

**EXPERT PATIENT EDUCATION VERSUS
ROUTINE TREATMENT**



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The candidate confirms that the work submitted is her own and that appropriate credit has been given where reference has been made to the work of others. This copy has been supplied on the understanding that it is copyright material and that no quotation from the thesis may be published without proper acknowledgement.

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Abstract

This study aims to evaluate a different approach to diabetes patient education. It begins with an overview of the epidemiology of Type 2 diabetes in recognition that although there have been major developments over the years in identifying and treating diabetes, people with diabetes are still dying prematurely and their quality of their life is still poor when compared to those without the condition.

Chapter 2 reviews definitions of health, health behaviour models, relevant international literature and its impact on national policy. Most countries are currently at the experimental stage of developing therapeutic and self-management education programmes. However, routine patient education in Europe and the United States is still based largely on biomedical models.

A systematic review of group-based, therapeutic and self-management education programmes for adults with Type 2 diabetes is presented in Chapter 3. This reveals that these approaches to diabetes education improve diabetes control, enhance patient knowledge of diabetes and reduce the requirement for diabetes medication. There is also some evidence to suggest there is increased self-management skills, self-empowerment, quality of life and treatment satisfaction, although further research is recommended to confirm those findings.

The tutor's manual for the expert patient programme "X-PERT" is presented in Chapter 4. This was written to encourage the delivery of the X-PERT programme to adults living with Type 2 diabetes. It is designed to illustrate the theories of empowerment and patient activation. Delivery and content of this six-session, group-based, health professional-led diabetes expert patient programme is described in detail.

The research proposal for the randomised controlled trial is presented in Chapter 5. A brief background summary is followed by a full description of development of the X-PERT trial, demographic aspects of Burnley, Pendle and Rossendale and the research design. The intervention group was invited to attend the X-PERT programme whilst the control group received routine diabetes treatment.

The X-PERT trial tests the hypothesis that delivery of a professional-led, community based, diabetes-specific expert patient programme for adults with Type 2 diabetes based

on the theories of patient empowerment and patient activation would: (1) develop the skills and confidence needed for patients to be able to make informed decisions regarding their diabetes self-management; (2) improve biomedical, lifestyle and psychosocial outcomes both in the short term (four months) and longer-term (14 months); (3) meet the International Diabetes Federation (IDF) structure and process standards regarding diabetes education.

The results, presented in Chapter 6, support each of the three aspects of the hypothesis stated above. The expert patients, compared with the control group, improved their diabetes control, became more knowledgeable about their diabetes, had a greater sense of empowerment, increased their self-management skills and food related quality of life. Many of the IDF diabetes education standards were also addressed.

Chapter 7 considers the strengths and limitations of the trial. It then concludes that a structured, group-based approach to patient education, using models of patient empowerment and activation, offers an improved approach to the treatment of Type 2 diabetes, a serious, expensive and increasing international problem. Pressures on NHS resources from diabetes and its complications are large. Offering people living with diabetes the skills and confidence to self-manage their condition could bring immense benefits, both to those with the condition and to the NHS.

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Abbreviations

ADA	American Diabetes Association
ADDQoL	Audit of Diabetes-Dependent Quality of Life
BMI	Body mass index
BPR PCT	Burnley, Pendle and Rossendale Primary Care Trust
CDE	Certified Diabetes Educator
CHD	Coronary heart disease
CHO	Carbohydrate
CI	Confidence interval
CONSORT	Consolidated Standards of Reporting Trials
CVD	Cardiovascular disease
DBP	Diastolic blood pressure
DECS	Diabetes Education Consultative Section
DES	Diabetes Empowerment Score
DETR	Department of the Environment, Transport, and the Regions
DHSS	Department of Health and Social Services
DOH	Department of Health
DTSQc	Change in Diabetes Treatment Satisfaction Questionnaire
EASD	European Association for the Study of Diabetes
ELHA	East Lancashire Health Authority
FAO	Food and Agriculture Organisation of the United Nations
FBG	Fasting blood glucose
FSA	Food Standards Agency
GDM	Gestational diabetes mellitus
GI	Glycaemic index
GP	General practitioner
HbA1c	Glycated haemoglobin
HDL cholesterol	High density lipoprotein cholesterol
IDDM	Insulin-dependent-diabetes-mellitus
IDF	International Diabetes Federation
IFG	Impaired fasting glucose
IOTF	International Obesity Task Force
IGT	Impaired glucose tolerance
LDL cholesterol	Low density lipoprotein cholesterol
LDSAG	Local diabetes services advisory group
LDSIG	Local diabetes services implementation group
MDRTC	Michigan Diabetes Research and Training Centre
MODY	Maturity-onset diabetes of the young
MUFA	Monounsaturated fatty acids
NICE	National Institute for Clinical Excellence
NIDDM	Non-insulin-dependent-diabetes
NHS	National Health Service
NSF	National Service Framework
OHA	Oral hypoglycaemic agents
OGTT	Oral glucose tolerance test
PCG	Primary Care Group
PCTs	Primary Care Trusts

PGCE	Post graduate certificate in education
PUFA	Polyunsaturated fatty acids
RCT	Randomised controlled trial
RDA	Recommended daily allowance
SBP	Systolic blood pressure
SD	Standard deviation
SDSCA	Summary of Diabetes Self-Care Activities
SFA	Saturated fatty acids
TPE	Therapeutic patient education
WHO	World Health Organisation
X-PERT	Expert Patient Education versus Routine Treatment

Chapter 1: Type 2 Diabetes Mellitus

1.1 Introduction

Diabetes is becoming a more common condition worldwide. It can affect people of all ages in every population. This chapter sets the scene for the thesis and begins with the definition and classification of, and the diagnostic criteria for, diabetes. An overview of the epidemiology of Type 2 diabetes follows, with discussions on prevalence, prevention and current treatments. The chapter draws to an end by discussing past developments, personal and NHS costs, and opportunities for the future.

1.2 Definition

Diabetes mellitus* is a condition where chronic hyperglycaemia occurs from defects in insulin secretion, insulin action or both. Characteristic symptoms may be thirst, polyuria, polydipsia, blurring of vision, weight loss and infections (WHO Working Group 1998), although some individuals remain symptom free.

1.3 The history of diabetes

The word “diabetes” is of Greek origin and denotes a *siphon*. The term “mellitus” is a descriptive adjective from the Latin word for honey. Medical historians have divided the history of diabetes into five periods, each characterised by advancing medical knowledge and scientific inquiry (Sanders 2001). These phases are:

- the Descriptive Period: describing and naming the disease;
- the Diagnostic Period: learning how to diagnose the disease;
- the Experimental Period: learning what causes the disease;
- the Therapeutic Era: learning how to treat the disease;
- the Era of Complications: learning about additional health problems.

The first three periods are briefly described in Table 1.1. The treatment of diabetes and possible long-term complications are discussed in other sections of this chapter.

* In this thesis, the term diabetes refers to diabetes mellitus.

Table 1.1 The history of diabetes

THE DESCRIPTIVE PERIOD	
Ancient Egypt (2000-1200BC)	This earliest recorded reference to diabetes occurred around 1550 BC and described remedies “to eliminate urine which is too plentiful” (see figure 1.1 on page 5).
Greek Medicine Hippocrates (460-377BC) Claudius Galen (130-201 AD) Aretaeus (130-200 AD)	This physician stressed the influence of diet, exercise and lifestyle on health and gave caution against fad diets. Referring to diabetes as “diarrhoea of the urine”, Galen incorrectly defined the kidney as the relevant site of action. The first physician to use the term “diabetes”, this medic described the condition as ‘the melting down of the flesh and limbs into urine’.
Hindu Medicine (100BC – 700 AD)	The Hindus described diabetes as “honey urine” approximately a thousand years before the Europeans added “mellitus” to the term “diabetes”. (See William Cullen post). It was also noted that the condition could be inherited, or acquired as a result of obesity. Treatment consisted of generous administration of purgatives and emetics. The importance of prevention was emphasised and treatment involved weight reduction, physical activity and a diet rich in carbohydrates with added honey.
Arabian Medicine Avicenna (980-1037) Moso Maimonides (1138-1204)	This Persian physician described a wasting away of the body, infections, non-healing wounds and diabetic gangrene. Maimonides believed that the condition was more likely to occur in warm countries, possibly as a result of the sweetness of the waters of the Nile.
THE DIAGNOSTIC PERIOD	
Paracelsus (1493-1541)	A Swiss physician, he believed that the human body was composed of three basic substances: sulphur, mercury, and salt. When he evaporated diabetic urine he recovered what he thought was salt. He concluded that salt was the cause of diabetes and prescribed anodynes. He believed that the vapour from the anodynes would flow to the kidneys and extinguish the excessive thirst.
Andreas Vesalius (1514-1564)	The Belgian physician correctly identified the pancreas and described it as an organ comprising several glands.
Regnier de Graaf (1641-1673)	In 1664, this Dutch anatomist provided the first modern description of the pancreas and its external secretions.
Thomas Willis (1621-1675)	An English physician, he referred to diabetes as “the pissing evil” and provided what may be one of the earliest descriptions of diabetic peripheral neuropathy. He claimed that diabetes was primarily a disease of the blood and not the kidneys. Interestingly, he also cited other causes, including “ill manner of living” and depression.

Table 1.1 (continued)

Matthew Dobson (1735-1784)	A Yorkshire man, he was the first to demonstrate the presence of sugar in the urine and blood of patients with diabetes. His explanation for the emaciating effect of diabetes was the large proportion of "alimentary matter" being excreted by the kidneys before it could be absorbed and applied to nutrition. The observations made by Willis, along with Dobson's experiments, established the diagnosis of diabetes.
William Cullen (1710-1790)	This physician was responsible for the introduction of the term "diabetes mellitus".
John Rollo (d.1809)	This medic recommended nutrition therapy for the treatment of diabetes. He proposed a diet low in carbohydrate and high in fat and protein following his observation that "vegetable matter" caused increased amounts of sweet urine (see figure 1.2 on page 4).
Appolinaire Bouchardat (1806-1886)	This French physician observed, in the 19 th century, that shortages of food and food rationing during the German siege on Paris had resulted in a disappearance of sugar in the urine and an increased sense of well being. He recommended fasting and exercise for the treatment of the condition.
Frederick Allen (1869-1962) and Elliott Joslin (1879-1964)	In the early 1900s, these physicians advocated that severe dietary restriction ("starvation therapy") was the only hope for management of diabetes. That remained the single approach to prevention of the diabetic coma until the discovery of insulin in 1921.
THE EXPERIMENTAL PERIOD	
Claude Bernard (1813-1878)	During the first half of the 19 th century, Bernard discovered that the liver released a substance that affected blood glucose levels.
Oscar Minkowski (1858-1931)	Minkowski demonstrated in an experiment with dogs that the removal of the pancreas resulted in fatal diabetes. That was a turning point in determining the endocrine function of the pancreas.
Claude Bernard (1813-1878)	A French physician, he discovered that glycogen, the precursor of glucose, was stored in the liver and he discounted the role of the pancreas as the cause of diabetes.
Paul Langerhans (1847-1888)	Although known to have identified the pancreatic islets, Langerhans did not manage to pinpoint their function. Twenty-four years later those pancreatic islets were named "islets of Langerhans" by Laguesse, a French histologist.
Joseph von Mering (1849- 1908) and Oscar Minkowski (1858-1931)	In continuing experiments with dogs, Mering and Minkowski discovered that the removal of the pancreas resulted in diminished ability to heal and decreased resistance to infection. The dogs fell into a diabetic coma and died. Post mortem results indicated that their livers contained very small quantities of glycogen.
Eugene Lindsay Opie (1873-1971)	In 1901, Opie established the association between failure of the islet cells and diabetes mellitus.
Stanley Rossiter Benedict (1884- 1936)	In 1907, Benedict introduced the first test to estimate the approximate amount of glucose in urine. It quickly became common for people with diabetes to test their urine at home using Benedict's solution.

Table 1.1 (continued)

Nicholas Paulescu (1869-1931)	This Romanian biochemist prepared a pancreatic extract that he named pancreine which, when injected into a dog, produced a temporary reduction in blood glucose levels. Although he published his findings in August 1921, he failed to gain recognition for his contribution to the discovery of insulin.
Frederick Banting (1891-1941) and Charles Best (1899-1978)	These Canadian scientists identified the pancreatic extract, isletin and demonstrated a dramatic reduction in urinary and blood glucose. In March 1922, they published a report detailing the administration of isletin in seven cases of human diabetes. Leonard Thompson, a 14-year-old boy was later known as the first person to be treated with insulin.

Figure 1.1

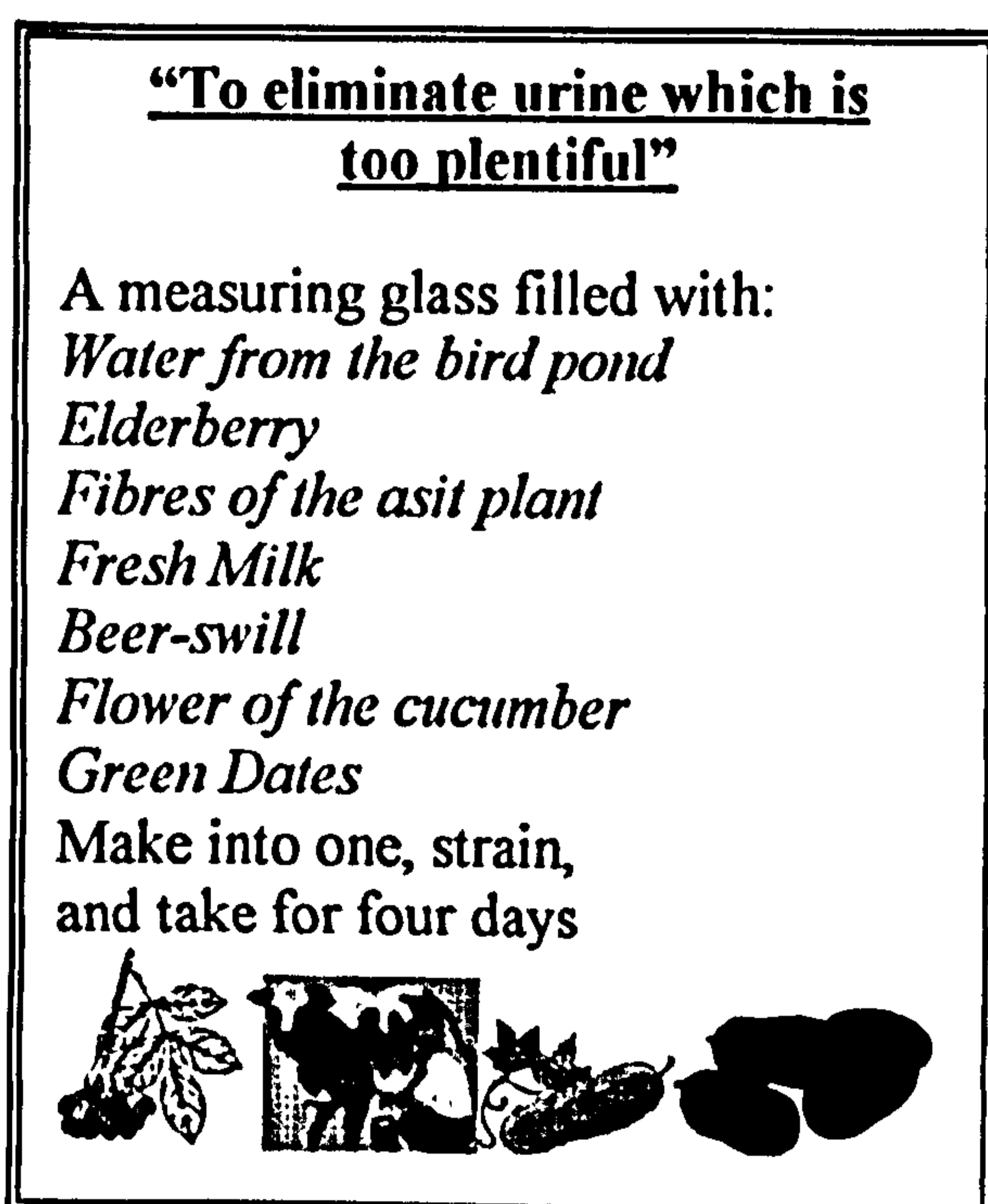


Figure 1.1 Diabetes remedy.

Figure 1.2

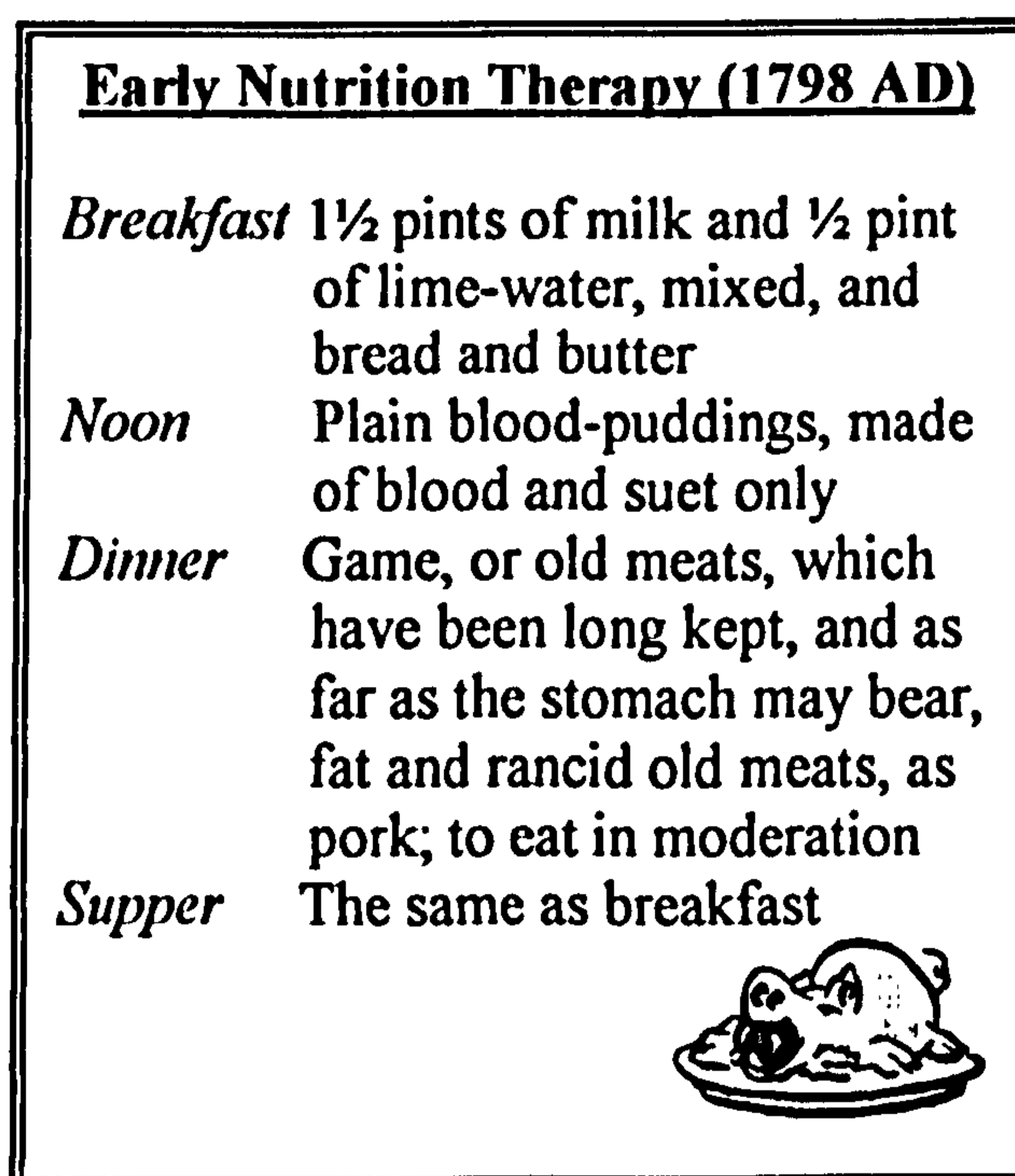


Figure 1.2 A diet for people with diabetes, prescribed by Rollo in 1798

Source: Sanders LJ. *The Philatelic History of Diabetes*. American Diabetes Association, 2001.

1.4 Classification

In 1965, the World Health Organisation (WHO) proposed a classification of diabetes mellitus based on the age of recognised onset (WHO Expert Committee 1965). That classification was later modified by the US National Diabetes Data Group (National Diabetes Data Group 1979) and the WHO (WHO Expert Committee on Diabetes Mellitus 1980) where two major classes of diabetes mellitus were proposed: insulin-dependent-diabetes-mellitus (IDDM), otherwise known as Type 1, and non-insulin-dependent-diabetes (NIDDM), or Type 2. However, that classification was further revised in 1985 (WHO 1985a) when the terms Type 1 and Type 2 were omitted, the terms IDDM and NIDDM being retained. Other types of diabetes included impaired glucose tolerance (IGT) and gestational diabetes mellitus (GDM). The 1985 report

became widely accepted and used internationally. It represented a compromise between clinical and aetiological classification, leading to the grouping of patients in a clinically useful manner, even when the specific cause or aetiology was unknown.

Diabetes classifications were further revised in 1997 by the American Diabetes Association (ADA). It revised the diagnostic criteria and introduced another new category called impaired fasting glucose (IFG) (ADA Expert Committee on the Diagnosis and Classification of Diabetes Mellitus 1997). That most recent classification attempts to categorize diabetes according to disease aetiology rather than treatment. At around the same time, WHO also revised its 1980/1985 classification (WHO Working Group 1999). The aetiological classification again equated IDDM with Type 1 diabetes and NIDDM with Type 2 diabetes. The new classification has addressed the fact that many people with NIDDM require insulin to treat their diabetes. Table 1.2, below, summarises the current classification of diabetes mellitus (ADA Expert Committee on the Diagnosis and Classification of Diabetes Mellitus 1997).

Table 1.2 Aetiological classification of diabetes mellitus

AETIOLOGICAL CLASSIFICATION OF DIABETES MELLITUS

- Type 1 diabetes, historically known as IDDM, results from absolute insulin deficiency and more commonly presents acutely before the age of 30.
- Type 2 diabetes, historically known as NIDDM, results from a relative deficiency of, or insensitivity to, insulin and is more commonly diagnosed over the age of 40. It affects 75-90% of all people with diabetes.
- Other specific forms of diabetes, such as genetic defects in β -cell function (e.g. MODY syndromes*); genetic defects in insulin action (e.g. leprechaunism); diseases of the exocrine pancreas (e.g. pancreatitis); endocrinopathies (e.g. acromegly); drug or chemical induced diabetes (e.g. glucocorticoids); infections (e.g. congenital rubella); uncommon forms of immune-mediated diabetes (e.g. anti-insulin receptor antibodies), and other generic syndromes that are sometimes associated with diabetes (e.g. Down's syndrome).
- Gestational diabetes mellitus

*MODY = maturity-onset diabetes of the young due to specific genetic defects of glucokinase, or hepatic nuclear factors.

1.5 Diagnostic criteria

The major difference in the diagnostic criteria for diabetes after revision was the lowering of the diagnostic value of the fasting plasma glucose concentrations from the former level of 7.8 mmol/l to 7.0 mmol/l and above. This lowered blood glucose level is thought to compare with equal diagnostic significance to the two-hour post-load concentration which remains the same at 11.1 mmol/l (ADA Expert Committee on the Diagnosis and Classification of Diabetes Mellitus 1997; WHO Working Group 1999). The fasting glucose test is carried out by taking a blood sample in the morning after the patient has fasted from midnight. The post-prandial glucose assessment is based on an oral glucose tolerance test (OGTT). A 75g oral glucose challenge is given to the patient and blood samples are then taken to assess the two-hour plasma glucose response.

Impaired glucose regulation includes IGT and IFG and refers to a metabolic state intermediate between normal glucose homeostasis and diabetes. However, IFG and IGT are not interchangeable and they represent different abnormalities of glucose regulation: one in the fasting state and one post-prandial. IFG is defined as a fasting venous plasma glucose 6.1-6.9 mmol/l, whereas IGT is two-hour plasma glucose 7.8 – 11.1 mmol/l.

Table 1.3 Diagnostic criteria for diabetes mellitus, IFG and IGT

Diagnostic Criteria for Diabetes Mellitus, IFG and IGT		
	Venous plasma glucose, (mmol/l)	
	Fasting	120 minutes after glucose load
Normal	≤ 6.0	≤ 7.8
Impaired fasting glucose	6.1 - 6.9	---
Impaired glucose tolerance	< 7.0	7.8 - 11.0
Diabetes mellitus	≥ 7.0	≥ 11.1

N.B. In the absence of symptoms, a diagnosis of diabetes must be confirmed by a second diagnostic test, i.e. a fasting, random, or repeat glucose tolerance test, on a separate day.

The 1997 ADA criteria recommended that the OGTT should not be routinely used to identify either diabetes or IGT. That recommendation has led to a great deal of controversy (Gerstein 2001). Although both IFG and IGT have increased risks of progressing to diabetes and macrovascular disease, it has been demonstrated that IGT is

more sensitive than IFG and it would therefore identify more people who are at risk of progressing to Type 2 diabetes (Shaw et al. 1999). Moreover, it has been suggested that post load hyperglycaemia is an early risk factor for cardiovascular disease and may be a stronger predictor of cardiovascular events than fasting hyperglycaemia (DECODE Study Group of the European Diabetes Epidemiology Group 2001). Shaw and colleagues have recommended that IFG be diagnosed at a lower limit of 5.8 mmol/l to define a group more similar to the group with IGT (Shaw et al. 2000).

1.6 Epidemiology

1.6.1 World prevalence

Diabetes is now one of the most common non-communicable diseases in the world and is considered a global health problem. It is the fourth or fifth leading cause of death in developed countries and has become an epidemic in many developing countries (Sicree, Shaw, & Zimmet 2003). Prevalence of diabetes in adults worldwide was estimated at 135 million (or 4.0% of the population) in 1995 (King, Aubert, & Herman 1998). In 2003, it was estimated that 194 million people (5.1%) aged between 20 and 79 years have diabetes. That figure is expected to increase to 333 million adults (6.3%) by the year 2025 (Sicree, Shaw, & Zimmet 2003). It is thought that developing countries will experience the major part of the numerical increase (170%) compared to a 42% increase in developed countries (King & Rewers 1993). In 2003, the region with the greatest number of persons with diabetes was Europe. However, by 2025, that is expected to shift to the South-East Asian region, although the region's prevalence of 7.5% will still be lower than that of North America, estimated at 9.7%, and Europe at 9.1% (Sicree, Shaw, & Zimmet 2003).

Mean prevalence (Type 1 and Type 2 diabetes) in the age range 30-64 years for different regions is shown in Table 1.4 on page 8 (WHO/OMS 2001). The African and Asian region includes *Arab, Bantu, Creole, Chinese, Indian, Malay and Tai* populations. The American region includes *American Indian, Brazilian, Colombian, U.S. non-Hispanic white, U.S. non-Hispanic black and U.S. Hispanic* populations. The European region includes *Italian, Maltese, Polish and Russian* populations. Finally, the Pacific region includes *Aboriginal Australian, Melanesian, Micronesian, and Part Polynesian and Polynesian* populations. The data shows that although the mean prevalence is similar for each region there are large variations within regions.

It is felt that social and behavioural changes, with the rise in obesity and the decline in physical activity levels, together with an increased longevity, are the main factors for the recent global explosion of Type 2 diabetes (Campbell 2001). The condition has, in the past, been erroneously referred to as *mild diabetes* because it is often asymptomatic as far as the classical symptoms of diabetes are concerned, such as thirst and polyuria (Campbell & Leslie 1997). Prevention and control programmes are needed to stem the rising epidemic of diabetes and its complications (Amos, McCarty, & Zimmet 1997).

Table 1.4 Mean prevalence of diabetes (per cent population) in the age range 30-64 years in their respective geographical regions, including highest and lowest prevalence populations

Study Population	Men		Women	
	Crude rate rate	Age-adjusted	Crude rate rate	Age-adjusted
African and Asian	9.2	10.1	8.0	9.1
Highest: Indian (Fiji)	19.4	23.6	18.1	20.3
Lowest: Bantu (Mara)	1.1	1.0	0.4	0.4
American	10.9	10.9	10.7	10.8
Highest: American Indians USA (Pima & Papago)	47.6	49.4	48.9	51.1
Lowest: American Indians Chile (Mapuches)	0.00	0.00	1.1	1.4
European	6.9	6.3	7.2	6.4
Highest: Italian (Laurino)	11.4	10.7	13.0	9.8
Lowest: Russian (Novosibirsk)	2.1	1.8	4.0	3.6
Pacific	9.1	9.5	9.4	10.6
Highest: Aboriginal (Bourke)	25.6	24.0	19.0	20.9
Lowest: Melanesian (Papua New Guinea)	0.0	0.0	0.0	0.0

Adapted from the WHO <http://www.who.int/ncd/dia/databases2.htm>

1.6.2 UK prevalence

In the UK diabetes is recognised as one of the most common chronic disorders (Keen et al. 1995). Approximately 1.67 million adults aged between 20 and 79 years (or 3.9% of the population) have diabetes (Sicree, Shaw, & Zimmet 2003), although a further million are thought to have diabetes without yet knowing it (Diabetes UK 2003b). Approximately 85% of people diagnosed with diabetes in England have Type 2 diabetes (DOH 2001a).

1.6.3 Children and adolescents

Epidemiological changes are not confined to Type 2 diabetes. Most population-based registers of Type 1 diabetes in children report significant increases in incidence with time, although the aetiology is not fully understood (Green & Patterson 2001). Also of concern, but not documented in the figures above, is the dramatic increase in the number of children developing Type 2 diabetes (Rosenbloom et al. 1999). Although there is a strong hereditary component to the disease, the recent increases observed in diabetes prevalence have occurred too quickly to be the result of increased gene frequency and altered gene pool, emphasising the importance of environmental factors such as physical inactivity and obesity in the development of Type 2 diabetes (ADA 2000). This thesis focuses solely upon adults with diabetes and, from now on, reference will only be made to adults living with Type 2 diabetes.

1.6.4 Obesity and diabetes

Obesity is now commonly defined in adults as a Body Mass Index (BMI) $\geq 30\text{Kg/m}^2$. It is, in simple terms, an excess storage of body fat. It develops from an excess of energy intake compared with energy expenditure. In adult men of average weight, fat comprises 15-20% of the total body weight, while in women that proportion is greater at 25-30%. The precise definition of obesity remains controversial for a number of reasons: firstly, because the distribution of weight within a given population forms a continuous curve rather than division into discrete populations of obese and non-obese individuals, and secondly, because differences in weight between individuals relate not only to variations in body fat but also to frame size and muscle bulk (Allahabadia & Kumar 2002). However, an excellent correlation has been made between BMI and percentage body fat in large populations (Deurenberg, Westrate, & Seidell 1991). WHO and the International Obesity Task Force (IOTF) definitions of obesity are shown in Table 1.5 below.

Table 1.5 Classification of overweight and obesity in adults according to BMI

BMI (Kg/m ²)	Grade	Classification
< 18.4	-----	Underweight
18.5 – 24.9	Pre-obese	Healthy: desirable weight
25 – 29.9	Obesity Grade I	Overweight: should lose weight
30- 39.9	Obesity Grade II	Obese: need to lose weight
≥ 40	Obesity Grade III	Very obese: must lose weight

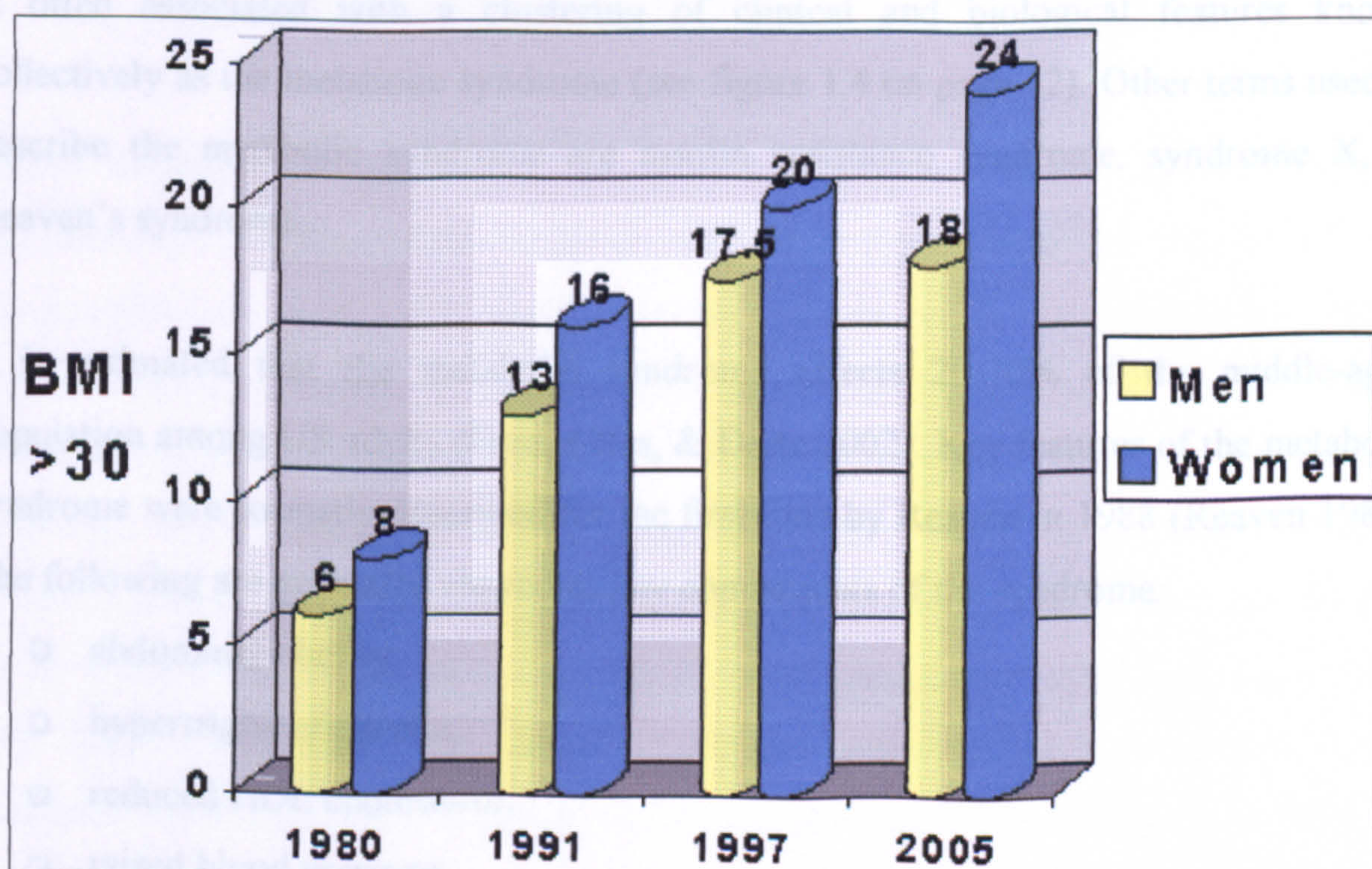
Source: (WHO/OMS 1998)

Type 2 diabetes is the most significant medical consequence of obesity (WHO/OMS). The UK *Health of the Nation* targets (Nutrition and Physical Activity Task Forces 1994) were that by the year 2005 the percentage of people aged 16-64 years who were obese would be reduced from the 1986/87 baseline of 8% of men and 12% of women to no more than 6% and 8% respectively. However, by 1998 the respective figures had increased to 17% and 21% and those figures are predicted to rise further by 2005 (see figure 1.3 below).

WHO, despite its historical focus on malnutrition and starvation, has raised concerns regarding the problem of over-nutrition. In 1998 WHO Consultation on Obesity proclaimed that, “the epidemic projections for the next decade are so serious that public health action is urgently needed” (WHO 1998a). Two years later it again called for urgent action as diabetes was, by then, affecting developing countries as well as industrialised countries (WHO 2000b).

Even in the developing countries, a pattern of rapidly escalating obesity and its co-morbidities is becoming apparent in certain sections of society (Prentice 2000). Potential conditions associated with obesity are Type 2 diabetes, coronary heart disease, insulin resistance, dyslipidaemia, and some site-specific cancers, such as colorectal, uterine, cervical and ovarian cancer (Jung 1997).

Figure 1.3 The UK rising epidemic of obesity



Source: (DOH 2003b)

Type 2 diabetes is the most significant medical consequence of obesity (WHO/OMS 1998). In a prospective study of 114,281 nurses aged 30-55 years, after adjustment for age, BMI was the dominant predictor of risk of developing Type 2 diabetes (Colditz et al. 1995). In women the risk was shown to:

- rise above a BMI of 22 kg/m²;
- increase fivefold at a BMI of 25 kg/m²;
- increase 28-fold at a BMI of 30 kg/m²;
- increase 93-fold above a BMI of 35 kg/m².

A weight gain of 8 –10.9 kg correlated to a 2.7 fold increase in the risk of developing Type 2 diabetes compared to those whose weight remained stable (Colditz et al. 1995). In a study of 51,529 men aged 40-57 years, there was found to be an increased risk of developing Type 2 diabetes above a BMI of 24 kg/m². Having adjusted for age, the risk was shown to:

- increase two fold at BMI 25-26.9 kg/m²;
- increase 6.7 fold at BMI 29-30.9 kg/m²;
- increase 42-fold at BMI 35 kg/m² or above (Chan et al. 1994).

1.6.5 Insulin resistance and the metabolic syndrome

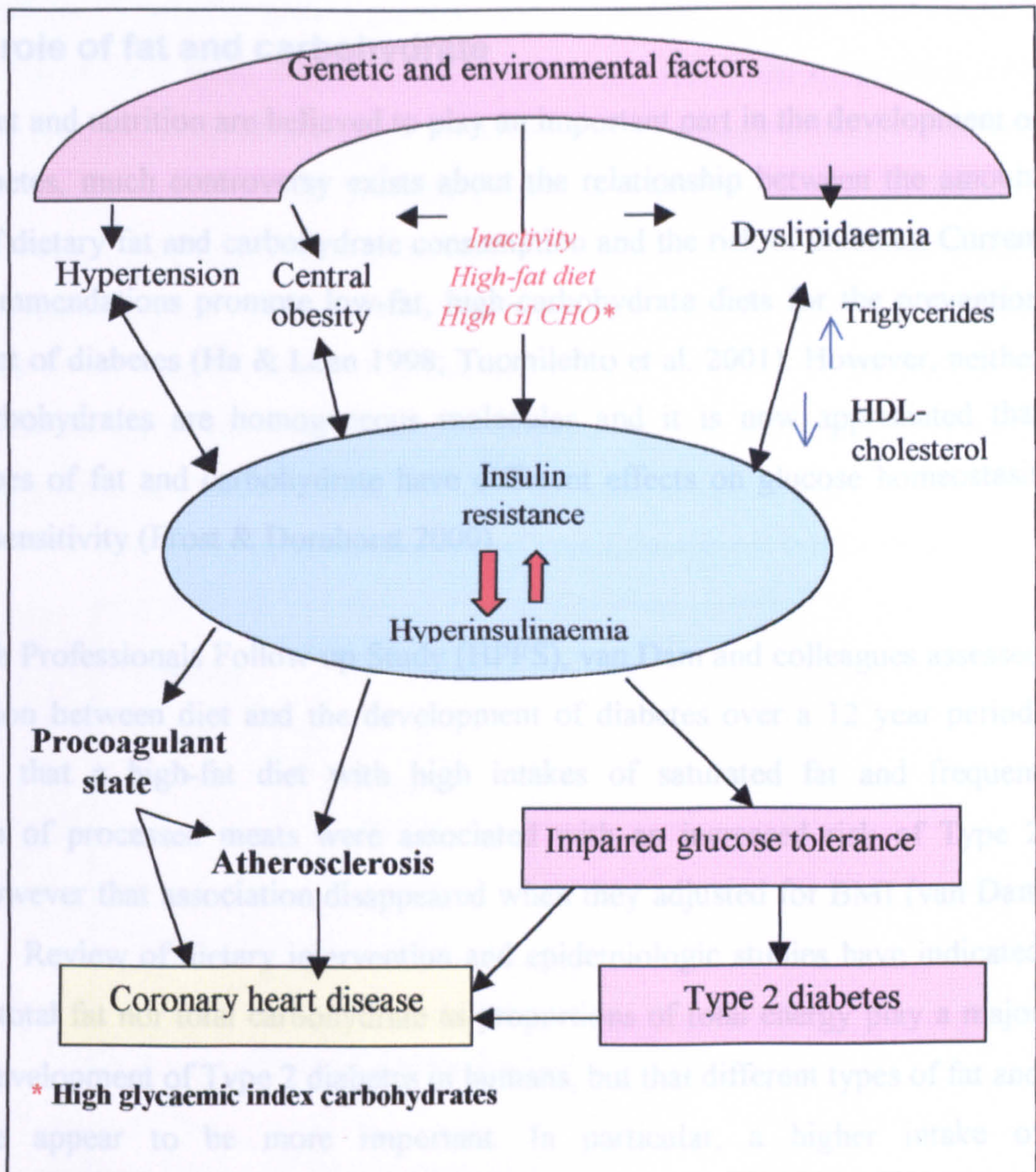
The term “insulin resistance” indicates a situation where the biological effect of insulin is reduced. The presence of insulin resistance is implied when there is normo- or hyperglycaemia alongside hyperinsulinamia (Krentz & Bailey 2001). Insulin resistance is often associated with a clustering of clinical and biological features known collectively as the metabolic syndrome (see figure 1.4 on page 12). Other terms used to describe the metabolic syndrome are insulin resistance syndrome, syndrome X, or Reaven’s syndrome.

It is estimated that the metabolic syndrome affects 20-30% of the middle-aged population among US adults (Ford, Giles, & Dietz 2002). Key features of the metabolic syndrome were formally described for the first time by Reaven in 1988 (Reaven 1988).

The following are generally viewed as key components of the syndrome:

- abdominal obesity;
- hypertriglyceridaemia;
- reduced HDL cholesterol;
- raised blood pressure;
- glucose intolerance or overt hyperglycaemia.

Figure 1.4 The metabolic syndrome



Source: adapted from Krentz & Bailey 2001

Insulin resistance is regarded as the central abnormality of the entire syndrome. Recommendations have been made to add that characteristic to the list of key components, as well as other common effects such as: microalbuminuria, hyperuricaemia, procoagulant changes in the blood and dysfunction of the endothelium (Ford, Giles, & Dietz 2002). A tool has been developed to identify the metabolic syndrome: the measurement of “hypertriglyceridaemic waist”. It was found that, in middle-aged men, a new clinical phenotype defined by waist circumference greater than 90 cm combined with fasting triglyceride levels of greater than 2.0 mmol/l suggested a high likelihood of finding the clustering features of the metabolic syndrome. It was concluded, therefore, that emphasis should be placed on the management of waist

measurement rather than weight and it was proposed that waist circumference was an inexpensive “vital sign” that should be measured in all patients (Lemieux et al. 2002).

1.6.6 The role of fat and carbohydrate

Although diet and nutrition are believed to play an important part in the development of Type 2 diabetes, much controversy exists about the relationship between the amount and types of dietary fat and carbohydrate consumption and the risk of diabetes. Current dietary recommendations promote low-fat, high-carbohydrate diets for the prevention and treatment of diabetes (Ha & Lean 1998; Tuomilehto et al. 2001). However, neither fats nor carbohydrates are homogeneous molecules and it is now appreciated that different types of fat and carbohydrate have different effects on glucose homeostasis and insulin sensitivity (Frost & Dornhorst 2000).

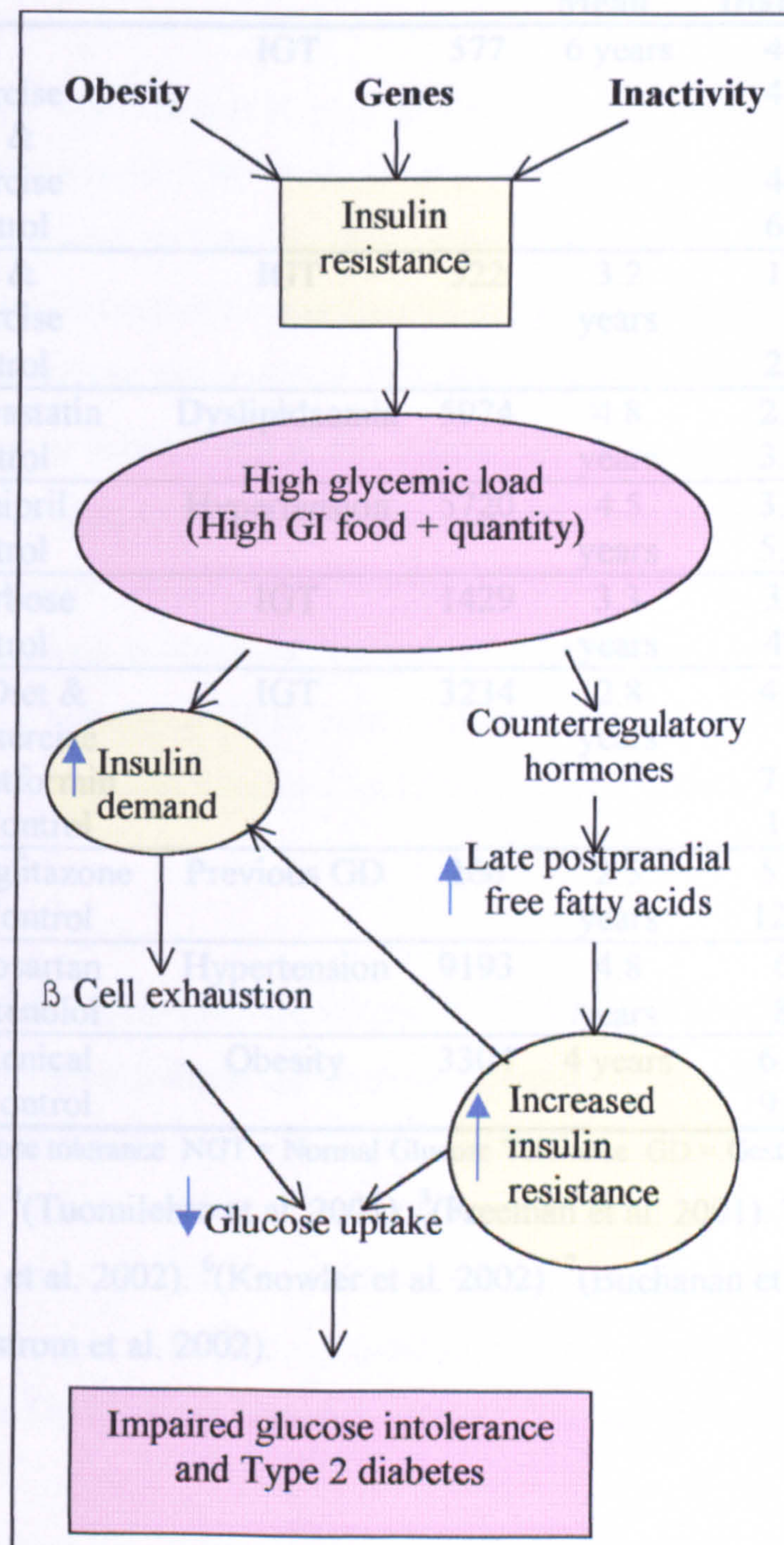
In the Health Professionals Follow-up Study (HPFS), van Dam and colleagues assessed the association between diet and the development of diabetes over a 12 year period. They found that a high-fat diet with high intakes of saturated fat and frequent consumption of processed meats were associated with an increased risk of Type 2 diabetes. However that association disappeared when they adjusted for BMI (van Dam et al. 2002). Review of dietary intervention and epidemiologic studies have indicated that neither total fat nor total carbohydrate as proportions of total energy play a major part in the development of Type 2 diabetes in humans, but that different types of fat and carbohydrate appear to be more important. In particular, a higher intake of polyunsaturated fat and long-chain n-3 fatty acids could be beneficial, if consumed instead of saturated and trans-fat, and could appreciably reduce the risk of developing Type 2 diabetes (Hu, van Dam, & Liu 2001).

Glycaemic index (GI)

GI is the ranking of carbohydrate foods based on their post-prandial response on blood glucose levels. The clinical utility of the GI remains controversial (Pi-Sunyer 2002). However, current evidence indicates that the GI is a useful concept and the WHO nutritional body, WHO/FAO, now recommends that dietary carbohydrates be classified according to their glycaemic index (FAO/WHO 1997). An international table of glycaemic index and glycaemic load values is available and classifies over 750 types of food (Foster-Powell, Holt, & Brand-Miller 2002). Glucose load is the GI for a particular type of food multiplied by its dietary carbohydrate content.

However, the GI database needs further development and refinement particularly in different populations and in the context of mixed meals. Future epidemiological studies about the association between dietary glucose load and the prevention and treatment of diabetes should include large sample sizes and a longer follow-up to produce more robust results (Hu, van Dam, & Liu 2001). In the meantime, enough evidence does exist to support a theory that a low GI diet, incorporating a greater amount of fibre and minimally processed whole grain products, will lower the glycaemic and insulinaemic responses to carbohydrate. The traditional concept of “simple” versus “complex” carbohydrates is no longer useful in predicting the risk of Type 2 diabetes or in achieving optimum glycaemic control and this has been replaced with a proposed model incorporating glycaemic load (figure 1.5) (Willett, Manson, & Liu 2002).

Figure 1.5 Proposed mechanisms for the development of Type 2 diabetes due to high glycaemic load



Adapted from
(Willett, Manson,
& Liu 2002)

1.6.7 Prevention

The prevention of Type 2 diabetes has been an area of interest for many years and has recently attracted increasing interest, possibly due to the escalating burden of Type 2 diabetes upon resources worldwide. Also the results from several intervention trials have been published, many of which have demonstrated the potential for lifestyle changes or medication to reduce the development of diabetes in people with impaired glucose tolerance (Table 1.6).

Table 1.6 Summary of the diabetes prevention trials

Trial	Intervention	Patient Details	N ^o in Trial	Follow-up Mean	Incidence of Diabetes	Risk Reduction
Da Quing ¹	Diet	IGT	577	6 years	44%	31%
	Exercise				41%	46%
	Diet & Exercise				46%	42%
	Control				68%	-----
FDPS ²	Diet & Exercise	IGT	522	3.2 years	11%	58%
	Control				23%	-----
Freeman et al. ³	Pravastatin Control	Dyslipidaemia	5974	4.8 years	2.3% 3.4%	30% -----
Yusuf et al. ⁴	Ramipril Control	Hypertension	5720	4.5 years	3.6% 5.4%	34% -----
STOP-NIDDM ⁵	Acarbose Control	IGT	1429	3.3 years	32% 42%	25% -----
DPP ⁶	Diet & exercise	IGT	3234	2.8 years	4.8%	58%
	Metformin				7.8%	31%
	Control				11%	-----
Buchanan et al. ⁷	Troglitazone Control	Previous GD	266	2.5 years	5.4% 12.1%	55%
LIFE ⁸	Losartan	Hypertension	9193	4.8 years	6%	25%
	Atenolol				8%	-----
XENDOS ⁹	Xenical Control	Obesity	3304	4 years	6.2% 9.0%	37% -----

IGT = Impaired Glucose tolerance NGT = Normal Glucose Tolerance GD = Gestational Diabetes

¹(Pan et al. 1997). ²(Tuomilehto et al. 2001). ³(Freeman et al. 2001). ⁴(Yusuf et al. 2001). ⁵(Chiasson et al. 2002). ⁶(Knowler et al. 2002). ⁷(Buchanan et al. 2002). ⁸(Dahlöf et al. 2002). ⁹(Sjostrom et al. 2002).

The intensive lifestyle approach to diabetes prevention appears to offer more protection than medication. The Da Qing IGT and Diabetes study, the Finnish Diabetes Prevention Study (DPS) and the US Diabetes Prevention Programme (DPP) all clearly show that patients who participated in an individualised diet and exercise programme greatly reduced their risk of developing Type 2 diabetes. However, in reality, people may use drugs because they are easier and convenient. It is questionable whether diabetes prevention through medication is a sensible long-term option. Treatment by medication alone tends to be a life-long requirement and all medication has potential adverse effects. On the other hand, a healthier lifestyle offers patients potential benefits over and above the treatment of IGT. The question is whether healthcare professionals would be providing adequate treatment if they were to continue prescribing medication in place of encouraging an intensive lifestyle approach (Deakin 2003a; Marks 2003).

In the DPS patients were set five targets: to reduce body weight by more than 5%; to reduce total fat intake to less than 30% of total calories; to reduce saturated fat to less than 10% of total calories; to increase fibre intake to at least 15g per 1000 calories, and to participate in physical activity for at least 30 minute each day. In those who achieved four or five of the targets, not one case of diabetes was diagnosed. However, in those who didn't manage to achieve any of the targets, 35% developed diabetes. Individuals who lost 5% body weight experienced a 47% risk reduction in developing diabetes and those who lost 11% body weight gained the benefit of a 63% risk reduction. Subsequent outcome collection and analysis at 12 and 18 months post study has shown that although there was initially a slight deterioration in the risk reduction at 12 months (58% down to 45%), that had stabilised by 18 months (risk reduction 44%) (Tuomilehto 2002).

Tuomilehto and colleagues have developed a 'Diabetes Prediction Risk Score' that predicts the risk of an individual developing diabetes. It is based on age, BMI, diet, hypertension, previous gestational diabetes, glucose level, and family history. A score of less than seven indicates a less than 1% chance of developing diabetes and a score above seven suggests a greater than 50% chance of developing diabetes. That type of scoring system is thought to be a cheaper and more effective way of predicting diabetes than performing an OGTT on all high-risk patients (Tuomilehto 2002).

The intensive lifestyle approach in the DPP comprised 16 individual sessions followed by maintenance of individual and group sessions with supervised exercise sessions. The aim was to achieve a 7% weight loss by consuming between 1200-2000 Kcal/day with less than 25% fat and by taking 30 minutes of exercise each day. The lifestyle approach was more effective in leaner, older participants and the metformin medication intervention had better results for more obese individuals. Body weight reduction was, however, the strongest predictor for preventing diabetes; a 15 kg weight loss equated to zero risk of developing diabetes. Individuals who did not manage to lose weight had a 15 times greater risk of developing diabetes.

The DPP was expensive with each case costing \$25,000. The 'Number Needed to Treat' with the intensive lifestyle approach to prevent just one case of diabetes is seven people with IGT (Diabetes Prevention Program Research Group 2002). Outcomes were only achieved in a motivated selected sample of people with IGT. Initially 30,000 people were identified for the trial, but only 3,000 of them provided written consent to participate. That suggested that 27,000 individuals were not interested in lifestyle change. Of the participating individuals, only 50% initially achieved the weight loss target and that percentage reduced to just 38% at the final data collection (Snoek 2002).

Diabetes prevention could be a very costly health promotion strategy. Developed countries would find it very difficult to provide the resources to repeat the intensive lifestyle intervention from the DPP on a population level and, in developing countries where the diabetes epidemic is projected to be greater, it would be a colossal task. Even if resources were available, it would be interesting to monitor how many people at high risk of developing diabetes would carry out protective lifestyle behaviours. Another important factor to take into consideration is that the education and training of healthcare professionals would be an essential prerequisite to increasing public awareness of IGT and its consequences. A recent UK survey reported that 47% of GPs were unaware that IGT leads to Type 2 diabetes (Davis et al. 1987).

1.7 Principles of treatment

1.7.1 Aims and objectives

The current aim of treatment for Type 2 diabetes is focused upon optimising quality of life:

To maximise the quality of life of all people with diabetes and reduce their risk of developing the long-term complications of diabetes (DOH 2001a).

The active involvement of patients in their own care is the cornerstone of good diabetes management, for it is the person with diabetes who plays the most crucial role in the process, and hence their self-motivation is essential.

International collaborations, such as the Saint Vincent Declaration in Europe in 1989, have set targets for improvements in care. That declaration resulted from a meeting between various representatives of European government health departments and patient organisations under the aegis of the European Regional Office of WHO and the International Diabetes Federation. The meeting produced unanimous agreement on a series of general goals and five-year targets.

The following targets were agreed in the St Vincent Declaration (DOH & Diabetes UK 1995):

- reduce cases of new blindness by at least one third;
- reduce numbers of people entering end stage renal failure by at least one third;
- reduce the rate of limb amputations for diabetic gangrene by at least a half;
- cut mortality and morbidity from coronary heart disease in people with diabetes;
- improve the outcome of pregnancies in women with diabetes.

Diabetes UK has made recommendations for the standard of healthcare that people with diabetes should expect (Diabetes UK 2001b) (see figure 1.6 on page 19).

Figure 1.6 Diabetes UK standards “what care people should expect”

When diagnosed with diabetes people should receive:

- a full medical examination;
- a talk with a registered nurse with a special interest in diabetes;
- a talk with a state registered dietitian;
- a discussion of the implications of diabetes e.g. occupation, driving, insurance, prescription charges etc;
- information about Diabetes UK services and the local branch;
- if treated with oral hypoglycaemic agents, discussion about the possibility of hypoglycaemia and how to treat;
- if treated by diet alone, or a combination of diet and tablets, instruction on blood or urine testing, what the results mean and supplies of equipment.

Once the diabetes is reasonably controlled, there should be:

- on going education about diabetes and the positive effects of exercise;
- access to the diabetes team at regular intervals (ideally every 4-6 months);
- contact with any member of the healthcare team for specialist advice;
- education sessions at a rate appropriate to an individual’s ability to assimilate the information;
- a formal medical review by a doctor experienced in diabetes;

At the annual review, the following should be undertaken:

- weight record and calculation of BMI;
- urine test for protein;
- blood sample to measure long-term diabetes control;
- discussion of home monitoring results, if appropriate;
- blood pressure check;
- vision check and examination of the back of the eyes;
- legs and feet examined to check circulation and nerve supply;
- injection sites examined if on insulin;
- an opportunity to discuss coping measures for diabetes.

Source: Diabetes UK, 2001

1.7.2 Organisation of care

Diabetes care is increasingly being delivered, not only in hospitals, but also in primary and community care settings. Existing information, infrastructure, systems and services do not always meet the needs of people with diabetes. A review of diabetes services in England and Wales focused mainly on a small sample of hospitals but also included surveys of health authorities, general practices and patients. The results showed variable levels of care, with many services struggling to cope with the current demand. It is predicted that pressure upon current services will increase as patient numbers rise.

Summaries of some of the findings are presented in figure 1.7 below (Audit Commission for Local Authorities and the National Health Service 2000).

Figure 1.7 Testing Times: some key findings

<p>More patients are now being managed within primary care, but standards vary:</p> <ul style="list-style-type: none"> • practice nurses working alone operate one third of clinics; • less than one third of practices have routine access to a dietitian or chiropodist; • four in 10 practices lack referral guidelines to secondary care; • health professionals delivering services in community settings do not always have the training or support that they need; • many primary care organisations are unable to establish the number of people with diabetes in their care; • only a quarter of general practices are able to provide patient held records for people with diabetes. <p>Hospitals are not always providing the best care:</p> <ul style="list-style-type: none"> • patients report delays in clinics and insufficient time with staff; • patient education was inadequate at half of the hospitals visited; • ethnic minority patients are twice as likely to report gaps in their knowledge and understanding of diabetes; • numbers of doctors and nurses vary fourfold; • two thirds of patients report that they have received no education in the last year; • one fifth of patients report a lack of opportunity to talk to other patients.

Source: The Audit Commission, 2000

The Delivery Strategy for the National Service Framework for Diabetes in England (DOH 2003a) is attempting to address these findings in a variety of ways:

- by encouraging Primary Care Trusts (PCTs) to develop clinically-led, managed diabetes networks. These will be an extension to the Local Diabetes Services Advisory Group (LDSAG) and will bring together all the key players in diabetes care, including people with diabetes, clinical champions and healthcare managers. The managed networks will have direct accountability to the PCTs and will be a major step towards a situation where diabetes care is managed mainly within primary care;
- by supporting an education and training programme for all healthcare staff involved in the treatment and management of people with diabetes to ensure that people with diabetes receive evidence-based and appropriate education and advice by a named contact within the healthcare team;
- by encouraging all PCTs to develop group-based structured and ongoing education programmes that provide accurate and consistent education and advice to people with diabetes and their carers;

- by setting up practice-based registers that will provide the basis for call and recall for regular review, clinical care, monitoring and clinical audit;
- by providing patients with access to their medical records so that they can work in partnership with healthcare professionals.

Those objectives, if achieved, will improve the quality and consistency of diabetes care. However, there have been concerns regarding the availability of resources to implement the delivery strategy. Extra resources for the NHS were announced in the 2002 Budget. Although that provided for the largest ever sustained increase in NHS funding, no resources have been ring-fenced for diabetes services. Local decisions about health priorities will influence whether adequate resources are made available for the development and improvement of diabetes services.

1.7.3 Education

Effective ongoing education, matched to each patient's ability and capacity to learn, can enable people with diabetes to take responsibility for their own health. People with diabetes should also be empowered to obtain the maximum benefit from healthcare services so that, as far as possible, they develop the skills and the confidence to make informed decisions regarding their diabetes self-care. Health behaviour models and theories will be discussed in detail in Chapter 2.

1.7.4 Importance of glycaemic control

Type 2 diabetes has a major impact on health and survival and could be termed a *silent killer* (Campbell 2001). People living with Type 2 diabetes are two to four times more likely to develop cardiovascular disease (IDF 2001) and have significantly higher cardiovascular death rates than people without diabetes (Roper et al. 2001). Coronary heart disease and stroke are thought to be the result of persistently raised blood glucose that exacerbates both atherosclerosis and arteriosclerosis of the arteries supplying the heart and brain, and raised blood pressure. Foot ulceration, ('diabetic foot') is the most common reason for people with diabetes to be admitted to hospital in the UK (Young et al. 1994). It is a result of nerve damage (neuropathy) and lack of blood supply (ischaemia). If an ulcer becomes infected and gangrenous, amputation can become necessary. People with diabetes are 15 times more likely to need amputation than people without the condition (Bild et al. 1989). Diabetic retinopathy is an eye disease caused by damage to the small blood vessels at the back of the eye. It is considered to be the leading cause of blindness in people of working age (Evans 1995). Diabetic

nephropathy, (kidney disease caused by diabetes), is one of the most serious complications of diabetes and is a major cause of fatal kidney failure (Cameron & Challah 1986). It is caused by excess blood glucose damaging the small blood vessels in the kidneys, and by raised blood pressure.

The United Kingdom Prospective Diabetes Study (UKPDS Group 1998b) has provided evidence that the life threatening complications of Type 2 diabetes can be reduced by ensuring optimum levels of both blood glucose and blood pressure. A more recent observational study of complications in Type 2 diabetes has demonstrated that for every per cent reduction in glycated haemoglobin, there was a corresponding reduction in risk of 21% for any end point related to diabetes, a reduction of 21% for deaths related to diabetes, 14% for myocardial infarction and 37% for microvascular complications (Stratton et al. 2000). Each 10 mmHg decrease in systolic blood pressure was associated with reductions in risk of 12% for any complication related to diabetes, 15% for deaths related to diabetes, 11% for myocardial infarction and 13% for microvascular complications (Adler et al. 2000). Therefore, any reduction in glycated haemoglobin and blood pressure is likely to reduce the risk of complications, with the lowest risk being in those cases where with HbA1c values are in the normal range (< 6.0%) and systolic blood pressure values less than 120 mm Hg.

The National Institute for Clinical Excellence (NICE) is the Clinical Guidelines Programme for England and Wales. It is the independent organisation responsible for providing guidance about treatments and services for those in England and Wales eligible for NHS care. Its guidance is for healthcare professionals and patients and their carers and it is designed to help them make decisions about treatment and healthcare. NICE has written or commissioned a series of guidelines on the clinical management of Type 2 diabetes and its associated problems: prevention and management of foot problems (Hutchinson et al. 2000); retinopathy – early management and screening (NICE 2002d); renal disease – prevention and early management (NICE 2002c); managing blood glucose levels (NICE 2002b); management of blood pressure and blood lipids (NICE 2002a).

1.7.5 Diet and physical activity

UK dietary guidelines for the management of diabetes have recently been updated (Nutrition Subcommittee of the Diabetes care Advisory Committee of Diabetes UK 2003). Important changes from previous recommendations of Diabetes UK (formerly

the British Diabetic Association) (BDA Nutrition Sub-Committee 1992) include greater flexibility in the proportions of energy derived from carbohydrate and monounsaturated fat, further liberalisation in the consumption of sucrose, more active promotion of foods with low glycaemic index, and greater emphasis on promoting physical activity levels. Those recommendations are more in line with the European (Ha & Lean 1998) and American (ADA 2003) nutritional and physical activity recommendations for the management of diabetes. Table 1.7 provides a brief overview of those recommendations.

Table 1.7 Summary of the dietary and physical activity recommendations for adults with diabetes

Recomm- endation	European	American	UK
Energy	If overweight: energy deficit of 500 Kcal per day aiming for a 10Kg weight loss.	Standard weight reduction diets. Added exercise and behaviour strategies are essential for long-term success.	If overweight: energy deficit of 500 Kcal per day aiming for 1-2 Kg weight loss per month.
CHO	Carbohydrate (CHO) with monounsaturated fat (MUFA) should provide 60-70% of total energy.	CHO rich in dietary fibre or with low GI is recommended along with veg, legumes, fruits and cereal-derived CHO.	The total CHO in meals/snacks is more important than GI. CHO from whole grains, fruits, vegetables, and low fat milk is recommended.
Sucrose	As sucrose does not produce a greater rise in plasma glucose than isocaloric amounts of starch, sucrose and sugary food does not have to be restricted and may provide up to 10% of the daily energy derived from carbohydrate.	More active promotion of carbohydrate foods with a low glycaemic index.	
Protein	10-20% of total Kcal (should not exceed this level). 0.8 Kg per Kg of body weight if microalbuminuria or nephropathy.	15-20% total daily energy. Protein requirement may be greater than Recommended Daily Allowance (RDA) if poor diabetes control exists	Not > 1g per kg body weight.

Fat	<p>Saturated (SFA) and trans-unsaturated fatty acids should provide less than 10% total energy. Polyunsaturated fats (PUFA) should not exceed 10%. Olive and rapeseed oils recommended (Dietary cholesterol less than 300mg/day in US and European recommendations only).</p> <p>Oily fish consumption encouraged in all recommendations with oily fish supplements to reduce plasma triglyceride levels in the US recommendations but not in the European and UK recommendations.</p>		
Alcohol	<p>A daily amount equivalent to one or two glasses of wine per day is acceptable. Those on insulin / sulphonylureas need to consume alcohol with CHO food to prevent hypo's.</p>	<p>No more than two alcohol drinks per day. One drink (15g alcohol) is equivalent to 12 oz beer, 5 oz wine or 1.5 oz distilled spirits.</p>	<p>Sensible drinking as recommended to the general population: maximum 14 units per week for women and 21 units per week for men, with 1-2 alcohol-free days each week.</p>
Physical activity	<p>Walking for four hours per week to achieve a 2000 Kcal / week deficit.</p>	<p>Thirty minutes of moderate physical activity on most days of the week.</p>	<p>20-30 minutes of physical activity on most days.</p>

The benefit of physical activity on the metabolic syndrome and Type 2 diabetes has already been documented. Larsen et al demonstrated the beneficial effect of exercise on glycaemia and insulin levels (Larsen et al. 1997) and Lehmann *et al.* reported a 20% reduction in fasting plasma triglyceride concentrations, an increase in HDL cholesterol, a significant lowering of both systolic and diastolic blood pressure and a fall in the waist to hip ratio (Lehmann et al. 1995). The best time to promote physical activity is at the stage when the individual is newly diagnosed, because that is when motivation for behaviour change is at its highest (Legge 1997). However, the duty to recommend an increase in physical activity does not fall to any single healthcare professional: it is the responsibility of all, and consequently it is easy for such advice to become overlooked within the current clinic consultations process.

1.7.6 Medication and insulin

When non-pharmacological treatments are unable to achieve or maintain adequate glycaemic control, oral hypoglycaemic agents are indicated. Figure 1.8 below briefly describes the different types of medication available.

Figure 1.8 Oral hypoglycaemic agents

Sulphonylureas

These are the most commonly prescribed diabetes tablets. They work mainly by stimulating the β -cells in the pancreas to release more insulin. They are therefore dependent on the patient having adequate residual β -cell function. The principal difference between the various types of sulphonylureas is the duration of action. There are few side effects but weight gain is common. Regular meals and snacks are necessary to prevent hypoglycaemia.

Biguanides

Metformin is the only biguanide currently prescribed in the UK. This drug works by reducing hepatic gluconeogenesis and hepatic glycogenolysis and by enhancing insulin stimulated glucose uptake and glycogenesis by skeletal muscle. It does not, as a rule, cause hypoglycaemia or weight gain, although gastrointestinal complaints such as diarrhoea and nausea are common. Patients are advised to begin on a small dose and increase as tolerated to reduce the impact of side effects.

Alpha-Glucosidase Inhibitors

Acarbose competitively inhibits the activity of alpha glucosidase enzymes in the brush border of the small intestine. It slows down digestion of carbohydrates and extends the digestive process lower down into the gut. Some carbohydrate malabsorption often occurs causing excessive flatulence, diarrhoea and abdominal discomfort.

Thiazolidinediones (Glitazones)

A relatively new class of agents, these tablets have been developed to enhance insulin sensitivity. They achieve a slow blood glucose-lowering effect in Type 2 diabetes, often taking two or three months to achieve maximum benefit. NICE has published technology appraisals for the use of rosiglitazone and pioglitazone. They are not indicated unless the patient is unable to take metformin and insulin secretagogues as combination therapy or where diabetes control remains unsatisfactory despite taking combination therapy (NICE 2000; NICE 2001).

Prandial Glucose Regulators

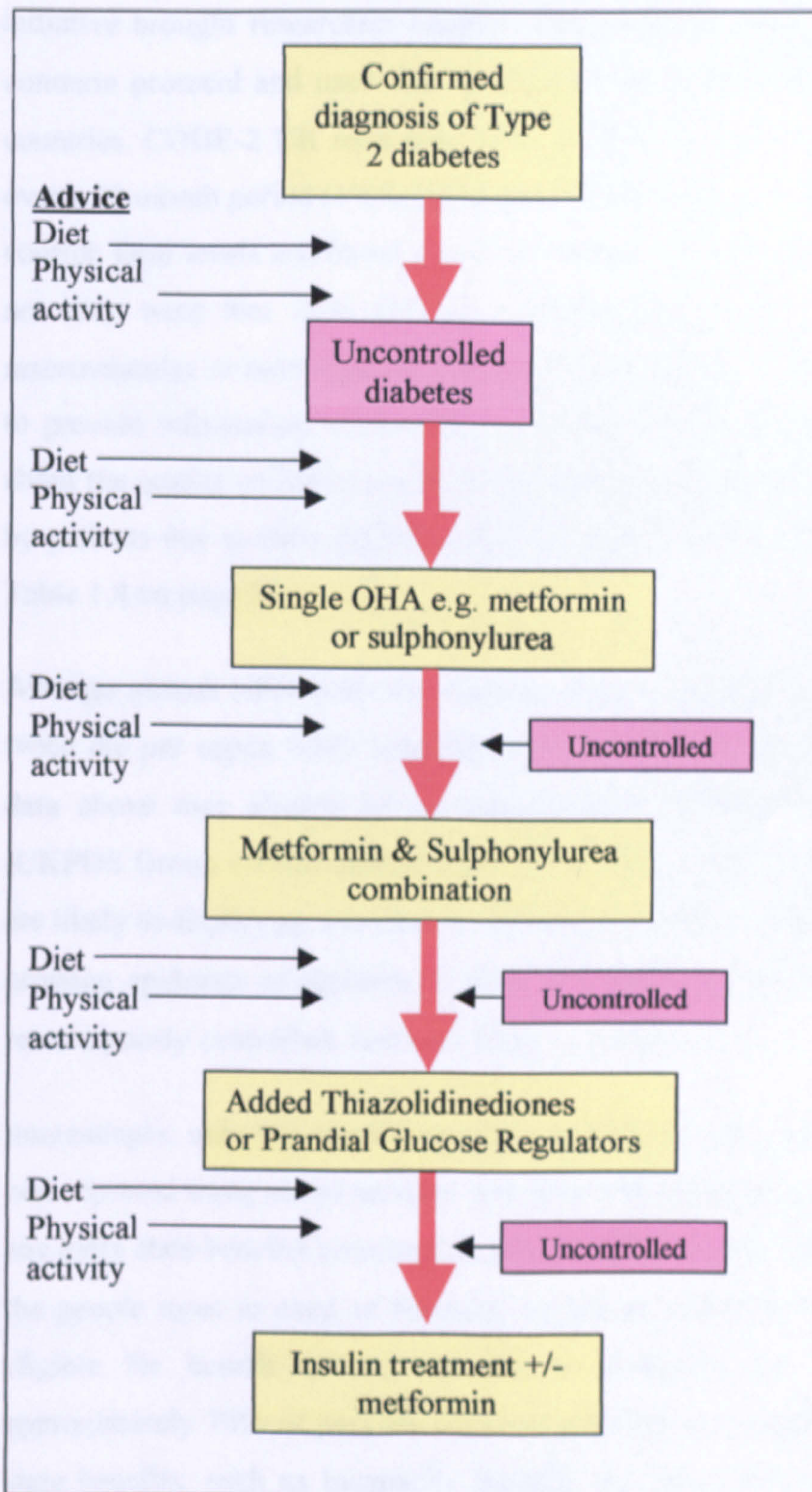
The normal acute phase of insulin release is diminished or absent in Type 2 diabetes. Two types of prandial glucose regulators are available in the UK: repaglinide and nateglinide. They are both rapidly absorbed and offer a prompt but short-lived stimulatory effect on insulin secretion. Taking the drug just before a meal enables peak insulin secretion to coincide with meal digestion.

Source: (Gadsby 2001)

When oral agents in combination are unable to achieve or sustain optimum metabolic control, it is often necessary to switch to insulin. However, statistics from the Diabetes Audit and Research in Tayside Scotland (DARTS) database has shown that only one in three people with Type 2 diabetes have adequate adherence to a single oral hypoglycaemic agent. Poor adherence with complex drug regimens are likely to be a major obstacle in the treatment of optimum metabolic control (Donnan, MacDonald, &

Morris 2002) and many people may commence insulin treatment for this reason. Figure 1.9 presents an algorithm for the treatment of Type 2 diabetes.

Figure 1.9 The current treatment of Type 2 diabetes



In the UK about 20-25% of adults with Type 2 diabetes are estimated to require insulin within 10 years of diagnosis, although a greater proportion of patients would probably benefit from the administration of insulin in any event. (Krentz & Bailey 2001). There is a vast choice of insulin available in the UK, ranging from rapid-acting analogues and short, medium and long-acting varieties to mixed insulin and analogue mixtures. Different types of insulin have unique 'onset, peak and duration' levels and can remain effective from a minimum of four hours up to a maximum of 36 hours. Each patient

requiring insulin should have a full assessment to prescribe a suitable blend of insulin and to ensure a regimen that will improve metabolic control and quality of life with minimum disruption and inconvenience to the patient.

1.8 The economics of diabetes care

Two recent studies have estimated the economics of diabetes and diabetes care (Diabetes UK 2000; Williams et al. 2001; Williams et al. 2002). CODE-2 and T²ARDIS are landmark studies of the economics of diabetes and diabetes care. The CODE-2 initiative brought researchers together from eight European countries. They agreed a common protocol and used that to measure the health care costs of diabetes in their countries. CODE-2 UK used data from medical records to identify NHS resource use over a 12 month period (1998/1999) and collected data on clinical outcomes (glycaemic control, lipid levels and blood pressure). Patients were grouped according to whether or not they were free from diabetes complications, or had developed microvascular, macrovascular or both types of complications. The main contribution of T²ARDIS was to provide information on a wider set of costs than had been available before. Data about the quality of life of people with diabetes and about loss of earnings experienced by patients due to their diabetes were collected. The main findings are summarised in Table 1.8 on page 28.

Average annual NHS costs for treating Type 2 diabetes are equivalent to more than twice the per capita NHS expenditure in the UK. Having regard to current costs, the data above may already be an underestimate. Publication of the UKPDS findings (UKPDS Group 1998b) and the National Service Framework for diabetes (DOH 2001a) are likely to display an increase in medication costs for Type 2 diabetes. Also, with the growing epidemic of diabetes, if more than half the people living with the condition remain poorly controlled, costs are likely to escalate further.

Interestingly, only 9% of patients who reported extreme problems with mobility or self-care reported using social services and those with diabetes complications did not receive any extra state benefits compared to those with no complications. That may indicate that the people most in need of financial assistance either do not know that they may be eligible for benefit or are not able to complete the relevant forms. Although approximately 70% of patients who lost earnings as a result of their diabetes received state benefits, such as Incapacity Benefit, the value claimed was more than £10,000 below the value of the lost income. More than 80% of carers reported financial strain and the majority of them were assuming a carer role for more than 60 hours each week. That level of responsibility could well suggest that financial strain may be only one aspect of the overall burden facing people who care for those with diabetes (Holmes et al. 2003).

Table 1.8 Summary of the findings from T²ARDIS and CODE-2 studies

Variable	Main finding
Metabolic control	More than half of the Type 2 diabetes population remained poorly controlled (i.e. HbA _{1c} > 7.5%)
Diabetes complications	Comorbidity was high with one in four patients having microvascular complications and one in eight having macrovascular complications
Outpatient appointments	On average, a person with diabetes had 17.4 encounters with a health professional in a year. That equated to three hours of contact each year.
Annual patient costs	Average annual NHS costs for the care of someone with Type 2 diabetes were £1,500 - £1,700. Those experiencing both micro- and macrovascular complications cost 2.6 times more (£2,277) than those with no such complications.
Hospital admission costs	Costs of all admissions and day cases amounted to £545 - £721 per patient per annum, which translated to between 36% and 41% of total annual spend per patient with Type 2 diabetes. Those with micro- and macrovascular complications were 6.4 times more expensive than those without.
Personal costs	Annual expenditure by people with diabetes amounted, on average, to £230 per person. Their carers incurred additional costs of around £160 per year.
Lost earnings	For patients of working age and their carers, 6% of patients and 12% of carers reported either an inability to work or a need to work part time due to their diabetes. The average lost income for patients was £14,000 per year, and for carers £11,000 per year.
Quality of life	People with diabetes reported a significantly poorer quality of life compared with that of the general population. That was mainly due to mobility problems, pain and discomfort. Quality of life deteriorated considerably more for those patients experiencing diabetes complications.

1.9 Summary

There is no question that there have been major developments over the years in identifying, treating and improving the quality of life for people with diabetes. However, people with diabetes are still dying prematurely and their quality of life can still be poor in comparison with that of people without the condition. Recent studies have shown that there is scope to delay the development of Type 2 diabetes and possibly to prevent it altogether. It has also been shown that mortality and morbidity can be dramatically reduced if effective treatment that ensures optimum blood glucose levels and blood pressure readings is provided. Nevertheless, it is predicted that the prevalence of diabetes worldwide will more than double during the next 20 years, primarily as a result of the rising epidemic of obesity and the metabolic syndrome. It is clear that diabetes has been shown to be a costly condition, not just for the NHS but also for patients and their carers. In England and Wales, the National Service Framework for Diabetes is a recent public health document that addresses these concerns. Innovative healthcare delivery arrangements are urgently required in the 21st century to implement the Framework and result in real benefits for people with diabetes, their carers and the health service.

Chapter 2: Health Behaviour Change

2.1 Introduction

Health is a complex issue and “being healthy” has many definitions. This chapter gives a brief review regarding the components of health, health behaviour models, relevant international literature and its impact on national policy. These will then be related to the varying models available for the practice of patient education. The routine approach to diabetes patient education within Europe and the United States will then be compared and contrasted. Components of health behaviour and patient education models will then be linked to the development of the intervention which is the subject of this thesis, the diabetes expert patient programme, X-PERT.

2.2 Society and health

Good health is a fundamental goal for people and the societies in which they live. Individuals hope for a life free from illness and pain, and societies, through the acts of government, promote policies designed to counteract ill health (Moon 1995).

2.2.1 Definition of health

The World Health Organisation (WHO) defined health as “a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity” (WHO 1946). However, that definition has been criticised as idealistic because it suggests that people are unhealthy unless they have attained complete physical, mental and social well-being (Aggleton 1990). The definition also implies a static state whereas life is anything but static. A more recent definition encapsulates a holistic view of health by suggesting that emotional, spiritual and societal aspects of health need to be considered (Ewles & Simnett 2003).

- Physical health is the most obvious dimension of health, and is concerned with the mechanistic functioning of the body.
- Mental health is the ability to think clearly and coherently.
- Sexual health is concerned with the practice of safe sex in the prevention of sexually transmitted diseases and unwanted pregnancies.
- Social health means the ability to make and maintain relationships.

The identification of these different aspects of health verifies the complexity of defining health.

- **Spiritual health** for some people is connected with religious beliefs and practices; for others it is to do with principles of behaviour and being at peace with oneself.

To

- **Environmental health** is influenced by public health policy. Examples of determinants of health affected by policies are poverty, education, transport, housing, a safe workplace, legislation, and immunisation.

will

- **Societal health** considers the society in which people live. Women cannot be healthy when their contribution to society is undervalued, neither black nor white people can be healthy in a society where racism undermines human worth; unemployed people cannot be healthy in a society that values only people in paid employment.

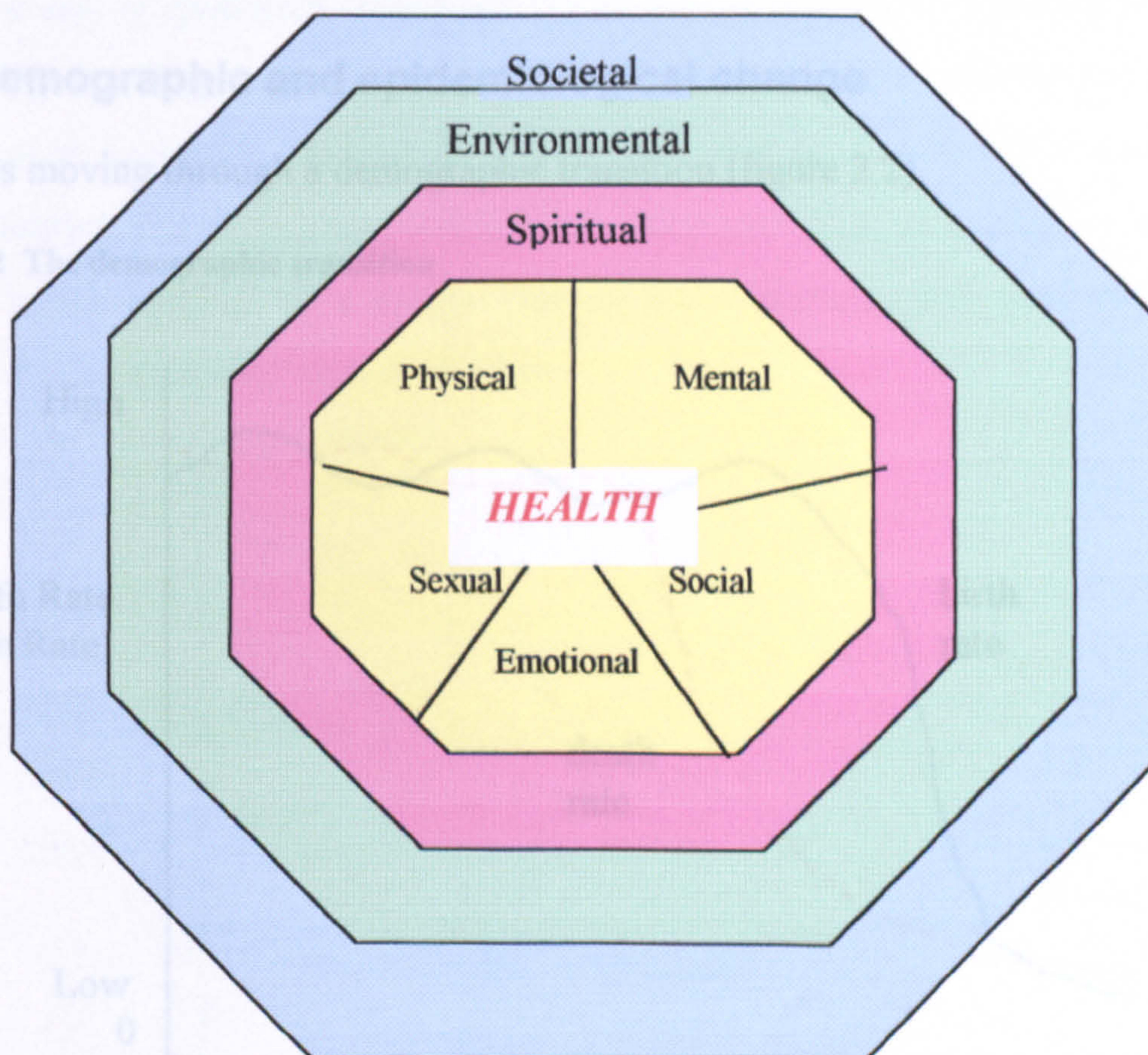
A more

WHO's current definition is: 'the extent to which an individual or group is able, on the

Figure 2.1 denotes the varying dimensions of health and is adapted from the work of Aggleton (Aggleton 1990).

Health is, therefore, a resource for everyday life, not the objective of living; it is a positive concept emphasizing social and personal resources.

Figure 2.1 The determinants of health



The identification of those different aspects of health verifies the complexity of defining health. However, dividing people's lives into categories such as 'physical' and 'spiritual' is impractical, as all aspects of health are interrelated and interdependent (Ewles & Simnett 2003).

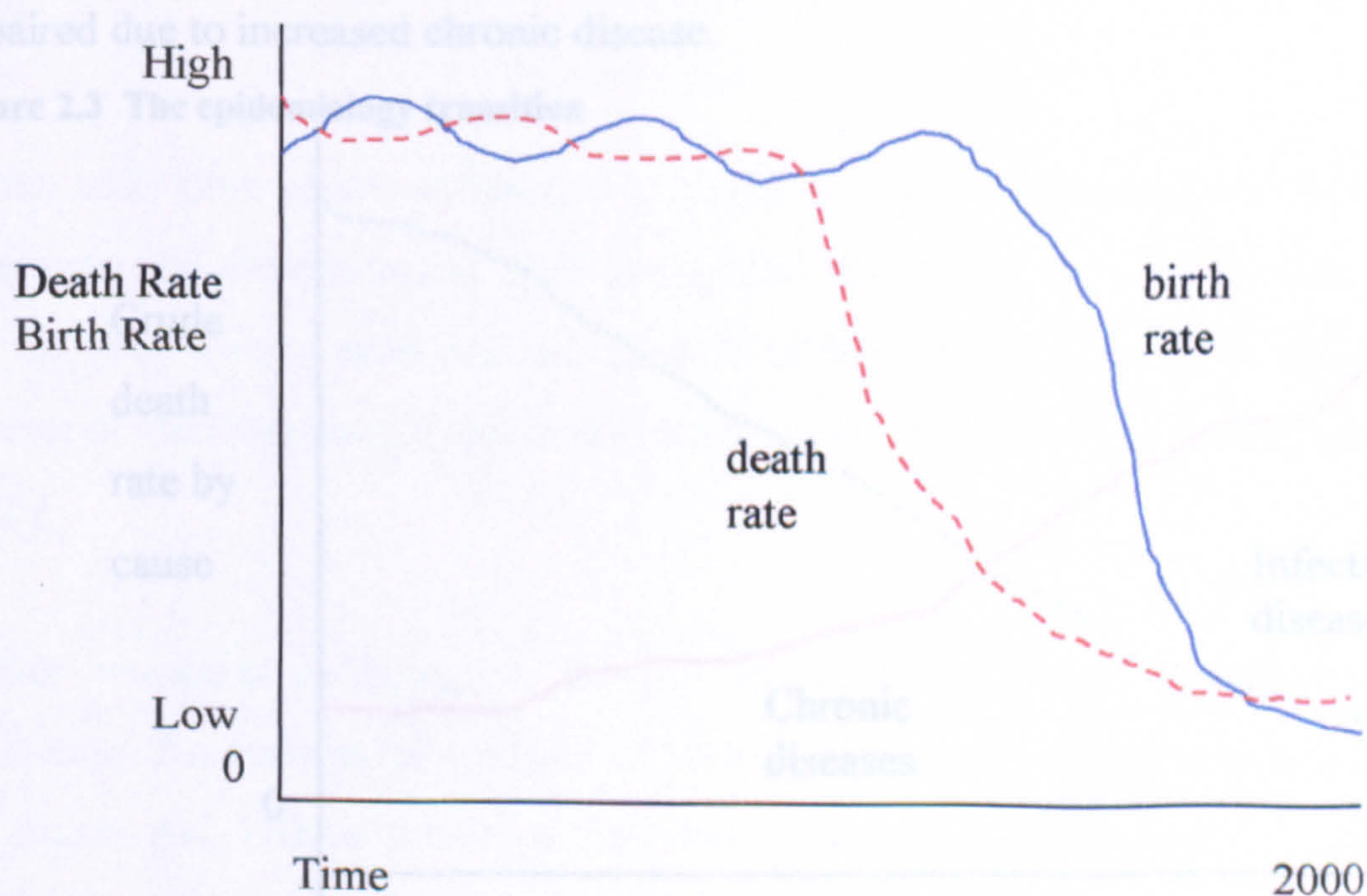
To the general public, being healthy may just mean 'not being ill'. Health can be taken for granted and only appreciated when lack of health interferes with everyday life. Health means different things to different people and it has been shown (Calnan 1987) that middle-class women associate good health with being fit, active and able to cope with a crisis whereas working class women perceive good health as never being ill and the ability to 'get through the day'.

A more recent WHO definition of health encompassed both an individual and a societal responsibility, and envisaged self-empowerment as a means of improving quality of life. WHO's current definition is: *'the extent to which an individual or group is able, on the one hand, to realise aspirations and satisfy needs: and, on the other hand, to change or cope with the environment. Health is, therefore, a resource for everyday life, not the objective of living; it is a positive concept emphasizing social and personal resources, as well as physical capacities'* (WHO 1985b).

2.2.2 Demographic and epidemiological change

Society is moving through a demographic transition (figure 2.2).

Figure 2.2 The demographic transition

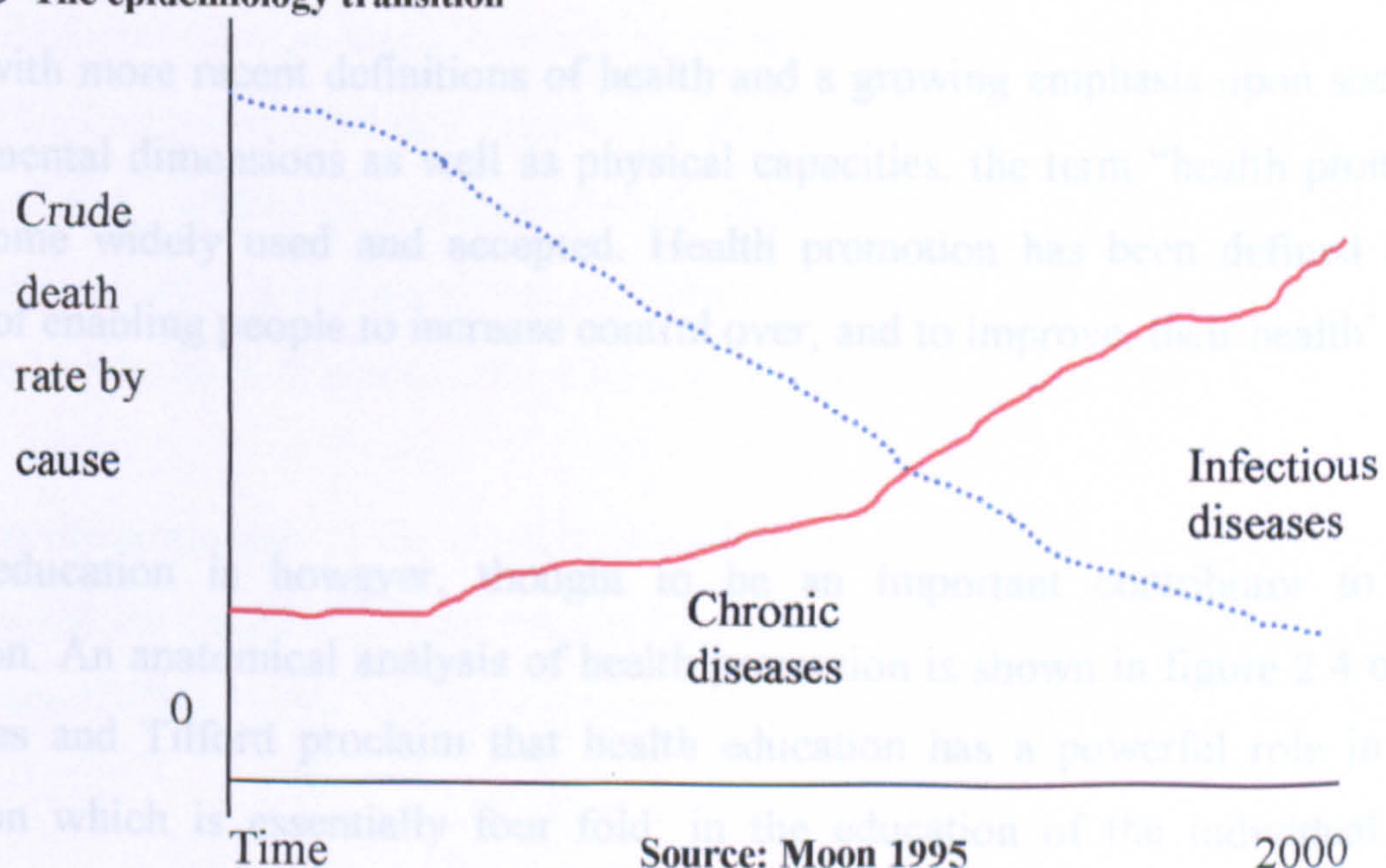


Source: (Moon 1995)

The demographic transition is a simplistic model that can be used to compare 'real-world' situations. During the *high stable phase*, the population remains stable with new births replacing deaths. The next phase is *early transition* where birth rate is maintained but death rates decline steadily. The consequence of early transition is a rapid natural increase in the population. Population growth levels off as the birth rate begins to fall and this is called the *late transition*. The final stage of the transition is the *low stable phase* where there are substantial numbers of elderly people in the population and little or no population growth. Although most industrialised countries are well advanced through the transition, some less developed countries exhibit the characteristics of earlier phases; cultural factors may influence a high birth rate and economic and political factors may result in raised death rates due to poverty, famine, war, environmental degradation and poor availability of health care (Moon 1995).

The late transition in developed countries resulted mainly from social and public health measures and immunisation programmes prior to the development of the NHS. In more recent years, developed countries have moved through another transition: the epidemiological or mortality transition (Moon 1995). That transition is a linear process, showing the shift from a situation dominated by *infectious* disease to one of *degenerative* or *chronic* diseases (see figure 2.3 below). That model incorporates four stages: the *age of epidemics*, where infectious disease resulted in a greatly reduced life expectancy; *receding epidemics* where infectious diseases were controlled and therefore had less of an impact on the mortality; the *age of chronic disease* where a reduction in infant mortality and an increase in life expectancy was seen, and *delayed degenerative disease*, which resulted in a further rise in life expectancy but quality of life was impaired due to increased chronic disease.

Figure 2.3 The epidemiology transition



Developed countries are presently experiencing the fourth stage of the epidemiology transition, with chronic diseases being the major cause of present-day mortality and morbidity, and the aetiology being multifaceted. Modern industrialised life, with excessive consumption of calories especially in the form of fat, reduced physical activity, easy access to alcohol, tobacco and transport, and stress are but a few of the determinants. Life expectancy has increased from 48 years to 80 years for women, and from 44 years to 75 years for men. However, large numbers of people still suffer premature death, or have their quality of life impaired, by avoidable ill health (DOH 1999).

2.3 Health education/health promotion

2.3.1 Comparing health education and health promotion

During the 1970s, the term “health education” emphasised an individual approach to behaviour change and was based on the theory that individuals were responsible for their own health (Ewles & Simnett 2003). Health education has been defined as *‘any intentional activity that is designed to achieve health or illness related learning, i.e. some relatively permanent change in an individual’s capability or disposition. Effective health education may, thus, produce changes in knowledge and understanding or ways of thinking; it may influence or clarify values; it may bring about some shift in belief or attitude; it may facilitate the acquisition of skills; it may even effect changes in behaviour or lifestyle’* (Tones & Tilford 1994, page 11). In recent years health education has been criticised for being too focused on individual lifestyle and too quick to lay blame on the individual for health conduct and lifestyle choices (Ewles & Simnett 2003).

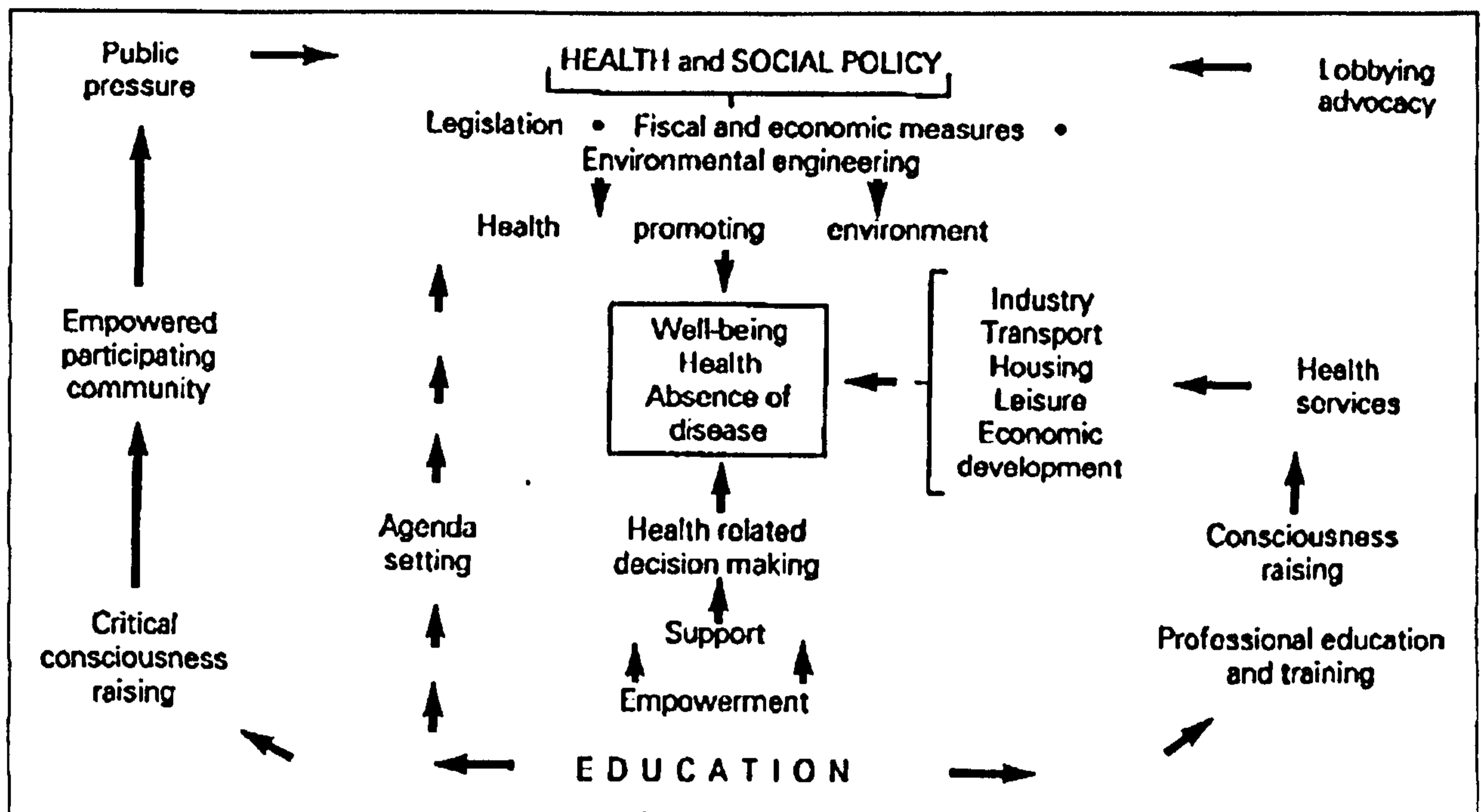
In line with more recent definitions of health and a growing emphasis upon social and environmental dimensions as well as physical capacities, the term “health promotion” has become widely used and accepted. Health promotion has been defined as *‘the process of enabling people to increase control over, and to improve, their health’* (WHO 1986).

