The Development and Evaluation of a Home Based Behavioural Nutrition Education Programme for Adults with Cystic Fibrosis

A thesis submitted in accordance with the requirements of the University of Surrey for the degree of Doctor of Philosophy

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Abstract

Malnutrition remains a major clinical problem in Cystic Fibrosis (CF). As the degree of underweight correlates closely with reduced survival, interventions are needed which optimise nutritional outcomes.

The focus of this thesis was on developing a home based behavioural nutrition education programme for adults with CF and assessing its effectiveness on nutritional status, knowledge and other psychosocial measures using a randomised control study design.

Chapter 2 describes the development of the “Eat well with CF” programme, which used a framework of Social Cognitive Theory. The next investigations aimed to test the programme both with consumers and with peers. The results showed that adults with CF would be motivated to take part and felt they would learn from the programme. The peer review demonstrated that the programme was rated highly with regard to content, accuracy and information.

In Chapter 3 the effectiveness of “Eat well with CF” was tested in a randomised trial (n=74) using a control group who received standard care. The results demonstrated a trend towards an increase in weight. After 6 months the average weight gain in the intervention group was 0.57 kg compared to control weight gain of 0.09 kg (p=0.545, 95%CI -1.07-2.0). Subjects undertaking the “Eat well with CF” programme had significantly increased their self-efficacy to cope with their diet, (p=0.003, 1.19-5.67), their specific nutritional knowledge (p<0.001, 4.05-7.38) and their reported dietary fat intake (p=0.014, 0.76-6.50) compared to the control group. At 12 months, the average weight gain was 0.02 kg in the control group and 1.14kg in the intervention group with no statistical differences between the two groups. The intervention group continued to show a marked and significant improvement in CF specific nutritional knowledge and self-efficacy score.

Chapter 4 examines the reasons for subject non-participation in the study, which led to the development of an audio version of “Eat well with CF”.

The positive results of the process evaluation detailed in chapter 5 highlight the significant personal enjoyment and benefit received by the participants.
These studies combine to demonstrate the utility, acceptability and efficacy of “Eat Well with CF”. In addition they challenge traditional dietetic practice. We suggest this novel behavioural education approach could enhance current dietetic practice, to improve outcomes and lead to life long maintenance of optimal nutritional status for adults with CF.
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<th>Description</th>
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<tbody>
<tr>
<td>BIA</td>
<td>Bioelectrical Impedance Analysis</td>
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<td>BMI</td>
<td>Body Mass Index</td>
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<tr>
<td>BMD</td>
<td>Bone Mineral Density</td>
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<tr>
<td>CF</td>
<td>Cystic Fibrosis</td>
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<tr>
<td>CFRD</td>
<td>Cystic Fibrosis Related Diabetes</td>
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<tr>
<td>DEXA</td>
<td>Dual Energy X-ray Absorptiometry</td>
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<tr>
<td>DIOS</td>
<td>Distal Intestinal Obstructive Syndrome</td>
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<tr>
<td>FEV1</td>
<td>Forced Expiratory Volume in 1 second</td>
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<tr>
<td>FFM</td>
<td>Fat Free Mass</td>
</tr>
<tr>
<td>Kg</td>
<td>Kilogram</td>
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<tr>
<td>LBM</td>
<td>Lean Body Mass</td>
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<tr>
<td>MI</td>
<td>Motivational Interviewing</td>
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<tr>
<td>PERT</td>
<td>Pancreatic Enzyme Replacement Therapy</td>
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<tr>
<td>PI</td>
<td>Pancreatic Insufficient</td>
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<tr>
<td>PS</td>
<td>Pancreatic Sufficient</td>
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<tr>
<td>REE</td>
<td>Resting Energy Expenditure</td>
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<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
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<tr>
<td>TEE</td>
<td>Total Energy Expenditure</td>
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<tr>
<td>QoL</td>
<td>Quality of Life</td>
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Publications arising from this work

Submitted Papers


Published abstracts


**Oral presentations:**


3. A randomised controlled trial of a behavioural nutrition education programme “Eat Well with CF” for adults with CF.”, Copenhagen, Denmark June 2006
28th European CF conference.

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1. Nutritional Management of the Adult with Cystic Fibrosis

1.1 Introduction

Cystic fibrosis (CF) is the most common autosomal recessive genetic disorder in the Caucasian population. The incidence is estimated as one in every 2500 live births (Lewis et al., 1999). CF is a multisystem disorder that exhibits extremely variable symptoms. It is characterised by thick viscid secretions in the airways and the intestines, excessive salt secretion in the sweat, pancreatic insufficiency caused by blockage of the pancreatic duct with mucus, male infertility and sometimes liver failure. Clinically CF is most commonly characterised by recurrent pulmonary infections, pancreatic exocrine insufficiency, leading to maldigestion and malabsorption of fat and protein and excessive losses of sweat electrolytes (Liou et al., 2001).

Since the discovery of the CF gene in 1989 there has been an increase in understanding of the disease. The CF gene codes for a 1480 amino acid protein called CF transmembrane conductance regulator protein (CFTR). CFTR is an important cAMP-regulated chloride channel found on the apical surface of epithelial cells lining the airways, intestines, biliary tree, pancreatic ducts, vas deferens and the sweat ducts. A defect in the CFTR protein causes abnormal chloride transport, with decreased chloride transport and increased sodium re-absorption. Abnormal chloride transport results in decreased fluid secretion, leading to the plugging of ducts and secondary dysfunction of the organs involved. Since 1989, there have been over 1000 mutations of the CFTR gene identified, most are very rare (Jackson and Pencharz, 2003), and the 12 commonest mutations are responsible for over 90% of cases of CF (Riordan et al., 1989, Kerem et al., 1989). The most common mutation, Delta F508, a loss of a phenylalanine residue at position delta F508 on the long arm of chromosome 7, accounts for approximately 70% of all mutant CFTR chromosomes worldwide. The next most common mutations are G542X, G551D, N1303K and W128X, each account for only 1 – 2.5 percent of known CF chromosomes.

Genotype is typically represented by two disease causing mutations residing on separate alleles. Phenotype, (the clinical outcome) is characterized by observable and/or measurable clinical features manifested in a patient. Genotype-Phenotype studies assess the relationship
between these 2 categories. Analysis of particular CFTR mutations in subjects with Pancreatic Insufficiency (PI) and Pancreatic Sufficiency (PS) revealed 2 categories of alleles; severe and mild. A severe allele confers PI only if paired with another severe allele. A mild allele sustains pancreatic function in a dominant fashion, even if the second mutation is severe. Overall there is a good association between specific CFTR alleles (severe or mild) and exocrine pancreatic function (Zielenski, 2000).

Pancreatic sufficient subjects generally have less severe symptoms, better lung function and less gastrointestinal complications than those who are Pancreatic Insufficient and this results in longer survival (Durie and Forstner, 1989). The American Cystic Fibrosis foundation reported the median survival for PS subjects as 56 years compared to the median survival for PI subjects of 29 years (FitzSimmons, 1996).

The clinical course of CF is variable but it has been suggested this may be related to specific genetic defects. Improvements in treatment have increased life expectancy. The median predicted survival for a patient born in 1970 was 16 years, for those born in the 1990s it is approximately 40 years and continuing to rise (Elborn et al., 1991). The number of subjects surviving into adulthood is rapidly increasing by approximately 150/year in the UK (Dodge et al., 1997). Chronic pulmonary disease is the main cause of morbidity and mortality, with lung function (Forced Expiratory volume in one second, FEV1) a good predictor of survival in CF. More recently the role of nutrition as a significant factor in determining survival has been recognised (Corey et al., 1988). Poor weight gain, weight loss and inadequate nutrition continue to be a problem in many subjects and contribute to substantial morbidity. The close relationship between nutrition, lung function and the clinical course of CF has been illustrated in a large cross sectional and longitudinal analysis of 3,298 German subjects. Malnourished children of all ages were shown to have significantly worse lung function than their normally nourished counterparts (Steinkamp and Wiedemann, 2002). Similarly a longitudinal study investigating 319 children aged 6-8 years revealed children who gained more weight at an appropriate and uninterrupted rate had a better FEV1 trajectory (Peterson et al., 2003). There is increasing evidence from epidemiological studies that optimal nutrition is important for the long term health of subjects with CF. One recent investigation found that in young children, nutritional status at age 3 predicts lung function at age 6 (Konstan et al., 2003). Studies have shown that nutritional status as measured by the Body Mass Index (BMI) is a good prognostic indicator (Mahadeva et al., 1998). A recent cross sectional study involving 33 subjects, used
4 methods to estimate percentage body fat and concluded that a simple calculation of BMI was adequate to measure nutritional status in adults with CF (Hollander et al., 2005). Sharma et al (Sharma et al., 2001) demonstrated that percentage ideal weight was an accurate independent predictor of survival at 5 year follow up.

The typical therapeutic regime for the patient with CF is highly complex and time consuming. Most treatment takes place at home with subjects responsible for their own care. This involves daily physiotherapy, administration of nebulised antibiotics, pancreatic enzyme supplements with food and a special diet (Littlewood and Taylor, 2002). This includes consuming 120-150% of normal daily energy requirements based on age and gender (Hubbard and Mangrum, 1982). In a recent 2 year prospective study of chronic illness, adolescents with CF spent 1.5 hours a day managing their illness (Kettler et al., 2002). Enzyme supplementation relies on patient and family knowledge of how to adjust enzyme dose according to the fat content of food.

The management of nutrition in CF subjects is crucial to their well-being and influences the outcome of the disease process. In addition, improving nutrition correlates with better overall outcomes including lung function (Konstan et al., 2003).

**Survival and Incidence**

During the last 30 years improvements in diagnosis and treatment have resulted in a marked increase in life expectancy (Dodge et al., 1997). Thirty years ago subjects with CF were expected to die in infancy or childhood, now most can expect to survive into adulthood. Britton et al (Britton, 1989) analysed mortality data for England and Wales from 1959 to 1986, and reported median age at death as 6 months in 1959 and 17 years in 1986. Social class, sex and region of residence were cited as potential independent determinants of survival of subjects with CF. The estimates of disease incidence have been virtually constant between 1967 and 1994 (Lewis et al., 1999). This study observing cohort survival data showed each successive cohort since 1986 had improved survival (Lewis et al., 1999). The authors suggest the increasing percentage of subjects achieving 30 years of age adds to the evidence that the adult population is set to continue to grow for some time.
One of the largest epidemiological studies to date in CF, which investigated over 21,000 subjects in the USA, reported survival in 1-20 year olds to be poorer in females than males. Females were shown to be 60% more likely to die before the age of 20 than males. Nutritional status, pulmonary function and airway microbiology were shown as strong predictors of mortality. The “Gender Gap” was not explained by a variety of potential risk factors, the exact reason for the male advantage is still not clear (Rosenfeld et al., 1997).

An international comparison of median age of death from CF showed a marked difference exists in the median age of death between 10 countries in North America, Europe and Australasia (Fogarty et al., 2000). This study also confirms previous findings that females have a worse prognosis than males, and that social class is a strong determinant of survival, with poorer outcomes in those from disadvantaged groups. However, the extent of the effect of social class on survival is not known as some of this may be due, for example in the USA, to access to healthcare being dependant on insurance status.

1.2 History of Nutritional Intervention

In 1979, contrary to the commonly accepted prognostic criteria at the time Gurwitz et al suggested that nutritional factors may be as important as lung disease in the ultimate prognosis for CF (Gurwitz et al., 1979). In 1979 Kraemer et al demonstrated that relative underweight was most pronounced in children with pulmonary symptoms, the degree of underweight correlating inversely with survival (Kraemer et al., 1978). Later reports confirmed the influence of nutritional status on the course of pulmonary disease, (Luder et al., 1989a, Gaskin et al., 1990). A retrospective study in a Danish centre, designed to evaluate the impact of major changes in nutrition and in antimicrobial treatment over several decades, reported normal growth in CF subjects. This was achieved by an unrestricted diet and individual guidance on the addition of pancreatic enzymes (Nir et al., 1996).

In recent years the dietary management of CF has changed dramatically. Early advice suggested a low fat diet and this resulted in decline of subjects to such an extent that growth failure was said to be an inevitable consequence of the disease process. By the 1980’s it had become clear that growth failure was largely attributable to adherence to a low fat, low energy diet, prescribed to manage PI and subsequent steatorrhoea. A comparative study of two cystic fibrosis clinic populations of similar size and age distribution (Corey et al., 1988) found a
marked difference in median ages of survival, 21 years in Boston versus 30 years in Toronto. After the age of 10 years there was a dramatic difference in survival between the 2 centres. Pulmonary function was not different between the 2 clinic populations. Males and females attending the Toronto clinic were taller than those in the Boston clinic and the males in Toronto were heavier. The only main difference in the management between clinics was nutritional care. Superior nutritional status was suggested as the reason for the higher survival rate in the Toronto population. The approach the Boston clinic took included a low fat, high carbohydrate diet, the rationale being reduction in fat would improve bowel symptoms; this was similar practice to many other centres during this time. The Toronto clinic followed an aggressive nutritional policy advocating a high calorie/ high fat diet with additional and relatively high dose of pancreatic enzyme replacement to aid digestion. Although fat malabsorption occurred, with more effective and extra enzyme supplements, net absorbed energy increased and resulted in better growth. This landmark study changed the dietary management of CF throughout the world to a high fat diet with adequate pancreatic enzyme replacement therapy (PERT). Following this study, frequency, prevalence and mortality patterns of CF were analysed in 3,795 Canadian subjects, documented in the Canadian Patient Data Registry between 1970-1989 (Corey and Farewell, 1996). In Quebec, dramatically improved survival in the 1980’s coincided with a change from a restricted fat diet to a high fat diet. Improved survival in Ontario in the 1970’s accompanied this change in dietary therapy, which the author suggested may account for the good survival throughout the study period in Eastern Canada. The primary objective of nutritional management in adults is to achieve and maintain goal weight.

In most CF centres around the world, nutrition support is now viewed as an integral part of the multidisciplinary care of subjects and aggressive dietary programs have been instituted to prevent malnutrition (Littlewood and Taylor, 2002). Prognosis and BMI has been improved by subjects attending specialist centres (Mahadeva et al., 1998, British Paediatric Association, 1988, Collins et al., 1999). In a survey conducted by Walters et al., adults attending specialist centres who received more intensive care, had better symptom control and were more satisfied with the service provided, than those attending general clinics (Walters et al., 1994).

The importance of nutritional management has been emphasised in the UK by the CF Trust guidelines stipulating the requirement for a Specialist Dietitian as an essential part of the
multidisciplinary team (CF Trust, July 1996). The candidate was involved in the formulation of guidelines by the CF Trust Nutrition Working Party for the nutritional management of the patient with CF (Littlewood and Taylor, 2002).

**BMI** has been shown to be an important predictor of pre-transplant survival (Dosanjh, 2002) (Liou et al., 2001). Recent reports have indicated that depletion of lean body mass in subjects awaiting transplant is associated with a higher rate of mortality (Schwebel et al., 2000). In addition, there was an association between poor nutrition and poor surgical outcome (Nomori and Kobayashi, 1994). Several studies indicate it may be important to try to improve BMI prior to lung transplantation in order to improve survival (Nomori and Kobayashi, 1994, Sharples et al., 1993). One study reported subjects with a BMI less than 17Kg/m² had an increased risk of dying in the first 90 days following transplant surgery (Madill et al., 2001). Further studies are needed to examine fully the impact of pre transplant intervention on post transplant outcome in this population (Dosanjh, 2002).

In routine clinical practice, BMI is accepted as the most appropriate global marker of nutritional status in adults; however, BMI does not provide any information about body composition and does not detect subtle alterations in body composition. A major consequence of malnutrition in CF subjects is loss of lean body mass (LBM) or fat free mass (FFM) and subsequent impairment of respiratory muscle function (Sermet-Gaudelus et al., 2003). Recent studies have shown a significant proportion of adults with CF have low percentage fat free mass (FFM) (Ionescu et al., 2000). This is important, as it has been suggested that depletion of FFM is associated with more severe CF lung disease (Ionescu et al., 2002). McNaughton (2000) highlighted the importance of measurement of body composition in children, finding that weight based indicators of nutritional status may underestimate the prevalence of malnutrition in children with CF compared with those derived from direct measures of LBM, such as using total body potassium.

The use of a reliable and accurate method for measuring body composition is important both for assessing nutritional status and effectively evaluating the impact of nutritional interventions in CF. Various methods are available for the determination of body composition. Methods include Dual Energy X-ray Absorptiometry (DEXA), Bioelectrical Impedance Analysis (BIA), anthropometric measures, and Total Body Potassium. There are few studies in adults comparing the different methods of measuring body composition. There
are limitations with the above-mentioned methods such that routine body composition measurement is not practical and is confined to research centres with the necessary equipment at the present time.

BIA and anthropometric indices are quick and relatively simple to perform in most settings (King et al., 2005), however the limitations of these measurements are that they rely on prediction equations which were developed using data from healthy individuals, thus estimates of body composition in CF subjects using these equations may not necessarily be accurate. Several authors conclude that disease specific equations need to be developed in order for BIA to be a useful tool for assessing body composition in CF and that at present, it is not acceptable (Azcue et al., 1993 Pichard, 1999). Skin fold thickness measurements are usually taken from 4 body sites; consequently, results will be influenced by body fat distribution. Skin fold thickness may therefore underestimate % body fat in very lean CF subjects (Gray et al., 1990). Recent work in adults with CF suggests skinfold thickness and BIA have limited application in CF, as they incorrectly estimate fat free mass compared to DEXA (King et al., 2005).

The use of DEXA for assessment of bone mineral density in clinical management has increased over the last 3 or 4 years, following the discovery of low bone mineral density in CF subjects (Haworth et al., 1999). The radiation dose provided by DEXA is considered low enough to be safe for both single and repeated measures to be taken (Laskey, 1996). DEXA is increasingly being used to measure body composition in CF (Haslam et al., 2001, Ionescu et al., 2000, Ionescu et al., 2002, Salamoni et al., 1996). The advantages of DEXA include safety and high precision. The whole body is scanned, therefore avoiding inaccurate measurement due to differences in distribution of body fat. Limitations include the expense and non-transportable nature of the equipment. The procedure necessitates the patient to lie still for 15-40 minutes, which may prove difficult for some subjects with a chronic cough.

Ideally measures of body composition need to be used in conjunction with simple height and weight measures to correctly identify subjects who are malnourished and require nutritional intervention. As yet no one, simple, inexpensive, reliable and valid test is available that can be used universally in a clinical and research setting with children and adults with CF. However, two recent studies involving 33 and 50 subjects respectively suggested a simple calculation of BMI, an easy, quick, safe and low cost method that should remain the gold
standard approach to estimate and track nutritional status in adults and children with CF (Hollander et al., 2005, Pedreira et al., 2005).

1.3 The Aetiology of undernutrition

The aetiology of undernutrition is complex and interrelated. Anthony (1999) Suggested organic, psychosocial, environmental and behavioural factors affect dietary intake and growth in CF, as shown in figure 1-1.
1.1 Organic Causes

- Pancreatic Dysfunction, Malabsorption
- Concurrent diseases
  - Hepatobiliary
  - Diabetes
  - Osteoporosis

Non Organic/ Psychosocial Causes

- PATIENT FACTORS
  - Poor appetite
  - Poor disease related knowledge of diet/treatment
  - Poor diet

- BODY IMAGE FACTORS
  - Psychosocial
    - Desire to be thin
    - Eating disorders

Increased energy requirements

Inadequate dietary energy intake

- Impaired immunity
- Increased susceptibility to infection
- Increased frequency and duration of pulmonary exacerbations
- Increased respiratory effort

- Poor growth
- Weight loss
- Delayed pubertal development
- Decrease in total body nitrogen
- Decrease in muscle mass
- Decline in nutritional status

Terminal phase of the disease - severe pulmonary dysfunction and malnutrition
1.4 Organic Causes - Pathogenesis of energy imbalance

A state of negative energy balance may exist in CF for a number of reasons. Many subjects find it difficult to maintain an adequate energy intake because of anorexia associated with the presence of infection. It is now recognized that growth retardation in CF subjects is due to unfavourable energy balance as opposed to being an inherent factor of the disease itself. The pathogenesis of energy imbalance is complex and Pencharz (1983) suggested it is determined by three factors: energy losses, energy expenditure and energy intake. See figure 1-2. Durie and Pencharz (1992) proposed this model to explain the aetiology of the energy deficit in the CF patient, which helps to explain the complex set of interdependent variables contributing to chronic malnutrition and growth failure in CF.
Figure 1-2 The aetiology of the energy deficit in CF, adapted from Durie and Pencharz (1992).
1.4.1 Energy expenditure

There is reasonable agreement that there is an increased energy need in subjects with CF compared to the normal population. There have been many studies focusing on Resting Energy Expenditure (REE) and Total Energy Expenditure (TEE). A summary flowchart is provided (see Figure 1-3).

**Figure 1-3 Resting Energy Expenditure and Total Energy Expenditure in CF**

```
Total Energy Expenditure (TEE)

Resting Energy Expenditure (REE)

REE raised in many studies, WHY?

Is it Genotype? Is it Infection?

STUDIES
Problematic:
- Small numbers
- Different age groups
- Not longitudinal
- Some not controlled for: Lung function Genotype

SUMMARY
As Pulmonary function decreases, REE increases

TEE = REE + Activity + Diet induced Thermogenesis

Is TEE consistently raised?

MAYBE? IF SO WHY?

Limited physical activity? Poor appetite?

Methodological problems in Measurement Different age groups studied
```
1.4.1.1 **Resting Energy Expenditure**

A number of studies have focused on energy expenditure in CF subjects. Measurement of energy expenditure by open-circuit indirect calorimetry convincingly shows that Resting Energy Expenditure (REE) is 10-20% higher in CF subjects compared with controls of the same age and sex in both children and adolescents (Vaisman et al., 1987, Buchdahl et al., 1988, Stallings, 2005).

Resting energy expenditure (REE) in subjects with CF has been shown in several studies to exceed predicted values. The increase in REE in children and adults correlates well with deterioration in lung function and decline in nutritional status (Vaisman et al., 1987, Fried et al., 1991). This indicates that the increased energy expenditure of breathing as lung function declines leads to increased energy requirements. Clinically it is considered subjects require 120–150% of normal energy requirements on a daily basis.

**Is genotype a factor in the aetiology of increased resting energy expenditure?**

Controversy still exists over whether genotype has an influence on REE. O'Rawe et al showed a significant contribution to resting metabolic rate in 78 CF children associated with specific mutations that is not explained by declining pulmonary function (O'Rawe et al., 1992). Thomson et al reported that genotypic variations in energy balance are detectable early in the course of CF and are unrelated to lung inflammation (Thomson et al., 1996). However the limiting factors in this study were: very small sample size (n=18), all infants were under 2 years and pre-symptomatic and, in addition, nutritional status and lung function were not controlled for. This is relevant given the evidence that lung function and nutritional status have an effect on REE. In addition one study has suggested caution when interpreting results of measurement of REE in infants, as the level of arousal in the infant can have an impact on the level of basal metabolic rate (Bines and Truby, 2004). More recent studies have shown when these factors are controlled for there is no significant difference in REE with different genotypes in infants and children (Spicher et al., 1991, Tomezsko et al., 1994, Zemel et al., 1996).

The majority of the work investigating the causes of increased energy expenditure in CF has involved infants and children, due to the fact that the disease has primarily been a disease of childhood. With advances in treatment more patients are now surviving into adulthood and further work is required to examine the relationship between lung disease and its
inflammatory processes and energy expenditure in adults with CF. In summary, the contribution of a genetic component to hypermetabolism in CF remains unclear but end stage respiratory failure is usually associated with under nutrition suggesting that as lung function declines meeting energy requirements is more of a challenge in both children and adults with CF.
Pencharz suggested there is not a primary defect in energy metabolism in infants with CF. It is not until the lung function falls below FEV1 less than 85% predicted that REE increases (Pencharz and Jackson, 2002). These findings were further supported in a recent study which showed infants with CF and normal lung function did not have elevated energy expenditure compared to healthy controls (Bines et al., 2002). Decreased weight gain in CF infants was not because of any defect in energy expenditure or in dietary intake, but was attributed to the maldigestion/malabsorption in the infant with untreated pancreatic insufficiency.

Work recently carried out in Australia showed children with CF had raised REE, the increase being greater in females than males. PI, severe mutations and the female sex were shown to be the main contributing factors to elevated REE in subjects with CF with near normal pulmonary function. The authors suggested that the increased energy expenditure in females with CF might explain their difficulty in maintaining normal growth and contribute to their shorter life expectancy (Allen et al., 2003).

A recent study from Norway illustrated a close correlation between lung damage and increased caloric requirements (elevated REE) reflecting the complex interaction between lung inflammation, bacterial infection, malnutrition and possibly the nature of the mutation in a vicious circle in CF subjects (Dorlochter et al., 2002).

Frequent pulmonary infections play an important role in the deterioration of lung function. The anorexia associated with infection and the energy and protein losses via increased sputum production affect nutritional intake and status (Anthony et al., 1999). Infection has been shown to increase REE (Thomson et al., 1996) and have an adverse effect on protein turnover (Shepherd et al., 1988). Antibiotic therapy has been shown to improve acute inflammation and respiratory function in several reports (Castro et al., 2002), but the effect antibiotic therapy has on REE is controversial, mainly dependent on the way in which REE is calculated. In this study 17 subjects, mean age 13.6 years were hospitalised during a chest infection and anthropometry, body composition (bioelectrical impedance), spirometry and indirect calorimetry data collected at the beginning and end of therapy. In CF subjects with infective exacerbations, a course of antibiotics reduced REE expressed in terms of Kcal/Kg fat free mass/day only marginally, whereas REE expressed as a % of predicted values decreased significantly. Variables measured to assess individual’s nutritional status slightly improved by the end of antibiotic therapy. The authors suggested infective exacerbations are among the causes of increased REE in CF. These findings mirror those of Stallings (1998)
who found a significant increase in REE in an acute exacerbation expressed as % predicted, but no significant difference in REE normalised for differences in fat free mass. Two earlier studies showed a significant decrease in REE expressed either way, by the end of an antibiotic course (Steinkamp et al., 1993, Naon et al., 1993). A more recent study showed an improved nutritional status following IV antibiotic therapy, in 16 subjects. The authors suggested this was attributable to an increase in energy intake and a decrease in REE after the antibiotics, rather than a decrease in TEE. They hypothesised the reduction in REE was probably compensated for by an increase in physical activity (Beghin et al., 2003).

There is clear evidence that as lung function deteriorates there is a curvilinear increase in resting metabolic rate (Fried et al., 1991). This study reported a curvilinear increase in REE with an FEV1 less than 85% predicted.

The exact cause of an increase in REE in CF subjects remains unclear, and as yet unproven. It appears to be more closely associated with pulmonary function and infection than genotype. Work carried out in Toronto suggested that the increase in REE with a fall in lung function is likely to be because of the effects of increased cytokines secondary to worsening infection (Pencharz and Durie, 1993). Even when REE is increased, it is only of practical significance if TEE is increased.

1.4.1.2 Total Energy Expenditure

Total Energy Expenditure (TEE) is the sum of resting energy expenditure (50-60%) activity induced energy expenditure (30-40%) and diet induced thermogenesis (Turcic and Michaud, 1998). An increase in REE does not necessarily imply an increase in TEE, because the latter also includes the physical cost of exercise. TEE may be raised in CF, although controversy exists with regard to the factors responsible and whether an increase in TEE is a consistent observation. There are now two published studies, in which data suggest TEE, measured using the doubly labelled water method is not raised in pre-symptomatic infants with CF (Bronstein et al., 1995), or in subjects 8–24 years with mild lung disease (Spicher et al., 1991). The latter study assessed REE with open circuit indirect calorimetry and TEE by the heart rate method. Spicher studied 13 subjects and concluded that in free-living conditions, CF subjects can compensate for their increase in REE by a reduction in spontaneous physical activities or other yet undefined mechanisms. More recently McCloskey et al showed in
young adults with moderately severe respiratory disease TEE is maintained or decreased during an exacerbation despite an increase in REE when they are treated in hospital but energy intake is maintained, the limitations of this study being the small cohort (n =11) (McCloskey et al., 2004). Shepherd in 1988 found a 25% increase in TEE in children by using the doubly labelled water technique (Shepherd et al., 1988). A later longitudinal study however found only significantly higher REE in babies less than 3 months (Wainwright, 1996). These findings have not been replicated by other researchers, who report non-significant differences in resting and total energy expenditure in infants with mild disease (Bines et al., 2002).

A recent study investigating longitudinal measurement of TEE using the doubly labelled water method in 12 pre-symptomatic infants with CF at specified ages, showed that infants have increased energy requirements by 6 months of age (Davies et al., 2002). Tomezsko measured TEE in 19 children and 25 controls and showed TEE was 15-20% higher for body weight in the CF subjects. This observation could however be interpreted as the result of relatively unrestricted physical activity in a group of well CF children (Tomezsko et al., 1994).

It has been suggested that the energy cost of physical activity is lower in CF subjects with normal lung function (Johnson et al., 2006). Another study demonstrated a decrease in the energy cost of physical activity after intravenous antibiotic therapy in standardised conditions, the authors suggest this is probably due to the decreased energy cost of breathing (Beghin et al., 2005).

