Tables 4.7A through 4.7C, compliance with weight recommendations was unrelated to compliance with other aspects of dietary compliance. Similarly, compliance with carbohydrate spacing was not (significantly) associated with variation compliance (Table 4.7F). However, carbohydrate spacing and variation compliances were significantly associated with carbohydrate composition compliance although the associations were was not straight-forward (Tables 4.7D and 4.7E). Individuals who were non-compliant both before and after the programme (NN) with spacing and variation recommendations were more likely to also be non-compliant with carbohydrate composition at both assessments. However, subjects who were classified as compliers (CC) with spacing or variation compliance were not necessarily compliant with carbohydrate composition. Similarly, improvement in compliance (NC) in carbohydrate composition was not associated with improvements in spacing or variation compliance.

Associations between the four types of compliance were also analysed using only the measurements made at the six month follow-up assessment. Similar results were obtained, that is, statistically significant associations were observed only between (a) carbohydrate composition compliance with spacing compliance and (b) carbohydrate composition compliance with variation compliance.

C. Predictors of Dietary Compliance

To identify characteristics measured at the initial assessment which might predict subsequent compliance with dietary recommendations, the four compliance groups (three for

carbohydrate composition) were compared on all initial variables expressed in categories. All initial measurements which were significantly associated with compliance to carbohydrate composition, spacing and variation recommendations are listed in Tables 4.8.A through 4.8.C. The discriminant functions and the reliability of predictions using the formulae to predict compliance of individuals are given in Tables 4.9.A through 4.9.C. Factors associated with weight compliance were not determined in this analysis due to the high proportion of the sample who were at ideal weight initially and remained so and the small number of overweight clients (eight) who complied with the programme's recommendation to reduce weight (NC) (Table 4.6).

As might be expected, the factors most highly associated with carbohydrate composition compliance were initial carbohydrate and fat composition (Table 4.8.A). Not surprisingly, those who met the goal for carbohydrate composition before and after the programme (CC) had a significantly higher mean intake of carbohydrate and a lower mean intake of fat (as a percentage of energy) than either the NC or NN groups. Individuals who met the carbohydrate composition goal initially and at follow-up also had a higher mean protein intake (as a percentage of energy) and lower mean values for blood glucose and glycosylated haemoglobin at the initial assessment. Non-compliers (NN) with carbohydrate composition had poorer mean scores for initial carbohydrate spacing. However, these associations were not statistically significant when adjusted for 28 comparisons.

Three variables measured at the baseline assessment were associated with carbohydrate spacing compliance; the initial

spacing score, relative body weight and initial fasting serum triglycerides (Table 4.8.B). By definition, the groups who met the goal for adequate spacing at the initial assessment (CN and CC) had much lower mean scores for spacing than those who did not meet the goal initially (NN and NC). However, initial spacing scores did not distinguish between the non-compliers likely to remain so from those likely to improve, that is between (NN and NC), or between compliers likely to remain compliant (CC) or to become non-compliers (CN). Those who were classified as non-compliers with recommended spacing at both assessments had a significantly greater mean relative body weight (clinically and statistically) than other groups. Also, the initial mean values for triglycerides differed between the four groups, the significant difference being between the CN group and the NN group. However, when adjusted for 28 comparisons, this difference was not statistically significant.

Similar to the pattern observed for other kinds of compliance, variation compliance was most highly associated with the initial variation score (Table 4.8.C). However, no sigificant differences were noted in baseline variation scores between initial non-compliers who improved from those who did not, that is between (NC and NN) and between initial compliers who became non-compliant from those who remained compliant (CN and CC). Non-compliers with variation at both assessments (NN) had a lower mean intake of carbohydrate and higher mean relative weight and variation scores than other groups.

From discriminant analyses, the only significant predictors of carbohydrate composition and variation compliance were the initial levels of carbohydrate composition and variation scores (Tables 4.9.A and 4.9.C). For spacing compliance, both the initial spacing score and relative body weight were predictive of compliance (Table 4.9.B). The reliability of the predition equations based on these variables is indicated in the tables by the percentage correctly classified, that is 62.5%, 56.7% and 46.2% for carbohydrate composition, spacing and variation compliance, respectively.

No significant associations were observed between dietary compliance and other variables measured at the initial assessment including demographic characteristics, diabetic history, knowledge, health beliefs or current psychological dysfunction. Family member's behaviour was also unrelated to dietary compliance of their diabetic relatives. Their attendance at the programme, their willingness to keep initial or follow-up food records, the composition of their diets or their success at weight reduction did not improve the likelihood of dietary compliance of the diabetics.

When discriminant analyses were applied to the subsets of diabetic subjects for whom complete data were available for knowledge, health beliefs and biochemical results, the results were similar. None of these variables entered the discriminant functions and the significant predictors were the same as when the full set of subjects were used.

D. The Relationship Between Dietary Compliance and Biochemical Goals

Contingency Tables 4.10.A through 4.10.D show the

percentages of the sample who met the programme's dietary goals and who had acceptable values for blood glucose, glycosylated haemoglobin, serum cholesterol and triglycerides at the follow-up assessment. No statistically significant associations were observed between compliance with weight, spacing or variation recommendations and any of the biochemical measurements. However, carbohydrate composition compliance was related to both measures of glycaemic control (Table 4.10 A). Those who consumed at least 45% of energy as complex carbohydrate initially and at follow-up were less likely to have elevated blood glucose or glycosylated haemoglobin values six months after the programme than non-compliers at both assessments. Those who did not meet the carbohydrate goal at entry to the programme but did so afterwards (NC) did not necessarily achieve acceptable glycaemic control; they were equally divided between "acceptable" and "elevated" categories on both blood glucose and glycosylated haemoglobin. The association between carbohydrate compliance and blood glucose was not statistically significant when adjusted for 16 comparisons.

The percentage of the sample with elevated serum cholesterol values (greater than 6.5mmol/l) was so small (5.4%) that no relationship with dietary compliance could have been detected. Thus, to check whether cholesterol was related to any of the dietary compliance measures, the proportions of the sample above and below the median cholesterol value were compared using the median test. However, still no significant associations were observed.

When the analyses of the relationships between dietary compliance and biochemical measurements were repeated using only

measures of compliance and biochemistry obtained at the six month follow-up, no significant associations were observed.

TABLE 4.5

PRE/POST STUDY

DIETARY AND WEIGHT COMPLIANCE BEFORE AND AFTER AN EDUCATION PROGRAMME FOR INSULIN-DEPENDENT DIABETICS

A. CARBOHYDRATE COMPOSITION COMPLIANCE
(at least 45% of energy from compliance carbohydrate)

n = 108

PRE-PROGRAMME[a]	POST PROGRAMME: Compliant %	Non-compliant %	Total %
Compliant	10.2	3.7	13.9
Non-compliant	28.7	58.4	87.1
TOTAL	38.9	62.1	100.0

McNemar's Statistic (X^2) = 20.83, df = 1, p = less than 0.00001***

B. FAT COMPOSITION COMPLIANCE
(limited to 30% or less of energy intake)

n = 108

PRE-PROGRAMME	POST PROGRAMME: Compliant %	Non-compliant %	Total %
Compliant[c]	5.6	3.7	9.3
Non-compliant	15.7	75.0	90.7
TOTAL	21.3	78.7	100.0

McNemar's Statistic (X^2) = 8.05, df = 1, p = 0.0046*

Table 4.5 (continued)

C. CARBOHYDRATE SPACING COMPLIANCE
(Scores less than .07)

n = 106[b]

PRE-PROGRAMME[a]	POST-PROGRAMME Compliant	Non-compliant	Total
	%	%	%
Compliant	14.2	17.9	32.1
Non-compliant	16.98	50.9	67.9
TOTAL	31.2	68.8	100.0

McNemar's Statistic (X^2) = 0.03, df = 1, p = 0.87

D. CARBOHYDRATE VARIATION COMPLIANCE
(Scores less than .03)
n = 106[b]

PRE-PROGRAMME[a]	POST-PROGRAMME Compliant	Non-compliant	Total
	%	%	%
Compliant	14.2	15.1	29.3
Non-compliant	19.8	50.9	70.7
TOTAL	34.0	66.0	100.0

McNemar's Statistic (X^2) = 0.68, df = 1, p = less than 0.41

Table 4.5 (continued)

E. MET WEIGHT GOAL[c]

n = 108

PRE-PROGRAMME[a] WEIGHT (% OF IDEAL)	POST-PROGRAMME WEIGHT (% OF IDEAL) LE 110	GT 110	Total
	%	%	%
LE 110	65.7	6.5	72.2
GT 110	6.5	21.3	27.8
TOTAL	72.2	27.8	100.0

McNemar's Statistic (X^2) = 0.00, df = 1, p = 1.00

(a) Although "compliance" is somewhat of a misnomer in describing pre-programme dietary behaviour, it is used here to distinguish those who met dietary and weight goals prior to the programme from those who did not meet the goals.

(b) Two subjects were eliminated from the analysis of spacing and variation compliance because they only completed three-day food records.

(c) This table does not show the proportions of subjects who were compliant and non-compliant with weight recommendations because weight compliance was defined as weight loss for overweight subjects and weight maintenance for others. For frequency of compliers and non-compliers see Figure 4.2.E and Table 4.6.

TABLE 4.6

PRE/POST STUDY

NUMBERS OF SUBJECTS IN EACH OF THE FOUR COMPLIANCE GROUPS

COMPLIANCE VARIABLE	COMPLIANCE GROUP[a] CC	CN	NC	NN	TOTAL
Weight[b]	68	10	9	21	108
Carbohydrate composition	11	4[b]	31	62	108
Carbohydrate spacing	15	19	18	54	106[c]
Carbohydrate variation	15	16	21	54	106[c]

(a) CC: compliler before and after the programme
CN: compliler before and non-compliler after the programme
NC: non-compliler before and compliler after the programme
NN: non-compliler before and after the programme

(b) For the analyses of associations between dietary compliance and other variables, these subjects were combined with the "CC's" because their mean carbohydrate intake at follow-up was closest to that of the CC group.

(c) One return only kept a three-day food record so was eliminated from the analyses of spacing and variation compliance.

TABLE 4.7

PRE/POST STUDY

ASSOCIATIONS BETWEEN FOUR TYPES OF DIETARY COMPLIANCE IN 108 INSULIN-DEPENDENT DIABETICS

A. THE RELATIONSHIP BETWEEN WEIGHT COMPLIANCE AND CARBOHYDRATE COMPOSITION COMPLIANCE

n = 108

WEIGHT COMPLIANCE GROUP	CARBOHYDRATE COMPOSITION COMPLIANCE GROUP			
	CC	NC	NN	TOTAL
	%	%	%	%
CC	6.5	20.4	36.1	63.0
CN	0.0	3.7	5.6	9.3
NC	1.9	2.8	3.7	8.3
NN	1.9	1.9	15.7	19.4
TOTAL	10.2	28.7	61.1	100.0

$X^2 = 7.89$, df = 6, p = 0.25

B. THE RELATIONSHIP BETWEEN WEIGHT COMPLIANCE AND CARBOHYDRATE SPACING COMPLIANCE

n = 106[(a)]

WEIGHT COMPLIANCE GROUP	SPACING COMPLIANCE GROUP				
	CC	CN	NC	NN	TOTAL
	%	%	%	%	%
CC	9.4	13.2	14.2	25.5	62.3
CN	1.9	0.0	0.9	6.6	9.4
NC	1.9	1.9	0.0	4.7	8.5
NN	0.9	2.8	1.9	14.2	19.8
TOTAL	14.2	17.9	17.0	50.9	100.0

$X^2 = 15.38$, df = 9, p = 0.08

TABLE 4.7 (continued)

C. THE RELATIONSHIP BETWEEN WEIGHT COMPLIANCE AND CARBOHYDRATE VARIATION COMPLIANCE

n = 106[a]

WEIGHT COMPLIANCE GROUP	VARIATION COMPLIANCE GROUP				
	CC	CN	NC	NN	TOTAL
	%	%	%	%	%
CC	9.4	12.3	14.2	26.4	62.3
CN	1.9	0.0	1.9	5.7	9.4
NC	0.0	0.9	1.9	5.7	8.5
NN	2.8	1.9	1.9	13.2	19.8
TOTAL	14.2	15.1	19.8	50.9	100.0

$X^2 = 11.2$, df = 9, p = 0.26

D. THE RELATIONSHIP BETWEEN CARBOHYDRATE COMPOSITION COMPLIANCE AND SPACING COMPLIANCE

n = 106[a]

CARBOHYDRATE COMPOSITION COMPLIANCE GROUP	CARBOHYDRATE SPACING COMPLIANCE GROUP				
	CC	CN	NC	NN	TOTAL
	%	%	%	%	%
CC	3.8	0.9	2.8	1.9	9.4
NC	6.6	8.5	4.7	9.4	29.2
NN	3.8	8.5	9.4	39.6	61.3
TOTAL	14.2	17.9	17.0	50.9	100.0

$X^2 = 19.8$, df = 6, p = 0.003*

* (p less than 0.05 after adjustment for six comparisons)

TABLE 4.7 (continued)

E. THE RELATIONSHIP BETWEEN CARBOHYDRATE COMPOSITION COMPLIANCE AND CARBOHYDRATE VARIATION COMPLIANCE

n = 106[(a)]

CARBOHYDRATE COMPOSITION COMPLIANCE GROUP	VARIATION COMPLIANCE GROUP				
	CC	CN	NC	NN	TOTAL
	%	%	%	%	%
CC	0.9	3.8	3.8	0.9	9.4
NC	6.6	4.7	7.5	10.4	29.2
NN	6.6	6.6	8.5	39.6	61.3
TOTAL	14.2	15.1	19.8	50.9	100.0

X^2 = 18.06, df = 6, p = 0.006*

F. THE RELATIONSHIP BETWEEN CARBOHYDRATE SPACING AND VARIATION COMPLIANCE

n = 106[(a)]

CARBOHYDRATE SPACING COMPLIANCE GROUP	VARIATION COMPLIANCE GROUP				
	CC	CN	NC	NN	TOTAL
	%	%	%	%	%
CC	2.8	3.8	4.7	2.8	14.2
NC	3.8	4.7	4.7	4.7	17.9
CN	2.8	1.9	2.8	9.4	17.0
NN	4.7	4.7	7.5	34.0	50.9
TOTAL	14.2	15.1	19.8	50.9	100.0

X^2 = 16.66, df = 9, p = 0.054

* p less than .05 after adjustment for six comparisons

(a) Two individuals were eliminated from this analysis because they completed only three-day food records.

TABLE 4.8

PRE/POST STUDY

A. BASELINE FACTORS ASSOCIATED WITH CARBOHYDRATE COMPOSITION COMPLIANCE

n = 108

COMPLIANCE GROUP

VARIABLE	NN (n = 66)	NC (n = 31)	CC (n = 11)	F[a]	df	p
	x ± sem	x ± sem	x ± sem			
PRE-PROGRAMME CARBOHYDRATE INTAKE (percent of energy)	34.64 ± 0.76	36.71 ± 1.00	50.72 ± 1.8	34.12	2 105	0.00001***
PRE-PROGRAMME FAT INTAKE (percent of energy)	42.21 ± 0.86	41.70 ± 1.15	30.82 ± 1.71	13.93	2 105	0.000001***
PRE-PROGRAMME PROTEIN INTAKE (percent of energy)	15.83 ± 0.30	16.48 ± 0.41	17.73 ± 0.76	3.18	2 105	0.045#
PRE-PROGRAMME BLOOD GLUCOSE (mmol/l) (n = 107)[b]	10.65 ± 0.58	10.87 ± 0.88	7.32 ± 0.72	3.78	2 104	0.027#
PRE-PROGRAMME GLYCOSYLATED HAEMOGLOBIN (percent of energy) (n = 55)[c]	9.0 ± 0.37	9.37 ± 0.57	7.13 ± 0.31	4.89	2[e] 38	0.013#
PRE-PROGRAMME SPACING SCORE (square root)(n = 106)[d]	0.51 ± 0.04	0.36 ± 0.05	0.37 ± 0.06	3.62	2 103	0.03#

N.B. All variables listed in Tables 4.7 are those for which statistically significant differences (at p less than .05) were observed between compliance groups. However, when the critical p values were adjusted for 28 statistical tests (according to the Bonferroni test) only the p values indicated with *'s were statistically significant.

TABLE 4.8 (continued)

\# p greater than .05 after adjustment for 28 comparisons.
*** p less than .001 after adjustment for comparisons of 28 prediction variables.

(a) Significant differences in analyses of variance were due to the following pairs:

Carbohydrate:	NN & NC, NC & CC
Fat:	NN & CC, NC & CC
Protein:	No group was significantly different after adjustment for 3 pairwise comparisons
Blood glucose:	NN & CC, NC & CC
Glycosylated haemoglobin:	NC & CC
Spacing score:	NC & CC

(b) One subject did not have a fasting blood test.

(c) 53 subjects did not have an initial test for glycosylated haemoglobin because it was only introduced during the second year of the study.

(d) 2 subjects were eliminated from the analysis of spacing compliance because they kept only three-day food records.

(e) Welch's F, p and df values were reported because the variances between groups were significantly different (Levenes' test).

TABLE 4.8 (continued)

B. BASELINE FACTORS ASSOCIATED WITH CARBOHYDRATE SPACING COMPLIANCE
(n = 106[a])

VARIABLE	COMPLIANCE GROUP NN (n = 54)	NC (n = 18)	CN (n = 19)	CC (n = 15)	F[b]	df	p
	x ± sem	x ± sem	x ± sem	x ± sem			
PRE-PROGRAMME SPACING SCORE (square root)	0.56 ± 0.03	0.64 ± 0.07	0.17 ± 0.02	0.17 ± 0.02	37.07	3 102	0.00001***
PRE-PROGRAMME WEIGHT (percent of Ideal)	110.5 ± 1.92	98.11 ± 2.19	102.16 ± 2.48	100.27 ± 2.93	7.41[c]	3 40	0.0005*
PRE-PROGRAMME TRIGLYCERIDES (log_{10})	0.24 ± 0.03	0.18 ± 0.04	0.08 ± 0.05	0.12 ± 0.04	3.82	3 102	0.01#
AGE (years)	47.24 ± 2.12	36.89 ± 2.62	41.16 ± 3.62	38.73 ± 3.99	2.96	3	0.035#

After adjustment for 28 predictor variables

* p less than .05

*** p less than .001

\# p greater than .05 after adjustment for 28 comparisons

(a) Significant differences in analyses of variance were due to the following pairs:
Spacing score: NN & CC, NN & CN, NC & CC
Weight: NN & NC, NN & CC
Triglycerides: NN & CN
Age: NN & NC

(b) 2 subjects were eliminated from the analysis of spacing compliance because they only kept three-day food records

(c) Welch's F, p and df values were reported because the variances between groups were significantly different.

TABLE 4.8 (continued)

C. BASELINE FACTORS ASSOCIATED WITH CARBOHYDRATE VARIATION COMPLIANCE
(n = 106[a])

VARIABLE	COMPLIANCE GROUP NN (n = 54) x ± sem	NC (n = 21) x ± sem	CN (n = 16) x ± sem	CC (n = 15) x ± sem	F[b]	df	p
PRE-PROGRAMME VARIATION SCORE (square root)	0.34 ± 0.02	0.30 ± 0.02	0.11 ± 0.01	0.11 ± 0.01	45.79[c]	3 47	0.00001***
PRE-PROGRAMME CARBOHYDRATE INTAKE (percent of energy)	34.1 ± 0.89	39.4 ± 1.41	39.9 ± 1.92	38.1 ± 1.70	5.35	3 102	0.001*
PRE-PROGRAMME WEIGHT (percent of Ideal)	109.14 ± 1.82	101.3 ± 2.8	98.7 ± 3.62	104.1 ± 2.53	3.55	3 105	0.017
PRE-PROGRAMME SPACING SCORE (square root)	0.53 ± 0.04	0.39 ± 0.05	0.34 ± 0.06	0.37 ± 0.07	3.34	3 102	0.022#

After adjustment for 28 predictor variables

* p less than .05

*** p less than .001

\# p greater than .05 after adjustment for 28 comparisons

(a) 2 subjects were eliminated from the analysis of carbohydrate variation compliance because they only kept three-day food records.

(b) Significant differences in analyses of variance were due to the following pairs:
Variation score: NN & CN, NN & CC
Carbohydrate: NN & NC, NN & CN
Weight: NN & CN
Spacing score: NN & CN

(c) Welch's F, p and df values were reported because the variances between groups were significantly different.

TABLE 4.9

PRE/POST STUDY

CLASSIFICATION MATRIX AND DISCRIMINANT FUNCTIONS FOR DIETARY COMPLIANCE

A. CARBOHYDRATE COMPOSITION COMPLIANCE (n = 104)[a]

MEASURED COMPLIANCE	PREDICTED COMPLIANCE[b] NN	NC	CC	PERCENT CORRECT
NN	35	23	5	55.6
NC	9	20	2	64.5
CC	0	0	10	100.0
TOTAL	44	43	17	62.5%

(a) 4 subjects had missing data for predictor variables.

(b) Based on the jacknifed classification using pre-programme carbohydrate composition as the only predictor, individuals were classified into categories with largest Z value derived from the following equations -

Z_{NN} = -18.83 + 1.02 x pre-programme carbohydrate composition

Z_{NC} = -20.99 + 1.08 x pre-programme carbohydrate composition

Z_{CC} = -36.82 + 1.45 x pre-programme carbohydrate composition

TABLE 4.9 (continued)

B. CARBOHYDRATE SPACING COMPLIANCE
(n = 104)[a]

MEASURED COMPLIANCE	PREDICTED COMPLIANCE[b] NN	NC	CN	CC	PERCENT CORRECT
NN	30	15	6	2	56.6
NC	3	11	0	3	64.7
CN	0	0	9	10	47.4
CC	0	0	6	9	60.0
TOTAL	33	26	21	24	56.7%

(a) 4 subjects had missing data for predictor variables.

(b) Based on the jacknifed classification using pre-programme spacing score and initial percent ideal weight as predictors, individuals were classified into categories with largest Z value derived from the following equations -

$$Z_{NN} = -43.99 + -4.33 \times \text{pre-programme spacing score} + 0.75 \times \text{pre-programme percent ideal weight}$$

$$Z_{NC} = -35.21 + -7.03 \times \text{pre-programme spacing score} + 0.65 \times \text{pre-programme percent ideal weight}$$

$$Z_{CN} = -38.38 + -4.11 \times \text{pre-programme spacing score} + 0.73 \times \text{pre-programme percent ideal weight}$$

$$Z_{CC} = -37.03 + -4.07 \times \text{pre-programme spacing score} + 0.72 \times \text{pre-programme percent ideal weight}$$

TABLE 4.9 (continued)

C. CARBOHYDRATE VARIATION COMPLIANCE
(n = 104)[a]

MEASURED COMPLIANCE	PREDICTED COMPLIANCE[a] NN	NC	CN	CC	PERCENT CORRECT
NN	25	22	0	5	48.1
NC	8	8	0	5	38.1
CN	0	0	7	9	43.8
CC	0	0	7	8	53.3
TOTAL	33	30	14	27	46.2%

(a) 4 subjects had missing data for predictor variables.

(b) Based on the jacknifed classification using pre-programme variation score as the predictor, individuals were classified into categories with largest Z value derived from the following equations -

Z_{NN} = -5.12 + 21.70 x pre-programme variation score

Z_{NC} = -4.24 + 18.99 x pre-programme variation score

Z_{CN} = -1.78 + 7.05 x pre-programme variation score

Z_{CC} = -1.82 + 7.41 x pre-programme variation score

TABLE 4.10.A

PRE/POST STUDY

RELATIONSHIP BETWEEN CARBOHYDRATE COMPOSITION COMPLIANCE AND BIOCHEMICAL VARIABLES MEASURED SIX MONTHS AFTER AN EDUCATION PROGRAMME FOR INSULIN-DEPENDENT DIABETICS

1. RELATIONSHIP BETWEEN CARBOHYDRATE COMPOSITION COMPLIANCE AND FASTING BLOOD GLUCOSE

	CARBOHYDRATE COMPOSITION COMPLIANCE GROUP n = 96[a]			
POST-PROGRAMME BLOOD GLUCOSE (mmol/l)	CC n = 11 %	NC n = 27 %	NN n = 58 %	TOTAL %
LT 10.0	90.9	44.4	67.2	63.5
GE 10.0	9.1	55.6	32.8	36.5
TOTAL	100.0	100.0	100.0	100.0

$X^2 = 8.15$, df = 2, p = 0.017#

2. RELATIONSHIP BETWEEN CARBOHYDRATE COMPLIANCE AND GLYCOSYLATED HAEMOGLOBIN

	CARBOHYDRATE COMPOSITION COMPLIANCE GROUP n = 95[a]			
POST-PROGRAMME GLYCOSYLATED HAEMOGLOBIN (%)	CC n = 10 %	NC n = 27 %	NN n = 58 %	TOTAL %
LT 9.0	100.0	55.6	56.9	61.1
GE 9.0	0.0	44.4	43.1	38.9
TOTAL	100.0	100.0	100.0	100.0

$X^2 = 7.14$, df = 2, p = 0.0028*

p greater than .05 when adjusted for 16 comparisons

* p less than .05

TABLE 4.10.A (continued)

3. RELATIONSHIP BETWEEN CARBOHYDRATE COMPOSITION COMPLIANCE AND SERUM CHOLESTEROL

POST-PROGRAMME SERUM CHOLESTEROL (mmol/l)	CARBOHYDRATE COMPOSITION COMPLIANCE GROUP n = 95[c]			
	CC n = 11	NC n = 26	NN n = 58	TOTAL
	%	%	%	%
LT 5.0[e]	36.4	46.2	53.4	49.5
GE 5.0	63.6	53.8	46.6	50.0
TOTAL	100.0	100.0	100.0	100.0

$X^2 = 1.25$, df = 2, p = 0.054

4. RELATIONSHIP BETWEEN CARBOHYDRATE COMPOSITION COMPLIANCE AND SERUM TRIGLYCERIDES

POST-PROGRAMME SERUM TRIGLYCERIDES (mmol/l)	CARBOHYDRATE COMPOSITION COMPLIANCE GROUP n = 95[c]			
	CC n = 11	NC n = 26	NN n = 58	TOTAL
	%	%	%	%
LT 2.0	63.6	61.5	58.6	60.0
GE 2.0	36.4	38.5	41.4	60.0
TOTAL	100.0	100.0	100.0	100.0

$X^2 = 0.13$, df = 2, p = 0.94

TABLE 4.10.B

PRE/POST STUDY

RELATIONSHIP BETWEEN CARBOHYDRATE SPACING COMPLIANCE AND BIOCHEMICAL MEASURES

1. RELATIONSHIP BETWEEN CARBOHYDRATE SPACING AND FASTING BLOOD GLUCOSE

n = 94[a,d]

	CARBOHYDRATE COMPOSITION COMPLIANCE GROUP				
POST-PROGRAMME FASTING BLOOD GLUCOSE (mmol/l)	CC n = 14 %	CN n = 15 %	NC n = 16 %	NN n = 49 %	TOTAL %
LT 10.0	64.3	66.7	75.0	57.1	62.8
GE 10.0	35.7	33.3	25.0	42.9	37.2
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 1.79$, df = 3, p = 0.62

2. RELATIONSHIP BETWEEN CARBOHYDRATE SPACING AND GLYCOSYLATED HAEMOGLOBIN

n = 93[b,d]

	CARBOHYDRATE COMPOSITION COMPLIANCE GROUP				
POST-PROGRAMME GLYCOSYLATED HAEMOGLOBIN (%)	CC n = 14	CN n = 14 %	NC n = 16 %	NN n = 49 %	TOTAL %
LT 9.0	64.3	57.1	50.0	63.3	60.2
GE 9.0	35.7	42.9	50.0	36.7	39.8
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 1.04$, df = 3, p = 0.79

TABLE 4.10.B (continued)

3. RELATIONSHIP BETWEEN CARBOHYDRATE SPACING AND FASTING SERUM CHOLESTEROL
n = 93[c,d]

POST-PROGRAMME SERUM CHOLESTEROL (mmol/l)	CARBOHYDRATE COMPOSITION COMPLIANCE GROUP				
	CC n = 14 %	CN n = 15 %	NC n = 16 %	NN n = 48 %	TOTAL %
LT 5.0[e]	66.7	37.5	58.8	45.8	49.5
GE 5.0	33.3	62.5	41.2	54.2	50.5
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 3.19$, df = 3, p = 0.36

4. RELATIONSHIP BETWEEN CARBOHYDRATE SPACING AND FASTING SERUM TRIGLYCERIDES
n = 93[c,d]

POST-PROGRAMME SERUM TRIGLYCERIDES (mmol/l)	CARBOHYDRATE COMPOSITION COMPLIANCE GROUP				
	CC n = 14 %	CN n = 15 %	NC n = 16 %	NN n = 48 %	TOTAL %
LT 2.0	64.3	60.6	68.8	54.2	59.1
GE 2.0	35.7	40.0	31.3	45.8	40.9
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 1.26$, df = 3, p = 0.94

TABLE 4.10.C

PRE/POST STUDY

RELATIONSHIP BETWEEN CARBOHYDRATE VARIATION COMPLIANCE AND BIOCHEMICAL GOALS MEASURED SIX MONTHS AFTER AN EDUCATION PROGRAMME FOR INSULIN-DEPENDENT DIABETICS

1. RELATIONSHIP BETWEEN CARBOHYDRATE VARIATION AND FASTING BLOOD GLUCOSE

n = 94[a,d]

	VARIATION COMPLIANCE GROUP				
	CC	CN	NC	NN	TOTAL
POST-PROGRAMME BLOOD GLUCOSE (mmol/l)	n = 14	n = 12	n = 20	n = 48	
	%	%	%	%	%
LT 10.0	50.0	83.3	75.0	56.3	62.8
GE 10.0	50.0	16.7	25.0	43.8	37.2
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 5.3$, df = 3, p = 0.15

2. RELATIONSHIP BETWEEN CARBOHYDRATE VARIATION AND GLYCOSYLATED HAEMOGLOBIN

n = 93[b,d]

	VARIATION COMPLIANCE GROUP				
	CC	CN	NC	NN	TOTAL
POST-PROGRAMME GLYCOSYLATED HAEMOGLOBIN (%)	n = 14	n = 11	n = 19	n = 49	
	%	%	%	%	%
LT 9.0	64.3	63.6	63.2	57.1	60.2
GE 9.0	35.7	36.4	36.8	42.9	39.8
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 0.41$, df = 3, p = 0.94

TABLE 4.10.C (continued)

3. RELATIONSHIP BETWEEN CARBOHYDRATE VARIATION AND SERUM CHOLESTEROL
n = 93(c,d)

	VARIATION COMPLIANCE GROUP				
POST-PROGRAMME SERUM CHOLESTEROL (mmol/l)	CC n = 13 %	CN n = 12 %	NC n = 20 %	NN n = 48 %	TOTAL %
LT 5.0	66.7	80.0	31.8	52.4	49.5
GE 5.0	33.3	20.0	68.2	47.6	50.5
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 2.25$, df = 3, p = 0.52

4. RELATIONSHIP BETWEEN CARBOHYDRATE VARIATION AND FASTING SERUM TRIGLYCERIDES
n = 93(c,d)

	CARBOHYDRATE COMPOSITION COMPLIANCE GROUP				
POST-PROGRAMME SERUM TRIGLYCERIDES (mmol/l)	CC n = 13 %	CN n = 12 %	NC n = 20 %	NN n = 48 %	TOTAL %
LT 2.0	38.5	75.0	70.0	56.3	59.1
GE 2.0	61.5	25.0	30.0	43.8	40.9
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 4.69$, df = 3, p = 0.19

TABLE 4.10.D

PRE/POST STUDY

RELATIONSHIP BETWEEN WEIGHT COMPLIANCE AND BIOCHEMICAL GOALS

1. RELATIONSHIP BETWEEN WEIGHT COMPLIANCE AND FASTING BLOOD GLUCOSE

n = 96[a]

	WEIGHT COMPLIANCE GROUP				
POST-PROGRAMME BLOOD GLUCOSE (mmol/l)	CC n = 59 %	CN n = 9 %	NC n = 9 %	NN n = 19 %	TOTAL %
LT 10.0	57.6	77.8	77.8	68.4	53.5
GE 10.0	42.4	22.2	22.2	31.6	36.5
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 2.66$, df = 3, p = 0.45

2. RELATIONSHIP BETWEEN WEIGHT COMPLIANCE AND GLYCOSYLATED HAEMOGLOBIN

n = 95[b]

	CARBOHYDRATE COMPOSITION COMPLIANCE GROUP				
POST-PROGRAMME GLYCOSYLATED HAEMOGLOBIN (%)	CC n = 58 %	CN n = 9 %	NC n = 9 %	NN n = 19 %	TOTAL %
LT 9.0	53.4	66.7	77.8	73.7	61.1
GE 9.0	46.6	33.3	22.2	26.3	38.9
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 3.86$, df = 3, p = 0.28

TABLE 4.10.D (continued)

3. RELATIONSHIP BETWEEN WEIGHT COMPLIANCE AND FASTING SERUM CHOLESTEROL
n = 95[c]

POST-PROGRAMME SERUM CHOLESTEROL (mmol/l)	WEIGHT COMPLIANCE GROUP				
	CC n = 59 %	CN n = 8 %	NC n = 9 %	NN n = 19 %	TOTAL %
LT 5.0	54.2	50.0	66.7	26.3	49.5
GE 5.0	45.8	50.0	33.3	73.7	50.5
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 5.68$, df = 3, p = 0.13

4. RELATIONSHIP BETWEEN WEIGHT COMPLIANCE AND FASTING SERUM TRIGLYCERIDES
n = 95[c]

POST-PROGRAMME SERUM TRIGLYCERIDES (mmol/l)	WEIGHT COMPLIANCE GROUP				
	CC n = 59 %	CN n = 8 %	NC n = 9 %	NN n = 19 %	TOTAL %
LT 2.0	59.3	62.5	77.8	52.6	60.0
GE 2.0	40.7	37.5	22.2	47.4	40.0
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 1.65$, df = 3, p = 0.65

Reasons for incomplete data are as follows -

(a) 12 subjects of the 108 returns did not have fasting blood tests.

(b) The glycosylated haemoglobin result for one subject was not returned from the laboratory.

(c) Insufficient serum was obtained for serum lipid analyses on 1 subject.

(d) 2 subjects only kept a three-day food record so were eliminated from the analyses of spacing and variation compliance.

(e) The median of the post-programme serum cholesterol values (5.0 mmol/l) was used as the cut-off point because the majority of subjects had values less than 6.5 mmol/l.

CHAPTER 5

RESULTS - RANDOMISED CONTROLLED TRIAL

SECTION

CHAPTER 5

RESULTS

RANDOMISED CONTROLLED TRIAL

5.1 ATTRITION OF STUDY SUBJECTS

Fourteen education programmes for adult insulin-dependent diabetics were held during the study period (between April 1980 and July 1981) the first two of which were regarded as a "dress rehearsal". Of the 150 diabetics who enrolled in the education programmes over the 16 month study period 142 were registered into the study whilst eight were ineligible; four because they were under 18 years of age, two did not speak, read or write English fluently and two others were not insulin-dependent. Figure 5.1 illustrates the recruitment of subjects into the study and the loss of subjects over various stages of the study.

Approximately equal numbers were randomly assigned to Streams 1 and 2 (59 and 61, respectively) and 22 were non-randomly assigned to Stream 2-B. Reasons for inclusion in the latter group were as follows: 12 were enrolled in the first two education programmes (the study "dress rehearsal"), nine were enrolled in the programme too late to attend the three month pre-assessment, and one was considered an "urgent" referral.

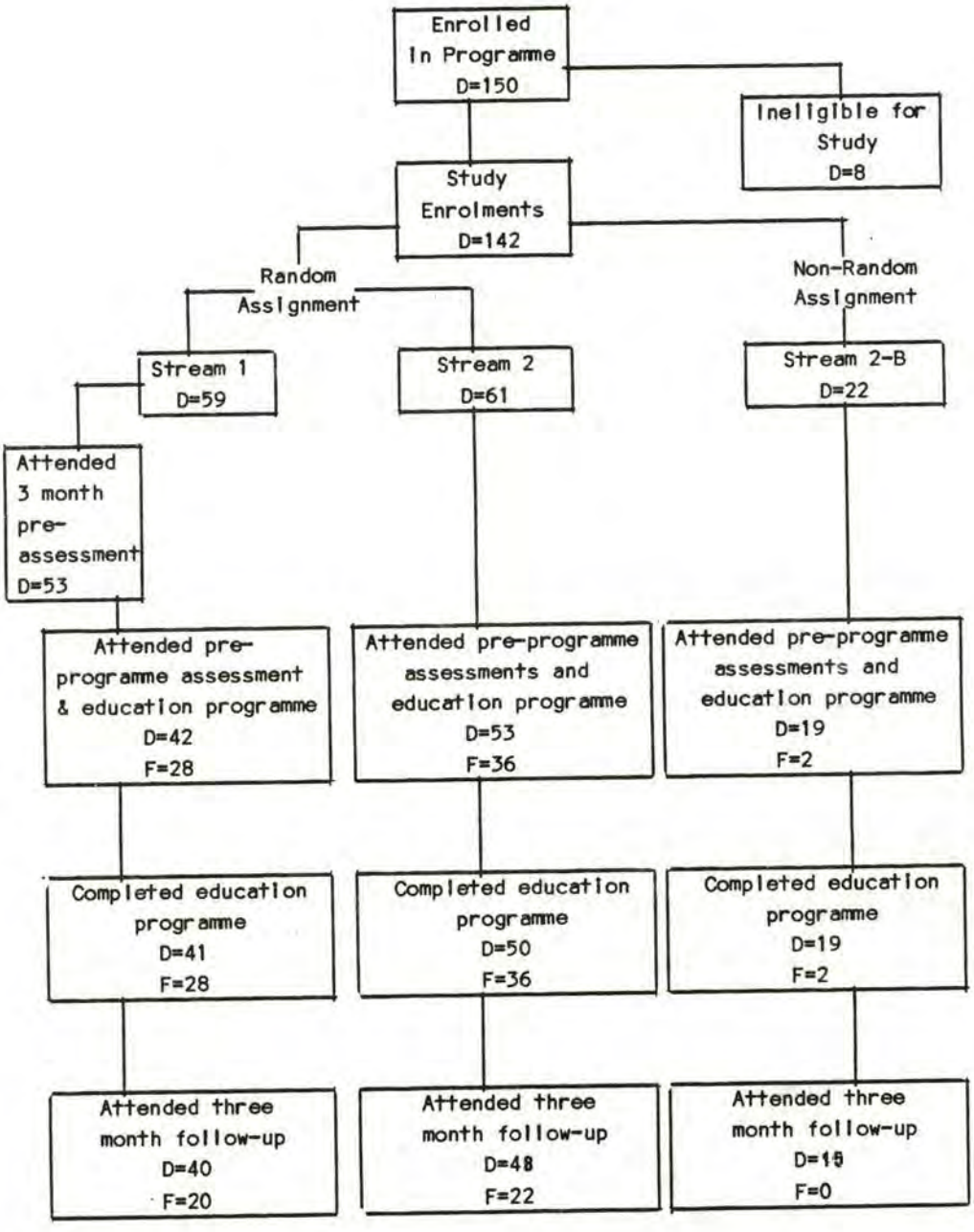
Of the 142 diabetics who were included in the study and assigned to one of the three streams, 17 did not appear at their first appointment or education session. The percentages of this occurrence in Streams 1, 2 and 2-B were similar, being 10%, 13% and 14%, respectively. Reasons given by study subjects or relatives when contacted by telephone included: "could not get time off work" (2), "Severe illness not related to diabetes" (5),

FIGURE 5.1

RANDOMISED CONTROLLED TRIAL

ATTRITION OF STUDY SUBJECTS AT VARIOUS STAGES OF A RANDOMISED CONTROLLED TRIAL OF A DIABETES EDUCATION PROGRAMME

1980 - 1981



D=Diabetics
F=Family members

"too many other commitments at the present time" (4), death (1), physician did not want diabetic to attend (2) and family problems (1). The remaining two could not be contacted.

For Stream 1, four additional study subjects were lost at the three month pre-assessment due to their inability to complete the food record or urine collection. Reasons given for inability to complete assessments were: "going away on holidays" (1), "too much trouble" (2), and "other problems" (1). These individuals did not attend the education programme three months later. One diabetic who was unable to complete the food record at the pre-assessment due to "emotional problems" continued on to attend the programme and completed subsequent food records. Further attrition occurred in Stream 1 subjects between their three month pre-assessment and the education programme. Six of the 48 who completed the first assessments did not attend the education programme due to hospitalisation (2), recent amputation (1), work and other commitments (3).

A very low drop-out rate (5% or less) was observed during the five-week education programme for all three groups. Drop-outs were those who missed more than one education session. At this stage, only one subject dropped out of Stream 1, and two out of Stream 2. There were no programme drop-outs from Stream 2-B.

Between the education programme and three month follow-up assessments, very few study subjects were lost in each of the three groups. Subjects who returned for follow-up are referred to henceforth in this report as "returns" and those who did not as "non-returns". Reasons given for not returning were as follows: moved to other States (2), serious illness (2), emotional and

family problems (1), work commitments (2), and a new baby and no transport (1). Thus, response rates to follow-up were high when calculated as percentages in each group who actually attended the programme, i.e. 95%, 96% and 79% from Streams 1, 2 and 2-B respectively. However, response rates were somewhat lower when they were calculated as either percentages of those who were included in the study or as percentages of those who attended their first appointment at the Centre. The response rates to follow-up using the numbers assigned to each group as the denominators were: 67.7%, 78.6% and 68.1% for Streams 1, 2 and 2-B, respectively. As percentages of those who kept their first appointments at the centre, the response rates were 75.4%, 90.5% and 78.9% indicating a higher return rate for Stream 2 subjects.

Seventy-six diabetics (53%) who enrolled in the study were accompanied to the education programme by a family member or close friend. Twenty-eight family members attended the programme with Stream 1 diabetics and 20 of these (71.4%) returned for the three month follow-up assessment. Of the original 36 family members who accompanied Stream 2 diabetics, 22 of these (61.1%) returned for reassessments. Only two family members attended with diabetics assigned to Stream 2-B and neither of these returned three months after the programme.

Co-operation rates with the request for keeping food records for the randomly assigned subjects (Streams 1 and 2) are shown in Table 5.0.1 at each assessment. The percentages of "reliable" records were calculated from the numbers of study subjects who kept their first appointment at the Centre. Potential study subjects who had made a booking for the programme

or pre-assessments but did not appear at their appointments were excluded from the denominator since they were unaware of the requirement of keeping food records.

As shown in Table 5.0.1, co-operation rates at all of these assessments were relatively high for diabetics and decreased primarily due to the attrition of study subjects rather than to increases in refusals or unreliable records. The percentages of completed records at the first assessment were greater than 90% for both Streams, but decreased to 75.9% and 88.6% at follow-up for Streams 1 and 2 respectively.

Co-operation with record keeping procedures amongst family members was also high at the initial assessment (greater than 90%) but decreased to 64% and 58% for Streams 1 and 2 after the programme, due to the lower return rate for family members.

5.2 INITIAL SIMILARITIES AND DIFFERENCES BETWEEN STREAMS

To determine whether Streams 1 and 2 differed initially, they were compared on all variables measured at the first assessment (three months prior to the programme for Stream 1 and immediately prior to it for Stream 2). Due to the small number of subjects in Stream 2-B (non-randomly assigned group), it was excluded from further analysis of results.

In most respects, i.e., demographic characteristics, dietary intakes, biochemical status, health beliefs, knowledge of diabetes and perceived quality of diabetic life, Streams 1 and 2 were similar (Tables 5.1.1 through 5.1.5). Statistically significant differences were observed only for insulin dose, percentage of energy contributed by protein, and the composition

of family member's diets. The mean insulin dose for Stream 2 diabetics was approximately ten units less than for Stream 1 subjects and this difference was statistically significant (Table 5.1.1). The composition of the diets in both groups was similar with the exception of protein which was slightly but significantly higher in Stream 1 (Table 5.1.2). However, the composition of diets of the family members of the two streams differed in several respects. Family members who accompanied Stream 2 diabetics to the education programme consumed significantly less of their energy as complex carbohydrate and protein, but more as alcohol and refined sugar than the family members of Stream 1. These differences should, however, be interpreted with caution due to the number of statistical tests carried out. With 40 comparisons between streams, it would be expected that differences for two variables would be significant at p less than .05 by chance alone. If the significance level were adjusted according to the Bonferroni rule, p values would need to be less than .001 to be considered statistically significant. Thus, none of the differences between streams reported here would have been significant.

Although not statistically significant, a larger proportion (40%) of Stream 2 had been referred for education by the team's endocrinologist compared with only 21% from this source for Stream 1 (Table 5.1.1). Also, Stream 1 had a greater proportion of missing data about the presence of diabetic complications because the endocrinologist was unable to complete clinical examinations on everyone during the routine assessments, but had recent data on this variable for most of the patients whom he referred to the programme.

5.3 INITIAL SIMILARITIES AND DIFFERENCES BETWEEN RETURNS AND NON-RETURNS

Diabetics who did not return (non-returns) for re-assessments three months after the education programme, differed significantly from those who did (returns) in several respects (Tables 5.2.1 through 5.2.5). Non-returns tended to be older, retired, and to reside outside the Northern Metropolitan Region (Table 5.2.1). They were also more likely to have had diabetes for less than a year, to have been hospitalised in the previous year for diabetes, to attend the programme without a family member and have missed the clinical assessment for presence of diabetic complications (Table 5.2.1). The latter result is likely to be attributable to the higher proportion of non-returns who were in Stream 1 (although this difference was not statistically significant). Significant differences were also noted for knowledge; non-returns knew significantly less about diabetes at the initial assessment than those who returned (Table 5.2.4). Three items on the "perceived quality of life" questionnaire were significantly different between the two groups (at p less than .05). Non-returns felt more "able than usual to eat out", less "difficulty than usual with injections" and "with controlling diabetes" than did the returns (Table 5.2.5). However, when the Bonferroni rule was applied, the only significant difference between returns and non-returns was the proportion of family members who attended the programme.

There were no significant differences between returns and non-returns for baseline measures of health beliefs, and dietary or biochemical measures (Table 5.2.2 through 5.2.4). However, non-

returns had a higher mean percentage of ideal weight than returns, although this difference was not statistically significant.

5.4 THE EFFECT OF ASSESSMENTS AND OF THE EDUCATION PROGRAMME ON OUTCOMES

Figures 5.2a through 5.5b depict the means and standard errors of all continuous outcome variables for the two streams at each assessment. Details of the statistical tests (analyses of variance and McNemar's statistics) are shown in Set 3 of the tables (Tables 5.3.1 through 5.3.4) for the effects of assessment only and in Set 4 (Tables 5.4.1 through 5.4.5) for programme effects.

Dietary Variables

No significant changes were noted in any of the dietary variables for Stream 1 between the assessments made three months before and immediately before the education programme (Figures 5.2.a through 5.2.d and Table 3.1.A). Thus, keeping food records and the weight assessment alone did not appear to have any effect on dietary compliance.

Significant improvements, were, however, observed for both Streams 1 and 2 in fat and carbohydrate intake assessed immediately before and three months after the education programme (Figure 5.5.2b and Table 5.4.1A). The absolute percentage of energy contributed by fat was significantly reduced by 5.85% and 4.43% for Streams 1 and 2 respectively, whilst complex carbohydrate increased by 7.15% and 6.89% respectively. It can be seen from Figures 5.2a and b that the mean percentage intakes of carbohydrate and fat were similar for Streams 1 and 2 immediately before and three months after the programme and that the groups

Figures 5.2

Plots Of Means And Standard Errors For Dietary Variables For Two Streams Of Diabetics

At Assessments Before And After An Education Programme

1980 - 1981

Figure 5.2 a
Complex Carbohydrate
Intake Of 87 Diabetics

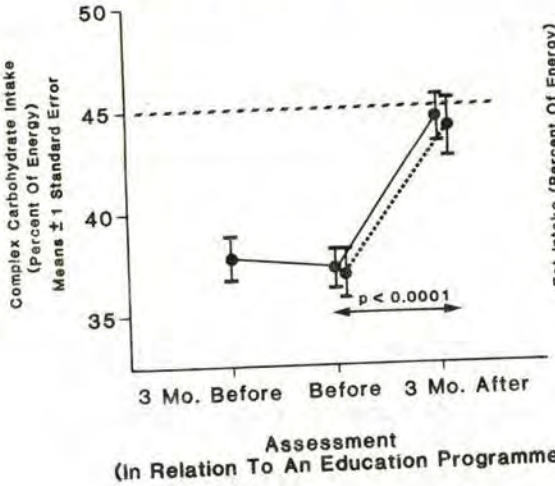


Figure 5.2 b
Fat Intake Of 87 Diabetics

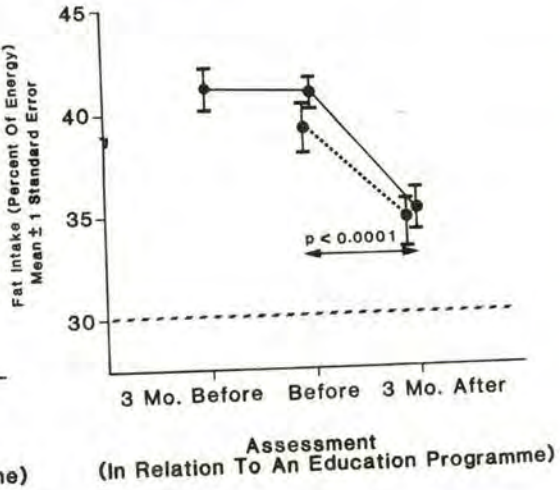


Figure 5.2 c
Protein Intake Of 87 Diabetics

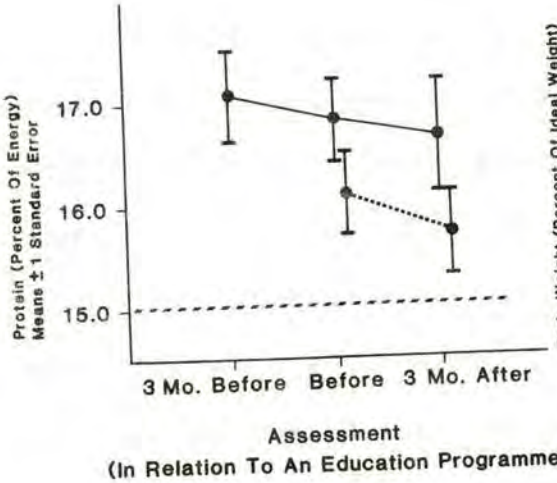
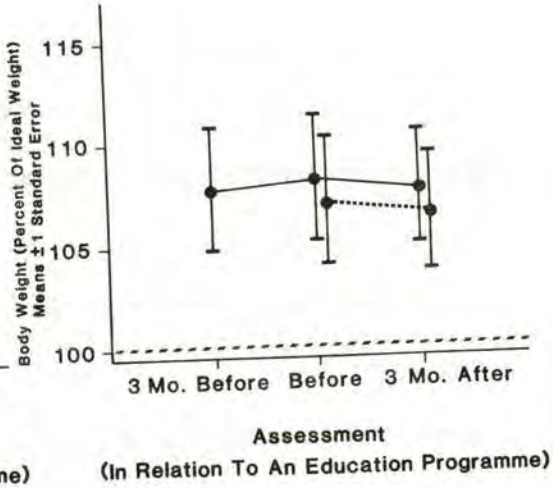


Figure 5.2 d
Body Weight Of 88 Diabetics



Legend:

——— Stream 1

..... Stream 2

- - - - - - Goal

Figures 5.3

Plots Of Means And Standard Errors For Dietary Variables For Family Members Of Two Groups Of Diabetics Before And After An Education Programme

1980 - 1981

Figure 5.3 a
Complex Carbohydrate Intake
Of 39 Family Members

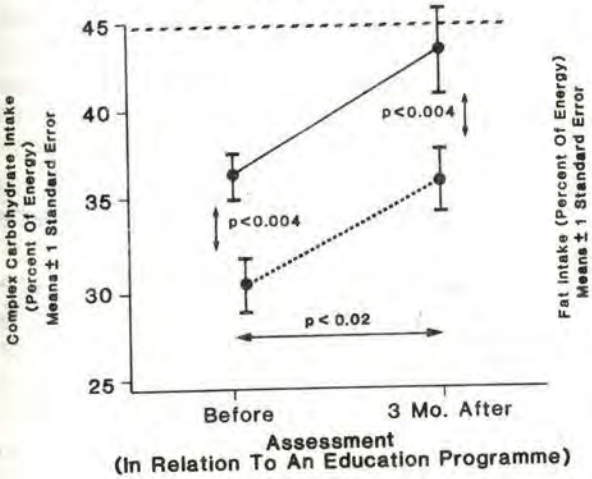


Figure 5.3 b
Fat Intake Of 39 Family Members

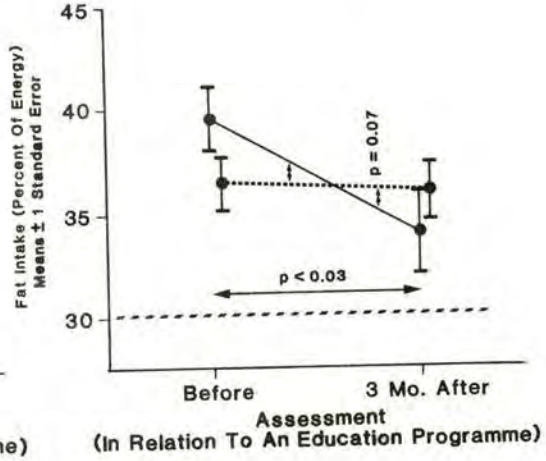


Figure 5.3 c
Protein Intake Of 39 Family Members

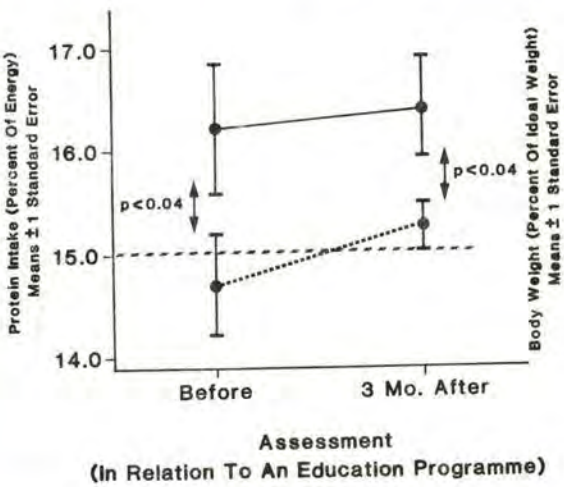
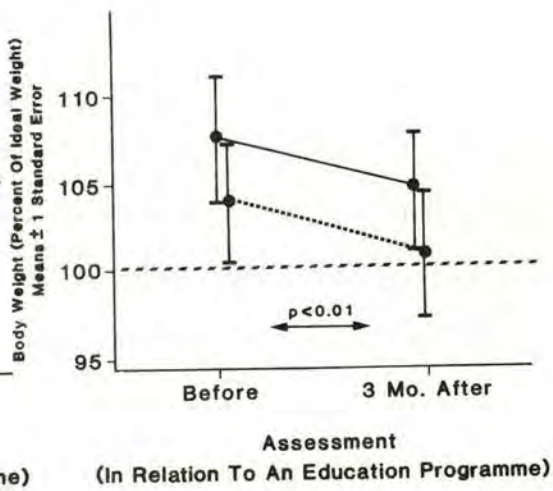


Figure 5.3 d
Body Weight Of 42 Family Members



Legend:

——— Family Members Of Stream 1

..... Family Members Of Stream 2

- - - - - - Goal

modified their diets by similar amounts. For neither group, however, did the mean values for percentage of energy for fat and complex carbohydrate reach the programme's recommendations of 30% and 45% respectively.

For other dietary variables, including relative weight, the percentage of energy contributed by protein, the proportion above and below the median for alcohol, sugar, carbohydrate spacing and variation scores, there were no significant differences between assessments before and after the programme for either Streams 1 or 2 (Tables 5.4.1A and 5.4.1B). With the exception of carbohydrate spacing, the lack of significant changes in these variables are not surprising since they were within the acceptable range initially.

The family members who attended the programme with Stream 1 diabetics showed similar patterns of change in the composition of their diets. They reduced their fat and increased complex carbohydrate intakes whilst protein, alcohol and sugar remained about the same (Figures 5.3a through d and Tables 5.4.2A and B) .

Family members who accompanied Stream 2 diabetics to the programme showed somewhat different responses. Whilst they increased the percentage of energy from complex carbohydrate and made no change in protein, the initial and final values for these variables were significantly lower than for Stream 1 family members. In contrast to the significant decrease in fat intake observed for the other group, Stream 2 family members made no change in fat intake as a percent of energy (Figure 5.3b). Clearly, their mean fat intake before the programme was considerably lower than for stream 1 but afterwards, was

approximately 2% greater. However, these differences between groups were not statistically significant (Table 5.4.2A) due to the small sample size and consequently the large standard errors.

Both groups of family members lost weight (approximately 3% of ideal) between pre- and post-assessments and the change was statistically significant (Table 5.4.2A). However, this and other results must be interpreted with caution since less than two-thirds of the original sample of family members returned for re-assessment.

Biochemical Measures

Group means for biochemical variables remained relatively stable for Stream 1 between the three month pre-assessment and measurements made just before the programme (Figure 5.4 a through d). There was a slight rise in fasting blood glucose, but this was not statistically significant (Table 5.3.2).

Compared with the clinical criteria specified in the "methods" section, initial mean values for Stream 1 were slightly elevated for glycosylated haemoglobin and fasting blood glucose and these remained so at the second assessment. Mean serum cholesterol however was well within the normal range and remained so. For Stream 2, mean baseline values for the measures of glucose control were slightly elevated, but were well within the acceptable range for serum cholesterol.

For clinical interpretation, median triglyceride values were computed for each Stream at each assessment. They were (in mmols/l) for Stream 1: 1.95, 2.00 and 1.85, and for Stream 2: 1.75 and 1.95. All of these values were within the specified clinically acceptable range.

Figures 5.4

Plots Of Means And Standard Errors For Biochemical Measurements From Insulin Dependent Diabetics Before And After An Education Programme

1980 - 1981

Figure 5.4 a
Glycosylated Haemoglobin
For 87 Diabetics

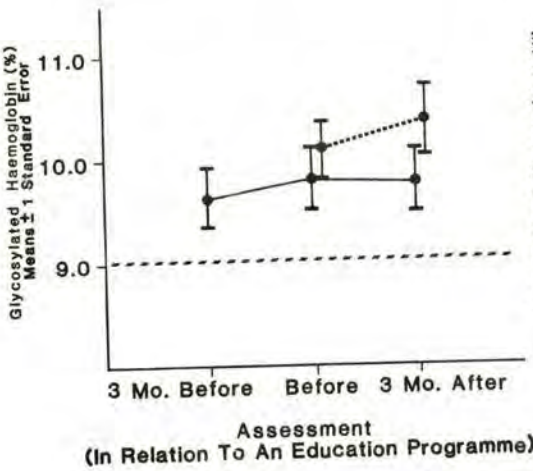


Figure 5.4 b
Fasting Blood Glucose
For 86 Diabetics

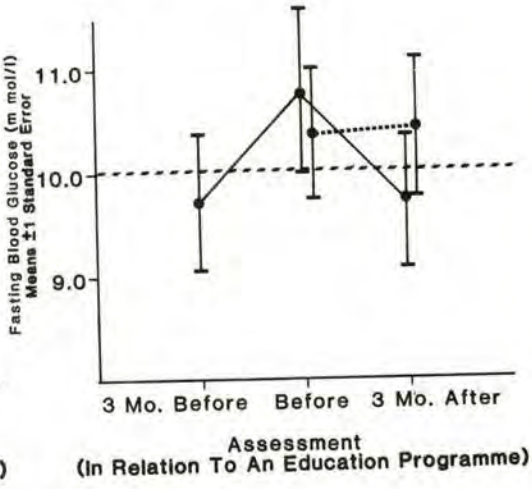


Figure 5.4 c
Fasting Serum Cholesterol
For 85 Diabetics

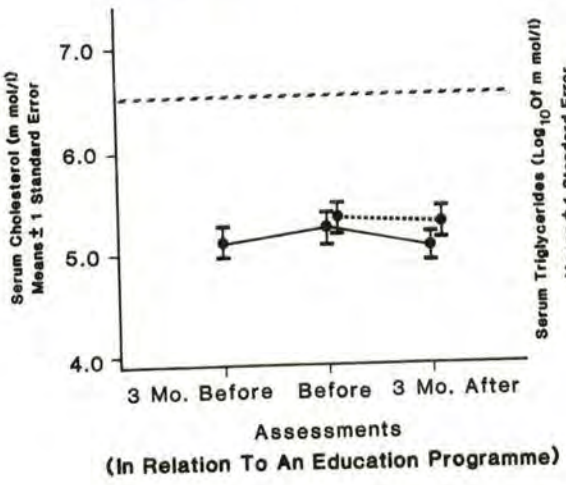
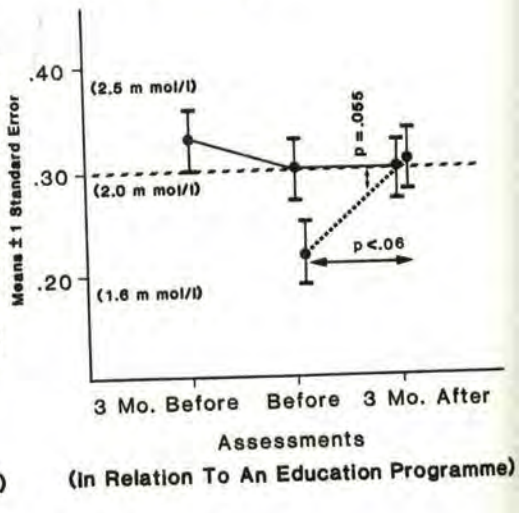


Figure 5.4 d
Fasting Serum Triglycerides
For 85 Diabetics



Legend:

——— Stream 1

..... Stream 2

- - - - - - Upper Limit Of Acceptable Range

The results of analyses of variance showed no statistically significant programme effects in biochemical outcomes (Table 5.4.2). However, the interaction term approached statistical significance ($p = .055$) suggesting that the pattern of change in triglycerides differed between the two streams. The mean triglyceride value on a logarithmic scale for Stream 2 was (statistically) significantly lower than for Stream 1 at the assessment immediately prior to the programme and increased (though not statistically significantly) to a final value similar to Stream 1 at the post-programme assessment (Figure 5.4d). The differences in mean values between assessments for the biochemical measures were not clinically significant as defined in the methods section. Thus, it appears that neither the assessments themselves, nor the programme had any statistically significant effect on glycaemic control, serum cholesterol or triglycerides of these diabetics as a group.

Health Beliefs

Similar to the results for other outcome variables, the proportion of Stream 1 subjects above and below the median for health belief scores were not altered as a result of the assessment alone (Table 5.3.3). Median scores before the programme for this group indicated that, in general, they believed self-care regimens to be moderately efficacious and perceived themselves to be moderately compliant with diet, susceptible to the complications, they had faith in the care they received from doctors, they had relatively little difficulty with adherence to their diets, and with controlling weight (if overweight). Baseline scores for Stream 2 (Table 5.4.3A through F) were similar

to those for Stream 1, except that they perceived the self-care regimens as slightly more efficacious, and had more faith in their doctor's care. However, these initial differences between streams did not reach statistical significance.

At the post-programme assessment, scores for two health beliefs; perceived efficacy of self-care regimens and faith in doctor had increased significantly for Stream 1 only (Table 5.4.3B and F). Final scores for these beliefs were similar to the initial and final scores for Stream 2. No statistically significant changes in other health beliefs were observed. Interestingly, the proportion of subjects with scores above the median for perceived dietary compliance at the baseline assessment was approximately 55% for both groups, but decreased to 47% in Stream 2 and increased to 70% in Stream 1 (Table 5.4.3C).

Knowledge

Mean knowledge scores for diabetics at the baseline assessment were low, only 59.7% and 60.5% of possible correct responses for Streams 1 and 2 respectively (Figure 5.5a). Stream 1 did not appear to improve their knowledge scores simply as a result of assessment, reflected by the lack of change in their mean score between the assessments three months before and immediately before the programme (Figure 5.5a and Table 5.3.1A).

However, both Streams 1 and 2 significantly increased knowledge about diabetes after attending the education programme (Table 5.4.1.A). Final mean scores represented approximately 80% of the total possible and could be considered adequate for self-management.

Figures 5.5

Plots Of Means And Standard Errors For Knowledge Scores For Diabetics And Family Members Before And After An Education Programme

1980 - 1981

Figure 5.5 a

Knowledge Score For 86 Diabetics

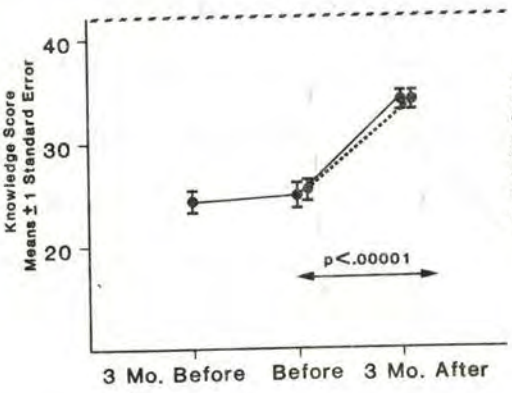
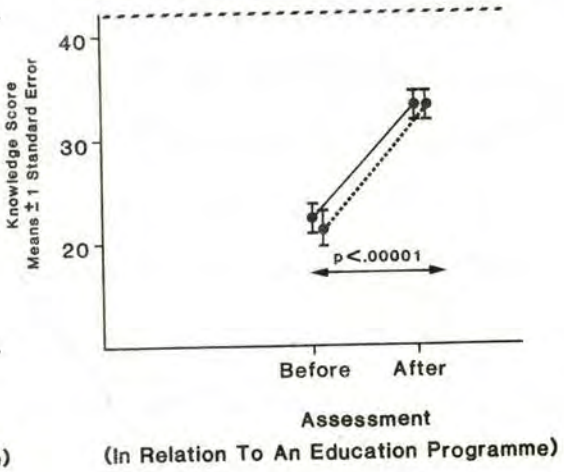


Figure 5.5 b

Knowledge Score For 38 Family Members



Legend:

——— Stream 1

····· Stream 2

- - - - - - Total Possible Score

Similar results were noted for family members who attended the programme. Their mean scores at the baseline assessment were approximately 50% of the total possible, whereas final scores for correct answers approached 80% in both groups (Figure 5.5b and Table 5.4.2A).

Perceived Quality of Diabetic Life

Mean scores for individual items and the score over all items from the Quality of Diabetic Life Questionnaire did not differ significantly for Stream 1 between assessments three months prior and immediately prior to the programme (Table 5.3.4). Differences between pre- and post-programme scores were not assessed because the wording of the questionnaire differed at these two assessments. However, post-programme mean scores are shown for Streams 1 and 2 in Table 5.4.5. With the exception of a higher perceived "ability to travel" by Stream 2, there were no significant differences between the two streams in the perceived quality of diabetic life for individual items or in their mean scores over all items. By comparison with pre-programme mean scores shown in Table 5.1.5, all post-programme scores appear higher suggesting that diabetics perceived their quality of life to be higher after they attended the education programme. For no items did the groups feel "worse than before" the programme, that is, were mean scores less than three.

5.5 DIETARY COMPLIANCE RATES BEFORE AND AFTER EDUCATION

The percentages of subjects in each stream who met the dietary goals before and after the programme are shown in Tables 5.5.1.A through E. Only 12.5% of Stream 1 and 17% of Stream 2 consumed at least 45% of their energy as complex

carbohydrate prior to the programme whilst afterwards, 57.5% and 42.6%, respectively, achieved this goal (Table 5.5.1). A very small portion (less than 10%) of subjects initially met the goal for a low fat intake but this increased to 20% and 26% for Streams 1 and 2 after the programme (Table 5.5.2). These changes in compliance rates were statistically significant for both streams. However, no significant changes were observed for either stream in the proportion of subjects who were compliant with carbohydrate spacing or variation recommendations before and after; two thirds to three quarters of them initially deviated from the goal and remained non-compliant at the follow-up.

For overweight subjects, the achievement of ideal weight was not required for them to be considered "compliers". Nonetheless, it is useful to consider the proportions of subjects who were overweight or within the ideal range before and after the programme. Table 5.5.E shows that at the pre-programme assessment, approximately one-third of subjects in Streams 1 and 2 were overweight and this proportion decreased only slightly after the programme; two overweight subjects in Stream 1 and one in Stream 2 were no longer considered overweight at the three month follow-up assessment. Only two subjects (one in each Stream) who were within the ideal range initially, were greater than 110% of ideal at follow-up.