Health education is however, thought to be an important contributor to health promotion. An anatomical analysis of health promotion is shown in figure 2.4 on page 35. Tones and Tilford proclaim that health education has a powerful role in health promotion which is essentially four fold: in the education of the individual which

empowers them to make informed decisions, in the development and appropriate use of health services, in agenda setting, and in raising consciousness which can result in public pressure on health and social policies. It has been suggested (Tones & Tilford 1994, page 7) that it is possible to condense the concept of health promotion into an essential formula:

$$\text{Health Promotion} = \text{Health Education} \times \text{Healthy Public Policy}$$

Figure 2.4 The contribution of health education to health promotion



Source: (Tones & Tilford 1994), page 7)

2.3.2 International perspective

Changes in the practice of health promotion and health education are the result of historical developments that have had profound effects, first on health education and then on health promotion. Fifty years ago, the creation of the WHO as part of the United Nations provided an international mechanism for the systematic collection, validation and development of experience relevant to survival and for an improvement in quality of life. The transmission of that experience to society was the responsibility of health education and health promotion (WHO 2002b). The development of health education/promotion was carried out at world conferences, and the findings have been published in a number of resolutions, charters, declarations and reports.

Numerous developments in the conceptualisation of health and in the delivery of health care followed the declaration that emerged from the **Alma Ata, Primary Health Care Conference** (WHO 1978). The most important feature of that declaration was that:

- health is a basic human right. (That principle took some aspects of health out of the remit of the medical profession and into that of politicians and the legal profession);
- inequalities in health among population groups and regions are not acceptable. The concept of 'health for all' was adopted;
- primary care, with the national health system bringing health care as close as possible to where people live and work, is essential health care. Primary care is the first level of contact for individuals, the family and the community.

The First International Conference on Health Promotion met in Ottawa, Canada in 1986. It was strongly influenced by contributors from Toronto who introduced the concept of 'Healthy Cities'. The conference produced a charter for action to achieve 'Health for All by the Year 2000' (WHO 1986). The conference was a response to growing expectations of a new public health movement, namely to build a healthy public policy, create supportive environments, strengthen community action, develop personal skills and re-orientate health services.

The Second International Conference on Health Promotion was held in Adelaide, Australia in 1988. It was concerned with the development of healthy public policies, characterised by a concern with health and equity in all areas of policy including the accountability for the policy impact on health (WHO 1988). The main aim was to create a supportive environment that would enable people to more easily make healthy choices and develop a healthier lifestyle. The value of health was redefined to link economic, social and health policies into an integrated action plan characterised by equity, easy access and positive developments.

The Third International Conference on Health Promotion was held in Sundsvall, Sweden (WHO 1991) The main topic was the creation of supportive environments for health. A statement was issued that stated that communities, countries and governments should all participate in creating a supportive environment by addressing inequality, poverty, and access to essential health care. The theme remained focused on health promotion and emphasised the importance of community participation.

The next development for a supportive environment was the United Nations Conference on Environment and Development (United Nations General Assembly 1992) that was held in Rio de Janeiro. Agenda 21 was a leading document that emerged and was signed by 179 Heads of Government. It continued the theme of community participation and advised that all local councils should consult with the community to produce a focused plan, a “Local Agenda 21”. It was recognised that local people have the requisite local knowledge to make sensible decisions for the future local population (WHO 2002a).

The fourth health promotion conference was held in Jakarta, Indonesia and was the first international conference on health promotion to be held in a developing country. Evidence was presented to show that health education and health promotion strategies contribute to health improvement and disease prevention in both developing and developed countries. The Jakarta Declaration Leading Health Promotion into the 21st Century (WHO 1997) identified five priorities, which were confirmed in the *Resolution on Health Promotion* adopted by the 51st World Health Assembly (WHO 1998b):

- 1) to promote social responsibility for health
- 2) to increase investments for health development
- 3) to consolidate and expand partnerships for health
- 4) to increase community capacity and ‘empower’ the individual in matters of health
- 5) to secure an infrastructure for health promotion.

The fifth global conference on health promotion: bridging the equity gap was held in Mexico City in June 2000. Termed “Bridging the gap”, it was the last in a series of ground breaking international conferences on health promotion. *Health promotion: bridging the equity gap* aimed to tackle the priorities for health promotion in the 21st century that had been identified at Jakarta. It was recognised that continued efforts will always be required to strengthen the evidence base on which health promotion policies and practices are founded, to reinforce political skills and actions for health promotion, and to re-orientate health services towards health promotion and primary prevention (WHO 2000a).

2.3.3 National public health approaches

Since the NHS was first established, political rule has fluctuated. In 1964 the Labour party started to plan the NHS reforms that were finalised by the Conservative government and put into effect by the Labour government in 1974. It has been

suggested that changes in government did not yield major changes in policy and the NHS reforms have been categorised as the 'post-war consensus' (Kendall 1995, page 166). The election of Mrs Thatcher as Prime Minister has been identified as the end of the 'post-war consensus'. That is because she developed within the Conservative party, a particular political ideology. First, there was a belief in the virtues of the market and that the market was more efficient and more responsive to people's needs than state provision. Secondly, there was emphasis upon individualism and a belief that the individual was wholly self-reliant and responsible for her or his own actions (Kendall 1995).

Speculation arose that the themes addressed at the Alma Ata conference in 1978, namely the concept of health promotion and addressing the issue of inequalities in health, were far removed from the government's priority agenda. Indeed, when the Black Report (DHSS 1980), was submitted to the Secretary of State, he refused to endorse the reports' recommendations on the grounds of what he perceived to be unrealistic and unnecessary costs (Kendall 1995). However, as international concern with health inequalities continued, more evidence to support the need for action became available (HEC 1987). The government continued to advocate the importance of individual responsibility for health behaviour and failed to support the strengthening of health policy to address health inequalities (Kendall 1995). The NHS experienced its most significant cultural shift since its development with the introduction of the internal market, outlined in the *Working for Patients* White Paper (DOH 1989) and the NHS and Community Care Act (DHSS 1989). The government encouraged, but did not enforce, the establishment of self-governing NHS Trusts and General Practice Fund Holders (GPFHs). Many health service employees believed that the structure was effectively a two-tier system and that it promoted lack of uniformity in patient care.

The need for healthy public policy was finally recognised with the publication of the *Health of the Nation* White Paper (DOH 1992). Although, the paper recognised the need to concentrate on health promotion as much as health care, its theme centred on the pre Alma Ata era with an individualised health education approach. The clear and challenging targets were unrealistic. For example, the target for reducing the incidence of obesity by one third by 2005, (from 8% in men and 12% in women, to 6% in men and 8% in women) will not be met. By 1997, the incidence of obesity increased to 17% in men and 20% in women and the prevalence is still escalating in epidemic proportions (DOH 2003b).

In 1997 there was a change in government with a resulting change in approach. *The New NHS Modern & Dependable* (DOH 1997) abolished the internal market, and replaced contracting with commissioning.

The government also supported recommendations from the international health promotion conferences. The second health inequalities report, *Independent inquiry into Inequalities in Health*, (Acheson 1998) stated that there were unacceptable inequalities in health and that the health gap between the different socio-economic groups had widened since publication of the Black Report in 1980. The government addressed many of the health inequality issues in the White Paper *Saving Lives: Our Healthier Nation* (DOH 1999). That White Paper was similar to *The Health of the Nation White Paper* (DOH 1992) in respect of the challenging targets it set for improving the nations' health.

There were however substantial differences in the theories underpinning the 1992 White Paper and the 1999 White Paper. The latter:

- recognised that some factors that harm people's health are beyond the control of the individual and that health policy requires action from a joint partnership between central government, local government and the individual;
- proposed the development of National Service Frameworks for specific conditions and groups of individuals. Those were anticipated to ensure high and consistent standards of care across the country and to work towards meeting the targets set out in the White Paper;
- emphasised the increase in people living with chronic disease and recognised that those people were *experts* at living with their condition. *Expert patient* programmes were put forward as a new initiative for the future.

Since the 1999 White Paper, further publications have built on the philosophy outlined above and there has been a gradual transformation and re-organisation of healthcare services and healthcare delivery. The NHS Plan (DOH 2000) set clear objectives for a patient-centred service, with all components of the NHS working together to develop partnerships at all levels of care: between patients, their carers and NHS staff; between the health and social care sectors; across different government departments; between the public sector, voluntary organisations and private providers. The discussion document *Shifting the Balance of Power within the NHS: Securing Delivery* (DOH 2001b)

proposed organisational changes required to deliver the reforms set out in the *NHS Plan*. The main 'shift in power' was that Primary Care Trusts (PCTs) would take the lead in assessing the need for healthcare and planning, securing health services and health promotion initiatives. The latest National Service Framework to be published (DOH 2001a) (DOH 2003a) continues with the empowering vision set out during the international health promotion conferences by setting standards and delivery strategies to enable people to increase control over, and to improve, their health.

2.3.4 Health care settings

The budget for health education and health promotion activities remains at less than 1% of the total health budget, health programmes are often ad hoc and issue based, using health education in isolation from health promotion. Modern training in health promotion is lacking and many health education approaches lack evaluation (WHO 1997).

Health promoting activities range from health education programmes (primary, secondary or tertiary); preventative health services, such as, immunisation; community-based work (with differing degrees of community participation); organisational development; healthy public policies; environmental health measures; economic and regulatory activities. The competencies for those activities are taxing: managing, planning and evaluating; educating, facilitating and networking; influencing policy and practice; marketing and publicising and communicating effectively (Ewles & Simnett 2003).

In order for a health promotion initiative to be successful, communication needs to reach the individual, gain his or her attention and be understood and accepted before behaviour change can occur. At each stage, failure is possible. Probably one of the most difficult stages of communication is for the individual to accept the health promotion message. If the individual has beliefs or traditions that contradict the message, or if they lack confidence that they can make the change, the initiative will be unsuccessful. The type of approach or model that the health promoter uses to deliver the message will influence the outcome and the success of the health promotion initiative. Table 2.1, overleaf, provides a brief overview of five approaches to health promotion.

The health promoter using the *medical approach* would define health as freedom from disease and would use a didactic/persuasive or paternalistic method to ensure that the recipient complied with the prescribed advice. Those using the *behaviour change*

approach aim to change people's individual attitude and behaviour so that they adopt a healthy lifestyle. The health educator of that approach believes that a healthy lifestyle is in the best interests of society and sees it as their responsibility to encourage people to adopt the lifestyle they advocate. The *educational approach* concerns the delivery of information to ensure knowledge and understanding of health issues, which in turn enable well-informed decisions to be made. Those using the *patient or client-centred* approach work with individuals, using the process of empowerment, to help them to identify what they want to know and to take action to achieve their desired result.

Table 2.1 Five approaches to health promotion

	Aim	Health Promotion Activity	Important Values	Example: Diabetes
Medical	Freedom from medically defined disease and disability	Promotion of medical intervention to prevent or ameliorate ill health	Patient compliance with preventive medical procedures	<i>Aim:</i> optimum diabetes control <i>Activity:</i> instruct patients what to do to achieve optimum control
Behaviour Change	Individual behaviour conducive to freedom from disease	Attitude and behaviour change to encourage adoption of healthier life	Healthy lifestyle as defined by the health promoter	<i>Aim:</i> behaviour changes to adopt a healthier lifestyle <i>Activity:</i> persuasive education to promote change
Educational	Individual with knowledge and understanding enabling well-informed decisions to be made and acted upon	Information sharing, exploration of values/attitudes, development of skills required for healthy living	Individual right of free choice. Health promoter's responsibility to identify educational content	<i>Aim:</i> Individual understanding of the importance of optimum diabetes control <i>Activity:</i> sharing diabetes aims and building self-management skills
Patient-Centred	Working with patients on their own terms	Only address health issues identified by the patient.	Patients treated as equals. Self-empowerment	<i>Aim:</i> Issues only considered and discussed if patient identifies it as a concern
Societal Change	Physical and social environment that enables choice of healthier lifestyle	Political/social action to change physical/social environment	The right and need to make the environment health-enhancing	<i>Aim:</i> Develop policies to allow healthy living to be possible for all <i>Activity:</i> Lobby the government to reduce the cost of healthier food

Source: Ewles & Simnett (2003)

Finally, in the *societal* approach, the health promoter believes that poor health is attributable to society and not to the behaviour of the individual. The aim is therefore to change the physical, social and economic environment in order to make it more conducive to good health (Ewles & Simnett 2003).

2.4 Models of behaviour change

Health-related behaviour change is a very complex process involving many psychological, social and environmental factors. Models of behaviour change are derived from theory and attempt to provide an explanation of behaviour change. They provide frameworks to simplify the theory and to enable it to be put to practical use. The models and theories of health behaviour represent a significant step towards an understanding of why some people actively seek out health care and others do not. However, there are two main drawbacks to reliance upon models of behaviour change (Conner & Norman 1995):

- the theories assume that people think about risks in a detailed, rational fashion. In fact, people may modify their behaviour for vague and illogical reasons;
- with the various reformations of the models and theories, the distinction between many of them has become blurred.

There is, therefore, still considerable uncertainty in predicting the circumstances under which people will, or will not, engage in healthy behaviour. Four widely used health behaviour models are discussed below.

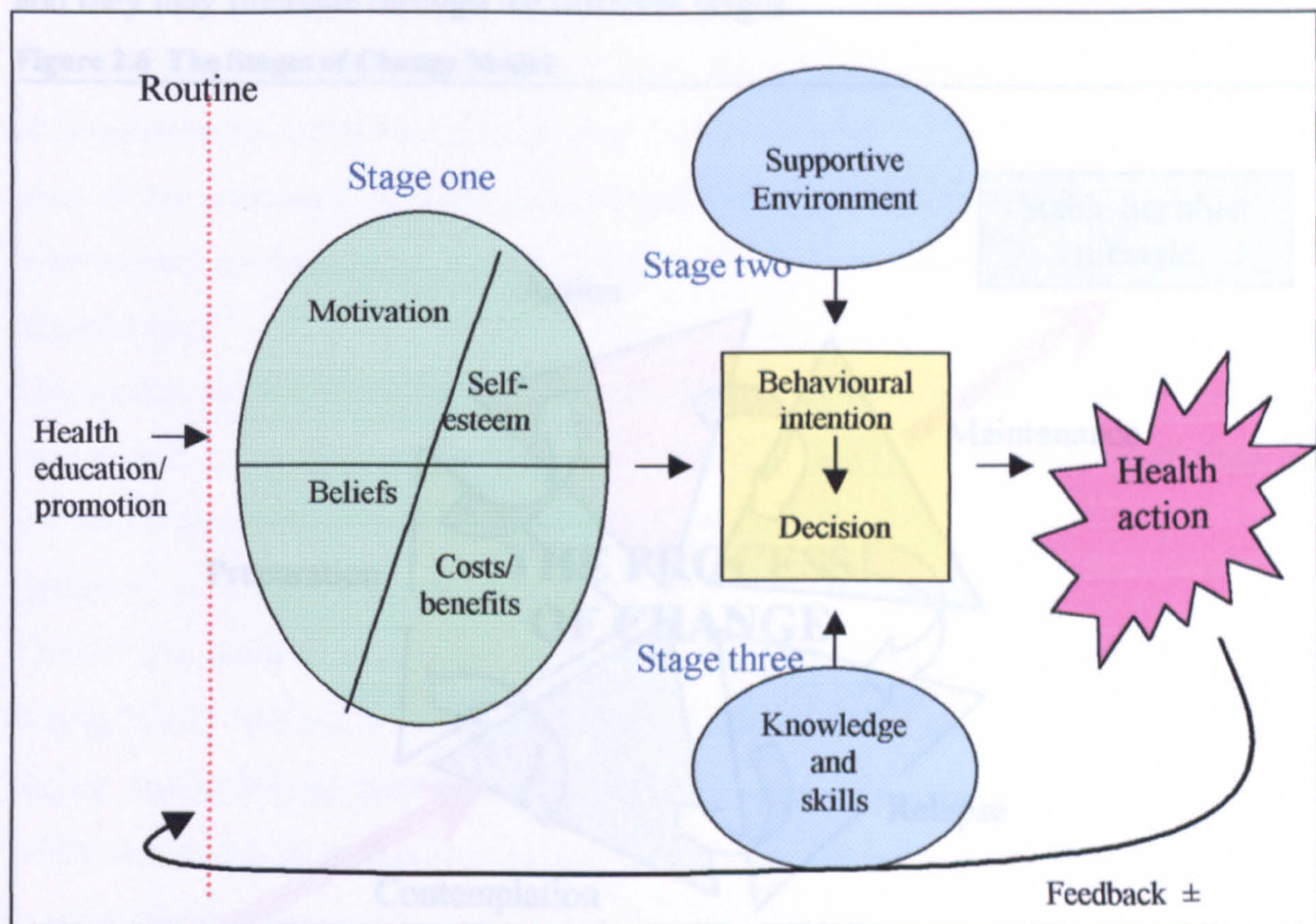
2.4.1 The Health Action Model

Tones suggests that health decisions and actions are influenced by an individual's beliefs, values, motivation, self-esteem and expectations (Tones & Tilford 1994). The health action model was initially developed as a framework for health education; it has also been shown to be compatible with health promotion theory (Ewles & Simnett 2003).

The Health Action Model is essentially a three-stage model (refer to figure 2.5 overleaf). The initial stage is an interactive system incorporating routine behaviour,

motivation, self-esteem, beliefs, and perceived costs and benefits for taking action to improve health. It assumes that if an individual has high self-esteem, that individual will be more motivated to identify a behaviour intention and make a decision for health action. The second stage demonstrates how the physical, cultural and socio-economic aspects of the environment may affect the health intention decision and the final stage demonstrates how skills and knowledge may influence health action.

Figure 2.5 The Health Action Model



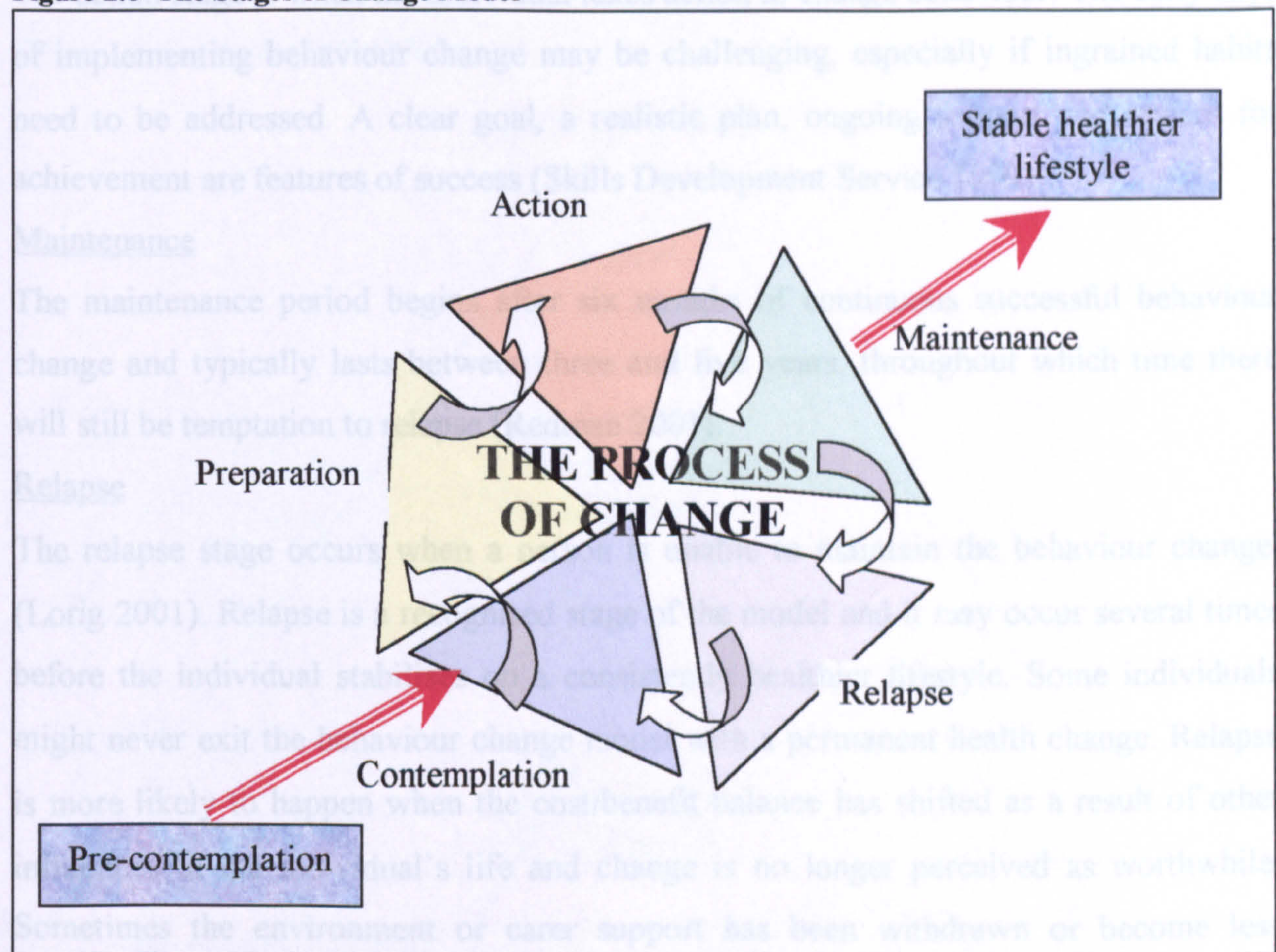
The feedback mechanism may be positive or negative and has the potential to change the normative system and stage one (Tones & Tilford 1994). For example, if an individual resolves, as a health action, to start walking for 30 minutes each day, and achieves that health action, their routine behaviour will have improved which may then positively impact on the components in all stages of the health model. The model is based on empowerment: increasing the control that people have on their lives.

2.4.2 Stages of Change Model

The Stages of Change Model was originally developed by Prochaska and DiClemente in 1986 to explain behaviour change in relation to addictive behaviours such as smoking. It has since been adapted for use in lifestyle behaviour change (HEA 1994).

Many people in receipt of primary health care services are not interested in changing unhealthy lifestyle behaviour. It is important to have an understanding of behaviour change to be familiar with the numerous phases that an individual has to master in order to make the transition from contemplating a change to implementing and maintaining a changed behaviour. There are seven stages of change (see figure 2.6 below) and it is assumed that the individual moves through discrete stages in the process before fully adopting the new behaviour. Individuals do not necessarily proceed in a linear fashion and they may fluctuate through the different stages.

Figure 2.6 The Stages of Change Model



Source: adapted from HEA 1994

Pre-contemplation

The pre-contemplation stage precedes entry into the change circle itself. There may be no awareness of the need for change or alternatively, a failure to accept that change is necessary. A primary feature is, therefore, that motivation to change habits or lifestyle is lacking. Information and feedback from the health promoter may raise awareness but a prescriptive approach would be less likely to be effective.

Contemplation

At this stage, there may be some awareness of the problem but also have a marked ambivalence towards doing anything about it. Behaviour may fluctuate between considering a change and rejecting change. The role of the professional is to encourage

the decisional process towards change. Motivational interviewing has been shown to be successful in these circumstances (Skills Development Service 1999).

Preparation

The preparation stage is engaged when the perceived benefits of change seem, to the individual to outweigh the costs of the change and when there is a belief that change is not only possible but also worthwhile. The preparation stage is characterised by obtaining extra knowledge, skills and support in order to move into the action phase.

Action

The action stage is when the individual takes action to change behaviour. The early days of implementing behaviour change may be challenging, especially if ingrained habits need to be addressed. A clear goal, a realistic plan, ongoing support and reward for achievement are features of success (Skills Development Service 1999).

Maintenance

The maintenance period begins after six months of continuous successful behaviour change and typically lasts between three and five years, throughout which time there will still be temptation to relapse (Redman 2001).

Relapse

The relapse stage occurs when a person is unable to maintain the behaviour change. (Lorig 2001). Relapse is a recognised stage of the model and it may occur several times before the individual stabilises on a consistently healthier lifestyle. Some individuals might never exit the behaviour change model with a permanent health change. Relapse is more likely to happen when the cost/benefit balance has shifted as a result of other influences in the individual's life and change is no longer perceived as worthwhile. Sometimes the environment or carer support has been withdrawn or become less effective thus making it seem too difficult to maintain the change (Ruggiero 2000).

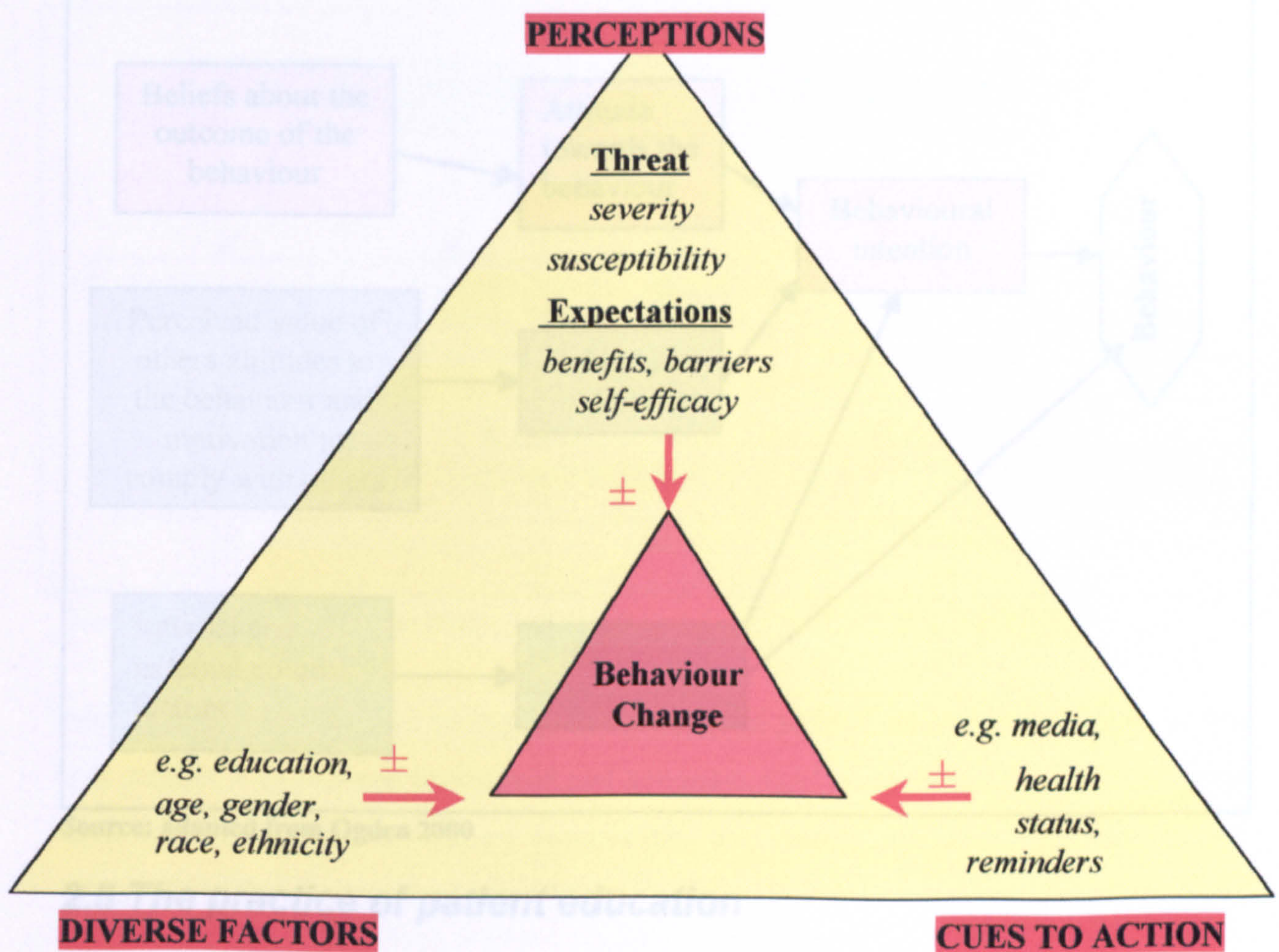
2.4.3 The Health Belief Model

A diagrammatic picture of the health belief model is shown in figure 2.7 on page 46. Redman (2001) discusses how readiness to take action and engage in health-related behaviours depends on a number of factors:

- *susceptibility*. An individual's beliefs about whether he or she is likely to contract an illness;
- *severity*. The degree to which an individual perceives the consequences of having an illness to be severe;
- *benefits*. The potential to be gained from a particular course of action that will reduce the health threat;

- *barriers*. Any decision to act will have consequences that may cause distress, whether physical, psychological, social or financial;
- *self-efficacy*. The confidence of the individual to carry out the action and be successful;
- *cues to action*. Cues are stimuli that trigger appropriate health behaviour. These can be either internal (for example, perception of body health) or external (for example, mass media);
- *diverse factors*. These include demographic, ethnic, social and personality factors that may influence health behaviour.

Figure 2.7 The Health Belief Model



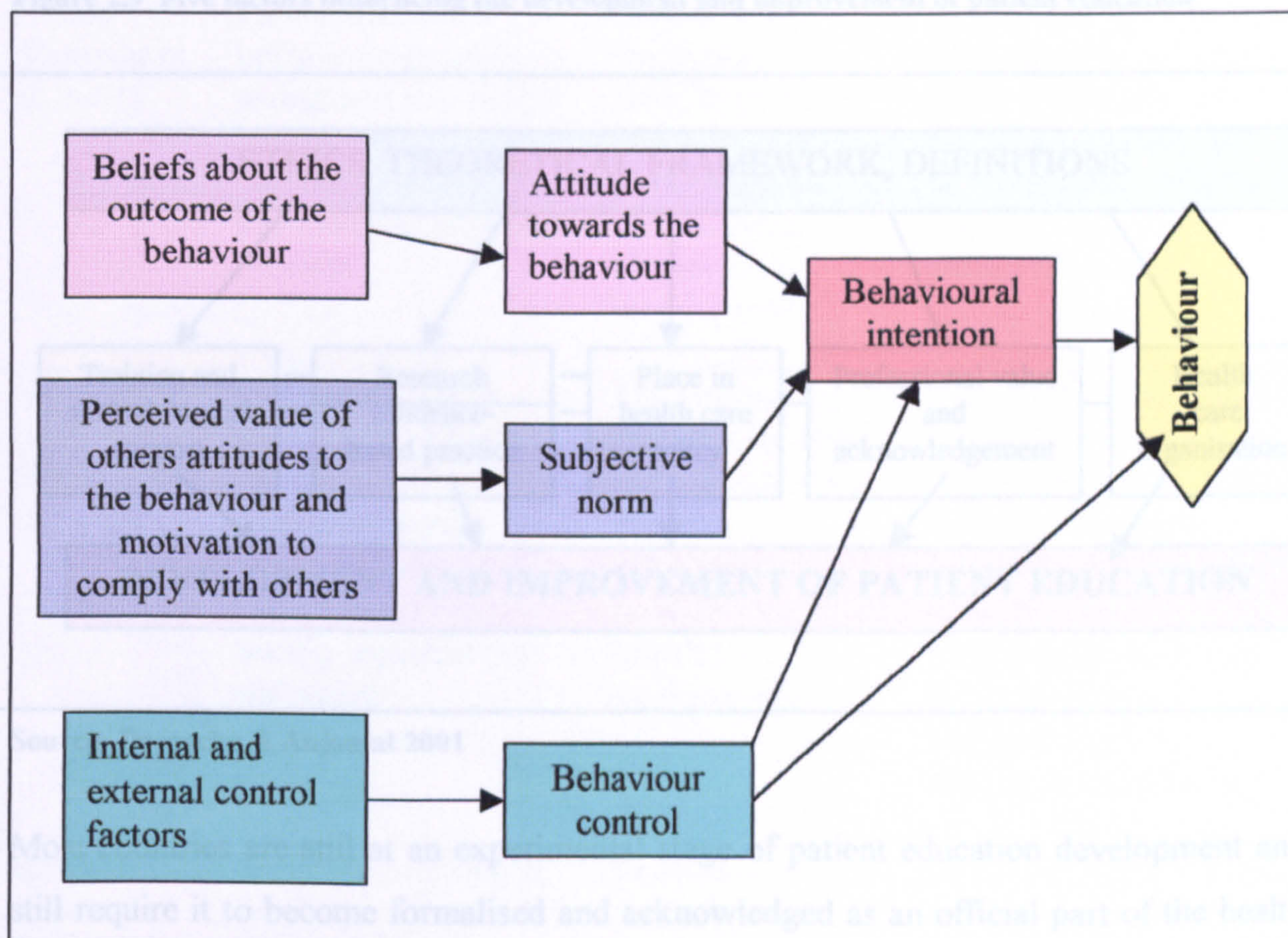
2.4.4 The Theory of Planned Behaviour

The Theory of Planned Behaviour states that the actual performance of a particular behaviour is largely dependent on three beliefs: attitude and beliefs towards a behaviour, subjective norm and perceived behavioural control (Ogden 2000) (see figure 2.8 on page 47). Therefore the individual would only change behaviour if they believed that the new behaviour would lead to outcomes that they valued. Behaviour change would also depend on their perception of social norms and pressures to perform a behaviour, for example, if another person such as a health professional recommended

them to carry out the health action, they would only carry it out if they valued the health professional's recommendations, and had the motivation to comply with the recommendation. Finally, internal control factors such as skills, knowledge and information, and external control factors, such as resources and opportunities, relate to perceived behavioural control. This model suggests there is high correlation between intention and behaviour (Lorig 2001) and assumes that people usually behave in a rational manner being in control of their health behaviour (Conner & Norman 1995).

(Deccache & Aujoulat 2001).

Figure 2.8 The Theory of Planned Behaviour



Source: adapted from Ogden 2000

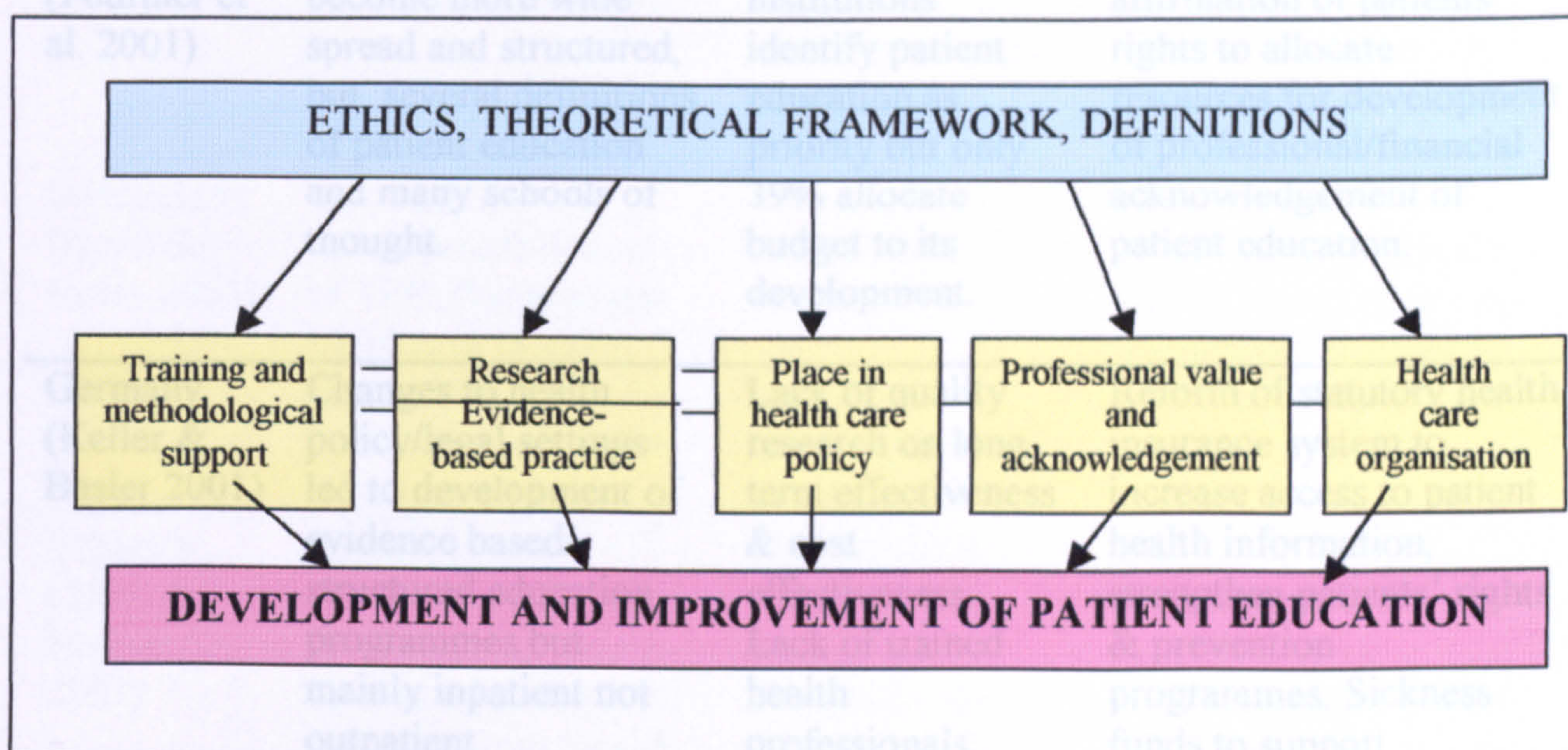
2.5 The practice of patient education

Patient education is defined as *all the educational activities directed to patients, including aspects of therapeutic education, health education and clinical health promotion* (Visser, Deccache, & Bensing 2001). Patient education is a central part of the practice of all health professionals. While the modern movement of patient education into healthcare is now 35 years old, the field has evolved slowly because it faced a history of paternalism in not sharing information with patients (Redman 2001). Previously, patient education was not theory based because there was not enough evidence that the use of theories made any difference to the effectiveness of patient

education. However today if education programmes are planned without theoretical underpinnings it is considered to be poor practice (Lorig 2001).

Five factors influencing the development and improvement of patient education have been identified. Those are: training and methodological support; research and evidence-based practice; funding and a place in health care policy; professional value and acknowledgement; and the organisation of care and education (see figure 2.9 below) (Deccache & Aujoulat 2001).

Figure 2.9 Five factors influencing the development and improvement of patient education



Source: Deccache & Aujoulat 2001

Most countries are still at an experimental stage of patient education development and still require it to become formalised and acknowledged as an official part of the health care system. Table 2.2 (below) summarises the present situation regarding patient education in Europe and the United States.

Table 2.2 The practice of patient education in Europe and the United States

Country	Present Situation	Identified Problems	Possible Solutions and Future plans
United Kingdom (Skelton 2001)	Awareness of limitations but patient education still dominated by medical-centred approach	Gap between theory and practice. Patient education falls behind patient-centred models.	Encourage practice of evidence based patient education. Identify key providers. Encourage lay involvement. Raise the status of patient education.

(Table 2.2 continued)	Present Situation continued	Problems continued	Possible Solutions continued
The Netherlands (Bensing, Visser, & Saan 2001)	Special coordinators for patient education available. Patient-centred information materials developed. Diabetes education included on government policy and legal papers	Effective use of information materials. The need for counselling and coordination of care.	Two-way communication and counselling. Clear role definitions for health providers. Communication training. Quality control of patient education. Empowerment of patient organisations. Theoretical base for education programmes.
France (Fournier et al. 2001)	Patient education become more wide spread and structured, but, several definitions of patient education and many schools of thought.	93% of health institutions identify patient education as priority but only 39% allocate budget to its development.	Rely on clarification and affirmation of patients' rights to allocate resources for development of professional/financial acknowledgement of patient education.
Germany (Keller & Basler 2001)	Changes to health policy/legal settings led to development of evidence based/structured education programmes but mainly inpatient not outpatient programmes.	Lack of quality research on long-term effectiveness & cost effectiveness. Lack of trained health professionals.	Reform of statutory health insurance system to increase access to patient health information, strengthen patients' rights & prevention programmes. Sickness funds to support outpatient patient education and training.
Belgium (Deccache & Ballekom 2001)	Support from French Ministry of Health & 98% of hospitals in French regions provide patient education programmes. Move from patient instruction to patient participation.	In Flemish region- no government support and patient education programmes rare. Little professional value of patient education	Ministry of Health to pay more attention to patient's rights. Patient participation and responsibility in health. Training health professionals. Fund patient education programmes.
Finland (Ojanlatva 2001)	Patient education seen as health education. Initiatives locally planned and delivered but not based on hospital policies or strategies.	No national mandated policies/practices/procedures of patient education. Education didactic in nature.	A shift from health education and patient education based on medical model to a model based on self-care. Further development of peer education initiatives.

(Table 2.2 cont.)	Present situation	Identified problems	Possible solutions
Sweden (Rosenqvist 2001)	Patients have a legal entitlement to full information about their illness and take an active role in decisions about care. Example of good practice is group study circles with facilitators	Health professionals working within medical-centred patient education model.	Training of physicians and health care staff in a patient-centred approach leading to patient-centred education & patient reflection & action.
Italy (Marcolongo et al. 2001)	Delivery of therapeutic patient education (TPE) aiming for patient empowerment.	Poor evaluation of education programmes. Lack of time and health care staff to deliver TPE.	Systematic evaluation & acknowledgement of TPE. Financial resources, education & training for TPE. Development of national & regional centre for TPE.
Switzerland (Assal & Golay 2001)	The lead in development/delivery of TPE. Postgraduate training of health professionals. Publication of WHO report on TPE	TPE is not an international standard. (WHO Working Group 1998).	Joint international collaboration to develop variety of curricula for training health care providers in TPE.
Hungary (Trinn & Molnar 2001)	Organised and effective system of in/out-patient patient-centred education resulting from Health Promoting Hospital initiative.	Most medical personnel lack theoretical knowledge and technical skills for effective patient education.	Training of health professionals and development of competencies to deliver effective patient education.
Estonia (Härm 2001)	Patient-oriented approach to health promotion/patient education involving multi-professional teamwork in primary care and hospitals.	No problems identified. No mention of evaluation, audit, and research.	Development of high quality health promotion programmes and intensified preventive activities with trained nurses integrated with physicians and health education coordinators
United States (Roter, Stashefsky-Margalit, & Rudd 2001)	Patient education evolved from medically dominated origin to one supporting patient empowerment. A move from compliance terminology and more emphasis on patient autonomy, reflection and problem solving.	Lack of 'quality of life' outcomes Difficulties in engaging elderly/poor/ethnic minorities. Literacy level of Internet patient education higher than average reading ability.	Transformation of patient education will depend on the success of empowerment agenda. Challenge health professionals to test commitment in meeting patient needs & encouraging patients to identify own needs and goals.

2.5.1 Comparison with health education

The field that patient education is most closely related to is health education. Redman (2001) compared those two fields, a summary of which can be found in Table 2.3 below.

Table 2.3 Comparison of patient education and health education

Focus	Patient Education	Health Education
Philosophy	Medical referral for behaviour change to address specific conditions	Self-referral and behaviour change to promote good health
Unit of service	Patients and their families	Specific populations
Delivery system	Part of clinical care	Campaigns including mass media and the workplace
Content	Individualised advice, instruction, development of self-management skills	Population awareness of risk factors and health behaviours
Theory base	Biomedical and chronic disease models	Health education/health promotion theory
Ethical concerns	Scientific stability and cultural basis regarding what patients are asked to do. Prescriptive approach resulting in over-reliance on the health service and loss of confidence	Scientific stability and cultural basis regarding what patients are asked to do. Manipulation by government and victim blaming if activity not carried out
Literature	Disease/condition specific	Public health literature
Challenges	Development of patient education standards and the uniform adoption of a patient-centred approach	More initiatives including scientific enquiry with evaluation

Source: adapted from Redman 2001

2.5.2 Group versus individual approach

Most patients receive education about their condition through individual consultations. Although such consultations may address clinical problems, they are unlikely to induce long-term health behaviours, especially if the information and knowledge offered during those visits is perceived to be in conflict with daily actions and habits. In that situation the advice may be easily ignored or forgotten by the patient. Introducing group education programmes to the healthcare system may benefit patients because they would receive longer exposure to interactive techniques and positive dynamics, and they may identify with other members of the group (Trento et al. 2001). For the health care providers, group education programmes would take the same amount of time, or potentially less time, than seeing the patient on an individual basis. Targeted one-to-one medical interventions would become more rewarding and less repetitive (Trento et al. 2001).

There have been recent recommendations in the UK for group based education programmes to be made available for all people with diabetes (DOH 2003a; NICE 2003b). However, scientific evaluation of group education programmes is in its infancy. Chapter 3 reports on a systematic review that was undertaken to evaluate the effectiveness of group based self-management strategies for people with Type 2 diabetes.

2.5.3 Principles of adult learning

Adult learners perform better when they are involved in the learning process. Effective educators therefore appreciate the importance of participatory learning methods (Knowles 1978). An old Chinese proverb is a simple way to summarise the importance of active participation: *I hear, I forget; I see, I remember; I do, I understand*. A significant finding from research literature is that when adult learners learn something from 'doing' as opposed to traditional didactic methods, they become highly self-directing (Dornan & David 2000). Figure 2.10 on page 53 states the principles of adult learning.

The importance of reflection in adult learning is paramount. People make decisions and act as a result of two types of conduct: routine action and reflective action. Routine action involves carrying out routine activities in an automatic fashion whereas reflective action is concerned with weighing up all aspects of the situation and making a conscious decision about what to do. Reflection, therefore, means learning from past experience and taking active control over what is done and how it is done (see figure 2.11 below) (Girod 2001).

Figure 2.11 Principles of reflection

<p>Reflection consists of:</p> <ul style="list-style-type: none"> ○ thinking about an experience; ○ exploring that experience in terms of feelings and significant features; ○ processing the significance features and identify learning; ○ effects on future practice

Of all the characteristics that affect a patient's achievements within adult education, self-esteem is perhaps the most influential. It seems that, in order to encourage a

conceptual shift from a passive, absolutist acceptance of 'external' knowledge to a more questioning, reflective, evaluative mode of operation, the patients have to believe in themselves. Patients who are used to didactic presentation methods become dependant upon the external source of knowledge and so undervalue their own experience. Those patients are often unable to see the value of an adult-centred approach and may insist upon returning to the secure world of the didactic prescription by encouraging the health professional to resume a leadership role (Department of Educational Studies 1997).

Figure 2.10 Principles of adult learning

- 1) It is important for adults to direct themselves. They learn most effectively when they identify their own learning needs and set their own goals.
- 2) The teacher's role is thus to enable or facilitate learning rather than to direct it. Teachers who adopt this approach often refer to themselves as facilitators.
- 3) Adult learners are generally most ready to learn things that they can apply immediately to existing problems or to their own situation. They do not, on the whole, learn if it is not meaningful to them or their family.
- 4) Adult learners bring with them a wealth of experience, which should be seen as a resource, and to which new learning should be related.
- 5) Adult learners can help each other, because of their experiences, and should be encouraged to do so.
- 6) Adults learn best from being active (not passive), by doing and experiencing, for which they need a safe environment where they feel accepted.
- 7) Adult learners should be encouraged to carry out continuous evaluation of their own learning. Teachers should use this evaluation to fit the learning process to the learners needs.

Source: adapted from Ewles & Simnett 2003

2.5.4 Patient-centred approach

It has been said that there are two principal models of patient education, the traditional medical-centred model and a patient-centred approach (Fahrenfortt 1987). The two models are distinct with respect to their underlying assumptions and concerns. Patient education within the medical model focuses on 'the problem' of patient control or non-compliance. The patient-centred model, by contrast, seeks to elicit and satisfy those needs that patients express themselves, and views that as the first step towards

encouraging patients to take greater control over their own health. Health professionals plan 'for' patients in the first model; they plan 'with' patients in the second (see Table 2.4 below).

Table 2.4 Comparison of medical-centred and patient-centred approaches

Medical-centred model	Patient-centred model
Compliance	Autonomy
Adherence	Patient participation
Planning for patients	Planning with patients
Behaviour change	Empowerment
Passive patient	Active patient
Dependence	Independence
Professional determines needs	Patients define needs

Source: adapted from (Skelton 2001)

Overall, there is fairly strong evidence to suggest that some interventions promoting patient-centred care in the clinical consultation may lead to significant increases in the patient centeredness of the consultation process. There is currently, however, no gold standard measure for patient centeredness, and that area needs further work if the patient-centred approach is to be properly assessed (Lewin et al. 2003). Another area of neglect in the patient centeredness approach is the development of patient information materials. A recent review has shown that current information materials for patients omit relevant research-based data, fail to give a balanced view of the effectiveness of different treatments, ignore uncertainties, adopt a patronising tone, and do not promote a participative approach to decision making (Barth et al. 1991).

In order for the patient-centred approach to be universally accepted, health care providers need to be trained in chronic disease management and therapeutic patient education (TPE) (WHO Working Group 1998). The WHO report acknowledges that health professionals tend to talk to patients about their disease rather than to train them in the daily management of their condition, and although physicians are competent in diagnosis and selection of medication, they have not had the opportunity to develop skills to address the educational, social and psychological aspects of the condition.

TPE is designed to train patients in the skills of self-managing or adapting treatment to their particular chronic disease. Different types of TPE have been introduced in various health care settings but they have often been arbitrarily designed and poorly taught. There is an obvious need for better quality educational programmes with a therapeutic content (WHO Working Group 1998). In order to meet that need, health professionals

would first have to be trained in how to deliver the programmes and it has been recommended that by 2010, all Member States should have ensured that health professionals have acquired appropriate knowledge, attitudes and skills to protect and promote health (WHO Working Group 1998). Figure 2.12 below lists the competencies expected of health care providers of TPE.

Figure 2.12 Competencies required for therapeutic patient education

- Health care providers should be able, individually and in teams, to:
1. adapt their professional behaviour to patients and their disease, whether acute or chronic;
 2. adapt their professional behaviour to patients, individually, and in their families and groups;
 3. constantly adapt their roles and actions to those of the health care and education teams with whom they cooperate;
 4. communicate empathetically with patients;
 5. recognise the needs of patients;
 6. take account of the patients' emotional state, their experience and their representations of the disease and its treatment;
 7. help patients to learn;
 8. educate patients in managing their treatment and in using the available health, social and economic resources;
 9. help patients to manage their way of life;
 10. educate and advise patients about the management of crises and about factors that interfere with the normal management of their condition;
 11. select patient-education tools;
 12. use and integrate the above tools in the care of patients and in the patients' learning process (contract with patients);
 13. take account of the educational, psychosocial and social dimensions of long-term care;
 14. evaluate patient education for its therapeutic effects (clinical, biological, psychological, educational, social, economic) and make the indicated adjustments;
 15. periodically evaluate and improve the educational performance of health care providers.

Source: Report of a WHO Working Group on Therapeutic Patient Education, 1998

The following obstacles have, however, been identified, which may delay or prevent healthcare professionals attaining the recommended competencies (WHO Working Group 1998):

- **lack of human resources** i.e. the lack of healthcare professionals trained in TPE or learner-centred education to guide projects in TPE. That may be linked with their professional tradition and culture;

- **tradition and culture of the healthcare professionals.** Basic training of most health care providers favours acute medicine and results in a pervasive biomedical approach, based principally upon diagnosis and the selection of the therapeutic regimen. The introduction of TPE is a challenge to the established culture of health care professionals;
- **insufficient teamwork.** TPE requires effective teamwork. However, in practice, health professionals may work in the same programme but do not always share the same values about the care and education of patients. There is little consensus among leading health care specialists regarding patient-centred education;
- **insufficient motivation within institutions and among policy-makers and health professionals.** The career-success and promotion of health care providers is dependant to a greater degree upon the number of their publications in professional journals than upon positively impacting on the quality of life of their patients. There are too few models available for how to overcome the resistance of health professionals to stimulate a demand for TPE. Little is also known about the most effective methods of motivating health authorities to instigate continuing education programmes for health professionals;
- **conservatism of educational institutions.** Teachers in educational institutions make traditional decisions regarding future education programmes. They also bemoan the fact that they have too little time for their own training. Once again, little is known about how to motivate organisations to teach health professionals the requisite competencies to enable them to deliver TPE to patients;
- **difficulty in assuring valid evaluation.** TPE has not been sufficiently evaluated or validated, and there are no criteria against which to measure the quality of TPE. That deficiency is linked with the lack of teaching staff competent in TPE and in the process of evaluation. It is therefore difficult to substantiate the expected decrease in expenditure on health care;
- **lack of educational resources.** The lack of training centres and competent teachers specialised in TPE is a major obstacle to training vast numbers of health

professionals. There is ignorance of suitable existing centres and the creation of new centres would require considerable funding;

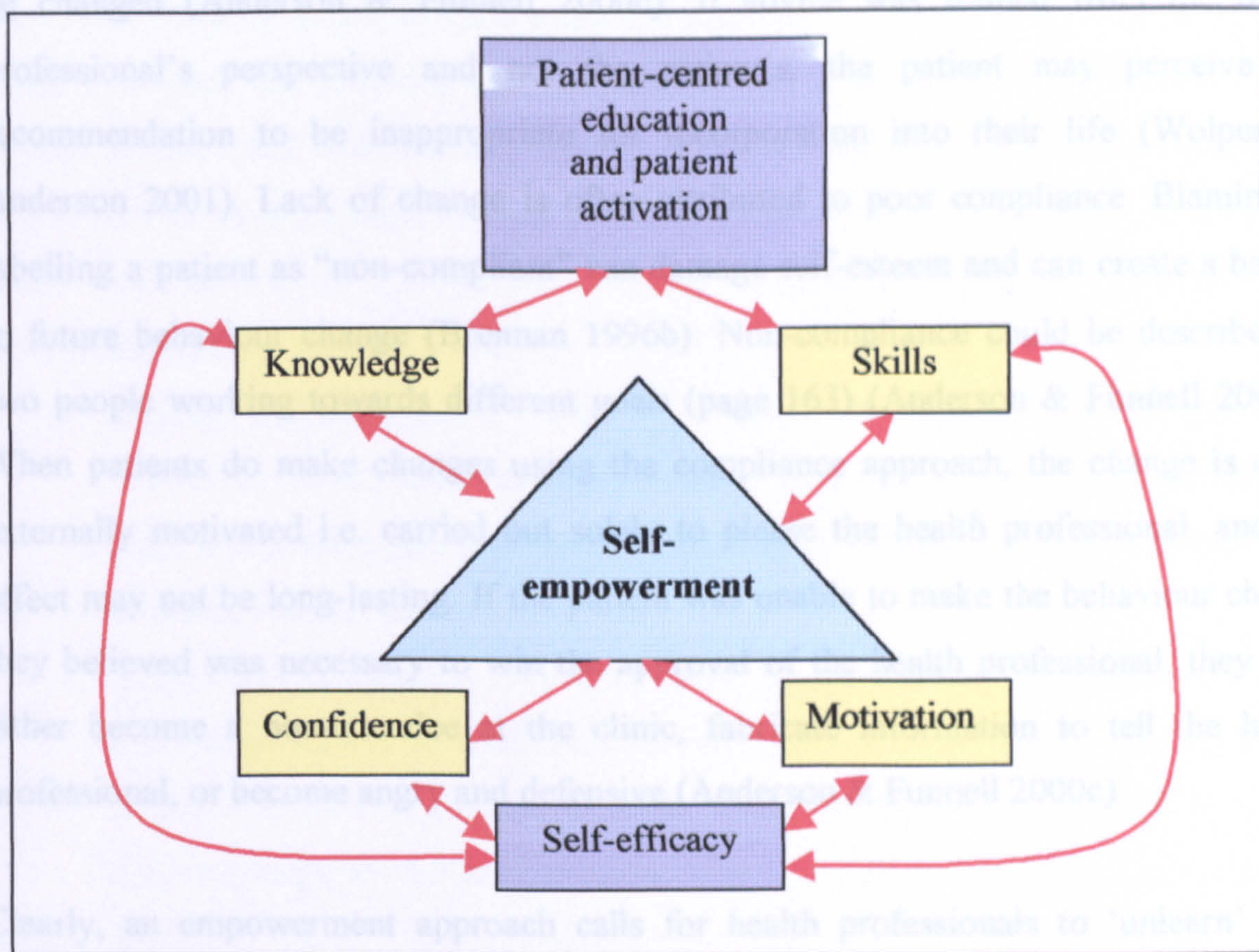
- **lack of financial resources.** Although assigned the lowest priority among the obstacles, the health care culture of ‘time is money’ means that not enough professional time is reserved for training. So long as TPE remains a low priority, financial resources will remain scarce.

2.5.5 Empowerment

Patient empowerment means different things to different people and therefore many definitions exist, some of which are stated below:

- ‘helping people discover and use their innate ability to gain mastery over their diabetes’(Anderson & Funnell 2000a);
- ‘believing that it is possible to, and having the abilities to, identify the alternatives in any situation, to choose one on the basis of one’s values, priorities, and commitments’(Brown & Piper 1995);
- ‘involving five key features: acceptance, affect, autonomy, alliance and active participation’ (Skinner & Cradock 2000);
- ‘encouraging people to participate as equal partners in decisions about the health care they receive’ (Paterson 2001);
- ‘having the knowledge, skills, attitudes and self-awareness to influence behaviour and that of others in order to improve quality of life’ (Funnell, Anderson, & Arnold 1991).

Although these and many more definitions vary in detail, the overriding philosophy is the same: empowerment cannot be given or taught, it is a process that people do for themselves (Rodgers & Walker 2002). The root of empowerment is to recognise that every person is an autonomous being, living an individual daily existence in which choices about actions and activities are constantly being made. The influence of health professionals is to recognise and emphasise that principle, while enabling the person to have enough knowledge to make informed choices about his or her actions and activities (Walker 1998). A diagrammatical model of empowerment has been devised by the author of this thesis and is shown in figure 2.13, overleaf.

Figure 2.13 The Empowerment Model

It has been recommended that patient empowerment be adopted as a new philosophical approach to patient care (Anderson 1995). Traditional patient education is built around the medical-centred model of care. The patient is viewed as a recipient of the 'health expert's' knowledge and is expected to accept and comply with prescriptive regimens. Although patient self-management is increasingly recognised as being important the lack of parity results in a trend towards unchecked reliance and dependency on the health educator (Brennan 1996a).

During the routine conduct of their lives, however, patients make a series of choices about eating, physical activity, stress management, safety when driving etc. Those choices combined have a far greater impact on patients' overall health and quality of life than the decisions made by the health professionals providing their care. Health professionals may plead, persuade, cajole, threaten or advise patients regarding their health care, but once the patient leaves the clinic, that professional has no control over the patient's self-management choices. The patient can ignore any recommendation no matter how important the educator believes that recommendation to be (Anderson & Funnell 2000c).

It is not always the case that people are unwilling to change; they may be unwilling to be changed (Anderson & Funnell 2000c). If advice was framed from the health professional's perspective and not the patient's, the patient may perceive the recommendation to be inappropriate for incorporation into their life (Wolpert & Anderson 2001). Lack of change is often attributed to poor compliance. Blaming or labelling a patient as "non-compliant" can damage self-esteem and can create a barrier to future behaviour change (Brennan 1996b). Non-compliance could be described as two people working towards different goals (page 163) (Anderson & Funnell 2000a). When patients do make changes using the compliance approach, the change is often externally motivated i.e. carried out solely to please the health professional, and the effect may not be long-lasting. If the patient was unable to make the behaviour change they believed was necessary to win the approval of the health professional, they may either become a non-attender at the clinic, fabricate information to tell the health professional, or become angry and defensive (Anderson & Funnell 2000c).

Clearly, an empowerment approach calls for health professionals to 'unlearn' their traditional approach to education by becoming empowering rather than controlling. They would need to develop the ability to facilitate and enable, rather than instruct and persuade. However, the underlying assumption of many practitioners is that an invitation to patients to participate as equal partners in the consultation is sufficient to guarantee their empowerment. Paterson investigated that assumption and found that health professionals may believe they are facilitating patient self-empowerment by inviting patients to engage in participatory decision-making, but their behaviours and practices may actually inhibit or negate their intended goal. Paterson concluded that health professionals might talk of empowerment in interactions with people but then act according to the traditional education model where he or she is the ultimate decision maker (Paterson 2001).

Tools to aid health professionals facilitate patient self-empowerment (Anderson & Funnell 2000b) and measure the change in individual empowerment scores are available (Anderson et al. 2000). Empowerment is the underpinning theoretical base for the diabetes expert patient programme and therefore those tools and strategies will be discussed in the *diabetes expert patient programme* chapter (Chapter 4) and the *methods* chapter (Chapter 5).

2.5.6 Discovery Learning

Discovery learning means that the tools and information needed to solve a problem or learn a concept are provided and the learner makes sense of them (Bruner 1966). Bruner believed that students learn best by discovery and that the learner is a problem solver who gains knowledge through discovery. His theory has four components and is based on constructivism i.e. that by reflecting on experiences, learners construct their own understanding (Bruner 1960):

- curiosity and uncertainty. Experiments should be designed in a way that helps learners to be motivated and able to learn. One way of encouraging a desire to learn and to undertake problem solving is by devising problem solving activities in which learners explore solutions;
- structure of knowledge. The tutor must specify the ways in which a body of knowledge should be structured so that it can be most readily grasped by the learner. Any idea or problem or body of knowledge can be presented in a form simple enough so that any particular learner can understand it in a recognisable form.
- sequencing. Effective sequences of instruction should be specified and this should lead the learner through the content in order to increase their ability to grasp, transform and transfer what is learned to their personal needs and circumstances.
- motivation. Movement from extrinsic rewards, such as tutor's praise, toward intrinsic rewards inherent in solving problems or understanding the concepts is desirable.

2.5.7 The expert patient concept

As discussed in section 2.2.2, people are living longer. But for many, long periods of time pass with a reduced quality of life due to the development of a chronic condition. It is clear that the doctor patient relationship is changing and has to change further. The historic 'doctor knows best' approach is being replaced with a doctor patient partnership. When acute diseases dominated as the main cause of ill health, the doctor was the best judge of the health of the patient. Patients knew nothing of clinical matters and they could not be expected to know what was best for them (Kennedy 2003).

As chronic conditions have replaced acute disease as the major cause of mortality and morbidity, increasing volumes of health information have become available through the

media and on the Internet. On average, people with diabetes spend around three hours per year with a health professional. That means that the patient is left to manage his or her own condition for the other 8757 hours of the year (DOH 2002). That further demonstrates why helping patients with chronic disease to understand and take responsibility for their condition is so important if patient outcomes are to be optimised. Patients are becoming more interested in their own health and in making sure that the treatment they receive meets their needs. They are no longer passive receivers of health care, but consumers with choices who are entitled to expect good quality care (Illman 2000).

Health professionals have often reported, “my patient understands their condition better than I do”. The knowledge and experience held by patients and the potential they have to improve their quality of lives has only recently been recognised (DOH 1999) and the emphasis is beginning to shift. Patients are beginning to become key decision-makers in the treatment process. By ensuring that knowledge of their condition is developed to a point where they are empowered to take some responsibility for its management and that they work in partnership with health and social care providers, patients can develop greater control over their lives (DOH 2001b).

It is not enough to assume that patients will receive accurate information through the media and Internet. Promising interventions for the empowerment of patients require further evaluation (Wensing & Grol 1998). Patient self-management programmes are not simply about educating or instructing patients about their condition and then measuring success on the basis of patient compliance. They can be designed to build skills, confidence and facilitate the process of patient empowerment. The ‘expert’ patient would then be equipped to take effective control and make informed decisions regarding their chronic condition (DOH 2001c).

There are two types of empowering self-management programmes (DOH 2001c). First are those delivered by health professionals. They are condition-specific and aim to develop knowledge and skills associated with that particular condition. Second are the lay-led programmes that address how the illness impacts on daily life.

Dose adjustment for normal eating (DAFNE) (DAFNE Study Group 2002) is an example of a professional-led, self-management programme specific for adults with

Type 1 diabetes. Although the programme is known as DAFNE throughout the UK, the original model was developed in Germany (Berger & Muhlhauser 1995). Self-management programmes are common practice in many parts of Europe and have led to improved health status and quality of life.

The Centre for Patient Education Research, Stanford University, California developed a model for lay-led self-management programmes over 30 years ago. The course aimed to develop five, core self-management skills: problem solving, decision-making, resource utilisation, development of effective partnerships with health care providers, and taking action. The self-management programme is characterised by three distinct features:

- it has been developed using the experiences of people living with long-term illnesses;
- it is run in communities with a heterogeneous group of people;
- it is lay-led, which means lay tutors all of whom are living with a long-term condition deliver the programme.

The chronic disease self-management programme is presently being piloted as the Expert Patients Programme within the NHS in England. The project is funded by the Department of Health and is being evaluated by the University of Manchester with the intention that generic self-management programmes will become mainstreamed within all NHS areas by 2007 (DOH 2001c).

2.5.8 The theoretical basis of the X-PERT programme

The four behaviour change models discussed in section 2.4 (page 42) have several components in common, such as self-efficacy, motivation, education, belief and costs/benefits. Those components were considered in the design and development of the intervention (diabetes expert patient programme, see Chapter 4). The principles of adult learning, group education, the patient-centred approach, empowerment and discovery learning were the main contributors to the theoretical component of the programme. The evaluation of this diabetes education, self-management programme is the basis of this thesis and is reported in Chapters 5,6 and 7.

Self-efficacy, motivation and belief were addressed by delivering **group-based, patient-centred education** that encouraged the participants to become actively involved in **discovery learning** and identify individual **costs and benefits** from adopting certain health promoting behaviours. **Empowerment** has been described as having five components: acceptance, active participation, affect, autonomy, and alliance

(Skinner & Craddock 2000). These were integral to the design of the education programme. Participants with diabetes were valued and accepted as being experts at living with their condition. Participants were encouraged to take active participation in the learning process and to discuss their feelings towards living with their condition and the affect it has on their day-to-day lives. They were encouraged to have autonomy by working in alliance with health care professionals to identify successful strategies for diabetes self-management.

2.6 Summary

It has been shown that although the WHO definition of health has changed over time to encapsulate a more holistic view, health is still a very complex issue and being healthy means different things to different people. International conferences have taken a leading role in health promotion concepts and principles, in the recognition of the relationship between health and self-empowerment. The resulting declarations, charters and reports have taken time to impact on national policies and the health promoting empowerment philosophy has only just begun to emerge.

Currently, the success of health education or health promotion initiatives in changing health behaviour frequently depends on the type of approach that the educator has chosen to use. However, there are few evidence-based guidelines on which to base recommendations. There is, furthermore, a shortage of staff trained in health promotion and funding to deliver and evaluate initiatives is scarce. A number of models that attempt to explain health behaviour and illustrate the impetus for health action have been identified. Components from those models with the principles of adult learning, group education, the patient-centred approach, empowerment and discovery learning were the main contributors to the theoretical component of the diabetes expert patient programme described in Chapter 4.

Patient education in Europe and the United States is still based on the biomedical model and although recommendations from international conferences on health promotion are gradually being integrated into health and legal policy, most countries are still in the experimental stage of developing therapeutic and self-management education programmes. Although recent literature encourages the evolution of the expert patient, the evidence base for the expert patient concept is in its infancy and further evaluations are necessary before expert patient programmes can be recommended as routine practice.

Chapter 3: Systematic Review: group-based self-management strategies in people with Type 2 diabetes

3.1 Introduction

A systematic review of group-based, self-management education programmes for adults with Type 2 diabetes has been carried out and is presented in this chapter. A brief review of previous work carried out in this field was undertaken in 2001 and a systematic review protocol was written, which was then accepted by the Cochrane Metabolic Disorder and Endocrine Review Group and published on the Cochrane Collaboration website (Deakin et al. 2001). The review was completed in September 2003 and is currently awaiting peer review by the Cochrane review group prior to publication. The chapter is organised in the format of a standard research paper starting with an abstract and concluding with implications for practice and future research.

3.2 Abstract

Background: diabetes mellitus is one of the most common chronic disorders in the western world and it is now clear that Type 2 diabetes is a progressive condition that should never be considered the 'mild' form of diabetes. It has been recognised that adoption of self-management skills by the person with diabetes is necessary in order to manage their diabetes. However, the most effective method for delivering education and teaching self-management skills is unclear.

Objectives: to assess the effects of group-based, patient-centred education on: clinical outcomes (diabetes metabolic control, blood pressure, body weight and body mass index and lipid profile); lifestyle outcomes (self-management skills and diabetes knowledge); psychosocial outcomes (quality of life, empowerment/self-efficacy and treatment satisfaction).

Search strategy: the following electronic databases were searched from the beginning of each database up until January/February 2003: The Cochrane Library; MEDLINE; CINAHL; ERIC; ASSIA; AMED; PsycINFO; EMBASE; LILACS; Database of Abstracts of Reviews of Effectiveness (DARE); NHS Economic Evaluation Database (NHS EED); British Education Index (BEI); British Nursing Index (BNI); Web of Science and National Research Register. Conference proceedings and reference lists of articles were also searched and contact was made with experts in the field.

Selection criteria: randomised controlled trials (RCTs), controlled clinical trials (CCTs), controlled before-and-after studies (CBAs) and interrupted time series (ITS) which evaluated group-based education programmes for adults with Type 2 diabetes compared with routine treatment, waiting list control or no intervention. Studies were only included if the length of follow-up was six months or more and the group education programme was at least one session with the minimum of six participants.

Data collection & analysis: two reviewers independently extracted data and assessed study quality with high interrater agreement. A meta-analysis was performed if there were enough homogeneous studies reporting an outcome at either four to six months, 12-14 months, or two years, otherwise the studies were summarised in a descriptive manner.

Main results: thirteen papers describing 11 studies were included, involving 1532 participants. Nine studies were RCTs and two, CCTs. The methodological quality of the studies was moderate to poor due to unclear allocation concealment, lack of intention-to-treat analyses, and unclear blinding of the outcome assessor. Heterogeneity was low for the majority of meta-analyses. However, if significant heterogeneity was present, the source was identified by a sensitivity analysis. The results of the meta-analyses in favour of group-based diabetes education programmes were: reduced glycated haemoglobin at four to six months (1.08%;95% CI: 0.40% to 1.76%, P=0.002), at 12-14 months (0.82%;95% CI: 0.65% to 0.99%, P<0.00001) and two years (0.97%; 95% CI: 0.54% to 1.40%, P<0.00001); reduced fasting blood glucose levels at six months (1.66 mmol/l; 95% CI: 0.74 mmol/l to 2.58 mmol/l, P=0.0004), at 12 months (1.17mmol/l; 95% CI: 0.72 mmol/l to 1.63 mmol/l, P<0.00001), and two years (1.57 mmol/l; 95% CI: 1.05 mmol/l to 2.10 mmol/l, P<0.00001); reduction in diabetes medication (odds ratio 11.79, 95% CI: 5.17 to 26.90, P<0.00001); reduced body weight at 12-14 months (1.16Kg; 0.25Kg to 2.97Kg, P=0.02); improved diabetes knowledge at four-six months (SMD 0.70; 95% CI: 0.22 to 1.18, P=0.004), at 12-14 months (SMD 0.83; 95% CI: 0.52 to 1.14, P<0.00001) and two years (SMD 1.27; 95% CI: 0.82 to 1.73, P<0.00001); reduced systolic blood pressure at four to six months (5.37mmHg: 95% CI: 1.21mmHg to 9.53mmHg, P=0.01), borderline statistical significance for diastolic blood pressure (2.65 mmHg; 95% CI: -0.28 to 5.57mmHg, P=0.08); and borderline statistical significance for triglyceride level at four-six months (0.24 mmol/l; 95% CI: -0.04 mmol/l to 0.52 mmol/l, P = 0.09).

No adverse effects were reported. There was no evidence of group-based education programmes having an effect on the following outcomes: body weight ($P=0.11$) and body mass index (BMI) ($P=0.71$) at four-six months or BMI at 12-14 months ($P=0.70$); total mortality ($P=0.77$); systolic and diastolic blood pressure at 12-14 months ($P=0.22$, $P=0.95$ respectively); total cholesterol level at four-six months ($P=0.71$) and 12-14 months ($P=0.34$) and triglyceride level at 12-14 months ($P=0.31$).

For the results analysed in a descriptive manner, there was some evidence that group education programmes led to patient empowerment at both four months ($P<0.001$) and 14 months ($P=0.006$) and increased freedom to eat and drink at four months ($P=0.05$ to $P<0.001$) and 14 months ($P=0.05$ to $P=0.01$). However, there was no evidence of a generalised improvement in quality of life until two years ($P<0.001$) and four years ($P<0.009$) with every point gained for quality of life costing just US\$ 2.12. There was some evidence that participants who had attended group education sessions increased their physical activity levels, increased self-monitoring of blood glucose levels and urinalysis, improved dietary intake with less percentage energy from saturated fat and more fruit and vegetables, improved health behaviour conduct, and increased foot care and monitoring. They were found to be more satisfied with treatment and, at four years, had less progression to diabetic retinopathy.

Reviewers' conclusions: group-based self-management strategies in people with Type 2 diabetes are effective by improving fasting blood glucose levels, glycated haemoglobin and diabetes knowledge at four to six months, 12-14 months and two years. Reductions in the requirement for diabetes medication is also apparent as are reductions in blood pressure at four to six months, body weight at 12-14 months and a tendency for reduced triglyceride levels at four to six months. There is also some evidence that group education participants experience greater empowerment, better quality of life, increased self-management skills and treatment satisfaction. However, due to the small numbers of studies included in the review, their moderate to low research design quality scores and the small number of studies measuring blood pressure, quality of life, empowerment/self-efficacy, improved treatment satisfaction and cost effectiveness, further research evaluating patient-centred group-based diabetes education programmes is needed to confirm these findings.

3.3 Background

3.3.1 Diabetes mellitus and its complications

Diabetes mellitus is one of the most common chronic disorders in the western world. Type 2 diabetes affects large numbers of people from a wide range of ethnic groups and at all social and economic levels. It is estimated that 194 million people worldwide, or 5.1% of the adult population, currently have diabetes and that will increase to 333 million (6.3% of the adult population by 2025) (Sicree, Shaw, & Zimmet 2003). It is felt that lifestyle changes, with diets high in saturated fat and decreased physical activity, together with an increased longevity, are the main factors in the dramatic increase of Type 2 diabetes. Type 2 diabetes, previously referred to as non insulin dependent diabetes mellitus (NIDDM) or mature onset diabetes is more commonly diagnosed over the age of 40. It affects 75-90% of all those with diabetes (Keen et al. 1995). An economic study 'Type 2 diabetes: Accounting for a major Resource Demand in Society in the UK' (Diabetes UK 2000) has shown that microvascular and macrovascular complications increase UK NHS costs more than five fold and diabetes presently consumes 9% of NHS inpatient resources. The annual direct healthcare costs of diabetes worldwide for people aged between 20 and 79 is estimated to be at least 153 billion international dollars. If predictions for diabetes prevalence are correct, total direct healthcare expenditure on diabetes worldwide will be between 213 and 396 billion international dollars in 2025, which will be between 7% and 13% (Williams 2003) of total healthcare expenditure.

Diabetes mellitus is a metabolic disorder resulting from a defect in insulin secretion, insulin action, or both. A consequence of this is a chronic hyperglycaemia (i.e. elevated levels of plasma glucose) with disturbances of carbohydrate, fat and protein metabolism. Although the onset of Type 2 diabetes is usually less dramatic than that of Type 1, both types of diabetes carry a risk of multiple, disabling, yet potentially preventable complications (DCCT Research Group 1993; UKPDS Group 1998b). Diabetes greatly increases the risk of coronary heart disease and stroke. Cardiovascular disease is the primary cause of death in industrialized countries. It is also set to overtake infectious diseases as the most common cause of death in many parts of the less developed world. People with diabetes are between two and four times more likely to develop cardiovascular disease than people without diabetes, making it the most common complication of diabetes (IDF 2001). Between 70 and 80% of people with diabetes die from cardiovascular disease (Tapp, Shaw, & Zimmet 2003). Other long-

term consequences of diabetes mellitus include retinopathy, nephropathy and neuropathy; it is a leading cause of blindness, end-stage renal failure and limb amputation. For a detailed overview of diabetes mellitus, please see 'Additional information' in the information about the Metabolic and Endocrine Disorders Group on the Cochrane Library (see 'About the Cochrane Collaboration', 'Collaboration Review Groups'). For an explanation of the methodological terms, see the main Glossary on the Cochrane Library.

It is now clear that Type 2 diabetes is a progressive condition and ought never to be considered the 'mild' form of diabetes. It should always be taken seriously and the objective of treatment should be to achieve and maintain long-term near-normal blood glucose and blood pressure levels. As already discussed in Chapter 1, the United Kingdom Prospective Diabetes Study (UKPDS Group 1998b), the largest clinical research study of diabetes ever conducted, has provided evidence that the life threatening complications of Type 2 diabetes can be reduced by a combination of optimal blood glucose and blood pressure levels. More recent studies have shown that each 1% reduction in glycated haemoglobin was associated with the reductions in risk of 21% for any end point related to diabetes, 21% for deaths related to diabetes, 14% for myocardial infarction and 37% for microvascular complications (Stratton et al. 2000). Each 10 mmHg decrease in systolic blood pressure was associated with reductions in risk of 12% for any complication related to diabetes, 15% for deaths related to diabetes, 11% for myocardial infarction and 13% for microvascular complications (Adler et al. 2000; Stratton et al. 2000). Therefore, any reduction in glycated haemoglobin and blood pressure is likely to reduce the risk of complications with the lowest risk being in those with HbA1c values in the normal range (< 6.0%) and systolic blood pressure values less than 120 mmHg.

3.3.2 Self-management skills

It has been recognised that adoption of self-management skills (i.e. the learned ability to perform an act competently) by the person with diabetes is necessary to enable them to manage their diabetes (WHO Working Group 1998). Nutritional intake and modification of lifestyle are the cornerstone of treatment for Type 2 diabetes. Although the provision of effective ongoing education and support is necessary to equip people with the knowledge, skills, attitudes and motivation required to manage their diabetes care effectively (DOH & Diabetes UK 1995), the most effective method for delivering education and teaching self-management skills is unclear.

Effective management lies almost entirely in the hands of the patient who lives with the condition. However, a health professional-centred approach based on the medical model is still traditionally used. That model of care may neglect the psychosocial and emotional aspects of the disease and could be one of the main reasons why only 7% of adults with diabetes manage to follow all the steps deemed by practitioners to be necessary for optimal management and good glycaemic control, including dietary modification, physical activity regime, compliance with medication and monitoring diabetes control (Griffin et al. 1998).

3.3.3 Standards

Individual countries have developed their own standards. The United States of America, for example, has developed 'National Standards for Diabetes Self-Management Education' (Mensing et al. 2003). The American standards define structure (organisation, needs assessment, program management, program staff, curriculum and participant access), process (assessment, plan and implementation, follow-up) and outcomes (program outcome evaluation, participant outcome evaluation) as the core components to diabetes education programmes, along with skilled and experienced health care professionals with recent education in diabetes, educational principles, and behaviour change strategies. The German model, 'intensified insulin treatment' prescribed as routine treatment for Type 1 diabetes, has been developed by Michael Berger in Düsseldorf and is based on the Assal model of therapeutic education (Muhlhauser, Jorgens, & Berger 1983). It is a five-day structured in-patient training programme in intensive insulin therapy and self-management. This programme has since been adapted and delivered as an out-patient course (Kronsbein et al. 1988) and formed the basis of the DAFNE (Dose Adjustment For Normal Eating) project in the UK. Although the model was originally developed for people with Type 1 diabetes, there are now papers evaluating its effectiveness for people with Type 2 diabetes (Domenech et al. 1995; Gruesser et al. 1993; Pieber et al. 1995).

The International Diabetes Federation has published 'International Curriculum for Diabetes Health Professional Education' (IDF Consultative Section on Diabetes Education (DECS) 2002). A curriculum is a detailed plan with overall aims and evaluation process for the education programme. The mission of the Diabetes Education Consultative Section (DECS) is to provide access to expertise in diabetes education, both for people with diabetes and for health professionals. The DECS publication provides a collection of modules designed to train health professionals to the

appropriate level so that they feel competent to deliver the education required by people with diabetes. Diabetes experts developed those modules with input from educators around the world. The DECS has more recently published 'International Standards for Diabetes Education' (IDF Consultative Section on Diabetes Education (DECS) 2003), which has been organised into structure standards, process standards and outcome standards. The standards serve to assist in the planning of health services, to prioritise resource allocation, to lend support to the lobby for the funding and recognition of diabetes education, to identify competencies required by those who deliver diabetes education, to provide a benchmark against which the quality of care can be evaluated and improved, to provide a basis for accrediting organisations and to assist individual diabetes educators to acquire the necessary credentials.

In the UK, a report with recommendations and examples of good practice (Naqib 2002) was followed shortly afterwards by guidance for the use of patient education models for diabetes (NICE 2003b). The guidelines recommended that educational interventions should reflect established principles of adult and active learning, be provided through an appropriately trained multidisciplinary team to groups of people with diabetes (unless group work was considered unsuitable for a particular individual) and take into account culture, ethnicity, disability and geographical issues. The UK public health document 'Saving Lives: Our Healthier Nation (DOH 1999) acknowledged that in the past, too little has been done to help people with chronic disease play a part in managing their own condition. The Chief Medical Officer set up a task force to design an expert patients programme to address the needs of one in three of the total population who will suffer from a chronic disease or disability in their lifetime (DOH 2001). The term 'expert patient programme' suggests that the patient will have an opportunity to become an 'expert' in self-managing their condition. Based on the work of Lorig in the United States (Lorig et al. 1999) and the UK Challenging Arthritis programme (Barlow, Turner, & Wright 2000), there is increasing evidence that people have improved self-efficacy and general health and reduced incapacity upon becoming empowered to take the lead themselves in managing their chronic disease. People are empowered when they have knowledge, skills, attitudes and self-awareness necessary to influence their own behaviour and that of others in order to improve the quality of their lives (Funnell, Anderson, & Arnold 1991). The World Health Organisation alluded to empowerment in its paper on health promotion as "the process of enabling people to increase control over, and to improve, their health" (WHO 1978). Self-efficacy is a belief. People who

have self-efficacy expectations believe that they are capable of performing a given activity.

The World Health Organisation Report (WHO Working Group 1998) on therapeutic patient education also recognised the importance of patient-centred education in the effective management of chronic disease. Patient-centred education is the close involvement of patients and carers in the planning of the education, such as soliciting the patient's opinions, concepts, ideas, feelings and questions, offering support, and allowing the patient to be involved in decision making. In contrast, traditional education is didactic in nature and tends to be delivered in lecture format. The report makes recommendations about the ideal content of a specific education programme for health care providers in the field of prevention of chronic diseases and therapeutic patient education.

3.3.4 Systematic reviews and other evidence

Diabetes UK (formerly the British Diabetic Association) commissioned a review of the educational and psychosocial interventions for adults with diabetes (Griffin et al. 1998). It reviewed seven meta-analyses (Brown 1988; Brown 1990; Brown 1992; Mazzuca 1982; Mullen, Green, & Persinger 1985; Padgett et al. 1988; Posavac 1980), one review (Wing 1993) and 57 published controlled trials. More than 3000 papers were identified by a more general search unconstrained by search terms relating to study design. The three reviews by Brown underlined the volume of work in diabetes patient education and have shown that education is beneficial but that the size of the effect depends on the outcome, the nature of the measure, the length of the study and the age of the participants. The degree to which the approach to educational intervention affected the outcome was not addressed. It was concluded that evaluations of education have been of variable, but frequently poor, quality and prone to selection and measurement bias. There has also been inadequate description of each intervention. Attrition rates were reported in about half of the studies and only 8% performed an intention-to-treat analysis. Those omissions led to bias, misunderstanding and poor generalisability of findings. Self-reported measures were shown to overestimate effects and important health outcomes, such as quality of life and cardiovascular disease risk. Cost seemed rarely to have been assessed. In the meta-analysis there was a large degree of heterogeneity, as broad classes of patient variables were grouped together to produce effect sizes. Posavac undertook a meta-analysis of education programmes for patients with chronic disease (not restricted to diabetes). The search strategy was less rigorous

than that undertaken by Brown and studies were included if the title suggested that 'an empirical evaluation', including a control or comparison group, had been carried out. As with the Brown reviews, patient education emerged as beneficial but the effect varied according to the outcome measure. As a consequence of the limited search strategy and the small number of identified trials, publication bias was a worry and reduced the quality of the review.

Mazzuca made more effort to differentiate the educational interventions and to assess relative as well as absolute effect sizes. That report added further weight to the notion that education is beneficial and supported the belief that some forms of education (behavioural) were more effective than others (didactic). However, there were several limitations, with the search strategy missing many studies identified by Brown. Mullen also reviewed different interventions for all people with chronic disease. Studies were included if they had a control group or pre-test/post-test design and measured knowledge and/or adherence. Seventy studies were identified and a scoring system divided the studies into seven educational principles. The underlying message was that education was beneficial, particularly if based on sound educational principles. As with the other reviews, interventions were poorly described in the individual trials and educational, psychological, or behavioural science theory was rarely discussed. The final meta-analysis was that of Padgett and colleagues. They estimated the overall effectiveness of educational and psychosocial interventions for people with diabetes. One hundred and ten studies met the inclusion criteria and those were scored for methodological quality. Effect sizes were calculated for 94 studies of which 14% were randomised trials. The finding that education was beneficial was confirmed once more. Dietary instruction produced the largest effects, but tended to be evaluated in the short term with physical measures such as weight and metabolic control. Although the review by Wing was not a meta-analysis, it described the lessons learnt from 15 years of trial work, looking at behaviour modification for obesity with Type 2 diabetes. Wing concluded that behavioural approaches were required, rather than simple education, and that health professionals may need training in behaviour modification techniques.

Therefore, the Diabetes UK literature review showed that an increasing number of trials have been undertaken, mainly in secondary care in the United States. There were important differences in culture, social structure and health care delivery. Those differences could threaten generalisability of the results to other parts of the world. The

studies tended to be small and short-term; the education programmes were more likely to be based on a lecture format, and the studies had many methodological weaknesses. However, trials that appeared to incorporate a social cognition model or involved patient activation tended to produce more positive results. The meta-analyses have many limitations with poor descriptions of the sample characteristics, the interventions and the underpinning theoretical model. Publication bias was almost certainly present in some of the reports, but it has not been formally assessed with techniques such as a funnel plot. The quality of the design and measurement used in each study was associated with the size of the outcome, yet none of the meta-analyses attempted a sensitivity analysis to gain a clearer idea of the true effect of the interventions. Although the age of participants, the type of diabetes and so on was associated with effect size, authors continued to review heterogeneous studies. Consistent conclusions run through the seven reports but that may be because the authors were all subject to similar biases (Griffin et al. 1998).

The NHS Centre for Reviews and Dissemination, University of York reviewed the evidence for the effectiveness of self-management interventions for Type 2 diabetes. The Effective Health Care bulletin is divided into two sections, the first dealing with renal complications and the second half with the promotion of self-management (Khan et al. 2000). The interventions considered in the bulletin were generally provided in addition to the information sharing that should be an integral part of routine patient care. The interventions included in the review were assigned to three broad categories: information and skills, cognitive-behavioural, and patient empowerment. Both individual and group methods were included. It was concluded that further research is necessary to determine whether interventions to promote self-management had positive significant long-term effects.

More recent reviews have evaluated the effectiveness of self-management training in Type 2 diabetes (Norris et al. 2002; Norris, Engelgau, & Narayan 2001; Steed, Cooke, & Newman 2003; van Dam et al. 2003). Norris 2001 evaluated 72 studies and found short-term (less than six months) positive effects of self-management on knowledge, frequency and accuracy of self-monitoring blood glucose, self-reported dietary habits and glycaemic control. With longer follow-up, interventions that used regular reinforcement were sometimes effective in improving glycaemic control with patient collaboration possibly being more effective than didactic prescription. No studies demonstrated the effectiveness of self-management training on cardiovascular disease-

related events or mortality and no economic analyses included indirect costs. Performance, selection, attrition, and detection bias were common in studies reviewed, limiting external generalisability. Norris 2002 performed a meta-analysis of the effect of self-management training on glycaemic control. On average, glycated haemoglobin decreased by 0.76% (95% CI: 0.34%-1.18%) more than the control group at immediate follow-up and by 0.26% (95%CI: 0.05%-0.48%) at four months or longer follow-up. Metabolic control improved in line with additional contact time between participant and educator; there was a decrease in glycated haemoglobin of 1% for every 23.6 hours (95% CI: 13.3hr-105.4hr) of contact. Norris 2002 concluded that although self-management training improved diabetes control at immediate follow-up, the benefit declined between one and three months after the intervention ceased, suggesting that learned behaviours can change over time. Steed 2003 reviewed 36 self-management and psychosocial interventions on psychosocial outcomes and found that depression seemed to be particularly improved following psychosocial interventions, whereas quality of life showed greater improvement following self-management interventions. There was no convincing evidence to further support the use of didactic education programmes. Van Dam 2003 reviewed eight publications evaluating the effects of the modification of provider-patient interaction and consulting style on diabetes self-care and diabetes outcomes. Patient behaviour-focused interventions, the enhancement of patient participation by assistant-guided patient preparation for visits to doctors, empowering group education and automated telephone management were found to be more effective than focusing on provider behaviour to change health professional consulting style into a more patient-centred one. However, although there was evidence that self-management training was effective, all four recent reviews called for further research by way of well-designed and long-term studies.

Educational programmes are frequently defined as complex interventions where it is often difficult to define the 'active ingredient'. If a programme is shown to be effective, that may be due to any combining theoretical model used, the skills of the educator, the venue, the rapport between the participants and so on. If it is clear to those who read the results of a trial how the intervention can be transported and put into operation in other contexts, then it may not be essential to discover the precise mechanisms of action (Medical Research Council 2000). However, if sufficiently homogeneous good quality complex interventions are systematically reviewed, the active ingredient is more likely to become apparent.

3.4 Aims

As a result of the increasing prevalence of diabetes and increasing pressure on staff resources, more patients are receiving diabetes education by attending group-based programmes. None of the above reviews have evaluated the effectiveness of self-management training delivered in a group format. This systematic review aims to evaluate previous research into group-based, patient-centred educational programmes for people with Type 2 diabetes. Particular attention will be placed on programmes that attempted to increase self-management skills, self-efficacy or self-empowerment and to measure their impact on metabolic control, patient satisfaction and quality of life. Information gained will be used to further develop expert patient programmes for people with Type 2 diabetes.

3.5 Objectives

To assess the effects of group-based (six or more people), patient-centred diabetes education on clinical, lifestyle and psychosocial outcomes both in the short (four to six months) and longer-term (>12 months) compared with routine care delivered on a one-to-one basis, or a combination of the two.

To observe whether the setting (primary/secondary care), the educator (physician, nurse, dietitian, other health professional, peer educator), the type of educational model or the duration/intensity of the group-based education programme affects the outcomes.

3.6 Criteria for considering studies for this review

Types of studies

The Cochrane Effective Practice and Organisation of Care (EPOC) review group guidelines were used for study type. Studies were included if they were a randomised controlled trial (RCT), a controlled clinical trial (CCT), a controlled before and after study (CBA) or interrupted time series (ITS) and then only if they fulfilled the inclusion criteria.

Interventions involved a single or series of group sessions. Only studies that assessed outcome measures six months or more from baseline were included in this study.

Types of participants

Participants were all adults with diagnosed Type 2 diabetes, regardless of gender or ethnicity. Ideally, the diagnostic criteria for Type 2 diabetes should have been described

in the trial. In order to be consistent with changes in classification and diagnostic criteria of the disease through the years, the diagnosis should have been established using the standard criteria that were valid at the beginning of the trial (ADA Expert Committee on the Diagnosis and Classification of Diabetes Mellitus 1997; National Diabetes Data Group 1979; WHO 1985a; WHO Expert Committee on Diabetes Mellitus 1980; WHO Working Group 1999).

The review excluded interventions that were specific for maturity onset diabetes of the young (MODY) or for pregnant women.

Types of interventions

Group-based educational programmes that met the following criteria:

- specific for people with type 2 diabetes;
- delivered in primary or secondary care;
- based on learner/patient-centred education;
- included or excluded family and friends;
- had a minimum of six participants in each group;
- was a minimum of one session lasting for one hour.

Comparison Group:

The intervention group was compared with participants that were either:

- undergoing routine treatment (receiving the standard of care recommended in that country e.g. regular follow-up with the required health professionals and a full diabetes annual review);
- remaining on a waiting list;
- experiencing no intervention i.e. the present healthcare was continued.

Types of outcome measures

Clinical outcomes:

- glycated haemoglobin (%) (primary outcome);
- fasting blood glucose (mmol/l);
- body weight (Kg)/body mass index (BMI)(Kg/m²);
- blood pressure (systolic/diastolic) (mmHg);
- lipid profile (total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides) (mmol/l);

- diabetes complications (myocardial infarction, angina, heart failure, stroke, renal failure, neuropathy, retinopathy, peripheral vascular disease);
- diabetes-related mortality (death from myocardial infarction, stroke, peripheral vascular disease, renal disease, hyper- or hypoglycaemia or sudden death);
- adverse effects e.g. increased hypoglycaemia.

Lifestyle outcomes:

- self-management skills (including dietary habits and physical activity levels);*
- diabetes knowledge;*
- psychosocial outcomes;
- quality of life;*
- empowerment/self-efficacy;*
- patient treatment satisfaction.*

(Diabetes education studies are generally too short-term to assess incidence of diabetes complications and mortality. Therefore, the main outcome will be glycated haemoglobin. It has been shown (UKPDS-35 2000) that a 1% reduction in glycated haemoglobin reduces the risk of developing diabetes complications by 21%).

* ideally measured using standard (validated) questionnaires

Timing Of Outcome Assessment:

Short term: four to six months

Long term: 12 months or more

3.7 Search strategy for identification of studies

Electronic searches

The following electronic databases were searched from the date on which records began up until January/February 2003: The Cochrane Library; MEDLINE; CINAHL; ERIC; ASSIA; AMED; PsycINFO; EMBASE; LILACS: Database of Abstracts of Reviews of Effectiveness (DARE); NHS Economic Evaluation Database (NHS EED); British Education Index (BEI); British Nursing Index (BNI); Web of Science and National Research Register. Conference proceedings and reference lists of articles were also searched and contact was made with experts in the field.

The following MEDLINE search strategy was adapted for use with the other databases.
TYPE 2 DIABETES (The Cochrane Metabolic and Endocrine Disorders Group search strategy)

1. "diabetes mellitus, non insulin dependent"[MeSH Terms]
2. "insulin resistance"[MeSH Terms]
3. "obesity in diabetes"[MeSH Terms]
4. "impaired glucose tolerance"[Title/Abstract]
5. "glucose intolerance"[Title/Abstract]
6. "insulin resistance"[Title/Abstract]
7. "mody"[Title/Abstract]
8. "dm2"[Title/Abstract]
9. "niddm"[Title/Abstract]
10. "iidm"[Title/Abstract]
11. "non insulin dependent"[Title/Abstract]
12. "noninsulin dependent"[Title/Abstract]
13. "noninsulindependent"[Title/Abstract]
14. "type 2 diabet*"[Title/Abstract]
15. "type ii diabet*"[Title/Abstract]
16. "nonketotic diabet*"[Title/Abstract]
17. "non ketotic diabet*
18. "adult onset diabet*"[Title/Abstract]
19. "late onset diabet*
20. "metabolic syndrom*"[Title/Abstract]
21. "plurimetabolic syndrom*"[Title/Abstract]
22. or/1-21
23. dermatomyositis[MeSH Terms]
24. Myotonic dystrophy[MeSH Terms]
25. Diabetes insipidus[MeSH Terms]
26. dermatomyositis[Title/Abstract]
27. myotonic dystroph*[Title/Abstract]
28. diabet* insipidus[Title/Abstract]
29. or/23-28
30. 22 not 29

EDUCATION

31. "education"[MeSH Terms]

- 32."self care"[MeSH Terms]
- 33"patient education"[MeSH Terms]
- 34"self efficacy"[MeSH Terms]
- 35"behavior therapy"[MeSH Terms]
- 36"empowerment"[Title/Abstract]
- 37"self care"[Title/Abstract]
- 38"education*"[Title/Abstract]
- 39"self efficac*"[Title/Abstract]
- 40"program*"[Title/Abstract]
- 41"group method*"[Title/Abstract]
- 42"group management"[Title/Abstract]
- 43"evaluation*"[Title/Abstract]
- 44"lifestyle"[Title/Abstract]
- 45"behavio?r* therap*"[Title/Abstract]]
- 46or/31-45

TRIAL DESIGN (adopted from the Cochrane Effective Practice and Organisation of Care Review Group (EPOC))

- 47."randomized controlled trial"[Publication Type]
- 48."randomized controlled trials"[MeSH Terms]
- 49."random allocation"[MeSH Terms]"random"[Title/Abstract]
- 50."allocat*"[Title/Abstract]
- 51."assign"[Title/Abstract]
- 52."controlled clinical trial"[Publication Type]
- 53."clinical trial"[Publication Type]
- 54."clinical trials"[MeSH Terms]
- 55."clinical trial*"[Title/Abstract]
- 56."double blind method"[MeSH Terms]
- 57."single blind method"[MeSH Terms]
- 58."single blind*"[Title/Abstract]
- 59."single mask*"[Title/Abstract]
- 60."double blind*"[Title/Abstract]
- 61."double mask*"[Title/Abstract]
- 62."placebos"[MeSH Terms]
- 63."placebo"[Title/Abstract]
- 64."research design"[MeSH Terms]

- 65."comparative study"[MeSH Terms]
- 66."evaluation studies"[MeSH Terms]
- 67."follow up studies"[MeSH Terms]
- 68."prospective studies"[MeSH Terms]
- 69."control stud*"[Title/Abstract]
- 70."volunteer study"[Title/Abstract]
- 71."intervention studies"[MeSH Terms]
- 72."intervention stud*"[Title/Abstract)
- 73."pretest*"[Title/Abstract]
- 74."pre test*"[Title/Abstract]
- 75."posttest"[Title/Abstract]
- 76."post test*"[Title/Abstract]
- 77.or/47-77
- 78. 30 and 46 and 78 (limit to human)

Handsearching

Attempts were made to identify additional studies by searching the reference lists of relevant trials and reviews.

Other search strategies

Some of the authors of relevant identified studies and other experts (authors of reviews and well known diabetes educators) were contacted in order to obtain additional references, unpublished trials, or ongoing trials.

3.8 Methods of the review

3.8.1 Trials selection

Two independent reviewers (TD and CM) scanned the titles, abstract sections and keywords of every record retrieved. Full articles were retrieved for further assessment if the information suggested that the study:

1. included patients with Type 2 diabetes mellitus, and
2. evaluated a patient-centred group-based education programme,

Wherever there was any doubt regarding the existence of these criteria, the complete article was retrieved for clarification. Interrater agreement for study selection was measured using the kappa statistic (Cohen 1960). Any differences in opinion were

discussed and, if necessary, resolved by a third party (JC). There were no instances where it was necessary to contact the authors or the review group editorial base.

3.8.2 Quality assessment of trials

The quality of reporting of each randomised trial was assessed largely on the quality criteria specified by Schulz and by Jadad (Jadad et al. 1996; Schulz et al. 1995). In particular, the following factors were studied:

1. Minimisation of selection bias - a) was the randomisation procedure adequate? b) was the allocation concealment adequate?
2. Minimisation of attrition bias - a) were withdrawals and dropouts completely described? b) was analysis by intention-to-treat?
3. Minimisation of detection bias - were outcome assessors blind to the intervention?

Based on those criteria, studies were broadly subdivided into the following three categories (see Cochrane Handbook):

A - all quality criteria met: low risk of bias.

B - one or more of the quality criteria only partly met: moderate risk of bias.

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

3.8.3 Data extraction

1. General information: published/unpublished, title, authors, reference/source, contact address, country, urban/rural etc., language of publication, year of publication, duplicate publications, sponsoring, setting.
2. Trial characteristics: design, duration, randomisation (and method), validated questionnaires, allocation concealment (and method), blinding (patients, outcome assessors), check of blinding.
3. Intervention(s): Comparison group included (routine treatment, waiting list, no intervention), intervention(s) (theoretical model, duration, timing),
4. Participants: sampling (random/convenience), exclusion criteria, total number and number in comparison groups, sex, age, ethnicity, Body Mass Index, pre-existing medical conditions, educational history, standards of diabetes care, intervention delivered by primary or secondary care, diagnostic criteria, duration of diabetes, similarity of groups at baseline (including any co-morbidity), assessment of compliance, withdrawals/losses to follow-up (reasons/description), subgroups.

5. Outcomes: outcomes specified above (also: what was the main outcome assessed in the study?), any other outcomes assessed, other events, length of follow-up, quality of reporting of outcomes.

6. Results: for outcomes and times of assessment (including a measure of variation), if necessary converted to measures of effect specified below; intention-to-treat analysis.