A review of energy balance in CF (Reilly et al., 1997) suggested it may be relevant to consider other research on energy balance in disease states where recurrent infections are a feature, for example HIV infection. Studies in adults with HIV have established the main cause of muscle wasting is reduced energy intake as a consequence of the profound anorectic effect of frequent infective episodes (Macallan et al., 1995). TEE is unusually low in subjects with the most pronounced wasting, caused primarily by limited physical activity. TEE is highest in subjects who maintain their weight. This may in part reflect a positive association between activity and appetite (Macallan et al., 1995). Long et al (2002) suggested it is possible that the physical activity levels in the general population are able to influence appetite responses. Appetite responses are dependent to some extent upon previous energy intake and are sensitive to energy deficits induced through differences in intake.
There is good evidence that even if REE is raised due to infection/inflammation there is often a decline in the energy expended on physical activity because subjects are ill and hence have greatly reduced physical activity (Spicher et al., 1991, Johnson et al., 2006). The energy expended on physical activity is a quantitatively important and highly variable component of TEE. The reduction in activity may compensate for any increase in REE associated with acute respiratory infection. Methods of measuring energy expenditure make it difficult to discern whether a true deviation in energy expenditure occurs in all subjects with CF. Conflicting results of TEE studies may reflect a difference due to the marked different ages of populations studied.

To summarise, these studies emphasize the importance of individual longitudinal measurement of energy expenditure in CF subjects, in which all components of energy balance are measured, due to the unpredictable and variable nature of the disease. In order to determine if REE and TEE are consistently raised, a large longitudinal cohort study is required.

1.4.2 Energy losses

Malabsorption in CF occurs mainly as a result of maldigestion secondary to PI. PI occurs in 85-90% of CF subjects (Shwachman, 1975), and only 1-2% of total pancreatic capacity for secreting enzymes is required to prevent maldigestion (Durie and Pencharz, 1992). Without pancreatic enzyme replacement therapy, up to 80% of fat can be recovered in stools because of lipase deficiency. Carbohydrate digestion tends to be normal as salivary amylase compensates for pancreatic amylase deficiency. Decreased bicarbonate and bile acid secretion further impairs digestion and absorption; duodenal pH is abnormally low due to inadequate neutralization of gastric hyperacidity by bicarbonate (Turck and Michaud, 1998).

Despite recent advances in the effectiveness of pancreatic enzyme preparations and increased awareness of education about dose adjustment according to the fat content of food (Basketter et al., 2000, Stapleton et al., 2000), excess losses still occur. Murphy estimated that stool energy losses accounted for 10 - 15% of gross energy intake in CF subjects; three times higher than expected in normal healthy subjects (Murphy et al., 1991). Other factors including liver disease, with inadequate bile salt secretion, mucosal absorptive abnormalities,
diabetes if inadequately controlled leading to glycosuria, and abnormal bile salt metabolism may also contribute to energy losses.

### 1.4.3 Energy Intake

Energy intakes of 120-150% of the recommended daily allowance for normal individuals have been recommended for CF subjects (Dodge, 1988).

Factors that may affect oral intake include appetite, gastro-oesophageal reflux, chronic constipation and advanced lung disease, which can cause excessive coughing, vomiting and anorexia. Recurrent lung exacerbations often lead to reduced appetite, which can contribute to anorexia. Behavioural and psychological difficulties associated with eating have also been shown to impact on energy intake (Stark et al., 1997).

Although little has been published on the dietary intakes of CF adults and adolescents, a recent study showed mean energy and protein intakes for subjects on diet alone, (not receiving artificial enteral feeding) failed to meet the recommended levels (White et al., 2004). Most studies indicate children and young adults with CF do not meet their recommended energy requirements (Buchdahl et al., 1989, Luder et al., 1989b, Costantini et al., 1988, MacDonald et al., 1988, Daniels et al., 1987, Bell et al., 1984, Hubbard and Mangrum, 1982; Powers, 2003; Stark, 2005; Tomezsko, 1992,(Walkowiak and Przyslawski, 2003; Bowen, 1991; Kawchak, 1996). Research suggests that this is primarily due to non-adherence with dietary recommendations. This is not necessarily deliberate but due to lack of understanding of the complex diet that is required (Passero et al., 1981, Bell et al., 1984, Gudas et al., 1991). It has been reported that parents of children with CF find coping with the diet one of the most stressful parts of the treatment regimen. This is probably due to the high levels of knowledge and skills required to integrate a special diet into the family's eating habits.

Current evidence suggests that chronic sub-optimal energy intake is common in children with CF and may get worse as the disease progresses (Reilly et al., 1997). Adults with respiratory exacerbation often suffer negative energy balance and consequent deterioration in nutritional status largely as a result of compromised energy intake during the period of infection. Reilly suggested that short periods of very low energy intake, superimposed on prolonged poor food intake, might be the main reason why malnutrition develops in this population. Sub-optimal
energy intake is likely to make a major contribution to growth failure and malnutrition in CF (Reilly et al., 1997).

This suggests nutritional interventions should aim to improve energy intake between acute episodes of infection and in particular following a pulmonary exacerbation. Table 1-1 summarises the main energy intake studies in the last 25 years.
<table>
<thead>
<tr>
<th>Author</th>
<th>Date</th>
<th>N</th>
<th>Age range</th>
<th>Energy intake</th>
</tr>
</thead>
<tbody>
<tr>
<td>White et al</td>
<td>2004</td>
<td>94</td>
<td>17-30 years</td>
<td>117% EAR  Only 40% subjects 120% EAR</td>
</tr>
<tr>
<td>Powers et al</td>
<td>2003</td>
<td>35 CF 35 control</td>
<td>7-36 months</td>
<td>Infants CF (6m-1yr) 103% RDA Infants control 82% RDA Toddlers CF (1-3 yrs) 89% RDA Toddlers control 83% RDA</td>
</tr>
<tr>
<td>Kawachak et al</td>
<td>1996</td>
<td>25 CF 25 control</td>
<td>6-13 yrs</td>
<td>100-107% RDA - age 108-122% RDA – weight</td>
</tr>
<tr>
<td>Stark et al</td>
<td>1995</td>
<td>32 CF 29 control</td>
<td>2-5 yrs</td>
<td>95% RDA – age</td>
</tr>
<tr>
<td>Morrison et al</td>
<td>1994</td>
<td>50</td>
<td>0.75-25 yrs</td>
<td>97% RDA</td>
</tr>
<tr>
<td>Ellis et al</td>
<td>1992</td>
<td>30 CF 30 control</td>
<td>5-17 yrs</td>
<td>CF 92% RDA Control 91% RDA</td>
</tr>
<tr>
<td>Tomezsko et al</td>
<td>1992</td>
<td>22 CF 23 control</td>
<td>5-10 yrs</td>
<td>CF 111% WHO-age, 106% RDA Control 97% WHO – age, 93% RDA</td>
</tr>
<tr>
<td>Buchdahl et al</td>
<td>1989</td>
<td>20</td>
<td>5-17 yrs</td>
<td>118% WHO – weight 99% WHO – median wt/age</td>
</tr>
<tr>
<td>Luder et al</td>
<td>1989</td>
<td>37</td>
<td>2-27 yrs</td>
<td>94% RDA – age</td>
</tr>
<tr>
<td>Constantini et al</td>
<td>1988</td>
<td>73</td>
<td>3-24 yrs</td>
<td>44 % &lt;= 95% RDA - age 56% &gt;= 95% RDA – age</td>
</tr>
<tr>
<td>McDonald et al</td>
<td>1988</td>
<td>90</td>
<td>3-25 yrs</td>
<td>95-119% RDA – age</td>
</tr>
<tr>
<td>Kindstedr et al</td>
<td>1988</td>
<td>35</td>
<td>1-65 yrs</td>
<td>7-10 yrs 75% RDA - age 11-14 yrs 106% RDA – age</td>
</tr>
<tr>
<td>Daniels et al</td>
<td>1987</td>
<td>36 CF 57 control</td>
<td>0.7 – 1.2 yrs</td>
<td>CF &lt; 5 yrs 119% RDA – age Control 82% CF 5-12 yrs 108% RDA – age Control 96%</td>
</tr>
<tr>
<td>Bell et al</td>
<td>1984</td>
<td>15</td>
<td>10-17 yrs</td>
<td>112% WHO – weight</td>
</tr>
<tr>
<td>Hubbard et al</td>
<td>1982</td>
<td>33</td>
<td>3-50 yrs</td>
<td>49% &lt;100% RDA – age 45% &gt;100-150% RDA – age 6% &gt; 150% RDA – age</td>
</tr>
<tr>
<td>Bell et al</td>
<td>1981</td>
<td>23</td>
<td>Adolescent, female</td>
<td>103% WHO – weight 93% WHO- ideal body weight</td>
</tr>
</tbody>
</table>

**Key:**

- **EAR:** UK Estimated Average Requirements (Department of Health, 1991)
- **RDA:** UK Recommended Daily Amounts (Department of Health, 1979)
- **WHO:** World Health Organisation recommendations (WHO et al., 1985)
1.5 Concurrent Diseases

1.5.1 Hepatobiliary Disease.

There is evidence to suggest the prevalence of liver disease increases with age in CF, with a rising prevalence up to the age of 20 years (Colombo et al., 1996). Liver cirrhosis occurs in association with portal hypertension and oesophageal varices in 2-5% of adult subjects (Sokol and Durie, 1999).

There is no treatment to date that has been shown to either prevent or modify the chronic biliary liver disease of CF and the emphasis of management has been directed towards treating complications.

At present there is no proven therapy for liver disease in CF. Ursodeoxycholic acid is the first drug which shows potential as treatment for the underlying liver disease, and has been shown to be beneficial for some subjects (Colombo et al., 1996), but there is no evidence to suggest it will halt the progression of liver disease. Appetite and oral intake may be reduced in subjects with liver disease; in addition, advanced liver disease with multifocal biliary cirrhosis may result in inadequate bile salt secretion resulting in severe fat malabsorption.

Liver transplantation may be an appropriate option if subjects have relatively well-preserved lung function. Following transplantation there is usually an improvement in nutritional status and lung function (Noble-Jamieson et al., 1996).

1.5.2 Diabetes

Cystic fibrosis related diabetes (CFRD) is becoming increasingly common, as the median age of survival of subjects with CF continues to rise (Lanng et al., 1995) and is predominantly a disease of adolescents and young adults, and the prevalence increases with age. Subjects with CFRD present at a mean age of 20 years (Lanng et al., 1995, Finkelstein et al., 1988). Undiagnosed CFRD may present with recent significant weight loss as a consequence of glycosuria. CFRD shares features of both type 1 and type 2 diabetes, but is a distinct clinical entity. There are many factors unique to CF that influence glucose metabolism including: increased energy expenditure, malabsorption, glucagon deficiency, undernutrition, liver dysfunction, acute and chronic infection and abnormal intestinal transit time (Hardin and Moran, 1999). The primary aim for nutritional management is to maintain normal nutritional status in those developing CFRD (Wilson et al., 2000). The dietary strategy aims to
normalise blood glucose levels and to protect from future microvascular complications. Cases of diabetic microvascular complications have emerged in recent years, (Dolan, 1986, Lanng et al., 1994, Hardin and Moran, 1999), although macrovascular complications remain uncommon. A balance in dietary management between stabilization of blood glucose concentration and maintenance of a high-energy intake is needed. Conflicts between dietary therapy of CF and diabetes should always be resolved in favour of the CF diet. The majority of subjects with CFRD are treated with insulin. Dietary restriction should be minimised and restriction of simple carbohydrate, and hence calories, is not an appropriate method of glycemic control.

1.5.3 Osteoporosis

As a consequence of increased survival in CF, new complications of the disease are emerging. Cross-sectional studies have shown that Bone Mineral Density (BMD) is reduced in adults with CF (Aris et al., 1998, Haworth et al., 1999, Elkin et al., 2001). This population have an increased rate of fracture compared to the general population (Elkin et al., 2001, Aris et al., 1998). Low BMD results from reduced bone development in childhood and an accelerated rate of bone loss in adolescence. There are numerous risk factors for the development of low bone mineral density including malnutrition, calcium and vitamin D malabsorption, diabetes, oral corticosteriod use and decreased physical activity. The strongest and most consistent correlate of BMD is severity of respiratory disease, (Elkin et al., 2001, Conway et al., 2000, Haworth et al., 1999).

1.6 Non-organic causes of undernutrition

In addition to the energy imbalance evident in CF, there are many other factors that may contribute to a poor nutritional status.

1.6.1 Poor Appetite

A poor appetite is a common feature for many CF subjects, particularly associated with pulmonary infection. Anecdotally, subjects can often identify the start of a chest infection by a sudden and dramatic loss in appetite. Vomiting, excessive coughing and expectoration of a large volume of sputum may all contribute to a reduction in appetite. The loss of appetite in
these subjects tends to follow a pattern, decreasing prior to and during a chest infection and a subsequent improvement once the infection is treated and the patient shows clinical improvement. In clinical practice appetite is difficult to measure and quantify and there is little work specifically exploring appetite regulation in CF. One of the roles of the dietitian in the CF clinic is to offer advice and counselling to try and improve appetite.

Poor appetite can also result as a consequence of Distal Intestinal Obstructive Syndrome (DIOS). Sometimes known as meconium ileus equivalent, this is a relatively common gastrointestinal complication of CF. The term encompasses a range of clinical conditions varying from partial to complete intestinal obstruction. It is reported to occur in between 10 – 47% of subjects, (Rosenstein and Longbaum, 1983) and is more common over 15 years of age (Andersen et al., 1990). Disordered intestinal motility may also contribute to the occurrence of DIOS. Presentation is highly variable ranging from recurrent cramping abdominal pain to complete intestinal obstruction, with abdominal distension, tenderness and vomiting (Kopelman, 1991); the exact causes are unknown, although predisposing factors may include inadequate pancreatic enzyme dose, dehydration (Hodson et al., 1976), lack of dietary fibre, opioid addiction and anti-cholinergic drugs (Koletzko et al., 1989). Symptoms usually respond to medical management and surgical intervention is rarely necessary (Kopelman, 1991). A full dietetic review of patient’s pancreatic enzyme dose and compliance, fibre and fluid intake is appropriate following an episode, to try to minimise the recurrence of DIOS.

In addition to the problems with appetite, the high fat, high calorie diet advocated for subjects with CF is opposed to the general healthy eating principles guiding the rest of the UK population (Health Education Authority, in partnership with the Department of Health and the Ministry of Agriculture, 1996). For many people with CF, with reduced desire to eat, several factors make food selection a complicated and difficult process. These include the plethora of low fat, low calorie foods available in supermarkets, the complexity of food labelling, cost and the mixed media messages focusing on food, nutrition and “healthy eating”.

1.6.2 Disease related knowledge

Disease related nutritional knowledge in children and their families with CF has been shown to be poor in a number of studies, with gaps in knowledge and misconceptions apparent
(Geiss et al., 1992, Boyle et al., 1976, Tropauer et al., 1970, Strauss and Wellisch, 1981, Savage and Callery, 2005). For families to successfully manage a chronic illness requires a high level of compliance with therapy and studies suggest good factual knowledge can contribute to improved compliance (Meyers et al., 1975).

Several studies have reported general knowledge to be satisfactory in CF subjects, but these results should be interpreted with caution as they are based mainly on impressions and do not look at specific aspects of the disease (Tropauer et al., 1970, Strauss and Wellisch, 1981, Boyle et al., 1976).

Early work conducted in America by Bell (1984) revealed lack of basic nutrition knowledge in 31 females with CF. They reported interesting misconceptions about the energy content of food. When interviewed, 80% of subjects considered they were not following a special diet. Bartholomew (Bartholomew et al., 1993b) confirmed subjects confusion over dietary regimens, with less than 20% of subjects questioned about knowledge of CF mentioning diet as a part of treatment.

Further work has confirmed gaps in basic nutrition knowledge in CF subjects. Two studies looking specifically at nutrition knowledge in children and adults with CF highlighted major gaps in knowledge of diet and enzyme application. McCabe surveyed 21 children and showed almost half were unaware that nuts contained fats but thought Coca-Cola contained fat (McCabe, 1996). A study undertaken at Papworth Hospital Adult CF centre, showed 37% of subjects made no variation in enzyme dosage with meals of differing fat content, because they were unaware they needed to do so (Basketter et al., 2000). Similar gaps in knowledge were supported in the results of an Australian study in children with CF and their adult carers (Stapleton et al., 2000).

A cross-sectional survey was conducted among 60 families with a child with CF to assess their medical knowledge of the illness. It showed subjects and families were less well informed about respiratory symptoms and nutrition than about general CF facts, physiotherapy and gastroenterology symptoms and treatment. Many subjects did not know that pancreatic enzymes were necessary with all meals and snacks and that the dosage was linked to the amount of fat in the meal. Twenty five percent of subjects thought, if eaten regularly, an apple rather than a slice of fruitcake would result in greater weight gain. Ninety percent of subjects, 80% of siblings and 50% of parents believed fats should be totally excluded from the CF diet. The authors suggested if left uncorrected the misconceptions,
gaps and errors identified in family members knowledge of CF could result in inadvertent non-compliance in treatment of the patient (Henley and Hill, 1990). Later work by Conway et al (Conway et al., 1996) confirmed important gaps in the knowledge subjects with CF have about their illness persist into adult life. The author hypothesized adult subjects may still have significant gaps in their knowledge due to parents and professional caregivers neglecting to appropriately upgrade the information given to the younger patient. Greater knowledge about their illness is essential for the independence and sense of control that must accompany the patient’s graduation into adult life. Conway suggests health professionals need to appraise the patient’s state of knowledge to enable appropriate education delivery and correct any misconceptions (Conway et al., 1996).

Increasing survival rates in CF have changed the boundaries of care from that of an exclusive childhood illness to one that affects children and adults. The transition from childhood to adult life is a time of major psychological and physical change. It is also a critical time for forging new relationships, developing self-identity and becoming comfortable with body changes. This can be difficult enough for the general teenage population but is magnified by chronic ill health.

Transition from a paediatric to an adult centre is a crucial time for both parent and patient. Transition usually takes place around 16 years of age; hence the age of patients treated in most adult centres ranges from 16 up to mid 50’s. The adult clinics are composed of adolescent and adult patients, but for simplicity, will be referred to as “adult clinics” throughout this thesis. The aim during the transitional period from paediatric to adult care is to ensure a transfer of responsibility for decisions surrounding the care and essential knowledge from parent to patient. Nolan (1986) reported children with CF relied heavily on their parents for information about CF. This highlights the importance of the transition phase for successful transfer of knowledge. In the adult centre, subjects can be encouraged to take on more responsibilities, taking more decisions for their own care and accepting the consequences of these actions (Conway, 1998).

We assume subjects transferring to an adult centre have good understanding of the basic nutrition facts, following previous contact with a dietitian, in the paediatric setting. This is often not the case; lack of knowledge, gaps and misconceptions have been demonstrated in this patient group (Henley and Hill, 1990). The amount of time available to provide these
basic facts in a clinic environment, in addition to tailoring a specific treatment plan is limited. For these reasons, a resource that incorporates the basic nutrition facts would be a valuable education tool for this patient group at this particularly vulnerable time, which is immediately on entry to an adult care setting.

1.7 Efficacy of nutritional intervention in CF

Historically, treatment targeting nutritional status has been conducted using standard dietetic practice of one-to-one nutritional counselling, oral nutritional supplements and medical interventions including enteral and parenteral feeding. Several studies have shown supplemental enteral feeding results in positive changes in body composition and growth velocity and increases the patient’s ability to participate in activities of daily living (Levy et al., 1985).

Other benefits of enteral feeding include improvements in body fat, lean body mass, muscle mass, height and improved muscle strength (Levy et al., 1986). Brief periods of energy supplementation in chronically malnourished subjects have transient effects (Shepherd et al., 1986). It is evident that long-term approaches to artificial supplemental feeding may achieve and maintain normal nutrition in subjects who are unable to meet their energy needs. To produce lasting benefit, many studies have shown enteral feeding should be continued long term to achieve significant improvement in catch up growth, lung function and positive changes in body composition (Steinkamp and von der Hardt, 1994, Boland et al., 1986). Although catch up growth is not relevant in an older population, positive changes in body composition are crucial such as maintaining lean body mass as these are linked to improved outcomes and life expectancy.

Parenteral nutrition is an option for short-term maintenance of nutrition after surgery. Several studies have shown a clinical improvement in nutritional status (and lung function) with supplementary parenteral feeding (Shepherd et al., 1980, Lester et al., 1986). Shepherd et al administered parenteral nutrition providing 90-100% of recommended daily allowance and permitted oral food intake, providing over 130% of recommended daily allowance for 3 weeks. The study demonstrated weight gain and improved respiratory function at 6 months. However, the numbers were small and these results have not been confirmed in other studies. Although parenteral feeding may be successful as short-term treatment, it has few real benefits over enteral nutrition. The cost, risk of complications and complexity of
administering it means it is not a routine therapy for subjects with CF (Littlewood and Taylor, 2002).

The invasive nature of both enteral and parenteral feeding means it is not a practical first line intervention. The provision of oral protein calorie supplements is one of a number of interventions used to improve nutritional status and precede the use of enteral feeding. The use of oral nutritional supplements is less invasive than artificial feeding but little work has been undertaken to investigate the effectiveness of these supplements in cystic fibrosis. One study has shown that dietary supplements are difficult for subjects to comply with on a day to day basis and have an unpleasant flavour (Yassa et al., 1978). A Cochrane Systematic review was designed to examine the evidence that in children with chronic diseases, oral protein calorie supplements alter daily nutritional intake, nutritional indices, survival and quality of life and are associated with adverse effects, e.g. Diarrhoea, vomiting, reduced appetite. The reviewers concluded that only a small number of trials assessing these products in children with CF have been conducted. The authors were unable to draw any firm conclusions based on the limited data. Two trials with only 13 subjects in total were identified as producing data of limited value. In these trials, few statistical differences could be found between treatment and control groups, apart from a change in total fat intake at 3 months. The authors recommended a series of large randomised controlled trials (RCT) to investigate the use of these products (Poustie et al., 2000). A multi-centre RCT of calorie supplements has recently been completed in 102 children (The CALICO Trial). This aimed to evaluate the use of calorie supplements in CF and to assess their benefits to nutritional status and growth. The findings of this study demonstrated that long term use of oral protein energy supplements did not result in an improvement in nutritional status or other clinical outcomes in children with CF. The authors suggested oral protein energy supplements should not be regarded as an essential part of the management of this group of children (Poustie et al., 2006). An intervention which is equally as effective but is less invasive or unpleasant that could be implemented early on in the course of the disease would therefore have significant implications for the nutritional treatment of these subjects.

1.8 Behavioural factors

The concept of a behavioural contribution to inadequate food and therefore energy intake in CF comes from a variety of sources. Recent studies have indicated behavioural factors, such
as parent and child behaviours during mealtimes, may contribute to the lack of compliance to dietary recommendations in young children with CF. Children with CF engage in behaviours incompatible with eating, i.e. eating slowly, talking instead of eating, feeling full early in the meal, complaining of abdominal pain (Stark et al., 1990). In a study by Crist et al, parents of children with CF reported multiple mealtime difficulties at a significantly higher rate than parents of healthy children, including dawdling and spitting out food (Crist et al., 1994). The parents who reported more problems had children with lower calorie intakes. In later work by Stark, children with CF were reported to take twice as long to eat a meal as their healthy peers (Stark et al., 1995). More recent work by the same group showed that although school age children with CF did not display higher frequency of behaviours incompatible with eating compared to those without CF, they were still not achieving the desired 120% of the recommended energy requirements (Stark et al., 2005). Quittner showed in 1991, the most frequently reported area of difficulty for parents of preschool children with CF was managing mealtime behaviour (Quittner et al., 1991).

A report investigating feeding disordered versus non-problem eaters, in the general paediatric population, indicated feeding disordered children engaged in higher levels of disruptive mealtime behaviour. This behaviour included food refusal, non-compliance, complaining, playing with food, oppositional behaviour and lower levels of chewing during mealtimes (Sanders et al., 1993). Clearly mealtimes are a difficult time for parents of children with CF because of the pressure to ensure their child receives adequate nutritional intake. Nutritional counselling alone may not be sufficient to promote optimal calorie intake because it addresses the problem of what to feed a patient with CF but does not tackle the issue of how to get subjects to consume more calories.

Adaptive eating behaviours are hypothesized to result in improved calorie intake and weight gain that would delay or possibly prevent the need for artificial feeding at a later stage of disease progression (Stark et al., 1996).

The majority of this work investigating feeding practices and behaviour has been conducted in children; there is no work of this nature with adolescents and adults. The importance of these findings however relates not only to mealtime behaviours during childhood, but continue throughout the patient’s life. The food behaviours and associations learned in childhood are manifest in the adolescent and adult clinics.
1.8.1 **Body image and Eating disorders**

There has been little work focusing on body image and the incidence of disordered eating in CF. Poor perception of body image has been reported to be related to poor self-esteem, depression and anxiety. Poor body image perception has the potential to influence the patient’s self-management, compliance and motivation, and perception of body image can be improved through psychological and educative interventions (Wenninger et al., 2003). Recent work from Germany involved the development of a diagnostic scale for body image measurement in CF (Wenninger et al., 2003).

The largest study to date in adults compared 221 male and female CF adults with 148 healthy male and female controls with regard to actual, perceived and desired body shape, BMI and body satisfaction, eating behaviours and attitudes. The authors reported control males accurately perceived their body shape/BMI and were content with it. CF males viewed their BMI as greater than it actually was and desired to be much heavier. Control females viewed their body shape/BMI as less than it actually was and desired to be even slimmer. CF females perceived BMI as less than it actually was but were happy with their perceived shape/weight. The authors concluded that more problems with food and eating behaviour were associated with less body satisfaction and reduced self-esteem (Abbott et al., 2000). The authors confirmed these findings in more recent work assessing the impact of gender, perceptions and disease severity on quality of life in CF (Gee et al., 2003).

In contrast, Walters et al (Walters, 2001) found young women with CF overestimated their weight, while men underestimated their weight, when compared with their actual body weight. This study concluded that perception of self as underweight was an important factor in determining nutritional behaviour and those who perceived themselves as underweight were more likely to be adherent to nutritional interventions.

Adolescents with chronic illnesses may be vulnerable to the development of eating disorders but few studies have focused on eating disorders in CF. The authors of a review of 13 cases of eating disorders in CF, while acknowledging their sample was too small to make clear conclusions, suggested that psychological and psychogenically induced eating disorders should be considered in the differential diagnosis of nutritional disorders in CF (Pumariega et al., 1986).
There is need for further research into body image, weight perception and eating behaviour in subjects with CF, in order to inform on appropriate education methods and strategies.

1.9 Behavioural intervention

The failure to maintain nutritional status by oral diet alone in many subjects with CF has led to the development of more invasive and complex methods of improving nutritional status such as enteral feeding. However, findings of a Meta analysis of nutrition intervention methods for weight gain in CF reveal behavioural intervention to be as effective in improving weight gain as more invasive methods. The authors concluded that there was a need for randomised clinical trials with specific behavioural interventions (Jelalian et al., 1998).

The most recent review of adherence in CF reported that behavioural techniques provide a practical way to increase adherence to CF treatment regimens. The authors suggest studies of selected behavioural techniques should include relatively large sample sizes, control groups, multiple assessment methods (e.g. self-report, parent-report, biological indices, physiological measurements), treatment integrity checks to ensure the behavioural technique is being used, and designated follow up periods. They concluded by suggesting interventions should be actively researched and that adherence to CF treatment recommendations is critical for longevity (Bernard and Cohen, 2004).

From the clinical dietitian's perspective, current nutritional management tends to follow the medical model of information gathering, advice and treatment given in a hospital setting (Littlewood and Taylor, 2002). Although standard dietetic care has resulted in improvements in nutritional status of subjects with CF (Mahadeva et al., 1998), many practitioners recognize that the hospital setting may not be the ideal location for learning to occur and that many subjects fail to adhere to the ideal dietary regimen (Anthony et al., 1998). The dietary intervention required for treatment of CF is complex. It requires the patient to have a high level of nutritional knowledge and, in addition, a range of skills to enable them to put knowledge into action within the home environment on a day-to-day basis. It is the acquisition of skills by subjects that is not readily achievable within the acute environment.
Theories of education and learning suggest that learning occurs in a social context and, in addition, that reinforcing behaviour change is very important. In order to develop effective methods of nutrition education, dietitians need to be aware of the evidence base of the effective elements of interventions.

Behaviourally focused nutrition education uses a set of learning experiences to facilitate the adoption of food and nutrition related behaviours that are conducive to health and well-being. The behaviours addressed are identified from the needs, perceptions, motivations and desires of the target audience. This evidence suggested that dietetic practice and hence efficacy could be enhanced by an alternative approach to nutrition education for subjects with chronic illness, such as CF.