5.6 CHANGE IN CONTINUOUS DIETARY VARIABLES

Although a considerable proportion of individuals did not meet the dietary goals after the programme, many made substantial changes in the desired direction. Table 5.6.1A shows that for both Streams 1 and 2 approximately 60% of subjects increased their

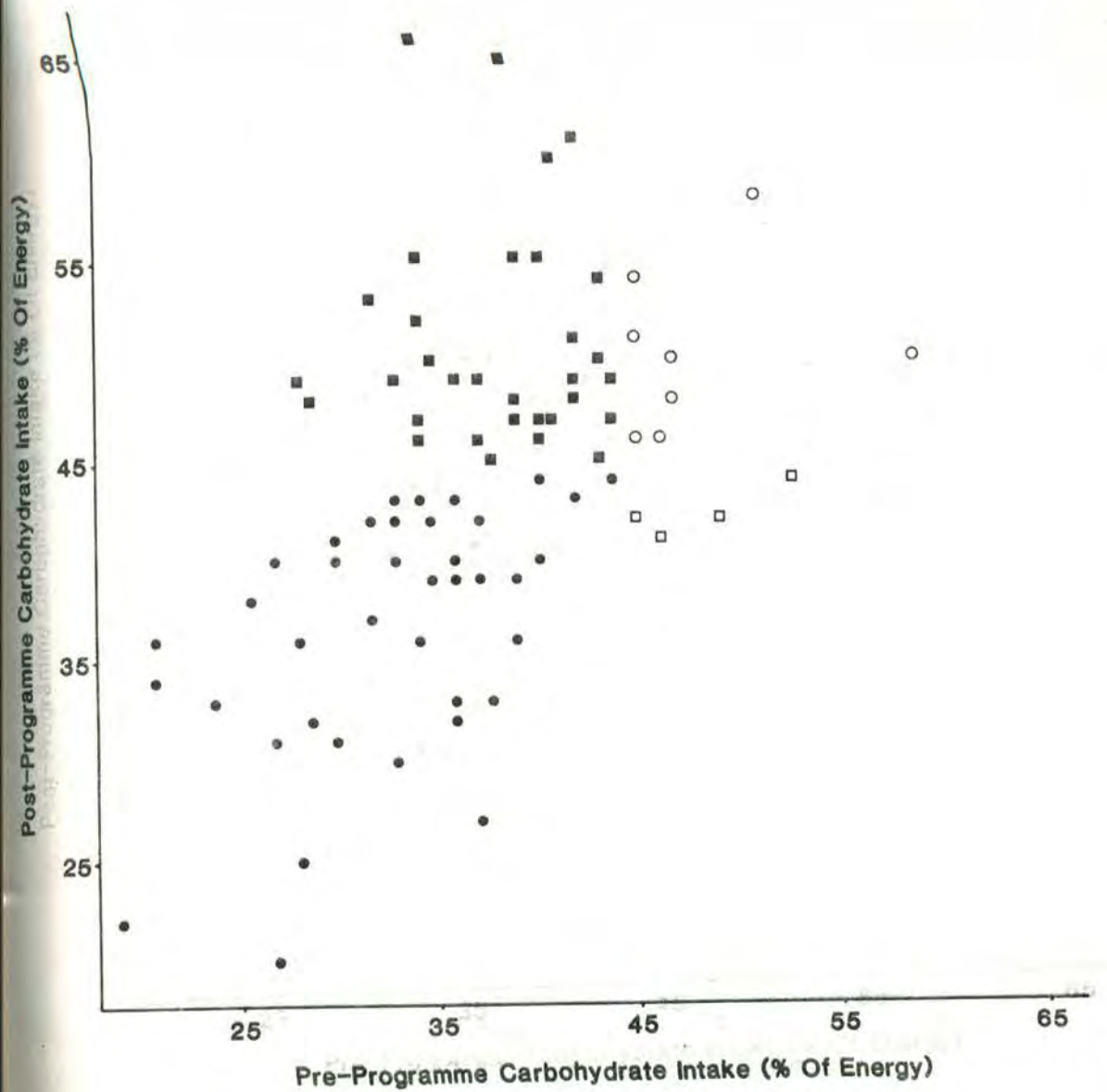
carbohydrate intake by at least 5% of energy and one-third of these increased by at least 10% of energy intake. Similar results were obtained for the decrease in fat intake (Table 5.6.1B.)

The proportion of the two streams for which weight losses, gains or little change was observed are shown in Table 5.6.1C. Of the 15 Stream 1 subjects who were overweight at the assessment immediately before the programme, eight of these had lost at least 5% of their ideal weight three months afterwards. For Stream 2, five of the original 16 overweight subjects lost at least 5% of ideal weight over the study period. None of the overweight subjects gained equal to or greater than 5% of ideal weight and only a small proportion of subjects initially within the ideal range gained more than 5% of ideal.

The number of the sample classified into each of the four compliance groups (CC, CN, NC and NN) are shown in Figures 5.6.a through 5.6.e.

5.7 ASSOCIATIONS BETWEEN FOUR TYPES OF DIETARY COMPLIANCE

For the analyses of associations between compliance and other variables, individuals from the two streams were combined because there were no significant differences between Streams 1 and 2 in the proportions of subjects who were compliant or non-compliant with any of the four types of dietary compliance before or after the programme. Two associations between the four aspects of dietary compliance were observed (Table 5.7.1). Those who were non-compliant with carbohydrate variation recommendations at both assessments also tended to be non-compliant with carbohydrate composition. Similarly, non-compliers with spacing were also likely to be non-compliers with variation. However, these



LEGEND:

- ● Non-Compliers Before And After The Programme
- ■ Non-Compliers Before And Compliers Afterwards
- ○ Compliers Before And Afterwards
- □ Compliers Before And Non-Compliers Afterwards

FIGURE 5.6.a Compliance with recommendations for complex carbohydrate intake (greater than or equal to 45% of energy) assessed before and three months after an education programme for insulin-dependent diabetics. (Randomised Controlled Trial)

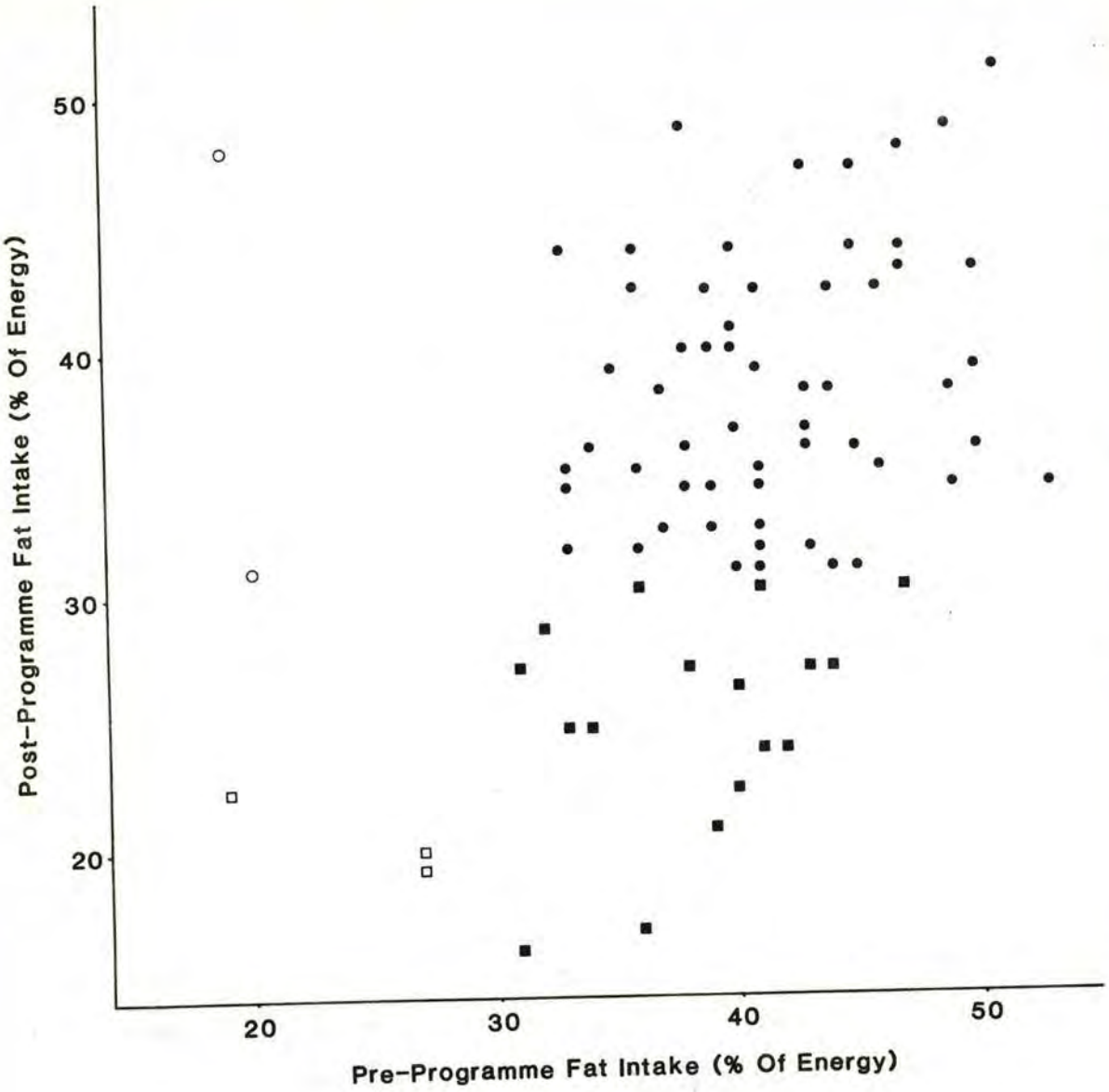
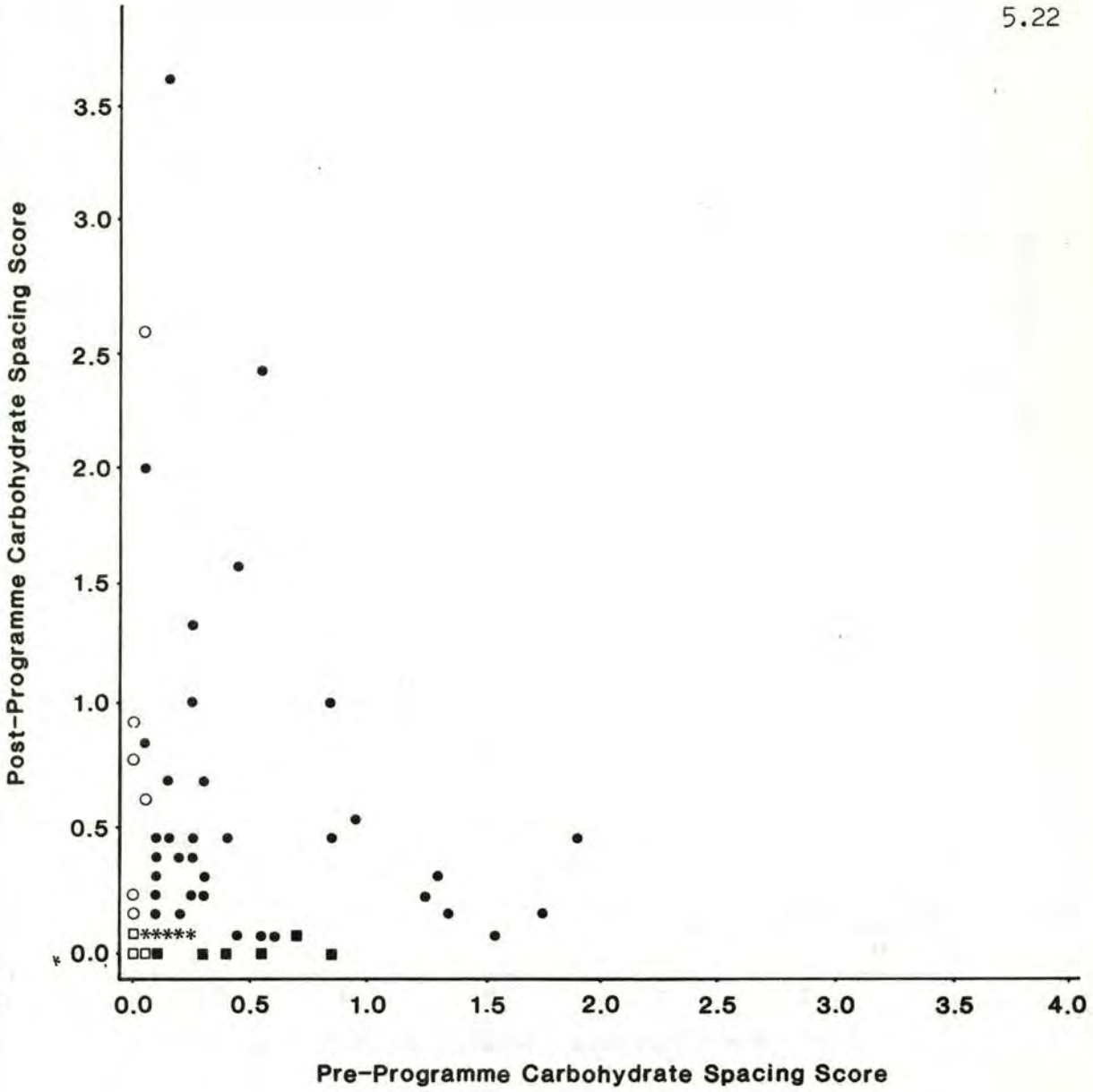


FIGURE 5.6.b Compliance with recommendations for fat intake (less than or equal to 30% of energy) assessed before and three months after an education programme for insulin-dependent diabetics. (Randomised Controlled Trial)



LEGEND:

- ● Non-Compliers Before And After The Programme
- ■ Non-Compliers Before And Compliers Afterwards
- ○ Compliers Before And Afterwards
- □ Compliers Before And Non-Compliers Afterwards

FIGURE 5.6.c Compliance with recommendations for carbohydrate spacing (scores less than .07) assessed before and three months after an education programme for insulin-dependent diabetics. (Randomised Controlled Trial)

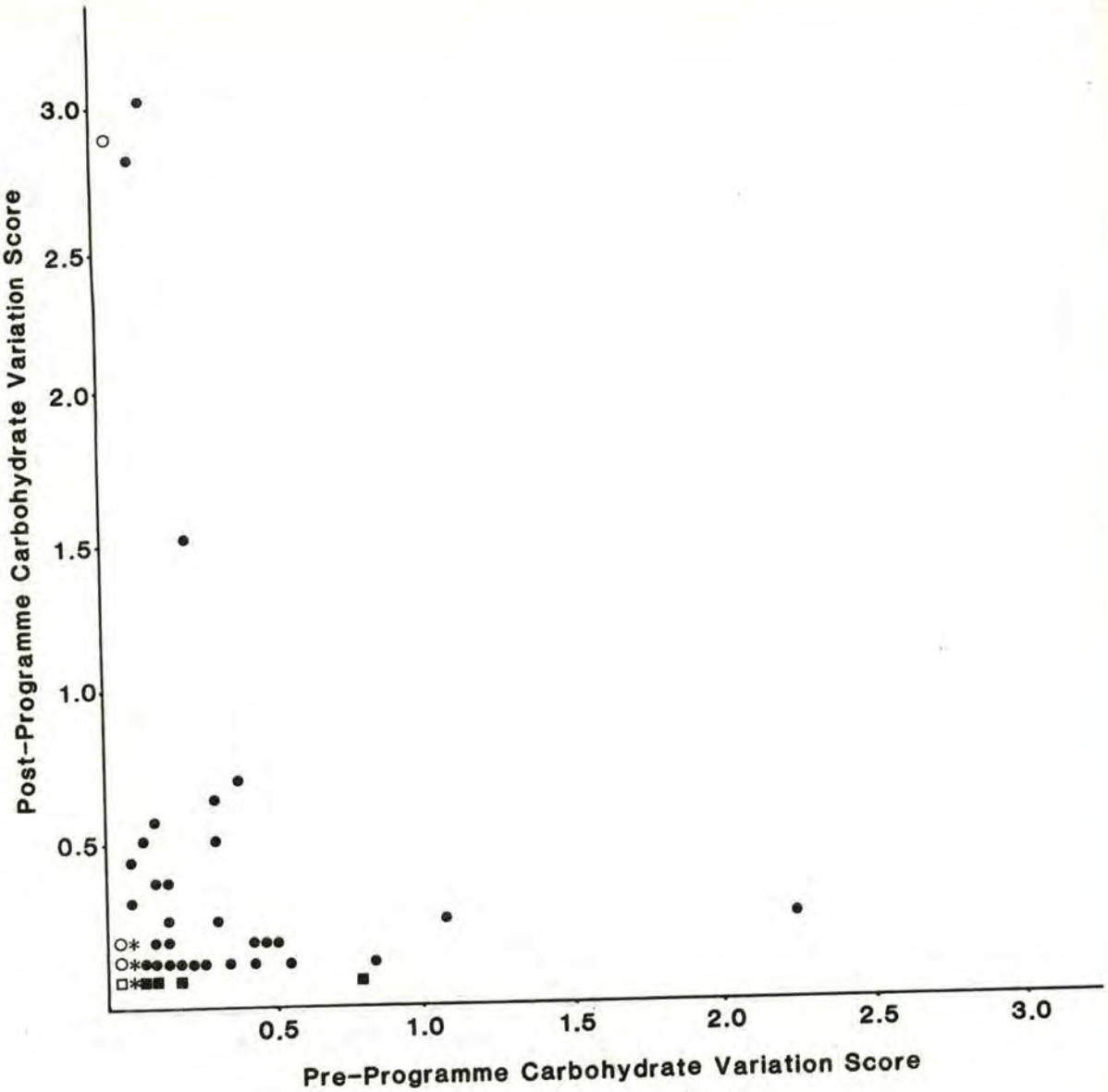
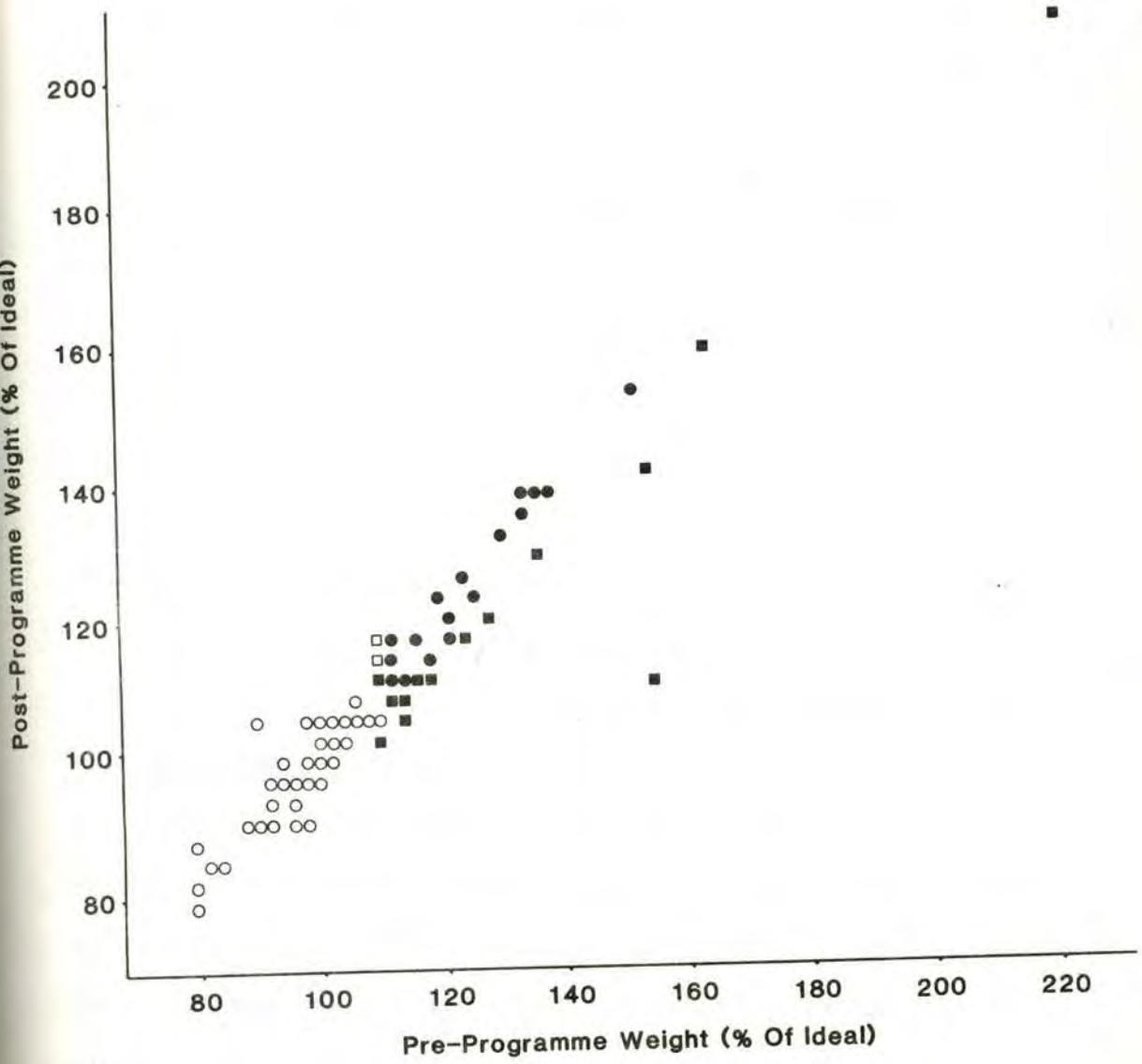


FIGURE 5.6.d Compliance with recommendations for carbohydrate variation (scores less than .03) assessed before and three months after an education programme for insulin-dependent diabetics. (Randomised Controlled Trial)



LEGEND:

- ● Non-Compliers Before And After The Programme
- ■ Non-Compliers Before And Compliers Afterwards
- ○ Compliers Before And Afterwards
- □ Compliers Before And Non-Compliers Afterwards

FIGURE 5.6.e Compliance with recommendations for weight, assessed before and three months after an education programme for insulin-dependent diabetics. (Randomised Controlled Trial)

associations were not statistically significant when adjusted for six comparisons. Compliance with weight recommendations was unrelated to compliance with other dietary recommendations.

5.8 PREDICTORS OF DIETARY COMPLIANCE

Significant associations between any of the 34 variables measured at the baseline assessment and subsequent compliance with carbohydrate composition, spacing and variation recommendations are shown in Tables 5.7.1A through F. As in the pre/post study, factors associated with or predictive of weight compliance were not analysed due to the small number of subjects who changed in weight over the study period.

Carbohydrate Composition

Factors measured at the pre-programme assessment which were found to be associated with carbohydrate composition compliance included initial intakes of carbohydrate, fat and alcohol, pre-programme serum cholesterol and the health belief score for perceived dietary compliance (Tables 5.7.2A through C). Not surprisingly, those who were initially closer to the carbohydrate goal before the programme were more likely to achieve it at follow-up. Compliers initially and finally (CC) also had lower fat and alcohol intakes (as percentages of energy) and a lower mean serum cholesterol at the pre-programme assessment than other groups. Also the group who were initially non-compliant but became compliant (NC) had a significantly higher serum cholesterol than the other groups before the programme (Table 5.7.2A). Perceived dietary compliance was also predictive of subsequent compliance with the carbohydrate composition recommendation. The proportions above the median (high perceived compliance) were

greatest in the CC group (89%), followed by the NC group (64%) and the NN group (41%) (Table 7.4A).

Carbohydrate Spacing

Compliance with the carbohydrate spacing recommendation was significantly associated with several continuous and categorical variables including pre-programme spacing score, age, glycosylated haemoglobin, referral source, perception of weight status and faith in doctor. By definition, those who were compliant initially and remained so (CC) or became non-compliant (CN) had significantly better (lower) scores for carbohydrate spacing prior to the programme than initial non-compliers. Also, compliers at follow-up (CC and NC) tended to be older (by a mean of ten years) and to have lower means for glycosylated haemoglobin than either group of non-compliers (NN, CN) (Table 5.7.2B). Significantly more of the non-compliers with spacing recommendations (NN and CN) were referred by the programme's endocrinologist (Table 5.7.3). Also non-compliers initially (NN and NC) had significantly greater faith in their doctors than non-compliers (Table 5.7.4B). Two other health beliefs were associated with carbohydrate spacing compliance although the associations were not statistically significant. Non-compliers (NN) tended to perceive themselves as less compliant and to have more difficulties with dietary compliance than any of the other groups.

Carbohydrate Variation

Compliers with carbohydrate variation recommendations had lower initial scores for variation, lower fasting blood glucose and glycosylated haemoglobin values and had a slightly higher mean age (Table 5.7.2C). They also tended to perceive themselves as

more compliant with dietary recommendations at the pre-programme assessment (Table 5.7.4.C). Although not statistically significant, initial compliers (CC, CN) perceived less difficulty with following their diets at entry to the programme than initial non-compliers (NN, NC).

When the appropriate adjustments were made for the number of variables (34) compared with each type of compliance only the pre-programme carhobydrate intake, and spacing and variation scores remained statistically significant.

The ability of the continuous variables to predict dietary compliance was tested by discriminant ayalyses and the results are shown in Tables 5.7.6A through C. Categorical variables could not be used in this analysis and so their validity as predictors could not be tested.

Carbohydrate composition compliance was predicted correctly in 70% of cases using initial carbohydrate intake (as a percentage of energy) and serum cholesterol level as the predictors. Fat intake did not enter the discriminant functions because fat and carbohydrate intake were highly related. On the basis of the predictor variables, only a few subjects were grossly misclassified as compliers when they were non-compliers at both assessments (NN). The majority of misclassifications was with the improvers (NC) (Table 5.7.6A).

Carbohydrate spacing compliance was predicted correctly in only 49% of cases on the basis of the pre-programme spacing score and age (Table 5.7.6B). Glycosylated haemoglobin did not enter the discriminant function because it's association with spacing compliance was relatively weak.

Membership in compliance groups for carbohydrate variation was predicted correctly in only 45% of cases on the basis of pre-programme variation scores (Table 5.7.6C). Other continuous variables which were found to be associated with variation compliance in the one-way analysis of variance (age, blood glucose, glycosylated haemoglobin) were not strongly associated and thus did not enter the discriminant functions.

The majority of health beliefs measured after the education programme were not significantly associated with dietary compliance. (Tables 5.7.5A through C). Only perceived dietary compliance was significantly related to carbohydrate composition compliance; higher proportions of those who were compliant at the follow-up assessment (NN and CC) were above the median score for perceived dietary compliance at this assessment. Although there were differences in the proportions of subjects above the medians for some health beliefs, these differences did not reach statistical significance.

5.9 THE RELATIONSHIP BETWEEN DIETARY COMPLIANCE AND ACHIEVEMENT OF BIOCHEMICAL GOALS

Tables 5.8.1A through D show the percentages of the sample in each compliance group who met the biochemical goals after the programme and who did not. Approximately half of the subjects had acceptable levels of fasting blood glucose at the follow-up assessment whilst only about one-third had acceptable glycosylated haemoglobin levels. The majority of subjects had serum cholesterol levels within an acceptable range whereas only about half had acceptable values for serum triglycerides.

Compliance with carbohydrate composition recommendations was significantly associated with the glycosylated haemoglobin measurement (Table 5.8.1A). Those who were non-compliant at both assessments were more likely to have an elevated value. Also, those who were initially non-compliant but increased their carbohydrate intake were more likely to be within the acceptable range for this measurement at follow-up. A similar trend was observed for fasting blood glucose although the association was not statistically significant.

Compliance with carbohydrate variation was also related to both measures of glycaemic control, although these associations were not statistically significant when critical p values were adjusted for 16 comparisons (Table 5.8.1C). Nonetheless, those subjects compliant with carbohydrate variation recommendations at the initial assessment (CC and CN) tended to have lower blood glucose and glycosylated haemoglobin values than initial non-compliers (NC, NN). Improvement in variation compliance (NC) was not, however, associated with better control as judged from either the blood glucose or haemoglobin A_1 measures.

Carbohydrate spacing compliance was not related to achievement of any of the biochemical goals at the follow-up assessment (Table 5.8.1B). Surprisingly, serum lipids were unrelated to any of the four types of dietary compliance assessed in this study.

Similar results were obtained when compliance to each dietary recommendation, measured only at the three month follow-up assessment were checked in relation to biochemical measures made at that time. Those who met the goals for carbohydrate composition

at follow-up were significantly more likely to have acceptable levels of glycosylated haemoglobin. However those who met spacing and variation goals at the follow-up were not more likely to achieve good diabetic control or acceptable serum lipids than those who did not meet the goals.

5.10 VALIDITY OF FOUR-DAY WEIGHED FOOD RECORDS

Prior to the analysis of the relationship between 24-hour urinary urea and protein intake calculated from food records an attempt was made to check the adequacy of the urine collections. Seven subjects had reported that they did not collect all of their urine for the full 24 hours and so their data were eliminated from further analysis. For the remainder of subjects, the measured 24-hour urinary creatinine values at each assessment were compared with predicted creatinine excretion. Contrary to expected, over half (60%) of measured 24-hour urinary creatinine values exceeded the predicted values by at least 20% and for one-third of subjects measured values exceeded the predicted by at least 35%.

These results suggested that either the urine collection period exceeded 24 hours for most subjects or that the prediction formula was inappropriate for these diabetic subjects. Laboratory error in creatinine determination was also considered possible, since creatinine assay methods have also been shown to result in a discrepancy between predicted and measured creatinine (Cockcroft and Gault 1976). To determine the effect of laboratory methods on creatinine values, 20 frozen aliquots of 24-hour urines were randomly selected from all samples with creatinine values greater than 140% of predicted or less than 60% of predicted. The results of analyses of these duplicates by the Renal Research Laboratory

showed good agreement for most values; only 4 values were substantially different when the results of the two methods were compared.

Although the explanation for the apparent under-estimation of predicted creatinine or the over-estimation of measured values could not be identified, it appeared that urinary creatinine values were not useful in identifying errors in 24-hour urine collections. Hence, the analysis of relationships between urinary urea and food record protein were done excluding only the results which were known to be inadequate collections and without any further correction for the adequacy of the urine collections.

The relationship between individual estimates of protein intake from 24-hour urinary urea values and from food records are shown in Figures 5.7.A through G. The correlation coefficients were, for Streams 1 and 2 respectively, 0.5 and 0.6 at their first assessment. Post-programme correlations were slightly lower but similar for both groups (0.4 and 0.5 for Streams 1 and 2 respectively). The lowest correlation was observed at the immediate pre-programme assessment for Stream 1 ($r=0.21$). None of these correlations were statistically significant, that is the observed associations could have occurred by chance.

Thus, these results show that whilst there was some association between protein intake calculated from dietary records and from 24-hour urinary urea excretion, there were considerable discrepancies in values for individuals at all assessments and, in particular at the second (pre-programme) assessment for Stream 1.

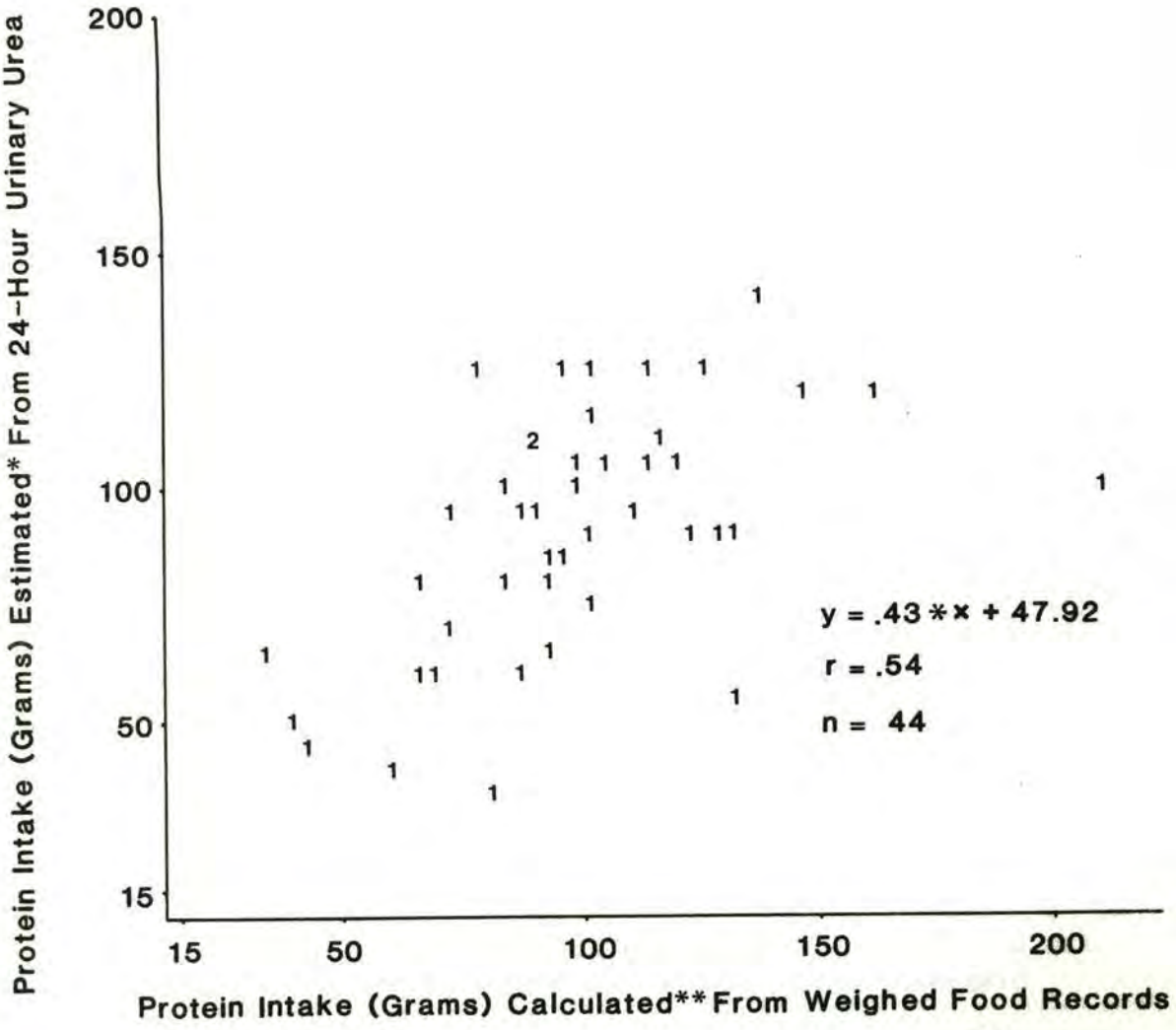


FIGURE 5.7.a The correlation between protein intake calculated from weighed dietary records and from 24-hour urinary urea, assessed three months before an education programme for insulin-dependent diabetics in Stream 1.

* estimated protein = urinary urea/24 hours x 0.175 + 20

** the average protein intake was calculated from two days of a four-day food record (the day before and the day of a 24-hour urine collection)

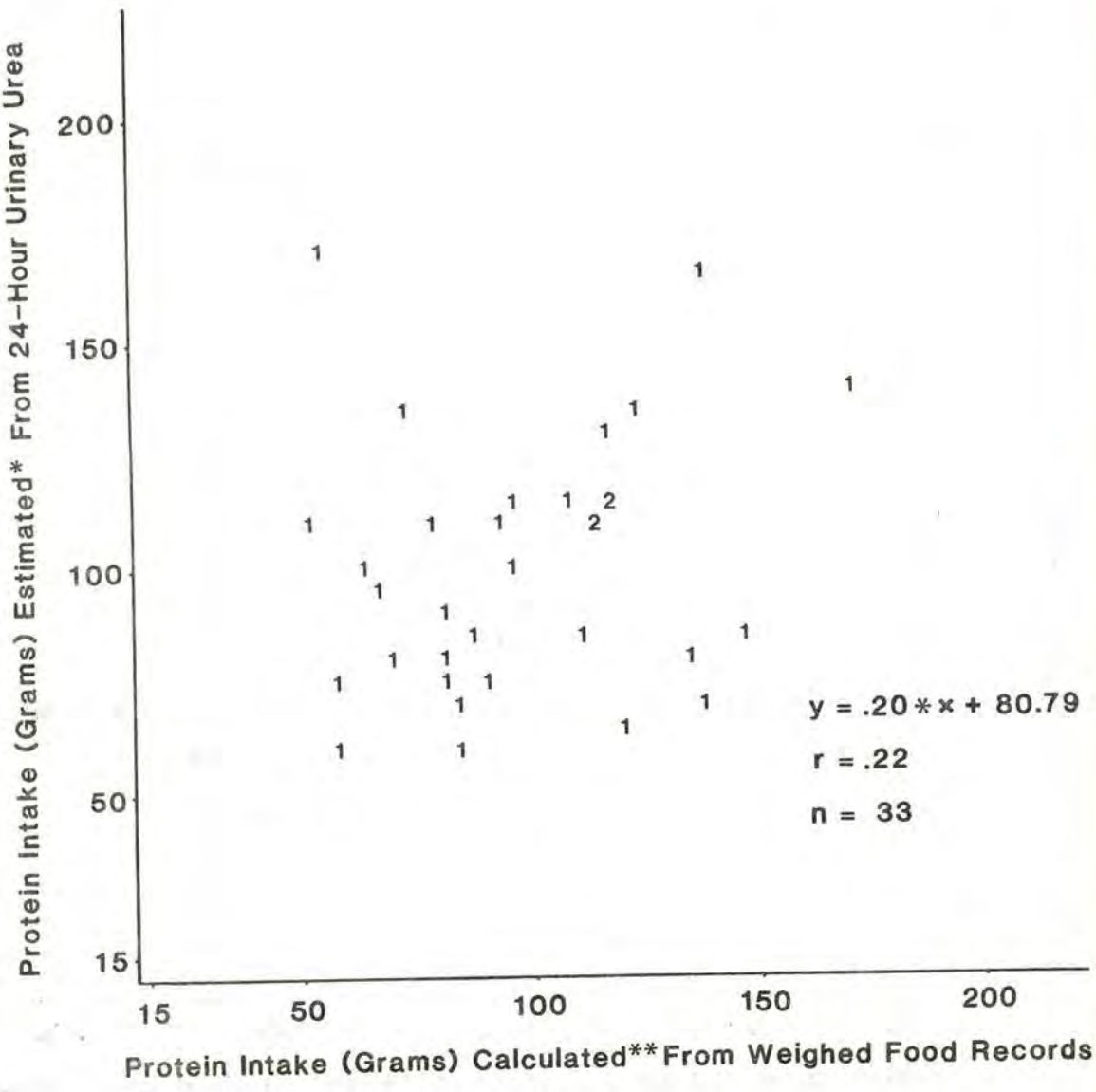


FIGURE 5.7.b The correlation between protein intake calculated from weighed dietary records and from 24-hour urinary urea, assessed immediately before an education programme for insulin-dependent diabetics in Stream 1.

* estimated protein = urinary urea/24 hours x 0.175 + 20

** the average protein intake was calculated from two days of a four-day food record (the day before and the day of a 24-hour urine collection)

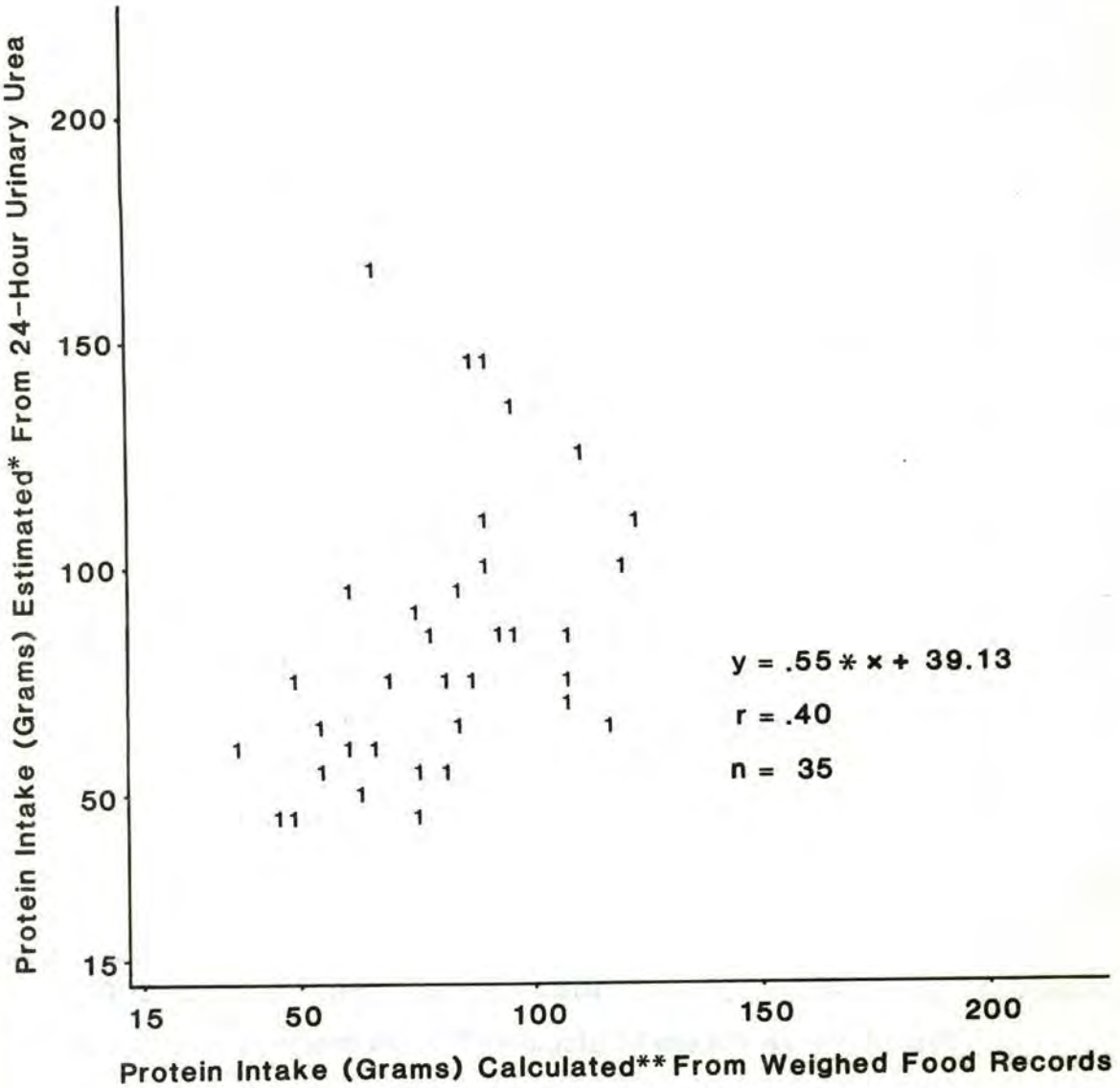


FIGURE 5.7.c The correlation between protein intake calculated from weighed dietary records and from 24-hour urinary urea, assessed three months after an education programme for insulin-dependent diabetics in Stream 1.

* estimated protein = urinary urea/24 hours x 0.175 + 20

** the average protein intake was calculated from two days of a four-day food record (the day before and the day of a 24-hour urine collection)

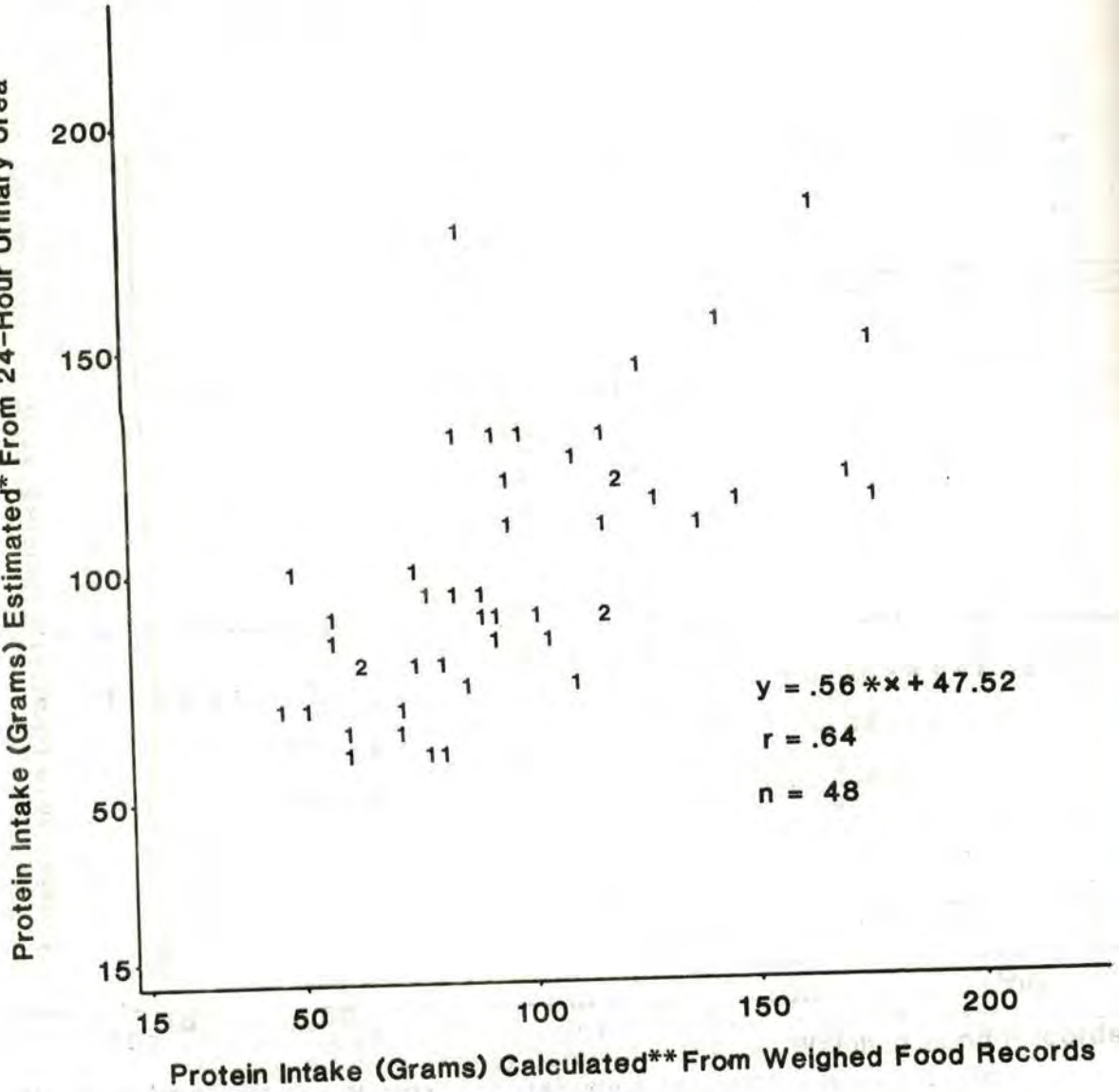


FIGURE 5.7.d The correlation between protein intake calculated from weighed dietary records and from 24-hour urinary urea, assessed immediately before an education programme for insulin-dependent diabetics in Stream 2.

* estimated protein = urinary urea/24 hours x 0.175 + 20

** the average protein intake was calculated from two days of a four-day food record (the day before and the day of a 24-hour urine collection)

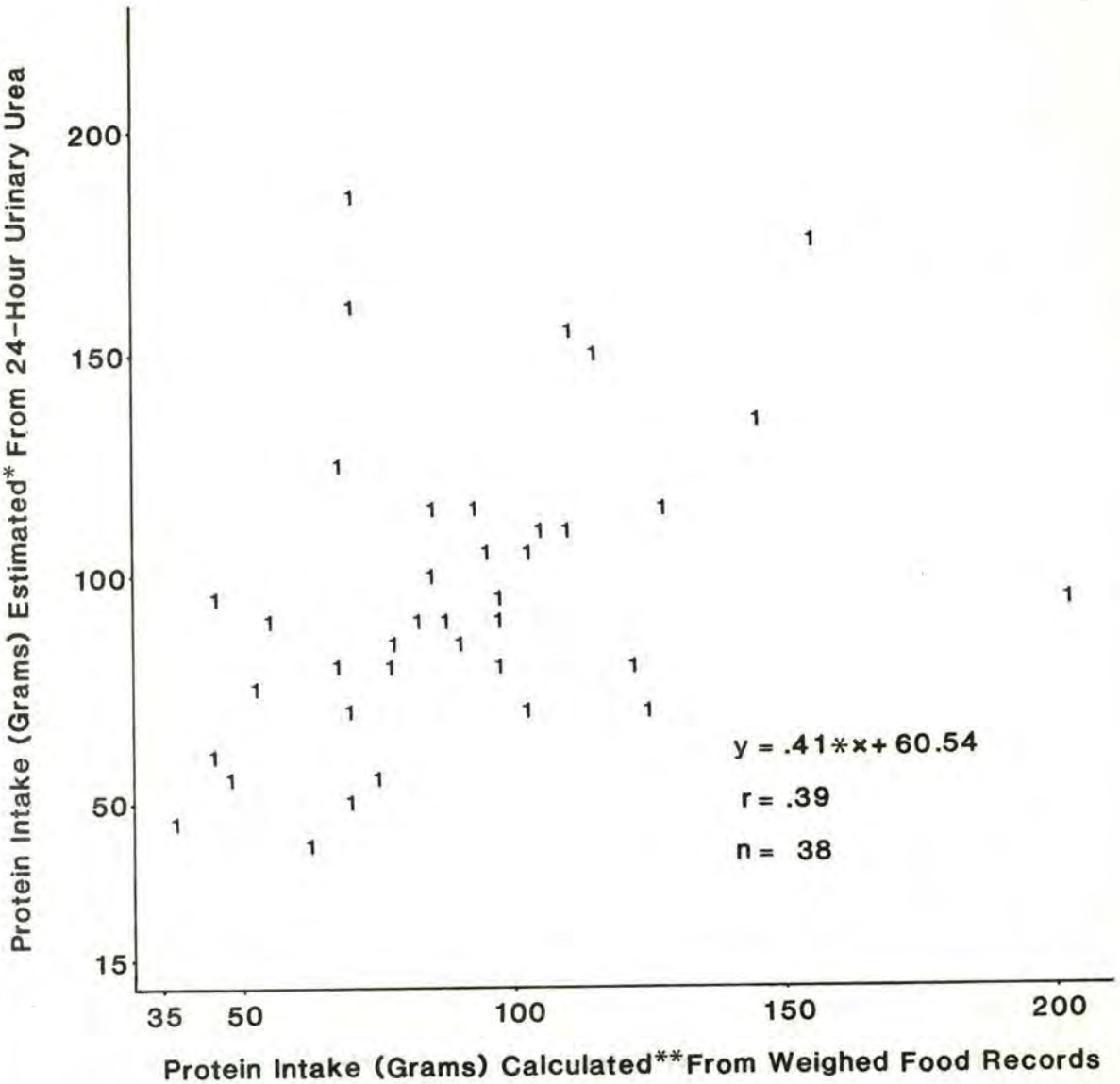


FIGURE 5.7.e The correlation between protein intake calculated from weighed dietary records and from 24-hour urinary urea, assessed three months after an education programme for insulin-dependent diabetics in Stream 2.

* estimated protein = urinary urea/24 hours x 0.175 + 20

** the average protein intake was calculated from two days of a four-day food record (the day before and the day of a 24-hour urine collection)

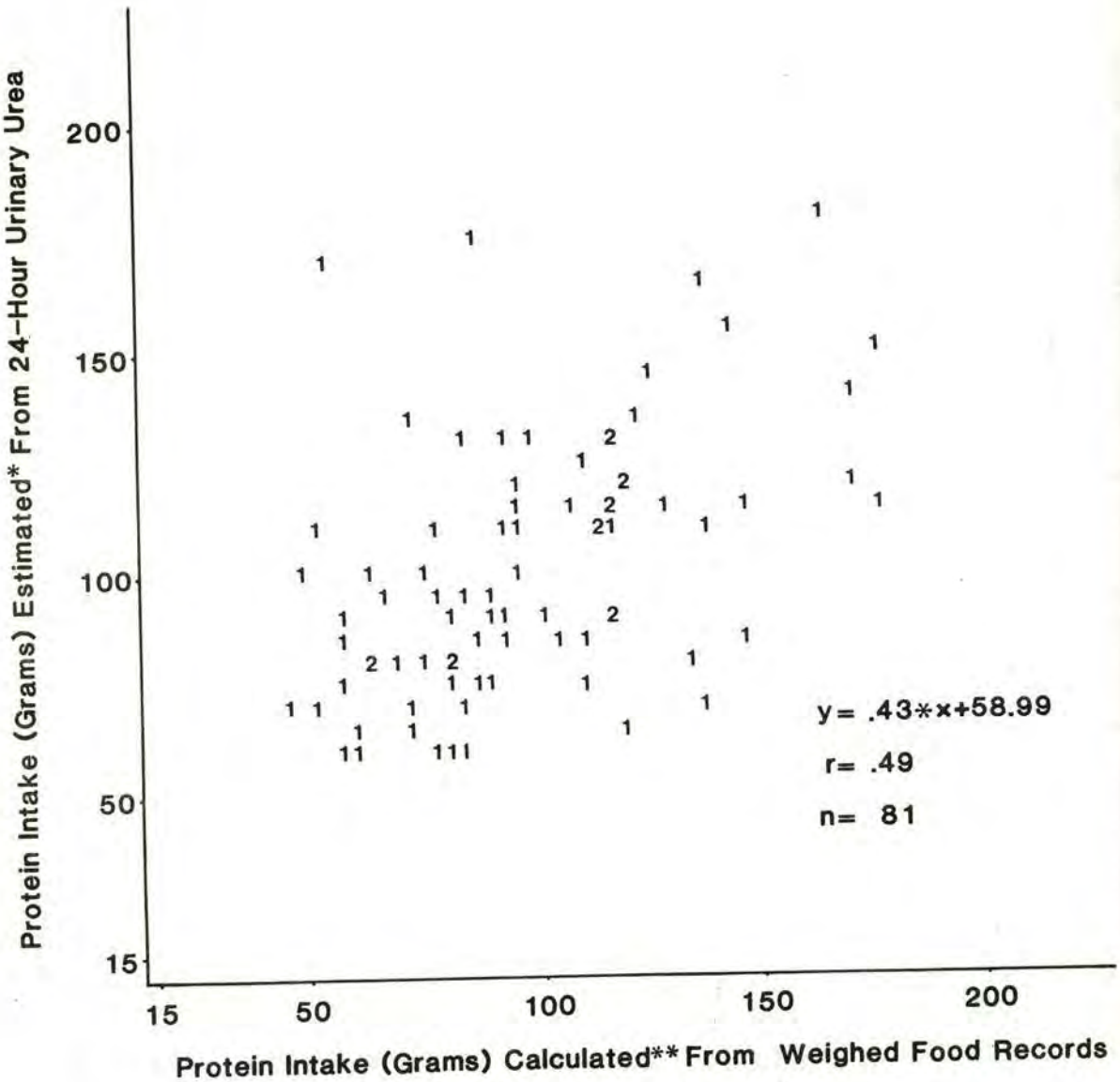


FIGURE 5.7.f The correlation between protein intake calculated from weighed dietary records and from 24-hour urinary urea, assessed immediately before an education programme for insulin-dependent diabetics (Streams 1 and 2 combined)

* estimated protein = urinary urea/24 hours x 0.175 + 20

** the average protein intake was calculated from two days of a four-day food record (the day before and the day of a 24-hour urine collection)

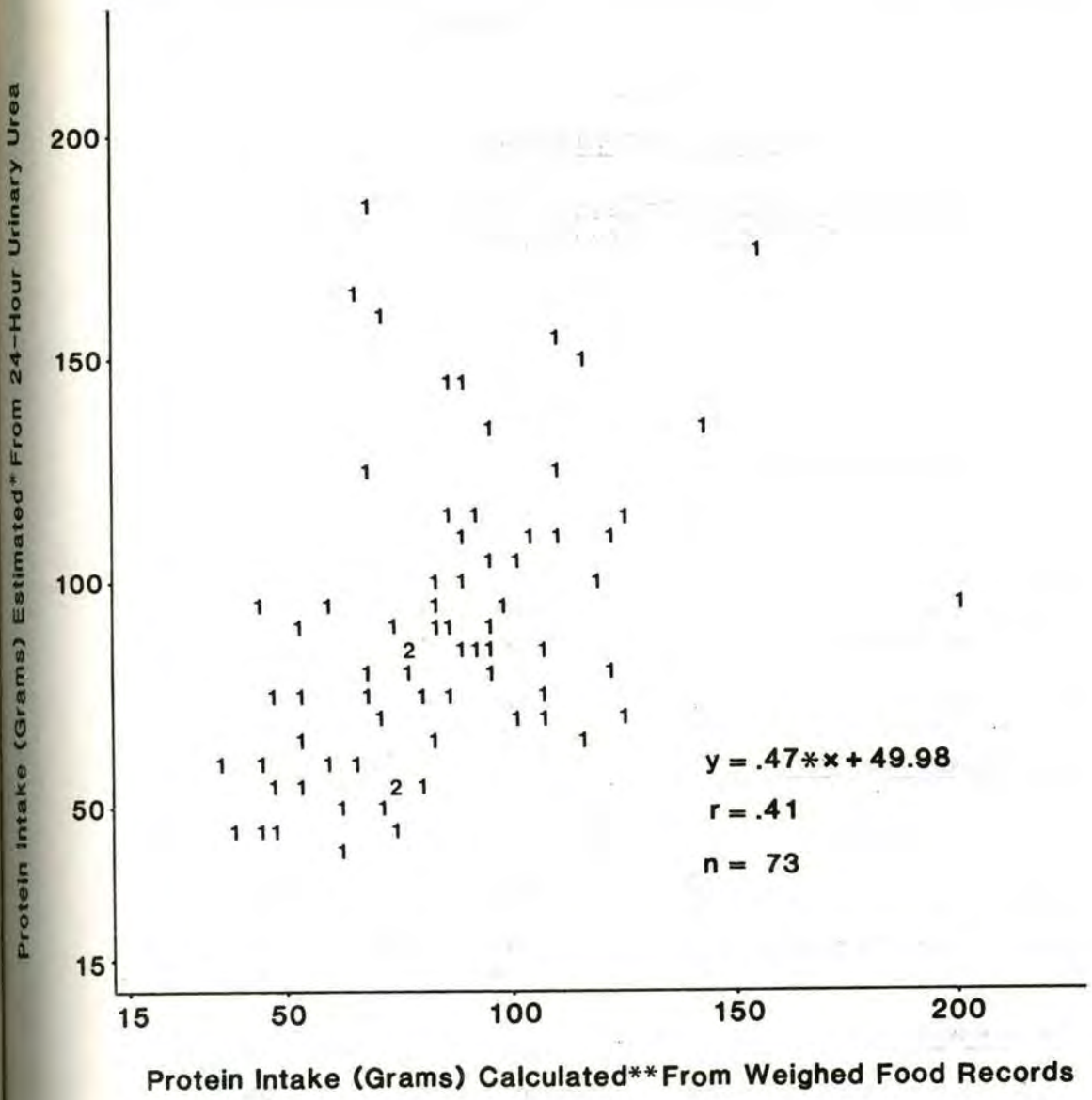


FIGURE 5.7.g The correlation between protein intake calculated from weighed dietary records and from 24-hour urinary urea, assessed three months after an education programme for insulin-dependent diabetics (Streams 1 and 2 combined)

* estimated protein = urinary urea/24 hours x 0.175 + 20

** the average protein intake was calculated from two days of a four-day food record (the day before and the day of a 24-hour urine collection)

TABLE 5.0.1

RANDOMISED CONTROLLED TRIAL

CO-OPERATION OF DIABETICS AND FAMILY MEMBERS WITH KEEPING FOUR-DAY WEIGHED FOOD RECORDS

	STREAM 1 n=53[a]		STREAM 2 n=53[a]	
	n	%[b]	n	%[b]
1. THREE MONTH PRE-ASSESSMENT				
A. DIABETICS				
attended	53	100	-	-
"reliable" records	48	90.6	-	-
doubtful & incomplete records	1	1.9	-	-
refused	2	3.8	-	-
unable to keep	2	3.8	-	-
2. PRE-PROGRAMME ASSESSMENT				
A. DIABETICS				
attended	42	79.2	53	100
"reliable" records	40	75.2	53	100
doubtful & incomplete records	1	1.8	0[c]	0
refused	1	2.4	0	0
B. FAMILY MEMBERS				
attended	28	100	36	100
"reliable" records	28[d]	100	33	91.6
doubtful & incomplete records	0	0	1	2.8
refused	0	0	2	5.6
3. THREE MONTH POST-ASSESSMENT				
A. DIABETICS				
attended	40	79.2	48	90.6
"reliable" records	40	79.2	47	88.6
doubtful & incomplete records	2	3.8	1[d]	1.9
refused	0	0	0	0
B. FAMILY MEMBERS				
attended	20	71.4	22	61.1
"reliable" records	18[d]	64.3	21[d]	58.3
doubtful & incomplete records	0	0	0	0
refused	2	3.8	1	1.2

(a) number of diabetics who attended the first assessment.

(b) percentages of the 53 subjects in each stream.

(c) two were asked to re-do food records due to incompleteness and inaccuracy.

(d) one individual was asked to re-do food record due to inaccuracies in weights.

TABLE 5.1.1

RANDOMISED CONTROLLED TRIAL

COMPARISON BETWEEN STREAMS 1 & 2 FOR DEMOGRAPHIC AND DIABETIC HISTORY VARIABLES

	STREAM 1 n=53 % (a)	STREAM 2 n=53 % (a)	X^2	df	p
AGE (years)					
18 - 30	26	30	4.3	3	0.24
31 - 45	23	34			
46 - 60	28	26			
Greater than 60	23	9			
SEX					
Female	40	57	3.06	1	0.08
Male	60	43			
DURATION OF DIABETES					
Less than 1 year	26	23	0.30	3	0.95
1 to 4 years	17	17			
5 to 10 years	23	26			
More than 10 years	34	34			
SOCIAL CLASS					
Sydney Norms					
A 4%	5	7	3.72	4	0.45
B 19.1%	36	38			
C 56.6%	34	43			
D 20.4%	8	4			
Retired	15	6			
(b) Missing	2	2			
REFERRAL SOURCE					
Programme Endocrinologist	21	40	5.92	3	0.12
Other Doctor	15	17			
Other Health Professional	23	17			
Non-Health Professional	41	24			
(b) Missing	0	2			
GEOGRAPHIC AREA OF RESIDENCE					
Northern Metrop.	62	66	1.8	2	0.41
Other Metrop.	25	28			
Outside Metrop.	13	6			
FAMILY MEMBER/FRIEND ATTENDED PROGRAMME					
Yes	53	67	1.93	1	0.16
No	47	33			
HOSPITALISED IN LAST YEAR FOR DIABETES					
Yes	53	47	0.34	1	0.56
No 47	53				
RECEIVED DIETARY ADVICE IN LAST THREE YEARS					
Yes	96	94	0.21	1	0.65
No	4	6			
PREVIOUS ATTENDANCE AT AN EDUCATION PROGRAMME					
Yes	15	15	0.2	1	0.89
No	77	83			
(b) Missing	8	2			

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TABLE 5.1.1 (continued)

	STREAM 1 n = 53	STREAM 2 n = 53	X^2	df	p
	%(a)	%(a)			
PRESENCE OF DIABETIC COMPLICATIONS					
Yes	51	57	0.48	1	0.49
No	26	40			
(b&c) Missing	23	4			
NUMBER OF INJECTIONS PER DAY					
1	55	51	0.15	1	0.70
2 or 3	45	49			
PRESENCE OF CURRENT PSYCHOLOGICAL DISTURBANCE	22.6	32.1	0.67	1	0.41
INSULIN DOSE (mean $\pm$ sem)	$\bar{x} \pm$ sem	$\bar{x} \pm$ sem	+		
	47.1 $\pm$ 3.67	36.7 $\pm$ 2.49	2.35	103	0.02#

(a) Percentages may not add to 100 due to rounding.

(b) Not included in significance test.

(c) 13 individuals in Stream 1 and 4 individuals in Stream 2 did not have clinical examinations because the endicrinologist was called away for hospital emergencies during assessment appointments.

p greater than .05 after adjustment for comparisons of 40 variables.

TABLE 5.1.2

RANDOMISED CONTROLLED TRIAL

INITIAL SIMILARITIES AND DIFFERENCES BETWEEN STUDY GROUPS FOR DIETARY VARIABLES

	STREAM 1 n=53	STREAM 2 n=53	t	df	p
	$\bar{x} \pm$ sem	$\bar{x} \pm$ sem			
I. CONTINUOUS VARIABLES	n=48[a]	n=53			
DIABETICS					
A. Dietary Composition (percent of energy)					
protein	17.35 ± .41	16.07 ± .38	2.3	99	0.02#
fat	41.02 ± .84	38.98 ± .97	1.6	99	0.11
complex carbohydrate	37.90 ± .82	37.0 ± 1.15	0.67	99	0.50
B. Percent of "ideal" weight	108.00 ± 2.34	107.9 ± 2.99	0.00	99	0.97
FAMILY MEMBERS					
A. Dietary Composition (percent of energy)	n=28	n=33[b]			
protein	15.7 ± .52	14.3 ± .40	2.3	59	0.02#
fat	41.1 ± 1.10	37.5 ± 1.28	2.1	59	0.09#
complex carbohydrate	35.1 ± 1.30	30.1 ± 1.09	3.0	59	0.009#
B. Percent of "ideal" weight	n=27[c] 107.2 ± 3.26	n=33 104.1 ± 2.64	0.73	58	0.46
II CATEGORICAL VARIABLES[d]					
DIABETICS	%[e]	%[e]	X^2	df	p
Sugar (% of energy)					
None	12.5	7.5	1.40	2	0.49
LE 5%	70.8	67.9			
GT 5%	16.7	24.5			
Alcohol (% of energy)					
None	56.3	41.5	4.79	2	0.09
LE 5%	27.1	22.6			
GT 5%	16.7	35.8			
Carbohydrate Spacing					
LT Median (.17%)	45.8	52.8	0.49	1	0.48
GE Median	54.2	47.2			
Carbohydrate Variation					
LT Median (.086)	50.0	49.0	0.00[f]	1	1.0
GE Median	50.0	51.0			
FAMILY MEMBERS	n=28	n=33			
Sugar[g]					
LE 5%	28.6	24.2	0.01	1	0.93
GT 5%	71.4	75.8			
Alcohol					
None	46.4	21.2	12.14	2	0.002#
LE 5%	39.3	21.2			
GT 5%	14.3	57.6			

/ 2 ...

TABLE 5.1.2 (continued)

KEY

* p greater than 0.05 after adjustment for comparisons of 40 variables

(a) 5 diabetics in Stream 1 who attended the first assessment did not complete four-day food records

(b) 3 family members (of Stream 2 diabetics) who attended the programme did not complete four-day food records

(c) 1 family member (of Stream 1 diabetics) declined to be weighed.

(d) Due to skewed distribition, data were grouped into categories and chi square tests were done.

(e) percentages may not add to 100 due to rounding

(f) Yates' corrected chi square was 0 when calculated from a very small Pearson chi square.

(g) Category for "none" in analysis of sugar intake was eliminated for family members since everyone reported consuming sugar.