A template data extraction form was developed and tested for suitability. Minor amendments were made before use. Before final data extraction, the data extraction form was sent to the Metabolic and Endocrine Disorders Group Editorial Base for approval. Data extraction and data entry were performed independently in duplicate by two evaluators (TD and CM). Differences in data extraction were discussed and if necessary resolved by consensus with a third reviewer (JC) referring back to the original article. If data was missing in a published report (see data extraction list), the reviewers tried to contact the first author.

3.8.4 Data analysis

Data was summarised statistically only if it was available, sufficiently similar (homogeneous), and of sufficient quality. Assessment of the consistency of effects across studies is an essential part of a meta-analysis without which the generalisability of the findings of the meta-analysis cannot be determined. Heterogeneity can be caused by the variability or differences between studies in key characteristics (clinical heterogeneity) quality (methodological heterogeneity) and effects (heterogeneity of results). Outcomes that were not significantly homogeneous for meta-analysis due to variations in measurement design, baseline characteristics, validated questionnaires, length of follow-up or missing data were summarised in a descriptive nature.

A popular test for heterogeneity (Cochran's Q) examines the null hypothesis that all studies are evaluating the same effect. The test is known to be poor at detecting true heterogeneity among studies as significant, especially when there are only a small number of studies included in the meta-analysis. In this instance, heterogeneity was tested for using a new quantity, I^2 , which described the percentage of total variation across studies that was due to heterogeneity rather than chance. It was a better measure of consistency between trials in the meta-analysis (Higgins et al. 2003). I^2 values of 25%, 50% and 75% were classified as low, moderate, and high heterogeneity respectively.

The dichotomous data (e.g. mortality, medication reduction) used a random effect approach (it is unreasonable to assume that there is one 'true' effect underlying the data that is constant across different populations) and the odds ratio (O-E) summary statistic with the DerSimonian and Laird method. The meta-analytical model for the continuous data (e.g. weight, blood pressure, glycated haemoglobin) used a random effect approach with the weighted mean difference by the DerSimonian and Laird method. However, if the results across studies were conceptually the same but measured in a different way (e.g. scores on depression could be reported as means or as the percentage of patients who were depressed at some point after an intervention), standardised mean differences were used.

Subgroup analyses

Ideally a subgroup analysis would have been performed for the following confounding factors:

1. ethnicity e.g. strategies for South Asian compared to those for white Caucasian people.
2. theoretical model underpinning the education programme e.g. empowerment versus didactic model.
3. duration of education programme e.g. single session compared to series of sessions.
4. age e.g. 30 to 60 year olds compared with those aged above 60 years.
5. gender e.g. single sex versus mixed sex sessions.
6. education delivered within primary or secondary care.

In fact, subgroup analyses were performed only if, in the meta-analysis, there were sufficient studies and the results for the primary outcome were significant.

Sensitivity analyses

Sensitivity analyses were performed (if appropriate and if a sufficient number of studies were included in the meta-analysis) in order to explore the influence of the following factors on effect size:

Repeating the analysis:

1. excluding unpublished studies;
2. taking account of study quality, as specified above;
3. excluding any very long or large studies to establish how much they dominate the results;
4. excluding studies which had been published in a foreign language and then translated;

5. excluding studies with less than 100 participants and length of follow-up less than 12 months.

A funnel plot was also performed in order to assess small study or publication bias for glycated haemoglobin at 12 to 14 months follow-up.

3.9 Description of studies

Trials identified

Electronic searches undertaken in January and February 2003 identified 5497 citations of which 899 were duplicates. The titles and abstracts of 4598 citations were independently reviewed by TD and CM and 183 citations either met the inclusion criteria or required sight of the full paper before a decision could be made. Thirteen abstracts required translation, of which eight were written in Spanish, three in Portuguese and two in German. A further 10 papers were identified by hand searching and by contacting experts in the field, which gave a total of 193 papers required for data extraction. Of these, three foreign language papers were unobtainable through the British Library or through inter-library loans. Two of these were written in Spanish (Luna Arriola & Merino Ramírez 1994; Saenz Hernaiz et al. 1992) and one in Chinese (Fan, Zhu, & Zhang 1999). Twelve papers required translation: five were written in Spanish (Bundo 1993; Cabrera-Pivaral et al. 2000; Cabrera-Pivaral et al. 2001; Llamas et al. 2002; Lozano et al. 1999; Lozano del Hoyo et al. 1996), six in German (Haisch et al. 1996; Haisch & Remmele 2000; Hanefeld et al. 1996; Hardinghaus et al. 1996; Jungmann & Jungmann 1997a; Rebell et al. 2002) and one in French (Girard, Dautat, & Moinade 1986). Of the 190 full papers obtained, 19 were duplicates reporting either the same data or follow-up data (Arauz et al. 1997; Arauz et al. 2001; Domenech et al. 1994; Domenech et al. 1995; Hanefeld et al. 1991; Hanefeld et al. 1996; Hansen & Drivsholm 2002; Jungmann & Jungmann 1997b; Jungmann & Jungmann 1997a; Keyserling et al. 2000; Keyserling et al. 2002; Miller et al. 2002a; Miller et al. 2002b; Norris, Engelgau, & Venkat Narayan 2001a; Norris, Engelgau, & Venkat Narayan 2001b; Renders et al. 2000; Trento et al. 1998; Trento et al. 2002; Trento et al. 2001).

Interrater agreement

Agreement between the two reviewers (TD and CM) was high with a Kappa statistic of 0.85. Some data was unclear and discussion and differences of opinion were resolved via discussion without the need to involve a third independent assessment (JC).

Excluded studies

The systematic review of the 190 full papers led to the exclusion of 177 papers involving 172 studies. Reasons for exclusion were: lack of control group; length of follow-up being too short; absence of the pre-specified outcomes; intervention group in receipt of individual appointments in addition to the group programme; delivery of group-based education programme to the control group; not all participants having Type 2 diabetes; narrative papers, and group-based education programme that did not focus on diabetes self-management education. Several studies were excluded on more than one ground as can be seen in the excluded studies table (Appendix 1a and 1b).

Included studies

A total of 14 papers, reporting 11 studies, met the inclusion criteria. However, one duplicate paper was a conference proceeding written in Spanish (Domenech et al. 1994). The abstract was translated and, as it contained the same data as the English language paper, it was deemed unnecessary to have the full paper translated. Thirteen papers were therefore analysed (Brown et al. 2002; Deakin et al. 2003a; Domenech et al. 1995; Heller et al. 1988; Holtrop et al. 2002; Kronsbein et al. 1988; Lozano et al. 1999; Pieber et al. 1995; Rickheim et al. 2002; Trento et al. 1998; Trento et al. 2002; Trento et al. 2001; Zapotoczky et al. 2001) in order to evaluate the 11 studies. Three trials were carried out in the United States (Brown et al. 2002; Holtrop et al. 2002; Rickheim et al. 2002), two in the United Kingdom (Deakin et al. 2003a; Heller et al. 1988), two in Austria (Pieber et al. 1995; Zapotoczky et al. 2001), one in Argentina (Domenech et al. 1995), one in West Germany (Kronsbein et al. 1988), one in Spain (Lozano et al. 1999) and one in Italy. The Italian trial had three published papers which reported follow-up at 12 months, two and four years (Trento et al. 1998; Trento et al. 2002; Trento et al. 2001). Only one of the translated papers (Lozano et al. 1999) met the inclusion criteria sufficiently to contribute to the review.

From this point forward, those 13 included papers, which provide data on 11 studies, will be referenced with the primary author and date of publication only.

Study design

The studies included in the review were randomised controlled trials, with the exception of two studies that were clinical controlled trials (Domenech 1995; Pieber 1995). The length of follow-up was six months for three of the trials (Holtrop 2002; Pieber 1995; Rickheim 2002), 12 to 14 months for six of the trials (Brown 2002; Deakin 2003; Domenech 1995; Heller 1988; Kronsbein 1988; Zapotoczky 2001), and two years for

one trial (Lozano 1999). As stated above, the Trento study reported follow-up at one year (Trento 1998), at two years (Trento 2001) and at four years (Trento 2002).

Participants

A total of 1532 participants were included in the 11 trials with 742 (48%) in the intervention group. The smallest study included 36 participants (Zapotoczky 2001) and the largest study, 314 participants (Deakin 2003). The proportion of men and women was roughly the same in each group with the exception of one trial (Holtrop 2002) that recruited only women. All trials recruited adults with Type 2 diabetes and the mean age of participants was between 51 and 65 years. Seven papers (Brown 2002; Deakin 2003; Heller 1988; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002) evaluating five trials reported age range. The age ranges were similar with the lower age bracket being 30-35 years and the highest age bracket being 71-85 years. One trial recruited Mexican Americans (Brown 2002); another recruited 25% South Asians and 75% white Caucasians (Deakin 2003). Two other trials (Holtrop 2002; Rickheim 2002) reported that 95% of participants were Caucasian but did not report ethnicity of the other 5% of participants. Duration of diabetes was reported in nine trials; in seven of those, it was between six and nine years (Brown 2002; Deakin 2003; Domenech 1994; Kronsbein 1988; Lozano 1999; Pieber 1995; Trento 1998); in one trial it was less than a year (Rickheim 2002) and in another trial (Heller 1988) participants were newly diagnosed. Inclusion criteria for entry into individual trials is outlined in the 'characteristics of included studies' table (Appendix 2).

Interventions

All trials evaluated a group-based diabetes education programme. Programmes varied in duration with the least intensive being three hours per year for two years (Lozano 1999) and three or four hours per year for four years (Trento 1998; Trento 2001; Trento 2002). Eight trials described programmes that ranged from six to fifteen hours of group-based education over a period of between four weeks and 10 months (Deakin 2003; Domenech 1995; Heller 1988; Holtrop 2002; Kronsbein 1988; Pieber 1995; Rickheim 2002; Zapotoczky 2001) with the most intense education programme being 52 hours over one year (Brown 2002). Seven of the 11 group education programmes were held in primary care (Brown 2002; Deakin 2003; Domenech 1995; Holtrop 2002; Kronsbein 1988; Lozano 1999; Pieber 1995) with the remaining four being delivered in hospital diabetes centres (Heller 1988; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002;

Zapotoczky 2001). The educators were all health professionals, with the exception of one study where the educators were lay health advisors (Holtrop 2002). Three of the group education programmes were delivered by physicians (Domenech 1995; Pieber 1995; Trento 1998; Trento 2001; Trento 2002) with Pieber 1995 securing additional help from office staff and Trento 1998; Trento 2001; Trento 2002 incorporating two physicians and an educationalist. Three group education programmes were delivered by a dietitian and a nurse (Brown 2002; Heller 1988; Rickheim 2002) with Brown 2002 also involving community workers. Two programmes were delivered by dietitians working alone (Deakin 2003; Zapotoczky 2001), one by a nurse working alone (Lozano 1999) and one by paramedical staff (physician assistants) (Kronsbein 1988). Five studies reported that a family member or friend was also invited to attend the programme (Brown 2002; Deakin 2003; Domenech 1995; Heller 1988; Trento 1998; Trento 2001; Trento 2002), one study stated that the programme was for patients only (Pieber 1995) and in the remaining five studies, participation of family or friends was unclear.

The theoretical model that was used to plan the group-based education programme was only reported in five studies. Three of those (Domenech 1995; Kronsbein 1988; Pieber 1995) had adapted the Diabetes Treatment and Teaching Programme (DTTP) which was originally developed in Germany for adults with Type 1 diabetes (Muhlhauser, Jorgens, & Berger 1983) and was based on therapeutic patient education (WIIO Working Group 1998). One study (Deakin 2003) was based on patient-centred education and used an empowerment model developed in the US (Anderson & Funnell 2000a). Another study based the education on four different models: an adult learning model, a public health model, a health belief model and a transtheoretical model (Rickheim 2002). Lozano 1999 stated that the group education programme was 'participatory' and Trento 1998 described their programme as 'structured'. Eight studies (Deakin 2003; Domenech 1995; Heller 1988; Kronsbein 1988; Pieber 1995; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002; Zapotoczky 2001) provided information about the number of patients invited to attend the group education programme. The smallest groups comprised four to six participants (Heller 1988; Kronsbein 1988) and the largest groups comprised 16 to 18 patients (Deakin 2003) and (Zapotoczky 2001).

In seven studies, the comparison group received routine treatment (Deakin 2003; Domenech 1995; Heller 1988; Holtrop 2002; Lozano 1999; Trento 1998; Trento 2001;

Trento 2002; Zapotoczky 2001). In one study, the control group was placed on a waiting list to receive the group education programme after the study (Brown 2002). Two studies stated that the control group received routine treatment as well as being placed on a waiting list for the education programme (Kronsbein 1988; Pieber 1995), and in one study (Rickheim 2002) the comparison group received five hours of individual appointments. Routine treatment was defined as separate individual appointments with a dietitian, practice nurse and general practitioner (Deakin 2003), 15 to 20 minutes with a multidisciplinary diabetes team every three months (Trento 1998; Trento 2001; Trento 2002) or an individual appointment with a dietitian every three months (Zapotoczky 2001).

Outcome measures

All trials included in the review assessed the primary outcome that was glycated haemoglobin (HbA1c). Those assessments were made at either four to six months (Brown 2002; Deakin 2003; Heller 1988; Holtrop 2002; Pieber 1995; Rickheim 2002), 12-14 months (Brown 2002; Deakin 2003; Domenech 1994; Heller 1988; Kronsbein 1988; Lozano 1999; Trento 1998), two years (Lozano 1999; Trento 2001) or 4 years (Trento 2002). Eight studies stated that the HbA1c measurement was standardised (Brown 2002; Deakin 2003; Domenech 1995; Heller 1988; Kronsbein 1988; Pieber 1995; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002) and in three studies it was unclear whether HbA1c was standardised or not (Holtrop 2002; Lozano 1999; Zapotoczky 2001). Only one study identified HbA1c in the inclusion criteria, with participants requiring a HbA1c reading of more than 7% to participate in the study. Only two trials assessed fasting blood glucose at six months (Brown 2002; Heller 1988); four trials assessed it at 12 months (Brown 2002; Heller 1988; Lozano 1999; Trento 1998), two trials at two years (Lozano 1999; Trento 2001) and one trial at four years (Trento 2002). For the other main outcomes, four trials assessed diabetes knowledge at four to six months (Brown 2002; Deakin 2003; Pieber 1995; Rickheim 2002), six at 12-14 months (Brown 2002; Deakin 2003; Heller 1988; Kronsbein 1988; Lozano 1999; Trento 1998), two at two years (Lozano 1999; Trento 2001) and one at four years (Trento 2002). Domenech 1995 assessed diabetes knowledge only in the intervention group. All knowledge questionnaires were validated except for two studies, where it was unclear whether the questionnaire had been validated or not (Brown 2002; Domenech 1995). The level of participant empowerment/psychosocial self-efficacy was assessed in only two studies (Deakin 2003; Rickheim 2002) and different measurement

tools were used. Quality of life was assessed in three studies (Deakin 2003; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002), again using different validated measures.

With regard to additional outcomes, five studies assessed body mass index (BMI) at four to six months (Brown 2002; Deakin 2003; Holtrop 2002; Pieber 1995; Rickheim 2002), four studies at 12-14 months (Brown 2002; Deakin 2003; Lozano 1999; Trento 1998), two studies at two years (Lozano 1999; Trento 2001) and one study at four years (Trento 2002). Four studies assessed body weight at four to six months (Deakin 2003; Heller 1988; Pieber 1995; Rickheim 2002), five at 12-14 months (Deakin 2003; Heller 1988; Kronsbein 1988; Trento 1998; Zapotoczky 2001) and the long-term follow-up studies of Trento assessed body weight at two years (Trento 2001) and four years (Trento 2002). Systolic and diastolic blood pressure was assessed in only two studies; at four to six months (Deakin 2003; Pieber 1995) and at 12-14 months (Deakin 2003; Zapotoczky 2001). Lipid profile was assessed between four to six months in three studies (Brown 2002; Deakin 2003; Pieber 1995) and between 12-14 months in three studies (Brown 2002; Deakin 2003; Zapotoczky 2001) with one study assessing triglyceride level only (Kronsbein 1988).

Diabetes self-management skills were assessed in six studies as follows:

1. self-care activities questionnaire (validated) and dietary intake using a validated food frequency questionnaire (Deakin 2003);
2. a validated health behaviour conduct questionnaire (Trento 1998; Trento 2001; Trento 2002);
3. self-reported activity levels (frequency and duration) (Rickheim 2002);
4. self-monitoring of blood glucose levels (Lozano 1999);
5. self-monitoring of urinalysis (Kronsbein 1988);
6. a 'stages of change' questionnaire (Holtrop 2002) assessed confidence to make changes in diet and activity. Outcomes were, however presented, as a pre-test/post-test comparison within the intervention group and no data was shown for the control group.

Satisfaction with treatment was assessed in only one study (Deakin 2003) and change in diabetes medication was assessed in five studies (Domenech 1995; Kronsbein 1988; Pieber 1995; Rickheim 2002; Deakin 2003). A cost-effectiveness analysis was performed at a four year follow-up (Trento 2002) and the cost of delivering the programme was estimated in Brown 2002.

Three studies recorded the number of deaths (Deakin 2003; Kronsbein 1988; Trento 1998; Trento 2001; Trento 2002) but did not identify whether the deaths were diabetes related. One study recorded diabetes complications (creatinine, albuminuria, diabetic retinopathy, foot ulcers) at two years (Trento 2001) and four years (Trento 2002).

3.10 Methodological quality of included studies

Based on the quality criteria outlined in the section entitled 'Quality assessment of the trials' on page 81, two studies were classified as having a moderate risk of bias (Deakin 2003; Zapotoczky 2001), and seven studies as having a high risk of bias (Brown 2002; Heller 1988; Holtrop 2002; Kronsbein 1988; Lozano 1999; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002). Both clinical controlled trials were identified as being at risk of having one or more of the quality criteria not met (Domenech 1995; Pieber 1995). Interrater agreement of trial quality was 0.63 and agreement was reached following discussion between the two reviewers.

Method of randomisation

Only three of the randomised controlled trials described the method of randomisation. Two used random permuted blocks (Deakin 2003; Rickheim 2002) and one used random table numbers (Trento 1998; Trento 2001; Trento 2002).

Allocation concealment

Allocation concealment was only noted in one study (Deakin 2003). The remaining eight randomised controlled trials made no reference to allocation concealment (Brown 2002; Heller 1988; Holtrop 2002; Kronsbein 1988; Lozano 1999; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002; Zapotoczky 2001).

Intention-to-treat analysis

Three studies reported analysis to be by intention-to-treat (Deakin 2003; Heller 1988; Trento 2002). The Trento study however, only reported the intention-to-treat analysis at the four year assessment and not in the two earlier papers (Trento 1998; Trento 2001). An intention to treat analysis was not needed for one study since the drop-out rate was nil and all participants were re-assessed at follow-up (Zapotoczky 2001). Intention to treat analysis was not performed in six studies (Brown 2002; Domenech 1995; Holtrop 2002; Kronsbein 1988; Lozano 1999; Pieber 1995) and it was unclear whether such analysis had been undertaken by Rickheim 2002.

Losses to follow-up

Losses to follow-up were described in all studies except one (Brown 2002). Losses to follow-up ranged from 0% in one study (Zapotoczky 2001) to 25% in the intervention group and 45% in the control group in another study (Domenech 1995).

Blindness of treatment

It was not possible to blind participants as to their allocation to the respective groups. However, two studies attempted to blind the control group to the fact that they were the controls by presenting 'routine treatment' as an individual appointment intervention (Deakin 2003; Rickheim 2002).

Outcome assessment

Details of blinding of the outcome assessors were not described in any of the trials.

Number of participants in the study

Only three studies presented a power calculation and based recruitment numbers on the calculation (Deakin 2003; Kronsbein 1988; Lozano 1999). A further two studies referred to a power calculation but the data was not provided (Holtrop 2002; Trento 2002). The number of participants recruited in each study ranged from 36 (Zapotoczky 2001) to 314 (Deakin 2003).

Other comments on quality

One study reported different outcomes at baseline than at follow-up. For example, BMI was assessed at baseline but weight was assessed at the one year follow-up (Domenech 1995). Another study compared knowledge score and fasting blood glucose levels between the intervention and control group at follow-up but did not present baseline data for those (Heller 1988). Holtrop 2002 presented some outcomes without standard deviations and reported P-values without presenting the actual data. Although baseline data was presented by Zapotoczky 2001, statistical tests were not performed to detect if the two groups were similar at baseline.

3.11 Results

3.11.1 Heterogeneity

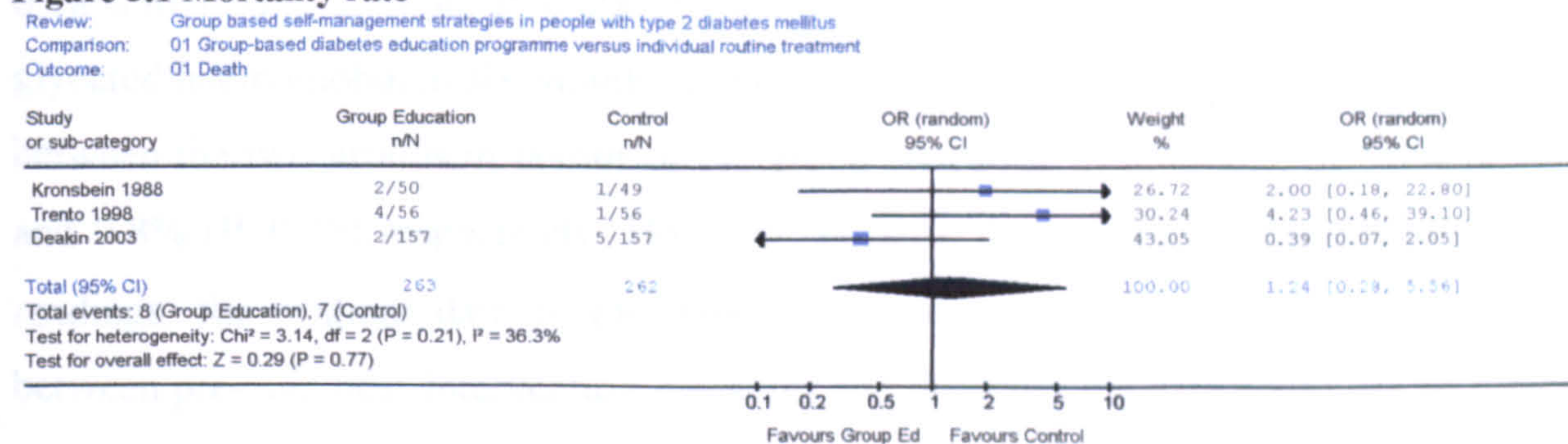
A test for heterogeneity, I^2 value (Higgins et al. 2003) was performed for each outcome before a meta-analysis was carried out. Outcomes that had significant heterogeneity (>50%) were subject to a sensitivity analysis to detect, if possible, the source of heterogeneity. Outcomes that could not be analysed statistically were summarised in a descriptive manner.

3.11.2 Effect of the intervention (meta-analysis)

Mortality

At the 12-14 month outcome assessment, there had been a total of 15 deaths reported from three studies with a combined total of 525 participants. There was low heterogeneity ($I^2 = 36.3\%$). One study reported more deaths in the control group (Deakin 2003), whereas two studies reported more deaths in the intervention group (Kronsbein 1988; Trento 1998). Overall there were eight deaths in the intervention group and seven deaths in the control group. Participation in a group-based diabetes education programme, therefore, did not affect mortality rate (odds ratio 1.24, 95% CI: 0.28 to 5.56, $Z=0.29$, $P=0.77$) (figure 3.1).

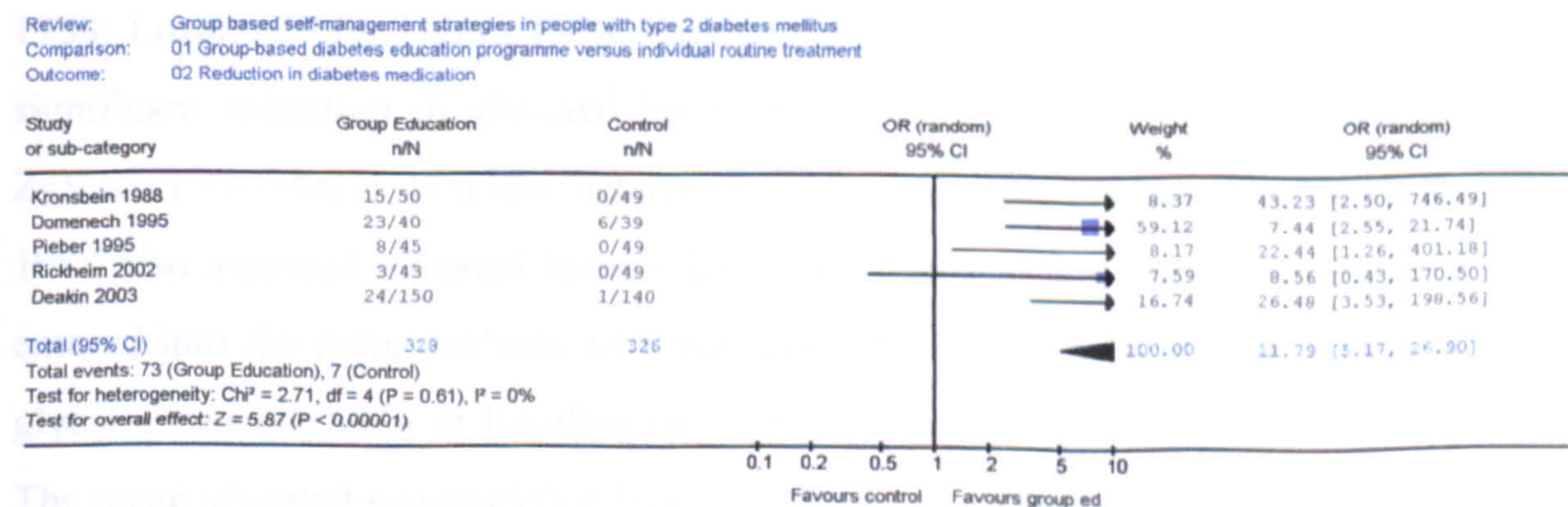
Figure 3.1 Mortality rate



Reduction in Diabetes Medication

Five studies (Domenech 1995; Kronsbein 1988; Pieber 1995; Rickheim 2002; Deakin 2003) with a combined total of 654 participants reported outcomes on diabetes medication and with no heterogeneity between the studies ($I^2 = 0\%$). A medication decrease was classed as a reduction in the type or quantity of OHAs prescribed or the number of units of insulin injected. Group-based diabetes education programmes led to a significant reduction in diabetes medication at 12-14 months (odds ratio 11.79, 95% CI: 5.17 to 26.90, $Z=5.87$, $P<0.00001$) (figure 3.2).

Figure 3.2 Reduction in diabetes medication at 12 to 14 months

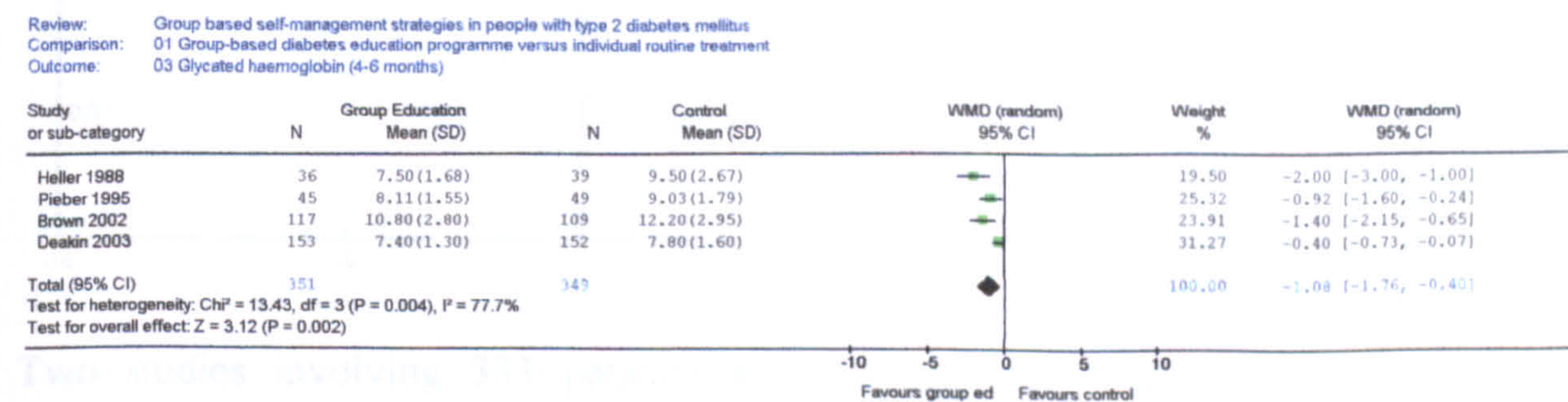


Glycated Haemoglobin

Four studies assessing glycated haemoglobin at four to six months and involving 700 participants were included in a meta-analysis (Brown 2002; Deakin 2003; Heller 1988;

Pieber 1995) (figure 3.3). There was an overall significant reduction in glycated haemoglobin of 1.08% (95% CI: 0.40% to 1.76%, $Z=3.12$, $P=0.002$) for participants who had been allocated to the group-based diabetes education programme. However, there was high heterogeneity between the studies ($I^2 = 77.7\%$) and that was investigated via a sensitivity analysis to explore reasons for the heterogeneity. Deakin 2003 had reported a significant reduction in glycated haemoglobin of 0.4% at four months whereas the other three studies had reported significant reductions at six months (between 0.92% and 2.00%). When the Deakin 2003 study was removed from the equation and the meta-analysis repeated, heterogeneity reduced significantly ($I^2 = 36.7\%$) and the overall reduction in glycated haemoglobin was greater (1.35%; 95% CI: 0.78% to 1.93%, $Z=4.60$, $P<0.00001$). Holtrop 2002 and Rickheim 2002 also assessed glycated haemoglobin at six months and observed a difference in glycated haemoglobin between the two groups in favour of the group education programme, of 0.4% ($P=0.7$) and 0.8% ($P=0.05$) respectively. However, because there were differences in baseline readings, the original data in the paper had been analysed as the mean difference between pre- and post-intervention measures and therefore the data could not be entered into the meta-analysis.

Figure 3.3 Glycated haemoglobin at 4 to 6 months



At the 12-14 months' follow-up, seven studies involving a total of 1044 participants were included in a meta-analysis (Brown 2002; Deakin 2003; Domenech 1995; Heller 1988; Lozano 1999; Trento 1998; Zapotoczky 2001) (figure 3.4). There was an overall significant reduction in glycated haemoglobin of 0.82% (95% CI: 0.65% to 0.99%, $Z=9.63$, $P<0.00001$) with low heterogeneity between the studies ($I^2 = 18\%$). Kronsbein 1988 also assessed glycated haemoglobin at 12 months but those results could not be entered into the meta-analysis, as there was a difference between the groups for mean glycated haemoglobin at baseline (intervention group 7.1% and control group 6.5%). The mean glycated haemoglobin level was adequate, especially for 1988 when the study was published, and therefore much more emphasis was placed on withdrawal of diabetes medication. A funnel plot for glycated haemoglobin was performed at the 12-

14 months follow-up to detect any small sample or publication bias. The plot resembled a symmetrical inverted funnel and it was therefore concluded that bias was absent (see figure 3.5 below).

Figure 3.4 Glycated haemoglobin at 12 to 14 months

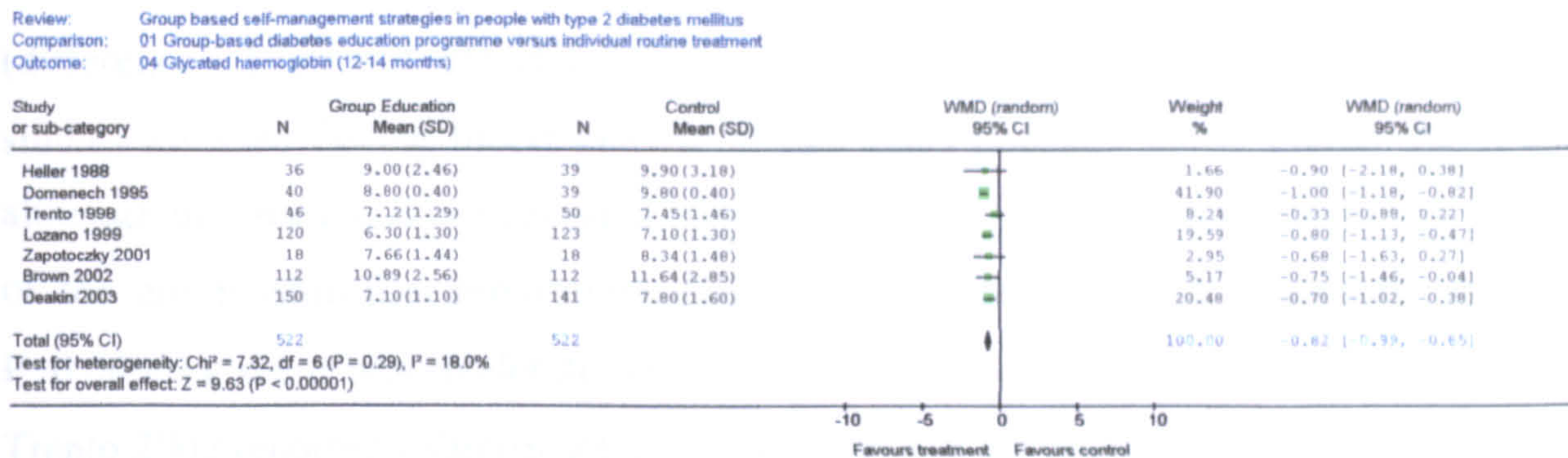
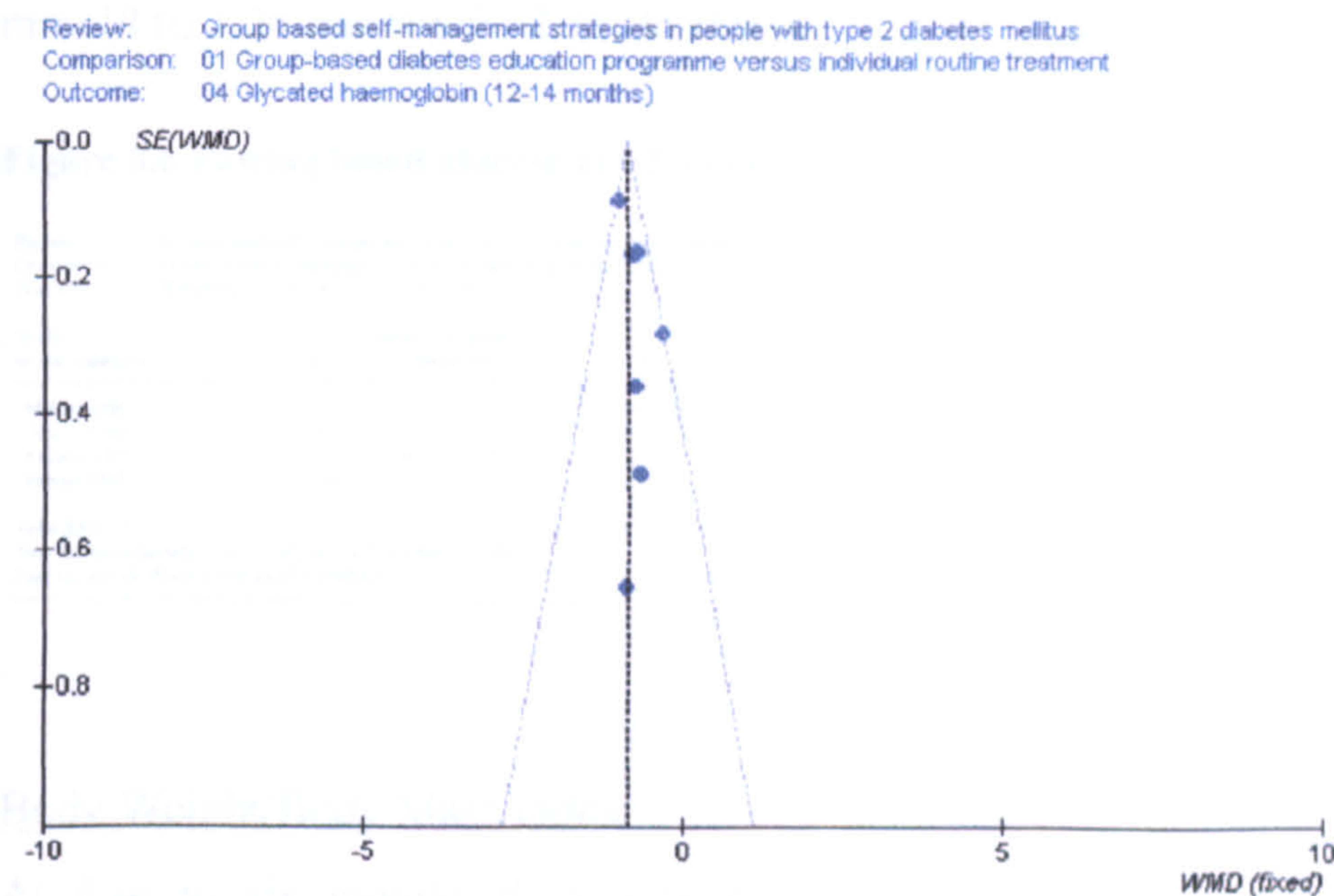


Figure 3.5 Funnel plot for glycated haemoglobin



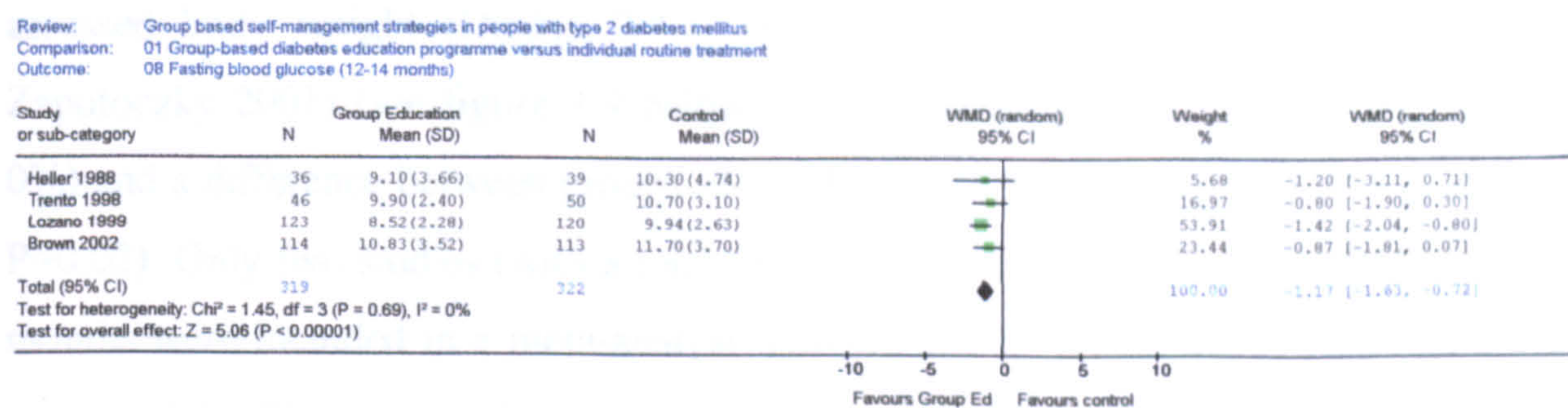
Two studies involving 333 patients assessed glycated haemoglobin at two years (Lozano 1999; Trento 2001) with no heterogeneity between the studies ($I^2 = 0\%$). There was a significant reduction in HbA1c for the patients allocated to the group-based diabetes education programme as compared to the control group (0.97%; 95% CI: 0.54% to 1.40%, $Z=4.44$, $P<0.00001$). At the four years follow-up, one study involving 90 patients assessed glycated haemoglobin (Trento 2002) and found a significant reduction in the group education group compared to the control group (1.6%; 95% CI: 0.91% to 2.29%, $Z=4.53$, $P<0.00001$).

Fasting Blood Glucose

One study (Brown 2002) with 229 participants reported lower fasting blood glucose levels at six months in the group education programme participants compared to the

control group (difference 1.66 mmol/l; 95% CI: 0.74 mmol/l to 2.58 mmol/l, $Z=3.53$, $P=0.0004$). Four studies assessed fasting blood glucose at 12 months (Brown 2002; Heller 1988; Lozano 1999; Trento 1998) with no heterogeneity between studies ($I^2 = 0\%$) (see figure 3.6 below). There was an overall significant improvement in patients allocated to the group education programme compared with those in the control group (difference 1.17mmol/l; 95% CI: 0.72 mmol/l to 1.63 mmol/l, $Z=5.06$, $P<0.00001$). Two studies assessed fasting blood glucose at two years (Lozano 1999; Trento 2001) and although the meta-analysis revealed significant improvement of 1.57 mmol/l in favour of the group education programme (95% CI: 1.05 mmol/l to 2.10 mmol/l, $Z=5.88$, $P<0.00001$), there was moderate heterogeneity between the two studies ($I^2 = 63.6\%$). Trento 2002 reported a significant difference between groups at the four years follow-up in favour of the group education programme (difference 1.70 mmol/l; 95% CI: 0.16 mmol/l to 3.24 mmol/l, $Z=2.16$, $P=0.03$).

Figure 3.6 Fasting blood glucose at 12 months



Body Weight/Body Mass Index

At four to six months there was no evidence that group-based diabetes education programmes had an impact on body weight or BMI. Four studies, having a combined total of 566 participants, assessed body weight (Deakin 2003; Heller 1988; Pieber 1995; Rickheim 2002) (see figure 3.7 overleaf). There was low heterogeneity ($I^2 = 31.3\%$). Overall reduction in body weight was 2.13 Kg more than in the control group but that difference was not statistically significant (95% CI: -0.45 Kg to 4.71 Kg, $Z=1.62$, $P=0.11$). Four studies involving 718 participants assessed BMI (Brown 2002; Deakin 2003; Pieber 1995; Rickheim 2002) with no heterogeneity between studies ($I^2 = 0\%$) (see figure 3.8 on page 96). There was a difference between groups of 0.16 Kg/m² in favour of group education but, as in the case of body weight, that difference was not statistically significant (95%CI: -0.68 Kg/m² to 1.00 Kg/m², $Z=0.37$, $P=0.71$).

Figure 3.7 Body weight at 6 months

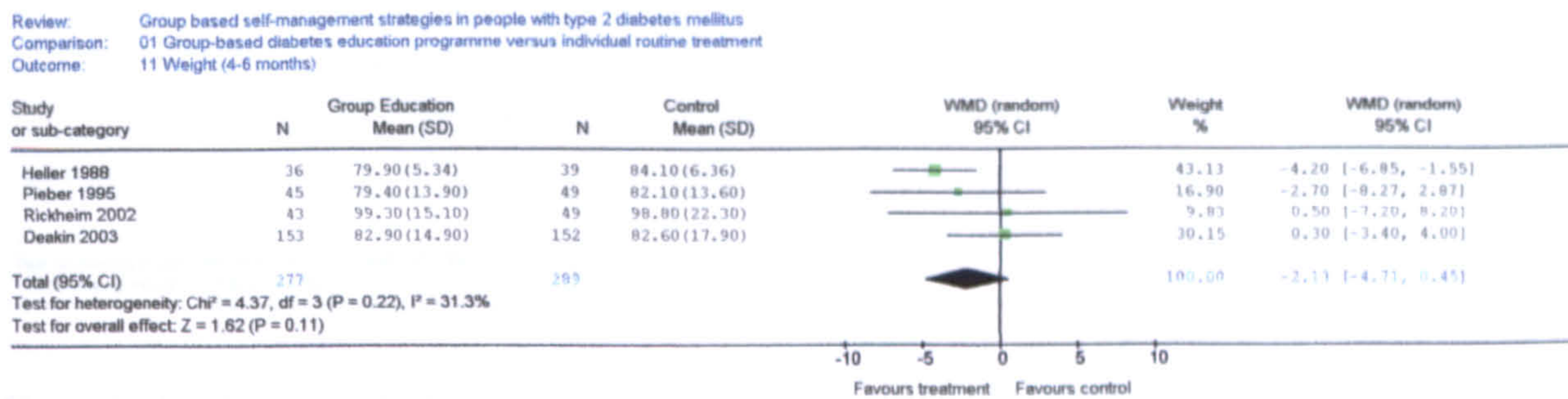
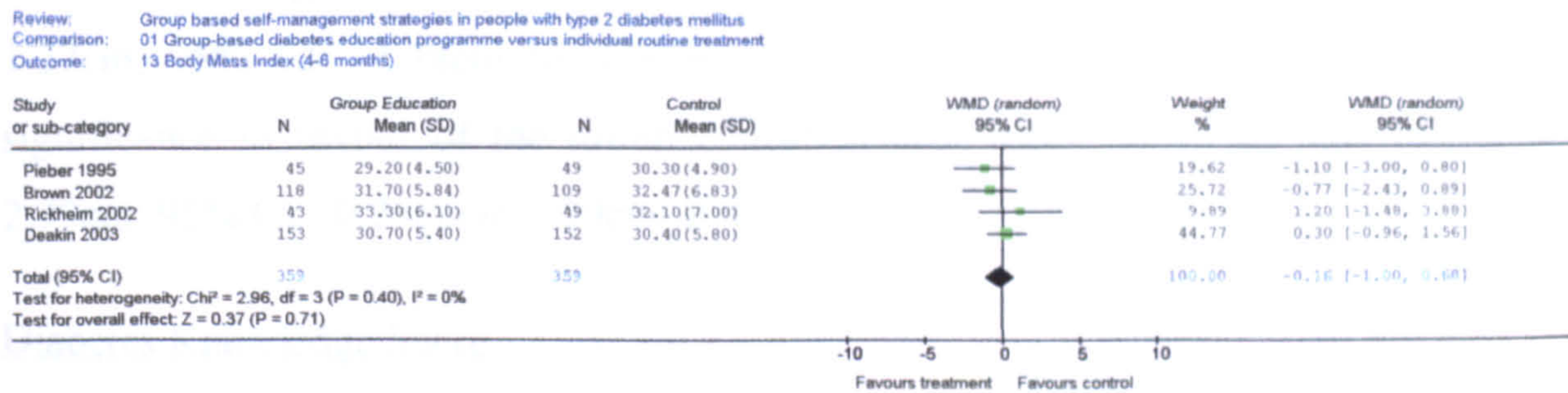


Figure 3.8 BMI at 6 months



At 12-14 months there was a small amount of evidence in favour of the group education programme improving body weight but not BMI. Five studies, involving 591 patients, assessed body weight (Deakin 2003; Heller 1988; Kronsbein 1988; Trento 1998; Zapotoczky 2001) (see figure 3.9 below) with no heterogeneity between studies ($I^2 = 0\%$) and a difference between groups of 1.61Kg (95% CI: 0.25 Kg to 2.97 Kg, $Z=2.32$, $P=0.02$). Only two studies (with a total of 418 participants) that assessed BMI at 12-14 months were included in a meta-analysis (Brown 2002; Deakin 2003) (see figure 3.10 on page 97). There was a benefit to the participants in the group programme of 0.24 Kg/m^2 but that was not statistically significant (95% CI: -1.01 Kg/m^2 to 1.49 Kg/m^2 , $Z=0.38$, $P=0.70$). Lozano 1999 also assessed BMI at 12 months, but because the baseline data for BMI was different, it could not be included in the meta-analysis. The mean difference between pre-and post-intervention measures was 0.4 Kg/m^2 at one year in favour of the group education programme but that had diminished by the two year follow-up. Baseline differences were also present for BMI in Trento 1998; Trento 2001; Trento 2002. The mean difference between pre-and post-intervention measures was 0.6 Kg/m^2 at one year, 0.5 Kg/m^2 at two years and 0.8 Kg/m^2 at four years in favour of the group-based diabetes education programme.

Figure 3.9 Body weight at 12 to 14 months

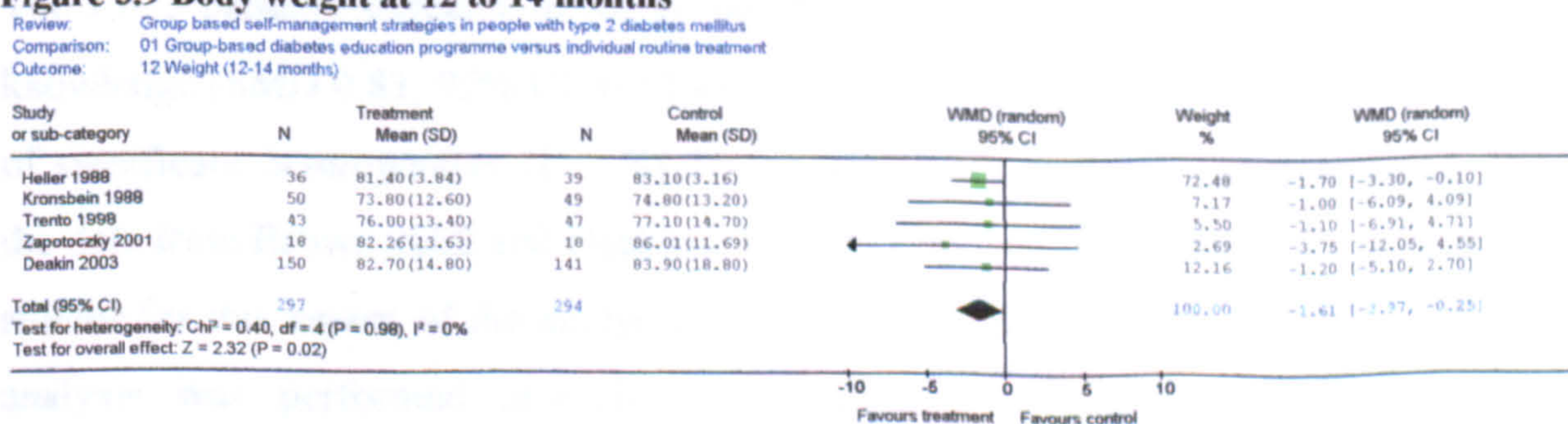
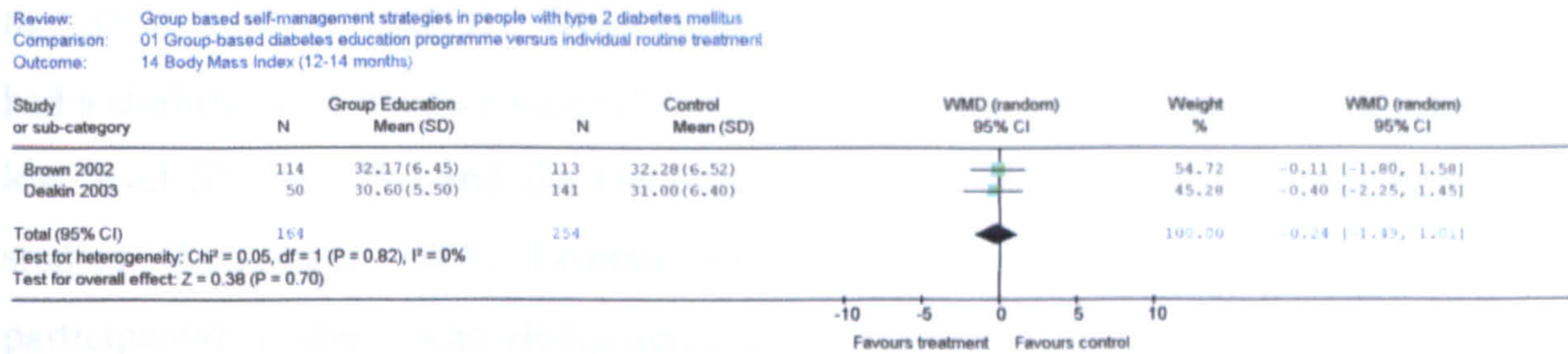


Figure 3.10 BMI at 12 to 14 months

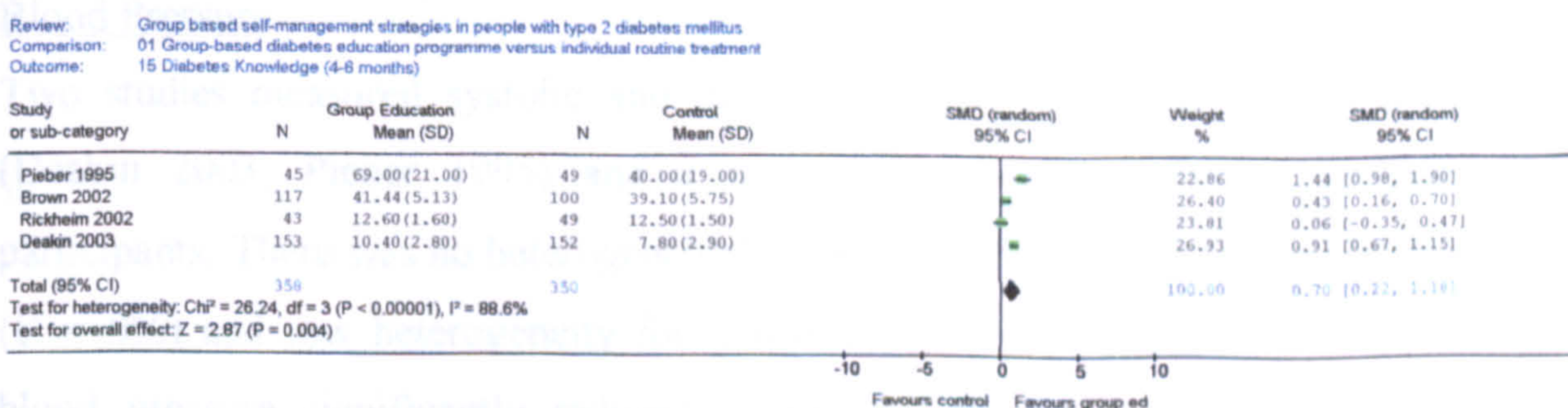


One study (Deakin 2003) measured waist circumference at both four and 14 months. There was no significant difference between the two groups at four months (difference 1.27cm; 95% CI: -1.78cm to 4.06cm, $P=0.44$) but there was statistical borderline significance in favour of the group education programme at 14 months (difference 2.79cm; 95% CI: -0.25cm to 5.59cm, $P=0.06$).

Diabetes Knowledge Score

Four studies with a combined total of 708 participants measured diabetes knowledge at four to six months (Brown 2002; Deakin 2003; Pieber 1995; Rickheim 2002) (see figure 3.11 below). Participants allocated to the group programme had greater diabetes knowledge scores (standardised mean difference [SMD] 0.70; 95% CI: 0.22 to 1.18, $Z=2.87$, $P=0.004$). As the studies had used different validated questionnaires to measure knowledge, the statistical method used was the standardised mean difference. However, there was still high heterogeneity between studies ($I^2 = 88.6\%$). A sensitivity analysis was performed by removing each study, one by one, from the meta-analysis but heterogeneity remained high ($I^2 = 80-90\%$).

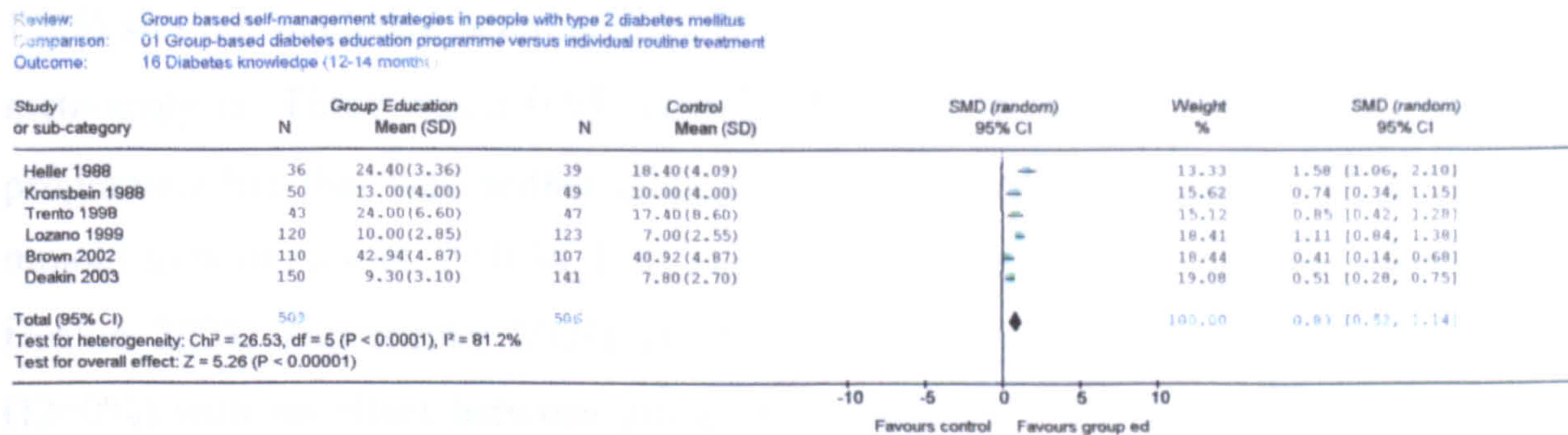
Figure 3.11 Diabetes knowledge at 4 to 6 months



Six studies measured diabetes knowledge at 12-14 months (Brown 2002; Deakin 2003; Heller 1988; Kronsbein 1988; Lozano 1999; Trento 1998) (see figure 3.12 on page 98). The 1,015 patients allocated to the group education programme had increased diabetes knowledge (SMD 0.83; 95% CI: 0.52 to 1.14, $Z=5.26$, $P<0.00001$). However, as a result of significant heterogeneity ($I^2 = 81.2\%$), a sensitivity analysis was performed. When the data from Brown 2002 and Deakin 2003 was removed, those being the least positive studies for this aspect of the analysis, heterogeneity reduced ($I^2 = 57.8\%$) and a meta-analysis was performed involving 507 participants. Knowledge score remained

significantly greater in participants allocated to the group programme (SMD 1.05; 0.74 to 1.35, $Z=6.73$, $P<0.00001$). When Heller 1988 was also removed, on the ground that it had a slightly more positive score than the other studies, heterogeneity reduced to a very low level ($I^2 = 18.7\%$) and the meta-analysis was repeated using the remaining three studies (Kronsbein 1988; Lozano 1999; Trento 1998, combined total of 432 participants). Diabetes knowledge remained significantly greater for the participants in the group education programme (SMD 0.95; 95% CI: 0.72 to 1.18, $Z=8.18$, $P<0.00001$).

Figure 3.12 Diabetes knowledge at 12 to 14 months



Two studies measured diabetes knowledge at two years (Lozano 1999; Trento 2001) and both gave significant results. When those studies were summarised statistically in a meta-analysis the intervention participants were shown to have a significantly greater knowledge score than the controls (SMD 1.58; 95% CI: 0.16 to 3.00, $Z=2.18$, $P=0.03$). There was, however, significant heterogeneity ($I^2 = 96.4\%$). At four years Trento 2002 measured diabetes knowledge and found that increased diabetes knowledge remained in the patients allocated to the group programme (SMD 1.27; 95% CI: 0.82 to 1.73, $Z=5.48$, $P<0.00001$).

Blood Pressure

Two studies measured systolic and diastolic blood pressure at four to six months (Deakin 2003; Pieber 1995) and a meta-analysis was performed including 399 participants. There was no heterogeneity between the studies for systolic blood pressure ($I^2 = 0\%$) and low heterogeneity for diastolic blood pressure ($I^2 = 28.3\%$). Systolic blood pressure significantly reduced in patients allocated to the group education programme (5.37mmHg; 95% CI: 1.21mmHg to 9.53mmHg, $Z=2.53$, $P=0.01$). There was a small difference, of borderline significance, for diastolic blood pressure (2.65 mmHg; 95% CI: -0.28 to 5.57 mmHg to 0.28 mmHg, $Z=0.38$, $P=0.08$).

At 12-14 months, two studies measured blood pressure (Deakin 2003; Zapotoczky 2001). There was no heterogeneity between the studies for systolic blood pressure ($I^2 = 0\%$) but significant heterogeneity for diastolic blood pressure ($I^2 = 67.9\%$). Although

there was a small reduction in respect of systolic blood pressure, it was not statistically significant (2.61mmHg; 95% CI: -1.52mmHg to 6.74 mmHg to 1.52, Z=1.24, P=0.22). There was no significant difference between groups for diastolic blood pressure (-0.13 mmHg; 95% CI: -4.75 mmHg to 4.48 mmHg, Z=0.05, P=0.95). No studies reported blood pressure measurements beyond 14 months.

Lipid Profile

There were no significant differences between the two groups in respect of total cholesterol. At four to six months, three studies (Brown 2002; Deakin 2003; Pieber 1995) showed moderate heterogeneity ($I^2 = 55.7\%$) and included 629 participants in a meta-analysis. There was a 0.05 mmol/l difference in favour of the group education programme but that was neither clinically nor statistically significant (95% CI: -0.22 mmol/l to 0.30 mmol/l, Z=0.38, P=0.71). At 12-14 months, three studies (Brown 2002; Deakin 2003; Zapotoczky 2001) involving 552 patients displayed no heterogeneity ($I^2=0\%$) with no effect between groups (0.09 mmol/l, 95% CI: -0.09 mmol/l to 0.26 mmol/l, Z=0.95, P=0.34).

With regard to triglyceride levels at four to six months, three studies (Brown 2002; Deakin 2003; Pieber 1995) with a total of 628 patients and low heterogeneity ($I^2 = 10.5\%$) were included in the meta-analysis with a borderline effect for the group education programme (0.24 mmol/l; 95% CI: -0.04 mmol/l to 0.52 mmol/l, Z=1.68, P=0.09). Four studies measured triglycerides at 12-14 months (Brown 2002; Deakin 2003; Kronsbein 1988; Zapotoczky 2001) with low heterogeneity between studies ($I^2 = 15.1\%$) and including 652 participants with no effect between groups (-0.14 mmol/l; 95% CI: -0.41 mmol/l to 0.13 mmol/l, Z=1.01, P=0.31).

3.11.3 No meta-analysis

Empowerment/self-efficacy

Deakin 2003 assessed the level of empowerment and psychosocial self-efficacy experienced by the 314 participants using a validated questionnaire (Anderson 2000b). At four months there was a significant difference in total empowerment score between the two groups in favour of the group education programme (difference 0.3; 95% CI: 0 to 0.6, P<0.001). That was the case for the three sub scales: psychosocial adjustment to diabetes (difference 0.3; 95% CI: 0 to 0.6, P=0.002); readiness to change (difference 0.4; 95% CI: 0.2 to 0.5, P<0.001); and setting and achieving goals (difference 0.3; 95% CI: 0.2 to 0.5, P<0.001). At 14 months, empowerment scores were still significantly higher amongst patients allocated to the group education programme: the total

empowerment score was 3.5 for the group education programme participants as opposed to 3.2 for the control group (difference 0.3; 95% CI: 0.04 to 0.6, $P=0.006$); psychosocial adjustment to diabetes (difference 0.3; 95% CI: 0.02 to 0.7, $P=0.005$); readiness to change (difference 0.3; 95% CI: 0.1 to 0.5, $P=0.001$); and setting and achieving goals (difference 0.2; 95% CI: 0.05 to 0.4, $P=0.02$).

Rickheim 2002, a study involving 92 patients, measured psychosocial adjustment to diabetes with a validated questionnaire and evaluated at six months. Both the intervention and control group significantly improved their psychological adjustment to diabetes ($P<0.01$) but there was no statistical significance between the two groups ($P=0.64$).

Quality of Life

Two studies measured quality of life at 4-6 months (Deakin 2003; Rickheim 2002) using different validated questionnaires (Bradley 1999; Ware 1994 respectively). It was not possible to synthesize and summarise those statistically, as the scales were too dissimilar. Deakin 2003 found no overall improvement in general quality of life but in respect of the sub-scales there was highly significant improvement in participants allocated to the group education programme: freedom to eat (difference 1.7; 95% CI: 0.8 to 2.5, $P<0.001$); enjoyment of food (difference 1.2; 95% CI: 0.2 to 2.1, $P=0.046$); and freedom to drink (difference 1.5; 95% CI: 0.4 to 2.5, $P=0.005$). Rickheim 2002 found that participants in both the intervention and control groups significantly improved their score on the SF-36 mental scale ($P<0.01$ for the group allocated to group education and $P=0.04$ for the control group), but there was no significant difference between the groups ($P=0.82$). Neither group had a higher score for the SF-36 physical score at six months (Intervention group $P=0.63$, control group $P=0.93$) and there was no significant difference between the groups ($P=0.69$).

At 12-14 months, two studies measured quality of life. Deakin 2003 used the same validated questionnaire as that used at six months; Bradley 1999 and Trento 1998 used a translated and revalidated diabetes quality of life questionnaire from the Diabetes Control and Complications Trial (DCCT 1988). It was not possible to synthesize and summarise those statistically because the scales were ranked in opposite directions. At 14 months Deakin 2003 reported similar results to those at four months, namely no significant improvement in overall quality of life, but significant improvements for the sub-scales: freedom to eat (difference 1.1; 95% CI: 0.2 to 2.1, $P=0.04$); enjoyment of

food (difference 1.1; 95% CI 0.1 to 2.0, $P=0.05$); and freedom to drink (difference 1.5; 95% CI: 0.5 to 2.6, $P=0.01$). Trento 1998 did not find a significant difference in quality of life at 12 months but reported a significant improvement in quality of life at two years (Trento 2001, $P<0.001$) and at four years (Trento 2002, $P<0.009$).

Self-management

Six studies measured some aspect of self-management (Deakin 2003; Holtrop 2002; Kronsbein 1988; Lozano 1999; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002). However, the variety of self-management tasks and measures resulted in a descriptive summary of the findings.

Deakin 2003 measured self-care activities using a validated questionnaire (Toobert 1994) and reported that at four months, participants allocated to the group education programme had significantly increased their self-management scores for exercise ($P<0.001$), foot care ($P=0.008$) and self monitoring of blood glucose levels ($P=0.009$). At 14 months, self-management scores had remained significant in respect of exercise ($P=0.02$) and foot care ($P=0.003$) but there was no significant difference between the groups for self-monitoring of blood glucose levels ($P=0.17$). Food intake was measured with a validated food frequency questionnaire (Little 1999) and, at four months reported that the participants allocated to group education had increased energy intake from carbohydrate (difference 4.1%; 95% CI: 0.4% to 7.9%, $P=0.03$), total sugars (difference 5.1%; 95% CI: 2.4% to 7.9%, $P<0.001$) and fruit and vegetables (difference 1.0 portion; 95% CI: 0.2 to 1.8 portions, $P=0.01$) when compared with the control group. At 14 months the participants were likely to be consuming more fibre than the participants in the control group (difference 3.8g; 95% CI: 0.03g to 7.6g, $P=0.05$), more sugars (difference 6.6%; 95% CI: 3.4% to 9.9%, $P<0.001$) possibly from the extra 2 portions of fruit and vegetables per day (difference 2.2 portions; 95% CI: 1.1 portions to 3.2 portions, $P<0.001$); and less saturated fat (difference 1.1%; 95% CI: 0.0% to 2.3%, $P=0.05$).

Rickheim 2002 measured self-reported physical activity and found no difference within groups (intervention group, $P=0.38$; control group, $P=0.39$) or between the two groups ($P=0.83$). Lozano 1999 measured the percentage of participants who carried out self-monitoring of blood glucose levels and found a significant difference between the two groups in favour of the group education programme at both one and two years ($P<0.005$). Kronsbein 1988 measured the percentage of participants who were carrying

out urinalysis at 12 months and reported a significant difference between participants allocated to the group programme and those in the control group (72% versus 2%; 95% CI: 57% to 83%, $P < 0.0001$). Holtrop 2002 reported that the group programme participants made positive movement in stages of change for five behaviours: physical activity ($P = 0.003$); reduction of high fat foods ($P = 0.008$); consumption of five portions of fruit and vegetables ($P < 0.0001$); consumption of three meals daily ($P = 0.9$); limitation of refined sugar intake to one product per day or less ($P = 0.001$). However, the statistical analysis was performed on pre-test means versus post-test means for the intervention group and no data was provided for the control group. Trento developed and validated a health behaviours questionnaire and reported that the score was significantly greater for the group education participants than for the controls at one year (Trento 1998, $P < 0.005$), two years (Trento 2001, $P < 0.001$) and four years (Trento 2002, $P < 0.001$).

Treatment Satisfaction

One study (Deakin 2003), using a validated questionnaire, measured change in treatment satisfaction and found that participants in both the group education programme and the control group were more satisfied with their treatment than they were at baseline. However, the group education participants were significantly more satisfied with treatment at four months (difference in score 4.4; 95% CI: 2.6 to 6.1, $P < 0.001$) and 14 months (difference in score 3.7; 95% CI: 1.5 to 6.0, $P = 0.002$).

Cost Effectiveness

Brown 2002 reported that the cost of providing the intervention (52 contact hours over 12 months) was US \$384 per person assuming that costs of monitoring supplies were eligible for third-party reimbursement. However, a cost effectiveness analysis was not carried out. Trento 2002 calculated that, over the study period, group care required 196 minutes and US \$756.54 per patient, compared with 150 minutes and US \$665.77 for the control patients. That finding indicated that an additional US \$2.12 was spent per point gained in the quality of life score.

Complications

Only one study monitored the presence of diabetes complications and it reported no significant differences between the group education participants and controls in respect of diabetic retinopathy and foot ulcers at two years (Trento 2001). It found however, that at four years, diabetic retinopathy had progressed more slowly amongst participants that had attended the group education programme ($P < 0.009$).

3.11.4 Adverse effects

No adverse effects were reported for the group education participants or the controls.

3.11.5 Subgroup analyses

Ethnicity

Six studies did not provide data about the ethnic background of the participants (Domenech 1995; Heller 1988; Kronsbein 1988; Lozano 1999; Pieber 1995; Trento 1998; Trento 2001; Trento 2002; Zapotoczky 2001). Although two studies (Domenech 1995; Rickheim 2002) stated the percentage of white Caucasian participants, no information was provided about the ethnic background of the other participants. Deakin 2003 reported that 80 out of 314 (25.5%) participants were from a South Asian background, the remaining 234 participants being white Caucasian. A subgroup analysis was carried out for the primary outcome, glycated haemoglobin, at four months and 14 months. Both analyses showed statistically significant differences between the intervention and control group in favour of the group-based education programme. All participants recruited in the Brown 2002 study were Mexican Americans. However, there was not enough data provided for any ethnic group to perform a subgroup analysis for ethnicity.

Theoretical model

Only five studies identified the theoretical model underpinning the group education programme and those were based around therapeutic patient education, patient activation and empowerment (Deakin 2003; Domenech 1995; Kronsbein 1988; Pieber 1995; Rickheim 2002). A subgroup analysis was performed with two studies that had reported glycated haemoglobin at four to six months (Deakin 2003; Pieber 1995). A significant reduction in glycated haemoglobin was present in favour of the group education participants and this was in line with the results of the main meta-analysis on glycated haemoglobin (Heterogeneity, $I^2 = 45.8\%$) (0.57%; 95% CI: 0.09% to 1.05%, $Z=2.34$, $P=0.02$). A subgroup analysis was performed with two studies that had reported glycated haemoglobin at 12-14 months (Deakin 2003; Domenech 1995) and had resulted in similar findings to those of the main meta-analysis, namely significantly improved diabetes control for participants allocated to the group education programme (0.88%; 95% CI: 0.59% to 1.17%; $Z=5.99$, $P<0.00001$). However, moderate heterogeneity was present ($I^2 = 61.9\%$). It was not possible to include Kronsbein 1988 or Rickheim 2002 in the subgroup analysis as they had not been included in the original meta-analysis owing to baseline differences in glycated haemoglobin.

Duration of education programme

The least intensive group education programmes delivered by Lozano 1999 and Trento 1998, both of which incorporated only three to four hours of education during the first year, had similar results in respect of glyated haemoglobin as those resulting from the most intensive programme that delivered 52 hours of education and support in the same time period.

Gender

All studies included an even mix of males and females except for Holtrop 2002 that recruited females only. That study was not included in the meta-analysis for glyated haemoglobin because of baseline differences and no subgroup analysis was therefore performed.

Primary/secondary care

Three of the four studies included in the glyated haemoglobin meta-analysis at four to six months were delivered in primary care (Brown 2002; Deakin 2003; Pieber 1995). One was delivered at a hospital diabetes unit (Heller 1988). The latter reported a slighter greater improvement in glyated haemoglobin. However, when a subgroup analysis was performed on the primary care studies, the significant reduction in glyated haemoglobin remained for group education participants (0.83%: 95% CI: 0.25% to 1.44%, $Z=2.70$, $P=0.007$). When the studies based at a hospital diabetes unit (secondary care) were removed from the 12 - 14 month meta-analysis on glyated haemoglobin (Heller 1988; Trento 1998; Zapotoczky 2001) and a subgroup analysis was carried out on the four studies delivered in primary care (Brown 2002; Deakin 2003; Domenech 1995; Lozano 1999), there was very low heterogeneity between studies ($I^2 = 8.8\%$) and the significant reduction in glyated haemoglobin remained (0.89%: 95% CI: 0.74% to 1.04%, $Z = 11.58$, $P<0.00001$).

Number of participants in the group education programme

Two of the studies (Deakin 2003; Zapotoczky 2001) had larger groups comprising between 16 and 18 patients (and some carers) in each diabetes education programme. A subgroup analysis was performed to detect whether large groups reduced the effectiveness of the intervention and that was shown not to be the case. There was no heterogeneity between the two studies ($I^2 = 0\%$) and glyated haemoglobin at 12-14 months remained significantly reduced in respect of the group education participants (0.70%: 95% CI: 0.40% to 1.00%, $Z=4.54$, $P<0.00001$).

Educator

Three of the group-based education programmes were delivered by physicians trained in adult education principles (Domenech 1995; Pieber 1995; Trento 1998; Trento 2001; Trento 2002). Two studies evaluated glycated haemoglobin at 12 months (Domenech 1995; Trento 1998). A sub-group analysis excluding those studies resulted in there being no heterogeneity between the remaining studies delivered by a nurse (Lozano 1999), a dietitian (Deakin 2003; Zapotoczky 2001) or a combination of the two (Brown 2002; Heller 1988). The effect size for nurses and/or dietitians delivering the group education programme was shown to be similar to that of the full meta-analysis; 0.75% reduction ($P < 0.00001$) compared to 0.82% reduction ($P < 0.00001$). The two studies that had not been included in the 12-14 month meta-analysis for glycated haemoglobin because of baseline differences in HbA1c were the study that had used trained lay health advisors to deliver the group education programme (Holtrop 2002) and the study in which physician assistants had delivered the programme (Kronsbein 1988).

3.11.6 Sensitivity analysis

Sensitivity analyses have been performed as required to detect and explain the source of heterogeneity between studies. All studies were published papers with the exception of one (Deakin 2003) which was, at the time of the review, published as three conference abstracts and submitted as a full paper for publication. When the Deakin 2003 study was excluded from the meta-analysis at four to six months and the meta-analysis repeated, the effect size for glycated haemoglobin was slightly better in favour of the group education programme with a 1.35% reduction ($P < 0.00001$) compared with the 1.08% reduction ($P = 0.002$) calculated in the main meta-analysis. However, at 12-14 months the effect size remained the same, 0.84% reduction ($P < 0.00001$) compared with the 0.82% reduction ($P < 0.00001$) calculated in the main meta-analysis. None of the studies were graded 'A' for quality and only two studies were graded 'B' (Deakin 2003; Zapotoczky 2001) (see quality assessment of trials in the section entitled "Methods of the review" starting on page 80). When the meta-analysis was repeated including only those studies assessed as being of better quality (Deakin 2003; Zapotoczky 2001), the effect size (reduction in glycated haemoglobin for the group education participants) at 12-14 months remained highly significant, 0.70% reduction ($P < 0.00001$) compared with the 0.82% reduction ($P < 0.00001$) seen in the main meta-analysis. None of the studies included were large multi-centre trials and therefore a sensitivity analysis was not carried out in respect of trial size. One of the studies was written in Spanish and was translated before being included in the review (Lozano 1999). Removal of that study

from the 12-14 month meta-analysis for glycated haemoglobin did not change the effect size or statistical significance, 0.79% reduction ($P<0.00001$) compared to the 0.82% reduction ($P<0.00001$) calculated in the main meta-analysis. Removal of all studies having less than 100 participants from the 12-14 month meta-analysis on glycated haemoglobin left three studies to be re-analysed (Brown 2002; Deakin 2003; Lozano 1999). The effect size for reduction in glycated haemoglobin in the group education participants remained constant, 0.75% reduction ($P<0.00001$) compared to the 0.82% reduction ($P<0.00001$) calculated in the main meta-analysis.

3.12 Discussion

3.12.1 Summary

The review systematically evaluated 13 papers, that provided data for 11 studies, looking at group-based, patient-centred educational programmes for people with Type 2 diabetes and found that these programmes resulted in clinically and statistically significantly improved health outcomes. The studies showed that patients attending group education programmes had reduced glycated haemoglobin of 1.08% (95% CI: 0.40% to 1.76%, $P=0.002$) at four to six months and when the source of heterogeneity was removed, (Deakin 2003) the reduction in glycated haemoglobin was 1.35% (95% CI: 0.78% to 1.93%, $P<0.00001$). Deakin 2003 reported a smaller effect size at four months (two months post-intervention) than the other studies at six months and that may be due to the fact that glycated haemoglobin is a measure of diabetes control over a period of approximately three months, and therefore, the four month assessment may have been too close to baseline for improvements in diabetes control to be apparent. Reduced glycated haemoglobin was 0.82% (95% CI: 0.65% to 0.99%, $P<0.00001$) at 12-14 months. Two of the studies followed up at two years and the results indicated that the improved metabolic control was still apparent (0.97%; 95% CI: 0.54% to 1.40%, $P<0.00001$) One study showed continued benefit at four years (1.60%; 95% CI: 0.91% to 2.29%, $P<0.00001$). The two studies that were not included in the meta-analysis at four to six months due to baseline differences had smaller effect sizes (0.4%, 0.8%) than the meta-analysis result (1.08%) but still favoured the group-based diabetes education programme. The study not included in the meta-analysis at 12-14 months (Kronsbein 1988) only had a very small effect size of 0.2% in favour of the group programme. However, that study had been published in 1988 before the benefits of optimal glycaemic control had been established. The mean baseline glycated haemoglobin level in that study was good (7.1%) and participants were encouraged to reduce diabetes medication rather than to improve their diabetes control. There was also a significant

reduction in fasting blood glucose levels amongst group programme participants at four to six months (1.66 mmol/l; 95% CI: 0.74 mmol/l to 2.58 mmol/l, $P=0.00004$), 12-14 months (1.17 mmol/l; 95% CI: 0.72 mmol/l to 1.63 mmol/l, $P<0.00001$), two years (1.57 mmol/l; 95% CI: 1.05 mmol/l to 2.10 mmol/l, $P<0.00001$) and four years (1.70 mmol/l; 95% CI: 0.16 mmol/l to 3.24 mmol/l, $P=0.03$). Five studies showed that by attending a group education programme, patients were able to significantly reduce their diabetes medication (odds ratio 11.79; 95% CI: 5.17 to 26.90, $P<0.00001$).

There was no indication that group-based diabetes education programmes impacted on body weight or body mass index at four to six months. However at 12-14 months, there was some evidence that the group education programme reduced body weight (1.61 Kg; 95% CI: 0.25Kg to 2.97 Kg, $P=0.02$) but that was either insufficient weight loss to affect body mass index, or alternatively no effect may have been seen in BMI because only two studies were included in the meta-analysis whereas five studies were included for the body weight meta-analysis. One study (Deakin 2003) presented data to suggest that the programme could reduce waist circumference (2.8cm; 95% CI: -0.3cm to 5.6cm, $P=0.06$). Diabetes knowledge was significantly improved in the group education participants at four to six months ($P<0.00001$), 12-14 months ($P<0.00001$), two years ($P=0.03$) and four years ($P<0.00001$) although significant heterogeneity existed between the studies at four to six months and two years. At four to six months patients allocated to the group education programme experienced a significant reduction in systolic blood pressure (5.37mmHg; 95% CI: 1.21mmHg to 9.53mmHg, $P=0.01$) and a borderline significant reduction in diastolic blood pressure (2.65mmHg; 95% CI: -0.28mmHg to 5.57mmHg, $P=0.08$). However, there were no clinical or statistically significant reductions in systolic or diastolic blood pressure at 12-14 months.

There was no evidence at any of the time periods that group-based diabetes education programmes positively impact on total cholesterol levels. There was a borderline clinically and statistically significant result for reduction in triglyceride level at four-six months (0.24mmol/l; 95%CI: -0.04mmol/l to 0.52mmol/l, $P=0.09$) but not at 12-14 months.

There was strong evidence from one study (Deakin 2003) that measured patient self-empowerment, that attending a patient-centred, group-based diabetes education programme significantly improved empowerment and psychosocial self-efficacy at both four months ($P<0.001$) and 14 months ($P<0.001$). Only two studies measured quality of

life and there was no evidence that the group education participants experienced overall improved quality of life at four to six months or 12-14 months, although they did experience a significantly better quality of life for the food and drink variables (Deakin 2003). One study reported significantly improved quality of life at both two years (Trento 2001, $P < 0.001$) and four years (Trento 2002, $P < 0.009$). There was evidence that the group education programme improved self-management skills as a result of self-monitoring of blood glucose levels (Deakin 2003; Lozano 1999) and urinalysis (Kronsbein 1988), consumption of a healthier diet (Deakin 2003; Holtrop 2002), foot care (Deakin 2003) and improved health behaviours (Trento 1998; Trento 2001; Trento 2002). There was conflicting evidence in respect of physical activity. Deakin 2003 reported a positive effect at both four months ($P < 0.001$) and 14 months ($P = 0.02$); Rickheim 2002 reported no effect ($P = 0.83$). Treatment satisfaction was only measured in one study (Deakin 2003) but that study indicated improved satisfaction amongst group participants ($P < 0.001$). Although Brown 2002 estimated the cost per patient of attending the programme, there was only one study that reported a cost effectiveness analysis. In that study US \$2.12 was spent per patient for every point gained on the quality of life score (Trento 2002). There was no evidence that group-based diabetes education programmes reduced the incidence of acute complications (hypoglycaemia/hyperglycaemia) but there was a small amount of evidence for a reduction in chronic complications: Trento 2002 reported a reduced progression to diabetic retinopathy at four years.

The studies were carried out in various developed countries within Europe and in the United States, but there were no studies from developing countries. Although ethnicity was reported in some of the studies, there was not enough information to perform a subgroup analysis for ethnicity. However, there is evidence that delivery of the programme to ethnic minority groups in a language that they are familiar with still delivers the benefits for glycated haemoglobin (Brown 2002; Deakin 2003). Although the theoretical model underpinning the programme was not always visible, there is evidence that if the programme is based on therapeutic patient education with participatory/empowering and adult-centred principles, it is likely to be effective. However, only one study measured patient empowerment and further research would be necessary to confirm those findings. Only three studies measured blood pressure and that may reflect on the year that studies was undertaken, as the benefits of optimal blood pressure for people with Type 2 diabetes have only been evident since the publication of the United Kingdom Diabetes Prospective Study (UKPDS-33 1998). The two studies

that followed up beyond 12-14 months were the only studies that repeated the intervention on an annual basis and that may be why they continued to obtain significant clinical and statistical results. Subgroup analysis provided evidence that group-based diabetes education programmes were equally effective when delivered in primary and secondary care by any health professional who was trained to deliver the programme. There was less evidence for the delivery of the programme by trained lay health workers or physician assistants. There was no evidence to suggest that group education programmes were less effective when delivered to larger groups of 16 to 18 participants. It was not possible to detect whether programmes were more successful if a family member or friend was also invited to participate, as four studies did not indicate whether patients were accompanied or not. Ten studies compared the group programme with a waiting list control and/or routine treatment. One study (Rickheim 2002) delivered the group education programme to the control group except that delivery was via individual appointments rather than a group environment. It resulted in the control group having five hours of one-to-one education. However, a significant improvement in glycaemic control of those allocated to the group education programme was apparent when compared to those receiving the intensive individual education ($P=0.05$). Therefore an intensive individual approach, which is probably unrealistic given the prevalence of diabetes and the projected epidemic (Sicree 2003), was shown to be less effective than a group education programme.

3.12.2 Limitations of the review

The quality of studies included in the review were assessed as either moderate or poor quality based on the criteria by Jadad 1996 and Schulz 1995. The randomisation procedure was generally adequate, as were the descriptions of drop-outs. There was a lower percentage of drop-out compared to the findings from other reviews of diabetes education (Griffin 1998; Norris 2001). The three factors that impacted on quality were (1) only one study stated that there was allocation concealment, (2) only two studies analysed the data by intention to treat and (3) it was unclear whether outcome assessors were blind to the intervention. However, unlike a drug/placebo trial, it is very difficult to provide allocation concealment and blind the outcome assessors for a group-based educational intervention and several of the studies were delivered before analysis by intention-to-treat was recommended.

The review included only 13 papers, which reported 11 studies and involved 1532 patients. Because of variety in programme content, outcomes and length of follow-up,

when it was possible to perform a meta-analysis the number of studies included in each analysis was small. It was not possible to carry out a meta-analysis for several of the main outcomes of the review (such as self-management skills, empowerment/self-efficacy and quality of life) due to significant heterogeneity between studies. Educational interventions are complex interventions and it is difficult to identify the active ingredient(s) with any precision. Therefore, although the review has shown that group-based diabetes education programmes result in clinical, and statistically significant health outcomes, the exact mechanism of action can be contemplated but not identified.

3.12.3 Generalisability and applicability of results

As with all clinical trials, it is possible that patients who participated in the studies may not be truly representative of the local adult population with Type 2 diabetes, as people who volunteer to take part in clinical trials tend to be a more committed and motivated subgroup and generally receive more attention when participating in a clinical trial. Although having motivated participants will not affect differences between the two groups, as both the intervention and control groups are part of the motivated subgroup, it may affect the generalisability of the results if group education programmes are provided as routine treatment. Delivering group-based diabetes education programmes to the general adult population with Type 2 diabetes may result in a bigger drop-out rate and smaller effect sizes. The 11 studies were carried out in different developed countries throughout Europe and the United States. Although not clearly stated, it is presumed that the majority of participants were mainly white Caucasians with others being of South Asian and Mexican American descent. There will, therefore, have been lingual and cultural diversity as well as differences in the respective healthcare systems. The results of this review are therefore generalisable to adults with Type 2 diabetes in many different developed countries and there is no evidence to suggest that group-based self-management strategies would not be suitable for developing countries as long as the group-based diabetes education programme was delivered in a familiar language and was sensitive to the culture of the population. The funnel plot represented the studies that assessed glycated haemoglobin at 12-14 months and reported almost perfect symmetry. That indicates that small study or publication bias was not present, suggesting that the results are generalisable.

Routine diabetes education is still dominated by the traditional model in which doctors, nurses, dietitians and other members of the health care team interact with patients on a

one-to-one basis. That style of treatment leads to active prescription of diet, medication and advice about healthy practices but may not stimulate effective patient motivation and behaviour change (Trento 2002). However, the scarcity of time and resources have led to more diabetes teams in primary and secondary care contemplating and commencing group-based diabetes education programmes. Many national (DOH 2001b; DOH 2003; NICE 2003; Mensing 2003) and international (DECS 2003) standards now recommend group education programmes. However, this is the first systematic review to evaluate their effectiveness. If the results from this review can be translated to routine care, the 1% reduction in glycated haemoglobin may reduce the risk of developing secondary complications of diabetes by 21% (UKPDS-35 2000).

3.13 Reviewers' conclusions

3.13.1 Implications for practice

The 11 studies included in this systematic review provide evidence that group-based diabetes education programmes for adults with Type 2 diabetes result in clinically important improvements in health outcomes for glycated haemoglobin, fasting blood glucose levels and diabetes knowledge at four to six months and 12 months follow-ups. If the group education programme is repeated on an annual basis, benefits in glycated haemoglobin, fasting blood glucose and diabetes knowledge may be longer-term (two to four years). Adults with Type 2 diabetes attending a group education programme may also benefit from reduced blood pressure and triglyceride level at four to six months but those effects are likely to be much more short-term than, for example, small reductions in body weight, which were apparent at 12-14 months. There is some evidence that group education programmes can, both at four to six months and 12-14 months, reduce the requirement for diabetes medication, improve diabetes and healthy living self-management skills, increase patient self-empowerment and improve food related aspects of quality of life. At longer-term follow-up (two to four years), group education programmes may still result in improved quality of life and reduce the progression to diabetic retinopathy.

There is no evidence to suggest that programmes delivered in either primary or secondary care are more effective. There is also no evidence to suggest that the programme is more effective if delivered by a physician, dietitian or nurse as long as the health professional is trained to deliver a diabetes education programme. However, there is less evidence to support delivery of group education programmes by trained lay

health workers or physician assistants. Programmes based on therapeutic patient education using the principles of empowerment, participation and adult learning have proved to be effective. Delivery of the group-based diabetes education programme to groups of 4-6 participants or 16-18 participants does not appear to alter the effectiveness of the education, nor does the duration of the programme impact on effectiveness. It has however been observed that repeating the programme on an annual basis results in long-lasting benefits to health and psychosocial outcomes.

3.13.2 Implications for research

As the review is based on only 11 studies and many outcomes resulted from the synthesis of just two or three studies, further studies are required to confirm:

- 1) the theoretical model underpinning the programme. Are group education programmes more effective if based on therapeutic patient education incorporating empowerment, participation and adult learning principles?
- 2) the effect of group education programmes on blood pressure readings. Findings concluding the benefits of optimum blood pressure are relatively new due to the more recent findings regarding the benefits of optimum blood pressure;
- 3) the degree of treatment satisfaction. As the patients' voice has become much more important in the delivery of healthcare interventions, more information is required as to whether patients find group education programmes acceptable;
- 4) the effect of group education programmes on quality of life;
- 5) the effectiveness of the programme for ethnic minority groups. Further research is required before it can be confirmed that diabetes group education is appropriate for all people from all ethnic backgrounds;
- 6) the reduced risk of developing the secondary complications of diabetes;
- 7) the cost effectiveness of delivering group-based self-management strategies for people with Type 2 diabetes;
- 8) the effectiveness of peer educators in delivering group based diabetes education programmes.

Chapter 4: The Expert Patient (X-PERT) Programme

4.1 Introduction

A diabetes self-management education programme for adults with Type 2 diabetes has been designed and developed by the author of this thesis. The expert patient programme “X-PERT” is a six-session, group-based, health professional-led programme. This has been written to encourage the delivery of the X-PERT programme to adults living with Type 2 diabetes. It is designed to illustrate the theories of empowerment and patient activation. This chapter commences with details regarding the development of the diabetes expert patient programme (X-PERT), tutors manual and visual aids. The content of the tutor’s manual is then presented.

4.2 Development of the X-PERT Programme

Experience gained since qualifying as a state registered dietitian in July 1993, working as a diabetes specialist dietitian from 1996 and completion of a Post Graduate Certificate in Education (PGCE) in adult education in 1998, led to a conviction that dietetic input and general education of people with diabetes was not as effective as it could be. Standard care, as stated above, is generally provided on an individual one-to-one basis and, within Burnley, Pendle and Rossendale, adults with newly diagnosed diabetes receive dietetic appointments lasting thirty minutes. Regular follow-ups were infrequent and only 24% of people with diabetes were currently receiving an annual review (Deakin 2000a). Even then the duration of an appointment averaged only 15 minutes.

With this in mind, it seemed appropriate to move away from the traditional dietetic review to experiment with more patient-centred approaches. Initially ‘one-off’ group education sessions lasting for two hours were organised to provide up-to-date information to a group of between 15 and 20 people. Family members or friends were also invited. Supermarket tours for groups of people with diabetes were also well received. The local branch of Diabetes UK was involved with both developments. Evaluations were extremely positive. In 1999, 28 group-based diabetes education sessions were delivered to 404 people with diabetes and their carers. The majority of participants found the sessions had benefited them (36% a great deal; 59% quite a lot). The most useful aspects of the sessions were thought to be obtaining information on: diet; medication; what is diabetes?; future developments; meeting people with similar

problems. Requests for more information about food and diabetes, causes of diabetes, coping with diabetes and physical activity were received and suggestions made that there should be a series of sessions (Deakin 2000b). Public meetings held by local Primary Care Groups confirmed the popularity of the group education sessions and those evaluations were fed back verbally to the Nutrition and Dietetic Department.

The concept of a diabetes expert patient programme was then developed. Initially it was thought that a multi-disciplinary team would deliver the structured diabetes self-management programme. However, as a result of funding difficulties, the current shortfall in staff resources and the fact that the secondary care diabetes team was dubious about the empowerment approach to diabetes education, the proposal was amended to involve a single diabetes educator. That had advantages as well as disadvantages and will be discussed further in Chapter 7 (section 7.3.2). The original proposal described a 10 week diabetes expert patient programme that included sessions with a psychologist, a diabetes specialist nurse, a podiatrist and physical exercise instructor. After having to relinquish inputs from the first three professionals, it was decided to reduce the length of the programme to six weeks but to still invite an exercise facilitator from the local 'exercise on prescription' scheme to attend one session to inform participants about the referral system and the contents of the exercise scheme.

The education programme is based on two theoretical models. The first is an empowerment model developed in America. That is a five step model that encourages participants to (1) identify their own problems concerning lifestyle and self-management of diabetes, (2) explore the problem, (3) identify possible solutions, (4) commit to action by choosing one possible solution and (5) evaluate whether the solution worked for them and if it didn't why it didn't and what could be learnt from the experience (Anderson & Funnell 2000b). The second model on which the education programme is based is patient activation and uses the proverb *'I hear, I forget; I see, I remember; I do, I understand'* to encourage interactive patient centred exercises. *"There is an intimate and necessary relation between the processes of actual experience and education. There are many ways to learn and for many of us we learn better by doing"* (Dewey 1938). The models of empowerment and discovery learning are discussed in Chapter 2.

The contents of the information sharing aspects are based on national and international evidence-based guidelines and will be updated as and when new guidelines and literature are published. Several visual aids have been created to aid learning through vision and to help develop an understanding of complex and scientific information in a simplistic but accurate manner to aid self-management of diabetes. Their development was derived from theories of discovery learning and constructivism (Chapter 2, section 2.5.6.).

Although the approach has been developed as a scripted manual, it will be necessary for the tutor to have expertise in the treatment and management of diabetes and a good grounding in skills required to deliver adult education. Many participants have queries and questions, which may not have been covered in the manual and these will need to be addressed to satisfy the individuals need and provide a patient-centred service. It is anticipated that if the X-PERT programme is implemented as routine treatment, health professional competence-based training modules will also be required.

The X-PERT Programme is a specially designed patient education programme to provide patients with the confidence, knowledge and skills necessary to self-manage their diabetes. It is not a set of strict instructions that dictate behaviour change and then measure success based on levels of compliance, but a new tried and tested approach to patient education based on the theories of empowerment and patient activation.

Participants with Type 2 diabetes and a supportive family member or friend are invited to attend six, two-hour sessions of empowering education, experimentation, demonstration and discussion. Each participant gets a blank copy of the newly devised “Diabetes Health Profile” which they themselves will complete to monitor their own progress by self-testing and obtaining the relevant information from their diabetes care team.

Health professional tutors require a copy of the scripted X-PERT manual and a CD ROM containing patient handouts and access to the relevant visual aids. It is recommended that 15-18 people with Type 2 diabetes be registered onto each course, which, including family members and friends who choose to attend, will result in a group size of between 20 and 24 people. Patients also receive a manual that includes background reading, exercises and information on the content covered in each session.

4.3 The Expert Patient (X-PERT) Programme manual

Healthy living with diabetes: taking control

Scripted manual for tutors

As a tutor of the X-PERT Programme, you will deliver the six-week programme. You may wish to involve a health or dietetic assistant to help organise group activities, facilitate discussions and serve refreshments.

Preparatory reading

- NICE guidelines for the management, treatment and education of people with diabetes (NICE 2000; NICE 2001; NICE 2002a; NICE 2002d; NICE 2002b; NICE 2002c; NICE 2003a; NICE 2003b) (Health professional and patient versions available www.nice.org.uk);
- Local diabetes management protocols and guidelines;
- Balance for Beginners (Diabetes UK 2003a);
- Diabetes UK. 'Recommendations for the management of diabetes in primary care'. 2000; <http://www.diabetes.org.uk/infocentre/carerec/primary.htm>;
- UK, European and American nutritional recommendations (Diabetes UK 2003d); (ADA 2003; Ha & Lean 1998)
- Glycaemic index (Colagiuri, Foster-Powell K, & Miller JB 2000);(Diabetes UK 2001a; Foster-Powell, Holt, & Brand-Miller 2002; Frost & Dornhorst 2000; Leeds et al. 1998; Willett, Manson, & Liu 2002)
- Type 2 Diabetes in Practice (or similar book) (Krentz & Bailey 2001);
- The Art of Empowerment: Stories and Strategies for Diabetes Educators (Anderson & Funnell 2000a).

Aim

To develop self-empowerment in people with Type 2 diabetes to enable them to develop the knowledge, skills and confidence to make informed decisions regarding lifestyle and diabetes self-management.

Objectives

By the end of the six-week programme, group members will be able to:

- state what a diabetes health profile is and supply a meaning, purpose and normal range for each health result. Part of that process is to encourage group members to have more confidence to discuss test results with the diabetes care team;
- describe what 'blood glucose' is, where it comes from and how blood glucose levels are controlled with lifestyle, tablets and insulin;

- recognise that the only long-term solution to weight loss/weight maintenance is permanent and sensible lifestyle changes and not quick-fix diets;
- acknowledge that different carbohydrate foods digest and release glucose into the blood at different rates. They should also be able to differentiate between at least one high, medium and low glycaemic index food;
- state the main differences between that which is generally perceived as the correct diet for people with diabetes and a life-long sensible eating plan;
- appreciate not only why increased physical activity is good for health but also how it can especially help to improve healthy living with diabetes;
- identify why blood pressure control is as important as blood glucose control in preventing the long-term complications of diabetes;
- recognise what the short-term complications of diabetes are and how these may be avoided and treated if necessary;
- recognise what the longer-term complications of diabetes are and how individuals can reduce their risk of developing them;
- increase self-management of diabetes by setting individual goals and action plans to address individual problems.

Materials

- A blank name badge for everyone (reusable).
- Visual aids (listed below).
- Pencils.
- Flipchart stand with paper and pens.
- Patient manual with practical exercises and evidence-based information sheets.
- Glucose tablets and/or Lucozade™ to treat hypoglycaemia if necessary.
- Blood glucose meters: participants may find that testing their blood glucose improves their self-management skills and overall diabetes control. If possible obtain sponsorship from a pharmaceutical company to provide blood glucose meters. Organise a 30-minute session after the first, second or third week and invite the representative to demonstrate the correct testing technique and provide meters to participants who require them.

Visual aids

- 'What is diabetes' interactive poster.
- Carbohydrate (starch, sugar and glucose) models.
- Glycated haemoglobin (HbA1c) model.
- Blood pressure balloon model.

- Seesaw energy balance model.
- Body Story 'Fat Attack' video.
- Balance of good health model.
- Glycaemic index display.
- Glycaemic index quiz.
- British Heart Foundation: Guide to Food Labelling leaflet.
- Longer-term complications display board.
- Longer-term complications poster.
- Atherosclerosis model (drinking straw, lard and black treacle).
- Atherosclerosis plaque.
- Physiology of the eye model.
- The function of the kidney model.

LEARNING METHODS

- Discussion
- Group exercises with active participation
- Free-thinking

ROOM ORGANISATION

- Have the seating organised so that the participants are sat in a semi-circle facing the tutor. All participants should be able to see the flip chart and visual aids.

MATTERS OF GENERAL IMPORTANCE

During this programme give the group plenty of opportunity to work things out for themselves since that process is fundamental to self-empowerment. As a guide, for every piece of information you give them, you should ask them at least one question.

Self-empowerment is about ENCOURAGEMENT not EMBARRASSMENT. Never label an answer as incorrect; instead encourage the participants to provide an alternative response.

Read out the open question and allow the group to discuss it before reading the answer you were looking for.