Behavioural interventions have thus far only focussed on young children and adolescents. A review of the literature including Medline, Cinahl and the Cochrane database revealed no studies involving adults. To date, the work undertaken in children with CF has originated from the USA and Australia (Stapleton, 1998). These dietary intervention studies in young children using home based nutrition education have indicated that behavioural factors may contribute to lack of dietary adherence in CF (Sanders et al., 1997, Stark et al., 1995). However, the concept of home-based education for adults with CF has not been investigated.

These studies provide support for the efficacy of behavioural intervention combined with increasing nutritional knowledge in the treatment of malnutrition, but are limited by small sample size and lack of randomised control trials.

In 1992 the US Consensus Conference report on nutrition and CF advocated prevention and early intervention via nutritional education and behavioural intervention to promote optimal growth in all CF subjects (Ramsey et al., 1992).

Early behavioural interventions developed by Stark et al (Stark et al., 1996) reported encouraging results in small numbers of children. Teaching parents of children with CF behavioural child management strategies that specifically educated parents how to motivate their children to eat more food produced significant improvements in the children's oral intake post treatment compared to pre treatment. It is difficult to generalise from the results of Stark's work, due to small patient numbers, lack of control groups and the limited age groups studied (Stark et al., 1990, Stark et al., 1993, Stark et al., 1996).
Bell and colleagues followed on from their work on patient knowledge to evaluate the effects of a 5 week summer programme to develop appropriate attitudes and provide information about foods as a step in the process of modifying food choice behaviour. Despite the lack of objective measures of improvement, the evaluation suggested a behaviour modification programme could be a worthwhile motivating influence (Bell et al., 1984).

Over several years an American research team led by Bartholomew developed the Cystic Fibrosis Family Education Programme for children and their parents (Bartholomew et al., 1991, Bartholomew et al., 1997). The intervention was based on the Social Cognitive Theory (SCT) constructs of self-efficacy, outcome expectations, social reinforcement and behavioural capability (Parcel and Baranowskii, 1981). SCT intervention methods of goal setting, reinforcement, modelling, skill training and self monitoring were translated into specific strategies and organised into learning activities for parents and children. The programme was implemented as an integral part of medical care for 104 subjects in a CF centre, with 95 subjects from an alternative centre as controls. Participants benefited from the programme, showing improvements in knowledge of CF care, beliefs about their ability to perform self-management and self-management behaviours.

Thus it would appear that there is a gap between knowledge and behaviour about nutrition in CF. This was further highlighted whilst the candidate was part of the CF Trust Nutrition Working Group (Littlewood and Taylor, 2002), several issues were raised including the paucity of evidence for the use of nutritional supplements and invasive feeding techniques and the apparent gap between knowledge and behaviour.

1.10 Literature review and review of the models of health education and promotion.

To have a strong theoretical base and to achieve the overall aim of developing the home based nutritional programme for adults with CF in the UK, the first objective was to review the currently used models of health promotion and health education in order to establish which methods and strategies may be applicable to this particular target audience. This was completed using both electronic databases (Medline & Cinhahl) and the Cochrane Library. A review of the use of theory in major health education journals identified 51 theoretical
formulations discussed or applied in 116 theory-based articles (Glanz et al., 1997). The most frequently employed theories were Social Cognitive Theory (SCT) (23 articles), The Theory of Reasoned Action (19 articles) and the Health Belief Model (16 articles). A summary of the major models used in health promotion is provided in section 1.10.1.

1.10.1 Summary of the major models used in health promotion

1.10.1.1 Social Cognitive Theory
Social Cognitive Theory is concerned with the learning that occurs within a social context among humans. SCT explains human behaviour in terms of a continual reciprocal complex model in which personal factors and behaviour and environmental influences interact. Basic conceptualisations in SCT include the importance of reinforcement for behaviour, but they emphasize the role of personal expectations. This means what a person learns is a result of 3 things, the environment, the person’s cognitive process (what he or she expects to occur) and the actual behaviour of the person. Learning is therefore a dynamic, interrelated process where a change in one component may well initiate a change in another (Bandura, 1977a).

The general principles of SLT
1. People can learn by observing the behaviour and the outcomes of that behaviour in others.
2. An observable change in behaviour is not necessary for learning to occur
3. Reinforcement is valuable but may act less directly on the actual learning process and reinforcement may be direct, vicarious or self-managed
4. Cognitive processes are necessary for learning to occur (if people are to engage in a specific behaviour they must know what the behaviour is and how to perform it)

The other construct related to the cognitive component of this theory that has been widely received in health promotion is self-efficacy. (Bandura, 1977b) That is one’s situational perception of his or her ability to succeed or fail at a particular task (Self-efficacy).

1.10.1.2 The Theory of Reasoned Action and Theory of Planned Behaviour
The Theory of Reasoned Action and the Theory of Planned behaviour present frameworks to study attitudes towards behaviour rather than the behaviours themselves. According to the theory of reasoned action model, a person’s attitude toward a behaviour along with his or her beliefs about what significant others think the person should do and how important their
opinions are to him or her form the individuals intention to engage in a certain behaviour. This theory takes into account the influence other people have over someone’s behaviour.

The theory of planned behaviour takes the preceding model one step further. This theory acknowledges there are situations that may include a component not under voluntary control, such as an addiction. This model adds the construct of perceived behavioural control. This element is considered to be the result of past experience and anticipated problems that determine the persons perceived ease or difficulty of performing the behaviour, (Ajzen, 1977).

1.10.1.3 The Health Belief Model
The Health Belief Model is a very comprehensive model, which investigates components of behaviour not examined in any other model. The health belief model provides a unique perspective on the complexity of understanding behaviour and considers multiple social, ecological, and environmental factors that can influence behaviour. Basic precepts of the model are that first, people must believe they are susceptible to health problems and secondly that the problems have undesirable consequences. These constructs have to be formed before people will make the effort to change their behaviour. People must also believe the health problems can be prevented, delayed or minimized. In this model, health perception is the basis of all behaviour (Becker 1974).

While social cognitive theory and the health belief model remain prominent in health psychology and public health, the use of stages of change as a central concept of the Transtheoretical Model of Change (Prochaska et al., 1992) has also become widespread in recent years.

1.10.1.4 The Transtheoretical model of Change
The Transtheoretical Model of Change is a systematic integration of the heterogeneous field of psychotherapy. Using studies of people with addictive behaviour, researchers noted that people change, with and without assistance, but that, in all cases, people who change tend to move through a series of stages toward change before they actually do change behaviour. Central to the theory is that people can also regress into earlier stages and this model accepts that “relapse” is acceptable and can be part of the process of change. Prochaska’s version of the “stages of change” is as follows (Prochaska, 1991).
- Precontemplation
- Contemplation
- Preparation
- Action
- Maintenance

The authors of the review of theory in major health education journals previously mentioned (Glanz et al., 1997) suggested that not only did no single theory or model dominate the field but also that there had been relatively few publications which were methodologically vigorous with strong and explicit theoretical underpinnings other than in a few key settings such as schools and the workplace. In 1997 Glanz and Oldenburg (Glanz and Oldenburg, 1997) extended the review to include not only the use of theories in health promotion and health education, but also preventative medicine and health psychology. They illustrated that SCT and the Health Belief Model remained prominent and the use of the Stages of Change as a central concept of the Transtheoretical Model of change had become more widespread. SCT emphasizes the importance of observing and modelling the behaviours, attitudes and emotional reactions of others. It explains human behaviour in terms of continuous reciprocal interaction between cognitive, behavioural and environmental influences.

A Cochrane review identified a nutrition education research review entitled "The effectiveness of Nutrition education and implications for nutrition education policy, programs and research: a review of research" (Contento et al., 1995). The authors aimed to answer the question, "does nutrition education work and if so, what are the successful elements across interventions?" Their goal was to reveal the implications of the findings for nutrition education programme implementation, research and policy. This included 217 nutrition education intervention studies. The authors suggested nutrition education works in general and interventions that use educational methods directed at behavioural change as a goal were more effective than interventions that focused on dissemination of information with the assumption that such information will result in change in attitudes and behaviours.

The report suggested more effective programmes have the following characteristics:

- Take into account the motivations of particular population groups
• Involve self assessment and feedback  
• Require active participation  

The authors concluded successful programmes are those that are behaviourally focused and based on appropriate theory and prior research.

A review of trials in adolescent health promotion revealed that many published programmes had no theoretical base. These tended to be less successful, for example, a nutrition intervention programme in Greece for lower secondary schools (Hassapidou et al., 1997). This did not result in major changes in the dietary habits of children as it was purely education provision and had no skills improvement.

In a paper reviewing self-care practices in adolescence, it was shown that younger adolescents with a chronic illness demonstrate better self-care practices and better health than older adolescents. A variety of factors such as cognitive maturity, self-esteem, self-efficacy and perception of control over outcomes all seem to influence how adolescents implement self-care practices (Deatrick et al., 1998). Studies have shown adolescents who continue to rely on their parents to assist with illness related care evidenced better control of their illness (Ingersoll et al., 1986). Ingersoll (1986) also showed parental involvement often decreased as children reached adolescence and adherence also declined. This indicated that an important transition period occurs between childhood and adolescence when parents and their young adolescent must openly discuss their expectations and how assumptions of self-care practices related to their illness will evolve.

Studies have reported adolescents who improve their self-care behaviour also enhanced their physiological outcomes including respiratory function in adolescents with CF (Bartholomew et al., 1993b). This suggests that to be effective, interventions must specifically target self-care behaviours because knowledge and attitudes are not sufficient to produce behaviour change. Self-care is an important part of adolescents' development as they move toward greater independence and establish their identity.
In summary, the literature indicates a lack of studies exploring behavioural nutrition education programmes in adults with CF. In addition, to be effective, health education strategies should be based on an appropriate theory. A review of the theories used in health education showed that no single theory dominates. A summary of the major models of health promotion was used as a tool to assist in the process of establishing the most appropriate theory on which to base the education programme.

Social Cognitive Theory (SCT) is one of the more formally developed theories of health behaviour. It can be usefully employed to understand the different stages involved in changing behaviours such as physical activity, diet and nutrition and smoking. Illustrative examples of applications of SCT, incorporating the stage of change model such as the Fresh Start programme (Graham-Clarke and Oldenburg, 1994) and the Stanford 5 City project (Farquhar et al., 1990), suggested that SCT may be the optimal model to use. The Fresh Start Programme was developed in Australia with the aim of reducing patient's risk of cardiovascular disease through lifestyle changes involving smoking cessation, increasing physical activity and dietary change. Subjects were randomised to receive either routine care or lifestyle counselling using video assistance or lifestyle counselling using a video and self-instructional material. The programme was evaluated in a randomised controlled trial in 3 regions around Sydney. Following the success of the study, use of the Fresh Start Programme was extended to over 500 physicians. Many published community based and individual health behaviour change and health promotion programmes have been based on SCT (Lewis et al., 1989, Matheson et al., 1991), utilizing techniques that emphasize the cognitive and social mediators of behaviour, these include the Minnesota Heart Health programme (Carlaw et al., 1984) and the Pawtucket Heart Health Programme (Lefebvre et al., 1987). The group and individual counselling methods based on these approaches have been found effective in calorie reduction for weight control and have been adapted for use in studies of reduction in fat and sodium intakes (Bowen et al., 1994, Lasser et al., 1995, McCann and Borbjerg, 1998). This provides some evidence that SCT can be used effectively within a therapeutic environment and not just for health promoting lifestyle interventions.

SCT explains how people acquire and maintain certain behavioural patterns and also provides the basis for intervention strategies. SCT is attractive for health education and health promotion programmes. By incorporating a concern for environment, people and behaviour,
SCT provides a framework for designing and implementing comprehensive behavioural change programmes.

Dietary change is a complex process, influenced by many factors other than knowledge. These include motivation, attitude, demographics and social and personal circumstance. It is acknowledged that effective health promotion incorporates the gaining of knowledge with a behaviour change. Standard dietetic management of CF in the UK has traditionally focused on what changes should be made. Behavioural psychology emphasises how to make the changes. Studies have shown for nutrition education to be effective the two principles must come together (Brownell and Cohen, 1995).

Following the investigation to review which theory may be the most appropriate on which to base the education programme, SCT was considered to be the most suitable model. SCT has been successfully used as a framework in numerous health education programmes including two children’s CF education programmes (Stapleton, 1998, Bartholomew et al., 1997).

1.11 Summary

Nutrition and pulmonary health are inextricably intertwined and good nutrition is essential for longevity and good quality of life in CF. The factors contributing to malnutrition are multifactorial both physiological and psychological. Nutritional intervention has traditionally focused on individual dietary counselling, the use of oral nutritional supplements, and the more invasive enteral and parenteral feeding. The long-term benefits of enteral feeding have been demonstrated in this patient group. Evidence proving the benefits of the less invasive nutritional supplements is lacking, in addition, the oral supplements are not always well liked or well tolerated, particularly if taken for long periods of time and not necessarily effective (Poustie et al., 2006). Enteral and parenteral feeding are invasive modalities, highlighting subjects body image concerns, particularly relevant in an adolescent and adult population (Littlewood and Taylor, 2002). Behavioural factors have been shown to contribute to the lack of compliance to dietary recommendations in children with CF. Work on early behavioural intervention developed by Stark and Bartholomew report encouraging results in small numbers of children (Bartholomew et al., 1991, Stark et al., 1996). Poor disease CF related knowledge has been reported in a number of studies, including nutrition and enzyme knowledge in both children, adolescents and adults. Adolescents with CF not only have to
deal with the normal changes expected with puberty, but also have to manage with the transition of assuming responsibility for their care from their parents and transition of their clinical care from a paediatric to an adult team. Often this is associated with attending a new hospital with different staff. Health practitioners often incorrectly assume a good basic level of knowledge about CF on transition from paediatric to adult care.

A major challenge in developing new treatment regimens is to achieve a partnership with adolescents to ensure that new programmes are both effective and acceptable to the adolescent who will be responsible for implementing them (Kettler et al., 2002). A Meta analysis of nutrition intervention methods in CF has shown that behavioural interventions to be as effective in improving weight gain as the more invasive methods, although all of the work to date on behavioural interventions has focused on children. The research undertaken in America and Australia, in children with CF, supports the efficacy of behavioural intervention combined with increasing nutritional knowledge in the treatment of malnutrition.

In conclusion although most of the work to date has been carried out in children and young adults, there is a need for an adult education programme, which can be supported specifically by the studies revealing lack of knowledge about nutrition and pancreatic enzyme replacement therapy in adolescents and adults with CF (Basketter et al., 2000, Conway et al., 1996). In addition, the paucity of evidence for the use of nutritional supplements in adults and the evidence that adults do not achieve the recommended energy intakes (White et al., 2004), suggests that there is a need for new and innovative ways in which to reach adults with CF.
1.12 Aims of the Thesis

This thesis aimed to:

1) Develop a theoretically based home-based nutrition education and behaviour modification programme for adults with CF.

2) Consumer test the programme and assess the face validity by a peer review process.

3) Evaluate the effectiveness of the programme in a randomised controlled study design comparing the intervention with standard dietetic care.

4) Evaluate the impact of the intervention on:
   1. Measures of nutritional status in adults with CF
   2. General nutrition knowledge and CF specific nutrition knowledge.
   3. Self-efficacy for adults with CF to better manage their diet and pancreatic enzyme replacement therapy.
   4. Reported dietary fat intake.
   5. Quality of life measures.

5) Utilise the stages of change behavioural model to assess the usefulness of this model, to identify subjects most likely to benefit from an intervention and to plot subject’s stage of change as they complete the intervention.

6) Evaluate participant satisfaction about the programme and conduct a process evaluation study in order to provide evidence for best practice.
The hypotheses to be tested were:

Adults with CF completing a home based nutrition education programme will have;

1. an improved nutritional status compared with those receiving dietetic standard care.
2. an improvement in specific nutrition knowledge compared with those receiving dietetic standard care, and
3. an improvement in self efficacy regarding their ability to cope with a special diet, compared with those receiving dietetic standard care.

A flow diagram Figure 1-4 illustrates an overview of the thesis.
Figure 1-4 Summary/overview of the Thesis

Summary/overview of the thesis
Volume 1

Identification of the clinical problem
Literature review

Consumer concerns
Development of a behavioural nutrition education programme
Peer review, consumer testing and pilot study

Randomised controlled trial
New education programme versus standard care

Non participation in the study
Investigating barriers to non-participation
Chapter 4

Participation in the study
Process evaluation
Chapter 5

Conclusions and implications for practice

Volume 2 - "Eat Well with CF"
2. Development and testing of the programme “Eat Well with CF”.

This chapter details the development, subject acceptability testing and peer review of the home based behavioural nutrition education programme “Eat Well with CF” for adults with cystic fibrosis.

A complete copy of “Eat Well with CF” is provided in volume 2, examples of some of the content are provided later in this chapter.

Ethical approval for this study was obtained from Huntingdon Local Research Ethics Committee in February 2000 and extended in February 2002.

A flow diagram Figure 2-1 describes the process of the development phase.
Figure 2-1 Flow diagram showing the process of development of the “Eat Well with CF” programme.

INITIAL FIELDWORK

Review of health education/health promotion models

2.1.1. Consumer involvement

2.1.2. PROGRAMME DEVELOPMENT

2.1.3. Reading age assessment

Critique by Independent Psychologist

2.1.4. Consumer acceptability review

2.1.5. Peer review

2.1.6. Programme Adaptation

Final programme production “Eat Well with CF”

2.1.7. Pilot testing
From the literature review which aimed to identify a theoretical model on which to base the education programme, it appeared that Social Cognitive Theory (SCT) was the most suitable model; however some concern was raised as to the suitability of using this process with adults with a chronic disease such as CF. Therefore, it was decided to involve the consumers, (adults with CF) in the process to establish the acceptability of the approach.

The aim was to investigate appropriate motivational factors and the acceptability of using the SCT approach to adults with CF.

Method
CF participants were asked to take part in a focus group whilst they were attending hospital for annual review. Informed consent was obtained and ethical approval was obtained from the Royal Brompton local ethics committee. Subjects from another centre were used to preserve the Papworth Hospital subjects for the planned randomised trial. Participants were asked to take part if they were over the age of 18 years, were clinically free from acute infection and not on the transplant waiting list. A total sample of 12 subjects, (7 female, 5 male) from a range of socio-economic groups with CF completed the 1-hour session (mean age 27 years, range 18 – 40 years). Three focus groups, each containing 4 participants were held at the Royal Brompton Hospital, London. A semi-structured discussion process using open-ended questions was implemented. The subjects were shown an Australian education and behaviour change programme, developed for children with CF and their carers. The programme “Go and Grow with CF” provides comprehensive information on nutrition related topics targeted for children of primary school age; it also provides a system of small incremental steps to facilitate behaviour change and a structured approach to reinforcing the behaviour (Stapleton, 1998). The main line of questioning was based around 4 topics: educational content, motivational influences to change, the use of peer or ‘buddy’ support and the preferred format of the programme. It also included a reward system that is integral to the SCT approach. All focus groups were taped and later transcribed verbatim and analysed for emergent themes using a long table approach, in which the responses were coded and classified into topic orders prior to analysis (Britten, 1995) (Watson, 2002).
2.1.1 Results of consumer feedback focus groups

Educational content
All participants believed a nutrition education programme was a good idea and would be keen to take part if one was available as they felt there was room for improvement in their cooking skills. This is demonstrated by the following representative but example quotes:

- "Foods good for calories, that would be useful"
- "Students like me don't know how to cook"
- "I would like to learn more about cooking"
- "I can't cook"
- "When I move out of home I need to learn how to cook"

Interestingly, participants acknowledged a lack in their basic nutritional knowledge, as demonstrated by the following example quotes:

- "I was never told much as a kid"
- "There is a lot about CF that I don’t know"
- "It would be interesting and useful to have the basic nutrition facts"

Motivational influences to change
The participants suggested that motivating factors could only be realized by individuals, but that being able to identify with the experiences of others was important, this is illustrated by the following quotes:

- "It would motivate me to read about other people’s experiences"
- "If it meant my weight improved, that would be enough of a reward, because it would make me better in the long run."

The focus groups revealed that identifying motivational factors and setting goals for the programme needed to be individualized and participants needed to feel they were gaining something for themselves, as demonstrated by the following:
"In all honesty I wouldn't read a pack, I need to get something out of it, what's in it for me?"

"If I had a goal I would try and achieve it"

**Peer or buddy support**

Participants felt they should be offered the choice of having a supporter attend the workshop element of the programme with them. This is illustrated as follows:

"It will make you feel like someone is doing it with you. It's a good idea to educate our friends about CF"

"I wouldn't like anyone to come with me, I'd be better on my own"

**Preferred format**

All participants emphasised the importance of the presentation of the education programme. They expressed a preference for the programme being presented as a whole rather than given in sections and, in particular, it was not to look like homework.

"Make the information good, that's more important than the presentation"

"Make sure it doesn't look like homework"

"Try not to be cool, that doesn't work"

"It doesn't need to be catchy"

"I might loose the sections if they were sent separately"

"It's better to receive it all at once then you can flick through and know what is coming in the following weeks"

"It's irritating getting sent small sections"

A section on adult issues was emphasised as being relevant. The female subjects also stressed the importance of not having too much emphasis on weight gain, but more on body image and muscle toning.

**2.1.2 Programme development**

As the results of the consumer group discussions were positive, it was decided to produce a programme, with Social Cognitive Theory (SCT) as a theoretical framework, to enable individuals to gain more control over their diet and pancreatic enzyme replacement therapy
(PERT). To assist in the production of a specifically tailored and targeted programme, the information provided by the focus groups was incorporated into the resource. The programme was entitled “Eat Well with CF” and SCT was used as the model to assist adolescents/adults in the process of translating nutrition information into behaviour and action. The programme focuses on learning in the home environment in combination with group workshops at the hospital for peer support.

The Key features of the programme were:

1. Learning in the home environment
2. Gender specific information
3. Flexibility
4. A structured, integrated system of reinforcing behaviour change

The programme (see volume 2) applies the SCT constructs of:

1. Behavioural capability; providing comprehensive information on the main aspects of nutrition in relation to the adult with CF.
2. Self-efficacy; using a system of small incremental steps to facilitate behaviour change, e.g. The breakfast challenge (see page 70)
3. Re-enforcement; Optional social reinforcement was provided by parents/partners who wanted to be involved in the programme. Reinforcement was also provided by patient’s self-monitoring and recording tasks, and regular prompts in the top right hand corner of the challenge pages of the programme (see below). The principal investigator provided external reinforcement in the form of weekly telephone calls and twice monthly newsletters.

“Eat Well with CF” comprised of modules of learning that are structured to take individuals 30 - 40 minutes per week to complete at home over a 10 week period. Each module comprises between 3-6 pages of text. (This applies the SCT construct of behavioural capability – providing structured comprehensive information). The modules incorporate information on a variety of topics including: energy and fat, digestion and enzymes, appetite, adult issues and diabetes. The programme was designed to be gender specific, with both a male and female version produced, which allowed relevant gender issues to be discussed. Each section
concludes with a challenge. Subjects are guided to set small incremental goals to help increase the SCT construct of self-efficacy, for example, the snack challenge, subjects are guided to plan a high calorie snack 3 times a day for a week, and they are then challenged to consume these snacks more often than they would usually do. The subjects are guided through the 10 weeks of nutrition information, through 6 steps to help establish new behaviour (Figure 2-2). The information provided is designed to equip subjects with the knowledge and skills necessary to be capable of achieving desirable behaviours.

**Figure 2-2 6 Steps to establishing new behaviours – adapted from Stapleton (1998).**

- **Step 1** PLAN  
  - Identify the challenge  
  - Plan the reward

- **Step 2** ACTION  
  - Try the change  
  - Monitor progress daily

- **Step 3** FEEDBACK  
  - Review impact of change  
  - Modify as necessary

- **Step 4** PRACTICE  
  - Continue with change

- **Step 5** CONTINUE  
  - Incorporate behaviour into daily life

- **Step 6** GET THERE  
  - Maintain behaviour
An example of one of the challenges in the “Eat Well with CF” programme is illustrated below.

Challenge 3 Week 3
The breakfast challenge

_The goal this week is_ to eat breakfast if you don’t already, and to have more energy and fat at breakfast than previously.

Breakfast doesn’t need to be eaten as soon as you get up, many people don’t feel like eating much then. It could be once you are at work or school, before lessons or before you start the days work.

Breakfast doesn’t have to be cereal or toast, be inventive - anything that appeals to you – have it. Don’t worry if it isn’t usual “breakfast food”

_(SCT THEORY - SELF-EFFICACY)_

_How do I achieve this week’s goal?_

Write down 4 of your usual breakfasts, give details of

What it is ..........................................................................................................................

How much you eat ...........................................................................................................

How much you spread on bread/toast, if anything ......................................................

Also in this week’s challenge consider how you can fortify the breakfast as in the previous “fortify your snack “challenge

What's in it for me?

By having breakfast every morning it helps you achieve your goals, by eating 200-300 calories at least, before you start the day.

_(SCT THEORY - REINFORCEMENT)_
REMEMBER
Eat high energy/fat snack in between meals

(SCT CONSTRUCT - REINFORCEMENT)
A summary of the format of the "Eat Well with CF" education programme is provided in Table 2-1.

**Table 2-1 “Eat Well with CF” Content Format Summary**

<table>
<thead>
<tr>
<th>Week</th>
<th>Topic title</th>
<th>Knowledge</th>
<th>Goal setting</th>
<th>Motivation</th>
<th>Telephone call by Dietitian</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Workshop 1</td>
<td>Introduction</td>
<td>Dietary Analysis</td>
<td>Energy and Fat</td>
<td>The snack challenge</td>
</tr>
<tr>
<td></td>
<td>Workshop 1</td>
<td>Introduction</td>
<td>Goal setting</td>
<td>Energy and Fat</td>
<td>The snack challenge</td>
</tr>
<tr>
<td>2</td>
<td>Increasing the calories in your food</td>
<td>Fortify your snack challenge</td>
<td></td>
<td>Newsletter 1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>Digestion and Enzymes</td>
<td>Taking enzymes with a new food</td>
<td></td>
<td>Newsletter 2</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>Malabsorption</td>
<td>Watching for malabsorption</td>
<td>Workshop 2 Exploring adult issues</td>
<td>Review of goals. Progress so far Encourage Motivation</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Malabsorption</td>
<td>Watching for malabsorption</td>
<td>Workshop 2 Exploring adult issues</td>
<td>Review of goals. Progress so far Encourage Motivation</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Body image, food labelling</td>
<td>Body image exercise. The shopping trip challenge</td>
<td></td>
<td>Newsletter 3</td>
<td>6</td>
</tr>
<tr>
<td>7</td>
<td>Nutrition and exercise</td>
<td>How many calories are burnt</td>
<td></td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>8</td>
<td>Fibre</td>
<td>The fibre challenge</td>
<td></td>
<td>Newsletter 4</td>
<td>8</td>
</tr>
<tr>
<td>9</td>
<td>Appetite Alcohol</td>
<td>My appetite</td>
<td></td>
<td></td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td>Diabetes (optional)</td>
<td></td>
<td></td>
<td>Newsletter 5</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Workshop 3</td>
<td>Summary and review</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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2.1.3 **Reading age and independent psychologist critique.**

The programme was assessed for age appropriate language by an independent former literary editor. The reading age was considered appropriate for young adults. It was also critiqued by a research psychologist; experienced in working with adults with CF, who assisted in the development of the body image section.

2.1.4 **Consumer acceptability review.**

The aim of this phase of the project was to test "*Eat Well with CF*" with consumers. The consumer acceptability study involved subjects from Seacroft Hospital, Leeds. This is one of the largest specialist care centres for adults with CF in the United Kingdom, with a similar patient mix to Papworth Hospital. This base was also chosen as it has an untapped population that has had no previous contact with a programme of this nature. Consumers were selected from those individuals that were inpatients at the time the evaluation took place. Ethical approval was obtained from the Leeds Health Authority/St James’s and Seacroft University Hospitals Clinical Research Ethics Committee in December 2000. As each patient was recruited to the study they received a volunteer information leaflet, this explained the aims of the study and what participation would entail. Full informed consent was obtained.

Qualitative research was used to undertake the evaluation in order for opinions to be given and for the consumer to have the opportunity to expand their ideas fully.

Seven consumers were asked to spend the afternoon reading the pack and were informed they would be interviewed by semi structured questions the following day to ascertain their feelings towards the different aspects and aims of the programme. The individual interviews were recorded on tape and then transcribed verbatim and the results for each question were reported under general themes specific to the aims of the project.

All participants of the consumer acceptability study felt that their nutrition knowledge would be improved by completing the programme and that their eating habits would change as a result of such an intervention. Motivation factors for taking part were also explored. Most participants felt that having a supporter for the programme would be useful, competitions
included as part of the programme may or may not be useful (this depended on the age of the participant) and that the planned workshops, newsletters and phone calls from the dietitian would all be helpful in keeping them on track at home to complete the programme.

2.1.5 **Face validity of “Eat Well with CF” by peer review.**

A peer review process was used for the face validity of the “Eat Well with CF” programme to be confirmed in terms of its content, appearance and age appropriateness and to identify any aspects that may be missing from the programme and to highlight areas for change.