TABLE 5.1.3

RANDOMISED CONTROLLED TRIAL

BASELINE SIMILARITIES AND DIFFERENCES BETWEEN

STREAMS 1 & 2 FOR BIOCHEMICAL MEASURES

	STREAM 1 n=51(a)			STREAM 2 n=51(a)			t	df	p
	mean	±	sem	mean	±	sem			
Fasting Blood Glucose (mmol/l)	9.6	±	.52	10.8 (n=53)(b)	±	.63	1.45	100	0.15
Glycosylated Haemoglobin (%)	9.6	±	.27	10.1	±	.25	1.41	102	0.16
Fasting Serum Cholesterol (mmol/l)	5.1	±	.13	5.4	±	.14	1.31	100	0.19
Fasting Serum Triglycerides (mmol/l) (Log_{10})	0.34	±	.03	0.24	±	.03	2.53	100	0.01#

(a) two individuals in each stream were unable to attend appointments for fasting blood tests

(b) two non-fasting individuals had an initial glycosylated haemoglobin determination

(c) logarithms to base ten were used because the distributions were highly skewed.

p greater than .05 after adjustment for 40 variables

TABLE 5.1.4

RANDOMISED CONTROLLED TRIAL

BASELINE COMPARISON OF SCORES FOR KNOWLEDGE AND HEALTH BELIEFS FOR TWO STUDY GROUPS

	STREAM 1	STREAM 2	t	df	p
	$\bar{x} \pm$ sem	$\bar{x} \pm$ sem			
	n=49(a)	n=51(a)			
Knowledge (42 possible points)	$23.2 \pm .99$	$24.9 \pm .88$	1.72	98	0.19
	STREAM 1 n=51(b)	STREAM 2 n=50(b)	x^2	df	p
	%(e)	%(e)			
(c) Health Beliefs					
1) Perceived susceptibility to health problems					
LT median (0.56)	49.0	46.9(e)	(f)	1	0.99
GE median	50.1	53.1			
	n=47(g)				
2) Perceived efficacy of diabetic regimens					
LT median (2.39)	59.6	40.0	2.97	1	0.08
GE median	40.4	60.0			
3) Perceived dietary compliance					
LT median (2.30)	47.1	48.0	0.00	1	1.00
GE median	52.9	52.0			
4) Perceived difficulties with dietary compliance					
LT median (0.19)	45.1	52.0	0.25	1	0.62
GE median	54.9	48.0			
	(n=31)(h)	(n=30)(h)			
5) Perceived difficulties controlling weight					
EQ median (0)	51.6	50.0	0.00	1	1.00
GT median	48.4	50.0			
6) Faith in Doctor					
LT median (0.90)	37.3	20.0	2.88	1	0.09
EQ median	62.7	80.0			

(a) four individuals in Stream 1 and two in Stream 2 did not complete an initial knowledge questionnaire.
(b) two individuals in Stream 1 and three in Stream 2 missed initial interview appointments.
(c) due to highly skewed distributions of these scores, median tests were used to determine differences.
(d) percentages may not add to 100 due to rounding
(e) one person responded in stream 2 "don't know" to all items under "susceptibility"
(f) Yates' corrected chi square was 0 when calculated from very small pearson chi square
(g) the questions concerning perceived efficacy were mistakenly omitted from four questionnaires at the first assessment
(h) twenty persons in each Stream responded "not applicable" to these questions.

TABLE 5.1.5

RANDOMISED CONTROLLED TRIAL

DIFFERENCES BETWEEN STREAMS 1 AND 2 IN BASELINE SCORES FOR PERCEIVED "QUALITY OF DIABETIC LIFE"

QDL	ITEM[c]	SCORES[b] STREAM[a] (n=50[a]) $\bar{x} \pm$ sem	STREAM[a] (n=51[a]) $\bar{x} \pm$ sem	t	df	p
1.	Managing diabetes	3.20 ± 0.11	2.96 ± 0.12	1.47	99	0.14
2.	Dealing with hypo's	3.12 ± 0.11	2.98 ± 0.10	0.93	99	0.35
3.	Confusion about diet	3.26 ± 0.13	3.04 ± 0.14	0.61	99	0.24
4.	Overwhelmed with self-care tasks	3.08 ± 0.12	3.24 ± 0.13	0.90	99	0.37
5.	Feeling restricted	3.14 ± 0.14	3.26 ± 0.13	0.61	99	0.55
6.	Frustrated with diet	3.04 ± 0.14	2.96 ± 0.14	0.41	99	0.68
7.	Able to eat out	3.10 ± 0.11	3.12 ± 0.10	0.37	99	0.91
8.	Able to do physical activity	2.88 ± 0.10	2.86 ± 0.13	0.10	99	0.92
9.	Irritable	2.94 ± 0.12	3.10 ± 0.15	0.82	99	0.41
10.[d]	Embarrassment about diabetes	3.36 ± 0.13	3.48 ± 0.14	0.63	98	0.52
11.[d]	Uncertainty about complications	3.06 ± 0.12	3.14 ± 0.13	0.47	96	0.64
12.	Seeking doctor's care	3.08 ± 0.10	3.02 ± 0.12	0.39	99	0.70
13.	Difficulty with injections	3.38 ± 0.11	3.28 ± 0.14	0.58	99	0.56
14.	Understanding diabetes control	3.20 ± 0.10	3.20 ± 0.11	0.03	99	0.98
15.[d]	Controlling blood fats	2.82 ± 0.11	2.62 ± 0.12	1.23	96	0.22
16.	Preventing severe hypos	3.12 ± 0.10	3.17 ± 0.12	0.36	99	0.72
17.	Able to travel	2.94 ± 0.13	2.86 ± 0.13	0.42	99	0.67
18.[d]	Confidence about controlling blood sugar	3.15 ± 0.10	2.86 ± 0.12	1.79	99	0.08
19.[d]	Able to find help	3.41 ± 0.10	3.22 ± 0.12	1.24	95	0.22
Average score over all items		3.11 ± 0.06	3.07 ± 0.07	0.26	99	0.61

(a) two individuals in each of Streams 1 and 2 did not complete an initial QDL questionnaire.

(b) scores ranged from 1 to 5; 5 indicated feeling "much better than usual", 1 "much worse than usual" and 3 "the same as usual".

(c) for exact wording of questions see QDL questionnaire in Appendix.

(d) responses were missing for some questions as follows:
Question 10: 1 missing (stream 2)
Questions 11, 15: 1 missing (stream 1), 2 missing (stream 2)
Questions 18, 19: 4 missing (stream 1)

TABLE 5.2.1

RANDOMISED CONTROLLED TRIAL

COMPARISON BETWEEN RETURNS & NON-RETURNS FOR DEMOGRAPHIC AND DIABETIC HISTORY VARIABLES

	RETURNS n=88	NON-RETURNS n=18	X^2	df	p
	%(b)	%			
AGE (years)					
18 - 30	30.1	16.7	8.59	3	0.04*
31 - 45	29.5	22.2			
46 - 60	28.4	22.2			
Greater than 60	11.4	38.8			
SEX					
Female	47.7	50.0	(d)0.00	1	1.00
Male	52.3	50.0			
DURATION OF DIABETES					
Less than 1 year	19.3	50.0	8.21	3	0.042*
1 to 4 years	17.0	16.7			
5 to 10 years	27.3	11.1			
More than 10 years	36.4	4.5			
SOCIAL CLASS					
Sydney Norms					
A 4%	8.1	0.0	14.8	4	0.005**
B 19.1%	41.9	16.7			
C 56.6%	38.4	44.4			
D 20.4%	5.8	5.5			
Retired	5.8	33.3			
(c) Missing (n)	2	0			
REFERRAL SOURCE					
Programme Endocrinologist	31.0	27.8	2.53	3	0.47
Other Doctor	17.2	11.1			
Other Health Professional	17.2	33.3			
Non-Health Professional	34.5	27.8			
(c) Missing (n)	1	0			
GEOGRAPHIC AREA OF RESIDENCE					
Northern Metrop	65.9	55.6	0.70	2	0.70
Other Metrop.	25.0	33.3			
Outside Metrop.	9.1	11.1			
FAMILY MEMBER/FRIEND ATTENDED PROGRAMME					
Yes	68.2	22.2	11.34	1	0.000**
No	31.8	77.8			
HOSPITALISED IN LAST YEAR FOR DIABETES					
Yes	43.2	83.3	8.097	1	0.004*
No	56.8	16.7			
RECEIVED DIETARY ADVICE IN LAST THREE YEARS					
Yes	95.5	94.4	(d)0.00	1	1.00
No	4.5	5.6			

/ 2 ...

TABLE 5.2.1 (continued)

	RETURNS n=88	NON-RETURNS n=18	X2	df	p
	%(b)	%			
PREVIOUS ATTENDANCE AT AN EDUCATION PROGRAMME					
Yes	17.9	5.9	(d)0.00	1	1.00
No	82.1	94.1			
(c) Missing (n)	4	1			
PRESENCE OF DIABETIC COMPLICATIONS					
Yes	60.0	85.7	0.89	1	0.35
No	40.0	14.3			
(c) Missing (n)	3	11			
NUMBER OF INJECTIONS PER DAY					
1	48.9	72.2	2.40	1	0.12
2 or 3	51.1	27.8			
PRESENCE OF CURRENT PSYCHOLOGICAL DISTURBANCE					
Yes	28.9	33.3	0.01	1	0.91
No	72.1	66.7			
Missing (n)	2	3			
STREAM					
1	45.4	72.2	(d)3.28	1	0.07
2	54.5	27.8			
INSULIN DOSE	43.0 ± 2.34	35.9 ± 6.91	t= 1.15	df= 103	0.25

* Not Statistically significant (p greater than .05) after adjustment for 40 comparisons
** Statistically significant at p less than .001 after adjustment for 40 comparisons
(b) percentages may not add to 100 due to rounding
(c) "missing" category not included in significance test
(d) Yates' corrected chi square was 0 when caclulated from a very small Pearson chi square

TABLE 5.2.2

RANDOMISED CONTROLLED TRIAL

INITIAL SIMILARITIES AND DIFFERENCES BETWEEN RETURNS AND NON-RETURNS FOR DIETARY VARIABLES

	RETURNS $\bar{x} \pm$ sem	NON-RETURNS $\bar{x} \pm$ sem	t	df	p
I. CONTINUOUS VARIABLES					
DIABETICS	n=87[a]	n=14[a]			
A. Dietary Composition					
protein	16.5 ± 0.31	17.86 ± 0.65.	1.65	99	0.10
fat	39.9 ± 0.72	40.1 ± 1.54	0.10	99	0.94
complex carbohydrate	37.4 ± 0.77	37.6 ± 1.91	0.10	99	0.93
	(n=88)	n=18			
B. Percent of "ideal" weight	107.5 ± 2.18	110.6 ± 3.24	0.62	99	0.54
FAMILY MEMBERS					
A. Dietary Composition	n=57[b]	n=4			
protein	15.1 ± 0.35	13.5 ± 1.32	1.16[d]	59	0.25
fat	39.0 ± 0.91	41.3 ± 4.19	0.61	59	0.54
complex carbohydrate	32.4 ± 0.95	32.7 ± 2.56	0.10	59	0.92
	n=56[c]	n=4			
B. Percent of "ideal" weight	105.03 ± 2.12	112.9 ± 8.5	0.94	58	0.35

II. CATEGORICAL VARIABLES

DIABETICS[d]	RETURNS n=87	NON-RETURNS n=14	X^2	df	p
	%[e]	%[e]			
Sugar			1.40	2	0.49
None	12.5	7.5			
LE	70.1	67.9			
GT 5%	16.7	24.5			
Alcohol			4.79	2	0.09
None	10.3	7.1			
LE	67.8	78.6			
GT 5%	21.8	14.3			
Carbohydrate Spacing			0.68	1	0.41
LT Median (.178)	51.7	35.7			
GE Median	48.3	64.8			
Carbohydrate Variation			0.00[f]	1	1.00
LT Median (.086)	49.4	50.0			
GE Median	50.6	50.0			

/ 2 ...

TABLE 5.2.2 (continued)

	RETURNS % (e)	NON-RETURNS % (e)	X2	df	p
FAMILY MEMBERS	n=57	n=4			
Sugar (g)					
LE 5%	26.3	25.0	0.00 (f)	1	1.00
GT 5%	73.7	75.0			
Alcohol					
None	31.6	50.0	0.60	2	0.74
LE 5%	29.8	25.0			
GT 5%	38.6	25.0			

(a) one diabetic "return and four diabetic "non-returns" did not keep an initial four-day food record.

(b) three family members of diabetic "returns" did not keep an initial four-day food record.

(c) one family member who completed an initial four-day food record did not wish to be weighed

(d) due to the highly skewed distributions of sugar, alcohol, spacing and variation, the data were grouped into categories and chi square tests were used

(e) percentages may not add to 100 due to rounding

(f) Yates' corrected chi square was 0 when calculated from a very small Pearson chi square.

(g) The category of "None"for sugar intake was eliminated for family members because everyone reported consuming sugar.

TABLE 5.2.3

RANDOMISED CONTROLLED TRIAL

BASELINE SIMILARITIES AND DIFFERENCES BETWEEN RETURNS AND NON-RETURNS FOR BIOCHEMICAL MEASURES

	RETURNS	NON-RETURNS	t	df	p
	$\bar{x} \pm$ sem	$\bar{x} \pm$ sem			
	(a) (n=87)	(a) (n=15)			
Fasting Blood Glucose (mmol/l)	10.15 ± 0.45	10.31 ± 1.09	0.14	100	0.89
	(n=87)	(b) (n=17)			
Glycosylated Haemoglobin (%)	9.89 ± 0.19	9.86 ± 0.55	0.03	102	0.94
	(n=87)	(n=17)			
Fasting Serum Cholesterol (mmol/l)	5.27 ± 0.11	5.29 ± 0.24	0.10	100	0.92
	n=(87)	(n=15)			
(c) Fasting Serum Triglycerides (mmol/l) (Log_{10})	0.28 ± 0.02	0.34 ± 0.04	1.14	100	0.26

(a) one individual who returned and three who did not return for follow-up were unable to attend initial fasting blood tests

(b) two non-fasting individuals had an initial glycosylated haemoglobin determination

(c) logarithms to base 10 were used because the distributions were highly skewed.

TABLE 5.2.4

RANDOMISED CONTROLLED TRIAL

COMPARISON OF BASELINE SCORES FOR KNOWLEDGE AND HEALTH BELIEFS FOR RETURNS AND NON-RETURNS

	RETURNS	NON-RETURNS	t	df	p
	$\bar{x} \pm$ sem n=86 (a)	$\bar{x} \pm$ sem n=14 (a)			
Knowledge (42)	24.9 ± 0.68	19.8 ± 1.17	3.03	98	0.003 #
Missing (No. of subjects)	2	4			

Health Beliefs (b)	RETURNS (n=85) (c) %	NON-RETURNS (n=16) (c) %	X^2	df	p
(1) Perceived susceptibility to health problems	(n=84) (d)				
LT Median (0.56)	46.4	56.3	0.2	1	0.65
GE Median	53.6	43.8			
(2) Perceived efficacy of diabetic regimens	(n=82) (e)	(n=15)			
LT Median (2.39)	48.8	53.3	0.002	1	0.97
GE Median	51.2	46.7			
(3) Perceived dietary compliance					
LT Median (2.30)	47.1	50.0	(g) 0.000	1	1.00
GE Median	52.9	50.0			
(4) Perceived difficulties with dietary compliance					
LT Median (0.19)	49.4	43.8	.02	1	0.88
GE Median	50.6	56.3			
(5) Perceived difficulties with weight control	(n=52) (f)	(n=9) (f)			
EQ Median (0)	51.9	44.4	.003	1	0.96
GT Median	48.1	55.5			
(6) Faith in doctor					
LT Median (0.90)	28.2	31.3	(g) .000	1	1.00
EQ Median	71.8	68.8			

(a) two "returns" and four "non-returns" did not complete an initial knowledge questionnaire
(b) due to the highly skewed distributions of these scores, median tests were used to determine significance of differences
(c) three "returns" and four "non-returns" missed their initial interview appointments
(d) one person responded "don't know" to all items under susceptibility
(e) the questions concerning perceived efficacy were mistakenly omitted from four questionnaires at the first assessment.
(f) thirty-three "returns" and seven "non-returns" responded "not applicable" to items under "Difficulty with Weight Control".
(g) Yates' corrected chi square was 0 when calculated from a very small Pearson chi square.

p greater than .05 after adjustment for 40 comparisons

TABLE 5.2.5

RANDOMISED CONTROLLED TRIAL

DIFFERENCES BETWEEN "RETURNS" AND "NON-RETURNS" IN BASELINE SCORES FOR PERCEIVED "QUALITY OF DIABETIC LIFE"

QDL	ITEM[c]	SCORES[b] RETURNS (n=86)[a] $\bar{x} \pm$ sem	NON-RETURNS (n=15)[a] $\bar{x} \pm$ sem	t	df	p
1.	Managing diabetes	3.03 ± 0.09	3.34 ± 0.19	1.30	99	0.20
2.	Dealing with hypo's	3.01 ± 0.08	3.28 ± 0.25	1.21	99	0.22
3.	Confusion about diet	3.11 ± 0.10	3.40 ± 0.29	1.12	99	0.26
4.	Overwhelmed with self-care tasks	3.11 ± 0.09	3.47 ± 0.27	1.50	99	0.13
5.	Feeling restricted	3.10 ± 0.09	3.73 ± 0.35	1.76	99	0.09
6.	Frustrated with diet	2.98 ± 0.11	3.13 ± 0.26	0.57	99	0.57
7.	Able to eat out	3.04 ± 0.08	3.53 ± 0.19	2.36	99	0.02#
8.	Able to do physical activity	2.86 ± 0.09	2.93 ± 0.25	0.32	99	0.76
9.	Irritable	2.99 ± 0.10	3.20 ± 0.31	0.78	99	0.43
10.[d]	Embarrassment about diabetes	3.74 ± 0.10	3.67 ± 0.33	0.84	98	0.41
11.[d]	Uncertainty about complications	3.06 ± 0.08	3.36 ± 0.34	0.85	96	0.41
12.	Seeking doctor's care	3.02 ± 0.08	3.27 ± 0.23	1.17	97	0.24
13.	Difficulty with injections	3.22 ± 0.09	3.93 ± 0.28	2.91	99	0.03#
14.	Understanding diabetes control	3.13 ± 0.07	3.60 ± 0.25	1.78	99	0.09
15.[d]	Controlling blood fats	2.68 ± 0.08	2.93 ± 0.27	1.07	96	0.29
16.	Preventing severe hypos	3.09 ± 0.08	3.47 ± 0.22	1.70	99	0.09
17.	Able to travel	2.87 ± 0.09	3.07 ± 0.28	0.77	99	0.44
18.[d]	Confidence about controlling diabetes	2.90 ± 0.08	3.57 ± 0.27	2.36	95	0.03#
19.[d]	Able to find help	3.31 ± 0.08	3.57 ± 0.20	1.36	95	0.18
Average score over all items		3.04 ± 0.04	3.38 ± 0.18	3.33	99	0.08

P greater than .05 after adjustment for 20 comparisons.

(a) 2 individuals who returned and 3 who did not return for follow-up assessment did not complete an initial QDL questionnaire.

(b) scores ranged from 1 to 5; 5 indicated feeling "much better than usual", 1 "much worse than usual" and 3 "the same as usual".

(c) for exact wording of questions see QDL questionnaire in Appendix.

(d) responses were missing for some questions as follows:
Question 10: missing for 1 return
Questions 11, 15: missing for 2 returns and 1 non-return
Questions 18, 19: missing for 3 returns and 1 non-return

TABLE 5.3.1.A

RANDOMISED CONTROLLED TRIAL

EFFECTS OF ASSESSMENT ONLY ON CONTINUOUS DIETARY VARIABLES AND KNOWLEDGE SCORES:

Paired t Tests Between Means at Assessments Three Months Prior and Immediately Prior to Education

	3 months Pre-Programme	Pre-Programme			
	X ± sem	X ± sem	t	df	p
A. Composition (n=39)[a] (% of energy)					
Protein	17.1 ± 0.47	16.8 ± 0.41	0.63	38	0.53
Fat	41.1 ± 0.91	41.0 ± 0.75	0.17	38	0.86
Complex carbohydrate	38.0 ± 0.88	37.5 ± 0.88	0.67	38	0.51
B. Body weight (n=42) (% of Ideal)	107.9 ± 2.99	108.4 ± 2.99	0.64	41	0.52
C. Knowledge of self-care (n=39)[a]	24.4 ± 1.0	25.1 ± 1.13	1.18	38	0.24

(a) Of the 42 Stream 1 subjects who attended the assessment immediately prior to the education programme, 1 subject did not keep a food record at the first assessment and 2 subjects did not complete one at the second assessment.

(b) 3 subjects did not complete a knowledge questionnaire at the assessment immediately prior to the programme.

TABLE 5.3.1.B

RANDOMISED CONTROLLED TRIAL

EFFECT OF ASSESSMENT ON CATEGORICAL DIETARY VARIABLES:

Differences In Proportions Above and Below the Median (or Goal) Between Assessments Three Months Prior and Immediately Prior to Education

1. CARBOHYDRATE SPACING SCORES (n=39)

	IMMEDIATELY PRIOR TO EDUCATION		
THREE MONTHS PRIOR TO EDUCATION	Below Median %	At or Above Median %	Total %
Below Median	27.5	20.0	47.5
At or Above Median	25.0	27.5	52.5
TOTAL	52.5	47.5	100.0

McNemar's Statistic X^2 = 0.22, df = 1, p = 0.64, median = .186

2. CARBOHYDRATE VARIATION SCORES (n=39)

	IMMEDIATELY PRIOR TO EDUCATION		
THREE MONTHS PRIOR TO EDUCATION	Below Median %	At or Above Median %	Total %
Below Median	37.5	12.5	50.0
At or Above Median	12.5	37.5	50.0
TOTAL	50.0	50.0	100.0

McNemar's Statistic X^2 = 0.00, df = 1, p = 1.00, median = .0875

TABLE 5.3.1.B (continued)

3. SUGAR INTAKE (n=39)
(percent of energy)

THREE MONTHS PRIOR TO EDUCATION	IMMEDIATELY PRIOR TO EDUCATION			
	NONE	LE 5%	GT 5%	TOTAL
NONE	5.0	7.5	0.0	12.5
LE, 5%	2.5	47.5	20.0	70.0
GT 5%	0.0	7.5	10.0	17.5
TOTAL	7.5	62.5	30.0	100.0

McNemar's Statistic $X^2 = 3.28$, df = 2, p = 0.19

4. ALCOHOL INTAKE (n=39)
(percent of energy)

THREE MONTHS PRIOR TO EDUCATION	IMMEDIATELY PRIOR TO EDUCATION			
	NONE	LE 5%	GT 5%	TOTAL
NONE	40.0	10.0	2.5	52.5
LE, 5%	12.5	17.5	2.5	32.5
GT 5%	0.0	2.5	12.5	15.0
TOTAL	52.5	30.0	17.5	100.0

McNemar's Statistic $X^2 = 1.11$, df = 3, p = 0.77

TABLE 5.3.2

RANDOMISED CONTROLLED TRIAL

EFFECTS OF ASSESSMENT ONLY ON BIOCHEMICAL VARIABLES:

Paired t Tests Between Means at Assessments
Three Months Prior and Immediately Prior to Education

(n=39)[a]

	3 month Pre-Assessment $\bar{x} \pm$ sem	Pre-Programme Assessment $\bar{x} \pm$ sem	t	df	p
Fasting blood glucose (m mol/l)	9.7 ± .64	10.6 ± .78	1.35	38	0.18
Glycosylated Haemoglobin (%)	9.7 ± .28	9.83 ± .33	0.94	38	0.35
Fasting serum cholesterol (m mol/l)	5.11 ± .16	5.25 ± .16	1.06	38	0.29
Fasting serum Triglycerides (Log_{10}, m mol/l)[b]	0.33 ± .03	0.31 ± .03	.069	38	0.49

(a) 3 individuals were unable to attend appointment for blood tests

(b) logarithms to base 10 were used because the distribution of triglycerides values was highly skewed

TABLE 5.3.3

RANDOMISED CONTROLLED TRIAL

EFFECTS OF ASSESSMENTS ON HEALTH BELIEFS:

Differences in Proportions of Stream 1 Subjects Above and Below the Median at Assessments Three Months Prior and Immediately Prior to an Education Programme

A. PERCEIVED SUSCEPTIBILITY TO HEALTH PROBLEMS

n=39[a]

THREE MONTHS PRIOR TO EDUCATION	IMMEDIATELY PRIOR TO EDUCATION: LT[b] Median %	GE Median %	Total %
LT Median[b]	35.9	17.9	53.8
GE Median	12.8	33.3	46.2
TOTAL	48.7	51.3	100.0

McNemar's Statistic $X^2 = 0.33$, df = 1, p = 0.56, median = 0.63

B. PERCEIVED EFFICACY OF SELF-CARE REGIMENS

n = 36[a]

THREE MONTHS PRIOR TO EDUCATION	IMMEDIATELY PRIOR TO EDUCATION: LT[b] Median %	GE Median %	Total %
LT Median[b]	25.0	5.6	30.6
GE Median	16.7	52.8	69.4
TOTAL	41.7	58.3	100.0

McNemar's Statistic $X^2 = 2.0$, df = 1, p = 0.16, median = 2.2

TABLE 5.3.3 (continued)

C. PERCEIVED COMPLIANCE WITH DIETARY RECOMMENDATIONS

n = 40[a]

THREE MONTHS PRIOR TO EDUCATION	IMMEDIATELY PRIOR TO EDUCATION: LT[b] Median %	GE Median %	Total %
LT Median[b]	32.5	17.5	50.0
GE Median	10.0	40.0	50.0
TOTAL	42.5	57.5	100.0

McNemar's Statistic X^2 = 0.82, df = 1, p = 0.37, median = 2.33

D. PERCEIVED DIFFICULTIES WITH DIET

n = 40[a]

THREE MONTHS PRIOR TO EDUCATION	IMMEDIATELY PRIOR TO EDUCATION: LT[b] Median %	GE Median %	Total %
LT Median[b]	32.5	12.5	45.0
GE Median	10.0	45.0	55.0
TOTAL	42.5	57.5	100.0

McNemar's Statistic X^2 = 0.11, df = 1, p = 0.74, median = 0.2

E. PERCEIVED DIFFICULTIES WITH WEIGHT CONTROL

n = 22[a]

THREE MONTHS PRIOR TO EDUCATION	IMMEDIATELY PRIOR TO EDUCATION: EQ[b] Median %	GT Median %	Total %
EQ Median[b]	40.9	4.5	45.5
GT Median	9.1	45.5	54.5
TOTAL	50.0	50.0	100.0

McNemar's Statistic X2 = 0.33, df = 1, p = 0.56, median = 0

TABLE 5.3.3 (continued)

F. FAITH IN DOCTOR'S CARE

n = 40[a]

THREE MONTHS PRIOR TO EDUCATION	IMMEDIATELY PRIOR TO EDUCATION: LT[b] Median %	GE Median %	Total %
LT Median[b]	30.0	10.0	40.0
GE Median	10.0	50.0	60.0
TOTAL	40.0	60.0	100.0

McNemar's Statistic $X^2 = 0.00$, df = 1, p = 1.00, median = 1

(a) Reasons for incomplete data on health beliefs for Stream 1 at the first two assessments are as follows:

(i) of the 42 diabetics who returned for assessments prior to the programme, two missed their appointment for a health belief interview.
(ii) one individual responded "don't know" to all items under "susceptibility".
(iii) the questions concerning "perceived efficacy" were mistakenly omitted from four questionnairs at the first assessment.
(iv) 18 individuals responded with "not applicable" to items conccerning "weight control".

(b) Medians were obtained from health belief scores of three month pre- and pre-programme assessments, combined (Stream 1)

TABLE 5.3.4

RANDOMISED CONTROLLED TRIAL

PERCEIVED "QUALITY OF DIABETIC LIFE" SCORES 3 MONTHS BEFORE AND IMMEDIATELY PRIOR TO AN EDUCATION PROGRAMME FOR DIABETICS

STREAM 1
n=41[a]
SCORES[b]

QDL	ITEM[c]	3 MONTHS BEFORE $\bar{x} \pm$ sem	IMMEDIATELY BEFORE $\bar{x} \pm$ sem	t	df	p
1.	Managing diabetes	3.12 ± 0.12	2.98 ± 0.13	1.40	40	0.24
2.[d]	Dealing with hypo's	3.07 ± 0.13	3.03 ± 0.10	0.10	39	0.76
3.	Confusion about diet	3.20 ± 0.13	3.24 ± 0.16	0.09	50	0.76
4.	Overwhelmed with self-care tasks	3.00 ± 0.11	3.17 ± 0.12	1.60	40	0.21
5.	Feeling restricted	3.07 ± 0.15	3.12 ± 0.11	0.14	40	0.71
6.	Frustrated with diet	2.95 ± 0.15	2.95 ± 0.16	0.00	40	1.00
7.	Able to eat out	2.98 ± 0.12	3.02 ± 0.10	0.10	40	0.75
8.	Able to do physical activity	2.83 ± 0.10	2.88 ± 0.10	0.16	40	0.16
9.[d]	Irritable	2.85 ± 0.12	3.00 ± 0.14	1.00	39	0.32
10.[d]	Embarrassment about diabetes	3.28 ± 0.15	3.38 ± 0.14	0.66	38	0.42
11.[d]	Uncertainty about complications	2.92 ± 0.11	2.94 ± 0.13	0.04	37	0.84
12.[d]	Seeking doctor's care	3.05 ± 0.11	3.15 ± 0.09	0.66	38	0.42
13.[d]	Difficulty with injections	3.25 ± 0.11	3.30 ± 0.15	0.07	39	0.79
14.[d]	Understanding diabetes control	3.13 ± 0.10	3.00 ± 0.10	1.00	39	0.32
15.[d]	Controlling blood fats	2.77 ± 0.12	2.64 ± 0.12	0.86	38	0.36
16.[d]	Preventing severe hypos	3.07 ± 0.11	3.00 ± 0.08	0.47	39	0.50
17.[d]	Able to travel	2.93 ± 0.13	2.95 ± 0.12	0.03	39	0.87
18.[d]	Confidence about controlling blood sugar	3.11 ± 0.10	2.92 ± 0.12	2.70	35	0.11
19.[d]	Able to find help	3.38 ± 0.16	3.38 ± 0.15	0.00	35	1.00
Average score over all items		3.05 ± 0.05	3.06 ± 0.06	0.02	40	0.88

(a) 1 individual who returned for the pre-programme assessment did not complete a QDL questionnaire.

(b) scores ranged from 1 to 5; 5 indicated feeling "much better than usual", 1 "much worse than usual" and 3 "the same as usual".

(c) for exact wording of questions see QDL questionnaire in Appendix.

(d) responses were missing for some questions as follows:
Questions 2, 9, 13, 14, 16, 17: missing for 1 subject
Questions 10, 12, 15: missing for 2 subjects
Question 11: missing for 3 subjects
Questions 18, 19: missing for 5 subjects

TABLE 5.4.1A

RANDOMISED CONTROLLED TRIAL

EFFECTS OF EDUCATION ON CONTINUOUS DIETARY VARIABLES AND KNOWLEDGE FOR (Streams 1 & 2):

Repeated Measures Analysis of Variance for Assessments Immediately Before and Three Months After Education

	Source	df[c]	Mean Square	F	P
A. Composition of diet (% of energy)					
Protein n=87[a]	Between streams	1	28.36	2.34	0.13
	Residual	85	12.11		
	Between assessments	1	0.87	0.19	0.67
	Interaction	1	2.52	0.54	0.46
	Residual	85	4.64		
Fat n=87[a]	Between Streams	1	47.43	0.66	0.42
	Residual	85	71.78		
	Between assessment	1	954.80	28.90	0.0001**
	Interaction	1	3.26	0.10	0.75
	Residual	85	33.04		
Complex Carbohydrate n=87[a]	Between Streams	1	0.22	0.00	0.96
	Residual	85	103.32		
	Between assessments	1	0.09	62.30	0.0001**
	Interaction	1	32.52	0.00	0.96
	Residual	85			
B. Body Weight (% of Ideal) n=88	Between Streams	1	34.44	0.04	0.83
	Residual	86	774.14		
	Between assessments	1	30.93	3.26	0.07
	Interaction	1	4.10	0.43	0.51
	Residual	86	9.48		
C. Knowledge of Diabetes n=86[b]	Between Streams	1	20.48	0.32	0.57
	Residual	84	64.98		
	Between assessments	1	3297.7	293.94	0.001*
	Interaction	1	0.00	0.00	0.99
	Residual	84	11.21		

* p less than .05 after adjustment for comparisons of 19 outcome variables
** statistically significant at p less than 0.01 after adjustment for comparisons of 19 outcome variables.
(a) one individual who returned for follow-up did not complete a four-day food record
(b) two individuals who returned did not complete a knowledge questionnaire
(c) one degree of freedom due to mean is not shown here.

TABLE 5.4.1.B

RANDOMISED CONTROLLED TRIAL

EFFECT OF EDUCATION ON CATEGORICAL DIETARY VARIABLES FOR STREAMS 1 AND 2

1. REFINED SUGAR INTAKE (% OF ENERGY)

STREAM 1 (n=40)

BEFORE EDUCATION	AFTER EDUCATION: NONE	LE 5%	GT 5%	TOTAL
	%	%	%	%
NONE	5.0	2.5	0.0	7.5
LE 5%	0.0	50.0	10.0	60.0
GT 5%	7.5	22.5	2.5	32.5
TOTAL	12.5	75.0	12.5	100.00

McNemar's Statistic X^2 = 5.92, df = 3, p = 0.12

STREAM 2 (n=47)[b]

BEFORE EDUCATION	AFTER EDUCATION: NONE	LE 5%	GT 5%	TOTAL
	%	%	%	%
NONE	2.1	6.4	0.0	8.5
LE 5%	6.4	51.1	8.5	66.0
GT 5%	0.0	12.8	12.8	25.6
TOTAL	8.5	70.3	21.3	[a]100.1

McNemar's Statistic X^2 = 0.40, df = 2, p = 0.81

TABLE 5.4.1.B (continued)

2. ALCOHOL INTAKE (% OF ENERGY)

STREAM 1 (n=40)

BEFORE EDUCATION	AFTER EDUCATION: NONE	LE 5%	GT 5%	TOTAL
	%	%	%	%
NONE	40.0	10.0	0.0	50.0
LE 5%	7.5	20.0	2.5	30.0
GT 5%	0.0	5.0	15.0	20.0
TOTAL	47.5	35.0	17.5	100.00

McNemar's Statistic $X^2 = 0.48$, df = 2, p = 0.79

STREAM 2 (n=47)[(b)]

BEFORE EDUCATION	AFTER EDUCATION: NONE	LE 5%	GT 5%	TOTAL
	%	%	%	%
NONE	29.8	6.4	4.3	40.5
LE 5%	17.0	6.4	2.1	25.5
GT 5%	2.1	14.9	17.0	34.0
TOTAL	48.9	27.7	23.4	100.00

McNemar's Statistic $X^2 = 7.11$, df = 2, p = 0.06

TABLE 5.4.1.B (continued)

3. SPACING SCORES

STREAM 1 (n=40)

BEFORE EDUCATION	AFTER EDUCATION: LT Median[c]	GE Median	TOTAL
	%	%	%
LT Median[c]	25.0	22.5	47.5
GE Median	25.0	27.5	52.5
TOTAL	50.0	50.0	100.0

McNemar's Statistic $X^2 = 0.05$, df = 1, p = 0.82, median = 0.1677

STREAM 2 (n=47)

BEFORE EDUCATION	AFTER EDUCATION: LT Median[c]	GE Median	TOTAL
	%	%	%
LT Median[c]	40.4	17.0	57.4
GE Median	8.5	34.0	42.6
TOTAL	48.9	51.1	100.00

McNemar's Statistic $X^2 = 1.33$, df = 1, p = 0.25, median = 0.1677

TABLE 5.4.1.B (continued)

4. VARIATION SCORES

STREAM 1 (n=40)

BEFORE EDUCATION	AFTER EDUCATION: LT Median[c]	GE Median	TOTAL
	%	%	%
LT Median[c]	27.5	17.5	45.0
GE Median	25.0	30.0	55.0
TOTAL	52.5	47.5	100.0

McNemar's Statistic X^2 = 0.53, df = 1, p = 0.47, median = 0.0792

STREAM 2 (n=47)

BEFORE EDUCATION	AFTER EDUCATION: LT Median[c]	GE Median	TOTAL
	%	%	%
LT Median[c]	38.3	10.6	48.9
GE Median	17.0	34.0	51.1
TOTAL	55.3	44.7	100.0

McNemar's Statistic X^2 = 0.69, df = 1, p = 0.41, median = 0.0792

(a) percentages do not add to 100 due to rounding

(b) one individual in Stream 2 who returned for re-assessment did not complete a four-day food record

(c) medians for spacing and variation were obtained from scores before and after the programme for the two streams combined.

TABLE 5.4.2

RANDOMISED CONTROLLED TRIAL

EFFECT OF EDUCATION ON BIOCHEMICAL OUTCOMES:

Repeated Measures Analysis of Variance for Streams 1 & 2

At Assessments Immediately Before and Three Months After Education

	Source	df[b]	Mean Square	F	P
Glycosylated Haemoglobin (%) n=87[a]	Between streams	1	6.38	0.85	0.36
	Residual	85	7.54		
	Between assessments	1	0.18	0.13	0.72
	Interaction	1	2.03	1.46	0.23
	Residual	85	1.39		
Fasting Blood Glucose (mmol/l) n=86[a]	Between Streams	1	1.11	0.04	0.85
	Residual	84	31.63		
	Between assessment	1	10.26	1.13	0.29
	Interaction	1	13.43	1.48	0.23
	Residual	84	9.08		
Fasting Serum Cholesterol (mmol/l) n=85[a]	Between Streams	1	0.66	0.42	0.52
	Residual	83	1.58		
	Between assessments	1	0.46	2.15	0.15
	Interaction	1	0.20	0.93	0.34
	Residual	83	0.21		
Fasting Serum Triglyceride (log_{10}, mmol/l) n=85[a]	Between Streams	1	0.05	0.95	0.33
	Residual	83	0.06		
	Between assessments	1	0.09	3.52	0.06
	Interaction	1	0.10	3.80	0.05#
	Residual	83	0.03		

p greater than .05 after adjustment for 19 comparisons

(a) reasons for incomplete data are as follows:

(i) Blood collection was unsuccessful in one individual at follow-up.
(ii) One subject was unable to attend the follow-up session fasting
(iii) The results from the lipid laboratory were not returned for one individual from whom an insufficient blood sample was obtained.

(b) one degree of freedom due to mean is not shown here.

TABLE 5.4.3

RANDOMISED CONTROLLED TRIAL

EFFECT OF EDUCATION ON HEALTH BELIEFS : MEDIAN TESTS FOR STREAMS 1 & 2 AT ASSESSMENTS IMMEDIATELY BEFORE AND 3 MONTHS AFTER EDUCATION

A. "PERCEIVED SUSCEPTIBILITY TO HEALTH PROBLEMS"

STREAM 1 (n=36)[a]

	AFTER EDUCATION		
BEFORE EDUCATION	LT Median[b] %	GE Median %	TOTAL %
LT Median[b]	25.0	16.7	41.7
GE Median	11.1	47.2	58.3
TOTAL	36.1	63.9	100.0

McNemar's Statistic X^2 = 0.40, df = 1, p = 0.53, median = 0.53

STREAM 2 (n=44)[a]

	AFTER EDUCATION		
BEFORE EDUCATION	LT Median[b] %	GE Median %	TOTAL %
LT Median[b]	36.4	18.2	54.6
GE Median	11.8	34.1	45.5
TOTAL	47.8	52.3	100.1[c]

McNemar's Statistic X^2 = 0.69, df = 1, p = 0.41, median = 0.63

TABLE 5.4.3 (continued)

B. "PERCEIVED EFFICACY OF DIABETIC SELF-CARE REGIMENS"

STREAM 1 (n=37)[a]

BEFORE EDUCATION	AFTER EDUCATION: LT Median[b] %	GE Median %	TOTAL %
LT Median[b]	35.1	27.0	62.1
GE Median	8.1	29.7	37.8
TOTAL	43.2	56.7	99.9[c]

McNemar's Statistic $X^2 = 3.77$, df = 1, p = 0.05#, median = 2.4

STREAM 2 (n=45)[a]

BEFORE EDUCATION	AFTER EDUCATION: LT Median[b] %	GE Median %	TOTAL %
LT Median[b]	20.0	22.2	42.2
GE Median	11.1	46.7	57.8
TOTAL	31.1	68.9	100.0

McNemar's Statistic $X^2 = 1.67$, df = 1, p = 0.20, median = 2.4

p greater than .05 after adjustment for comparisons of 19 outcome variables

TABLE 5.4.3 (continued)

C. "PERCEIVED COMPLIANCE WITH DIETARY REGIMEN"

STREAM 1 (n=37)[a]

	AFTER EDUCATION		
	LT Median[b]	GE Median	TOTAL
BEFORE EDUCATION	%	%	%
LT Median[b]	29.7	16.2	45.9
GE Median	0.0	54.1	54.1
TOTAL	29.7	70.3	100.0

McNemar's Statistic $X^2 = 6.0$, df = 1, p = 0.01*, median = 2.33

STREAM 2 (n=45)[a]

	AFTER EDUCATION		
	LT Median[b]	GE Median	TOTAL
BEFORE EDUCATION	%	%	%
LT Median[b]	26.7	17.8	44.5
GE Median	26.7	28.9	55.6
TOTAL	53.4	46.7	100.1[c]

McNemar's Statistic $X^2 = 0.53$, df = 1, p = 0.47, median = 2.33

* p greater than .05 after adjustment for comparisons of 19 outcome variables.

TABLE 5.4.3 (continued)

D. "PERCEIVED DIFFICULTIES WITH FOLLOWING DIET"

STREAM 1 (n=37)[a]

BEFORE EDUCATION	AFTER EDUCATION: LT Median[b] %	GE Median %	TOTAL %
LT Median[b]	24.3	16.2	40.5
GE Median	32.4	27.0	59.4
TOTAL	56.7	43.2	99.9 (c)

McNemar's Statistic X^2 = 2.0, df = 1, p = 0.16, median =0.105

STREAM 2 (n=45)[a]

BEFORE EDUCATION	AFTER EDUCATION: LT Median[b] %	GE Median %	TOTAL %
LT Median[b]	42.2	11.1	53.3
GE Median	11.1	35.6	46.7
TOTAL	53.3	46.7	100.00

McNemar's Statistic X^2 = 0.00, df = 1, p = 1.0, median =0.105

TABLE 5.4.3 (continued)

E. "PERCEIVED DIFFICULTY WITH WEIGHT CONTROL"

STREAM 1 (n=20)[a]

BEFORE EDUCATION	AFTER EDUCATION: EQ Median[b] %	AFTER EDUCATION: GT Median %	TOTAL %
EQ Median[b]	55.0	5.0	60.0
GT Median	15.0	25.0	40.0
TOTAL	70.0	30.0	100.00

McNemar's Statistic $X^2 = 1.0$, df = 1, p = 0.32, median = 0

STREAM 2 (n=22)[a]

BEFORE EDUCATION	AFTER EDUCATION: EQ Median[b] %	AFTER EDUCATION: GT Median %	TOTAL %
EQ Median[b]	40.9	4.5	45.4
GT Median	22.7	31.8	54.6
TOTAL	63.6	36.4	100.00

McNemar's Statistic $X^2 = 2.66$, df = 1, p = 0.10, median = 0

TABLE 5.4.3 (continued)

F. "FAITH IN DOCTOR"

STREAM 1 (n=37)[a]

BEFORE EDUCATION	AFTER EDUCATION: LT Median[b] %	AFTER EDUCATION: GE Median %	TOTAL %
LT Median[b]	18.9	24.3	43.2
GE Median	5.4	51.4	56.8
TOTAL	24.3	75.7	100.00

McNemar's Statistic $X^2 = 4.46$, df = 1, p = 0.03#, median = 1

STREAM 2 (n=44)[a]

BEFORE EDUCATION	AFTER EDUCATION: LT Median[b] %	AFTER EDUCATION: GE Median %	TOTAL %
LT Median[b]	9.1	11.4	20.5
GE Median	15.9	63.6	79.5
TOTAL	25.0	75.0	100.00

McNemar's Statistic $X^2 = 0.33$, df = 1, p = 0.56, median = 1

(a) Reasons for incomplete data are as follows:
- (i) three "return" subjects in Stream 1 and three in Stream 2 were unable to attend health belief interview appointments at either the pre- or post-assessments.
- (ii) 1 subject in each Stream responded "don't know" to all items under "perceived susceptibility."
- (iii) 17 subjects in Stream 1 and 23 in Stream 2 responded "not applicable" to questions concerning "difficulty with weight control" at either the pre- or post-assessment.
- (iv) 1 individual in Stream 2 responded "don't know" to questions regarding "faith in doctor."

(b) Grand medians were obtained from health belief scores combined for the two streams at pre- and post-assessments.

(c) percentages do not add to 100 due to rounding.

p greater than .05 after adjustment for comparisons of 19 outcome variables.

TABLE 5.4.4

RANDOMISED CONTROLLED TRIAL

PERCEIVED QUALITY OF LIFE SCORES AFTER AN EDUCATION PROGRAMME FOR STREAMS 1 AND 2

QDL	ITEM[c]	STREAM 1 (n=39)(a) $\bar{x} \pm$ sem	STREAM 2 (n=48)[a] $\bar{x} \pm$ sem	t[b]	df	p
1.	Managing diabetes	4.26 ± 0.10	3.92 ± 0.14	1.87	86	0.065
2.	Dealing with hypo's	3.95 ± 0.13	3.86 ± 0.14	0.47	86	0.63
3.	Confusion about diet	3.85 ± 0.20	4.02 ± 0.14	0.75	86	0.46
4.	Overwhelmed with self-care tasks	3.64 ± 0.17	3.45 ± 0.14	0.88	86	0.38
5.	Feeling restricted	3.64 ± 0.17	3.75 ± 0.13	0.55	86	0.59
6.	Frustrated with diet	3.51 ± 0.20	3.31 ± 0.15	0.84	86	0.40
7.	Able to eat out	3.33 ± 0.13	3.38 ± 0.10	0.32	86	0.75
8.	Able to do physical activity	3.43 ± 0.14	3.37 ± 0.10	0.41	86	0.69
9.	Irritable	3.42 ± 0.12	3.57 ± 0.13	0.85	85	0.399
10.[a]	Embarrassment about diabetes	3.39 ± 0.12	3.57 ± 0.13	0.99	83	0.33
11.[a]	Uncertainty about complications	3.92 ± 0.17	3.71 ± 0.15	0.89	85	0.37
12.[a]	Seeking doctor's care	3.79 ± 0.14	3.67 ± 0.13	0.60	85	0.55
13.[a]	Difficulty with injections	3.55 ± 0.15	3.63 ± 0.12	1.09	85	0.67
14.[a]	Understanding diabetes control	3.97 ± 0.17	4.19 ± 0.12	1.08	83	0.28
15.[a]	Controlling blood fats	3.76 ± 0.19	4.04 ± 0.10	1.40	84	0.16
16.[a]	Preventing severe hypos	3.76 ± 0.15	4.06 ± 0.11	1.60	85	0.11
17.[a]	Able to travel	3.47 ± 0.14	3.86 ± 0.12	2.05	85	0.04#
18.[a]	Confidence about controlling blood sugar	4.03 ± 0.17	4.08 ± 0.12	0.26	84	0.79
19.[a]	Able to find help	4.18 ± 0.15	4.18 ± 0.12	0.03	85	0.99
Average score over all items		3.73 ± 0.09	3.77 ± 0.08	0.10	86	0.75

(a) reasons for incomplete data are as follows:-
- (i) one individual in Stream 1 was not given the QDL Questionnaire,
- (ii) one individual omitted page two of the questionnaire (items 9-19)
- (iii) tow individuals skipped questions 10 and 14.
- (iv) one individual skipped items 15 and 18.

(b) two sample t test

p greater than .05 after adjustment for comparisons of 20 mean scores (individual items plus total score).

(c) for exact wording of questions see QDL questionnaire in Appendix

TABLE 5.4.5A

RANDOMISED CONTROLLED TRIAL

EFFECT OF EDUCATION ON CONTINUOUS DIETARY VARIABLES AND KNOWLEDGE:
Repeated Measures Analysis of Variance for Family Members of Streams1 & 2
At Assessments Immediately Before and Three Months After Education (n=42)

	Source	df(c)	Mean Square	F	P
A. Composition of diet (% of energy)					
Protein n=39(a)	Between streams	1	34.46	4.35	0.04*
	Residual	37	7.92		
	Between assessments	1	30.5	1.16	0.29
	Interaction	1	0.59	0.23	0.63
	Residual	37	2.63		
Fat n=39(a)	Between Streams	1	8.51	0.15	0.70
	Residual	35	56.81		
	Between assessment	1	183.34	4.84	0.03*
	Interaction	1	37.88	0.10	0.75
	Residual	37	37.88		
Complex Carbohydrate n=39(a)	Between Streams	1	195.36	4.42	0.04*
	Residual	37	44.21		
	Between assessments	1	89.67	6.45	0.02*
	Interaction	1	20.95	1.51	0.23
	Residual	37	13.91		
B. Body Weight (% of Ideal) n=42	Between Streams	1	283.89	0.60	0.44
	Residual	40	476.25		
	Between assessments	1	166.63	6.62	0.01*
	Interaction	1	0.03	0.00	0.97
	Residual	40	25.16		
C. Knowledge of Diabetes n=86(b)	Between Streams	1	4.75	0.06	0.81
	Residual	36	81.28		
	Between assessments	1	2489.80	112.93	0.001**
	Interaction	1	2.96	0.13	0.72
	Residual	36	22.05		

* not statistically significant (at p less than .05) after adjustment for comparisons of seven outcome variables

** statistically significant at p less than .01 after adjustment for comparisons of seven variables.

(a) two family members who returned with diabetics did not keep a food record at the follow-up assessments and one other did not keep an initial food record.

(b) two family members who returned did not complete a second knowledge questionnaire and two others did not complete an initial knowledge questionnaire.

(c) one degree of freedom due to mean is not shown here.

TABLE 5.4.5.B

RANDOMISED CONTROLLED TRIAL

EFFECT OF EDUCATION ON CATEGORICAL DIETARY VARIABLES
FOR FAMILY MEMBERS OF STREAMS 1 AND 2

1. SUGAR INTAKE
(% of energy)

Stream 1 (n=18)[a]

	AFTER EDUCATION		
BEFORE EDUCATION	LE 5%[b]	GT 5%	Total
	%	%	%
LE 5%	16.7	16.7	33.3
GT 5%	38.9	27.8	66.7
TOTAL	55.6	44.4	100.0

McNemar's Statistic X^2 = 1.6, df = 1, P = 0.21

Stream 2 (n=21)[a]

	AFTER EDUCATION		
BEFORE EDUCATION	LE 5%[b]	GT 5%	Total
	%	%	%
LE 5%	20.6	4.8	33.3
GT 5%	9.5	57.1	66.7
TOTAL	38.1	61.9	100.0

McNemar's Statistic X^2 = 0.33, df = 1, P = 0.56

TABLE 5.4.5.B (continued)

2. ALCOHOL INTAKE
(% of energy)

Stream 1 (n=18)[a]

BEFORE EDUCATION	AFTER EDUCATION: NONE	LE 5%	GT 5%	Total
	%	%	%	%
NONE	27.8	11.1	0.0	38.9
LE 5%	22.2	11.1	11.1	44.4
GT 5%	0.0	11.1	5.6	16.7
TOTAL	50.0	33.3	16.7	100.0

McNemar's Statistic $X^2 = 0.67$, df = 2, P = 0.72

Stream 2 (n=21)

BEFORE EDUCATION	AFTER EDUCATION: NONE	LE 5%	GT 5%	Total
	%	%	%	%
NONE	14.3	4.8	0.0	19.0
LE 5%	14.3	4.8	0.0	19.0
GT 5%	14.3	9.5	38.1	61.9
TOTAL	42.9	19.0	38.1	100.0

McNemar's Statistic $X^2 = 0.60$, df = 3, P = 0.11

(a) 2 family members who returned with Stream 1 diabetics and 1 who returned with a subject in Stream 2 did not complete four day food records at the follow-up assessment.

TABLE 5.5.1

RANDOMISED CONTROLLED TRIAL

COMPLIANCE WITH DIETARY AND WEIGHT RECOMMENDATIONS FOR STREAMS 1 AND 2 BEFORE AND THREE MONTHS AFTER PARTICIPATION IN AN EDUCATION PROGRAMME

A. CARBOHYDRATE COMPOSITION COMPLIANCE
(At least 45% of energy from complex carbohydrate)

Stream 1 (n=40)

POST-PROGRAMME

PRE-PROGRAMME[a]	Compliant %	Non-Compliant %	Total %
Compliant	10.0	2.5	12.5
Non-Compliant	47.5	40.5	87.5
TOTAL	57.5	42.5	100.0

McNemar's Statistic X^2 = 16.20, df = 1, p = 0.0001***

Stream 2 (n=47)[b]

POST-PROGRAMME

PRE-PROGRAMME[a]	Compliant %	Non-Compliant %	Total %
Compliant	10.6	6.4	17.0
Non-Compliant	31.9	51.1	83.0
TOTAL	42.6	57.5	100.0

McNemar's Statistic X^2 = 8.00, df = 1, p = 0.0047*

* p less than .05 after adjustment for 10 comparisons

*** p less than .001 after adjustment for 10 comparisons

TABLE 5.5.1 (continued)

B. FAT COMPOSITION
(Limited to 30% or less of energy)

Stream 1 (n=40)

POST-PROGRAMME

PRE-PROGRAMME[a]	Compliant %	Non-Compliant %	Total %
Compliant	0.0	2.5	2.5
Non-Compliant	20.0	77.5	97.5
TOTAL	20.0	80.0	100.0

McNemar's Statistic $X^2 = 5.4$, df = 1, p = 0.019#

Stream 2 (n=47)[b]

POST-PROGRAMME

PRE-PROGRAMME[a]	Compliant %	Non-Compliant %	Total %
Compliant	6.4	2.1	8.5
Non-Compliant	19.2	72.3	91.5
TOTAL	25.6	74.4	100.0

McNemar's Statistic $X^2 = 6.4$, df = 1, p = 0.01#

p GT than .05 after adjustment for 10 comparisons

TABLE 5.5.1 (continued)

C. CARBOHYDRATE SPACING
(Spacing scores less than .07)

Stream 1 (n=40)

POST-PROGRAMME

PRE-PROGRAMME[a]	Compliant %	Non-Compliant %	Total %
Compliant	15.0	17.5	32.5
Non-Compliant	12.5	55.0	67.5
TOTAL	27.5	72.5	100.0

McNemar's Statistic $X^2 = 0.33$, df = 1, p = 0.056

Stream 2 (n=47)

POST-PROGRAMME

PRE-PROGRAMME[a]	Compliant %	Non-Compliant %	Total %
Compliant	14.9	8.5	23.4
Non-Compliant	10.6	66.0	76.6
TOTAL	25.5	74.5	100.0

McNemar's Statistic $X^2 = 0.11$, df = 1, p = 0.74

TABLE 5.5.1 (continued)

D. CARBOHYDRATE VARIATION
(Variation scores less than 0.03)

Stream 1 (n=40)

POST-PROGRAMME

PRE-PROGRAMME[a]	Compliant %	Non-Compliant %	Total %
Compliant	10.0	7.5	17.5
Non-Compliant	12.5	70.0	82.5
TOTAL	22.5	77.5	100.0

McNemar's Statistic $X^2 = 0.50$, df = 1, p = 0.479

Stream 2 (n=47)

POST-PROGRAMME

PRE-PROGRAMME[a]	Compliant %	Non-Compliant %	Total %
Compliant	14.9	14.9	29.8
Non-Compliant	12.8	57.4	70.2
TOTAL	27.7	72.3	100.0

McNemar's Statistic $X^2 = 0.077$, df = 1, p = 0.781

TABLE 5.5.1 (continued)

E. MET WEIGHT GOALS

Stream 1 (n=40)

POST-PROGRAMME WEIGHT
(% of Ideal)

PRE-PROGRAMME WEIGHT	LE 110	GT 110	Total
	%	%	%
LE 110	60.0	2.5	62.5
GT 110	7.5	30.0	37.5
TOTAL	67.5	32.5	100.0

McNemar's Statistic $X^2 = 1.00$, df = 1, p = 0.32

Stream 2 (n=48)

POST-PROGRAMME WEIGHT
(% of Ideal)

PRE-PROGRAMME WEIGHT	LE 110	GT 110	Total
	%	%	%
LE 110	64.6	2.1	66.7
GT 110	4.2	29.2	33.3
TOTAL	68.8	31.3	100.0

McNemar's Statistic $X^2 = 0.33$, df = 1, p = 0.56

(a) Although "compliance is somewhat of a misnomer in describing pre-programme dietary behaviour, it is used here to distinguish those who met dietary and weight goals prior to the programme from those who did not meet the goals.

(b) One "return" subject in Stream 2 did not complete a four-day food record.

TABLE 5.5.2

RANDOMISED CONTROLLED TRIAL

NUMBERS OF SUBJECTS IN EACH OF THE COMPLIANCE GROUPS FOR STREAMS 1 AND 2 COMBINED n=88

(RETURNS ONLY)

COMPLIANCE VARIABLE	COMPLIANCE GROUP[a]				
	CC	CN	NC	NN	TOTAL
Weight	55	2	13	18	88
Carbohydrate composition	6	3[b]	34	53	87[c]
Carbohydrate spacing	13	11	10	53	87[c]
Carbohydrate variation	11	10	11	55	87[c]

(a) CC: compliler before and after the programme
CN: compliler before and non-compliler after the programme
NC: non-compliler before and compliler after the programme
NN: non-compliler before and after the programme

(b) For the analysis of associations between compliance and other variables these individuals were combined with "CC's" because their final carbohydrate intakes were only slightly less than 45% (closest to the mean for the CC group)

(c) One "return" in Stream 2 did not complete a four-day food record at the follow-up assessment.

TABLE 5.6.1

RANDOMISED CONTROLLED TRIAL

CHANGE IN DIETARY VARIABLES FOR STREAMS 1 AND 2
BETWEEN PRE- AND POST-PROGRAMME ASSESSMENTS

A. CHANGE IN COMPLEX CARBOHYDRATE INTAKE(†)
(% of energy)

Stream 1 (n=40)

INITIAL CARBOHYDRATE INTAKE (% of energy)	INCREASE GE 10%	INCREASE 5%-9%	LITTLE CHANGE	DECREASE 5%-9%	TOTAL
GE 45% (goal)	0.0	5.0	7.5	0.0	12.5
LT 45%	27.5	27.5	30.0	2.5	87.5
TOTAL	27.5	32.5	37.5	2.5	100.0

Stream 2 (n=47)(a)

INITIAL CARBOHYDRATE INTAKE (% of energy)	INCREASE GE 10%	INCREASE 5%-9%	LITTLE CHANGE	DECREASE 5%-9%	DECREASE GE 10%	TOTAL
GE 45% (goal)	2.1	2.1	4.3	8.5	0.0	17.0
LT 45%	34.0	23.4	21.3	2.1	2.1	82.9
TOTAL	36.1	25.5	25.6	10.6	2.1	99.9(b)

TABLE 5.6.1 (continued)

B. CHANGE IN FAT INTAKE(†)
(% of energy)

Stream 1 (n=40)

INITIAL CARBOHYDRATE INTAKE (% of energy)	INCREASE GE 10%	INCREASE 5%-9%	LITTLE CHANGE	DECREASE 5%-9%	DECREASE GE 10%	TOTAL
LE 30% (goal)	0.0	0.0	0.0	0.02	2.5	2.5
GT 30%	27.5	27.5	40.0	2.5	0.0	97.5
TOTAL	27.5	27.5	40.0	2.5	2.5	100.0

Stream 2 (n=47)(a)

INITIAL CARBOHYDRATE INTAKE (% of energy)	INCREASE GE 10%	INCREASE 5%-9%	LITTLE CHANGE	DECREASE 5%-9%	DECREASE GE 10%	TOTAL
LE 45% (goal)	0.0	4.3	2.1	0.0	2.1	8.5
GT 30%	23.4	19.2	42.6	2.1	4.3	91.6
TOTAL	23.4	23.5	44.7	2.1	6.5	100.1(b)

TABLE 5.6.1 (continued)

C. CHANGE IN WEIGHT (†)
(% of Ideal)

Stream 1 (n=40)

INITIAL WEIGHT	LOST GE 5% IDEAL	LITTLE CHANGE	GAINED GT 5% IDEAL	TOTAL
	%	%	%	%
Ideal LE 110%	5.0	50.0	7.5	62.5
Somewhat overweight (111-120% Ideal)	10.0	2.5	0.0	12.5
Overweight (GT 120% Ideal)	10.0	15.0	0.0	25.0
TOTAL	25.0	67.5	7.5	100.0

Stream 2 (n=48)

INITIAL WEIGHT	LOST GE 5% IDEAL	LITTLE CHANGE	GAINED GT 5% IDEAL	TOTAL
	%	%	%	%
Ideal LE 110%	4.2	58.3	4.2	66.7
Somewhat overweight (111-120% Ideal)	4.2	14.6	0.0	18.8
Overweight (GT 120% Ideal)	6.3	8.3	0.0	14.6
TOTAL	14.7	81.2	4.2	100.0 (b)

(a) One individual in Stream 2 who returned for follow-up did not complete a four-day food record.

(b) Percentages do not add to 100 due to rounding.

(†) Due to small expected values in several cells, the significance of differences were not tested.

TABLE 5.7.1

RANDOMISED CONTROLLED TRIAL

ASSOCIATIONS BETWEEN FOUR TYPES OF DIETARY COMPLIANCE FOR STREAMS 1 AND 2 COMBINED

A. THE RELATIONSHIP BETWEEN WEIGHT COMPLIANCE AND CARBOHYDRATE COMPOSITION COMPLIANCE (n=87)

CARBOHYDRATE COMPOSITION COMPLIANCE GROUP	WEIGHT COMPLIANCE GROUP				
	NN	NC	CN	CC	TOTAL
NN	13.8	6.9	1.1	28.7	50.6
NC	6.9	4.6	1.1	26.4	39.1
CC	0.0	3.4	0.0	6.9	10.3
TOTAL	20.7	14.9	2.3	62.1	100.0

$X^2 = 5.92$, df = 6, p = 0.43

B. THE RELATIONSHIP BETWEEN WEIGHT COMPLIANCE AND CARBOHYDRATE SPACING COMPLIANCE (N=87)

CARBOHYDRATE SPACING COMPLIANCE GROUP	WEIGHT COMPLIANCE GROUP				
	NN	NC	CN	CC	TOTAL
NN	14.9	6.9	2.3	36.8	60.9
NC	1.1	0.0	0.0	10.3	11.5
CN	1.1	5.7	0.0	5.7	12.6
CC	3.4	2.3	0.0	9.2	14.9
TOTAL	20.7	14.9	2.3	62.1	100.0

$X^2 = 13.55$, df = 9, p = 0.14

TABLE 5.7.1 (continued)

C. THE RELATIONSHIP BETWEEN WEIGHT COMPLIANCE AND CARBOHYDRATE VARIATION COMPLIANCE
(n=87)

CARBOHYDRATE VARIATION COMPLIANCE GROUP	WEIGHT COMPLIANCE GROUP				
	NN	NC	CN	CC	TOTAL
NN	16.1	11.5	2.3	33.3	63.2
NC	2.3	1.1	0.0	9.2	12.6
CN	1.1	1.1	0.0	9.2	11.5
CC	1.1	1.1	0.0	10.3	12.6
TOTAL	20.7	14.9	2.3	62.1	100.0

$X^2 = 6.30$, df = 9, p = 0.71

D. THE RELATIONSHIP BETWEEN CARBOHYDRATE COMPOSITION COMPLIANCE AND SPACING COMPLIANCE
(n=87)

CARBOHYDRATE COMPOSITION COMPLIANCE GROUP	SPACING COMPLIANCE GROUP				
	NN	NC	CN	CC	TOTAL
NN	33.3	5.7	5.7	5.7	50.6
NC	21.8	3.4	4.6	29.2	39.1
CC	5.7	2.3	2.3	0.0	10.3
TOTAL	60.9	11.5	12.6	14.9	100.0

$X^2 = 5.6$, df = 6, p = 0.47

TABLE 5.7.1 (continued)

E. THE RELATIONSHIP BETWEEN CARBOHYDRATE COMPOSITION COMPLIANCE AND CARBOHYDRATE VARIATION COMPLIANCE (n=87)

CARBOHYDRATE COMPOSITION COMPLIANCE GROUP	VARIATION COMPLIANCE GROUP				
	NN	NC	CN	CC	TOTAL
NN	40.2	2.3	5.7	2.3	50.6
NC	17.2	9.2	5.7	6.9	39.1
CC	5.7	1.1	0.0	3.4	10.3
TOTAL	63.2	12.6	11.5	12.6	100.0

$X^2 = 16.73$, df = 6, p = 0.010#

F. THE RELATIONSHIP BETWEEN CARBOHYDRATE SPACING COMPLIANCE AND CARBOHYDRATE VARIATION COMPLIANCE (n=87)

SPACING COMPLIANCE GROUP	VARIATION COMPLIANCE GROUP				
	NN	NC	CN	CC	TOTAL
NN	44.8	5.7	6.9	3.4	60.9
NC	3.4	3.4	0.0	4.6	11.5
CN	9.2	0.0	2.3	1.1	12.6
CC	5.7	3.4	2.3	3.4	14.9
TOTAL	63.2	12.6	11.5	12.6	100.0

$X^2 = 20.33$, df = 9, p = 0.016#

p greater than .05 when adjusted for 6 comparisons

TABLE 5.7.2

RANDOMISED CONTROLLED TRIAL

A. BASELINE FACTORS (CONTINUOUS VARIABLES) ASSOCIATED WITH CARBOHYDRATE COMPOSITION COMPLIANCE

VARIABLE	NN (n=53)	NC (n=34)	CC (n=9)	F[(a)]	df	p
	$\bar{x} \pm$ sem	$\bar{x} \pm$ sem	$\bar{x} \pm$ sem			
PRE-PROGRAMME CARBOHYDRATE INTAKE (percentage of energy)	34.09 ± 1.09	38.15 ± 0.74	48.44 ± 1.54	22.22	2 84	0.00001***
PRE-PROGRAMME FAT INTAKE (percentage of energy)	40.98 ± 1.12	40.03 ± 0.67	32.56 ± 2.28	5.49[(b)]	2 21	0.012#
PRE-PROGRAMME SERUM CHOLESTEROL (m mol/l)	5.18 ± 0.14	5.70 ± 0.19	4.87 ± 0.25	4.03	2 84	0.021#

p greater than .05 after adjustment for 34 comparisons

(a) Significant differences in analyses of variance were due to the following pairs:
carbohydrate: NN & NC, NN & CC, NC & CC
fat: NN & CC, NC & CC
cholesterol: NC & CC

(b) Welch's F, p and df values were reported because the variances between the groups were significantly different (Levene's test)

TABLE 5.7.2 (continued)

B. BASELINE FACTORS (CONTINUOUS VARIABLES) ASSOCIATED WITH CARBOHYDRATE SPACING COMPLIANCE

(n=86)

COMPLIANCE GROUP

VARIABLE	NN (n=53)	NC (n=10)	CN (n=11)	CC (n=13)	F[(a)]	df	p
	x ± sem	x ± sem	x ± sem	x ± sem			
PRE-PROGRAMME SPACING SCORE (square root)	0.63 ± 0.06	0.56 ± 0.08	0.15 ± 0.09	0.16 ± 0.04	10.33	3 83	0.0001**
AGE (years)	37.2 ± 1.67	52.1 ± 4.2	38.6 ± 4.04	49.77 ± 4.37	6.05	3 83	0.0009*
PRE-PROGRAMME Glycosylated Haemoglobin	10.5 ± 0.29	8.6 ± 0.47	9.9 ± 0.51	9.3 ± 0.41	3.57	3 83	0.017#

* p less than .05 after adjustment for comparisons of 34 predictor variables

** p less than .01 after adjustment for comparisons of 34 predictor variables

\# p greater than .05 after adjustment for 34 comparisons

(a) Significant differences in analyses of variance were due to the following pairs:
Spacing score: NN & CC
age: NN & NC, NN & CC
glycosylated haemoglobin: NN & NC

TABLE 5.7.2 (continued)

C. BASELINE FACTORS (CONTINUOUS VARIABLES) ASSOCIATED WITH CARBOHYDRATE VARIATION COMPLIANCE

(n=87)

VARIABLE	COMPLIANCE GROUP NN (n=55)	NC (n=11)	CN (n=10)	CC (n=11)	F[(a)]	df	p
	x ± sem	x ± sem	x ± sem	x ± sem			
PRE-PROGRAMME VARIATION SCORE (square root)	0.47 ± 0.04	0.32 ± 0.06	0.11 ± 0.01	0.11 ± 0.009	9.67	3 83	0.0001**
PRE-PROGRAMME FASTING BLOOD GLUCOSE (mmol/l)	11.26 ± 0.63	12.26 ± 1.45	7.91 ± 0.96	7.90 ± 0.81	5.54[(b)]	3 23	0.005#
PRE-PROGRAMME GLYCOSYLATED HAEMOGLOBIN (%)	10.31 ± 0.27	10.56 ± 0.58	9.67 ± 0.57	8.41 ± 0.49	3.44	3 83	0.02#
AGE (years)	37.87 ± 1.85	45.27 ± 4.67	43.70 ± 4.29	49.46 ± 3.53	2.84	3 83	0.04#

** p less than .01 after adjustment for comparisons of 34 predictor variables

p greater than .05 after adjustment for 34 comparisons

(a) Significant differences in analyses of variance were due to the following pairs:
Variation score: NN & CC, NN & CN, NC & CC, NC & CN
Blood glucose: NN & CC
Glycosylated haemoglobin: NN & CC
Age: No group was significantly different after adjustments for 6 pairwise comparisons

(b) Welch's F, p and df values were reported because the variances between groups were significantly different (Levene's test)

TABLE 5.7.3

RANDOMISED CONTROLLED TRIAL

BASELINE FACORS (CATEGORICAL VARIABLES) ASSOCIATED WITH DIETARY COMPLIANCE

A. RELATIONSHIP BETWEEN CARBOHYDRATE COMPOSITION COMPLIANCE AND ALCOHOL INTAKE (n=87)[b]

ALCOHOL INTAKE (% of energy)	COMPLIANCE GROUP NN %	NC %	CC %	TOTAL
NONE	34.1	50.0	77.8	44.8
LE 5%	22.7	35.3	22.2	27.6
GT 5%	43.2	14.7	0.0	27.6
TOTAL	100.0	100.0	100.0	100.0

$X^2 = 13.13$, df = 4, p = 0.010#

B. RELATIONSHIP BETWEEN CARBOHYDRATE SPACING COMPLIANCE AND REFERRAL SOURCE (n=87)[b]

REFERRAL SOURCE	COMPLIANCE GROUP NN %	NC %	CN %	CC %	TOTAL
D.E.A.P. Endocrinologist	35.8	0.0	50.0	23.1	31.4
Other doctor	17.0	30.0	10.0	15.4	17.4
Other Health Professional	11.3	50.0	0.0	23.1	16.3
Other	35.8	20.0	40.0	38.5	34.9
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 16.68$, df = 9, p = 0.05#

(a) Only two categorical variables were significantly associated with dietary compliance

(b) One subject in Stream 2 did not complete a four-day food record at the follow-up assessment

\# p greater than .05 after adjustment for 34 comparisons

TABLE 5.7.4.A

RANDOMISED CONTROLLED TRIAL

THE RELATIONSHIP BETWEEN PRE-PROGRAMME HEALTH BELIEFS AMD CARBOHYDRATE COMPOSITION COMPLIANCE (n=84)[a]

HEALTH BELIEF (percent above median at pre-programme assessment)	COMPLIANCE GROUP NN (n=41) %	NC (n=33) %	CC (n=9) %	X^2	df	p
1. Perceived susceptibility[b] (n=82)	41.5	62.5	66.7	4.01	2	0.14
2. Perceived efficacy of regimens	54.8	33.3	11.9	1.25	2	0.54
3. Perceived dietary compliance	40.5	63.6	88.9	8.74	2	0.013#
4. Perceived difficulty with diet	59.5	45.5	44.4	1.72	2	0.43
5. Perceived difficulty with weight control[c] (n=53)	55.2	36.8	40.0	1.66	2	0.44
6. Faith in doctor	73.8	66.7	66.7	0.51	2	0.77

p greater than .05 after adjustment for comparisons of 34 predictor variables

TABLE 5.7.4.B

RANDOMISED CONTROLLED TRIAL

THE RELATIONSHIP BETWEEN PRE-PROGRAMME HEALTH BELIEFS AND CARBOHYDRATE SPACING COMPLIANCE

(n=84)[a]

HEALTH BELIEF (percent above median at pre-programme assessment)	COMPLIANCE GROUP NN (n=51) %	NC (n=9) %	CN (n=11) %	CC (n=12) %	X^2	df	p
1. Perceived susceptibility[b] (n=82)	55.8	44.4	63.6	30.0	3.03	3	0.39
2. Perceived efficacy of regimens	50.0	60.0	54.5	36.4	1.31	3	0.73
3. Perceived dietary compliance	44.2	80.0	63.6	72.7	6.68	3	0.08
4. Perceived difficulty with diet	63.5	30.0	36.4	36.4	6.83	3	0.08
5. Perceived difficulty with weight control (n=53)	48.7	33.3	57.1	25.0	1.34	3	0.72
6. Faith in doctor	73.1	100.0	54.5	45.5	8.97	3	0.03#

p greater than .05 after adjustment for comparisons

TABLE 5.7.4.C

RANDOMISED CONTROLLED TRIAL

THE RELATIONSHIP BETWEEN PRE-PROGRAMME HEALTH BELIEFS AND CARBOHYDRATE VARIATION COMPLIANCE

(n=84)[a]

HEALTH BELIEF (percent above median at pre-programme assessment)	COMPLIANCE GROUP NN (n=53) %	NC (n=9) %	CN (n=10) %	CC (n=11) %	X^2	df	p
1. Perceived susceptibility (n=82)[b]	51.9	63.6	44.4	50.0	0.81	3	0.85
2. Perceived efficacy of regimens	44.4	63.6	66.7	50.0	2.48	3	0.47
3. Perceived dietary compliance	44.4	54.5	77.8	90.0	9.26	3	0.026#
4. Perceived difficulty with diet	59.3	6.36	22.2	30.0	6.87	3	0.076
5. Perceived difficulty with weight control (n=53)[c]	51.3	20.0	66.7	0.0	5.34	3	0.148
6. Faith in doctor	70.4	63.6	77.8	70.0	0.48	3	0.92

p greater than .05 after adjustment for comparisons of 34 predictor variables

(a) 4 subjects missed their initial interview appointment

(b) 2 subjects responded "don't know" to all items under "susceptibility"

(c) 31 subjects responded "not applicable" to questions concerning "difficulty with weight control"

TABLE 5.7.5.A

RANDOMISED CONTROLLED TRIAL

RELATIONSHIP BETWEEN POST-PROGRAMME HEALTH BELIEFS AND CARBOHYDRATE COMPOSITION COMPLIANCE (n=83)[a]

HEALTH BELIEF (percent above median at pre-programme assessment)	COMPLIANCE GROUP NN (n=41) %	NC (n=33) %	CC (n=9) %	X^2	df	p
1. Perceived susceptibility	46.3	60.6	55.6	0.47	2	1.52
2. Perceived efficacy of regimens	46.3	63.6	44.4	0.28	2	2.49
3. Perceived dietary compliance	36.6	72.7	100.0	17.15	2	0.0002*
4. Perceived difficulty with diet	73.2	78.8	55.6	1.96	2	0.37
5. Perceived difficulty with weight control (n=55)[b]	34.5	20.0	33.3	1.26	2	0.53
6. Faith in doctor's care (n=82)[c]	75.0	63.6	100.0	4.89	2	0.87

* Statistically significant at p less than .05 after adjustment for 34 comparisons

TABLE 5.7.5.B

RANDOMISED CONTROLLED TRIAL

THE RELATIONSHIP BETWEEN POST-PROGRAMME HEALTH BELIEFS AND CARBOHYDRATE SPACING COMPLIANCE (n=83)[a]

HEALTH BELIEF (percent above median at pre-programme assessment)	COMPLIANCE GROUP NN (n=51) %	NC (n=9) %	CN (n=11) %	CC (n=12) %	X^2	df	p
1. Perceived susceptibility to complications	60.8	22.2	54.5	41.7	5.29	3	0.15
2. Perceived efficacy of regimens	49.0	55.6	54.5	66.7	1.26	3	0.74
3. Perceived dietary compliance	49.0	77.8	63.6	75.0	4.69	3	0.19
4. Perceived difficulty with diet	82.4	55.6	72.7	50.0	6.94	3	0.07
5. Perceived difficulty with weight control (n=55)	29.7	0.0	50.0	18.2	2.32	3	0.50
6. Faith in doctor's care (n=82)	70.6	88.9	80.0	66.7	1.80	3	0.61

TABLE 5.7.5.C

RANDOMISED CONTROLLED TRIAL

THE RELATIONSHIP BETWEEN POST-PROGRAMME HEALTH BELIEFS AND CARBOHYDRATE VARIATION COMPLIANCE (n=83)[a]

HEALTH BELIEF (percent above median at pre-programme assessment)	COMPLIANCE GROUP NN (n=53) %	NC (n=9) %	CN (n=10) %	CC (n=11) %	x^2	df	p
1. Perceived susceptibility to complications	52.8	44.4	70.0	45.5	1.67	3	0.64
2. Perceived efficacy of regimens	47.2	77.8	60.0	54.5	3.15	3	0.37
3. Perceived dietary compliance	50.9	66.7	50.0	90.9	6.5	3	0.089
4. Perceived difficulty with diet	79.2	77.8	50.0	63.4	4.37	3	0.22
5. Perceived difficulty with weight control (n=55)[b]	36.8	0.0	16.7	20.0	4.22	3	0.24
6. Faith in doctor (n=82)[c]	76.9	66.7	60.0	72.7	1.45	3	0.69

Reasons for incomplete data are as follows:

(a) 5 subjects missed their health belief interview appointment at the post-assessment.