General time plan for each weekInformation sharing activities

Information sharing & skill development: 75 minutes

Break

Communicating & networking: 15 minutes

Lifestyle experiment

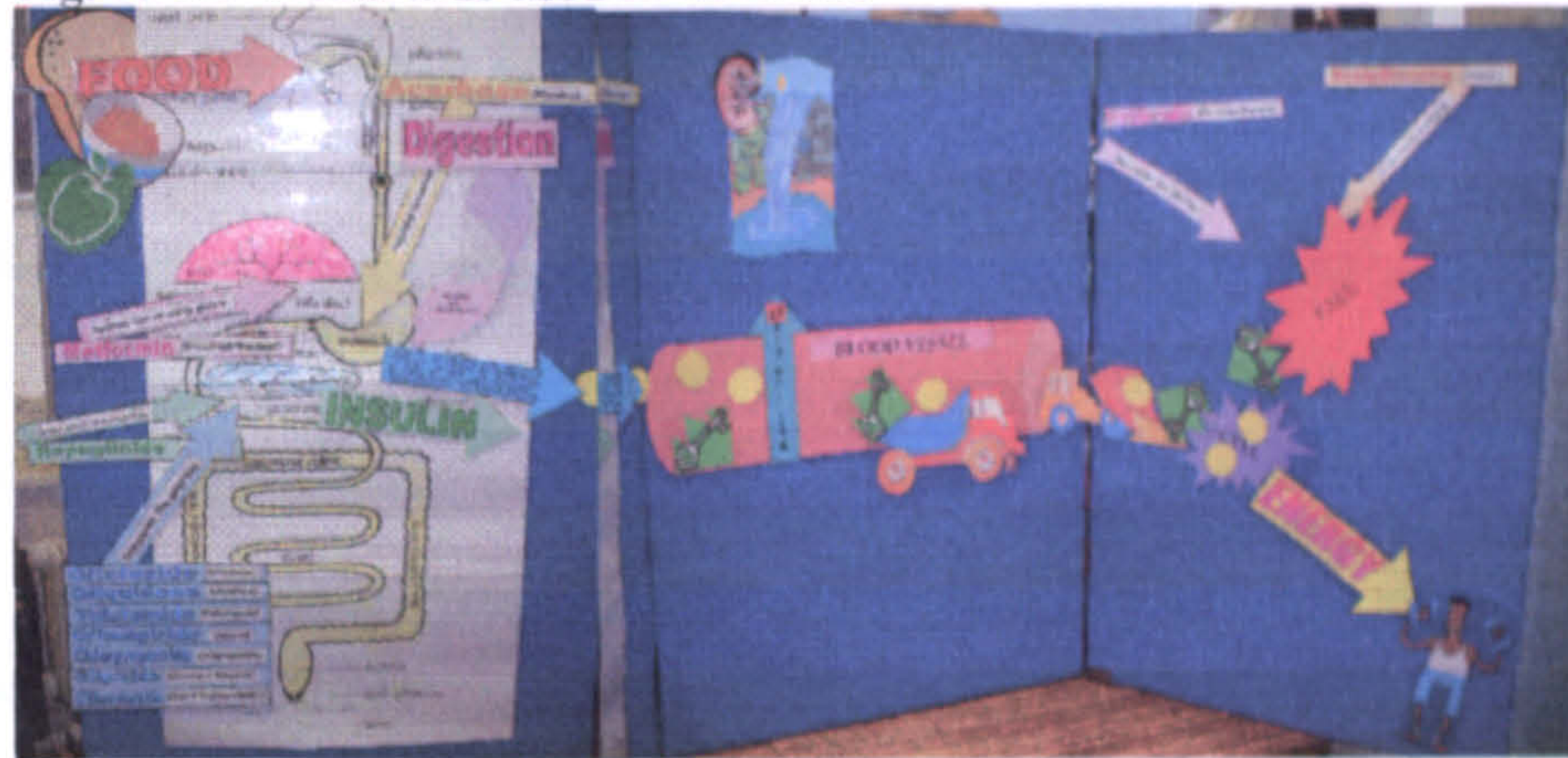
Empowerment and goal setting: 30 minutes

TOTAL 2 hours

4.3.1 Week one - what is diabetes?

Overview

Figure 4.1 Visual aids used in week one



The group explores the process of carbohydrate food digestion and the resulting rise in blood glucose levels. The visual aids (illustrated in figure 4.1 above) help people to identify the symptoms of diabetes and how these may be alleviated by lifestyle changes and, if necessary, medication and/or insulin. The role of obesity and physical inactivity are also discussed in the aetiology of Type 2 diabetes with the emphasis on lifestyle change.

Introduction (10 minutes)

Firstly, hand out the manuals, name badges and a felt-tipped pen as the participants enter the venue and ask them to write their first name on both the manual and the name badge visible to other participants. Secondly, introduce yourself and the expert patient programme. A sample introduction appears below:

Tutor: *Hello, I am (name) and I will be delivering the diabetes expert patient programme over the next six weeks. I am a (state qualifications/status e.g. diabetes specialist dietitian/nurse, practice nurse) and have been working in diabetes care for the past (how many?) years. You have all been given the dates and times of the six-week programme. The programme is displayed on the first page of your manual. It will be advantageous to attend every session but if, for whatever reason you cannot attend, please let me know and I will keep the written material for you and if possible give you a brief summary of the subjects discussed. All participants who complete the course will receive a certificate of attendance.*

Thirdly, you should point out that you will be conducting a supermarket tour on the fourth session. Identify local supermarkets and explain that you can only take up to 10 people on a single tour. Explain that if there are 20 people you can do two tours and these can be at different supermarkets. Confirm the chosen supermarket(s) and the time of the tour(s) and ask the participants to write their names against the supermarket of

their choice during the break. Make sure that you are not over-subscribed for any tour. Keep the list to remind people about the dates and times of their chosen tour at the end of week three. Arrange the tours by liaising with the supermarket manager.

Fourthly, tell the group about the expert patient programme manual. A sample explanation appears below:

Tutor: *You all received a pack when you arrived today. In the front you will notice a programme for the six-week expert patient programme. Every week you will receive written background information to place in the relevant section in the manual. The manual is for you to keep, refer to, and share with others. At the moment the information is up-to-date, but like all health recommendations, new evidence is constantly being published. To remain informed you may wish to become a member of Diabetes UK and receive regular mailings written for people with diabetes. This will currently cost you between £8 and £20, depending on individual circumstances, for a year membership. I have information regarding Diabetes UK and application forms – feel free to take one when we break for refreshments.*

Identifying common problems (10 minutes)

The purpose of this exercise is to demonstrate that the problems people experience with their diabetes are common to many participants.

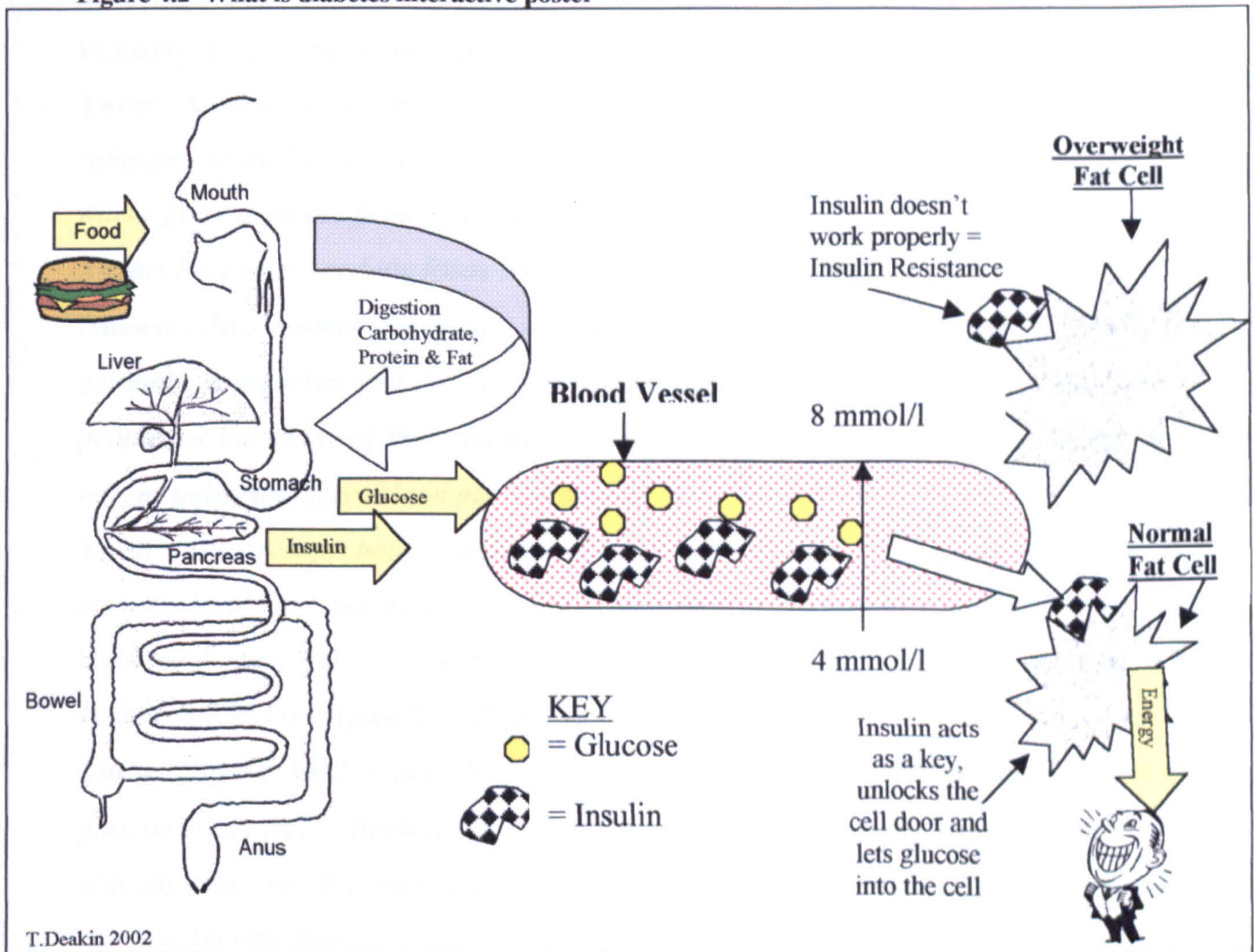
1. Ask the participants to organise themselves into pairs (ideally they should not already know the other person).
2. Each participant has just **one minute** to introduce themselves to their partner and state the **two main problems** they have with their diabetes.
3. Each person in turn will then introduce their partner to the whole group and identify their partner's **two main problems** (If carers are involved in the group they should state two main problems that arise from living with somebody with diabetes).
4. **Write on your flipchart** the problems identified e.g. tiredness, difficulty losing weight, fear of hypos, inconsistent treatment messages, remembering medication, perceived restricted diet etc.
5. Read aloud to the group the list of problems from the exercise.
6. Tell the group that the programme intends to address these problems and to help the group to deal with them. State also that individuals will have an opportunity to address these problems further in the goal-setting activity at the end of each session.

Activity one: Exploring diabetes (30 minutes)

Ask the question 'what is diabetes?' and write down the comments of the participants on the flip chart. You will probably get responses such as 'too much sugar' or 'not enough insulin'. Thank the participants and commence the group exercise.

Using 'visual aid 1', which is a large poster with stick-on labels/images (see figure 4.2 below which is a diagram of the completed poster) start the group exercise by sticking the food label and food onto the poster. Spread the rest of the labels either on the floor or on a low table. Throughout the following 30 minutes, work through the group exercise encouraging the participants to be actively involved in placing the labels in the correct places. This exercise must be carried out whilst paraphrasing leading questions to help participant understanding.

Figure 4.2 What is diabetes interactive poster



(visual aid 1)

An example of the type of discussion you need to encourage appears below:

Tutor: Lets start from the beginning. When we eat food what happens to it?

Answer: *Digestion* (Ask for a volunteer to stick the digestion label on the poster).

Tutor: Ok, so we know that food digests in the stomach and gut. Does anyone know the three main nutrients that the food breaks down into? Participants will either read the answer from the 'digestion' label or know the correct answer.

Answer: *'Carbohydrate (starch and sugars), protein and fat'*

Tutor: *Which nutrient is important in diabetes?*

Answer: *Carbohydrate. Carbohydrate includes both starchy and sugary foods. All starchy and sugary foods break down into glucose and raise blood glucose levels.*

Tutor: *Why do I say blood glucose levels instead of blood sugar levels?*

Answer: *It is glucose that is found in the blood and not sugar. People commonly refer to diabetes as 'too much sugar' and healthcare professionals also tend to use the term 'blood sugar levels' in an attempt to simplify things. However, this can be misleading as it gives the impression that diabetes is all about the quantity of table sugar in the blood.*

Tutor: *Please raise your hand if you thought that diabetes was all about the quantity of table sugar in your blood?*

Probably quite a few or the majority of participants will respond.

Tutor: *As you can see this is a very common concept. However, we now know it is 'glucose' in the blood and not table sugar. For the rest of this activity we will explore where glucose comes from and how it arrives in the blood.*

Tutor: *Do protein or fatty foods raise blood glucose levels?*

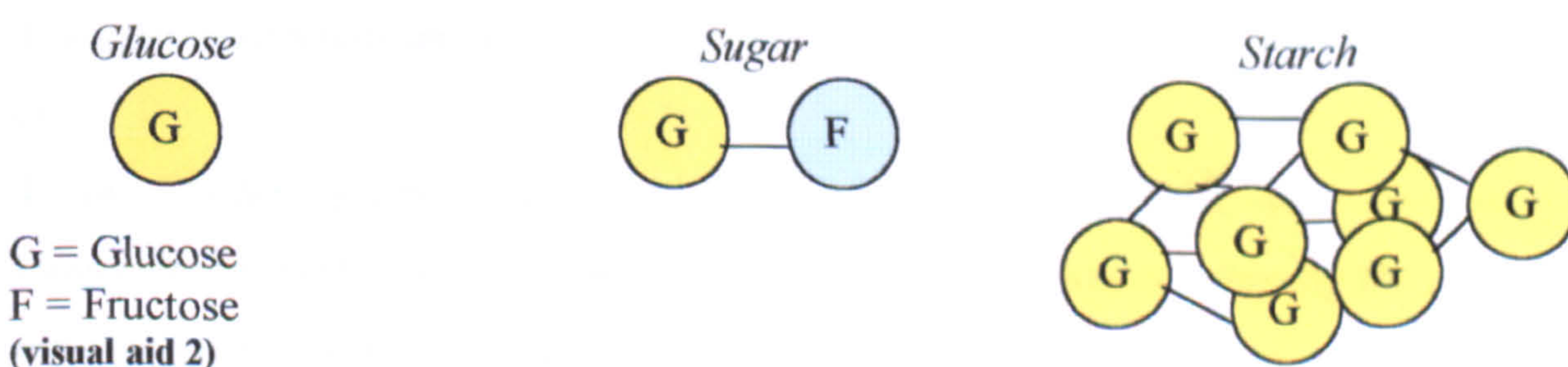
Answer: *No, protein foods, for example meat, fish and eggs and fatty foods, for example, margarine and oils, do not directly affect blood glucose levels. However, if people eat too many of these foods they may gain weight. We will discuss shortly how weight gain can affect blood glucose levels.*

Tutor: *Lets recap, both starchy and sugary foods are called carbohydrates. All carbohydrate food digests into glucose, which raises blood glucose levels.*

Hold up 'visual aid 2'; which comprises small ping-pong balls stuck together with cocktail sticks (see figure 4.3 below).

Tutor: *Starchy food is just 'lots of glucose stuck together'. When starch digests the glucose is set free. Alternatively, sugar (or sucrose to give it it's correct name) is one glucose and one fructose stuck together and when sugar digests the glucose and fructose become free'.*

Figure 4.3 Carbohydrate models



Now demonstrate this by pulling a few ping-pong balls free and explain that this is what happens when carbohydrate digests in the gut.

Tutor: *What happens to the glucose now? Where does it go? (Refer back to visual aid 1) Does anybody wish to put the glucose label and glucose molecules (yellow circles) in the right place?*

Make sure that the glucose arrow points from the stomach to the blood vessel and the glucose molecules are in the blood vessel.

Tutor: *What should happen to the glucose now? Why do we need glucose?*

Answer: *We need glucose for energy - just like we put petrol in the car to allow the car to run, human beings need a constant supply of glucose to provide them with the energy to breathe, move and function every day.*

Tutor: *So how do we get energy from glucose? Where does the glucose have to go? What is required for this process to happen? Have a look at the remaining labels and see if you can piece together the remaining picture.*

Encourage the group to place the following labels in the correct place: the insulin arrow from the pancreas to the blood vessels; the insulin (black and white check shape) in the blood vessel; an arrow to show that both the glucose and insulin travel to the cell wall; the insulin fitting like a key onto the cell wall allowing glucose to enter the cell; the glucose being converted to energy.

Tutor: *So now we know that the glucose from carbohydrate food passes into the blood vessel and is then carried to body cells with insulin. The insulin allows the glucose to pass into the cell where it is converted into energy. What happens then if the pancreas stops producing enough insulin?*

Answer: *Blood glucose levels will rise above the normal range for the general population (3–7 mmol/l) and the person will feel tired because they are no longer producing enough energy.*

Tutor: *Alternatively, people may be producing enough insulin but because they are overweight, their fat cells are bigger. How do you think bigger fat cells effect the lock and key action of insulin? Try to fit the insulin to the cell wall of the overweight cell, what do you notice?*

The participants will see that the insulin does not fit properly to the cell wall of the large cell.

Tutor: *You have probably heard the term insulin resistance. Well, when the insulin no longer fits properly on the cell wall, it becomes less efficient at allowing the glucose to pass through into the cell and glucose builds up in the blood just like it does when the*

pancreas stops producing enough insulin. So what happens to the extra glucose in the blood? Where does it go? Which labels / images describe what happens?

Encourage the participants to look at the labels/images that still remain and choose the image that best describes what happens to the glucose. Steer the participants towards choosing the picture of the waterfall. Discuss how the extra glucose flows out in the urine drawing out with it extra water. Link these actions to the symptoms of diabetes i.e. tiredness, thirst, dry mouth, frequent urination etc.

Tutor: *Now we know that if there is a shortage of insulin or the insulin does not work properly, blood glucose levels rise in the blood and can spill out in the urine causing symptoms of diabetes i.e. dry mouth, thirst, frequent urination and lack of energy. Once diabetes has been diagnosed it is important to have regular blood tests to see if blood glucose levels are being controlled. There are different methods for assessing blood glucose levels: random blood glucose; fasting blood glucose; and glycated haemoglobin or HbA1c. What are these tests and what do they mean?*

Support the group in exploring the differences between the various blood glucose tests and develop an understanding within the group of the necessity for each one.

Answer: *Blood glucose tests give an indication of the amount of glucose in the blood at the time when the blood sample is taken. Therefore it does not give information about how well that individual's diabetes is controlled overall. One way to perform a blood glucose test involves pricking the finger and placing a drop of blood on a test strip. The test strip is then analysed by a blood glucose meter. Alternatively, a blood sample may be taken from a vein in the arm and analysed at the hospital. A fasting blood glucose test is taken when the person has not eaten anything overnight or for approximately 12 hours. A random blood glucose test is taken any time.*

Tutor: *What is the ideal pre-meal blood glucose range in people with diabetes?*

Answer: *The ideal pre-meal blood glucose range in people with diabetes is 4 – 7 mmol/l.*

Tutor: *A blood glucose test taken two hours after a meal gives an indication of how well the body is controlling the glucose from the last meal. What would a reading above 10 mmol/l suggest?*

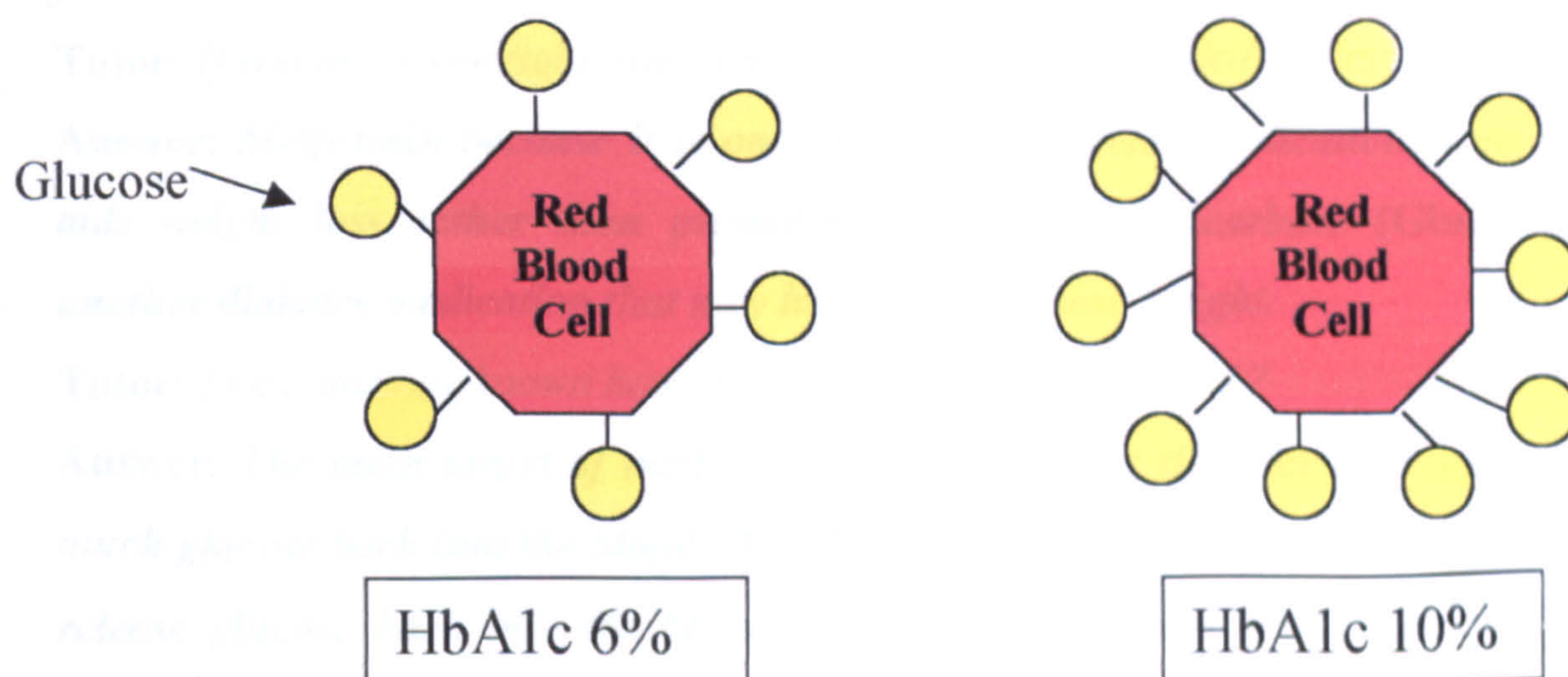
Answer: *Either the carbohydrate portion of the meal is too large or the individual is not using enough glucose due to inactivity or the tablets/insulin are not controlling blood glucose levels adequately and a review is required.*

Tutor: *What is the glycated haemoglobin (HbA1c) test?*

Answer: *This blood test is normally taken from the vein in your arm and sent to the hospital laboratory to be analysed. It is the most important tool to help you and your diabetes care team understand how well your diabetes is controlled. The test shows the average level of glucose in your blood over the last two or three months. People without diabetes usually have an HbA1c of between 4.0% and 6.3%. A person with diabetes is considered to have excellent diabetes control if they have an HbA1c below 6.5%. Generally speaking the lower the HbA1c, the lower the risk of developing problems due to diabetes. Depending on your own circumstances it is recommended that you aim for a level below 7% but for some people a level up to 7.5% may be acceptable.³ You will need to discuss an appropriate level of diabetes control with your diabetes care team.*

One easy way of visualising glycated haemoglobin is to think about glucose sticking to red blood cells (draw diagram on flipchart or show visual aid 3 – figure 4.4).

Figure 4.4 Glycated haemoglobin (HbA1c) model



(visual aid 3)

Tutor: *Can anybody suggest why there may be a problem if there is too much glucose attached to the red blood cells for too long?*

Answer: *If too much glucose remains in the blood for too long, the blood may become too thick or too sticky. This increases the future risk of developing health problems due to diabetes. The potential longer-term complications of diabetes will be discussed in week five of the course.*

Medication and insulin

Tutor: *Initially most of you will have been advised to follow a healthier diet and do more physical activity as a means of controlling your diabetes. Some of you will still be controlling your diabetes solely through maintaining a healthier lifestyle. Others may*

³ National Institute for Clinical Excellence, *Management of Type 2 diabetes (Management of blood glucose)*. September 2002.

be taking medication and/or insulin in addition to a healthier lifestyle. At what point would somebody require medication or insulin and how do these treatments work?

Answer: If a healthier lifestyle – through sensible eating and increased physical activity – are unsuccessful in controlling blood glucose levels, with the result that the majority of blood glucose tests score above 7 mmol/l (HbA1c result above 7%), that would suggest the pancreas is either not producing enough insulin or the insulin it is making is not working properly i.e. insulin resistance.

Tutor: There are many different diabetes medications. Can anybody name medications that have been shown to reduce insulin resistance?

Answer: The glitazones e.g. rosiglitazone (Avandia®) or pioglitazone (Actos®). Metformin (Glucophage®) has also been shown to help insulin work better. Most medications have two names, the general name and the trade name. This can be quite confusing, but generally both names will be on the packet. It may help you if you are familiar with both names.

Tutor: If you are overweight, which medication is recommended as first line treatment?

Answer: Metformin because it is one of the few diabetes medications that actually aids weight loss rather than promoting weight gain. Acarbose (Glucobay®) is another diabetes medication that may help people to lose weight.

Tutor: Does anybody know how metformin and acarbose work?

Answer: The main target of metformin is prevention of the liver from releasing too much glucose back into the blood. We all store glucose in the liver. Between meals we release glucose back into the blood to keep blood glucose levels stable. However, people with diabetes have been shown to release too much glucose causing the blood glucose levels to rise too high. Metformin also helps insulin to work more effectively. Symptoms of bloating, wind and reduced appetite are all known side effects of metformin. You can reduce these side effects by starting on a small dose and gradually increasing it. Acarbose works in a different way to metformin. It slows down the digestion of carbohydrate food. Blood glucose levels therefore rise more slowly, allowing the insulin more time to clear the glucose. This medication helps weight control because the food stays in the stomach for longer, thereby reducing the appetite.

Tutor: Which medications have we not discussed yet?

Answer: A class of medications called sulphonylureas, the most commonly prescribed one is gliclazide (Diamicron®, Diaglyk®). They work mainly by stimulating the

pancreas to make more insulin. They are normally taken before meals once or twice a day.

Tutor: *There is one more type of diabetes medication that we have not discussed. Does anybody know what it is?*

Answer: *A newer class of tablets called prandial glucose regulators. There are currently two medications in this category: repaglinide (NovoNorm®) and nateglinide (Starlix®). These work in a similar way to sulphonylureas but they are usually taken with a meal and they only work whilst the food is digesting, thereby reducing the risk of hypoglycaemia.*

Tutor: *In week one of your manual you will see a Diabetes UK summary of medications. Have we discussed all of the diabetes medication that you are currently taking? Any questions? There is also an information sheet about different types of insulin. Because there are only a few participants taking insulin, we haven't the time to discuss each possible regimen today. Most of you will get specific information regarding your insulin from your diabetes care team. However, if you have questions, please ask after the session.*

If individuals ask questions and you are not absolutely sure of the correct answer, it is advisable to inform them that you will find out before the next session.

Tutor: *Before we move on, what happens if you forget to take your tablets?*

Answer: *If it is only one or two hours since you missed a dose, then take the tablet(s) as soon as you remember. However, if it is longer than two hours then leave them and take your next tablets at the usual time. Do not double your next dose – Why not?*

Answer: *You would be at an increased risk of developing low blood glucose levels/hypoglycaemia.*

Tutor: *These recommendations are only a guideline. Your diabetes care team may recommend another course of action depending on your personal circumstances. However, missing your tablets on a regular basis will affect your diabetes control. What can you, or do you, do to remind yourself to take your medication correctly?*

Ideas may include purchasing a dispensary container, keeping the medication by the kettle, setting an alarm clock etc.

Activity two: Diabetes Health Profile

Tutor: *You will see a section in your manual called 'diabetes health profile' (figure 4.5). The diabetes health profile form shows you the main factors that your diabetes care team (doctor, nurse, dietitian etc.) take into consideration when they monitor your*

diabetes. These are **your** health results and it may help you to self-manage your diabetes if you know what these health results are and what they mean.

EXPLANATION OF HEALTH RESULTS AND NORMAL RANGES

Body Mass Index (refer participants to the BMI handout in their manuals, an example of which is shown in figure 4.6 below)

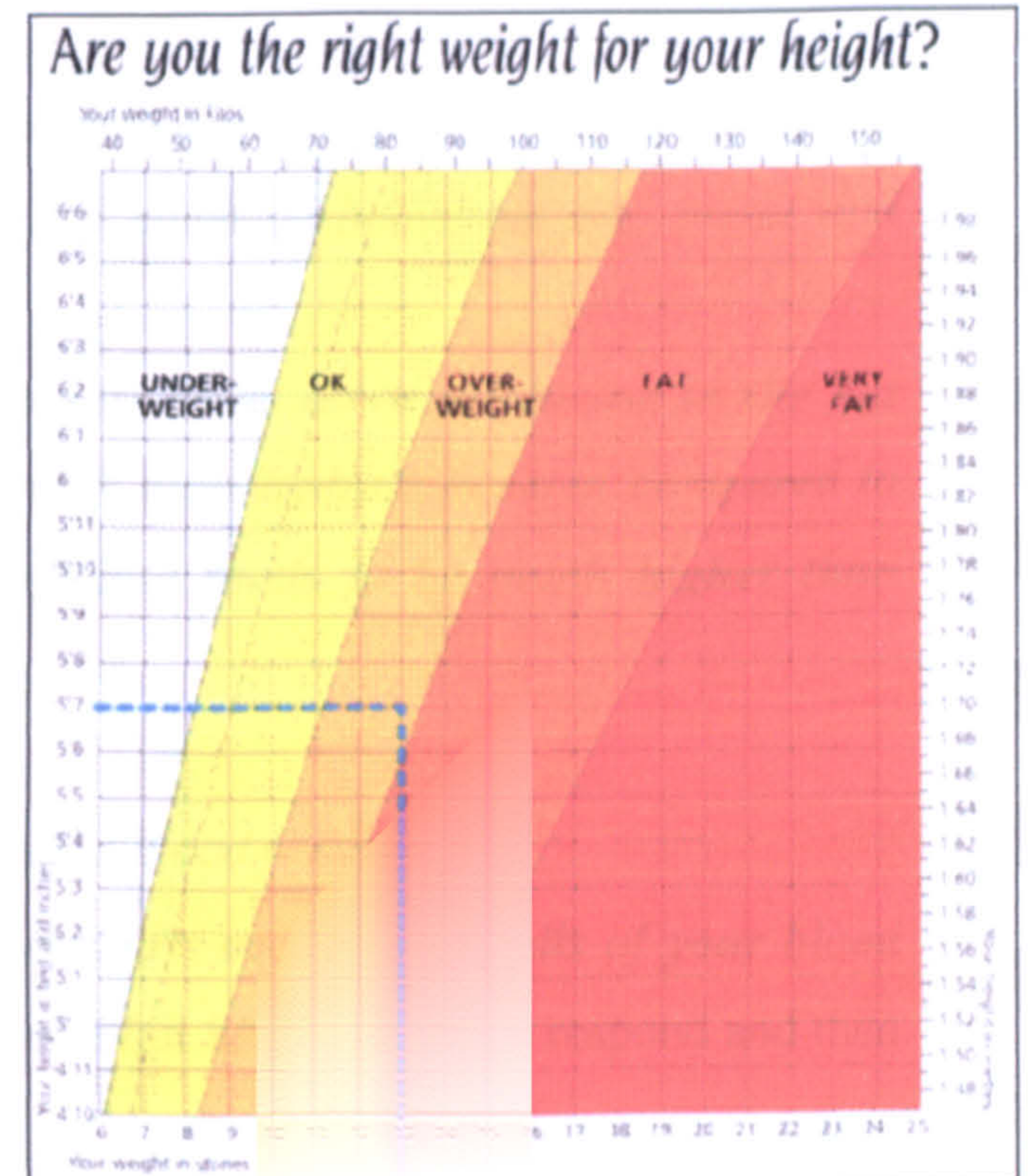
Tutor: Can anybody tell us why these health results are recorded and what they mean? Lets start with Body Mass Index (BMI). What is BMI?

Figure 4.5 Diabetes health profile

DIABETES HEALTH PROFILE FOR		
	RESULT	NORMAL RANGE
Weight Kg (st lb)		
Height M (ft inch)		
BMI (Kg/m ²) (weight for height calculation)		20 – 25 = healthy 26 – 30 = overweight 30+ = obese
Waist Size (inches)		Men: Less than 37 inches is healthy Women: Less than 32 inches is healthy
Blood Glucose (mmol/l)		Pre-meal: between 4 - 7 2 hrs after meal: less than 10
HbA1c (%) (Average blood glucose)		Less than 6.5% is excellent 6.5–7.0% is good 7.0–7.5% is OK Above 7.5% is poor control
Blood Pressure (mmHg)		Below 140/80 is good Between 140/80 and 160/90 lifestyle changes / medication Above 160/90 lifestyle change and medication needed
Total Cholesterol (mmol/l)		Less than 5.0
HDL (mmol/l) (good cholesterol)		More than 1.2
LDL (mmol/l) (bad cholesterol)		Less than 3.0
Triglyceride (mmol/l)		Less than 1.7 excellent Less than 2.3 good

(Source: Deakin 2000)

Figure 4.6 BMI calculator



(Source Food Standards Agency)

Answer: BMI is an assessment of people's weight for height and gives an indication of whether somebody is underweight (BMI below 20), normal weight (BMI 20-25), overweight (BMI 25-30) or very overweight (BMI over 30). Ask participants to turn to the relevant page in their manual and use the chart to estimate their own BMI.

Waist circumference

Tutor: If we can calculate BMI, which you have just told me is an indicator of whether you are a healthy weight for your height, then why is the waist measurement also useful?

Answer: If people gain weight around their middle, they are at a greater risk of developing heart disease. However, if people are more prone to storing excess weight on their bottom and thighs, they are less likely to develop heart disease.

There is no time scheduled into the expert patient programme sessions for a waist measurement exercise to be performed, but you could quickly explain the correct way to

take the measurement at home: the appropriate measurement site is midway between the lower rib and hip bone. Tell your group not to pull the tape too tight, stand relaxed and breathe out gently. **Demonstrate.**

Blood glucose levels

Tutor: *We have already discussed how a single blood glucose test does not give a full picture of overall diabetes control. Therefore the diabetes health profile form uses the glycated haemoglobin (HbA1c) test. What does this mean again?*

Answer: *The test is an indication of the average blood glucose level over the last 8-12 weeks (2-3 months).*

Tutor: *What would happen to your diabetes control if you kept your activity levels and diabetes medication the same but ate twice as much carbohydrate e.g. bread and potatoes throughout the day?*

Answer: *All carbohydrates (sugars and starches) break down to glucose in the gut and raise blood glucose levels. If twice as much carbohydrate is eaten compared to the usual intake you would expect blood glucose levels to be much higher than normal.*

Blood pressure

Tutor: *Now we move onto blood pressure. What is blood pressure?*

Answer: *It is the amount of force your blood exerts against the walls of your blood vessels.* **Tutor:** *What do the two readings mean?* Wait for the group to respond and then summarise.

Answer: *The first and larger number (systolic pressure) is the pressure against the blood vessel wall when the heart beats and pumps the blood into the vessel. The second and smaller number (diastolic blood pressure) is the pressure against the vessel wall when the heart is at rest.*

Take a modelling balloon and a small hand pump. Pump air into the balloon to demonstrate the heart pumping blood into the blood vessel and explain that the force/pressure on the side of the balloon would be equivalent to the systolic blood pressure. Now let the air out of the balloon and ask the participants to state what is the pressure in the 'blood vessel' now? (refer to visual aid 4).

Tutor: *What is hypertension?*

Answer: *Hypertension is raised blood pressure. For people with diabetes this means readings above 140/80. For the general population hypertension is diagnosed when readings rise above 160/90. The guidelines are stricter for people with diabetes because the combination of raised blood glucose levels and raised blood pressure can*

lead to the development of longer-term complications of diabetes. If blood pressure readings are raised, another two readings should be taken over a two-month period to confirm the diagnosis.

Tutor: *Why is hypertension called the silent killer?*

Answer: *Experiencing raised blood pressure on an ongoing basis does not have any physical symptoms and therefore it is harder for people to understand the importance of obtaining blood pressure goals if they do not feel poorly. Raised blood pressure is very common in people with diabetes. However, controlling blood pressure is as important for preventing longer-term complications of diabetes as obtaining good blood glucose control.*

Tutor: *What could you do to reduce your blood pressure?*

Answer: *Reduce body weight, increase physical activity, reduce dietary salt intake, increase calcium intake from milk and dairy foods, and have more fruit and vegetable to increase potassium intake. There is an information sheet on blood pressure in your manual.*

Blood fats

Tutor: Finally what about blood fats? What is cholesterol?

Answer: *Cholesterol is a fat that is present in our blood. Often people with diabetes can have a raised cholesterol level. This is caused by the body itself producing too much cholesterol or by an excess intake of animal (saturated) fat.*

Inform the group that identification of foods that contain high levels of saturated fat will take place during weeks two and four.

Tutor: *What is the difference between good and bad cholesterol? How can we have too much bad cholesterol in our blood? Why is this harmful?*

Answer: *Your total cholesterol level is the combination of 'good' (HDL) and 'bad' (LDL) cholesterol. Good (HDL) cholesterol helps to clear the blood of bad (LDL) cholesterol (ask the group to refer to the relevant sections on the health profile sheet). Too much total cholesterol (above 5 mmol/l), or 'bad' cholesterol at a level above 3 mmol/l or 'good' cholesterol less than 1.2 mmol/l all increase the risk of heart disease.*

Inform participants that dietary modifications shown to improve the blood fat profile will be discussed during the supermarket tour. Advise also that cholesterol-lowering medications may also be necessary in conjunction with lifestyle change.

Tutor: *What are triglycerides?*

Answer: *Triglycerides are another type of fat in the blood. Triglyceride levels are often raised in people with diabetes. There are specific changes you can make to your lifestyle that help to reduce the triglyceride level. Examples are increased consumption of oily fish, weight loss and a controlled alcohol intake. These lifestyle changes will be discussed in more detail throughout the programme.*

Self-awareness

Provide pencils to the participants and ask them to complete the *diabetes health profile* with their health results. If they do not know what their health results are, ask them to estimate what they think they might be. Encourage them to take the *diabetes health profile* with them when they next have an appointment with the diabetes care team and to complete it with their actual results. After all, they are *their* health results!

If participants have specific questions regarding their own health profile, remember that you do not have access to their medical records and therefore can only give general advice. However, there is a section on the back of the diabetes health profile form where they can write down any personal queries and discuss these with their diabetes care team during subsequent visits.

BREAK (15 minutes)

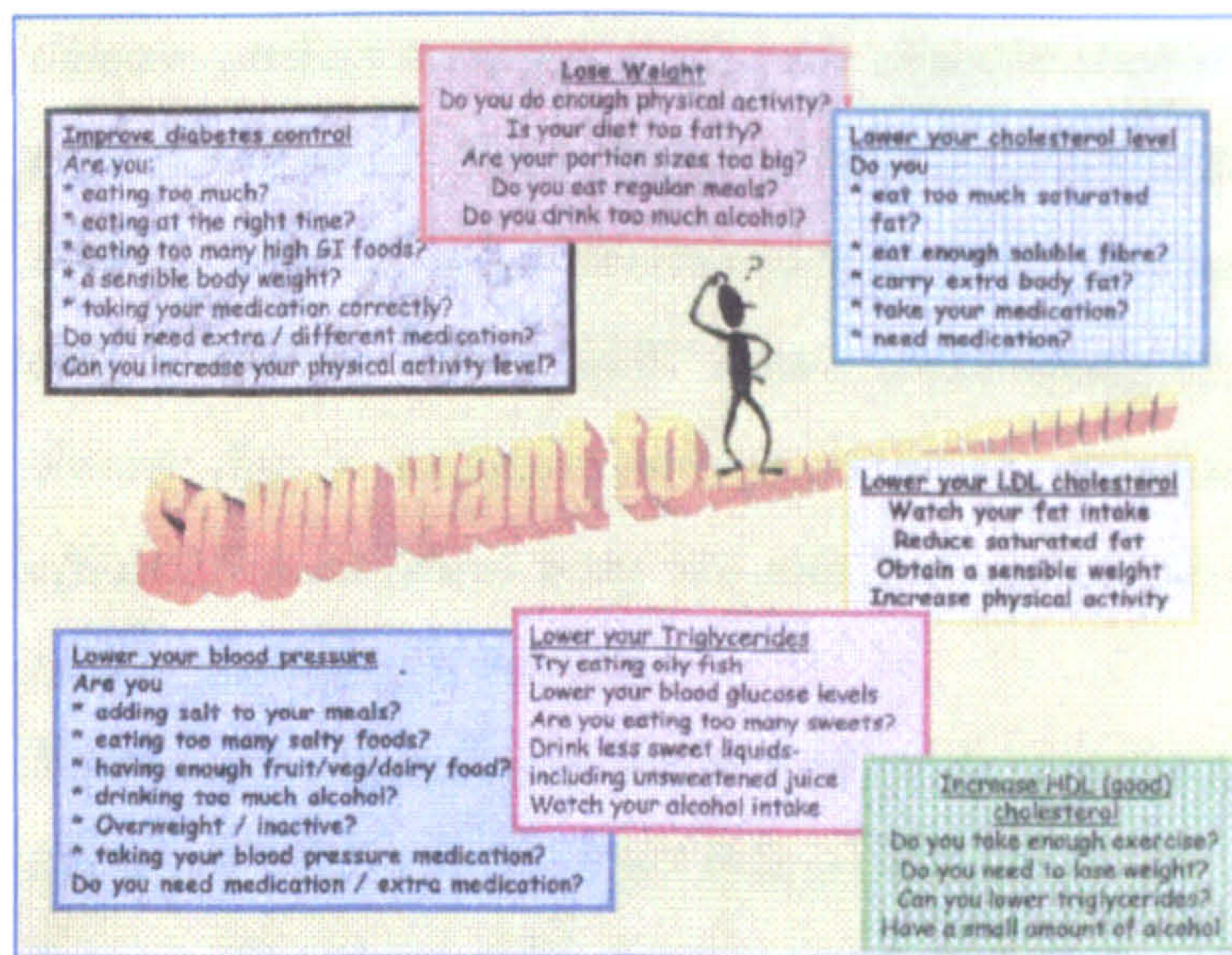
If possible obtain a budget for refreshments as this will help to build a rapport between participants. This is also an excellent opportunity to encourage healthier snacks by providing natural nuts, dried fruit, oatcakes, malt loaf, etc. You could even encourage home baking of low fat fruit loaves for example by providing samples and photocopying the recipes.

4.3.2 Lifestyle experiment

Overview

The final 30 minutes of each session is allocated to the “lifestyle experiment”. Participants are encouraged to complete their *diabetes health profile*. The lifestyle experiment session is not didactic in nature and it is intended to enable people to make informed decisions regarding their health results.

Figure 4.7 Patient handout 'so you want to.....'



The participants receive a one-page handout called 'So you want to.....' (see figure 4.7).

If they wish to improve certain aspects of their health the checklists are useful pointers to help them make lifestyle changes that will bring about the desired effect.

These sessions are intentionally

named 'lifestyle experiment' because 'experimenting' is less likely to make people feel like a failure if they try something and it doesn't work. This section of the manual includes exercises intended to raise motivation, increase the driving forces for change, and remove or reduce the restraining ones. Each week people are encouraged to try a different experiment or to continue with one already started. Participants keep a record of any experiments undertaken and learn from past experiences (see figure 4.8 below).

Figure 4.8 Patient worksheet to encourage monitoring of experiments

Problem	Lifestyle Experiment	Start Date	Stop Date	Result	Comments
Unfit	e.g. Walk for 20 mins, 3 times per week	14/4/01	21/4/01	OK	Almost didn't make it once - but feel better afterwards Will continue
Overweight	e.g. Change from full-fat milk to semi-skimmed milk	21/4/01	28/4/01	Difficult!	Couldn't stand it at first, it's getting a little better now. Will try for one more week!
Tired	e.g. Will start monitoring blood glucose levels 4 times / week before meals and 2 times / week 2 hours after meals	28/4/01	5/5/01	No Problem	Once I got use how to do it - it didn't take any time and made me feel more in control of my blood glucose levels.

Each lifestyle experiment session to last 30 minutes every week

Tutor: *The 'lifestyle experiment' section incorporates the goal-setting part of the empowerment model. The health service was developed at a time when acute illness was the main cause of ill health, such as infectious and bacterial diseases. Health professionals were, at that time, trained to take charge of patients' health, often because patients were too unwell to do anything themselves.*

However, there has been a shift in the nation's health with a huge decline in acute disease and an increase in chronic disease such as diabetes, heart disease, cancer and arthritis. You all have diabetes but you may also have other chronic conditions. On average people with diabetes consult health professionals for just three hours each year and spend the other 8,757 hours self-managing their diabetes. Recent studies have shown that a didactic and prescriptive approach by health professionals may be effective in the short term but that it does not produce long-lasting positive results for people with chronic disease.

How many of you have been told to do something by a health professional that you know will not work for you? (Discuss)

Tutor: *Who is the 'expert' in how best to live with diabetes?*

Answer: *The person with diabetes. You are all more experienced about living with diabetes than a professional who does not have the condition and each one of you will have a slightly different experience.*

Tutor: *Therefore who is better placed to define problems and set goals to address those problems?*

Answer: *A well-informed person with diabetes is in a better position to define and explore his/her own diabetes related problem, to identify possible solutions and to commit to action.*

Tutor: *The theory attached to this part of the expert patient programme is that you can be encouraged to define your own problems associated with diabetes, identify possible solutions and commit to action. This way you are more likely to achieve your goal. We all have ideas about how we can make our lifestyle healthier but sometimes we have difficulty committing ourselves to change.*

In the lifestyle experiment section of your manuals you will see a goal setting form. Let's work through this.

Goal setting

1. Identify a problem

Tutor: *At the start of today's session you all shared with us two problems you were having with your diabetes. I'm handing out a sheet with four titles. Under 'identifying a problem' write down what your main problem is.*

E.g. "Boring and restricted diet"

2. Explore possible solutions

Tutor: *Based on what you've learnt today what do you think could be a possible solution to your problem? Write down as many ideas as possible.*

E.g. “Based on what I have learnt today I am not going to confine myself to the foods I previously felt were good and safe. Instead I am going to try and increase the variety of foods in my diet. There are a lot more foods that are good for me like, dried fruit, but I was excluding them because I felt they were bad for my diabetes.”

“ I could also start to self-monitor my blood glucose levels to see how different meals affect my diabetes.”

“I could try to be more active, this could help me burn off more calories and help me to worry less about my diet.”

3. Commitment to action

Tutor: Choose one or two possible solutions from the above list that you feel you could actually carry out and state how you are going to do it.

“I am going to go to a supermarket next week with a friend who I’ve met on the course. We will attempt to purchase a more varied selection of food. I will also see my GP and request testing strips for my blood glucose meter and start to monitor my blood glucose levels.”

“I am going to start walking with Mrs X for 10 minutes each day and to try to gradually build up to 20 –30 minutes each day.”

4. Evaluation

Tutor: Now state how long you are going to commit to your chosen action for and when you may have an idea whether it has worked or not.

“I have just had a blood test to assess my average blood glucose control. During the last 2 – 3 months, my diabetes has not been well controlled. I will try my new approach and go back to my GP in three months and ask him if he will repeat the HbA1c blood test.”

Tutor: I will give you five minutes to complete this form and we will then discuss your responses.

Tutor: How did you feel filling out the form? Have you identified possible solutions? This is a four-step approach to goal setting that was developed by Bob Anderson and Martha Funnell at the Michigan Diabetes Research & Training Centre. You will also notice in your manual the lifestyle experiment form with three examples provided by people with diabetes. The form allows you to log your experiments and there are three blank forms for your use. If you require extra forms please ask. At the bottom you will notice that you are being encouraged to be SMART⁴. Be Specific – what are you going to do and when? Is it Measurable - can you measure the time it takes, how frequently you do it? Is it Achievable – on a scale of 1 to 10 how confident are you that you can

⁴ SMART is an acronym for a process that encourages efficiency in time management and conduct.

achieve the goal? If you are not very confident i.e. a score of only two or three, should you be choosing that goal? Is it Realistic – can it be continued long-term? Finally, time – set yourself a Timescale for trying the experiment and if successful, a timescale to achieve the goal. Why do you think it is called an experiment?

Answer: If it doesn't work out for you, you haven't failed. It was an experiment, learn from your experience and try something else.

Tutor: The other materials in the lifestyle section of your manual are there to help you set goals. We will quickly go through them now but hopefully you will look at them in more detail at home:

'So you want to.....' What does this handout give you?

Answer: It offers some pointers in the right direction if you wish to improve your health results (Read out one or two examples if there is time).

Tutor: 'Your health'..... How will these questions help you?

Answer: The list of questions will help you identify reasons and motivation for change.

Tutor: 'Driving forces versus restraining forces'..... What are driving and restraining forces? Can you give me an example?

Answer: Driving forces are motivation for change and restraining forces are barriers to change. This exercise is really useful if you are not sure whether you can achieve the change. For example if the goal is weight loss, the necessary change may be eating less food and increasing physical activity. The motivation i.e. driving forces to make the change may be looking and feeling healthier, improved diabetes control, fitting into clothes in your wardrobe that you haven't worn for several years etc. However, the restraining forces or barriers that are preventing you making a change may be friends tempting you with biscuits, feeling unsafe to go out for a walk or eating when you are bored.

You may find that you can add things to your driving forces for example putting a picture of your grandchildren on your fridge. This may remind you that you want to stay healthy to see them grow up. You may remind yourself that you don't wish to increase your diabetes medication/have to take diabetes medication and you know that this is less likely to happen if you manage to lose weight.

You may remove restraining forces by asking your friend to supply fruit when you visit instead of biscuits or even better ask her/him to go for a walk with you. You will see how small steps can help make change more acceptable.

Tutor: Finally 'Questions to help'as I said we learn from our mistakes so this exercise encourages you to evaluate and learn from your goal setting.

We will discuss goal setting in the lifestyle experiment session every week. We will either discuss these as one large group or split into smaller groups. We will learn from each another about what we each find useful, experiments that have worked and experiments that have been less successful. These discussions will help other group members set their own goals. Hopefully, these sessions will help you feel more empowered. By empowerment we mean feeling more knowledgeable, skilful and confident to make informed decisions regarding your diabetes and lifestyle.

If there is time remaining, either have a general whole group discussion regarding goal setting or split the participants into groups of four or five and ask them to discuss possible goals. When the two-hour session comes to an end, thank the participants for coming and make sure they are clear about the arrangements for the following week. Ask participants to bring their manuals and name tags to every session.

4.3.3 Week two - weight management

Overview

Figure 4.9 Energy balance model Figure 4.10 Body story video



Visual aid 5



Visual aid 6



Visual aid 5 (repeated)

A simple seesaw approach (see figure 4.9 above) clearly shows the concept of energy balance. Pictures of common foods eaten throughout the day and pictures of different physical activities, such as, dog walking, bowling, swimming, and gardening have been selected and laminated to illustrate an explanation of energy balance. A video recorded from the Channel 4 programme 'Body Story – Fat Attack' is also used (see figure 4.10 above). It presents as a light hearted picture, drawing out the disadvantages of 'crash dieting' while emphasising the advantages of physical activity and sensible eating when trying to lose weight.

'The Balance of Good Health' (see figure 4.11 overleaf) should then be discussed and the participants encouraged to analyse their own diet, including estimating the number of portions of food they consume from each food group on a typical day and how that

deviates from government recommendations. Simple exercises are provided if participants wish to set themselves experiments to work towards improving their diet.

Figure 4.11 The 'Balance of Good Health' model



Visual aid 7

The final part of the weight management session takes the form of a discussion about the benefits of physical activity. A local exercise consultant is invited to talk to the participants about the 'exercise on prescription' scheme.

Activity one: energy balance (10 minutes)

Present the handout pack to the participants as they arrive and advise them to place it in the 'week two' section of their manuals. Welcome the group and inform them that you are going to cover weight management, the balance of good health and the benefits of physical activity. Use visual aid 5 (seesaw model) to demonstrate energy balance.

Tutor: *In theory, energy balance is simple. If the calories required from food and drink are equal to the calories burnt during the breathing process, physical activity and general living, what happens to a person's weight?*

Demonstrate this by quickly using the laminated illustrations to place a similar number of food pictures and physical activity pictures on the respective sides of the seesaw to indicate that weight remains stable.

Answer: *Their weight remains stable. What happens if the person starts eating more?*

Add to the illustration the pictures of extra large food portions, the whole packet of biscuits and the whole bottle of wine. Watch the weight gain side of the seesaw rise.

Answer: *Their body weight increases.*

Now remove the extra food until the seesaw is stable again and add more pictures showing physical activity. Watch the weight loss side of the seesaw rise.

Tutor: *What happens if somebody starts being more active?*

Answer: *They burn more calories and this helps them to lose weight.*

Tutor: *What do you think is the best way to lose weight?*

Answer: *A combination of reducing food intake by 500 calories per day and an increase in physical activity has been shown to be the most successful way of reducing weight. A common approach to weight loss is to go on a diet for a limited period of time. However, more permanent changes to lifestyle are required for long-term success.*

Tutor: *On average, a woman requires 2000 calories each day to maintain her weight and a man requires 2500 calories. In the handout pack you received today you have a copy of the Schofield equation. This allows you to calculate your exact calorie requirement using your age, current body weight and physical activity level. There is an example that shows you how to do the calculation. I will demonstrate this in the lifestyle experiment session after the break.*

Activity two: fat attack video (20 minutes)

Tutor: *We will now watch a video recorded from Channel 4 which clearly shows, in quite a humorous fashion, that crash diets don't work.....*

Visual Aid 6: Body Story – Fat Attack video (show the video and discuss afterwards).

Tutor: *What are the main messages in this video?*

Answer: *That going on a strict diet can appear to be successful initially but the weight loss is mainly water. Before long the weight loss slows down because losing fat is a much slower process than losing water. Also, the body detects that food intake has been dramatically reduced and stops burning as many calories to guard against famine. Generally it is only a matter of time before the person starts craving high fat and sugary food and a struggle develops to fight those cravings. It is rare for people to resist such cravings for long with the result that the 'diet' is broken. A sensible eating plan (as opposed to a diet), which allows people to continue to eat their favourite foods in small amounts, and simultaneously increase their physical activity levels has been shown to be a more successful and desirable approach.*

Activity three: balance of good health (20 minutes)

Tutor: *We have learnt that a sensible eating pattern is more effective than going on a diet. What does "sensible eating" mean? We will use the 'Balance of Good Health' model to explore a sensible approach to eating.*

Display Visual Aid 7: Balance of Good Health tabletop model with plastic food models and empty food cartons.

Tutor: *What are the five main food groups that contribute to our daily intake?*

Answer: *Fruit and vegetables, starchy carbohydrates, milk and dairy food, protein foods, and fatty/sugary foods.*

Tutor: *How many portions of each of these food groups should we have each day and what is a portion?*

Work through each food group asking the participants to place relevant food models on the correct section of the 'Balance of Good Health' and to state the recommended range of daily portions. Use the 'Balance of Good Health' information sheet in the 'week two' section of the manual as a guideline. After the activity, refer the participants to the information and example sheets in their manual. The example sheets give suggestions as to how many portions from each food group would constitute a total daily intake of 1100 calories, 1600 calories, 1800 calories, 2100 calories and 2800 calories respectively.

Tutor: *You will notice a blank 'Balance of Good Health' sheet in your manual. During the lifestyle experiment session after the break, I will ask you to choose a typical day and complete this form to assess how many portions from each group you are currently eating. You can then use the Dietary Action Plan to compare your diet with current recommendations and estimate how many calories you are consuming on a daily basis. You will be able to decide whether you think this is appropriate or not. The Dietary Action Plan may help you to experiment with healthy patterns of eating in order to find a combination that is suitable for you.*

Activity four: low fat versus high fat diet (10 minutes)

Tutor: *As you will know, high fat diets contain a lot more calories than low fat diets. The yellow sheet in this week's section of your manual describes two diets, one on either side of the page. Which diet is the low fat one and which is the high fat one? Can anybody estimate the number of calories in each diet and guess the percentage contribution of fat?*

Answer: *Diet number one is the low fat diet providing 1,871 calories and 19% fat; diet two provides 4,420 calories and 48% fat.*

Tutor: *I am handing out the answer sheet with the analysed diet and you may agree that both diets could be typical diets consumed by many. Why have I shared this information with you?*

Answer: *You don't have to starve yourself to lose weight. The quantity of food in the low and high fat diet is similar. Making small changes to reduce the quantity of fat in the diet will dramatically reduce calories.*

Activity five: physical activity (15 minutes)

Tutor: We all know that physical activity is good for us. Can you state some of the benefits?

Write responses on a flip chart and briefly go through them:

- more energy;*
- improved sleep at night;*
- increased strength / greater stamina;*
- lower risk of heart disease or stroke;*
- reduces depression;*
- healthier bones;*
- helps weight control;*
- improves blood glucose control;*
- improves blood cholesterol levels;*
- reduces blood pressure.*

Tutor: Ok, we all know that being more active will improve our health. Recent research has shown that 30 minutes of walking each day has tremendous benefits to health. Very quickly can you give me other ideas of how you can become more active.....?.

Add these to a separate list on the flipchart and briefly discuss them. Provide leaflets to inform participants about the local 'exercise on prescription' courses if these are available locally or invite a local 'exercise on prescription' facilitator to come and talk to the participants after the session.

Tutor: What do you need to be aware of if you do start to take more exercise?

Answer: If we are more active, we use more glucose (fuel) to make the extra energy that the body requires. Therefore, more glucose is drawn out from the blood into body cells. If the physical activity is either prolonged or vigorous and people are taking insulin or certain tablets for their diabetes, they may find that their blood glucose levels drop below 4 and this is classed as a 'hypo'. Preventing hypoglycaemia is possible by either reducing insulin/medication before exercising or having an extra carbohydrate snack before and after exercising (Warn participants that an extra snack may not be necessary for less intensive activity). You should discuss with your diabetes care team which of the two is the better option for you. Symptoms of, and treatment for, hypoglycaemia are discussed in more detail during week five.

BREAK (15 minutes)

Lifestyle experiment (30 minutes)

Discuss the experiments that participants have attempted during the past week and ask if they have found goal setting useful. What have they learnt from the experience?

Ask for a volunteer who is prepared to give their weight, age and activity level (if nobody volunteers, use your own or invent one). Demonstrate, by writing on the flip chart, how to calculate individual calorie requirements. Inform participants that you are unable to calculate everybody's daily calorie needs during the session but that they can either stay behind at the end of the session if they need your help, or calculate their own at home. State that you will check the calculations next week if anybody would like that.

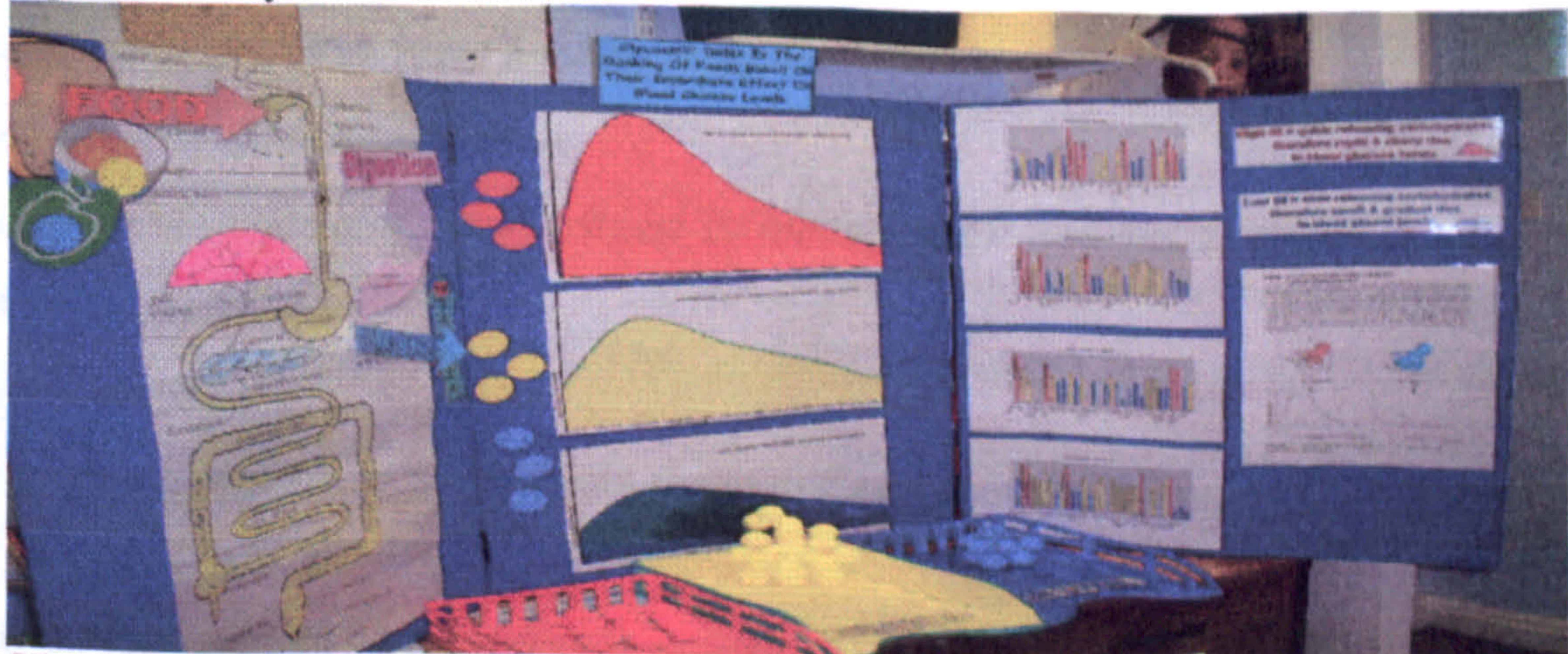
Now ask for a volunteer to provide an example of their daily food and drink intake (If nobody volunteers, ask the participants to invent a typical diet). Draw the 'Balance of Good Health' model on the flip chart and, with active participation from the group, demonstrate how to complete the exercise. Split the participants into groups of four or five and ask them to write down a typical day's food and drink intake. Working together as a group, ask the participants to complete the 'Balance of Good Health' forms (as you did on the flip chart) writing the foods in the correct section and identifying the number of portions from each food group. The group can then discuss their dietary action plans, identifying goals and setting themselves experiments to improve their diet.

The tutor and the tutor's assistant: You should move around the groups, giving assistance where necessary. At the end of the session ask people to continue working on their dietary action plans at home and invite them to contact you by phone with any queries. Inform the group that you will discuss the plans again next week.

4.3.4 Week three - glycaemic index

Overview

Figure 4.12 Glycaemic index visual aids



Visual aid 8

The glycaemic index is the ranking of foods based on their immediate effect on blood glucose levels. The theory that different carbohydrate foods exhibit different effects on blood glucose levels is now well researched and dispels the myths surrounding the 'sugar free' diet. Frost and Dornhorst have reviewed the evidence base for the glycaemic index and concluded that consideration of it when making dietary recommendations may lead to additional health benefits (Frost & Dornhorst 2000). Diabetes UK has provided patient information recommending the use of the glycaemic index (GI) (Diabetes UK 2001a).

Models have been developed to increase understanding of the GI concept (see figure 4.12 on page 139). The models were made from small balls connected with cocktail sticks and that structure was intended to show how all carbohydrate foods are made from building blocks of glucose. In simple terminology, the difference between high and low glycaemic foods is that the latter are constructed more securely; they break down more slowly and therefore release glucose more slowly into the blood. A quiz has also been developed. Photographs were taken of 120 common food and drink items. These were downloaded onto a computer, printed, cut out and laminated. In this session the participants are split into four teams and each team is provided with an envelope containing the pictures. The teams are asked to rank each food as high, intermediate or low GI, and to estimate for each type of food how big the portion size would have to be to provide the same carbohydrate as one slice of bread (10-15g). An important concept for the participants to understand is that for optimum diabetes control it is not the amount of sugar in food or drink that they need to be aware of, but the quantity and quality of carbohydrate.

Activity one: explanation of glycaemic index (35 minutes)

Have Visual Aid 8 'The Glycaemic Index Display' set up at the front of the room where all the participants can see it. Welcome the participants as they arrive.

Tutor: *Today we are discussing how the quantity and quality of carbohydrate affects blood glucose levels. If we refer back to week one, what is carbohydrate?*

Answer: *Starchy and sugary foods*

Tutor: *When starches and sugars digest in our stomach and small intestine, what do they break down into?*

Answer: *Glucose*

Tutor: *If the carbohydrate food breaks down quickly, how will this affect blood glucose levels?*

Point to the red chart as you discuss the answer.

Answer: *There will be a surge of glucose flowing into the blood. The body will not be able to cope with the glucose and therefore there will be a sharp rise in blood glucose levels.*

Tutor: *Alternatively, if the carbohydrate foods break down slowly, how will blood glucose levels be affected?*

Point to the blue chart as you discuss the answer.

Answer: *There will be a much slower rise in blood glucose levels, which will allow the body to handle the glucose load and produce energy a lot more efficiently. The glucose levels will be less likely to rise too high.*

Tutor: *There has been a lot of research into carbohydrates over the last few years. Originally we were led to believe that all starchy foods broke down and released glucose slowly and that sugary food released glucose much more quickly. Is this correct?*

Answer: *No, we now know that some starchy foods release glucose much more quickly than sugary foods.*

Tutor: *We can demonstrate this with models (pick up the red ball model). Lets pretend that this is a fast releasing carbohydrate. Carbohydrate is just lots of glucose stuck together. You can see that the structure is quite flimsy and pulls apart quite easily. So when this carbohydrate is eaten it releases its glucose into the blood quickly (point to the red chart). When would eating this type of carbohydrate be advantageous?*

Answer: *When an individual is having a 'hypo' i.e. experiencing low blood glucose levels and therefore needs to raise them quickly.*

Tutor: *Can you give me some examples of quick releasing carbohydrate foods?*

Answer: *Lucozade™, glucose tablets, old potatoes, white & wholemeal bread, cornflakes etc. You will probably get participants stating sugar, jam, pop etc. You should advise that these are intermediate carbohydrates, not quick releasing ones.*

Tutor: *Many of you probably think that sugar is a quick releasing carbohydrate. That is not entirely correct. Sugar, or sucrose to give its correct name, is made up from glucose and fructose whereas starch is made up purely from glucose. The fructose part of the sugar slows down its digestion and it is therefore classed as an intermediate releasing carbohydrate. Therefore most sugar containing foods such as jam and pop are also intermediate releasing. However, next week when we do the supermarket tour, we will look at food labels and you will see that some sugary food still has a high GI because, instead of containing sugar, it has a large quantity of glucose or glucose syrup added.*

As a general rule of thumb, the more processed the food, the quicker it digests and releases its glucose. People are often surprised to find that white and wholemeal bread release glucose at the same rate – why is this?

Answer: *The modern milling grinders process flour to a very fine consistency. Brown and wholemeal flour is ground to the same very fine consistency as white flour and therefore bread made from these flours release glucose at the same rate. Granary and stone ground flours produce bread that release glucose more slowly.*

Tutor: *This model (pick up the blue model – throw it in the air and catch it) represents slow releasing carbohydrates. What is different about it?*

Answer: *The structure is stronger and therefore tougher to break down. Consequently the glucose is released much more slowly into the blood (point to the blue chart).*

Tutor: *Can you give me some examples of slow releasing carbohydrates?*

Answer: *Fruits and vegetables; milk, yoghurts and fromage frais; nuts, seeds and pulses; All-Bran™, Porridge and Museli.....*

Tutor: *The ranking of carbohydrate foods according to their effect on blood glucose levels is called 'Glycaemic Index'. Carbohydrate foods that release glucose quickly are called high glycaemic index foods or high GI foods. Slow releasing carbohydrate foods are called low glycaemic index or low GI foods. Research has shown that individuals that eat more low GI foods have better diabetes control, better weight control and reduced heart disease risk.*

However, a note of caution: just because two teaspoons of sugar has less effect on blood glucose levels than a slice of bread or baked potato, does this mean we should encourage people to eat sugar instead of bread and potatoes?

Answer: *No. Many quick releasing or high GI foods are nutritious foods that provide the body with many nutrients. You may wish to replace white or wholemeal bread with granary or seeded bread; or cornflakes for museli; old potatoes for new potatoes, but to simply swap a high GI food for intermediate releasing sugar would not be a healthy choice. However, the GI concept does allow people more freedom with their diet and does dispel the myth that the diet has to be sugar free. People with diabetes can incorporate fresh fruit, dried fruit, malt loaf, cakes and desserts into a healthy balanced diet without feeling guilty.*

Activity two: glycaemic index quiz (40 minutes)

Split the group into four teams. Using Visual Aid 9 'The GI Quiz' give each team an envelope (A, B, C or D) with the relevant quiz sheet.

Tutor: *We have discussed how the quality of carbohydrate is important for good health and optimum diabetes control. Does the quantity of carbohydrate also matter?*

Answer: *All carbohydrate food breaks down into glucose and passes into the blood where it raises blood glucose levels. The higher the consumption of carbohydrate, the greater an effect it will have on blood glucose levels.*

Tutor: *An average slice of bread or piece of fruit contains around 10-15g of carbohydrate. It is easy to compare the quantity of other carbohydrates to a slice of bread. For example, how much table sugar would give us the same quantity of carbohydrate as a slice of bread?*

Answer: *2-3 teaspoons.*

Tutor: *Each group has been given an envelope. In the envelope you will find 16 pictures of food or drink. Working as a group, make an educated guess as to whether each item has a low, intermediate or high GI. Also estimate the portion size that would be needed to give you the same carbohydrate as a slice of bread. Just before we break for refreshments I will give you the answer sheet. You can swap your quiz sheet with another team and they will mark it for you. You will receive one point for the correct GI and one point for the correct portion size. The maximum points awarded are 32. The four answer sheets will be included in your 'week three' handouts, which will be distributed during the break.*

BREAK (15 minutes)

Consume refreshments and distribute the week three handouts for the manual. Display a copy of the book 'A Pocket Guide to the Glucose Revolution for People with Diabetes' which has been reviewed by Diabetes UK. The review is included in the handouts.

Lifestyle experiment (30 minutes)

For the first 15 minutes, discuss how the participants have been doing with their 'Dietary Action Plans' during the last week and ask if anybody wishes to share their experiments/goal setting experiences with the group (10 minutes).

After the discussion, ask the participants to re-assemble into the same groups as the previous week and refer them back to their completed 'balance of good health' sheets. Now ask them to observe their typical day's diet and mark each food/drink with either 'H' for high GI, 'I' for intermediate GI or 'L' for low GI. By way of assistance, invite them to consider the quiz answers and the GI charts displayed in 'week three' of their manuals. The groups should then be encouraged to discuss how they would be able to

lower the overall GI of their diet by swapping some high GI foods for low or intermediate ones. Inform the groups that they should experiment with this over the following two weeks and that you will discuss the lifestyle experiment session further in week five.

For the next 5 minutes, refer participants to the self-management forms in their manuals.

Tutor: *In week one we said that achieving optimum diabetes control meant obtaining a glycated haemoglobin or HbA1c of 6.5% or less. However, for some individuals achieving an HbA1c of 7.5% or less may be more advisable. Has anybody found out what his or her glycated haemoglobin is? If not then I'm sure that your diabetes care team will be happy to give you your last blood test result. If your result is too high what can you do about it?*

Answer: *Working through this self-management form may help you to improve your diabetes management.*

Read through the form and answer questions as they arise.

Tutor: *As we discussed in week one, self-management is the key to healthy living and good diabetes control. If you wish to improve your blood glucose levels then completing this form will help you. Try experimenting over the next two weeks. If you have any queries then please telephone me or ask me after the supermarket tour next week. We will discuss your progress in week five.*

Before participants leave make sure that everybody is aware of the time and meeting place for their supermarket tour. Also inform the group that it will not be necessary for them to bring their manuals.

4.3.5 Week four: supermarket tour

Overview

Figure 4.13 Example of supermarket tour



Figure 4.14 Guide to food labelling

Guide to Food Labelling	
A lot	A Little
10.0g of sugars	2.0g of sugars
20.0g of fat	3.0g of fat
5.0g of saturates	1.0g of saturates
3.0g of fibre	0.5g of fibre
0.5a of sodium	0.1a of sodium

(visual aid 10)

The supermarket tour (see figure 4.13 on page 144) has been a successful development in diabetes service provision within Burnley, Pendle and Rossendale, East Lancashire. Evaluations from previous tours have shown that it provides participants with the practical knowledge they desire whilst dispelling the myth that people with diabetes need a special diet. The learning process is a two-way one because it also helps the tutor to gain insight into the nutritional habits of different ethnic groups.

The tour

Welcome the participants and inform them that the tour will take between 1½ and 2 hours. As you progress around the supermarket, encourage people to ask questions as they arise. Reassure participants that you will be available afterwards to answer any queries regarding their lifestyle experiments. Have a GI pocket book for diabetes available and refer to it as necessary. Distribute Visual Aid 10 'Guide to Food Labelling' (see figure 4.14 on page 144) which has been adapted from the British Heart Foundation literature.

***Tutor:** You will probably find this leaflet useful for reading and understanding food labels. The handy reckoning card helps you to identify whether food and drink contains 'a little' or 'a lot' of total fat, saturated fat, sugar, fibre and salt. When you look at a food label, if the food is something you will eat in large amounts such as a ready prepared meal, you would look at the 'amount per serving'. However, for snacks, other foods and drinks you would look at the 'per 100g' information.*

For your diabetes and blood glucose control, which is of greater importance: total carbohydrate or total sugars?

***Answer:** You will recall from the session on glycaemic index last week that the quality and quantity of carbohydrate is more important than sugar intake.*

Encourage participants to read food labels, looking in particular at fat, total carbohydrate and fibre. Explain that the ingredients are listed in order so that the one there is most of is at the top of the list and the one there is least of is at the bottom of the list. Having discussions around the points below will help people to obtain a better understanding of nutrition, health and diabetes.

Cereals

***Tutor:** Which cereal contains more sugar and which cereal has the largest effect on blood glucose levels – Cornflakes or All Bran™?*

***Answer:** All Bran™ (20g sugar/100g) contains more sugar than Cornflakes (8g sugar/100g). However, Cornflakes are a highly processed cereal with low fibre content and so they digest into glucose quickly. Whereas All Bran™ breaks down into*

glucose much more slowly, resulting in a much more gradual increase in blood glucose levels.

Look at the food labels of other cereals and point out that the lower GI and healthier cereals generally tend to be the ones with either oats, fruit and/or nuts, for example, museli, Fruit & Fibre, porridge, Fruitful Shreddies™, Fruitabix™ etc. Weetabix, Shredded Wheat and Special K™ are not quite as processed as Cornflakes and Rice Krispies and are therefore intermediate GI.

Fresh fruit, dried fruit and fruit juice

Tutor: *Should people with diabetes have a restricted intake of these foods?*

Answer: *These foods were previously restricted due to their sugar content. We now know that fruit and fruit products break down into glucose slowly and therefore have less of an impact on blood glucose levels than we previously thought. Therefore fruit is encouraged and people do not need to worry about meeting the five a day recommendations for fruit and vegetables. As with the general population, fruit juice should remain at one glass per day, as it is less nutritious than the whole fruit.*

Regular meals and snacks

Tutor: *Why are regular meals important? Are snacks necessary for everybody with diabetes?*

Answer: *Although it has been shown that regular meals help to achieve better diabetes control. It appears that snacks are not necessary for all people with diabetes. Each individual should decide whether snacks between meals are important for them. They should base this decision on individual preference, their daily activity levels, and their treatment of their diabetes.*

Red meat

Tutor: *We are frequently led to believe that red meat is bad for us – is this true?*

Answer: *No, several cuts of red meat are now less than 5% fat and half of this fat is monounsaturated fat, which does not increase blood cholesterol levels. Therefore there is no need for people to ‘cut-out’ red meat from their diet. Individuals may choose leaner cuts of meat and cook it in a suitable manner (grill, bake, fry with monounsaturated oil) and still obtain a healthy and varied diet.*

Fats

Tutor: *Why are we advised to reduce saturated (animal) fat? Which foods are the main sources of saturated fat?*

Answer: *Saturated fats are found in butter, lard, cream, cheese, fatty cuts of meat etc. These fats raise bad (LDL) cholesterol levels and increase the risk of heart disease.*

Polyunsaturated fat e.g. sunflower margarines and oils have been shown to reduce total cholesterol levels but also have been shown to reduce the good (HDL) cholesterol. A common misconception is that polyunsaturated fat contains less calories – however all fats contain same amount of calories (1 tablespoon oil = 100 calories).

Tutor: What effect does monounsaturated fat have on the body and which oils/spreads contain a greater proportion of monounsaturated fat?

Answer: Monounsaturated fat has been shown to reduce total cholesterol levels but, unlike polyunsaturated fat, it is beneficial for good (HDL) cholesterol. Monounsaturated fat is also a lot more stable in the body and less likely to cause cell damage. Therefore individuals are advised to use oils and margarines, which contain a greater proportion of monounsaturated fat.

Tutor: Look on the food labels for margarines and oils. Which ones contain more monounsaturated fat?

Answer: Olive and rapeseed oil (many vegetable oils are pure rapeseed oil), Olivio™, Utterly Butterly™, and supermarkets own brand of olive oil/rapeseed margarines are some popular choices.

Tutor: Most of you have probably heard about margarines that claim to reduce cholesterol level e.g. Flora Pro-Active™ and Benecol™. Are these sensible choices?

Answer: Research studies have shown that when the daily recommended quantity of these spreads are consumed, total blood cholesterol levels are reduced. However, the daily recommended amount is 25-30g. Therefore people may actually end up eating more fat and calories in their diet. Further studies are required to assess the long-term impact. Individuals therefore need to decide themselves whether the extra cost for these products is necessary.

Remind people that there are other dietary modifications that reduce blood cholesterol levels.

Eggs and prawns

Tutor: Should the number of eggs eaten each week be restricted for people with diabetes? Do you need to avoid prawns?

Answer: Cholesterol in food does not increase blood cholesterol levels – saturated fat is the culprit. Eggs do contain cholesterol but they are not too high in saturated fat. Therefore eggs may be incorporated into a healthy, varied diet as a protein portion and do not have to be restricted to only 2 per week. Also, although prawns contain

cholesterol, they are actually very low in fat and a great source of selenium – it's just the prawn sauce that you should be careful with!

Fibre

Tutor: *Which fibrous foods have a beneficial effect on blood glucose and blood cholesterol levels?*

Answer: *There are two types of fibre. Insoluble fibre, found in wholemeal bread and wholegrain cereals, has little effect on blood glucose levels but helps to prevent constipation. However, soluble fibre, found in oats, beans, peas, pulses, fruit and vegetables, delays fat and glucose absorption into the blood. These foods can help to control both blood glucose and blood cholesterol levels.*

Oily fish

Tutor: *Why are we encouraged to eat more oily fish?*

Answer: *Oily fish has been shown to reduce blood fats (triglycerides). Two or three portions of oily fish each week reduce the risk among people with existing heart disease of having a heart attack. The omega-3 fatty acids in oily fish have also been shown to reduce pain and morning stiffness associated with rheumatoid arthritis.*

If people prefer to take supplements, it may be advantageous to take the higher strength capsules or high strength fish oil to ensure adequate intake of the fatty acids.

Tutor: *You will receive an information sheet on omega-3 fatty acids next week.*

Reduce salt

Tutor: *Reducing salt in the diet will help to do what?*

Answer: *Reducing salt intake helps to control blood pressure. This is not always easy as many manufactured foods have high levels of salt e.g. bread and cereals. It is however possible to omit salt in home cooking or certainly to reduce it. You should be aware of heavily salted foods such as smoked products and savoury snack and processed food. Ensuring an adequate intake of calcium e.g. milk and dairy food, and potassium from fruit and vegetables also helps to reduce sodium (salt) levels in the blood and can therefore be beneficial to blood pressure levels.*

Make sure that people have time to ask their own questions as you move around the store. At the end of the session, give all the participants a summary handout of the tour and advise them to place it in week four of their manuals. Thank everybody for coming and remind participants that you are back at the normal venue at the normal time next week for session number five.

4.3.6 Week five: possible complications of diabetes

Overview

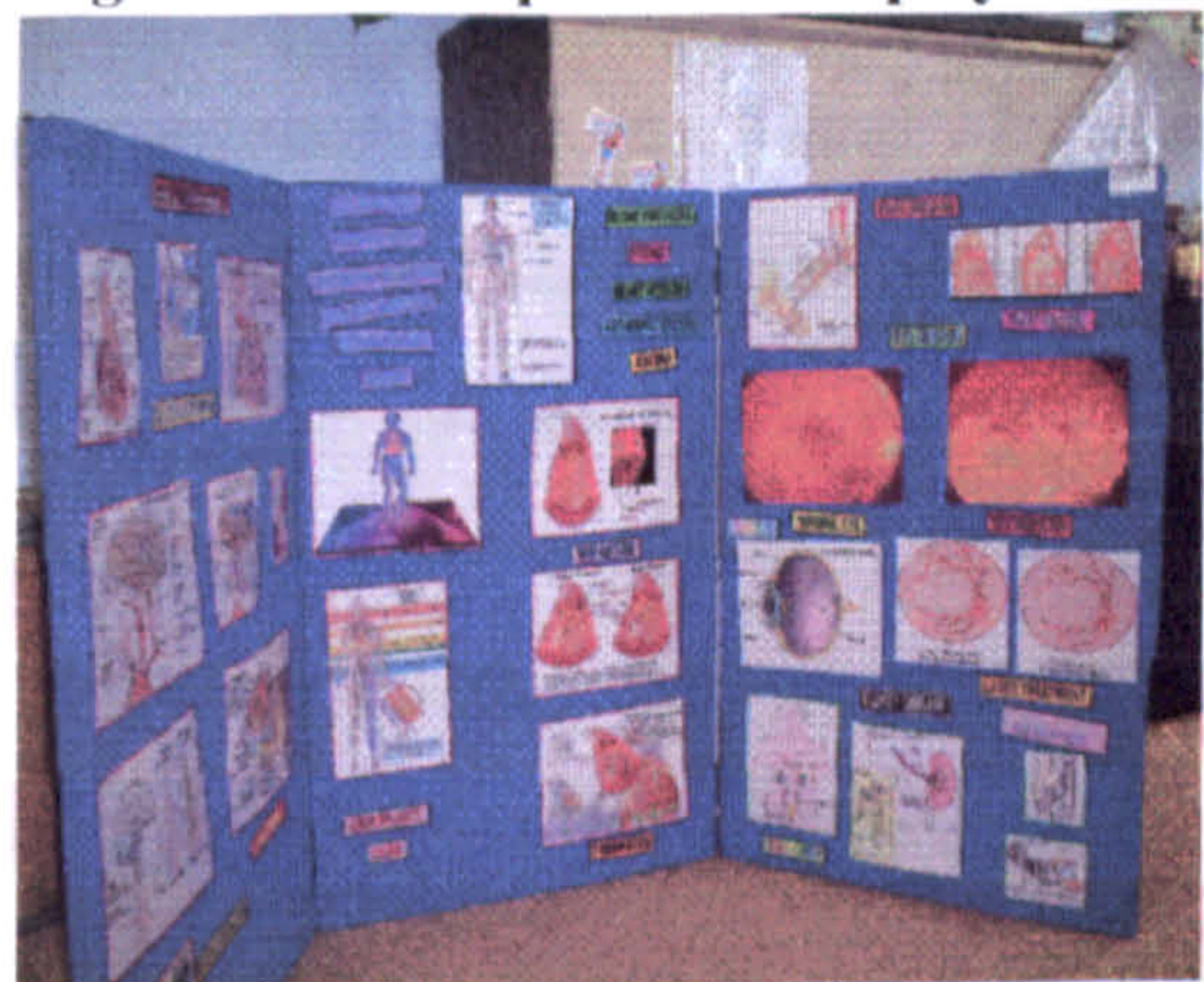
This session is intended to be informative without being too alarming. The session starts with a group activity to define hypoglycaemia, hyperglycaemia and to discuss how to reduce the risk of these short-term complications of diabetes. Activity Two aims to present the facts of the potential longer-term problems of diabetes. Participants are presented with the evidence that optimum blood glucose and blood pressure control, along with healthy living, reduces the risk of developing secondary complications. (Stratton et al. 2000). Visual aids (see figures 4.15 & 4.16 below) have been developed to explain cardiovascular disease, nephropathy, neuropathy and retinopathy in simple terms. Individuals are also informed about Diabetes UK guidelines that indicate what to expect from an annual review, which procedures to follow in order to detect early signs of complications and the treatments available for such complications. The session is based on patient activation and participants are encouraged to be as involved as possible.

Figure 4.15 Materials used in the session



Visual aids 13 to 16

Figure 4.16 Complications display board



Visual aid 11

Activity one: short-term complications (15 minutes)

Hypoglycaemia

Tutor: *What is hypoglycaemia and what increases the risk of having a 'hypo'?* (Write responses on the flipchart).

Answer: *Hypos occur when the blood glucose level drops too low. This can happen if the person with diabetes does any of the following* (add extra points to the list if necessary):

- misses a meal;*
- doesn't eat enough carbohydrate e.g. an omelette with salad contains very little carbohydrate;*
- is a lot more active than normal;*

- *takes too many tablets / injects too much insulin by mistake;*
- *drinks alcohol on an empty stomach or drinks too much alcohol.*

Hot weather may also cause hypoglycaemia in individuals injecting insulin, as the heat causes it to be absorbed quicker.

Tutor: *What are the symptoms?*

Answer: *These are different for everybody but the following are common symptoms:*

- *shaking;*
- *sweating;*
- *confusion;*
- *tingling in mouth;*
- *headache;*
- *mood changes (often bad temper);*
- *blurred vision;*
- *hunger;*
- *unsteadiness.*

Tutor: *What is the quickest way to treat hypos?*

Answer: *Pure glucose because it is immediately released into the blood. A glass of Lucozade™ or three glucose (Dextrose) tablets are good examples. Other carbohydrates (sugar and starch) will work but not quite as quickly. If glucose is not available, high GI foods are recommended. Once the hypoglycaemia has been treated, it is advisable to have your meal as soon as possible. Failing that, a carbohydrate snack such as a piece of fruit, slice of malt loaf or yoghurt would be of benefit. If you still feel 'hypo' have more glucose and if possible test your blood to make sure that the blood glucose level has risen above 4 mmol/l.*

Hyperglycaemia

Tutor: *OK, we know what hypoglycaemia is – what is hyperglycaemia?*

Answer: *Persistent raised blood glucose levels, above 7 mmol/l before meals and above 10 mmol/l after meals.*

Tutor: *How can blood glucose levels rise too high?*

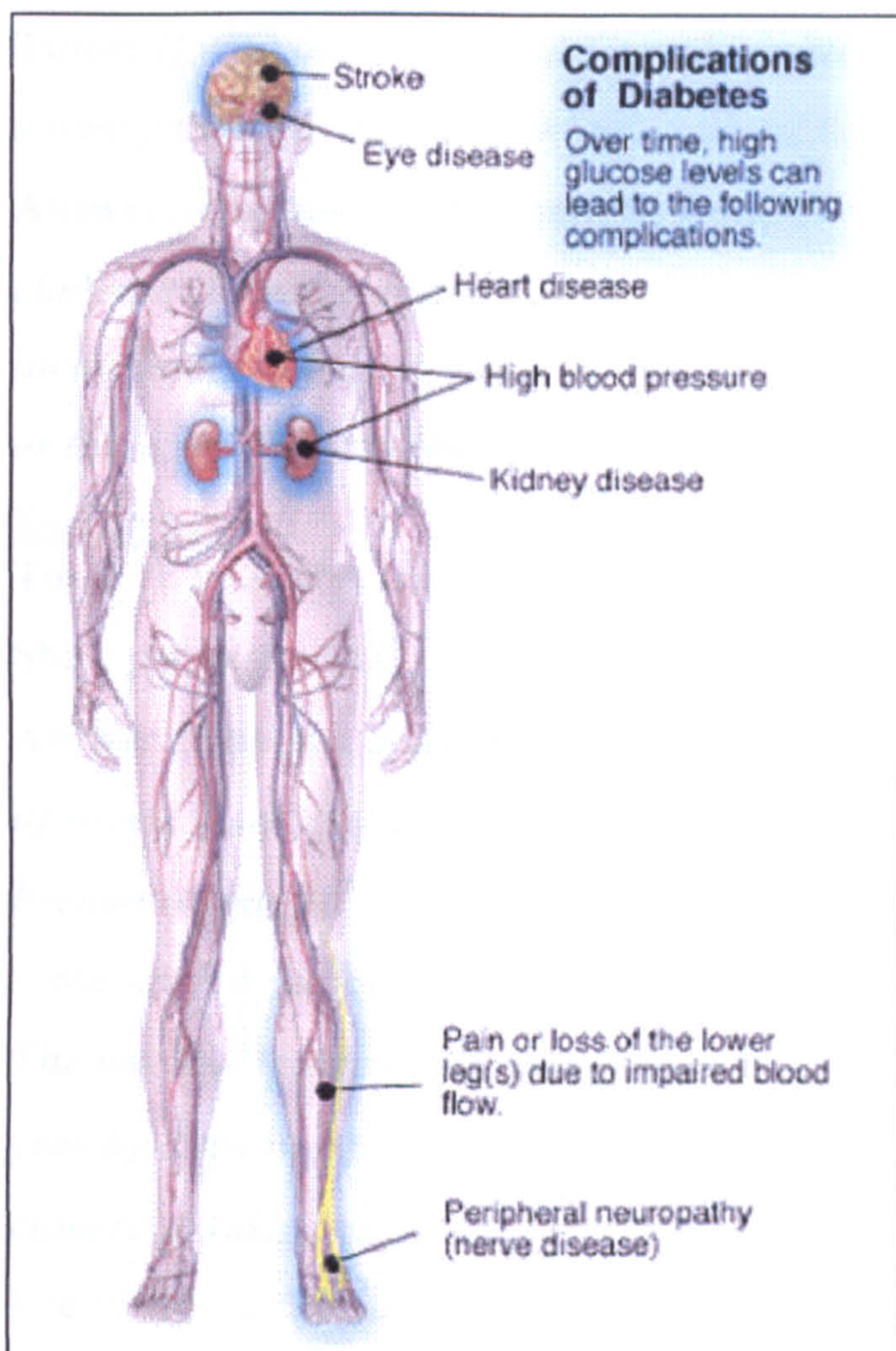
Prompt the group to respond with the following and briefly discuss each one:

- *eating too much carbohydrate i.e. starches or sugars;*
- *illness (being ill causes body cells to release more glucose from storage. You need to continue to take diabetes medication even if not eating and contact your diabetes care team for further advice if the problem persists);*

- *being less active than normal (less energy used so less carbohydrate needed – compare to a car, the fewer miles travelled, less petrol is used!);*
- *forgetting to take your insulin or diabetes tablets or taking them incorrectly;*
- *requiring more medication (you may arrive at this conclusion if you have worked through the self-management form distributed in week three).*

Activity two: longer-term complications (60 minutes)

Figure 4.17 Complications poster



Have visual aid 10 'the longer-term complications display board' (see figure 4.16 on page 149) set up at the front of the room but conceal it until after the next activity.

Attach visual aid 12. It is a poster (see figure 4.17 opposite) showing a diagram of a body with its major organs. In addition there are seven red arrows. Attach the poster to the wall or flip chart and ask participants to state what the possible long-term complications of diabetes are. Then ask them to attach the red arrows so that they point to the areas of the body that are affected by those complications. The arrows need to point to the head (stroke); eyes

(retinopathy); heart (heart attack); circulation (blood pressure and peripheral vascular disease); kidneys (nephropathy); feet and legs (sensory neuropathy); stomach, gut, bladder and sex organs (autonomic neuropathy). Try to cover the following points in the discussion while putting the emphasis on prevention.

Heart and Circulation

Tutor: *One of the main causes of heart and circulation problems is the result of the build up of fatty deposits (cholesterol) on the linings of the blood vessels.*

Demonstrate this by putting a small quantity of *lard* down a drinking straw (Visual Aid 13 'Atherosclerosis'). Now try to pour Ribena™ down the straw.

Tutor: *Lets assume that the straw is a blood vessel, the lard represents fatty cholesterol deposits in the blood vessel and the Ribena™ is blood. What happens to the blood flow?*

Answer: *The blood flow becomes impaired. This can cause further damage to the blood vessels.*

Tutor: *What can happen then?*

Answer: *The blood vessel can become completely blocked. If this occurs in the brain it is known as a stroke. If it happens in the blood vessels leading to the heart it is a heart attack or in the leg, thrombosis.*

Pass around visual aid 14 'The atherosclerosis plaque'

Tutor: *If your diabetes is not controlled and your blood glucose levels remain high for a long period of time, will this affect blood flow?*

Answer: *Yes, this will further impair the flow of blood around the body. Raised blood cholesterol levels, raised blood glucose levels and raised blood pressure levels all increase the risk of developing the longer-term complications of diabetes. When two or three of these conditions are present, the risk increases.*

Eye problems

Tutor: *Why might a person with diabetes develop problems with their eyes?*

Show participants the model of the eye (visual aid 14).

Answer: *Damage to the tiny blood vessels at the back of the eye is caused as a result of raised blood glucose levels and raised blood pressure levels. The tiny blood vessels become damaged and leaky, affecting eyesight (Use the model to point to the blood vessels at the back of the eye). This can progress unnoticed until eyesight is affected. The medical term used is 'Retinopathy'. You need to have an eye check at least once a year by a trained person, e.g. an optometrist, who will usually use a retinal-screening camera to take a picture of the blood vessels at the back of your eye.*

Use visual aid 10 and show the participants the two pictures of the back of the eye and ask the group which is the normal eye and which is the damaged eye (The correct answer is written on the back of the respective photos).

Tutor: *If the eye is damaged can anything be done?*

Answer: *Yes, laser treatment is very effective at sealing the leaky blood vessels and preventing the damage from getting any worse. However, early treatment is vital before too much damage has been done.*

Foot problems

Tutor: *Diabetes may cause problems to your lower legs and feet. Why is this?*

Answer: *Diabetes can cause nerve damage to the legs and feet (sometimes also to the arms and hands). This is called neuropathy and can result in numbness, tingling and pain.*

Tutor: *What are people advised to do to reduce their risk of developing foot problems?*

Answer: *Nerve damage may cause a loss of sensation in the feet and lower legs, and therefore people are advised to check their feet daily for any injury that may have occurred and gone unnoticed. To reduce the risk of damage occurring, it is also advisable to have well fitting shoes, not to walk around in bare feet and not to put feet on heated appliances (hot water bottles/radiators). People with diabetes have the right to see a chiropodist/podiatrist free of charge and need to have their feet and legs checked at least once a year by a trained health professional to detect nerve or circulation problems. Many treatments are available if you are experiencing pain. Please ask your diabetes care team.*

Kidney problems

Tutor: *Why would the body not work properly without kidneys? What is the function of the kidneys?*

Answer: *In simplistic terms, the kidney is basically a filter, filtering waste and excess water out of the body and retaining blood and nutrients like protein.*

Tutor: *Why might somebody with diabetes have an increased risk of developing kidney damage?*

Answer: *Raised blood pressure and raised blood glucose levels damage the tiny blood vessels that supply the kidneys and therefore damage the filtering system.*

Show visual aid 15, 'three sieves' (one perfect, one with tiny holes in it that allow small particles through e.g. chick peas, and the third sieve that has a large tear in it that allows a 'ping-pong' ball through). Ask the group what these show and prompt them to respond with:

- *the perfect sieve equates to a healthy kidney;*
- *the sieve with the tiny holes equates to a kidney becoming leaky and letting small amounts of protein (microalbuminuria) into the urine;*
- *the sieve with large tear equates to a large quantity of protein leaking into the urine causing kidney disease (Nephropathy).*

Tutor: *How are your kidneys checked to see if there is damage?*

Answer: *All that is required is a simple urine test. The urine is tested to see if there is any protein present. Protein is present in the urine of approximately 50% of people with diabetes. Depending on the level of protein in a simple urine test you may be asked to collect your urine for a 24 hour period. It is important to have a urine check for protein at least once a year, because if there is damage to the kidneys, treatments are available to reduce the risk of the problem becoming worse.*

Stomach, Gut, Bladder and Sex Organs

Tutor: *Has anybody heard of autonomic neuropathy? Does anybody know what it is?*

Answer: *This is damage to the nerves that control involuntary activities such as digestion,*

Tutor: *How can damage to these nerves affect the body?*

Answer: *If the nerves to the stomach become damaged, that may delay digestion resulting in bloating and nausea. Damage to the nerves in the gut may result in either diarrhoea or constipation. If the nerves in the bladder are affected, you may not be able to tell if your bladder is full of urine. Both men and women may be affected by nerve damage to their sex organs resulting in dryness for women and erectile dysfunction for men. There are treatments for all of these conditions and you should speak to your diabetes care team if you are currently experiencing any of them.*

Prevention

Tutor: *All the longer-term complications of diabetes are largely preventable. What could you do to reduce your risk? Or if you are already experiencing problems how can you reduce the risk of them getting worse? (Write down the responses on a flipchart making sure that all the options below have been discussed):*

- obtain good blood glucose and blood pressure control;*
- achieve optimum blood cholesterol levels;*
- lose weight if necessary;*
- stop/reduce smoking;*
- reduce saturated (animal) fat;*
- use monounsaturated oils/spreads in preference to saturated/polyunsaturated ones;*
- increase physical activity levels, aiming for 30 minutes of walking each day or equivalent;*
- eat more fruit and vegetables, aiming for at least five portions each day;*
- eat more wholegrain food and less processed food;*
- eat more soluble fibre.*

Tutor: *It is also very important to undergo all the regular investigations and tests. If complications are detected early, treatments, combined with healthy lifestyle changes will help prevent the problem(s) becoming worse.*

BREAK (15 minutes)

Offer refreshments and distribute the 'week five' packs, informing participants to place them in the relevant section of their manuals. Encourage participants to observe and discuss the complications display board.

Lifestyle experiment (30 minutes)

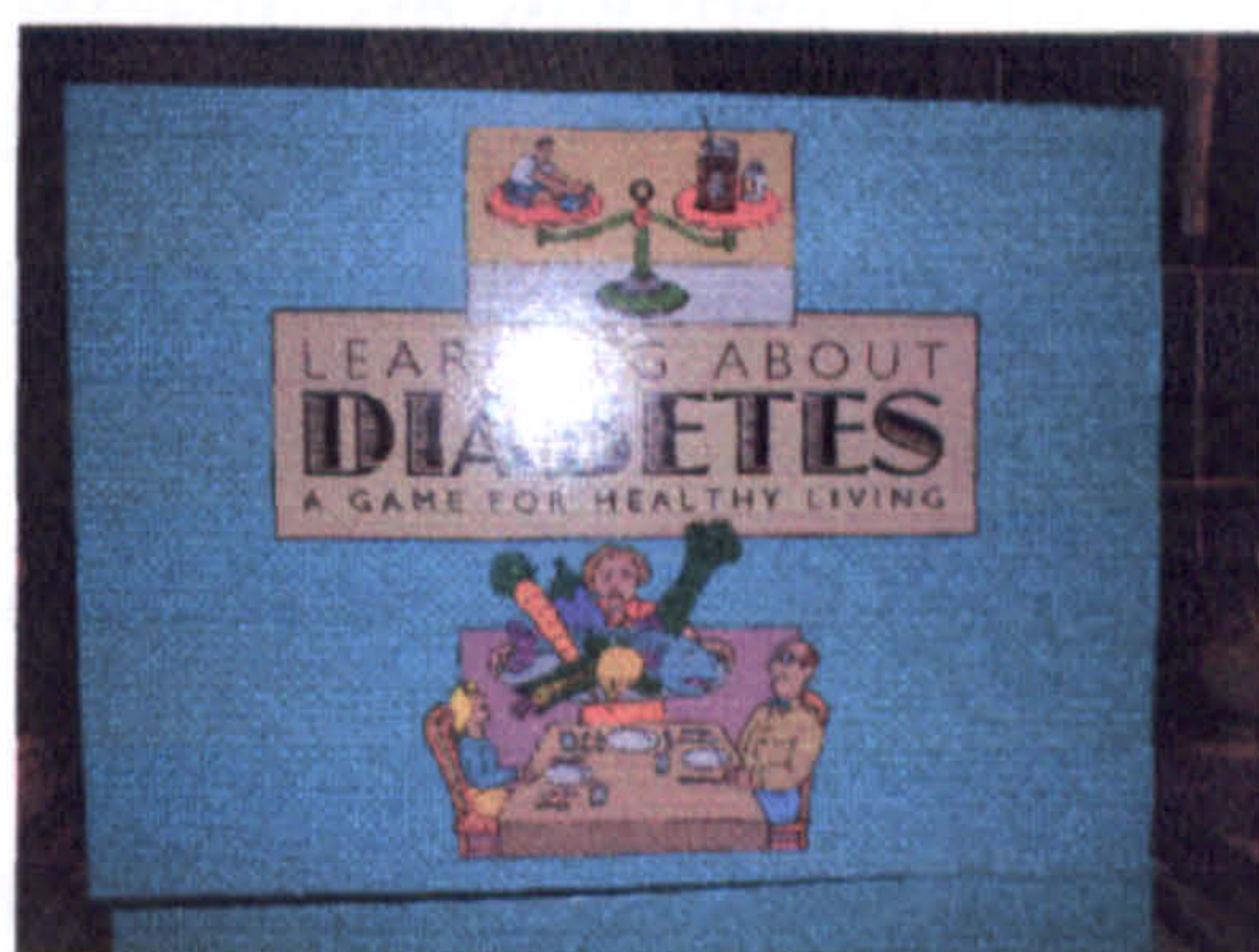
Ask how many participants have completed the self-management form. Facilitate group discussion regarding individual experiments that have arisen from the Dietary Action Plans, glycaemic index exercise and self-management forms. Alternatively, if the group prefers, split into smaller working groups. Ideally, participants will have more confidence to share their experiences (positive and negative). They may then acquire new ideas from other group members. Continue for 30 minutes if the group is having a lively discussion. However if, after 15 minutes, discussions are subsiding, split the participants into smaller groups and hand out one of the three case studies. Ask the group to read through the case study and answer the questions at the bottom. Give the groups around five minutes to do this and then discuss each case study before concluding the session.