Expert dietitians in CF were selected from membership of the UK Dietitians CF Interest Group, a national group who are all specialist dietitians. Subjects were selected using the following criteria: were working at one of the main adult CF centres in the UK, and therefore were used to managing a similar patient population to Papworth Hospital and all had over 7 years individual experience in working with CF. Of the 45 members of the group, this procedure led to 5 dietitians being asked to participate in the peer review process and were sent a copy of “Eat Well with CF” along with a peer review questionnaire (Appendix 1) and were asked to return the questionnaire by the specified date.

Respondents in the peer review process were asked to rate each section of the pack on a scale of 1-5 and then to make appropriate comments if necessary. Qualitative questions were also asked to ascertain the overall impression and suitability of the programme and also if any omissions had been made. The CF dietitians participating in the peer review process were asked to score each section of the programme in relation to its content, appearance and age appropriateness. They were asked to rate their responses according to the following criteria: poor, satisfactory, good, very good or excellent. A total of 8 sections were reviewed. These were: the introduction and chapters on energy and fat, digestion and enzymes, adult issues, appetite and diabetes, the appendix and the programme overall. To illustrate the results succinctly, a cross section of the results of 5 of these sections is given.

Two out of five reviewers (40%) rated the content and appearance of the introduction as excellent. Age appropriateness was classified as good by 4 (80%). The content of the fat and
energy section was rated as good by 3 (60%) and very good by 2 (40%) and 2 (40%)
reviewers considered the appearance as good and 3 (60%) as very good.

The content of the digestion and enzyme chapter was classified as good by 3 (60%) dietitians,
as very good by 1 (20%) and excellent by 1 (20%). The appendix was rated as poor or satisfactory for all classifications. The content of the programme overall was scored as good by 2 (40%), as very good by 2 (40%) and excellent by 1 (20%). The appearance of the overall programme was rated as very good by 3 reviewers (60%) and excellent by 1 (20%). The age appropriateness was ranked as good by 5 (100%).

The results showed that the dietitians rated the pack highly with regard to content, accuracy and information provided except the appendix, which was rated poorly and was subsequently removed. The content of the programme was generally considered to be good; however it was felt certain points needed to be clarified, particularly in the energy and fat section.

The section on body image was also criticized in providing a too idealized body picture. It was suggested that the section on diabetes was only relevant to those subjects with the condition, so this was made an optional extra for those who have diabetes. Some reviewers questioned the reading age of the programme as it contained long words in certain sections. However, reading age was tested prior to peer review and found to be appropriate for adults. Interestingly, subjects completing the review did not comment on the language used, therefore no changes were made to the programme. The comments of the peer reviews were otherwise positive and have confirmed the unique nature of "Eat Well with CF."

### 2.1.6 Programme adaptation

The "Eat Well with CF" education programme was modified following the results of the peer review and consumer acceptability study, by the following:

- Grammatical and punctuation changes.
- Complete review of the body image section and removal of the body image pictures.
- Slight modification to the content of the Fat and Energy section, to clarify certain points highlighted in the peer review.
- Removal of the appendices which contained information on useful websites.
2.1.7 Pilot testing

Twenty subjects with CF at Papworth Hospital were recruited to the pilot study over an eight-week period. Subjects were randomly assigned to either the behavioural intervention group (n=10) or a control group (n=10). The pilot was successful in demonstrating that the trial could be carried out according to the study protocol and therefore the data collected as part of the pilot has been integrated into the main study which is described in Chapter 3. However, the valuable experience of the pilot study lead to some changes with respect to the procedure of the full trial, as follows:

1. Recruitment to the pilot study was a very slow process, as it was carried out by a research nurse not known to the subjects. For the full RCT the principal investigator, who was in regular contact with the subjects, therefore would carry out recruitment, in an attempt to speed up the process.

2. An independent source would be responsible for scoring all the questionnaires to eliminate any risk of bias by the principal investigator.

3. The pilot study highlighted the burden of self care that the participants undertake and therefore this must be taken into consideration with respect to the amount of additional work the study involved, this reinforced the belief that subjects would not be prepared to keep complex diet records repeatedly.

2.1.8 Discussion

The aim of the initial phase of the study was to confirm that SCT was the most appropriate theory of intervention on which to base the education programme. Qualitative methodology (focus groups) enabled the needs of this CF population group to be highlighted. Consumers were used to guide and comment on the appropriateness of the programme. The consumer acceptability tests and peer review process revealed the need for a nutrition education programme, participants openly acknowledging a lack in their basic nutrition knowledge, despite previous contact with dietitians.
It was an interesting finding that subjects themselves recognised their lack of 'basic' nutrition knowledge. This is despite the fact that since childhood they had seen a dietitian frequently and yet some fundamental areas of knowledge enabling compliance with dietary prescription were unknown. Examination of the potential reasons for this include dietetic contact having been with parents during childhood and subsequent failure to transfer knowledge from parent to child at the time of transition to the adult centre, or limited access or time with a dietitian. This suggests practitioners should not overestimate patient knowledge and skills.

The consumer acceptability study also illustrated that the adult consumers would be keen to participate in the programme and would be motivated to complete it.

The process of developing the "Eat Well with CF" education programme involved in depth literature reviews of health promotion models. This ensured the programme was grounded in the most appropriate theory. The authors of a Cochrane review on Nutrition Education, found that nutrition education works in general and interventions that use educational methods directed at behavioural change as a goal were more effective than interventions that focused on dissemination of information with the assumption that such information will result in change in attitudes and behaviours (Contento et al., 1995).

Social Cognitive Theory was used as a framework for establishing behaviours in the newly developed programme “Eat Well with CF”, which combines flexibility, learning in the home environment and a structured, integrated system of reinforcing behaviour change.

Focus group methods are a relatively simple and accessible way to collect information from the target group, using a discussion outline, although they are labour and time intensive. This enabled us to gain a broad understanding of why participants think and act the way they do. The use of focus groups with adults attending another CF treatment centre allowed an informed approach to developing content, motivational factors and inhibitors of behaviour to be established, without Papworth hospital’s subjects being involved.

This method of nutrition education, involving adult subjects learning in their home environment, goal setting and completing challenges to reinforce behaviour change is very different to the traditional model of one to one patient consultation in a hospital setting that dietitians have followed.
Dietitians have traditionally functioned as nutritional advisors rather than behaviour change agents. Dietetics originated as a hospital based profession with the traditional dietetic interview being firmly based on the model of the doctor-patient medical consultation, which uses direct persuasion and motivation to get people to change their behaviour. This implies dietitians need to review and re-think the traditional way subjects are seen. Practically this involves considering how to utilise Social Cognitive Theory within dietetic practice.
3. *A randomised controlled trial of a behavioural home based nutrition education programme* “Eat Well with CF” in adults with CF.

The following flowchart details the progress of participants through the randomised trial.
Figure 3-1 Flow chart describing planned timelines of subjects through the randomised trial of the new behavioural nutrition education programme “Eat Well with CF”

Jan 2003 - June 2004
RECRUITMENT

BASELINE MEASURES

April 2003
February 2004
May 2004

randomisation of group A
randomisation of group B
randomisation of group C

May 2003 A
Mar 2004 B
June 2004 C

Intervention
‘Eat well with CF’
Educational Programme
Workshop 1 (week 1)
Weekly phone call from Dietitian
Bi-weekly Newsletter sent by post
Workshop 2 (week 5)
Workshop 3 (week 10)

10 WEEKS

July 2003 A
May 2004 B
Aug 2004 C

3 month post intervention outcome measures

Oct 2003 A
Aug 2004 B
Nov 2004 C

6 month outcome measures
6-month outcome measures
Process evaluation and Non-Participation study

July 2004 A
May 2005 B
Aug 2005 C

12 month post
Intervention outcome measures
12-month outcome measures
3.1 Methods

3.1.1 Participants/Recruitment procedure.

Papworth Hospital is a recognised regional specialist centre for adults with CF. The available population of adults with CF was 180 in 2002; this was increasing by approximately 20 per year. The population at Papworth Hospital NHS Trust in 2002 was 104 males, 76 females; the total number of adults in UK with CF (December 2002) was 3700 (McCormick et al., 2002). Thus 5% of the UK adult CF population were being treated at the Papworth Hospital adult centre. Of these 180 subjects, 9 subjects were pancreatic sufficient (5%) 171 were therefore pancreatic insufficient (95%). Thirty nine were treated for diabetes (22%). With regard to genotype, 40% (n=73) of this cohort were homozygous DF508, 26% (n= 47) were heterozygous DF508.

The employment status of the current population was as follows: Three (2 %) were at school , 34 (19%) in higher education, 40 (22%) unemployed, 63 (35%) full time work, 26 (14%) part time work and 14 (8%) were full time homemakers.

An average of 20 subjects was seen per week in out patient clinics. Recruitment took place at each clinic, consecutively from January 2003 – June 2004. Subjects were given an information sheet at the beginning of the clinic and then had the opportunity to ask questions and discuss further with the dietitian at the end of the clinic.

Inclusion criteria

Subjects aged 16 and over were invited to participate in the study if they were able to understand written English.

Exclusion criteria

Subjects on the heart/lung transplant waiting list were excluded because they may have been unable to complete the study (i.e. receive a transplant or die on the waiting list, approximately 5-6 subjects). Other exclusion criteria included pregnancy or lactation, or if the patient was already participating in another study.

Full informed consent was obtained. Ethical approval was obtained from Huntingdon Local Research Ethics Committee in February 2002.

Recruitment to the study was forced to cease after 74 subjects had been recruited in June 2004. This was due to the new segregation rules aiming to stop the patient to patient spread of pseudomonas, applied to all CF subjects in the UK at that time (Littlewood, 2004).

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The implications of this report were that subjects must be separated where possible and only subjects growing the same type of organism in their sputum attend the clinics on the same day.

As a consequence of these changes to practice, recruitment ceased as the study was unable to be carried out as per the original protocol, due mainly to the inability to conduct the group workshops which featured as part of the intervention.

3.1.2 The Interventions

Subjects were randomly assigned to either the behavioural intervention group or control. Subjects were informed by telephone to which group they had been assigned. The following describes what happened in each of these groups.

3.1.2.1 Behavioural Intervention group

Subjects were informed by telephone and in writing the dates and times of the Intervention Workshops. If subjects were unable to attend the initial workshop, the programme "Eat Well with CF" was sent by recorded delivery to the subject's house. The information provided at the workshop was summarised in a telephone call from the dietitian, explaining how to commence on the programme.

The "Eat Well with CF" programme included three group workshops (week 1, week 5 and week 10). Participants were informed of the dates and times of all workshops at the time of randomisation. The participants were informed when to commence the programme and were instructed to complete 1 section per week for the 10-week period. The participants were telephoned weekly by the dietitian and received a newsletter by post every two weeks.

Workshop 1 - introductory workshop

The aims of the workshop were:

1. To explain the process.
2. To motivate participants.
3. To help individuals set their goals.
4. To provide an overview of the content of the programme.
5. To provide an education session on the basic nutrition facts: protein, fat and carbohydrate.
The workshop took place during week 1. Subjects were informed of the date and venue of the workshop in advance and asked to return a reply slip to inform if they were attending. All workshops ran from 9.30am until 1pm and took place on the hospital site, lunch was provided and travel expenses were reimbursed.

The format of the workshop is detailed in Appendix 5. The Director of the Adult CF Centre was present to welcome the subjects, explain the background and importance of the study and thank them for being involved.

The workshop was designed to be informal. The subjects were informed why and how the study began and were provided with a brief overview of the focus group work prior to the programme development and the patient acceptability study and peer review.

Subjects were asked to complete the dietary analysis section at the beginning of the programme and set themselves goals for the programme and if they had a supporter present, i.e. partner, friend or parent, they were asked to set goals. A brief informal discussion surrounding the types of goals chosen was then held.

The subjects were given a short education session based on the first 3 topics in the education programme, namely fat, protein, carbohydrate and calories.

A 15-item nutrition quiz (Appendix 6) was used as a means of prompting discussion around a variety of nutrition questions and encouraging subjects to work together. Any questions were answered throughout the session.

Workshop 2

An interim workshop was held during week 5; the aims of the workshop were:

1. To act as a forum for reviewing progress.
2. To answer questions, regarding the programme or related subjects arising from the programme content.
3. To provide an education session about nutrition and exercise.
4. To explain the content of the remainder of the programme.
5. To encourage motivation.

The format of the second workshop is detailed in Appendix 7. The session commenced with an informal discussion reviewing patient’s individual goals and their feelings about how they were progressing with the programme.
The education section was based on ‘Exercise and Nutrition’. A short introduction on aerobic and anaerobic exercise was provided, followed by a discussion about body composition. The CF Specialist Physiotherapist led a short session on the energy cost of exercise and an explanation of the different types of aerobic and anaerobic exercise.

A 15-point group nutrition Quiz, (Appendix 8) was used as a means of informally testing what subjects had learned from the programme. All questions were based on principles that had been covered in the preceding 5 weeks of the programme.

**Workshop 3**

A final workshop concluded the programme and encouraged continuation of the dietary changes made (Week 10). The format of the workshop is detailed in Appendix 9.

The aims of the workshop were:

1. To review overall goals/ aims of participants.
2. For the participants to informally re-analyse their diets to see if it had changed.
3. To complete the process evaluation questionnaire.
4. To complete the post intervention outcome questionnaires.
5. To discuss strategies for subjects to continue with the changes made.
6. To conclude the education programme.

The workshop commenced with an informal discussion about "Eat Well with CF" Prompted by the workshop leader, who asked questions about whether the subjects had enjoyed the sessions, what they had found most useful and if they felt they had learned from the sessions.

The final nutrition quiz was used as an informal means of assessing progress of the final 5 weeks of the programme (See appendix 10).

Subjects were asked to complete the dietary analysis section and review if and how their diet had changed from the dietary analysis they completed in the first workshop. The group were then asked to look back at their goals and review if they achieved their goals and if they had not, could they give reasons for not achieving what they had set out to achieve.

An informal discussion focusing on how the participants could continue with the changes they had made to their diet followed. Finally participants were asked to complete the process evaluation questionnaire and the post intervention outcome measures questionnaires. The role of the dietitian changed from individual counselling to group facilitation.
Potential limitations of the Education programme

During the recruitment procedure, following informal discussion with several subjects regarding their reasons for not participating in the study, it became evident that reading ability was a barrier to not being involved. As a consequence of this, a formal one to one interview was carried out with 21 subjects (see Chapter 4) asking a number of questions surrounding reasons for not wanting to participate. The results of this revealed that an alternative medium to transmit the information contained in the programme should be considered. It was concluded an audio version of the education programme might be a valuable tool to aid those subjects with poorer reading skills.

Audio version of "Eat Well with CF"

Male and female audio cassette and DVD versions of "Eat Well with CF" were made. The recording process took place in a fully equipped sound recording studio; an actress was used to provide the voiceover. These steps were taken to enhance the production of a highly professional, quality end product (See volume 2).

Due to the time involved in requesting ethical approval and completing the one to one interviews and subsequent organisation of the audiotape production, only Group C were provided with the written and audio version of "Eat Well with CF".

3.1.2.2 Control group

The control group was requested to continue to attend their clinic appointments as usual. This group continued to receive standard dietetic care from a single dietitian. Standard dietetic care is defined as being seen at CF clinic appointments (3 monthly intervals, on average) and during in patient stays 2-4 times per week.

3.1.2.3 Assessment of adequacy of Pancreatic Enzyme Replacement Therapy (PERT).

At the baseline stage of the trial it was considered important that subjects had adequate fat absorption. The ideal tool for evaluating fat absorption in this population would be a 3-day faecal specimen collection plus a 4-day dietary record to enable calculation of the coefficient of fat absorption. For the purpose of this trial this was not practical, due in part to adult subjects being universally unwilling to collect faecal specimens for 3 days and the time
involved for the subject. It was considered that subjects being required to give 3-day faecal specimens would hamper recruitment and it seemed unlikely this would provide additional useful information in a population already well treated with PERT. For the purpose of this study we planned to use fat microscopy. This provides only an indication of the adequacy of pancreatic enzyme supplementation. Following the pilot study, the first 20 subjects had faecal specimens taken and fat microscopy test performed. From the results of this test no subjects required adjustment of pancreatic enzymes. Adjustment/optimisation of PERT is now routine clinical practice when new subjects attend Papworth Hospital and as part of the annual review process. The usefulness of the fat microscopy test is limited as it provides only an indication of the fat content in the specific small sample of stool. In addition subjects were very reluctant to give samples and this was significantly hampering the recruitment process. It was therefore decided the faecal microscopy test would provide little additional information in this study, and not performing fat microscopy would improve recruitment.

The outcome measures were repeated for the intervention group at the end of the intervention 3 months and at 6 months and 12 months post intervention, and for the control group at 6 months and 12 months post intervention.

Questionnaires and clinical data were numerically coded for the purpose of database management. Data was entered in code into a spreadsheet (Microsoft Excel – version 6.0).

3.1.3 Primary Outcome

The primary outcome was weight change at 6 and 12 months.

**Anthropometric measures**

Subjects were weighed in kilograms (Kg) to the nearest 0.1Kg in usual clothes without shoes, using SECA medical scales. Height was measured using SECA, model 225, mobile measuring unit (SECA Ltd, medical scales and measuring systems, Birmingham, UK), at baseline (using standard techniques), post intervention in the intervention group (3 months) and at 6 and 12 months in the control and intervention groups.

Body Mass Index (BMI), the ratio between weight in kilograms divided by the height in metres squared (Weight Kg/Height m$^2$) was calculated for each subject.
Pulmonary status.

Forced expiratory volume in one second (FEV1) is a routinely used measure of lung function. The results of FEV1 are interpreted in relation to normal range reference values (Knudson et al., 1983). FEV1 was measured by a trained technician at baseline, post intervention in the intervention group (3 months) and at 6 and 12 months.

Pancreatic status as defined by PERT and genotype were recorded for all subjects from hospital records.

3.1.4 Secondary outcome variables

Subjects were administered the following questionnaires after recruitment. The battery of questionnaires were collated with measures that were considered relevant, but it was important that the task was not too onerous for the subjects, therefore it was decided not to complete food records because of the difficulties in completion, inaccuracies in the various measures available and the additional burden on the subject.

3.1.4.1 General and Specific Nutrition Knowledge.

As subjects follow a specific diet that is opposite in nutritional composition (i.e. a high fat diet) to that which is recommended to the general population, both general and specific nutrition knowledge were tested. The questionnaire to measure general knowledge was one adapted for use for parents of children with CF and has been tested for reliability in previous research (Rogers et al., 1980). This questionnaire consists of 21 multiple-choice questions; one score is given for each correct answer, a maximum total of 21 points (Appendix 2).

Specific nutrition knowledge was tested using a 52 point self reported questionnaire designed to elucidate the subjects knowledge and perceptions about CF, nutritional knowledge about CF and enzyme replacement therapy (Appendix 2). The questionnaire used was adapted and validated from a questionnaire used for parents of children with CF in Australia and (Stapleton, 1998), the reliability of which has been ascertained. For the purpose of scoring the questionnaire is split into 2 sections. For the main body of the questionnaire, 1 point is given for each correct answer, up to a maximum of 55 points. A short section assessing bowel habits is scored as 1 point for each positive answer with a total of 9 points. The points are summed to provide a total.
3.1.4.2 Self-efficacy.

Self-efficacy is defined as the degree to which one believes that performing a particular behaviour is possible. It has been shown previously to be a reliable predictor of short and long-term success in health behaviour research, such as stopping smoking. As self-efficacy is a situation specific phenomenon, a self-efficacy questionnaire was developed using the methods of Bandura (Bandura, 1977). It consisted of 9 questions relating to food and meal provision, in which responders are asked to rate on a scale of 0-3 how confident they are in performing a certain task (Appendix 2), the maximum score was 27.

3.1.4.3 Dietary intake.

Dietary fat and energy intake was assessed using the ‘Short Fat’ questionnaire. This is a 17 item self reported food frequency questionnaire designed to measure behaviour related to dietary fat consumption and was used to classify subjects according to their fat intake. It has been found to be reliable and has been validated against other scales measuring attitude, behaviour and knowledge in relation to dietary fat (Dobson et al., 1993) (Appendix 2). Scoring is based on a maximum of 63 points for the 17 questions.

3.1.4.4 Health Related Quality of life.

Quality of Life (QoL) was measured using a CF specific, health related, patient derived, fully tested and validated method (Gee et al., 1999). This comprises 52 items across 9 CF specific domains. These are: physical functioning, social functioning, treatment issues, chest symptoms, emotional responses, body image, interpersonal relationships, career concerns, concerns for the future plus 2 general health perception and 2 global health related QoL questions (Appendix 2). Each domain is scored separately. The score for each is converted into a percentage.
3.1.4.5 Stages of Change.

Stages of change were measured using a 3-item questionnaire assessing the readiness of an individual to make dietary change, from pre-contemplation through to action and maintenance. This tool has been advocated for enhancing dietary counselling. It enables an understanding of an individual’s motivation to change their dietary habits (Prochaska and DiClemente, 1992) (Appendix 2).

The questionnaire used was designed for this particular population as there has been no previous work investigating stages of change in relation to dietary change in adults with CF.

The subjects were asked to respond to each of the following questions:

1. ‘Describe how you feel about changing your diet/ improving your weight’.
2. ‘It would be difficult for me to change my diet/ improve my weight, in the next month’.
3. ‘I intend to change my diet/improve my weight in the next month’.

There were five potential responses relating to the five stages of change: pre-contemplation, contemplation, preparation, action and maintenance.

To aid ease of interpretation of the data and due to the potentially small numbers in each stage of change, the 5 potential responses from the stages of change questionnaire were grouped together to form two categories. These were ‘Consideration’ and ‘Action’, responses were categorised in the following way:

- pre-contemplation, contemplation and preparation were grouped together under the heading of ‘Consideration’.
- action and maintenance were grouped together and labelled ‘Action’.

This method of classifying the first three stages as motivational/consideration and the later two stages actionable has been reported as a method to interpret stages of change questions in previous research (Prochaska and DiClemente, 1992, Greene et al., 1994, Curry et al., 1992).

3.1.5 Reliability testing and test re-test validity of questionnaires

Reliability testing of all the questionnaires used in the study was undertaken using a test re-test procedure with 10 subjects not recruited to the RCT. Subjects were asked to complete each of the questionnaires at the start of their in-patient stay and again at the end of their in-patient stay 2 weeks later, or in Clinic at the start of IV antibiotic therapy and then again 2 weeks later.
The mean difference in test scores between test 1 and test 2 is given in Table 3-1. The data was not normally distributed therefore non-parametric tests were applied. The Wilcoxon signed ranks test for 2 related samples was used and P values reported. The results of the reliability testing of the questionnaires are shown in Table 3-1.

**Table 3-1 Results of test re-test reliability testing of questionnaires**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Test 1 mean score</th>
<th>Test 2 mean score</th>
<th>Mean difference</th>
<th>SD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self efficacy</td>
<td>17.4</td>
<td>17.7</td>
<td>0.3</td>
<td>2.110</td>
<td>0.670</td>
</tr>
<tr>
<td>General nutrition</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge</td>
<td>11.1</td>
<td>11.8</td>
<td>0.7</td>
<td>2.16</td>
<td>0.395</td>
</tr>
<tr>
<td>CF Specific</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge</td>
<td>37.9</td>
<td>37.3</td>
<td>0.6</td>
<td>3.627</td>
<td>0.765</td>
</tr>
<tr>
<td>Short Fat</td>
<td>28.9</td>
<td>28.6</td>
<td>0.3</td>
<td>1.88</td>
<td>0.914</td>
</tr>
<tr>
<td>Quality of life</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-10 (%)</td>
<td>70.1</td>
<td>72.6</td>
<td>2.5</td>
<td>11.8</td>
<td>0.944</td>
</tr>
<tr>
<td>11-14 (%)</td>
<td>80.4</td>
<td>81.6</td>
<td>1.25</td>
<td>9.43</td>
<td>0.901</td>
</tr>
<tr>
<td>15-17 (%)</td>
<td>73.5</td>
<td>75.0</td>
<td>1.42</td>
<td>15.7</td>
<td>0.611</td>
</tr>
<tr>
<td>18-21 (%)</td>
<td>83.2</td>
<td>84.1</td>
<td>1.1</td>
<td>12.3</td>
<td>0.966</td>
</tr>
<tr>
<td>22-29 (%)</td>
<td>86.0</td>
<td>83.1</td>
<td>2.9</td>
<td>14.2</td>
<td>0.514</td>
</tr>
<tr>
<td>30-35 (%)</td>
<td>49.4</td>
<td>48.0</td>
<td>1.38</td>
<td>13.8</td>
<td>0.863</td>
</tr>
<tr>
<td>36-45 (%)</td>
<td>72.0</td>
<td>65.6</td>
<td>6.33</td>
<td>8.15</td>
<td>0.28</td>
</tr>
<tr>
<td>46-48 (%)</td>
<td>81.1</td>
<td>73.3</td>
<td>7.77</td>
<td>8.36</td>
<td>0.27</td>
</tr>
<tr>
<td>49-52 (%)</td>
<td>77.5</td>
<td>73.7</td>
<td>3.75</td>
<td>8.43</td>
<td>0.167</td>
</tr>
</tbody>
</table>

There were no significant differences between the mean scores for test 1 and the mean scores for test 2.
3.1.6 Construct Validity or Internal Reliability

Internal reliability is important when measuring nutritional knowledge. Cronbach’s alpha is the ratio between individual scores to the total variability in the questionnaire. Cronbach’s alpha scores were calculated for the questionnaires. These were found to be satisfactory with alpha scores ranging from 0.62-0.95 on all measures used.

The results of the Cronbach alpha scores are shown in table 3-2.

Table 3-2 Internal reliability scores for psychometric questionnaires used.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Cronbach’s alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self - efficacy</td>
<td>0.85</td>
</tr>
<tr>
<td>‘Short fat’ questionnaire</td>
<td>0.69</td>
</tr>
<tr>
<td>General nutrition Knowledge</td>
<td>0.62*</td>
</tr>
<tr>
<td>Specific nutrition Knowledge</td>
<td>0.77</td>
</tr>
<tr>
<td>Quality of life</td>
<td>0.95</td>
</tr>
</tbody>
</table>

- Cronbach’s alpha for general nutrition knowledge was 0.58, this improved to 0.62 by removal of items 7 and 15.

3.1.7 Other measures

Socio-economic status and education.

Socio-economic status (SES) and the education level achieved by the subjects were measured using a questionnaire specifically designed for this CF population but adapted from personal correspondence with Dr Walters (2002) (Appendix 3).

Prior to the questionnaire being developed the various methods for classifying SES were reviewed. There are several ways of classifying SES in subjects and these are broadly:
1. Occupation - the method used in Sarah Walters’s (2002) surveys was to assign a socioeconomic class to each responder based upon their own occupation if employed. If not, then they were assigned the class of their spouse/partner, or if single then that of their father, and if no father then that of their mother. This assigns a socioeconomic status to the majority of subjects.

2. Educational achievement – Walters (2002) asked about education in surveys of adults with CF. This was broadly divided into GCSE or equivalent, A’level or equivalent, some further education (non-university qualifications) or higher education (degree). From personal correspondence with Dr Walters she expressed the view that this method is becoming less useful because it appears the majority of people pass GCSE’s and very many people take further qualifications that do not necessarily enhance socioeconomic status.

3. If it is not possible to interview or see the subjects directly, another way is to assign a socioeconomic status based upon the postcode where they live. There are many indices derived to do this, such as the Townsend Score, Jarman Score, Carstairs Index, or the IMD (Index of Multiple Deprivation). All are based on Census variables.

There are problems with all these methods as applied to the CF population, but from discussions with Dr Walters it was decided that the most appropriate method for this study was classification based upon employment. This is reasonably good at identifying the type of household from which the person with CF comes, whether it is with parents, a spouse or solo. This classification however is potentially flawed when the person with CF is unemployed and also has no contact with their parents (for example, where a person with CF is poor, lives alone and on benefits but their parents are quite wealthy and do not help with the person with CF’s income). It also has limitations when parents are contributing considerably to the person with CF (e.g. that person is working part time in a low paid job, living independently but in a house or flat that parents have purchased for them). In reality, the majority of subjects are working and living independently, or living with parents, (either working or not).

In addition, it was considered appropriate to measure educational achievement. There may however be potential difficulties with this measure. People with CF may not have had time to complete education (e.g. in this age group, many will be full time students). Also there is an age cohort effect, for example older people with CF coming from a culture where higher
qualifications were not the norm and a younger person coming from a culture where achieving an undergraduate degree is the norm.

The questionnaire was subsequently developed encompassing current or recent employment and educational achievement.

The questionnaires were analysed and the results collated, and where necessary, personal communication with the subjects was carried out to clarify any outstanding points.

Education was broadly divided into 4 categories;

- **A** - Educated to GCSE level or equivalent
- **B** - Educated to `A level or equivalent
- **C** - Educated to further education or higher education degree
- **D** - Achieved higher degree (e.g. PhD, Masters)

Socio-economic status was classified using the National Statistics Socio-Economic Classification (NS-SEC) (National office for Statistics, 2000). This classification has been developed from a sociological classification that has been widely used in pure and applied research, known as the “Goldthorpe schema”. The decision to adapt the Goldthorpe classification as the basis for the NS-SEC was made because it is widely used and accepted internationally. It is conceptually clear and has been reasonably validated both in criterion terms as a measure and in construct terms as a good predictor of health and educational outcomes. The NS-SEC is a properly constructed and validated classification and is a flexible occupationally based classification. The NS-SEC consists of 8 classes, or a reduced 5-class system can be used. For the purpose of this study, the simplified 5-class version was used, with 2 additional classes (long term ill health and student).