(b) 28 subjects responded "not applicable" to questions concerning "difficulty with weight control"

(c) 1 subject responded "don't know" to all questions concerning "faith in doctor"

TABLE 5.7.6.A

RANDOMISED CONTROLLED TRIAL

CLASSIFICATION MATRIX AND DISCRIMINANT FUNCTIONS
FOR CARBOHYDRATE COMPOSITION COMPLIANCE
(n=86)

	PREDICTED COMPLIANCE[a]			
MEASURED COMPLIANCE	NN	NC	CC	Percent Correctly Classified
NN	30	10	4	68.2
NC	8	21	4	63.6
CC	0	0	9	100.0
TOTAL	38	31	17	69.8%

(a) Based on jacknifed classification using pre-programme carbohydrate composition and serum cholesterol as the predictors. Individuals were classified into the compliance category with the largest Z value derived from the following equations:

$$Z_{NN} = -36.11 + 1.08 \times \begin{matrix}\text{Pre-programme}\\ \text{Carbohydrate}\\ \text{Compliance}\end{matrix} + 6.39 \times \begin{matrix}\text{Pre-programme}\\ \text{Cholesterol}\end{matrix}$$

$$Z_{NC} = -44.43 + 1.21 \times \begin{matrix}\text{Pre-programme}\\ \text{Carbohydrate}\\ \text{Compliance}\end{matrix} + 7.09 \times \begin{matrix}\text{Pre-programme}\\ \text{Cholesterol}\end{matrix}$$

$$Z_{CC} = -52.59 + 1.47 \times \begin{matrix}\text{Pre-programme}\\ \text{Carbohydrate}\\ \text{Compliance}\end{matrix} + 6.42 \times \begin{matrix}\text{Pre-programme}\\ \text{Cholesterol}\end{matrix}$$

TABLE 5.7.6.B

RANDOMISED CONTROLLED TRIAL

CLASSIFICATION MATRIX AND DISCRIMINANT FUNCTIONS FOR CARBOHYDRATE SPACING COMPLIANCE (n=86)

	PREDICTED COMPLIANCE[a]				
MEASURED COMPLIANCE	NN	NC	CN	CC	Percent Correct
NN	24	12	13	4	45.3
NC	2	6	0	2	60.0
CN	0	0	7	4	63.6
CC	0	2	5	5	41.7
TOTAL	26	20	25	15	48.8%

(a) Based on jacknifed classification using pre-programme spacing score (square root) and age as predictors. Individuals were classified into the compliance category with the largest Z value from the following equations:

$$Z_{NN} = -7.42 + 5.81 \times \text{Pre-programme Spacing Score (Square Root)} + 0.23 \times \text{Age at Pre-programme Assessment}$$

$$Z_{NC} = -11.09 + 5.50 \times \text{Pre-programme Spacing Score (Square Root)} + 0.31 \times \text{Age at Pre-programme Assessment}$$

$$Z_{CN} = -5.93 + 1.78 \times \text{Pre-programme Spacing Score (Square Root)} + 0.22 \times \text{Age at Pre-programme Assessment}$$

$$Z_{CC} = -8.79 + 2.03 \times \text{Pre-programme Spacing Score (Square Root)} + 0.29 \times \text{Age at Pre-programme Assessment}$$

TABLE 5.7.6.C

RANDOMISED CONTROLLED TRIAL

CLASSIFICATION MATRIX AND DISCRIMINANT FUNCTIONS
FOR CARBOHYDRATE VARIATION COMPLIANCE
(n=86)

	PREDICTED COMPLIANCE[a]				
MEASURED COMPLIANCE	NN	NC	CN	CC	Percent Correct
NN	23	23	0	9	41.8
NC	2	6	0	0	54.5
CN	0	0	4	5	44.4
CC	0	0	5	6	54.5
TOTAL	25	29	9	23	45.3%

(a) Based on jacknifed classification using pre-programme variation score (square root) as the predictor. Individuals were classified into the compliance category with the largest Z value from the following equations:

$$Z_{NN} = -3.058 + 7.17 \times \text{Pre-programme Variation Score}$$

$$Z_{NC} = -2.19 + 4.97 \times \text{Pre-programme Variation Score}$$

$$Z_{CN} = -1.47 + 1.64 \times \text{Pre-programme Variation Score}$$

$$Z_{CC} = -1.48 + 1.73 \times \text{Pre-programme Variation Score}$$

TABLE 5.8.1.A

RANDOMISED CONTROLLED TRIAL

RELATIONSHIP BETWEEN CARBOHYDRATE COMPOSITION AND BIOCHEMICAL VARIABLES MEASURED THREE MONTHS AFTER AN EDUCATION PROGRAMME FOR INSULIN-DEPENDENT DIABETES

1. RELATIONSHIP BETWEEN CARBOHYDRATE COMPOSITION COMPLIANCE AND FASTING BLOOD GLUCOSE (n=85)[a]

POST-PROGRAMME BLOOD GLUCOSE (m mol/l)	COMPLIANCE GROUP CC (n=9) %	NC (n=33) %	NN (n=43) %	TOTAL %
LT 10.0	55.6	69.7	41.9	54.1
GE 10.0	44.4	30.3	58.1	45.9
TOTAL	100.0	100.0	100.0	100.0

$X^2 = 5.84$, df = 2, p = 0.05#

2. RELATIONSHIP BETWEEN CARBOHYDRATE COMPOSITION COMPLIANCE AND GLYCOSYLATED HAEMOGLOBIN (n=85)[a]

POST-PROGRAMME GLYCOSYLATED HAEMOGLOBIN %	COMPLIANCE GROUP CC (n=9) %	NC (n=33) %	NN (n=43) %	TOTAL %
LT 9.0	66.7	45.5	20.9	35.3
GE 9.0	33.3	54.5	79.1	64.7
TOTAL	100.0	100.0	100.0	100.0

$X^2 = 9.26$, df = 2, p = 0.0098#

p greater than .05 after adjustment for 16 comparisons

TABLE 5.8.1.A (continued)

3. RELATIONSHIP BETWEEN CARBOHYDRATE COMPOSITION COMPLIANCE AND FASTING SERUM CHOLESTEROL (n=84)(b)

POST-PROGRAMME SERUM CHOLESTEROL (m mol/l)	COMPLIANCE GROUP CC (n=9) %	NC (n=33) %	NN (n=42) %	TOTAL %
LT 5.07	66.7	39.4	54.8	50.0
GE 5.07	33.3	60.6	45.2	50.0
TOTAL	100.0	100.0	100.0	100.0

$X^2 = 2.87$, df = 2, p = 0.24

4. RELATIONSHIP BETWEEN CARBOHYDRATE COMPOSITION COMPLIANCE AND FASTING SERUM TRIGLYCERIDES (n=84)(b)

POST-PROGRAMME SERUM TRIGLYCERIDES (m mol/l)	COMPLIANCE GROUP CC (n=9) %	NC (n=33) %	NN (n=42) %	TOTAL %
LT 2.0	33.3	54.5	52.4	51.2
GE 2.0	66.7	45.5	47.6	48.8
TOTAL	100.0	100.0	100.0	100.0

$X^2 = 1.32$, df = 2, p = 0.52

TABLE 5.8.1.B

RANDOMISED CONTROLLED TRIAL

RELATIONSHIP BETWEEN CARBOHYDRATE SPACING COMPLIANCE AND BIOCHEMICAL GOALS

A. SPACING COMPLIANCE BY FASTING BLOOD GLUCOSE (n=85)[a]

POST-PROGRAMME FASTING BLOOD GLUCOSE (m mol/l)	COMPLIANCE GROUP CC (n=13) %	CN (n=11) %	NC (n=10) %	NN (n=51) %	TOTAL %
LT 10.0	61.5	72.7	60.0	47.1	54.1
GE 10.0	38.5	27.3	40.0	52.9	45.9
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 2.99$, df = 3, p = 0.39

B. SPACING COMPLIANCE BY GLYCOSYLATED HAEMOGLOBIN (n=85)[a]

POST-PROGRAMME GLYCOSYLATED HAEMOGLOBIN (%)	COMPLIANCE GROUP CC (n=13) %	CN (n=11) %	NC (n=10) %	NN (n=51) %	TOTAL %
LT 9.0	38.5	27.3	60.0	31.4	35.3
GE 9.0	61.5	72.7	40.0	68.6	64.7
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 3.38$, df = 3, p = 0.34

TABLE 5.8.1.B (continued)

C. SPACING COMPLIANCE BY FASTING SERUM CHOLESTEROL (n=84)[b]

POST-PROGRAMME SERUM CHOLESTEROL[c] (m mol/l)	COMPLIANCE GROUP CC (n=13)	CN (n=11)	NC (n=10)	NN (n=50)	TOTAL
	%	%	%	%	%
LT 5.07	46.2	54.5	70.0	46.0	50.0
GE 5.07	53.8	45.5	30.0	54.0	50.0
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 2.09$, df = 3, p = 0.55

D. SPACING COMPLIANCE BY FASTING SERUM TRIGLYCERIDES (n=84)[b]

POST-PROGRAMME SERUM TRIGLYCERIDES (m mol/l)	COMPLIANCE GROUP CC (n=13)	CN (n=11)	NC (n=10)	NN (n=50)	TOTAL
		%	%	%	%
LT 2.0	46.2	45.5	60.0	52.0	51.2
GE 2.0	53.8	54.5	40.0	48.0	48.8
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 0.60$, df = 3, p = 0.896

TABLE 5.8.1.C

RANDOMISED CONTROLLED TRIAL

RELATIONSHIP BETWEEN CARBOHYDRATE VARIATION COMPLIANCE AND BIOCHEMICAL VARIABLES MEASURED 3 MONTHS AFTER AN EDUCATION PROGRAMME

A. CARBOHYDRATE VARIATION COMPLIANCE BY FASTING BLOOD GLUCOSE (n=85)[a]

POST-PROGRAMME BLOOD GLUCOSE (m mol/l)	COMPLIANCE GROUP CC (n=11) %	CN (n=10) %	NC (n=10) %	NN (n=54) %	TOTAL %
LT 10.0	81.8	80.0	60.0	42.6	54.1
GE 10.0	18.2	20.0	40.0	57.4	45.9
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 9.13$, df = 3, p = 0.027#

B. CARBOHYDRATE VARIATION COMPLIANCE BY GLYCOSYLATED HAEMOGLOBIN (n=85)[a]

POST-PROGRAMME GLYCOSYLATED HAEMOGLOBIN %	COMPLIANCE GROUP CC (n=11) %	CN (n=10) %	NC (n=10) %	NN (n=54) %	TOTAL %
LT 9.0	63.6	60.0	30.0	25.9	35.3
GE 9.0	36.4	40.0	70.0	74.1	64.7
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 8.74$, df = 3, p = 0.033#

p greater than .05 after adjustment for 16 comparisons

TABLE 5.8.1.C (continued)

C. CARBOHYDRATE VARIATION COMPLIANCE BY SERUM CHOLESTEROL (n=84)[b]

POST-PROGRAMME SERUM CHOLESTEROL[c] (m mol/l)	COMPLIANCE GROUP CC (n=11)	CN (n=10)	NC (n=10)	NN (n=53)	TOTAL
	%	%	%	%	%
LT 5.07	63.6	40.0	60.0	47.2	50.0
GE 5.07	36.4	60.0	40.0	52.8	50.0
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 1.79$, df = 3, p = 0.62

D. CARBOHYDRATE VARIATION COMPLIANCE BY FASTING SERUM TRIGLYCERIDES (n=84)[b]

POST-PROGRAMME SERUM TRIGLYCERIDES (m mol/l)	COMPLIANCE GROUP CC (n=11)	CN (n=10)	NC (n=10)	NN (n=53)	TOTAL
		%	%	%	%
LT 2.0	63.6	60.0	70.0	43.4	51.2
GE 2.0	36.4	40.0	30.0	56.6	48.8
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 3.69$, df = 3, p = 0.296

TABLE 5.8.1.D

RANDOMISED CONTROLLED TRIAL

RELATIONSHIP BETWEEN WEIGHT COMPLIANCE AND BIOCHEMICAL GOAL ACHIEVEMENT 3 MONTHS AFTER THE EDUCATION PROGRAMME

A. WEIGHT COMPLIANCE BY FASTING BLOOD GLUCOSE
(n=85)[a]

POST-PROGRAMME BLOOD GLUCOSE (m mol/l)	COMPLIANCE GROUP CC (n=53)	CN (n=2)	NC (n=13)	NN (n=17)	TOTAL
	%	%	%	%	%
LT 10.0	50.9	50.0	69.2	52.9	54.1
GE 10.0	49.1	50.0	30.8	47.1	45.9
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 1.43$, df = 3, p = 0.697

B. WEIGHT COMPLIANCE BY GLYCOSYLATED HAEMOGLOBIN
(n=86)

POST-PROGRAMME GLYCOSYLATED HAEMOGLOBIN	COMPLIANCE GROUP CC (n=54)	CN (n=2)	NC (n=13)	NN (n=17)	TOTAL
%	%	%	%	%	%
LT 9.0	35.2	50.0	30.8	35.3	34.9
GE 9.0	64.8	50.0	69.2	64.7	65.1
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 0.30$, df = 3, p = 0.96

TABLE 5.8.1.D (continued)

C. WEIGHT COMPLIANCE BY FASTING SERUM CHOLESTEROL
(n=85)

POST-PROGRAMME CHOLESTEROL	COMPLIANCE GROUP CC (n=54)	CN (n=2)	NC (n=13)	NN (n=16)	TOTAL
	%	%	%	%	%
LT 5.07	51.9	50.0	53.8	37.5	49.4
GE 5.07	48.1	50.0	46.2	62.5	50.6
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 1.14$, df = 3, p = 0.77

D. WEIGHT COMPLIANCE BY FASTING SERUM TRIGLYCERIDES
(n=85)

POST-PROGRAMME SERUM TRIGLYCERIDES	COMPLIANCE GROUP CC (n=54)	CN (n=2)	NC (n=13)	NN (n=16)	TOTAL
		%	%	%	%
LT 2.0	55.6	0.0	46.2	43.8	50.6
GE 2.0	44.4	100.0	53.8	56.3	49.4
TOTAL	100.0	100.0	100.0	100.0	100.0

$X^2 = 2.98$, df = 3, p = 0.39

(a) 3 "returns" were unable to attend the appointment for blood tests at the post-programme assessment.

(b) an insufficient volume of blood for serum lipid analyses was obtained from 1 subject.

(c) the median of the cholesterol values at the post-programme assessment was used as the cut-off point because the majority of subjects had values below 6.5 m mol/l.

CHAPTER 6

DISCUSSION

SECTION

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CHAPTER 6

DISCUSSION

INTRODUCTION

The discussion is prefaced by a summary of the results of both studies and comments about the possible influence of the research methods (issues of sampling, the validity and reliability of the food records and statistical significance) on the findings.

The results obtained from study questions concerning the attrition of study subjects, the differences between "returns" and "non-returns" and between streams are discussed within the context of sampling. A discussion of the implications of the results for diabetes education programmes is then presented, followed by recommendations for further research.

6.1 SUMMARY OF RESULTS

The results for the substantive research questions from the pre/post study and the randomised controlled trial are summarised in Table 6.1.

The findings for the effect of the programme were generally consistent between the two studies and showed significant improvements in some aspects of dietary compliance, knowledge about diabetes management and selected health beliefs for diabetics and their family members. The lack of statistically significant changes in any of the outcome variables during the "control" phase of the randomised controlled trial suggests that the observed changes were due to the educational intervention rather than to the assessments themselves.

With respect to the dietary outcomes, responses to the programme which were observed in both studies comprised: - a) significant improvements in the composition of the diets of diabetics and family members (an increase in the percentage of energy contributed by complex carbohydrate and a decrease from fat; b) a significant decrease in the relative body weight of family members; and c) no significant changes in the carbohydrate spacing or variation scores, or in the relative weight of diabetics.

Prior to the programme, diabetics and their family members had inadequate knowledge of diabetes management procedures but in both studies they significantly increased their knowledge scores.

The results for health beliefs assessed in the randomised controlled trial are not directly comparable to results from the pre/post study because the health beliefs of interest, the questionnaire and its administration differed between the two studies. The results of the pre-post study showed statistically significant shifts in the desired directions for perceptions of susceptibility to the complications of diabetes, the efficacy of diet to improve health and barriers to dietary compliance. In the randomised trial, significant improvements occurred for Stream 1 only in the perceived efficacy of diabetic self-care regimens, perceived compliance with diet and faith in their doctor's care. There were no significant changes in health beliefs for Stream 2 between pre- and post- assessments. The scores for quality of life (rct only) indicated that programme participants felt better about most aspects of diabetic life, after the programme.

TABLE 6.1

SUMMARY OF RESULTS FOR PRE/POST STUDY AND RANDOMISED CONTROLLED TRIAL

	PRE/POST	RCT
I. The Effect of the Education Programme on Outcomes		
A. Dietary Compliance		
Diabetics:		
Complex carbohydrate composition	+	+
Fat	+	+
Protein	0	0
Alcohol	0	0
Sugar	0	0
Carbohydrate spacing	0	0
Carbohydrate variation	0	0
Relative Body Weight	0	0
Family Members composition		
Complex carbohydrate	+	+
Fat	+	+ (str.1)
Protein	+	0
Alcohol	0	0
Sugar	+	0
Relative Body Weight	+	+
B. Biochemical Outcomes		
Fasting blood glucose	0	0
Glycosylated haemoglobin	0	0
Fasting serum cholesterol	0	0
Fasting serum triglycerides (str.2)	-	-
C. Knowledge		
Diabetics	+	+
Family members	+	+
D. Health Beliefs		
Susceptibility to complications	+	0
Concern about complications	0	N/A
Interference of lifestyle by diabetes	0	N/A
Barriers to dietary compliance	+	N/A
Efficacy of self-care regimens	+	+ (str.1)
Perceived dietary compliance	N/A	+ (str.1)
Difficulty with diet	N/A	0
Difficulty with weight control	N/A	0
Faith in doctor	N/A	+ (str.1)
E. Quality of Diabetic Life	N/A	+

Table 6.1 (continued)

	PRE/POST	RCT
II. Association between four aspects of dietary compliance		
Weight with carbohydrate composition	0	0
Weight with spacing	0	0
Weight with variation	0	0
Carbohydrate composition with spacing	+	0
Carbohydrate composition with variation	+	+
Spacing with variation	0	+
III. Baseline Factors Associated with and predictors of Dietary Compliance (Carbohydrate composition, spacing and variation compliance)		
Carbohydrate composition	(p) +	(p) +
Fat composition	-	-
Spacing score	(p) -	(p) -
Variation score	(p) -	(p) -
Weight	(p) -	0
Blood glucose	-	-
Glycosylated Haemoglobin	-	-
Serum cholesterol	0	(p) -
Serum triglycerides	-	0
Age	0	(p) +
IV. Relationship between dietary compliance and achievement of Biochemical Goals		
Fasting blood glucose	+ (carb)	+ (var)
Glycosylated haemoglobin	+ (carb)	+ (carb var)
Fasting serum cholesterol	0	0
Fasting serum triglycerides	0	0

\+ Significant change in the desired direction or direct association with compliance

0 No significant change or association

\- Significant change in an undesired direction, or inverse association with compliance

N/A Not applicable - not evaluated

(p) Predictor from discriminant analyses

(a) No significant changes were observed during the "control" phase of the RCT for any of the outcome measures.

The education programme was found to have no statistically significant effect on diabetic control of programme participants in either study as measured by fasting blood glucose or glycosylated haemoglobin. The mean values for measures of blood glucose control were slightly above the upper limit of the acceptable range before the programme and returned to acceptable levels after education in the pre/post study and for Stream 1 in the randomised controlled trial. For Stream 2 however, slight increases occurred in fasting blood glucose and glycosylated haemoglobin between pre- and post- assessments. Due to the large standard errors, these changes were not statistically significant.

An undesired increase in serum triglycerides was noted in the pre/post study and for Stream 2 in the randomised controlled trial, although no change occurred for Stream 1 over the study period. The changes in triglycerides were not significantly related to changes in carbohydrate intake or other dietary variables. The increase in triglycerides of Stream 2 was significantly associated with an increase in fasting blood glucose levels of these subjects. In the pre/post study, there appeared to be an increasing secular trend in measured triglyceride values over the study period, although the reasons for this were not apparent.

The results of both studies indicated that compliers with one aspect of the diabetic diet regimen were not necessarily compliant with others. Compliance with weight recommendations was unrelated to compliance with other aspects of the dietary regimen. Some aspects of compliance, as judged by the various measures of carbohydrate intake were related, but the results were inconsistent between the two studies.

In both studies, compliance with the recommended 45% of energy as complex carbohydrate was significantly associated with achievement of acceptable levels of blood glucose and/or glycosylated haemoglobin. However, serum lipid levels at follow-up were not associated with compliance to any aspect of the dietary regimen.

6.2 THE SAMPLE

Clearly, the study samples in both of these studies cannot be assumed to be representative of the population of insulin-dependent diabetics in New South Wales. Their willingness to attend the education programme and to undergo extensive and repeated assessments distinguishes them from other diabetics.

However, evidence to suggest that the subjects of these studies were not a homogeneous group of highly informed, motivated, "model" diabetics is derived from their initial descriptive data and from responses to the programme. The samples in both studies (approximately 250 diabetics) were, in fact, a heterogeneous group of diabetics in terms of their age, duration of diabetes, referral source, social class and experience of recent hospitalisations for diabetes. Although a higher proportion of these subjects came from the professional social class compared to the Sydney population norms (Vinson 1974), one-third of them were from the lower middle class.

Neither the diabetic subjects nor their family members were well-informed prior to the programme about practical aspects of diabetes self-management as indicated by initial mean knowledge scores.

Despite the fact that most subjects had received recent dietary advice from a dietitian, very few were consuming diets considered by the majority of dietitians in New South Wales to be balanced in

composition[1] or appropriate for the achievement of good metabolic control. Although diabetics who attended an intensive programme such as this, might be expected to be highly motivated to follow the recommendations, the results showed that only about one-third of the subjects in both studies achieved the dietary goals at the time of follow-up assessment.

The majority of these subjects could not be considered to be in "good" diabetic control prior to the programme; one-third to over one-half of the subjects in both studies had elevated levels of fasting blood glucose and glycosylated haemoglobin at their first assessment and over half of the subjects in the randomised controlled trial were found to have clinical signs of the complications of diabetes.

The similarity of our study subjects to the population of diabetics in New South Wales, who are willing to attend education programmes of a comparable nature to our own is difficult to assess since such data on other local programmes have not been published.

However, from the published data available on overseas populations, our study sample appears to be dissimilar to those obtained in the majority of other studies of dietary compliance and diabetes education (i.e. working class diabetics seeking medical care from clinics or youths attending a summer camp). Thus, the differences in our sample in terms of age and social class, the reason for seeking care (and our lack of provision of medical care), and the educational setting, limits the comparability of our results with the majority of previous dietary compliance research.

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[1]Mensch, M. Personal Communication. A recent unpublished survey of dietitians in N.S.W. indicated that the majority recommended complex carbohydrate intake of at least 45% of energy.

The generalisability of the results of our studies may also be limited by the bias which may have occurred through the attrition of study subjects at various stages of the research. The loss of 30% of diabetic subjects in the randomised trial prior to the attendance at the education programme and the further 20% loss at the follow-up assessment may have inflated the observed compliance rates and other successful effects of the programme. Contrary evidence comes from the analyses of predictors of dietary compliance which showed that the most significant predictor of dietary compliance at follow-up was the initial level of compliance. Since non-returns did not differ from returns on initial dietary measures, it is unlikely that they would all be found to be non-compliers if they were re-assessed. Moreover, a substantial proportion of non-returns gave legitimate reasons for their inability to attend the follow-up assessments. Because the timing of the follow-up was crucial in the randomised trial (plus or minus two weeks of the appointment), potential returns were lost due to lengthy hospitalisations, holidays or business trips, factors quite independent of their compliance with diet.

Despite the complex assessment procedures used in these two studies, the response rates to the follow-up assessments (approximately 75%-80%) were superior to those obtained in the majority of evaluation studies of diabetes education programmes, but the considerable non-response rates of family members to follow-up assessments severely limits the generalisability of the findings on diet and knowledge in this group.

Was the assignment of subjects to streams truly random? Baseline observations on the streams indicated no significant dif-

ferences between them in initial fat and carbohydrate intake, relative weight, knowledge, health beliefs or quality of life score. While a few differences between streams on initial demographic and other characteristics were found, these were not statistically significant when the large number of comparisons was taken into account. One such difference was the proportion of subjects in each stream who were referred by the programme's endocrinologist (20% of Stream 1 compared with 40% of Stream 2) although the cause of this occurrence is not clear. While random assignment procedures were not "human-proof", the staff were aware of the need to adhere strictly to them. Also the person responsible for random assignment was not acquainted with subjects nor was she aware of who their medical practitioners were. Thus, "favouritism" in assigning the endocrinologist's patients to Stream 2 was unlikely to have occurred, although this possibility cannot be excluded. The random assignment book was also checked to see whether the endocrinologist's patients tended to book in "clusters" which may have coincided with "clusters" of random numbers designated for Stream 2. However, no such pattern was apparent. Thus, the observed difference most likely occurred by chance, although unidentified deviation from the protocol must also be considered possible.

The importance of the difference between streams in referral source (and source of medical care) is uncertain. The similarities between them on most baseline measurements and in their responses to the programme on dietary and most other outcome variables suggests that the difference in referral source was not particularly important for the variables of most interest in this study. However, the observed differences between streams in health belief and triglyceride responses may have been influenced by the fact that more of Stream 2 were medically managed by the team's endocrinologist.

6.3 THE VALIDITY AND RELIABILITY OF THE FOUR-DAY FOOD RECORDS

Central to the interpretation of results concerning the effect of the education programme on dietary compliance and the predictors of dietary compliance is the validity and reliability of the four-day food records. Observations of dietary change may not have been valid because individuals may have inaccurately reported their eating behaviour (particularly at the follow-up assessment when they knew what to do) or they may have altered what they ate only during the record-keeping period. Although we have limited evidence about how indicative these four days were of usual eating habits, we have some evidence that the majority of subjects recorded their food intakes accurately.

Evidence in favour of their accuracy is suggested by the compliance rates before and after the programme. If subjects had falsified their food records, it might be expected that a majority of them would have been considered compliant with the dietary recommendations. However, less than one-third of the samples of both studies were classified as compliant with any of the dietary recommendations before or after the programme.

Evidence from the comparison of protein intakes calculated from food records and that from 24-hour urinary urea values also suggests that food records were likely to be valid for the estimated changes for the group in dietary variables. With the exception of the very low correlation for Stream 1 obtained at the assessment immediately prior to the programme, the correlation coefficients observed in the randomised trial were of a similar order to those considered by other investigators to provide "acceptable" evidence of the validity of dietary methods (Johnstone et al 1980, Huse et al 1973). Nonetheless,

the discrepancies between urea and recorded protein intakes for individuals in our study raise some doubt about either the validity of our estimates of dietary intakes (for individuals) from food records or of the urinary urea values in reflecting dietary protein intake.

Protein intakes estimated from urinary urea excretion were higher, in general, than the dietary records would indicate. Although this may have been due to under-reporting of food intake, it may also have resulted from over-collection of urine or to an increased urea excretion associated with poorly-controlled diabetes. The possibility that most individuals collected their urine for at least 20% longer (5 hours) than the 24-hour period cannot be excluded, given the higher than predicted creatinine results, but this explanation is unlikely. Systematic laboratory error also appears improbable since urea and creatinine determinations by another laboratory on duplicate urine samples yielded similar results.

A more plausible explanation for the higher than expected 24-hour urinary urea and creatinine values is that their excretion was altered by the diabetic state. In the normal physiologic state, urea excretion is directly related to protein intake. However, in situations of physiologic stress, such as in poor metabolic control of diabetes, urea and creatinine excretion are both increased due to increases in the glomerular filtration rate, in protein catabolism and/or decreased tubular reabsorption of urea associated with diuresis (Harper 1971). Thus, it is possible that diabetic subjects who participated in the randomised controlled trial, two-thirds of whom had elevated glycosylated haemoglobin levels, also had associated increased urinary urea and creatinine excretion irrespective of protein intake. Under these circumstances, the validity of urinary urea

values in reflecting protein intake is questionable. Thus, no conclusions may be drawn about the validity of the food records from these results.

How representative the four-day estimates of dietary composition, spacing and variation were of the usual eating patterns of our subjects is uncertain. While subjects were encouraged to eat as normally as possible during the record-keeping period, the act of recording food intake may have altered eating behaviour, although we have no evidence of this. The results of the food record study of 17 diabetics indicated that for these subjects, four-day food records accurately represented the dietary intakes calculated from a full seven days for composition of the diet and carbohydrate variation scores. For spacing compliance, the results were somewhat less reliable.

To identify whether the observed dietary changes could have occurred merely as a result of seasonal variation in dietary composition, the means and standard errors for carbohydrate and fat intake (as a percentage of energy) measured during each month of the year were plotted and were compared in a one-way analysis of variance. Pre- and post-assessment means were compared separately. For two-thirds of the subjects, their pre-assessment occurred during winter or spring months, but post-assessments were spread relatively evenly throughout the seasons. Mean fat composition was relatively stable over the months of the year but mean carbohydrate intake varied somewhat with no discernible pattern over the year. However, due to the extremely small numbers assessed in some months of the year, the means were quite unstable and the standard errors were large. Thus, the lack of significant differences for mean fat and carbohydrate

intake between months of the year does not provide conclusive evidence that there was no significant seasonal variation in composition of the diet. Nonetheless, the distribution of follow-up assessments throughout the seasons limits the possibility that the observed improvements in diet were due to a systematic bias from a seasonal effect on food intake.

6.4 STATISTICAL SIGNIFICANCE OF RESULTS

The detection of significant programme effects and predictors of compliance is, to some extent, dependent on the number of variables under investigation, the number of study subjects, the sensitivity of the techniques of statistical analyses and the error of the measurements.

The probability of detecting programme effects when they did not occur (a Type 1 error) is increased with the number of statistical tests carried out. In these evaluation studies, a variety of programme effects were assessed, resulting in approximately 20 statistical tests. Consequently, a statistically significant change (at p less than .05) could have occurred by chance in at least one outcome variable. However, our observations of significant improvements in eight variables in the pre/post study and ten in the randomised controlled trial suggests that these improvements were not detected simply as a matter of chance. Moreover, when the critical significance levels were adjusted for the number of outcomes, the adjustments did not alter the significance of the majority of findings. However, the large number of comparisons made in the analysis of factors associated with compliance makes it likely that, with the exception of initial dietary compliance, the few statistically significant associations observed between compliance and other factors were due to

chance. In fact, most of these factors did not remain statistically significant when the Bonferroni adjustment was applied.

Clearly it is desirable to minimise the number of outcome variables. As discussed in Chapter 2, other investigators have dealt with this problem by combining aspects of compliance, or diabetic control, or both, into one score or index. However, as Marston (1970) argues, such a score lacks sensitivity in detecting and describing compliance and therefore, its use is to be discouraged, particularly when compliance to various aspects of a regimen are not closely associated. Evidence from these studies suggests that the use of a combined score for compliance would probably have masked the improvement in carbohydrate composition compliance and perhaps inflated the changes in other aspects of compliance. On the other hand, by analysing individual components of dietary compliance, the necessary adjustments for the large number of statistical tests reduced the power to detect significant programme effects or predictors of compliance.

Type I errors may also occur in chi square analyses when the cell frequencies are small which in turn may exaggerate the X^2 value (Hill 1977). Thus, the observed associations between the various aspects of dietary compliance could have resulted from the zero frequencies in several of the cells of the contingency tables.

However, identical significant associations between compliance behaviours were obtained when the analysis was repeated on a two-fold table (complier or non-complier at the follow up). The replication of results indicates that the observed associations were unlikely to result simply from the cell frequencies of zero.

The possibility that significant programme effects or predictors of compliance were undetected (a Type II error) must also be considered. The slight improvements which occurred in other aspects of dietary compliance, measures of blood glucose control and health beliefs, may not have been statistically significant because of the large standard errors of these measurements and the relatively small sample sizes in both studies. For example, the observed difference of 1 mmol/l in blood glucose between pre- and post- assessment would have resulted in a statistically significant result if the sample size had been marginally larger i.e. 150 (using a 2-tailed test with power of 80% at a significance level of $p = 0.05$).

The need to analyse change in some variables (i.e. some dietary variables and health beliefs) using non-parametric methods may have reduced the sensitivity in identifying slight changes in these variables and in the significance of them. For example, significant decreases were observed after the programme in the pre/post study for family members in the mean percentage of energy consumed as alcohol and sugar. However, these results were not replicated in the randomised controlled trial when changes in sugar and alcohol were assessed by testing the difference in proportions of subjects above and below median intakes before and after the programme.

6.5 THE EFFECTS OF THE EDUCATION PROGRAMME ON OUTCOMES OF INTEREST

Dietary Compliance

These studies mark the first rigorous evaluation of the effects of an intervention on the dietary behaviour of insulin-dependent diabetics. In view of the recent volume of literature advocating higher carbohydrate and lower fat diets for diabetics than has been

conventionally recommended, our results suggest that such changes are possible to effect, at least in the short-term, by educational methods.

The hypothesis that the positive improvements in composition of the diets of diabetics and family members were due to the education programme is supported by the observed lack of change in diets during the "control" phase of the randomised controlled trial. It could be argued that the changes in composition of the diet merely reflected a secular trend in the diets of Australians. However, since no such trend has been identified and since the baseline composition of the diets of our subjects was similar in both studies, although measured two to three years apart, this possibility appears unlikely.

The programme could not be considered entirely successful at achieving its dietary goals, even with respect to compliance with a balanced composition of the diet, since only one-third of subjects achieved the goal of 45% complex carbohydrate and only one-fourth of them reduced fat intakes to 30% or less of energy intake. Clearly, these goals are difficult to achieve given the high-fat nature of the apparent consumption of the average Australian (1977) and the widespread practice by health practitioners to recommend low-carbohydrate diets for diabetics (West 1980).

The 90% success achieved by Weinsier et al (1974) in encouraging 18 diabetics to adhere to a 30% fat diet over a 20 week trial, and the 50% good to fair adherence rates for men in the National Diet-Heart Study to diets of 30-35% fat, suggests that compliance to such diets is possible on a "trial" or experimental basis, even for extended periods of time. However, when the regimen is recommended on a life-time basis, such as in our study, compliance rates are likely to be lower.

The lack of effectiveness of the education programme in assisting the majority of overweight diabetics to reduce weight is not surprising in view of the lack of success of several other diabetes education programmes and of other weight reduction interventions at changing this difficult area of behaviour. (Stern et al 1976, Glanz 1980, Watts 1980).

Our results for weight change were similar to those obtained in the only two other controlled studies. Bowen et al (1961) and Tagliacozzo et al (1974) observed no reduction in the average weight of diabetics who participated in an experimental education programme compared with a control group, although weight losses occurred for some of the experimental patients. Considered together, these results indicate that diabetes education strategies are ineffective in achieving weight reduction in overweight diabetics.

The unexpected success of family members in achieving substantial weight reduction is difficult to interpret, in view of the programme's lack of success with overweight diabetics. The low return rate for follow-up assessment by family members may indicate that only compliers with the dietary recommendations returned. Alternatively, the dietary regimen recommended to family members was less complex than for diabetics (with a focus on weight and composition) and may have been less difficult for them to implement. The requirement for such frequent meals and snacks may indeed make it more difficult to the insulin-dependent diabetic to reduce weight. Nonetheless, as Watts (1980) suggested, diabetes educators should begin to utilize and evaluate strategies for weight reduction which have shown more promise in the behavioural and psychological literature than have educational approaches.

The education programme was also unsuccessful in improving compliance of diabetics with recommendations to space their carbohydrate intake throughout the day and to minimise its variation between days. This was an unexpected result in view of the focus of the education programme and of the dietary regimen on counting and measuring carbohydrate portions carefully to assure adherence to the recommended number of "portions" at each meal and snack.

Similarly low rates of compliance with carbohydrate spacing and variation recommendations have been observed by others who have used quantitative measures of compliance (Williams et al 1967, Henry et al 1981). The latter authors observed compliance to be equally poor regardless of whether subjects were placed on a carbohydrate-controlled regimen or a freely selected diet. Although the spacing of carbohydrate throughout the day and the maintenance of a constant daily intake are widely advocated by health practitioners, these aspects of the regimen appear to be the most tedious and may be unachievable in the long-term by the majority of diabetics. The necessity for close adherence to such fixed recommendations has also been questioned since some diabetics appear to achieve good control and avoid hypoglycaemic episodes despite considerable departure from the recommendations (Dorchy et al 1977). Individuals with partially insulin-dependent diabetes (West 1980) may not need to closely regulate carbohydrate intake due to their residual islet cell function (ibid).

A trend in diabetic management is now underway which favours the use of home blood glucose results (assessed by patients from home monitoring machines) to provide guidelines for the recommended carbohydrate intake at each meal (Tattersall 1979). Thus, the recommen-

dation for spacing and variation may become more flexible in relation to blood glucose levels prior to each meal. However, the effectiveness of this approach to the dietary regimen and its application to the majority of diabetics has not been evaluated.

Universally, dietary regimens for insulin-dependent diabetics emphasise the exclusion of refined sugar from the diet and the consumption of very little alcohol. The results from the randomised controlled trial showed that although very few subjects (less than 10%) reported consuming no refined sugar at the baseline assessment, the majority were consuming only modest amounts (less than 5% of total energy).

The quantity of alcohol recorded during the dietary record period was also moderate; 50% consumed no alcohol and a further one-third consumed less than the 5% limit. Thus, although there was no significant change in these variables during the study, non-compliance with these recommendations did not appear to be a substantial problem either before or after the programme. Our compliance rates with the recommendation to limit refined sugar intake appear comparable to those obtained by others (Kirkham and Wood 1980 and Bolt and Miller 1967).

It is, of course, possible that our estimates of sugar and alcohol intake from food records were lower than actually consumed because sources of these in the diet are easily identified and hence, food records may have been falsified to coincide with the programme's recommendations. However, the likelihood of this occurrence is difficult to assess.

Biochemical Goals - Measures of Blood Glucose

The lack of significant change in blood glucose control of our subjects after participation in the education programme is not surprising since we had no brief to alter the insulin prescription of these patients.

The appropriateness of insulin therapy as well as type of diabetes can profoundly influence blood glucose control despite high compliance with diet. Yet, our inability to assess the insulin therapy or endogenous insulin production of these study subjects limits any conclusion about the impact of the education programme or the influence of observed dietary changes on diabetic control.

The lack of change in diabetic control following participation in a diabetes education programme has been observed by others, particularly by investigators with no role in the medical management of their programme clientele (Bowen et al 1961, Weinsier et al 1974, Graber et al 1977).

By contrast, reports of education programmes which have a role in the stabilisation and medical management have observed significant improvements in the metabolic control of patients who require stabilisation. (Noviks 1976, Runyan 1975). These results suggest that the effectiveness of educational interventions can be usefully enhanced by combining them with medical interventions, although the effects of a combined approach on compliance behaviour as well as health indices needs to be evaluated.

While the lack of control over insulin-management is the most plausible explanation for the lack of improvement in the metabolic control of programme participants, the magnitude of the dietary

changes may have been insufficient to influence diabetic control. The recommendation for a 45% complex carbohydrate diet was not expected to improve diabetic control per se, but rather it was expected to promote the maintenance of diabetic control whilst reducing the health risks associated with the consumption of a high-fat diet. Thus, our finding that compliance with the complex carbohydrate goal was associated with better metabolic control, was unexpected. The lack of deterioration in control on high-carbohydrate diets has been documented in numerous studies but those in which an improvement has been demonstrated generally contain higher levels of carbohydrate and/or a high fibre content (Simpson et al 1981, Anderson et al 1980).

The high proportions of non-compliance with the recommendations to space complex carbohydrate intake throughout the day and to vary it minimally from day to day as well as to reduce weight, could also have contributed to the lack of improvement in diabetic control, since deviations from these aspects of the regimen are thought to precipitate hypo- and hyperglycaemia. However, the results of our study provide little evidence that compliance with spacing, variation and weight recommendations results in better metabolic control in the absence of manipulation of insulin dosage.

Another factor which may have contributed to the lack of a statistically significant improvement in glycosylated haemoglobin levels was the limited time period over which study subjects were assessed in the randomised controlled trial. A reduction in glycosylated haemoglobin levels can be expected only within the life of a red cell (approximately 120 days) (Davis et al 1978). Thus, the lack of consistent clinical or statistical improvements in biochemical measurements in the randomised controlled trial compared with the slight (but

not statistically significant) improvements observed in the pre/post study could have come from the shorter time span over which changes were monitored in the randomised controlled trial. However, such an argument is not applicable to fasting blood glucose which varies widely on a daily (and hourly) basis and may be influenced immediately by dietary changes or insulin therapy (Molnar 1978).

The differences in patterns of change in measures of glucose control between Streams 1 and 2 were not statistically significant. However, the results are suggestive that factors apart from diet affected diabetic control, since both groups appeared to make similar dietary changes over the study period.

Measures of Blood Lipids

In non-diabetics, an increase in complex carbohydrate and a reduction in total fat intake has been associated with a decrease in serum cholesterol levels (Lewis et al 1981). In studies of diabetics, conflicting results have been obtained (Reaven et al 1979). The lack of a reduction in the serum cholesterol levels of our subjects could have resulted from a number of factors. First, the mean cholesterol level of these subjects was unusually low at the baseline assessment which indicated that they were dissimilar to samples in many studies of cholesterol-lowering diets. However, other investigators have found the incidence of hypercholesterclemia to be low amongst diabetics (Moore et al 1979, Goldberg 1981, Billimoria et al 1976, Nikkila and Hormila 1978).

Also, our inability to assess the polyunsaturated to saturated fat ratio of the diets of our subjects leaves the dietary assessment incomplete. Thus the lack of serum cholesterol response could have been due to a lack of change in the p:s ratio despite the reductions in total fat intake.

The mean reduction in fat intake for the group was approximately 5% of energy, which may have been insufficient to achieve an observable reduction in serum cholesterol, particularly when cholesterol levels were relatively low prior to the programme.

The possibilities that either the estimates of dietary intake or of serum cholesterol were not valid, cannot be excluded but are unlikely. All the available evidence suggests that the dietary estimates for the group were valid and reliable. As well, the quality control data supplied by the St. Vincent's Hospital Lipid Research Laboratory indicated that the quality control sera gave reproducible results over the study period and their daily mean values for all test samples remained stable during this time.

The cause(s) of the clinically significant rise in serum triglycerides in the pre/post study and for Stream 2 in the randomised trial are not apparent. The explanation in the former study was thought to be that an upward secular trend in triglyceride values occurred over the first year of the study, since both pre- and post-values increased during this time. This was discussed at length in the publication in Chapter 4 and will thus not be repeated here (Webb et al 1982). Such a trend was not observed in the rct since for Stream 1, mean triglyceride levels remained stable over the study period.

Because high-carbohydrate diets have resulted in increased triglycerides in some diabetics (Reaven et al 1979), the documented dietary changes in these studies could have inadvertently caused the rise in triglycerides in Stream 2 subjects. However, when percentage carbohydrate intake, and other components of dietary composition, together with the changes in these variables were compared in a regression analysis with triglyceride levels and changes in triglyceride levels, no associations were observed.

Elevated serum triglycerides have been frequently found to accompany elevated glycosylated haemoglobin and fasting plasma glucose levels in diabetics (Peterson et al 1977, Molnar 1978, Aleyassine 1980, Wilmshurst et al 1973). Thus, the blood glucose and glycosylated haemoglobin values were also included in the regression analysis. For Stream 2, increases in blood glucose levels between pre-and post-assessments were significantly related to increases in serum triglycerides. Although this finding does not exonerate the dietary regimen or the education programme, it is suggestive that other factors, apart from the diet, may have caused this potentially harmful outcome.

Non-compliance with the 12-hour fast prior to fasting blood tests may also have occurred although it is unlikely that one stream would be more compliant than the other.

The conservative approach is to assume that the dietary changes adopted by programme participants and/or the lack of medical intervention caused the rise in serum triglyceride levels of some subjects in these studies. On this assumption, it is necessary for the programme to monitor more closely the biochemical effects of dietary changes and to tailor them as required. However, tailoring the dietary regimen on the basis of pre-programme triglyceride levels would not be useful since triglyceride rises occurred in individuals with acceptable baseline values.

Health Beliefs

The effect of diabetes education on health beliefs or similar attitudes have been reported in only two rigorous evaluation studies and the results indicated that education had no significant effect

compared with that of a control group (Bowen et al 1961, Tagliacozzo et al 1974).

Although we reported significant changes in three health beliefs in the pre/post study, no comparison group was available to confirm that these changes were attributable to participation in the education programme (Webb et al 1982). However, the lack of significant change in health beliefs during the 'control' phase of the randomised controlled trial, provides some evidence that health belief changes were linked with participation in the education programme.

Nonetheless, it cannot be concluded that the programme had a major impact on the health beliefs of participants, because when the significance levels were adjusted for the number of outcome variables, none of the changes in health beliefs were statistically significant in either study. Moreover, the differences in health belief responses for Streams 1 and 2 suggest that factors other than the education programme influenced beliefs.

In the pre/post study, the changes in perceptions of susceptibility to the complications of diabetes, efficacy of the dietary regimen and barriers to dietary compliance were consistent with the programme's emphasis on personal vulnerability to the complications of diabetes, the regimen as a method of prevention and skills for adapting the regimen to individual life styles. The lack of change in perceived susceptibility to other health problems provides evidence that the effects were specific for diabetes-related health problems. The reduction in perceived barriers to dietary compliance may have been due to increased patient satisfaction with the flexibility in food selection offered by the recommended dietary regimen or from learning to cope with the restrictions of the diet.

In the randomised trial, the improvement noted for Stream 1 in perceived dietary compliance was consistent with our observations of dietary improvements from the food records. The lack of change in perceived compliance for Stream 2 is surprising given that their observed improvements in diet were similar to those of Stream 1. The change in perceived efficacy of self-care regimens coincided with a return of blood glucose values for many Stream 1 subjects to within the acceptable range after the programme and with slight reductions in glycosylated haemoglobin levels. However, for Stream 2, no change in perceived efficacy or blood glucose levels was observed. The increase in "faith in doctor" for Stream 1 cannot be explained, however, the large difference between Streams 1 and 2 on this variable before the programme suggests that either Stream 1 were particularly sceptical of their doctor's care or that Stream 2 were particularly satisfied. It is possible that because more of Stream 2 were patients of the team's endocrinologist, that they expressed more faith in his care. After the programme, Stream 1 may have linked faith in their own doctors with that of the team's endocrinologist due to their contact during the programme with a competent diabetic specialist who was prepared to deal with their individual problems.

Alternatively, it is possible that the changes in health belief scores reflected an increase in knowledge or a desire to please the team by giving complimentary responses, although the likelihood of this explanation is difficult to assess.

Knowledge

The substantial and significant increase in knowledge about diabetes management observed for diabetics and family members in both studies provides evidence that cognitive learning occurred. That this

was a result of the education programme is supported by the lack of observed change in the mean knowledge score for Stream 1 during the "control" phase of the randomised controlled trial. With the exception of one controlled investigation by Tagliacozzo et al (1974), other evaluations of education programmes for diabetics have demonstrated similar success in improving knowledge scores of programme participants in the short-term (Stulb 1968, Etzwiler and Robb 1972, Brock 1978, Chandalia and Bagrodia 1976, McDonald & Kaufman 1963, Young et al 1969, Tani & Hankin 1971, Bowen et al 1961, Salzer 1975).

However, the results of several investigations have shown that knowledge about diabetes deteriorates with the passage of time after diabetes education (Schnatz et al 1976, Lawrence and Cheely 1980, Whitehouse et al 1979). These results raise some doubt about whether the D.E.A.P. will have a lasting impact on diabetes-related knowledge.

More importantly, it can be argued that while adequate knowledge of diabetes self-management is essential for appropriate self-care, it is an insufficient outcome on which to justify time-consuming eduational interventions, Graber et al (1977) and Watts (1980) in their reviews cited examples of such educational evaluations which demonstrated no other effects on programme participants, particularly on aspects of behaviour change or health.

Quality of Diabetic Life

The results of the QDL questionnaire indicated that diabetics felt better about all measured aspects of diabetic life after participation in the education programme than before. QDL items with the

highest mean scores at the post-programme assessment included confidence about managing diabetes, controlling blood sugar, and dealing with "hypos", knowing how to prevent complications, where to find help and understanding diabetes. Items for which there was least perceived difference after the programme were: ability to eat out or to do physical activity, embarrassment about diabetes and irritability with family and friends. Thus, it appears that the programme had most impact on feelings of confidence about knowing how to care for diabetes and least impact on selected aspects of life-style and feelings about having diabetes.

The lack of significant change for Stream 1 in mean scores for QDL items between the three-month pre- and pre-programme assessments indicates that the assessments themselves had no significant effect on perceived quality of life and in addition, provides some evidence that the questionnaire was reliable over time.

Only one other evaluation of diabetes education measured attitudes which resembled selected QDL items and no difference was observed (Bowen et al 1961) in the magnitude of change between the experimental and control groups. It is difficult to assess the comparability of their results with ours since the details of the attitude instrument were not given.

Possible Biases in the Interpretation of Programme Effects

The observed "effects" of a programme may be due to the operation of numerous biases rather than to the intervention itself (Sackett 1979, Green 1977). In these studies, the effects of several factors may have biased the results.

For participants, the education programme involves considerable time at the centre as well as contact with professionals and other

diabetics. The effect of this attention from the D.E.A.P. team from other group members and the length of time devoted to dealing with the problems of diabetes may have produced the observed changes in dietary variables and knowledge. The assessments themselves involved substantial attention (from the D.E.A.P. and the group) which was given to Stream 1 subjects at the commencement of the three month "control" period. However, they did not receive a formalised "attention placebo" of an additional 30 hours of professional and small group contact. Thus, the relative effects of attention and time vs. other aspects of the education programme on compliance and other outcomes in this study cannot be assessed. However, it was the aim of this evaluation to assess the impact of the combination of strategies used, rather than to study their individual contributions to the observed outcomes.

The effect of the evaluation itself on the behaviour of the D.E.A.P. team (the Hawthorne effect) may also have biased the results in either direction. It is possible that the team "tried harder" to achieve the desired effects than if the evaluation were not occurring. Alternatively, to minimise the possibility of harmful outcomes, team members may have been more conservative in their intervention procedures (e.g. diets more carefully prescribed, or withholding recommendations to alter insulin dosage) than otherwise would have been the case.

A conventional technique for minimising the Hawthorne effect, is to "blind" the therapists to the nature of the group (experimental or control) to whom they are adminstering therapy (Hill 1971). In these studies, the use of such procedures were both impossible and inappropriate because all subjects received the experimental interven-

tion and because the team were intimately involved in the assessment procedures and in using the results in the educational programme.

The likelihood of the Hawthorne bias operating in these studies cannot be assessed. However, because the intervention and data collection period extended over a relatively long period of time (four years), the chances of significant sustained alterations in behaviour by the D.E.A.P. team due to being "scrutinized" are less likely than might have been the case in a shorter study.

A related factor which may have affected the observed programme outcomes is the change in the educational process which occurred over the four years of the study. It was difficult for members of the team to keep the intervention procedures standardised throughout the study periods. The difficulties involved in adherence to standard intervention procedures throughout an evaluation have been described by several specialists in health programme evaluation and summarised by Frankle and Owen (1978). They state: "conscientious practitioners within a programme will change their methods as they discover areas and means for improvement ... especially if it is a complex, long-range programme". A two-year pilot development phase was undertaken prior to the initiation of the pre/post study and subsequently every effort was made to keep the major educational procedures standardised through the study periods. However, some alteration in the educational processes may have occurred, particularly in view of the improvement in educational expertise of the team, the feedback of results of the pre/post study during the early phases of the randomised controlled trial. Boredom and fatigue due to the demands of service and to the constant repetition in conducting educational programmes was reported by team members during final phases of both studies and may have adversely influenced the programme's effectiveness.

The effects of these factors on dietary compliance and other programme outcomes are masked by "averaging" the results over the entire study period. Unfortunately, the small number of subjects limits our ability reliably to assess differences in effects during various phases of the study programme's development.

Finally, the possible favourable or unfavourable biases introduced as a result of the timing of the follow-up assessments must be considered, as described by Sackett (1979) and Green (1977).

Dietary compliance may improve over time in programme participants, since major changes in eating habits (such as the change to a high carbohydrate diet) may take time. Alternatively, subjects may "backslide" with the passage of time and without the ongoing support of the team. The similarities in the findings in dietary change and compliance rates between the pre/post study and the randomised controlled trial suggest that there is little difference in compliance measured three or six months after participation in the programme, although, a three to six month follow-up period is insufficient to ascertain the long-term impact of the programme.

6.6 ASSOCIATIONS BETWEEN THE FOUR ASPECTS OF COMPLIANCE WITH A DIABETIC DIET REGIMEN

The lack of association observed between compliance with weight recommendations and with other aspects of the diabetic diet regimen is not surprising, given that the behaviours necessary to control weight differ substantially from those required to alter the composition of the diet or to minimise the variation between days in nutrient intake.

Compliance with other aspects of the dietary regimen were related to each other, probably because they were, to some extent, all

measures of aspects of carbohydrate intake. However, the observed associations do not suggest that all were measures of the same behaviour or that compliance behaviour was consistently high or low since only 30-45% of the non-compliers with one aspect of the regimen were non-compliant with others.

These findings reinforce the notion that "compliance" with diabetic diets cannot be viewed as a single entity. The regimen is complex and compliance with the components varies, perhaps depending on which behaviour an individual finds most difficult to change. Thus, a general score or rating for dietary compliance may obscure high compliance with some recommended behaviours and low compliance with others. Such ratings would therefore, not be useful in counselling nor in evaluating the effects of compliance-improving strategies.

6.7 PREDICTORS OF DIETARY COMPLIANCE

Of the variables measured in this study, the most consistent predictor of compliance was the baseline level of "compliance" with the particular aspect of the dietary regimen. These results are consistent with the findings from the general compliance literature suggesting that the best predictor of compliance is the degree of behavioural change required by the regimen (Haynes et al 1979).

Of course, by including in the discriminant analyses, the initial dietary variables which partially defined the compliance groups, it would be expected that they would be most strongly predictive of compliance and thereby diminish the importance of other factors. However, the practical purpose of these analyses was to determine any characteristics which could be measured before the programme to screen

potential compliers from non-compliers. Thus, dietary variables proved to be of primary importance.

Biochemistry, weight and age were also useful in predicting subsequent compliance with some aspects of the regimen, although the significant predictors varied between the two studies.

It appears that baseline biochemical measures were associated with subsequent dietary compliance. Those who were most likely to improve on carbohydrate composition had the highest levels of cholesterol initially. However, those with high baseline levels of blood glucose and glycosylated haemoglobin were not necessarily more likley to be compliant. Thus, these results are only suggestive that the level of diabetic control and lipids at the baseline assessment may have motivated some individuals to improve their compliance with the dietary regimen. Whether individuals were aware of their biochemical status prior to receiving the results of the initial assessments is uncertain, and hence no conclusions may be drawn about the value of the feedback of results of the biochemical assessments.

Compliance with the carbohydrate spacing recommendations decreased with increasing relative weight. This may be due to the widely held belief that eating regular meals and/or between-meal snacks are directly opposed to the achievement of weight loss. Thus, overweight individuals, may eat less frequently and consume more of their carbohydrate in one meal period. Adequate spacing was also associated with increasing age which may be attributable to more routine eating habits associated with middle and old age or to an increased motivation to adopt health maintenance practices. These associations of various factors with spacing compliance must be viewed with some caution since, on the basis of the reliability study, as

many as one-third of the subjects may have been misclassified as compliers when they were non-compliers.

The usefulness of the predictors as screening measures to identify diabetics likely to benefit from the education programme is limited by the unreliability of the compliance classifications based on the discriminant functions. For carbohydrate composition, approximately two thirds of subjects were classified correctly, on the basis of the prediction equation, whereas for spacing and variation, the predictions were correct for less than half of the subjects.

With the exception of age, the demographic characteristics (e.g. sex, social class) of these insulin-dependent diabetics were not associated with, nor predictive of compliance with carbohydrate composition, spacing and variation recommendations. These results are consistent with the majority of findings from investigations of compliance with regimens in diabetes (Keiding et al 1952, Wharton et al 1972, Dahlberg et al 1947, Bloom Cerkoney and Hart 1980 and Tunbridge and Wetherill 1970) and for compliance with other regimens as summarised by Haynes et al (1979).

Neither knowledge nor the majority of health beliefs proved to be useful predictors of dietary compliance in these studies. While, as reported in Chapter 2, the relationship between dietary compliance and knowledge has not been examined directly in previous studies of diabetics, the co-existence of inadequate diabetes-related knowledge and low compliance with other self-care regimens (or with several combined regimens) has been observed by several investigators (Stone 1961, Watkins et al 1967, Holland 1968, Wysocki et al 1978, Tagliacozzo et al 1970).

Our results concerning the lack of significant relationships between health beliefs and aspects of dietary compliance with a diabetic diet are consistent with those obtained by Bloom Cerkoney and Hart (1980).

However, ours appears to be the first investigation of the predictive ability of health beliefs for dietary compliance of diabetics. Similar to our own results, investigators of compliance with a hypertensive medication regimen found that health beliefs measured before intervention were not useful in predicting subsequent compliance in their setting (Taylor et al 1979).

The replication of these negative results from the pre/post study in the randomised trial makes it likely that the results were reliable. However, it is also possible that the health belief questionnaires, the scoring or analysis procedures were too insensitive to detect associations with compliance. This may be particularly relevant in the latter study when the associations with health beliefs were tested as binary data. Their predictive ability could thus not be tested in discriminant analyses. However, with the exception of perceived dietary compliance, the lack of significant associations suggests that they would not have entered the discriminant analyses.

6.8 RELATIONSHIP BETWEEN DIETARY COMPLIANCE AND ACHIEVEMENT OF BIOCHEMICAL GOALS

Whether high compliance with the recommended regimen results in achievement of the treatment goal is of interest to the medical and dietetic practitioner, the compliance investigator, and the patient (Sackett 1976). If high compliance is not rewarded by achievement of

the treatment goal, the efficacy of therapy is questionable and some are of the opinion that such regimens should not be recommended (ibid.). On the other hand, if treatment goals are achieved in spite of non-compliance, it is suggested that there is little point to the energy invested by all concerned in the process of behaviour change .

However, diabetes is a complex metabolic disorder in which multiple therapies are usually required to achieve short- and long-term goals. As discussed earlier, ease of blood glucose control is dependent not only on diet therapy but also on insulin management and on the type of diabetes.

Under the circumstances of these studies (i.e. our inability to alter therapies other than diet and the heterogeneity of the sample with respect to the "types" of insulin-dependent diabetes), a close relationship between dietary compliance and metabolic control of diabetes would not be expected. In view of these limitations and the lack of association between compliance and diabetic control observed by others, it is surprising that significant relationships were observed in our study.

The increase in percentage of energy contributed by complex carbohydrate (with associated reduction in fat intake) was related to achievement of good diabetic control. Although this relationship has been demonstrated in studies of the efficacy of diet, it has not been previously documented in field studies of larger samples of a heterogeneous group of diabetics.

The lack of relationship observed between compliance with carbohydrate spacing and variation measures of biochemical control may be due to the lack of efficacy of these dietary factors or as discussed previously, overriding factors such as insulin-therapy, type of diabetes etc.

In view of the emphasis placed on maintenance of ideal weight to achieve good diabetic control, the lack of relationship we observed between relative weight and metabolic control was unexpected. Similar results were obtained by Streja et al (1981) who observed that neither relative weight nor substantial weight reductions were associated with metabolic control of diabetes as measured by fasting blood glucose. The authors concluded that because relative body weight does not appear to have a direct effect on metabolic control, nutritional counselling should focus on other aspects of the diabetic diet regimen. The lack of relationship between relative body weight and metabolic control was unexpected.

It may be possible that the majority of overweight subjects in our sample had Type II diabetes but had been placed on insulin therapy to achieve optimum control. Alternatively, these subjects may have been on larger doses of insulin to control diabetes, although we did not assess insulin dose as an indicator of diabetic control.