Remind participants that next week is the final session. Invite participants to bake a low fat/high fibre cake and bring it along to the session for other participants to sample.

4.3.7 Week six: questions and evaluation

Overview

Figure 4.18 'Living with Diabetes' game



Source: American Diabetes Association

Figure 4.19 Participants sampling adapted recipes



For the last session, participants have been encouraged to adapt recipes by reducing saturated fat and increasing fibre content. Some individuals may bring in a sample of home baking for the group to taste (see figure 4.19 above). The participants play the 'Living with Diabetes' board game (see figure 4.18 above). The group is split into teams. Questions have been developed on the topics covered during the previous five weeks. Correct answers allow the team to progress down the board stumbling across "penalties" and "rewards" in place of snakes and ladders. The winning team is the first one to make it to the final. Feedback from these sessions is very positive because

participants are able to reflect on how much they have learnt. Everybody that completes the programme is awarded a certificate. Each participant is asked to complete an evaluation sheet to rate the expert patient programme. The questions ask about enjoyment of the sessions, their usefulness and the perceived effect on participants' health.

Activity one: resources (15 minutes)

Welcome the participants as they arrive and inform them that you have brought along a selection of information leaflets that they may find useful including: Diabetes UK resources and membership details, pharmaceutical literature, recipes, local Diabetes UK branch programme, Exercise on Prescription information, and MedicAlert[®] flyers.

Allow the group 15 minutes to browse through the leaflets and select the ones they will find useful. Make sure there is a hole punch available to enable leaflets to be filed in the manuals.

Activity two: Living with Diabetes game (60 minutes)

Split the group into six teams.

Tutor: This game has been purchased from the American Diabetes Association. It is a game that resembles other board games such as Snakes and Ladders. However, in order to progress down the board your team must answer the diabetes related questions correctly. The first team to arrive at the finish receives a prize. If in the time allocated, no team manages to finish, then the team who is furthest down the board will win.

Sort the American question cards and remove the questions that do not directly relate to European recommendations and guidelines or those that use different measurement levels for biomedical results. Instead, use question cards that question and reinforce the information delivered during the diabetes expert patient programme.

Tutor: Please also use this time to ask questions and discuss any of the topics that arise.

Participants will generally be surprised at how much information they have absorbed over the preceding six weeks. Present each individual in the winning team with a prize such as a small packet of dried apricots or pharmaceutical freebies (BMI calculator, waist circumference tape measure etc.).

BREAK (15 minutes)

Offer refreshments together with any healthy eating cakes supplied by the participants.

Lifestyle experiment (20 minutes)

Whole group or a number of smaller group discussions regarding the Dietary Action Plans, glycaemic index exercise, self-management forms, physical activity and other goals, and the way forward. Ask whether participants intend to continue with these experiments?

Evaluation forms (10 minutes)

Hand out the expert patient evaluation forms.

Tutor: We are handing out an evaluation form for the diabetes expert patient programme. For each week we are asking you to score each week for enjoyment, usefulness and the perceived impact on your health. A score of zero indicates the most negative response, whereas a score of 10 indicates a very positive evaluation. These evaluations are important as they allow future programmes to be modified and improved where necessary. If possible please complete the form before you leave. However, if this is not possible, please take a pre-paid envelope and use this to return the evaluation form.

4.4 Summary

This chapter has presented the scripted tutor's manual for the delivery of the diabetes expert patient programme "X-PERT". The effectiveness of the programme has been evaluated by a randomised controlled trial and this evaluation is the subject of the remaining three chapters. Chapter 5 discusses the development and detail of the clinical trial. Chapter 6 presents the results and Chapter 7 highlights the strengths and limitations of the programme and clinical trial before conclusions and recommendations for future practice and research are drawn. Although the programme has been designed to enable the programme to be delivered in a similar manner to the clinical trial, it is appreciated that different patient groups may have slightly different needs and the manual will need to be adapted accordingly. The manual will also need to be updated as new evidence-based guidelines become available.

Chapter 5: The Research Proposal



EXPERT PATIENT EDUCATION VERSUS ROUTINE TREATMENT

5.1 Introduction

This chapter presents the research proposal for the randomised controlled trial. A brief background summary is followed by a description of the development of the X-PERT trial, the demographic aspects of Burnley, Pendle and Rossendale and the research design. An argument for and against an epistemological approach to the research design than follows. The X-PERT trial tests the hypothesis that delivery of a professional-led, community based, diabetes-specific expert patient programme for adults with Type 2 diabetes based on the theories of patient empowerment and patient activation will: (1) develop the skills and confidence needed for patients to be able to make informed decisions regarding their diabetes self-management; (2) improve biomedical, lifestyle and psychosocial outcomes both in the short term (four months) and longer-term (14 months); (3) meet the International Diabetes Federation (IDF) structure and process standards regarding diabetes education.

5.2 Background

5.2.1 Type 2 diabetes

The background section summarises previous material for those who read this chapter in isolation. Diabetes is a chronic condition that arises when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin produced. It is one of the most challenging health problems of the 21st century, currently affecting 194 million people worldwide and estimated to affect 333 million by 2025 (Sicree, Shaw, & Zimmet 2003) (see Chapter 1 for more detailed information about Type 2 diabetes).

It is well recognised that obesity is a major factor in the aetiology of Type 2 diabetes and it contributes to poor glycaemic control, hypertension and dyslipidaemia (Wilding

2000). A 10% reduction in body weight has been shown to significantly improve glycaemic control, blood pressure and lipid measurements, and reduce diabetes mortality by 30% (Lean et al. 1990). It has also been shown that social deprivation leads to a poor diabetes outcome (Evans et al. 2000). Over recent years, it has been the health and well-being of people living in the most run-down communities that has suffered the most (Acheson 1998). Successful health education programmes in the past have tended to widen inequality because they targeted the more affluent and better educated sector of society who were likely to take more notice and change their behaviour (DOH 1999). A large proportion of patients with lower socio-economic status have never received diabetes education (Coonrod, Betschart, & Harris 1994). Attendance at patient education classes in diabetes management has been positively related to self-testing (Lennon et al. 1990). It has also been suggested that there may be less adequate provision of services for those with social deprivation, and strategies in diabetes services should be considered in order to improve the standards of care offered (Ward 1994).

5.2.2 Health behaviour change

It is now recognised that effective diabetes management lies almost entirely in the hands of the patient who lives with the condition (DOH & Diabetes UK 1995). However, as discussed in Chapter two, present health care delivery is often based on the acute model of care. Within this framework the health professional is the 'expert' and informs the 'patient' what they feel is the correct treatment for optimal care. The patient is often viewed as a recipient and performer of regimens that are to be accepted and obeyed.

Present diabetes education is largely theory based and delivered to individuals within a clinical setting. Follow-up is infrequent due to the increasing numbers of people with diabetes and limited availability of resources. Many people with diabetes find the current delivery of service inadequate and have difficulty putting the theory into practice (Pooley & Gerrard 1999). Those findings may be one of the reasons why, although the benefits of good control are known, there is still a large percentage of individuals whose overall glycaemic control is unsatisfactory (Clark 2000).

Descriptive articles exploring patient empowerment and a more autonomous approach to patient education have started to emerge in healthcare journals (Skinner & Cradock 2000). Although international reports have acknowledged that the consultation with the health professional should become a 'dialogue between experts' based on an empowerment model and learner centred education, (DOH & Diabetes UK 1995) little

work has been done in this area. Education is not merely about giving information, it must be designed to enable patients to self-manage the treatment of their condition while maintaining or improving their quality of life. It is not the case that many people are unwilling to change their behaviour but that they are unwilling to be changed (Anderson & Funnell 2000c). (For more information about health and health behaviour change, see Chapter 2).

5.2.3 Diabetes education

A report to Diabetes UK recognised that the majority of studies evaluating diabetes education programmes for people with diabetes have been based within secondary care in America (see Chapter 3) (Griffin et al. 1998). The report recommends that more research should be carried out within primary care in the United Kingdom. A systematic review of group-based diabetes education programmes is presented in Chapter 3.

5.2.4 Public health policy

In 1997 the Government set out its plans for the modernisation of the NHS in a White Paper *The New NHS: Modern and Dependable* (DOH 1997). It outlined a ten year programme for the development of health and social care, which described a vision of the Health Service as one that:

- tackles the causes of ill-health and health inequalities;
- removes barriers between services;
- ensures uniformly high standards;
- guarantees that services are cost effective;
- makes services more accessible and more convenient for patients.

That was followed by *Saving lives: our healthier nation* (DOH 1999), which recognised that as many as 17.5 million adults may be living with a chronic disease. It set out a vision for a new, more patient-centred NHS and confirmed a commitment to help people living with long-term conditions to take more control over their health and improve their quality of life through an Expert Patients Programme. (Refer to Chapter 2 for a full history and discussion regarding public health policy). The Expert Patients Task Force was set up, chaired by the Chief Medical Officer, to make recommendations for such a programme. The task force published a report: *'The Expert Patient: A New Approach to Chronic Disease Management for the 21st Century'* (DOH 2001c). **However, there remains much uncertainty about the most appropriate and**

effective strategy for educating and empowering people with diabetes to accomplish beneficial behavioural changes. There is, as yet, no published empirical, study that has tested the empowerment model in its entirety and, until such data emerges the model, although promising, can only be argued for on philosophical grounds (Skinner & Cradock 2000).

5.2.5 Development and reflection

The research proposal was developed in 1999 based on the dietetic service evaluations (reported in Chapter 4, section 4.2). That was prior to the government's publication of its intentions with regard to expert patient programmes. The research proposal '*EXpert Patient Education versus Routine Treatment*' with the acronym '*X-PERT*' proposed a plan to deliver a professional-led diabetes expert patient programme to adults with Type 2 diabetes and to compare outcomes with those resulting from routine treatment. The overriding aim was to ensure that the education programme was patient-centred and provided an opportunity for individuals with diabetes to increase self-empowerment by developing the skills and confidence to take more control over, and to self-manage their diabetes. This study aimed to recruit individuals with Type 2 diabetes who live within deprived areas. The proposed group-based diabetes education sessions had potential to add value to the present diabetes care system. It was thought that they could improve diabetes control, reduce the risk of developing secondary complications and positively impact on diabetes knowledge, treatment satisfaction and quality of life.

Registration for a PhD was initially at The Institute for Health, Lancaster University. The proposal involved action research and initially did not include a control group. However, with such a complex intervention, it would be difficult to assess the size of any Hawthorne effect. Advice was sought from experts in the field and emails were sent to the following:

- 1) Dr Steve Morton (steve.morton@elancs-ha.nwest.nhs.uk)
- 2) Dr Melanie Davies (research@lri.org.uk)
- 3) Professor Kinmonth (ALK25@Medschl.cam.ac.uk)
- 4) Mr Chas Skinner (chas@r.d.dircon.co.uk)
- 5) D.Barker (d.barker@man.ac.uk)
- 6) Pete Bower (pete.bower@man.ac.uk)

Several helpful responses were received and Dr Morton, Director of Public Health for East Lancashire Health Authority suggested that the proposal should be presented to the Public Health Department. The presentation took place in July 2000 and constructive feedback was received.

The gold standard method for evaluating interventions at the level of the individual is the randomised controlled trial. While it is argued that randomised trials are the optimal design for evaluating interventions to improve the organisation of health services, they should only be considered when there is genuine uncertainty about the effectiveness of an intervention (Grimshaw et al. 2001). Critics of randomised trials frequently express concerns that the tight inclusion criteria of trials, or the artificial constraints placed upon participants, limit the generalisability of the findings (Victora et al. 2004). While this is a particular concern in efficacy (explanatory) studies of health technologies, it is likely to be less of a problem when studying pragmatic trials (Stephenson & Imrie 1998).

In non-randomised designs, there are potentially greater threats to internal validity and less ability to account for them. The design and conduct of non-randomised studies are at least as methodologically challenging as the design and conduct of randomised trials. As with randomised trials, the external validity of non-randomised trials may also be poor if they are conducted in a small number of study sites that are not representative of the population to which the researcher wishes to generalise (Grimshaw et al. 2001). Therefore it was decided, in this instance, that an epistemological methods were appropriate to either accept or reject the research hypothesis.

It was suggested by Dr Andrew Clark that Professor Rhys Williams at the Nuffield Institute for Health, University of Leeds would be a suitable person to offer expert advice. The Institute for Health Research, Lancaster University has an excellent reputation for qualitative research but did not tend to evaluate health using quantitative approaches and randomised controlled trials. Therefore, after consultation with Professor Janet Cade at the Nuffield Institute for Health, University of Leeds, PhD registration was transferred to the Nuffield Institute for Health with supervision provided by Professor Cade and Professor Williams. Final minor amendments were made to the research proposal following presentation to the Public Health Division and Nutrition and Epidemiology Group at the Nuffield Institute for Health in November 2000.

5.2.6 Funding

Table 5.1 Funding applications

<i>Date</i>	<i>Organisation</i>	<i>Grant Scheme</i>	<i>Outcome</i>	<i>Money Awarded</i>
<i>April 1999</i>	NHS (Executive) North West	Training Fellowship Scheme	Unsuccessful	None
<i>April 2000</i>	British Dietetic Association	BDA General & Education Trust	Successful	£20,024
<i>April 2000</i>	PPP Healthcare Medical Trust	Older People Outline Application	Invited to make full proposal	None
<i>April 2000</i>	Novo Nordisk UK Research Foundation	Support for Clinical Projects	Successful	£1,000
<i>April 2000</i>	NHS (Executive) North West	Training Fellowship Scheme	Unsuccessful	None
<i>May 2000</i>	Department of Health	Inequalities in Health Research Initiative	Unsuccessful	None
<i>May 2000</i>	Sir Halley Stewart Trust	Project grant	Unsuccessful	None
<i>June 2000</i>	British Council for Prevention of Blindness	Performa for grant	Invited to make full application	None
<i>July 2000</i>	PPP Healthcare Medical Trust	Older People	Two rounds of peer review Unsuccessful	None
<i>July 2000</i>	Prevention of Blindness	Project grant	Unsuccessful	None
<i>August 2000</i>	British Heart Foundation	Project Grant	Unsuccessful	None
<i>August 2000</i>	Diabetes UK	Diabetes Development Project Grant	Unsuccessful	None
<i>September 2000</i>	Burnley Healthcare NHS Trust	Application for salary (4 days/wk) For 1 year	Successful	£16,000
<i>January 2001</i>	Pendle PCG	Application for ad hoc money	Successful	£10,000
<i>April 2001</i>	NHS (Executive) North West	Training Fellowship Scheme	Successful	£67,314
<i>March 2002</i>	Pendle PCG	Application for ad hoc money	Successful	£10,000

Several databases were examined in the search for appropriate funding organisations, the most helpful database was '*RD Info – A Digest of Health-Related Research Funding and training Opportunities*'. In total, 13 applications were made to nine funding organisations and three applications were made to two local health care organisations. Table 5.1 above summarises those applications. The majority of applications were made

whilst the author was working full-time as a state registered diabetes dietitian at East Lancashire Hospitals NHS Trust (formerly Burnley Healthcare NHS Trust).

From the applications described above, £124,338 was awarded towards the project. Enquiries were also made of industrial companies supplying nutritional products and diabetes/obesity medications to the NHS. Nutricia, a clinical nutrition company, donated £75 towards the project for the blood pressure monitoring device and Roche Diagnostics donated £500 for the transportable height measure and body weight/body fat scales. The local branch of Diabetes UK awarded £250 towards books and equipment.

5.2.7 Setting, ethnicity and deprivation scores

The setting for the study was the Burnley, Pendle and Rossendale area in East Lancashire in the North West of England (see figure 5.1 and figure 5.2 below). There is a GP registered population of 254,527 (ELHA 2001a) and the prevalence of diagnosed diabetes is estimated at between 6,000 and 8,000 people. The ethnic minority population in Burnley, Pendle and Rossendale has increased from 6.4% in 1991 (ELHA 1999) to 9.6% in 2001 (Office for National Statistics 2003) (see table 5.2 overleaf). The prevalence of Type 2 diabetes has been shown to be up to six times more common in people of South Asian decent (DOH 2001a).

Figure 5.1 Map of the United Kingdom



Figure 5.2 Map of Burnley, Pendle & Rossendale

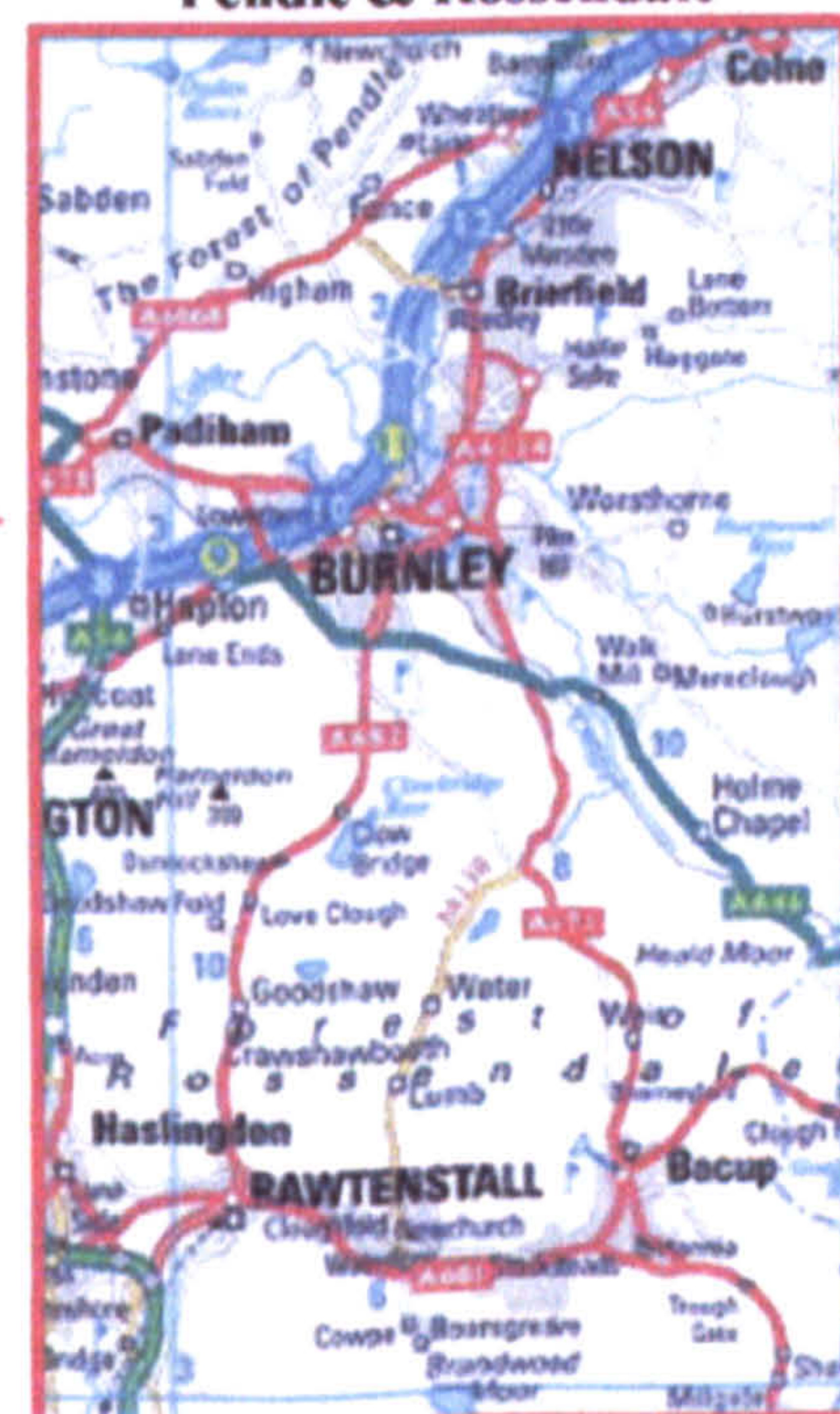


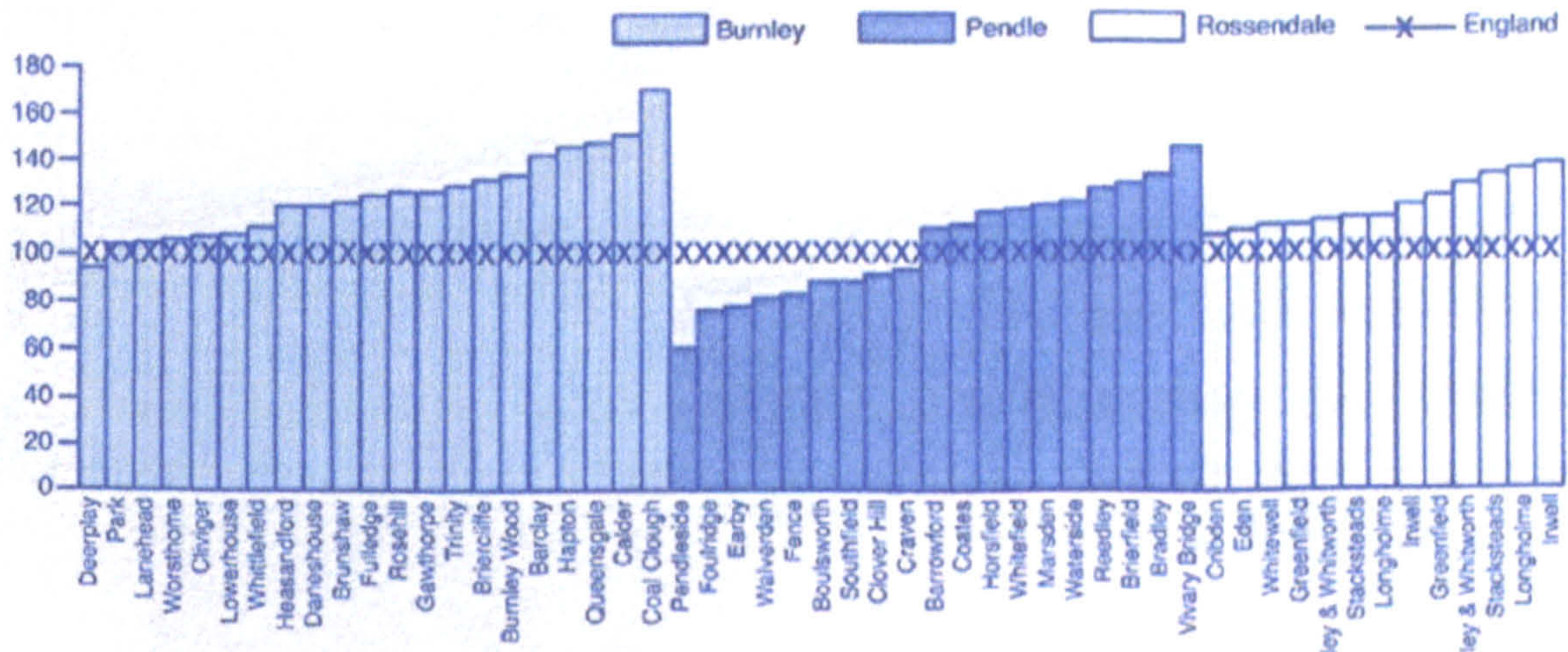
Table 5.2 Ethnic minority population based on the 2001 Census

<i>Area</i>	<i>Total population</i>	<i>Ethnic minority population</i>	<i>Predominant ethnic origin</i>
<i>Burnley</i>	89,000	7,290 (8.2%)	Pakistan: Sunni Muslim (62%) Bangladesh: Sylhetis Muslim (19%)
<i>Pendle</i>	90,300	13,635 (15.1%)	Pakistan: Sunni Muslim (92%)
<i>Rossendale</i>	65,800	2,500 (3.8%)	Pakistan: Sunni Muslim (38%) Bangladesh: Sylhetis Muslim (33%)
<i>Total</i>	245,100	23,425 (9.6%)	

Source: Office of National Statistics

When compared to the rest of the country, Burnley, Pendle and Rossendale have relatively poor health and within each locality there are examples of exceptionally poor health. That is reflected in the high figures for premature death in the area as a whole (see figure 5.3 below).

The major causes of premature death in Burnley, Pendle and Rossendale are heart disease, respiratory disease and injury. For example, deaths from ischaemic heart disease are 34% above the national average; 15.9% of the population in Burnley, Pendle and Rossendale report a long term illness, and the number of people admitted to hospital with a diabetes related illness is greater than the national average (ELHA 2001a).

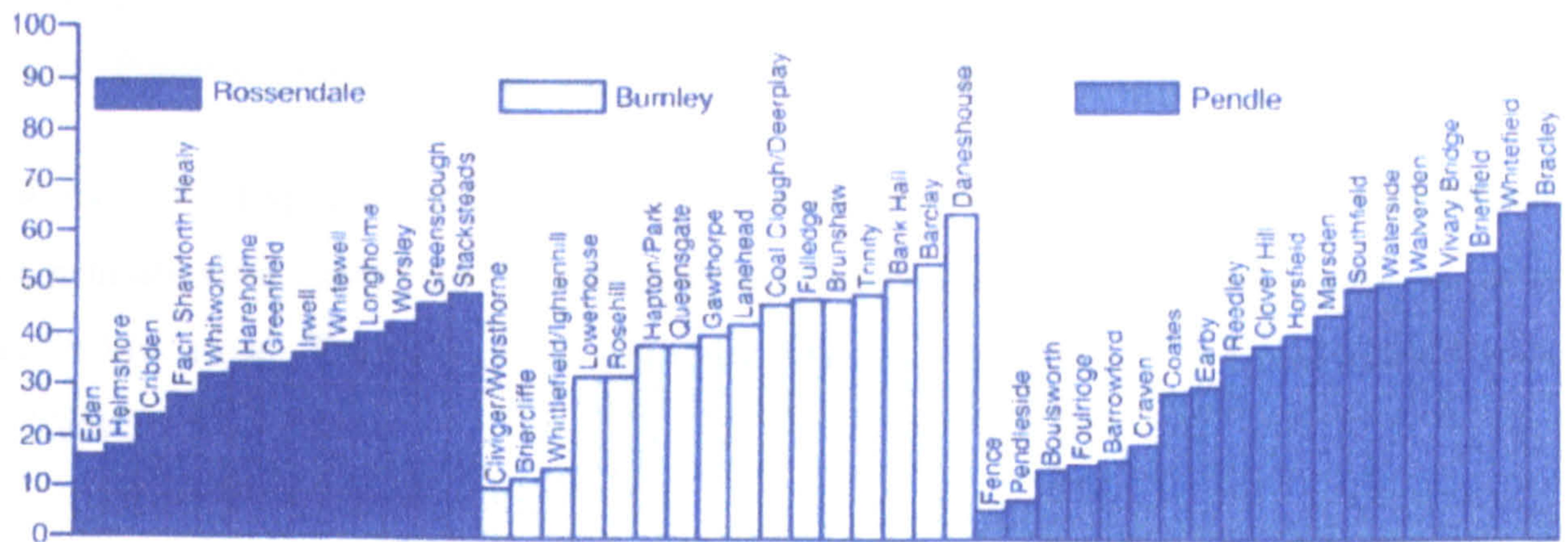
Figure 5.3 Standardised mortality ratios for under 75 years, 1996-1998

Source ELHA 2001

There are significant differences in the living standards experienced within the Burnley, Pendle and Rossendale areas. For example, using the DETR 2000 method described below on page 168, Daneshouse in Burnley is ranked the sixth most impoverished ward in the country, whereas Fence in Pendle is ranked 7788th out of 8414 in terms of nationwide poverty ratings (see figure 5.4 overleaf) (ELHA 2001a). Daneshouse is an area largely populated by people from a South Asian background. It has been shown that ethnic minority populations have higher rates of unemployment and are more likely to be housed in either overcrowded or poorer quality accommodation (ELHA 1999).

Although there is a range of deprivation across the area, 56% of the wards in Burnley, Pendle and Rossendale fall within the worst 25% of wards nationally in terms of housing conditions and unemployment related poverty. This is reflected in unhealthy lifestyles with higher than average levels of smoking and poor diets (ELHA 2001a).

Figure 5.4 Indices of deprivation 2000



There are three common methods used to estimate deprivation; the Jarman Score, the Townsend Score, and the Department of the Environment, Transport and the Regions (DETR) indicators. Most methods try to measure geographical populations rather than individuals or social groups (Avon NHS 2003; National PCG/T Database 2003).

Jarman Score

The Jarman score was developed 20 years ago as a measure of General Practice workload and is often used as an assessment of deprivation. It has been used by the Department of Health to determine additional “deprivation” payments to GPs. The scores were re-calculated for the 1991 census, using the same census variables as 1981. The calculation of the Jarman score consists of the three stages: data identification, weighting and aggregation. Eight census variables, each of which is individually weighted, are used in the calculation:

- ❑ percentage of people in households who are aged 65 or over and living alone (weighted at 6.62);
- ❑ percentage of the people living in households who are aged under 5 (weighted at 4.64);
- ❑ persons in households of one person over 16 with one or more children under 16 as a percentage of all persons in households (weighted at 3.01)
- ❑ persons in households headed by a person in socio-economic group 11 (unskilled workers) as a percentage of all residents in households (weighted at 3.74);
- ❑ economically active persons aged 16 and over who are unemployed and seeking work (weighted at 3.34);

- ❑ persons in households with more than one person per room as a percentage of all residents in households (weighted at 2.88);
- ❑ persons aged one year or over with a usual address one year before the census that is different from the present usual address as a percentage of total residents (weighted at 2.68);
- ❑ people in households headed by a person born in the new Commonwealth or Pakistan as a percentage of all residents in households (weighted at 2.50).

The mean for England and Wales is 0. An area with a high score has a greater demand for primary care, based on the characteristics of the resident population, than an area with a low score. Extreme scores are those above 32 (rounded to 30 by the Department of Health).

Townsend Material Deprivation Score

The Townsend score is made up by looking at four census variables:

- ❑ unemployment - percentage of economically active residents aged between 16 and 59 for women and 16 and 64 for men who are unemployed;
- ❑ car ownership - percentage of private households who do not possess a car;
- ❑ owner occupation - percentage of households not owner occupied;
- ❑ overcrowding - percentage of private households with more than one person per room.

The data is taken from the 1991 census. The variables combine to form an overall score ranking a particular area relative to others. The higher the score, the more deprived the area. The average is 0.

DETR 2000

The Department of the Environment, Transport, and the Regions (DETR) have produced several ward and local authority level deprivation scores looking at different aspects of deprivation. The six domains they have used are:

- ❑ income;
- ❑ employment;
- ❑ health deprivation and disability;
- ❑ education;
- ❑ skills and training;

- housing and geographical access to services.

In addition, there is an overall score and rank for every ward in England called the Index of Multiple Deprivation 2000 and a supplementary score and rank on Child Poverty. The combined score is a combination of all six domains. Each of the six domains uses a variety of data, mainly taken from social services, which are then weighted according to importance and combined to create a score. The score is then used to rank the wards so that '1' is the most deprived and 8414 is the least deprived in England. It is the rank, and not the score that should be used.

Table 5.3 Advantages and disadvantages from using different deprivation scores

<i>Deprivation Score</i>	<i>Advantages</i>	<i>Disadvantages</i>
<i>Jarman Score</i>	<ol style="list-style-type: none"> 1. It can be used to look at small areas 2. A diverse range of measurement contributes to the score. 	<ol style="list-style-type: none"> 1. Differences within wards are often masked as there can be great variation of deprivation within a particular ward 2. The data is more than 10 years out of date. 3. It does not indicate the proportion of people that are deprived within an area 4. It is biased towards the urban population
<i>Townsend Score</i>	<ol style="list-style-type: none"> 1. It can be used to look at small areas 2. It is highly correlated with measures of ill health e.g. Standard Mortality Ratios. 3. As it is the sum of standardised scores, it is easy to calculate. 	<ol style="list-style-type: none"> 1. The data is more than 10 years out of date 2. It does not indicate the proportion of people that are deprived within an area 3. It is a better indicator of deprivation within urban areas than rural areas
<i>DETR 2000</i>	<ol style="list-style-type: none"> 1. Uses recent data which is updateable 2. Can distinguish between different aspects of deprivation 3. Gives the proportion of people that are deprived for the income and employment domains 	<ol style="list-style-type: none"> 1. Some of the domains, such as housing, are derived from only a few different sources 2. The variables are weighted differently, so that one source can be more important than another, with justification not clear 3. The score contains the access domain which does not mirror the other deprivation measures and is more reflective of rural need than urban needs 4. Data is not available below ward level

Each method for assessing deprivation has its advantages and disadvantages and those are identified in Table 5.3 (above). As it is a national priority to tackle health

inequalities (DOH 1997; DOH 1999) (Evans et al. 2000) and as it has been suggested that low socio-economic status leads to poor diabetes outcomes, an attempt was made to recruit participants from socio-economic deprived areas throughout Burnley, Pendle and Rossendale. Since the intention was to recruit participants for the study from general practices, it was decided that tracking the number of deprivation payments made to GPs based on Jarman scores would be an effective way of identifying practices with a higher percentage of registered patients who were classed as socio-economically deprived.

5.3 Methods

The study was carried out in three phases: phase one commencing in January 2001 in the Burnley district; phase two commencing in July 2001 in the Pendle district; phase three commencing in January 2002 in the Rossendale district.

5.3.1 Hypothesis

Health professional led, group-based and patient-centred expert patient programmes for adults with Type 2 diabetes improve self-empowerment, self-management skills and positively impact on diabetes control.

Aim of the expert patient programme (X-PERT):

to develop, monitor and evaluate a community based *expert patient programme* for adults with type 2 diabetes.

Immediate objective: to empower patients to have more responsibility, better self-management skills and better personal control over their diabetes.

Longer-term objective: to improve diabetes specific quality of life and diabetes control and promote a healthier lifestyle.

Sub-group analysis: to assess the effectiveness of the education programme for South Asian participants with diabetes.*

* Although the study was not powered for sub-group analysis, the high percentage of South Asian residents within Burnley, Pendle and Rossendale and the increased prevalence of diabetes among that ethnic group, encouraged the view that a sub-group analysis for the primary outcome (glycated haemoglobin) would be of interest.

5.3.2 Ethical approval

The original research proposal based on action research (with no control group) was submitted to the Burnley, Pendle and Rossendale Local Research Ethics Committee in June 2000. It was accepted subject to one or two minor amendments. However, the

application was re-submitted in September 2000 with the revised proposal for a randomised controlled trial. Although ethical approval was obtained, the committee expressed concern regarding the feasibility of recruiting 300 adults with Type 2 diabetes. A response was returned to the chairman of the committee stating that the high prevalence of diabetes in the district (between 6,000 and 8,000 people) indicated that problems with recruitment would be unlikely. The final correspondence from the Ethics Committee dated 10th October 2000 stated '*I am satisfied with your comments regarding recruitment of subjects to the study and formal ethical approval is now granted for the study to proceed*' (Appendix 3).

5.3.3 Recruitment

Recruitment of general practices

An application was made to the Family Health Services Manager at the former East Lancashire Health Authority seeking the number of deprivation payments by band by GPs for Burnley, Pendle and Rossendale. Deprivation payments data was received for Burnley and Pendle but details regarding deprivation payments for Rossendale were held by the former Rossendale Primary Care Group and not East Lancashire Health Authority. A formal application to Rossendale Primary Care Group requesting such information was refused on the ground of GP confidentiality. There was an opportunity for appeal through the Local Medical Committee but that process would have taken several months and the timescale for the study could not accommodate such action. General practices from the Rossendale area were therefore invited to take part in the study if they were situated in one of the wards in the poorest quartile for housing based on the DETR Index of Deprivation (see figure 5.4 on page 169) (ELHA 2001b).

When a practice was identified as receiving a high volume of deprivation payments (Burnley and Pendle) or noted to be situated in a deprived ward (Rossendale), the practice was contacted and a meeting arranged with the practice manager, lead GP and/or practice nurse. The details of the study were discussed and a practice information sheet (Appendix 4a) provided, stating both the aims and objectives of the study and what was required from the practice. If the practice agreed to participate in the study, a practice consent form (Appendix 4b) was supplied for completion. Participating practices then provided a list of names, addresses and telephone numbers of all registered patients with Type 2 diabetes.

Recruitment of participants

On receipt of the patient list from participating practices, an invitation letter with a patient information leaflet (Appendix 5a) was sent to patients who met the inclusion criteria (see section 5.2.4 below). If the patient had a name suggesting that they were from a South Asian background, two letters and information leaflets were sent, one written in English and one written in Urdu. Recruitment was based on the presumption of a 20% response rate. The information leaflet was adjusted from the template produced by the UK Multi-Centre Research Ethics Committees and stated:

- the purpose of the study;
- why individuals had been chosen;
- whether individuals had to take part;
- what would happen if they did take part;
- information regarding programme one (control group) and programme two (intervention group) and how individuals would be randomly placed;
- the benefits of taking part;
- what happens when the research stops;
- what happens if an individual has a complaint
- whether involvement in the study would be kept confidential;
- what would happen to the results of the study;
- who had reviewed the study;
- contact details for further information.

Patients were requested to register their interest before a specified date by returning a tear-off slip with their name, address and telephone number in the supplied pre-paid envelope. Contact was then made with the patient, usually by telephone, providing an opportunity for the patient to ask questions and discuss the study in more detail and for the principal researcher to check that each individual met the inclusion criteria. Afterwards, if they were still willing to take part in the study, a home visit was arranged to obtain written consent (patient consent form, Appendix 5b) and collection of the baseline outcomes. If patients did not have access to a telephone, a letter was sent informing them that a home visit would be made on a certain date and at a certain time and requesting that they contact the researcher at the dietetic department if the date or time was inconvenient.

5.3.4 Participants

Inclusion Criteria

Adults with diagnosed Type 2 diabetes who could speak and understand English or Urdu and were registered with a general practice that had consented to take part in the study.

Exclusion Criteria

In the interests of a pragmatic study, exclusion was restricted only to those patients with Type 2 diabetes who met the following criteria:

- ❑ below the age of 30 years (as those individuals were more likely to have Type 1 diabetes or childhood Type 2 diabetes);
- ❑ housebound, terminally ill with a pre-existing medical condition or living with severe learning difficulties that would prevent diabetes self-management;
- ❑ unable to understand or speak English or Urdu languages.

5.3.5 Study Design

Well-designed and properly conducted randomised controlled trials (RCTs) provide the best evidence on the efficacy of health care interventions (Ford, Giles, & Dietz 2002). However, trials may either be explanatory or pragmatic. Explanatory trials generally measure efficacy i.e. the benefit a treatment produces under ideal conditions, often using carefully defined subjects in a research clinic. Pragmatic trials measure effectiveness i.e. the benefit the treatment produces in routine clinical practice (Roland & Torgerson 1998). Educational interventions tend to be complex interventions which are built from a number of components. It is not easy to define the “active ingredients” of a complex intervention and it is recommended that all components are described clearly to allow replication of the intervention without defining the active ingredient(s) (Medical Research Council 2000).

The study design involved a prospective, pragmatic randomised controlled trial to evaluate the complex intervention. An intention to treat analysis collected and analysed data, where possible, from all participants regardless of whether they completed the intervention or control education programme.

Power calculation

The primary outcome was glycated haemoglobin (HbA1c) and it was calculated that 64 participants were required in each group in order to have 80% power to detect an absolute difference in HbA1c levels of one percentage point between groups. That

assumed the 5% significance level with a standard deviation of 2%. However, the aim was to recruit 300 participants (150 in each group) to allow for attrition and smaller differences in glycated haemoglobin between the two groups. A one percent difference between groups was thought to be worthwhile as it may significantly reduce the risk of developing diabetes complications (Stratton et al. 2000).

Randomisation

Patients had an equal probability of assignment to the intervention group or the control group. Individual randomisation, as opposed to cluster randomisation, was performed separately for each education programme using computerised random permuted blocks generated by a statistician. The block size was 30 with a ratio of 1:1 for allocation to the intervention or control group. In order to maintain blinding to allocation, the patient information leaflet stated that the study was designed to compare the effectiveness of an individual approach to diabetes education (diabetes education programme one) with that of a group approach (diabetes education programme two). Sealed opaque envelopes containing a study identification number and allocation into programme one or programme two were prepared, sealed and signed by a person not involved in the research project and they were opened in the presence of the patient during the home visit in order to conceal allocation from the principal researcher who was responsible for enrolling participants.

Blinding

As described above, an attempt was made to blind participants to treatment assignment. However, it was not possible to blind those administering the routine treatment intervention for the control group, nor was it possible to blind the principal researcher who was delivering the diabetes expert patient programme to the intervention group. Outcome assessments were carried out in the main by a community nurse and a health care assistant who were blinded to treatment assignment, although, as a result of time and funding constraints, some assessments were carried out by the principal researcher. All outcome data was entered onto a computerised database anonymously using the participant identification number. Biomedical outcomes were entered by the principal researcher and the lifestyle and psychosocial outcomes, collected via validated questionnaires, were double entered by a private company, Bureau Support Services. All statistical analysis was carried out by the principal researcher using the anonymous database.

5.3.6 Interventions

Control Group (diabetes education programme one)

Described in the patient information leaflet as ‘diabetes education programme one’ this was actually routine treatment for individuals with Type 2 diabetes. Participants received an individual appointment from a GP or practice nurse and a state-registered dietitian within the three-month active intervention period. That provided an opportunity for participants to be updated about recent developments, have routine assessments and discuss any concerns about their diabetes care.

Diabetes expert patient programme (diabetes education programme two)

Members of the intervention group were invited to attend the six-week diabetes expert patient programme in addition to informal routine treatment. Once the expert patients had participated in the course they once again received routine care, as there was no formal follow-up arranged.

The diabetes expert patient programme involved six, weekly sessions, each lasting two hours (for a brief overview see Table 5.4 on page 178 and for a detailed description see the scripted manual presented in Chapter 4). All sessions were based on the theoretical models of patient activation and empowerment and aimed to develop skills and build confidence to enable patients to make informed decisions regarding their diabetes self-care.

Each programme was delivered within the community. The venues were easily accessible to all participants and had facilities available for the preparation of refreshments. Separate sessions were held for Urdu speaking South Asian participants, where a translator was present. If participants failed to attend one session, they received a telephone reminder. If they failed to attend two sessions, no further contact was made during the programme, but an intention-to-treat analysis was carried out to collect outcome data.

The expert patient programme was designed and delivered by a diabetes research dietitian (TD) who took on the role of a diabetes educator based on the USA model. The dietitian had engaged in extra training in adult education (PGCE); diabetes treatments; behaviour change and empowerment, and venepuncture. Lesson plans were prepared for each session to provide structure, but the pace of learning and specific discussions were guided by the needs of the participants.

Table 5.4 Content of the Expert Patient (X-PERT) Programme

<i>The Expert Patient Programme</i>	
<i>Topic</i>	<i>Description</i>
<i>Week 1: What is diabetes?</i>	Explore what happens to food when we eat it, self-monitoring of diabetes, diabetes treatments, feelings about living with diabetes. Dispel myths by using visual educational materials.
<i>Week 2: Weight management</i>	Examine the 'balance of good health' model and use food models to distinguish between food containing protein, fat and carbohydrate. Inform about sensible eating whilst exploring barriers in doing so. Advise about the benefits of exercise and give practical examples including information about local exercise-on-prescription schemes.
<i>Week 3: Glycaemic Index</i>	Perform a group task, developed to show the effect of quantity and quality of carbohydrate food on blood glucose levels. Use ping-pong ball models and laminated food pictures to dispel the myths surrounding glucose, sucrose and starch.
<i>Week 4: Supermarket Tour</i>	Address some common confusion surrounding dietary fat, sugar and food labelling. Encourage a diet that is enjoyable, variable and balanced whilst dispelling the concept of 'good' and 'bad' foods.
<i>Week 5: Complications & Prevention</i>	Discuss how to reduce the risk of developing longer-term complications through lifestyle changes, treatment and regular monitoring. Use visual educational aids to explore, in layman terms, nephropathy, retinopathy, arteriosclerosis, blood pressure etc.
<i>Week 6: Evaluation & Question time</i>	Play "Living with diabetes", a board game purchased from the American Diabetes Association to bring the expert patient programme to a close in a relaxed manner, reinforcing the main messages whilst encouraging participants to reflect on how much they have learnt.
<i>Goal Setting: Last 20 minutes each week</i>	The final 20-30 minutes each week involves the goal setting component of the empowerment model. Participants obtain and examine their health results, the implications of them and acceptable ranges. If participants make an informed decision to work on improving any of their health results, they work through the five step empowerment model. Psychosocial aspects of diabetes and barriers to change are also addressed. An important aspect of the empowerment model is to respect the decisions made by some of the participants not to goal-set.
<i>Patient Manual</i>	Resource manual given to participants at the beginning of the course. Background reading, health results and goal setting material added each week as appropriate.

Critical components

- ❑ The theoretical models 'patient-activation' and 'empowerment' that underpin the programme.
- ❑ Group sessions.

- Intensive education.

Secondary components

- Standard education.
- Accessibility.

Secondary components will be controlled for. The control group will receive routine treatment involving standard education delivered by a multidisciplinary team (practice nurse or GP and a dietitian). Those individual appointments will be equally as accessible as the X-PERT Programme i.e. provided within a primary care setting.

Potential confounders

There are several potential confounders such as age, sex, diabetes treatment, BMI, pre-existing medical conditions, educational history, the standard of existing diabetes care and socio-economic background. However, the randomisation of 150 participants into a control group should be an adequate strategy to control for those factors.

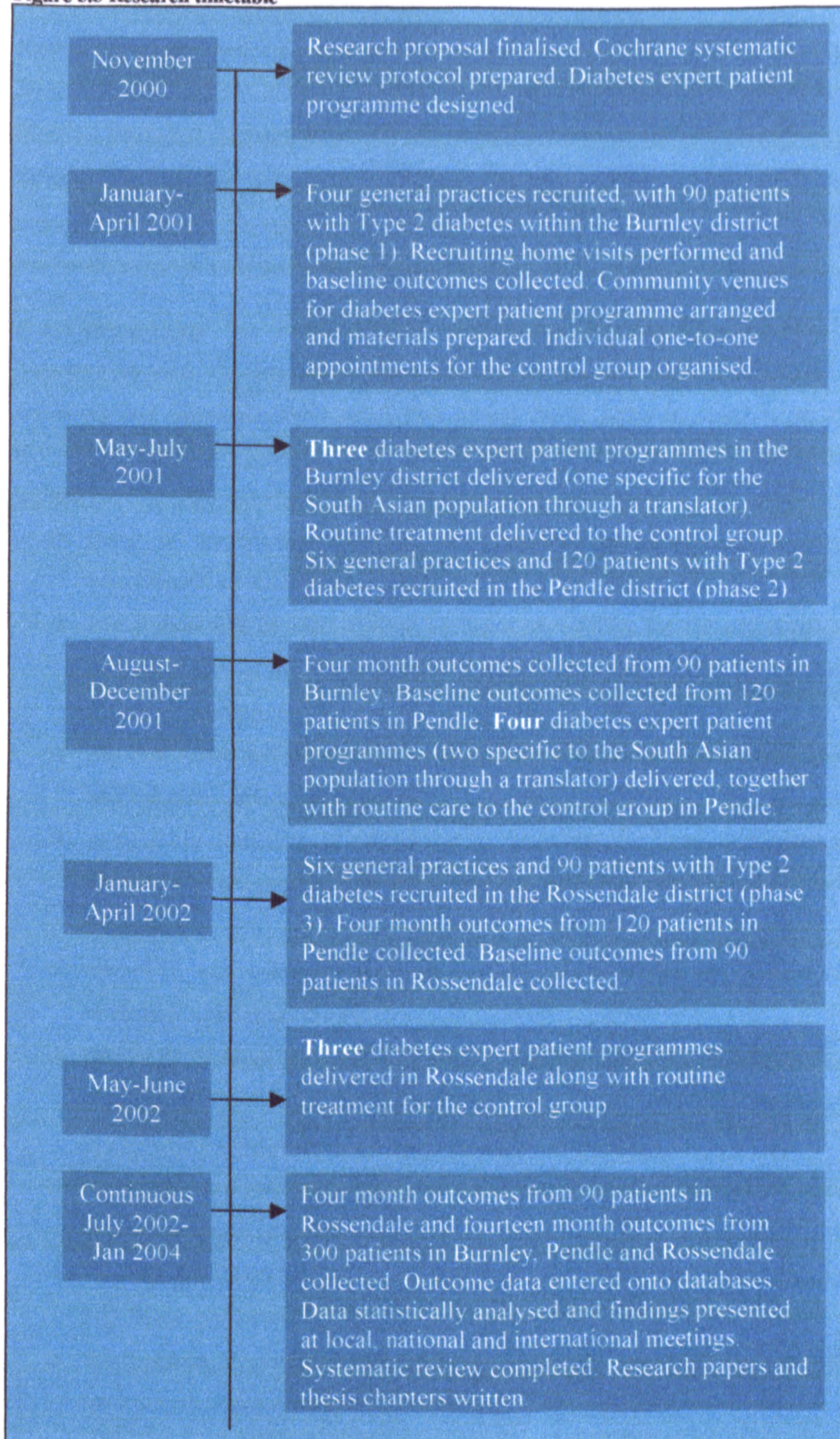
5.3.7 Detailed plan

At the recruiting home visit, the following steps took place:

- participants were asked to provide their written consent to the research project by signing a patient consent form;
- a data collection sheet was completed for each patient and the following information was recorded: GP name and practice; the year diabetes was diagnosed; treatment history for diabetes; treatment history for any conditions associated with diabetes such as blood pressure; any existing known diabetes complications;
- an opaque signed and sealed envelope was opened to reveal whether the patient had been allocated to diabetes education programme one (control) or diabetes education programme two (intervention). The patients' identification number for the trial was also stated and that was written on their consent form and data collection sheet;

- the participants were also informed that their details would be passed onto the surgery so that the individual appointment with the practice nurse or GP could be arranged. If the patient had been allocated to programme two, they were able to choose which of the diabetes expert patient programmes in that locality they would like to attend. They received an information sheet with the venue, dates and times of the six sessions. South Asian participants were invited to attend a session to be delivered with the help of an Urdu speaking translator. Two translators were involved in the delivery of the X-PERT Programme to South Asian participants, one of which was an NHS employee and was experienced in translating during group-based education sessions. The other translator was a dietetic student with less experience and due to funding and time limitations training was not possible;
- biochemical baseline outcomes (see section 5.4.3, page 183) were collected and a questionnaire distributed to enable collection of the lifestyle and psychosocial baseline outcomes (see section 5.4.3, page 184). The patient's trial identification number was written in the top left hand corner of the questionnaire and the importance of completing the full questionnaire was explained. The questions that were deemed to be difficult or confusing were drawn to the attention of the patient and guidance for completion was given. Questionnaires were available in English or Urdu for South Asian participants. Participants were asked to return the questionnaire in the pre-paid envelope before commencing the education programme. If the questionnaire was not returned, the participants received a gentle telephone or written reminder;
- all subjects were informed that they may attend their respective programmes with a family member or close friend;
- four months from baseline (two-month post diabetes education programme) and 14 months from baseline (12 months post diabetes education programme), the biomedical, lifestyle and psychosocial outcomes were repeated (see the timetable in figure 5.5 overleaf).

Figure 5.5 Research timetable



5.4 Evaluation: structure, process and outcome

Evaluation of the diabetes expert patient programme was based on the International Standards for Diabetes Education (IDF Consultative Section on Diabetes Education (DECS) 2003) and was split into three sets of standards: structure, process and outcome. Structure and process evaluation is a qualitative and descriptive assessment whereas outcome evaluation is a quantitative evaluation that compares the mean results from the intervention group with those of the control group.

5.4.1 Structure

Structure provides the framework for a diabetes service and describes the personnel, resources and physical environment that should be in place in order to provide a diabetes education programme. The diabetes expert patient programme was evaluated against the following standards:

- there is documented evidence of organisational/institutional support for education as an integral part of diabetes care;
- one person will be identified as having responsibility for the organisation and administration of the diabetes education service to ensure that the process and outcome standards can be met;
- physical space and education resources are conducive to learning and based on individual/community needs;
- an advisory committee is established to ensure that the views and values of all stakeholders are represented in the ongoing planning and delivery of diabetes education;
- teamwork and communication are evident among those providing diabetes education and management;
- personnel involved in diabetes education have a sound clinical understanding of diabetes, are knowledgeable about teaching and learning skills and diabetes self-management practices;
- the competence and performance of personnel involved in diabetes education is reviewed at least annually;
- diabetes education covers topics based on individual assessment and fosters acquisition of knowledge leading to self-management of diabetes;
- relationships are fostered with available community resources such as diabetes associations, blind society, social services.

5.4.2 Process

Process standards describe the process of diabetes education and the steps required to prepare, implement and evaluate the education programme. The diabetes expert patient programme was evaluated against the following standards:

- diabetes education is based on the ongoing learner-centred needs assessments of individuals and/or communities;
- plans for diabetes education programmes are learner-centred and subject to ongoing review and modification;
- implementation of diabetes education that is learner-centred and facilitates cognitive learning, behaviour change and self-management and that extends to families, caregivers and communities, where appropriate;
- education is provided in a professional and ethical manner and is learner-centred and evidence-based where possible;
- the diabetes education service will be recognised by, and accessible to, the community;
- the effectiveness and quality of education will be annually assessed and linked to outcomes and the services will be reviewed on the basis of the assessment;
- educational and clinical research are undertaken to provide an evidence base for practice.

5.4.3 Outcome

Outcome evaluation is based on the premise that, if the diabetes education programme had been successful, patient biomedical, lifestyle and psychosocial measurements would have improved.

Biomedical

Venous blood samples were analysed at a central laboratory. The primary outcome, glycated haemoglobin (HbA_{1c}) was measured using the diabetes control and complications aligned method. The reference range for people without diabetes was 4.0 – 6.3%. A full lipid profile included total, LDL and HDL cholesterol and triglycerides. Blood pressure was measured, conforming to accepted methods (Ramsay et al. 1999), using a digital blood pressure monitor. Acceptable ranges for blood lipids and blood pressure were obtained from recent guidance reports (NICE 2002a). Body weight was measured using the calibrated electronic scales. Participants were asked to remove shoes and wear light clothing. The same scales were used throughout the study. A portable sonic machine was used to measure height. BMI (Kg/m²) was calculated from height

and weight measurements. The Tanita body fat monitor measured body fat to $\pm 0.5\%$ precision using bioelectrical impedance analysis. The recommended technique for measuring waist circumference was used (Després, Lemieux, & Prudhomme 2001).

Lifestyle

Validated questionnaires (Appendix 6) were used to measure diabetes knowledge (Fitzgerald et al. 1998), food intake (Little et al. 1999), and Diabetes Self-Care Activities (SDSCA) (Toobert & Glasgow 1994). Diabetes knowledge was assessed by 14 multiple choice questions, the lowest possible score being zero and the highest, 14. Food intake assessment obtained information about portion size (small, medium, large) and frequency of consumption (number of times eaten per day, week or month) for 42 common food items. The SDSCA questionnaire is a self-report measure of the frequency of completing different regimens activities over the preceding seven days. It measures: diet (four questions); exercise (two questions); blood testing (two questions); foot care (five questions); medication taking (three questions). Raw scores from each measure were converted to standard scores. Those were then averaged to form a composite score for each regimen behaviour.

Psychosocial

Validated questionnaires (also shown in Appendix 6) were used to measure Diabetes Treatment Satisfaction (DTSQ_C) (Bradley 1994), Audit of Diabetes-Dependent Quality of Life (ADDQoL) (Bradley et al. 1999), and diabetes empowerment (Anderson et al. 2000). Diabetes treatment satisfaction was determined at baseline with eight questions (scored 0-36). Two individual items measured perceived frequency of hypoglycaemia and hyperglycaemia (scored 0-6) in which higher scores indicated greater frequency of low or high blood glucose levels. Change in treatment satisfaction was measured using the same questions with different scoring: 'much more satisfied' and 'much less satisfied' (scored -18 to +18). The ADDQoL questioned 18 important aspects of life including dietary enjoyment and freedom. Each question was scored for impact on life and importance with a range from -9 (maximum negative impact of diabetes) to +9 (maximum positive impact of diabetes). Three individual questions relating to food and drink were analysed individually together with a mean quality of life score. The Diabetes Empowerment Scale (DES) measured the patients' self-efficacy related to managing the psychosocial aspects of diabetes (9 statements); assessing dissatisfaction and readiness to change (9 statements); setting and achieving diabetes goals (10 statements). Statements were scored 'strongly disagree' (1 point) through to 'strongly

agree' (5 points). Average scores were calculated for each subscale, followed by an overall empowerment score.

Justification for choice of outcomes

Type 2 diabetes affects all aspects of life. Previous research has, however, focused mainly on biochemical outcomes (Griffin et al. 1998). The measurement of diabetes control and other important clinical outcomes in people with Type 2 diabetes is necessary if the effectiveness of the diabetes expert patient programme is to be properly evaluated. However, in order to test the hypothesis that the theories underpinning the education programme - empowerment and patient activation - increase the skills and confidence to make informed decisions regarding diabetes self-management, measurements of patient self-empowerment and lifestyle changes (self-care activities and food intake) are necessary. Although it is recognised that knowledge on its own does not change behaviour, knowledge of diabetes remains an important outcome, since a patient needs to have knowledge in order to make informed choices about his or her actions and activities (Walker 1998). Quality of life and satisfaction with treatment have recently become more important outcomes in health care evaluations, as it is increasingly being acknowledged that "health" encompasses the whole person, and not just clinical variables (Ewles & Simnett 2003) and that living with diabetes may have a detrimental effect on quality of life scores (Rubin 2000).

5.5 Statistical analysis

It is important to be able to detect whether any observed difference in treatments is genuine or could reasonably have arisen by chance. Significance tests measure statistical inference. However, the estimate of the magnitude of treatment differences should also be measured and confidence limits are a useful method of statistical estimation. The statistical software package SPSS for Windows version 11.0 was used for all analysis. Outcome data from the expert patient and routine treatment groups was compared at baseline, four and 14 months. An intention-to-treat-analysis was carried out. For normally distributed data, unpaired, two tailed t-tests were used and for non-normal data, non-parametric tests were used (Mann-Whitney).

5.6 Summary

Although it has now been recognised that effective management of Type 2 diabetes lies in the hands of the person with the condition, the most effective method of encouraging diabetes self-management is still unknown. This study tests the theories of patient empowerment and patient activation by delivering a diabetes expert patient programme to patients with Type 2 diabetes. Evaluation of biomedical, lifestyle and psychosocial outcomes were assessed by carrying out a randomised controlled trial that, where possible, conformed to the CONSORT statement. The research proposal was developed following reflection about current services for people with diabetes, enlistment of patients' views, liaison with the local branch of Diabetes UK and consultation with experts in the field. The diabetes expert patient programme was also assessed against diabetes education international standards for structure and process. General practices and patients were recruited from socio-economic deprived areas of Burnley, Pendle and Rossendale, East Lancashire. Statistical analysis used both parametric and non-parametric tests to compare the mean results from patients allocated to receive the diabetes expert patient programme and those allocated to receive routine treatment.

Chapter 6: Results

6.1 Introduction

This chapter presents the results from the randomised controlled trial. It starts with the recruitment statistics, followed by a detailed description of baseline characteristics and flow of the participants throughout the trial. The findings from the structure and process evaluation are then presented, followed by the biomedical, lifestyle and psychosocial outcomes, which have been assessed both in the short term (four months) and longer term (14 months). Unplanned outcomes are discussed and the chapter concluded with an overview of presentations undertaken at scientific meetings.

6.2 Recruitment

6.2.1 General practices

Four practices in Burnley and six practices in Pendle were invited to take part in the study. The sole criterion for selection was that they received the highest percentage of deprivation payments per total list size (see Table 6.1 on page 188). In Rossendale, six practices situated in the top 15% of deprived wards nationally were invited to be involved in the study (see Table 6.2 on page 189). All were supportive of the study, completed the practice consent form and provided a list of registered patients with Type 2 diabetes. However, the majority of practices classified diabetes as either insulin dependant or non-insulin dependant as opposed to Type 1 or Type 2 diabetes. To identify whether individual patients had Type 2 diabetes based on the WHO criteria (WHO Working Group 1999), diagnostic and treatment data for each patient was obtained from either the GP, practice nurse or the patients' medical records. Information regarding total list size was available for the practices in Burnley and Pendle and the mean prevalence of diagnosed and registered Type 2 diabetes was calculated for the 10 practices as 2.7% (range 1.8% to 5.0%).

6.2.2 Adults with Type 2 diabetes

Although ethical approval had been obtained, which meant that it was permissible to contact patients by letter or telephone, two of the practices (practices two and three in Table 6.1 overleaf) requested that their patients be contacted only by letter. Mailshots were sent to all patients initially, but in two practices (Burnley 1 and Burnley 4) the recruitment process was helped by following-up the letter with a telephone call. That was found to be the most successful way of recruiting South Asian participants. Where

prospective participants did not have a telephone, verbal communication about the research was given by making a home visit.

Burnley 2, which did not want the recruiting invitation letters to display the Burnley Healthcare NHS Trust logo, supplied its own letterhead paper and had the lowest recruitment rate for the Burnley area. The GP or practice nurse at many practices edited the list of patients with Type 2 diabetes by crossing off patients that they felt would be unsuitable to participate in the research. The main reasons for unsuitability were old age (above 80 years), residency in a nursing home, or being confused or immobile. Some practices were happy for mailshots to be sent to all patients so that individuals could make the decision whether to participate or not. Burnley 4 is situated in an area with a high population of South Asian people originating from Pakistan and Bangladesh. As materials for the study were available in Urdu and English, mailshots were only sent to Urdu-speaking South Asian people and not Bengali speaking South Asians.

Table 6.1 Detailed practice information

Practice	List Size (n)	Deprivation Payments n (%)	Patients with Type 2 Diabetes n (%)	Number of invitations sent	Recruitment Rate n (%)
Burnley 1	5,920	461 (7.8%)	118 (2.0%)	111	33 (29.7%)
Burnley 2	5,800	535 (9.2%)	107 (1.8%)	80	12 (15.0%)
Burnley 3	4,336	495 (11.4%)	84 (1.9%)	49	16 (32.7.0%)
Burnley 4	3,109	2,647 (85.1%)	155 (5.0%)	79	30 (40.0%)
Pendle 1	10,387	2,334 (22.5%)	256 (2.5%)	256	36 (14.1%)
Pendle 2	3,692	1,071 (29.0%)	67 (1.8%)	67	15 (22.4%)
Pendle 3	2,726	914 (33.5%)	69 (2.5%)	54	9 (16.7%)
Pendle 4	3,578	1,251 (35.0%)	118 (3.3%)	116	18 (15.5%)
Pendle 5	2,775	1,016 (36.6%)	87 (3.1%)	84	12 (14.3%)
Pendle 6	3,412	1,366 (40.0%)	145 (4.2%)	145	31 (21.3%)
TOTAL	45,735	12,090 (26.4%)	1,216 (2.7%)	1041	212 (20.4%)

Table 6.2 Practice and recruitment information for phase three in Rossendale

Practice	Ward	Rank of IMD*	Patients with Type 2 Diabetes (n)	Number of invitations sent	Recruitment Rate n (%)
1	Worsley	885	44	23	7
2	Worsley	885	237	186	30
3	Worsley	885	37	25	6
4	Greensclough	1087	155	127	30
5	Stacksteads	1217	85	78	7
6	Longholme	1257	130	64	22
TOTAL			688	503	102 (20.3%)

* IMD = Index of Multiple Deprivation: 1 = most deprived, 8414 least deprived.

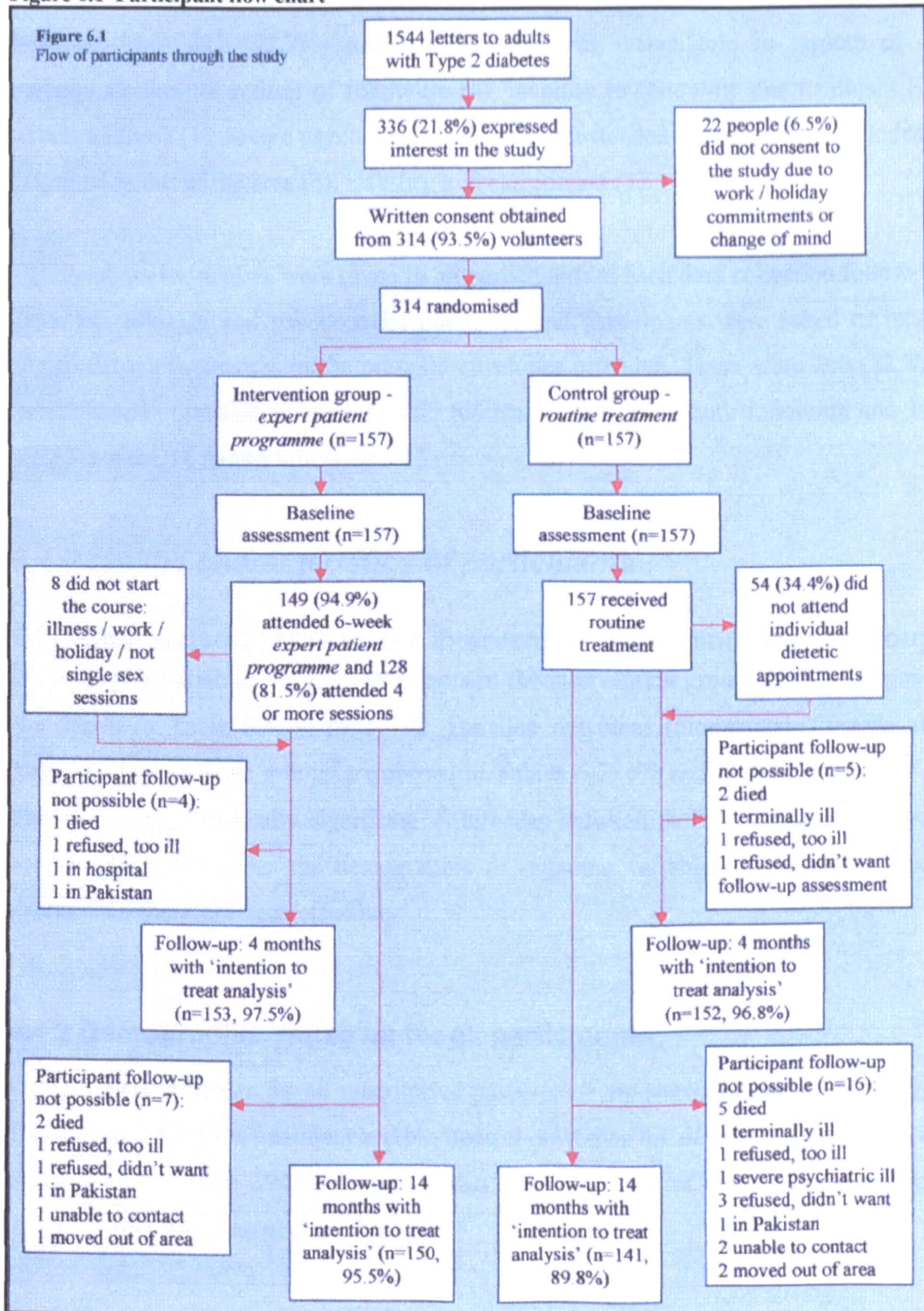
In Rossendale, six practices were recruited, providing a total of 688 qualifying patients. As only 1% of the Rossendale population belong to the Pakistan South Asian ethnic group (ELHA 1999) it was perceived that it would be difficult to recruit either 30 female or 30 male Urdu or English speaking participants. Mailshots were therefore sent only to Caucasian patients.

6.3 Participant flow

A summary of participant flow can be seen in figure 6.1 on page 190. Letters of invitation were sent to 1544 adults with Type 2 diabetes. Notification was received in respect of 13 people who had either died or moved out of the area. There were 336 (21.8%) replies from people who wished to take part in the study, of which 314 (93.5%) provided written consent. Baseline assessments were carried out for all 314 participants.

In total, 314 participants were randomized to intervention group (expert patient programme) or control group (routine treatment). Eight participants did not attend the six-week programme: three owing to illness; two owing to work and one owing to holiday commitments; two Asian women did not wish to attend mixed sex sessions.

Figure 6.1 Participant flow chart



Of the 149 (95%) participants who did attend, 128 (81.5%) attended four or more sessions. For those receiving routine care, 103 (65.6%) attended individual dietetic appointments. An intention to treat analysis was carried out and data was analysed from 307 participants at the four month follow-up. Data was unavailable in respect of seven participants owing to: refusal of follow-up (1); inability to follow-up owing to illness

(3); extended trip to Pakistan (1); death (3). At 14 months, outcomes were collected and analysed from 291 (92.7%) participants. Data was unavailable in respect of 23 participants due to: refusal of follow-up (4); inability to follow-up due to illness (2); terminal illness (1); severe psychiatric illness (1); an extended trip to Pakistan (2); death (7); moving out of the area (3); inability to make contact (3).

Validated questionnaires were given to all participants at each data collection follow-up to collect lifestyle and psychosocial outcomes and participants were asked to return completed questionnaires in the pre-paid envelopes provided. There were 260 (82.8%) questionnaires returned at baseline, 209 (66.6%) at the four month follow-up and 191 (60.8%) at the 14 month follow-up.

6.4 Baseline characteristics of participants

6.4.1 Comparison between the intervention group and control group

Demographic variables for the participants in the intervention group and control group are shown in Table 6.3 on page 192. Baseline outcomes (biomedical, lifestyle and psychosocial) for both groups are shown in Tables 6.7, 6.9 and 6.10 in section 6.5.3. There were no statistically significant differences between the intervention group and control group for either the demographic or outcome variables. The randomisation process had therefore been effective.

6.4.2 Demographic variables for all participants

Demographic variables for all randomised participants are shown in Table 6.4 on page 193. Baseline diabetes treatment and biomedical outcomes for all participants are shown in Table 6.5 on page 194. Both tables also show the data for each individual ethnic group: white Caucasian and South Asian.

The mean age of the participants at recruitment was 61.5 years (SD 10, range 30-85) and there were slightly more males, 162 (52%), than females 152 (48%). The mean duration of living with diabetes was 6.7 years (SD 6.5, range 0-36). Eighty-three (26%) participants were being treated with diet alone, 178 (57%) with tablets, and 53 (17%) with insulin. Of those treated with tablets, 110 (61.8%) received one type of diabetes medication, 67 (37.6%) two types and one (0.6%) three types.

Table 6.3 Comparison between the intervention and control group for demographic variables

Variable (mean)	Intervention group (SD)	Control group (SD)	Difference mean (95% CI)	P-value
Age (yrs)	61.3 (9.7) n=157	61.8 (11.0) n=157	0.5 (-1.8 to 2.8)	P=0.64
Time with diabetes (yrs)	6.7 (6.4) n=157	6.7 (6.7) n=157	0.0 (-1.4 to 1.5)	P=0.96
Age left full time education	15.3 (2.0) n=122	16.2 (5.4) n=112	0.9 (-0.5 to 1.9)	P=0.10
Qualifications -mean score*	1.4 (2.2) n=107	1.5 (2.2) n=103	0.1 (-0.4 to 0.7)	P=0.55
Employment -ever had a job¹	1.1 (0.3) n=133	1.1 (0.2) n=120	0.0 (-0.1 to 0.0)	P=0.21
-job at present²	1.84 n=118	1.76 n=105	0.1 (-0.2 to 0.0)	P=0.15
-mean job score³	5.74 (1.5) n=130	5.53 (1.5) n=117	-0.2 (-0.6 to 0.2)	P=0.27
Marital status -mean score⁺	1.65 (1.1) n=133	1.74 (1.0) n=121	0.1 (-0.2 to 0.4)	P=0.46

*Qualification codes: CSE=1, GSE=2, GCSE=3, City & Guilds=4, 'A' Levels=5, Teaching diploma/HNC=6, Degree=7

¹ever had a job: 1=yes, 2=no.

²do you have a job at the moment: 1=yes, 2=no.

³retired: 1=yes, 2=no

⁴job code: 1=manager, 2=supervisor, 3=foreman/woman, 4=self-employed, 5=other, 6=retired, 7=housewife, 8=unemployed

⁺Marital status: 1=married/living as married, 2=divorced, 3=widowed, 4=single, 5=separated

Out of the 234 participants who responded to the question, 195 (83%) had left full time education at the age of 16 or younger. Only 15 participants (7%) had continued in full time education beyond the age of 19 years. The majority of participants did not hold any academic qualifications (128 participants, 61%). Six participants (3%) reported their highest qualification to be of CSE standard, while 13 (6%) participants had obtained a degree.

Although 235 participants (90%) reported that they were, or had previously been, in paid employment, only 89 of the 186 participants who responded to the question, indicated that they had worked during the previous 10 years. Only 44 participants (17%)

were working when they entered the study. The reasons for not working were retirement (157 participants, 60%); being a housewife (28 participants, 11%) and unemployment

Table 6.4 Demographic variables for all participants, white Caucasians & South Asians

	All	White Caucasian	South Asian
Number, n	314	234	80
Mean age (SD)(yrs)	61.5 (10.4)	64.1 (9.7)	54.0 (8.5)
Range (yrs)	30-85	30-85	42-82
30 < 40 years	3 (1%)	3 (1%)	-
40 < 50 years	45 (14%)	13 (6%)	32 (40%)
50 < 60 years	84 (27%)	57 (24%)	27 (34%)
60 < 70 years	107 (34%)	90 (39%)	17 (21%)
70 < 80 years	65 (21%)	62 (26%)	3 (4%)
≥ 80 years	10 (3%)	9 (4%)	1 (1%)
Age left full time education			
Number of responses, n	234	208	26
Mean (SD) (years)	15.8 (4.2)	15.6 (3.9)	17.2 (5.8)
≤ 16 years	195 (83%)	179 (86%)	16 (62%)
17 – 18 years	24 (10%)	18 (9%)	6 (23%)
≥ 19 years	15 (7%)	11 (5%)	4 (15%)
Highest qualification			
Number of responses	210	179	31
None	128 (61%)	106 (59%)	22 (71%)
CSE	6 (3%)	5 (3%)	1 (3%)
'O' level	26 (12%)	25 (14%)	1 (3%)
GCSE	3 (2%)	1 (1%)	2 (7%)
'A' level	5 (2.5%)	5 (3%)	-
City & Guilds	24 (11%)	22 (12%)	2 (7%)
Teaching diploma/HNC	5 (2.5%)	4 (2%)	1 (3%)
Degree	13 (6%)	11 (6%)	2 (7%)
Employment history			
Number of responses	260	216	44
Ever had a paid job	235 (90%)	209 (97%)	26 (59%)
- Manager	40 (15%)	36 (17%)	4 (9%)
- Foreman	5 (2%)	5 (2%)	-
- Supervisor	30 (12%)	27 (13%)	3 (7%)
- Self-employed	41 (16%)	35 (16%)	6 (14%)
Presently working	44 (17%)	36 (17%)	8 (18%)
If not,			
- Housewife	28 (11%)	14 (7%)	14 (32%)
- Unemployed	12 (5%)	3 (1%)	9 (21%)
- Retired	157 (60%)	149 (69%)	8 (18%)
- Student	-	-	-
- Other	19 (7%)	17 (8%)	2 (5%)
Last paid employment			
Number of responses	186	166	20
- ≤ last 10 years ago	89 (48%)	83 (50%)	6 (30%)
- 10 to 20 years ago	62 (33%)	59 (36%)	3 (15%)
- ≥ 20 years ago	25 (13%)	22 (13%)	3 (15%)
- never worked	10 (5%)	2 (1%)	8 (40%)
Marital status			
Number of responses	254	212	42
Married/living as married	167 (66%)	129 (61%)	38 (91%)
Divorced	19 (7%)	18 (9%)	1 (2%)
Widowed	50 (20%)	47 (22%)	3 (7%)
Separated	3 (1%)	3 (1%)	-
Single	15 (6%)	15 (7%)	-

(12 participants, 5%). In respect of questions relating to marital status, 167 out of the 254 participants who provided information (66%) stated that they were either married or living together as married. Fifty (20%) were widowed, 19 (7%) divorced, 3 (1%) separated and 15 (6%) were single.

Only 38 participants (12%) had a BMI within the healthy weight range (BMI 20 to 24.9 Kg/m²), and just 11 (7%) females and 37 (23%) males had a waist circumference within the healthy range (less than 80cm and 94 cm respectively). Levels of obesity were high, with 146 participants (47%) being in the obese (BMI \geq 30 Kg/m²) or very obese range (BMI > 40 Kg/m²), and 124 females (83%) and 83 males (52%) had waist circumferences within the highest tertile (greater than 88 cm for females and greater than 102 cm for males).

Table 6.5 Biomedical and treatment variables

	All	White Caucasian	South Asian
Number, n	314	234	80
Females	152 (48%)	115 (49%)	37 (46%)
Males	162 (52%)	119 (51%)	43 (54%)
Time with diabetes			
Mean (SD) (years)	6.7 (6.5)	7.0 (6.9)	5.6 (5.3)
Range (years)	0-36	0-36	0-21
Treatment of diabetes			
Lifestyle alone	83 (26%)	65 (28%)	18 (22%)
Lifestyle and tablets	178 (57%)	124 (53%)	54 (68%)
Lifestyle and insulin	53 (17%)	45 (19%)	8 (10%)
Body Mass Index n	310	230	80
Mean (SD) (Kg/m ²)	30.7 (5.5)	30.9 (5.5)	30.1 (5.5)
Range	19.9 – 52.0	19-52	21-50
< 24.9 Kg/m ²	38 (12%)	26 (11%)	12 (15%)
25 to 29.9 Kg/m ²	126 (41%)	88 (39%)	38 (48%)
30 to 39.9 Kg/m ²	131 (42%)	105 (46%)	26 (32%)
\geq 40 Kg/m ²	15 (5%)	11 (5%)	4 (5%)
Waist circumference n	150	114	36
Mean female cm (SD)	102 (15)	100 (15)	108 (14)
Range cm	71-152	71-152	76-140
< 80 cm female	11 (7%)	10 (9%)	1 (3%)
80 to 88 cm female	15 (10%)	15 (13%)	-
>88 cm female	124 (83%)	89 (78%)	35 (97%)
Number n	161	118	43
Mean male cm (SD)	104 (11)	104 (11)	102 (10)
Range cm	81-132	81-132	86-124
<94 cm	37 (23%)	26 (22%)	11 (26%)
94 to 102 cm	41 (25%)	26 (22%)	15 (35%)
>102 cm	83 (52%)	66 (56%)	17 (40%)

Glycated haemoglobin n	314	234	80
Mean % (SD)	7.7 (1.6)	7.7 (1.5)	7.7 (1.6)
Range	5.1 – 14.0	5.1-13.6	5.4-14.0
≤ 6.0%	39 (12%)	31 (13%)	8 (10%)
6.1% - 7.0%	83 (27%)	58 (25%)	25 (31%)
7.1% - 8.0%	88 (28%)	63 (27%)	25 (31%)
8.1% - 9.0%	60 (19%)	47 (20%)	13 (16%)
9.1% - 10%	21 (7%)	17 (7%)	4 (5%)
≥10%	23 (7%)	18 (8%)	5 (6%)
Systolic blood pressure n	313	233	80
Mean (SD) (mmHg)	148 (22)	150 (21)	139 (23)
Range	88 – 240	88-233	101-240
≤ 140 mmHg	123 (39%)	76 (33%)	47 (59%)
Diastolic blood pressure n	313	233	80
Mean (SD) (mmHg)	82 (12)	82 (12)	84 (10)
Range	53 – 122	53-122	63-117
≤ 80 mmHg	138 (44%)	110 (47%)	28 (35%)
Total cholesterol n	304	229	75
Mean (SD) (mmol/l)	5.0 (1.0)	5.1 (1.1)	4.8 (0.9)
Range	1.4-9.3	1.4-9.3	2.9-6.8
≤ 5 mmol/l	167 (55%)	122 (53%)	45 (60%)
LDL cholesterol n	277	212	65
Range	0.6-5.6	0.6-5.6	0.6-4.3
Mean (SD) (mmol/l)	2.7 (0.8)	2.8 (0.9)	2.6 (0.8)
≤ 3 mmol/l	174 (63%)	126 (59%)	48 (74%)
HDL cholesterol n	301	227	74
Range	0.6-2.8	0.6-2.8	0.7-1.7
Mean (SD) (mmol/l)	1.3 (0.3)	1.3 (0.4)	1.2 (0.2)
≥ 1.1 mmol/l	194 (65%)	152 (67%)	42 (57%)
Triglycerides n	299	226	73
Range	0.4-8.4	0.4-8.4	0.7-7.2
Mean (SD) (mmol/l)	2.4 (1.3)	2.4 (1.2)	2.5 (1.4)
≤ 2.3 mmol/l	172 (58%)	130 (58%)	42 (58%)

There were 39 participants (12%) who had excellent diabetes control with glycated haemoglobin levels within the normal non-diabetic range (below 6%). Eighty three participants (27%) had good diabetes control with glycated haemoglobin levels between 6.1% and 7.0%. However, 81 participants (26%) had poor diabetes control (HbA1c above 8%) and 23 participants (7%) had very poor control with glycated haemoglobin levels above 10%. Only 123 participants (39%) had systolic blood pressure levels within the recommended range and 138 (44%) had diastolic blood pressure within the recommended range. Between 55% and 65% of participants met the targets for lipid profile variables.

Comparison between the white Caucasian participants and South Asian participants

The South Asian participants were, on average, 10 years younger than the white Caucasian participants with the majority (74%) being in their 40s and 50s. South Asian

participants had, however, been diagnosed with diabetes for a similar number of years as the white Caucasian participants. Less than 50% of South Asian participants completed all the questions regarding education, employment history and marital status (see Table 6.4 on page 193). Those who did were, on average, one and a half years older than the white Caucasian participants when leaving full time education (17.2 years and 15.6 years respectively) with 15% remaining in full time education beyond the age of 19 years. A greater percentage of the South Asian participants indicated that they did not hold any formal qualifications (71% compared to 59% of white Caucasians).

South Asian participants were less likely than the white Caucasian participants to have ever been in paid employment (59% and 97% respectively). A greater percentage of them were housewives (32% as against 7% of white Caucasians) or unemployed (21% and 1% respectively). South Asian participants were more likely to be married (91% and 61% respectively) and fewer South Asian participants were divorced (2% and 9% respectively), widowed (7% and 22% respectively) or single (0% and 7% respectively).

With regard to treatment for diabetes, more South Asians participants were prescribed tablets (68% compared to 53% of white Caucasians) and fewer were prescribed insulin (10% and 19% respectively). Mean BMI was slightly less for the South Asian participants than it was for the white Caucasians (30 Kg/m² and 31 Kg/m² respectively) with more South Asian participants in the overweight range (48% and 39% respectively) and less in the obese range (37% and 51% respectively). South Asian females were more likely to have a waist circumference in the highest tertile (97% compared to 78% of white Caucasians) whereas South Asian males were less likely to have a waist circumference in the highest tertile (40% compared to 56% of white Caucasians). Mean glycated haemoglobin levels were the same in both ethnic groups and there was similar distribution across the ranges. Mean systolic blood pressure measurements were lower in the South Asian participants than the white Caucasians (139 mmHg and 150 mmHg respectively) with 59% of South Asians compared to 33% of white Caucasians having readings below 140 mmHg. However, South Asian participants were less likely to meet diastolic blood pressure targets (35% compared to 47% of white Caucasians). Mean total and LDL cholesterol were lower in the South Asian participants than the white Caucasian participants (total cholesterol 4.8 mmol/l and 5.2 mmol/l respectively; LDL cholesterol 2.6 mmol/l and 2.8 mmol/l respectively) with a greater percentage of South Asian participants meeting national recommendations (total cholesterol, 60% compared to 53% of white Caucasians; LDL

cholesterol, 74% and 59% respectively). However, HDL cholesterol was lower in the South Asian participants compared to the white Caucasians (1.2 mmol/l and 1.3 mmol/l respectively) with less South Asian participants meeting national targets (57% and 67% respectively). Triglyceride levels were similar in both ethnic groups.

6.5 Evaluation: structure, process and outcome

6.5.1 Structure

The diabetes expert patient programme and its impact on local diabetes services was evaluated against the 'structure' standards of the International Diabetes Federation (described in Chapter 5, section 5.4.1). Those standards are stated below along with the results from the evaluation.

a) There is documented evidence of organisational/institutional support for education as an integral part of diabetes care.

As a result of national guidelines (DOH 2001a) and the local X-PERT project, the author of this thesis was asked by Burnley, Pendle and Rossendale Primary Care Trust (BPR PCT) to chair a patient empowerment and education subgroup for the Local Diabetes Services Implementation Group (LDSIG). A representative sample of empowered expert patients and their carers, a member of the local branch of Diabetes UK and two health care professionals met for five focus groups within a six-month period and devised a report stating recommendations for the delivery of diabetes education locally (Appendix 7). The X-PERT Programme was put forward as an example of good practice and as a result, the PCT intends to support diabetes education as an integral part of diabetes care.

b) One person will be identified as having responsibility for the organisation and administration of the diabetes education service in such a way that the process and outcome standards can be met.

The author of the thesis designed, developed and delivered the X-PERT programme throughout Burnley, Pendle and Rossendale and has therefore taken the lead in the organisation and administration of diabetes education in the locality. These programmes have been funded by a research grant and so the future delivery of diabetes education programmes, including assessment of process and outcome standards, is not guaranteed.

c) Physical space and education resources are conducive to learning and based on individual/community needs.

There are several, easily accessible, health centres and community venues within

Burnley, Pendle and Rossendale that were available for the delivery of the diabetes education programmes. Education resources, such as the visual aids, patient manuals, display board, flip chart, and television with video, were either hand made, purchased or borrowed. All educational materials have been developed to encourage learning through patient activation and these have, where necessary, been adapted for use with the local South Asian population.

d) An advisory committee is established to ensure that the views and values of all stakeholders are represented in the ongoing planning and delivery of diabetes education.

Stakeholders involved in the design, development and delivery of the X-PERT programme were the patients, the local branch of the Diabetes UK, BPR PCT dietetic department and the Nuffield Institute for Health, University of Leeds. Since the implementation of the X-PERT programme, the LDSIG and BPR PCT management team has taken a vested interest in diabetes education and will be involved in the future planning of diabetes education programmes.

e) Teamwork and communication are evident among those providing diabetes education and management.

There is currently little teamwork and communication between individual general practices, the specialist diabetes team based at the acute Trust (East Lancashire Hospitals NHS Trust) and the local branch of Diabetes UK. Diabetes education is often provided in an inconsistent and 'ad hoc' fashion that results in many patients receiving conflicting advice. Although the X-PERT programme was implemented to address those issues by delivering structured education, it has not addressed teamwork and communication issues. Because the programme was delivered within a very tight time schedule, the involvement from each practice was minimal. Each practice nurse was invited to participate in the programme but only one nurse was able to attend the sessions owing to volume of work.

f) Personnel involved in diabetes education have a sound clinical understanding of diabetes, are knowledgeable about teaching and learning skills and diabetes self-management practices.

The author of the thesis and the tutor of the X-PERT programme is a diabetes specialist dietitian who has taken extra training in adult education, health behaviour change principles and the aetiology, treatments and complications of diabetes. There is currently no standardised certification of training programmes for primary and secondary care staff involved in the delivery of diabetes education and therefore health

professionals receive training in an ad hoc fashion with few being knowledgeable about adult education principles.

g) The competence and performance of personnel involved in diabetes education is reviewed at least annually.

There is currently no system in place within BPR PCT to review the competence and performance of health professionals involved in diabetes education.

h) Diabetes education covers topics based on individual assessment and fosters acquisition of knowledge leading to self-management of diabetes.

The X-PERT programme is a group education programme designed to facilitate the identification by participants of individual problems associated with diabetes. It was envisaged that participants wishing to explore possible solutions to their respective problem would acquire more knowledge and improve their self-management of the condition. For individual appointments with patients, the dietetic department uses a locally written protocol, which involves making an individual assessment and providing information to encourage diabetes self-management. Recommendations for the management of diabetes in primary care are available (Guy et al. 1997) but these are outdated. Neither local implementation nor evaluation has been evident.

i) Relationships are fostered with available community resources such as diabetes associations, blind society, social services.

Both the diabetes management team within BPR PCT and the author of the X-PERT programme have an excellent relationship with the local branch of Diabetes UK. Venues belonging to social services were used in Burnley for the implementation of the X-PERT programmes with possibilities for joint working projects in the future.

6.5.2 Process

The X-PERT programme was evaluated against the process standards described in Chapter 5.4.2. Those process standards and the results of the evaluation are shown below:

a) Diabetes education is based on the ongoing learner-centred needs assessments of individuals and/or communities.

The X-PERT programme was designed taking into consideration the learner-centred needs of individuals with Type 2 diabetes and the community in which they live. As the diabetes education programme is based on theories of empowerment and patient activation, patients identified their own needs and developed the skills and confidence to explore possible actions to increase diabetes self-management.

b) Plans for diabetes education programmes are learner-centred and subject to ongoing review and modification.

Ten X-PERT programmes have been delivered and each programme was modified slightly in order to meet the needs of the participants. For example, participants attending a programme in Burnley elected to miss out the supermarket tour because several of them had mobility problems. The tour was replaced with an activity whereby participants brought empty food cartons, wrappers and labels to the session and discussions similar to those forming part of the supermarket tour took place. Any participants from the group who would have liked to attend a supermarket tour were invited to attend one of the tours arranged for another programme. Each programme was evaluated using a patient evaluation form (Appendix 8). Participant evaluation is covered in more detail on pages 201 to 204.

c) Implementation of diabetes education is learner-centred and facilitates cognitive learning, behaviour change and self-management and is extended to families, caregivers and communities where appropriate.

As shown in the outcome results (section 6.5.3, starting on page 204) the X-PERT programme facilitated skill development, self-directed behaviour change and diabetes self-management. Participants were encouraged to attend the programme with a family member or friend and approximately one quarter to one third of participants brought somebody with them. Whole communities were not directly involved although 'word of mouth' was a powerful indicator of community interest. This is discussed further in Chapter 7.

d) Education is provided in a professional and ethical manner and is learner-centred and evidence-based where possible.

The X-PERT programme was delivered in a high quality and professional manner and was adapted to be suitable for the local Urdu speaking South Asian population. The content was prepared from the latest evidence-based guidelines and was updated as appropriate.

e) The diabetes education service will be recognised by and accessible to the community.

As the X-PERT programme was evaluated with a randomised controlled trial, only 16 practices were invited to take part in the research and half of the participants received the control education programme, which was routine care. Therefore the education programme service is currently not available to all those with Type 2 diabetes. The programme has been recognised as an example of good practice and, in

2003, it won national awards from Diabetes UK and the National Obesity Forum. It is hoped that BPR PCT will implement the programme as routine treatment in the future.

f) The effectiveness and quality of education will be annually assessed, linked to outcomes, and the services will be reviewed on the basis of the assessment.

A participant evaluation was carried out after each programme. Biomedical, lifestyle and psychosocial outcomes were collected at four months and at 14 months. Future programmes will be reviewed based on that assessment.

g) Educational and clinical research are undertaken to provide an evidence base for practice.

Participant outcomes were collected at baseline, four and 14 months and compared to a control group. The results of the randomised controlled trial have provided, and will continue to provide an evidence base for the future delivery of diabetes education. If the X-PERT programme is implemented as routine treatment, it is hoped that educational and clinical research will continue.

Participant evaluation

Attendance registers were taken for each X-PERT programme. Participants were classed as attendees if they attended at least four out of the six sessions and those participants received an attendance certificate. For a summary of attendance for each programme see Table 6.6 on page 202. In total, 128 (81.5%) participants attended four or more sessions. The attendance rate was greater for the white Caucasian participants than for the South Asians (100 (86%) and 28 (68%), respectively; $P=0.01$). The reasons for that finding are discussed in Chapter 7. In 51% of cases, the tutor was informed in advance if individuals were unable to attend a future session.

Process evaluation was carried out upon completion of the programme in order to assess acceptability, enjoyment and usefulness of the intervention and its perceived impact on health. Participants were asked to complete the evaluation questionnaire and the results were as follows (see figure 6.2 on page 203):

- 129 participants (82%) returned the questionnaire;
- 97% (95% CI: 94% to 100%) enjoyed the whole programme, with weight management being the most popular session;

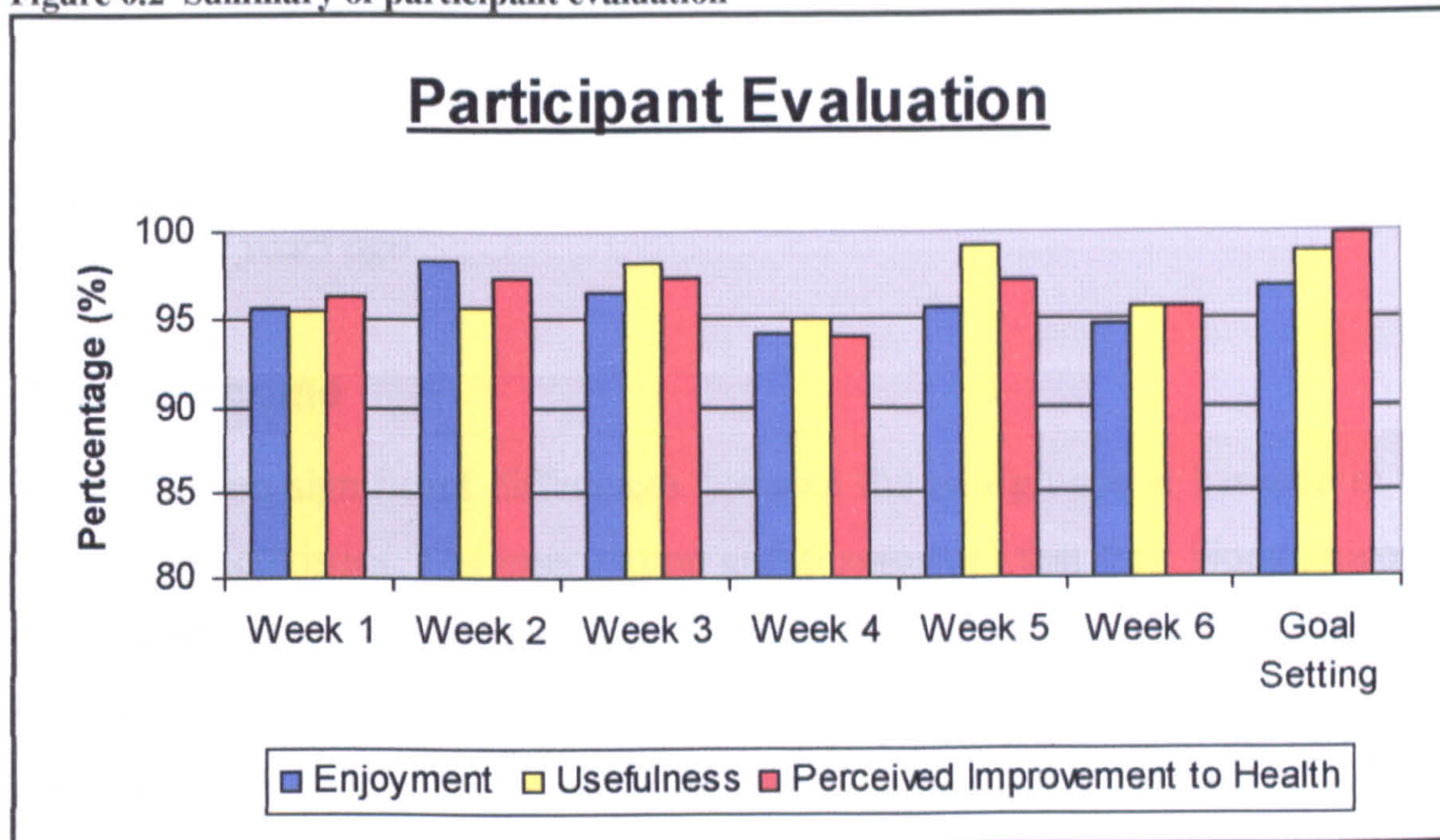
- 99% (95% CI: 95% to 100%) found the programme useful, diabetes complications being the most useful topic;
- 96% (95% CI: 93% to 99%) perceived that attending the expert patient programme would improve their health with 99% stating that the time spent on goal setting would have the greatest impact;
- Six weekly sessions were reported 'just right' for 72% of participants (95% CI: 64% to 80%) with 16% requesting more sessions. 80% were satisfied with 2-hour sessions (95% CI: 73% to 87%);
- 91% stated that knowledge gained equipped them with the skills to help other people with diabetes (95% CI: 86% to 96%).

Table 6.6 Participant attendance

Programme	No. of Attendees	1 Week	2 Week	3 Week	4 Week	5 Week	6 Week	Number of attendees
Burnley 1	15	13	14	11	9	12	11	12/15 (80%)
Burnley 2	15	13	12	13	14	12	11	14/15 (93%)
Burnley 3 South Asian ^a	15	11	8	11	8	6*	8	9/15 (60%)
Pendle 1	18	13	13	15	9	13	14	14/18 (78%)
Pendle 2	17	16	14	15	11	13	9	13/17 (76%)
Pendle 3 South Asian ^b	12	8	7	7	7	8	10	8/12 (67%)
Pendle 4 South Asian ^c	14	11	10	10	11	10	10	11/14 (79%)
Rossendale 1	16	15	13	13	15	13	12	14/16 (88%)
Rossendale 2	16	14	12	11	13	9	12	14/16 (88%)
Rossendale 3	19	16	18	16	16	16	17	19/19 (100%)
TOTAL	157	130 (83%)	123 (78%)	122 (78%)	113 (72%)	112 (71%)	114 (73%)	128/157 (82%)

^aMale and female South Asian participants ^bMale South Asian participants only ^cFemale South Asian participants only *Racial riots in Burnley

Figure 6.2 Summary of participant evaluation



Participants often wrote additional comments on the evaluation forms, a sample of which can be seen below:

'This is the first time in 10 years of being a diabetic that anybody has told me these things'

'I am certain that I would not have gained more than 20% of the knowledge I have about diabetes had I not attended this course. I believe that diabetics will respond better to education delivered in this way, rather than the ad hoc information handed out by busy Consultants/GPs/Practice Nurses. This course should be essential for all newly diagnosed diabetics'

'I feel I have gained a lot more knowledge about diabetes, which I can use for myself and at the hospital, with elderly patients. I will show my file to the boss'

'Very glad to be offered the course, much appreciated (Thank you NHS!). Feel much encouraged in dealing with myself and more understanding with latest knowledge'

'Some very useful information gleaned from this course. Will certainly change my attitude to diabetes control and lifestyle'

'I realised by coming to the sessions, how little I knew about diabetes. I found these sessions really useful'

'I am more at ease with diabetes from what I have learnt and able to control it better'

'I was very impressed – the sessions had been delivered in a manner that had obviously gone beyond that required to make them understandable'

'The course was really enjoyable and educational and has helped me to understand diabetes more fully regarding my husband and also in helping other people with diabetes who I come into contact with in my work in the community and in helping myself to adopt a healthier lifestyle. Wish we had this education years ago'

'Don't feel as frightened as I did.....feel more confident in myself...things explained so that anybody & everybody can understand'

'I think this course was really helpful in helping me understand diabetes as all demonstrations were in laymen's language' 'This programme should have been implemented years ago'

6.5.3 Outcome

There were no significant differences between the two groups at baseline in terms of patient characteristics. The intervention group perceived that their blood glucose levels had recently been high compared with the perception of the control group. However, there was no difference in baseline glycated haemoglobin levels and that result may therefore have been due to increased diabetes awareness before commencing the X-PERT programme.