The classes are as follows:

1. Managerial and professional occupations
2. Intermediate occupations
3. Small employers and own account workers
4. Lower supervisory and technical occupations
5. Semi-routine and routine occupations
6. Long term ill health
7. Student
3.1.8 Sample size calculation

As most nutritional management is focused around the absolute body weight and/or the body mass index, the primary outcome measure of weight gain at 6 months and 12 months was used. The sample size was estimated using patient weight data collected between 1998-2000. In order to estimate an achievable target weight gain, data on existing subjects was reviewed. Using standard dietetic methods, CF patients’ currently receiving care increase their body weight by 1.25 Kg/year (SD 3Kg). Using the newly developed behavioural nutrition education programme we expect weight gain to increase by 3 Kg in the first year (SD 3Kg). With 80% power and 2-sided significance of 5 %, the sample required was 46 participants in each group. Assuming 5 -10 % drops out recruitment of 100 subjects was necessary.

3.1.9 Randomisation

Subjects were randomly assigned to either the behavioural intervention group or control (standard care), stratified for low/high disease risk, to reduce potential group bias. High risk was defined as subjects who had <= 30% predicted Forced Expiratory Volume in 1 second (FEV1) or who were receiving supplemental enteral feeding or who had diabetes. This was due to the end stage nature of the disease, which is often associated with poor appetite and deteriorating nutritional status. They were stratified by disease severity into the intervention or control group. Randomisation was organised in the hospital’s Research and Development Unit and supervised by the project statistician, Linda Sharples, independently of the investigator. Randomisation was performed using a minimisation process in order to keep the numbers in the intervention and control groups equivalent. Having a roughly constant caseload throughout the study period eased the practicality of managing cohorts of subjects through the study protocol. The study could not be blinded to either the subjects or the investigator due to the nature of the intervention. Those subjects in the intervention group needed to attend the hospital more frequently than usual to attend workshops. Travelling expenses to these additional hospital visits were reimbursed.

3.1.10 Data Analysis

Primary data for weight outcomes were analysed by intention-to-treat with all subjects followed up irrespective of compliance. A completers analysis was carried out for those who
completed the 6 and 12 month follow up. The primary analysis compares changes in weight (Kg) between baseline and 6 and 12 months and uses analysis of variance or non-parametric equivalents as necessary. Pearson chi-squared tests were used to explore the relationship between categorical data, such as education classification and socio-economic status in completers versus non-completers.

All statistical analysis was carried out using Statistical Package for Social Sciences, (SPSS) Version 14.

All data were tested for normality using the Kolmogorov – Smirnov statistic. Parametric tests were used for the data found to be normally distributed. Intra group analysis was conducted using paired T- tests, analysing the difference from the start and end measurements.

Independent samples T-test was used to assess any difference in outcomes between intervention and control groups from baseline to 6 months and baseline to 12 months.

Analysis of variance (ANOVA) was used to compare the difference in outcomes between the control and intervention to the variation within the groups, at 6 and 12 months. Repeated measures analysis of variance was used to investigate any evidence of a difference between the groups over the whole period of investigation.

Data which were not normally distributed were analysed using non parametric equivalents.

Two sets of analysis were performed, the first set was on the basis of an intention to treat (ITT) basis to allow for variation caused by drop-outs, with baseline values carried forward for missing values. A further analysis was carried out using completer’s analysis in those subjects who provided data at all time points.

In addition to the standard statistical analysis, an exploratory Complier Average Causal Effect (CACE) analysis was used to estimate the treatment effect (Sommer, 1990, Angrist, et al 1996).
3.2 Results
Subjects were recruited per protocol and the numbers through the study are described in Figure 3.2.
Figure 3-2 Flow of subjects through the 6 and 12 month stages of the study

**Eligible subjects (n=180)**
- Randomised (n = 74)
- Refused (n=96)
  - Excluded (n = 10)

**Allocation**
- Allocated to Control group (n = 37)
  - Baseline measures completed (n=34)
    - Moved centre (n=1)
    - Non returned questionnaires (n=2)
- Allocated to Intervention group (n = 37)
  - Baseline measures completed (n=34)
    - Moved centre (n=1)
    - Non returned questionnaires (n=2)

**Follow-up**
- 6 month follow up (n = 32)
  - Moved centre (n = 1)
  - Died (n=1)
- 12 month follow up (n = 25)
  - Died (n=1)
  - Lost to follow up (n = 6)
- Post intervention follow up (n = 29)
  - Withdrawn from study (n=3)
  - Lost to follow up (n =2)
  - 6 month follow up (n = 28)
    - Died (n = 1)
- 12 month follow up (n = 23)
  - Died (n=1)
  - Lost to follow up (n = 4)

**Completed**
- Completed (n= 25)
- Completed (n= 23)
Comparisons between the control and intervention group were made at baseline (Table 3-3). The control group were heavier at baseline than the intervention group, although this level did not reach significance (p=0.23). The control group were also taller than the intervention group, although this level did not reach statistical significance (p=0.352). As a consequence of the control group being heavier and taller than the intervention group there was no significant difference in mean BMI between the intervention and control groups or between different genotypes. There was no significant difference in sex, genotype or FEV1 between the groups.

Table 3-3 Measurement of baseline data for subjects post randomisation comparing the control with the intervention group.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention</th>
<th>Control</th>
<th>Independent samples</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=34</td>
<td>N=34</td>
<td>T-test</td>
</tr>
<tr>
<td>Sex M (%)</td>
<td>20 (59%)</td>
<td>20 (59%)</td>
<td></td>
</tr>
<tr>
<td>F (%)</td>
<td>14 (41%)</td>
<td>14 (41%)</td>
<td></td>
</tr>
<tr>
<td>Age mean (SD)</td>
<td>25.2 (7.09)</td>
<td>23.8 (5.88)</td>
<td>0.89 0.37</td>
</tr>
<tr>
<td>Range (years)</td>
<td>16.8 - 43.7</td>
<td>16.9 -38.1</td>
<td></td>
</tr>
<tr>
<td>Genotype and BMI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DF508 Homo</td>
<td>23 (68%)</td>
<td>17 (50%)</td>
<td>-0.14 0.88</td>
</tr>
<tr>
<td>Mean BMI (SD)</td>
<td>21.2 (2.8)</td>
<td>21.3 (2.8)</td>
<td></td>
</tr>
<tr>
<td>DF508 Hetero</td>
<td>9 (26%)</td>
<td>12 (35%)</td>
<td>-0.51 0.62</td>
</tr>
<tr>
<td>Mean BMI (SD)</td>
<td>21.3 (2.8)</td>
<td>21.9 (2.6)</td>
<td></td>
</tr>
<tr>
<td>Other Genetics</td>
<td>2 (5.8%)</td>
<td>5 (15%)</td>
<td>-1.67 0.16</td>
</tr>
<tr>
<td>Mean BMI (SD)</td>
<td>18.3 (1.2)</td>
<td>22.2 (3.1)</td>
<td></td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>58.2 (10.6)</td>
<td>61.3 (10.2)</td>
<td>-1.21 0.23</td>
</tr>
<tr>
<td>Height (Metres)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>1.65 (0.08)</td>
<td>1.67 (0.09)</td>
<td>-0.94 0.35</td>
</tr>
<tr>
<td>BMI (Kg/M2)</td>
<td>21.0 (2.8)</td>
<td>21.6 (2.6)</td>
<td>-0.91 0.19</td>
</tr>
<tr>
<td>FEV1(% predicted)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>54.9 (25.3)</td>
<td>62.7 (22.3)</td>
<td>-1.25 0.22</td>
</tr>
</tbody>
</table>
The BMI distribution in this study population was compared to that of the UK CF database population (Cystic Fibrosis Centre Directors, 2002), Table 3-4, and they demonstrated similar patterns of BMI. The only exceptions being that the percentage of subjects with BMI between 15-19 are lower and the percentages of those with BMI 19-21 are higher in the study population. (See figure 3-3).

Table 3-4 BMI Distribution in the study population compared to the UKCF Database population 2002.

<table>
<thead>
<tr>
<th>BMI Range (Kg/m²)</th>
<th>UKCF Database population (N)</th>
<th>Study population(N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;15</td>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>15-17</td>
<td>153</td>
<td>1</td>
</tr>
<tr>
<td>17-19</td>
<td>518</td>
<td>9</td>
</tr>
<tr>
<td>19-21</td>
<td>766</td>
<td>26</td>
</tr>
<tr>
<td>21-23</td>
<td>658</td>
<td>15</td>
</tr>
<tr>
<td>23-25</td>
<td>384</td>
<td>8</td>
</tr>
<tr>
<td>25-27</td>
<td>181</td>
<td>6</td>
</tr>
<tr>
<td>27-29</td>
<td>72</td>
<td>3</td>
</tr>
<tr>
<td>&gt;29</td>
<td>60</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2822</strong></td>
<td><strong>68</strong></td>
</tr>
</tbody>
</table>
Figure 3-3 The distribution of BMI in the study population compared with the UKCF database population 2002 (UK CF Database University of Dundee (2002))
3.3.1 Education and Socio-economic status

There were no significant differences in education level and socio-economic status (SES) between the two groups, the results are shown in Table 3-5:

Table 3-5 Education level and Socio-economic status for the intervention and control groups of the study population (n=68)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N= 34</td>
<td>N= 34</td>
</tr>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>1</td>
<td>6 (18%)</td>
<td>4 (11.5%)</td>
</tr>
<tr>
<td>SES Status</td>
<td>9 (26%)</td>
<td>5 (15%)</td>
</tr>
<tr>
<td>2</td>
<td>2 (6%)</td>
<td>2 (6%)</td>
</tr>
<tr>
<td>3</td>
<td>13%</td>
<td>3 (9%)</td>
</tr>
<tr>
<td>4</td>
<td>4 (12%)</td>
<td>4 (11.5%)</td>
</tr>
<tr>
<td>5</td>
<td>5 (15%)</td>
<td>3 (9%)</td>
</tr>
<tr>
<td>6</td>
<td>7 (20%)</td>
<td>13 (38%)</td>
</tr>
<tr>
<td>Education</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>A</td>
<td>16 (47%)</td>
<td>14 (41%)</td>
</tr>
<tr>
<td>B</td>
<td>10 (29%)</td>
<td>11 (32%)</td>
</tr>
<tr>
<td>C</td>
<td>7 (21%)</td>
<td>7 (21%)</td>
</tr>
<tr>
<td>D</td>
<td>1 (3%)</td>
<td>2 (6%)</td>
</tr>
</tbody>
</table>

In order to test for differences between the groups, Chi squared was used for the categorical variables. Subjects classified in education groups C and D and SES groups 1 and 2, 3 to 5, 6 and 7 were combined in order to obtain sufficient numbers in each category for the chi squared test to be valid. There were no significant differences in either educational attainment (see table 3-6) or SES (see table 3-7) between the groups.

There was no significant difference in education level between the groups as illustrated by the Chi squared 0.24 (p=0.89).
Table 3-6 Comparisons between education classification in the intervention and the control groups.

<table>
<thead>
<tr>
<th>Education classification</th>
<th>Intervention (N)</th>
<th>Control (N)</th>
<th>Pearson Chi squared</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>16 (47%)</td>
<td>14 (41%)</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>10 (29%)</td>
<td>11 (32.5%)</td>
<td></td>
</tr>
<tr>
<td>C + D</td>
<td>8 (24%)</td>
<td>9 (26.5%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>34</td>
<td>34</td>
<td>Chi sq = 0.24 P=0.89</td>
</tr>
</tbody>
</table>

There was no significant difference in SES classification between the groups as illustrated by the Pearson Chi squared 2.32 (p=0.31).

Table 3-7 Comparisons between Socio-economic status classification in the intervention and the control groups.

<table>
<thead>
<tr>
<th>SES classification</th>
<th>Intervention</th>
<th>Control</th>
<th>Pearson Chi squared test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2</td>
<td>15 (44%)</td>
<td>9 (26.5%)</td>
<td></td>
</tr>
<tr>
<td>3-5</td>
<td>7 (21%)</td>
<td>9 (26.5%)</td>
<td></td>
</tr>
<tr>
<td>6-7</td>
<td>12 (35%)</td>
<td>16 (47%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>34</td>
<td>34</td>
<td>Chi sq = 2.32 P=0.31</td>
</tr>
</tbody>
</table>
3.3.2 Baseline results for secondary outcomes for intervention and control

There were no significant differences between groups in the results of the baseline questionnaires, which are given in table 3-8 below.

Table 3-8 Self-efficacy, general and specific nutrition knowledge and reported fat intake baseline questionnaire scores for intervention and control groups, (continued on the next page).

<table>
<thead>
<tr>
<th>Questionnaire (max score)</th>
<th>Intervention Mean (SD) N=34</th>
<th>Control Mean (SD) N=34</th>
<th>Independent samples t-test T P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy score (max 27)</td>
<td>17.9 (5.2)</td>
<td>17.8 (5.7)</td>
<td>0.06 0.95</td>
</tr>
<tr>
<td>General Nutrition Knowledge score (max 21)</td>
<td>10.5 (2.9)</td>
<td>10.9 (2.8)</td>
<td>-0.55 0.59</td>
</tr>
<tr>
<td>CF Specific Knowledge score (max 55)</td>
<td>35.2 (8.4)</td>
<td>36.8 (5.8)</td>
<td>-0.92 0.36</td>
</tr>
<tr>
<td>Reported fat intake score (max 63)</td>
<td>31.7 (7.2)</td>
<td>31.9 (8.4)</td>
<td>-0.94 0.93</td>
</tr>
</tbody>
</table>
Table 3-8 Continued - Quality of life baseline questionnaire scores for intervention and control groups.

<table>
<thead>
<tr>
<th>Quality of life score</th>
<th>Median (Interquartile range) N=34</th>
<th>Median (Interquartile range) N=34</th>
<th>MannWhitney U</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-10 (%) Physical functioning</td>
<td>88.2 (71.6 - 95.0)</td>
<td>88.3 (77.9 - 97.0)</td>
<td>517</td>
<td>0.45</td>
</tr>
<tr>
<td>11-14 (%) Social functioning</td>
<td>91.6 (83.3 - 100)</td>
<td>93.7 (75.0 - 100)</td>
<td>556</td>
<td>0.94</td>
</tr>
<tr>
<td>15-17 (%) Treatment issues</td>
<td>75.0 (55.5 - 100)</td>
<td>77.7 (61.6 - 94.4)</td>
<td>571</td>
<td>0.95</td>
</tr>
<tr>
<td>18-21 (%) Chest symptoms</td>
<td>79.1 (65.6 - 91.7)</td>
<td>81.3 (61.5 - 95.8)</td>
<td>536</td>
<td>0.93</td>
</tr>
<tr>
<td>22-29 (%) Emotional responses</td>
<td>87.5 (79.1 - 95.8)</td>
<td>84.4 (68.2 - 92.2)</td>
<td>442</td>
<td>0.09</td>
</tr>
<tr>
<td>30-35 (%) Concerns for the future</td>
<td>58.3 (41.7 - 72.2)</td>
<td>52.8 (36.1 - 68.1)</td>
<td>501</td>
<td>0.45</td>
</tr>
<tr>
<td>36-45 (%) Interpersonal relationships</td>
<td>70.0 (60.8 - 84.6)</td>
<td>65.8 (49.6 - 81.7)</td>
<td>501.5</td>
<td>0.35</td>
</tr>
<tr>
<td>46-48 (%) Body image</td>
<td>66.6 (50.0 - 83.3)</td>
<td>75.0 (55.5 - 84.7)</td>
<td>510.5</td>
<td>0.41</td>
</tr>
<tr>
<td>49-52 (%) Career issues</td>
<td>64.5 (45.8 - 83.3)</td>
<td>79.1 (57.3 - 88.5)</td>
<td>477.5</td>
<td>0.22</td>
</tr>
</tbody>
</table>

Note

*Section 46-48 on body image was a very small section, with 3 questions based on how CF had made participants feel about their weight/height. As these questions were based on subjective feelings they are liable to vary at different time periods.
3.4 Post intervention results

3.4.1 Weight

The next few sections will investigate the primary outcome measure, which was weight change at 6 and 12 months following the intervention versus control. The initial analysis was based on an intention to treat basis and the secondary analysis presented is for completers only.

Prior to randomisation, subjects were classified as “high” or “low” risk and stratified into the intervention or control groups, Table 3-9 shows the mean (SD) of weight and BMI at baseline and 6 and 12 months and independent samples t-test showing any differences between the two groups.

The difference in weight and BMI between the “high” risk and “low” risk subjects was statistically significant at all time points; this demonstrated why it was important to stratify these subjects into the control and intervention groups.
Table 3-9 Mean (SD) weight and BMI of high risk and low risk subjects at baseline, 6 and 12 months.

<table>
<thead>
<tr>
<th>Mean (SD)</th>
<th>High risk</th>
<th>Low risk</th>
<th>Independent samples t-test</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (Kg)</td>
<td>N=24</td>
<td>N=44</td>
<td>T</td>
<td>P</td>
</tr>
<tr>
<td>Baseline</td>
<td>55.0 (8.7)</td>
<td>62.4 (10.4)</td>
<td>-2.95</td>
<td>0.004*</td>
</tr>
<tr>
<td>6 months</td>
<td>55.9 (9.3)</td>
<td>62.5 (10.7)</td>
<td>-2.45</td>
<td>0.017*</td>
</tr>
<tr>
<td>12 months</td>
<td>56 (8.8)</td>
<td>62.5 (11.3)</td>
<td>-2.32</td>
<td>0.024*</td>
</tr>
</tbody>
</table>

| Mean (SD)    |                  |                      |
| BMI(Kg/m²)   |                  |                      |
| Baseline     | 20.0 (2.2)       | 22.1 (2.7)           | -3.23 | 0.002* | -3.4,-0.8            |
| 6 months     | 20.3 (2.3)       | 22.1 (2.7)           | -2.61 | 0.011* | -3.1,-0.4            |
| 12 months    | 20.4 (2.4)       | 22.2 (2.5)           | -2.70 | 0.009* | -3.09,-0.5           |

* denotes statistical significance, p<0.05

3.4.1.1 Intention to treat analysis

Table 3-10 shows the mean weight outcomes for the intervention and control groups at each time period, independent samples t-tests were used to assess any difference in these outcomes between the intervention and control groups. ITT analysis was completed with baseline values carried forward to replace missing data.
Table 3-10 Mean weight (SD) and BMI for Intervention (n=34) and Control groups (n=34) at Baseline, 6 and 12 months.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Time period</th>
<th>Intervention Mean (SD) N=34</th>
<th>Control Mean (SD) N=34</th>
<th>Independent samples t-test T</th>
<th>P</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (Kg)</td>
<td>Baseline</td>
<td>58.2 (10.6)</td>
<td>61.3 (10.2)</td>
<td>-1.20</td>
<td>0.231</td>
<td>-8.11,1.99</td>
</tr>
<tr>
<td></td>
<td>6 months</td>
<td>59.8 (11.2)</td>
<td>60.4 (10.4)</td>
<td>-0.23</td>
<td>0.816</td>
<td>-6.12,4.84</td>
</tr>
<tr>
<td></td>
<td>12 months</td>
<td>59.4 (11.1)</td>
<td>61.0 (10.9)</td>
<td>-1.05</td>
<td>0.296</td>
<td>-9.46,2.95</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>Baseline</td>
<td>21.0 (2.8)</td>
<td>21.6 (2.6)</td>
<td>-1.30</td>
<td>0.196</td>
<td>-6.00,1.25</td>
</tr>
<tr>
<td></td>
<td>6 months</td>
<td>21.5 (2.8)</td>
<td>21.3 (2.3)</td>
<td>0.30</td>
<td>0.764</td>
<td>-1.20,1.60</td>
</tr>
<tr>
<td></td>
<td>12 months</td>
<td>21.4 (2.7)</td>
<td>21.6 (2.3)</td>
<td>-0.21</td>
<td>0.832</td>
<td>-1.61,1.30</td>
</tr>
</tbody>
</table>

There were no significant differences in weight or BMI between the groups at any time period. The results are illustrated in figures 3-4 and 3-5.
Figure 3-4 Mean weight at baseline, 6 and 12 months for the intervention and control groups, with error bars indicating standard error of the mean (SEM), using the primary ITT analysis.
Figure 3-5 Mean BMI at baseline, 6 and 12 months for the intervention and control groups, with error bars indicating standard error of the mean (SEM), using the primary ITT analysis.

3.4.1.2 Change in weight outcomes at 6 and 12 months

The following tables 3-11, 3-12 show the changes in weight outcomes between the groups from baseline to 6 months, and from baseline to 12 months.

Table 3-11 Mean (SD) changes in body weight and BMI from baseline to 6 months comparing the intervention and control groups.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group Mean change (SD)</th>
<th>n</th>
<th>Control group Mean change (SD)</th>
<th>n</th>
<th>Independent samples T-Test T</th>
<th>P</th>
<th>95% CI of the difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (Kg)</td>
<td>0.57(2.4)</td>
<td>34</td>
<td>0.09(3.6)</td>
<td>34</td>
<td>0.61</td>
<td>0.545</td>
<td>-1.07, 2.0</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>0.19(0.84)</td>
<td>34</td>
<td>-0.06(1.21)</td>
<td>34</td>
<td>0.98</td>
<td>0.332</td>
<td>-0.26, 0.77</td>
</tr>
</tbody>
</table>
Table 3-12 Mean (SD) changes in outcome measure of BMI and weight from baseline to 12 months of the control group compared to the intervention group.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group Mean change (SD)</th>
<th>n</th>
<th>Control group Mean change (SD)</th>
<th>n</th>
<th>Independent samples T-Test T</th>
<th>P</th>
<th>95% CI of the difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (Kg)</td>
<td>1.14(3.2)</td>
<td>34</td>
<td>0.02(5.1)</td>
<td>34</td>
<td></td>
<td>1.02</td>
<td>0.308</td>
</tr>
<tr>
<td>BMI(Kg/m²)</td>
<td>0.43(1.2)</td>
<td>34</td>
<td>-0.06(1.6)</td>
<td>34</td>
<td></td>
<td>1.35</td>
<td>0.18</td>
</tr>
</tbody>
</table>

There was a mean increase of 0.57Kg in the intervention group at 6 months and 1.14Kg at 12 months. There was a mean increase of 0.09Kg in the control group at 6 months and 0.02Kg at 12 months. Although this was not statistically significant, a mean weight gain of 1.14Kg over 12 months is clinically very important in this population.

3.4.1.3 Analysis of variance (ANOVA)

Analysis of variance is commonly used in the collection of clinical data in which a subject receives a treatment and then a response is measured on several occasions over a period of time. A common approach to such data as has been illustrated in the previous sections is to carry out a 2 sample t-test at each time separately and consider at what time the difference become significant. This is misleading, as the significance is a property of the sample rather than the population. The difference may not be significant because the sample is small and the difference to be detected is small in the population. Further if we do this for each time point, we are carrying out multiple significance tests and as each test only uses a small part of the data we are loosing power. It is better to ask if there is any evidence of a difference between the control and intervention groups over the whole period of observation.

If we use all the data to estimate variance we will have more degrees of freedom and hence a more powerful comparison, this is done by using analysis of variance (ANOVA).

Univariate ANOVA was used to compare the variation between the groups to the variation within the groups.
This ANOVA was completed with the difference in weight as the dependant variable, the intervention and control groups as fixed factors with a covariate of baseline weight. There was no statistically significant difference in weight or BMI between the groups when adjusted for baseline values as illustrated in table 3-13.

Table 3-13 Difference in weight and BMI between the intervention (n=34) and the control groups (n=34) adjusted for baseline measures.

<table>
<thead>
<tr>
<th>Time period</th>
<th>Mean difference (95%CI)</th>
<th>F Ratio</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight 6 months (Kg)</td>
<td>0.38 (-1.18, 1.94)</td>
<td>F 1,63 = 0.237</td>
<td>0.628</td>
</tr>
<tr>
<td>Weight 12 months (Kg)</td>
<td>1.02 (-1.19, 3.22)</td>
<td>F 1,63 = 0.857</td>
<td>0.358</td>
</tr>
<tr>
<td>BMI 6 months (Kg/m²)</td>
<td>0.20 (-0.30, 0.71)</td>
<td>F 1,63 = 0.648</td>
<td>0.424</td>
</tr>
<tr>
<td>BMI 12 months (Kg/m²)</td>
<td>0.43 (-0.25, 1.11)</td>
<td>F 1,63 = 1.594</td>
<td>0.212</td>
</tr>
</tbody>
</table>
3.4.1.4 Repeated measures ANOVA

Although there was a weight change in the intervention group at 6 and 12 months, this difference was not statistically significant from the control. A repeated measures ANOVA was carried out to see if there was any significant difference in weight or BMI post treatment, when considering the treatment phase (intervention to 12 months) overall. Simple contrasts were completed in which each follow up is compared with baseline.

Table 3-14 Repeated measures ANOVA for weight and BMI with baseline weight as a covariate and treatment as a between group factor.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Mean difference (95% CI)</th>
<th>F Ratio</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (Kg)</td>
<td>0.756 (-1.02, 2.53)</td>
<td>F 1,60 = 0.722</td>
<td>0.399</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>0.355 (-0.20, 0.91)</td>
<td>F 1,60 = 1.624</td>
<td>0.207</td>
</tr>
</tbody>
</table>

There was no overall significant weight difference post-treatment between groups, adjusted for baseline (p=0.399). The average increase in weight over the 6-12 month period (i.e. the treatment effect) adjusted for baseline was 0.76Kg (95% CI –1.02,-2.53).

There was no overall difference in BMI post-treatment between groups, adjusted for baseline BMI (p=0.207). The average increase in BMI over the 6-12 month period for the intervention group (treatment effect) adjusted for baseline was 0.355 Kg/m² (95% CI –0.202,-0.913).
3.4.1.5 Measuring the treatment effect

Standard statistical practice employs an intention-to-treat comparison in which one compares those randomised to treatment and control without reference to whether they actually received the treatment. Intention-to-treat comparisons estimate the programmatic effectiveness of a treatment rather than its 'biologic efficacy'. ‘Biologic efficacy’ is the effect of the treatment for all persons who receive the therapeutic agent to which they were assigned. It measures the biologic action of treatment among compliant persons.

Intention-to-treat analyses as previously acknowledged, ignores whether or not the patient received the experimental treatment according to the trial’s protocol, and thus attempts to answer the question of what will happen if there is a change in patient management (since a proportion of subjects will not undertake the treatment advice).

If we assume there are two groups of subjects: the “compliers” who would take the treatment if randomised to the treatment and would take the control if randomised to the control; and the “never-takers” who would never take the treatment regardless to which group they were randomised. A Complier Average Causal Effect (CACE) analysis makes extra, uncheckable assumptions and estimates the effect of treatment, rather than randomisation, in the group of “compliers”.” (Angrist et al., 1996, Sommer, 1990).

The CACE analysis is defined to be the intention to treat analysis effect in the “complier” subgroup of patients.

In the general case, one can assume that every patient could have a variety of different treatments, T and consequently, if they were to receive a specific treatment then the outcome of interest would be Y(t). A causal effect is defined to be the difference, within, a patient of Y(t1)-Y(t2), for two specific treatments of interest. When there are only two choices of treatments, then the causal effect only exist in the subgroup of “compliers”, and its size corresponds to the CACE.

The instrumental variables technique produces a consistent estimate of the causal effect under the following assumptions

- The Stable Unit Treatment Value Assumption. This assumes that each patient's choice of treatment and outcome is not influenced in any way by other patient.
- Randomisation really is random. This guarantees that the effect of randomisation is only transmitted through its influence on which treatment is received.
- The exclusion restriction. This says that if a patient were to receive the same
treatment in either arm (i.e. they are a never taker) then their outcome would be identical.

- Non-zero average causal effect of randomisation on treatment. This assumes that on average the incidence of receiving the treatment is different between the randomised arms—the randomisation does have some influence on which treatment is received.
- Monotonicity. This says that there are no patients who do the opposite to which they are assigned. In the case of the current study, patients who were assigned to “no education” control arm could not go onto the educational intervention arm, due to how the trial was designed.

Compliance was measured from the start of the study until completion. The definition of “compliance” was, those participants in the intervention group who:

- attended at least one of the three group workshops held in the hospital or made apologies and kept in close contact by e-mail (for those in full time employment) and completed the post-intervention questionnaires, and answered and responded to at least two of the five fortnightly phone calls (that were used to monitor progress).

Using the above criteria the intervention group in this study consisted of 7 non compliant patients and 27 compliant patients.
Table 3-15 Instrumental Variable (IV) analysis of weight and BMI using a CACE approach.