6.9 IMPLICATIONS AND RECOMMENDATIONS FOR THE D.E.A.P. AND SIMILAR DIABETES EDUCATION PROGRAMMES

1. Implement in other settings

This is the first trial to be reported of the effect of a diabetes education programme on the dietary behaviour of participants. The programme package, as described by Tupling (1981) and summarised in Chapter 3 of this thesis has been shown to be effective in improving compliance with a higher carbohydrate regimen for diabetics and their family members who attended the programme. This achievement is in accordance with recently formulated policies for diabetics (American Diabetic

Association 1979 and the Dietetic Liaison Committee of the Australian Diabetes Society), and for the general public (Australian Dietary Guidelines 1980, and Dietary Goals for Americans 1977). Thus, the application of the strategies used within the D.E.A.P. may improve the effectiveness of those attempting to encourage higher compliance with the recommended composition of diets for diabetics and for the general public.

2. Incorporate medical intervention into the education programme

The programme's lack of effectiveness in improving the metabolic control of diabetics confirms the observations from other evaluations that educational strategies, separated from the medical management of diabetics are largely ineffective in improving the metabolic control. However, results from the limited evaluations of programmes which have a major stabilisation and medical management component indicate that such strategies can be effective in achieving the short-term treatment outcomes of improved glycaemic control for participants. The impact of such combined medical/educational interventions on compliance or other outcomes has not been determined.

It is therefore recommended that the D.E.A.P. and other strictly educational programmes for diabetics incorporate a medical management component into their routine intervention procedures, particularly aimed at those who enter the education programme in poor metabolic control. Such interventions may take the form of revising insulin-therapy, home blood glucose monitoring, closer collaboration with the medical practitioners of the programme attenders and/or consultations regarding appropriate insulin management. Without such a revision, it is doubtful that the

educational interventions will be adequate to achieve their stated goal of improving the health status of diabetics.

3. Implement and evaluate specialized strategies for overweight clients

The education programme's demonstrated lack of success in assisting the majority of overweight clients to reduce weight confirms the results of the majority of other evaluations in showing a variety of educational strategies to be ineffective in the difficult area of weight reduction. It is thus recommended that additional or alternative strategies be directed towards the portion of the programme's clientelle for whom weight reduction is advisable for the achievement of good diabetic control. Strategies which have shown more promise in the behavioural and psychological literature for short-term weight loss and long-term maintenance need to be implemented within the context of a programme for diabetics and subsequently evaluated for their effectiveness with this specialized population.

4. Tailor the dietary regimen more closely to individuals and monitor for its effects on biochemical measures

In view of the emphasis placed on compliance with carbohydrate spacing and constant carbohydrate recommendations within the dietary regimen and the education programme, the lack of success observed in these two studies suggests that another approach is needed. Evidence is conflicting concerning the necessity of adherence to such recommenations in order to achieve good diabetic control. It appears that individual responses vary depending on the type of diabetes, the type of carbohydrate and the form in which it is consumed.

It is therefore recommended that aspects of the dietary regimen concerning spacing and variation of daily carbohydrate intake be more individually tailored to programme participants and monitored for the effects of compliance with these on diabetic control. It is also recommended that the effects of increasing carbohydrate intake be more closely monitored for the effects on diabetes control and serum triglycerides.

5. Continuing Evaluation

The generalisability of the programme's effects to other populations of diabetics and implemented by other personnel is unknown. Moreover, the relative effectiveness of the various components and strategies used within the D.E.A.P. is uncertain. Thus, any attempts to replicate the D.E.A.P. as a whole or in part in other settings requires evaluation to assess its effects on a wide spectrum of outcomes including cognitive, behavioural, attitudinal and health indices.

It is recommended that the D.E.A.P., following a major revision and pilot testing of some of its intervention strategies (discussed previously), revise and continue on-going evaluation with a focus on biochemical and dietary outcomes. It is also suggested that a one- to two-year follow-up assessment be carried out on the subjects of the randomised controlled trial to assess the long-term effects of the education programme.

6.10 RECOMMENDATIONS FOR FURTHER STUDY

1. Whether the observed improvements in dietary composition, knowledge and attitudes will be maintained by programme participants over time is uncertain. The effects of the passage of

time and of the withdrawal of D.E.A.P. team support needs to be identified over a much longer period of time (i.e. 2 to 5 years) than was possible in these studies. Such research is crucial in identifying the need for frequency and timing of follow-up.

2. Considerable revision and additions to the D.E.A.P. may be implemented as a result of these evaluations. Consequently, on-going evaluation is crucial to identify the effects of any major change, since negative as well as positive effects may occur.

3. The cause of the rise in triglycerides which occurred in these two studies could not be identified. Further study is needed to assess more carefully the explanation of this potentially harmful outcome.

4. The relative effectiveness of the strategies used within the D.E.A.P. is uncertain. Whether individual components can be implemented with the same degree of effectiveness as the entire package is a question of practical importance, since the D.E.A.P. is time-consuming, expensive and labour-intensive. In settings where resources available for educating diabetics are limited, "compromise" education programmes tend to be implemented, particularly in small hospitals and in country areas. A high priority is to devise a manageable, practical evaluation scheme which can serve as a monitoring device for these less intensive programmes.

5. Within the Sydney Metropolitan area and the State of New South Wales, several major education programmes have been established, all of which have common objectives but serve apparently different populations of diabetics and use dissimilar regimens as well as educational and medical strategies.

To identify the differences in characteristics of the populations served and the effectiveness of the various programmes in achieving their stated objectives, it would be desirable to implement a multi-centre evaluation using similar evaluation methods and instruments. The information from such an evaluation could be used to strengthen existing programmes and/or as a basis on which to refer clients to various centres.

CHAPTER 7

CONCLUSIONS

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CONCLUSIONS

1. A descriptive evaluation of the Diabetes Education and Assessment Programme at the Royal North Shore Hospital of Sydney, carried out between 1978 and 1980 showed evidence of positive changes in programme participants in dietary compliance, knowledge of diabetes management and selected health beliefs, assessed six months after the programme. Similar results were obtained in a randomised controlled trial conducted from 1980 to 1981, which confirmed that these positive changes were attributable to the education programme rather than to the effect of participation in the assessments themselves.

   Diabetics and their family members who attended the programme and returned for follow-up assessments increased their complex carbohydrate intake and reduced fat intake in accordance with the programme's recommendations. On this regimen, the diabetics did not gain weight and their family members lost weight. Prior to the programme, diabetics and family members had inadequate knowledge of the rationale and procedures for self-management, but their knowledge scores increased considerably after the programme.

   The education programme appeared to influence favourably some of the health beliefs measured in these studies. Consistent with the programme's emphasis on personal vulnerability to ill-health and compliance with the regimen as a means of prevention, significant increases were observed in subjects' perceptions of

susceptibility to the complications of diabetes, their self-assessed compliance with the dietary regimen, efficacy of the self-care regimens, and faith in the doctor's care. Barriers to dietary compliance significantly decreased (in the pre/post study) possibly due to the increased flexibility and choice on this dietary regimen. However, the lack of consistent improvements in the same health beliefs between streams suggests that factors other than the education programme may have influenced health beliefs.

2. The results of both studies showed that the education programme had no significant effect on body weight of diabetics, metabolic control of diabetes, carbohydrate spacing or variation scores or serum cholesterol. The majority of diabetics were not overweight at the baseline assessment. However, of those who were overweight initially, only one-third lost weight after participation in the education programme. The mean values for measures of fasting blood glucose and glycosylated haemoglobin did not alter significantly between pre- and post-assessments. Initially, one-third of subjects in the pre/post study and two-thirds in the randomised controlled trial were judged to be in poor glycaemic control and these proportions did not change after the programme.

Mean fasting serum cholesterol levels of subjects in both studies were well within the normal range at the baseline assessment and no significant changes were observed at the follow-up assessment. An undesired increase in mean fasting serum triglycerides was noted in the pre/post study and for Stream 2 in the randomised controlled trial, but the reasons for

these increases are unclear. In the former study, an upward trend in the pre-education triglyceride values was observed over the first year of the study, which suggests that the increase was attributable to secular variation in the study population triglyceride values, or unidentifiable variation in laboratory or sample collection methods.

In the randomised controlled trial, the initial triglyceride values and the patterns of change over the study period differed for the two streams; the mean for Stream 1 was initially at the upper limit of the acceptable range and remained so whilst that for Stream 2 was well within the normal range initially but increased to the upper limit of the acceptable range. These changes in triglyceride levels were not significantly related to observed changes in diet or weight but they were significantly related to increases in fasting blood glucose. Thus, it appears that the triglyceride increase for Stream 2 resulted from a slight deterioration in control of diabetes. Nonetheless, its occurrence in both studies indicates a need for further enquiry as to the causes and methods to prevent the recurrence. If individual biological sensitivities to the recommended dietary changes are responsible for an increase in fasting blood glucose and triglycerides, the regimen may need to be more closely tailored for individuals and monitored for its effects on biochemical indices.

The lack of apparent success of the education programme to improve participants' compliance with spacing, variation and weight recommendations and in assisting those with poor metabolic control of diabetes to achieve better control, clarifies areas of need for revision and re-evaluation of the programme.

3. The results from both studies showed that individuals who were compliant with one aspect of the diabetic diet regimen were not necessarily compliant with others. Weight compliance was not significantly associated with any other aspect of dietary compliance, but there was a tendency for subjects who were at their ideal weight (before and after the programme) to be non-compliant with spacing recommendations at both assessments. Other aspects of dietary compliance were related to one another (statistically significantly) although the associations were complex and the results between studies were inconsistent.

   These results suggest that dietary compliance or non-compliance is not a generalised behavioural response but rather that compliance with various aspects of the dietary regimen varies between and within individuals. Thus, a combined rating or score for dietary compliance with a diabetic diet regimen may not be useful in identifying non-compliance or detecting changes in the various recommended dietary behaviours.

4. In neither study could compliance with the four aspects of the diabetic diet regimen be predicted reliably from measurements made at the baseline assessments of any variables including demographic characteristics of clients, knowledge, health beliefs, duration of diabetes, treatment characteristics or referral source. The best predictor of subsequent compliance with dietary recommendations was the initial level of compliance. Those who had the least change to make were more likely to achieve the dietary goals at follow-up. However, the practical application of the prediction equations generated from initial dietary data is limited since, on this basis, one-third

to one-half of the subjects were incorrectly classified into compliance categories.

5. By contrast to the findings of several other investigators, compliance with some aspects of the dietary recommendations was associated in these studies with the achievement of acceptable metabolic control of diabetes. Compliance with the recommendations to consume a diet composed of 45% of calories from complex carbohydrate and no more than 30% from fat was associated with the achievement of good metabolic control of diabetes; compliers were more likely to have levels of blood glucose and glycosylated haemoglobin within a clinically acceptable range. Carbohydrate variation compliance was also associated with good glycaemic control; those who had more constant daily intakes of carbohydrate were more likely to achieve good control. However, no association was observed in either study between biochemical measurements and compliance with weight or carbohydrate spacing recommendations. Blood lipid levels at the follow-up assessment were not related to dietary compliance.

6. Using the 24-hour urinary urea as the criterion of validity, the four-day food record estimates of protein intake appeared to be valid for the group before and after the programme. However, for individuals, there were considerable discrepancies between protein intakes calculated from food records and from 24-hour urinary urea, suggesting that either the food records or the 24-hour urine collections (or both) inaccurately reflected protein intake of individuals. No conclusions may be drawn from these results about the validity of assessments of carbohydrate or fat intake or compliance with the programme's recommendations concerning these nutrients.

7. The results of these two programme-evaluation studies have shown the D.E.A.P. to be effective in the short-term in moving towards the achievement of some of its objectives for insulin-dependent diabetics. Further planning and study is needed to identify more effective but economically feasible strategies which can be implemented to assist the majority of clients to reach the dietary goals and achieve good metabolic control of diabetes. Continuing programme evaluation is also necessary to determine (a) the long-term effects of the programme, (b) the effects of any subsequent major programme revisions and (c) the effectiveness of the programme package and its components implemented in other settings, by others teams and tailored to local needs.

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APPENDICES

APPENDIX 2.1

CRITERIA FOR EVALUATING STUDIES OF COMPLIANCE IN DIABETES AND DIABETIC EDUCATION

(Adapted from Haynes, Taylor and Sackett, 1979)

PURPOSE OF STUDY

3 evaluation of compliance improving strategy (or effect of educational strategy on other outcome)

2 trial of efficacy of diet or study of relationships between compliance and treatment outcomes

1 determinants of compliance

0 survey of compliance

DESCRIPTION OF THE DIABETIC DIET REGIMEN

Points

2 complete description that would permit the reader to replicate the regimen with precision i.e. name of diet, composition, energy level or intended effect on body mass, foods excluded, format in which diet prescription is presented to patients.

1 incomplete description

0 no description or regimen can only be inferred

(not applicable to studies not evaluating compliance).

NOTE: may be described in another article and referenced.

DEFINITION OF COMPLIANCE

2 replicable by reader (i.e. how were individuals assigned to compliance categories, how far from dietary goals could they deviate?)

1 vague definition

0 no definition

(not applicable to studies not evaluating compliance)

COMPLIANCE MEASURES

2
(a) appropriate and valid for the purpose of the study and the operational definition of dietary compliance:

(includes use of food records for assignment of individuals to compliance categories for qualitative definitions of compliance, self-ratings acceptable only in large surveys - not in trials of compliance - improving strategies or factors related to compliance, recall methods acceptable for description of group),

and

(b) complete reporting of details of measurements:

(i.e. verbatim questions asked if self-rating of compliance was used, what aspects of diet history were used, how 24-hour recall interviews were done and by whom,

1 apparently appropriate methods but inadequately described

0 measures not stated or inappropriate (or substituted biochemical measurement e.g. blood glucose for measurement of dietary compliance)

Bonus A: when multiple measures used (e.g. weight + 24 hr. recall)

Bonus B: when biochemical measures used in addition to other measures

NOTE: if multiple measures are used and they score differently, score for each measure is shown in table.

DESCRIPTION OF COMPLIANCE-IMPROVING STRATEGY

Points

2 replicable by reader (i.e. specified at least four of the following: what the clients and instructors do at the programme (the process), whether it is group or individual education, number of patient contacts or counselling sessions, types of health professionals involved, description of audio-visual and/or written materials)

1 vague description

0 no description

NOTES:

(a) Not applicable in surveys of compliance or cross sectional studies of determinants

(b) may be described in another article and referenced

STUDY DESIGN

Points

4 randomised trial

3 quasi-experimental, "before and after" (with or without control group)

2 analytic (cohort, case-control)

1 descriptive (e.g. single patient group studied at one point in time, may include comparisons made between compliers and non-compliers).

Bonus A: for use of inception cohort (those newly diagnosed or beginning treatment at the same time)

SELECTION AND SPECIFICATION OF THE STUDY SAMPLE

Points

3 random population sample, or three or more hospitals/clinics in a geographical area or regional programme/referral centre and adequate description of demographic features

(must include five of the following: age, sex, race, SES, marital/family status, type of diabetes, duration of diabetes)

2 same as for 3, but inadequate demographic description of clientelle or of area served (includes studies which appear to serve a region, as in 3, but not stated)

1 grab sample or single clinic (including adequate description of demographic features of sample) or poor response rates (LT 80%) to samples as in 3

0 same as for 1, but inadequate demographic description

Bonus A: inception cohort

Bonus B: indication of the proportion of patients excluded

Bonus C: indication of "consecutive admissions" or "all patients" during a stated time period OR of a single clinic population with at least 80% follow-up.

DATA ANALYSIS AND REPORTING

Points

2
(a) Appropriate statistical tests (or descriptive statistics) for type of study, data and sample size:

(includes reporting of compliance rates to single behaviours when several are measured, reporting results of all measures made, reporting compliance rates for the whole group under study (although sub-group rates may also be reported)

and

(b) complete reporting of all relevant details of tests and results:

(includes use of paired tests when matched control group or repeated measures used, comparison between change in experimental group vs control group if a control group used, adjustments made to critical values when large numbers of comparisons made, use of all data in the determination of factors related to compliance, all relevant descriptive statistics used, test appropriate for numerical scale used to measure compliance.

1 appropriate statistical procedures but inappropriate interpretation, incomplete reporting (i.e. report/compliance rates to several behaviours together or incomplete analyses)

0 no statistics, or methods not stated, or inappropriate statistical procedures.

Bonus:

A for reporting original data from which the reader may carry out appropriate statistical tests

B in compliance studies relating compliance to the treatment goal, e.g. blood glucose, serum cholesterol, presence or absence of complications of diabetes, hospitalisations for diabetes-related causes

C for reporting complete compliance distribution (in three or more categories or intervals) (vs group means or dichotomous data)

APPENDIX 3.1

DIABETES EDUCATION AND ASSESSMENT PROGRAMME

TIMETABLE

SESSION 1 (Monday evening 7-9 p.m., all team*)

1. Introduction to the members of the team and the nature of the programme.
2. Airing of problems you wish to solve by coming to the programme.
3. Themes of the programme.
4. What you can expect from the programme and what we expect from you.
5. Instruction and practice in keeping a four-day food record.
6. Instruction in keeping a 24-hour urine collection.
7. Random blood glucose test.
8. Haemoglobin A_1 test.
9. Check out your knowledge of diabetes.

Individual Assessments Appointments (the following Monday)

* Return for individual appointments at which time the following assessments take place -

Weights, heights and skinfold measurements,
Blood pressure,
Diet problems,
A look at your feet.

SESSION 2 (Monday evening 7-9 p.m., Dr. Sulway and Sr. Harris)

1. What is diabetes? Myths and facts about its causes and symptoms.
2. Treatment methods and aims of treatment.
3. Ketones simply explained: their significance for you.
4. Insulins.
5. Diabetic Control and how to judge it.
6. Can you tell how your diabetes is going by the way you feel?
7. Summary. "The Lazy Pancreas" - colour T.V. film.

SESSION 3 (Thursday (10 days later) 7.45 a.m.-3.30 p.m. all team)

1. Fasting blood glucose and blood fats samples.
2. Individual injection technique assessment.
3. Breakfast.

4. Hyperglycaemia: the problems and complications which uncontrolled diabetes causes your body.

5. Morning tea.

6. What the computer said about your diet.

7. Individual recommendations from the dietitian.

8. The 'bread and potato' myth. Why do we recommend a carbohydrate portion diet?

9. How to count carbohydrate portions.

10. Using the "Traffic Light Guide to Food".

11. Random blood glucose sample.

12. Urine testing technique.

13. Lunch.

14. Experimenting with New Foods: Cooking tomorrow's lunch. Low calorie meals, calculating portions in recipes.

15. Afternoon tea.

16. Summary of the day's information and activities.

SESSION 4 (Friday (the next day) 7.45 a.m. - 3.30 p.m., all team).

1. Fasting blood glucose and blood fats samples.

2. Individual injection technique assessments.

3. Breakfast.

4. Hypoglycaemia: What's a 'hypo' and how to recognise it, treatment problems and anxieties 'hypos' cause you and your family. How to prevent them.

5. Glucagon: A quick, reliable home treatment for severe 'hypos' which will help you stay out of hospital.

6. Health risks and special precautions for preventing 'hypos'.

7. Morning tea.

8. Sharpen up your injection technique.

9. Urinalysis: comments and feedback.

10. Balancing your diet: What's wrong with an unbalanced diet? How portions can help. How much protein and fat is too much? Individual problems (slimming).

11. Lunch.

12. Exercise - how it can help control your blood sugar and your weight.

13. Contracts, problems.

14. Quiz.

15. Summary and review of the day's information and activity.

SESSION 5 (Wednesday evening (the following week) 7-9 p.m., nutritionist and psychologist).

1. Diet hassles. Problems encountered during the week. What's getting in the way of following the dietary recommendations.

2. High and low calorie eating, how much fat is in food?

3. Filling and unfilling portions.

4. What to do about high cholesterol and triglycerides.

5. How to solve problems with high blood sugars. How the diet can help.

6. What about alcohol for diabetics? How much is too much?

7. Special diet foods for diabetics. Are they safe? Which ones are O.K.?

SESSION 6 (Thursday evening, 7-9 p.m., following Session 5, Dr. Sulway and Sr. Harris)

HOW TO CONTROL YOUR DIABETES - PUTTING IT ALL TOGETHER

1. Action of major insulin types.

2. Use of urine tests to monitor control.

3. Adjusting your insulin and diet to cope with sick days, parties, driving, travelling and busy schedules.

4. How is your control? What's it like now? (Feedback of blood results). What can you do to improve it?

5. Monitoring your control at home with the reflectance meter.

6. The shared responsibility between you and your doctor. What should you expect of your doctor?

7. What can you expect from yourself? Individual help needed?

8. Follow-up appointments.

1 Month Follow-up Review - Individual appointment (1 hour).

3-6 Month Follow-up Review - 2 group sessions (early morning).

Dates and times to be arranged at Session 6.

* Team members: Dr. Sulway, endocrinologist; Sr. Gillian Harris, nursing sister; Ms. Jane Atkinson, nutritionist; Ms. Hilary Tupling, psychologist; Ms. Karen Webb, nutritionist, evaluator; Mrs. Joyce Taylor, secretary; Mrs. Alison Owen, Clerk.

APPENDIX 3.2

Excerpted from: Tupling, H. You've Got To Get Through the Outside Layer. Sydney: Diabetes Education and Assessment Programme, 1981.

Section 4 Educational exercises for use in programmes

4.1 Exercises used in Programmes 1 and 2

Introductory Exercise

(Time: 20-30 minutes)

Objectives

- Start the process of group formation.
- Set the scene for sharing of problems and concerns.
- Allow the individuals in the group to get to know each other informally while sharing a structured task.
- Identify important questions, expectations and concerns for the group, as well as ambivalences or areas where individual counselling is necessary.
- Provide a bridge between individual problems and what information, experiences and resources the programme will offer.

Materials

- White board, felt-tipped pens, butcher's paper.

Procedure

- Explain that it is important that the programme meets the needs of everyone, and in order to achieve this the team needs to know what other problems people have.
- Ask group members to separate from people whom they already know and to form small groups (4-5 people) to discuss one or two of the following questions—writing on butcher's paper (anonymously)—and other questions or concerns that they have which they would like answered.
- Possible trigger questions (write on white board):

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1 What are my day-to-day concerns and problems about diabetes?
2 What problems do I hope to solve by attending the programme?
3 How do I feel about coming to the programme (and what have I left in order to come)?
4 What do I want my relative or friend to gain from the programme?
5 What questions do I have (about my diabetes) which I feel have never been satisfactorily answered?

- When each group has produced a number of questions and has come to a standstill, attach butcher's paper to the walls and suggest that members walk around and look at each other's questions.
- Review the kinds of questions yourself, commenting on similarities

and differences, noting when different questions are likely to be answered, pointing out those which are not likely to be dealt with and possible resources available for handling them.
- Ask different team members to comment briefly on their roles in the programme with reference to questions which are their own speciality.

Comments
- At the D.E.A.P. we used to believe that this kind of process could only be utilised *after* people in the group had become more relaxed with each other. Now that we have introduced it as the first exercise in the programme we have realised that our previous caution was unnecessary and, we suspect, reflected our own anxiety with a new group of people.

What's your blood sugar level?

(Time: 20-30 minutes—excluding time taken for blood samples)

Objectives
- To explore what is meant by 'diabetic control'.
- To raise awareness that feeling well is not necessarily an indication of good diabetic control.
- To focus on whether or not a person can tell how high or low his/her blood sugar level is.
- To inform as to more accurate ways of assessing diabetic control.

Materials
- Reflectance meter, blood glucose reagent strips and automatic finger pricker OR blood sample for glucose determination by venepuncture.
- Butcher's paper with graph of blood glucose values plus normal range marked.

Procedure
- Before taking a blood test, ask individuals to guess or assess what they think their blood sugar level is, either in mmols/l or categories: low, normal, high, very high.
- Check with them why they have guessed a particular level.
- If you can, do a few non-diabetic blood samples as well.
- Plot the blood glucose results anonymously on the poster together with what each person guessed, e.g.
- Also give individuals their own results.
- Ask the group to look at the poster and generally comment: it is usually noticeable that people only 'feel' their blood sugar level when it is low, and these symptoms can be written on the poster.
- Comment yourself on the results, especially with reference to what other people/groups have found—as well as this one.
- Go over why it is that non-diabetic results are all in the normal range.
- If there are any obvious reasons for high/low values, e.g. sickness, 'hypos', etc., this is the time to point them out.
- Explore more accurate ways of maintaining blood sugars than relying on feelings.

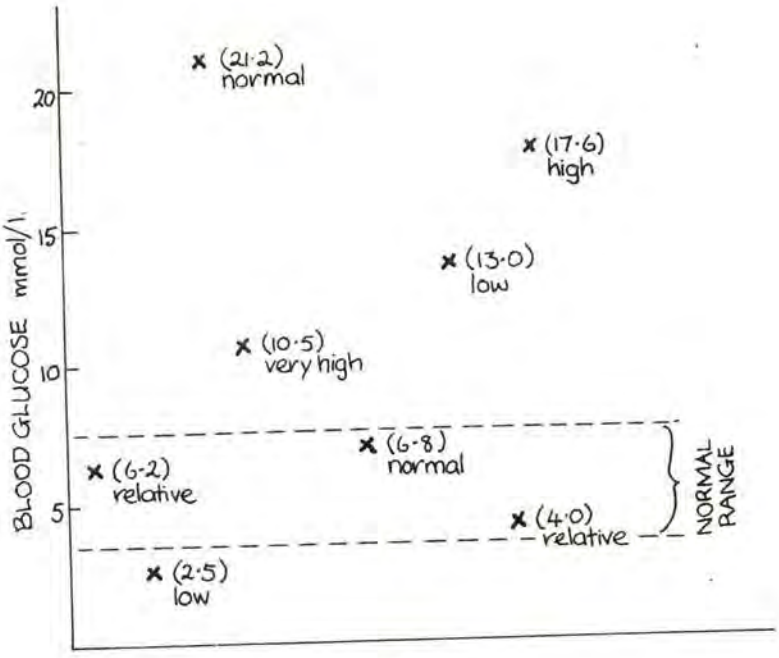


Fig. 1

Comments

- At least 50 per cent of our groups don't guess their blood sugar correctly, but it's natural to think you can, as there are no feedback systems to indicate that anything's wrong until values are very high or very low.
- The point of this exercise is not to be superior to the group or indicate an attitude of 'I know better than you'.
- Often people can get quite anxious when they realise they've been trusting their feelings in error. It is important to go over the feelings they *can* trust (e.g. usually low blood sugar values) and to spend time on what to do instead (e.g. home glucose monitoring).
- Frequently, it is not realised that blood glucose levels fluctuate during the day—you may need to stress the reasons for this.
- Unless a person volunteers his/her result to the group, we make it a practice not to share individual results, though this can be done as a result of the group consensus.

What does your pancreas look like?

(International draw-a-pancreas competition)
(Time: 15–20 minutes)

Objectives

- Explore myths, fears and fantasies about what is going on inside a person's body who has diabetes.
- Inform the group of the nature and function of the pancreas. Correct misinformation and fears of body or tissue damage.

Materials

- White board or poster picture of abdomen outline on which position of diaphragm is roughly drawn.

Procedure
*Diabetes physician:** 'Do you know what your pancreas looks like when you have diabetes? I've drawn this elaborate drawing here.'

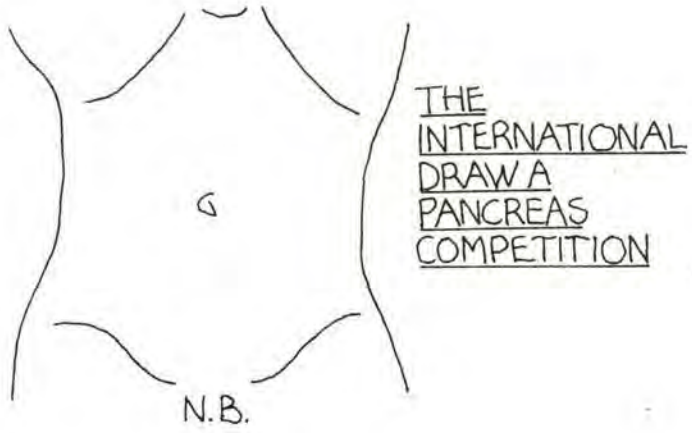


Fig. 2

'This is the bottom of your rib cage. That's your 'belly button' or umbilicus ... and they're (pointing to NB) the naughty bits.'
Nurse educator 'So who's our first contestant. I think Joe X would like a go. How about it?'

The nurse educator has mentally selected some likely starters. She needs 2–3 diabetics of more extrovert or inquisitive personality and a relative or two as volunteer contestants.
Diabetes physician 'Go on, be a devil. We want to know this ... You understand the task? What does your pancreas look like compared with somebody's about the same age? Say I was a surgeon—you'd be unlucky if I were—and I was removing your appendix and was inquisitive enough to look across to see what your pancreas looked like. Could I tell that you had diabetes by looking at it? And there are prizes, aren't there Gill?'
Nurse educator 'There are some lovely prizes for the correct answer. If it's a gent it's a kiss from me, and if it's a lady a kiss from Martyn in the attractive urine-testing room. We've got our lips all puckered up.'

The contestants need some patter, encouragement and support for their efforts because the rest of the group is likely to laugh at the contestants' attempts (though they could do no better in fact). The volunteer will need prompting ... 'What about its colour? What about its surface? What about its size?' etc.

This is another way of fossicking out entrenched and commonly held beliefs by diabetics about self-damage.

*This style may not be to everyone's taste or personality but it works if you're a showman. You can modify it to your own style.

Here is a typical group's efforts:

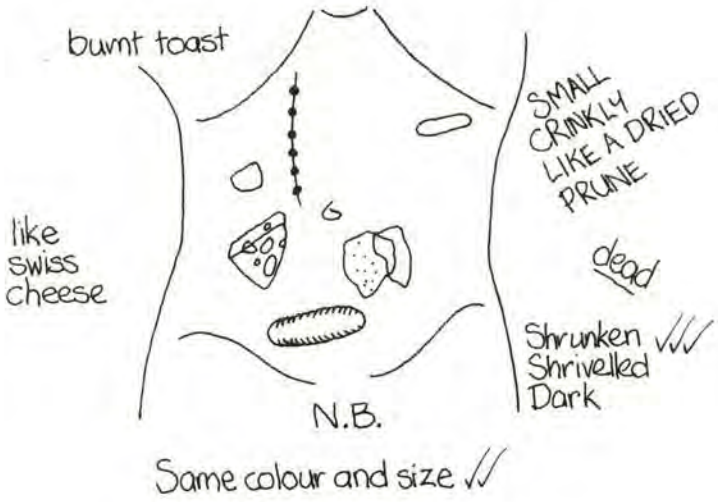


Fig. 3

Review the information gathered and correct misinformation. Stress the healthy functional parts of the pancreas.
(*Note:* Islets make up only 3 per cent of volume, length is about half of body width, colour is salmon—cream normally.)

Comments

- We have had a wide variety of reactions to this exercise from 'it's childish' to 'my pancreas is like a rotten apple'. Others have been that it smells bad, its surface is caved in, it's got holes in it like Swiss cheese, it's like a piece of charred, burnt toast, it's greenish, etc.
- These fantasies don't do much for a person's feeling of well-being and health.
- The exercise is usually quite light-hearted, with a lot of humour, though it obviously has a serious side.
- It is a valuable exercise for relatives and friends of diabetic group members who may also be misinformed or have unspoken fears.

Why did I get diabetes?

(Time: 20–30 minutes)

Objectives

- Clarify and explore the reasons people developed diabetes.
- Alleviate guilt or blame (both for diabetic and relative, e.g. parents).
- Inform as to what is *known* about the causes of diabetes.

Procedure

- In small groups (4–5) ask participants to discuss why they think they developed diabetes OR
- Why they think their relative developed diabetes.

. List group summary of causes.
. Go through list commenting on the reality of each.
. Pay particular attention to any causes which may lead to self-blame, e.g., eating too many lollies/sweet food, falling downstairs and breaking a leg (accidents, eating the wrong foods).
Note: No one's to blame.

Comments
. People often blame themselves for getting diabetes and sometimes even wonder if it is punishment for some minor transgression.
. These feelings can result in self-torture and 'if only I hadn't'.
. They are not conducive to self-care and positive action.

4.2 Complications of uncontrolled diabetes (Time 1-1½ hours)

Objectives
. To clarify and present a realistic and sensitive picture of the problems of poor control.
. To stress the preventable nature of most of these.
. To uncover and deal with myths associated with diabetes.
. To arouse *motivating* anxiety as opposed to overwhelming fear.

Materials
. Butcher's paper, felt-tipped pens and hand-drawn diagrams (for group leader).
. We've found that a two-dimensional drawing of the eye is too difficult for people to comprehend. We use the analogy to a camera to explain the structure and function of the eye and have a small, non-gruesome model* of an eye which can be disassembled. One half of the retina is normal; the other half shows background retinopathy of mild degree.
. For large vessel disease, we use a 30 cm length of polyvinyl chloride tubing about 6 cm in diameter. At one end we've put a 'sludge' of yellow plasticine to illustrate atheromatous deposits. 'We start our lives with smooth-walled blood vessels like this (show clear end) and as a result of poor diet we develop deposits like this (show plasticined end).'

Procedure
. In small groups ask participants to discuss the following questions:
a. Which body problems, as far as I am aware, are associated with poor control in the long term (i.e. high blood sugars and high blood fats)?
b. How likely am I to get them? (Explain that non-diabetics are also susceptible to some of them. Which ones?)
c. If any of them occur, is it possible to reverse them? If so, how? What can be done?
d. Are these problems preventable? If so, how?
. The above will take approximately 20 minutes.
. Ask each group to read out what they have come up with for the first question.

*Courtesy of Charles E. Frost (Aust.)

. Cross out any problems which are NOT associated with poorly-controlled diabetes (in our experience, most groups consider that the liver—for example—is inevitably damaged).
. Using pre-prepared diagrams, explain the way in which poorly-controlled diabetes can damage tissues and organs:

High blood fats cause large blood vessel damage (clots, arteriosclerosis, gangrene, strokes);

High blood sugars cause tiny blood vessel damage (peripheral circulation damage, damage to kidney and retina), nerve tissue damage, loss of sensation, impotence.

. Ask the group for their assessment of their susceptibility as diabetics and non-diabetics. Place this in the context of health problems in the community (i.e. the general problem of cardio-vascular disease etc.).
. Check out with the group their understanding of reversible/preventable elements of the problem.
. Again, place this in context—the effect of yesterday's treatment, recent advances, e.g. laser treatment for retinopathy, etc.
. Stress the HOW of prevention as well as the hope for reversing/healing damage which has been done.

Comments

. At the D.E.A.P. this session precedes two days of dietary feedback, information and practice as to the initial way to get (back) into good control. Having aroused anxiety, we follow it immediately with strategies and action plans for changing behaviour. The results of the four-day computerised dietary analysis are given back in the next session and any dietary problems that might be contributing to poor control are revealed, together with recommendations for change.
. We frequently refer back to this session on complications to reinforce the rationale for the dietary suggestions, e.g. reducing fat in the diet.
. We don't show slides of mutilated feet, etc. though sometimes a group member will talk about a problem he or she has experienced, e.g. eye damage.

4.3 Dietary assessment and feedback

Keeping a food record

Introduction

When we first started thinking about assessing people's diets, none of the team believed it would be feasible to ask clients to keep a weighed food record over a number of days. The standard dietary procedure was to ask the person to remember what they had eaten over the last 24 or 48 hours and to work with that information. It was obvious, however, that people were affected not only by memory lapses, but also by the difficulty they had in accurately estimating weights and how they thought the dietitian was assessing what they said. The result was an assessment that no one, including the dietitian, believed in, hence the recommendations

based on inadequate data about current eating habits. Worse still, we felt, and research confirmed, that clients made few dietary changes as a result of our diet intervention. This stimulated us to risk asking clients to keep a weighed food record—even though we knew it was a time-consuming and tedious task. By computerising the record, it became possible to use much more of the information obtained than could be processed by hand, and to give back to clients accurate results which they could use as a basis for change.

Having decided to try this method, the next problem was to sell it to our clients, making the assumption that if we 'sold' it in the right way most people would respond favourably. This assumption has proved fairly correct: very few clients (less than 10 per cent) keep such inadequate records that it is impossible to code them, and even fewer refuse to keep them. Since we feel that the food record is such an essential part of the dietary sessions, there is a catch—no food record, no dietary recommendations. In addition, the dietitians feel that by using a computer to make recommendations for change they can avoid an authoritarian role and be helpers and resource people.

The basic assumptions behind this assessment are:

a. That most people, in good faith, believe they are following the diet that they have been prescribed.
b. That people are unaware of what's in the food they eat.
c. That most people are unaware of what constitutes a 'balanced' or healthy diet.
d. That their current conceptions are often based on inadequate information, advertising prejudices and childhood learning.
e. That everyone (diabetics and non-diabetics) can benefit, in health terms, from learning more about food.

How to keep a food record

Objectives

. To raise client awareness of what he/she is doing now—as opposed to what he/she *thinks* he/she is doing.
. To motivate clients to keep honest, accurate records.
. To provide a basis for recommendations for change.
. To assess existing dietary problems.

Materials

. Scales, blank recording forms, sample (filled in) record forms and food items which can be used for demonstration.
. Scales, packets of food record sheets and sample instructions.

Procedure

. Explain the purpose and nature of the food record.
. Give each group member copies of the sample and blank record forms.
. Using one group member's recalled breakfast/lunch/etc. demonstrate how to record the meal, where appropriate using the food item available (e.g. bowl, cornflakes, milk, etc.).
. Invite questions. If they're not mentioned, deal with eating out, estimating, leftovers, recipes, alcohol, etc.

Hints for motivating people

- This is a unique opportunity to find out what your diet *really* looks like.
- Everyone else in the room is doing one—remember that when you feel like hurling the scales out of the window.
- The time-honoured computer principle—garbage in, garbage out.
- Provides an opportunity to solve problems with hypoglycaemia and hyperglycaemia, and weight or high blood fats.
- We're not here to judge you. This is a resource for you to use, but it's expensive so use it responsibly (P.S. we won't code badly kept records).
- It's your body and you've only got one—this is a way of finding out how to look after it more lovingly.
- Keeping a food record is like bashing your head against a brick wall—great when you stop! But it's only four days out of your life!
- Provide sample copies of the print-out which they will receive to indicate the kind of feedback (See Appendix 2).
- You can decide not to keep a record—but people who do tend to feel quite left out.
- There is no point carefully following your diet for the days of the record—that won't tell you (or us) anything about what you normally do.

Comments

- Finally before people leave, loaded down with their packets and scales, make sure they have a practice at weighing and recording in front of you.
- After the recording period, food records need to be checked for adequacy—preferably by the person who is to code them, with the client available to answer queries.
- After coding and analysis, each computer print-out needs to be checked by the dietitian for possible errors or inconsistencies. Individual comments can also be included at this stage by the dietitian.

Using the computer print-out feedback

(Time: 30-45 minutes)

Objectives

- Feedback to clients and assessment of their diets.
- Raise awareness of the problems existing therein.
- Start using the results to generate new ways of dealing with those problems.
- Connect eating behaviour with health problems.

Materials

- Individual print-outs for each group member.
- Butcher's paper for posters.

Procedure

Either:

- Hand back print-outs to each person and allow time for reading and studying.

. Ask for general reactions to the results (e.g. surprised, shocked, pleased, etc.).
. Any questions.
. Provided the group agrees, start making a chart of group problems, e.g.
How many people are overweight.
How many have a very unbalanced diet.
How many people are eating too much/too little protein, fat, complex carbohydrate, sugar, alcohol, etc.
. Explore the differences between diabetic and non-diabetic members of the group.
. Discuss dietary beliefs, myths and fallacies revealed in the results.
. Introduce ways of dealing with each problem explaining the possible health risks in leaving things the way they are.
OR
. Prior to handing back print-outs, sort group into smaller groups according to shared problems (e.g. overweight, excess sugar consumption, etc.).
. After these groups have been formed, hand back print-outs and ask them to make a poster of the collective results (as above).
. Ask each group to identify their main problem and pool ideas about how to deal with these.

4.4 Dietary exercises (Time: 30 minutes)

What's in food?

Objectives

. To find out how people are currently classifying food and stimulate thought and discussion about these categories.
. Expose myths about what is in food and correct misinformation.
. Aid in teaching the dietary recommendations by referring to real foods and how they fit in to the diet—which are carbohydrate portions, high calorie, free, etc.

Materials

. A trolley, or box, of food items, of which many are the real thing (e.g. empty packets, cartons, tins, etc.) including oil, margarine, butter, flour, biscuits, pasta, rice, fruit and dried fruit, vegetables, food models of meat and fish, mixed dishes,* low calorie and regular soft drinks and jellies, skim, full fat and sweetened yoghurt, tonic water, alcohol (beer and wine), varieties of special diabetic foods, nuts and peanut butter, etc.
. Six labels on which is written 'carbohydrate (complex)', 'protein', 'fat', 'sugar (refined, simple carbohydrate)', 'alcohol' and 'free'.

Procedure

. Explain to the group that following the dietary recommendations involves accurately assessing what's in food and that this isn't always easy because foods are often mixtures and deceptive.
. Place each label on a separate chair or small table in the middle of the group explaining what each means to you.

*Colour pictures from magazines are useful.

Fig. 4

- Ask for two volunteers to sort the food from the trolleys on to the tables. If the food is a mixture, ask for the main constituent to be used as the important category.
- When they have finished, ask other group members to examine the items on each table and re-sort where they think fit.
- Continue until the group as a whole is satisfied.
- Comment on how they have sorted the items, moving any which have been misclassified, explaining why you are moving them.
- Leave the tables present and visible while moving on to the dietary recommendations so that people can refer back to the categories.

Comments

- This exercise is always a lot of fun and ribald comments about the nature of carrots help!
- Always thank the volunteers when they have finished—they've put their knowledge on the line, and need to be appreciated for that.
- We try to make sure that at least one man volunteers to encourage the idea that men need to be responsible for their own diets.
- This exercise often leads to discussion about food advertising and the misleading promotion of some products as 'healthy'. It can also lead to discussion of people's knowledge (or lack of it) of food.
- Three variations of this exercise are:
  a. For health professionals and paramedical personnel: sort the food into those items which you think diabetic diets allow—in restricted quantities or freely—or don't allow.
  b. For weight reduction groups: sort the food into those items you would avoid on your diet (fattening), those you would eat freely (not fattening) and those you would allow yourself in small quantities.

c. For teenagers: sort the food into 'junk' food and 'O.K.' food.

- If you are using one of the above variations of the exercise, we found that it helps to use the group's own words to provide the categories as opposed to imposing your own, e.g. 'What do you think the principles of a diabetic diet are? What are the recommendations based on?' or 'What's the difference between a diabetic diet and a non-diabetic diet?'
- It's a good idea to be aware of the kinds of foods commonly eaten (and misclassified) by the particular group and include lots of them.
- A final word: people who have diabetes are generally much better at doing this exercise than others.

What's a balanced diet?

Objectives

- Inform the group as to the nature and composition of a balanced diet* in food terms.
- Explore current thoughts, myths and prejudices about what is meant by a balanced diet.
- Plant the idea that everyone, not just diabetics, needs a balanced diet.

Materials

- Two large posters on which are pasted a day's meals in food models. One of them, a very unbalanced day, the other balanced (See Figs 5 and 6 for sample).

Fig. 5

*As recommended by the U.S. Senate Committee on Nutrition and Human Needs and in line with the dietary goals for Australians, i.e. less than 30 per cent fat, and 45 per cent or more complex carbohydrate (see Bibliography—Truswell, 1980).

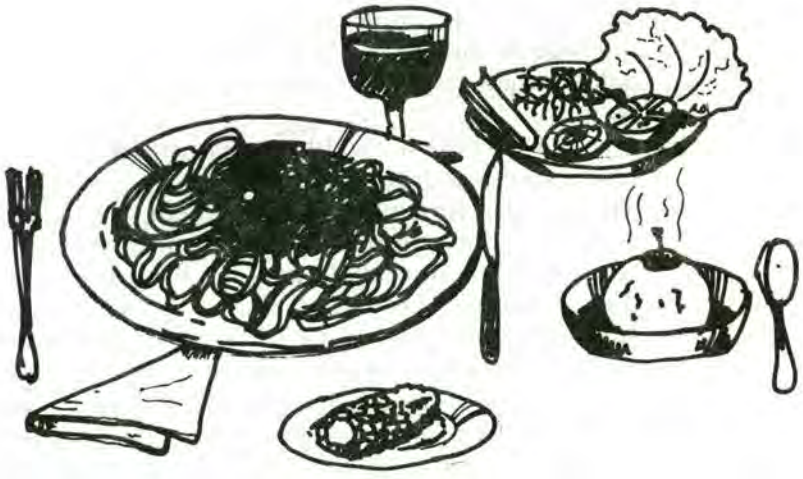


Fig. 6

Procedure

- Each group leader holds up one card and explains what he/she has had to eat that day.
- OR (if only one leader) explain as two different days of your own food intake.
- Ask the group to assess which day's meals are
  a. more fattening
  b. more balanced/'healthy, well-balanced'
  c. which poster represents the day's food intake most like their own.
- At each stage question them as to the rationale for each choice (e.g. 'Well, it contains lots of salad', etc.).
- Emphasise that you mean healthy and well-balanced for *everyone*.
- When discussion has ranged long enough for the group to have presented lots of ideas (often conflicting) about what is meant by a well-balanced diet, explain what is meant from a nutritional standpoint.
- Write the percentage of calories contributed by each nutrient—fat, carbohydrate, alcohol and sugar—for each day's intake.
- Explain the rationale for maintaining a balanced diet and the kinds of problems associated with an unbalanced diet.
- Explore, with the group, their reactions to your information.
- Ask people to discuss how they could begin to balance their diets in real food terms.

Comments

- After we have done this exercise we hand back each group member's individual computer print-out. We use the print-outs (plus summaries of the group's diet problems) to help clients focus on their own dietary balance.
- We keep the posters in view so that people can compare their individual assessment with these models.
- Inevitably, in our experience, most group members will opt for the unbalanced day as more healthy—usually because it contains very little complex carbohydrate.

. The myth that complex carbohydrate, per se, is fattening is one of the biggest hurdles we have to overcome when asking people to balance their diets, so we tend to spend a fair amount of time talking about it.
. People who have a weight problem are particularly anxious about eating more complex carbohydrate.
. The idea that protein is good for you in vast quantities usually goes along with the 'carbohydrate is fattening' myth. It is important to spend time talking about people's fear of what might happen to them if they stop eating all that steak. A few examples of calorie values help in this exercise, particularly how many calories come from the fat found in high protein foods.
. This exercise also works with health professionals or others who are interested in food but have been subjected to inadequate diet information and sold 'fad' diets. It is not uncommon for someone in the group to have tried a 'fad' or unbalanced diet and who, on reflection, will state that they felt unwell or very tired during that period.

Where's the fat in my diet coming from?

Objectives
. Alert people to hidden sources of fat in their diets.
. Give practice in using food composition tables resource material.
. Examine ways to reduce the fat content in each person's diet (while still having tasty, appetising food).

Material
. White board, felt-tipped pens, food composition tables.

Procedure
. Ask each member of the group to identify favourite and or frequently-eaten foods which may be high in fat. Write these on the board.
. Ask each person to look up the food(s) they have chosen in the food composition tables and call out the grams of fat and calorie values of the food. Use average serves or—if eaten in different quantities—the amount they would normally eat.
. Add to the list any foods which:
a. are commonly eaten and have a high fat content
b. provide a clear contrast to those mentioned, e.g. skim milk products, jacket potatoes as opposed to chips.
. Check group for their reactions to the list.
. Ask each member to identify foods they could (easily) cut down on and how.
. Try to keep suggestions practical—e.g. very few people can eat dry bread but they might be able to *halve* the amount of butter or margarine they use.
. In the group, explore ways of cooking and adapting recipes to reduce the amount of fat/meat used.

Comments
. There are usually a few shocks in store for people in this exercise—particularly for would-be, none-too-successful dieters.

. Making the change from high fat to low fat intake is time-consuming. It's O.K. to do it gradually and probably easier on the palate.
. If you've been doing this in your own diet, a few suggestions from your own experience may help—both in terms of what you feel about it and practical tips.
. This is a good time to explore with group members the benefits of cutting down fat in the whole family's diet as well as the possible resistances thereto, and ways of handling these.
. In the D.E.A.P. we usually do this exercise just after we give people back the results of their serum lipids tests (cholesterols and triglycerides). Therefore this information is often much needed and valued.

Sweet tooth or where's the sugar in my diet?

Objectives
. Help identify the amount of refined sugar in different foods.
. Explore ways of cutting down refined sugar in people's diets.
. Identify foods (and the amount thereof) which can be used for insulin reactions and before strenuous exercise.

Materials
. A bag of food models (or actual containers) of refined sugar or honey-containing foods.
. List of the sugar content of given quantities of the above foods.
. Butcher's paper and felt-tipped pens.

Procedure
. Ask the group to reach a consensus on rating the foods in the bag from the most to the least sugar-containing items. Ask them to write this order on the butcher's paper.
. Provide a list of the sugar content of the foods in the bag.
. With the aid of the list ask group members to write the number of teaspoons of sugar in a given quantity of each food.
. Discuss ways in which each member can reduce his/her sugar intake in a practical way.
. Have each person with diabetes identify the foods, and the necessary quantities to consume to treat insulin-reactions and before strenuous exercise.

Comments
. This is often a more important exercise for non-diabetics than diabetics.
. It can be adapted for different groups, e.g. for teenagers the bag may contain a selection of foodstuffs available from the local milk bar or beach café.
. When people have this information they may not choose to avoid sugar altogether but may choose the less sugar-containing foods.
. It is surprising to people how much sugar they consume by having one or two teaspoons in each cup of tea or coffee if they drink seven or eight cups in a day.
. It helps to have cookbooks around which present attractive ways of

making sweets and desserts without sugar. It's even better if you can have some of these dishes around for tasting.

- In the D.E.A.P. programme, we have a cooking session in which everyone rolls up their shirt sleeves, dons aprons and gets into cooking dishes (recipes adapted) which use the dietary principles we are teaching, and we all eat them for lunch next day.

Chinese banquet or eating out

(Or 'I can't go out to eat because I don't know how to follow my diet if I do.')

Objectives

- Expand choices and knowledge about how to follow dietary recommendations in difficult places (such as, in restaurants).
- Help people to develop resources for handling culturally different foods.
- Decrease perceived dietary and social restrictions.

Materials

- Menus from Chinese restaurants.
- Chinese cooking, recipe books; food models.
- Calorie counters/food composition tables/*The Traffic Light Guide to Food*

Procedure

- Form small groups and ask each to solve one of the following problems.

  Fred and Eileen are going to the annual company dinner which is being held at Ah Wong's Palace Chinese Cuisine Extraordinaire. Eileen has just visited the doctor and he has put her on two injections of insulin and four portions for her evening meal. She comes home despondent. 'I can't go, Fred', she wails, 'And now that the doctor has that new blood test he'll know if I don't take my insulin or eat more than I should ... You go, I'll stay home and wash my hair'. Fred looks miserable, 'Maybe we can work out what you can have ...' What do they work out?

  OR

  Josephine and Napoleon (Poly to his friends) are celebrating that it IS tonight, but first they're having a secluded dinner for two at the local Chinese restaurant. Poly is concerned that he doesn't blow all his efforts at weight reduction. He needs three portions and he's worked out that he can have 500 calories for his celebration meal. Work out a menu for them.

  OR

  Make up your own problem, using people's names from the group and appropriate kinds of diet problems they have in their lives.
- If food models are available, ask the groups to present the solution visually as well as verbally.
- After about 15 minutes ask each group to share their solutions and comment on each other's.
- Check whether people think that there are issues still unresolved about eating out. Using the group, explore ways of coping with them.

Comments

- This kind of exercise needs to be done after people have had a reasonable time to understand and practise with basic foods in their everyday diet.
- It can also raise issues such as how to deal with giving oneself an insulin injection while away from home (when, where, etc.), how to become practised at guessing food quantities, whether to let other people know that they have diabetes and handling strenuous physical activity.
- Many people with diabetes restrict themselves unnecessarily in social situations, either because they lack confidence or they are embarrassed about dealing with an unknown situation, or because they lack understanding or knowledge about how to apply the principles of their diet to the different/new foods.
- This is an example of using an imaginary situation in which clients can use new information to experiment safely with new solutions to old problems and gain confidence in mastering them.
- There are obviously endless variations on this theme. Amongst those we use are:
  a. The all-Australian barbecue.
  b. Italian, Lebanese, French (etc.) foods.
  c. Formal dinner parties/cocktail parties/weddings.
  d. Planning a day's meals (e.g. 1200 calories—10 portions).
- This is also a good time to check whether someone actually has a social engagement coming up which they feel might be a problem, and the possible ways they might approach it (including whether or not *they* can give themselves permission *not* to follow their diet and the possible implications of this).

4.5 Practical problems with diabetes

'Guesstimating' portions

Objectives

- To stress the importance of measuring certain foods (i.e. complex carbohydrate) as a means of being able to guess/estimate accurately in other situations.
- To emphasise the difficulty of knowing what is in food simply by 'looking' at it.
- To identify foods for which counting portions is difficult, and to give some practice in doing this.

Materials

- A variety of cooked and uncooked foods, most of which are portion complex carbohydrate foods, e.g. rice, pasta, bread, biscuits, sultanas, nuts, milks, etc.
- A variety of different shaped plates, glasses, bowls and serving dishes.
- Measuring cups and scales.
- *The Traffic Light Guide to Food**/calorie counters/food composition tables.

*A manual for counting carbohydrate portions (see Bibliography).

Procedure

- Split the group into pairs and ask one of each pair to go into another room (or somewhere out of view).
- The partner who is left prepares a variety of meals containing 'n' portions, using the different foods and serving dishes, and measuring and looking up in the Guide the quantities required.
- He/she asks the partner to guess
  a. the quantity of the food, and
  b. the number of portions on the plate.
- Then check how accurate the guesses were.
- The two swap roles and repeat the procedure.

Comments

- Start with simple foods and work up to a more complicated problem.
- Measuring food is probably one of the most difficult parts of the diabetic regimen. This is also a time when people can air feelings about it.
- Emphasise that it's better to be 'good' at guessing than inaccurate or not to estimate at all.
- Many people like to think that a serve is the same as a portion. (One of our clients once ate 12 portions at a meal because he was sure that the rice serve was 'about a cup and that there were three portions'. When he measured the bowl from which he had eaten it held three or four cupfuls.)

APPENDIX 3.3

DIABETES EDUCATION AND ASSESSMENT PROGRAMME

FOOD RECORD SUMMARY AND DIET ASSESSMENT

SUBJECT NUMBER: 588
NAME
DATE OF RECORD: 25,09,81

SECTION 1:WEIGHT DIAGNOSIS

FROM LIFE ASSURANCE TABLES,THE IDEAL WEIGHT FOR A PERSON OF YOUR HEIGHT IS: 60.0 KG
= YOUR ACTUAL WEIGHT IS: 72.7 KG

YOU ARE THEREFORE 121.2% OF YOUR IDEAL WEIGHT

*COMMENTS: FROM THIS ASSESSMENT YOU NEED TO:
REDUCE YOUR WEIGHT/BODY FAT

*CAUTION: BEING OVERWEIGHT INCREASES
*THE DIABETIC'S RISK OF POOR DIABETIC
*CONTROL,AND INCREASES EVERYONE'S RISK
*OF HIGH BLOOD FATS AND HEART DISEASE

SECTION 2:YOUR ACTUAL FOOD INTAKE

THE SUMMARY OF YOUR FOOD INTAKE ON THE DAYS YOU KEPT A RECORD IS AS FOLLOWS:

	YOUR TOTAL CALORIES	ALL YOUR CALORIES COME FROM: PROTEIN (GRAMS)	FAT (GRAMS)	CARBOHYDRATE TOTAL (GRAMS)	= COMPLEX (GRAMS)	+ SUGAR (GRAMS)	ALCOHOL (GRAMS)
DAY 1	1726.	76.4	99.9	133.8	130.5	3.4	0.0
DAY 2	2025.	94.0	118.9	152.7	151.0	1.6	0.0
DAY 3	1534.	54.6	59.3	206.1	200.3	5.8	0.0
DAY 4	1594.	73.2	58.5	165.5	159.3	6.2	19.6
AVERAGE OVER 4 DAYS	1720.	74.6	84.1	164.5	160.3	4.3	4.9

*NOTE: THERE ARE APPROXIMATELY:
- 7 GRAMS PROTEIN IN ONE OUNCE MEAT,CHEESE,FISH OR ONE EGG
- 5 GRAMS FAT IN A TEASPOON OF OIL,BUTTER,OR MARGARINE
- 4 GRAMS SUGAR IN A TEASPOON OF HONEY OR SUGAR
- 15 GRAMS COMPLEX CARBOHYDRATE IN A SLICE OF BREAD OR PIECE OF FRUIT;ETC
- 10 GRAMS ALCOHOL IN ONE DRINK OF BEER,WINE,OR SPIRITS

* COMMENTS: THE BEST GUIDE TO WHETHER YOU ARE EATING THE RIGHT NUMBER OF CALORIES IS YOUR WEIGHT. IF YOU ARE TOO FAT, YOU NEED TO CUT CALORIES; IF YOU ARE MAINTAINING YOUR IDEAL WEIGHT, YOUR CALORIES ARE MOST LIKELY O.K.

*CAUTION: DRINKING TOO MUCH ALCOHOL
*AT ONE GO INCREASES THE DIABETIC'S RISK OF A SEVERE HYPO.
*IT ALSO INCREASES EVERYONE'S RISK OF PUTTING ON WEIGHT,
*DEVELOPING LIVER DISEASE,AND VITAMIN & MINERAL DEFICIENCIES

THERE ARE: 4 CALORIES IN EVERY GRAM OF CARBOHYDRATE, 4 CALORIES IN EVERY GRAM OF PROTEIN,
7 CALORIES IN EVERY GRAM OF ALCOHOL AND 9 CALORIES IN EVERY GRAM OF FAT

*ASSESSMENT: YOUR CALORIES ARE TOO HIGH - IF YOU ARE NOT ALREADY ON A WEIGHT REDUCING DIET
WE SUGGEST THAT YOU REDUCE YOUR CALORIES BY 25%
*THE FOLLOWING RECOMMENDATIONS HAVE BEEN MADE FOR YOU:- DAILY CALORIE INTAKE: 1264. (APPROXIMATELY) CONSISTING OF:-
47. GRAMS PROTEIN, 49. GRAMS FAT, 158. GRAMS COMPLEX CARBOHYDRATE (NOTE: CALORIES FROM ALCOHOL ARE NOT INCLUDED)

SECTION 3: THE BALANCE OF YOUR DIET

WE HAVE TAKEN YOUR AVERAGE FOOD INTAKE AND WORKED OUT THE PERCENTAGE OF YOUR CALORIES COMING FROM EACH NUTRIENT.

FROM PROTEIN SOURCES YOU GOT 17.% OF YOUR CALORIES COMPARED TO A RECOMMENDED 12 - 15 % (FROM PROTEIN) *NOTE: AS RECOMMENDED BY THE U.S. SENATE COMMITTEE ON NUTRITION AND HUMAN NEEDS

FROM FAT IN YOUR FOOD, YOU GOT 44.% OF YOUR CALORIES COMPARED TO A RECOMMENDED 30 % (FROM FAT)

CARBOHYDRATE FOODS GAVE YOU 38.% OF YOUR CALORIES COMPARED TO A RECOMMENDED 45 - 60 % (FROM COMPLEX CARBOHYDRATE)
THIS INCLUDED -COMPLEX 37.%
-SUGAR 1.% - CALORIES FROM SUGAR SHOULD NOT EXCEED 5 % OF TOTAL CALORIES

ALCOHOL CONSUMED PROVIDED 2.% OF YOUR CALORIES
(IT IS SUGGESTED THAT CALORIES FROM ALCOHOL NOT EXCEED 5 % OF TOTAL CALORIES)

*COMMENTS: BALANCE SCORE = 4
* THIS AVERAGE INTAKE IS VERY UNBALANCED.
*
* NOTE: EATING TOO MUCH SUGAR INCREASES YOUR CHANCES OF GETTING FAT,
* ACQUIRING FALSE TEETH, AND POOR NUTRITIONAL STATUS

*CAUTION: HAVING AN UNBALANCED DIET PLACES *
*YOU AT RISK FOR DEVELOPING HIGH BLOOD FATS, *
*VITAMIN & MINERAL DEFICIENCIES, LOW ENERGY, *
*AND GENERAL ILL HEALTH. *

*RECOMMENDATIONS: TRY TO ACHIEVE A MORE BALANCED DIET BY FOLLOWING THE RECOMMENDATIONS MADE IN SECTION 2. *

SECTION 4: VITAMINS AND MINERALS

WE HAVE ANALYSED YOUR AVERAGE FOOD INTAKE FOR THE FOLLOWING VITAMINS AND MINERALS:-
CALCIUM, IRON, VITAMIN A, THIAMINE, RIBOFLAVIN, NIACIN, AND VITAMIN C.
WE HAVE COMPARED YOUR INTAKE WITH THE "RECOMMENDED DIETARY ALLOWANCES" FOR AUSTRALIANS.

*COMMENTS: YOUR FOOD INTAKE ON THESE DAYS SHOWED ADEQUATE AMOUNTS OF THESE NUTRIENTS. *

*NOTE: ADJUSTING YOUR CALORIE RECOMMENDATIONS:

IF THE RECOMMENDATIONS MADE FROM YOUR FOOD RECORD DO NOT WORK AFTER CONSCIENTIOUSLY (1) FOLLOWING THEM -
THAT IS, YOU FAIL TO MAINTAIN OR MOVE TOWARDS YOUR WEIGHT GOAL - USE THIS RULE TO ADJUST THEM:
- FOR EVERY 100 CALORIES (UP OR DOWN) ADJUST BY:
3 GRAMS PROTEIN + 3 GRAMS FAT + 15 GRAMS CARBOHYDRATE
- AND CHECK WHAT YOU ARE DOING WITH YOUR DIETITIAN

SECTION 5: CARBOHYDRATE SPACING AND VARIATION

WE HAVE ANALYSED THE CARBOHYDRATE CONTENT OF EACH MEAL FOR THE AMOUNT (IN GRAMS) OF COMPLEX CARBOHYDRATE AND REFINED SUGAR OR HONEY IT CONTAINED. WE HAVE ALSO WORKED OUT THE PORTIONS IN EACH MEAL - A 'PORTION' IS 15 GRAMS OF COMPLEX CARBOHYDRATE.
NOTE: THERE IS OFTEN SOME SUGAR IN PROCESSED FOODS - EVEN THOSE THAT DONT TASTE PARTICULARLY SWEET.

DAY		BREAKFAST	M.T.	LUNCH	A.T.	DINNER	SUPPER	OTHER	TOTAL
1	TOTAL CARBOHYDRATE (GRAMS)	48.3	0.0	20.6	0.0	64.9	0.0	0.0	133.8
	SUGAR CONTENT (GRAMS)	.3	0.0	0.0	0.0	3.1	0.0	0.0	3.4
	COMPLEX CARBOHYDRATE (GRAMS)	48.0	0.0	20.6	0.0	61.8	0.0	0.0	130.5
	*PORTIONS	3.	0.	1.	0.	4.	0.	0.	9. *
2	TOTAL CARBOHYDRATE (GRAMS)	54.3	0.0	40.2	0.0	51.8	6.3	0.0	152.7
	SUGAR CONTENT (GRAMS)	.3	0.0	0.0	0.0	0.0	1.3	0.0	1.6
	COMPLEX CARBOHYDRATE (GRAMS)	54.0	0.0	40.2	0.0	51.8	5.0	0.0	151.0
	*PORTIONS	4.	0.	3.	0.	3.	0.	0.	10. *
3	TOTAL CARBOHYDRATE (GRAMS)	70.3	26.6	51.4	0.0	57.9	0.0	0.0	206.1
	SUGAR CONTENT (GRAMS)	.4	0.0	5.4	0.0	0.0	0.0	0.0	5.8
	COMPLEX CARBOHYDRATE (GRAMS)	69.8	26.6	46.0	0.0	57.9	0.0	0.0	200.3
	*PORTIONS	5.	2.	3.	0.	4.	0.	0.	13. *
4	TOTAL CARBOHYDRATE (GRAMS)	69.1	12.5	30.0	0.0	53.9	0.0	0.0	165.5
	SUGAR CONTENT (GRAMS)	.3	2.9	0.0	0.0	3.1	0.0	0.0	6.2
	COMPLEX CARBOHYDRATE (GRAMS)	68.9	9.6	30.0	0.0	50.9	0.0	0.0	159.3
	*PORTIONS	5.	1.	2.	0.	3.	0.	0.	11. *

IF YOU WISH TO FOLLOW THE SUGGESTIONS MADE IN SECTION 2 - WE RECOMMEND THE FOLLOWING PORTION PATTERN FOR YOU:

*SUGGESTED PORTIONS	3.	1.	3.2	1.	3.	1.	11. *

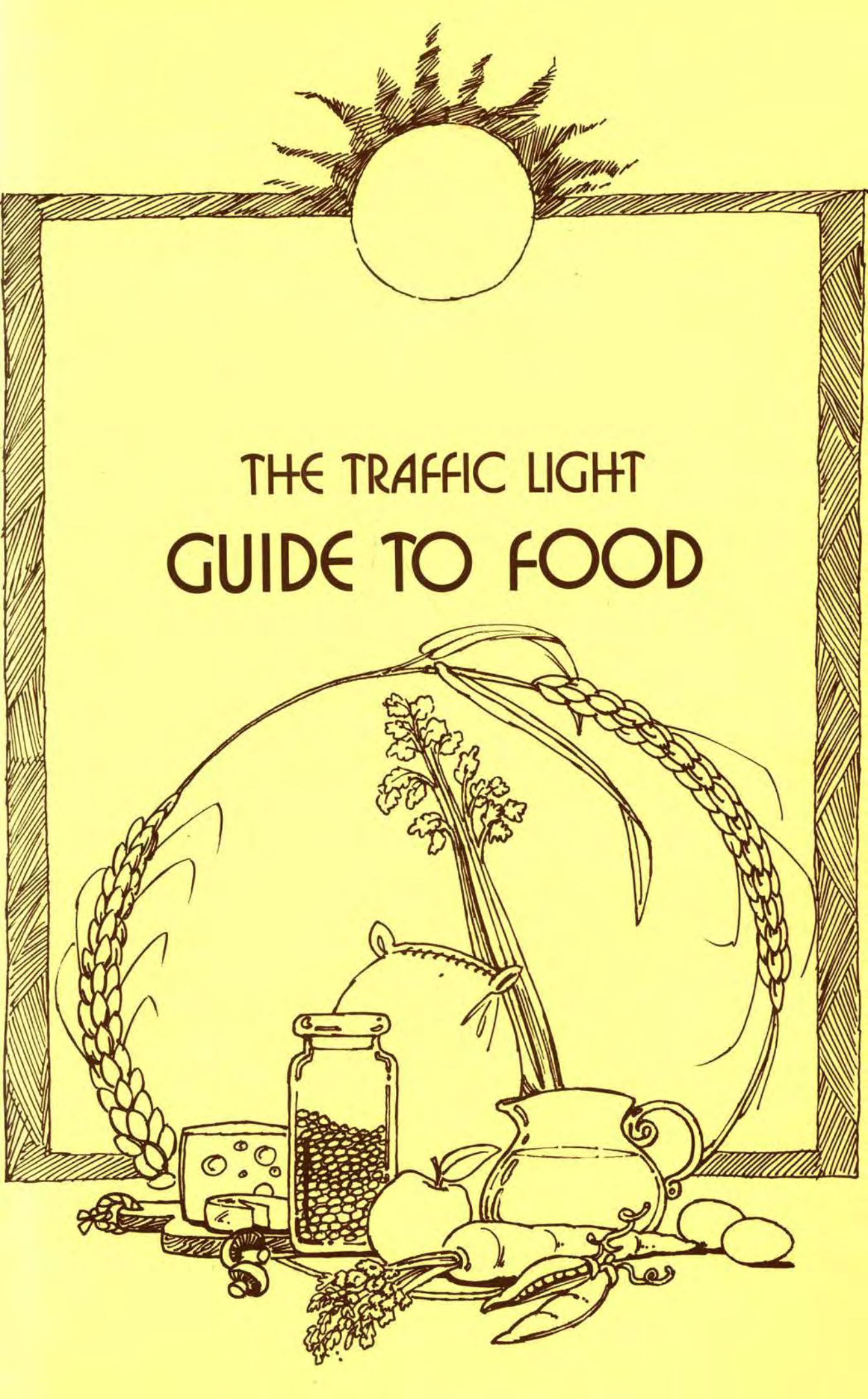
*COMMENTS: YOU MISSED EATING COMPLEX CARBOHYDRATE IN 9 MEALS ON THESE DAYS
*(SPACING) YOUR PORTIONS WERE SIGNIFICANTLY DIFFERENT FROM THE RECOMMENDED ON :-
* 2 OUT OF 4 MORNING PERIODS (BREAKFAST & M.T.)
* 2 OUT OF 4 AFTERNOON PERIODS (LUNCH & A.T.)
* 0 OUT OF 4 EVENING PERIODS (DINNER & SUPPER)
*(VARIATION) - THE VARIATION IN YOUR PORTIONS FROM DAY TO DAY WAS:-RATHER HIGH

* CAUTION! MISSING CARBOHYDRATE AT MEALS AND SNACKS PLACES YOU AT RISK OF HYPOS.
* A LARGE VARIATION IN YOUR CARBOHYDRATE INTAKE MEANS YOU ARE MORE LIKELY TO HAVE HIGH - AND - LOW BLOOD SUGARS.