BIOMEDICAL OUTCOMES (see Table 6.7 on page 206)

At four months, there was a significant difference (0.4%; 95% CI: 0.1% to 0.7%; $P=0.02$) in the mean HbA_{1c} between the expert patient and routine treatment groups. There was a greater significant difference at 14 months (0.7%; 95% CI: 0.3% to 1.0%, $P<0.001$) (see figure 6.3 overleaf). Systolic blood pressure was 5 mmHg lower in the intervention group (95% CI: 0-9mmHg; $P=0.06$) at four months with borderline statistical significance. At 14 months the expert patient group showed a 7 mmHg reduction in systolic blood pressure. The control group also experienced a reduction (4 mmHg) at 14 months and there was therefore no statistically significant difference between the two groups (difference 3.1 mmHg; 95% CI: -1.6 to 7.9, $P=0.19$) (see figure 6.4 overleaf). The expert patient group experienced a small reduction in diastolic blood pressure at both four and 14 months with a 1.7 mmHg difference between the intervention and control group that was neither clinically nor statistically significant (see figure 6.5 overleaf). There was no statistical difference between the groups in the short or longer term in respect of lipid profile. Although not statistically significant, body weight, BMI and body fat showed a general trend towards a reduction compared to controls and waist circumference showed a borderline statistically significant reduction at 14 months (see figures 6.6 to 6.9 overleaf).

Figure 6.3 Glycated haemoglobin

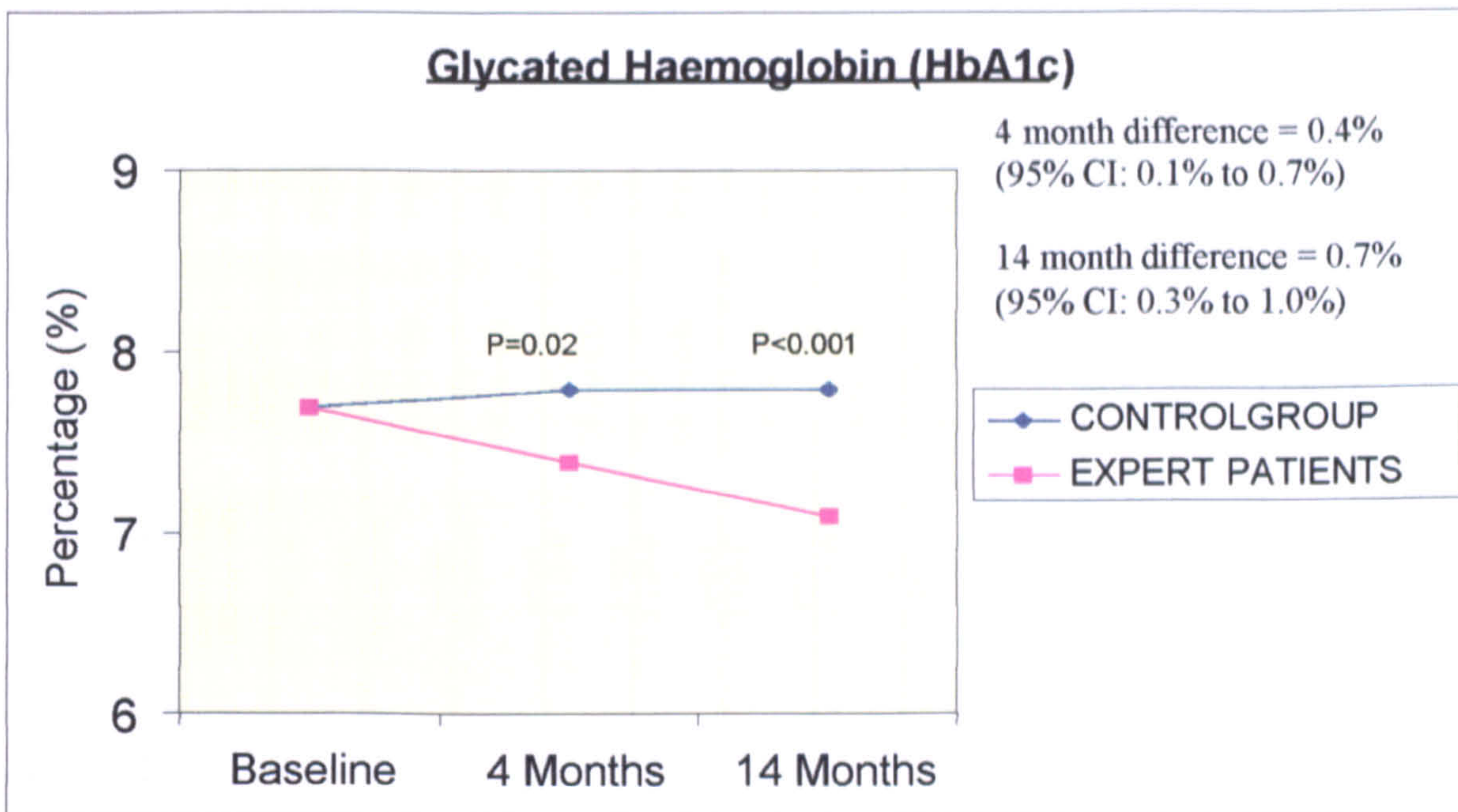


Figure 6.4 Systolic blood pressure

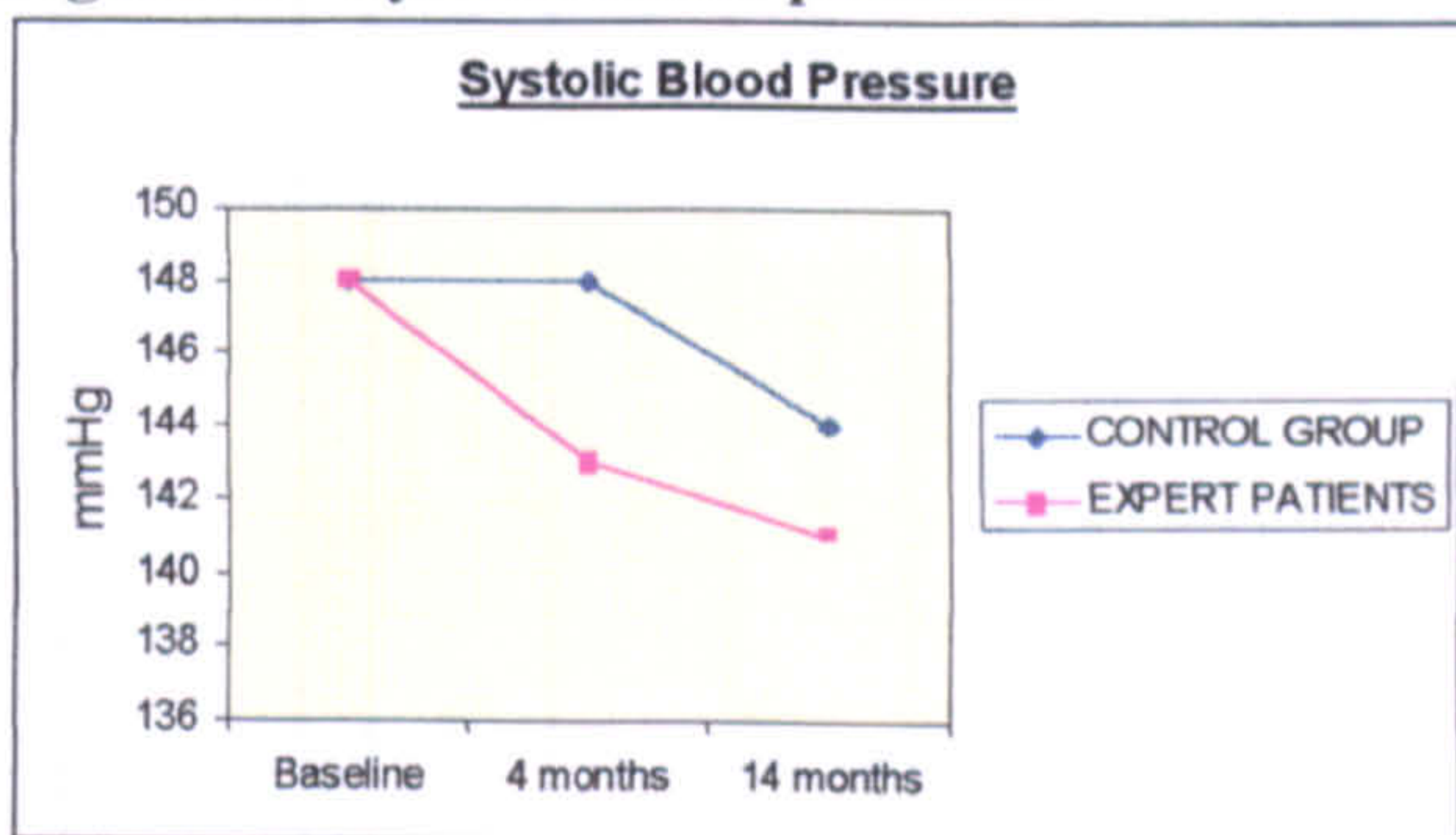


Figure 6.5 Diastolic blood pressure

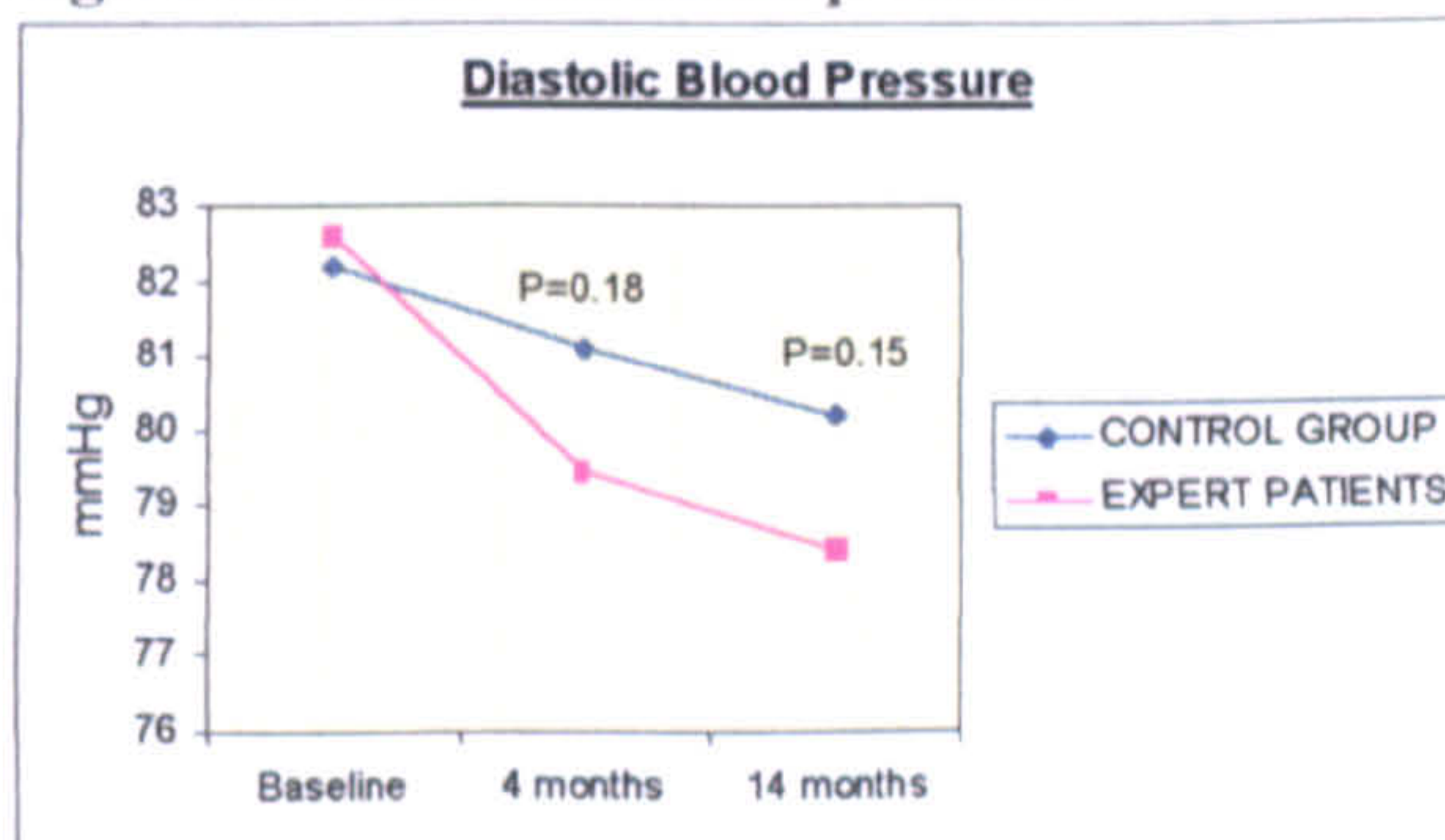


Figure 6.6 Body weight

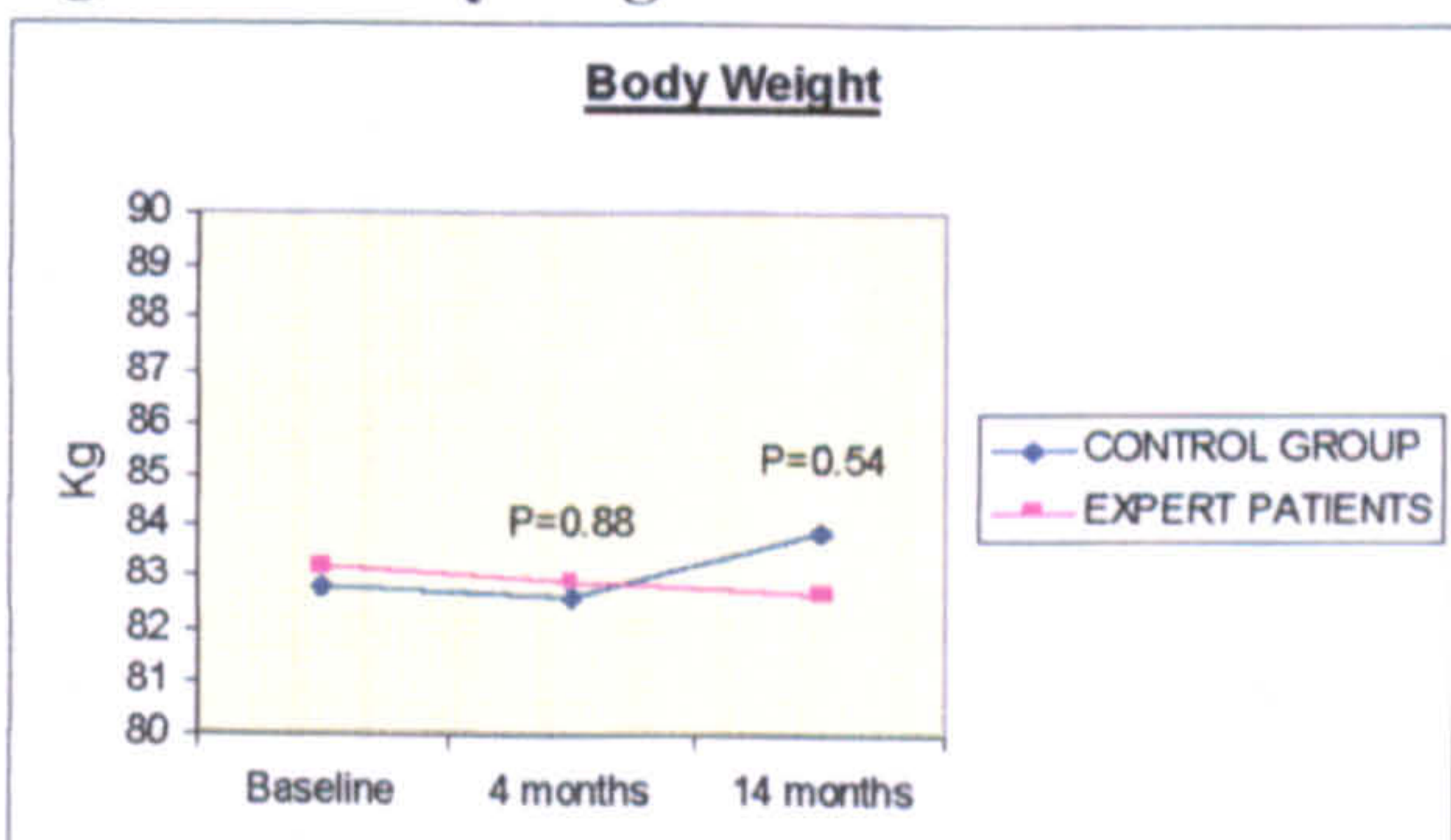


Figure 6.7 BMI

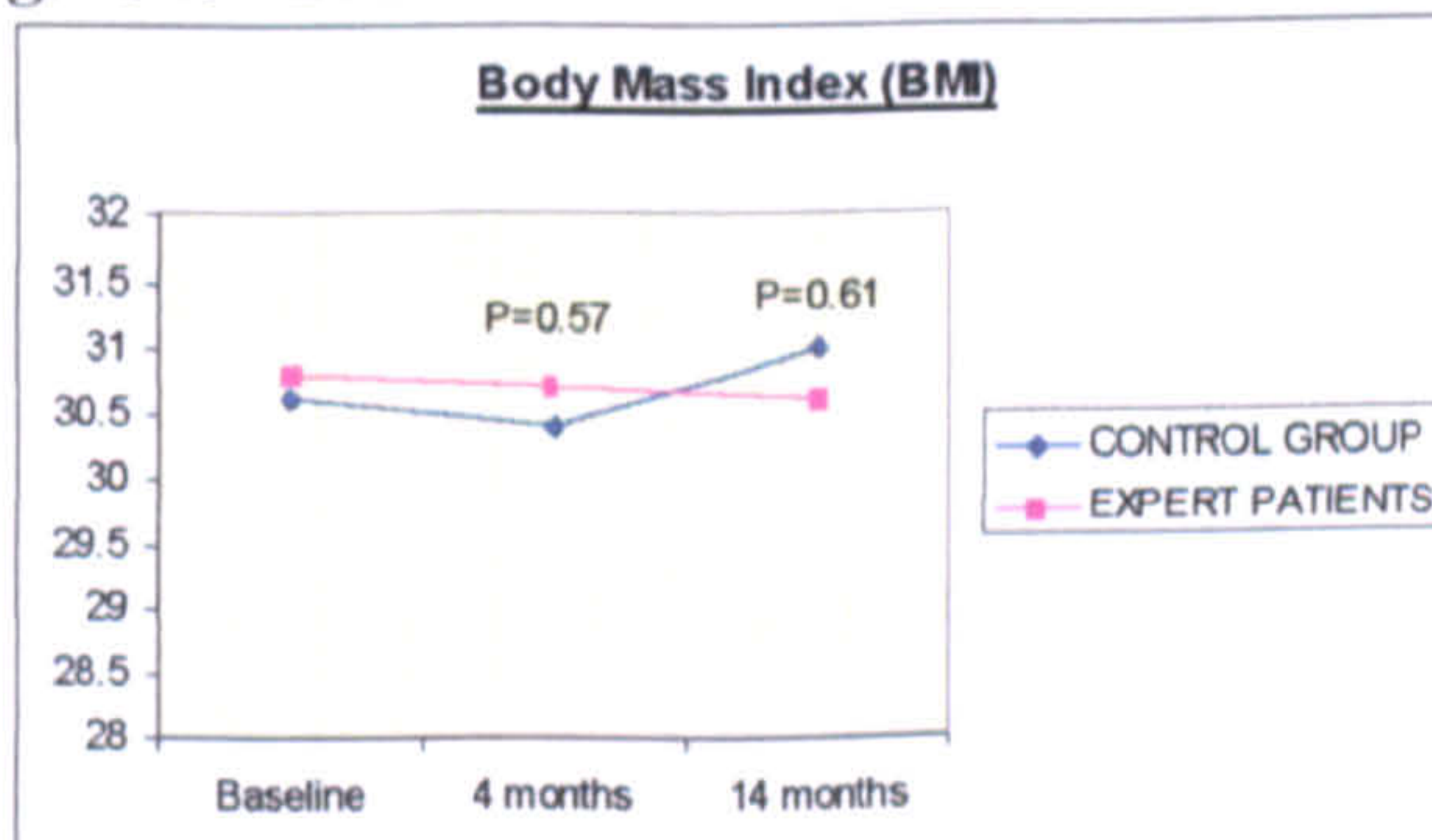


Figure 6.8 Waist circumference

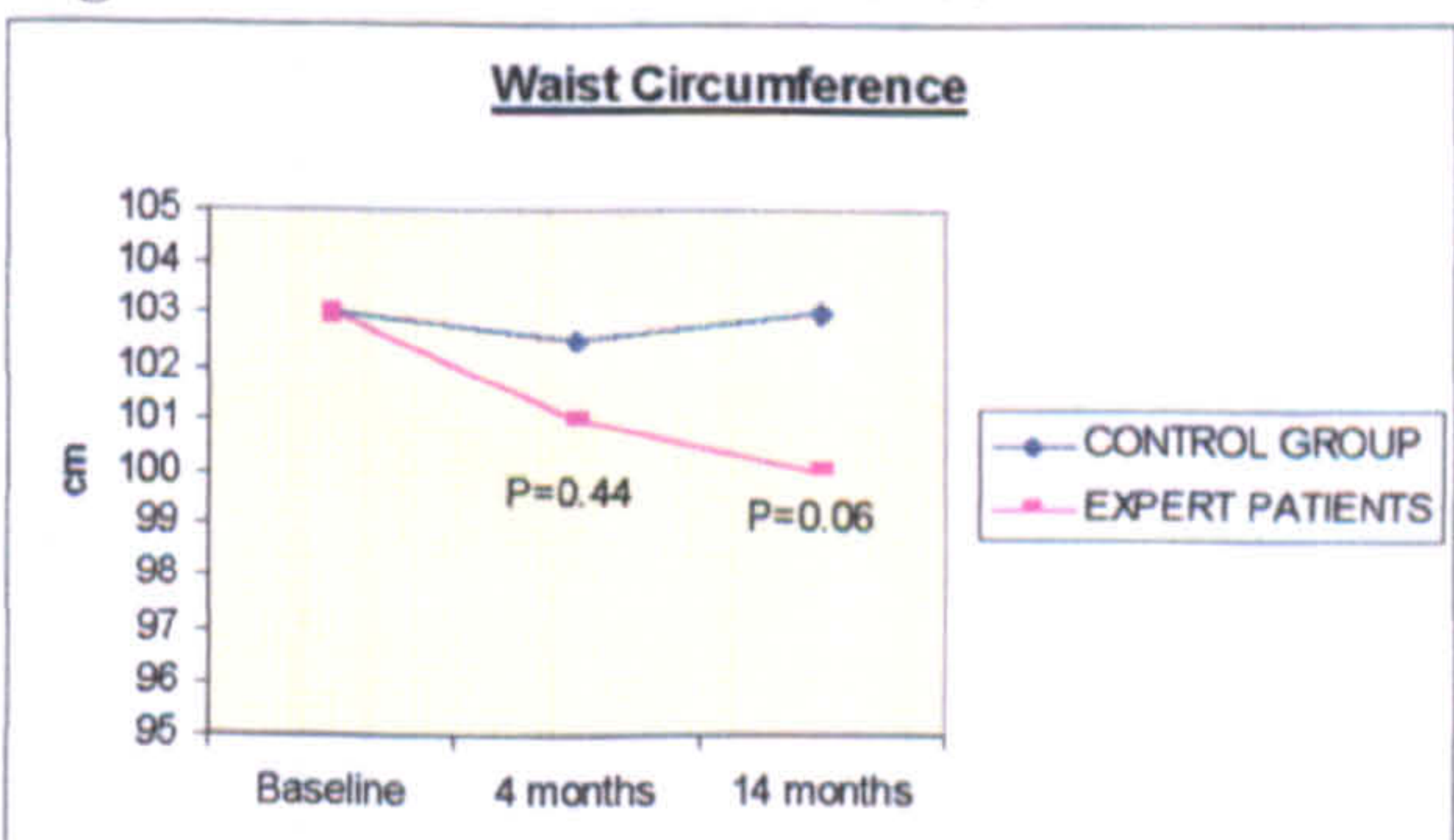


Figure 6.9 Body percentage fat

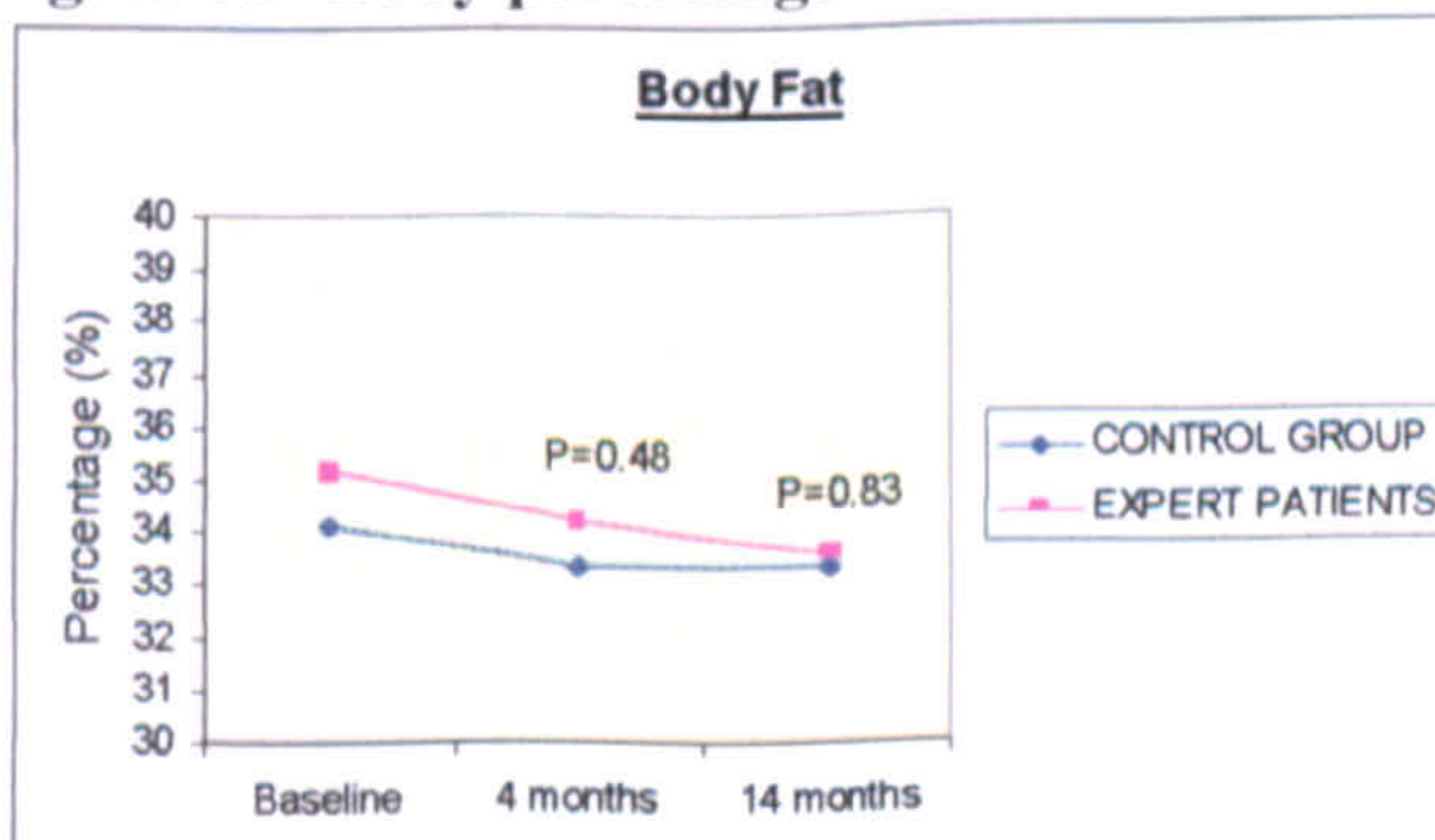


Table 6.7 Biomedical outcomes: differences between the intervention (expert patient programme) group and the control (routine treatment) group

OUTCOMES	BASELINE				FOUR MONTH DATA				14 MONTH DATA			
	Intervention Group (SD)	Control Group (SD)	Difference: mean (95% CI)	P-value	Intervention group (SD)	Control group (SD)	Difference: mean (95% CI)	P-value	Intervention group (SD)	Control group (SD)	Difference: mean (95% CI)	P-value
HbA _{1c} (%)	7.7 (1.6) n=157	7.7 (1.6) n=157	0.0 (-0.3 to 0.4)	P=0.85	7.4 (1.3) n=152	7.8 (1.6) n=149	0.4 (0.1 to 0.7)	P=0.02	7.1 (1.1) n=150	7.8 (1.6) n=141	0.7 (0.3 to 1.0)	P<0.001
Systolic BP (mmHg)	147.5 (19.8) n=157	147.8 (23.7) n=157	0.3 (-4.6 to 5.1)	P=0.92	142.6 (18.8) n=150	147.8 (22.7) n=149	4.6 (-0.2 to 9.3)	P=0.06	141.3 (16.8) n=149	144.4 (23.5) n=140	3.1 (-1.6 to 7.9)	P=0.19
Diastolic BP (mmHg)	82.6 (11.0) n=157	82.2 (12.2) n=157	-0.4 (-3.0 to 2.2)	P=0.78	79.4 (9.5) n=150	81.1 (12.3) n=149	1.7 (-0.8 to 4.2)	P=0.18	78.4 (9.6) n=149	80.2 (10.9) n=140	1.7 (-0.6 to 4.1)	P=0.15
Total Cholesterol (mmol/l)	5.1 (1.1) n=154	4.9 (1.0) n=150	-0.2 (-0.4 to 0.1)	P=0.19	4.9 (1.0) n=144	5.0 (1.0) n=142	0.1 (-0.1 to 0.4)	P=0.31	4.8 (1.1) n=148	4.7 (1.0) n=139	-0.1 (-0.3 to 0.1)	P=0.37
HDL Cholesterol (mmol/l)	1.3 (0.3) n=153	1.3 (0.4) n=148	0.0 (-0.1 to 0.1)	P=0.82	1.2 (0.3) n=142	1.2 (0.4) n=141	0.0 (0.0 to 0.1)	P=0.40	1.1 (0.4) n=145	1.1 (0.4) n=135	0.0 (-0.1 to 0.1)	P=0.94
LDL Cholesterol (mmol/l)	2.7 (0.9) n=140	2.7 (0.8) n=137	0.0 (-0.2 to 0.2)	P=0.84	2.7 (0.9) n=133	2.8 (0.8) n=129	0.1 (-0.1 to 0.3)	P=0.37	2.7 (0.9) n=140	2.7 (0.8) n=131	0.0 (-0.3 to 0.1)	P=0.54
T Cholesterol (mmol/l)	4.3 (1.3) n=153	4.2 (1.1) n=148	-0.1 (-0.4 to 0.2)	P=0.44	4.4 (1.3) n=141	4.4 (1.3) n=140	0.0 (-0.3 to 0.3)	P=0.79	4.7 (1.3) n=145	4.7 (1.4) n=135	0.0 (-0.3 to 0.3)	P=0.96
Triglyceride (mmol/l)	2.5 (1.4) n=151	2.3 (1.1) n=148	-0.3 (-0.6 to 0.0)	P=0.06	2.3 (1.2) n=142	2.4 (1.4) n=140	0.1 (-0.2 to 0.4)	P=0.56	2.1 (1.1) n=145	2.0 (1.2) n=135	-0.5 (-0.3 to 0.2)	P=0.70
Body Weight (kg)	83.2 (14.5) n=156	82.8 (17.6) n=154	-0.4 (-4.0 to 3.2)	P=0.84	82.9 (14.9) n=149	82.6 (17.9) n=145	-0.3 (-4.1 to 3.5)	P=0.88	82.7 (14.8) n=148	83.9 (18.8) n=139	1.2 (-2.7 to 5.2)	P=0.54
BMI (kg/m ²)	30.8 (5.3) n=156	30.6 (5.7) n=154	-0.3 (-1.5 to 1.0)	P=0.67	30.7 (5.4) n=149	30.4 (5.8) n=145	-0.4 (-1.7 to 0.9)	P=0.57	30.6 (5.5) n=148	31.0 (6.4) n=139	0.4 (-1.0 to 1.7)	P=0.61
Body Fat (%)	35.2 (9.6) n=151	34.1 (9.2) n=142	-1.1 (-3.2 to 1.1)	P=0.34	34.2 (9.4) n=144	33.4 (9.0) n=141	-0.8 (-2.9 to 1.4)	P=0.48	33.6 (9.3) n=139	33.4 (9.2) n=134	-0.2 (-2.4 to 1.9)	P=0.83
Waist Size (cm)	103 (12) n=156	103 (14) n=155	0 (-4 to 2)	P=0.76	101 (12) n=149	102.5 (14) n=145	1 (-2 to 4)	P=0.44	100 (11) n=148	103 (14) n=136	3 (0 to 6)	P=0.06

*Values are means (standard deviations) unless stated otherwise

Subgroup Analysis

The primary outcome glycated haemoglobin was analysed separately for the white Caucasian and South Asian participants (see Table 6.8 below). At baseline there were no significant differences between the expert patients and the control groups for either of the white Caucasian or South Asian participant subgroups. At four months, the white Caucasian expert patients showed a slight but statistically non-significant difference in glycated haemoglobin levels compared to the control group (difference 0.2%; 95% CI: -0.2% to 0.6%, $P=0.25$). However, there was a highly significant statistical difference between the expert patients and the control group in the South Asian subgroup (difference 1.0 %; 95% CI: 0.3% 1.7%, $P=0.004$). At 14 months expert patients in both subgroups showed a statistically significant improvement in glycaemic control compared to the control group (white Caucasian subgroup difference 0.6%; 95% CI: 0.3% to 1.0%, $P=0.001$ and South Asians subgroup difference 0.8%; 95% CI: 0.1% to 1.5%, $P=0.02$).

Table 6.8 Sub-group analysis comparing white Caucasian and South Asian participants

	All participants			White Caucasian Participants			South Asian Participants		
	Expert patients % (SD)	Control patients % (SD)	Difference (%) P value	Expert patients % (SD)	Control patients % (SD)	Difference (%) P value	Expert patients % (SD)	Control patients % (SD)	Difference (%) P value
Baseline	7.7	7.7		7.7	7.6		7.5	7.8	
HbA1c	(1.6)	(1.6)	0	(1.6)	(1.5)	0.1	(1.5)	(1.8)	0.3
	n=157	n=157	$P=0.85$	n=115	n=119	$P=0.70$	n=42	n=38	$P=0.36$
4 mths	7.4	7.8		7.4	7.6		7.5	8.5	
HbA1c	(1.3)	(1.6)	0.4	(1.4)	(1.4)	0.2	(1.0)	(1.9)	1.0
	n=152	n=149	$P=0.02$	n=112	n=113	$P=0.25$	n=40	n=36	$P=0.004$
14 mths	7.1	7.8		7.0	7.6		7.5	8.3	
HbA1c	(1.1)	(1.6)	0.7	(1.1)	(1.5)	0.6	(1.0)	(1.9)	0.8
	n=150	n=141	$P<0.001$	n=109	n=106	$P=0.001$	n=41	n=34	$P=0.02$

LIFESTYLE OUTCOMES (see Table 6.9 on page 209)

Diabetes knowledge scores improved in the expert patients compared with those of the control group at both four ($P<0.001$) and 14 months ($P=0.04$). The number of days each week that the expert patients were exercising, performing blood glucose monitoring and foot care self-management activities significantly increased in comparison with the frequency of those activities within the routine treatment group at four months (difference 0.9 day, $P<0.001$; 0.7 day, $P=0.008$; 0.9 day, $P=0.009$; respectively). That increase remained statistically significant in respect of exercise and foot care at 14 months (difference 0.9 day, $P=0.02$; 0.6 day, $P=0.003$; respectively) but not in respect of

self-monitoring of blood glucose levels (difference 0.5 day, $P=0.17$) (see figures 6.10 to 6.12 below).

Figure 6.10 Exercise frequency

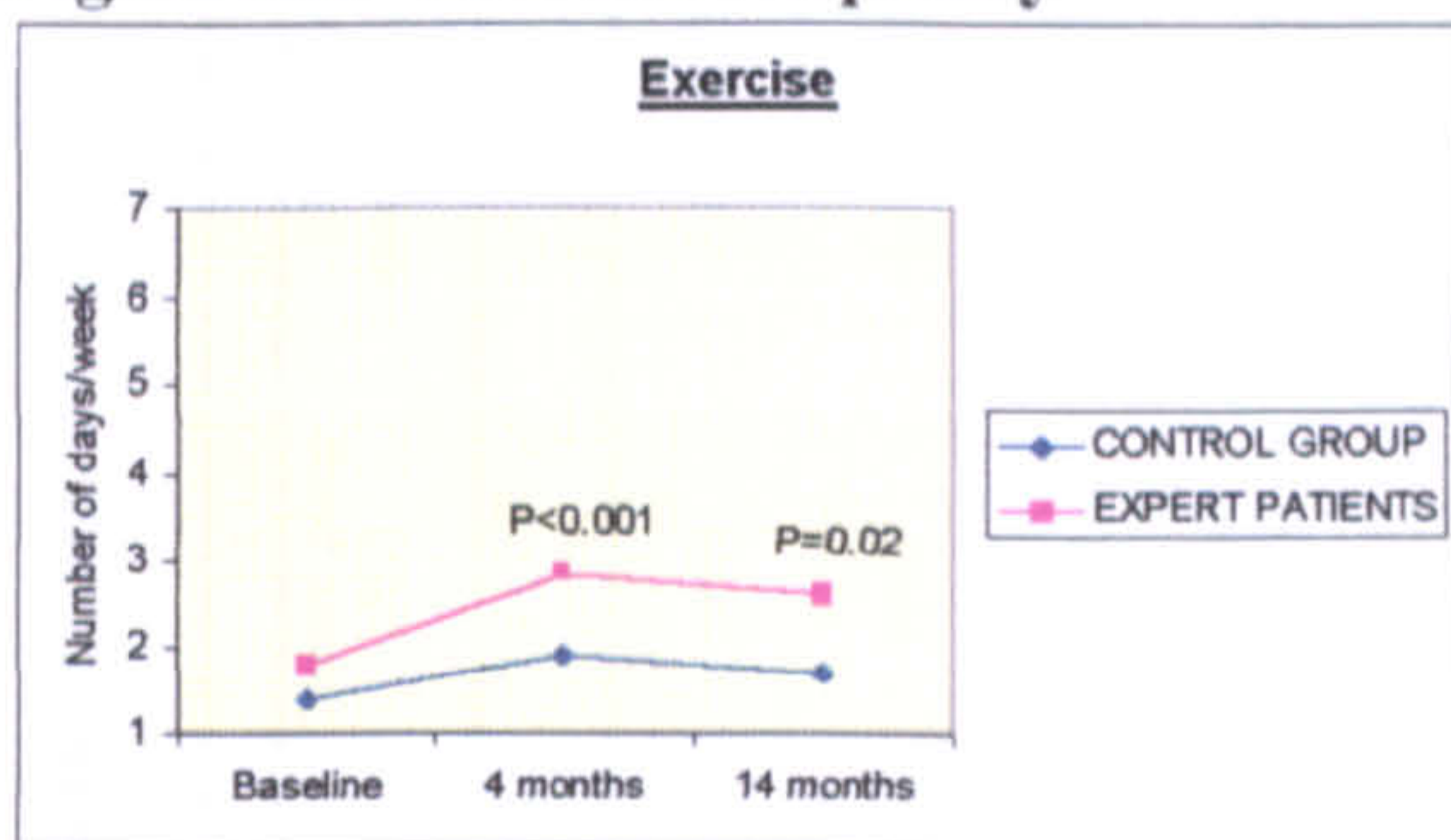


Figure 6.11 Foot care frequency

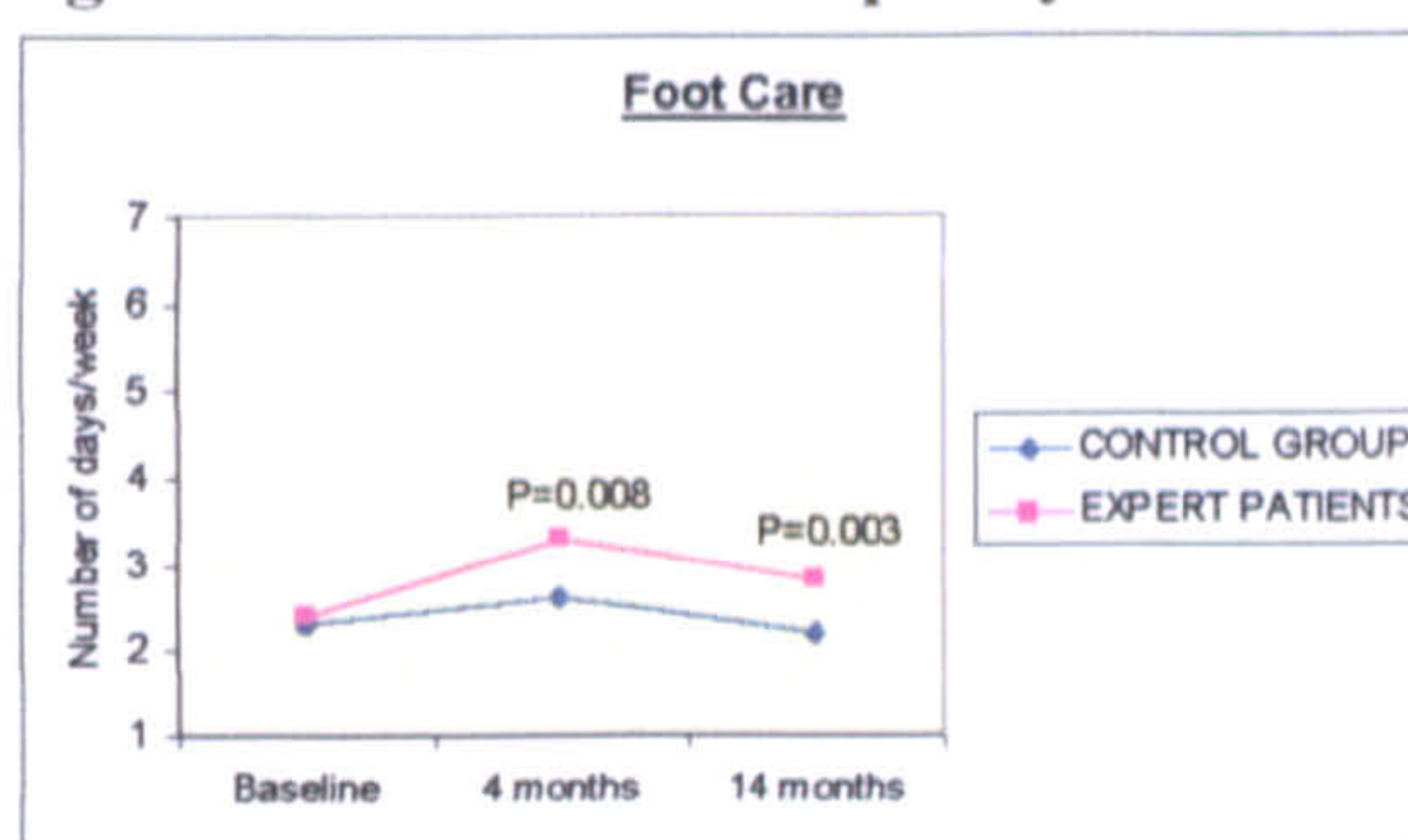
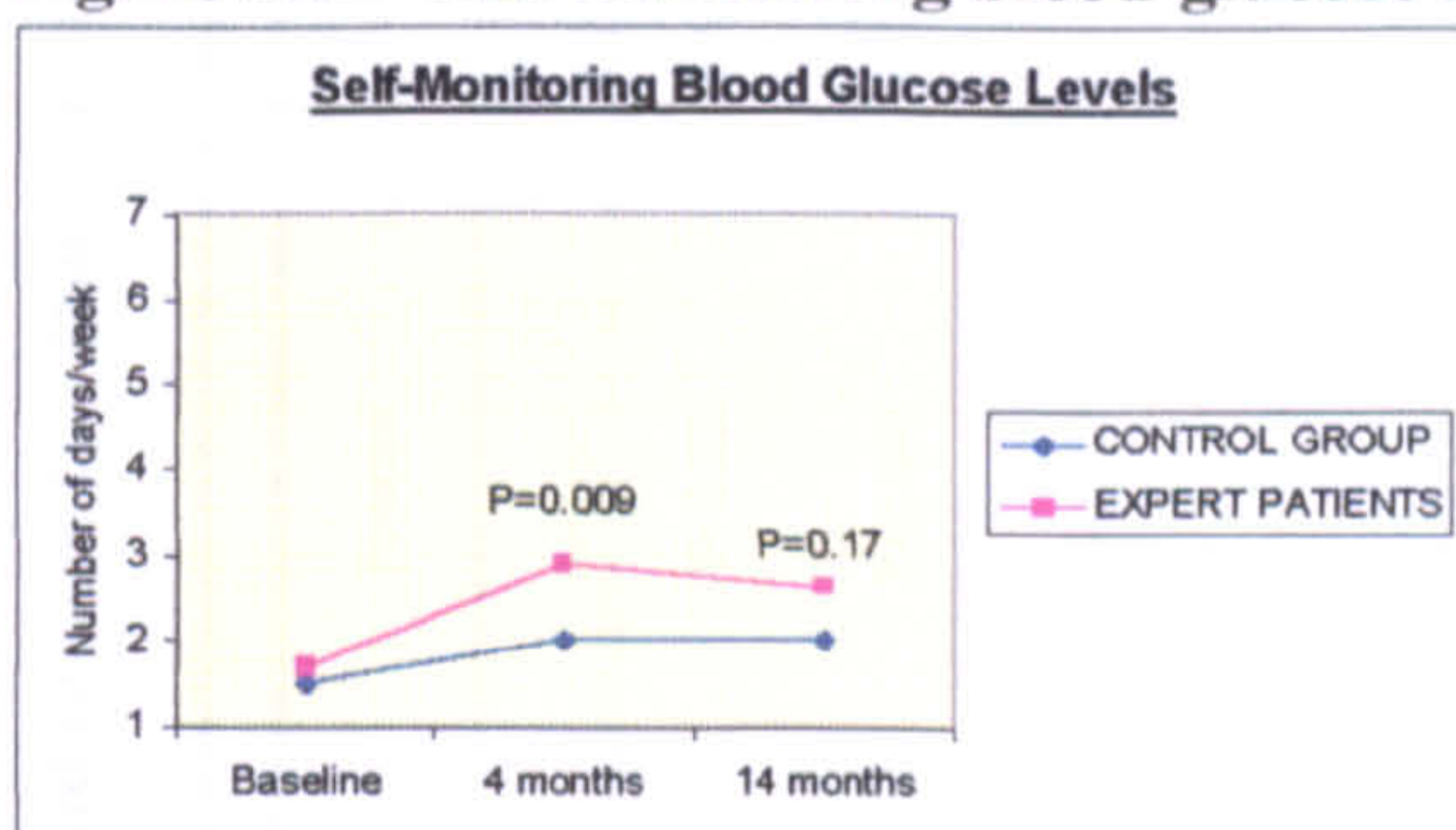


Figure 6.12 Self-monitoring blood glucose frequency



The in-depth food frequency questionnaire indicated that the intervention group was consuming one extra portion of fruit and vegetables each day (95% CI: 0.2 to 1.8 portions; $P=0.01$) at four months and two extra portions each day (95% CI: 1.1 to 3.2 portions; $P<0.001$) at 14 months (see figure 6.13 on page 210). That contributed to a greater percentage of energy from sucrose, total sugars, and carbohydrate at four months (difference 2.2%, $P=0.001$; 5.1%, $P<0.001$; 4.1%, $P=0.03$; respectively) and 14 months (difference 2.7%, $P<0.001$; 6.6%, $P<0.001$; 3.3%, $P=0.07$; respectively) (see figures 6.14 to 6.16 on page 210). However, the percentage of energy from starch remained unchanged at four months (difference 1.0%, $P=0.6$) and was reduced at 14 months (difference -3.4 %, $P=0.04$) (see figure 6.17 on page 210). The amount of added table sugar reduced in both the expert patient group and the routine treatment group with no statistical differences between the groups at four months (difference 0.4g, $P=0.82$) or 14 months (difference 1g, $P=0.85$) (see figure 6.18 on page 210). Fibre (non-starch polysaccharide) intake increased in both groups, with a statistically significant difference between the expert patients and control group at 14 months (difference 3.8g, $P=0.05$) (see figure 6.19 on page 210). There was a trend towards reduced fat intake in the expert patient group that became borderline statistically significant at 14 months for total fat (difference 2.7%; 95% CI: -0.3% to 5.6%, $P=0.07$) and statistically significant for saturated fat (difference 1.1%; 95% CI: 0% to 2.3%, $P=0.05$) (see figures 6.20 to 6.21 on page 210).

Table 6.9 Lifestyle outcomes: differences between the intervention (expert patient programme) group and the control (routine treatment) group.

OUTCOMES	BASELINE DATA				FOUR MONTH DATA				14 MONTH DATA			
	Intervention Group (SD)	Control Group (SD)	Mean (95% CI)	P-value	Intervention group (SD)	Control group (SD)	Difference: mean(95% CI)	P-value	Intervention group (SD)	Control group (SD)	Difference: mean(95% CI)	P-value
Diabetes Knowledge ¹	7.5 (3.5) n=135	7.0 (3.1) n=125	-0.5 (-1.3 to 0.3)	P=0.09	10.4 (2.8) n=107	7.8 (2.9) n=95	-2.7 (-3.5 to -1.9)	P<0.001	9.3 (3.1) n=99	7.8 (2.7) n=91	-1.5 (-2.3 to -0.7)	P=0.04
Self-care Healthy diet	2.2 (1.4) n=128	2.5 (1.2) n=113	0.2 (-0.1 to 0.6)	P=0.3	2.7 (1.1) n=111	2.5 (1.2) n=91	-0.2 (-0.5 to 0.1)	P=0.22	2.1 (1.0) n=94	2.0 (1.2) n=85	-0.05 (-0.4 to 0.3)	P=0.68
Exercise	1.8 (2.3) n=128	1.4 (2.5) n=111	-0.4 (-1.0 to 0.2)	P=0.1	2.8 (2.2) n=110	1.9 (2.6) n=90	-0.9 (-1.6 to -0.3)	P<0.001	2.6 (2.4) n=91	1.7 (2.7) n=85	-0.9 (-1.6 to -0.1)	P=0.02
Foot care	2.4 (1.4) n=132	2.3 (1.5) n=119	-0.1 (-0.5 to 0.3)	P=0.6	3.3 (1.2) n=112	2.6 (1.5) n=93	-0.7 (-1.1 to -0.4)	P=0.008	2.8 (1.3) n=98	2.2 (1.4) n=91	-0.6 (-1.0 to -0.2)	P=0.003
Blood testing	1.7 (2.8) n=124	1.5 (2.7) n=106	-0.2 (-1.0 to 0.5)	P=0.4	2.9 (2.4) n=109	2.0 (2.7) n=90	-0.9 (-1.6 to -0.2)	P=0.009	2.6 (2.7) n=93	2.0 (2.6) n=86	-0.5 (-1.3 to 0.3)	P=0.17
Medication taking	3.7 (2.5) n=120	3.6 (2.4) n=96	-0.1 (-0.8 to 0.6)	P=0.2	4.1 (2.1) n=104	4.1 (2.1) n=78	0.0 (-0.6 to 0.6)	P=0.45	3.7 (1.7) n=86	3.3 (2.2) n=78	-0.4 (-1.0 to 0.2)	P=0.11
Food Freq ² Energy (Kcal/day)	1473 (933) n=125	1550 (1094) n=109	76 (-185 to 338)	P=0.56	1452 (824) n=108	1565 (1028) n=93	113 (-145 to 371)	P=0.39	1724 (1811) n=100	1687 (1589) n=91	-37 (-525 to 451)	P=0.88
Fruit & Veg (portions/day)	2.8 (1.8) n=114	2.9 (2.2) n=101	0.1 (-0.4 to 0.7)	P=0.64	4.4 (2.6) n=105	3.4 (2.8) n=83	-1.0 (-1.8 to -0.2)	P=0.01	5.2 (3.8) n=100	3.1 (3.5) n=91	-2.2 (-3.2 to -1.1)	P<0.001
% Energy from carbohydrate	50.6 (11.7) n=125	49.0 (11.9) n=109	-1.6 (-4.7 to 1.4)	P=0.30	54.0 (12.6) n=108	49.9 (14.3) n=93	-4.1 (-7.9 to -0.4)	P=0.03	53.5 (13.2) n=97	50.2 (11.2) n=87	-3.3 (-6.9 to 0.3)	P=0.07
% Energy from total sugars	17.4 (7.0) n=123	17.4 (6.7) n=109	0.1 (-1.7 to 1.8)	P=0.95	23.1 (10.1) n=108	18.0 (9.4) n=93	-5.1 (-7.9 to -2.4)	P<0.001	25.8 (13.4) n=97	19.2 (8.0) n=87	-6.6 (-9.9 to -3.4)	P<0.001
% Energy from starch	33.5 (11.6) n=125	31.8 (11.7) n=108	-1.7 (-4.7 to 1.3)	P=0.28	30.8 (12.2) n=108	31.9 (16.0) n=93	1.0 (-2.9 to 5.0)	P=0.60	27.6 (10.5) n=97	30.9 (11.6) n=87	3.4 (0.15 to 6.6)	P=0.04
% Energy from sucrose	6.5 (3.4) n=121	6.5 (3.6) n=106	0.00 (-0.9 to 0.9)	P=1.00	9.2 (4.8) n=107	7.0 (4.1) n=88	-2.2 (-3.5 to -0.9)	P=0.001	9.9 (6.1) n=97	7.2 (3.7) n=87	-2.7 (-4.2 to -1.3)	P<0.001
% Energy from fat	28.7 (9.6) n=125	29.5 (9.5) n=109	0.8 (-1.7 to 3.2)	P=0.54	26.4 (10.2) n=108	28.8 (10.5) n=93	2.4 (-0.5 to 5.2)	P=0.11	26.6 (11.3) n=97	29.3 (8.9) n=87	2.7 (-0.3 to 5.6)	P=0.07
% Energy from saturated fat	9.9 (3.9) n=125	10.6 (4.5) n=109	0.8 (-0.3 to 1.8)	P=0.17	9.2 (4.1) n=107	10.0 (4.3) n=93	0.8 (-0.4 to 2.0)	P=0.18	9.2 (4.3) n=97	10.3 (3.6) n=87	1.1 (0.0 to 2.3)	P=0.05
Non-starch Poly-saccharides ³ (g/day)	14.2 (9.8) n=125	14.2 (10.1) n=108	0 (-1.7 to 3.22)	P=0.96	16.7 (7.5) n=108	15.3 (11.9) n=92	1.3 (-1.3 to 4.1)	P=0.35	19.6 (13.2) n=100	15.8 (13.2) n=91	3.8 (0.03 to 7.6)	P=0.05

¹ Values are means (standard deviations) unless stated otherwise. ² Multiple choice questions: scored from 0 – 14. ³ Food frequency assessment

³ Self-care activities: scored by a self-report measure of the frequency of completing different regimens activities over the preceding seven days

Figure 6.13 Fruit & vegetable intake

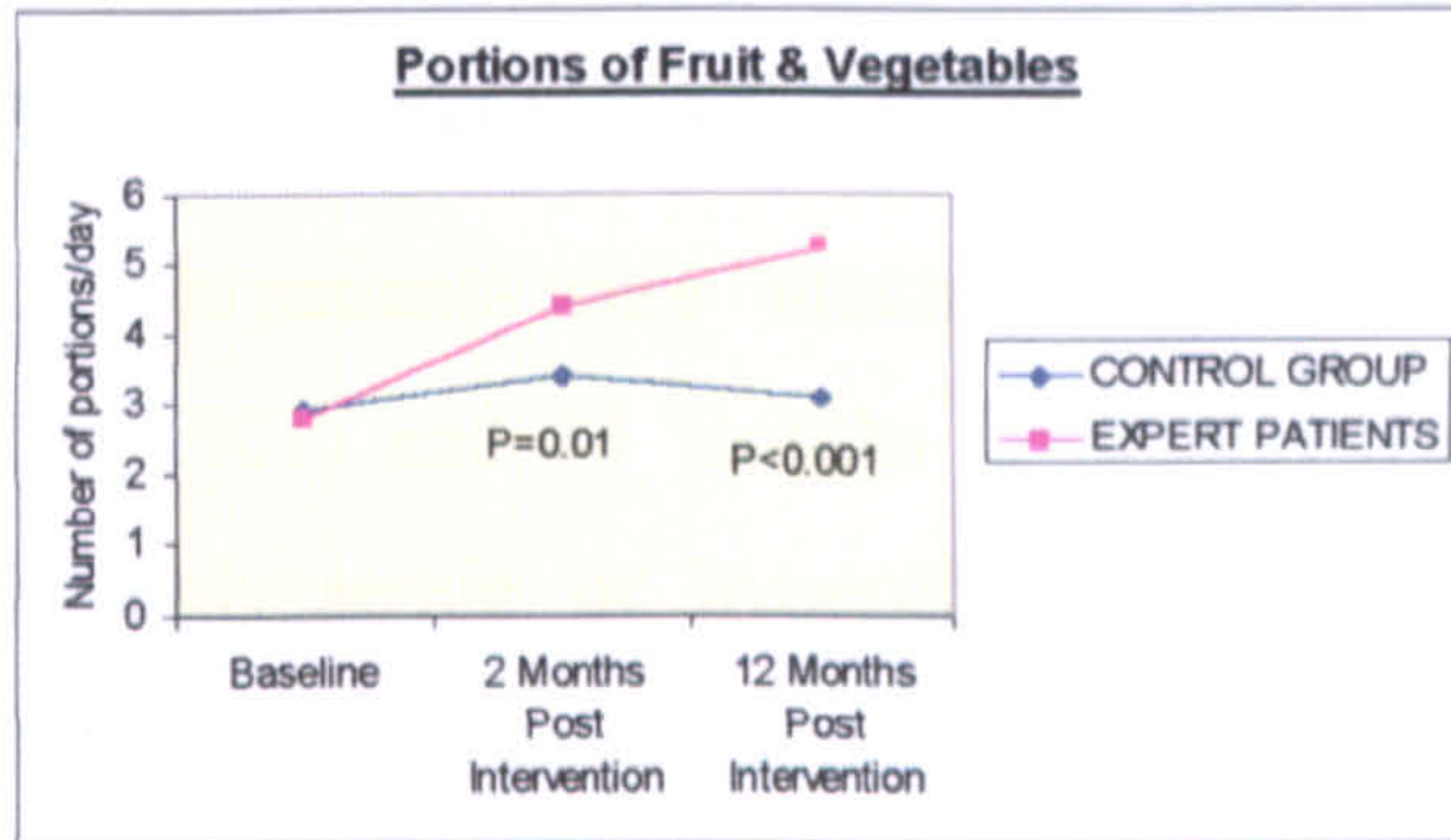


Figure 6.14 Sucrose intake

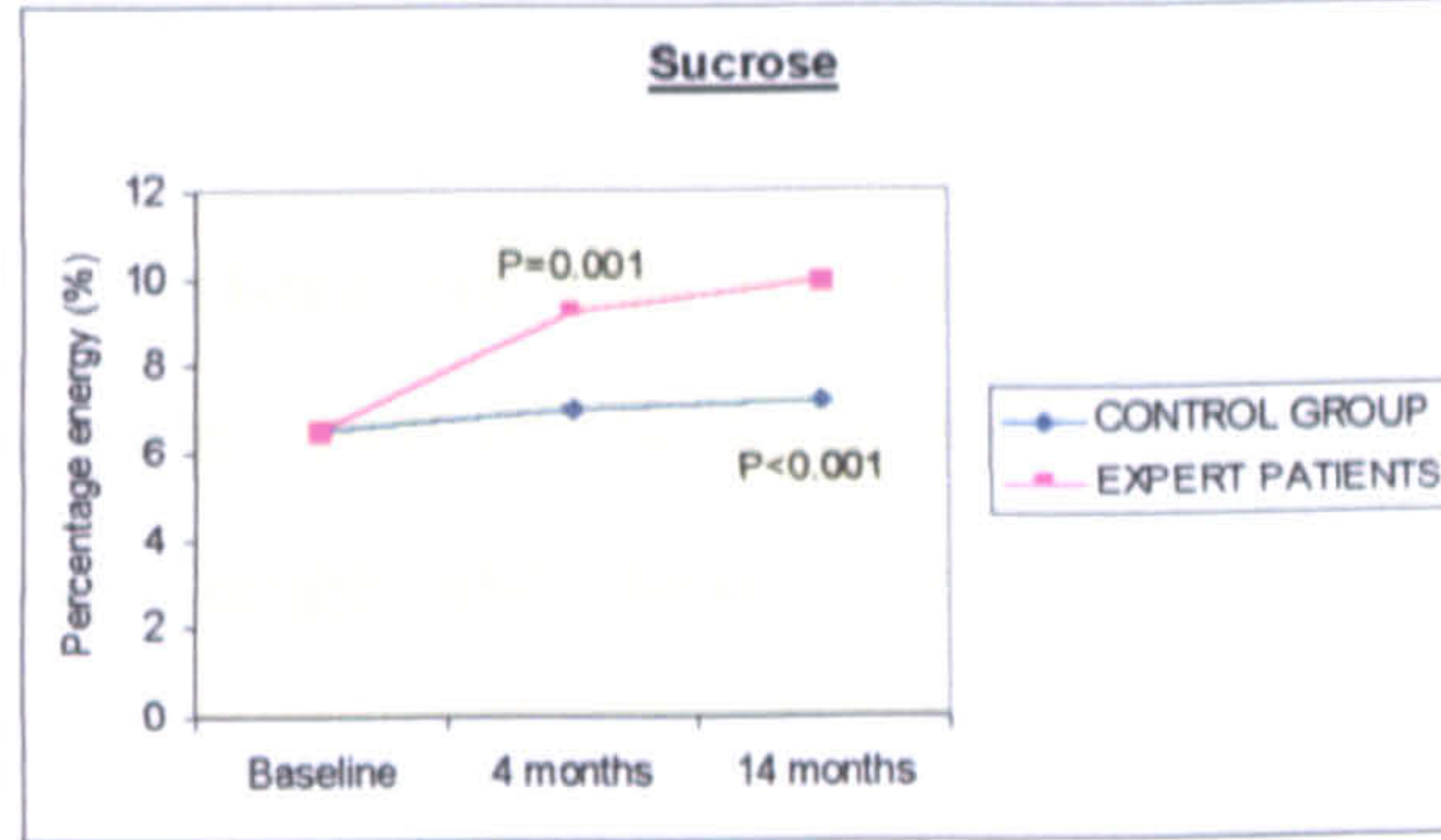


Figure 6.15 Total sugar intake

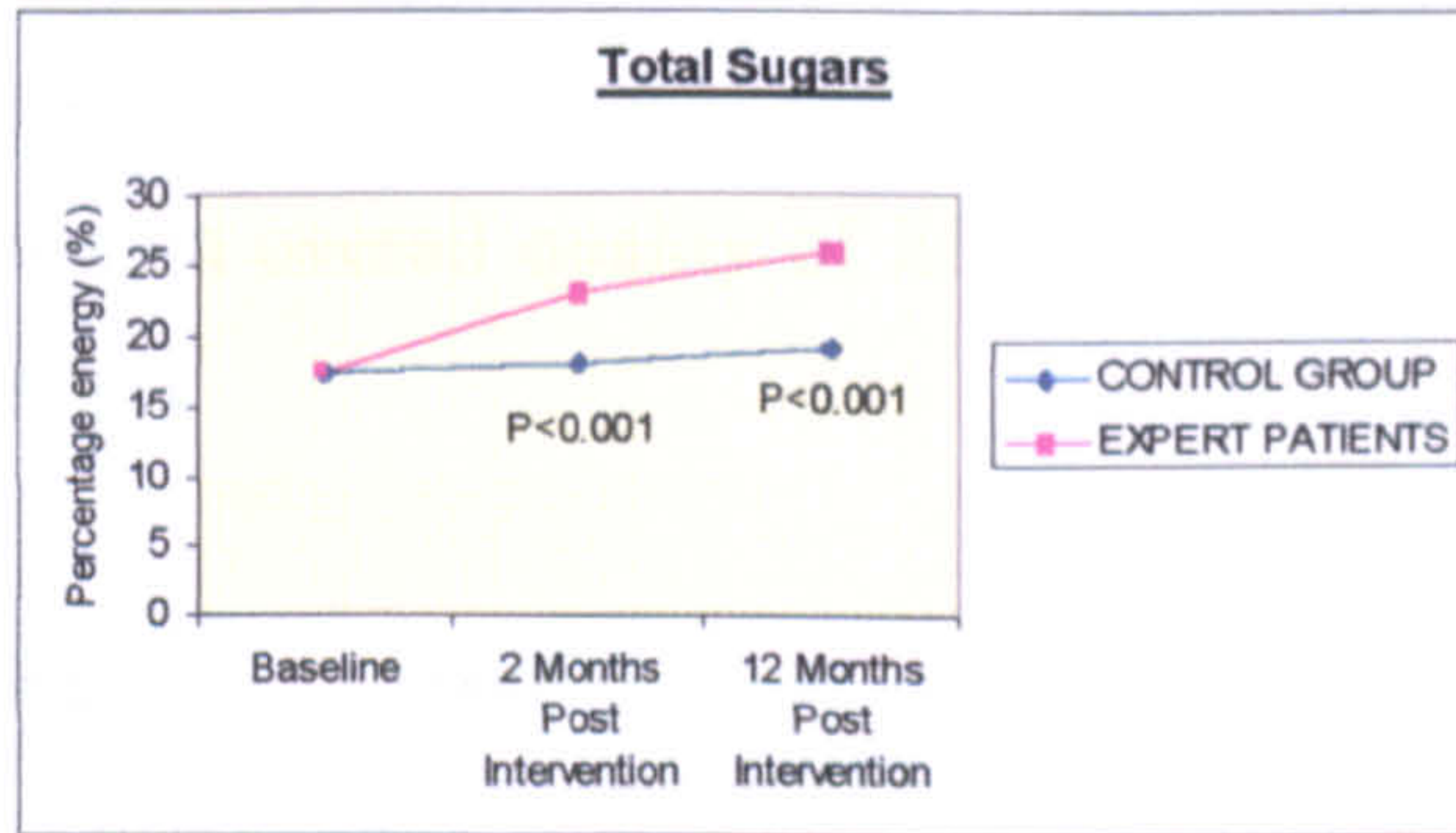


Figure 6.16 Carbohydrate intake

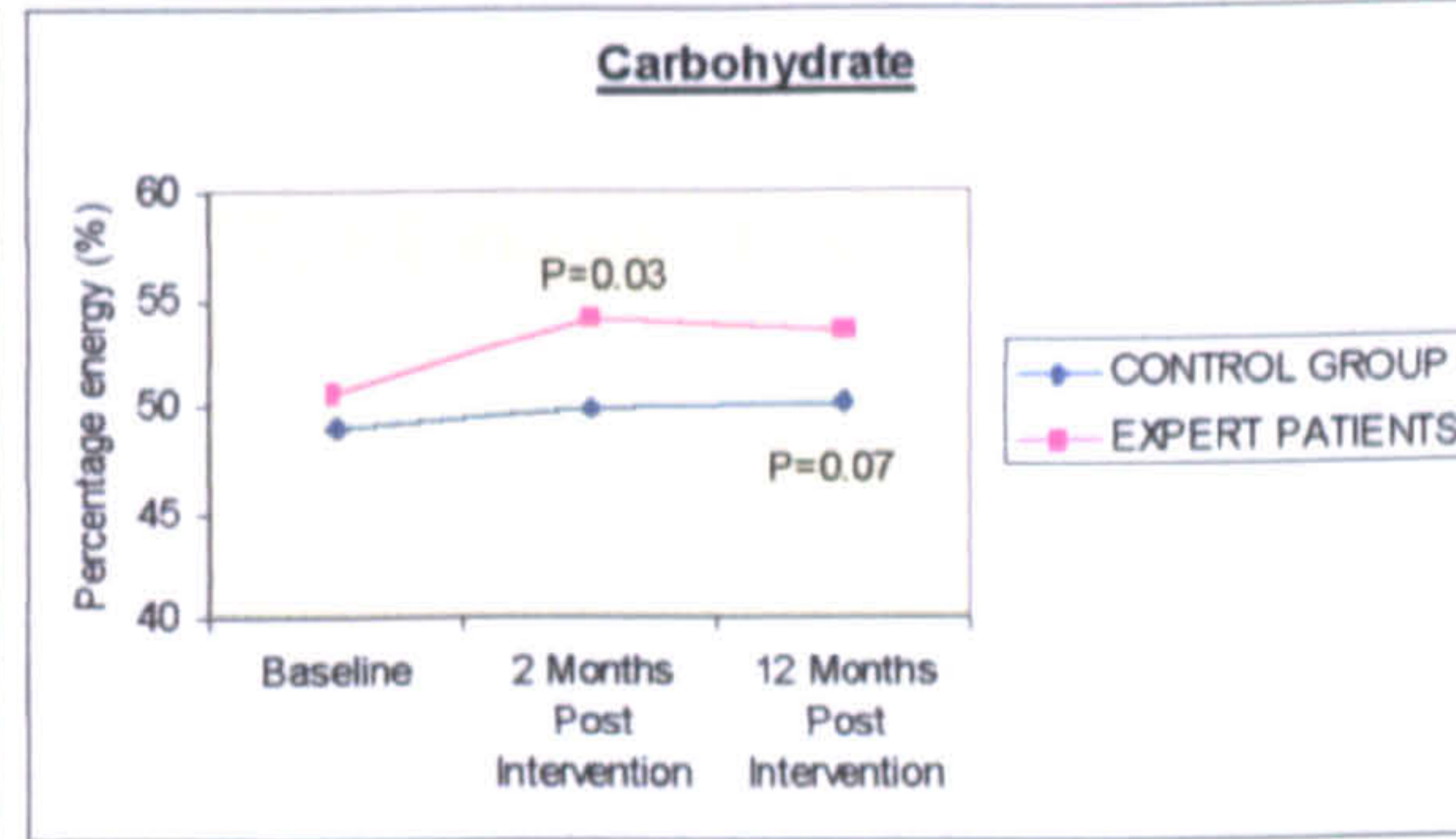


Figure 6.17 Starch intake

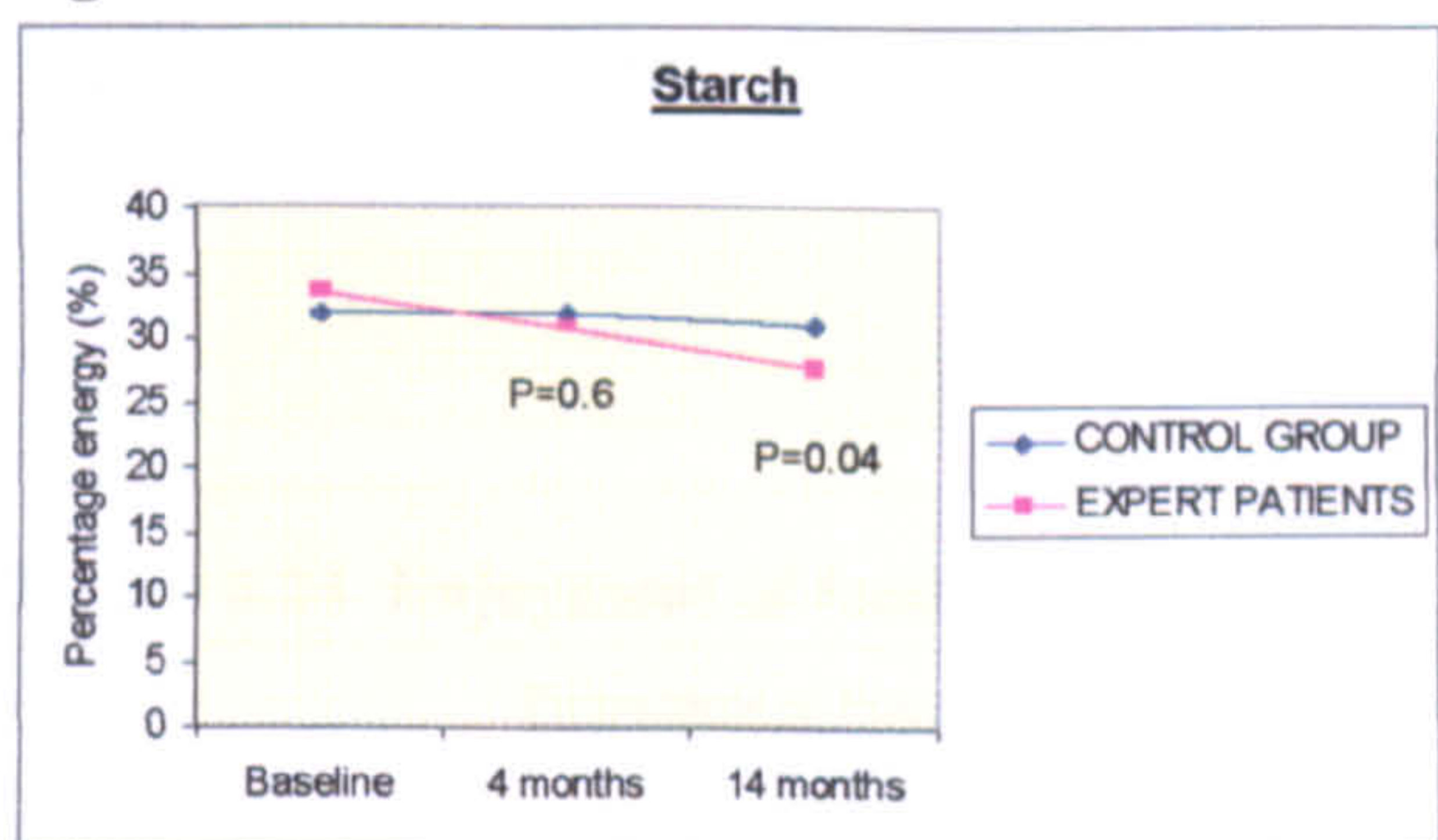


Figure 6.18 Added sugar intake

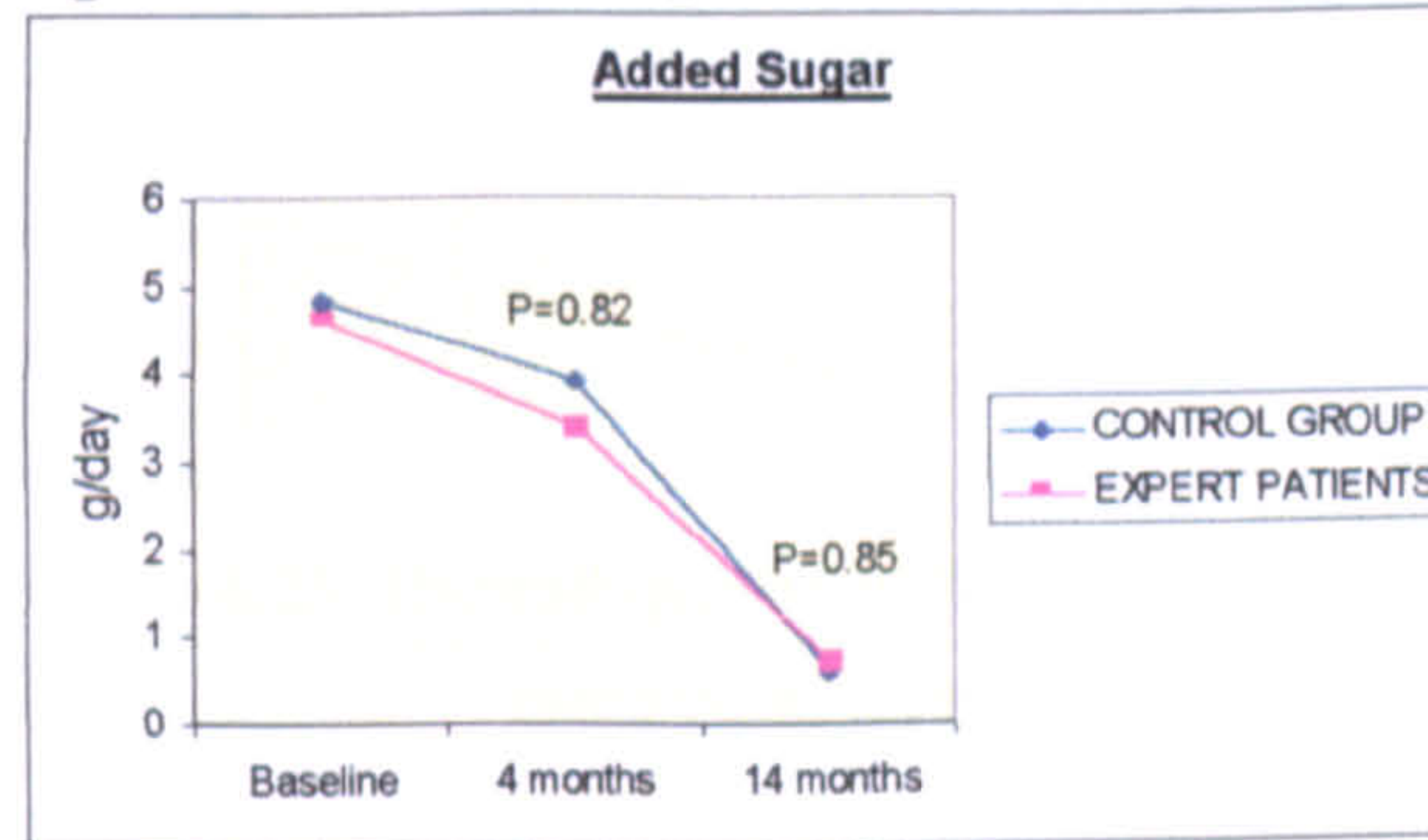


Figure 6.19 Fibre intake

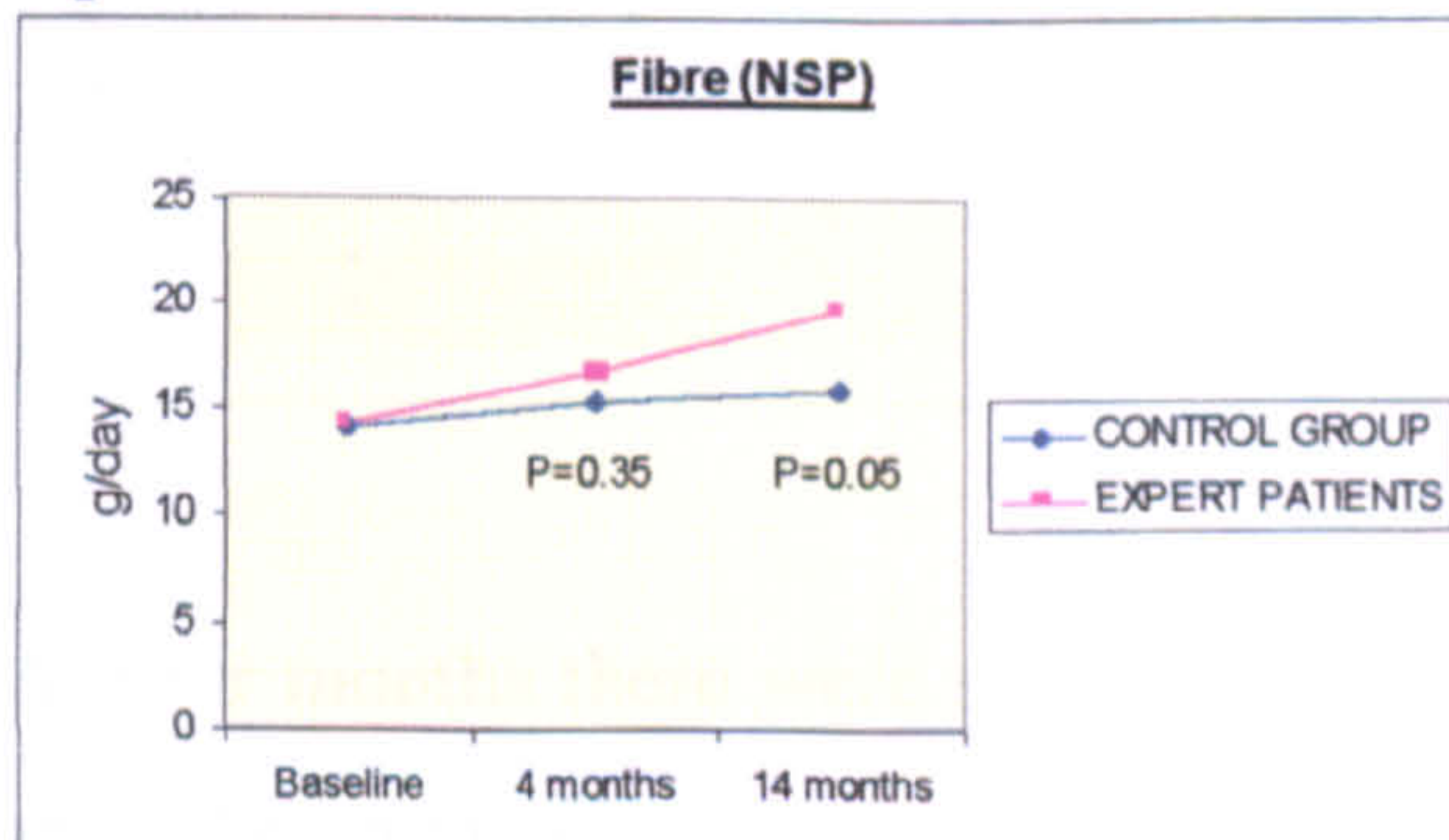


Figure 6.20 Total fat intake

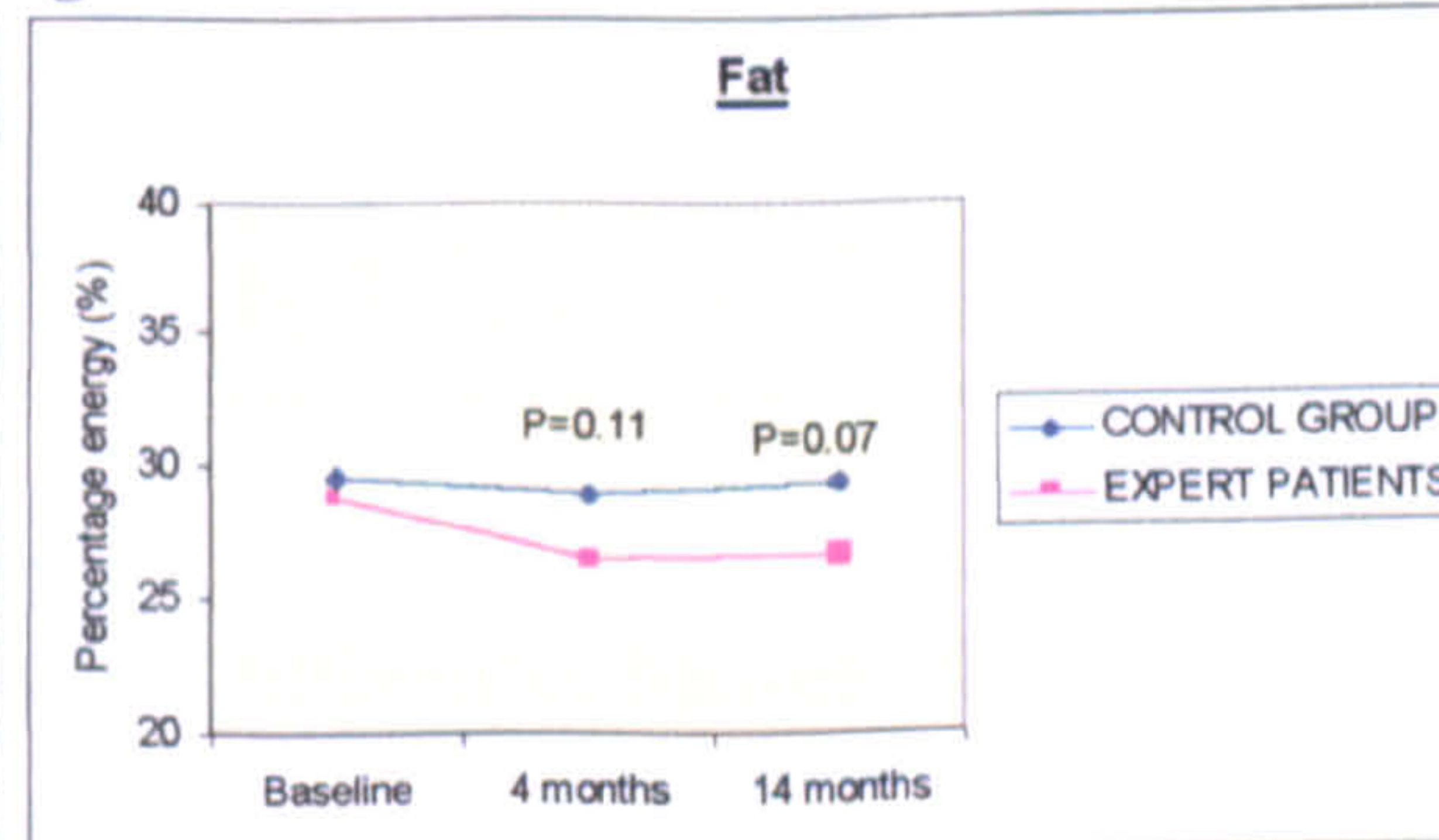
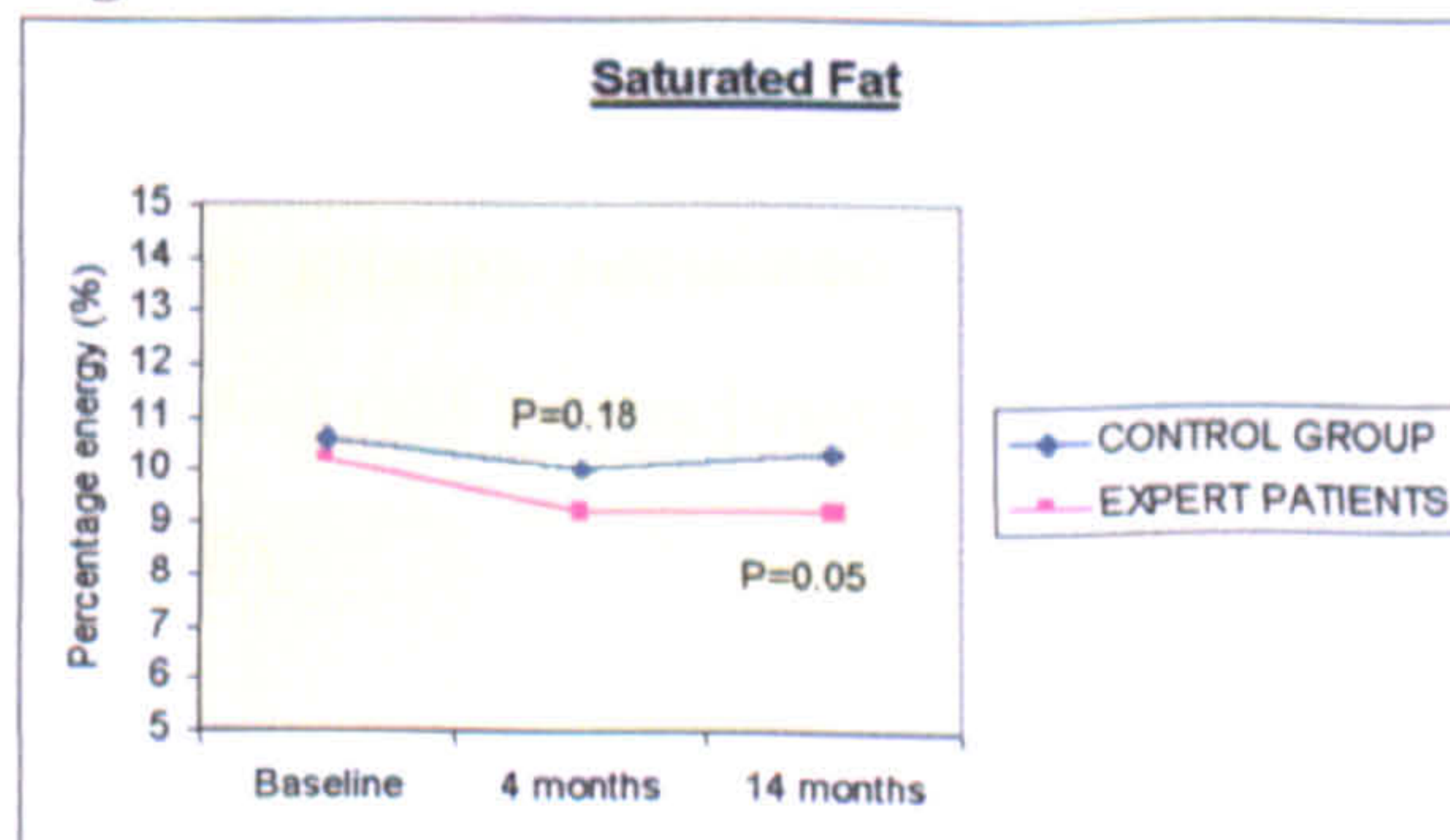


Figure 6.21 Saturated fat intake



PSYCHOSOCIAL OUTCOMES (see Table 6.10 on page 212)

Expert patients were “much more satisfied” with their diabetes treatment at four months ($P < 0.001$) and 14 months ($P = 0.002$) than were controls. Self-reported frequency of hypoglycaemia or hyperglycaemia did not change and there were no differences between groups at four and 14 months. The expert patients showed significant improvements, compared with controls, in the negative impact of diabetes on freedom to eat (four months $P < 0.001$; 14 months $P = 0.04$) and drink (four months $P = 0.005$; 14 months $P = 0.01$) and enjoyment of food (four months $P = 0.05$; 14 months $P = 0.05$), but not on overall quality of life (four months $P = 0.77$; 14 months $P = 0.59$) (figures 6.22 to 6.25).

Figure 6.22 Freedom to eat

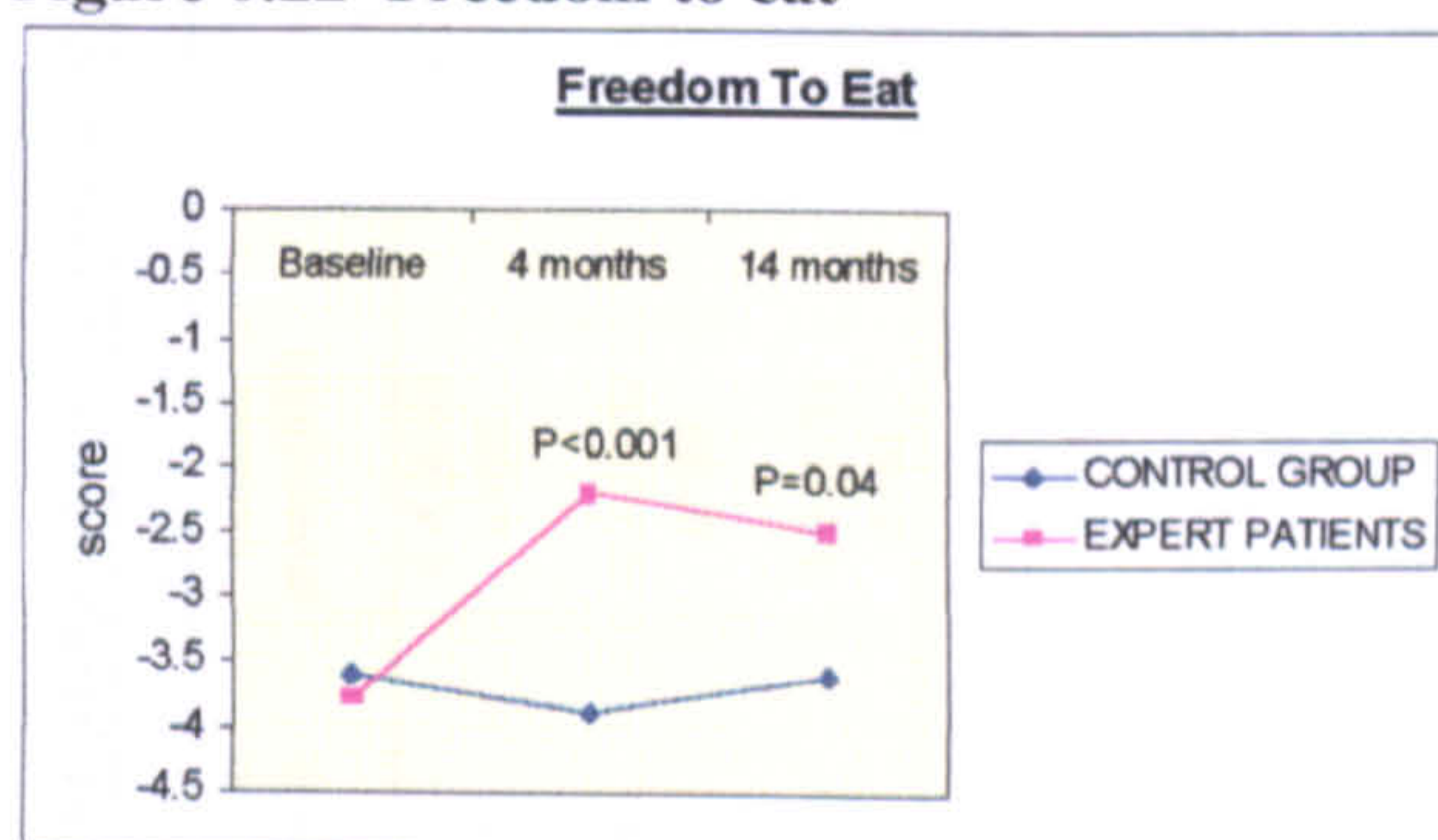


Figure 6.23 Freedom to drink

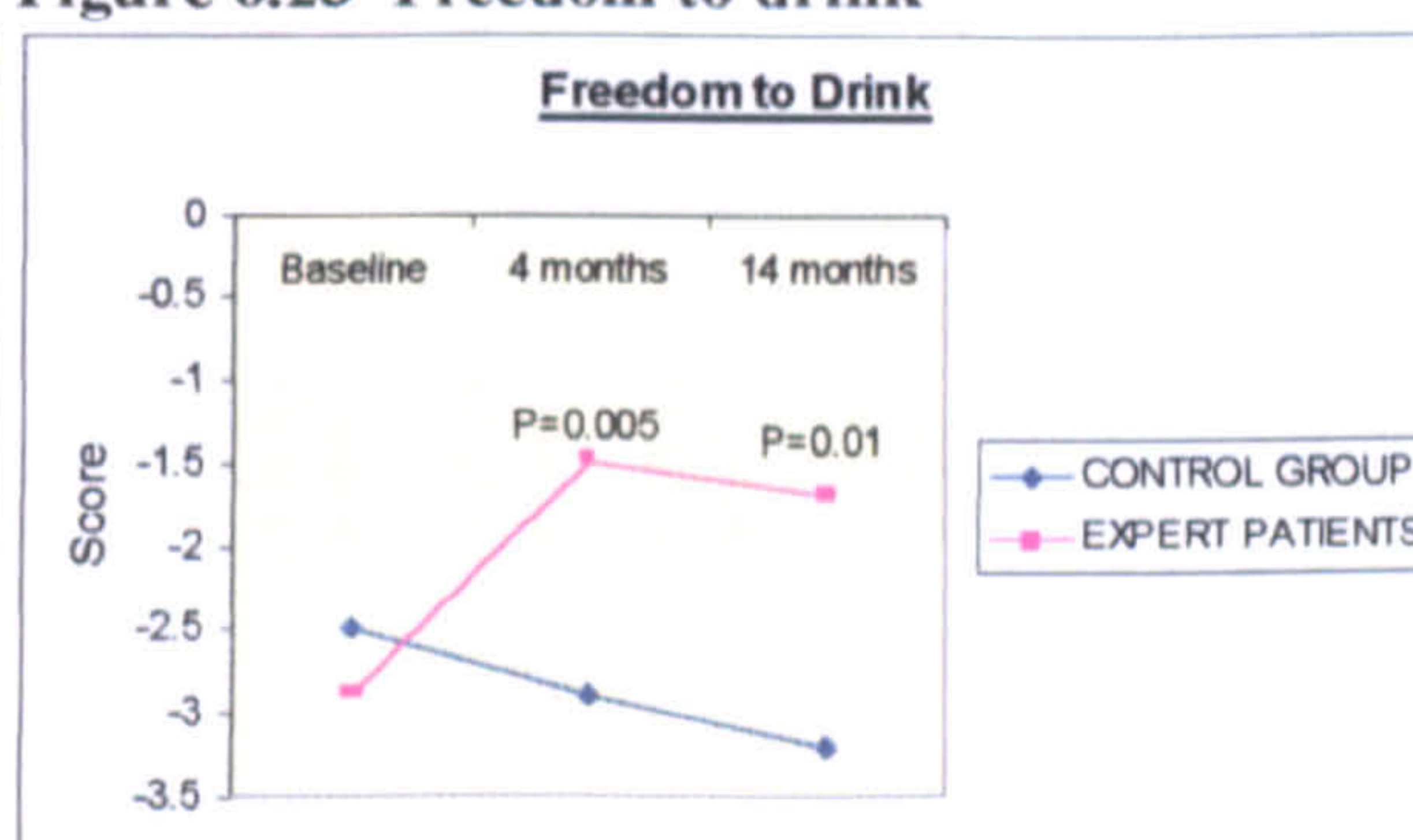


Figure 6.24 Enjoyment of food

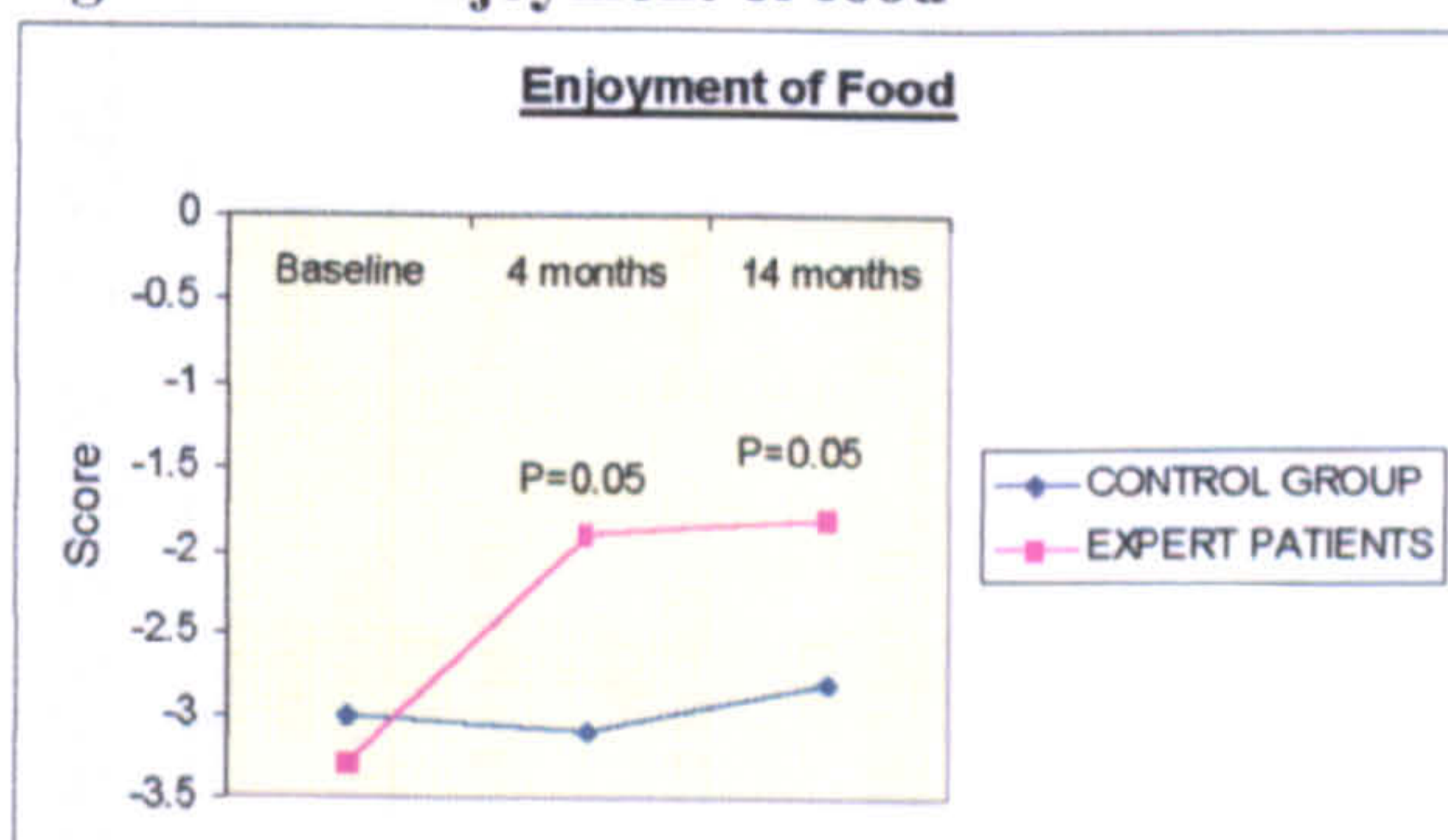
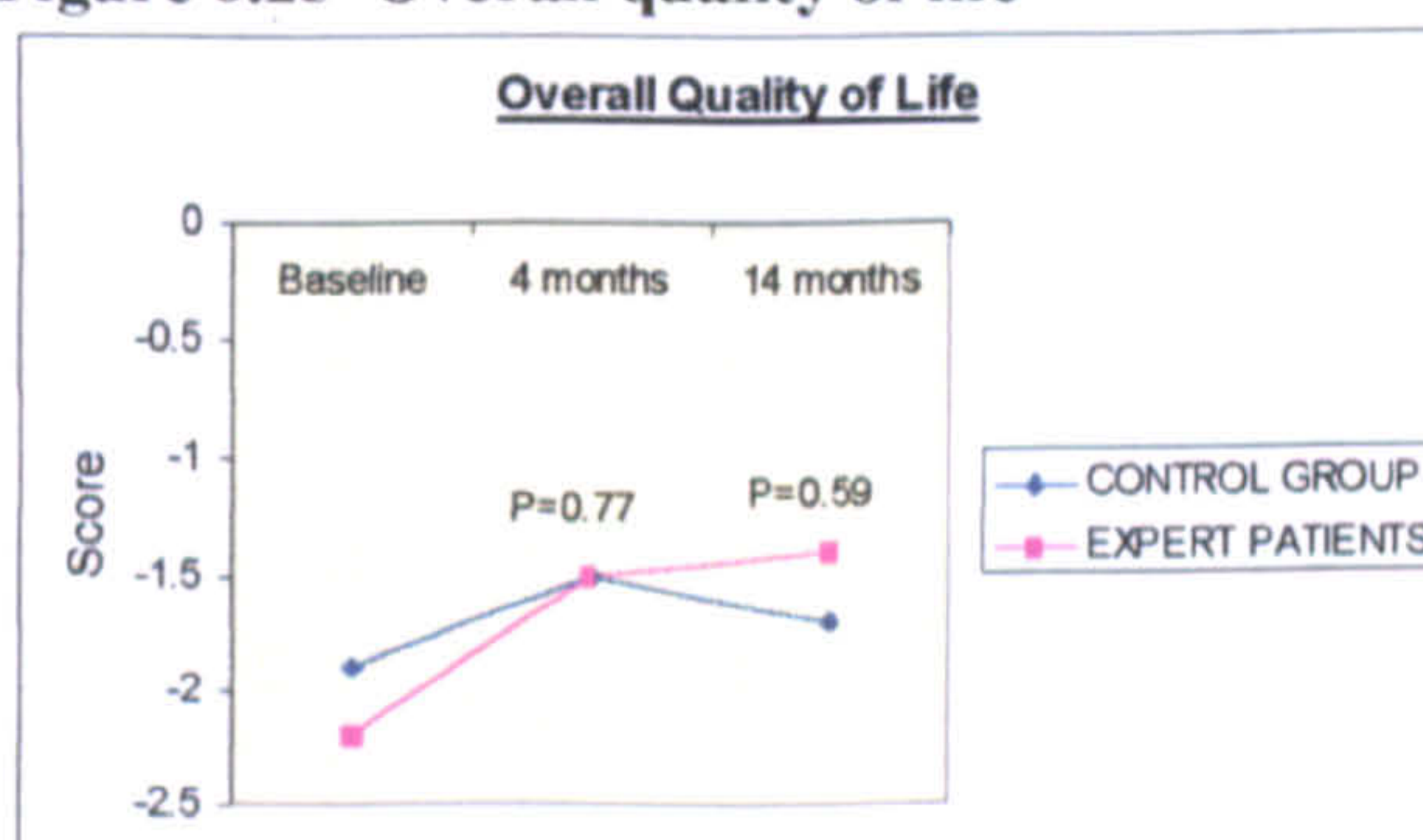


Figure 6.25 Overall quality of life



At four months there were significant statistical differences between the expert patients and the controls for the total empowerment score ($P < 0.001$) and for subscales comprising the total empowerment score: psychosocial adjustment ($P = 0.002$), readiness to change ($P < 0.001$); goal setting ($P < 0.001$). At 14 months significant statistical differences between the two groups remained: total empowerment score ($P = 0.006$), psychosocial adjustment ($P = 0.005$), readiness to change ($P = 0.001$), goal setting ($P = 0.03$) (figures 6.26 to 6.29).