<table>
<thead>
<tr>
<th>Response</th>
<th>Period</th>
<th>Estimate</th>
<th>Std Error</th>
<th>Z statistic</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (Kg)</td>
<td>6 months</td>
<td>0.6416</td>
<td>1.1687</td>
<td>0.55</td>
<td>0.5840</td>
</tr>
<tr>
<td></td>
<td>12 months</td>
<td>1.3586</td>
<td>1.1939</td>
<td>1.14</td>
<td>0.2574</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>6 months</td>
<td>0.2881</td>
<td>0.3759</td>
<td>0.77</td>
<td>0.4449</td>
</tr>
<tr>
<td></td>
<td>12 months</td>
<td>0.5445</td>
<td>0.3840</td>
<td>1.42</td>
<td>0.1588</td>
</tr>
</tbody>
</table>

From the Instrumental variable analysis, if an individual patient complied with the Education programme it was estimated they would increase their weight by 0.64Kg in 6 months and 1.35Kg in 12 months, these analyses, does not give any further evidence of a statistically significant effect of the intervention. The weight gain demonstrated using the CACE approach however is clinically relevant in the context that many CF subjects have a low weight and are aiming to increase it. It would be advantageous to be able to inform subjects that providing they comply with the intervention, they could expect an average weight gain of 1.35Kg in 12 months.

Selection bias

There was strong evidence of a selection effect for weight (the systematic difference between compliers and never-takers). That is, the outcome that would have been observed in each patient if they had received the control treatment i.e. standard dietetic intervention (adjusted for weight, height and BMI).

There was an estimated difference between compliers and never takers of 2.59Kg (s.e.0.705) i.e. compliers were on average 2.59Kg lighter than never takers. This is not surprising, as we would expect lighter subjects to be more motivated to comply than heavier subjects. The heavier subjects may not consider they have any nutritional problems and therefore do not see any perceived benefit in completing the programme, hence do not comply.
3.4.1.6 Completers analysis

A secondary completers analysis was conducted to identify any differences between the control and the intervention groups in only those subjects who returned completed data, as an example of best effect. Table 3-16 shows mean values for weight outcomes at baseline and 6 and 12 months, independent samples t-tests were used to assess any difference in outcomes between intervention and the control group’s weights for completers.

Table 3-16 Mean weight (SD) and BMI (SD) for intervention and control at baseline, 6 and 12 months using completers’ data.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention N=23 Mean (SD)</th>
<th>Control N=25 Mean (SD)</th>
<th>Independent samples t-test</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight baseline (Kg)</td>
<td>59.2 (9.7)</td>
<td>59.4 (10.0)</td>
<td>-0.11</td>
<td>0.913</td>
</tr>
<tr>
<td>Weight 6 months (Kg)</td>
<td>59.5 (10.0)</td>
<td>60.2 (10.8)</td>
<td>-0.23</td>
<td>0.823</td>
</tr>
<tr>
<td>Weight 12 months (Kg)</td>
<td>59.9 (9.7)</td>
<td>60.6 (11.2)</td>
<td>-0.23</td>
<td>0.819</td>
</tr>
<tr>
<td>BMI baseline (Kg/m²)</td>
<td>21.3 (2.8)</td>
<td>21.2 (2.7)</td>
<td>0.18</td>
<td>0.855</td>
</tr>
<tr>
<td>BMI 6 months (Kg/m²)</td>
<td>21.5 (2.8)</td>
<td>21.3 (2.5)</td>
<td>0.26</td>
<td>0.796</td>
</tr>
<tr>
<td>BMI 12 months (Kg/m²)</td>
<td>21.5 (2.7)</td>
<td>21.3 (2.3)</td>
<td>0.35</td>
<td>0.724</td>
</tr>
</tbody>
</table>

There were no significant differences in weight or BMI between the groups at baseline, 6 or 12 months.
Table 3-17 ANOVA showing the difference between the control and intervention groups for weight and BMI at 6 months and 12 months adjusted for baseline weight in completers (n=48) only.

<table>
<thead>
<tr>
<th>Time period</th>
<th>Mean difference (95%CI)</th>
<th>F Ratio</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight 6 months(Kg)</td>
<td>-0.37 (-2.35, 1.60)</td>
<td>F 1,42 = 0.148</td>
<td>0.70</td>
</tr>
<tr>
<td>Weight 12 months(Kg)</td>
<td>-0.40 (-2.95, 2.14)</td>
<td>F 1,42 = 0.102</td>
<td>0.75</td>
</tr>
<tr>
<td>BMI 6 months(Kg/m²)</td>
<td>0.07 (-0.58, 0.72)</td>
<td>F 1,42 = 0.052</td>
<td>0.82</td>
</tr>
<tr>
<td>BMI 12 months(Kg/m²)</td>
<td>0.15 (-0.68, 0.98)</td>
<td>F 1,42 = 0.140</td>
<td>0.71</td>
</tr>
</tbody>
</table>

This ANOVA was completed with the difference in weight as the dependent variable, the intervention and control groups as fixed factors with a covariate of baseline weight.

There are smaller mean differences in weight outcomes in the completers analysis compared to the Intention-to-treat analysis; this could be partly attributable to the reduced sample size. This could also be attributable to the fact that compliant subjects were more likely to have a lower baseline weight. We could hypothesise that these subjects would be more likely to have lower lung function, more chest infections and therefore find it more difficult to gain weight than the non-completers. There were no significant differences between the groups.

The impact of the programme on secondary outcomes will be investigated throughout the next few sections. Secondary outcomes were: CF specific nutrition knowledge, general nutrition knowledge, and self-efficacy, reported fat intake, quality of life and stages of change.
3.4.2 Specific nutrition knowledge and general nutrition knowledge

This next section investigates the change in the secondary outcomes of CF specific and general nutrition knowledge. These were measured at 6 and 12 months following the intervention/control, the initial analysis was based on an intention-to-treat analysis with baseline values carried forward to replace missing data.

3.4.2.1 Change in CF specific nutrition knowledge and general nutrition knowledge outcomes between the groups from baseline to 6 and 12 months.

The mean change in CF specific and general nutrition knowledge from baseline to 6 months and from baseline to 12 months is shown in tables 3-18 and 3-19.

Table 3-18 Mean change in CF specific and general nutrition knowledge scores from baseline to 6 months comparing the control group and the intervention group.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group Mean change (SD)</th>
<th>n</th>
<th>Control group Mean change (SD)</th>
<th>n</th>
<th>Independent samples T-Test T</th>
<th>P</th>
<th>95% CI of the difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>CF Specific nutrition knowledge</td>
<td>5.63(5.4)</td>
<td>34</td>
<td>0.34(3.6)</td>
<td>34</td>
<td>5.24</td>
<td>&lt;0.001*</td>
<td>3.01, 7.47</td>
</tr>
<tr>
<td>General nutrition knowledge</td>
<td>-0.12(3.2)</td>
<td>34</td>
<td>0.20(2.6)</td>
<td>34</td>
<td>-0.44</td>
<td>0.654</td>
<td>-1.7, 1.10</td>
</tr>
</tbody>
</table>

* Denotes statistically significant difference between the control and intervention groups.
Table 3-19 Mean (SD) change in CF specific and general nutrition knowledge from baseline to 12 months comparing the control group and the intervention group.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group Mean change (SD)</th>
<th>n</th>
<th>Control group Mean change (SD)</th>
<th>n</th>
<th>Independent samples T-Test T</th>
<th>P</th>
<th>95% CI of the difference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CF Specific nutrition knowledge</strong></td>
<td>3.81(4.2)</td>
<td>34</td>
<td>0.74(3.1)</td>
<td>34</td>
<td>3.44</td>
<td>&lt;0.001*</td>
<td>1.29, 4.85</td>
</tr>
<tr>
<td><strong>General nutrition knowledge</strong></td>
<td>0.42(2.7)</td>
<td>34</td>
<td>-0.37(4.3)</td>
<td>34</td>
<td>1.07</td>
<td>0.288</td>
<td>-0.67, 2.26</td>
</tr>
</tbody>
</table>

* Denotes statistically significant difference between control and intervention groups.

3.4.2.2 Specific nutrition knowledge

There was a mean increase in specific nutrition knowledge of 5.63 points from baseline to 6 months and 3.81 points at 12 months in the intervention group, and a mean change of 0.34 points at 6 months and 0.74 points at 12 months in the control group. This reports a highly significant difference between the groups (p=<0.001) at both time periods and substantiates the second hypothesis that adults with CF completing a home-based nutrition education programme will have an improvement in specific nutrition knowledge following completion of the programme. The mean specific nutrition knowledge scores at all time periods are illustrated by the following graph (figure 3-6).
Figure 3-6 Specific nutrition knowledge score at baseline, 6 and 12 months for the intervention and control groups, with error bars indicating standard error of the mean (SEM), using primary ITT analysis.

* p < 0.001, ** p < 0.001
3.4.2.3 General nutrition knowledge

There was a mean decrease in general nutrition knowledge of -0.12 points from baseline to 6 months and 0.42 points from baseline to 12 months in the intervention group, and a mean change of 0.20 points from baseline to 6 months and -0.37 points from baseline to 12 months in the control group. The mean general nutrition knowledge scores at all time periods are illustrated in Figure 3-7.

Figure 3-7 General nutrition knowledge scores at baseline, 6 and 12 months for the intervention and control groups, with error bars indicating standard error of the mean (SEM), using primary ITT analysis.
3.4.2.4 Univariate analysis of variance

This ANOVA was completed with the difference in knowledge scores as the dependant variable, the intervention and control groups as fixed factors with a covariate of baseline knowledge score.

*Table 3-20 Difference in CF specific and general nutrition knowledge scores at 6 and 12 months between the intervention and the control groups adjusted for baseline knowledge.*

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean Difference (95%CI) at 6 months</th>
<th>F Ratio</th>
<th>P</th>
<th>Mean Difference (95%CI) at 12 months</th>
<th>F Ratio</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>General nutrition knowledge</td>
<td>-0.38 (-1.99, 1.22)</td>
<td>F 1,63 = 0.233</td>
<td>P = 0.631</td>
<td>1.15 (-0.80, 3.12)</td>
<td>F 1,63 = 1.419</td>
<td>P = 0.240</td>
</tr>
<tr>
<td>Specific nutrition knowledge</td>
<td>5.71 (4.05, 7.38)</td>
<td>F 1,63 = 47.07 P = &lt;0.001*</td>
<td></td>
<td>4.33 (2.32, 6.33)</td>
<td>F 1,63 = 18.91 P = &lt;0.001*</td>
<td></td>
</tr>
</tbody>
</table>

* Denotes statistical significance

As detailed in table 3-20, the difference in CF specific nutrition knowledge scores between the intervention and the control groups remain highly significant following univariate analysis of variance. The intervention group have a statistically significant increase in specific nutrition knowledge score following the intervention compared to the control group.
3.4.2.5 The Completers analysis

Independent samples t-tests were used to assess any absolute differences in knowledge at baseline between the intervention and control groups for completers. This is illustrated in Table 3-21.

Table 3-21 Mean general and CF specific nutrition knowledge scores (SD) for intervention and control at baseline, 6 and 12 months, completers only.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention group N=23 Mean (SD)</th>
<th>Control group N=25 Mean (SD)</th>
<th>Independent samples t-test</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>General nutrition knowledge at baseline</td>
<td>11.1 (2.7)</td>
<td>11.3 (2.6)</td>
<td>-0.28</td>
<td>0.775</td>
</tr>
<tr>
<td>General nutrition knowledge at 6 months</td>
<td>11.6 (2.9)</td>
<td>10.9 (3.8)</td>
<td>0.65</td>
<td>0.519</td>
</tr>
<tr>
<td>General nutrition knowledge at 12 months</td>
<td>12.10 (2.6)</td>
<td>11.2 (3.8)</td>
<td>0.84</td>
<td>0.407</td>
</tr>
<tr>
<td>CF Specific nutrition knowledge at baseline</td>
<td>36.9 (6.7)</td>
<td>37.4 (5.1)</td>
<td>-0.23</td>
<td>0.823</td>
</tr>
<tr>
<td>CF Specific nutrition knowledge at 6 months</td>
<td>42.7 (3.9)</td>
<td>37.5 (5.2)</td>
<td>3.8</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>CF Specific nutrition knowledge at 12 months</td>
<td>41.8 (4.9)</td>
<td>38.9 (6.1)</td>
<td>1.70</td>
<td>0.096</td>
</tr>
</tbody>
</table>

* Denotes statistically significant difference between control and intervention groups using independent samples t-test.
Tables 3-22 and 3-23 show the mean difference in nutrition knowledge scores at 6 and 12 months between the groups using ANOVA and adjusting for baseline knowledge.

This ANOVA was completed with the difference in knowledge score as the dependant variable, the intervention and control groups as fixed factors with a covariate of baseline knowledge score.

Table 3-22 Mean difference in CF specific and general nutrition knowledge scores at 6 months between the intervention n=23 and the control group n=25 adjusted for baseline knowledge for completers only.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean Difference (95%CI)</th>
<th>F Ratio</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>General nutrition knowledge</td>
<td>0.81 (-0.93, 2.55)</td>
<td>F 1,42 = 0.888</td>
<td>0.351</td>
</tr>
<tr>
<td>Specific nutrition knowledge</td>
<td>5.43 (3.51, 7.30)</td>
<td>F 1,42 = 35.45</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

* Denotes statistically significant difference in specific nutrition knowledge between the intervention and control groups.

Table 3-23 Mean difference in CF specific and general nutrition knowledge scores at 12 months between the intervention n=23 and the control group n=25 adjusted for baseline knowledge for completers only.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean Difference (95%CI)</th>
<th>F Ratio</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>General nutrition knowledge</td>
<td>0.85 (-0.93, 2.64)</td>
<td>F 1,42 = 0.945</td>
<td>0.337</td>
</tr>
<tr>
<td>Specific nutrition knowledge</td>
<td>3.26 (1.31, 5.22)</td>
<td>F 1,42 = 11.417</td>
<td>0.002*</td>
</tr>
</tbody>
</table>

* Denotes statistically significant difference in specific nutrition knowledge between the intervention and control groups.

There was a highly statistically significant difference in CF specific nutrition knowledge between the groups at 6 months (p<0.001), with the intervention group increasing their specific knowledge scores and no change in the control group receiving standard care. This
effect is maintained at 12 months (p=0.002). There was no significant difference in general nutrition knowledge between the groups at any time period.
3.4.3 Self-efficacy

This section will focus on the change in self-efficacy score between the intervention and control groups. The primary analysis is based on an intention-to-treat with baseline values carried forward to replace missing data.

3.4.3.1 Changes in mean self-efficacy score between the groups from baseline to 6 and baseline to 12 months.

Table 3-24 shows the mean change in self-efficacy scores from baseline to 6 months and baseline to 12 months.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Intervention group Mean change (SD)</th>
<th>n</th>
<th>Control group Mean change (SD)</th>
<th>n</th>
<th>Independent samples T-Test</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy score at 6 months</td>
<td>3.15(5.3)</td>
<td>34</td>
<td>-0.17(4.2)</td>
<td>34</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>T 2.89</td>
<td>0.005*</td>
</tr>
<tr>
<td>Self-efficacy score at 12 months</td>
<td>4.17(5.1)</td>
<td>34</td>
<td>0.67(5.3)</td>
<td>34</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>T 2.28</td>
<td>0.027*</td>
</tr>
</tbody>
</table>

* Denotes statistical significance

There was a mean increase in the self-efficacy score in the intervention group of 3.15 points from baseline to 6 months and 4.17 points from baseline to 12 months. There was a mean change of -0.17 points from baseline to 6 months and 0.67 points from baseline to 12 months in the control group, this difference is statistically significant. This substantiates the third hypothesis that adults with CF completing a home-based nutrition education programme will have an improvement in self-efficacy following completion of the programme. The mean self-efficacy scores at all time periods are illustrated in figure 3-8.
Figure 3-8 Self-efficacy score at baseline, 6 and 12 months for the intervention and control groups, with error bars indicating the standard error of the mean (SEM), using primary ITT analysis.

(* p=0.003 ** p=0.019)

3.4.3.2 Analysis of variance

Analysis of variance demonstrates the difference in self-efficacy scores between the intervention and the control groups at 6 and 12 months. This ANOVA was completed with the difference in self-efficacy score as the dependant variable, the intervention and control groups as fixed factors with a covariate of baseline self-efficacy score. The difference was highly significant (p=0.003 at 6 months and p=0.019 at 12 months), see table 3-25.
Table 3-25 Difference in self-efficacy score at 6 and 12 months between the intervention and the control groups adjusted for baseline score.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean Difference (95%CI) at 6 months</th>
<th>F Ratio</th>
<th>P</th>
<th>Mean Difference (95%CI) at 12 months</th>
<th>F Ratio</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy</td>
<td>3.43 (1.19, 5.67)</td>
<td>F 1,63 = 9.475</td>
<td>P = 0.003*</td>
<td>3.38 (0.59, 6.18)</td>
<td>F 1,63 = 5.96</td>
<td>P = 0.019*</td>
</tr>
</tbody>
</table>

3.4.3.3 Completers analysis

Independent samples t-tests were used to assess any differences in self-efficacy outcomes between the intervention and control groups for completers. This is illustrated in Table 3-26.

Table 3-26 Mean self-efficacy score (SD) for intervention and control groups at baseline, 6 and 12 months for completers only.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention group N=23 Mean (SD)</th>
<th>Control group N=25 Mean (SD)</th>
<th>Independent samples t-test</th>
<th>95%CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy score at baseline</td>
<td>18.0 (5.6)</td>
<td>17.9 (4.4)</td>
<td>0.059</td>
<td>0.954</td>
</tr>
<tr>
<td>Self-efficacy score at 6 months</td>
<td>21.9 (4.4)</td>
<td>17.7 (5.1)</td>
<td>2.94</td>
<td>0.005*</td>
</tr>
<tr>
<td>Self-efficacy score at 12 months</td>
<td>22.6 (5.2)</td>
<td>19.3 (4.4)</td>
<td>2.21</td>
<td>0.032*</td>
</tr>
</tbody>
</table>

* Denotes statistically significant difference between the control and intervention groups.
Analysis of variance demonstrated the mean difference in self-efficacy scores between the intervention and control groups for completers at 6 and 12 months, which confirms the statistical significance of this finding.

This ANOVA was completed with the difference in self-efficacy score as the dependant variable, the intervention and control groups as fixed factors with a covariate of baseline self-efficacy score. See Table 3-27.

Table 3-27 Mean difference in self-efficacy score at 6 and 12 months between the intervention and the control groups adjusted for baseline self-efficacy for completers only.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean Difference (95%CI) at 6 months</th>
<th>F Ratio</th>
<th>P</th>
<th>Mean Difference (95%CI) at 12 months</th>
<th>F Ratio</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy</td>
<td>4.14 (1.6, 6.6)</td>
<td>F 1.42 = 11.15</td>
<td>0.002*</td>
<td>3.44 (0.93, 5.96)</td>
<td>F 1.42 = 7.67</td>
<td>0.009*</td>
</tr>
</tbody>
</table>
3.4.4 Reported dietary fat intake

This section investigates the secondary outcome of change in reported dietary fat intake between the intervention and control groups. As with the previous outcome analysis, the primary analysis is reported on an intention to treat basis with missing values replaced by baseline measures.

3.4.4.1 Change in reported fat intake between the groups from baseline to 6 months and baseline to 12 months.

Table 3-28 Mean (SD) change in reported fat intake from baseline to 6 months and baseline to 12 months using Intention to treat analysis.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group Mean change (SD)</th>
<th>n</th>
<th>Control group Mean change (SD)</th>
<th>n</th>
<th>Independent samples T-Test T</th>
<th>P</th>
<th>95% CI of the difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported fat intake score at 6 months</td>
<td>2.69(5.8)</td>
<td>34</td>
<td>-0.57(4.4)</td>
<td>34</td>
<td>2.67</td>
<td>0.010*</td>
<td>0.76, 5.76</td>
</tr>
<tr>
<td>Reported fat intake score at 12 months</td>
<td>1.03(4.8)</td>
<td>34</td>
<td>-0.85(4.1)</td>
<td>34</td>
<td>1.72</td>
<td>0.092</td>
<td>-0.31, 4.08</td>
</tr>
</tbody>
</table>

* Denotes statistically significant differences between the control and intervention groups.

Table 3-28 demonstrates that there was an increase in reported fat intake score of 2.69 points from baseline to 6 months and 1.03 points from baseline to 12 months in the intervention group and a mean decrease of -0.57 points at 6 months with a further decrease of -0.85 points at 12 months in the control group. This is highly significant between groups at 6 months (p=0.010), but not significant at 12 months (p=0.092). The mean reported fat intake scores at all time periods are illustrated in figure 3-9.
Figure 3-9 Reported fat intake score at baseline, 6 and 12 months, with error bars indicating standard error of the mean (SEM), using primary ITT analysis.

(*p=0.014)
3.4.4.2 Analysis of variance

This ANOVA was completed with the difference in reported fat intake score as the dependant variable, the intervention and control groups as fixed factors with a covariate of baseline reported fat intake score.

The mean difference in reported fat intake scores at 6 and 12 months between the intervention and the control groups is illustrated in table 3-29.

Table 3-29 Mean difference in reported fat intake scores at 6 and 12 months between the intervention and the control groups adjusted for baseline reported fat intake score.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Difference (95%CI)</th>
<th>F Ratio</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported fat intake at 6 months</td>
<td>3.63 (0.76, 6.50)</td>
<td>F 1,63 = 6.42</td>
<td>0.014*</td>
</tr>
<tr>
<td>Reported fat intake at 12 months</td>
<td>2.12 (0.17, 5.24)</td>
<td>F1,63 = 1.87</td>
<td>0.178</td>
</tr>
</tbody>
</table>
3.4.4.3 Completers analysis

Independent samples t-tests were used to assess any differences in reported fat intake outcomes between the intervention and control groups for completers. This is illustrated in Table 3-30.

**Table 3-30 Mean reported fat intake score (SD) for intervention and control at baseline, 6 and 12 months for completers only.**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention group N=23 Mean (SD)</th>
<th>Control group N=25 Mean (SD)</th>
<th>Independent samples t-test T</th>
<th>P</th>
<th>95%CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported fat intake score at baseline</td>
<td>30.9 (7.7)</td>
<td>33.2 (6.1)</td>
<td>-1.13</td>
<td>0.264</td>
<td>-6.59,1.85</td>
</tr>
<tr>
<td>Reported fat intake score at 6 months</td>
<td>33.7 (9.4)</td>
<td>32.1 (6.0)</td>
<td>0.65</td>
<td>0.517</td>
<td>-3.25,6.37</td>
</tr>
<tr>
<td>Reported fat intake score at 12 months</td>
<td>32.4 (8.8)</td>
<td>32.2 (5.9)</td>
<td>0.08</td>
<td>0.935</td>
<td>-4.51,4.89</td>
</tr>
</tbody>
</table>

Table 3-31 demonstrates the difference in results for fat intake score at 6 months and 12 months between the intervention and the control groups.

**Table 3-31 ANOVA showing difference in results for fat intake score at 6 months and 12 months between the intervention and the control groups adjusted for baseline fat intake.**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Difference (95%CI)</th>
<th>F Ratio</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported fat intake at 6 months</td>
<td>3.55 (0.22, 6.89)</td>
<td>F 1,42 = 4.63</td>
<td>0.037*</td>
</tr>
<tr>
<td>Reported fat intake at 12 months</td>
<td>1.93 (-1.45, 5.33)</td>
<td>F 1,42 = 1.33</td>
<td>0.256</td>
</tr>
</tbody>
</table>
This ANOVA was completed with the difference in reported fat intake scores the dependant variable, the intervention and control groups as fixed factors with a covariate of baseline reported fat intake score.

As with the intention-to-treat analysis the change in reported fat intake is significant at 6 months (p=0.037), but this effect was not maintained at 12 months (p=0.256).

### 3.4.5 Quality of life measures

This section details the results for the Quality of Life questionnaire. The data for quality of life was not normally distributed therefore non-parametric tests (Mann Whitney U) were applied.

The following tables show the median (interquartile range) Quality of Life scores at 6 and 12 months and the changes in Quality of Life measures between baseline and 6 months and baseline and 12 months between the intervention and control groups as tested by the Mann Whitney U test.

#### 3.4.5.1 Intention-to-treat

The initial analysis was based on an intention-to-treat basis.

Tables 3-32 and 3-33 demonstrate the median quality of life scores in the intervention and control groups and the Mann Whitney U statistic and P value show the difference in quality of life measures between the groups between baseline and 6 months and baseline and 12 months.
Table 3-32 Median (interquartile range) for quality of life actual scores in the intervention and control group, the Mann Whitney U statistic and P value showing the differences in quality of life measures between the groups between baseline and 6 months.

<table>
<thead>
<tr>
<th>Quality of life score at 6 months</th>
<th>Intervention (n=34) Median (Interquartile range)</th>
<th>Control (n=34) Median (Interquartile range)</th>
<th>Mann Whitney U</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-10 (%) Physical functioning</td>
<td>84.2 (76.7,96.2)</td>
<td>93.3(87.1,98.3)</td>
<td>428</td>
<td>0.93</td>
</tr>
<tr>
<td>11-14(%) Social functioning</td>
<td>93.8 (84.3,100)</td>
<td>93.7(80.2,100)</td>
<td>387</td>
<td>0.47</td>
</tr>
<tr>
<td>15-17(%) Treatment issues</td>
<td>77.7 (66.6,100)</td>
<td>80.5(66.6,94.4)</td>
<td>434.5</td>
<td>0.64</td>
</tr>
<tr>
<td>18-21(%) Chest symptoms</td>
<td>83.3(65.6,91.7)</td>
<td>85.4(77.6,97.9)</td>
<td>377</td>
<td>0.29</td>
</tr>
<tr>
<td>22-29(%) Emotional responses</td>
<td>92.7(79.6,97.9)</td>
<td>87.5(77.6,97.9)</td>
<td>299</td>
<td>0.04*</td>
</tr>
<tr>
<td>30-35(%) Concerns for the future</td>
<td>62.5(41.6,77.7)</td>
<td>54.1(38.8,65.9)</td>
<td>410.5</td>
<td>0.72</td>
</tr>
<tr>
<td>36-45 (%) Interpersonal relationships</td>
<td>71.6(50,86.2)</td>
<td>68.3(56.6,85.8)</td>
<td>431.5</td>
<td>0.97</td>
</tr>
<tr>
<td>46-48(%) Body image</td>
<td>72.2(50,94.4)</td>
<td>77.7(55.5,83.3)</td>
<td>429</td>
<td>0.93</td>
</tr>
<tr>
<td>49-52 (%) Career issues</td>
<td>64.5(50.0,83.3)</td>
<td>77.0(51.0,95.8)</td>
<td>405</td>
<td>0.66</td>
</tr>
<tr>
<td>Quality of life score at 12 months</td>
<td>Intervention (n=34) Median (Interquartile range)</td>
<td>Control (n=34) Median (Interquartile range)</td>
<td>Mann Whitney U</td>
<td>P</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-----------------------------------------------</td>
<td>--------------------------------------------</td>
<td>---------------</td>
<td>---</td>
</tr>
<tr>
<td>1-10 (%) Physical functioning</td>
<td>90(83.3,95)</td>
<td>88.3(68.3,97.9)</td>
<td>241</td>
<td>0.45</td>
</tr>
<tr>
<td>11-14(%) Social functioning</td>
<td>91.6(83.3,100)</td>
<td>85.4(76.0,98.9)</td>
<td>248.5</td>
<td>0.56</td>
</tr>
<tr>
<td>15-17(%) Treatment issues</td>
<td>77.7(66.6,94.4)</td>
<td>78.7(51.4,88.8)</td>
<td>377</td>
<td>0.32</td>
</tr>
<tr>
<td>18-21(%) Chest symptoms</td>
<td>83.3(66.6,91.6)</td>
<td>83.3(67.7,98.9)</td>
<td>256.5</td>
<td>0.67</td>
</tr>
<tr>
<td>22-29(%) Emotional responses</td>
<td>93.7(85.4,97.9)</td>
<td>79.1(73.4,92.7)</td>
<td>264</td>
<td>0.79</td>
</tr>
<tr>
<td>30-35(%) Concerns for the future</td>
<td>75.0(55.5,80.5)</td>
<td>48.6(39.5,66.6)</td>
<td>198.5</td>
<td>0.10</td>
</tr>
<tr>
<td>36-45 (%) Interpersonal relationships</td>
<td>68.3(53.3,86.6)</td>
<td>74.2(50.5,81.3)</td>
<td>253.5</td>
<td>0.63</td>
</tr>
<tr>
<td>46-48(%) Body image</td>
<td>72.2(61.1,94.4)</td>
<td>69.4(61.1,83.3)</td>
<td>234.5</td>
<td>0.37</td>
</tr>
<tr>
<td>49-52 (%) Career issues</td>
<td>62.5(45.8,100)</td>
<td>81.3(59.4,91.6)</td>
<td>254</td>
<td>0.64</td>
</tr>
</tbody>
</table>

There were only minor changes in quality of life scores throughout the study period. There was one statistically significant difference between the control and the intervention group’s scores in quality of life at different time periods. There were no other significant differences between baseline and 6 and 12 months. Emotional responses were significantly different at 6 months (p=0.04) however this difference was not shown at 12 months. The emotional responses section of the quality of life questionnaire focuses on whether CF has made the subjects feel resentful, angry, embarrassed, and irritable or fed up, over the last two weeks. Due to the very immediate nature of the questions (i.e. over the last 2 weeks) this score is highly likely to change significantly at different time periods.
Figure 3-10 Bar chart illustrating median quality of life scores (%) in the intervention and control groups for all domains, at baseline, 6 and 12 months.
3.4.5.2 Completers analysis for the Quality of Life questionnaires

Table 3-34 Difference in quality of life measures between intervention (n=23) and control groups (n=25), between baseline and 6 and baseline and 12 months using completers data only.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Name of domain</th>
<th>Mann Whitney U 6 months</th>
<th>P</th>
<th>Mann Whitney U 12 months</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-10 (%)</td>
<td>Physical functioning</td>
<td>167</td>
<td>0.05*</td>
<td>200.5</td>
<td>0.61</td>
</tr>
<tr>
<td>11-14 (%)</td>
<td>Social functioning</td>
<td>244.5</td>
<td>0.85</td>
<td>196.5</td>
<td>0.54</td>
</tr>
<tr>
<td>15-17 (%)</td>
<td>Treatment issues</td>
<td>238.5</td>
<td>0.74</td>
<td>235</td>
<td>0.68</td>
</tr>
<tr>
<td>18-21 (%)</td>
<td>Chest symptoms</td>
<td>205</td>
<td>0.59</td>
<td>210</td>
<td>0.62</td>
</tr>
<tr>
<td>22-29 (%)</td>
<td>Emotional responses</td>
<td>220</td>
<td>0.45</td>
<td>149.5</td>
<td>0.07</td>
</tr>
<tr>
<td>30-35 (%)</td>
<td>Concerns for the future</td>
<td>220.5</td>
<td>0.46</td>
<td>131.5</td>
<td>0.03*</td>
</tr>
<tr>
<td>36-45 (%)</td>
<td>Interpersonal relationships</td>
<td>239</td>
<td>0.75</td>
<td>202</td>
<td>0.64</td>
</tr>
<tr>
<td>48-48 (%)</td>
<td>Body image</td>
<td>201.5</td>
<td>0.24</td>
<td>199</td>
<td>0.59</td>
</tr>
<tr>
<td>49-52 (%)</td>
<td>Career issues</td>
<td>190.5</td>
<td>0.15</td>
<td>178</td>
<td>0.28</td>
</tr>
</tbody>
</table>

* denotes statistical significance

There were two significant differences between the completer's intervention and control groups scores for quality of life, as illustrated in table 3-34. Those were physical functioning at 6 months, the control group scoring significantly higher than the intervention group, (mean rank 19.26, 26.91) this implied the control group felt that over the last 2 weeks CF had affected their physical functioning and mobility significantly less than the intervention group (p=0.05). The other significant difference was in the “Concerns for the future” section at 12 months, the control group scoring significantly higher than the intervention group, this
implied the control group had less concerns for the future at that time than the intervention group (p=0.03).