*RECOMMENDATIONS:-1.TRY NOT TO MISS OUT PORTION FOODS AT ANY MEAL
* 2.TRY TO EAT AS CLOSE TO THE RECOMMENDED PORTIONS AS POSSIBLE
* 3.TRY TO KEEP YOUR PORTIONS SIMILAR EACH DAY UNLESS YOU NEED MORE FOR STRENUOUS EXERCISE

THANK YOU FOR KEEPING THIS RECORD.WE HOPE THESE RESULTS ARE INTERESTING AND USEFUL TO YOU.

THE TRAFFIC LIGHT GUIDE TO FOOD



The **Traffic Light Guide** to Food has been developed by the nutritional staff employed by the Diabetes Education and Assessment Programme, a community education programme for persons with diabetes and their families.

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Copies of this booklet "The Traffic Light Guide to Food" can be obtained at a nominal cost from:

The **Diabetes Education and Assessment Programme**
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St. Leonards 2065 'Phone 43 3476
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YOUR TRAFFIC LIGHT GUIDE TO FOOD

CONTENTS

TRAFFIC LIGHT GUIDE INDEX

INDEX (Cont.)

INDEX (Cont.)

ABOUT THE TRAFFIC LIGHT GUIDE . . .

The Traffic Light Guide . . .

- **is a layman's** guide to reckoning the **carbohydrate** in food.
- **is not a complete** guide to what's in food.
  for further information about . . .

  calories, protein, fat and alcohol see **Simplified Food Composition Tables.**

  easy calculation of "portions" in recipes — see Page 37.

  "Portions" in brands of processed food see **Portions in Commercial Products.**
- **is not a diet in itself.** Does not tell you how many carbohydrate portions (Amber Light Foods) or how much protein and fat (Green Light Foods) to eat.
- is intended to be used with individualised "portion" recommendations **for you** from a dietitian.
- **is not a list** of **food** you should eat **every day** (but **is** a list of wide a variety of carbohydrate **substitutions** so that you can **vary** the **food** you eat **without varying the carbohydrate).**

WHAT'S A PORTION DIET? . . . *(and why?)*

- A portion is a **food exchange** that contains 15 g of "OK" carbohydrate.
- Portions refer only to the carbohydrate foods in the **Amber Light Section** — vegetables, grains, pulses, nuts, fruit, milk and products derived from them containing only a small percentage of added sugar or honey.
- Portions do **NOT** refer to **serves of food,** e.g. meat, cheese or fat in in **Green Light Section** or foods containing a high percentage of added sugar or honey such as chocolates or sweets in the **Red Light Section.**
- **"Portion" diets differ from "calorie" diets:**
  A "calorie" diet is one in which you measure or weigh **all** you food.
  A "portion" diet is one in which you only measure and space the "OK" (Amber Light) carbohydrate portions and learn to estimate and limit other foods so that you can achieve or maintain a desirable weight.
- Portion diets are **easy to use** because all carbohydrate portions are **interchangeable,** it is only a matter of accurate measuring or estimating these portions and following your recommended portion outline.
- We recommend an **individually tailored** "portion" diet for diabetics because it helps to solve some of the common problems that diabetics have with their **diets** and **health:**

  Common Diet Problems:
  Unbalanced: too much protein, fat, alcohol and sugar and too little carbohydrate (of the complex kind).
  Very irregular and erratic carbohydrate intakes.
  Too many calories/joules — but hungry all the time.

  Common Health Problems:
  Frequent "hypos" (low blood glucose).
  High blood glucose.
  High blood fats (cholesterol and triglycerides).
  Overweight.

MEASURE OR WEIGH YOUR FOOD

Level metric spoon and cup measures are used throughout the Traffic Light Guide to Food.

We have also given the mass (weights) of portion foods. We suggest that you **measure** foods instead of weighing them, as this is usually more convenient. The weights are given when metric cup and spoon measures are not appropriate and/or to enable you to calculate portions in your favourite recipes.

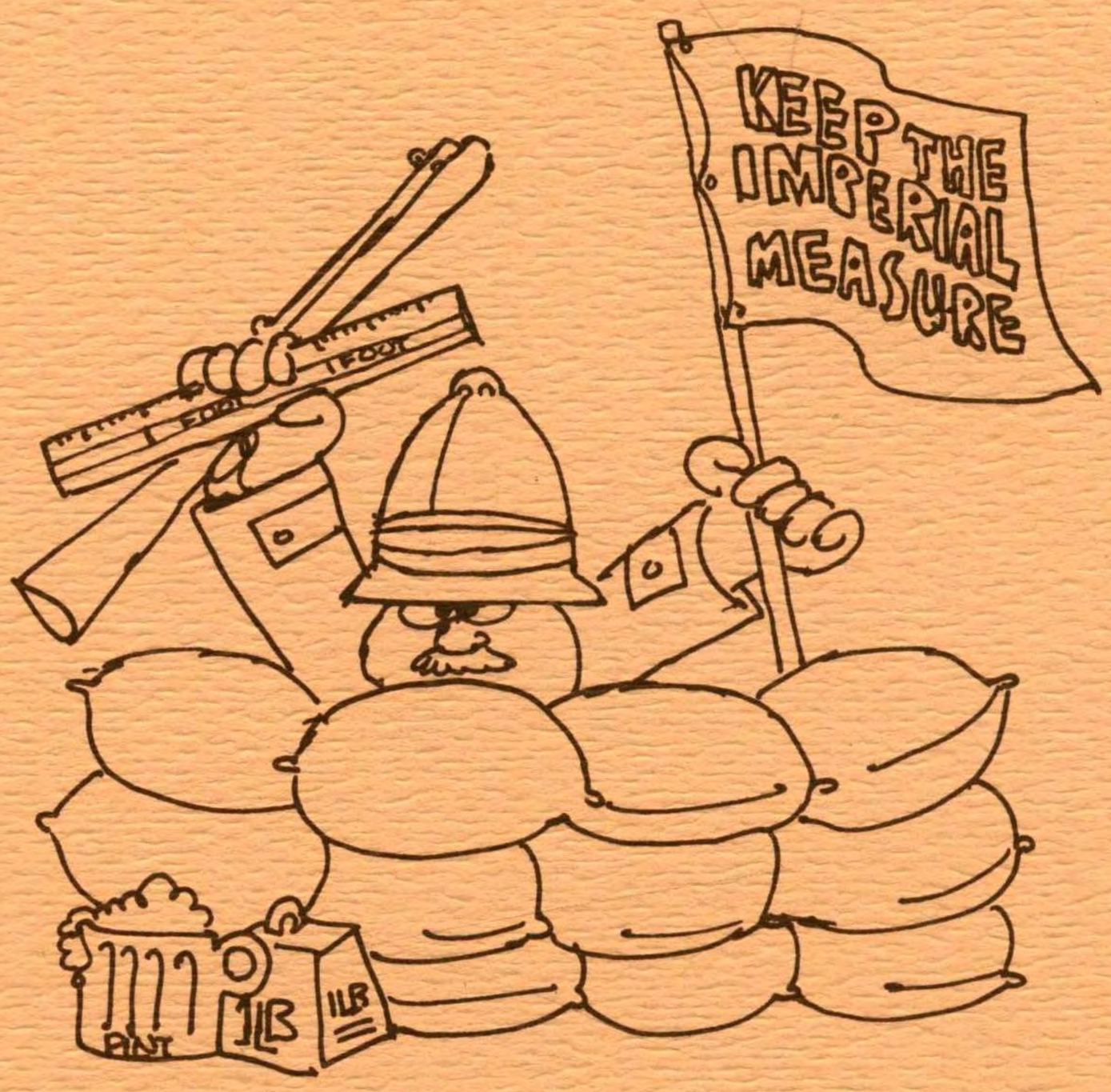
Note: The same **volume** of different foods **weigh** different amounts. The fluid ML or ounce guide on metric jugs can be used to measure the **volume** of foods but cannot be used to estimate the **weights** of foods. **Don't confuse the two!**

Example:

*Volume the same (1 cup/or 250 ml/ or 8 **fluid** ounces)*	=	*Different Weights*
1 cup dry rice	=	220 grams or 7 ounces
1 cup cooked rice	=	180 grams or 6 ounces
1 cup milk	=	250 grams or 8 ounces
1 cup whipped cream	=	119 grams or 4 ounces
1 cup cornflakes	=	25 grams or ¾ ounce

METRIC MEASURE

Liquid Metric Measure	Metric Spoon Measure	Metric Cup Measure
5 ML	1 teaspoon	
20 ML	4 teaspoons or 1 tablespoon	
60 ML	3 tablespoons	¼ cup
85 ML	4 tablespoons	⅓ cup
125 ML	6 tablespoons	½ cup
170 ML	9 tablespoons	¾ cup
250 ML	12 tablespoons	1 cup



THINKING IN METRIC . . .

Old System Imperial (British) System		Present System International System of Units (Metric System)	
Weight	in pounds (lb) and ounces (oz)	Mass	in kilograms (kg) and grams (g)
Length	in inches ('')	Length	in centimetres (cm).
Volume	in pints and ounces (oz)	Volume	in litres (L) and millilitres (ML)
(Food) Energy	in kilo calories (calories)	(Food) Energy	in kilo joules (joules)

Weight Conversion

Imperial Measure		Approximate Metric Measure
½ oz		15 g
1 oz		30 g
2 oz		60 g
3 oz		90 g
4 oz		125 g
8 oz		250 g
16 oz (1 lb)		500 g (½ kg)
2.2 lb	=	1 kg

Length Conversion

Imperial Measure	Approximate Metric Measure
¼''	5 mm
½''	1 cm (10 mm)
1''	2.5 cm
8''	20 cm
10''	25 cm

Liquid Volume Conversion

Imperial Measure	Metric Measure
1fluid oz	30 ML
5 fluid oz	150 ML
8 fluid oz	250 ML
20 fluid oz (1 pint)	600 ML

Energy Conversion

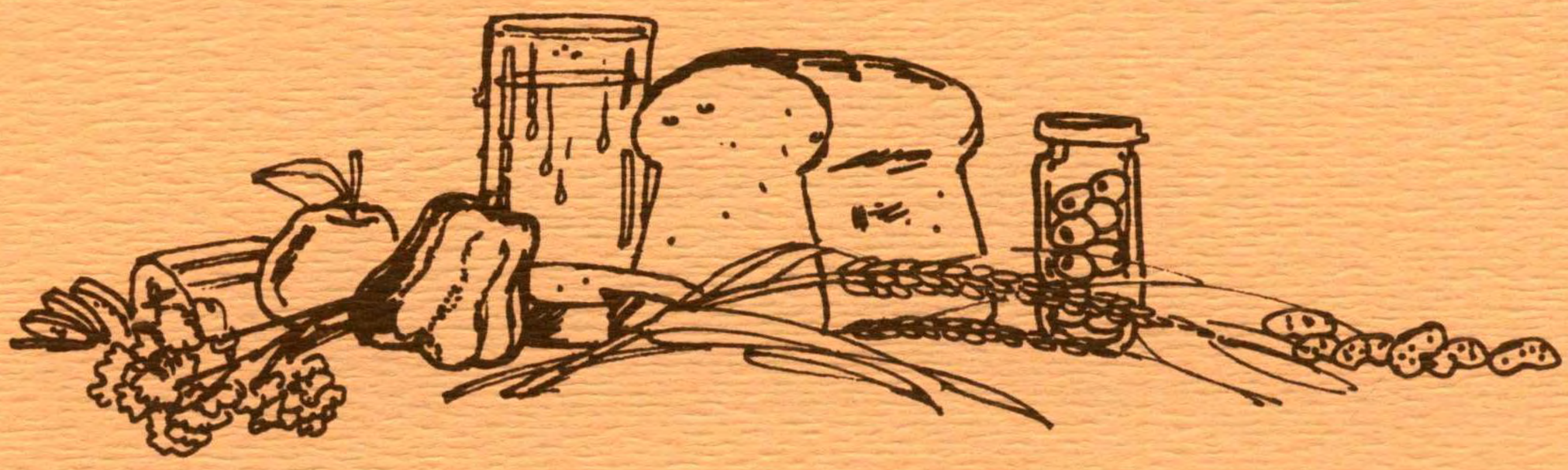
1 calorie	Approx. 4.2 joules

Temperature Conversion

Thermostat Setting °F	Thermostat Setting °C
150	70
200	100
250	120
300	150
350	180
400	200
450	230
500	260

To convert Fahrenheit to Centigrade: subtract 32, multiply by 5, divide by 9
To convert Centigrade to Fahrenheit: multiply by 9, divide by 5, add 32

NOTES



RED LIGHT FOODS
(not recommended)

These foods contain a significant amount of sugar or honey and if eaten may affect your blood sugar or weight! Different amounts of these foods affect diabetics in different ways, so it is best to avoid them except when treating a 'hypo' or before strenuous exercise.

Note: Some of these foods are not recommended for treating 'hypos' or before exercise, so see Special Section — Pages 27 & 28 for exact recommendations.

ALCOHOL in excessive amounts – see Page 32.

BISCUITS, CAKES AND PASTRIES
- Biscuits, sweet or cream
- Cream buns
- Doughnuts, sprinkled with sugar iced or filled with jam
- Pastry, sweetened
- Pies, sweet

CEREALS
- Cereals, sugar coated
- Commercial muesli

DESSERTS
- Cream substitutes
- Desserts, sweet, e.g. custard, rice puddings
- Instant puddings
- Jelly, sweetened

CONDIMENTS
- Chutney
- Jam
- Marmalade
- Pickles, sweet
- Salad dressings, sweetened
- Mayonnaise

DRINKS
- Cider, sweetened, non alcholic
- Cordials, sweetened
- Fruit juice drinks
- Soft drinks with sugar
- Tonic water

FRUITS
- Candied fruit peel
- Glace fruit
- Juice, sweetened or nectar
- Tinned or preserved in syrup

MEDICATIONS, sweetened
(See Sick Days Pamphlet)

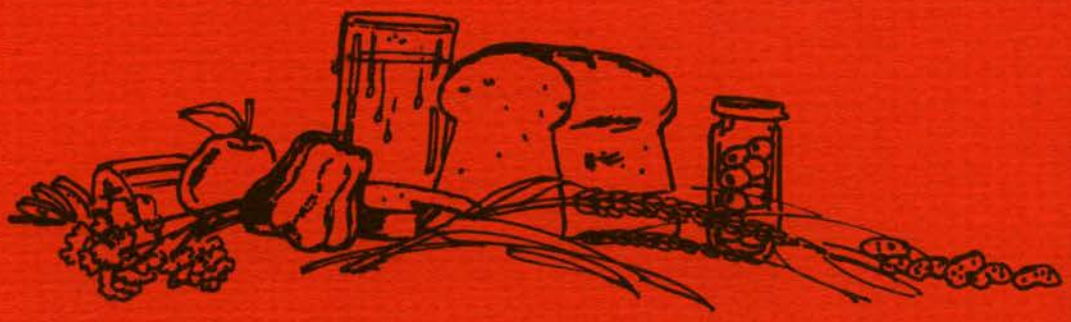
MILK PRODUCTS
- Sweetened condensed milk, full cream or skim
- Iceblocks, paddlepops, milk ices
- Ice creams, fancy or chocolate coated
- Fruit yoghurt (full cream, non fat, or frozen)

SPECIAL DIET FOODS
See Page 31.

SUGARS
- Glucodin
- Glucose
- Honey
- Malt
- Maple syrup
- Molasses
- Sugar, brown, white or raw
- Treacle

SWEETS AND LOLLIES
- Candy
- Chocolate
- Halva
- Health Food bars

NOTES . . .



AMBER LIGHT PORTION FOODS

(count, measure and space)

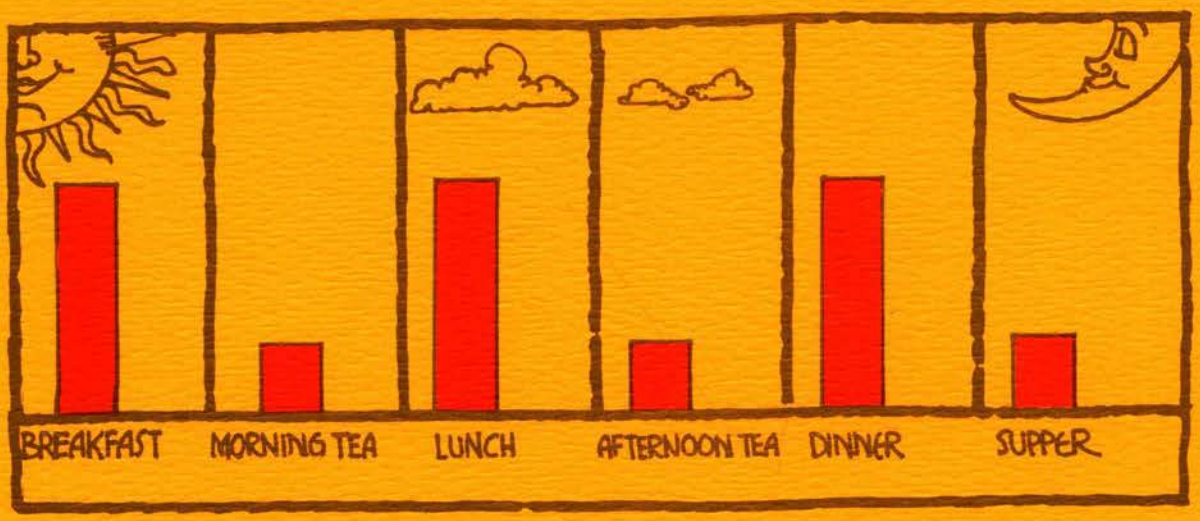
AMBER LIGHT FOODS
"OK" CARBOHYDRATE "PORTION" FOODS

- Choose your recommended number of "portions" of complex carbohydrate (the O.K. kind) from the Amber Light foods listed below at each meal and snack.

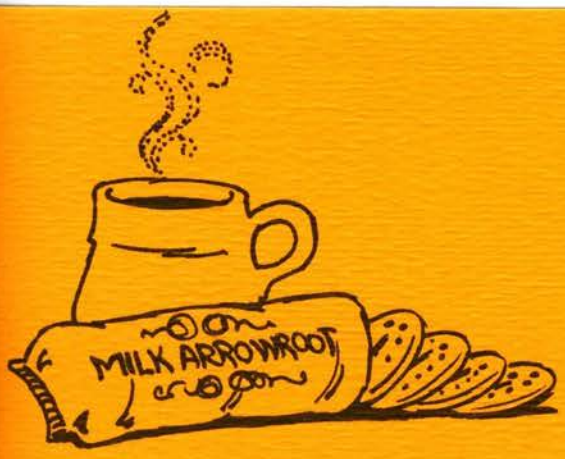
Biscuits	Milk and yoghurt
Breakfast cereals	Pulses, dried beans, and peas
Bread	Seeds and nuts
Flour, grains, pasta, rice	Take away, dining out and snack foods
Fruits, fresh	Vegetables
fruit juices	— starchy
dried fruit	— low carbohydrate
stewed, canned fruit	
unsweetened	

It is important to eat your recommended number of portions for each meal and space your portions evenly over the day to help keep your blood sugars normal.
My recommended portions are . . .

B'fast _____ **M.T.** _____ **Lunch** _____ **A.T.** _____ **Dinner** _____ **Supper** _____ **Total Day** _____



- Portion values have been calculated from the Australian Food Tables and Food Manufacturers Information. Values of a few foods were taken from the American Food Tables.
- Remember . . . one "portion" is a food exchange that contains 15 g of "OK" carbohydrate.
- Remember . . . "Portion" foods are equal in carbohydrate but not in food energy.
- For weight reducers, we have starred (*) the high fat and high energy foods so that you can limit or avoid these when selecting your portions — for exact joule/calorie counts — see Simplified Food Composition Tables. Also see Page 34 for suggestions.
- Caution: **Measuring** and/or **accurate estimating** and looking up the Amber Light list are very important in counting your portions.
- A portion diet can be used by persons without diabetes as well, to lose or maintain weight on a balanced diet. See a dietitian for individualised portion recommendations.
- **Weight Reducers** please note:
  Portion foods are **equal in carbohydrate,** but **not all are equal in food energy** (joules/calories).
  For example, 1 portion of potatoes, rice bread or fruit all contain about 250 joules (60 calories), but 1 portion of peanuts contain about 2,000 joules (500 calories), and a portion of full cream milk contains about 1,000 joules (240 calories).
  For **weight reducers** we have starred (*) the high fat and high energy foods so that you can limit or avoid these when selecting your portions — for exact joule/calorie counts see **Simplified Food Composition Tables.** Also see Page 34 for suggestions.



BISCUITS

	This much is equal to one (1) portion Mass/Weight	 Number of biscuits
*Cornish Wafer, *Golden Puff Milk Arrowroot, Milk Coffee, Oatcake Cookie, Ryvita, Sao	20 g	2
Morning Coffee, P.S. Cracker, Shredded Wheatmeal, Vitaweet	15 g	3
*Krispy Wheat, *Sesame Wheat Coffee 'n Tea, Thin Captain	15 g	4

	Eat this much to equal half (½) a portion Mass/Weight	 Number of Biscuits
*Cheddars, Kavli, *Jatz, Premium, *Plaza, *Mealmates, Salada, Wheat Toasts (each square)	10 g	3
*Chicken in a Bisket, *Beef Thins, *Crispy Bacon, *BBQ Shapes, *Pizza Snacks	20 g	5-6

For a complete listing, see portions in **COMMERCIAL PRODUCTS BOOKLET**

*Starred biscuits are high in fat and energy (joules/calories) so limit these when reducing weight.

BREAKFAST CEREALS

	This much is equal to one (1) portion Mass/Weight	 Metric measure
Commercial packaged cereals such as — Cornflakes, Rice Bubbles, Bran Flakes, Puffed Wheat, Special K	20 g	¾ Cup
Farina (Farax), dry	20 g	1½ Tbsp.
cooked	160 g	⅔ Cup
Porridge oats, oatmeal, dry	20 g	¼ Cup
cooked (1 part oats to 4 parts water)	125 g	½ Cup
Processed Bran (All Bran), Branbuds	20 g	½ Cup
Unprocessed Bran (see "Green Light" list)		
Semolina, dry	20 g	1½ Tbsp.
Shredded Wheat	20 g	1 Biscuit
Weetbix, Vita-brits	25 g	1½ Biscuits
Wheatgerm	30 g	⅓ Cup

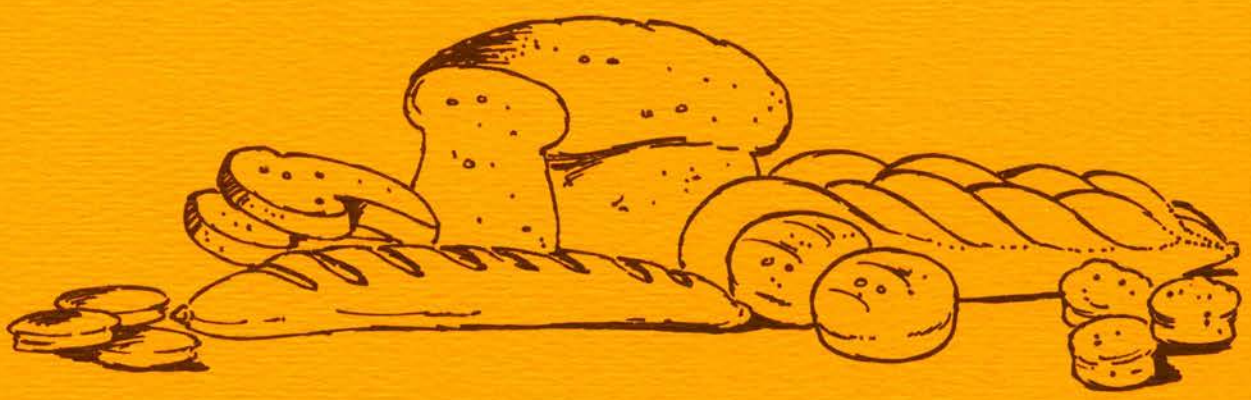
+ **SEE COMMERCIAL PRODUCTS BOOKLET**

BREAD

	Mass/Weight	Description	Portions
BREAD, white, brown wholemeal, multigrain, pumpernickel, rye, bran	30 g	1 slice	1
+protein increased (including protein increased bran breads)	20 g	1½ slices	1
fruit loaf, raisin bread	25 g	1 slice	1
BREADCRUMBS, soft	35g	¾ cup .	1
dried	15 g	1½ Tbsp.	1
dried seasoned stuffing mix	20 g	2 Tbsp.	1
BREAD ROLLS hot dog, hamburger horseshoe, salad	70 g	1 roll, 7.5 cm (3'')	2
small light dinner roll	30 g	1 roll	1
+starch reduced	35 g	6 small rolls	1
*CHAPATIS, (Indian flatbread)		1 of 13.5 cm (5½'') diam.	2
CORNBREAD		5 cm (2'') square	1
CRUMPET	110g	2 crumpets	2½
*DOUGHNUT, yeast leavened, without sugar, icing or jam	45 g	1	1
FRENCH BREAD STICK/ *GARLIC BREAD	30 g	2 slices 1.5 cm (½'') thick	1
LEBANESE FLATBREAD	100 g	1 flatbread 20 cm (8½'') diam.	4
MATZOH, Jewish bread	45 g	20 cm (7'') square	3
MUFFIN, English or bran	75 g	1 muffin	2
fruit	75 g	1 muffin	2½
PANCAKE, *Flapjack (American style)		1 thick 15 cm (6'') diam. 1.25 cm (½'') thick	1½
*Crepe (French style)			
*PAPPADAMS, (Indian Fried Bread)		2 thin 20 cm (6'') diam.	1½
large, uncooked		1 of 13.5 cm (5¼'') diam.	1
small,		4 of 9 cm (3½'') diam.	1
*PIKELET	45 g	2 medium	1
ROTIS (type of flatbread)	50 g	1 rotis 18 cm (7'') diam.	2
*SCONE, plain, pumpkin, cheese, herb		1 medium	1
fruit		1 small	1
*WAFFLE	50 g	1 of 14 cm (5'') diam.	1

+ Because diabetics often eat **too little** carbohydrate, we do not suggest using protein increased (therefore starch reduced) products.

* Starred foods are high in fat and energy (joules/calories) so limit these when reducing weight.



FLOUR, GRAINS, PASTA, RICE

	This much is equal to one (1) portion Mass/Weight	Metric Measure
ARROWROOT	20 g	1½ Tbsp.
BARLEY, pearl	20 g	1½ Tbsp.
BULGUR, (cracked wheat) dry	20 g	1½ Tbsp.
soaked, boiled	60 g	⅓ Cup
FLOUR, Buckwheat	20 g	1½ Tbsp.
Carob (St. John's bread)	20 g	1½ Tbsp.
Cornflour	15 g	1½ Tbsp.
Cornmeal (Polenta) (white or yellow)	15 g	2 Tbsp.
Gluten	60 g	½ Cup
Soy flour/grits, full fat	60 g	½ Cup
defatted	45 g	⅓ Cup
Rice flour	15 g	1½ Tbsp.
Rye flour	20 g	¼ Cup
White or wholemeal flour (wheat)	20 g	2 Tbsp.
Wheat germ	30 g	⅓ Cup
Kasha (Buckwheat groats)		⅓ Cup
OATMEAL, Rolled Oats, raw or processed dry	20 g	¼ Cup
PASTA, any type, dry (e.g. spaghetti, noodles, white or wholemeal, marcaroni, vegaroni, soyaroni	20 g	1½ Tbsp.
Pasta, any type, cooked to soft stage	70 g	½ Cup
Pasta, any type, cooked to firm stage	45 g	⅓ Cup
Pasta, any type, tinned in sauce	110 g	½ Cup
Cannelloni filling tubes, dry	20 g	2 tubes 7 cm (3'') long
*PASTRY, mix, dry	30 g	2 Tbsp.
case, baked, unsweetened	35 g	1/5th of 8'' diameter
Filo		1 sheet 15x20 cm (6''x8'')
READY MIX GRAVY POWDER	25 g	1½ Tbsp. (makes 1 cup)
RICE, brown/white, converted dry	20 g	1½ Tbsp.
loosely packed, cooked, hot	65 g	⅓ Cup
cold	70 g	½ Cup
SAGO, dry	20 g	2 Tbsp.
SEMOLINA, dry	20 g	2 Tbsp.
TAPIOCA, dry	15 g	1 Tbsp.

Note: Here is a quick ready reckoner for thickened sauce and gravy:

Count *meat gravy, *white sauce,
sauces on Chinese food
or thickened stews or casseroles ½ cup = ½ portion

*Starred foods are high in fat and energy (joules/calories) so limit these when reducing weight.

FRESH FRUITS

	This much is equal to one (1) portion			
	Wt. (with peel, seeds, etc)		Edible Wt.	
	Description	Mass/Weight (in grams)	Metric Measure	Mass Weight
APPLE, fresh	1 med., 7 cm (3'') diam.	125-135 g		110 g
APRICOTS, fresh	4 med., 3.5 cm (1½'') diam.	125-150 g	1 cup	135 g
*AVOCADO	1 whole, 8 x 10 cm (3¼'' x 4'')	295-305 g		240 g
BANANA	1 small, 15.5 cm (6'')	90-100 g		65 g
BLACKBERRIES			¾ cup	120 g
CHERRIES	15 medium	110-120 g	¾ cup	100 g
CHINESE GOOSEBERRIES (Kiwi fruit)	3 medium			
CUMQUATS, fresh	5 medium	105-110 g		100 g
CUSTARD APPLE	½ small	90-110 g		60 g
FIGS, fresh	2 small, 4 cm (1½'') diam.			80 g
†FRUIT SALAD, unsweetened			¾ cup	165 g
GOOSEBERRIES			1 cup	140 g
GRAPES	20 medium	100 g	¾ cup	90 g
GRAPEFRUIT	½ large 15.5 cm (6'')	320-330 g		160 g
GUAVA	1 medium	115-125 g		100 g
HONEYDEW MELON	½ small, 12.5 cm (5'') diam.	280-290 g		185 g
LIME	2 medium, 5 cm (2'') diam.	205-210 g		160 g
	2 small, 4 cm (1½'') diam.	165-170 g		125 g
LOGANBERRIES			¾ cup	105 g
LOQUATS	10	190-210 g		160 g
LYCHEES	10	210-220 g		150 g
MANDARINES	2 medium	145-155 g		130 g
MANGO	⅓ average	300-325 g	½ cup	90 g
MULBERRIES			¾ cup	100 g
NECTARINE	2 med., 4.5 cm (2'') diam.	100-110 g		90 g
ORANGE	1 med., 7.5 cm (3'') diam.	165-175 g		135 g
PASSIONFRUIT	2 med., 4.5 cm (2'') diam.	150-155 g	⅓ cup	75 g
PAW PAW (Papaya)	½ med., 9 cm (3½'') diam.	200-210 g	¾ cup	150 g
PEACHES, fresh	1 large 7.5 cm (3'') diam.	155-165 g	½ cup	140 g
PEAR, fresh	1 small, 5 cm (2'') diam.	120-130 g	¾ cup	100 g
PERSIMMONS	1 medium	95-105 g		80 g
PINEAPPLE, fresh	1 slice 9 cm (3½'') diam. 1.5 cm (¾'') thick		½ cup	110 g
PLUMS, fresh	3-4 small, 4 cm (1½'') diam.	105-115 g		100 g
POMEGRANATE	½ of 8.5 cm (3¼'') diam.	265-275 g		140 g
QUINCE, fresh			1 cup	100 g
RASPBERRIES			¾ cup	110 g

FRESH FRUITS

	This much is equal to one (1) portion			
	Fruit as Purchased	Fruit Edible Portion		
	Description	Mass/Weight (in grams)	Metric Measure	Mass Weight
‡ROCKMELON, whole	1 small, 15 cm (6'') diam.	500-510 g	1¾ cups	265 g
‡STRAWBERRIES	30 medium	190-200 g	1 cup	175 g
‡WATERMELON	½ of 1 slice, 2.5 cm (1'') thick	460-480 g	1¼ cups	230 g

*Avocados are high in fat and energy (joules/calories) so limit when reducing weight.

‡A small serve (less than ¼ portion) need not be counted in portion calculations.

DRIED FRUIT

	This much is equal to one (1) portion	
	Mass Weight of Edible Portion	Description
APPLE, dried	20 g	7 pieces
APRICOTS, dried	20 g	7 small halves (or 4 large)
BANANAS, dried	20 g	2 cm (¾'') diam. 1 small
CURRANTS	20 g	2 Tbsp.
DATES	20 g	3-4
FIGS, dried	20 g	1½
PEACHES, dried	20 g	3 halves
PEARS, dried	20 g	2 small halves
PRUNES	20 g	3-4 medium
RAISINS	20 g	1½ Tbsp. approx. 20 raisins
SULTANAS	20 g	1½ Tbsp. approx. 60 sultanas

FRUIT JUICES

	This much is equal to one (1) Portion Volume	Metric measure
APPLE JUICE, fresh or canned, unsweetened	125 ML	½ Cup
GRAPE JUICE, unsweetened	110 ML	½ Cup
GRAPEFRUIT JUICE, fresh or canned unsweetened	160 ML	⅔ Cup
LEMON, LIME JUICE, fresh	180 ML	¾ Cup
ORANGE JUICE, fresh (juice of one large orange or two small) or canned unsweetened	125 ML	½ Cup
PINEAPPLE JUICE, unsweetened	125 ML	½ Cup

STEWED AND CANNED FRUITS, UNSWEETENED

Description	This much is equal to one (1) portion Mass/Weight (drained)	Metric Measure (drained)
APPLE, dried, stewed without sugar	75 g	⅓ cup
tinned, unsweetened	125 g	½ cup
solid pie pack unsweetened	150 g	⅔ cup
puree, unsweetened	180 ML	¾ cup
APRICOTS, dried, stewed without sugar (7 halves)	80 g	⅓ cup
tinned, unsweetened	180 g	¾ cup
PEACHES, tinned, unsweetened (3 halves)	200 g	¾ cup
PEARS, tinned, unsweetened (3 halves)	180 g	¾ cup
PINEAPPLE, tinned, unsweetened (1½ rings)	150 g	½ cup
PLUMS, stewed without sugar	130 g	½ cup
QUINCE, stewed without sugar	100 g	1 cup
‡RHUBARB, stewed without sugar	400 g	4 cups
TWO FRUITS, tinned, unsweetened	180 g	¾ cup

‡A small serve (less than ¼ portion) need not be counted in portion calculations.

MILK AND YOGHURT

	This much is equal to one (1) portion	
	Mass/Weight	**Metric Measure**
BUTTERMILK, cultured	300 ml	1½ cups
powder, (uncultured)	35 g	4 Tbsp.
*CREAM (see "Green Light" List)		
*CHEESE (see "Green Light" List)		
* ICE CREAM, plain or flavoured (not fancy)	70 g	2 scoops
MILK, *whole fluid, skim fluid or *Hi Lo	340 ml	1½ cups
evaporated, *full cream or skim	160 ml	⅔ cup
*whole powdered	40 g	3½ Tbsp.
skim powdered	30 g	3 Tbsp.
*goat's whole fluid	340 ml	1½ cups
*milk flavoured with 1 Tbsp. Milo, Ovaltine, Quick, Actavite or malted milk powder	170 ml	¾ cup
‡*SOYBEAN MILK, powder	125 g	12½ Tbsp.
*WHEY, fluid	300 ml	1½ cups
powdered	20 g	2 Tbsp.
YOGHURT, *natural, full fat	200-225 g	1 carton
plain, non fat	200-225 g	1 carton
flavoured (see "Red Light" List)		

Note: Less than ⅓ cup milk (80 ml, ¼ portion) in tea or coffee with each meal or mid meal need not be counted when estimating portions.

Here is a quick ready reckoner for portions in milk.

Fluid milk:	**80 ml**	**⅓ cup**	=	**¼ portion**
Whole, Hi Lo	**125 ml**	**½ cup**	=	**⅓ portion**
Skim	**170 ml**	**¾ cup**	=	**½ portion**

*Starred foods are high in fat and energy (joules/calories) so limit when reducing weight. For example, use skim milk instead of full cream in drinks and cooking.

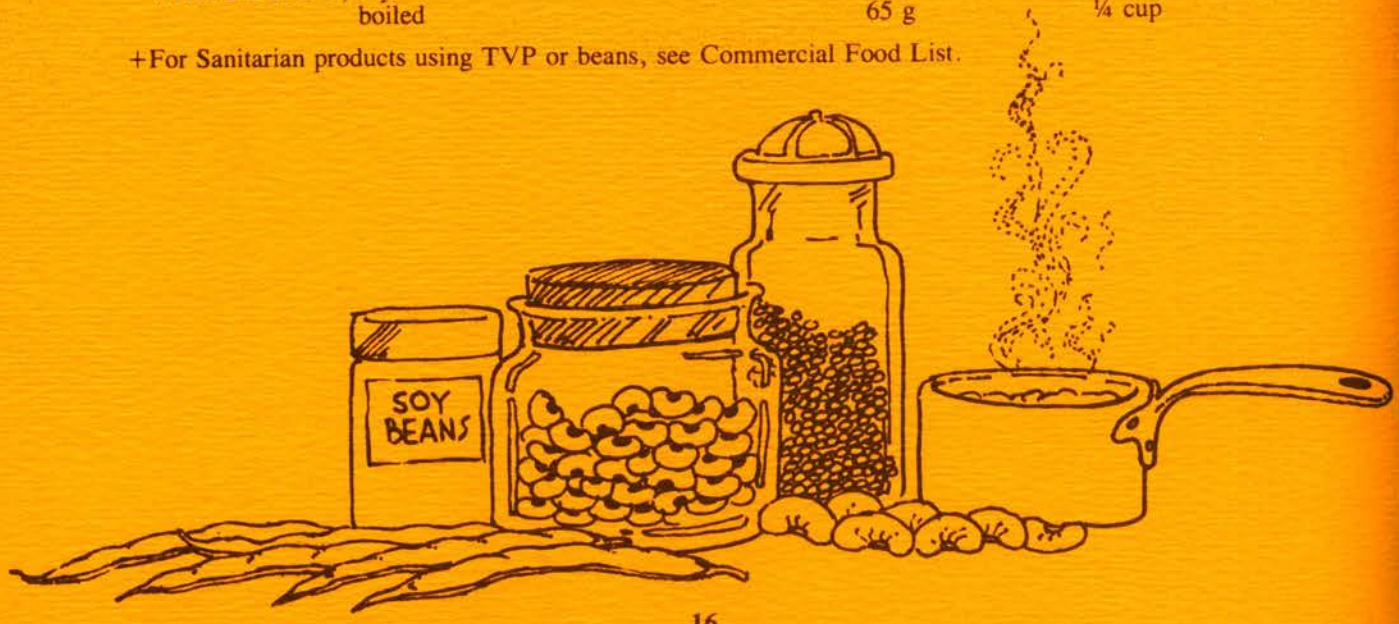
PULSES, DRIED BEANS AND PEAS

These foods are excellent sources of protein and other important nutrients, B vitamins and iron, but low in fat and energy (joules/calories).

See "Nature's Way" Cookbook for interesting ideas for tasty casseroles and salads using these instead of meat!

	This much is equal to one (1) portion Mass/Weight	Metric Measure
BAKED BEANS, canned	70 g	⅓ cup
BORLOTTI BEANS, raw	25 g	1½ Tbsp.
boiled	60 g	⅓ cup
BROAD BEANS, dried	25 g	1½ Tbsp.
raw	85 g	½ cup
boiled	210 g	1 cup
BUTTER BEANS, raw	30 g	1½ Tbsp.
boiled	90 g	½ cup
CHICK PEAS (Garbanzos), dried	25 g	1½ Tbsp.
boiled	65 g	¼ cup
HARICOT BEANS, mature, raw	25 g	1½ Tbsp.
boiled	65 g	⅓ cup
LENTILS, raw	25 g	1½ Tbsp.
boiled	75 g	⅓ cup
LIMA BEANS, green (immature), raw	65 g	¼ cup
boiled	75 g	½ cup
brown (mature), raw	25 g	1½ Tbsp.
boiled	60 g	⅓ cup
MIXED BEAN SALAD, canned	65 g	⅓ cup
MUNG BEANS, raw	25 g	1½ Tbsp.
sprouts, raw and boiled		See "Green Light" section
RED KIDNEY BEANS, raw	25 g	1½ Tbsp.
boiled	60 g	⅓ cup
SOYA BEANS — immature, raw	115 g	⅔ cup
boiled	150 g	1 cup
sprouts, raw or boiled		See 'Green Light" section
mature, dry	45 g	¼ cup
boiled	150 g	¾ cup
Soya bean curd (Tofu)		See "Green Light" section
Miso, Natto (Fermented soya beans)		See "Green Light" section
SPLIT PEAS, raw	25 g	1½ Tbsp.
boiled	70 g	⅓ cup
+TVP (Textured vegetable protein) dry	25 g	1½ Tbsp.
boiled	65 g	¼ cup
WHITE BEANS, dry	25 g	1½ Tbsp.
boiled	65 g	¼ cup

+For Sanitarian products using TVP or beans, see Commercial Food List.



SEEDS AND NUTS

Because nuts are often not eaten in amounts large enough to equal one portion, amounts to equal half a portion are given in this list.

	This much is equal to half (½) portion		
	Mass/Weight (in grams)	**Metric Measure**	**Description**
*ALMONDS, (shelled)	40 g	⅓ cup	Approx. 30
*BRAZIL NUTS, (shelled)	70 g	½ cup	Approx. 16 med. kernals
*CASHEW NUTS, (shelled)	30 g	¼ cup	Approx. 14 med.
*CHESTNUTS, (shelled)			
fresh	20 g	¼ cup	3 small
*COCONUT, dessicated (dried)	25 g	⅓ cup	
fresh	50 g		1 piece, 7.5 cm x 7.5 cm x 1 cm (3" x 3" x ⅜")
*HAZELNUTS, (shelled)	50 g	½ cup	Approx. 24
*MACADAMIA, (shelled)	50 g	½ cup	Approx. 24
*MIXED NUTS, (shelled)	40 g	¼ cup	
*PEANUTS, (unshelled)	55 g		Approx. 20
(shelled) raw or roasted	40 g	¼ cup	Approx. 50
*PEANUT BUTTER	40 g	2 Tbsp.	
*PECANS, (shelled), large	55 g	½ cup	
*PEPITAS (pumpkin seeds)			
shelled	50 g	⅓ cup	
*PINENUTS, (shelled)	50 g	⅓ cup	
*PISTACHIOS, (shelled)	50 g	½ cup	Approx. 60
*SESAME SEEDS	75 g	½ cup	
*SUNFLOWER SEEDS, (shelled)	40 g	¼ cup	
*WALNUTS, (shelled)	50 g	½ cup	Approx. 25 halves

*Starred foods are high in fat and energy (joules/calories) so limit these when reducing weight.

TAKE AWAY AND CONVENIENCE FOODS

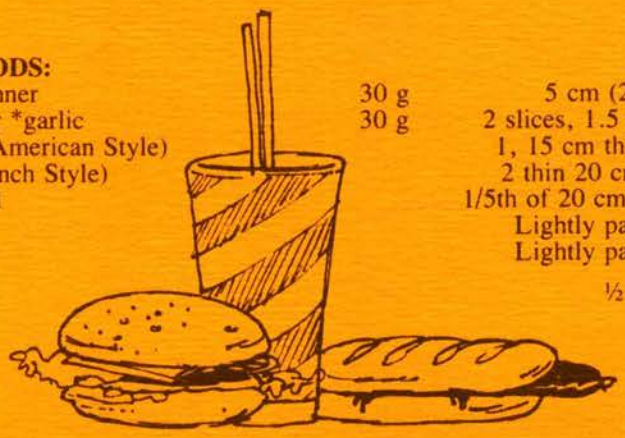
	Mass/Weight	Description	Approx. Portion
Baked Beans, canned	70 g	⅓ cup	1
*Battered chicken	200 g	2 average pieces	2
*Battered fish	150 g	1 large piece	1
*Battered prawns	120 g	3-4	1
Bread roll, average	60 g	7.5 cm (3'') diam.	2
*Chips, French fries	45 g	9-10 chips, 5 cm (2'') long	1
Chiko Roll	185 g		4
*Cornish Pastie	170 g	1	2½
*Crisps	30 g	12 whole crisps	1
*Cutlets, crumbed	160 g	2 large	1
*Fish cake, crumbed	100 g	1 cake	1
*Fish fingers, crumbed	100 g	5	1
Frankfurts, thick		4	1
thin		5	1
cocktail		10	1
Hamburger in bun		1 hamburger	2
Hot dog in bun		1 hot dog	2
Ice cream, plain or flavoured	35 g	1 scoop in cone	½
*Meat pie	170 g	10 cm (4'') square	2½
*Meat pie, large (family) size	450 g	1 pie, large	6
mini (party) size	60 g	1 pie, small	1
*Pizza — see Italian Foods			
*Potato scallops	120 g	3 of 7.5 cm (3'') diam.	1
*Rissoles, beef	100 g	2 rissoles	1
*Sausage roll	125 g	1 of 10cm x 5cm x 2.5cm	1½
*Sausages, thick	165 g	3 thick	1
thin	150 g	4 thin	1
Continental, e.g. Salami — see ''Green Light List''			
Spaghetti, tinned	110 g	½ cup	1

SNACK FOODS:

*Cheezels, Twisties	25 g	1 small packet	1
*Nuts, cashews	30 g	¼ cup (approx. 14 nuts)	½
peanuts	40 g	1small packet (approx. 50 nuts)	½
mixed	40 g	1 small packet (¼ cup)	½
*Pikelets		2 medium	1
Pretzels	25 g	15 pretzels	1
*Scones, plain, cheese		1 medium	1
fruit		1 small	1
Sultanas	40 g	Snack pack	2
Popcorn, unpopped	20 g	1 Tbsp.	1
popped, plain with salt	20 g	1½ cups	1
*popped, in fat	25 g	1½ cups	1

DINING OUT FOODS:

Bread roll, small dinner	30 g	5 cm (2'') diam.	1
Bread stick, plain or *garlic	30 g	2 slices, 1.5 cm (½'') thick	1
†*Pancake, flapjack (American Style)		1, 15 cm thick, 6'' diam.	1½
crepe (French Style)		2 thin 20 cm (8'') diam.	1½
*Pastry, unsweetened		1/5th of 20 cm (8'') diam. case	1
Rice, boiled, hot		Lightly packed ⅓ cup	1
*fried, hot		Lightly packed ½ cup	1
*Sauce, any		½ cup	1



	Description	Approx. Portions
INDIAN FOODS:		
*Chapatis	1 of 13.5 cm (5½'') diam.	2
*Dahll	½ cup	1
*Papadams, large	1 large (uncooked), diam. 13.5 cm (5½'')	1
small	4 small (uncooked), diam. 9 cm (3½'')	1
*Rotis	1 of 18 cm (7'') diam. (50 g)	2
ITALIAN FOODS:		
*Pizza, large	⅛ of 50 cm (20'') diam.	1½
small	⅛ of 35 cm (14'') diam.	1
Spaghetti noodles, cooked	1 cup	2
Cannelloni filling tubes	2 tubes	1
MIDDLE EASTERN FOODS:		
Bread, Lebanese flatbread	1 flatbread, 20 cm (8½'') diam.	4
*Felafel	2 of 2.5 cm (1'') balls	1
*Hummus	¼ cup	1
Tabouli	½ cup	1
Vine leaves, stuffed	6, each with 1 Tbsp. cooked rice filling	1
MEXICAN FOODS:		
Chilli Con Carne	½ cup	1
*Corn bread	1 of 5 cm (2'') square	1
*Corn chips	7 triangles	1
*Enchilada	2	1½
*Guacamole (avocado/sour cream dip)	½ cup	½
*Refried beans	½ cup	½
*Taco	2	½
*Tamale	2	1
canned	1	1
*Tortillas	2 of 15 cm (6'') diam.	1
*Tostada	1	2
CHINESE FOODS:		
*DIM SIMS	2	1
CHOP SUEY with meat or chicken, with vegetables, no noodles	1 cup	1
CHOW MEIN with meat or chicken, with noodles and vegetables	1 cup	1½
*MEAT, CHICKEN with noodles, no vegetables	1 cup	1½
VEGETABLE COMBINATION (no meat or noodles)	1 cup	½
*MEAT, CHICKEN with vegetables and nuts	1 cup	¾
SOUP, chicken noodle, long soup	1 cup	½
SOUP, short (containing 4 meat filled won tuns)	1 cup	½

*Starred foods are high in fat and energy (joules/calories) so limit these when reducing weight.

STARCHY VEGETABLES

Contrary to popular belief, most of these are quite low in energy (joules/calories), even corn and potatoes, and can be eaten regularly by weight reducers. Watch the butter and the margarine you put on them though!

See the Simplified Food Composition Tables for joules/calorie counts.

	This much is equal to **one (1) portion**		
	Mass/Weight	**Metric Measure**	**Description**
ARTICHOKE, GLOBE or French boiled	380 g		1 bud
BEANS, baked (canned)	70 g	⅓ cup	
BEANS, mixed (canned)	65 g	⅓ cup	
+BEANS, borlotti, kidney, raw	25 g	1½ Tbsp.	
boiled	65 g	¼ cup	
BEANS, broad	80 g	⅓ cup	
CORN, fresh, boiled	140 g	½ cup	1 medium cob, 19 cm x 4 cm (7½" x 1½")
CORN, canned, drained	80 g	½ cup	
canned, creamed	75 g	⅓ cup	
+LENTILS, raw	25 g	1½ Tbsp.	
boiled	75 g	⅓ cup	
MIXED VEGETABLES, frozen, cooked	110 g	½ cup	
PARSNIP, raw	90 g	⅔ cup	2 raw parsnips
cooked, diced	90 g	½ cup	21.5 cm (8½") long
PEAS, raw, shelled, boiled, frozen or fresh	110 g	⅔ cup	
PEAS, canned, drained	90 g	½ cup	
PEAS, dehydrated	25 g	1½ Tbsp.	
reconstituted	70 g	⅓ cup	
POTATO, dehydrated flakes	15 g	⅓ cup	
reconstituted with milk and fat	105 g	½ cup	
POTATO, *baked in fat	65 g		1 small 5 cm (2") diam.
baked in jacket	65 g		1 small 5 cm (2") diam.
boiled	75 g		1 small 5 cm (2") diam.
*chips	45 g		9-10 med., 5 cm (2") long
*crisps	30 g	1 small pkt.	12 whole crisps
mashed with milk and fat	115 g	½ cup	
*POTATO SALAD, canned or homemade	100 g	½ cup	
SWEET POTATO, *baked, boiled mashed	50 g	¼ cup	1 piece 4.5 cm x 5 cm (1¾" x 2")

*Starred foods are high in fat and energy (joules/calories) so limit these when reducing weight.

+For a more detailed list, see Pulses, Dried Beans and Peas on Page 16.

HALF PORTION VEGETABLES

These are lower in carbohydrate than starchy vegetables, but still must be counted if eaten in quantity.

A serve smaller than **half** the amounts given below (i.e. ¼ portion) need not be counted in portion calculations.

This much is equal to **half (½) portion**

	Mass/Weight	Metric Measure	Description
AUBERGINE — see Egg Plant			
BEANS, green, raw	120 g	1¼ cups	
boiled	120 g	1 cup	
BEETROOT, tinned	100 g		5 average slices
BRUSSELS SPROUTS	110 g	¾ cup	8-9 medium
CABBAGE, boiled	100 g	1 cup	
COLESLAW, raw	120 g	1 cup	
CARROTS, raw, grated	100 g	1 cup	2 of 16 cm long
boiled	100 g	⅔ cup	(7")
EGG-PLANT, raw	135 g	1⅓ cup diced	6 slices, .5 cm (¼") thick
cooked, drained	180 g	¾ cup diced	
KALE, raw	110 g		
boiled	110 g	1 cup	
KOHLRABI, raw	120 g	1 cup	
boiled	140 g	1 cup	
LEEKS, raw	125 g		4-5 leeks, 12.5 cm
boiled	145 g		(5") long
MUSHROOMS, dried	15 g		5-6 dry, 4 cm (1½") diam.
canned, button	250 g	1½ cups	
sliced in butter sauce	150 g	1 cup	
raw	310 g	1½ cups	18-20 medium
OKRA, raw	100 g		4 pods, 10 cm (4") long
steamed	100 g		
ONION, raw	90 g	¾ cup	2 small, 4.5 cm (2") long
boiled	90 g	¾ cup	
pickled			6 cocktail
PUMPKIN, raw	105 g		1 medium piece, 6.5 cm
boiled, mashed	105 g	½ cup	(2½") diam.
baked	80 g		
SWEDE	95 g	⅔ cup	
SAUERKRAUT, canned	200 g	1⅓ cups	
SQUASH, winter, boiled	85 g	½ cup	
TURNIPS, raw	120 g		
boiled	120 g	1 cup	
TOMATO, raw	165 g	¾ cup, diced	1 large, 2 medium
canned, drained	110 g	½ cup	
paste	85 g	4 Tbsp.	
puree	100 g	4½ Tbsp.	
juice	250 ML	1 cup	
VEGETABLE JUICE (e.g. V8, carrot)	250 ML	1 cup	
WATERCHESTNUT	10 g	3-4 wholenuts	
ZUCCHINI, raw	85 g		2 x 7.5 cm x 2.5 cm
boiled	85 g	¾ cup	(3" x 1")

NOTES

GREEN LIGHT FOODS

(go ahead but within speed limits)

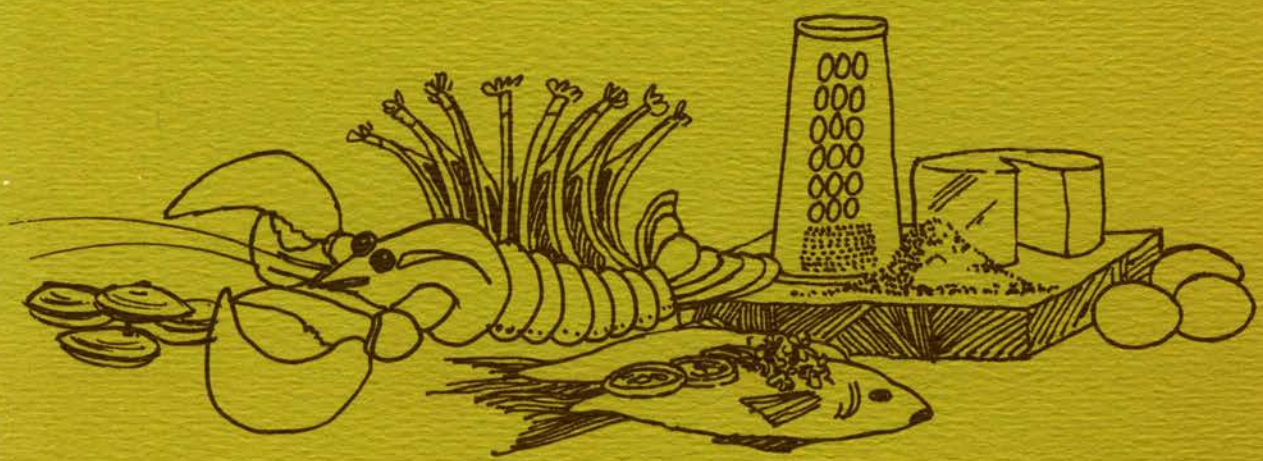
GREEN LIGHT FOODS

GO! BUT WITHIN SPEED LIMITS

- These foods contain **negligible amounts of carbohydrate.**

Meat	**Cheese**
Poultry	**Eggs**
Fish	**Fats and oils**

- Many of these foods are **high in food energy** (joules/calories), fat and cholesterol, so don't overdo them. See the Simplified Food Composition Tables for information about particular foods.
- Remember . . . A Green Traffic Light means **go ahead within speed limits** — but not at 100 kilometres per hour!
- For your particular "speed limits" see your dietitian for recommendations.



PROTEIN FOODS

CHEESE	*Altapol, *blue vein, *cream, *camembert, *cheddar, *cheese, spreads, *edam, *fetta, *parmesan, *swiss, low fat curd cheeses, e.g. cottage, ricotta.
EGGS	
FISH	Fresh, canned in brine or *oil. Caviar, roe.
MEATS	*Beef, *lamb, organ meats: brains, kidney, liver, sweetmeats, *pork, *processed: (*Continental sausage, *luncheon meats, *liverwurst), *bacon, *ham, rabbit, veal.
POULTRY	Chicken, *duck, turkey.
SHELLFISH & CRUSTACEANS	Crab, lobster, mussels, oysters, prawns, scallops.

OIL AND FAT FOODS — SLOW DOWN!

All these foods are high in food energy (joules/calories), so use in small amounts and limit these when reducing weight.

1 teaspoon of oil or fat has approximately 150 joules or 35 calories.

* Butter
* Copha (made from coconut oil)
* Cream, sour cream
* Dripping (beef fat)
* Lard (pork fat)
* Margarine, table or cooking, polyunsaturated or saturated
* Mayonnaise
* Oil, polyunsaturated or saturated
* Salad dressings
* Suet (fat around kidney)

Note: Many foods contain **hidden** fats, e.g. the marbling of fat through meat, or the fat in cheese, eggs, pastry and batter. These foods have been starred (*) throughout the Traffic Light Guide.

* Starred foods are high in fat and energy (joule/calories), so limit these when reducing weight.

FREE FOODS

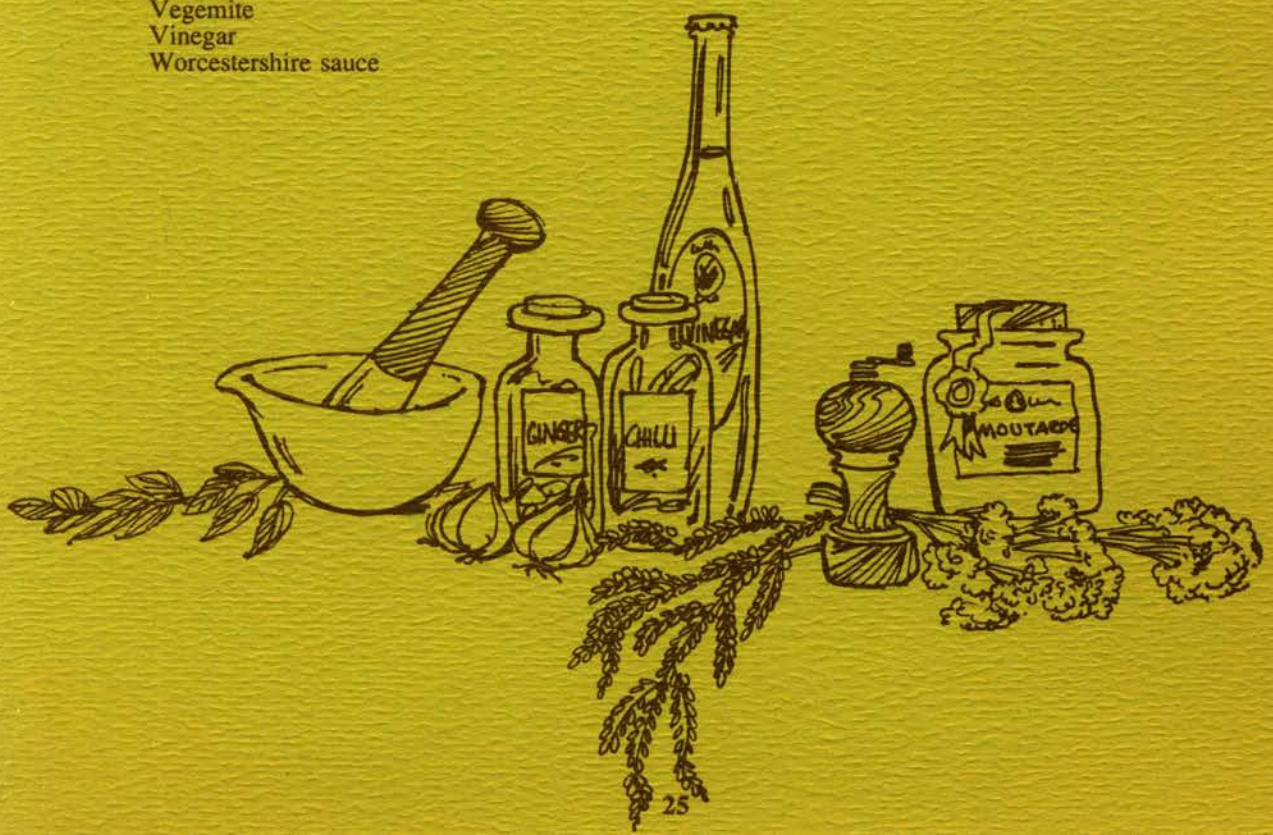
DO NOT COUNT AS CARBOHYDRATE PORTIONS
These foods can be eaten "freely" because they contain very few calories and nil carbohydrate.

BEVERAGES

Beef tea, Bonox, Bovril, Bovex, meat extracts
Clear broths
Coffee substitutes — Caffex, Caro, Ecco Bambu
Coffee beans, instant coffee powder, decaffeinated coffee
Coffee — black, no sugar
Coffee essence — unsweetened
Essences, e.g. vanilla, rum, etc.
Juice of one lemon or lime
Mineral water, unsweetened, e.g. Hepburn Spa, Taurina
Soda water
Soup cubes
Tea — black, no sugar
Tea, herbal
Water

CONDIMENTS, SPICES AND FLAVOURINGS.

Chillies
Fish pastes
Garlic
Gelatine
Ginger root
Herbs, e.g. mixed herbs, bay leaves, mint, parsley, oregano
Junket tablets
Marmite
Meat pastes
Mustard
Pectin
Promite
Soya sauce, Miso, Natto
Special diet foods, see Page
Stock cubes
Spices, e.g. salt, pepper, cinnamon, nutmeg, etc.
Tomato sauce — use sparingly, as it contains a small amount of sugar
Tomato sauce and chutney, unsweetened
Unprocessed bran
Vegemite
Vinegar
Worcestershire sauce



FREE VEGETABLES

UNMEASURED VEGETABLES — Do not count as carbohydrate portions. Most of these foods are very high in vitamins and minerals but very **low** in **calories** and **carbohydrate** and can be **eaten as desired.**

ASPARAGUS

BAMBOO SHOOTS

BEAN SPROUTS

BROCCOLI

CAPSICUM

CAULIFLOWER

CELERY

CHICORY

CHILLIES

CHIVES

CHOKO

CILANTRO (Coriander)

CUCUMBER

DILL PICKLES

ESCHALLOTS

FENNEL

GHERKIN — sour

LEMONS

LEAFY GREENS

LETTUCE

MARROW

OLIVES

PARSLEY

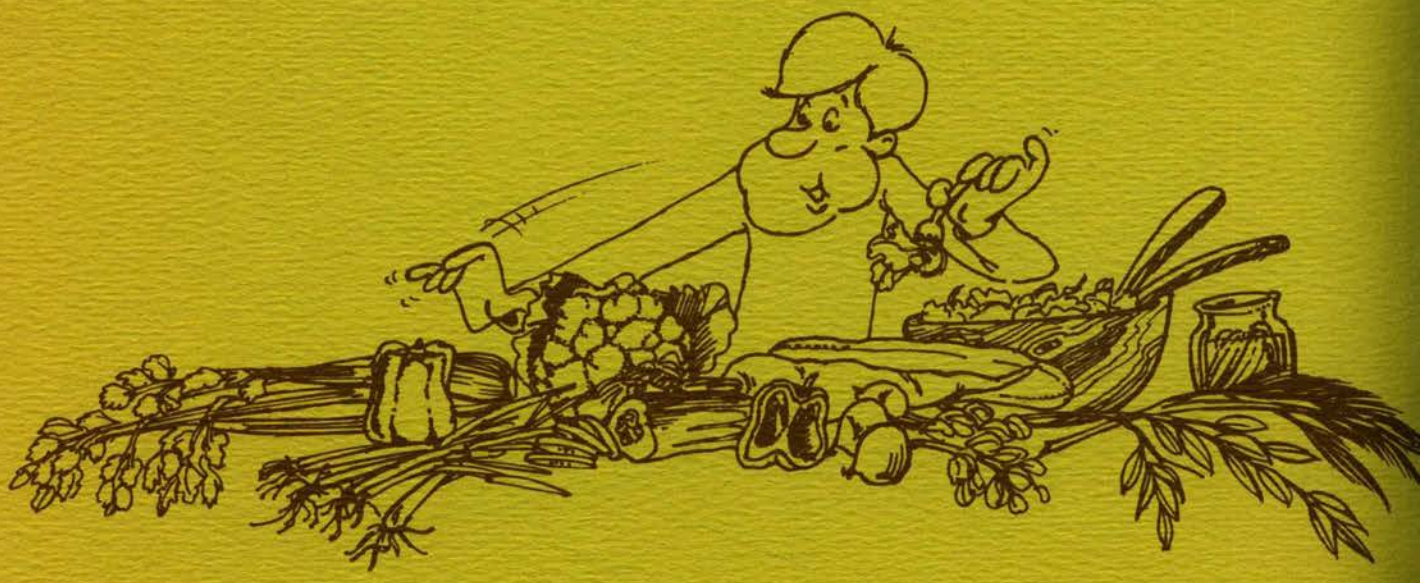
PICKLED CUCUMBER, dill unsweetened

RADISH

SILVERBEET

SPINACH

WATERCRESS



FOOD FOR "HYPOS" (LOW BLOOD GLUCOSE)

- **Always** treat a "hypo" with foods or beverages containing approximately 2-3 rounded teaspoons of sugar or honey (see suggestions below).
- **Always** take an extra carbohydrate portion food **immediately after** a hypo (unless meal follows within 15 minutes) — see Amber Light List.
- Carry with you at all times, a sweet food and a portion food that you like to treat hypos with.
- Prevent hypos by:
  1. Taking care with spacing and counting your carbohydrate portions each day.
  2. Taking precautions before exercise or when sick.
  3. Avoid drinking large quantities of alcohol (and always take some carbohydrate when drinking).
- Consult your doctor/dietitian if regular and severe "hypos" occur.
- Do not place anything in the mouth of an unconscious person because they may choke — seek medical attention.
- Consult your doctor for instructions on using Glucagon injections.

SUGGESTED FOODS FOR TREATING "HYPOS"

SWEET FOOD SUGGESTIONS FOR TREATING "HYPOS"

Each of these foods or beverages contains approximately two (2) rounded teaspoons (or 4 level metric teaspoons) of sugar.

SWEETS

1 jam or honey in packet, *small chocolate (approximately 6 small squares), e.g. Kit Kat or Tosca.
2 boiled sweets, Qban Barley Sugar.
3 butterscotch, Havapak Barley Sugar.
4 licorice allsorts, Fantales, Minties, lumps of sugar.
7 jelly beans, Jaffas, Freckles.
10 Lifesavers, Glucodin tablets.

SWEET BISCUITS, DESSERTS

½ cup sweet canned fruit.
2 sweet biscuits (*iced and *cream filled or fruit filled),toasted muesli crunchola bars.
1 scoop *ice cream + tbsp. (15 ML.) *syrup or topping.
1 *fancy or *chocolate coated ice cream.
1 *sweet cake, e.g. *lamington, *jam tart, *apple pie.

SWEET DRINKS

30 ml ordinary cordial added to a glass of water.
½ cup (125 ML) sweetened fruit juice, e.g. apricot or peach nectar.
¼ cup (60 ML) unsweetened fruit juice + 2-3 teaspoons sugar (1 pkt.).
½ cup (125 ML) ordinary soft drink.
¾ cup (180 ML) *chocolate milkshake or *flavoured milk.

Weight Watchers Note: Chocolate is a **very** high joule/calorie way of treating hypos. Example:

6 squares *chocolate = 110 calories or 460 joules
but 3 barley sugars = 50 calories or 210 joules

*These foods are high in fat and energy (joules/calories) and so limit these when reducing weight.