Table 6.10 Psychosocial outcomes: differences between the intervention (expert patient programme) group and the control (routine treatment) group

OUTCOMES	BASELINE DATA				FOUR MONTH DATA				14 MONTH DATA			
	Intervention Group (SD)	Control Group (SD)	Difference: mean (95% CI)	P-value	Intervention group (SD)	Control group (SD)	Difference: mean (95% CI)	P-value	Intervention group (SD)	Control group (SD)	Difference: mean (95% CI)	P-value
Diabetes Treatment ⁵ Satisfaction	24.5 (9.4) n=135	23.3 (12.1) n=125	-1.2 (-3.8 to 1.5)	P=0.73	11.2 (5.8) n=113	6.8 (6.9) n=96	-4.4 (-6.1 to -2.6)	P<0.001	9.5 (7.3) n=100	5.8 (8.2) n=91	-3.7 (-6.0 to -1.5)	P=0.002
Frequency of Hyperglycaemia	2.8 (1.9) n=125	2.1 (1.8) n=112	-0.7 (-1.2 to -0.3)	P=0.002	0.4 (1.8) n=110	0.3 (1.5) n=88	-0.1 (-0.6 to 0.3)	P=0.32	0.4 (1.9) n=100	0.1 (1.3) n=91	-0.3 (-0.7 to 0.2)	P=0.26
Frequency of Hypoglycaemia ⁶	1.2 (1.7) n=120	0.9 (1.5) n=107	-0.3 (-0.7 to 0.1)	P=0.13	-0.1 (1.6) n=105	0.0 (1.3) n=81	0.1 (-0.3 to 0.5)	P=0.99	-0.2 (1.6) n=100	0.0 (1.3) n=91	0.2 (-0.3 to 0.6)	P=0.13
ADDQoL ⁷												
'Freedom to eat as I choose'	-3.8 (3.0) n=110	-3.6 (3.4) n=105	0.2 (-0.7 to 1.0)	P=0.22	-2.2 (2.5) n=92	-3.9 (3.0) n=73	-1.7 (-2.5 to -0.8)	P<0.001	-2.5 (2.9) n=75	-3.6 (2.9) n=78	-1.1 (-2.1 to -0.2)	P=0.035
'Enjoyment of food'	-3.3 (2.8) n=107	-3.0 (3.3) n=99	0.3 (-0.6 to 1.1)	P=0.15	-1.9 (2.6) n=93	-3.1 (3.5) n=76	-1.2 (-2.1 to -0.2)	P=0.046	-1.8 (2.9) n=76	-2.8 (3.1) n=74	-1.1 (-2.0 to -0.1)	P=0.054
'Freedom to drink as I choose'	-2.9 (2.7) n=88	-2.5 (2.7) n=87	0.4 (-0.4 to 1.2)	P=0.14	-1.5 (3.0) n=72	-2.9 (3.3) n=68	-1.5 (-2.5 to -0.4)	P=0.005	-1.7 (2.8) n=64	-3.2 (3.2) n=61	-1.5 (-2.6 to -0.5)	P=0.014
Average Quality of life score	-2.2 (2.2) n=124	-1.9 (2.2) n=115	0.3 (-0.3 to 0.8)	P=0.19	-1.5 (1.7) n=111	-1.5 (1.7) n=91	0.0 (-0.5 to 0.5)	P=0.77	-1.4 (1.7) n=93	-1.7 (2.1) n=88	-0.3 (-0.8 to 0.3)	P=0.59
Total Diabetes Empowerment Score ⁸	2.9 (1.3) n=135	2.8 (1.4) n=125	-0.1 (-0.4 to 0.2)	P=0.86	3.6 (1.1) n=113	3.3 (1.1) n=96	-0.3 (-0.6 to 0.0)	P<0.001	3.5 (1.2) n=100	3.2 (1.1) n=91	-0.3 (-0.6 to -0.04)	P=0.006
3 subscales:												
1) Psychosocial adjustment to diabetes	3.0 (1.3) n=135	2.9 (1.4) n=107	-0.1 (-0.4 to 0.3)	P=0.72	3.7 (1.2) n=113	3.4 (1.2) n=96	-0.3 (-0.6 to 0.1)	P=0.002	3.7 (1.3) n=100	3.4 (1.2) n=91	-0.3 (-0.7 to -0.02)	P=0.005
2) Readiness to change	3.6 (0.6) n=123	3.6 (0.5) n=104	0.0 (-0.1 to 0.2)	P=0.78	4.0 (0.5) n=109	3.6 (0.5) n=92	-0.4 (-0.5 to -0.2)	P<0.001	3.9 (0.6) n=96	3.6 (0.6) n=89	-0.3 (-0.5 to -0.1)	P=0.001
3) Setting and achieving goals	3.6 (0.6) n=116	3.7 (0.7) n=104	0.1 (-0.1 to 0.2)	P=0.83	4.0 (0.5) n=108	3.7 (0.6) n=88	-0.3 (-0.5 to -0.2)	P<0.001	4.0 (0.6) n=92	3.8 (0.7) n=87	-0.2 (-0.4 to -0.05)	P=0.025

Values are means (standard deviations) unless stated otherwise

⁵ Scored 0-36 (baseline), -18 to -18 (2 months post-intervention), higher scores indicate greater diabetes treatment satisfaction.

⁶ Scored 0-6 (baseline), -3 to -3 (2 months post-intervention), higher scores indicate greater perceived frequency of hyperglycaemia/hypoglycaemia.

⁷ Scored from 9 (maximum negative impact) to -9 (maximum positive impact).

⁸ Scored 0-5, higher scores indicate either greater self-empowerment for either total score and/or subscales.

Figure 6.26 Psychosocial adjustment

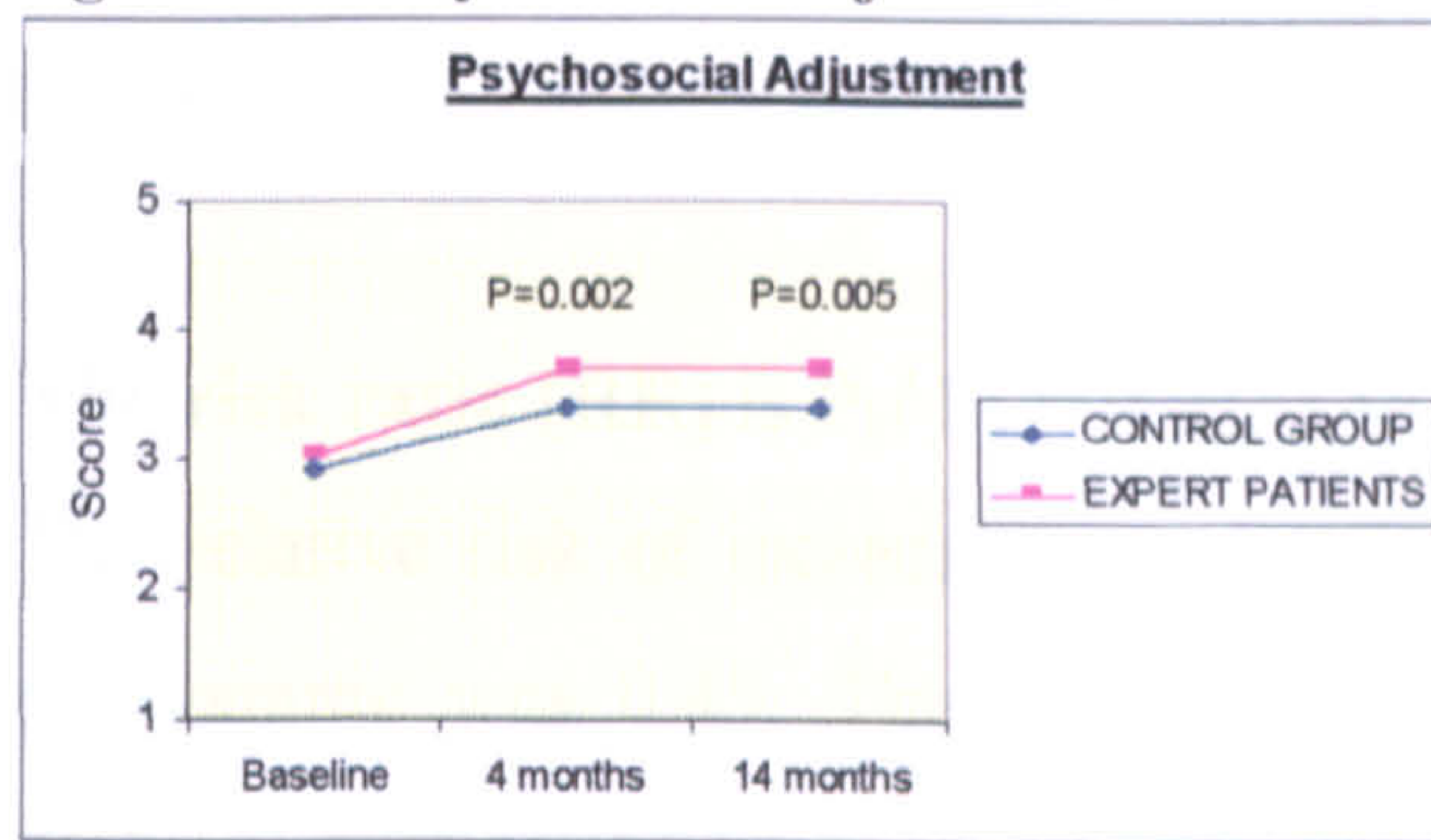


Figure 6.27 Readiness to change

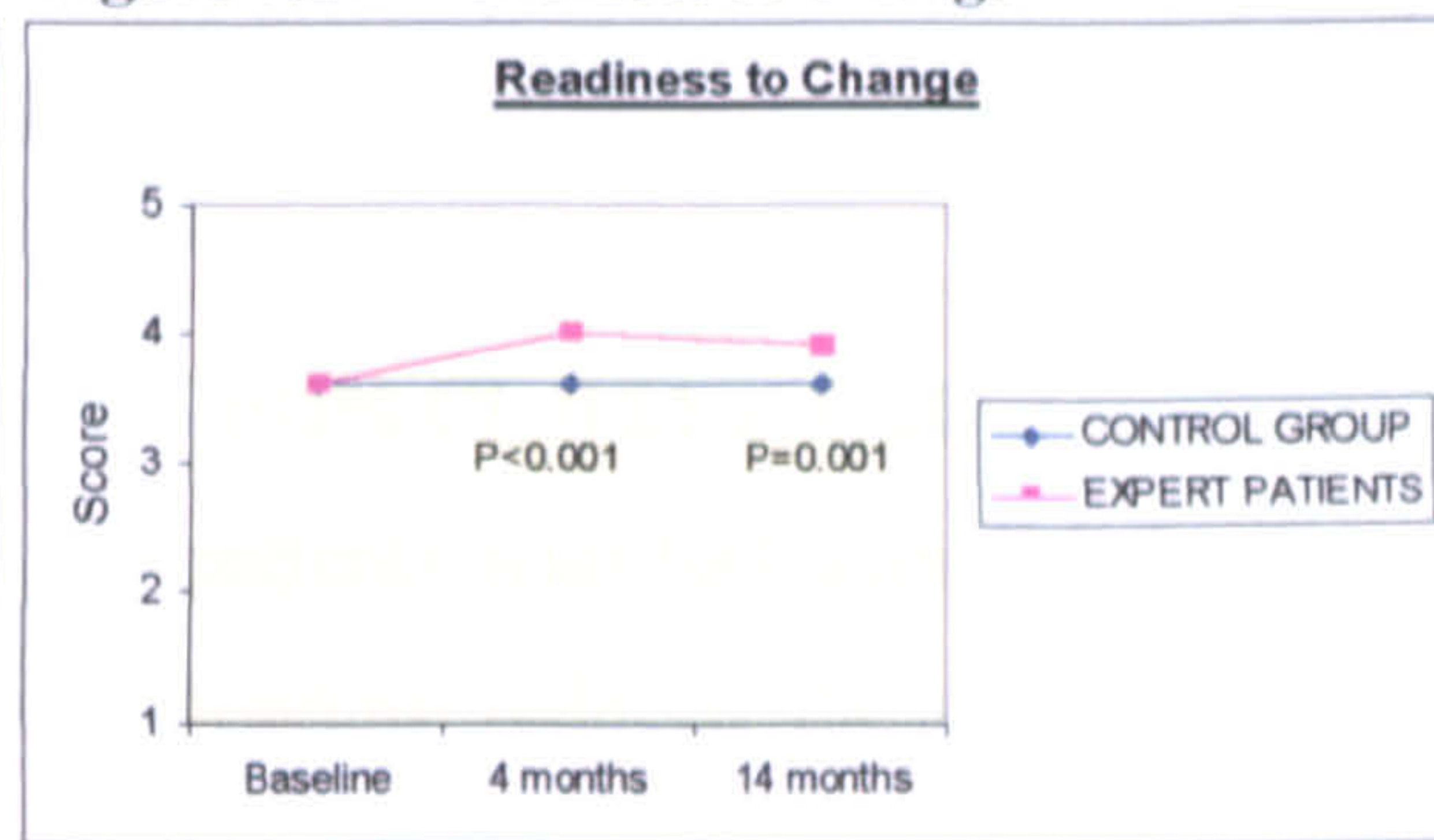


Figure 6.28 Setting and achieving goals

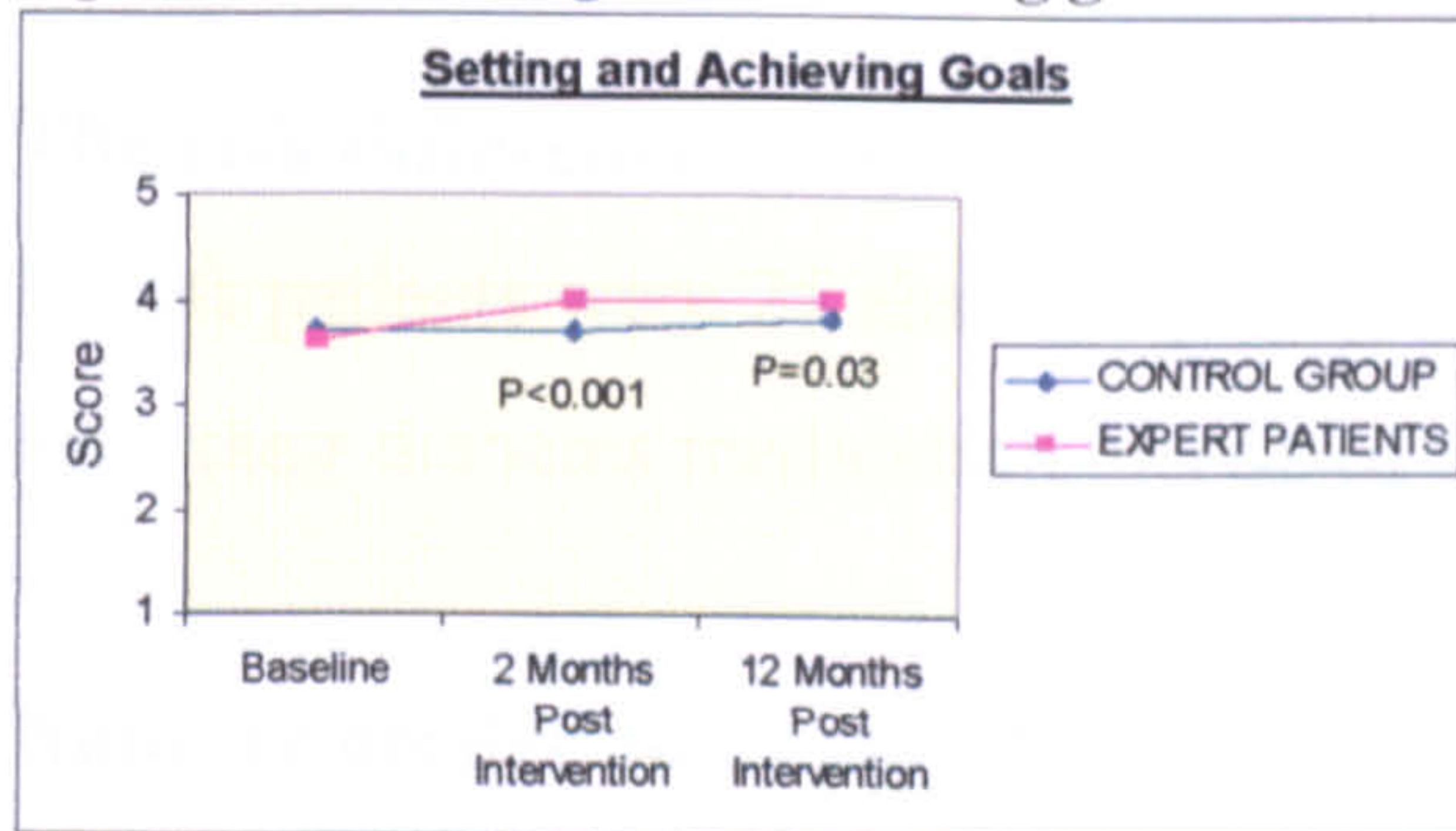
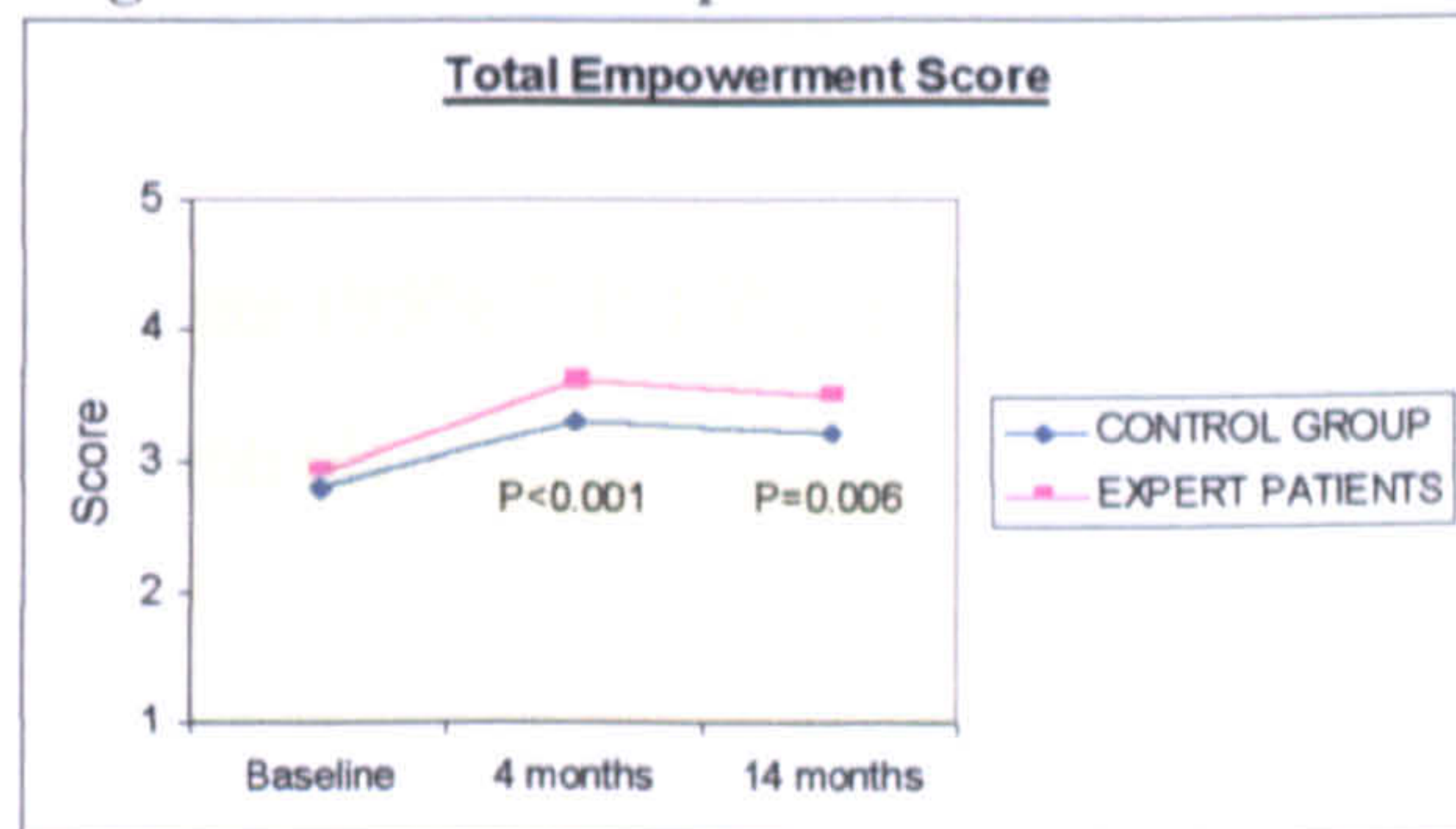


Figure 6.29 Total empowerment score



Diabetes medication

Self-reported medication prescribed for the treatment of diabetes was reviewed at 14 months and compared to that prescribed at baseline. A medication increase was defined as either of the following: progression from the treatment of diabetes with diet alone to a prescription for oral hypoglycaemic agents (OHAs); an increase in dose or change in type of OHA; progression onto insulin injections or an increase in the number of units of insulin injected. The numbers of expert patients and control patients requiring medication increase is shown in Table 6.11 below. A medication decrease was defined as a reduction in the type or quantity of OHAs prescribed or the number of units of insulin injected. Medication was classed as remaining the same if no changes had been made to the original baseline regimen. The number of expert patients and control patients receiving a medication decrease is shown in Table 6.12 overleaf.

Increase in diabetes medication

Table 6.11 Number of patients requiring an increase in their diabetes medication

	Increased medication	Did not increase medication	Entered
Expert patients	31	119	150
Control patients	65	76	141
TOTAL	96	195	291

The risk of the expert patients increasing diabetes medication was $31/150 = 0.21$ (P_1)

The risk of the control patients increasing diabetes medication was $65/141 = 0.46$ (P_2)

The risk ratio (RR) is $P_1 / P_2 = 0.21/0.46 = 0.45$ (95% CI: 0.31 to 0.64)

The relative risk of increasing medication for patients who had attended the X-PERT programme was 0.45. Thus the X-PERT programme reduced the risk of increasing diabetes medication by 55%.

The risk difference (RD) is $P_1 - P_2 = 0.21 - 0.46 = -0.25$ (95% CI: -0.36 to -0.15)

Expert patients were 25 absolute percentage points (95% CI: 15% to 36%) less likely to have their diabetes medication increased than controls.

Number needed to treat (NNT) is $1/RD = 1/0.25 = 4$ patients (95% CI: 3 to 7)

For every four patients who participated in the X-PERT programme, one patient could be spared an increase in their diabetes medication by the time of the 14-month follow-up.

Reduction in diabetes medication

Table 6.12 Number of patients whose diabetes medication was reduced

	Reduced medication	Did not reduce medication	Entered
Expert patients	24	126	150
Control patients	1	140	141
TOTAL	25	266	291

The likelihood of the expert patients reducing medication was $24/150 = 0.16$ (P_1)

The likelihood of the control patients reducing medication was $1/141 = 0.007$ (P_2)

The risk ratio (RR) is $P_1 / P_2 = 0.16/0.007 = 23$ (95% CI: 3 to 165)

The relative risk of reducing medication for patients who had attended the X-PERT programme was 23. Thus expert patients are 23 times more likely to reduce diabetes medication compared with control patients.

The risk difference (RD) is $P_1 - P_2 = 0.16 - 0.007 = 0.15$ (95% CI: 0.09 to 0.21)

Expert patients were 15 absolute percentage points (95% CI: 9% to 21%) more likely to reduce diabetes medication than controls.

Number needed to treat (NNT) is $1/RD = 1/0.15 = 7$ patients (95% CI: 5 to 11)

For every seven patients who participated in the X-PERT programme one patient could expect to have reduced their diabetes medication by the 14-month follow-up.

6.6 Unplanned outcomes

The randomised controlled trial collected individual biomedical, lifestyle and psychosocial outcomes and the participant evaluation assessed the content and delivery of the X-PERT programme for enjoyment, usefulness and perceived impact on health. The evaluation questionnaire also asked participants whether they believed that attending the programme might help other people with diabetes and 91% answered in the affirmative (see participant evaluation on page 201). Unplanned outcomes that resulted from patients attending the diabetes expert patient programme and that are likely to help other people with diabetes were as follows:

- lending diabetes expert patient manuals to relatives, friends and health professionals regardless of whether they themselves were living with diabetes;
- training as peer educators for the Department of Health lay-led chronic conditions expert patient programme;
- becoming a peer educator for their local general practice;
- forming a diabetes empowerment and education subgroup for the local diabetes services implementation group (LDSIG), writing a report with recommendations for the delivery of diabetes education within the locality, and making a presentation of the report to LDSIG and Primary Care Trust management;
- developing local support groups in Nelson and Haslingden;
- sitting on health care delivery committees and making presentations to give a laypersons perspective to aid the development of local and national diabetes services.

6.7 Presentation at scientific meetings

The X-PERT project has been presented at several national and international conferences:

- the participant evaluation data was presented at the European Association for the Study of Diabetes (EASD) Professional Annual Conference, Budapest, September 2002 (Deakin et al. 2002);

- the four month results were presented at the 2003 Diabetes UK Professional Annual Conference, Glasgow, March 2003 where the X-PERT project won the 2003 Diabetes Education Award (Deakin et al. 2003c);
- (Deakin 2003b) those four month results were also presented at the American Diabetes Association 63rd Scientific Session, New Orleans, June 2003 (Deakin et al. 2003b);
- the full results (four month and 14 month) were presented at the International Diabetes Federation Conference, Paris, August 2003 (Deakin et al. 2003a).

There has therefore been considerable national and international interest in the X-PERT programme.

6.8 Summary

The X-PERT project was well received from the start, with all 16 practices approached agreeing to take part in the research. Recruitment of participants met the predicted 20% response rate; 314 participants provided written consent; that was 14 more than the 300 participants originally proposed. The mean age of the participants was 62 years, although the South Asian participants were, on average, ten years younger. The mean duration of diabetes was 6.7 years. The participants were generally obese, with a waist circumference in the 'unhealthy' range (highest tertile). Although mean blood pressure readings were above the recommended level, mean lipid profiles were acceptable.

Ten diabetes expert patient (X-PERT) programmes were delivered to 157 participants, of which three programmes were delivered to Urdu-speaking South Asian participants through a translator. Attendance rate was excellent and participant evaluation showed that the patients had enjoyed the sessions, had found the information useful and felt that the programme would improve their health. Structure and process evaluation based on the International Diabetes Federation standards showed that the delivery of the diabetes expert patient programme allowed many standards to be met that otherwise would not have been addressed within Burnley, Pendle and Rossendale.

Outcome evaluation was carried out at four months and at 14 months and showed many biomedical, lifestyle and psychosocial health gains for participants who were assigned to the X-PERT programme. At baseline, one quarter of participants were advised to control their diabetes with lifestyle alone, just over half of the participants were prescribed hypoglycaemic tablets and almost one in five participants was injecting

insulin. Participants assigned to the X-PERT programme were more likely to reduce their diabetes medication and less likely to have an increase in prescribed medication compared to the control group.

The primary outcome, glycated haemoglobin, was significantly improved at four months and that improvement was not only maintained at 14 months, but glycaemic levels were further reduced. There were greater differences in glycated haemoglobin levels between the South Asian expert patients and the South Asian controls owing primarily to deterioration in the glycaemic control of the control group.

The expert patients increased self-management of diabetes by exercising, self-monitoring blood glucose levels and performing foot care more regularly, and they consumed a healthier diet consisting of more fruit, vegetables, and fibre and less saturated fat. They also became significantly more knowledgeable about their diabetes. Psychosocial variables improved with greater freedom to eat and drink, and increased enjoyment of food. Expert patients reported feeling more empowered by virtue of having improved psychosocial adjustment to diabetes, increased readiness to change and more likelihood to set and achieve goals. Attending the X-PERT programme also significantly improved treatment satisfaction scores.

Chapter 7: Discussion, Conclusion & Recommendations

7.1 Introduction

The final chapter of this study will commence with a brief résumé of its findings. This will be followed by a discussion of the strengths and possible limitations of the research methods and evaluation (structure, process and outcome) employed. The general application of the study will then be considered before conclusions are derived. Thereafter, by way of a refresher regarding the content of the thesis, a brief summary of each chapter will be presented, superseded by review of the overall evidence in favour of an empowerment approach to patient education. The chapter and thesis will draw to a close with a discussion about future implications of the study, from investigation to practice, and about the need for more research before effective patient education programmes can be further developed.

7.2 Résumé of findings

The X-PERT trial tested the hypothesis that delivery of a professional-led, community based, diabetes-specific expert patient programme for adults with Type 2 diabetes based on the theories of patient empowerment and patient activation would:

- (1) develop the skills and confidence needed for patients to be able to make informed decisions regarding their diabetes self-management;
- (2) improve biomedical, lifestyle and psychosocial outcomes both in the short term (four months) and longer-term (14 months);
- (3) meet the International Diabetes Federation (IDF) structure and process standards regarding diabetes education.

The study has not refuted any of the three aspects of the hypothesis. The expert patients became more knowledgeable about their diabetes and increased their self-management skills by exercising, taking care of their feet and choosing a healthier diet both in the short and longer-term. Although the frequency (number of days per week) of self-monitoring blood glucose levels was statistically significantly greater than that of the control group at four months, the half-day difference at 14 months may have occurred by chance. The empowerment score assessed patients' self-efficacy (perceived confidence) to self-manage their diabetes and it showed statistically highly significant differences between the expert patient and the control group in respect of the total empowerment score and the three subscales (psychological adjustment, readiness to change and goal setting) both in the short and in the long term.

The increased knowledge, skills and confidence impacted on biomedical measurements, significantly improving diabetes control at four months and further reducing glycaemic levels at 14 months. Although not statistically significant, the results indicated a trend towards reduced blood pressure, body fat and body weight. A 3 cm reduction in waist circumference is a clinically significant finding, although statistically a borderline significant difference (95% confidence intervals: 0 to 6 cm). Although there were no differences between the expert patients and the control group in respect of lipid profile, that was not surprising, as those mean readings were within the recommended range for total, LDL and HDL cholesterol.

As indicated above, the diabetes expert patient programme significantly improved lifestyle outcomes at both four months and at 14 months through physical activity levels, self-management skills and nutritional intake. It also positively impacted on psychosocial outcomes, both in the short and longer-term, through enhanced treatment satisfaction, improved quality of life through freedom to eat and drink and enjoyment of food, and as stated above, increased self-empowerment. Although expert patients experienced greater freedom to eat and drink, their energy intake did not increase and they did not gain weight. Extra carbohydrate was consumed by the expert patients in the form of total sugars, including sucrose, and that consumption may have resulted in a slight reduction in fat intake. Sucrose intake remained within healthy eating guidelines and it did not lead to a deterioration in diabetes control. Those findings accord with current dietary guidelines, further dispelling the myth of the sugar free diet (Nutrition Subcommittee of the Diabetes care Advisory Committee of Diabetes UK 2003). There were no differences between the expert patients and the control group in respect of table sugar intake. The extra fruit and vegetables consumed daily by the expert patients will have contributed to the increased sucrose and total sugar intake.

At baseline, both the expert patient group and the control group were consuming a similar quantity of fruit and vegetables each day (2.8 portions and 2.9 portions respectively) and those quantities compared with the mean national intake (2.7 portions for men and 2.9 portions for women) (Department for Environment 2000). At four months both the expert patient group and the control group had increased fruit and vegetable intake compared to the national average, although the expert patient group was consuming significantly more fruit and vegetables than the control group (4.4

portions and 3.4 portions respectively). At 14 months the expert patients were consuming two extra portions of fruit and vegetables each day compared with the control group (5.2 portions and 3.1 portions respectively). The X-PERT programme has therefore appeared to be an example of a successful health promotion strategy.

7.3 Strengths and limitations of the study

7.31 Methods

The following table summarises strengths and limitations in relation to the research design.

Table 7.1 Summary of the strengths and limitations for the methods and design of the study

<i>Strengths</i>	<i>Limitations</i>
Research Design	
The research design was achievable and appropriate to answer the research question.	A waiting list control group may have a more ethical approach but time constraints prevented this
Randomisation of individuals was still thought to introduce less bias than performing cluster randomisation.	Cross-contamination did occur between the intervention and control groups.
An attempt was made to conceal allocation of participants to the intervention or control group by describing the two programmes as individual or group education.	
Although total separation of implementation and evaluation of the study was not possible, two outcome assessors, not involved in the delivery of the diabetes education, were blinded to treatment allocation. The outcome database was also anonymous.	Only the expert patients were intended to receive their own health results, but due to the blinding of outcome assessors, all participants had access to them. Therefore, the control patients received more attention and better care than routine treatment.
The CONSORT statement was acknowledged and followed where possible.	Total separation of implementation and evaluation of the study was not possible due to practicalities, time and funding constraints. This limitation was acknowledged and addressed. Due to the nature of the interventions (education programmes), it was not possible to blind the health professionals to group allocation and this may have resulted in performance bias.

Attempts were made to present the programme in a manner that enables the intervention to be transported to, and put into operation in other contexts (Chapter 4)

The study was a complex intervention and it is not possible to identify the active ingredients with total precision. Process evaluation using qualitative methods was not possible due to funding and resource constraints

Recruitment

Minimum exclusion criteria.

Practice staff screening and excluding some patients.

Recruitment from mailshots rather than advertisement in the health centre or through local media.

Practice registers sometimes incorrect and not always up-to-date.

20% response rate acceptable for clinical trials.

Limited time to take advantage of word-of-mouth recruiting.

Telephone recruiting increased the response rate for the South Asian participants, especially when an Urdu speaking student was available.

Participant demographics

No important statistically significant differences between the intervention and control group showing that the randomisation had been effective.

Trial participants were a typical sub-group of people with Type 2 diabetes as the age at diagnosis and percentage of overweight or obese patients were the same as in the UKPDS study.

Different methods to assess socio-economic deprivation at ward level had to be used for Rossendale compared to those used for Burnley and Pendle. However, both methods identified practices that had great diversity in the socio-economic status of registered patients. Such diversity did not appear to effect group dynamics.

The differences in demographic variables between white Caucasian and South Asian participants supported previous findings.

Poorer return rate for the questionnaires from the South Asian participants may have biased the results, as more literate and educated participants may have responded, resulting in the South Asian sub-group appearing to be better educated than the true results may have shown.

Sub-group comparisons between the white Caucasians and South Asians, although interesting and supportive of previous findings, cannot be interpreted as facts, due to the small percentage (25%) of South Asian participants.

Research design

Although it has been suggested that randomised controlled trials are problematic in practice, with particular problems occurring regarding recruitment and randomisation (Pringle & Churchill 1995), the prospective, pragmatic randomised controlled trial used to evaluate the X-PERT programme was thought to be an achievable and appropriate research design to answer the research question. However, there was some cross-contamination between the two groups. Participants were randomised as individuals to receive either the X-PERT education programme or routine treatment. Therefore, for each general practice, there were some participants receiving the intervention and some allocated to the control group. There are many small communities within Burnley, Pendle and Rossendale and patients registered at the same practice tend to be acquainted. There were several instances where participants attending the group education programme shared the content of their course with control participants. Some expert patients even lent their X-PERT programme manuals to control patients. Many control patients subsequently requested a swap to the group education programme. Cross contamination might have been reduced if the trial had used cluster randomisation i.e. the general practice had been randomised to intervention or control rather than individual patients. That method of randomisation was considered when designing the trial but it was felt that some design features of a cluster trial may make it especially vulnerable to a range of threats that can introduce selection bias (Puffer, Torgerson, & Watson 2003) and it was decided that, even with the risk of cross contamination, individual randomisation was more appropriate for this study.

In an attempt to conceal allocation of the participants to the intervention or control group, the patient information leaflet described a group-based education programme and an individual education programme. Blinding of patients was important because knowledge of group assignments could influence responses to treatment. Patients who knew that they had been assigned to a new treatment might have displayed favourable expectations or increased anxiety, and patients assigned to routine treatment could feel discriminated against or reassured (Altman et al. 2001). Many of the individual education (control) patients complained that they were not benefiting from their programme. That was not a surprising finding as they were, in fact, the control group, receiving routine treatment. For other control group participants, the individual education programme specified in the study (i.e. individual appointments with the dietitian, practice nurse and GP) was an improvement on the 'routine treatment' previously received, which had not included referral to a dietitian. There was therefore a

mixed reaction from those in the control group depending on the standard of care that they were previously accustomed to.

Both groups received health assessments at baseline, four and 14 months and although it was intended that only the expert patients were to obtain their own health results, the control group patients also benefited from those assessments. The outcome assessors, blinded to treatment allocation (with the exception of the author, who delivered the X-PERT programme), discussed patients' results openly with all patients and answered queries regarding those results. Copies of the blood results for glycated haemoglobin and the lipid profile were sent to the respective GPs and, in many cases, treatment was changed as a result of those blood tests. Control patients therefore received better care and more attention than had previously been provided via routine treatment. In some instances, it may be deemed unethical to have half the participants in a clinical trial receiving routine treatment. A randomised controlled trial with a waiting list control group would have addressed this possible limitation. However, as outcomes were collected at 14 months from baseline, it was not possible within the time constraints to have a waiting list control.

Overwhelming evidence now indicates that the quality of reporting randomised controlled trials (RCTs) is less than optimal and that weakness arises from biased estimates of treatment effects. A group of scientists and editors developed the CONSORT (Consolidated Standards of Reporting Trials) statement (Altman et al. 2001) that facilitated critical appraisal and interpretation of RCTs by providing guidance to authors about how to improve the reporting of trials. That statement provided guidance for reporting the methods and the results of the trial that is the subject of this thesis. Ideally, total separation of delivery and evaluation is recommended for randomised controlled trials. However in this instance, practicalities and funding did not permit such separation and that has to be recognised as a possible limitation of the study. Also, although blinding of group allocation is recommended, not only for the patients, but also for all health professionals and researchers involved in the study, it was not possible in this study to blind the health professionals to group allocation. Performance bias might have occurred in respect of this, with the GP, practice nurse or dietitian providing routine treatment to the control patients, especially if the health professionals perceived that the trial was comparing the effectiveness of their treatment with that of group education. The author of this thesis was the diabetes educator who delivered the X-PERT programme. Although blinding to group allocation had not been possible,

performance bias was less likely because the content of the education programme was standardised, with weekly lesson plans, and the programme had been delivered to a group of patients rather than to individuals.

The author of this thesis was also the data analyst, which could potentially introduce bias. In an attempt to avoid bias, an anonymous database was used to analyse the results whereby the intervention group and control group were compared at baseline, four and 14 months. Statistical tests were performed on any differences between the two groups to detect whether those differences were likely to have occurred by chance or as a result of attending the X-PERT programme. T-tests were used for parametric data and the Mann-Whitney test was used for non-parametric data.

Educational programmes are often described as complex interventions where it is difficult to define the 'active ingredient' (Medical Research Council 2000). The effectiveness of the X-PERT programme may be due to several factors: the theoretical models used; the skills and motivation of the educator; the rapport between the participants; the patient manuals; the sharing of health records; goal setting; or a combination of all of these. This could be described as the black box theory i.e. the individual components of the intervention were identified before its implementation and outcomes were collected and analysed at time points after implementation, but the specific ingredients leading to the success of the education programme remain unknown. Process evaluation using qualitative methods may have identified the content of the 'black box' and strengthened the evaluation. However, funding and resource limitations prevented further evaluation on this occasion and may be seen as a limitation of the study. The use of the empowerment model successfully facilitated the process of self-empowerment in the patients, although the extent to which increased empowerment contributed to improved outcomes cannot be identified. Other recognised 'active ingredients' in the complex intervention were the visual aids, patient manuals and the participants' ability to obtain and understand their own health results. The author recognised that the sessions needed to be fun and refreshments were required to encourage the group to interact. Refreshments were also important to address 'Maslow's hierarchy of needs' (Benson & Dundis 2003) that physiological needs such as hunger and thirst need to be met before effective learning can take place. One lesson learnt regarding the supermarket tour was that no more than 10 participants could feasibly be invited to attend each tour.

The precise mechanism of action is likely to be a combination of all components. An attempt has therefore been made to present the programme in a manner that enables the intervention to be transported to, and put into operation in, other contexts (See Chapter 4 for a scripted description of the X-PERT programme).

Recruitment

All adults with Type 2 diabetes were invited to take part unless physical or cognitive restrictions prevented them from attending and actively taking part in the programme. The mean glycated haemoglobin of the participants at baseline was 7.7% with a standard deviation of 1.6%. That result revealed that many of the participants did not have poor diabetes control at the start of the trial and was considered a strength of the study. The recruitment criteria differed from many other diabetes education interventions that recruited only participants with poor diabetes control and who were therefore more likely to experience a positive outcome (Norris, Engelgau, & Narayan 2001). The sample size was also generous in comparison to other education studies (Griffin et al. 1998).

Although participants had been diagnosed with diabetes for a mean of seven years, individual patient data was diverse, with some participants having been diagnosed for less than one year and others having lived with diabetes for 36 years. Duration of diabetes was not specified in the inclusion or exclusion criteria as it was thought that people with Type 2 diabetes could learn to improve self-management skills and confidence in self-management regardless of how long they had lived with diabetes. Also, in the interest of a pragmatic study, the level of glycaemia was not specified in the inclusion or exclusion criteria. Type 2 diabetes is classified as a progressive condition and it was perceived that even if individuals had excellent diabetes control, attending the X-PERT programme might prevent deterioration in glycaemic control and might also prevent an increase in diabetes medication. Also, as outcomes other than glycated haemoglobin such as blood pressure, body weight, lipid profile, lifestyle, self-management skills, self-confidence, treatment satisfaction and quality of life, are also important health determinants for people with Type 2 diabetes, it was not justifiable to exclude potential participants on the basis of glycaemic control alone.

The recruitment response of 20% was typical of a randomised controlled study although the sample size was generous compared to other educational interventions (see the systematic review in Chapter 3). After the recruitment stage was over, volunteers who

had heard about the programme via word of mouth asked to be included in the study. Although they could not be accommodated on this occasion, such interest could serve to illustrate the effectiveness of “word of mouth” as a means of stimulating public interest and aiding recruitment. Two practices in Burnley gave consent for the initial mailshot to be followed-up with a telephone call which, although time consuming, improved the response rate. Telephone recruitment was shown to be particularly beneficial for the South Asian participants. For Burnley practice 4 (see Table 6.1, Chapter 6), telephone recruitment predominated and a random number table was used to select telephone numbers from the list of patients provided by the practice. In Pendle, 70 white Caucasian patients were recruited from the mailshot alone and telephone follow-up was only required to meet the target of 50 patients for the South Asian individuals.

A possible limitation of the study is that not all patients with Type 2 diabetes and registered with one of the 16 general practices were invited to take part in the study. At some practices, staff screened the list of patients and deleted the names of those they felt would be unsuitable to participate. Unsuitability was due mainly to old age or infirmity. Although the intention was to keep the study as pragmatic as possible and to let patients decide whether it was feasible for them to take part in it, the preferences of the individual practices were respected. Interestingly, in practices that allowed all patients to be contacted, some recruits were historic non-attendees and others were living with severe socio-economic deprivation. The homes of the latter individuals were frequently dirty with little or no working sanitation, often damp with no heating and containing little furniture.

Some of the patient lists received from the general practices were either incorrect or out of date. Notification was received in respect of several invitees that they had either passed away, moved out of the area or did not have Type 2 diabetes.

Participants

There were no statistically significant differences in demographic variables between the participants in the intervention group and the participants in the control group. The mean age of the participants was similar to that reported in other diabetes education studies involving patients with Type 2 diabetes (see the systematic review in Chapter 3). The mean age of the participants at diagnosis of diabetes (54 years) was the same as the mean age of participants newly diagnosed with Type 2 diabetes in the United Kingdom Prospective Diabetes Study (UKPDS Group 1998b). The fact that the South Asian

participants were, on average, ten years younger than the white Caucasian participants was not surprising as there is evidence that South Asian individuals develop Type 2 diabetes at an earlier age due to increased prevalence of central obesity and hyperinsulinaemia (Chaturvedi & Fuller 1996).

Although the aim of the study was to recruit patients from socio-economically deprived neighbourhoods, there was considerable diversity in the socio-economic status of the participants. However, such diversity did not appear to affect group dynamics (see the process evaluation discussion below in section 7.3.2). As stated in Chapter 5 (Table 5.3) the disadvantages of assessing the deprivation of a population using either the Jarman score or the DETR rank is that data is not available below ward level and there is often great variation within a particular ward.

The majority of participants left full-time education at the age of 16 or younger and compared with the national average of 16% (Office of National Statistics 2002), only 6% of participants had been educated to degree level. Although the mean age of leaving full time education was slightly higher for the South Asian participants, only 33% of them had completed the education questions compared with 89% of the white Caucasian participants. It may be surmised that better educated South Asian participants remained in full time education for a longer period, and those participants were more likely to read Urdu and/or English and complete the questionnaire, thereby biasing the results.

The response rate was better in respect of questions concerning employment, with 92% of white Caucasian and 55% of South Asian participants responding. Although not directly relevant to the study, there were major differences between the two ethnic groups. White Caucasian participants were more likely to have been in paid employment and to have held a managerial position. Although 17% of white Caucasian and 18% of South Asian participants were working when they were recruited into the study, of those not working, female South Asian participants were more likely to be housewives and overall, South Asian participants were 21 times more likely to be unemployed, whereas white Caucasian participants were almost four times more likely to be retired. South Asian participants were also more likely to be married, less likely to be divorced and less likely to be widowed, whereas the white Caucasian participants were more likely to be single. Those findings may reflect different cultural practices,

particularly the lower socio-economic status of the South Asian participants and their younger age.

Treatment of diabetes differed slightly for each ethnic group. A greater percentage of white Caucasian participants treated their diabetes with insulin (19% of white Caucasian compared with 10% of South Asians) and a correspondingly smaller percentage with tablets (53% and 68% respectively). There was, however, no difference in mean glycated haemoglobin levels or in the distribution of glycated haemoglobin levels between the two ethnic groups. That observation indicates that treatment differences between ethnic groups were probably not due to reluctance of the GPs to commence insulin in the patients who may have a language barrier and supports previous findings that South Asian individuals with Type 2 diabetes have greater insulin resistance and less insufficiency of insulin than white Caucasian individuals (Burden 1996; Chaturvedi 2000). Another interesting observation was that the South Asian participants had lower systolic blood pressure readings and were also more likely than white Caucasian participants to meet recommendations for total cholesterol and LDL cholesterol but less likely to meet HDL cholesterol recommendations. Once again those observations support previous findings (Shaukat 1996), (UKPDS Group 1998a).

Currently, over half of women and two-thirds of men in the UK are either overweight or obese (Campbell 2003). As explained in Chapter 1 (section 1.6.4), being overweight is a risk factor for developing Type 2 diabetes (Chan et al. 1994; Colditz et al. 1995). (Després, Lemieux, & Prudhomme 2001) The majority of individuals with Type 2 diabetes are obese (WHO Working Group 1999). The participants in this study appear to conform to national statistics: 88% of participants had a BMI of 25 Kg/m² or above. There was a greater percentage of South Asian participants in the overweight range (48% of South Asians compared with 39% of white Caucasians) and smaller percentage in the clinically obese range (32% and 46% respectively). Taking into consideration the increased prevalence of Type 2 diabetes and greater central obesity at lower BMI levels amongst South Asian adults, there have been recommendations that either the diagnostic criteria for obesity be lowered for South Asian participants to BMI \geq 27 Kg/m² (Shaukat 1996) or that the healthy weight recommended range be lowered to BMI 20 to 23 Kg/m² as opposed BMI 20 to 24.9 Kg/m² (WHO 2004).

Interestingly there are also important gender and ethnic differences for waist circumference. The baseline characteristics for the participants in this study showed that

83% of women compared with 52% of men had a waist circumference in the 'high risk' tertile. That difference was more pronounced for South Asian participants with 97% of women having a waist circumference in the 'high risk' tertile compared with 40% of South Asian males. Those gender differences in waist circumference may be explained by age and menopause-related changes in body fat distribution (Pascot et al. 1999; Toth et al. 2000). South Asian older females tend to be much more sedentary. Not only are they more likely to stay at home, but the younger female relatives also carry out the domestic work. 'Plumpness' is accepted as a sign of good health and affluence in the Asian culture (Hawthorne, Mello, & Tomlinson 1993). In comparison, not only do the Asian men appear to have increased occupational and leisure time physical activity levels, they also seem to be a lot more conscious about their body weight than their female counterparts.

7.32 Evaluation: structure, process and outcome

The table below summaries strengths and limitations for the study in respect of evaluation.

Table 7.2 Strengths and limitations of the study in respect of evaluation

<i>Strengths</i>	<i>Limitations</i>
Structure	
BPR PCT taken the lead in implementation of a structured and empowering approach to diabetes education.	Secondary Care Diabetes Team uninvolved in the development and delivery of the X-PERT Programme.
BPR PCT keen to support the continuation of the X-PERT Programme.	Funding has now come to an end.
The X-PERT Programme has received two national awards.	Used on isolated the X-PERT programme may not be effective. Health professional training alongside implementation is essential.
The successful development of visual aids and patient manuals especially for the X-PERT Programme. Translation of the patient manuals found to be unnecessary.	Continued production of the patient manuals would require sponsorship for bulk printing.
A network of lay-experts are now contributing to health service development.	Tension between empowered patients and practice staff clearly a predictable situation in a non-specialist environment and the need for professional training is paramount.

<p>The project gained tremendous support from the Nutrition & Dietetic Department, BPR PCT, Clinical Effectiveness Department, local branch of Diabetes UK, patients and their carers.</p>	<p>Teamwork between professionals providing diabetes education could be better.</p> <p>Only one practice nurse managed to attend the X-PERT Programme.</p>
Process	
<p>Participants have identified that they would like an annual follow-up and this should be incorporated into any future programme.</p> <p>Both intervention and control education programmes arranged at easily accessible, community venues.</p>	<p>No formal follow-up arrangements within the current X-PERT Programme with participants returning to routine treatment.</p> <p>No programmes held during the evenings or weekends therefore making it difficult or impossible for full-time workers to attend.</p>
<p>Attendance to the X-PERT Programme excellent.</p> <p>Intention-to-treat analysis carried out to reduce attrition basis.</p>	<p>Attendance rate for the control group not as good as that for the X-PERT Programme.</p>
<p>Lesson learnt from holding a mixed sex programme for South Asian participants and the 2nd and 3rd programmes were single sex resulting in better attendance.</p>	<p>Initial programme for South Asian group were not single sex sessions resulting in less good attendance rates.</p>
<p>Semi-structured interview carried out to seek the views of the South Asian expert patients.</p>	<p>Time and funding constraints prevented a semi-structured interview being carried out for all participants.</p>
Outcome	
<p>The return rate for the questionnaires was between 61% and 83% (and similar response from intervention and control group leading to an equal comparison).</p> <p>No important statistically significant differences between the intervention group and control group for baseline outcomes.</p> <p>Outcomes collected in the short and longer term.</p> <p>Between 93% and 100% biomedical outcomes collected.</p>	<p>Some questions in the questionnaire left unanswered which may be due to the length of the questionnaire or sections that the participants had difficulty understanding. Extra funding may have improved the questionnaire response rate by employing a research assistant blinded to treatment allocation and able to help participants in the completion of the questionnaires.</p> <p>No time or funding to 'double' translate and then re-validate the Urdu version of the questionnaire. However, only 30 of the 660 questionnaires were in Urdu.</p>

<p>The results of the study have not refuted any of the three aspects of the hypothesis.</p>	<p>Multiple comparisons may have resulted in experimentwise (type 1) errors.</p>
<p>Biomedical outcomes collected and analysed conforming to standardised and accepted methods. The use of validated questionnaires.</p>	<p>The three trained outcome assessors collected the biomedical outcomes but the percentage measurement error cannot be estimated although any errors are likely to be distributed equally between the intervention and control group.</p>
<p>The empowerment score and respective sub-scales was shown to be consistently greater in the expert patients at both four and 14 months which may further validate the empowerment questionnaire.</p>	<p>The validation of the HEA3 FFQ had shown under-reporting of energy intake in obese participants and this was likely to be the case in this study. However, the validation had shown that the percentage energy from macronutrients was both valid and reliable.</p>
<p>The expert patients experienced improved quality of life by increased freedom to eat and drink whilst at the same time improving other health variables including glycaemic control.</p>	<p>The expert patients experienced both increased treatment satisfaction and improved metabolic control although it cannot be identified whether one contributed to the other or whether the improvements occurred in synergy.</p>
<p>The longer-term assessment (14 month) of glycated haemoglobin improved from the short term assessment (4 month).</p>	<p>The South Asian expert patients maintained their level of glycaemia whilst the metabolic control in the control group deteriorated. Due to sub-group analysis with small numbers it cannot be identified whether this was a chance result or significant finding.</p>

Structure

Burnley, Pendle and Rossendale Primary Care Trust (BPR PCT) is at the forefront in implementation of a structured and empowering approach to diabetes education as recommended by the Department of Health (DOH 2001a),(DOH 2003a),(NICE 2003b). Its action has largely taken the form of support for the X-PERT Programme. To some degree the PCT has achieved its position by reacting to the demands of the expert patients themselves and the national awards received from Diabetes UK and the National Obesity Forum.

Funding for the X-PERT Programme of research is however now at an end. Continuation will depend upon safeguarding further funding in order that national and international objectives in diabetes education may be met. Discussions have been held

with the Director of the NHS Modernisation Agency, the Lancashire with Cumbria Workforce Development Confederation and a business case has been presented to the BPR PCT.

The education/empowerment programme developed for this research depended heavily on the purpose created visuals designed to explain complex and scientific information in a simplistic but accurate manner (see Chapter 4). Those proved invaluable to the participants, along with the patient manuals, which were still in regular use at the 14 month stage and beyond. The value of the manuals was illustrated by the fact that they were lent to, and copied for, relatives and friends. A network of lay-experts has begun to develop without external prompting.

Production of the 157 manuals by hand was an arduous task. The manuals included literature from national bodies such as Diabetes UK (Diabetes UK 2003c) and the Food Standards Agency (FSA 2003), together with information sheets produced by the Michigan Diabetes Research and Training Centre (MDRTC 2003) and adapted for the UK population. Sponsorship will be required to support bulk printing and/or production of a CD-Rom to facilitate any expansion of the project. Translation into Urdu was found to be unnecessary in that South Asian participants able to read Urdu could also read English. Illiterate participants were normally able to rely on younger members of the family to assist.

The Nutrition and Dietetic Department and the Clinical Effectiveness Team of the former Burnley Healthcare NHS Trust were enthusiastic supporters of the X-PERT project, alongside the local branch of Diabetes UK and the patients and their carers. A presentation to the public health department at the former East Lancashire Health Authority resulted in some positive criticism of the research design. That feedback led to the study taking the form of a pragmatic randomised controlled trial instead of the previously envisaged uncontrolled action research design. That change was a major one but it has benefited the project and its evaluation.

As a novel and experimental approach, the study did not however gain automatic support in all quarters. A presentation to the Secondary Care Diabetes Multidisciplinary Team resulted in the team electing to distance themselves from the project. A request for one of their specialist diabetes nurses to assist with the project was rejected due to lack of resources for primary care. The team's decision to remain uninvolved in the

study had some slight negative impact on the project, in that a few participants experiencing dual care received advice delivered from two very different theoretical frameworks. Clearly, any future continuation or extension of the project will need to overcome those problems.

Overall, teamwork and communication between health professionals providing diabetes education within the BPR district could be improved upon. Hard pressed general practice has many calls on its time and diabetes education is often provided on an ad hoc basis within routine appointments and is based on the knowledge and beliefs of those responsible. Group education programmes, in the few instances where they exist are unstructured with no evaluation. There is little consistency, neither between nor within practices. Invitations to practice nurses to attend the X-PERT Programme in all 16 practices involved resulted in one attendee. She gained greatly from the programme, as did participants under her care from improved quality and consistency of advice. This is not to criticise those who did not attend. Many said they would have liked to do so but, with many other responsibilities, were unable to justify the time input. Coordination of resources is an area where improvements would need to be made if X-PERT patient empowerment was to become more widely available and meet IDF standards, safeguard NHS resources currently expended on secondary complications and, most importantly, improve the quality of life for patients with Type 2 diabetes.

Since returning to routine care there have been some examples of tension between practice staff and newly empowered patients. Where inconsistent or contradictory advice from practice staff has been queried by better informed patients, they have, in some instances, been told that 'they know too much for their own good' and have been forced to return to a more prescriptive regime that has defeated the empowerment gained. Clearly, although not foreseen, that consequence is an entirely predictable situation where professional staff, unable to keep abreast of every new development in every field, may feel threatened by increasingly informed patients. It indicates an important principle: the need for professional training and awareness to run alongside any new development such as the X-PERT Programme as presented here.

The scripted manual was written to increase the generalisability of the clinical trial. However, that manual could be a limitation of the empowerment model if used in isolation without health professional training. Although the manual is scripted, it will also be necessary for health professionals to be familiar with the theoretical base in

behaviour change and the principles of adult learning, group education, the patient-centred approach, empowerment and discovery learning (see Chapter 2). Lack of understanding regarding the theoretical base of the programme could result in the manual being delivered in a didactic manner with individual concerns and queries being ignored and should be avoided.

Process

The X-PERT programme has met the IDF process standards where possible. However, one possible limitation is that once the programme had ended, there was no formal follow-up arranged and participants were returned to routine treatment. To assess the ongoing learner-centred needs of the participants (process standard (a)), they were asked at the 14-month assessment whether they believed that the six-week programme was sufficient to meet their long-term needs or whether they felt that a follow-up session was required. The overwhelming majority of participants stated that an annual follow-up session would be useful to pose queries and to receive an update about the latest recommendations. That suggestion will be incorporated into any future development of the programme.

In respect of the IDF process standard (e), the diabetes education service has been acknowledged and accessed by the X-PERT programme participants but not by the remainder of the diabetes community within Burnley, Pendle and Rossendale. There are 48 practices within BPR PCT, with just 16 practices (33%) involved in the study. Implementation of the X-PERT or a similar programme throughout all practices is clearly needed for process standard (e) to be met. Educational and clinical research is not currently routinely practiced within the PCT but it is the ambition of the author to develop a research climate that would help to provide an evidence base for practice.

Attendance

As stated in Chapter 6, attendance at the X-PERT programme was excellent, with just eight participants (5%) not attending any session and 128 (82%) attending four or more sessions. One factor that aided the good attendance rate was that, although the participants were from a wide range of backgrounds, an excellent rapport developed between them. Bonds may have developed because all of the patients and their carers had something in common: they all lived with diabetes. However, some participants were engaged in full-time work and were therefore unable to attend every session. In

addition, several people who had initially been interested in the study could not participate at all due to work commitments. If the delivery of the X-PERT programme is to be continued, a more flexible approach to healthcare delivery may be required with evening and/or weekend courses being available. The attendance rate for the control group (103 patients, 66%) was not as good. The individual appointments were arranged within community venues to ensure that they were equally as accessible as the X-PERT programme and participants were given a choice of date and time. It has not been possible to ask the non-attendees in the control group why they chose not to attend. One explanation may be that they perceived the appointment would be no different to routine treatment previously received and therefore saw no benefit in attending.

Attendance at the first X-PERT programme delivered to the South Asian participants was not as good as the attendance rates for the white Caucasian sessions. Only nine participants (60%) attended more than half the sessions. Even though sensitivity had been shown towards cultural issues (seating had been appropriately arranged, it being unacceptable for South Asian women to sit adjacent to unrelated South Asian males) many women did not feel comfortable and dropped out of the programme. Later sessions for the South Asian participants proved more popular because single sex programmes were arranged. Another cultural difference observed between the two ethnic groups was that approximately one third of South Asian participants requested a telephone reminder the day before each session, whereas no such requests were made by white Caucasian participants. The importance attributed to time keeping was also notably different between ethnic groups: white Caucasian participants typically arrived at the venue either early or on time. If they were going to be late, an advance phone call was normally received. In contrast, the South Asian participants frequently entered the sessions up to 30 minutes late with apparent lack of concern. Although punctuality is a reflection of good manners within the white Caucasian culture, it would not appear to carry the same importance within the South Asian culture. Those findings could explain why, within the health care setting, South Asian patients are classed as poor attendees.

A dietetic student on placement conducted a qualitative semi-structured telephone interview with the South Asian participants to identify possible successful and unsuccessful strategies that could aid the future development and delivery of education programmes for the South Asian ethnic group. Although an attempt was made to contact all South Asian participants who had been invited to attend the X-PERT programme, the semi-structured interview was only conducted with 30 participants

(71%). It was Ramadan and many people were sleeping during the day. The student was an Urdu speaking South Asian female and she was therefore able to communicate with the participants in their own language.

X-PERT programme attendees (defined as participants who had attended four or more sessions) reported that their reason for attendance was to seize the opportunity to learn more about their diabetes and how to control it. All sessions were reported to have been enjoyable; participants enjoyed different aspects of the programme. One female found the timing of the sessions (1pm to 3pm) inconvenient, as she had to leave early to collect her children from nursery. Overall however, participants felt that the sessions had greatly improved their understanding of diabetes and they reported that they had subsequently made significant changes to their lifestyle in an attempt to self-manage their diabetes. The majority of changes concerned dietary intake, with several participants reporting an increased consumption of fruit and vegetables, replacement of butter or gee with vegetable or olive oil and introduction of portion size control. Many had also started a daily walking regime. Knowledge sharing with relatives and friends living within the community was also a common response:

'.....I told everyone at home, I also told my wife, who also has diabetes but who didn't attend the sessions. Her control improved....'

'....I have mentioned this to others and they seemed very happy and pleased for me. They also thought it was a very good idea.....'

' I have told other members of the family. They found the paperwork very interesting and liked reading the information.....'

The South Asian participants reported unanimously that the group-based diabetes education sessions were a *'good and fun way to learn'*. One gentleman said: *'from attending the sessions I have found that I have learnt more than going to my annual appointments. I'm therefore very sure that others will also benefit'*. Comments regarding the written information were: *'the notes were very good. Since I cannot read or write, I got my children to read them and translate them to me'* and *'They [the information sheets in the patient manual] were very useful, I can always refer back to them'*. These quotes suggest that provision of the patients manuals, even if they were not translated into Urdu, were very worthwhile. No suggestions were made with regard to changing the content of the programme.

The findings from the non-attendees (participants attending less than four sessions)

further emphasised the need for single sex sessions. The South Asian women who only attended one or two sessions stated *'I did not attend the sessions because men were also present and I did not find that comfortable'* *'If there had been separate sessions for women and men I would have attended the sessions'* *'I didn't like the sessions because they were mixed. I wanted to ask questions but felt shy'*. Other reasons for non-attendance were: *'I had work commitments and therefore I could not attend. However, I did learn from other members of the community who did attend'* and *'I wasn't able to attend because I was not feeling well'*. Even non-attendees believed that the X-PERT programme approach to diabetes education was necessary *'I think that there should be more of these education sessions, since the dietitian went into a lot of detail, which I never got from my normal appointments'*. Two non-attendees were less supportive of the group-based education approach *'I prefer home visits....'* *'I think that attending the clinic appointments are a good way to be informed about diabetes, since you get a one-to-one session with the dietitian, rather than learning in groups'*. The majority of non-attendees felt that they had benefited from the sessions they had attended. One participant said: *'The session about different foods and their effect on blood glucose levels was very good, I was so afraid of a lot of foods.....learning about portion sizes was also very useful'*.

An intention-to-treat analysis was undertaken to reduce the possibility of attrition bias and at four months, 153 participants (97.5%) assigned to the intervention group and 152 participants (96.8%) assigned to the control group received an outcome assessment. At 14 months, it proved more difficult to obtain outcome data for everyone and more especially for some individuals in the control group. However, 150 participants (95.5%) in the intervention group were assessed, along with 141 (89.8%) in the control group. Throughout the outcome assessment periods, some South Asian participants made extended visits, lasting several months, to relatives in Pakistan and it was therefore not possible for them to be included in the assessment. The difference between the number of participants in the intervention and control group receiving an assessment at 14 months was mainly due to death and refusal to participate in the outcome assessment (see Chapter 6, figure 6.1). Although the higher death rate in the control group compared with the expert patient group was probably a chance occurrence, the greater number of participants refusing the assessment in the control group may have been due to them being less satisfied with the treatment they received. It was not possible to make contact with three participants (one expert patient and two controls) at the 14-month assessment, although telephone calls were made on several occasions and, if possible,

messages left on answering machines. Several visits were also made to their homes, but with no success. The patient administration services were contacted at nearby hospitals to enquire whether they had been admitted to hospital and the GPs were also contacted. However, the whereabouts of all three patients remains unknown.

Outcomes

Thirty-eight outcomes were collected at baseline, 4 and 14 months. When several separate tests are performed the risk of experimentwise (or familywise) error increases. Therefore when the dependant variables are correlated with each another, such as weight, height, BMI, waist circumference and body fat, the use of discrete t-tests may not give the most accurate picture of the data due to type 1 errors (false positive). This may have been addressed by using a smaller P-value to define whether any differences between the two groups were due to chance or not i.e. $P < 0.01$ instead of $P < 0.05$. Alternatively a multivariate analysis of variance (MANOVA) may have been performed. However, statistics are designed to identify probabilities not certainties and many results from the t-tests and Mann-Whitney analyses were shown to be highly significant, in excess of $P < 0.001$. Confidence intervals were also calculated as another measure to assess the significance of differences between the two groups. Analysing the data by t-test or Mann-Whitney analyses also permitted the results to be compared with other research trials.

The number and percentage of data collections for each biomedical outcome were 314 (100%), 305 (97%) and 291 (93%) respectively (see Chapter 6, Table 6.7). During each patient follow-up assessment, a questionnaire was given to each participant to complete and return in a pre-paid envelope. The questionnaire collected responses to the validated questions for the lifestyle and psychosocial outcomes. Although the return rate of the questionnaires at baseline, four months and 14 months was 83%, 67% and 61% respectively, the numbers of responses to each assessment score were progressively lower (see Chapter 6, Tables 6.9 and 6.10). That result indicates that although the importance of answering each question was explained to participants, some questions were nevertheless left unanswered. The full questionnaire, being the synthesis of several validated questionnaires, was lengthy. Participants reported that it took between 20 minutes and one-hour 30 minutes to complete. Some participants did not understand some of the questions and had therefore left them blank; others returned the questionnaire, stating that they had spent a certain amount of time on the questions and were not prepared to spend any longer; some participants refused outright to complete

the questionnaire. In ideal circumstances and with extra funding, a research assistant blinded to treatment allocation would have been employed to help participants complete the questionnaire. However, a similar number of responses for each variable were extracted from both the expert patient group and the control group. Those allowed a fair comparison to be made between the two groups, although non-response bias may have been present since it cannot be assumed that the characteristics of the responders and non-responders were the same.

The advantage of using structured questionnaires is the ability to collect unambiguous and easy to count answers leading to quantitative data for analysis. However, this method of data collection assumes that the questions are worded and ordered in such a way that will be understood by all respondents (Bowling 1997). That assumption was clearly not satisfied in this instance. Several of the questionnaires originated from America and it is possible that the slight difference in terminology confused some of the participants. Minor alterations had been made to the knowledge questionnaire and, with hindsight, some of the words or phrases should have been altered in other questionnaires to make them more comprehensible by the UK participants. Such amendment had not been done to avoid the possibility of affecting validation of the questionnaire. However, the whole questionnaire was translated into Urdu for those South Asian participants who could not complete the English questionnaire themselves and who had no family member aiding them. It was explained to the South Asian participants that completion of the English version was preferred. Very few Urdu questionnaires were returned (30 questionnaires out of the 660 questionnaires, 4.5%). The overall return rate of the questionnaires in general was, not surprisingly, much lower for the South Asian participants owing to the language barrier and the higher percentage of illiterate participants. The translated version of the questionnaire was not re-validated and presents a possible flaw in the collection and analysis of data although, owing to the low number of Urdu questionnaires received and the reduced responses within each questionnaire, that factor is unlikely to affect the overall findings.

It was important that the questionnaires were both reliable (able to consistently obtain the same results) and valid (successful in measuring what they were supposed to measure). The reliability and validity of the brief 14-item diabetes knowledge test has been examined in two populations and has been shown to be appropriate for a variety of settings and patient populations (Fitzgerald et al. 1998). As discussed above (see "Outcomes" section on page 238) minor changes were made to the questionnaire to

make it appropriate for the UK population. For example, the phrase 'the way most American people eat' was changed to 'the way most people eat'.

The food frequency questionnaire (HEA3) was developed by the former Health Education Authority and has been validated in general practice (Little et al. 1999). One of the advantages of the HEA3 compared to other food frequency questionnaires is that it is easy to assess the balance of food types, such as portions of fruit and vegetables, compared with recommended guidelines. A disadvantage is that there is no feedback to identify which foods contribute the most to different macronutrient intakes such as fat or saturated fat. The HEA3 questionnaire was compared with an accepted standard, a seven-day weighed dietary record that had been validated using biomarkers and test-retest reliability. Percentage energy from consumption of fat and saturated fat, non-starch polysaccharides, fruit and vegetables and starchy foods consumed showed acceptable agreement with the standard. The validation had shown that the questionnaire was suitable for clinical work and research, although under-reporting of energy intake was common with up to 60% under-reporting of calorie intake if the participants were obese. As the mean BMI in the X-PERT study was 31Kg/m², it can be assumed that energy intake was under-reported by 60%. Rather than participants consuming a daily energy intake of around 1500 calories, which would have resulted in weight loss, they may have been consuming around 2400 calories per day.

The reliability and validity of the Summary of Diabetes Self-Care Activities Measure (SDSCA) has been reviewed (Toobert, Hampson, & Glasgow 2000). The validation involved seven different studies including a total of 1,988 people with diabetes. Participants in those studies were typically mature people who had lived with Type 2 diabetes for a number of years. The average inter-item correlations within scales were high, with the exception of specific diet and test-retest correlations, which were moderate. Based on those findings, recommendations were made by Toobert *et al* not to include questions about medication taking owing to lowered test-retest reliability and to omit the specific diet scale as it lacked internal consistency. Exclusion of those questions did not alter the findings in the X-PERT study as no significant differences were found between the expert patient group and the controls, neither at baseline, four months nor 14 months. It is very difficult to assess nutritional intake from just four questions and the findings from the detailed food frequency questionnaire offer much more information about the nutritional intake of the participants than does the SDSCA

questionnaire. Therefore, the only valid and reliable results from the SDSCA were those concerning exercise, foot self-care and self-monitoring of blood glucose levels.

A study has assessed the validity, reliability and utility of the Diabetes Empowerment Scale (DES) (Anderson et al. 2000). That scale is a measure of diabetes-related psychosocial self-efficacy. There are three subscales:

(1) managing the psychosocial aspects of diabetes: that subscale assesses the patient's perceived ability to obtain social support, manage stress, be self-motivating, and make appropriate diabetes-related decisions;

(2) assessing dissatisfaction and readiness to change: that subscale evaluates the patient's perceived ability to identify aspects of caring for diabetes that they are dissatisfied with and their perceived ability to determine when they are ready to change their diabetes self-management plan;

(3) setting and achieving goals: that subscale assesses the patient's perceived ability to set realistic goals and to reach them by overcoming obstacles.

The validation study involved 375 people living with diabetes and the psychometric properties of the DES were calculated. Although preliminary support for the reliability and validity of the DES was obtained, it was recommended that further research be carried out with different samples of people with diabetes to confirm the factor structure and subscale reliability (Anderson et al. 2000). The DES appeared to be a strong predictor of self-empowerment scores in the X-PERT trial. There were no differences between the expert patient and control groups at baseline and statistically significant differences between the two groups at both four and 14 months for the total empowerment score and the three subscales.

The Diabetes Treatment Satisfaction questionnaire (DTSQc) is an eight-item assessment that was originally developed for people with Type 1 diabetes and tablet-treated Type 2 diabetes, but it has more recently been used with a mixed general practice sample including those who treat their diabetes with diet alone. The DTSQc has proved to be highly reliable, with good validity and sensitivity to change. It has been identified as being most effective when used as one of a profile of important outcome measures, including metabolic control. Used in this manner, the DTSQc can help to identify instances where patient satisfaction is achieved at the expense of metabolic control or where metabolic control is only achieved at the expense of patient satisfaction (Bradley 1994). In the X-PERT trial the improvement observed in respect of the expert patients

in treatment satisfaction complimented the improvement in metabolic control and other clinical, lifestyle and psychosocial variables. What cannot be identified is whether the increased treatment satisfaction contributed to the improvement in the other outcomes, such as metabolic control, or whether the improvement in the other outcomes contributed to the increased treatment satisfaction.

The Audit of Diabetes Dependant Quality of Life (ADDQoL) is a reliable and valid measure of the effects of diabetes and its treatment on quality of life (QoL) (Bradley et al. 1999). Weighted scores allow identification of those domains of life that are important to a patient and that are negatively affected by diabetes. Bradley found that individual variation in response to ADDQoL items was considerable and there could be no automatic assumption that the impact of diabetes on quality of life was negative. Diabetes had greater reported impact on diabetes-specific domains such as enjoyment of food, worries about the future and travel, than on standard quality of life domains such as work, social life, friends and family. Insulin-treated patients and people living with diabetes complications reported a significantly greater negative impact of diabetes on most domains. The ADDQoL was found to demonstrate evidence of internal consistency reliability and preliminary evidence of validity and sensitivity to change. Within the X-PERT trial the ADDQoL showed sensitivity to change for the food and drink variables and those were the only domains found to be statistically significant between the expert patient and control group post-intervention. Improved quality of life regarding freedom to eat and drink, and enjoyment of food may have occurred owing to the emphasis placed on nutrition and lifestyle throughout the X-PERT programme. Increased knowledge may have encouraged participants to accept that the diet for people with diabetes need not be a special diet and that all foods are acceptable if the balance of foods in a meal/over a day is examined. Increased self-empowerment may have contributed to greater freedom to eat and drink, as expert patients were able to make decisions that were 'right for them' rather than following a prescribed diet from a health professional.

The biomedical variables collected during the X-PERT trial were generally both reliable and valid. All the blood samples were analysed at the same laboratory using standardised methods. As stated in Chapter 5 (section 5.4.3), blood pressure and waist circumference were measured using accepted methods: body weight was measured using the same scales, calibrated on a regular basis, and body fat was measured to $\pm 0.5\%$ precision. Three outcome assessors collected the biomedical outcomes from the

patients and each had been trained to use the standardised methods stated above. The percentage error involved in collecting the measurements is not known. However, any differences in the measurement method are likely to have been distributed equally between the intervention and control groups and would therefore be unlikely to affect the comparison and significance of findings between the two groups.

Although there were no statistically significant differences between the two groups in respect of blood pressure, there were clinically important reductions in both systolic and diastolic blood pressure in the expert patients. The same was true for the anthropometrical measurements, with the expert patients experiencing a trend towards reduced body weight, BMI, body fat and waist circumference compared with the outcomes for the control group patients. The clinically important three-centimetre reduction in waist circumference in the expert patients, although of statistical borderline significance, did suggest by the 95% confidence intervals (0 cm to 6 cm) that the X-PERT programme had impacted on waist circumference. The reduced waist circumference in expert patients may have resulted from the increased exercise frequency and is likely to have resulted also in an increase in insulin sensitivity, improved diabetes control and reduced requirement for diabetes medication.

The primary outcome, glycated haemoglobin, showed greater improvement at the longer-term follow-up (14 months) than the short-term follow-up (four months). That finding differed from previous research evaluating the effect of diabetes education programmes (Norris et al. 2002) and may be due to the theoretical models, empowerment and patient activation underpinning the X-PERT programme. Standard diabetes education programmes that instruct patients what to do and then measure success based on compliance can often lead to patients initially making changes to please the health professional, but because those changes may not be intuitive for that patient, they may not be continued in the long-term. The longer-term success of the X-PERT programme may be because patients developed the skills, knowledge and confidence to identify their own problems regarding their diabetes self-management and they were consequently able to experiment with behaviour and lifestyle change to identify what worked for them.

The only variable that showed a statistically significant result between the expert patients and control group at four months but not at 14 months was self-monitoring of blood glucose levels. One possible reason for that may be that the expert patients

initially increased self-monitoring of blood glucose whilst experimenting with their diabetes but as their understanding of factors affecting their blood glucose levels increased, they were able to reduce the frequency of blood glucose monitoring. Another possible reason is that a strict prescribing policy for blood glucose monitoring strips has been implemented locally, with many patients being told that they could only obtain enough monitoring strips to self-monitor their blood glucose levels once a day. Such changes to prescribing policies have probably resulted from the recent controversy about the benefits of self-monitoring of blood glucose levels (NHS Centre for Reviews and Dissemination 2002).

When analysing the results from the X-PERT programme, the only subgroup analysis performed was the primary outcome (glycated haemoglobin) by ethnic group and some interesting findings emerged (see Chapter 6, Table 6.8). There were no differences between the expert and control patients at baseline for either ethnic group. At four months, there were no significant differences between the expert and control patients in the white Caucasian subgroup, but there was a difference in glycated haemoglobin of 1.0% in the South Asian subgroup. That difference was statistically highly significant. At 14 months, expert patients in both subgroups experienced statistically significant differences in glycated haemoglobin compared with the control group. Therefore it can be deduced that attending the X-PERT programme had an immediate impact on the diabetes control of the South Asian participants, whereas benefits took longer to become apparent for the white Caucasian participants. Another difference between ethnic groups was that the white Caucasian expert patients experienced an improvement in diabetes control. The South Asian expert patients only maintained their glycaemic level at 7.5% although the South Asian control participants experienced a deterioration in glycaemic control. Explanations for that finding cannot be identified.

7.4 Generalisability

The X-PERT programme is more likely to be generalisable to all people with Type 2 diabetes because:

- the X-PERT trial was a pragmatic trial with minimum exclusion criteria;
- it recruited people with Type 2 diabetes from a mixture of socio-economic and ethnic backgrounds;
- it was delivered under normal conditions within the community;

- it differed from many randomised controlled trials that were conducted under extremely controlled conditions that bore very little resemblance to routine practice.

As with all trials, there is a risk that people change their behaviour as a result of being involved in research. They may become more interested in the topic, pay more attention to it or may change behaviour simply because someone (the investigator) is paying attention to them (Bowling 1997). This is called the Hawthorne effect and although it might be said that the expert patients may have produced better results because they were involved in a trial, the same could be said of the control patients, who received exactly the same treatment and attention apart from the intervention. Therefore, one would still expect the differences between the expert and control patients in the biomedical, lifestyle and psychosocial outcomes to remain if the X-PERT programme was delivered outside of research conditions.

7.5 Conclusions from this study

- To the author's knowledge, this is the first randomised controlled trial to evaluate (both in the short and longer term) a health professional-led diabetes expert patient programme for individuals with Type 2 diabetes based on the theories of empowerment and patient activation.
- The study design encouraged the findings to be as transferable as possible by keeping the exclusion criteria to a minimum. All adults with Type 2 diabetes were invited to take part unless either physical or cognitive restrictions prevented them from attending and actively taking part in the programme, or primary care staff felt that it was inappropriate for a particular individual to participate.
- The X-PERT programme was shown to improve biomedical outcomes (glycated haemoglobin, blood pressure and waist circumference), lifestyle outcomes (diabetes knowledge, exercise and foot care frequency, diet) and psychosocial outcomes (treatment satisfaction, food and drink related quality of life and self-empowerment) both in the short and longer term.
- No adverse effects were reported and expert patients were more likely to reduce diabetes medication and less likely to increase diabetes medication than control patients.

- The expert patients enjoyed the programme, found it useful and, immediately after attending the course, perceived that it would result in improvement to their health. The majority of expert patients believed that the knowledge and confidence gained from the programme would equip them with the skills to help others with diabetes.
- Many expert patients went on to become peer educators, to set-up diabetes support groups and to contribute to the Patient Empowerment and Education Sub-Group for the Local Diabetes Services Implementation Group (LDSIG). Several expert patients have become lay representatives of the Local Diabetes Services Advisory Group, and are helping to develop local diabetes services.

These findings provide an insight into possible solutions for treating what is a serious, expensive and increasing national problem. Pressures on NHS resources from diabetes and its complications are large (Williams et al. 2001). Any method of equipping people living with diabetes with the skills and confidence to self-manage their condition offers immense benefits, both to those with the condition and to the NHS.

7.6 Brief overview of the thesis

This thesis started with an overview of the epidemiology of Type 2 diabetes and recognised that although there have been major developments over the years in identifying and treating diabetes, people with diabetes are still dying prematurely and the quality of their life is still poor in comparison to those without the condition. Chapter 1 acknowledged that evidence now exists to show that achievement of optimum blood glucose and blood pressure levels dramatically reduce both morbidity and mortality. Chapter 1 also illustrated that criteria and frameworks exist that aim to improve diabetes care and that new and innovative health care delivery systems are required if improvements to patient health and well-being are to be delivered.

This thesis then discussed, in Chapter 2, health and health behaviour change. It acknowledged that health is a complex concept that lends itself to subjective interpretation, meaning different things to different people, and that the World Health Organisation (WHO) definition of health has evolved over time to encapsulate an increasingly holistic view. Chapter 2 went on to explain that although different approaches and models to health behaviour change are available, current knowledge is insufficient to predict the ideal circumstances for behaviour change and few evidence-

based guidelines exist. This chapter acknowledged that expert patient programmes are a relatively new concept within the UK and that there are two types of programmes: first, are the ones delivered by health professionals, these are condition specific, and aim to develop knowledge and skills associated with that condition; second, are the lay-led programmes that address how the illness impacts on daily life. Chapter 2 concluded by acknowledging that although most countries are in the experimental stage of developing therapeutic and self-management education programmes, routine patient education in Europe and the United States is still based on the biomedical model.

Chapter 3 concerned a review of the experimental stage of developing therapeutic and self-management education programmes. An extensive search strategy identified 5497 papers, of which 13 papers describing 11 studies had been included in the systematic review. The review assessed the effects of group-based, patient-centred diabetes education in adults with Type 2 diabetes. The results revealed that this type of approach to diabetes education improved diabetes control and knowledge of diabetes and reduced the requirement for diabetes medication. There was also some evidence to suggest that group-based therapeutic education increased self-management skills, self-empowerment, quality of life and treatment satisfaction, although it recommended that further research be carried out to confirm those findings. The review concluded that evidence currently exists to support the delivery of group-based self-management education programmes for the treatment of Type 2 diabetes.

The tutors manual for the X-PERT programme was presented in Chapter 4. The manual has been written to encourage the delivery of the X-PERT programme to adults living with Type 2 diabetes. Although the active ingredients of the X-PERT programme are difficult to identify, the scripted manual ensures that the delivery and content of the six-session, group-based, professional-led diabetes expert patient programme could replicate the programme delivered during the research trial. The manual clearly illustrates the theories of empowerment and patient activation that the education programme was based on. It discusses what diabetes is and explains weight management, glycaemic index, the supermarket tour, possible diabetes complications, the 'learning about diabetes' board game and the goal setting lifestyle experiment. It also describes the materials and visual aids that are an inherent part of the programme delivery.

The research proposal for the randomised controlled trial was presented in Chapter 5. Background information acknowledged that effective management of Type 2 diabetes lies in the hands of the person with the condition. As the research proposal had been written prior to undertaking the systematic review, Chapter 5 concluded that the most effective method of encouraging diabetes self-management was still unknown. The chapter then discussed the development of the X-PERT trial and the attempts to secure funding for it. Demographic information for Burnley, Pendle and Rossendale was also presented. The form that the research took was a prospective, pragmatic randomised controlled trial in which the intervention group was invited to attend the X-PERT programme whilst the control group received routine diabetes treatment. The hypothesis stated that the X-PERT programme would develop skills and confidence in adults with Type 2 diabetes and lead to informed decision-making about their diabetes self-management. The hypothesis went on to state that increased diabetes self-management would improve patients' biomedical, lifestyle and psychosocial outcomes. It was also hypothesised that delivery of the X-PERT programme being based on the criteria and standards from the International Diabetes Federation would improve the structure and process of diabetes education in the locality. Information about recruitment, interventions for the expert patient and control group, the timescale for the project, evaluation (structure, process and outcomes) and methods of statistical analysis, were also presented in Chapter 5.

Chapter 6 presented the results of the trial and those are discussed above in the section 7.2 ('Résumé of findings') and in section 7.5 ('Conclusions from this study').

7.7 Overall evidence for this approach

There is now clear evidence that therapeutic group-based diabetes education programmes for adults with Type 2 diabetes based on the theories of empowerment and patient activation are effective methods of health care delivery. The results from the X-PERT project, along with the findings from the systematic review, support the national (DOH 2001a; DOH 2001b; DOH 2003a; NICE 2003b) and international (IDF Consultative Section on Diabetes Education (DECS) 2003; WHO Working Group 1998) guidelines which are starting to emerge.

7.8 The Future Implications of this Study

7.8.1 Implications for Policy and Organisations

Extending the X-PERT programme so that it becomes routine treatment for adults with Type 2 diabetes would go a long way towards implementing the national (DOH 2001a; DOH 2001b; DOH 2003a; NICE 2003b) and international guidelines (IDF Consultative Section on Diabetes Education (DECS) 2002; IDF Consultative Section on Diabetes Education (DECS) 2003). The author has been liaising with BPR PCT for 12 months with regard to the future of diabetes education services within the district. Business cases have been submitted, meetings attended with representatives from the Workforce Development Confederation, and presentations delivered to the PCT briefing board. A workshop was presented at the NHS Modernisation Agency Conference, which resulted in a meeting with David Fillingham, Director of the Modernisation Agency. That workshop facilitated communication with Sue Roberts, Howard Arthur and Bev Bookless from the National Diabetes Support Team, Sarah Squire who takes the lead on Patient Involvement and Ruth Kennedy, the Chief Executive of the National Primary Care Development Team. BPR PCT has now formally acknowledged the X-PERT programme and the Chief Executive of the Trust is committed to ensuring delivery of the programme throughout the district.

7.8.2 Implications for Health Professional Training

The X-PERT tutor for the purposes of this study is a diabetes dietitian with specialist training in adult education who had also acquired other skills necessary for adoption of the role of 'diabetes educator' based on the US model. Introducing a diabetes educator to the healthcare team may also be a cost effective approach to diabetes education: only one health professional is required for delivery of the six-week programme to 16 participants.

Primary care health professional training is strongly recommended in order to avoid disempowerment of expert patients by the provision of conflicting, outdated, and prescriptive advice, and to develop skills to enable the delivery of an adult-centred group education programme. The empowerment model encourages the provision of evidence-based diabetes education in a less prescriptive manner, whilst facilitating and encouraging patients to accept more autonomy. However, caution must be taken to retain a balance between structured education and the patient-centred approach, as over-emphasis on either model has been shown to be ineffective (Kinmonth et al. 1998).

Certified diabetes educators (CDEs) exist in other countries but not in the UK. Developing the role of CDEs within the UK would help to address the problems arising from the delivery of inconsistent, conflicting and outdated messages. The introduction of CDEs would also allow the IDF process standards (f), (g) and (h) to be met. Those standards are explained in more detail in Chapter 6, Section 6.5.2. CDEs would also help to transform the current prescriptive approach to diabetes treatment favoured by some health professionals to one that is more empowering.

7.8.3 Implications for lay involvement in health services

Diabetes UK has recommended that informed patients can greatly contribute to the development of health care services (Wheeler 2002). The Department of Health advises that patients with chronic conditions should be invited to attend an expert patients programme where they could train to become expert patients. Expert patients have, themselves, potential to help other patients with chronic conditions develop the skills and confidence to live more effectively with their condition (DOH 2001c). This study delivered a diabetes expert patient (X-PERT) programme and developed 'expert patients' who were sufficiently confident and informed to be able to assist other people with diabetes and contribute to diabetes services development. BPR PCT, impressed with the working of the Patient Education and Empowerment Subgroup for the LDSIG, has stated its intention to develop a managed patients' network. The continuation of the X-PERT project will develop a community of expert patients who, if they wish, will be able to join and develop the patient network.

7.9 From Research to Practice

As stated in section 7.8.3 above, it would appear likely that the X-PERT programme will be implemented into routine practice within Burnley, Pendle and Rossendale. It is the intention to implement it at general practice level, with the plan that it would remain a primary care initiative delivered in the community. Practice staff, either GPs or practice nurses would be trained to deliver the programme to patients registered with Type 2 diabetes at their practice, possibly with help from a dietitian or health care assistant.

Numerous health professionals working in other geographical areas within the UK have enquired whether a scripted manual will become available for purchase and if so, when. Preliminary discussions have taken place with BPR PCT about the possibility of

developing national training courses for health professionals to enable them to learn the skills required to deliver the X-PERT programme. Participants attending the training programme would also receive a copy of the X-PERT programme manual and a set of the accompanying visual aids.

7.10 Future Research

- 1) The systematic review recommended that, as the review was based on only 11 studies and many lifestyle and psychosocial outcomes resulted from the synthesis of just two or three studies, further research would be needed to confirm that group-based education programmes are:
 - more effective if the theoretical models underpinning the programmes are based on therapeutic patient education, empowerment, patient participation and adult learning principles;
 - effective at lowering blood pressure readings;
 - effective at increasing treatment satisfaction and quality of life scores;
 - appropriate and effective for all ethnic groups;
 - effective at reducing the secondary complications of diabetes;
 - cost effective;
 - equally effective if delivered partly or solely by peer educators.
- 2) If certified diabetes educator roles are to be developed within the UK, that process would need to be piloted and evaluated as a research project in order to assess their impact on the education received by people with diabetes and to provide justification and an evidence base for new workforce development.
- 3) Participants who had attended the X-PERT programme clearly enjoyed greater freedom to eat and drink, whilst at the same time improving their metabolic control. However, the programme did not educate participants to adjust medication according to the carbohydrate content of the meal. Developing a 'dose adjustment for normal eating' (DAFNE) expert patient programme for individuals with Type 2 diabetes may add further benefits to glycaemic control and quality of life for those people.
- 4) Relevance for the self-management of a wide variety of other chronic conditions such as coronary heart disease, pre-diabetes and obesity.