3.4.6 The impact of treatment and disease progression on outcomes

Following the planned per protocol analysis, it became clear that body weight at any particular time point i.e. 6 and 12 months, could be affected by the current FEV1 (i.e. whether the person was unwell, needing antibiotics for a chest infection, being treated for a chest infection, or having just completed a course if antibiotics for a chest infection). It was therefore decided to complete a post hoc analysis examining the difference in weight between the intervention and control groups at 6 and 12 months adjusting for baseline weight and current FEV1. FEV1 was used as an indicator of current respiratory health.

The primary analysis was by intention to treat and the secondary analysis for completers only.

Table 3-35 Intention to treat analysis showing the mean FEV1 (SD) for control and intervention at baseline, 6 and 12 months.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention Mean (SD) N=34</th>
<th>Control Mean (SD) N=34</th>
<th>Independent samples t-test T</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV1% predicted at baseline</td>
<td>54.9 (25.3)</td>
<td>62.7 (22.3)</td>
<td>-1.25</td>
<td>0.218</td>
</tr>
<tr>
<td>FEV1% predicted at 6 months</td>
<td>54.8 (25.1)</td>
<td>62.1 (20.8)</td>
<td>-1.17</td>
<td>0.245</td>
</tr>
<tr>
<td>FEV1% predicted at 12 months</td>
<td>51.9 (24.1)</td>
<td>62.1 (21.5)</td>
<td>-1.54</td>
<td>0.132</td>
</tr>
</tbody>
</table>

There was a decrease in FEV1 from baseline to 6 and 12 months in the intervention group, as illustrated in table 3-35, which implies the intervention group’s disease severity worsened during the period of the study, this has significant implications for the weight outcome measures. This happened despite the stratification process which spread the most unwell subjects evenly across the two groups. Along with a decline in FEV1 during the study period, it would be expected that weight would also decline, as a consequence of worsening disease, however in the intervention group weight increased rather than decreased.

Mean FEV1 values at baseline, 6 and 12 months are illustrated in figure 3-11.
Figure 3-11 Mean FEV1 at baseline, 6 and 12 months, with error bars indicating standard error of the mean (SEM), using primary ITT analysis.

Table 3-36 shows the mean difference in FEV1 between the intervention and control groups for the primary ITT analysis. Table 3-37 shows the mean difference in FEV1 between the intervention and control groups for completers only.

The following ANOVA was completed with the difference in FEV1 as the dependant variable, the intervention and control groups as fixed factors with a covariate of baseline FEV1.
Table 3-36 Difference in FEV1 between the intervention and the control groups adjusted for baseline FEV1 (ITT analysis).

<table>
<thead>
<tr>
<th>Time period</th>
<th>Mean difference (95%CI)</th>
<th>F Ratio</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV1, 6 months</td>
<td>1.22 (-3.11 – 5.56)</td>
<td>F 1,63 = 0.316</td>
<td>0.576</td>
</tr>
<tr>
<td>FEV1, 12 months</td>
<td>1.53 (-4.62 – 7.68)</td>
<td>F 1,63 = 0.248</td>
<td>0.621</td>
</tr>
</tbody>
</table>

There were no significant differences in FEV1 between the intervention and control groups at 6 or 12 months.

Table 3-37 Difference in FEV1 between the intervention and the control groups adjusted for baseline using all available data (completers analysis).

<table>
<thead>
<tr>
<th>Time period</th>
<th>Mean difference (95%CI)</th>
<th>F Ratio</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV1, 6 months</td>
<td>0.72 (-5.06 – 6.5)</td>
<td>F 1,42 = 0.064</td>
<td>0.80</td>
</tr>
<tr>
<td>FEV1, 12 months</td>
<td>0.07 (-6.4 – 6.5)</td>
<td>F 1,42 = 0.001</td>
<td>0.98</td>
</tr>
</tbody>
</table>

To investigate weight outcomes and the relationship with baseline weight and FEV1, an ANOVA was used with weight change at 6 and 12 months with baseline weight and FEV1 as covariates. For weight at 6 months the overall ANOVA was not significant (F 1,63=0.116, p=0.73) and at 12 months the overall ANOVA was not significant (F 1,63=0.895, P=0.35).
3.4.7 Stage of Change

This section investigates the results from the Stage of Change questionnaire. Following the theory of Prochaska and DeClemente, modification of behaviour involves progression through 5 stages of change - pre-contemplation, contemplation, preparation, action and maintenance. Baseline measures of Stage of Change in the intervention and control groups are illustrated by figures 3-12, 3-13 and 3-14.
Figure 3-12 Baseline measures of ‘stage of change’ for the intervention and control groups for the question ‘Describe how you feel about changing your diet/ improving your weight’.

For question 1, there were 22 (65%) of the intervention subjects in the consideration stage at baseline and 10 (29%) in the action phase, the remaining 2 subjects (6%) failed to answer the question.

There were 23(68%) of the control subjects in the consideration stage at baseline and 11 (32%) in the action phase.
Figure 3-13 Baseline measures of stage of change for the intervention and control groups for the statement ‘It would be difficult for me to change my diet/ improve my weight, in the next month’.

For statement 2, there were 13 (38%) of the intervention subjects in the consideration stage at baseline and 18 (53%) in the action phase, the remaining 3 subjects (9%) failed to respond to the statement.

There were 16 (47%) of the control subjects in the consideration stage at baseline and 18 (53%) in the action phase.
For statement 3, there were 13 (38%) of the intervention subjects in the consideration stage at baseline and 18 (53%) in the action phase, the remaining 3 subjects (9%) failed to respond to the statement.

There were 21 (62%) of the control subjects in the consideration stage at baseline and 13 (38%) in the action phase.
3.4.7.1 Movement through the stages of change during the study for the intervention group

In order to measure individual movement through the model, the data for individual’s responses for each question/statement from baseline to 6 and 12 months were reviewed. Possible responses reflecting a forward movement through the stages of change model were identified and grouped into the following categories as described in table 3-38.

Table 3-38 Potential responses that demonstrated a forward movement through the Stage of change model from baseline to 6 and 12 months.

<table>
<thead>
<tr>
<th>Stage at baseline</th>
<th>Stage at 6 months</th>
<th>Stage at 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation</td>
<td>Action</td>
<td>Action</td>
</tr>
<tr>
<td>Action</td>
<td>Maintenance</td>
<td>Maintenance</td>
</tr>
<tr>
<td>Contemplation</td>
<td>Action</td>
<td>Maintenance</td>
</tr>
<tr>
<td>Preparation</td>
<td>Maintenance</td>
<td>Maintenance</td>
</tr>
<tr>
<td>Contemplation</td>
<td>Preparation</td>
<td>Action</td>
</tr>
<tr>
<td>Preparation</td>
<td>Action</td>
<td>Maintenance</td>
</tr>
<tr>
<td>Pre-contemplation</td>
<td>Contemplation</td>
<td>Contemplation</td>
</tr>
<tr>
<td>Pre-contemplation</td>
<td>Preparation</td>
<td>Preparation</td>
</tr>
<tr>
<td>Contemplation</td>
<td>Preparation</td>
<td>Preparation</td>
</tr>
</tbody>
</table>

These data allowed forward movement of individual subjects through the model over the time of the intervention and the control group to be categorised. These data are illustrated in the following figures:
Figure 3-15 Graphical representation of individual subjects in the intervention group, movement through the stages of change from baseline to 12 months for the question ‘Describe how you feel about changing your diet/ improving your weight’.

There was no change in responses for 7 subjects, missing data for 2 subjects and no logical forward sequence of change for 8 subjects. These data suggest that 11 subjects had moved into an action or maintenance phase over the 12 month period.
Figure 3-16 Graphical representation of individual subjects in the control group, movement through the stages of change from baseline to 12 months for the question 'Describe how you feel about changing your diet/ improving your weight'.

<table>
<thead>
<tr>
<th>Key:</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC = Pre-contemplation</td>
</tr>
<tr>
<td>C = Contemplation</td>
</tr>
<tr>
<td>P = Preparation</td>
</tr>
<tr>
<td>A = Action</td>
</tr>
<tr>
<td>M = Maintenance</td>
</tr>
</tbody>
</table>

There was no change in responses for 4 subjects, missing data for 3 subjects and no logical forward sequence of change for 11 subjects.

As can be see from figures 3-15 and 3-16, two subjects in the intervention group moved from the preparation stage to the action stage (1 in control), 2 moved from action to maintenance (1 in control), 3 moved from preparation to maintenance (4 in control), 4 subjects moved from preparation to action to maintenance whereas only one in the control made this significant movement from consideration to action.
Figure 3-17 Graphical representation of individual subjects in the intervention group, movement through the stages of change from baseline to 12 months, for the statement 'It would be difficult for me to change my diet/improve my weight, in the next month'.

There was no change in responses for 4 subjects, no missing data and no logical forward sequence of change for 5 subjects.
Figure 3-18 Graphical representation of individual subjects in the control group, movement through the stages of change from baseline to 12 months for the statement ‘It would be difficult for me to change my diet/improve my weight, in the next month’.

There was no change in responses for 5 subjects, missing data for 2 subjects and no logical forward sequence of change for 4 subjects.

As illustrated, 14 subjects in the intervention group moved from preparation to action (8 in control) and 8 from contemplation to preparation to action (14 in control). One patient in each group moved from pre contemplation to preparation.
Figure 3-19 Graphical representation of individual subjects in the intervention group, movement through the stages of change from baseline to 12 months for the statement ‘I intend to change my diet/improve my weight in the next month’.

There was no change in responses for 15 subjects, no missing data and no logical forward sequence of change for 5 subjects.
Figure 3-20 Graphical representation of individual subjects in the control group, movement through the stages of change from baseline to 12 months for the statement ‘I intend to change my diet/improve my weight in the next month’.

There was no change in responses for 10 subjects, no missing data and no logical forward sequence of change for 7 subjects.

Similar numbers of subjects moved from pre-contemplation to contemplation (3 intervention, 2 control) and from pre-contemplation to preparation (7 intervention, 5 control). Two subjects moved from contemplation to preparation in the intervention group, whereas 7 in the control group made this movement.

The numbers of subjects showing no logical forward sequence in their change pattern and the amount of missing data i.e. subjects not completing the questionnaire must be taken into consideration and will be further referred to in the discussion.
3.4.7.2 Sub group analysis of changes

Those subjects who followed a logical forward change sequence through the stage of change model from a ‘consideration’ stage to an ‘action’ stage from baseline to 12 months were grouped together from both the control and the intervention group and classified as the "change" group. Those subjects who showed no logical change sequence throughout the study period were classified as the "no change" group. Independent samples t-tests were performed to identify any differences in outcomes at 6 or 12 months in the "change" group compared to the "no change" group, the results are illustrated in table 3-39.

Table 3-39. Mean (SD) values for primary and secondary outcomes for the “change” group compared to the “no change” group and independent samples t-tests showing any differences between the groups at 6 months.

<table>
<thead>
<tr>
<th>Measure</th>
<th>“Change” group 6 months Mean (SD)</th>
<th>“No Change” group 6 months Mean (SD)</th>
<th>Independent samples t-test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=16</td>
<td>N=52</td>
<td>T</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>60.8 (9.4)</td>
<td>59.9 (10.8)</td>
<td>0.28</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>21.8 (2.4)</td>
<td>21.3 (2.7)</td>
<td>0.61</td>
</tr>
<tr>
<td>Self-efficacy score</td>
<td>21.6 (4.1)</td>
<td>19.1 (5.1)</td>
<td>1.74</td>
</tr>
<tr>
<td>Reported fat intake score</td>
<td>36.3 (8.3)</td>
<td>31.9 (7.2)</td>
<td>1.99</td>
</tr>
<tr>
<td>General nutrition knowledge score</td>
<td>12.2 (3.9)</td>
<td>10.7 (3.2)</td>
<td>1.42</td>
</tr>
<tr>
<td>Specific nutrition knowledge score</td>
<td>40.7 (4.8)</td>
<td>39.8 (5.0)</td>
<td>0.64</td>
</tr>
</tbody>
</table>
Table 3-40 Mean (SD) values for primary and secondary outcomes for the “change” group compared to the “no change” group and independent samples t-tests showing any differences between the groups at 12 months

<table>
<thead>
<tr>
<th>Measure</th>
<th>“Change” group 12 months Mean (SD)</th>
<th>“No Change” group 12 months Mean (SD)</th>
<th>Independent samples t-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>60.5 (9.0)</td>
<td>61.3 (11.3)</td>
<td>-0.26</td>
</tr>
<tr>
<td>BMI</td>
<td>21.6 (2.1)</td>
<td>21.5 (2.6)</td>
<td>0.11</td>
</tr>
<tr>
<td>Self-efficacy score</td>
<td>21.4 (5.6)</td>
<td>20.0 (5.5)</td>
<td>0.75</td>
</tr>
<tr>
<td>Reported fat intake score</td>
<td>34.4 (7.5)</td>
<td>31.2 (7.1)</td>
<td>1.37</td>
</tr>
<tr>
<td>General nutrition knowledge score</td>
<td>12.2 (3.7)</td>
<td>10.8 (3.3)</td>
<td>1.27</td>
</tr>
<tr>
<td>Specific nutrition knowledge score</td>
<td>41.8 (4.3)</td>
<td>38.8 (6.5)</td>
<td>1.63</td>
</tr>
</tbody>
</table>

The “change” group had higher scores for self-efficacy, reported fat intake, specific and general nutrition knowledge at 6 and 12 months compared to the “no change” group. The differences in all outcome measures were not statistically significant as demonstrated in table 3-40.

3.4.7.3 Best Performers

Subjects who achieved more than 4Kg weight gain throughout the study period were classed as “best performers”. The progress of these subjects through the stages of change was reviewed in order to investigate if the stage of change transitions could provide some clues as to why these subjects gained more weight than others. The following table 3-41 shows the baseline weight and FEV1 and 12 month weight and FEV1 for the “best performers”.
Table 3-41 Weight and FEV1 at baseline and 12 months for “best performers” for 9 subjects who gained 4kg or more.

<table>
<thead>
<tr>
<th>Patient number</th>
<th>Baseline weight (Kg)</th>
<th>Baseline FEV1(% pred)</th>
<th>Weight at 12 Months (Kg)</th>
<th>FEV1 at 12 Months (%pred)</th>
<th>Intervention/Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>66.6</td>
<td>29</td>
<td>76.4</td>
<td>33</td>
<td>I</td>
</tr>
<tr>
<td>2</td>
<td>66.1</td>
<td>47</td>
<td>71.9</td>
<td>59</td>
<td>C</td>
</tr>
<tr>
<td>3</td>
<td>53.7</td>
<td>48</td>
<td>58.2</td>
<td>37</td>
<td>C</td>
</tr>
<tr>
<td>4*</td>
<td>36.7</td>
<td>26</td>
<td>41.7</td>
<td>69*</td>
<td>I</td>
</tr>
<tr>
<td>5</td>
<td>56.5</td>
<td>51</td>
<td>61</td>
<td>46</td>
<td>I</td>
</tr>
<tr>
<td>6</td>
<td>63.4</td>
<td>24</td>
<td>69.2</td>
<td>28</td>
<td>C</td>
</tr>
<tr>
<td>7</td>
<td>68.1</td>
<td>35</td>
<td>74.8</td>
<td>49</td>
<td>C</td>
</tr>
<tr>
<td>8</td>
<td>89.3</td>
<td>91</td>
<td>95.1</td>
<td>89</td>
<td>C</td>
</tr>
<tr>
<td>9</td>
<td>88.2</td>
<td>110</td>
<td>93.2</td>
<td>110</td>
<td>C</td>
</tr>
</tbody>
</table>

* Subject was placed on the transplant list after intervention and received a double lung transplant.

As can be seen from table 3-41 of the 9 best performers, 3 were in the intervention group and 6 were in the control group.

It can also be seen that the “best performers” in the control group all weighed more than 60 Kg with one exception (53.7 Kg). We could hypothesise that the “best performers” in the control group were heavier and less unwell subjects, the mean baseline FEV1 of these subjects being 61.5 % (SD 33.7)

The “best performers” baseline weights in the intervention group ranged from 36.7 – 66.1. The mean FEV1 at baseline was 69.6% (SD 35.2) FEV1. Mean baseline weight for the “best performers” in the intervention group was 58.1 Kg (SD 26.08) and the control was 70.3 Kg (SD 10.7).

From the “best performers” group of those who completed all the stage of change questionnaires, 3 were in the change group and 5 in the no change group. This information does not really give us any clues as to why these subjects gained more weight than others in the study, except to suggest that some of these “best performers” were well subjects who had few nutritional difficulties.
If however, we look in detail at the best performer, subject number 1. This subject, who was in the intervention group, completed and complied with the study and increased weight from 66.6Kg to 76.4Kg during the study period. This subject moved through the stages of change from preparation at baseline to action at 6 months to maintenance at 12 months. This subject had previously received intensive dietetic advice and overnight nasogastric feeding but had always struggled to gain weight, until he undertook this study. This is an excellent example of how crucial it is to assess subjects’ stage of change prior to commencing the education programme, to ensure the programme is provided at the most appropriate time to encourage change of dietary behaviour to maximise weight outcomes.
3.4.8 Results of the intervention group with data collected immediately after subjects completed the 10 week intervention.

Following completion of the "Eat Well with CF" programme subjects completed a range of questionnaires which were used to assess the immediate impact of the intervention, prior to continuation of the 6 and 12 months follow-up periods. The results are illustrated in table 3-42.

From baseline to week 10, the weight of the intervention group had risen by 0.8 Kg, 58.3Kg (SD10.6) to 59.1 Kg (SD10.9) (p=0.066) and specific nutrition knowledge had improved from 35.07 points (SD 8.6) to 41.07 points (SD 5.7) (p<0.001), compared to baseline.

The weight changes were not statistically significant; however they are clinically relevant, taking into consideration how difficult it is to gain weight in an adult CF population. An increase of nearly 1Kg is very important. Self-efficacy and specific nutrition knowledge were significantly improved, which substantiates the hypothesis that those completing the new programme would have increased self-efficacy and nutrition knowledge than those in the control group. Not surprisingly there was no change in FEV1.

This information was useful in assessing the immediate impact of the programme in the intervention group only, prior to the formal 6 and 12 month follow up for all subjects.
Table 3-42 Baseline and post intervention measures for weight, BMI, FEV1, self-efficacy, reported fat intake, general and specific nutrition knowledge score, mean (SD) for the Intervention group using all available data.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Baseline value mean (SD) N=34</th>
<th>Post-intervention value mean (SD) N=34</th>
<th>Paired samples t-test T</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (Kg)</td>
<td>58.3(10.6)</td>
<td>59.1(10.9)</td>
<td>-1.90</td>
<td>0.06</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>21.1(2.8)</td>
<td>21.4 (2.8)</td>
<td>-1.68</td>
<td>0.10</td>
</tr>
<tr>
<td>FEV1(% predicted)</td>
<td>53.9(28.0)</td>
<td>53.8(26.1)</td>
<td>0.07</td>
<td>0.94</td>
</tr>
<tr>
<td>Self-efficacy score</td>
<td>18.0(5.4)</td>
<td>20.4(6.1)</td>
<td>-2.26</td>
<td>0.03*</td>
</tr>
<tr>
<td>Reported Fat intake score</td>
<td>31.8(7.5)</td>
<td>32.3(13.5)</td>
<td>-0.20</td>
<td>0.84</td>
</tr>
<tr>
<td>General nutrition Knowledge score</td>
<td>10.8(2.9)</td>
<td>11.8(2.6)</td>
<td>-1.83</td>
<td>0.08</td>
</tr>
<tr>
<td>Specific nutrition knowledge score</td>
<td>35.07 ( 8.6)</td>
<td>41.07 (5.7)</td>
<td>-4.89</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

3.4.9 Attrition rate

Subjects not completing the study

An examination of the reasons for not completing the study (attrition) provides valuable information as to reasons why the intervention may suit or not suit some population groups. All subjects who did not complete the study were followed up and a short exit interview ascertained the reasons for withdrawal. For these participant numbers see fig 3-2. (Flow of subjects through the 6 and 12 month stages of the study). No differences in overall attrition rate were seen between the intervention and control groups. The following analysis was conducted to investigate reasons why some of the participants did not complete the study, looking specifically at demographics and socioeconomic status.
Forty-eight subjects completed the study and twenty did not complete. Of these 20, 4 subjects died, 2 at 6 month follow up and 2 at 12 month follow up. Two subjects did not complete post intervention follow up and three withdrew from the study at this point. One subject defaulted from 6-month follow up and ten subjects defaulted from 12-month follow up.

There were more male subjects (n=15) in the non-completers group (NC) compared to females (n=5). This may be related to females being more interested in improving their weight and nutrition knowledge than their male counterparts. There was little gender difference in the completers group (C). There was no significant difference in genotype between the NC and C groups, with a Pearson Chi² value of 1.88 (p= 0.391). The NC group had a higher mean FEV1 (61.7) than the C group (57.6), though this was not statistically significant p=0.562. This could perhaps be attributable to the NC group feeling well and as a consequence CF has less impact on their everyday life such that they do not feel it necessary to complete the nutrition education programme.

The Education classification in the C group was evenly spread and not different from those in the NC group with a Pearson Chi² value of 1.36 (p=0.506). There was a trend towards statistically significant differences in Socio-economic status between the groups (Chi squared 5.63, p=0.056), with lower SES groups less likely to complete than higher groups.

There were no differences in sex or genotype for those subjects in the completers group compared to the non-completers group, as shown in table 3-43.
Table 3-43 Baseline characteristics of subjects completing (C) the study compared to those not completing (NC) the study for sex, genotype, education and social classification using non-parametric testing of potential differences between these groups.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Non completers N=20 (NC)</th>
<th>Completers N=48 (C)</th>
<th>Pearson Chi squared test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex M (%)</td>
<td>15 (75%)</td>
<td>25 (52%)</td>
<td>Chi sq = 2.38</td>
</tr>
<tr>
<td></td>
<td>5 (25%)</td>
<td>23 (48%)</td>
<td>P = 0.080</td>
</tr>
<tr>
<td>Genotype</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DF508 Homo</td>
<td>13 (65%)</td>
<td>27 (56%)</td>
<td>Chi sq = 1.88</td>
</tr>
<tr>
<td></td>
<td>4 (20%)</td>
<td>17 (35%)</td>
<td>P = 0.391</td>
</tr>
<tr>
<td>Other</td>
<td>3 (15%)</td>
<td>4 (8%)</td>
<td></td>
</tr>
<tr>
<td>Education classification</td>
<td>Non-completers N=20</td>
<td>Completers N=48</td>
<td>Pearson Chi squared test</td>
</tr>
<tr>
<td>A</td>
<td>11 (55%)</td>
<td>19 (40%)</td>
<td>Chi sq = 1.36 P=0.506</td>
</tr>
<tr>
<td>B</td>
<td>5 (25%)</td>
<td>16 (33%)</td>
<td></td>
</tr>
<tr>
<td>C + D</td>
<td>4 (20%)</td>
<td>13 (27%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>48</td>
<td></td>
</tr>
<tr>
<td>SES classification</td>
<td>Non-completers N=20</td>
<td>Completers N=48</td>
<td>Pearson Chi squared test</td>
</tr>
<tr>
<td>1-2</td>
<td>3 (15%)</td>
<td>21 (44%)</td>
<td>Chi sq = 5.63 P=0.056</td>
</tr>
<tr>
<td>3-5</td>
<td>5 (25%)</td>
<td>11 (23%)</td>
<td></td>
</tr>
<tr>
<td>6-7</td>
<td>12 (60%)</td>
<td>16 (33%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>48</td>
<td></td>
</tr>
</tbody>
</table>

There were no significant differences in the outcomes at baseline between the completers and non-completers. There was very little difference in weight, BMI or reported fat intake between the completers and non completers. The completers had a higher mean General Nutrition Knowledge score (p=0.094) and Specific Nutrition Knowledge score (p=0.252).
These did not reach statistical significance, but may be clinically relevant in that the completers were more likely to be those with better baseline nutritional knowledge.

Tables 3-44 and 3-45 show the primary and secondary outcome measures for both completers and non-completers with no significant differences between the groups for all measures.