FOOD FOR EXERCISE

(For diabetics on insulin)

- **Regular** strenuous exercise is good for diabetics of all ages, the same as it is for non-diabetics. It lowers risk of having a heart attack and it helps to get or stay slim.
- Diabetics on insulin need to take extra food to prevent "hypos" when doing strenuous exercise because exercise lowers blood sugar, just as insulin does.
- Strenuous exercise is any activity which speeds up your heart and makes you puff and sweat. Almost any exercise **can** be strenuous. Example: A game of golf can be **very strenuous** if you walk quickly, uphill, carry your own clubs and play 18 holes. Golf can be very non-strenuous if you play only 9 holes, walk slowly and use a golf buggy.

GUIDELINES FOR EXERCISE

SIMPLE SUGARS: Take equivalent to 2-3 teaspoons of sugar (or food containing that amount of sugar — (for examples see below) every 15-30 minutes.

PORTION FOODS: (Complex carbohydrate foods — Amber Light List) take approximately **one** to **two** extra carbohydrate portions per hour of strenuous exercise (examples below).

STOP EVERY HALF HOUR: (If possible) for a **carbohydrate boost.** This is to prevent "hypos" while you are exercising, which could be embarrassing and/or dangerous.

ALWAYS CARRY WITH YOU: One of the suggested sweets below, so that you can treat "hypos" quickly.

EXPERIMENT/ADAPT:
- General guidelines for "how much" and "what" extra food you need are given above. However these are only general guidelines. Each diabetic differs in the amount of extra food he requires to prevent "hypos." Adapt the above guidelines to **your needs** by experimenting.

FOOD OR BEVERAGE SUGGESTIONS FOR STRENUOUS EXERCISE

When doing exercise where you can stop for a break every 15-30 minutes, such as dancing, squash, tennis, golf bush walking, mountain climbing, swimming heavy cleaning, strenuous gardening, bowls.

Have one portion **per hour**		One sugar-containing food **every 15-30 minutes** (These foods and beverages contain 2 rounded teaspoons or 4 level teaspoons sugar)
Suggested Portions		
1 slice **bread** and but...	+	1 Tbsp. **honey** or 1 Tbsp. **jam**
1½ Tbsp. **sultanas** (½ snack pack)	+	*4 small squares of **chocolate** or small chocolate bar (e.g. Kit Kat)
½ **sandwich** (of any kind)	+	½ cup (125 ml) regular sweet **soft drink,** non alcoholic **sweet cider** or sweetened **fruit juice**
Biscuits, semi sweet or *savoury	+	Coffee or tea with **1½ pkts. sugar** or **4 lumps sugar** or 1 Tbsp. sweetened ***condensed milk** or 10 **Glucodin** tablets
1½ cups ***milk** **Or** *1 pkt. **chips,** Cheezels, Twisties (20-30 g pkt.)	+	**Sweets** — (Examples) 2 boiled sweets 2 Qban or 3-4 Havapak barley sugars 3 butterscotch 4 Minties 4 licorice allsorts 7 jelly beans or Jaffas 10 Life Savers
2 scoops of ***ice cream**	+	1 Tbsp. (20 ml) of any flavouring or syrup

When you find it difficult to stop strenuous exercise for a food break, or to predict **when** and **if** a break will be possible — such as surfing, skin diving, swimming, skiing, horseback riding, etc. **Take 2 to 3 extra portions plus a simple sugar food before beginning exercise** to be on the safe side. A slightly high blood sugar is better than a "hypo" while surfing or swimming, etc.

SUGGESTIONS INCLUDE

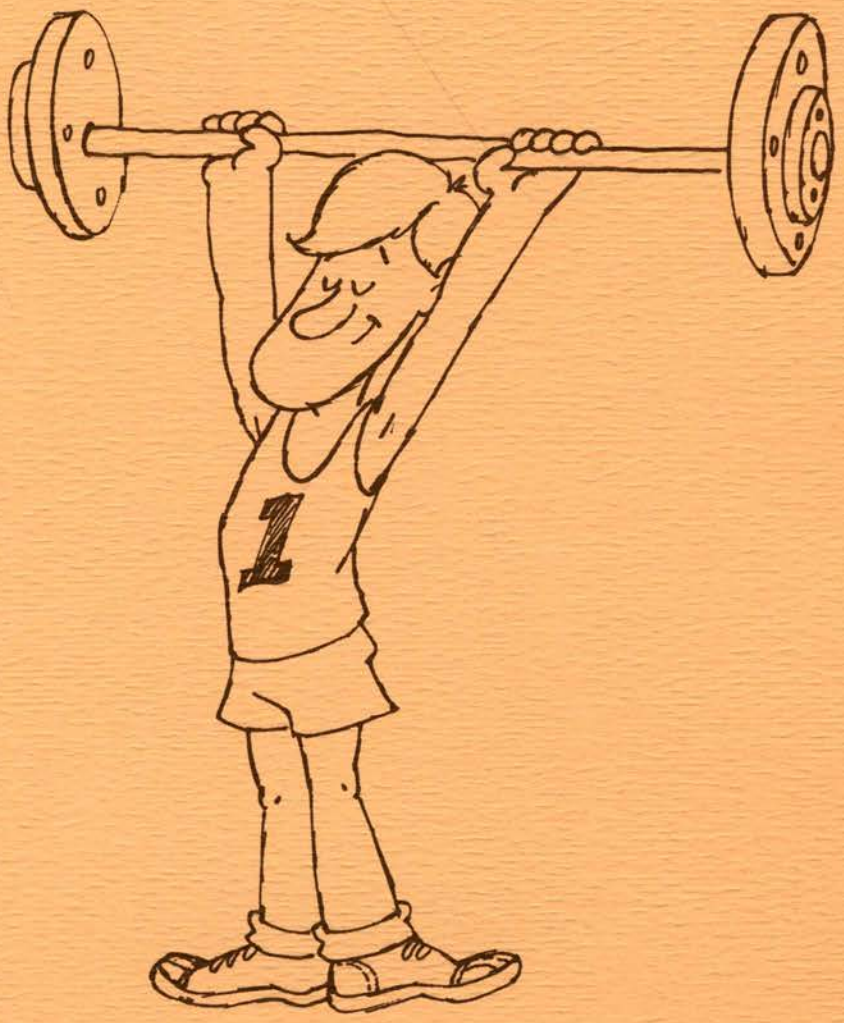
A sandwich + half (½) a glass of soft drink or sweetened fruit juice
*A packet of crisps + half (½) carton of flavoured *yoghurt.
A hamburger + ice cream.
*A milk shake
*1 carton of flavoured yoghurt.
*1 piece *cheese cake, *lamington or *apple pie

For some activities (water sports excepted) it is suggested that you **carry in your pocket** some of the suggested sweets previously listed or listed below and have a **carbohydrate boost every half hour.**

Food which contains 1 portion plus two rounded or 4 level teaspoons of sugar

1 packet of Space Food Sticks
* 2 Toasted Muesli Crunchola Bars
2 fruit filled biscuits
* 1 slice fruit cake
* 1 Polywaffle

*Starred foods are high in fat and energy (joules/calories) so limit when reducing weight.



FOOD FOR SICK DAYS

REMEMBER

Go to bed.
Never omit or reduce insulin dose.
Test your urine regularly for sugar and ketones. (Every four hours).
Refer to "Sick Days" pamphlet for more information.
Consult doctor for plan of action.
Eat according to guidelines below.

IF YOU ARE VOMITING OR HAVE DIARRHOEA

You must have some carbohydrate in the form of sugar on honey contained in beverages or light foods to prevent hypos.

You should use only clear fluids or sweets until diarrhoea or vomiting subsides, (avoid milk products for at least 24 hours).

Sip fluids in small amounts and slowly, rather than taking them in large amounts.

Drink lots of fluids to avoid dehydration (including some salty fluids such as broths, or Bonox, soda water or mineral water).

Suck sweets to help keep fluids down.

SUGGESTED CLEAR FLUIDS WHICH CONTAIN SUGAR (have 1 or 2 every hour)

Sweetened fruit juice or fruit nectars	½ cup
Flat Lemonade, Ginger Ale or Coke	½ cup
Sweet jelly	½ cup
Herbal tea plus 2 rounded teaspoons of sugar or honey	
Hot lemon drink made with lemon juice, water and 2 teaspoons of honey	

Note: Soda water mixed with fruit juice makes a nice drink and that combines sugar plus salt.

IF YOU DON'T FEEL AS HUNGRY AS USUAL (but don't have diarrhoea or vomiting).
Space and count your portions as you usually do, but choose soft foods that haven't been prepared with a lot of fat or spices.

Some suggested carbohydrate 1 portion ideas are:

Biscuits	2 plain sweet biscuits, e.g. milk arrowroot, milk coffee
Custard	170 ml (¾ cup) — made up as ¾ cup milk + ¾ Tab. custard powder
Fruit or unsweetened fruit juice, or unsweetened stewed fruit	1 small banana, ½ cup of orange juice, ⅓ cup unsweetened stewed apple
Ice cream	2 scoops
Mashed potato	½ cup
Milk	170 ml (¾ cup)
Porridge, cooked	½ cup
Rice, cooked	½ cup
†Soups	See Amber Light List, Recipe Book or portions in Commercial Products List
Toast, plain or raisin	1 slice

"SPECIAL DIET" FOODS FOR DIABETICS

These include:

2. **Carbohydrate Modified Products — not recommended**
   e.g.: protein increased (starch reduced) bread
   diet beer and wine
   diet soups

2. **Products made with High Joule/Calorie Sweeteners — not recommended**
   (such as Lactose, Fructose, Sorbitol, Mannitol)

   Examples include:

   Diabetic chocolate
   Diabetic jam
   Powdered sweeteners, e.g. Sweetaddin, Dieter, Sugarsweet
   Slimming biscuits, i.e. Limmits
   Diabetic "sugarless" wafers
   Rosehip Syrup — no added sugar

3. **Products made with Low Joule/Calorie Sweeteners — Saccharine and Cyclamate**
   (with or without **very small amounts** of high joule/calorie sweeteners) — **O.K. to use.**

   Examples include:

   Low-cal soft drinks — including low-cal tonic water
   Low-cal cordial, e.g. So-slim, Tubee, Cascade
   Diabetic jelly
   Sugarless gum
   Diabetic tinned fruit — see Page 14 or Commercial List.
   Low calorie salad dressings, e.g. Bestfoods
   Tomato sauce and chutney — no added sugar, e.g. Rosella
   Sweeteners, e.g. Hermesetes, Sucaryl, Sugarine, etc.

We do **not** recommend the first two groups of Special Diet Foods because:

- Many are a rip-off, i.e. expensive, misleading and unnecessary
- Many are high in joules/calories
- Many are "empty" calories
- Your body uses many of them the same as sugar containing foods
- If you are going to use "Special Diet" food, stick to the ones in category 3, above!

INFORMATION ABOUT ALCOHOLIC BEVERAGES FOR DIABETICS AND NON-DIABETICS

1. All alcoholic drinks contain lots of calories (mostly contributed by alcohol).
2. Alcoholic drinks should never be counted as portions. Although beer contains some carbohydrate, substituting beer for portion food could lead to a severe hypo.
3. Some alcoholic drinks contain lots of sugar, such as sweet wines and liqueurs.

There are several health risks you and your non-diabetic family and friends take by drinking alcohol.

HEALTH RISKS FOR EVERYONE

Do you realise that:

- Drinking an average of 90 grams of alcohol (approx. 9 drinks per day) may lead to alcoholism (an estimated 300,000 Australians are alcoholics).
- Drinking 60 grams of alcohol (6 drinks) per day for just six weeks **can** cause liver damage and/or high blood fats (high triglycerides).
- Regular drinking of more than 5% of your energy (joules/calories) 1-3 drinks per day can lead to vitamin deficiencies which may result in problems with digestion, fatigue, nerves, irritability, to name a few.
- Regular drinking often **leads to** overweight and obesity. Alcohol is **very** high in joules/calories.
- Drinking alcohol plus taking medications can cause many ill effects.
- Drinking and driving can result in serious motor accidents.

SPECIAL HEALTH RISKS FOR DIABETICS

Drinking alcohol, especially in large amounts and/or drinking without eating carbohydrate can lead to severe "hypos." This is because alcohol often lowers your blood sugar and then **impairs** your ability to recove from "hypos." This is a particular danger if you are drinking and driving.

To prevent this see the following recommendations:

RECOMMENDATIONS CONCERNING GROG

For the reasons previously listed, **we do not recommend** that diabetics (or non-diabetics) drink alcohol. However, if you choose to, we suggest that you:

- Drink small amounts (and only occasionally).
- Avoid **daily** drinking.
- Avoid drinking large amounts at one time — especially important for diabetics (this means more than 2-3 drinks in an evening).
- Avoid drinking when taking medication, driving or reducing weight.
- **Diabetics** should avoid sweetened alcoholic beverages such as liqueurs, sweet sherry, muscat, etc. because these contain sugar. (The occasional beer, dry wine or nip of spirits are preferable).
- **Diabetics** should always take a carbohydrate portion along with their drink to prevent "hypos" (foods like savoury biscuits or chips are often available).
- **Caution:** Be aware of the high joule/calorie content of all alcohol and most accompanying snacks. Example: 2 glasses wine plus a handful of nuts = 500 cals. (Check the Simplified Food Composition Tables).
- Even though beer contains some carbohydrate, we suggest that you do not substitute it for a portion food — just add it on to your portions that day.
- It's O.K. to use small amounts of dry wines and sherry in cooking. These contain **no carbohydrate** (and all the alcohol and joules/calories evaporate if simmered for about 5 minutes).
- **Cutting down** your alcohol drinking is often a **difficult** change to make because it is such a part of everyday life in Australia.

  Cutting down usually involves:

  — being able to be **different** from your friends — i.e. saying "no" after 2 beers;
  — substituting other beverages that you like so you don't feel as left out;
  — cut down gradually.

TOO FAT?

Being overweight **usually** means you have too much **fat** in your body.

Being too fat is **unhealthy,** especially for **diabetics.** If you are too fat, you are at a higher risk for:

- Having erratic and uncontrolled blood sugars.
- Developing high blood fats and early heart disease.
- Sudden death at any age.
- Developing many conditions, such as gout, gall bladder disease, varicose veins, surgical complications.
- To **reduce the fat** in your body, you must **decrease** the **food energy** (joules or calories) you **take in** and **increase** the **energy** you expend in **activity.**
- Some ways of reducing your food energy (joules/calories) are **healthier than others.** Since most Australians are over-eating protein, fat and alcohol, this is the obvious place to cut food energy (instead of cutting down complex carbohydrate intake).
- Diets which are high protein, high fat and low carbohydrate, are very unbalanced and can be harmful to your health.
- Exercise is under-rated as an important part of losing fat. Did you know that you could lose half-a-pound of fat a week by walking an extra half hour a day? (Without even dieting).

SOME SUGGESTIONS FOR SLIMMING

- Make sure you are eating a balanced diet. See your local dietitian.
- Do a quick check on your joule/calorie intake for the day, using the Simplified Food Composition Tables.
- Go for low joule/calorie portion foods. Watch out for the starred (*) ones!
- Experiment with low joule/calorie, but interesting and filling portion foods. The more boring your diet is, the less likely you are to stick to it!
- Accept the possibility of leaving the table still a bit hungry. That feeling of hunger will go in about 20 minutes, once your body starts using the food you've eaten.
- Watch out for those high energy snacks and left overs.
- Weigh yourself weekly and keep a record of your progress.
- Be patient, it often takes at least two weeks of dieting to show some results!
- **Become more active in everything you do,** i.e. take the stairs instead of the lift, stand more than you sit, walk to the shops instead of driving!
- You can burn 300-400 extra calories a day by looking for every little way to increase activity.
- Take up some strenuous exercise 2-3 times a week, i.e. squash, tennis, jogging, swimming, dancing — it's good for the waistline **and** good for the heart.
- Choose low joule/calorie portions before exercising (see Page 28).
- You may need to decrease your insulin when you are reducing your weight (see your doctor for guidelines on adjusting insulin).

WHAT TO DO ABOUT HIGH CHOLESTEROL . . .

The following suggestions have been shown to contribute to lowering or preventing high levels of fat in the blood.

They are listed in order of importance and effectiveness:

1. **Lose weight** (if you are overweight) and maintain close to ideal weight.
2. **Re-balance your diet.** Be sure to eat the recommended number of portions. Watch out for animal protein, fat and alcohol — cut down on these. Get enough complex carbohydrate.
3. **Decrease the fat** in your diet, particularly animal fat. Where possible, substitute low fat alternatives, e.g. cottage or ricotta cheese, low fat yoghurt, chicken, white fish.
4. **Use polyunsaturated vegetable oils and margarine** — but be aware that they're as fattening as other fats, e.g. butter.
5. **Limit the foods which are the very highest sources of dietary cholesterol:** — eggs, shellfish, liver, brains, kidney.
6. **Increase your physical activity and daily exercise.** This is good for your heart in other ways too!

Note: Get your blood fats checked annually — to make sure they're going in the right direction!

FOOD SUGGESTIONS FOR TRAVELLING

Driving your own vehicle on short or long trips . . .

Take precautions to prevent hypos by —

- Eat the right number of portions when driving.
- Avoid drinking, being overtired or overstressed, as early warning signs of hypos may be overlooked.
- At the earliest sign of a hypo, stop driving straight away and eat something sweet.
- Eat an extra carbohydrate portion every 1-2 hours on long distance drives as well as stopping for meal breaks and eating between meal snacks at the usual times. It's better to be safe than to have a hypo.
- Always keep in the car, a supply of easy to carry, compact, quick acting carbohydrate (sugar-containing food) such as lollies, chocolate, or sweet biscuits, **AND** long acting carbohydrate (portion foods) such as dried or fresh fruit, biscuits, nuts, crisps or pretzels.

On planes, coaches, rail travel or camping tours . . .

Be prepared for irregular meal times and unexpected exercise.

- To cope with delayed meals always carry a supply of sweet and portion foods (see suggestions above)
- Sightseeing excursions on foot may be real exercise. See page 28 for suggestions on what precautions to take.

For International Travel . . .

- See pamphlet on Travel and Driving for specific suggestions on coping with time zone differences
- Familiarise yourself with the local food in the countries you intend to visit. If you are unsure about what foods are likely to be portion foods or how to count them, ring your local dietitian.

GUIDELINES FOR CALCULATING PORTIONS IN YOUR FAVOURITE RECIPES

STEPS TO FOLLOW:

1. Identify all the ingredients in the recipe that contain carbohydrate portions.
2. Use the Amber Section or the Ready Reckoner (p. 38) to calculate the number of carbohydrate portions in the whole recipe.
3. Work out how much the recipe makes after cooking by measuring (e.g. cupsful of soup, tablespoons of sauce, number of biscuits, etc.,)
4. Calculate the portions in your serve.

EXAMPLE

DATE LOAF

Ingredients:	Carbohydrate?	Portions
3 Tablespoons margarine	No	—
2 cups self-raising flour	Yes	12
1 cup chopped (24) dates	Yes	8
1 egg	No	—
1 cup water	No	—
1 Tablespoon grated orange peel	No	—
mixed spice, cinnamon, nutmeg	No	—
		20 portions

Makes 1 loaf, cut into 20 thin slices

1 serve = 1 slice = 1 Portion

N.B. A serve smaller than ¼ portion need not be counted in portion calculations for that meal.

READY RECKONER

For calculating portions in recipes

ITEM	METRIC MEASURE	CARBOHYDRATE PORTIONS
CEREALS, GRAINS, FLOUR		
Bran — unprocessed	1 cup	⅔
Cornflakes	1 cup	1⅓
Wheatgerm	1 cup	3
Oats — raw	1 cup	4
Rice — raw	½ cup (6 Tab)	4
— cooked hot	1 cup	3
Bulgur (cracked wheat)		
— raw, dry	1 cup	8
— soaked, boiled	1 cup	3
Noodles — dry	450 g pkt	22½
— cooked	1 cup	2
Flour — cornflour	1 tablespoon	⅔
white or w'meal	1 cup	6
Breadcrumbs — dried	1 cup	8
Pastry — case, baked	1 whole, 8'' diam	5
— mix, dry	1 cup	6
Gravy — ready mix powder	3 tablespoons	2
Cocoa	½ cup	1½
BEANS		
Chick peas — raw	½ cup	4
— boiled	1 cup	4
Lentils — raw	½ cup	4
— boiled	1 cup	3
Kidney Beans — raw	½ cup	4
— boiled	1 cup	3
Soya beans, mature, raw	½ cup	2
— boiled	1 cup	1⅓
Split peas — raw	½ cup	4
— boiled	1 cup	3
DAIRY		
Milk (fluid, whole, skim or HiLo)	1 cup	⅔
— powdered, whole	1 cup	3½
— powdered, skim	1 cup	4
— evaporated	1 cup	1½
Yoghurt — plain	1 carton (200-225 g)	1
FRUIT		
Dried apricots	4 large or 7 small halves	1
Dates — chopped	1 cup	8
Prunes — chopped	1 cup	7½
Raisins	1 cup	8
Sultanas	1 cup	8
NUTS AND SEEDS		
Coconut — dessicated	1 cup	1½
Peanuts	1 cup	2
Sesame seeds	1 cup	1
Sunflower seeds	1 cup	2
Walnuts	1 cup	1

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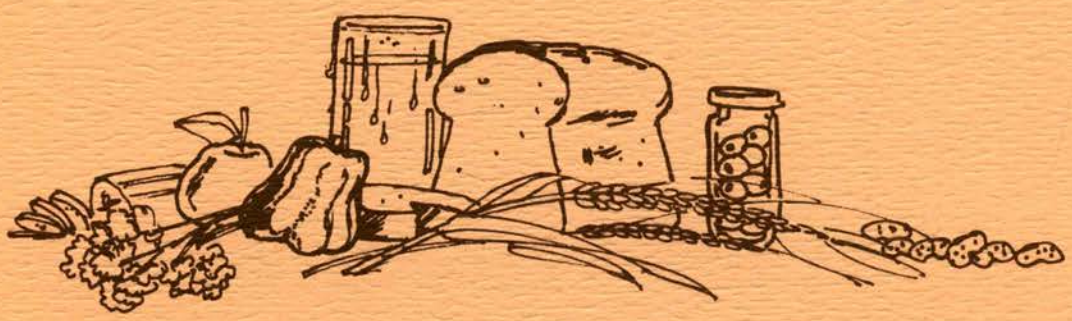

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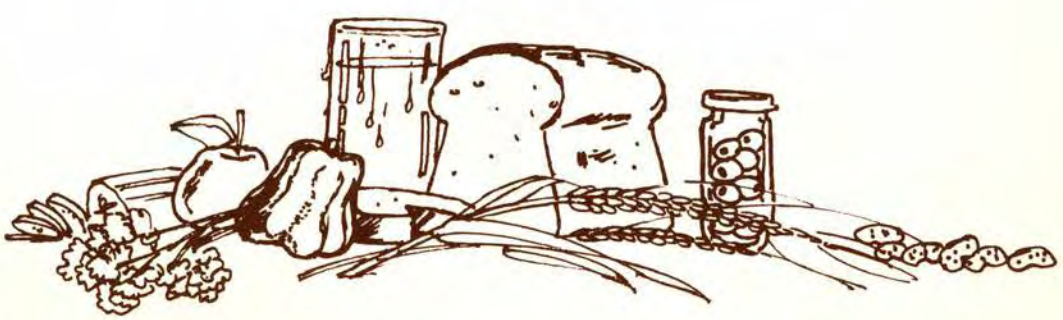
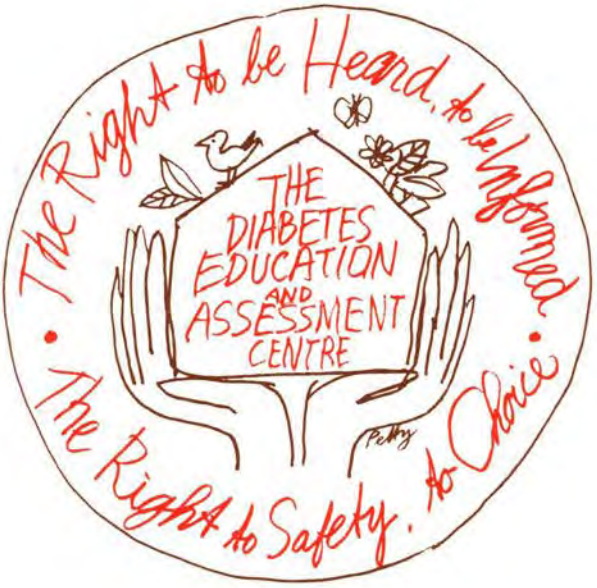


Diabetes



A course for people with diabetes, their families and friends.

WHAT'S THIS PROGRAMME ALL ABOUT?

Diabetics have a right to know what's happening to their bodies, to understand the reasons for their doctor's and dietitian's advice, and to sort out the changes they need to make in their daily lives to be healthy, while still enjoying life.

This programme gives a person with diabetes and his/her family or friends an opportunity to gain a clear and realistic understanding of this disorder, its symptoms, its treatment and its control.

This knowledge can be used to reduce the chances of getting serious complications and help to avoid unnecessary days in hospital.

This course is for people taking insulin injections as well as those treated by tablets or diet alone.

WHAT DOES THE COURSE COVER?

The programme ranges over a wide variety of topics that have real meaning and application to your daily living. Some of these are:–

- alcohol pros and cons
- shaping up with exercise
- Glucagon for emergencies
- driving and overseas travel
- handling hypos
- Somogyi effect
- coping with illness
- making injections less painful
- stress and diabetes
- putting the pleasure back into eating
- recent advances in treatment
- do-it-yourself blood sugar tests

– all this, and more, takes 30 hours over 4 weeks – designed to be interesting as well as informative.

WHO RUNS THE COURSE?

An experienced team, including a diabetic physician, a nutritionist, a psychologist/counsellor and a nurse educator run the sessions.

Each contributes specific knowledge to build up a complete picture of this disorder and its effects on your general health.

WHO CAN COME?

Diabetes involves your family and friends as well, so we strongly recommend that you bring a relative or close friend with you to all the sessions.

A special part of the programme is devoted to their needs also.

We also hold special programmes for teenagers, older age groups and professional groups.

HOW AND WHEN THE COURSE OPERATES

A doctor's referral is not required. Usually, we like you to notify your doctor that you are coming to the programme.

The course runs over four weeks with four night sessions and two full days.

Some individual appointments are also part of the course.

A small charge is made to cover meals, computerised food record, blood tests, pamphlets, recipes, etc.

If this cost presents a problem, other arrangements can be made.

"BUT I HAVE MILD DIABETES!"

No diabetes is mild. All diabetes can cause serious bodily problems if not cared for properly.

Every diabetic needs to know how to look after himself and this is not always as simple as it sounds.

"LOOK, I'VE HAD IT FOR YEARS AND KNOW ALL ABOUT IT"

Even old hands can learn new tricks.

This is understandable, considering the recent advances in home management of diabetes.

It is our experience that most people finish this course far more confident than before.

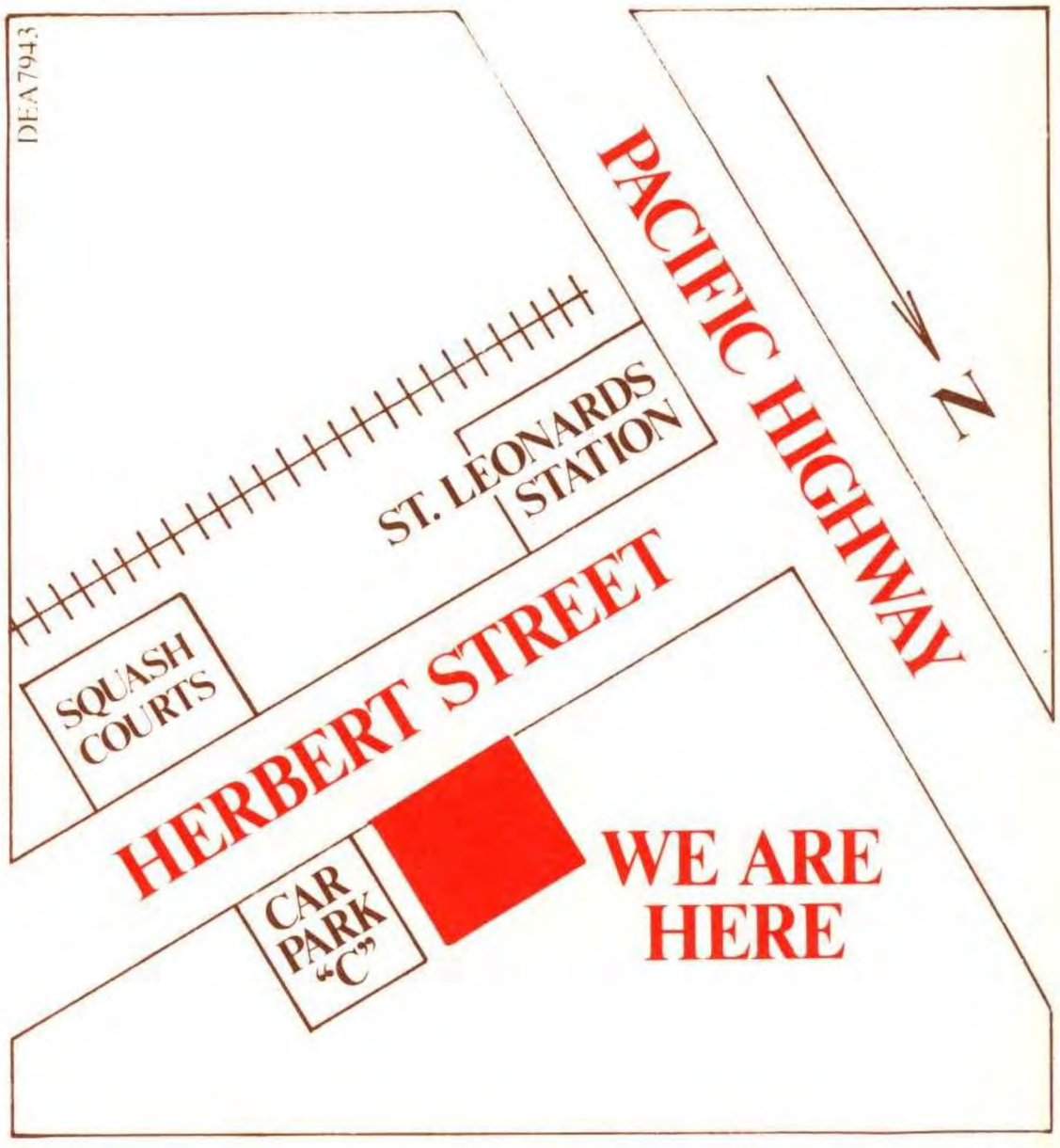
"WHERE'S IT HELD?"

In a cottage in pleasant surroundings in the grounds of the Royal North Shore Hospital (in Herbert Street, St. Leonards) almost opposite the 1812 Squash Courts.

For bookings and further information about this Centre's services phone:–

43 3476

438 4584



This is a special Community Health Programme of the Northern Metropolitan Region of the Health Commission of N.S.W. and the Royal North Shore Hospital of Sydney.

APPENDIX 3.6

DIABETES EDUCATION AND ASSESSMENT PROGRAMME

C/O ROYAL NORTH SHORE HOSPITAL

ST. LEONARDS. 2065.

APPLICATION FORM

MR/MRS/MISS/MS

NAME _____ SEX: M ___ F ___

_____ AGE: _____

_____ PHONE: HOME: _____

WORK: _____

DATE OF BIRTH DAY ___ MONTH ___ YEAR _____

OCCUPATION _____

LENGTH OF TIME SINCE DIAGNOSIS OF DIABETES _____

IS YOUR DIABETES TREATED BY INSULIN INJECTIONS? YES ___ NO ___

NAME AND ADDRESS OF GENERAL PRACTITIONER _____

_____

_____

NAME AND ADDRESS OF DIABETIC SPECIALIST _____

_____

_____

INFORMATION ABOUT PERSON(S) ATTENDING THE PROGRAMME WITH YOU

NAME	RELATIONSHIP TO YOU (E.G. FRIEND, WIFE ETC.)
_____	_____
_____	_____

TO ENSURE THAT OUR MAIL REACHES YOU, PLEASE NOTIFY US IF YOU INTEND CHANGING YOUR CURRENT ADDRESS. YOU WILL BE NOTIFIED OF THE DATES AND TIME OF THE PROGRAMME.

RNS

ROYAL NORTH SHORE HOSPITAL
St Leonards 2065 New South Wales
Telephone 438 0411 Cables Royshore

Reference

APPENDIX 3.7

CLINICAL EPIDEMIOLOGY EVALUATION UNIT
Telephone 438 7554

DIABETES EDUCATION & ASSESSMENT PROGRAMME 438 4584

Location

Herbert Street, St. Leonards
(Cottage opposite 1812 Squash Courts)

Dear

We are pleased to welcome you to the Diabetes Education and Assessment programme.

We have enclosed

1) a list of dates and times for your assessments and programme sessions

2) a map

3) a questionnaire for you to complete and bring with you to the first session

This course is extremely popular and there is a long waiting list of people anxious to attend. It is vital to attend all sessions because they are in sequence. If you honestly feel that you won't be able to come, please let us know and another person can take your place.

If required, we can provide a Doctor's Certificate for sessions when you have to take time off work.

A referral from your doctor is not necessary but you may wish to let him know that you are attending the programme.

Diabetes involves those who are close to you. It would be very helpful for you to bring a close friend or relative along to all sessions. Their needs are specially catered for.

Our programme is being asked by the Australian Government to participate in a study to find out the needs of diabetics and how to improve services available to them. Therefore, we are asking everyone who comes to the programme in the next year to participate in some assessments before and after going through the course. Your co-operation in this important study will be greatly appreciated.

The overall cost of the programme is $20 which includes literature, measuring utensils and meals for yourself and the relative or friend who comes with you. If the fee is difficult for you, please consult one of the team at the first session.

Yours sincerely,

[Redaction]

Dr. Martyn Sulway,
DIRECTOR

APPENDIX 3.8

DIABETES EDUCATION AND ASSESSMENT PROGRAMME

LIST OF PROGRAMMES AND ASSESSMENT

DATES AND TIMES

PROGRAMME/ ASSESSMENT	DATE	DAY OF WEEK	TIME
ASSESSMENT SESSION 1 (S-1)		MONDAY	7:15 AM to 9:30 AM
ASSESSMENT SESSION 2 (S-1)		MONDAY	7:15 AM to 9:30 AM
PROGRAMME 1		MONDAY	7:00 - 10:00 PM
INDIVIDUAL APPOINTMENT		MONDAY (day)	time to be arranged at prog 1
PROGRAMME 2		MONDAY	7:00 to 10:00PM
PROGRAMME 3		THURSDAY	7:45 AM to 3:30 PM
PROGRAMME 4			7:45 AM to 3:30 PM
PROGRAMME 5		WEDNESDAY	7:00 to 10:00 PM
PROGRAMME 6		THURSDAY	7:00 PM to 10:00 PM

PLEASE NOTE: For all early morning sessions please:

1. DO NOT eat or drink anything after midnight on the night before you come. (except water, black tea or coffee) (This is for a fasting blood test).
2. DO NOT take your injection or eat breakfast before you come.
3. BRING your insulin & syringes
4. BRING your relative or friend who is coming through the programme.
5. We will provide breakfast for you and your friend or relative.

APPENDIX 3.9

DIABETES EDUCATION AND
ASSESSMENT PROGRAMME

HEALTH AND TREATMENT DETAILS
QUESTIONNAIRE

NAME _____

DATE _____

The following information will be useful to us in planning programme sessions, and for our records. Please complete and bring with you to the first session. Your answers will be kept confidential.

1) Name and address of doctor (general practitioner)

_____

_____

_____

Name and address of diabetic specialist

_____

_____

_____

2) In general, how would you describe your health in the last six months? Please circle your answer.

Very good Good Fair Poor

Comments _____

_____

3) Over the last few weeks, how has your diabetes been going?

_____

_____

_____

4) Have you been hospitalised in the last 12 months because of your diabetes?

Yes _____

No _____

If Yes, please give details _____

_____

_____

_____

5) Do you have any other health or medical problems (besides diabetes) that you know of?

Yes _____
No _____

If Yes, please give details _____
_____
_____

6) Are you taking medicines for any condition other than diabetes? (such as heart or blood pressure)?

Yes _____
No _____

If Yes, please list the medicines

1. _____
2. _____
3. _____
4. _____

7) Comparing your weight today with your weight a year ago do you ..... (circle one answer)

Weigh more Weigh the same Weigh less

8) Do you consider yourself to be ..... (circle one answer)

Overweight Ideal weight Underweight

9) If your weight has changed over the last year, what do you think it was due to? (things such as control of diabetes, dieting, exercise, etc).

_____
_____
_____

10) If weight is a problem for you, has it been a problem .....? (Please circle the letter which goes with your choice)

a) all of your life
b) sometimes
c) just recently

11) What type of treatment are you on for your diabetes? (please circle the letter which goes with your answer)

a) insulin injections
b) tablets
c) diet alone
d) other

12) If you take insulin injections,

a) how long have you been taking insulin injections?_____

b) what type and amount of insulin do you use daily?

Morning dose TYPE _____ NO. OF UNITS _____ STRENGTH _____

Afternoon dose TYPE _____ NO. OF UNITS _____ STRENGTH _____

Evening TYPE _____ NO. OF UNITS _____ STRENGTH _____

13) If you take tablets for your diabetes
what brand and amount do you take daily?

BRAND _____ No. of tablets per day _____
OR per week _____

14) Have you ever been given a diet for your diabetes?

Yes _____
No _____

15) If Yes, from whom did you get your first diet?

doctor _____
dietitian _____
other _____

16) Have you been to see a dietitian since you were first diagnosed?

Yes _____
No _____

If No, skip to Question 17

If Yes, at which hospital or clinic?

_____

And, approximately how long ago was your last visit to a dietitian?_____

17) Are you following any kind of diet?

Yes _____
No _____

If Yes, describe what kind _____

_____

_____

_____

18) If you have been given a calorie recommendation, what number of calories have been recommended for you?

_____ calories

_____ don't know

19) If you have been given a "portion diet", what number of carbohydrate portions or carbohydrate substitutions have been recommended for you?

B'fast _____ M. Tea _____ Lunch _____ A. Tea _____

Dinner _____ Supper _____ Total Day _____

20) Do you have any dietary restrictions <u>other</u> than those for your diabetes?

Yes _____

No _____

If Yes what are those restrictions? _____

_____

_____

21) How often, in a year, do you visit the following health professionals? Please tick. (✓)

	More than twice a year	Twice a year	Once a year	Less than once a year	Never
a) Dentist					
b) Chiropodist (foot specialist)					
c) Eye specialist					
d) A doctor (G.P.)					
e) A diabetic specialist					
f) A dietitian					

22) When did you <u>last</u> have a blood sugar test? (from the vein)

_____

23) Do you own a self-testing blood sugar machine?

Yes ___

No ___

24) How did you first hear about our programme?

_____

_____

_____

25) Have you ever been to any other diabetes education programme?

Yes ___

No ___

If Yes where? _____

_____

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

APPENDIX 3.10

RANDOMISED CONTROLLED TRIAL

DATES OF ASSESSMENTS FOR EDUCATION GROUPS

DATES OF EDUCATION PROGRAMME (a)	STREAM 1 3 MONTH PRE-INTERVENTION	STREAMS 1 AND 2 3 MONTH POST-INTERVENTION	STREAM 2 6 MONTH POST-INTERVENTION ASSESSMENT (b)
DRESS REHEARSAL GROUPS			
1. 28 April to 28 May, 1980	---	19,26 Aug. 80	18,25 Nov. 80
2. 9 June to 9 July, 1980	21 April, 70 (7 weeks before programme)	7,14 Oct. 80	20,27 Jan. 80
STUDY GROUPS			
3. 14 July to 7 August, 1980	19,26 May, 80	3,10 Nov. 80	17,24 Feb. 80
4. 4 to 28 August 1980	9,17 June, 80	18,25 Nov. 80	3,10 Mar, 80
5. 13 October to 6 November, 1980	14,21 July, 80	17,24 Feb. 80	12,19 May, 81
6. 27 October to 20 Nov, 1980	18,25 Aug, 81	3,10 Mar, 81	9,16 June, 81
7. 17 November to 11 Dec. 1980	22,29 Sep, 80	17,24 Mar, 81	7,14 July, 81
8. 19 January to 12 February 1981	21,28 Oct. 80	12,19 May, 81	4,11 Aug, 81
9. 9 February to 12 March, 1981	18,25 Nov. 80	9,16 June, 81	15,22 Sep. 81
10. 16 March to 9 April, 1981	20,27 Jan. 80	7,14 July, 81	6,13 Oct. 81
11. 21 April to 14 May, 81	2,9 Feb. 81	4,11 Aug. 81	3,10 Nov. 81
12. 11 May to 4 June, 1981	16,23 Feb. 81	15,22 Sept. 81	17,24 Nov. 81
13. 8 June to 2 July, 1981	9,16 Mar, 81	29 Sept. 7 Oct, 81	1,8 Dec. 81
14. 13 July to 6 August, 1981	20,27 Apr. 81	2,9 Nov. 81	7,14 Feb. 82

N.B. Assessments will not be held during the Christmas period 15 December to 15 January when people alter their eating habits and/or go on holidays.

To eliminate possible influence of post-intervention subjects, pre-assessment clients cannot be assessed on some days as post-assessment clients.

(a) Dates of immediate pre-programme assessments for Streams 1 and 2 are the Monday after the first session of education programme.

(b) Due to poor subject "return" rates (53%) after the first 4 scheduled 6-month follow-ups, they were discontinued.

APPENDIX 3.11

CRITERIA FOR DISCONTINUATION OF RANDOMISED CONTROLLED TRIAL

The study will be discontinued if:-

A. The following deadlines are not met for any reason -

(i) pre-testing data gathering instruments by 15th April, 1980

(ii) dress rehearsal run-through of three month pre-assessment by 21st, 28th April

(iii) all instruments and procedures revised by 1st May, 1980

(iv) nursing sister and/or interviewer hired and trained by 1st May, 1980

(v) first study assessment by 12th May, 1980 and schedule of assessments listed in protocol adhered to ($\pm$ two weeks)

B. The subject drop-out or non-participation rate in assessments is high, i.e. a drop-out of greater than 25% occurred at any of the following points:-

1. Three-month pre-assesment (Stream 1 subjects) -

(i) do not keep appointment for three month pre-assessment

(ii) refuse to -

(a) complete food record adequately

(b) participate in any of the assessment procedures.

(To be determined by July, 1980 "dress rehearsal" group and first three study groups)

2. Pre-programme assessment (Stream 1 or 2 subjects) -

(i) refuse to participate in the assessment procedures immediately prior to entry into programme,

3. Education programme (Both Streams)

(i) do not appear at the first education programme

(ii) Stream 1 or 2 subjects fail to attend five out of six of the education programme sessions.

(To be determined by November, 1981 "dress rehearsal" groups and first on three study groups).

4. Three-month post-programme assessments (Both Streams) -

(i) Stream 1 or 2 subjects fail to return for a complete three month post-programme assessment.

(To be determined by end of November, 1980 on "dress rehearsal" group and first two study groups).

(II) funds become unavailable for the salary of myself (Karen Webb) or the current staff of the D.E.A.P.

(III) the D.E.A.P. staff for any reason, are unable to carry out the intervention programmes as scheduled in the protocol.

5. Six-month post-programme assessments (Stream 2) -

(I) Stream 2 subjects fail to return for or to complete six month follow-up assessments.

(To be determined by May, 1981 on "dress rehearsal" groups and first 3 study groups).

APPENDIX 3.12

SCHEDULE OF ASSESSMENT PROCEDURES FOR D.E.A.P. TEAM

1. 3 Month Pre-Intervention (RCT - Stream 1)

   First Morning (7:15 a.m.)

   1. Fasting blood sample (Venesection)
   2. Weights/Heights/Skinfolds
   3. Food record training + breakfast
   4. Urine collection instructions
   5. Health belief interviews
   6. Collect demographic questionnaire
   7. General Health questionnaire

   Second Morning (1 week later) 7.15 a.m.

   1. Fasting blood sample
   2. Weights
   3. Collect and check food record
   4. Health belief interviews on remaining subjects
   5. Quality of Life questionnaire
   6. Knowledge questionnaire
   7. Collect urine specimen

2. Pre-programme Assessments (Both Studies)

   Programme 1 (evening)

   1. Food record training
   2. Knowledge questionnaire
   3. Urine collection instructions

   Individual Appointments (1 week later)

   1. Collect and check food record
   2. Weights, Heights, Skinfolds
   3. Quality of Life questionnaire
   4. General Health questionnaire
   5. Health belief interview
   6. Collect 24-hour urine

   Programme 3 (7.15 a.m.)

   1. Fasting blood sample
   2. Weight

   Programme 4 (7.15 a.m.)

   1. Fasting blood sample

3. 3 and 6 Month Post-Education Assessments

First Morning 7.15 a.m.

1. Fasting blood sample
2. Weights/Heights/Skinfolds
3. Food record training and breakfast
4. Urine collection instructions
5. Health belief interviews
6. General Health questionnaire

Second Morning (7.15 a.m.)
(1 week later)

1. Fasting blood sample
2. Weights
3. Collect and check food record
4. Health belief interviews on remaining subjects
5. Quality of Life questionnaire
6. Knowledge questionnaire
7. Collect 24-hour urine

FOOD AND DRINK RECORD - EXAMPLE OF HOW TO RECORD YOUR FOOD AND DRINK

YOUR NAME M. MOUSE TODAY'S DATE 13.6.78 DAY OF WEEK WED.

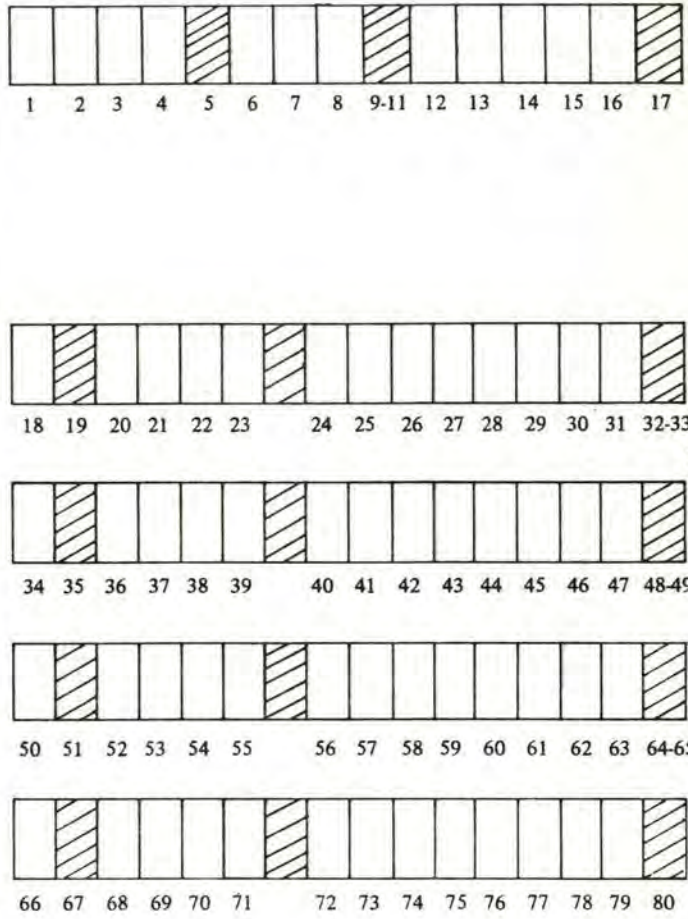
OFFICE USE ONLY

NOTE: ONLY ONE FOOD ITEM PER LINE PLEASE

PUT AN * BY THOSE FOODS WHICH ARE DESCRIBED ON RECIPE SHEETS

THIS IS NOT A DIET SHEET!

ITEMS FOOD OR BEVERAGE PLATE OR CUP	COOKING METHOD	BRAND OF FOOD	MEAL TIME	SCALE AMOUNT SERVED	READING AMOUNT LEFT	ANY HYPOS OR EXERCISE TIME?	NOTES
BOWL	—		B'FAST 7:30 A.M.	205			
CORN FLAKES	—	KELLOG'S		235			
MILK (ON CEREAL)		DIPLOMA - SKIM		355			dilution: 1 PART POWDER TO 2 PARTS WATER
MILK (IN TEA)		FULL CREAM - PETERS	V	20 MLS.			



APPENDIX 3.13

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FORM NUMBER 2

FOOD AND DRINK RECORD – EXAMPLE OF HOW TO RECORD YOUR FOOD AND DRINK 2

YOUR NAME M. MOUSE TODAY'S DATE 13·6·78 DAY OF WEEK WED.

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THIS IS NOT A DIET SHEET!

ITEMS FOOD OR BEVERAGE PLATE OR CUP	COOKING METHOD	BRAND OF FOOD	MEAL TIME	SCALE AMOUNT SERVED	READING AMOUNT LEFT	ANY HYPOS OR EXERCISE TIME?	NOTES
PLATE		—	B'FAST	120			
TOAST		TIP TOP WHITE		155			
BUTTER		NORCO		160			
APRICOT JAM		MRS. TREWENS	✓	165			

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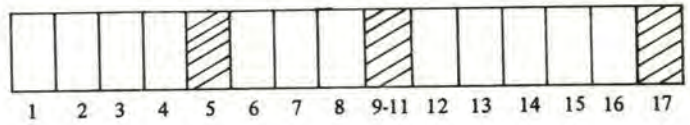

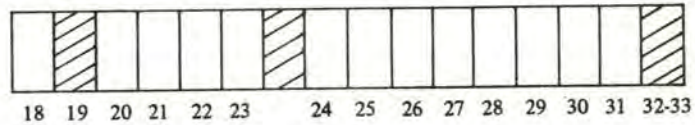

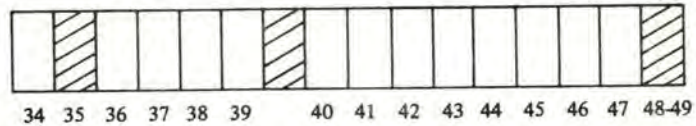

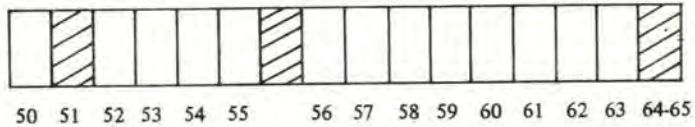

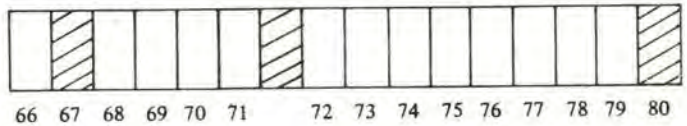

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FORM NUMBER 2

FOOD AND DRINK RECORD – EXAMPLE OF HOW TO RECORD YOUR FOOD AND DRINK

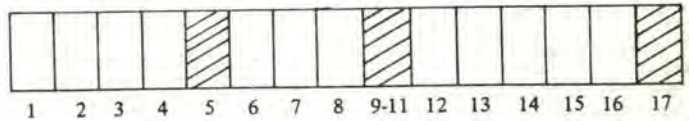
YOUR NAME M. MOUSE TODAY'S DATE 13·6·78 DAY OF WEEK WED.

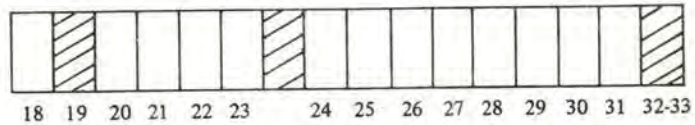
NOTE: ONLY ONE FOOD ITEM PER LINE PLEASE

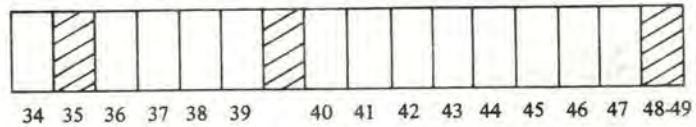
PUT AN * BY THOSE FOODS WHICH ARE DESCRIBED ON RECIPE SHEETS

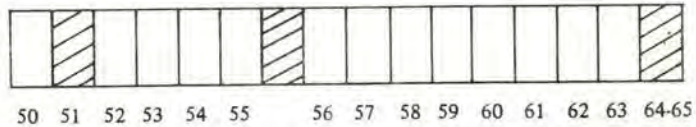
THIS IS NOT A DIET SHEET!

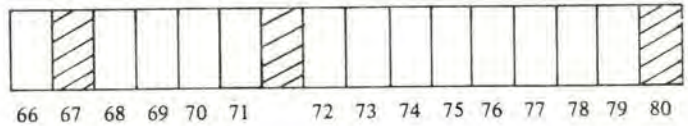
ITEMS FOOD OR BEVERAGE PLATE OR CUP	COOKING METHOD	BRAND OF FOOD	MEAL TIME	SCALE AMOUNT SERVED	READING AMOUNT LEFT	ANY HYPOS OR EXERCISE TIME?	NOTES
JELLY BEANS			11:30	7 jelly Beans 30g (weighed later)		Hypo 11:15 AM.	
BREAD (ROAST BEEF SANDWICH)		WHITE	LUNCH 1:30	4 Slices			ATE AT JOE'S DELI ESTIMATED
MARG.			↓	GENEROUS SPREAD ON ALL SLICES			
ROAST BEEF	RARE		↓	3 THIN SLICES ON EACH (JUST COVERED BREAD)			











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FOOD AND DRINK RECORD – EXAMPLE OF HOW TO RECORD YOUR FOOD AND DRINK

YOUR NAME M. MOUSE TODAY'S DATE 13.6.78 DAY OF WEEK WED.

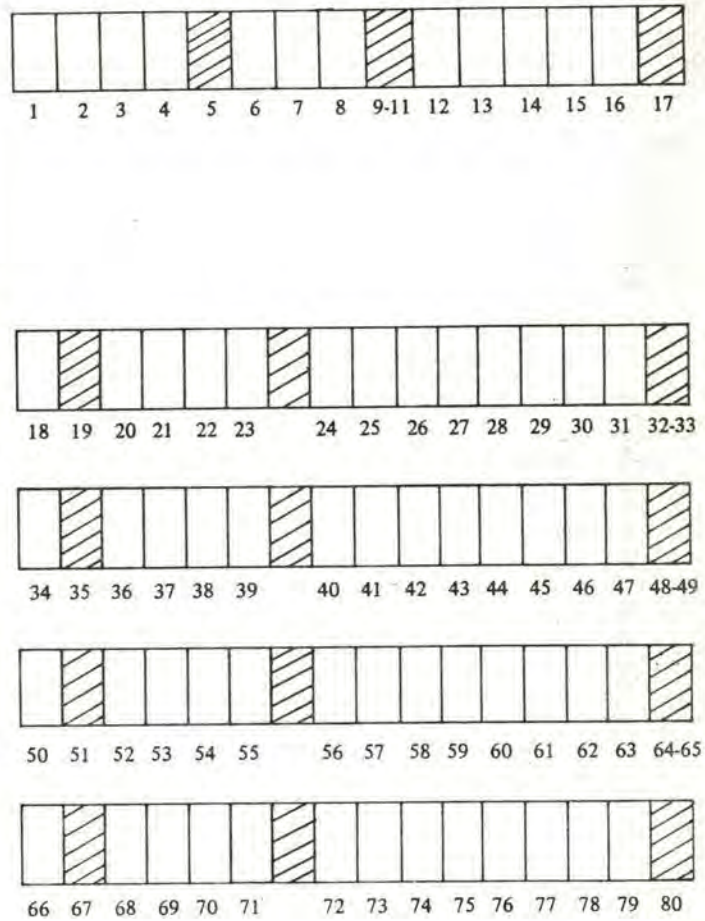
OFFICE USE ONLY

NOTE: ONLY ONE FOOD ITEM PER LINE PLEASE

PUT AN * BY THOSE FOODS WHICH ARE DESCRIBED ON RECIPE SHEETS

THIS IS NOT A DIET SHEET!

ITEMS FOOD OR BEVERAGE PLATE OR CUP	COOKING METHOD	BRAND OF FOOD	MEAL TIME	SCALE AMOUNT SERVED	READING AMOUNT LEFT	ANY HYPOS OR EXERCISE TIME?	NOTES
APPLE	—	GRANNY SMITH	A.T. 3:30	1 LARGE 130	CORE AND PIPS		weighed in Am. – took with me to work.
ORANGE JUICE		ORCHY	A.T. 4:30	300 mLs.		BEFORE GAME OF BOWLS	Bought at milk BAR
PLATE			DINNER 6:30	50			
Spaghetti NOODLES	BOILED WITH 1 TBSP OIL	MILANO (EGG TYPE)	↓	175			



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FOOD AND DRINK RECORD - EXAMPLE OF HOW TO RECORD YOUR FOOD AND DRINK

YOUR NAME M. MOUSE TODAY'S DATE 13·6·78 DAY OF WEEK WED.

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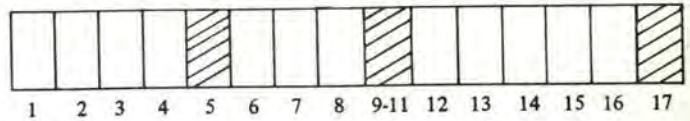
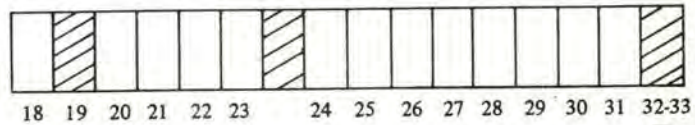
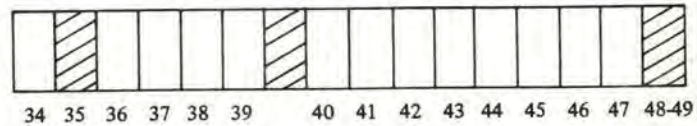
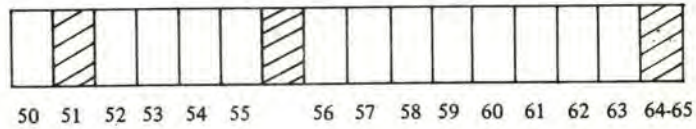
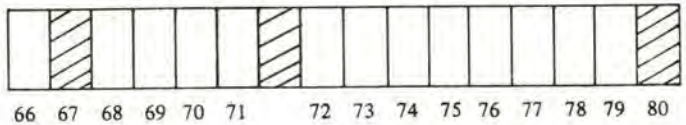
ITEMS: FOOD OR BEVERAGE PLATE OR CUP	COOKING METHOD	BRAND OF FOOD	MEAL TIME	SCALE: AMOUNT SERVED	READING: AMOUNT LEFT	ANY HYPOS OR EXERCISE TIME?	NOTES
Spaghetti BOLOGNAISE SAUCE *	See RECIPE	—	DINNER 6:30 p.m.	380			
TOSSED SALAD *	SEE RECIPE	—		440			
GLASS				130			
WINE		mc WILLIAMS CLARET	↓	280	ARE YOU KIDDING?		











S.O. 3540 D. West, Government Printer

RECIPE SHEET

NAME M. MOUSE

DAY OF WEEK WED.

INGREDIENTS	SCALE READING
SPAGHETTI BOLOGNAISE SAUCE	
PLATE	50
MINCE Beef, lean, RAW	305
TOMATOES IN TINS	250
TINS (EMPTY)	40
PLATE	50
ONION, CHOPPED	225
MUSHROOMS, FRESH	305
OIL	2 METRIC TBSP.
TOMATO PASTE	3 METRIC TBSP.
GARLIC, CRUSHED	2 CLOVES
RED WINE	½ CUP
WATER	½ CUP
TOSSED SALAD	
BOWL	
LETTUCE	120
TOMATOES	180
CAPSICUM	280
OIL	310
VINEGAR	1 TESP.
	1 TBSP.

APPENDIX 3.14

DIABETIC EDUCATION AND ASSESSMENT PROGRAMME

ROYAL NORTH SHORE HOSPITAL

HOW TO KEEP A FOUR-DAY FOOD AND DRINK RECORD

1. WHICH DAYS?

Wednesday morning first thing through Saturday nights' supper (four consecutive days, including 3 weekdays and one weekend day).

2. WHY DO A RECORD?

a) for a computer analysis of your food and drink
b) to help us plan the programme to meet your needs
c) for a study we are doing on the food and drink of diabetes and their families in Australia.

3. EAT NORMALLY OR STICK TO YOUR DIET?

During the four day period, it is very important that you eat as you normally do, including snacks, dining-out, parties, etc. If you alter what you eat just for the recording period, the programme may not be as much help to you and we will make wrong conclusions in our study. We are NOT checking up on you. No one will see your food records except the Education programme staff. If you wish your doctor and dietitian to receive a copy of the computer analysis, you can let us know when you have completed the education programme.

4. WHY DO YOU NEED TO BE SO CAREFUL AND THOROUGH ABOUT RECORD KEEPING?

The computer is very exact so you need to be, too. If you make mistakes, the computer will make mistakes in its calculations!

5. HOW AND WHAT DO YOU RECORD?

Study the example provided in your packet. A summary of the important rules are:

a) EVERYTHING you eat and drink for 4 days is to be recorded except water, black coffee or tea and medications (This includes food or drink which may not be 'on your diet', e.g. lollies, beer, etc.)

b) Record foods and weights before you eat or drink directly on the forms provided (not scrap paper). It's easy to make mistakes recopying foods and weights!

c) Write in only 1 food per line (bread and margarine are two foods).

d) Fill in as many spaces as you need for each meal and as many pages as you need for each day.

e) Start a new sheet for each day.

f) Write in meal and time.

g) Give us as much detail as possible. For example, whether bread is white, brown or wholemeal, whether fruit is peeled or unpeeled, meat is fatty or lean. Don't forget brand names if it is a commercial product.

h) Be sure to tell us cooking method, especially if any oil or fat is used.

i) If you are diabetic and have a "hypo" (low blood sugar reaction) during the food record period - record any food or drink that you treat it with and note this in "hypos" column.

j) If you take any extra food or drink especially for exercise, please note this in the "hypos and exercise" column.

6. HOW DO YOU WEIGH FOOD AND DRINK? (for 'amount served' & 'amount left' column)

a) Use the Salter Scales provided (these are very expensive and accurate)

b) Read the scales correctly: each small mark is equal to 5 grams each large mark 25 grams.

STEP 1

Zero the scale before weighing plate or cup by turning knob at the back of scale until dial points exactly to zero.

STEP 2

Put plate on scale. Record scale reading as follows.

ITEMS FOOD OR BEVERAGE PLATE OR CUP	COOKING METHOD	BRAND OF FOOD	MEAL TIME	SCALE AMOUNT SERVED	READING AMOUNT LEFT
Plate				325	

STEP 3

Add one item of food. Record scale reading

ITEMS FOOD OR BEVERAGE PLATE OR CUP	COOKING METHOD	BRAND OF FOOD	MEAL TIME	SCALE AMOUNT SERVED	READING AMOUNT LEFT
Plate				325	
Cheese				380	

STEP 4

Add next item of food. Repeat as above

ITEMS FOOD OR BEVERAGE PLATE OR CUP	COOKING METHOD	BRAND OF FOOD	MEAL TIME	SCALE AMOUNT SERVED	READING AMOUNT LEFT
Plate				325	
Cheese				380	
Bread				410	

EACH TIME, SIMPLY RECORD THE SCALE READING, DO NOT WORK OUT THE ACTUAL WEIGHT OF THE FOOD

7. HOW DO YOU WEIGH LEFT-OVER FOOD AND BONES?

a) IF ONLY ONE ITEM IS LEFT OVER

STEP 1

Zero the scale

STEP 2

Put plate or cup and left-over food or drink back on scale and record scale reading as follows :

ITEMS FOOD OR BEVERAGE PLATE OR CUP	COOKING METHOD	BRAND OF FOOD	MEAL TIME	SCALE AMOUNT SERVED	READING AMOUNT LEFT
Plate plus cheese					340

b) IF MORE THAN ONE ITEM IS LEFT OVER

STEP 1

Zero the scale

STEP 2

Put clean plate on scale and record as follows :

ITEMS FOOD OR BEVERAGE PLATE OR CUP	COOKING METHOD	BRAND OF FOOD	MEAL TIME	SCALE AMOUNT SERVED	READING AMOUNT LEFT
Plate					320

STEP 3

Put first left-over on plate and record scale reading as follows:

ITEMS FOOD OR BEVERAGE PLATE OR CUP	COOKING METHOD	BRAND OF FOOD	MEAL TIME	SCALE AMOUNT SERVED	READING AMOUNT LEFT
Plate					320
Bones					350

STEP 4

Add next item to plate and repeat as above

ITEMS FOOD OR BEVERAGE PLATE OR CUP	COOKING METHOD	BRAND OF FOOD	MEAL TIME	SCALE AMOUNT SERVED	READING AMOUNT LEFT
Plate					320
Bones					350
Potatoes					380

NOTE: For left-over foods which you cannot separate, record as follows:

ITEMS FOOD OR BEVERAGE PLATE OR CUP	COOKING METHOD	BRAND OF FOOD	MEAL TIME	SCALE AMOUNT SERVED	READING AMOUNT LEFT
Bowl plus cornflakes and milk					420

8. HOW DO YOU RECORD MIXED FOODS? (like casseroles, stews, salads)

   a) Use a recipe sheet provided

   b) Weigh all ingredients and record as per example for spaghetti in "M. Mouse" example FOOD RECORD

   c) Weigh your serve and record on food record

   d) Place an * next to recipes (as per example for meat sauce)

9. WHAT DO YOU DO WHEN YOU'RE EATING OUT?

   a) Take the scales if you can

   b) If not, estimate everything as accurately as possible

   c) Do not estimate in grams - estimate in cupsful, spoonsful or inches

   d) If you don't know how a food was prepared or what was in it - estimate major ingredients

   e) Clearly mark on record, meals or food items whose weights have been estimated rather than weighed

10. WHAT DO YOU DO IF YOU HAVE QUERIES?

    Ring us on 438 4584

11. WHAT DO YOU DO IF YOU'RE FED-UP WITH RECORDING?

    Congratulate yourself for putting in the effort to keep a food record and REMEMBER - this is only four days of your life and results may be invaluable to you and other diabetics.

HAPPY RECORDING!

APPENDIX 3.15

THE RELIABILITY OF FOUR-DAY FOOD RECORDS

IN ASSESSING DIETARY COMPLIANCE OF INSULIN-DEPENDENT DIABETICS

Seven-day food records are generally regarded as the best available method to assess quantitatively, the nutrient intake of individuals (Marr 1971). However, it is not always possible to obtain dietary records from subjects for a full seven days. When less than seven days are measured, it has been recommended that a pilot study be carried out on a sample of the proposed study population to identify how many and which days of the week are required to assess reliably the dietary variables of interest (Young and Trulson 1960).

In the proposed evaluation studies of the D.E.A.P., a four-day food recod was thought to be the longest period in which subjects would co-operate with record-keeping, particularly in view of the many other assessment procedures with which they were expected to co-operate. As well, there was a need to process the food records promptly for use in the education programme.

The choice of days of the week (Wednesday through Saturday) was based on the programme schedule and on the need to obtain a representative picture of food intake through the week (including at least one week-end day).

Aspects of dietary compliance of most interest in the proposed evaluation studies included:-

(a) the percentage of energy contributed by complex carbohydrate,
(b) carbohydrate spacing (or distribution) throughout 3 major meal periods during the day, and
(c) carbohydrate variation between days

Compliance with goals for protein, sugar and alcohol intake were also of interest.

The aim of this reliability study was to identify how accurately the four-day food records estimated dietary compliance in insulin-dependent diabetics as compared with compliance estimates based on seven-day records.

Methods

In November, 1976, seventeen insulin-dependent diabetics who were referred from the D.E.A.P. team's endocrinologist and a diabetic clinic at the Royal North Shore Hospital of Sydney volunteered for participation in the study. Although the volunteers had not attended the education programme, many of them were booked to attend and hence, they were thought to represent the prospective study population. The ages of the subjects ranged from 14 to 70 and there were eight males and nine females.

Subjects were asked to keep food records (in household measures) for seven consecutive days. They were trained in record-keeping procedures by the D.E.A.P. nutritionist and were visited at home on alternate days during the week of record-keeping to check for anomalies and inaccuracies and to provide encouragement for the continuation of the dietary records.

The dietary data from seven-day records were coded and processed by computer according to procedures described by Heywood et al (1978) and Zed et al (1977). The daily totals for energy, protein, complex carbohydrate, fat, sugar and alcohol were computed together with the average contribution of nutrients to average energy intake.

Carbohydrate spacing and variation scores were calculated from carbohydrate intake during each of the three daily meal periods, according to procedures described in Appendix 3.27. Differences between the means for four days of the record and for the full seven days were compared. In analyses of variance with days as the factor (Programme P_2V, BMDP manual, 1977). Individuals were classified as compliers or non-compliers for several aspects of the dietary regimen and the frequencies of misclassification were determined.