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Appendix List

Appendix 1a: Characteristics of excluded studies

1

Characteristics of excluded studies

Study ID	Reason for exclusion
ADA 2001	Not a controlled clinical trial, a descriptive paper
Agurs-Collins 1997	The control group received a group-based diabetes education programme
Araujo 1989	Not a controlled clinical trial, a descriptive paper (translated Portuguese paper)
Arauz 1997	Length of follow-up less than six months (translated Spanish paper)
Arauz 2001	No control group (translated Spanish paper)
Aráuz 2001	Duplicate paper (Arauz 2001)
Assal 1988	Not a controlled clinical trial, a descriptive paper
Barcelo 2001	Recruited participants with both Type 1 and Type 2 diabetes
Barnard 1982	<ol style="list-style-type: none"> 1. No control group 2. No group-based diabetes education programme 3. Length of follow-up less than six months
Barnard 1992	No control group
Basa 1995	No control group
Basina 2002	Editorial reviewing effectiveness of diabetes management with no intervention
Berger 1996	Descriptive paper of previous study with no control group
Berger 1999	No intervention, descriptive paper
Blenk 1994	Behavioural weight loss programme with exercise sessions and not a group-based diabetes education programme
Boehm 1993	Not comparing group-based diabetes education programme with routine treatment/waiting list or no intervention
Bouldin 2002	Review of clinical guidelines with no intervention
Bradshaw 1999	Not a group-based diabetes education programme
Brown 1988	Meta-analysis of educational interventions in diabetes care but not comparing group-based sessions with individual
Brown 1995	<ol style="list-style-type: none"> 1. No control group 2. Length of follow-up less than six months
Brown 1999	Pilot study for paper included in the review. Descriptive paper with no

	data presented.
Bundo 1993	A letter to respond to a previous paper and not a clinical controlled trial (translation of Spanish paper)
Burden 2000 1	Not a controlled clinical trial, a descriptive paper
Caballero 1998	Descriptive study with no control group
Cabrera-Pivaral 2000	Both intervention and control group received group-based diabetes education programme
Cabrera-Pivaral 2001	<ol style="list-style-type: none"> 1. The control group also received group-based diabetes education programme 2. Only outcomes LDL cholesterol/fasting blood glucose (translated Spanish paper)
Calle-Pascual 1992	<ol style="list-style-type: none"> 1. No primary outcome (HbA1c) 2. Research design unclear 3. Control group received group-based diabetes education programme
Campbell 1988	Both intervention and control group received group-based diabetes education programme
Campbell 1990	The control group received a group-based diabetes education programme
Campbell 1996	Trial comparing four interventions with the primary intervention being individual (not group-based) behavioural programme
Cetti 2002	Not a controlled clinical trial (translated Spanish paper)
Clark 1999	Descriptive paper not a controlled clinical trial
Clark 2001	Not a group-based diabetes education programme
Clement 1995	Review of diabetes self-management interventions and not group-based programmes
Cohen 1982	<ol style="list-style-type: none"> 1. Involved people with Type 1 and Type 2 diabetes 2. Length of follow-up less than six months 3. No HbA1c outcome 4. Majority of outcomes collected from intervention group only
Cooper 2001	Descriptive paper comparing meta-analyses on chronic disease patient education
Corabian	Systematic review of patient education in the management of Type 2 diabetes but not comparing group with individual sessions
Corbett 1999	<ol style="list-style-type: none"> 1. No control group 2. No group-based diabetes education programme

	3. Study recruited people with Type 1 and Type 2 diabetes
D'Eramo-Melkus 1992	Diabetes education programme included group and individual sessions.
de Weerd 1991	The trial included people with both type 1 and type 2 diabetes
DPP Research Group	Not a controlled clinical trial
Duan 1988	Not a controlled clinical trial. A descriptive chapter on diabetes education
Eakin 2002	Review of diabetes self-management interventions in disadvantaged populations but not comparing group with individual sessions
Eshaw 1994	1. Length of follow-up less than six months 2. Outcomes assessment only included BMI and dietary intake
Ezenwaka 2002	Not a controlled clinical trial
Falkenberg 1986	Control group also received group-based diabetes education programme
Fan 1999	Chinese paper unable to obtain through the British Library or inter-library loans
FEND 2000	Not a controlled clinical trial
Ferreira 2001	No control group
Fishbein 1993	Not a clinical trial, an observational paper
Fritsche 1999	1. No control group 2. In-patient diabetes education programme
Fukuda 1999	1. Study recruited people with Type 2 diabetes and impaired glucose tolerance 2. In-patient diabetes education programme
Funnell 1998	Diabetes education programme included group and individual sessions.
Gaede 2001	Diabetes education programme included group and individual sessions.
Gagliardino 2001	Not a clinical controlled trial
Gamsu 2002	No control group
Garcia 1996	No control group
García 1997	Not a controlled clinical trial
Gillibrand 2001	Diabetes education programme for nursing staff, not patients
Girard 1986	No control group (translated French paper)

Glasgow 1989	<ol style="list-style-type: none"> 1. Unclear outcomes 2. Length of follow-up less than six months
Glasgow 1992	Immediate group had outcome assessment follow-up at six months but delayed group only received posttest follow-up at three months.
Glasgow 2002	Intervention is not a group-based diabetes education programme
Gough 1990	<ol style="list-style-type: none"> 1. Not a controlled trial 2. Length of follow-up less than six months
Griffin 1999	Not a controlled clinical trial, an editorial
Haapa 1999	<ol style="list-style-type: none"> 1. Research design unclear 2. Both groups received group-based diabetes education programme. Intervention evaluated a follow-up module
Haisch 1996	<ol style="list-style-type: none"> 1. Not a group-based diabetes education programme 2. Length of follow-up less than six months 3. Research design not appropriate (translated German paper)
Haisch 2000	Both groups received group-based diabetes education programme (German paper)
Haisch 2002	No control group (translated German paper)
Halle 1999	<ol style="list-style-type: none"> 1. No control group 2. No group-based diabetes education programme
Halle 1999b	<ol style="list-style-type: none"> 1. No control group 2. Length of follow-up less than six months 3. Diabetes education programmes includes both group-based and individual sessions
Hampton 1988	An audit and not a clinical trial
Hanefeld 1991	<ol style="list-style-type: none"> 1. Diabetes education programmes includes both group-based and individual sessions 2. No primary outcome (HbA1c)
Hanefeld 1996	<ol style="list-style-type: none"> 1. Diabetes education programmes includes both group-based and individual sessions 2. No primary outcome (HbA1c) 3. German paper (translated)
Hansen 2002	Danish summary of Cochrane review on health professional diabetes education (Renders 2000)
Hardinghaus 1996	German paper (translated) with no control group
Hartwell 1986	The control group received a group-based diabetes education

	programme
Heath 1991	Weight loss competition with no control group
Henry 1997	1. Length of follow-up less than six months 2. Less than 6 participants in each diabetes education programme
Hughes 1999	1. Trial included people with both type 1 and type 2 diabetes 2. Research design unclear 3. Individual appointments (control) not routine treatment.
Hunter 1999	Not a controlled clinical trial, a descriptive paper
Jaber 1996	1. No group-based diabetes education programme 2. Length of follow-up less than six months
Jacobs 2000	1. No control group 2. Length of follow-up less than six months 3. No statistical tests
Jennings 1990	1. The trial design and outcomes don't meet the systematic review criteria 2. Length of follow-up less than six months
Jiang 1999	Length of follow-up less than six months
Julius 1993	The primary outcome is work absenteeism
Jungmann 1997	No control group (translated German paper)
Jungmann 1997b	No control group (translated German paper) (same paper as Jungmann 1997)
Jungmann 1997c	No control group (translated German paper) (same paper as Jungmann 1997)
Kaplan 1985	1. The control received a group-based diabetes education programme 2. Length of follow-up less than six months
Kaplan 1987	1. The control group received a group-based diabetes education programme 2. Outcomes not relevant
Kaplan 1987b	1. The control group received a group-based diabetes education programme 2. Research design not clear
Kendall 1987	Trial comparing two different group-based diabetes education programmes with no routine treatment group
Kendall 1990	1. Both groups received a group-based diabetes education programme 2. Only nutritional outcomes

Keyserling 2000	1. Intervention is individual behaviour counseling 2. Outcomes not appropriate
Keyserling 2002	Intervention included three group sessions and 12 monthly phone calls. Not possible to detect whether any effects are due to the group aspect or telephone calls
Krier 1999	The intervention group also received individual appointments as part of the intervention
Lacey 2000	Literature review of CHD risk management in diabetes education interventions
Laitinen 1993	The intervention group also received individual appointments as part of the intervention
Laitinen 1994	The intervention group also received individual appointments as part of the intervention
Larme 1998	Not a controlled clinical trial, a descriptive paper
Lazcano 1999	1. Length of follow-up less than six months 2. Only outcome data reported is fasting blood glucose
Levenson 2002	Both groups received group-based diabetes education programme
Ligtenberg 1998	1. Not a group-based diabetes education programme, exercise training 2. Length of follow-up less than six months
Llomas 2002	1. No control group 2. Length of follow-up unclear
Lo 1996	1. No group-based education programme 2. Length of follow-up less than six months
Lozano 1996	Length of follow-up less than six months (translated Spanish paper)
Luna Arriola 1994	Spanish dissertation unable to obtain
Madjarof 2001	1. No control group 2. Less than 6 participants in education programme 3. Length of follow-up unclear
Maljanian 2002	1. No control group 2. Less than 6 participants in education programme 3. Length of follow-up unclear
Mancino 2002	No group-based diabetes education programme
Martinez 1999	Unable to obtain paper from the British Library or inter-library loans
Maxwell 1992	Unable to obtain paper from the British Library or inter-library loans

Mayer-Davis 2001	<ol style="list-style-type: none"> 1. Both groups received 8 week education programme 2. Intervention is the type of evaluation. 3. Few outcomes & follow-up less than 6 months.
Mazucca 1986	<ol style="list-style-type: none"> 1. Study recruited people with Type 1 and Type 2 diabetes 2. Diabetes education programme included group and individual sessions.
McMurray 2002	<ol style="list-style-type: none"> 1. No control group 2. No group-based education programme
McNabb 1993	Trial design not appropriate and outcomes not reported for the comparison group
Miller 1999	<ol style="list-style-type: none"> 1. Length of follow-up less than six months 2. The only outcome is knowledge
Miller 2002	Length of follow-up less than six months
Miller 2002b	Length of follow-up less than six months
Miller 2002c	Length of follow-up less than six months
Morgan 1988	Not a group-based diabetes education programme
Muhlhauser 2002	Not a clinical controlled trial, descriptive paper
Mulrow 1987	Number of participants in each group-based education programme less than 6
Noel 1998	The control group received a group-based diabetes education programme
Norris 2001	Systematic review of diabetes self-management programmes but not reviewing group-based programmes
Norris 2001b	Short report of systematic review of self-management training and not group-based programmes
Norris 2002	Systematic review of diabetes self-management programmes with a meta-analysis of the effect on glycaemic control but not reviewing group-based programmes
Norris 2002b	A systematic review of disease and case management and not group-based diabetes education programmes
Norris 2002c	A systematic review of diabetes self-management education in the community but not group-based diabetes education programmes
Pacyk 2001	<ol style="list-style-type: none"> 1. No control group 2. Length of follow-up less than six months

Padgett 1988	Meta-analysis of education/psychosocial interventions on management of diabetes but not comparing group-sessions with individual
Rabkin 1983	Length of follow-up less than six months
Rachmani 2002	Not a group-based diabetes education programme
Raji 2002	Recruited people with Type 1 and Type 2 diabetes
Raz 1988	Diabetes education programme included group and individual sessions.
Rebell 2002	In-patient group-based diabetes education programme German paper (translated)
Renders 2000	Systematic review on health professional diabetes education
Ridgeway 1999	Diabetes education programme included group and individual sessions.
Rivera Tejada 1996	Not a controlled clinical study, a descriptive paper
Rubin 1991	1. The study includes people with Type 1 and Type 2 diabetes 2. No control group
Saenz Hernaiz 1992	Spanish paper unable to obtain via inter-library loans or the British library
Samaras 1997	The intervention was structured exercise sessions and not a group-based diabetes education programme
Sarkadi 2001	1. No control group 2. Retrospective paper
Scain 1986	1. No control group 2. Retrospective paper
Schiel 1999	1. In-patient diabetes education programme 2. Main outcome is self-monitoring of blood glucose levels
Scott 1984	Length of follow-up less than six months
Simmons 1992	Evaluation compared outcomes between attenders and non-attenders
Simmons 1996	1. Primary intervention is an exercise programme 2. Unclear research design
Steed 2003b	Length of follow-up less than six months
Sarwit 2002	Both the intervention and the control group received a group-based diabetes education programme
Swenson 2000	Not a controlled clinical trial
Tankova 2001	1. No control group 2. Study recruited participants with both Type 1 and Type 2 diabetes

Toobert 2002	Outcome measures not relevant
Unknown 1994	Short report of diabetes education programme
Unknown 2002	Not a controlled clinical trial
Uusitupa 1993	The intervention group received individual appointments as part of the intervention
Uusitupa 1996	No group-based diabetes education programme
Vaaler 2000	A review evaluating methods of achieving optimal glycaemic control and not group-based diabetes education programmes
Van 2000	1. No primary outcome (HbA1c) 2. Four interventions with two group programmes but no routine treatment or waiting list controls
Vanninen 1992	The intervention group received individual appointments as part of the intervention
Vanninen 1993	Not a group-based diabetes education programme, intensive diet and exercise delivered on an individual basis
Vazquez 1998	1. Length of follow-up less than six months 2. Nutrition outcomes only
Veldhuizen 1995	All three groups received a group-based diabetes education programme. The Intervention was a pharmaceutical care model
Wang 1998	1. No control group 2. The study recruited participants with Type 1 and Type 2 diabetes
Wheeler 2001	Not a clinical controlled trial, a descriptive paper
White 1986	The control group received a group-based diabetes education programme
Wierenga 1990	Not a controlled clinical trial, a qualitative study
Wilson 1987	Length of follow-up less than six months
Wing 1985	The control group received a group-based diabetes education programme
Wing 1988	Intervention involves self-monitoring blood glucose training and not a group-based diabetes education programme
Wing 1993b	Not a trial evaluating a group-based diabetes education programme
Wroe 1995	Not a controlled clinical trial, a conference report
Wroe 2000	Not a controlled clinical trial, a conference report

Wroe 2000b	Not a controlled clinical trial, a conference report
Wroe 2001	Not a controlled clinical trial, a conference report
Wroe 2001b	Not a controlled clinical trial, a conference report
Wroe 2001c	Not a controlled clinical trial, a conference report
Wroe 2002	Not a controlled clinical trial, a conference report
Wroe 2002b	Not a controlled clinical trial, a conference report

Appendix 1b: Excluded studies reference list

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Appendix 2: Characteristics of included studies

Group based self-management strategies in people with type 2 diabetes mellitus 1

Characteristics of included studies

Study ID	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
Brown 2002	<p>Trial design: Randomised controlled trial</p> <p>Ethics approval obtained: Yes</p> <p>Patient consent obtained: Yes</p> <p>Randomisation method: Unclear</p> <p>Length of follow-up: 1 year</p> <p>Blinding of posttest (P), educator (E), researcher (R): P = no, E = unclear, R = unclear</p> <p>Analysis by intention to treat: No</p> <p>Power calculation: Not stated</p>	<p>Setting: Community</p> <p>Country: US</p> <p>Number: IG = 128, CG = 128</p> <p>Age\pmSD: IG = 54.7\pm8.2, CG = 53.3\pm8.3</p> <p>Sex: IG = 40% M, CG = 32% M</p> <p>Ethnicity: Mexican Americans</p> <p>Duration of diabetes: IG = 7.6\pm5.8, CG = 8.1\pm6.9</p> <p>Socioeconomic status: Start county is the poorest county in Texas with high unemployment at 24.4%</p> <p>Education background: Not stated but language of preference = Spanish with 40% reading little or no English</p> <p>Drop out (%): Overall 10%</p> <p>Inclusion criteria: Between 35-70 years/diagnosed with Type 2 diabetes after 35 years/FBG > 140mg/dl or taken insulin or oral hypoglycaemic agents for > 1 year/willing to participate</p> <p>Exclusion criteria: pregnancy/medical condition where changes to diet or</p>	<p>Intervention: Group education programme delivered by nurse, dietitian & community worker.</p> <p>Duration: 52 hours over 12 months (12 weekly meetings + 14 biweekly sessions)</p> <p>Number of participants in group programme: Unclear including family/friends: Yes</p> <p>Control: Waiting list</p>	<p>Collected at 6 and 12 months</p> <p>1. HbA1c (%)</p> <p>2. Fasting blood glucose (mg/dl)</p> <p>3. Lipids (mg/dl)</p> <p>4. BMI (kg/m²)</p> <p>5. Health beliefs</p> <p>6. Diabetes knowledge (score)</p>	<p>1. Intervention group = IG, Control group = CG</p> <p>2. Figure 1 = recruitment and retention data unclear</p> <p>3. All participants received standard education before randomised</p>	<p>1. Intervention group = IG, Control group = CG</p>

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Year	Trial design	Setting	Intervention	Control	Outcome	Drop out (%)	Inclusion criteria	Exclusion criteria	Participants	Notes
2003	Trial design: Randomised controlled trial	Setting: Primary care	Intervention: Group education programme delivered by diabetes educator lasting for 6 consecutive weeks, each session 2 hours (total time = 12 hours)	Control: Routine treatment (individual appointments with dietitian and primary care team)	1. HbA1c (%) 2. Blood pressure (mmHg) 3. Weight (kg) 4. BMI (kg/m ²) 5. Waist circumference (inch) 6. Lipid profile including total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides (mmol/L) 7. Knowledge (score) 8. Self-management skills 9. Food frequency questionnaire 10. Treatment satisfaction 11. Quality of life 12. Empowerment score	Number: IG = 157, CG = 157 Age±SD: IG = 61.3±9.7, CG = 61.8±11.0 Sec IG = 48.4% M, CG = 54.8% M Ethnicity: IG = 116 white, CG = 118 white Caucasian/41 South Asian, CG = 118 white Caucasian/39 South Asian Duration of diabetes: IG = 6.6±6.4yr, CG = 6.7yr±6.7yr Socioeconomic status: Not stated Education background: Not stated	Inclusion criteria: Adults with Type 2 diabetes Exclusion criteria: Unable to attend programme or participate due to severe physical or mental impairment	exercise levels would be contraindicated		
1994	Conference proceeding					Drop out (%): IG = 4.5%, CG = 10.2%	Inclusion criteria: Adults with Type 2 diabetes Exclusion criteria: Unable to attend programme or participate due to severe physical or mental impairment			
1995	Trial design: Clinical	Setting: Primary care	Intervention: Group based	Control: Individual						

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Control group = CG	2. HbA1c reported with baseline characteristics but just weight at follow-up	3. Knowledge score only assessed in intervention group	4. Oral hypoglycaemic agents - number of people taking them reported at baseline but daily average reported at follow-up	1. Intervention group = IG, Control group = CG	B
structured teaching/treatment baseline:	1. HbA1c (%)	2. Knowledge score previously trained physician	Duration (intervention group only)	1. HbA1c (%) 2. Blood glucose (mmol/l) 3. Weight loss (kg) 4. Diabetes knowledge	Collected at 6 and 12 months:
Country: Argentina	Number: IG = 40, CG = 39	Age \pm -SD: IG = 52.7 \pm -3.1, CG = 53.1 \pm -1.1	Sec IG = 55% M, CG = 56% M	Setting: Hospital diabetes clinic	Intervention: Group
controlled trial	Ethics approval obtained: Yes	Patient consent obtained: Yes	Randomisation method: Not randomised - physicians trained to deliver education	Trial design: Randomised controlled trial	Education: Group
Blinding of patient (P),	Blinding of patient (P),	Blinding of patient (P),	Blinding of patient (P),	Ethics approval obtained: controlled trial	education programme, 4.5 hr for 3 consecutive weeks, 1.5 hr at both 3 & 6 months
Length of follow-up: One year	Length of follow-up: One year	Length of follow-up: One year	Length of follow-up: One year	Ethics approval obtained: controlled trial	Intervention: Group
Socioeconomic status: Reported to be the same in both groups but no data given	Socioeconomic status: Reported to be the same in both groups but no data given	Socioeconomic status: Reported to be the same in both groups but no data given	Socioeconomic status: Reported to be the same in both groups but no data given	Ethics approval obtained: controlled trial	Intervention: Group
Duration of diabetes: IG = 6.3 \pm -1.3, CG = 6.9 \pm -0.7	Duration of diabetes: IG = 6.3 \pm -1.3, CG = 6.9 \pm -0.7	Duration of diabetes: IG = 6.3 \pm -1.3, CG = 6.9 \pm -0.7	Duration of diabetes: IG = 6.3 \pm -1.3, CG = 6.9 \pm -0.7	Ethics approval obtained: controlled trial	Intervention: Group
Ethnicity: Not stated	Ethnicity: Not stated	Ethnicity: Not stated	Ethnicity: Not stated	Ethics approval obtained: controlled trial	Intervention: Group
Number: IG = 40, CG = 39	Number: IG = 40, CG = 39	Number: IG = 40, CG = 39	Number: IG = 40, CG = 39	Ethics approval obtained: controlled trial	Intervention: Group
Age \pm -SD: IG = 52.7 \pm -3.1, CG = 53.1 \pm -1.1	Age \pm -SD: IG = 52.7 \pm -3.1, CG = 53.1 \pm -1.1	Age \pm -SD: IG = 52.7 \pm -3.1, CG = 53.1 \pm -1.1	Age \pm -SD: IG = 52.7 \pm -3.1, CG = 53.1 \pm -1.1	Ethics approval obtained: controlled trial	Intervention: Group
Sec IG = 55% M, CG = 56% M	Sec IG = 55% M, CG = 56% M	Sec IG = 55% M, CG = 56% M	Sec IG = 55% M, CG = 56% M	Ethics approval obtained: controlled trial	Intervention: Group
Drop out (%): IG = 25%, CG = 45%	Drop out (%): IG = 25%, CG = 45%	Drop out (%): IG = 25%, CG = 45%	Drop out (%): IG = 25%, CG = 45%	Ethics approval obtained: controlled trial	Intervention: Group
Analyses by intention to treat: No	Analyses by intention to treat: No	Analyses by intention to treat: No	Analyses by intention to treat: No	Ethics approval obtained: controlled trial	Intervention: Group
Inclusion criteria: Not defined	Inclusion criteria: Not defined	Inclusion criteria: Not defined	Inclusion criteria: Not defined	Ethics approval obtained: controlled trial	Intervention: Group
Exclusion criteria: Newly diagnosed/age above 60 years/presence of advanced complications or other severe disease	Exclusion criteria: Newly diagnosed/age above 60 years/presence of advanced complications or other severe disease	Exclusion criteria: Newly diagnosed/age above 60 years/presence of advanced complications or other severe disease	Exclusion criteria: Newly diagnosed/age above 60 years/presence of advanced complications or other severe disease	Ethics approval obtained: controlled trial	Intervention: Group
Power calculation: not stated	Power calculation: not stated	Power calculation: not stated	Power calculation: not stated	Ethics approval obtained: controlled trial	Intervention: Group
Trial design: Randomised controlled trial	Trial design: Randomised controlled trial	Trial design: Randomised controlled trial	Trial design: Randomised controlled trial	Ethics approval obtained: controlled trial	Intervention: Group
Setting: Hospital diabetes clinic	Setting: Hospital diabetes clinic	Setting: Hospital diabetes clinic	Setting: Hospital diabetes clinic	Ethics approval obtained: controlled trial	Intervention: Group
Country: UK	Country: UK	Country: UK	Country: UK	Ethics approval obtained: controlled trial	Intervention: Group
Number: IG = 36, CG = 39	Number: IG = 36, CG = 39	Number: IG = 36, CG = 39	Number: IG = 36, CG = 39	Ethics approval obtained: controlled trial	Intervention: Group
Age \pm -SD: IG = 56.5, CG = 56.4	Age \pm -SD: IG = 56.5, CG = 56.4	Age \pm -SD: IG = 56.5, CG = 56.4	Age \pm -SD: IG = 56.5, CG = 56.4	Ethics approval obtained: controlled trial	Intervention: Group
Sec IG = 55%, CG = 41%	Sec IG = 55%, CG = 41%	Sec IG = 55%, CG = 41%	Sec IG = 55%, CG = 41%	Ethics approval obtained: controlled trial	Intervention: Group
Eligibility: Not stated	Eligibility: Not stated	Eligibility: Not stated	Eligibility: Not stated	Ethics approval obtained: controlled trial	Intervention: Group
Duration of diabetes: New diagnosed	Duration of diabetes: New diagnosed	Duration of diabetes: New diagnosed	Duration of diabetes: New diagnosed	Ethics approval obtained: controlled trial	Intervention: Group
Number of participants in name and diabetic	Number of participants in name and diabetic	Number of participants in name and diabetic	Number of participants in name and diabetic	Ethics approval obtained: controlled trial	Intervention: Group
Education: Diabetes specialist	Education: Diabetes specialist	Education: Diabetes specialist	Education: Diabetes specialist	Ethics approval obtained: controlled trial	Intervention: Group
Intervention: Group	Intervention: Group	Intervention: Group	Intervention: Group	Ethics approval obtained: controlled trial	Intervention: Group
Control: Routine treatment	Control: Routine treatment	Control: Routine treatment	Control: Routine treatment	Ethics approval obtained: controlled trial	Intervention: Group
Including family/friends: yes	Including family/friends: yes	Including family/friends: yes	Including family/friends: yes	Ethics approval obtained: controlled trial	Intervention: Group
group programme: 5 - 8	group programme: 5 - 8	group programme: 5 - 8	group programme: 5 - 8	Ethics approval obtained: controlled trial	Intervention: Group
Number of participants in medication (no/day)	Number of participants in medication (no/day)	Number of participants in medication (no/day)	Number of participants in medication (no/day)	Ethics approval obtained: controlled trial	Intervention: Group
90-120 min (total 6-8 hrs)	90-120 min (total 6-8 hrs)	90-120 min (total 6-8 hrs)	90-120 min (total 6-8 hrs)	Ethics approval obtained: controlled trial	Intervention: Group
4 weekly sessions lasting	4 weekly sessions lasting	4 weekly sessions lasting	4 weekly sessions lasting	Ethics approval obtained: controlled trial	Intervention: Group
Educator: Physician	Educator: Physician	Educator: Physician	Educator: Physician	Ethics approval obtained: controlled trial	Intervention: Group
Duration (intervention group only)	Duration (intervention group only)	Duration (intervention group only)	Duration (intervention group only)	Ethics approval obtained: controlled trial	Intervention: Group
2. Knowledge score	2. Knowledge score	2. Knowledge score	2. Knowledge score	Ethics approval obtained: controlled trial	Intervention: Group
1. HbA1c (%)	1. HbA1c (%)	1. HbA1c (%)	1. HbA1c (%)	Ethics approval obtained: controlled trial	Intervention: Group
3. Weight (kg)	3. Weight (kg)	3. Weight (kg)	3. Weight (kg)	Ethics approval obtained: controlled trial	Intervention: Group
4. Change in diabetes medication (no/day)	4. Change in diabetes medication (no/day)	4. Change in diabetes medication (no/day)	4. Change in diabetes medication (no/day)	Ethics approval obtained: controlled trial	Intervention: Group
5 - 8	5 - 8	5 - 8	5 - 8	Ethics approval obtained: controlled trial	Intervention: Group
Including family/friends: yes	Including family/friends: yes	Including family/friends: yes	Including family/friends: yes	Ethics approval obtained: controlled trial	Intervention: Group
Control: Routine treatment	Control: Routine treatment	Control: Routine treatment	Control: Routine treatment	Ethics approval obtained: controlled trial	Intervention: Group
group programme: 5 - 8	group programme: 5 - 8	group programme: 5 - 8	group programme: 5 - 8	Ethics approval obtained: controlled trial	Intervention: Group
Number of participants in medication (no/day)	Number of participants in medication (no/day)	Number of participants in medication (no/day)	Number of participants in medication (no/day)	Ethics approval obtained: controlled trial	Intervention: Group
90-120 min (total 6-8 hrs)	90-120 min (total 6-8 hrs)	90-120 min (total 6-8 hrs)	90-120 min (total 6-8 hrs)	Ethics approval obtained: controlled trial	Intervention: Group
4 weekly sessions lasting	4 weekly sessions lasting	4 weekly sessions lasting	4 weekly sessions lasting	Ethics approval obtained: controlled trial	Intervention: Group
Educator: Physician	Educator: Physician	Educator: Physician	Educator: Physician	Ethics approval obtained: controlled trial	Intervention: Group
Duration (intervention group only)	Duration (intervention group only)	Duration (intervention group only)	Duration (intervention group only)	Ethics approval obtained: controlled trial	Intervention: Group
2. Knowledge score	2. Knowledge score	2. Knowledge score	2. Knowledge score	Ethics approval obtained: controlled trial	Intervention: Group
1. HbA1c (%)	1. HbA1c (%)	1. HbA1c (%)	1. HbA1c (%)	Ethics approval obtained: controlled trial	Intervention: Group
3. Weight (kg)	3. Weight (kg)	3. Weight (kg)	3. Weight (kg)	Ethics approval obtained: controlled trial	Intervention: Group
4. Change in diabetes medication (no/day)	4. Change in diabetes medication (no/day)	4. Change in diabetes medication (no/day)	4. Change in diabetes medication (no/day)	Ethics approval obtained: controlled trial	Intervention: Group
5 - 8	5 - 8	5 - 8	5 - 8	Ethics approval obtained: controlled trial	Intervention: Group
Including family/friends: yes	Including family/friends: yes	Including family/friends: yes	Including family/friends: yes	Ethics approval obtained: controlled trial	Intervention: Group
Control: Routine treatment	Control: Routine treatment	Control: Routine treatment	Control: Routine treatment	Ethics approval obtained: controlled trial	

Group based self-management strategies in people with type 2 diabetes mellitus 4

Holtrop 2002			B
<p>educator (E), researcher (R): P = unclear, E = unclear, R = unclear Analysis by intention to treat: No Power calculation: Not stated</p>	<p>Socioeconomic status: Not stated Education background: Not stated Drop out (%): IG = 10, CG = 17% Inclusion criteria: New diagnosed diabetes/BMI > 27/age 30-75 yrs Exclusion criteria: Anyone with ketonuria/diagnosis made when inpatient</p>	<p>Including family/friends: Yes Control: Routine treatment - individual appointments with physician and dietitian at least at 3, 6 & 12 months</p>	<p>1. Intervention group = IG, Control group = CG P-values given without data and several SD missing</p>
<p>Trial design: Randomised controlled trial Ethics approval obtained: Unclear Patient consent obtained: Yes Randomisation method: Unclear Length of follow-up: 6 months Blinding of patient (P), educator (E), researcher (R): P = No, E = unclear, R = unclear Analysis by intention to treat: Yes Power calculation: Unclear</p>	<p>Setting: Primary care Country: US Number: IG = 67, CG = 65 Age +/- SD: IG = 58, CG = 65 Sex: IG = 0% M, CG = 0% M Ethnicity: IG = 95% Caucasian, CG = 95% Caucasian Duration of diabetes: Not stated Socioeconomic status: Not stated Education background: 86% achieved high school education Drop out (%): Unclear Inclusion criteria: >40 years/female/Type 2 diabetes/HbA1c > 7% in past 6 months/BMI > 27.3</p>	<p>Intervention: Group programme delivered by trained lay health advisors for six weekly 1 1/2 hour sessions (total time = 9 hours) Number of participants in group programme: Not stated including family/friends: Unclear Control: Routine treatment as required with family physician</p>	<p>Collected at 6 months: 1. HbA1c (%) 2. BMI 3. Dietary habits 4. Beliefs 5. Stages of change</p>

Group based self-management strategies in people with type 2 diabetes mellitus 5

Kronenberg 1988	<p>Trial design: Controlled clinical trial</p> <p>Ethics approval obtained: yes</p> <p>Patient consent obtained: Unclear</p> <p>Randomisation method: No randomisation</p> <p>Length of follow-up: 1 year</p> <p>Blinding of patient (P), educator (E), researcher (R): P = unclear, E = unclear, R = unclear</p> <p>Analysis by intention to treat: No</p> <p>Power calculation: Yes</p>	<p>Setting: Primary care</p> <p>Country: Germany</p> <p>Number: IG = 50, CG = 49</p> <p>Age\pmSD: IG = 63\pm9, CG = 63\pm8</p> <p>Sex: IG = 42% M, CG = 39% M</p> <p>Ethnicity: Not stated</p> <p>Duration of diabetes: IG = 7\pm5, CG = 7\pm6</p> <p>Socioeconomic status: Not stated</p> <p>Education background: Not stated</p> <p>Drop out (%): IG = 23%, CG = 21%</p> <p>Inclusion criteria: Fulfilling the WHO criteria for NIDDM (Type 2 diabetes)</p> <p>Exclusion criteria: Physical/mental handicaps that prevented participants from following education programme</p>	<p>Intervention: Group structured treatment and teaching programme (DITP) for 1 1/2 - 2 hours per week for 4 weeks (total time = 6-8 hours)</p> <p>Educator: Paramedical staff (physician assistants)</p> <p>Number of participants in group programme: 4-6</p> <p>Including family/friends: Unclear</p> <p>Control: Routine treatment whilst on waiting list</p>	<p>Collected at 12 months:</p> <ol style="list-style-type: none"> 1. HbA1c (%) 2. Weight (Kg) 3. Knowledge (score) 4. Lipids (mmol/l) 5. Glucosuria 6. No oral hypoglycaemic agents (%) 	<p>1. Intervention group = IG, Control group = CG</p>
Leanne 1999	<p>Trial design: Randomised controlled trial</p> <p>Ethics approval obtained: Not stated</p> <p>Patient consent obtained: Not stated</p> <p>Randomisation method: Not stated (classified by age &</p>	<p>Setting: Primary care</p> <p>Country: Spain</p> <p>Number: IG = 120, CG = 123</p> <p>Age\pmSD: IG = 63.8, CG = 64.7</p> <p>Sex: IG = 48% M, CG = 48% M</p> <p>Ethnicity: Not stated</p>	<p>Intervention: Health educational workshop lasting 1hr 30 min on two consecutive days and repeated in year two</p> <p>Educator: Nurses</p> <p>Number of participants in group programme: Unclear</p>	<p>Outcomes collected at 1 and 2 years:</p> <ol style="list-style-type: none"> 1. HbA1c (%) 2. Blood glucose (mg/dl) 3. BMI (Kg/m²) 4. Knowledge 5. Self-monitoring 	<p>1. Intervention group = IG, Control group = CG</p>

Group based self-management strategies in people with type 2 diabetes mellitus

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<p>Duration of diabetes: IG = 8.1, CG = 9.1 Including family/friends: Unclear Socioeconomic status: Unclear Control: Routine treatment</p>	<p>Duration of diabetes: IG = 7.6+/-5.6, CG = 6.9+/-6.1 Including family/friends: No group programme: 4-8 office staff Treatment and teaching Programme (DTP) consisting of 4 weekly sessions (total 6-8 hr) Educator: Physician and office staff Number of participants in group programme: 4-8</p>	<p>sex before randomisation) Length of follow-up: 2 yrs Blinding of patient (P), educator (E), researcher (R): P = unclear, E = unclear, R = unclear Analysis by intention to treat: stated Drop out (%): IG = 4%, CG = 3% Inclusion criteria: Not defined Exclusion criteria: Attended group education during the last two years/visitations which prevent attending sessions and self-management</p>	<p>IG = 42% M, CG = 47% Age +/-SD: IG = 63.9+/-8.2, CG = 65.4+/-11.2 Ethnicity: Not stated Duration of diabetes: IG = 7.6+/-5.6, CG = 6.9+/-6.1 Socioeconomic status: Not stated Length of follow-up: 6 months Blinding of patient (P), educator (E), researcher (R): P = unclear, E = unclear, R = unclear Drop out (%): IG = 13.5%, CG = 10.9% Inclusion criteria:</p>	<p>1. HbA1c (%) 2. Diabetes Knowledge (score) 3. BMI (kg/m²) 4. Lipid profile (mmol/l) 5. Diabetes medication (no/day) 6. Blood pressure (mmHg)</p>	<p>1. Intervention group = IG, Control group = CG 2. No in between group standards for changes to diabetes medication</p>	<p>1. Intervention group = IG, Control group = CG 2. No in between group standards for changes to diabetes medication</p>	<p>1. HbA1c (%) 2. Diabetes Knowledge (score) 3. BMI (kg/m²) 4. Lipid profile (mmol/l) 5. Diabetes medication (no/day) 6. Blood pressure (mmHg)</p>	<p>1. Intervention group = IG, Control group = CG 2. No in between group standards for changes to diabetes medication</p>
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Pieber 1995

B	<p>1. Intervention group = IG, Control group = CG 2. Large drop out rate - even with intention to treat 3. BMI (Kg/M2) 4. Diabetes Knowledge (score) 5. Adjustment to diabetes (ATT19) 6. Quality of life 7. Activity levels 8. Diabetes medication (% of participants taking)</p>	<p>Intervention: group diabetes education programme consisting of 4 sessions (total 7 hours) Educator: Nurse and dietitian Number of participants in group programme: 4-8 Including family/friends: unclear Control: Routine self-management education 5 (freq/duration) hours over 4 sessions (individual appointments) participants taking)</p>	<p>Setting: Diabetes centre Country: US Number: IG = 87, CG = 83 Age±SD: IG = 51.6±9.2, CG = 52.9±12.8 Sex: IG = 35.6% M, CG = 32.5% M Ethnicity: IG = 89.5% Caucasian, CG = 96.4% Caucasian Duration of diabetes: IG = 11±4.0, CG = 0.6±1.7 Socioeconomic status: Not stated</p>	<p>unclear Analysis by intention to treat: diabetes/absence of physical or mental conditions Power calculation: not stated preventing patients participating in programme Exclusion criteria: Not defined</p>	<p>Blinded by patient (P), educator (E), researcher (R): P = no, E = no, R = unclear Analysis by intention to treat: Yes Power calculation: Not stated Drop out (%): IG = 51%, CG = 41% Inclusion criteria: Newly diagnosed with Type 2 diabetes or no history of previous group diabetes education/referred to education centre Exclusion criteria: Not defined</p>
B	<p>1. Intervention group = IG, Control group = CG</p>	<p>Collected at 6 months: education programme</p>	<p>Diabetes centre</p>	<p>controlled trial Ethics approval obtained: Yes Pattern consent obtained: Yes Randomisation method: Block randomisation Length of follow-up: 6 months Blinding of patient (P), educator (E), researcher (R): P = no, E = no, R = unclear Analysis by intention to treat: Yes</p>	<p>Blinded by patient (P), educator (E), researcher (R): P = no, E = no, R = unclear Analysis by intention to treat: Yes Power calculation: Not stated Drop out (%): IG = 51%, CG = 41% Inclusion criteria: Newly diagnosed with Type 2 diabetes or no history of previous group diabetes education/referred to education centre Exclusion criteria: Not defined</p>

Group based self-management strategies in people with type 2 diabetes mellitus

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Treats	Trial design	Setting	Intervention	Collected at 1 year:	1. Intervention group = IG, Control group = CG
<p>Treats 1998</p> <p>Trial design: Randomised controlled trial Ethics approval obtained: Confirmed with principles stated in the Declaration of Helsinki Patient consent obtained: Yes Randomisation method: Random table numbers Length of follow-up: 1 year Blinding of patient (P), educator (E), researcher (R): P = unclear, E = blinded to which participants in control group, R = unclear Analysis by intention to treat: No Power calculation: Not stated</p>	<p>Diabetes outpatient department Country: Italy Number: IG = 55, CG = 57 Age+/-SD: IG = 61.6, CG = 61.0 Sex: IG = 47% M, CG = 61% M Ethnicity: Not stated Duration of diabetes: IG = 9.1 year, CG = 9.2 year Socioeconomic status: IG/CG Housewife - 15%/8% Retired - 21%/28% White collar worker - 4%/5% Blue collar worker - 9%/8% Other - 4%/7%</p>	<p>Structured group education programme every 3 months for 1 year (4 x 60/70 mins) Educator: Two physicians and educationalist Number of participants in group programmes: 10 Including family/friends: Yes but optional Control: Routine treatment</p>	<p>1. HbA1c (%) 2. FBG (mmol/l) 3. Weight (Kg) 4. BMI (Kg/m2) 5. Knowledge (score) 6. Conduct (score) 7. Quality of life (score) 8. Treatment</p>	<p>1. Intervention group = IG, Control group = CG</p>	
<p>Treats 2001</p> <p>Trial design: Randomised</p>	<p>Diabetes outpatient</p>	<p>Structured</p>	<p>Collected at 2 years:</p>	<p>1. Intervention group = IG, Control group = CG</p>	

Review Manager 4.2.2

18/01/2004

Group based self-management strategies in people with type 2 diabetes mellitus 9

<p>controlled trial Ethics approval obtained: Conformed with the principles stated in the Declaration of Helsinki Patient consent obtained: Yes Randomisation method: Random table numbers Length of follow-up: 2 years Blinding of patient (P), educator (E), researcher (R): P = unclear, E = blinded to who in control group, R = unclear Analysis by intention to treat: No Power calculation: Not stated</p>	<p>department Country: Italy Number: IG = 56, CG = 56 Age+/-SD: IG = 62, CG = 61 Sex: IG = 48% M, CG = 61% M Ethnicity: Not stated Duration of diabetes: IG = 9.4, CG = 9.8 Socioeconomic status: IG/CG Housewife - 14%/10% Retired - 24%/27% White collar worker - 4%/2% Blue collar worker - 7%/8% Other - 7%/9% Education background: Despite randomisation the CG were more educated Drop out (%): IG = 23%, CG = 16% Inclusion criteria: Type 2 diabetes treated with diet or oral hypoglycaemic agents who had attended clinic for at least one year Exclusion criteria: Not defined</p>	<p>education programme every 3 months for 2 years (1 hour x 3 = 8hr/2 yr) Educator: Two physicians and educationalist Number of participants in group programme: 10 Including family/friends: Yes - optional Control: Routine treatment</p>	<p>Control group = CG 2. Participant numbers at baseline reported slightly different than in 1998 paper</p>
<p>Treats 2002 Trial design: Randomised controlled trial Ethics approval obtained: Conformed with the principles stated in the Declaration of Helsinki</p>	<p>Setting: Diabetes outpatient department Country: Italy Number: IG = 56, CG = 56 Age+/-SD: IG = 62, CG = 61 Sex: IG = 48% M, CG = 61% M</p>	<p>Intervention: Structured education programme every 3 months for 2 years and 7 sessions in year 3 +4 (total 15 hrs/4yrs) Educator: Two physicians</p>	<p>1. Intervention group = IG, Control group = CG 2. Participant numbers at baseline reported slightly different than in 1998 paper</p>
	<p>Collected at 4 years: 1. HbA1c (%) 2. FBG (mmol/l) 3. Weight (Kg) 4. BMI (Kg/m²) 5. Lipids (mmol/l)</p>		

Group based self-management strategies in people with type 2 diabetes mellitus

P = unclear, E = unclear, R = unclear
unclear
Analysis by intention to treat: Not stated
No drop-outs
Power calculation: Not stated
Socioeconomic status: Not stated
Education background: Not stated
Drop out (%): 0%
Inclusion criteria: Not defined
Exclusion criteria: Not defined

Appendix 3: Ethical approval

East Lancashire 
Health Authority

Direct Line: 01282 610227

Your Ref:
Our Ref: SSP/AK/LRECBPR26731/33 Kenyon Road
Lomeshaye Estate
Nelson
Lancashire
BB9 5SZ

10 October 2000

Telephone: 01282 619909
Facsimile: 01282 610223Website: www.elancs-ha.nwest.nhs.ukMs T Deakin
Nutrition & Dietetic Department
Burnley General Hospital
BURNLEY GENERAL HOSPITAL

R E C E I V E D
11 OCT 2000

Dear Ms Deakin

EXPERT PATIENT EDUCATION VERSUS ROUTINE TREATMENT (X-PERT)

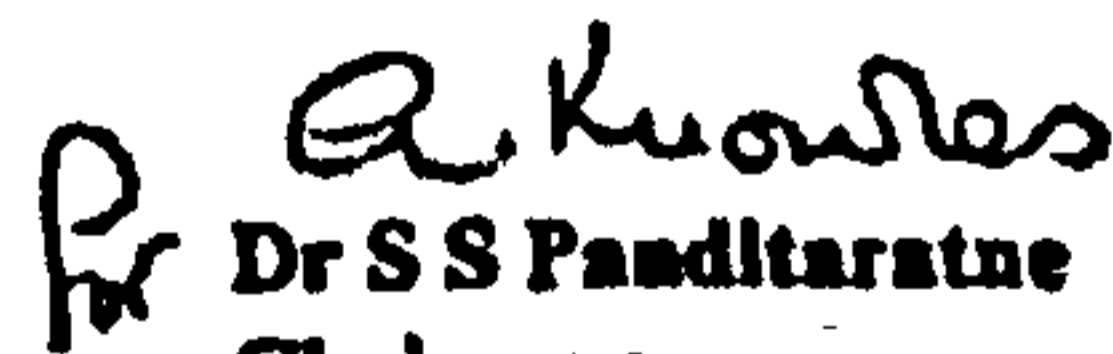
Thank you for your letter of 28 September 2000. I write to advise you that I am satisfied with your comments regarding recruitment of subjects to the study and formal ethical approval is now granted for the study to proceed in the district.

The study has been given approval only in relation to its acceptability from an ethical point of view. If departure from the methodology outlined in your application is contemplated, the Ethics Committee must be advised and the proposed changes approved.

Members are interested in following the progress of research projects and would welcome receipt of a final report when the work has been completed which will be received in confidence.

Please quote the above reference number on any future correspondence.

Yours sincerely


Dr S S Panditaratne
Chairman
Burnley, Pendle & Rossendale
Local Research Ethics Committee

Appendix 4a: Practice information letter

Burnley, Pendle & Rossendale
Primary Care Trust



NUTRITION & DIETETIC DEPARTMENT

Telephone: 01282 / 474632

Facsimile: 01282/474125

E-mail: trudi@bdeakin.fsnet.co.uk

Practice Information Letter

Dear

Re: Research study looking at diabetes education programmes for adults with type 2 diabetes

I am a diabetes specialist dietitian based at Burnley Healthcare NHS Trust. I am currently undertaking a clinical trial looking at the impact of diabetes education programmes on self-management skills and diabetes control in adults with type 2 diabetes. Patients will be identified from 10 GP practices. The purpose of this letter is to invite your practice to take part in the study. This research study is likely to benefit your patients and your practice as a whole, since you will have access to a diabetes specialist dietitian delivering diabetes education programmes at your health centre.

The collaborators are Professor Rhys Williams and Dr Janet Cade from the Nuffield Institute for Health, University of Leeds. Please see the attached research proposal for full details. The study is funded by Burnley Healthcare NHS Trust and The British Dietetic Association. The diabetes education programmes will be delivered to those adults with type 2 diabetes who are more likely to live within a socially deprived area. Your surgery has been selected as one which may be able to supply subjects meeting those criteria.

Your participation in the study would involve the following:-

- 1) Identifying patients with type 2 diabetes who presently receive their treatment within primary care. (I am prepared to do this with the help from staff within the practice).
- 2) Giving permission for the researcher to approach individuals who meet the inclusion criteria and invite them to take part in the study. The patient will be provided with a letter, information leaflet and consent form (see attached). Thirty people will be recruited from each practice.
- 3) The Practice Nurse and / or GP seeing 15 of the 30 recruited participants in the *diabetes education programme 1* for a routine care appointment within a 3 month period and referring the patient to the dietitians' department (if they are not already receiving dietetic care).
- 4) If possible providing a room for the delivery of the *diabetes education programme 2* (8 weekly sessions lasting 2 hours).

All information gained will be held in the strictest confidence and the names of neither the practice nor the patients will appear in any publicly accessible documentation. The research to be carried out has been approved by the Local Research Ethics Committee appointed by the Health Authority.

If you have any queries or if you would like to discuss any aspect of the study with me, then you are welcome to contact me by telephone 01282 / 474632. Please do feel free to discuss this letter with your colleagues. I would be obliged if you could inform me if your surgery is willing to take part by completing the enclosed consent form. I will then call at the surgery to collect it during the week commencing

Thank you in anticipation of your time and help in this study,
Yours sincerely

Trudi A Deakin (principal researcher)

Appendix 4b: Practice consent form

Burnley, Pendle & Rossendale
Primary Care Trust



DIABETES EDUCATION PROGRAMMES FOR PEOPLE WITH DIABETES

PRACTICE CONSENT FORM

PRACTICE:.....

ADDRESS:.....

.....

.....

I / we wish to accept the invitation and take part in the study by providing a list of patients who meet the inclusion criteria.

I have read the practice information letter and understand that information gained will be held with strict confidentiality. No personal identifiers will appear on any publicly accessible documentation.

The GP / practice nurse will make a routine appointment to see the 15 patients in the control group (diabetes education programme 1) within the 3 month active intervention stage.

I run a small practice and feel that there will not be 30 adults with type 2 diabetes who will agree to participate in the study. However, I do not mind supplying the patient information, which may then be clustered with another small local practice.

We have a room available for the *group-based diabetes education programme*.

I / we do not wish to take part in the study.

Reason:.....

.....

.....

.....

.....

Signed

Name (please print).....

Date.....

Appendix 5a: Patient information leaflet

1. What is the purpose of the study?

Diabetes is a condition that needs to be managed largely by individuals themselves. At the moment it is not known how it is best to develop the skills needed for this. The research aims to look at two ways of delivering diabetes education to people with type 2 diabetes.

2. Why have you been chosen?

Ten general practices within Burnley, Pendle and Rosendale have been chosen and have agreed to take part in the research. You have been chosen because you are registered with one of the GPs, have type 2 diabetes, and receive your diabetes care from your GP.

3. Do you have to take part?

It is entirely up to you to decide whether or not to take part in this research. If you do decide to take part you will be asked to sign a consent form. If you do take part you are still free to back out at any time and without needing to give a reason. This will not affect the medical care you receive from your GP or anyone else.



PATIENT INFORMATION LEAFLET



RESEARCH LOOKING AT 'DIABETES EDUCATION PROGRAMMES FOR PEOPLE WITH DIABETES'

4. What will happen to you if you take part?

You will receive one of two types of diabetes education. Everyone will be put into two groups and then compared. A computer, which has no information about the individual, selects the groups - i.e. the selection is by chance. Patients in each group then have a different treatment and these are compared.

Everybody who agrees to take part will be visited at his or her home four times over a 15-month period. At each visit, weight, height, waist size and blood pressure measurements will be taken and a sample of blood will be collected from a vein in your arm to assess your overall diabetes control and cholesterol level. You will also be asked to fill in brief questionnaires requesting information regarding your lifestyle (food & alcohol intake, exercise and smoking habits), knowledge about and confidence in looking after your diabetes, your present quality of life and satisfaction with diabetes treatment.

You may also be asked to take part in a one-to-one chat with a person carrying out this research. You will be asked your opinion of the education programme. You will also be asked if it has affected the way you look after your diabetes. If you are in agreement, these sessions may be recorded.

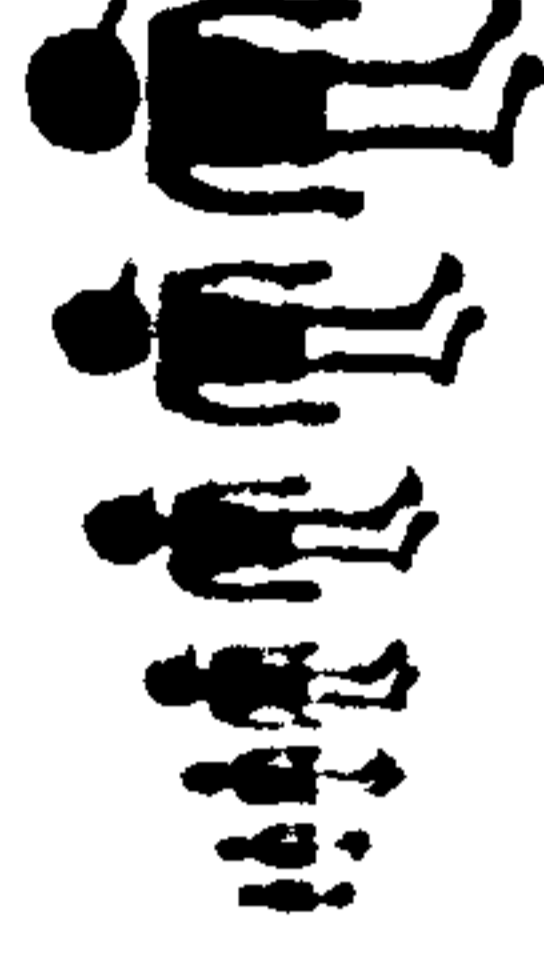


5. What do you have to do?

As described above, you will be included in one of two diabetes education programmes:

Programme 1

People given this programme will attend a diabetes education appointment with a practice nurse or GP at their own health centre. They will also see a dietitian either at their health centre or somewhere near their home. If they wish, they may bring along a family member or friend. These appointments will be within 3 months from the 1st home visit. This programme will be a chance to increase understanding of diabetes and how it is managed and to address some of the difficulties people have in controlling the condition.



OR

Programme 2

People given this programme will be part of a group session. This will involve attending 6 weekly sessions each lasting for 2 hours. These will be held during the day at the local health centre (apart from one session, which will be held in a local supermarket). If they wish, they may bring along a family member or friend. The aim is to become much more involved in managing the condition based on how people see and feel about the

9. Will your taking part in this study be kept confidential?

All information will be held in the strictest confidence and your name will not be available to anyone except those carrying out the research.

10. What will happen to the results of the research?

The final results will be assessed in 2½ years time and a report will be written. This will not include any individual information or names. The report will be available to you if you wish to see it and will be sent for publication in a medical journal.

11. Who has reviewed the study?

The research to be carried out has been approved by the Local Research Ethics Committee appointed by the Health Authority. As stated earlier, if at any time you decide to withdraw from the programme, any future care will not be affected.

12. Contact for further information

If you have any queries or would like to talk to someone about this research please phone 01282/474632 and ask to speak to Trudi Deakin.



disease. The adult education programme allows people to increase their understanding of the condition and how it is managed and to address some of the difficulties people have with controlling the condition. Sessions will be informal, sociable and informative allowing people to become an "expert" in their own diabetes care. Refreshments will be available at each session.

6. How will you benefit from taking part?

Whichever programme you are assigned to, we hope that you will become better informed about diabetes. This will help you to increase your diabetes management skills. The information we get from this study will help to improve the future treatment for people with diabetes.

7. What happens when the research study stops?

After the education programme, normal diabetes care will continue in the same manner as before the research project.

8. What happens if you have a complaint?

If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedure will be available to you.

Appendix 5b: Patient consent form

Burnley, Pendle & Rossendale
Primary Care Trust

**CONSENT FORM**

Title of Project: DIABETES EDUCATION FOR PEOPLE WITH TYPE 2 DIABETES

Name of Researcher: TRUDI DEAKIN

Please tick in the box

1. I confirm that I have read and understand the information leaflet for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of my medical notes may be looked at by responsible individuals from Burnley Healthcare NHS Trust and my name will not appear on any publicly accessible documentation. I give permission for these individuals to have access to my records.
4. I consent to 4 samples of blood being taken during the 15 month period. I understand that these will be analysed to assess my diabetes control and blood cholesterol level.
5. I agree to any unused blood being retained for possible inclusion in further studies. (If the remaining blood were to be used for future research we would contact you again in order to obtain written consent).
6. I agree to take part in the above study.

Name of Patient

Date

Signature

Researcher

Date

Signature

1 for patient; 1 for researcher; 1 to be kept with GP notes

Patient Identification Number

Appendix 6: Validated questionnaires

Burnley, Pendle & Rossendale
Primary Care Trust



PLEASE ANSWER THE FOLLOWING QUESTIONS

BACKGROUND:

1. Sex: Male Female

2. How old are you? _____ years old

3. How long ago were you told by a doctor that you had diabetes? _____ years

4. Which type of diabetes did your doctor say that you have?

insulin-dependent diabetes, also called juvenile or type 1 diabetes

non insulin-dependent diabetes, also called adult onset or type 2 diabetes
(some people with non insulin-dependent diabetes take insulin)

5. How often does your diabetes prevent you from doing your normal daily activities (eg: could not work)? Circle one number.

Frequently

7

6

5

4

3

2

Never

1

6. Have you ever attended a diabetes patient education program (a series of classes)?

No Yes (If "Yes", how many years ago? _____)

7. How would you rate your understanding of diabetes and its treatment? Circle one number.

Excellent						Poor
7	6	5	4	3	2	1

8. Are you now taking diabetes pills? Yes No
9. Are you now taking insulin? Yes No
10. Have you always treated your diabetes with insulin? Yes No
11. What is your height? _____
12. How much do you weigh? _____
13. Please circle the number that indicates how able you are to fit diabetes into your life in a positive manner.

Very Able						Not At All Able
7	6	5	4	3	2	1

14. Please circle the number that indicates how comfortable you feel asking your doctor questions about diabetes.

Very Comfortable						Not At All Comfortable
7	6	5	4	3	2	1

15. How old were you when you finished full time education? yrs old

16. Do you have any of the following qualifications? Tick all applicable

CSE	<input type="checkbox"/>	"A" Level, Highers	<input type="checkbox"/>
GCE "O" Level	<input type="checkbox"/>	Teaching diploma, HNC	<input type="checkbox"/>
GCSE	<input type="checkbox"/>	Degree	<input type="checkbox"/>
City & Guilds	<input type="checkbox"/>	None of these	<input type="checkbox"/>
Other	<input type="checkbox"/>	Describe:	

17. Have you ever had a paid job? Yes No

If yes, please answer for your current or most recent job

What is/was your job title?

Are/were you a Manager? Foreman/woman?
 Supervisor? None of these

Are/were you self-employed? Yes No

Do you have a job at present? Yes No

If no, how would you describe yourself?

Housewife Unemployed
 Retired Student

Other Describe

When did you last have paid employment 19 (year) or Never

19 What is your marital status?

Married or living as married	<input type="checkbox"/>	Divorced	<input type="checkbox"/>
Widowed	<input type="checkbox"/>	Single	<input type="checkbox"/>
Separated	<input type="checkbox"/>		

Diabetes Knowledge Score (please circle the correct answer)

- | | | |
|---|---|--|
| <p>1. The diabetes diet is:</p> <p>a. the way most people eat
b. a healthy diet for most people
c. too high in carbohydrate for most people
d. too high in protein for most people</p> | <p>2. Which of the following is highest in carbohydrate?</p> <p>a. Chicken
b. Cheese
c. Baked potato
d. Peanut butter</p> | <p>3. Which of the following is highest in fat?</p> <p>a. Low fat milk
b. Orange juice
c. Corn
d. Honey</p> |
| <p>4. Which of the following has the smallest effect on blood sugar?</p> <p>a. Any unsweetened food
b. Any dietetic food
c. Any food that says "sugar free" on the label
d. Any food that has less than 20 calories per serving</p> | <p>5. Glycosylated haemoglobin (haemoglobin A1) is a test that is a measure of your average blood glucose level for the past:</p> <p>a. day
b. week
c. 8-10 weeks
d. 6 months</p> | <p>6. Which is the best method for testing blood glucose?</p> <p>a. Urine testing
b. Blood testing
c. Both are equally good</p> |
| <p>7. What effect does unsweetened fruit juice have on blood glucose?</p> <p>a. Lowers it
b. Raises it
c. Has no effect</p> | <p>8. Which should <u>not</u> be used to treat low blood glucose?</p> <p>a. 3 hard candies
b. 1/2 cup orange juice
c. 1 cup diet soft drink
d. 1 cup skim milk</p> | <p>9. For a person in good control of their diabetes, what effect does exercise have on blood glucose?</p> <p>a. Lowers it
b. Raises it
c. Has no effect</p> |
| <p>10. Infection is likely to cause:</p> <p>a. an increase in blood glucose
b. a decrease in blood glucose
c. no change in blood glucose</p> | <p>11. The <u>best</u> way to take care of your feet is to:</p> <p>a. look at and wash them each day
b. massage them with alcohol each day
c. soak them for one hour each day
d. buy shoes a size larger than usual</p> | <p>12. Eating foods lower in fat decreases your risk for:</p> <p>a. nerve disease
b. kidney disease
c. heart disease
d. eye disease</p> |
| <p>13. Numbness and tingling may be symptoms of:</p> <p>a. kidney disease
b. nerve disease
c. eye disease
d. liver disease</p> | <p>14. Which of the following is usually <u>not</u> associated with diabetes:</p> <p>a. vision problems
b. kidney problems
c. nerve problems
d. lung problems</p> | |

Food Frequency Questionnaire

HEA3

Code No: _____

Please mark YOUR 'AVERAGE' SERVING/PORTION SIZE (small, medium, large) for different foods, and HOW OFTEN you eat them. If you do not normally eat the food, please put a zero (0) in the month column.

EXAMPLE SHOWN AT TOP OF TABLE: This person eats a large bowl of cereal four times a week and two slices of bread a day.

TBLSP = rounded tablespoon

TSP = rounded teaspoon

Food	Medium Serving	Your Serving Size			How Often		
		S	M	L	Day	Week	Month
Example: Bread	2 Medium Slices		✓		1		
Example: Cereal	Average bowl (3 TBLSP)			✓		4	
Bread/Cereal/Potatoes							
Bread/toast	2 medium slices						
Breakfast cereal	Average bowl (3 TBLSP)						
Crackers/Crispbread	3 crackers/slices crispbread						
Bun/roll	1 bun/roll						
Pitta/chapati	1 small piece (not 'mini')						
Rice/pasta/noodles	Average serving (6 TBLSP)						
Plantains/green bananas/sweet potatoes	1 plantain or green banana/ 2 sweet potatoes						
Potatoes (NOT chips)	3 egg sized potatoes						
Fruit/Vegetables							
Vegetables (fresh/frozen/tinned)	Medium serving (2 TBLSP)						
Salad	Medium serving (3 TBLSP)						
Stewed or tinned fruit	Medium serving (3 TBLSP)						
Fresh fruit	1 apple, orange, banana/ small bunch grapes/slice melon						
Fruit juice	Average glass (160 ml)						
Meat/Alternatives							
Lean meat/fish/chicken (no skin)	4 oz/4 fish fingers (=small pack of playing cards)						
Sausages/burgers/luncheon meat etc.	3 small sausages, 2 burgers. 2 slices luncheon meat						
All other meat (e.g. beef, chops etc. with visible fat, chicken with skin, bacon etc.)	4 oz (=small pack of playing cards)						
Sausage rolls/ meat pies	1 individual pie 2 sausage rolls						
Eggs	2 medium eggs						
Beans/lentils/dhal	3 TBLSP						
Nuts/peanut butter	1 tblsp/small bag						

Food Frequency Questionnaire

HEA3

Code No: _____

Food	Medium Serving	Your Serving Size			How Often		
		S	M	L	Day	Week	Month
Cakes, Puddings and Snacks							
Donut, cake	1 piece						
Pudding, fruit pie, Danish pastry	1 piece/average bowl						
Biscuits	3 small biscuits						
Chocolate	Small bar						
Ice cream	1 scoop. 1 choc ice, 1 King cone						
Crisps, peanuts etc.	1 small bag (25g)						
Sugar							
Sugar	1 TSP						
Drinks							
Squash/fizzy drinks	1 can (330 ml) average glass (250 ml)						
Diet/slimline/sugar free drinks	1 can 1 average glass						
Tea	1 cup						
Coffee	1 cup						
Alcoholic drinks	1 glass wine, ½ pint beer, 1 tot spirits/liqueur (pub measure)						
Fats							
Fried or oily food	E.g. medium portion chips (¾ cup), 2 fried eggs, 2 rashers fried bacon						
Margarine or butter	1 pat						
Low fat spread	1 pat						
Cooking oil/fat/ghee	1 level TBLSP						
Mayonnaise/oily salad dressing	1 level TBLSP						
Milk and Dairy							
Full fat milk	½ pint (200 ml)						
Semi-skimmed milk	½ pint (200 ml)						
Skimmed milk	½ pint (200 ml)						
Cheese	Small matchbox						
Yoghurt/cottage cheese/fromage frais	Small pot						

1) Low fat spread (e.g. Gold, Delight)

2) Very low fat spread (e.g. Gold Lowfat)

3) Do you use salt in cooking?

Do you add salt to food at the table?

If yes, do you add salt in suitable amount?

Food Frequency Questionnaire

IIEA3

Code No: _____

ADDITIONAL QUESTIONS

- 1) Do you usually use wholemeal/high fibre/granary bread Yes No
If yes, please specify type: _____
- 2) Do you use a high fibre breakfast cereal? Yes No
e.g. Alpen, muesli, all bran, Jordan's crunchy, shredded wheat, wectabix, porridge oats, shreddies, fruit and fibre
If yes, please specify type: _____
- 3a) Do you usually use brown or wholegrain rice or pasta or eat potatoes with skins on? Yes No
- b) If yes, please tick whichever you normally eat:
- | | | |
|--------------------------|------------------------------|-----------------------------|
| I). Wholegrain rice | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| II). Wholewheat pasta | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| III). Potatoes with skin | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
- 4a) Do you use low fat spread, low fat cheese or low fat yoghurt? Yes No
- b) If yes, please tick whichever you normally eat/use: Specify type: _____
- | | | |
|--------------------------|------------------------------|-----------------------------|
| I). Low fat hard cheese | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| II). Low fat soft cheese | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| III). Low fat yoghurt | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| IV). Low fat spread | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| V). Very low fat spread | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
- 5) What sort of oil/fat do you usually use for frying? (please tick one only)
- | | |
|---|------------------------------|
| I). Lard/dripping/butter or ghee | Yes <input type="checkbox"/> |
| II). Blended vegetable oil | Yes <input type="checkbox"/> |
| III). Polyunsaturated oil e.g. sunflower | Yes <input type="checkbox"/> |
| IV). Monounsaturated oil e.g. olive and nut | Yes <input type="checkbox"/> |
- 6) What kind of spreading fat do you usually use? (please tick one only)
- | | |
|---|------------------------------|
| I). Butter | Yes <input type="checkbox"/> |
| II). Ordinary margarine (e.g. Stork) | Yes <input type="checkbox"/> |
| III). Polyunsaturated margarine (e.g. sunflower) | Yes <input type="checkbox"/> |
| IV). Monounsaturated margarine (e.g. olive, rapeseed) | Yes <input type="checkbox"/> |
| V). Low fat spread (e.g. Gold, Delight) | Yes <input type="checkbox"/> |
| VI). Very low fat spread (e.g. Gold Lowest) | Yes <input type="checkbox"/> |
- 7) Do you use salt in cooking? Yes No
Do you add salt to food at the table? Yes No
If yes, do you add salt at the table without tasting Yes No

Diabetes Empowerment Score (DES)

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
In general, I believe that I:					
1. ...know what part(s) of taking care of my diabetes that I am satisfied with.	()	()	()	()	()
2. ...know what part(s) of taking care of my diabetes that I am dissatisfied with.	()	()	()	()	()
3. ...know what part(s) of taking care of my diabetes that I am ready to change.	()	()	()	()	()
4. ...know what part(s) of taking care of my diabetes that I am <u>not</u> ready to change.	()	()	()	()	()
5. ...can choose realistic diabetes goals.	()	()	()	()	()
6. ...know which of my diabetes goals are most important to me.	()	()	()	()	()
7. ...know the things about myself that either help or prevent me from reaching my diabetes goals.	()	()	()	()	()
8. ...can come up with good ideas to help me reach my goals.	()	()	()	()	()
9. ...am able to turn my diabetes goals into a workable plan.	()	()	()	()	()

Strongly
Agree

Agree

Neutral

Disagree

Strongly
Disagree

In general, I believe that I:

- | | | | | | |
|---|-----|-----|-----|-----|-----|
| 10. ...can reach my diabetes goals once I make up my mind. | () | () | () | () | () |
| 11. ...know which barriers make reaching my diabetes goals more difficult. | () | () | () | () | () |
| 12. ...can think of different ways to overcome barriers to my diabetes goals | () | () | () | () | () |
| 13. ...can try out different ways of overcoming barriers to my diabetes goals. | () | () | () | () | () |
| 14. ...am able to decide which way of overcoming barriers to my diabetes goals works best for me. | () | () | () | () | () |
| 15. ...can tell how I'm feeling about having diabetes. | () | () | () | () | () |
| 16. ...can tell how I'm feeling about caring for my diabetes | () | () | () | () | () |
| 17. ...know the ways that having diabetes causes stress in my life. | () | () | () | () | () |
| 18. ...know the positive ways I cope with diabetes-related stress. | () | () | () | () | () |
| 19. ...know the negative ways I cope with diabetes-related stress. | () | () | () | () | () |

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
In general, I believe that I:					
20. ...can cope well with diabetes-related stress.	()	()	()	()	()
21. ...know where I can get support for having and caring for my diabetes.	()	()	()	()	()
22. ...can ask for support for having and caring for my diabetes when I need it.	()	()	()	()	()
23. ...can support myself in dealing with my diabetes.	()	()	()	()	()
24. ...know what helps me stay motivated to care for my diabetes.	()	()	()	()	()
25. ..can motivate myself to care for my diabetes.	()	()	()	()	()
26. ...know enough about diabetes to make self-care choices that are right for me.	()	()	()	()	()
27. ...know enough about myself as a person to make diabetes care choices that are right for me.	()	()	()	()	()
28. ...am able to figure out if it is worth my while to change how I take care of my diabetes.	()	()	()	()	()

Summary of Diabetes Self-Care Activities Measure (SDSCA)

The question below ask you about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick

Diet

How many of the last SEVEN DAYS have you followed a healthy eating plan?

0 1 2 3 4 5 6 7

On average over the past month, how many DAYS PER WEEK have you followed your eating plan?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you eat five or more servings of fruit and vegetables

0 1 2 3 4 5 6 7

On how may of the last SEVEN DAYS did you eat high-fat foods such as red meat or full-fat dairy products?

0 1 2 3 4 5 6 7

Exercise

On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?

0 1 2 3 4 5 6 7

Blood Testing

On how many of the last SEVEN DAYS did you test your blood?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you test your blood the number of times recommended by your healthcare professional?

0 1 2 3 4 5 6 7

Foot Care

On how many of the past SEVEN DAYS did you check your feet?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you inspect the inside of your shoes?

0 1 2 3 4 5 6 7

Have you smoked a cigarette – even one puff – during the last SEVEN DAYS?

0 NO

1 YES If Yes, how many cigarettes did you smoke on an average day? Number _____

Self Care Recommendations

1A. Which of the following has your health care team (doctor, nurse, dietician, or diabetes educator) advised you to do? Please check all that apply:

- a. Follow a low-fat eating plan
- b. Follow a complex carbohydrate diet
- c. Reduce the number of calories you eat to lose weight
- d. Eat lots of food high in dietary fibre
- e. Eat lots (at least 5 servings per day) of fruits and vegetables
- f. Eat very few sweets
- g. Other (specify): _____
- h. You have not been given any advice about your diet by your health care team.

A. Which of the following has your health care team (doctor, nurse, dietician or diabetes educator) advised you to do? Please check all that apply:

- a. Take low level exercise (such as walking) on a daily basis.
- b. Exercise continuously for a least 20 minutes at least 3 times a week.
- c. Fit exercise into your daily routine (for example, take stairs instead of lifts, park a block away and walk, etc.)
- d. Engage in a specific amount, type, duration and level of exercise.
- e. Other (specify): _____
- f. You have not been given any advice about exercise by your health care team.

3A. Which of the following has your health care team (doctor, nurse, dietician, or diabetes educator) advised you to do? Please check all that apply:

- a. Test your blood glucose (sugar) using a drop of blood from your finger and a colour chart.
- b. Test your blood glucose using a machine to read the results.
- c. Test your urine for sugar.
- d. Other (specify): _____
- e. You have not been given any advice either about testing your blood or urine by your health care team.

4A. Which of the following medications for your diabetes has your doctor prescribed? Please check all that apply.

- a. An insulin shot 1 or 2 times a day.
- b. An insulin shot 3 or more times a day.
- c. Diabetes pills to control your blood glucose level.
- d. Other (specify): _____
- e. You have not been prescribed either insulin or pills for your diabetes.

Medications

5A. On how many of the last SEVEN DAYS, did you take your recommended diabetes medication?

0 1 2 3 4 5 6 7

-- OR --

6A. On how many of the last SEVEN DAYS did you take your recommended insulin injections?

0 1 2 3 4 5 6 7

7A. On how many of the last SEVEN DAYS did you take your recommended number of diabetes pills?

0 1 2 3 4 5 6 7

Foot Care

8A. On how many of the last SEVEN DAYS did you wash your feet?

0 1 2 3 4 5 6 7

9A. On how many of the last SEVEN DAYS did you soak your feet?

0 1 2 3 4 5 6 7

10A. On how many of the last SEVEN DAYS did you dry between your toes after washing?

0 1 2 3 4 5 6 7

Smoking

11A. (See Q8): If yes, at your last diabetes appointment, did anyone ask about your smoking status?

- 0. No
- 1. Yes

12A. At your last doctor's visit, did anyone counsel you about stopping smoking or refer you to a stop-smoking programme?

- 0. No
- 1. Yes

13A. When did you last smoke a cigarette?

- More than two years ago, or never smoked
- One to two years ago
- Four to twelve months ago
- One to three months ago
- Within the last month
- Today

ADDQoL

This questionnaire asks about your quality of life and the effects of your diabetes on your quality of life. Your quality of life is how good or bad you feel your life to be.

Please shade the circle which best indicates your response on each scale.

There are no right or wrong answers; we just want to know how you feel about your life now.

I) In general, my present quality of life is:

- | | | | | | | |
|-----------------------|-----------------------|-----------------------|-------------------------|-----------------------|-----------------------|-----------------------|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| excellent | very good | good | neither good
nor bad | bad | very bad | extremely
bad |

For the next statement please consider the effects of your diabetes, its management and any complications you may have.

II) If I did not have diabetes, my quality of life would be:

- | | | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| very much
better | much better | a little better | the same | a little worse | much worse | very much
worse |

Please respond to the 18 more specific statements on the pages that follow.

For each statement, please consider the effects of your diabetes, its management and any complications you may have on the aspect of life described by the statement.

In each of the following boxes:

- shade a circle to show how diabetes affects this aspect of your life;
- shade a circle to show how important this aspect of your life is to your quality of life.

Some statements have a "not applicable" option. Please shade this "not applicable" circle if that aspect of life does not apply to you.

<p>1a) If I did not have diabetes, my working life and work-related opportunities would be:</p> <p> <input type="radio"/> very much better <input type="radio"/> much better <input type="radio"/> a little better <input type="radio"/> the same <input type="radio"/> a little worse <input type="radio"/> much worse <input type="radio"/> very much worse </p>	<input type="radio"/> not applicable
<p>1b) This aspect of my life is:</p> <p> <input type="radio"/> very important <input type="radio"/> Important <input type="radio"/> somewhat important <input type="radio"/> not at all important </p>	

<p>2a) If I did not have diabetes, my family life would be:</p> <p> <input type="radio"/> very much better <input type="radio"/> much better <input type="radio"/> a little better <input type="radio"/> the same <input type="radio"/> a little worse <input type="radio"/> much worse <input type="radio"/> very much worse </p>	<input type="radio"/> not applicable
<p>2b) This aspect of my life is:</p> <p> <input type="radio"/> very important <input type="radio"/> Important <input type="radio"/> somewhat important <input type="radio"/> not at all important </p>	

<p>3a) If I did not have diabetes, my friendships and social life would be:</p> <p> <input type="radio"/> very much better <input type="radio"/> much better <input type="radio"/> a little better <input type="radio"/> the same <input type="radio"/> a little worse <input type="radio"/> much worse <input type="radio"/> very much worse </p>
<p>3b) This aspect of my life is:</p> <p> <input type="radio"/> very important <input type="radio"/> Important <input type="radio"/> somewhat important <input type="radio"/> not at all important </p>

<p>4a) If I did not have diabetes, my sex life would be:</p> <p> <input type="radio"/> very much better <input type="radio"/> much better <input type="radio"/> a little better <input type="radio"/> the same <input type="radio"/> a little worse <input type="radio"/> much worse <input type="radio"/> very much worse </p>	<input type="radio"/> not applicable
<p>4b) This aspect of my life is:</p> <p> <input type="radio"/> very important <input type="radio"/> important <input type="radio"/> somewhat important <input type="radio"/> not at all important </p>	

<p>5a) If I did not have diabetes, my physical appearance would be:</p> <p> <input type="radio"/> very much better <input type="radio"/> much better <input type="radio"/> a little better <input type="radio"/> the same <input type="radio"/> a little worse <input type="radio"/> much worse <input type="radio"/> very much worse </p>
<p>5b) This aspect of my life is:</p> <p> <input type="radio"/> very important <input type="radio"/> important <input type="radio"/> somewhat important <input type="radio"/> not at all important </p>

<p>6a) If I did not have diabetes, the things I could do physically would be:</p> <p> <input type="radio"/> very much increased <input type="radio"/> much increased <input type="radio"/> a little increased <input type="radio"/> the same <input type="radio"/> a little decreased <input type="radio"/> much decreased <input type="radio"/> very much decreased </p>
<p>6b) This aspect of my life is:</p> <p> <input type="radio"/> very important <input type="radio"/> important <input type="radio"/> somewhat important <input type="radio"/> not at all important </p>

7a) If I did not have diabetes, my holidays or leisure activities would be:

very much better
 much better
 a little better
 the same
 a little worse
 much worse
 very much worse

7b) This aspect of my life is:

very important
 important
 somewhat important
 not at all important

8a) If I did not have diabetes, ease of travelling (local or long distance) would be:

very much better
 much better
 a little better
 the same
 a little worse
 much worse
 very much worse

8b) This aspect of my life is:

very important
 important
 somewhat important
 not at all important

9a) If I did not have diabetes, my confidence in my ability to do things would be:

very much increased
 much increased
 a little increased
 the same
 a little decreased
 much decreased
 very much decreased

9b) This aspect of my life is:

very important
 important
 somewhat important
 not at all important

10a) If I did not have diabetes, my motivation to achieve things would be:

very much increased
 much increased
 a little increased
 the same
 a little decreased
 much decreased
 very much decreased

10b) This aspect of my life is:

very important
 important
 somewhat important
 not at all important

11a) If I did not have diabetes, the way society at large reacts to me would be:

very much better
 much better
 a little better
 the same
 a little worse
 much worse
 very much worse

11b) This aspect of my life is:

very important
 important
 somewhat important
 not at all important

12a) If I did not have diabetes, my worries about the future would be:

very much decreased
 much decreased
 a little decreased
 the same
 a little increased
 much increased
 very much increased

12b) This aspect of my life is:

very important
 important
 somewhat important
 not at all important

13a) If I did not have diabetes, my finances would be:

very much better
 much better
 a little better
 the same
 a little worse
 much worse
 very much worse

13b) This aspect of my life is:

very important
 important
 somewhat important
 not at all important

14a) If I did not have diabetes, my need to depend on others for things I would like to do for myself would be:

very much decreased
 much decreased
 a little decreased
 the same
 a little increased
 much increased
 very much increased

14b) This aspect of my life is:

very important
 important
 somewhat important
 not at all important

15a) If I did not have diabetes, my living conditions would be:

very much better
 much better
 a little better
 the same
 a little worse
 much worse
 very much worse

15b) This aspect of my life is:

very important
 important
 somewhat important
 not at all important

16a) If I did not have diabetes, my freedom to eat as I wish would be:

very much increased
 much increased
 a little increased
 the same
 a little decreased
 much decreased
 very much decreased

16b) This aspect of my life is:

very important
 important
 somewhat important
 not at all important

17a) If I did not have diabetes, my enjoyment of food would be:

very much increased
 much increased
 a little increased
 the same
 a little decreased
 much decreased
 very much decreased

17b) This aspect of my life is:

very important
 important
 somewhat important
 not at all important

18a) If I did not have diabetes, my freedom to drink as I wish (e.g. sweetened hot and cold drinks, fruit juice, alcohol) would be:

very much increased
 much increased
 a little increased
 the same
 a little decreased
 much decreased
 very much decreased

18b) This aspect of my life is:

very important
 important
 somewhat important
 not at all important

The Diabetes Treatment Satisfaction Questionnaire: DTSQs

The following questions are concerned with the treatment for your diabetes (including insulin, tablets, and/or diet) and your experience over the past few months. Please answer each question by circling a number on each of the scales.

1. How satisfied are you with your current treatment?
 very satisfied 6 5 4 3 2 1 0 very dissatisfied

2. How often have you felt that your blood sugars have been unacceptably high recently?
 most of the time 6 5 4 3 2 1 0 none of the time

3. How often have you felt that your blood sugars have been unacceptably low recently?
 most of the time 6 5 4 3 2 1 0 none of the time

4. How convenient have you been finding your treatment to be recently?
 very convenient 6 5 4 3 2 1 0 very inconvenient

5. How flexible have you been finding your treatment to be recently?
 very flexible 6 5 4 3 2 1 0 very inflexible

6. How satisfied are you with your understanding of your diabetes
 very satisfied 6 5 4 3 2 1 0 very dissatisfied

7. Would you recommend this form of treatment to someone else with your kind of diabetes?
 Yes, I would definitely recommend the treatment 6 5 4 3 2 1 0 No, I would definitely not recommend the treatment

8. How satisfied would you be to continue with your present form of treatment?
 very satisfied 6 5 4 3 2 1 0 very dissatisfied

Please make sure that you have circled one number on each of the scales

Appendix 7: Patient empowerment and education group report

*Local Diabetes Services
Implementation Group (LDSIG)
Patient Empowerment &
Education Sub-Group*

Empowerment

Self-Management

Health

Informed Decisions

Education

Confidence

Quality of Life

***The Patients Perspective
Report and
Recommendations***

***Diabetes Care
Burnley, Pendle & Rossendale PCT***

April 2003

Forward



The Patient Empowerment and Education Sub-Group of the Local Diabetes Services Implementation Group (LDSIG) is represented mainly by patients and carers.

In the past people who live with diabetes and people who care for them have not had a say in how local diabetes services are delivered. However, it has been shown that these people often know what they need to help them self-manage their condition.

When asked to be chair of the Patient Empowerment and Education Sub-Group, I was delighted to have the opportunity to work closely with patients and carers in putting together this report. I am extremely grateful to the members of the group for their time, commitment and contribution.

Trudi Deakin

Chair, Patient Empowerment and Education Sub-Group

Executive Summary

The LDSIG Patient Empowerment and Education Sub-group have met on five occasions. The group consists mainly of people with diabetes and carers. The following recommendations have been put forward to raise the quality of diabetes care people can expect locally within Burnley, Pendle and Rossendale. It is appreciated that some practices are already delivering some of the recommendations but the group would like to see more uniformity across the district.

- People with diabetes and their carers should be informed, when diagnosed, of local, national and electronic diabetes services and resources available. This may be in the form of a leaflet.
- There is a need for uniform care across the district. It was identified that at the moment healthcare differs greatly depending on where people live and who they receive their diabetes care from.
- Continuous health professional training is paramount. Conflicting messages from healthcare professionals were seen to be a major problem.
- Consistent, empowering and structured education programmes should be available for all. *Expert patient programmes* were put forward as an example of good practice. The local health professional-led diabetes specific programme was felt to develop the skills and confidence required for people to self-manage their diabetes. The Department of Health generic lay-led programme aids people to live more successfully with a chronic condition.
- The development of a 'diabetes educator' within each practice would enable knowledge to circulate. A named health professional with a special interest in diabetes would take the lead in diabetes education and advice. The diabetes educator would provide up-to-date and evidence-based information, not only to patients but to other health professionals as well.
- A reduction the multitude of appointments people have to attend could be replaced by delivery of diabetes education in the same place as a single package.
- A district wide 24 hour phone line run by trained people with specialist diabetes knowledge would be a good way of dealing with general enquires and emergencies.
- A fast track self-referral system for individuals to receive psychological care, if they should require it, to help them live more positively with their diabetes. Any service should be widely advertised throughout the district.
- A variety of diabetes education materials to reflect different cultures and learning styles are required. These should include patient manuals, videos, audiotapes and visual aids to develop diabetes understanding.
- Shared health records should be developed with people receiving a written copy of their health results: glycated haemoglobin, cholesterol profile, weight, BMI, waist

circumference, body percentage fat and blood pressure etc. All too often people are told verbally 'it's OK' without ever knowing the result.

- Chronic condition communication training for healthcare professionals and patients is crucial. People would like to see the didactic and prescriptive healthcare delivery replaced with a more empowering and confidence building approach i.e. working together in a more equal relationship to share information and develop joint care plans that encourage people living with diabetes to set their own goals.
- Local diabetes training events for both healthcare professionals and patients to attend would be an excellent way to build and share knowledge.
- A protocol for having blood tests taken prior to attending the clinic would be beneficial. Health results would then be available during the appointment to encourage effective treatment and goal setting.
- Flexible working depending on individuals' personal circumstances is necessary. For example, telephone appointments if people find it difficult to attend the clinic, email advice for those who are electronically minded, and evening/weekend appointments or education programmes for those who work full-time.
- Targeting the general population by providing more information to the public, including school children, about diabetes would help reduce the stigma attached to the condition and symptom awareness would aid early diagnosis.
- Allowing people with diabetes to continue self-management tasks while staying in hospital is an important aspect of self-empowerment. Presently, diabetes medication and insulin are handed out by staff on the ward, often at the incorrect time for that medication to be taken. This can be very frustrating and disempowering for people who are normally in charge of their own medication.

Introduction

Patient empowerment and education is a priority of the National Service Framework for Diabetes⁹. The *Local Diabetes Services Implementation Group* (LDSIG) recommended that a sub-group be formed to address patient empowerment and education locally. Initially it was anticipated that membership would mainly reflect health professionals' opinions with one or two patient representatives.

However, there is a need to ask patients and carers for their views and the government is encouraging this. It has been suggested that 'more confident and knowledgeable people may become useful members of Local Diabetes Services Advisory Groups or future committees that are set up to implement the National Service Framework Delivery Strategy.....'¹⁰. Upon accepting the position of Chair for the group, I felt that patient representation would drive the group forward with a new dimension by gathering real thoughts from real people who have to live with the chronic condition from day to day. People with diabetes and their carers know how they may become more empowered to self-manage their diabetes and how they would like to receive effective diabetes education.

Aims

The following aims were presented to the group:

1. Explore ways in which people would feel more confident to take personal control of their diabetes in order to deal with the following:
 - a) Lifestyle changes in respect of diet, physical activity, weight control and smoking.
 - b) Checking blood glucose and/or checking urine glucose levels to monitor and improve diabetes control.
 - c) Understanding of blood glucose control and prevention of hypoglycaemia (low blood glucose level) and hyperglycaemia (high blood glucose level).
 - d) Awareness and prevention of diabetes long-term complications to the eyes, feet, kidneys and heart.
 - e) Taking medications in the correct way and in the correct doses.
2. Express ideas and suggestions about how diabetes services can be improved, for example, how diabetes education should be delivered to people with diabetes and their families/carers. Discuss how these changes can be monitored and checked to see what differences they have made.
3. Assist in the development of, or purchase of, patient education materials (leaflets, models, visual aids, booklets etc.), which will be of use to people with diabetes of all ages and in all languages, and also for visually impaired people who have diabetes.

⁹www.doh.gov.uk/nsf/diabetes

¹⁰ Wheeler J (Editorial). *Patients hold the key to success*. Diabetes Update, Autumn 2002

4. Encourage people with diabetes, and also parents and carers where appropriate, to work confidently with diabetes health professionals in agreeing plans on how to share the care of their diabetes. These plans should be easy for everybody to understand and use.
5. Seek the viewpoint of all local people with diabetes on current diabetes services and how they feel services could be improved to encourage confident self-management of diabetes. This will, hopefully, help to improve patient satisfaction within Burnley, Pendle and Rossendale.
6. Link in with other Diabetes Sub Groups when necessary e.g. Health Professional Training Group, Diabetes Prevention Group, Foot Care Group etc.
7. Provide feedback (written or verbal) to *Local Diabetes Service Implementation Group* regarding developments and progress made.

Objectives

It was decided to address the above aims by holding five monthly meetings. These were held at Burnley Town Hall and the Temple Street Resource Centre, Burnley. There was equal patient and carer representation from Burnley, Pendle and Rossendale. Although a strict agenda was not planned and free thinking was encouraged, the following structure enabled all of the above aims to be discussed.

- Meeting One (23rd October 2002): Aim 1
- Meeting Two (11th December 2002): Aim 2
- Meeting Three (15th January 2003): Aim 3
- Meeting Four (12th February 2003): Aim 4
- Meeting Five (12th March 2003): Aim 5

This report has been prepared for the LDSIG (Aim 7) but will be made available for other diabetes sub-groups as necessary (Aim 6). Members of the group would welcome the opportunity to present the findings verbally to the wider local diabetes network.

Meeting One

Explore ways in which people would feel more confident to take personal control of their diabetes.

Phrases from a 'free thinking' session:

'Lack of information – leaflets on their own are not enough. Leaflets should be available to inform what services and help are available.'

'A good experience of diabetes care. Newly diagnosed and immediately educated by expert patient programme – very glad.'

'We need consistent advice – not conflicting.'

'More health professional education.'

'Two-way communication required between patients and health professionals.'

'We need realistic goals – cannot achieve everything.'

'Information and support that people receive when initially diagnosed is vital – if delivered correctly, individuals more likely to control diabetes.'

'Spouses, partners and family need to be involved in the education.'

'There should be an education centre for people to go to.'

'Health results should be shared between the health professional and the patient with explanations of what they mean and normal ranges.'

'People with diabetes require support, group education, knowledge about diabetes and supermarket tours – i.e. a structured education programme.'

'Practice nurses need to be more approachable and liaise more with specialists at the hospital to provide consistent information. Practice nurses have the advantage of knowing individuals and have the opportunity to review every three months. However, patients need to take the responsibility for their diabetes.'

'Doesn't feel comfortable to phone up the practice to request an appointment or ask for health results. Would liaise with general practice team more if thought it was OK to do so.'

'People need to be aware of services offered by the hospital.'

'Education needs to be culture sensitive. Found expert patient sessions useful because translator available and session used food models and supermarket tour.'

'Difficult getting an appointment with a practice nurse – they're too busy.'

'Would prefer to see all health professionals together – like at the hospital.'

'Conflicting advice – a serious problem.'

'Several health professionals still giving 'sugar-free' dietary advice. Should be trained to give up-to-date information.'

'Outside diabetes care – counselling required to learn to live with diabetes.'

'Treatment needs to be individualised.'

'Pharmacist needs to be involved in diabetes care. Pharmacist staff need to be trained and more informed regarding issues like sharps tins.'

'Health professionals need to take a personal interest in people with diabetes – and treat them as a whole person and not just a diabetic.'

'Communication skills required for both health professionals, people with diabetes and carers.'

'People with diabetes need to have the knowledge to be able to access correct information e.g. on the Internet.'

'GP's need to inform people about Diabetes UK.'

How do you feel that you could be helped in achieving some or all of the following: -

a) Lifestyle changes in respect of diet, physical activity, weight control and smoking.

- Expert Patient Programmes including the 'Department of Health lay-led chronic conditions course' and the local 'Health Professional-Led Diabetes Specific Course'. The former emphasises healthy living, fatigue management, living wills and communication with health professionals, whilst the latter encourages informed and knowledgeable diabetes self-management. Both programmes were seen to compliment one another.
- Being informed that insulin is a weight promoting hormone and that some diabetes tablets encourage weight gain
- Education visual aids e.g. video's (in all required languages)
- Effective self-management diabetes specific education
- Support from spouse, family and named health care professionals

b) Checking blood glucose and/or checking urine glucose levels to monitor and improve diabetes control.

- Blood glucose meters uniformly being given to all patients who wish to self-monitor
- Training provided to accurately monitor blood glucose levels

c) Understanding of blood glucose control and prevention of hypoglycaemia (low blood glucose level) and hyperglycaemia (high blood glucose level).

- Self-management education
 - Good relationship between patient and health care professional
- d) Awareness and prevention of diabetes long-term complications to the eyes, feet, kidneys and heart.
- Access to podiatrist / optometrist
 - Communication with healthcare professionals regarding the reason for investigations, additional referrals etc
 - Early education in a manner that is understandable to all people
 - Expert patient education
- e) Taking medications in the correct way and in the correct doses.
- Regular contact with diabetes team when trying new regimens
 - Diabetes self-management training
 - Pharmacy support i.e. drug information, pre-packaged daily medication
 - Being allowed to take own medication whilst in hospital

Summary

Presently there is a postcode lottery with care differing greatly depending upon where individuals live and who is caring for their diabetes. Advice is often given in an ad hoc and prescriptive manner. Conflicting messages from healthcare professionals cause confusion and mistrust. Lack of information for people with diabetes and their carers about the local and national services available further hinders diabetes self-management.

People with diabetes and their carers would feel more confident in controlling their diabetes if they received up-to-date, consistent and structured diabetes education. Individuals felt that communication with healthcare professionals could be improved to encourage joint goal setting and information sharing.

The cry for:

EDUCATION – of healthcare professionals to avoid conflicting messages

EDUCATION – of people with diabetes and carers to encourage effective diabetes self-management

EDUCATION – of the media and general public to early diagnosis and reduce stigma

Meeting Two

Express ideas and suggestions about how diabetes services can be improved, for example, how diabetes education should be delivered to people with diabetes and their families/carers. Discuss how these changes can be monitored and checked to see what differences they have made.

People have to self-manage their diabetes for an average 8,757 hours each year. How could people's knowledge and confidence be increased for successful diabetes self-management?

The right education delivered at the right time for the right duration by the right people!

How could diabetes services be improved?

People should be invited to attend a group-based education programme when initially diagnosed. All health professionals should have up-to-date knowledge regarding diabetes to prevent conflicting messages being given to the person with diabetes. It is generally felt that the consistency of advice is poor, especially regarding diet. Therefore it is recommended that practice nurse/GP training should be updated on a regular basis. Health professional training is paramount to the improvement of diabetes services.

Presently in the UK health professionals are 'experts' in their trained area e.g. medicine, nursing, dietetics, podiatry. To some lay people, it appears that professionals are 'precious' regarding their own subject area and do not wish other professionals to 'step on their toes'. This can increase the number of appointments that individuals have to attend and be time consuming. The USA model of 'diabetes educators' was put forward as a possible way of improving current services. A diabetes educator assigned to each general practice would take the education lead for all people with diabetes registered at that practice.

It was felt that all individuals with diabetes should have a health check at least once every six months to assess their health status. The results should then be mailed to the individual with a brief summary of their present diabetes control, lipid profile, blood pressure and weight/waist circumference etc. Too many people felt that all too often they were labelled as a 'diabetic' and the majority of health problems they sought advice for were often blamed on their diabetes. People feel that medical staff should take a holistic approach and recognise that, as with the general population, they do have other health problems as well.

Communication should be two-way between patients and health professionals. Presently some people with diabetes feel that they are 'instructed' what to do, but not 'actively' listened too. It is felt that there should be a more equal relationship, with the health professional imparting knowledge regarding the condition, medication, diet etc. and the patient sharing knowledge about living with the condition on a day-to-day basis and the difficulties they may be experiencing with self-management of diabetes. Many patients are too intimidated to speak out to professionals and this is more likely to lead to poor self-management. Also, it is felt that communication between different health professionals is sometimes poor.

Diabetes services may be improved if health professionals were better trained in communication and listening skills and patients were encouraged to actively participate in the consultation. Also,

having a regular meeting/training session so that all health professionals working within diabetes care can share experiences, discuss the latest research reports and up-date diabetes guidelines, may be beneficial. Some such meetings may include people with diabetes sharing their experience of living with the condition with health professionals.

Some people who attend hospital clinics felt that too many appointments are cancelled and re-arranged months ahead. Addressing this issue and reducing the frequency of this occurring was thought to improve diabetes services.

It was felt that many of the recommendations probably do not require extra resources but some new guidelines and the re-organisation of services. For example, structured group education programmes and expert patients trained as peer educators.

How should diabetes education be delivered?

It is felt that diabetes education should be delivered by people who understand the condition, for example, a specialist diabetes educator. An overwhelming number of people felt that everybody should have an opportunity to attend the six-week diabetes education programme (expert patient programme). Individuals who had attended the health professional-led expert patients programme felt that it had resulted in a time saving by reducing in the need to phone other health professionals. However, this should be backed-up on an individual basis with one-to-one consultations with the practice nurse and /or GP to discuss action plans and any personnel issues.

A video lending service to allow individuals, when diagnosed, to take an educational video home to watch with the family would further enhance the education process.

Being given a blood glucose meter and taught how to use it was thought to increase people's control and confidence over their blood glucose levels and therefore increase successful self-management skills. Also, being informed upon diagnosis, of possible secondary complications in an informative / visual manner would be more effective than use scare tactics later.

To improve the consistency of advice being given to patients it was felt that the six-week diabetes education programme should initially be delivered to practice staff. If this was not possible, then representatives from the practice should attend the programme when it was being delivered to people with diabetes. It was also felt that carers/ spouse should also be encouraged to attend, as diabetes does affect the whole family.

The proper delivery of diabetes education through the media (televise the expert patient programme?) and schools was thought to be important in the light of the anticipated future epidemic of diabetes and the ignorance that surrounds the condition generally.

People felt that all education should be delivered in a manner that encourages self-management of the condition. Didactic and prescriptive advice does not encourage people to find possible solutions to their own problems and any advice is more likely to be ignored. The introduction of the governments lay-led 'chronic disease self-management course' for people with chronic disease was felt to be a good example of a programme which helps people living with a chronic condition to find possible solutions and set goals to tackle their own health problems.

Presently, people felt that it was very difficult to receive back-up advice via the telephone. It was generally felt that telephones were either not answered, or that they delivered an instruction to leave a message on the answer machine. When messages were left, they were sometimes not acted upon. There was generally a demand for a 24-hour help line to be available for people with diabetes that was managed by people who were knowledgeable and up-to-date in diabetes management.

Finally, education should be delivered in an informal and relaxed setting which is local and easily accessible for all.

Meeting Three

To assist in the development of, or purchase of, patient education materials (leaflets, models, visual aids, booklets etc.), which will be of use to people with diabetes of all ages and in all languages, and also for visually impaired people who have diabetes.

Should educational materials be developed locally or purchased nationally e.g. Diabetes UK?

It was appreciated that each individual with diabetes has different learning styles and finds different learning materials helpful. It was recommended that a variety of written and visual educational materials should be made available to local people with diabetes.

Which education materials have you found useful? Why?

The following educational materials were held in high regard:

- Diabetes UK leaflets and booklets, although the cost implementation was appreciated.
- Visual aids e.g. models and pictures developed for the local diabetes expert patient programme.
- Patient diabetes self-management manual developed for the local diabetes expert patient programme.
- The Internet e.g. 'Diabetes UK' website, 'Talking Diabetes' website.

What type of education materials would you find useful? Why?

- A general practice loaning service for diabetes education videos in several languages.
- Video/website/CD ROM produced of the local diabetes expert patient programme (once again in languages that local people can understand).

In addition it was felt that a named contact person should be available to answer general questions and queries.

Meeting Four

Encourage people with diabetes, and also parents and carers where appropriate, to work confidently with diabetes health professionals in agreeing plans on how to share the care of their diabetes. These plans should be easy for everybody to understand and use.

How can people with diabetes / parents / carers be encouraged to work confidently with health professionals in agreeing plans on how to share the care of their diabetes?

People felt that adopting a non-hierarchical relationship with health professionals would give them more confidence to ask questions and to take more responsibility for their diabetes care.

Some individuals already have blood tests 2 weeks prior to their appointment with the GP/Practice Nurse and this was felt to be an example of good practice. The appointment can then be used as an opportunity to discuss the results and agree on future goals. Alternatively some people felt that obtaining their health results over the phone would be advantageous. Further discussion led to recommendations for telephone appointments with a named contact e.g. practice nurse. For this to happen it was felt that there should be a dedicated practice manager and specialist diabetes nurses and doctors within primary care.

Traditionally health professionals have been trained to instruct patients what to do and not to jointly discuss and agree targets. This approach has been shown not to be effective in the long term. However, concern was raised with regard to the reaction of health professionals having a more equal relationship with patients. If patients become more knowledgeable and informed about their condition, their expectation for good quality health care rises and they ask more questions. It was felt that some health professionals may not be familiar with this approach and provision of communication training should be made available.

At the meeting, there was representation from individuals registered with different practices across the district (Burnley, Pendle & Rossendale). It was recognised how different current diabetes care was depending on who the GP was. There was strong agreement that there should be uniform care across the district. No matter where an individual lives; they should expect the same high quality care for their diabetes. It was suggested that district diabetes protocols with health professional training would help address this issue.

How do you feel that the joint care plan / communication with the health professional should be documented (Medical vs. patient owned, paper vs. electronic)? How can we ensure that these are easy for everybody to understand and use?

Brainstorming raised several options. The most popular idea was to have 'shared' health records, with the actual record remaining in the hands of the health professional but the patient having access whenever they wished. Alongside this, people would like to receive a copy of their health results every time they had a blood test, investigation etc. Some individuals who have Internet access at home would like to be able to view their health records electronically whenever they wished.

People unanimously felt it was important as part of their self-management of their diabetes to know and understand their health results and have access to a joint care plan.

Two examples of joint care plans were discussed:

Children / Adolescents Care Plan (Burnley Healthcare NHS Trust)

An excellent example of a joint care plan but more specific for children and individuals with type 1 diabetes (Appendix 2).

Opening the Door to Diabetes Self-Management Care Plan (NDEI, New Jersey, USA)

Participants felt this was an excellent example for adults with diabetes and felt it could be modified for the local population (Appendix 3).

Meeting Five

Seek the viewpoint of all local people with diabetes on present diabetes services and how they feel services could be improved to encourage confident self-management of diabetes. This will, hopefully, help to improve patient satisfaction within Burnley, Pendle and Rossendale.

How would it be possible to seek the viewpoint from all local people with diabetes, especially regarding present diabetes services; how services could be improved; how to increase confident self-management of diabetes; how to improve patient satisfaction within Burnley, Pendle and Rossendale.

Several options were discussed: postal questionnaires; public meeting followed by feedback questionnaire; advertising in GP surgeries, hospital clinics or newspapers with free phone number for people to verbally discuss local diabetes services.

Participants felt that they provided good representation across the district and at the moment it would be time consuming and not cost-effective to seek the viewpoint from all local people with diabetes. If the above recommendations were implemented, it may then be possible to evaluate local diabetes care to assess if it had made a difference.

Out of the people with diabetes in the group the following statistics were observed:

- 50% have a named contact person for their diabetes care
- 90% have a dilated annual eye screen
- 60% have a annual foot check
- In those who require a glycated haemoglobin (HbA1c) test every 3 months due to poor control, change of medication etc, 75% had the test.
- In those who require a glycated haemoglobin (HbA1c) test every 6 months, 50% had the test.
- 10% receive a paper print-out of their test results
- 40% receive their health results verbally
- 50% were referred to a dietitian when first diagnosed with diabetes
- 50% have received advice regarding physically activity
- 50% work with health professionals to jointly set goals

N.B. These statistics were collected from members of the patient forum who are obviously more informed, empowered and effective diabetes self-manages compared to the general diabetes population.

Appendix 8: Patient evaluation form

Evaluation of Diabetes Expert Patient Programme

To allow future programmes to offer maximum benefits to people with diabetes, please take a few minutes to answer the questions below.

For each weekly session:

- 1) On a scale of 1 - 10 how did you enjoy the programme?
- 2) On a scale of 1 -10 how useful did you find the programme?
- 3) On a scale of 1 -10, do you think that the information gained will improve your health? *(Please circle the number that best fits your thoughts)*

Week 1: What is Diabetes?

1	2	3	4	5	6	7	8	9	10
Didn't Enjoy								Really Enjoyed	
1	2	3	4	5	6	7	8	9	10
Not Useful								Really Useful	
1	2	3	4	5	6	7	8	9	10
Won't improve my health								Will improve my health	

Week 2: Weight Management

1	2	3	4	5	6	7	8	9	10
Didn't Enjoy								Really Enjoyed	
1	2	3	4	5	6	7	8	9	10
Not Useful								Really Useful	
1	2	3	4	5	6	7	8	9	10
Won't improve my health								Will improve my health	

Week 3: Glycaemic Index

1	2	3	4	5	6	7	8	9	10
Didn't Enjoy								Really Enjoyed	
1	2	3	4	5	6	7	8	9	10
Not Useful								Really Useful	
1	2	3	4	5	6	7	8	9	10
Won't improve my health								Will improve my health	

Week 4: Supermarket Tour / Session

1	2	3	4	5	6	7	8	9	10
Didn't Enjoy								Really Enjoyed	
1	2	3	4	5	6	7	8	9	10
Not Useful								Really Useful	
1	2	3	4	5	6	7	8	9	10
Won't improve my health								Will improve my health	

Week 5: Possible Complications of Diabetes

1 2 3 4 5 6 7 8 9 10
Didn't Enjoy Really Enjoyed

1 2 3 4 5 6 7 8 9 10
Not Useful Really Useful

1 2 3 4 5 6 7 8 9 10
Won't improve my health Will improve my health

Week 6: Living with Diabetes Game / Questions

1 2 3 4 5 6 7 8 9 10
Didn't Enjoy Really Enjoyed

1 2 3 4 5 6 7 8 9 10
Not Useful Really Useful

1 2 3 4 5 6 7 8 9 10
Won't improve my health Will improve my health

Lifestyle Experiment: Setting yourself goals

1 2 3 4 5 6 7 8 9 10
Didn't Enjoy Really Enjoyed

1 2 3 4 5 6 7 8 9 10
Not Useful Really Useful

1 2 3 4 5 6 7 8 9 10
Won't improve my health Will improve my health

Do you feel that 6 weekly sessions are: a) Too few b) Just right c) Too many?
If your response was too few/too many - how many sessions do you think there should be?

How do you feel about the length of the sessions (2 hours): a) Too short b) Just right c) Too long?
If you think the sessions were too short/too long - how long do you feel the sessions should be?

Do you feel that the information you have gained would enable you to help somebody else with diabetes? a) Yes b) No c) Don't know

Any other comments.....
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.....
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Thank you for your time!