Results

The means and standard errors of complex carbohydrate and fat for each of the 17 subjects are shown in Tables 1 and 2 and are based on four-day and seven-day records. Individual values for protein, alcohol, sugar spacing and variation scores are not shown but the group means for these variables calculated from four and seven days are given in Table 3, along with details of the analyses of variance.

For the majority of subjects, there were only slight differences between four-day and seven-day estimates of the carbohydrate and fat composition of diets and the differences in group means were not statistically significant. For only two subjects (2 and 9) were the differences considerable; the four-day records underestimated the average percentage of carbohydrate while for fat the discrepancies for three subjects (2, 5 and 13) were not in the same direction (Table 2). Differences in the means for percentage of energy consumed as protein, alcohol and sugar as assessed on 4 days compared with seven days were not statistically significant (Table 3).

The means for individuals in spacing and variation scores (not shown) were different for several subjects particularly in spacing scores. For the group mean the four-day records yielded significantly lower (better) spacing scores than did the seven-day records. The mean variation score was also lower on the basis of four-days but this difference was not statistically significant.

Table 4 shows the frequency of misclassification of compliers and non-compliers on the basis of the four-day [compared with] seven-day records. Compliers were defined as those who (a) consumed at least 45% complex carbohydrate, (b) achieved carbohydrate spacing and variation scores of .07 and .03, respectively, or (c) consumed 5% or less of their energy intake as alcohol and refined sugar.

The frequencies of misclassification to compliance categories for carbohydrate composition, variation, alcohol and sugar intake were low i.e. 1, 2, 1, and 2, respectiveley. However, nearly one-third of subjects were misclassified as compliers with spacing recommendations from four-day records.

Discussion

These results suggest that for several aspects of dietary compliance of interest in the evaluation studies of the D.E.A.P., the four-day records provide sufficiently reliable estimates of the compliance level of individuals and of the group, when compared with seven days. Over 90% of the sample were correctly classified on compliance with carbohydrate composition, variation alcohol and sugar recommendations on the basis of four-day records. However, the estimates for spacing compliance appear to be somewhat unreliable since one-third of subjects were misclassified from four-day records. Thus, compliance with spacing tends to be overestimated using four-day records.

Clearly, the generalisability of these results is limited since the sample may not be representative of all insulin-dependent diabetics likely to attend the D.E.A.P. However, the very high rates of non-compliance are consistent with those we observed at the initial assessments in the pilot evaluation and in our later evaluation studies, suggesting that this sample of 17 were similar in baseline compliance to the D.E.A.P. programme participants.

Conclusions

Four-day records kept on Wednesday through Saturday gave reliable estimates of compliance with carbohydrate composition, sugar and alcohol, and carbohydrate variation recommendations for individual diabetics and for the group, as measured in our setting. However, four-day records over-estimated compliance with carbohydrate spacing recommendations.

For the purposes of compliance estimates in these evaluation studies of the D.E.A.P., i.e. measuring change in compliance and assessing factors relating to compliance, the four-day record appears to be a reasonable compromise. However, the results for the effects of the programme on compliance with spacing and predictors of spacing compliance may not be highly reliable since some non-compliers will be mis-classified as compliers.

APPENDIX 3.15

TABLE 1

CARBOHYDRATE

COMPARISON OF CARBOHYDRATE INTAKE (% of energy) CALCULATED FROM 7-DAY FOOD RECORDS AND FROM 4 DAYS (WEDNESDAY - SATURDAY) FOR 17 DIABETICS[a]

SUBJECT	AVERAGE OF 7 DAYS $\bar{x} \pm$ S.E.	AVERAGE OF 4 DAYS $\bar{x} \pm$ S.E.
1	40.66 ± 2.60	41.18 ± 2.04
2	35.47 ± 2.88	30.30 ± 2.65
3	29.06 ± 1.15	27.65 ± 1.74
4	43.41 ± 4.02	41.20 ± 6.43
5	30.33 ± 1.29	30.13 ± 1.28
6	36.96 ± 2.55	37.70 ± 4.35
7	32.69 ± 2.20	30.95 ± 2.78
8	33.04 ± 2.19	34.20 ± 3.95
9	33.53 ± 2.99	28.90 ± 3.74
10	30.94 ± 3.01	29.23 ± 3.60
11	32.94 ± 2.78	31.60 ± 4.55
12	32.89 ± 2.72	34.65 ± 4.28
13	43.47 ± 2.07	46.75 ± 2.00
14	35.34 ± 2.05	36.88 ± 3.05
15	31.44 ± 2.49	30.13 ± 3.80
16	34.96 ± 1.19	33.18 ± 2.69
17	40.59 ± 1.75	38.35 ± 0.94
Over all subjects	35.16 ± 1.08	34.29 ± 1.29

(a) only the differences between the group means were statistically tested - differences between 4 and 7 days for individuals were not. Details of analysis of variance shown in Table 3.

APPENDIX 3.15

TABLE 2

COMPARISON OF FAT INTAKE (% of energy) CALCULATED FROM SEVEN-DAY FOOD RECORDS AND FROM FOUR DAYS (WEDNESDAY - SATURDAY) FOR 17 DIABETICS[a]

FAT

SUBJECT	AVERAGE OF 7 DAYS $\bar{X} \pm$ S.E.	AVERAGE OF 4 DAYS $\bar{X} \pm$ S.E.
1	44.69 ± 2.48	44.45 ± 1.82
2	44.07 ± 3.60	50.05 ± 3.06
3	42.53 ± 2.43	45.30 ± 3.01
4	35.06 ± 3.50	37.23 ± 6.02
5	44.40 ± 3.90	39.55 ± 5.33
6	31.29 ± 1.83	30.58 ± 2.79
7	45.63 ± 3.64	48.33 ± 6.24
8	44.94 ± 2.89	43.05 ± 5.09
9	38.30 ± 1.94	39.18 ± 3.40
10	48.59 ± 2.87	48.83 ± 4.16
11	35.47 ± 2.37	32.03 ± 2.47
12	37.96 ± 1.59	39.25 ± 1.83
13	39.91 ± 2.39	35.90 ± 1.61
14	38.30 ± 1.49	36.60 ± 2.26
15	47.61 ± 1.07	47.58 ± 0.31
16	39.60 ± 2.08	41.50 ± 1.84
17	46.49 ± 2.49	44.28 ± 0.56
Over all subjects	41.11 ± 1.15	41.39 ± 1.41

APPENDIX 3.15

TABLE 3

COMPARISON OF ESTIMATES OF DIETARY COMPOSITION, SPACING AND VARIATION SCORES FROM FOUR-DAY FOOD RECORDS (WEDNESDAY - SATURDAY) WITH THOSE FROM SEVEN-DAY RECORDS: ANALYSES OF VARIANCE FOR 17 INSULIN-DEPENDENT DIABETICS

	7 days $\bar{x} \pm$ sem	4 days $\bar{x} \pm$ sem	df	$F^{\dagger\#}$	p
Complex carbohydrate	35.16 ± 1.08	34.29 ± 1.29	1,16	2.62	0.13
Fat	41.11 ± 1.15	41.39 ± 1.41	1,16	0.16	0.69
Protein	16.87 ± 0.64	16.74 ± 0.64	1,16	0.24	0.63
Sugar	3.51 ± 1.00	3.74 ± 1.09	1,16	1.49	0.24
Alcohol	3.36 ± 0.98	3.83 ± 1.14	1,16	1.15	0.30
Carbohydrate spacing	0.77 ± 0.20	0.34 ± 0.07	1,16	5.67	0.03*
Carbohydrate variation	0.24 ± 0.10	0.13 ± 0.18	1,16	1.03	0.32

F ratio shown is between days i.e. 4-day means vs 7-day means

* Statistically significant at $p < .05$

APPENDIX 3.15

TABLE 4

CLASSIFICATION MATRIX FOR DIETARY COMPLIANCE
BASED ON FOOD RECORDS OF SEVEN DAYS
AND FOUR DAYS FOR 17 INSULIN-DEPENDENT DIABETICS

A. CARBOHYDRATE COMPOSITION[a]

Seven days

Four days	Complier	Non-complier	Total
Complier	0	1	1
Non-complier	0	16	16
TOTAL	0	17	17

B. CARBOHYDRATE SPACING[b]

Seven days

Four days	Complier	Non-complier	Total
Complier	0	5	5
Non-complier	0	12	12
TOTAL	0	17	17

C. CARBOHYDRATE VARIATION[c]

Seven days

Four days	Complier	Non-complier	Total
Complier	1	2	3
Non-complier	0	14	14
TOTAL	0	16	17

APPENDIX 3.15

TABLE 4 (continued)

D. ALCOHOL (% of energy) (d)

Four days	Seven days: 0	LE 5%	GT 5%	Total
0	8	0	0	8
LE 5%	0	3	1	4
GT 5%	0	0	5	5
TOTAL	8	3	6	17

E. SUGAR INTAKE (% of energy) (d)

Four days	Seven days: LE 5%	GT 5%	Total
LE 5%	12	1	13
GT 5%	1	3	4
TOTAL	13	4	17

Compliers were those who -

(a) consumed at least 45% of energy contributed by complex carbohydrate

(b) obtained spacing scores of less than .07

(c) obtained variation scores of less than .03

(d) consumed 5% or less of energy intake as alcohol and sugar.

APPENDIX 3.16
DIABETES EDUCATION AND ASSESSMENT PROGRAMME

WEIGHT/BODY FAT INFORMATION

NAME _____ NUMBER ___ 1 2 3 4

STREAM NO. 5

ASSESSMENT NO. 6

WEIGHT 1 _____ Kg. Date _____ Time _____

WEIGHT 2 _____ Kg. Date _____ Time _____

AVERAGE _____ Kg. 7 8 9 10 11

HEIGHT _____ Cms 12 13 14

IDEAL WT. _____ Kg. 15 16 17 18

% IDEAL WEIGHT _____ % 19 20 21

Weight Category _____ 1 = OK
_____ 2 = reduce
_____ 3 = reduce slightly 22

SEX _____ 1 = female
2 = male 23

SKINFOLDS	1st	2nd	3rd	average				
triceps	___mm	___mm	___mm	___mm	24	25	26	27
biceps	___mm	___mm	___mm	___mm	28	29	30	31
subscapular	___mm	___mm	___mm	___mm	32	33	34	35
supraillac	___mm	___mm	___mm	___mm	36	37	38	39
TOTAL	___mm	___mm	___mm	___mm	40	41	42	43

Percent Bodyfat _____% 44 45 46 47

Date of Record _____ 48 49 50 51 52 53 54 55

Body Fat Standard _____% 56 57

Card Number 80

APPENDIX 3.17

Dear.....

During the time you have spent with us, several blood tests have been performed and we are now giving you the results.

B L O O D R E S U L T S

(Normal range.. 3.3 - 7.7 m.mol/l

.....Random blood sugar at.....m.mol/l

.....Fasting blood sugar at.....m.mol/l

.....Random blood sugar at.....m.mol/l

.....Fasting blood sugar at.....m.mol/l

.....Random blood sugar at.....m.mol/l

L I P I D R E S U L T S

C H O L E S T E R O L

(Normal range.. less than 6.5 m.mol/l

.....Fasting cholesterol .....m.mol/l

.....Fasting cholesterol .....m.mol/l

T R I G L Y C E R I D E S

(Normal range.. less than 1.8 m.mol/l

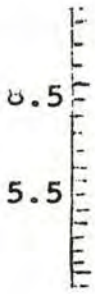
.....Fasting triglycerides .....m.mol/l

.....Fasting triglycerides .....m.mol/l

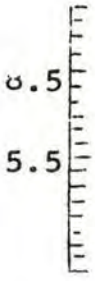
Cholesterol and triglycerides are waxy/fatty substances which circulate in the blood stream. When they build up too high they stick to the sides of the blood vessels and can eventually close the vessel and prevent blood from getting back to the heart. Many people in Australia, including non-diabetics have a problem with high blood fats.

F A S T H A E M O G L O B I N A1c R E S U L T S

.....



.....



The fast Haemoglobin is an index of diabetic control. It represents how much of the haemoglobin pigment inside the red cells is bound to glucose. This indicates the level that these red cells have been exposed to in the past four weeks. The normal range is 5.5% - 8.5%.

APPENDIX 3.18

DIABETES EDUCATION AND ASSESSMENT PROGRAMME

INSTRUCTIONS FOR 24-HOUR URINE COLLECTION

We would like you to collect exactly 24 hours of urine on .....at 8.00 a.m., through until ..... at 8.00 a.m. (It must be collected on one of the same days as the food record)

BE SURE TO THROW AWAY THE FIRST URINE SAMPLE ON THE FIRST DAY OF COLLECTION

We have provided 5 bottles for the collection.

The bottles contain preservative so do not rinse out

Remember to shake bottle with each specimen

Please refrigerate as soon as possible

Bring urine with you on.....

PLEASE TELL US ABOUT ANY MISTAKES IN COLLECTION

WHAT ABOUT URINE TESTS?

If using strip tests, dip in urine

If using clinitest, remove 5 drops

KNOWLEDGE QUESTIONNAIRE

NAME _____ DATE _____

DIRECTIONS

Read each item and decide which choice best completes the statement or answers the question. Please circle only one answer

1. The causes of people developing diabetes include -

   a) Eating too much sugar and other sweet foods
   b) Lack of effective insulin in the body
   c) Failure of the kidneys to control sugar in the urine
   d) I don't know

2. The best laboratory test for diagnosing diabetes is the -

   a) Urine test for sugar
   b) Urine test for acetone
   c) Blood test for sugar
   d) I don't know

3. In untreated diabetes the blood sugar is usually -

   a) Normal
   b) Increased
   c) Decreased
   d) I don't know

4. When a diabetic who routinely uses insulin increases his play or work, he most frequently will take -

   a) The same amount of insulin with additional food
   b) More insulin with less food
   c) Less insulin with the same amount of food
   d) I don't know

5. The effect of exercise is to -

   a) Lower the blood sugar level
   b) Raise the blood sugar level
   c) Increase sugar in the urine
   d) I don't know

6. Insulin causes blood sugar to -

   a) Increase
   b) Decrease
   c) Neither increase nor decrease
   d) I don't know

7. When a diabetic who routinely uses insulin becomes ill, he frequently requires -

   a) More insulin
   b) Less insulin
   c) No insulin
   d) I don't know

8. When injecting insulin, insert the needles into -

   a) Muscle tissue
   b) Skin
   c) Subcutaneous fatty tissue
   d) I don't know

9. When a diabetic changes from U-40 to U-80 insulin, he will need to take -

a) The same number of units of insulin
b) More units of insulin
c) Less units of insulin
d) I don't know

10. In the pregnant diabetic, the insulin requirements usually progressively -

a) Increase
b) Decrease
c) Stays the same
d) I don't know

11. When a diabetic is sick -

a) Carbohydrate intake should be sharply restricted
b) Foods other than carbohydrate should be increased
c) Carbohydrate in some form should be continued
d) I don't know

12. Insulin reaction or "hypo" is caused by -

a) Too much insulin or not enough food
b) Too much food and not enough insulin
c) Too little exercise
d) I don't know

13. When a diabetic has a "hypo" the amount of sugar in his blood is -

a) Unimportant
b) Usually high
c) Usually low
d) I don't know

14. When a diabetic begins to have a "hypo" he should immediately -

a) Take some insulin
b) Lie down and rest
c) Eat some sugar
d) I don't know

15. Food eaten by a diabetic to treat a "hypo" should be -

a) Subtracted from his next meal
b) Subtracted from the evening meal
c) Taken in addition to his total food allowance
d) I don't know

16. Routine urine tests for sugar are usually done -

a) Just before meals
b) One hour before meals
c) Two hours after meals
d) I don't know

17. Tests for ketones (Acetest tablets or Ketostix) turn the following colour when ketones are present -

a) Green
b) Blue
c) Purple
d) I don't know

18. A low blood sugar level is called -

a) Glycosuria
b) Hypoglycaemia
c) Hyperglycaemia
d) I don't know

19. The action of glucagon is to -

a) Raise the blood sugar
b) Lower the blood sugar
c) Neutralize insulin
d) I don't know

20. When urine is tested with Diastix a blue colour means -

a) Ketones present
b) Sugar present
c) No sugar present
d) I don't know

21. The presence of ketones in the urine of a diabetic is -

a) A warning sign of a "hypo"
b) A warning sign of ketoacidosis (very high blood sugars)
c) Unimportant
d) I don't know

22. When a person has a very high blood sugar (ketoacidosis) he may experience -

a) Sweating and convulsions
b) Rapid onset of coma
c) Thirst and excessive urination
d) I don't know

23. Which of the following possible complications is usually NOT associated with diabetes -

a) Changes in the eye
b) Changes in the kidney
c) Changes in the lung
d) I don't know

24. Large blood vessel damage (arteriosclerosis) is -

a) A special problem seen only in diabetics
b) A common problem seen earlier in diabetics than in non-diabetics
c) Responsible for eye problems
d) I don't know

25. Small blood vessel disease in diabetics is most readily recognised in the -

a) Feet and legs
b) Brain
c) Eyes and kidney
d) I don't know

26. Good care of the feet is important because diabetics often have -

a) Varicose veins
b) Corns and callouses
c) Poor circulation
d) I don't know

27. A diabetic treating a cut or abrasion should first -

a) Cleanse the cut with iodine or alcohol
b) Bandage the area
c) Cleanse with lukewarm water and soap
d) I don't know

28. When a diabetic drives, his main responsibility is to -

a) Have someone with him at all times
b) Eat more food if its been more than an hour since eating
c) Avoid driving long distances
d) I don't know

29. Which of the following methods of control should be used by all diabetics -

a) Diet
b) Oral
c) Insulin
d) I don't know

30. The best way to assess your diabetic control is -

a) A written record of daily urine or blood tests
b) Random urine test results
c) A single blood sugar test
d) I don't know

31. It is important to rotate injection sites from day to day because -

a) Insulin may be destroyed
b) Fat atrophy may develop
c) It doesn't make any difference
d) I don't know

32. On a diabetic portion diet, a portion refers to -

a) A normal serve of a carbohydrate food
b) 15 grams of food like bread, potato and rice
c) A normal serve of any food
d) A measured amount of carbohydrate foods that contain 15 grams of carbohydrate

33. In which of the following groups are all the foods carbohydrate portion foods -

a) Peas, oranges, eggs
b) Mayonnaise, low calorie soft drink, bran
c) Coconut, peanuts, yoghurt
d) Bread, milk, cheese

34. The healthy diabetic diet is different from the normal diet in that the diabetic diet needs to be -

a) Lower in carbohydrate
b) Kept constant in carbohydrate
c) Higher in protein
d) Lower in calories

35. Before strenuous exercise, diabetics need to -

a) Simply take an extra carbohydrate portion
b) Drink extra water
c) Eat more protein for energy
d) Take some food containing sugar and some extra portions of carbohydrate

36. When a diabetic shows 2% sugar in his urine, he should -

a) Reduce his carbohydrate at the next meal
b) Reduce his insulin
c) Eat the same amount of carbohydrate as usual and test urine regularly
d) Eat slightly more protein

37. One carbohydrate portion is found in -

a) 1 cup of milk
b) 1 cup of cornflakes
c) 1 cup of noodles
d) 1 cup of strawberries

38. If a diabetic needs 2 portions for morning tea and he has 2 jatz biscuits and 1 cup of milk he -

a) Is eating the right number of carbohydrate portions
b) Risks having a "hypo" before lunch
c) Is likely to get fat
d) Is on a slimming diet

39. An important risk in having an unbalanced diet, i.e. too much fat and protein is -

a) Becoming overweight
b) Developing vitamin deficiencies
c) Developing high cholesterol and possible heart troubles
d) I don't know

40. A healthy well-balanced diet is one which -

a) Contains a serve of protein at every meal
b) Has plenty of carbohydrate and moderate in fat and protein
c) Is low in carbohydrate, high in protein and moderate in fat
d) Contains lots of salads

41. Being overweight -

a) Doesn't matter more for diabetics than for other people
b) Makes diabetes harder to control
c) Is hereditary
d) Is something diabetics can't do much about when they are on insulin

42. Drinking alcohol -

a) Could cause a serious "hypo"
b) Is something diabetics are not supposed to do
c) Is no more dangerous for diabetics than others
d) Is more likely to cause liver disease in diabetics than in other people

43. Which of the following foods are <u>not</u> high in fat -

a) Steak
b) Polyunsaturated margarine
c) Bananas
d) Cheddar Cheese

44. A diabetic can eat or drink which of the following foods freely -

a) Steak
b) Mayonnaise
c) Choko
d) Dry wine

45. When a diabetic wants to reduce weight, he should:-

a) Cut down his carbohydrate
b) Reduce his insulin
c) Eat more serves of meat, cheese and salad
d) Follow a balanced reducing diet and reduce insulin

46. The most important things a diabetic with high cholesterol can do is -

a) Cut down on eggs and butter
b) Switch to polyunsaturated margarine and oil
c) Stay slim and eat less meat, cheese and fat
d) Eat more fruit, especially grapefruit

47. A diabetic's pancreas is -

a) A bit shrunken and darker in colour
b) Looks just like a non-diabetic's pancreas to the naked eye
c) Looks spotted to the naked eye
d) I don't know

48. The following things <u>DON'T</u> cause diabetes -

a) Viruses like mumps
b) Inherited tendency in the family
c) Being overtired too long
d) I don't know

49. The insulin you inject is -

a) A natural substance almost the same as human insulin
b) A foreign chemical that contributes to diabetic complications
c) Something you should try and take as little as possible
d) I don't know

50. Which of the following statements is true -

a) You can tell how your control is by the way you feel
b) Your blood sugar can be high and you can feel no symptoms
c) Blood sugar tests aren't necessary once your diabetes has been stabilized
d) I don't know

51. Specific diet foods sweetened with Sorbitol (like chocolate and Jam) are not recommended primarily because -

a) They are high calorie
b) They are dangerous
c) They cause blindness
d) They cause high urine sugars

o0o-o0o-o0o-

APPENDIX 3.20

DIABETES EDUCATION AND ASSESSMENT PROGRAMME

KNOWLEDGE QUESTIONNAIRE

NUMBER ☐ ☐ ☐ ☐ ☐ (1 2 3 4)

NAME _____ STR. NO. ☐ (5)

TODAYS DATE _____ ASSESS. NO. ☐ (6)

DIRECTIONS

Read each item and decide which choice best completes the statement or answers the question. Please circle the letter of the answer you choose. You can only choose one answer.

1. One cause of people developing diabetes is - OFFICE USE ONLY

   a) Eating too much sugar and other sweet foods
   b) A physical or emotional shock
   (c) Some viruses like mumps
   d) I don't know

   ☐ (7)

2. In poorly controlled diabetes, the blood sugar is usually -

   a) Normal most of the time
   (b) High most of the time
   c) Low most of the time
   d) I don't know

   ☐ (8)

3. A long walk, strenuous housework, or a game of tennis causes the blood sugar level to -

   (a) Decrease
   b) Increase
   c) Stay the same
   d) I don't know

   ☐ (9)

4. Insulin causes blood sugar to -

   a) Increase
   (b) Decrease
   c) Neither increase nor decrease
   d) I don't know

   ☐ (10)

5. When a diabetic on insulin gets an infection (s)he frequently needs-

   (a) A higher dose of insulin
   b) A lower dose of insulin
   c) Less carbohydrate
   d) I don't know

   ☐ (11)

6. When a diabetic has an illness -

   a) Carbohydrate intake should be sharply restricted
   b) Foods other than carbohydrate should be increased
   (c) Carbohydrate in some form should be continued
   d) I don't know

   ☐ (12)

7. When a diabetic has a "hypo" the amount of sugar in his blood is-

   a) Unimportant
   b) Usually high
   (c) Usually low
   d) I don't know

   ☐ (13)

8. When a diabetic feels that (s)he is about to have a "hypo" (s)he should immediately -

a) Eat some food of any kind
b) Eat some fruit or drink unsweetened fruit juice
c) Eat some food containing a fair amount of refined sugar
d) I don't know

14

9. If a diabetic takes food for a "hypo" just before a main meal (s)he should

a) Eat less food for that meal
b) Eat the same food but cut down the carbohydrate
c) Eat the usual amount of carbohydrate and other foods
d) I don't know

15

10. A low blood sugar level is called -

a) Glycosuria
b) Hypoglycaemia
c) Hyperglycaemia
d) I don't know

16

11. Glucagon injections are taken to

a) Raise the blood sugar
b) Lower the blood sugar
c) Neutralize insulin
d) I don't know

17

12. Ketones will be present in the urine of a diabetic

a) When he's taking too much insulin
b) When he hasn't been doing as much exercise as usual
c) The body is breaking down fat for any reason
d) I don't know

18

13. When a person has a very high blood sugar (ketoacidosis) he may experience -

a) Sweating and convulsions
b) Unconsciousness without warning
c) Thirst and excessive urination
d) I don't know

19

14. Which of the following is <u>not</u> one of the possible complications of poorly controlled diabetes -

a) Damage to the eye
b) Damage to the kidney
c) Damage to the lung
d) I don't know

20

15. Large blood vessel damage (arteriosclerosis) is -

a) A special problem seen only in diabetics
b) A common problem seen earlier in diabetics than in non-diabetics
c) Responsible for eye problems
d) I don't know

21

16. When a person wants to reduce weight in a healthy way, (s)he should -

a) cut down calories mainly from starchy foods
b) cut out sugar from the diet and eat more salads
c) cut down calories mainly from fatty foods
d) I don't know

22

17. In general, which of the following tells you <u>least</u> about how your diabetes is going -

a) a single blood sugar test done by your doctor
b) The way you feel
c) regular urine tests
d) I don't know

23

18. A diabetic should seek <u>urgent</u> medical advice if -

a) a urine test shows ketones and is free of sugar
b) vomiting and thirst develops
c) urine test shows 2% and ketone test is negative
d) I don't know

24

19. Good control of blood sugar over the years can prevent or minimize

a) diabetic damage to the liver
b) permanent nerve damage in the feet
c) cancer of the pancreas
d) I don't know

25

20. Good care of the feet is important because diabetics often -

a) have more ingrown toenails than non-diabetics
b) may not be able to feel cuts or infections
c) have more sensitive feet than other people
d) I don't know

26

21. A diabetic treating a cut or abrasion should -

a) Cleanse the cut with iodine or alcohol
b) Bandage the area
c) Cleanse with lukewarm water and soap
d) I don't know

27

22. When a diabetic drives, his <u>main</u> responsibility is to -

a) Have someone with him at all times
b) Eat more food if its been more than an hour since eating
c) Avoid driving long distances
d) I don't know

28

23. If a diabetic does not rotate his injection sites from day to day -

a) Insulin can accumulate
b) lumps and hollows may develop in the skin
c) Skin infections can occur
d) I don't know

29

24. On a diabetic portion diet, a portion refers to -

a) A normal serve of a carbohydrate food
b) 15 grams of food like bread, potato and rice
c) A measured amount of carbohydrate foods that contain 15 grams of carbohydrate
d) I don't know

30

25. In which of the following groups are all the foods carbohydrate portion foods -

a) Peas, oranges, eggs
b) peanuts, baked beans, bananas
c) Bread, milk, cheese
d) I don't know

31

26. The healthy diabetic diet is different from the normal diet in that the diabetic diet needs to be -

a) Lower in carbohydrate
b) Kept constant in carbohydrate
c) Lower in calories
d) I don't know

32

27. Before strenuous exercise, diabetics need to -

a) Take an extra carbohydrate portion
b) Eat more protein for energy
c) Take some food containing sugar and some extra portions of carbohydrate
d) I don't know

33

28. When a diabetic shows a 2% sugar in his urine, he should -

a) Reduce his carbohydrate at the next meal
b) Eat the same amount of carbohydrate as usual and test urine regularly
c) Increase his insulin dose at the next injection
d) I don't know

34

29. One carbohydrate portion is found in -

a) 1 cup of milk
b) 1 cup of cornflakes
c) 1 cup of pumpkin
d) I don't know

35

30. If a diabetic needs 2 portions for morning tea and he has 2 jatz biscuits and 1 cup of milk he -

a) Is eating the right number of carbohydrate portions
b) Risks having a "hypo" before lunch
c) Is likely to get fat
d) I don't know

36

31. A healthy well-balanced diet for everyone including diabetics is one which -

a) Contains a serve of protein at every meal and plenty of salads
b) Has plenty of carbohydrate and is moderate in fat and protein
c) Is low in carbohydrate, high in protein and moderate in fat
d) I don't know

37

32. An important risk in having an unbalanced diet, i.e. too much fat and protein is -

a) Becoming overweight
b) Developing vitamin deficiencies
c) Developing high cholesterol and possible heart trouble
d) I don't know

38

33. Being overweight -

a) Doesn't matter more for diabetics than for other people
b) May make your insulin less effective
c) Is something diabetics can't do much about when they are on insulin
d) I don't know

39

34. For the diabetic, drinking alcohol -

a) Could cause a serious "hypo"
b) Is something diabetics are not supposed to do
c) Is more likely to cause liver disease in diabetics than in other people
d) I don't know

40

35. Which of the following foods are <u>not</u> high in fat -

a) Steak
b) Polyunsaturated margarine
c) Bananas
d) I don't know

41

36. A diabetic can eat or drink which of the following foods freely -

a) Steak
b) Cheese
c) Cauliflower
d) I don't know

42

37. The most important thing a person with high cholesterol can do is -

a) Cut down on eggs and shellfish
b) Switch from butter to polyunsaturated margarine and oil
c) Stay slim and eat less fat of any sort
d) I don't know

43

38. To the naked eye a diabetic's pancreas looks -

a) A bit shrunken and darker in colour
b) like a non-diabetic's pancreas
c) Paler with small hollows in the surface
d) I don't know

44

39. Special diet foods sweetened with Sorbitol (like chocolate and jam) are not recommended because -

a) They are high calorie
b) They are dangerous
c) They cause high urine sugars
d) I don't know

45

40. Eye damage from long term poor control of blood sugar -

a) Doesn't occur until at least 10 years after diabetes has been diagnosed
b) May be present even if you can see perfectly well
c) Always causes blurred vision
d) I don't know

46

41. Good control of your diabetes means keeping your blood sugar as often as possible between -

a) 1 and 3 (mmol/litre)
b) 11 and 16 (mmol/litre)
c) 4 and 10 (mmol/litre)
d) I don't know

47

42. A person with normal blood cholesterol has values between

a) 10 and 13 (mmol/litre)
b) 3 and 6.5 (mmol/litre)
c) 6.5 and 10 (mmol/litre)
d) I don't know

48

Sc. 49 50

GENERAL HEALTH QUESTIONNAIRE

OFFICE USE ONLY

S. NUMBER _ _ _ _ _

ST. NO. _

A. NO. _

SC. _ _

NAME _____

DATE _____

APPENDIX 3.21

We would like to know how your health has been in the last few days. Please circle the most appropriate answer to each question.

HAVE YOU RECENTLY:

1. been able to concentrate on whatever you're doing	Better than usual	Same as usual	Less than usual	Much less than usual
2. lost much sleep over worry	Not at all	No more than usual	Rather more than usual	Much more than usual
3. felt that you are playing a useful part in things	More so than usual	Same as usual	Less than usual	Much less than usual
4. felt capable of making decisions about things	More so than usual	Same as usual	Less than usual	Much less than usual
5. felt constantly under strain	Not at all	No more than usual	Rather more than usual	Much more than usual
6. felt that you couldn't overcome your difficulties	Not at all	No more than usual	Rather more than usual	Much more than usual
7. been able to enjoy your normal day-to-day activities	More so than usual	Same as usual	Less so than usual	Much less than usual
8. been able to face up to your problems	More so than usual	Same as usual	Less so than usual	Much less than usual
9. been feeling unhappy and depressed	Not at all	No more than usual	Rather more than usual	Much more than usual
10. been losing confidence in yourself	Not at all	No more than usual	Rather more than usual	Much more than usual
11. been thinking of yourself as a worthless person	Not at all	No more than usual	Rather more than usual	Much more than usual

12.	been feeling reasonably happy, all things considered	No More so than usual	About same as usual	Rather more than usual	Much more than usual
13.	been managing to keep yourself busy and occupied	More so than usual	Same as usual	Rather less than usual	Much less than usual
14.	been getting out of the house as much as possible	More so than usual	Same as usual	Rather less than usual	Much less than usual
15.	been feeling on the whole that you've been doing things well	Better than usual	About the same	Less well than usual	Much less than usual
16.	been satisfied with the way you've carried out your task	Better than usual	About same as usual	Less well than usual	Much less than usual
17.	been taking things hard	Not at all	No more than usual	Rather more than usual	Much more than usual
18.	found everything getting on top of you	Not at all	No more than usual	Rather more than usual	Much more than usual
19.	been feeling nervous and strung-up all the time	Not at all	No more than usual	Rather more than usual	Much more than usual
20.	found at times you couldn't do anything as your nerves were too bad	Not at all	No more than usual	Rather more than usual	Much more than usual
21.	been having restless disturbed nights	Not at all	No more than usual	Rather more than usual	Much more than usual
22.	been managing as well as most people in your shoes	More so than usual	Same as usual	Rather less than usual	Much less than usual
23.	been able to feel warmth and affection for those near to you	Better than usual	About same as usual	Less well than usual	Much less than usual
24.	been finding it easy to get on with people	Better than usual	About same as usual	Less well than usual	Much less than usual

25.	spent much time chatting with people	Not at all	No more than usual	Rather more than usual	Much more than usual
26.	been finding life a struggle all the time	Not at all	No more than usual	Rather more than usual	Much more than usual
27.	been getting scared and panicky for no good reason	Not at all	No more than usual	Rather more than usual	Much more than usual
28.	felt that life is entirely hopeless	Not at all	No more than usual	Rather more than usual	Much more than usual
29.	been feeling hopeful about your own future	More so than usual	About same as usual	Less than usual	Much less than usual
30.	felt that life isn't worth living	Not at all	No more than usual	Rather more than usual	Much more than usual

DIABETES EDUCATION AND ASSESSMENT PROGRAMME

OFFICE USE ONLY

Q U E S T I O N N A I R E - 1

S. NUMBER _ _ _ _

Q.D.L.
APPENDIX 3.22

ST. NO. _

A. NO. _

DATE _____

We are doing a study on how diabetes affects peoples lives. Could you please tell us how you have been feeling over the past few weeks about the items below? Your answers will be held in strict confidence and only used in summaries of answers given by diabetics in our study. Please circle your answer for each item.

OVER THE PAST FEW WEEKS I HAVE BEEN ...

1.	Feeling confident about managing my diabetes	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
2.	Feeling confident about dealing with 'hypos' (low blood sugar reaction)	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
3.	Feeling confused about my diet	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
4.	Feeling overwhelmed with all the things I have to do to look after my diabetes	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
5.	Feeling restricted about the range of foods and drinks I can have.	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
6.	Feeling frustrated that the following of my diet hasn't helped my weight and/or blood sugars.	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
7.	Feeling able to eat out at Restaurants or friends'.	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
8.	Able to get out and do the physical activities I want to do.	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual

OVER THE PAST FEW WEEKS I HAVE BEEN ...

9.	Feeling irritable and cranky with family and/or friends	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
10.	Feeling somehow embarrassed about having diabetes	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
11.	Feeling uncertain about how to prevent complications	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
12.	Feeling confident about what checks on diabetes should be done by a doctor	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
13.	Feeling that injections are difficult for me.	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
14.	Understanding the reasons for what I need to do to control my diabetes.	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
15.	Feeling I know what to do if my blood fats are high. (cholesterol or triglycerides)	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
16.	Knowing how to avoid unconsciousness from a severe hypo (low blood sugar reaction)	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
17.	Feeling confident about travelling at home and abroad.	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
18.	Feeling confident about how to control my blood sugar.	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual
19.	Feeling confident that I know where to find help when I need it.	Much less than usual	Rather less than usual	The same as usual	Rather more than usual	Much more than usual

20. Is there any other way in which having diabetes has been affecting you? _____

_____

_____

DIABETES EDUCATION AND ASSESSMENT PROGRAMME

OFFICE USE ONLY

Q U E S T I O N N A I R E - 2

S. NUMBER _ _ _ _

Q.D.L.
APPENDIX 3.23

DATE _____

ST. NO. _

A. NO. _

We are doing a study on how diabetes affects peoples lives. Could you please tell us how you have been feeling since going through the Diabetes Education Programme, about the items below? Your answers will be held in strict confidence and only used in summaries of answers given by diabetics in our study. Please circle your answer for each item.

SINCE GOING THROUGH THE PROGRAMME I HAVE BEEN ...

1.	Feeling confident about managing my diabetes	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
2.	Feeling confident about dealing with 'hypos' (low blood sugar reaction)	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
3.	Feeling confused about my diet	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
4.	Feeling overwhelmed with all the things I have to do to look after my diabetes	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
5.	Feeling restricted about the range of foods and drinks I can have	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
6.	Feeling frustrated that the following of my diet hasn't helped my weight and/or blood sugars	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
7.	Feeling able to eat out at Restaurants or friends'.	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
8.	Able to get out and do the physical activities I want to do.	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before

SINCE GOING THROUGH THE PROGRAMME I HAVE BEEN ...

9.	Feeling irritable and cranky with family and/or friends	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
10.	Feeling somehow embarrassed about having diabetes	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
11.	Feeling uncertain about how to prevent complications	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
12.	Feeling confident about what checks on diabetes should be done by a doctor	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
13.	Feeling that injections are difficult for me	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
14.	Understanding the reasons for what I need to do to control my diabetes	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
15.	Feeling I know what to do if my blood fats are high. (cholesterol or triglycerides)	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
16.	Knowing how to avoid unconsciousness from a severe hypo (low blood sugar reaction)	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
17.	Feeling confident about travelling at home and abroad	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
18.	Feeling confident about how to control my blood sugar	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before
19.	Feeling confident that I know where to find help when I need it	Much less than before	Rather less than before	The same as before	Rather more than before	Much more than before

20. Is there any other way in which going through the Diabetes Education Programme has affected you? _____

_____

_____

APPENDIX 3.24

HEALTH BELIEF QUESTIONNAIRE

PRE/POST STUDY

DIABETIC EDUCATION AND ASSESSMENT PROGRAMME

NUMBER: _____ **DATE:** _____

The purpose of this questionnaire is to find out some of the difficulties diabetics have with diabetes and their diets. Please answer every question as well as you can. Your answers will remain confidential.

1. In general, how serious would you say your diabetic condition is?
(Tick the answer that applies)

   Very serious _____

   Somewhat serious _____

   Not at all serious _____

2. And how concerned would you say you were about your diabetes?
(Tick the answer that applies)

   Very concerned _____

   Somewhat concerned _____

   Not at all concerned _____

3. Do you feel that your diabetes will -
(please answer all of the following)

(a)	Last all your life?	Yes ____	No ____
(b)	Get better?	Yes ____	No ____
(c)	Go away?	Yes ____	No ____
(d)	Be curable within your lifetime?	Yes ____	No ____

4. What things do you think a person can do to keep from getting the complications of diabetes?

_____

_____

_____

_____

5. Diabetes sometimes stops people from doing or having the things they want in life. To what extent does diabetes interfere with your getting any of the following:

		Interferes a lot	Interferes a little	Does not Interfere
(a)	Having the job I want	____	____	____
(b)	Having the friends I want	____	____	____
(c)	Having the kind of family I want	____	____	____
(d)	Having the kind of sexual relationships I want	____	____	____
(e)	Going out and doing the things I want	____	____	____
(f)	Being as physically active as I want to be	____	____	____
(g)	Doing things on the "spur" of the moment as I would like	____	____	____
(h)	Travelling as much as I want	____	____	____
(i)	Having as many children as I want	____	____	____
(j)	Being as relaxed as I would like to be	____	____	____

/ 2 ...

6. Are there any other things that diabetes stops you from doing or having?

_____

_____

_____

_____

7. Here are some statements people have made about diets. Please indicate whether you agree, neither agree nor disagree, or disagree by placing a tick (✓) in the appropriate column.

		Agree	Neither agree nor Disagree	Disagree
(a)	The kind of foods and drinks I should have often are not easily available	____	____	____
(b)	If I follow my diet, I am hungry all of the time	____	____	____
(c)	I do not seem to have enough willpower to stick to my diet	____	____	____
(d)	My diet does not seem to work anyway	____	____	____
(e)	I feel like I get nagged about my diet	____	____	____
(f)	My diet requires me to eat and drink very differently from my family	____	____	____
(g)	I am often too full to eat all the food on my diet	____	____	____
(h)	One of my family members usually tells other people that I am on a special diet	____	____	____
(i)	There is not much anyone can do about his or her weight	____	____	____
(j)	No one, apart from me, really knows what I am supposed to eat	____	____	____
(k)	The diet is just too much trouble	____	____	____
(l)	The food on my diet is plain & boring	____	____	____
(m)	Sometimes I worry that following my diet can actually cause health problems	____	____	____
(n)	Following a diet is a lot of extra expense	____	____	____
(o)	I feel that members of my family do not "practice what they preach" when it comes to diet	____	____	____
(p)	The diabetic diet is very complicated to follow	____	____	____
(q)	My family has changed their eating habits a lot since I got diabetes	____	____	____
(r)	I do not really believe it is necessary to follow a diet all that closely	____	____	____
(s)	Sometimes I feel that members of my family try to tempt me to break my diet	____	____	____
(t)	I have always had a weight problem and there does not seem to be much I can do about it	____	____	____
(u)	I have been told to lose weight but I think I am okay the weight I am	____	____	____
(v)	No matter how much I diet, I never seem to lose weight	____	____	____

/ 3 ...

8.A Diabetics are often expected to follow many dietary recommendations such as those listed below. First, how closely would you say you follow each of them? (Please circle the number at which you would rate yourself)

		Not at all Closely						Very Closely
(a)	Limiting alcoholic drinks	1	2	3	4	5	6	7
(b)	Restricting sugar, honey and sweet foods	1	2	3	4	5	6	7
(c)	Eating a balanced diet	1	2	3	4	5	6	7
(d)	Eating at regular times	1	2	3	4	5	6	7
(e)	Measuring and weighing food	1	2	3	4	5	6	7
(f)	Working out portions or calories or substitutions at each meal or snack	1	2	3	4	5	6	7
(g)	Cutting down on food to lose weight or to keep slim	1	2	3	4	5	6	7
(h)	Eating extra food before exercise	1	2	3	4	5	6	7
(i)	Carrying extra food with you at all times	1	2	3	4	5	6	7
(j)	Taking enough sugar or food when feeling sick	1	2	3	4	5	6	7
(k)	Limiting fatty foods	1	2	3	4	5	6	7
(l)	Treating "hypos" appropriately	1	2	3	4	5	6	7

8.B Now, these dietary recommendations are sometimes difficult to follow. How difficult would you say each of the following recommendations is for you to follow?

		Not at all Difficult						Very Difficult
(a)	Limiting alcoholic drinks	1	2	3	4	5	6	7
(b)	Restricting sugar, honey and sweet foods	1	2	3	4	5	6	7
(c)	Eating a balanced diet	1	2	3	4	5	6	7
(d)	Eating at regular times	1	2	3	4	5	6	7
(e)	Measuring or weighing food	1	2	3	4	5	6	7
(f)	Working out portions or calories or substitutions at each meal or snack	1	2	3	4	5	6	7
(g)	Cutting down on food to lose weight or to keep slim	1	2	3	4	5	6	7
(h)	Eating extra food before exercise	1	2	3	4	5	6	7
(i)	Carrying extra food with you at all times	1	2	3	4	5	6	7
(j)	Taking enough sugar or food when feeling sick	1	2	3	4	5	6	7
(k)	Limiting fatty foods	1	2	3	4	5	6	7
(l)	Treating "hypos" appropriately	1	2	3	4	5	6	7

/ 4 ....

9. We are wanting to know specifically what makes it difficult to follow different dietary recommendations so that we can be more helpful to people.

   Can you please write down everything that makes it difficult for you to stick to any of the dietary recommendations listed on previous pages.

10. In general, how much would you say your diet interferes with your normal daily activities?

    Interferes a lot ____

    Interferes a little ____

    Does not interfere ____

11. Generally, who would you say looks after your diet? (Tick the appropriate answer)

    I look after it ____

    Another member of my household mostly looks after my diet ____

    No one looks after my diet ____

12. Following a diabetic diet sometimes gets in the way of doing the things people like to do. How much do you feel that following a diet does or could interfere with any of the things listed below? Please tick each item in the appropriate column.

Following a diabetic diet interferes with -	Interferes a lot	Interferes a little	Does not Interfere
(a) enjoyment of eating and drinking	____	____	____
(b) being as spontaneous as I would like	____	____	____
(c) going out with my friends as often as I would like	____	____	____
(d) dining out as often as I would like	____	____	____
(e) going to parties as often as I would like	____	____	____
(f) eating and drinking the things I would like	____	____	____
(g) being as comfortable in social situaions as I would like to be	____	____	____
(h) being as physically active as I would like	____	____	____

/ 5 ...

13. Would you say that you are the sort of person who has a routine lifestyle or a very unroutine and irregular lifestyle?

_____ very routine lifestyle

_____ very routine and irregular lifestyle

_____ somewhat in the middle

14. How effective do you feel that your prescribed diet is in controlling your diabetes and keeping you healthy? Please tick next to each item below whether you think your diet is very effective, somewhat effective, or not at all effective.

Is your diet effective in -	Very Effective	Somewhat Effective	Not effective at all	Don't know
(a) keeping your blood and urine sugars normal	_____	_____	_____	_____
(b) preventing serious hypos (very low sugars)	_____	_____	_____	_____
(c) controlling your weight	_____	_____	_____	_____
(d) controlling your blood fats (cholesterol and triglycerides)	_____	_____	_____	_____
(e) keeping you healthy and feeling energetic and well	_____	_____	_____	_____

15. Here are some statements that diabetics have made about doctors and dietitians. Please indicate with a tick ( ) whether you agree, somewhat agree, or disagree with each of these statements.

	Agree	Neither agree nor Disagree	Disagree
(a) Doctors do not seem to be able to do much for my diabetes	_____	_____	_____
(b) You have to use your own judgement in deciding how closely to follow a doctor's advice	_____	_____	_____
(c) Doctors do not seem to know enough about how to manage diabetes	_____	_____	_____
(d) Dietitians do not seem to understand the difficulties of following a diet	_____	_____	_____
(e) Doctors usually spend enough time with diabetics	_____	_____	_____
(f) I try to do exactly what the Doctor tells me to do	_____	_____	_____
(g) Dietitians are usually very practical and helpful	_____	_____	_____
(h) Doctors do not really believe that diet is very important for diabetics	_____	_____	_____
(i) I do not trust doctors to be able to tell what is wrong with me	_____	_____	_____
(j) Because everyone is an individual it is hard for dietitians to know exactly what food you require.	_____	_____	_____

/ 6 ...

		Very Satisfied	Somewhat Satisfied	Not at all Satisfied
16. 1.	In general how satisfied would you say you are with the care you get from doctors?	____	____	____
2.	and how satisfied are you with the help you have had from dietitians	____	____	____

17. Here is a list of people who sometimes make it harder or easier for us to look after our health and diabetes. How easy or difficult does each kind of person make it for you to look after your health and diabetes?

	Very Difficult			Neither harder nor easier			Very Easy	Don't Know
husband/wife	1	2	3	4	5	6	7	
Children	1	2	3	4	5	6	7	
Parents	1	2	3	4	5	6	7	
Other relatives	1	2	3	4	5	6	7	
Friends	1	2	3	4	5	6	7	
People at work	1	2	3	4	5	6	7	

18. What are some ways that other people listed above make it harder or easier for you to look after diabetes?

_____

_____

_____

_____

19. In general, family life has its problems. Where would you say your family falls on a scale from having just a few problems to having a great many problems.

Just a Few					A Great Many
1	2	3	4	5	6	7

20. We are interested in knowing the reasons that people come on their own to the education programme. If you came without a relative or friend, could you please tell us why?

_____

_____

_____

/7...

24. The following is a list of health problems or illnesses people sometimes get. Please read over the list and

(a) Tick (✓) each item in section 1 according to whether you have the problem now or are likely to ever get it.
(b) Then tick each item in Section 2 according to how concerned or worried you are about this problem, whether you have it or not.

BE SURE TO TICK ( ) NEXT TO EACH OF THE 23 HEALTH PROBLEMS IN BOTH SECTION 1 AND SECTION 2

HEALTH PROBLEMS	SECTION 1					SECTION 2		
	HOW LIKELY DO YOU THINK YOU ARE TO EVER GET THESE ILLNESSES OR PROBLEMS?					HOW CONCERNED OR WORRIED ARE YOU ABOUT GETTING OR HAVING THIS PROBLEM?		
	I don't know what this is	I have this problem now	Very likely to get	Somewhat likely to	Not at all likely	Very Concerned	Somewhat Concerned	Not at all Concerned
1. HEART TROUBLE	.....	.....	.....	.....	.....	.....	.....	.....
2. OVERWEIGHT	.....	.....	.....	.....	.....	.....	.....	.....
3. NUMBNESS IN FEET OR LEGS	.....	.....	.....	.....	.....	.....	.....	.....
4. LOSS OF EYESIGHT	.....	.....	.....	.....	.....	.....	.....	.....
5. BAD TEETH	.....	.....	.....	.....	.....	.....	.....	.....
6. CANCER	.....	.....	.....	.....	.....	.....	.....	.....
7. HIGH CHOLESTEROL	.....	.....	.....	.....	.....	.....	.....	.....
8. IMPOTENCE IN MALES (inability to get an erection for sexual intercourse)	.....	.....	.....	.....	.....	.....	.....	.....
9. EPILEPTIC FITS	.....	.....	.....	.....	.....	.....	.....	.....
10. FREQUENT PAIN	.....	.....	.....	.....	.....	.....	.....	.....

HEALTH PROBLEMS	SECTION 1					SECTION 2		
	HOW LIKELY DO YOU THINK YOU ARE TO EVER GET THESE ILLNESSES OR PROBLEMS?					HOW CONCERNED OR WORRIED ARE YOU ABOUT GETTING OR HAVING THIS PROBLEM?		
	I don't know what this is	I have this problem now	Very likely to get	Somewhat likely to	Not at all likely	Very Concerned	Somewhat Concerned	Not at all Concerned
11. KIDNEY DISEASE	.....	.....	.....	.....	.....	.....	.....	.....
12. POOR DIABETIC CONTROL	.....	.....	.....	.....	.....	.....	.....	.....
13. SEVERE HYPOGLYCAEMIC REACTION (low blood sugar that makes you unconscious)	.....	.....	.....	.....	.....	.....	.....	.....
14. MILD HYPOGLYCAEMIC REACTIONS	.....	.....	.....	.....	.....	.....	.....	.....
15. UNDERWEIGHT	.....	.....	.....	.....	.....	.....	.....	.....
16. GANGRENE	.....	.....	.....	.....	.....	.....	.....	.....
17. FREQUENT HEADACHES	.....	.....	.....	.....	.....	.....	.....	.....
18. FREQUENT ILLNESS	.....	.....	.....	.....	.....	.....	.....	.....
19. GETTING SICK FROM HIGH SUGARS (Ketoacidosis)	.....	.....	.....	.....	.....	.....	.....	.....
20. HIGH BLOOD PRESSURE	.....	.....	.....	.....	.....	.....	.....	.....
21. LIVER DISEASE	.....	.....	.....	.....	.....	.....	.....	.....
22. ALCOHOLISM	.....	.....	.....	.....	.....	.....	.....	.....
23. FEELING TIRED ALL THE TIME	.....	.....	.....	.....	.....	.....	.....	.....

APPENDIX 3.25

HEALTH BELIEF QUESTIONNAIRE

RANDOMISED CONTROLLED TRIAL

SUBJECT NUMBER ☐ ☐ ☐ ☐ (1 2 3 4)

STREAM NUMBER ☐ (5)

ASSESSMENT NUMBER ☐ (6)

INTERVIEWER NUMBER ☐ (7)

TIME INTERVIEW BEGAN _____ A.M. P.M. TODAY'S DATE _____

Hello, I'm _____ from a research unit of the Royal North Shore Hospital. We are doing a study so that services to diabetics in Australia can be improved. We would like your help with this important study by answering some questions, which should take about 30 minutes. The programme team will not see your answers and your name will not appear anywhere on the questionnaire so that comments are completely anonymous, so I would like you to be as frank as possible. There are NO right or wrong answers.

1. People say that having diabetes affects their lives in different ways - could you tell me whether having diabetes has interfered with your life in any of the following ways?

	Yes	No	
a) Your work or the regular things you do?	1	0	☐ 8
b) Social activities (like going out)?	1	0	☐ 9
c) Your family and family life?	1	0	☐ 10
d) Holidays and travel?	1	0	☐ 11
e) Your physical activity and recreation?	1	0	☐ 12
f) Your eating and drinking habits?	1	0	☐ 13
g) Your costs or expenses?	1	0	☐ 14
h) Your general health?	1	0	☐ 15
i) Your moods or feelings within yourself?	1	0	☐ 16
j) Any other ways?	1	0	☐ 17

2. Recently, how well controlled would you say your diabetes has been?

Very	Moderately	A little	Not at all	
3	2	1	0	☐ 18

3. Now, thinking back over all the time you have had diabetes, how well controlled would you say it has been most of the time?

Very	Moderately	A little	Not at all	
3	2	1	0	☐ 19

4. How do you generally tell how well controlled your diabetes is?

_____

_____

_____

5. People <u>sometimes</u> feel more concerned about their diabetes than at other times. In the last few weeks, how concerned have you been about your diabetes?

Very	Moderately	A little	Not at all	
3	2	1	0	☐ 20

Comments _____

_____

_____

6. Here are some health problems found in the community. How likely would you say you are to get each of these?

	Have now	Very	Mod.	A little	Not at all	DK	NA	
a) Hearing loss or deafness	4	3	2	1	0	8	9	☐ 21
b) Blindness	4	3	2	1	0	8	9	☐ 22
c) Kidney disease	4	3	2	1	0	8	9	☐ 23
d) Stomach Ulcers	4	3	2	1	0	8	9	☐ 24
e) Gangrene	4	3	2	1	0	8	9	☐ 25
f) Asthma attacks	4	3	2	1	0	8	9	☐ 26
g) Loss of feeling in feet and legs	4	3	2	1	0	8	9	☐ 27
h) Impotence (ASK IF MALE ONLY)	4	3	2	1	0	8	9	☐ 28
i) Heart disease	4	3	2	1	0	8	9	☐ 29

7. Do you think a person can do anything to keep from getting the long-term health problems of diabetes?

Yes	No	
1	0	☐ 30

8. Here are some things that people sometimes do to control their diabetes. From your experience how much do you think these things have helped to control your diabetes? Let's start with taking your insulin. How much would you say this has helped control your diabetes?

	Very	Moderately somewhat	A little	Not at all	Don't know	N/A	
(INTERVIEWER CONTINUE THROUGH THE LIST)							
a) taking your insulin	3	2	1	0	8	9	☐ 31
b) visiting your doctor	3	2	1	0	8	9	☐ 32
c) following a diet	3	2	1	0	8	9	☐ 33
d) testing your urine regularly	3	2	1	0	8	9	☐ 34
e) your physical activity	3	2	1	0	8	9	☐ 35
f) testing your blood sugar	3	2	1	0	8	9	☐ 36

g) Other, specify _____

9. And from your experience how much has your diet helped your weight?

Very	Moderately	A little	Not at all	D.K.	N/A	
3	2	1	0	8	9	☐ 37

Comments _____

_____

_____

_____

_____

10. If you followed your diet closely and this didn't seem to help your diabetes or keep your weight at a desirable level, which of these would be most like what you would do?

Follow more closely	Keep following	Relax a little	Give up following	Don't Know	
3	2	1	0	8	☐ 38

Comments _____

_____

11. When people get diabetes, they are often told to change several things about their eating habits. Some people are able to do these well and other people are not. I'd like to know how well <u>you feel you have been able to</u> do each of these things. The possible answers are on the card, as before.
Let's start with Eat 3 meals and snacks each day, how well you do on that?
(INTERVIEWER CONTINUE THROUGH LIST)

	Very	Moderately/ Somewhat	A little	not at all	don't know	n/a	
1) Eat 3 meals and 3 between meal snacks each day	3	2	1	0	8	9	☐ 39
2) Avoid sugar, honey and sweet foods	3	2	1	0	8	9	☐ 40
3) Stay (or get) slim	3	2	1	0	8	9	☐ 41
4) Measure or weigh food	3	2	1	0	8	9	☐ 42
5) Work out portions or calories or substitutions at each meal and snack	3	2	1	0	8	9	☐ 43
6) Limit alcoholic drinks	3	2	1	0	8	9	☐ 44
7) Limit foods high in fat	3	2	1	0	8	9	☐ 45
8) Eat a balanced diet	3	2	1	0	8	9	☐ 46

Comments _____

_____

_____

_____

12. Overall, how difficult would you say it is for you to stick your diet?

Very	Moderately	A little	Not at all	Don't know	n/a	
3	2	1	0	8	9	☐ 47

13. Here are some statements people have made about diets. I'd like you to tell me whether you agree or disagree with each one as I read them out.

	Agree	Disagree	Don't Know	Not Applicable	
a) the kinds of foods and drinks on my diet often aren't easily available	1	0	8	9	☐ 48
b) if I follow my diet, I'm hungry a lot of the time	1	0	8	9	☐ 49
c) I don't seem to have enough will-power to stick to my diet	1	0	8	9	☐ 50
d) my diet doesn't seem to work, anyway	1	0	8	9	☐ 51
e) I feel like I get nagged about my diet	1	0	8	9	☐ 52
f) my diet requires me to eat and drink very differently to those around me	1	0	8	9	☐ 53
g) I'm often too full to eat all the food on my diet	1	0	8	9	☐ 54
h) When I eat out, I sometimes feel afraid that people will find out that I'm a diabetic	1	0	8	9	☐ 55
i) No one, apart from me, really knows what food I'm allowed to eat	1	0	8	9	☐ 56
j) the diet is quite a lot of trouble	1	0	8	9	☐ 57
k) the food on my diet is plain and boring	1	0	8	9	☐ 58
l) sometimes I worry that following my diet will cause problems(like hypos or getting fat)	1	0	8	9	☐ 59

	Agree	Disagree	Don't Know	Not Applicable	
m) following a diet is quite a lot of extra expense	1	0	8	9	☐ 60
n) I feel that people around me don't practice what they preach, when it comes to their own eating habits	1	0	8	9	☐ 61
o) the diabetic diet is very complicated to follow	1	0	8	9	☐ 62
p) the people I live with have changed their eating habits a lot since I got diabetes	1	0	8	9	☐ 63
q) I don't really believe it's necessary to follow a diet all that closely	1	0	8	9	☐ 64
r) sometimes I feel that people around me try to tempt me to break my diet	1	0	8	9	☐ 65
s) I've always had a weight problem and there doesn't seem to be much I can do about it	1	0	8	9	☐ 66
t) I've been told to lose weight but I think I'm OK the weight I am	1	0	8	9	☐ 67
u) No matter how much I diet, I never seem to lose weight	1	0	8	9	☐ 68

14) IF LIVES WITH NO OTHER PEOPLE, SKIP TO QUESTION 17.

Thinking about the people you live with, how do they involve themselves in your diabetes?

_____

_____

_____

_____

_____

15) If you could change <u>anything</u> about what they do or say or feel with regard to your diabetes, what would it be?

_____

_____

_____

_____

16) Overall, how much help and support would you say you get from the people you live with for following a diet?

very/a lot	Moderately	A little	not at all	D.K.
3	2	1	0	8

☐ 69

17) I'd like you to imagine for a moment that you didn't have diabetes. How do you think your life might be different?

_____

_____

_____

_____

18) From whom do you get most of your medical care for your diabetes?

a) General practitioner? ___ 3

b) Diabetic specialist? ___ 2

c) Doctor at diabetic clinic ___ 1

d) Other ___ 0

☐ 70

IF ANSWERS b or c GO TO QUESTION 20

19) Have you ever visited a diabetic specialist?

Yes	No
1	0

☐ 71

20) Thinking about the doctor that you go to for most of your diabetic care, how satisfied would you say you are with the care you've had?

Very	Moderately	A little	Not at all	Don't know
3	2	1	0	8

☐ 72

21) Here is a list of statements that people have made about doctors. I'd like to know whether you agree or disagree with them. (In reference to the doctor you go to for your diabetes)

	Yes	No	
My doctor knows a lot about diabetes	1	0	☐ 73
My doctor spends enough time with me	1	0	☐ 74
My doctor usually takes an interest in me	1	0	☐ 75
My doctor usually explains things clearly	1	0	☐ 76
My doctor usually helps me to solve my problems with diabetes	1	0	☐ 77

22) From whom do you get most of your dietary advice for your diabetes?

1. Doctor ___ 2
2. Dietitian ___ 1
3. Other ___ 0 ☐ 78

(IF ANSWERS DIETITIAN ABOVE GO TO QUESTION 24)

23) Have you ever been to see a dietitian for advice on a diet for diabetes?

Yes	No	
1	0	☐ 79

24) In general <u>how satisfied</u> would you say you have been with the care you have had from <u>dietitians</u>?

Very	Moderately	A little	Not at all	
3	2	1	0	☐ 80

Comments _____

_____

25) People come to the Diabetes Education programme for different reasons. What brought you to the programme?

_____

_____

_____

_____

Thank you for participating in our study. This information will be very useful to us.

FOOD CODING ERROR FORM APPENDIX 3.26

Coder________________ Food Record____________________

NO. Of items______ Error rate____ Date__________________________

No. of errors______

Day	Meal Code	Food	Item Code Error		Weight Error	
			Coded As	Corrected	Coded as	Corrected

APPENDIX 3.27

MEASURES OF CARBOHYDRATE COMPLIANCE: PROCEDURES FOR ESTIMATING CARBOHYDRATE QUANTITY, SPACING AND VARIATION

Suppose that x_{ij} is the complex carbohydrate intake at meal period i for day j ($i = 1,2,3,$; $j = 1,2,3,4$) and ρ_i is the recommended intake for meal period i. To obtain a measure of the actual intake relative to the amount recommended, let

$$z_{ij} = \log x_{ij} - \log \rho_i \ .$$

Deviations from the recommendations can be assessed in terms of the following model for z_{ij}:

$$z_{ij} = \mu + \alpha_i + \beta_j + e_{ij}$$

where:

(i) μ represents the amount by which the average intake of carbohydrate differs from the recommended average (ideally $\mu = 0$),

(ii) α_i represents deviations for meal period i (ideally $\alpha_i = 0$),

(iii) β_j represents deviations for day j (ideally $\beta_j = 0$),

(iv) e_{ij} denotes the remaining variability (it is a random error term).

Achievement of the dietary goals in relation to quantity (i.e. $\mu = 0$), spacing (all α_i's $= 0$) and variation (all β_j's $= 0$) can be investigated using standard two factor analysis of variance (ANOVA).

ANOVA

Source	df	Sum of squares	Mean square
Quantity	1	$QSS = (\sum_{ij} z_{ij})^2/12$	$QMS = QSS/1$
Spacing	2	$SSS = (\sum_{i} Z_{i.}^2/4) - QSS$	$SMS = SSS/2$
Variation	3	$VSS = (\sum_{j} Z_{.j}^2/3) - QSS$	$VMS = VSS/3$
Residual	6	$RSS = TSS - QSS - SSS - VSS$	$RMS = RSS/6$
Total	12	$TSS = \sum_{ij} z_{ij}^2$	

The hypotheses that $\mu = 0$, $\alpha_i = 0$ for all i and $\beta_j = 0$ for all j can be tested using the variance ratios QMS/RMS, SMS/RMS and VMS/RMS respectively.

In addition the quantities QMS, SMS and VMS provide summary statistics of deviations from the recommended levels with respect to quantity, spacing and variation. Since these statistics have very skewed distributions, it is suggested that they be transformed to

$$Q = \sqrt{QMS}\ , \quad S = \sqrt{SMS} \quad \text{and} \quad V = \sqrt{VMS}$$

which have more symmetric distributions.

APPENDIX 3.28

CODING PROCEDURES FOR

DEMOGRAPHIC AND DIABETIC HISTORY AND TREATMENT DETAILS[a]

A. DEMOGRAPHIC DETAILS were coded from the application form as follows -

Sex: 1 = Female, 2 = Male

Age: In years (to the nearest year)

Duration of Diabetes (since diagnosis): In years (to the nearest tenth year)

Social Class: (Congalton, 4-point scale) A = 1, B = 2, C = 3, D = 4, Retired, not known = 8

Geographic Area of Residence: (by Sydney Metropolitan Health Regions) 1 = North, 2 = South, 3 = West, 4 = East, 5 = Sydney Met, 6 = outside Metropolitan

Relationship of Family member or friend who attended the programme: 1 = spouse, 2 = child, 3 = parent, 4 = sibling, 5 = friend (or other relative), 6 = other

B. DIABETIC HISTORY AND TREATMENT DETAILS were coded from the Health and treatment details questionnaire as follows -

a. Insulin dose: total number of units for the day (question 12)

b. number of injections per day: 1,2 or 3 (question 12)

c. hospitalized in previous year due to diabetes: 1 = yes, 2 = no (question 4)

d. previously given a diet for diabetes: 1 = yes, 2 = no (question 14)

e. seen a dietitian for dietary advice in past 3 years: 1 = yes, 2 = no (question 16)

f. previous attendance at an education programme about diabetes: 1 = yes, 2 = no (question 25)

g. referral source: (question 24)

Category	Code
programme endocrinologist =	1
other doctor =	2
other health professional =	3
other =	4

h. presence of diabetic complications: 1 = yes, 2 = no.

(a) Missing data were coded as "9".

APPENDIX 3.29

PRE/POST STUDY

PROCEDURES FOR SCORING HEALTH BELIEF QUESTIONNAIRE

I. FACTORS

Seven health belief dimensions or factors were selected from the 21-item questionnaire for scoring and analysis of change. (All questions were eliminated from the analysis which did not appear to discriminate between subjects at the pre or post-assessment or for which there were responses missing on several questionnaires). The seven factors used and the questionnaire items which comprised the factors were as follows -

Health belief factor	Question	Items
1. Perceived susceptibility to health problems	21	2,5,6,9,10,15,17,18,19,21, 22,23
2. Concern about developing health problems	21	same as above
3. Perceived susceptibility to complications of diabetes	21	3,4,7,8,11,12,13,14,16,19
4. Concern about getting the complications	21	same as in 3
5. Perceived interference of lifestyle by diabetes	5	all items
6. Barriers to dietary compliance	7	all items except q
7. Perceived efficacy of dietary regimens	14	all items

II. SCORES

A. Responses to individual items for each question were assigned scores as follows -

(i)	Susceptibility Question 21:	Very likely 2	Somewhat likely 1	Not at all 0
(ii)	Concern Question 21:	Very likely 2	Somewhat Likely 1	Not at all 0
(iii)	Interference Question 5:	A Lot 2	A Little 1	Not at all 0
(iv)	Barriers Question 7:	Agree 1	Neither Agree or Disagree 0	Disagree 0
(v)	Efficacy Question 4:	Very 2	Somewhat 1	Not at all 0

Missing and "don't know" and "have now" responses were tallied for subtraction from total possible score.

B. Total scores were derived for each health belief item as follows -

(I) Sum of scores for each item.

(II) Divided by total possible score (minus possible score for each item answered "don't know" and "have now" or missing.

APPENDIX 3.30

RANDOMISED CONTROLLED TRIAL

PROCEDURES FOR SCORING HEALTH BELIEF QUESTIONNAIRE

A. FACTORS

From the factor analysis of the first and follow-up health belief interviews, 24 health belief factors were identified. From those, six of the most important factors were selected. Individual items forming the components of the factors are given below.

Health Belief Factor	Factor Number From Analysis		Questionnaire Items Forming the Factors	
	Pre	Post	Questions(s)	Sub-items
1. Perceived susceptibility	3	4	6	a through l
2. Perceived efficacy	4	-	8	a,b,d,e,f (omit c)
3. Perceived compliance	1	3	11	1,2,4,5,7,8, (omit 3,6)
4. Perceived difficulties with diet	2	5	13	a,b,d,e,f,g,j,k, l,m (omit c,h,i, n,o,p,q,r)
5. Perceived difficulties with weight	5	2	13	s,t,u.
6. Perceived satisfaction with doctor's care	9	14	21	a through e

B. SCORING

1. Questions 6,8,11

For the first three factors, responses were obtained on a 4-point scale from "not at all" (0) to "very" (3). Possible responses also included "don't know" (5) and "not applicable" (8). For question 6 relating to susceptibility to health conditions "have now" (4) was also a possible response.

2. Questions 13, 21

For the last three factors, "yes" (1) or "no" (0) responses were possible as were "don't know" and "not applicable".

3. The scores for each of these factors were the sum of the codes (or scores) for each item, divided by the total number of items answered, (excluding those for which the response was missing, "have now", "don't know" or "not applicable".)

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