**Table 3-44 Results of outcomes for weight, BMI, FEV1, self-efficacy, general and specific nutrition knowledge and reported fat intake for completers compared to non-completers measured at baseline.**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Non completers Mean value (SD) N=20</th>
<th>Completers Mean value (SD) N=48</th>
<th>Independent samples t-test T P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight Kg(SD)</td>
<td>61.3 (11.8)</td>
<td>59.1(9.9)</td>
<td>-0.76 0.449</td>
</tr>
<tr>
<td>BMI Kg/m^2(SD)</td>
<td>21.6 (2.9)</td>
<td>21.3 (2.6)</td>
<td>-0.52 0.606</td>
</tr>
<tr>
<td>FEV1 (%pred)</td>
<td>61.7 (28.6)</td>
<td>57.6 (25.2)</td>
<td>-0.58 0.562</td>
</tr>
<tr>
<td>Self-efficacy score</td>
<td>18.5 (5.1)</td>
<td>18.2 (4.9)</td>
<td>-0.34 0.734</td>
</tr>
<tr>
<td>Short fat score</td>
<td>31.5 (9.7)</td>
<td>32.2 (6.9)</td>
<td>0.35 0.725</td>
</tr>
<tr>
<td>General Nutrition Knowledge score</td>
<td>9.8 (3.2)</td>
<td>11.3 (2.6)</td>
<td>1.69 0.094</td>
</tr>
<tr>
<td>Specific Nutrition knowledge score</td>
<td>34.5 (9.1)</td>
<td>36.7 (6.3)</td>
<td>1.15 0.252</td>
</tr>
</tbody>
</table>
Table 3-45 Results of the individual sub-sections of the Quality of life questionnaire scores for completers compared to non-completers measured at baseline

<table>
<thead>
<tr>
<th>Quality of life</th>
<th>Median (Interquartile range)</th>
<th>Non completers N=20 (29%)</th>
<th>Completers N= 48 (71%)</th>
<th>Mann Whitney U test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-10 (%) Physical functioning</td>
<td>87.3 (72.0-96.2)</td>
<td>89.1 (78.0-96.3)</td>
<td></td>
<td>463 0.479</td>
</tr>
<tr>
<td>11-14 (%) Social functioning</td>
<td>91.6 (83.3–100)</td>
<td>91.6 (76.0–100)</td>
<td></td>
<td>432 0.260</td>
</tr>
<tr>
<td>15-17 (%) Treatment issues</td>
<td>66.6 (55.5–77.7)</td>
<td>83.3 (61.6–94.4)</td>
<td></td>
<td>517.5 1.0</td>
</tr>
<tr>
<td>18-21 (%) Chest symptoms</td>
<td>83.3 (67.7–91.6)</td>
<td>79.1 (62.5–94.8)</td>
<td></td>
<td>427.5 0.242</td>
</tr>
<tr>
<td>22-29 (%) Emotional responses</td>
<td>83.3 (71.8–92.7)</td>
<td>87.5 (77.1–93.7)</td>
<td></td>
<td>508 0.902</td>
</tr>
<tr>
<td>30-35 (%) Concerns for the future</td>
<td>47.2 (36.1–63.9)</td>
<td>58.3 (39.5–72.2)</td>
<td></td>
<td>501.5 0.835</td>
</tr>
<tr>
<td>36-45 (%) Interpersonal relationships</td>
<td>65.8 (50.8–76.6)</td>
<td>68.3 (54.6–83.3)</td>
<td></td>
<td>502 0.841</td>
</tr>
<tr>
<td>46-48 (%) Body image</td>
<td>66.6 (51.4–81.9)</td>
<td>72.2 (55.5–88.8)</td>
<td></td>
<td>460.5 0.458</td>
</tr>
<tr>
<td>49-52 (%) Career issues</td>
<td>75.0 (58.3–83.3)</td>
<td>75.0 (50.0–90.6)</td>
<td></td>
<td>463.5 0.482</td>
</tr>
</tbody>
</table>
3.5 Discussion

This study aimed to evaluate the effectiveness of the “Eat Well with CF” intervention programme on measures of nutritional status, reported dietary fat intake and general and CF specific nutrition knowledge in adults with CF. It also aimed to evaluate the effectiveness of the programme on self-efficacy for adults with CF to better manage their diet and pancreatic enzyme replacement therapy and on quality of life measures.

In addition it aimed to assess the impact of the programme on the patients’ readiness to make dietary change, in order to provide an understanding of an individual’s motivation to alter their dietary habits.

The results demonstrated that those in the intervention group increased their weight post intervention and at 6 and 12 months, although these differences did not reach statistical significance compared to the control. The intervention group significantly increased their CF specific nutrition knowledge and self-efficacy at 6 and 12 months and their reported fat intake at 6 months although this effect was not continued at 12 months. There were only minor alterations in quality of life measures.

3.5.1 Primary Weight outcomes

The first hypothesis was that subjects who received the new education programme would have an improvement in nutritional status compared to the control group. This hypothesis was supported by the weight gain experienced by those in the intervention group and although not statistically significant, this is clinically relevant. The lack of statistical significance does not imply there is no effect just that we have failed to demonstrate one. A possible reason for this is that the current sample was too small to show that a difference exists. The difference in weight however is still important. This finding supports but does not substantiate the first hypothesis that adults with CF completing a home-based nutrition education programme will have an improved nutritional status. This does not however reach the expected 3Kg weight increase in the first year, which was the amount on which the original sample size was based.

The changing status of the whole CF clinic must be considered when investigating why the difference in weight was not statistically significant in the group used. The original sample size was based on information available at the time. In order to estimate an achievable target
weight gain, data on existing subjects was reviewed in 1999. Using standard dietetic methods, CF subjects receiving care at that time increase their body weight by an average 1.25 Kg/year (SD 3Kg). Using the newly developed behavioural nutrition education programme we expected weight gain to increase to 3 Kg in the first year (SD 3Kg). In 1999, the regional CF unit was in its infancy and many subjects referred were from small hospitals where they did not receive multidisciplinary CF centre intensive treatment. We suggest therefore these subjects were not achieving their full weight and lung function potential, hence during this period subjects new to the service increased their weight rapidly in the first year of intensive dietetic and medical treatment.

The adult regional unit is now well established (2006), good links have been forged with local paediatric clinics and the nutritional status of subjects referred to the adult centre is much improved. Weight gain in these subjects is therefore harder to achieve.

Another important factor to consider is that FEV1, as a measure of respiratory health, declined in the intervention group throughout the study period. One would expect a decline in FEV1 to be accompanied by a decline in weight. However in this study, despite a decline in FEV1, the intervention group did not show a corresponding decrease in weight. Declining health has been shown to be associated with significant weight loss (Bell et al., 1998). Therefore we suggest that the intervention group were a more acutely unwell cohort than the control group, during the period of the study. This has important ramifications, in that despite decreasing FEV1 in the intervention group, weight still increased. We hypothesise that if FEV1 had not declined in the intervention group during the study period, further increases in weight would have been demonstrated. This hypothesis is further supported by the results of the Quality of life questionnaires, in that the control group were a less unwell group who felt CF affected their physical functioning and mobility significantly less than the intervention group.

It is difficult to compare the weight gain achieved in this study to other studies investigating behavioural nutrition education programmes in adults as there have only been such programmes developed for children. Stark and colleagues (Stark et al., 1990, Stark et al., 1993, Stark et al., 1995, Stark et al., 1996, Stark et al., 2000) conducted a series of studies examining the use of behavioural techniques to increase dietary adherence for children with CF. The first study employed a behavioural intervention to increase the calorie intake of 5 children aged 5 – 12 years. The results indicated an increase in calorie consumption of 1,050
calories per day. These gains were maintained at 9 month follow up. These children also gained height and weight more rapidly than they had the previous 3-5 months prior to treatment. The authors concluded that the behavioural intervention successfully increased adherence to a high calorie diet. The study was then replicated with three mildly malnourished children, the results of this case study approach replicated the prior study’s findings and added further evidence for the utility of behavioural techniques to increase adherence to high calorie diets. All of these studies had very small samples, and no control groups (apart from one study where children acted as their own controls), although the replications conducted by Stark do increase the validity of the findings.

A randomised clinical trial of this nature in children was recently published by Powers et al (Powers et al., 2005). This study aimed to evaluate a randomised comparison of a behavioural and nutrition intervention (BEH) with usual care control condition (CTL) and to provide a replication of the impact of BEH by inviting the CTL group to receive BEH after 8 weeks. The study also aimed to examine the maintenance of BEH at 3 and 12 month follow up. The behavioural intervention included nutrition counselling to increase energy and child behavioural management training and to teach parents differential attention and contingency management skills. The behavioural intervention led to a greater increase in energy intake pre to post-treatment than the control group as measured by calories per day, at 3 and 12 month follow up, energy intake was maintained. These children also met or exceeded normal weight and height velocities. The authors suggest toddlers and pre-schoolers who have CF and received the behavioural intervention were able to meet the energy intake and recommendations for this disease and maintain these gains up to 12 months after treatment. They concluded that the behavioural intervention was promising, evidence based, early nutritional intervention for children with CF. A multicentre trial with 100 subjects is currently in process.

The majority of the studies conducted in this area have come from the work by Stark and colleagues, further studies in different settings are necessary to evaluate the external validity of these findings.

A study similar to the trial of the “Eat Well with CF” programme was conducted by Stapleton (2001) in children with CF, in Australia. This randomised trial involved 42 children and aimed to assess the impact of a behavioural nutrition education programme “Go and Grow with CF” on nutrition and pancreatic enzyme knowledge and self-management skills. The
results of this study revealed that the programme was effective in increasing knowledge in the short term. However this work did not assess the effect of the programme on weight outcomes.

Weight gain and growth in a paediatric population is evidently very different to that in an adult population and the two cannot therefore be directly compared. Children with CF are expected to consistently gain weight and height throughout the period of paediatric care. The US CF foundation patient registry (2002) defines the aim for nutritional management in children as achieving normal growth. For adults with progressively deteriorating lung disease and nutritional status, simply maintaining good nutrition and weight is a difficult task, which becomes increasingly more difficult as they get older (Turck and Michaud, 1998). Research has clearly shown that many adult subjects with CF are significantly underweight and declining health is associated with significant weight loss (Bell et al., 1998). The US CF foundation patient registry suggests the aim in adults is to maintain nutrition to as near to "normal" as possible (2002).

Another factor to consider is the evolving cystic fibrosis medical treatment and how that has changed during the 6 years of this study. In particular the pseudomonas segregation restrictions which have affected patient to patient contact.

A limitation of this study with respect to demonstrating improved weight outcomes is that the follow up period of 12 months may have been too short. It is crucial to consider that the study demonstrated a significant increase in specific nutrition knowledge and self-efficacy 12 months following the intervention. Self-efficacy has been shown to be a reliable predictor of short and long term success in performance of health behaviours such as stopping smoking (Bartholomew et al., 1993a). Therefore we can hypothesise that by improving knowledge and confidence, the subjects will have been provided with the skills to enable them to change their behaviour. The longer term effect of these changes could reveal a significant increase in weight, longer term follow up could elicit if this is indeed the case.
3.5.2 Secondary outcomes

3.5.2.1 CF specific and general nutrition knowledge

The second hypothesis was that adults with CF completing the home-based nutrition education programme would have an improvement in nutrition knowledge compared with those receiving standard dietetic care. This hypothesis was supported as the improvements in CF specific nutrition knowledge in the intervention group were statistically significant at 6 and 12 months. The only work of this nature carried out in children showed a significant increase in children's nutrition knowledge in the short term, but failed to demonstrate a long term effect (Stapleton, 2001). The results of this study have demonstrated a significant increase in specific nutrition knowledge in the short term, which were maintained longer term. There was no change in general nutrition knowledge throughout the study period. This could be because:

a) The intervention was not specifically designed to increase general nutrition knowledge and/or

b) The parameters assessed or the instruments used (questionnaires) were not sufficiently sensitive to detect such changes.

The main objective in using the general nutrition knowledge questionnaire was to assess baseline knowledge.

This study proved that CF specific nutrition knowledge can be significantly improved by completing the new “Eat Well with CF” education programme. It showed that baseline knowledge scores equated to the scores achieved in the original study where the instrument was described (Abraham et al., 1981), and this score remained relatively constant throughout the study period.

The Social Cognitive Theory (SCT) constructs maintain that an individual’s ability to perform certain behaviours depends on the acquisition of adequate knowledge (Bandura, 1977). Adequate levels of knowledge are required to enable subjects with CF to be capable of achieving nutritional recommendations and subsequently to optimise their nutritional status. Although improving knowledge does not necessarily mean behaviour will change, prior studies have shown benefit from improved knowledge (Glasgow et al., 1992, Miller et al., 2002, van den Arend et al., 2000). For years nutritionists have developed educational...
materials that have attempted to change dietary behaviour. However, most of these programmes were effective only in increasing knowledge and did not produce long term behaviour change (Molaison, 2002). Over time it has become evident that education is not enough to change behaviour for most people. “If knowledge were enough, no one would smoke and everyone would exercise!” (O’Donnell, 2005). When a person is motivated to make a behaviour change he or she will work to gain the knowledge and skills necessary to make that change and will create the opportunities to make it possible, if the person is not motivated to change, knowledge and skills will not necessarily cause change. The notion that behaviour change involves a process that occurs in increments and that involves specific and varied tasks is at the heart of the Transtheoretical Model (TTM) of intentional human behaviour change (Prochaska and DiClemente, 1992). This model offers an integrative framework for understanding the process of behaviour change, whether that change involves the initiation, modification or the cessation of a particular behaviour. Three factors are hypothesized to mediate the change process; those are self-efficacy and the pros and cons of changing (Lippke and Ziegelmann, 2006).

An improvement in knowledge needs to be combined with improvement in self-efficacy, provision of appropriate skills to encourage self-management and movement of subjects into the action stages of change to facilitate positive behaviour change. This was recently demonstrated in a study designed to assess the impact of a community based diabetes education programme, incorporating Social Cognitive Theory and the Stages of Change model (Chapman-Novakofski and Karduck, 2005). Long term change in knowledge as well as behaviour has been suggested as an ultimate measure of success in clinical nutrition care (Molaison, 2002). A strength of the “Eat Well with CF” programme is that by improving basic nutrition knowledge and aiming to provide some of the additional skills the patient requires (e.g. improving self-efficacy, enhancing self-management) they will be able to successfully translate nutritional messages into behaviour and action, although weight maintenance may be a long term measure of success because of the impact acute episodes can have on nutritional status.
3.5.2.2 Reported fat intake

The study aimed to evaluate the impact of the programme on reported dietary fat intake. The intervention group clearly showed a significant increase in reported fat intake at 6 months, although this effect was not maintained at 12 months. The apparent absence of a long term effect of a single exposure to the programme suggests that continued support and education is required to reinforce aspects related to the patient’s current stage of development and disease status.

It can be hypothesised that the increase in reported fat intake demonstrated could ultimately lead to an increase in weight, hence supporting the first hypothesis that the nutrition education programme will improve measures of nutritional status.

The approach to measuring reported fat intake in this study obtains information about ‘usual’ intake by covering both frequency and quantity of food consumed. It is a simple score which correlates with fat consumption in individuals. In the original study reporting the development of the ‘short fat’ questionnaire, there were strongly significant associations between the ‘short fat’ score and the scales of attitudes, behaviours and knowledge (Dobson et al., 1993). A review of the literature over a 15 year period revealed consistent empirical evidence of strong correlations between intentions and behaviour (Ajzen, 1989). So it is reassuring that intentions and stage of behaviour were equally strong associations with self-reported actual behaviour (Questionnaire score) in the study by Dobson (1993).

The present study provided the 10 week home based intervention “Eat Well with CF”, with very regular support and contact from the dietitian, but once the intervention had finished there was no formal follow up. The subjects then reverted to standard care, seeing a dietitian periodically in a clinic setting. It can be suggested that the short term effect of the programme on reported fat intake could be reinforced by providing regular, ongoing education and counselling as a feature of the programme.

Increasing awareness about nutrition and fat intake and improving nutrition knowledge will also enable subjects to improve self-management of pancreatic enzyme replacement therapy (PERT). This is a particularly important aspect to assist in controlling for malabsorption and hence improving nutritional status.
3.5.2.3 Self-efficacy

The third hypothesis was that adults with CF completing a home based nutrition education programme would have an improvement in self efficacy regarding their ability to cope with a special diet, compared with those receiving dietetic standard care. This hypothesis was proved and we have clearly shown that the increase in self-efficacy score in the intervention group was statistically significant both at 6 and 12 months.

Self-efficacy refers to a person’s belief in his or her own ability to carry out and succeed with a specific behaviour. Self-efficacy is a key element in motivation for change and is a reasonably good predictor of treatment outcome (Bartholomew et al., 1993a). The significance of the increase in self-efficacy demonstrated by this study is the future effect of this improvement in self-efficacy on self-management. By enhancing self-efficacy, subjects will feel more confident in their ability to follow the prescribed dietary regimen. As a consequence of this they are more likely to take control and manage their own disease and the treatment of the disease (CF).

Social Cognitive Theory proposes that behaviour change is mediated by people’s thinking patterns and that these patterns may be most readily changed when subjects experience a sense of self-efficacy. That is, for subjects behaviour to change he/she must believe that adopting a particular behaviour will lead to the desired outcome but also perceive that they are able to successfully execute the behaviour. The strength of subject’s convictions in their own effectiveness is likely to affect whether they will initiate a coping behaviour, how much energy they will expend on it and how long they will persist in the face of obstacles. The “Eat Well with CF” method of providing nutrition education is similar to the work undertaken by Luder (1989) in that it emphasizes assisting subjects to change their pattern of thought and increase their self-management skills. It is not however possible to compare our self-efficacy results with the work conducted by Luder and colleagues as no measurement of self-efficacy was undertaken.

The work undertaken by Bartholomew in children with CF and their carers (Bartholomew et al., 1997) demonstrated an improvement in knowledge, self-efficacy and self management behaviours in those subjects who participated in the intervention. There is no work to date measuring self-efficacy outcomes in behavioural nutrition education programmes for adults with CF therefore the results of this study cannot be compared to those from other studies. It
is possible however to review studies measuring the effect of a standard behavioural change programme on self-efficacy. Many studies relating to general health and smoking behaviours found overall increases in efficacy over the course of treatment and found self-efficacy to be related to short and long term success as a result of the programmes (Kaplan et al., 1984, Condiotte and Lichtenstein, 1981).

In various experimental studies, manipulations of self-efficacy have proven consistently powerful in initiating and maintaining change. (Condiotte and Lichtenstein, 1981, Prochaska and DiClemente, 1984). In one such study, self-efficacy for decreasing dietary fat intake was increased in college students during a nutrition course, fat intake was reduced and students with increased self-efficacy during the 3 month follow up were still reducing fat intake (De Wolfe, 1993). A more recent study was designed to evaluate the effectiveness of a behavioural based cardiac rehabilitation nutrition education programme compared to standard care. The authors reported greater increases in self-efficacy in the intervention group compared to the control group, although this did not yield significantly greater changes in dietary fat and carbohydrate intake as was hypothesized (Timlin et al., 2002).

A review of studies of self-efficacy as it relates to health practice was undertaken by Strecher (Stretcher et al., 1986). This review focused on cigarette smoking, weight control, contraception, and alcohol abuse and exercise behaviour. The authors found a consistently positive relationship between self-efficacy and health behaviour change and maintenance, and recommended incorporating the enhancement of self-efficacy into health behaviour change programmes (Stretcher et al., 1986).

A recent American study was designed to determine whether psychosocial, weight satisfaction and dietary pattern variables could discriminate between stage of change for fruit and vegetable intake among young men and women. The study indicated that self-efficacy operated to discriminate men in pre-action stages of fruit intake. The authors suggested young men appeared to need increased confidence in their ability to include fruit into their diets as they considered and/or committed to such a change (Horacek et al., 2002). This concept has been previously reported by Slater (1989), who found that self-efficacy accounted for variance in eating behaviour that was not explained by knowledge or demographic variables.

A study to test the effects of a classroom and internet educational intervention on self-efficacy for healthy eating in 121 participants revealed that students in the intervention group had
higher self-efficacy for healthy eating, more dietary knowledge and healthier usual food choices than did those in the comparison group (Long and Stevens, 2004). These finding are supported by several other studies in adolescents which reported that increased self-efficacy, dietary knowledge and usual food choices were significantly related to healthy eating behaviour (Edmundson et al., 1996, Cusatis and Shannon, 1996).

Long et al (2004) propose a simple model linking self-efficacy and eating behaviour in adolescents; this is illustrated in figure 3-21.

Figure 3-21 Hypothesised model of self-efficacy and eating behaviour in adolescents, adapted from Long et al (2004).

People often do not behave optimally, even though they have the knowledge to do so. The higher the level of perceived self-efficacy the greater the performance accomplishments. Strength of efficacy also predicts behaviour change. The stronger the perceived efficacy, the more likely are people to persist in their efforts, until they succeed (Bandura, 1982, Bandura et al., 1982).

People who have a sense of self-efficacy can bounce back from failure, they approach things in terms of how to handle them rather than worrying about what can go wrong. Incorporation of the self-efficacy concept into nutrition education programmes such as “Eat Well with CF” may give subjects a strategy for long term self-care management of their dietary regimen.

Self management can lessen the impact of a chronic illness and self-efficacy is a critical determinant of learning and performance of self-management behaviours. Enhancing self-efficacy through health education may be critical to learning and performing CF home care routines (Bartholomew et al., 1993a).
Self-management education has relied heavily on the fact that sufficient knowledge will translate into performance of the self-management behaviours, however research on self-management has failed to show a strong relationship between knowledge and behaviour. Improving subjects self-efficacy expectations regarding CF self-management behaviour may be a key factor leading to improving care for subjects with CF especially in a disease with a high burden of self care.

### 3.5.2.4 Quality of life (QoL)

The study aimed to assess the effectiveness of the intervention on quality of life measures. Despite improvements in treatment, CF remains a progressive and ultimately fatal multisystem disease that has a heavy treatment burden. Given this, a goal for intervention in CF should be to measure and improve health related QoL in relation to medical and psychosocial interventions.

Within the adult CF population, there are individuals at varying stages of the disease trajectory experiencing different clinical conditions (e.g. diabetes, awaiting lung transplant) and receiving different levels of interventions (e.g. nutritional support). The progressive nature of CF and the increase in treatment regimens have the potential to encroach on daily living and to affect the subjects' health related QoL. For this reason it was considered an important feature of the present study to measure the effects of the new programme on Quality of life.

The measure used in this study is a valid and reliable measure of health related quality of life for adolescents and adults with CF. It is a patient derived measure which includes domains and response scales which have been determined by the patient and are therefore meaningful to them (Gee et al., 2000).

Data relating to the sensitivity of the QoL questionnaire have indicated that the measure is able to detect transient changes in health status, which is relevant for its use in clinical trials (Gee et al., 2003). The aim of the quality of life measurement in this study was to evaluate
the impact of the behavioural intervention on the wider aspects of the patient's life. QoL fluctuates over time with changes in any or all of the domains. The questionnaire used was multidimensional and reflects the whole spectrum of a person's daily life.

QoL evaluation is an excellent way of determining the impact of treatments on how subjects feel and function. With a chronic disease a crucial requirement of any treatment should be a clear demonstration of its beneficial effects on daily activities and well-being. A person may feel and function better following an intervention but this may not be measurable by conventional clinical measures, for this reason subjects' views are crucial.

There were only minor changes in quality of life scores throughout the study period. There was one statistically significant difference between the control and the intervention group's scores in quality of life at different time periods. There were no other significant differences between baseline and 6 and 12 months. Emotional responses were significantly different at 6 months (p=0.04) however this difference was not shown at 12 months. The emotional responses section of the quality of life questionnaire focuses on whether CF has made the subjects feel resentful, angry, embarrassed, and irritable or fed up, over the last two weeks. Due to the very immediate nature of the questions (i.e. over the last 2 weeks) this score is highly likely to change significantly at different time periods.

There were two significant differences between the completers intervention and control groups scores for quality of life. The first was physical functioning at 6 months, the control group scoring significantly higher than the intervention group. It is unlikely this difference is attributable to participation in the trial. It seems more likely this is related to the intervention group being less well than the control group overall. The second significant difference was in the concerns for the future domain at 12 months. This section asks the patient about any concerns they have for the future because of their CF, it asks specifically about having a family, needing a transplant, CF shortening their life etc. The intervention group scored much higher than the control group (mean rank 25.74, 17.26), that is, the intervention group had less concerns for the future at that time than the control group (p=0.03). This effect was not seen at 6 months and it is unlikely that involvement in the current study would influence these concerns directly. There were no other significant differences between the groups at any time period.
It is difficult to conclude that there were any consistent differences in quality of life between the groups as there is no overriding pattern to the changes. The important point to note about the Quality of Life measures is that the first four sections (Physical and social functioning, treatment issues, chest symptoms and emotional responses) are very time specific, i.e. ask about feelings over the past 2 weeks. These are therefore likely to be very variable dependant on current chest condition and how unwell/well the patient is feeling. Particularly taking into consideration that a CF patient with a severe chest infection would feel very unwell, yet 2 weeks later following a hospital admission and an intravenous antibiotic course, could feel much improved. In this respect these measures are not likely to reflect changes as a consequence of the nutrition education programme. The remaining sections ask about general feelings surrounding specific topics (concerns for the future, interpersonal relationships, body image and career issues).

There are a limited number of studies investigating quality of life in adults with CF using the CF specific health related quality of life (HRQoL) questionnaire. The most recent is a cross sectional study exploring the associations between clinical variables and the HRQoL. This study involved subjects from two large CF centres in the UK. The authors reported a weak positive correlation between FEV1 % predicted and all domains of quality of life. As expected there was strong evidence that subjects who had received a lung transplant reported a higher HRQoL in physical and social functioning, chest symptoms and treatment issues. They concluded that while important associations were identified, much of the variance in HRQoL remained unexplained. They suggest a longitudinal study is required to investigate how the disease trajectory and associated treatments affect an individual’s quality of life (Gee et al., 2005).

3.5.2.5 Stage of change

The application of the stages of change model has been a major development in health behaviour research (Prochaska and DiClemente, 1992). The stages of change represent a key component of the Transtheoretical model, an innovative and comprehensive framework, which conceptualizes when and how behaviour change occurs. It describes a series of changes through which people pass as they change behaviour. In this model change is viewed as a progression from an initial pre-contemplation stage where the person is not currently
considering change to *contemplation* – where the individual undertakes a serious evaluation of considerations for or against change, to *preparation* – where planning and commitment are secured. Successful accomplishment of these initial stage tasks lead to taking *action* to make the specific behavioural change – if successful, action leads to the final stage of change – *maintenance* in which the person works to maintain and sustain long term change. Individuals move from being unaware or unwilling to do anything about the problem, to considering the possibility of change, then to becoming determined and prepared to make the change, and finally to taking action and sustaining or maintaining change over time. Individuals progress through these stages by implementing cognitive, experiential and/or behavioural activities. In addition, changes in decision making (balance between the pros and cons of changing) and self-efficacy are likely to occur in the process of behaviour change. Figure 3-22 illustrates proposed stages of dietary behaviour change model adapted from Sigman-Grant (1996).
This current study aimed to assess the impact of the education programme on the patient's readiness to make dietary change. In addition it aimed to provide an understanding of an individual's motivation to change their dietary habits. As has been clearly shown from the results those subjects who followed the stage of change model from a 'consideration' to an 'action' stage improved their self-efficacy, reported dietary fat intake, specific and general nutrition knowledge both at 6 and 12 months, more than those subjects who showed no logical sequence of change throughout the study period (table 3-42). Therefore we can conclude that an individual moving through the stages of change from a consideration phase to an action phase is more likely to improve outcomes than an individual who does not move from a 'consideration' to an 'action' phase.
The stage of change model has proven to be effective as a basis for developing interventions for changing addictive behaviours, particularly cigarette smoking (Prochaska and DiClemente, 1992). Only more recently has the model been applied to the promotion of dietary behaviour change. The studies which have examined health related dietary change using the stages of change model have mainly focused on examining fat reduction (Curry et al., 1992) (Sporny, 1995, Glanz et al., 1994, Greene et al., 1994, Finckenor and Byrd-Bredbenner, 2000), although it has also been applied to fibre intake (Glanz et al., 1994) and fruit and vegetable consumption (Ma et al., 2002, Campbell et al., 1994,(Sorensen et al., 1996, Brug et al., 1997, Cullen et al., 1998).

Each of these studies has tended to focus on the variation of different variables across the stages of change such as the advantages or disadvantages of the behaviour, dietary intake and various psychosocial variables. Although substantial evidence is provided to show that different variables vary considerably across the stages, there is still some question as to the extent to which such variables are actually predictive of change (Povey et al., 1998).

An investigation carried out to determine the stages of change for dietary fat and fruit and vegetable intake of cardiac subjects (n=226) entering a rehab programme, reported that subject’s percentage of energy from fat decreased linearly from the pre-contemplation stage to the maintenance stage. In addition daily servings of fruit and vegetables were lowest for those in the pre-contemplation stage and highest for those in the maintenance stage. The authors concluded that subjects were in different stages of change for two nutritional behaviours linked to the same disease. They suggest the need to assess subjects for food behaviours and apply different educational interventions for each food behaviour (Frame et al., 2001).

Further work investigating the stages of change in dietary fat reduction corroborate these findings and those of Curry et al (1992) for fat intake and Glanz et al (1994) for fat and fibre intake. In this study respondents, classified on the basis of self-report into the pre-contemplation through to the maintenance stage, ate progressively less fat and more fibre at each stage (Sporny, 1995).

Interpretations of the results from the stage of change questionnaire in our study are limited due to missing data for some subjects. In addition, for numerous subjects there was no logical sequence of change throughout the study. It could be that the subjects found this particular questionnaire more difficult complete and therefore failed to do so. The number of subjects who showed no logical sequence of change could indicate that the subjects experienced
difficulties understanding and interpreting the questions properly and therefore did not complete it thoroughly.

Prior research has suggested that the method of self-completion of questionnaires frequently used to categorize people into different stages of change is open to misinterpretations (Povey et al., 1999). Previous studies which have examined the extent to which people are aware of their actual diet (Lechner and Brug, 1997, Povey et al., 1998) report there to be a large discrepancy between the objective assessment of diet and self-rated, subjective intake. It could be argued that the use of self-completion questionnaires to categorize people into stages of change will always be prone to some form of bias. These include problems in the way in which questions are phrased or misconceptions of the question by the respondent (Glanz et al., 1994) and it is necessary to be aware of such possible limitations when interpreting the results. Several authors have suggested there is need for a combination of a dietary assessment method and a staging questionnaire for assessing stages of dietary change (Ni Mhurchu et al., 1997, Ma et al., 2003, Lechner and Brug, 1997).

The stage of change questionnaire would have been more suitable in a personal interview format, to avoid some of the previously discussed misinterpretations of the questionnaires and to elicit as much accurate information as possible from the subjects surrounding their feeling towards changing their dietary behaviour at different times.

In addition to the problems associated with the application of stage theories to health behaviour change, several authors have noted that differences between dietary behaviours and the addictive behaviours on which the model was originally based may cause problems for the model (Shepherd, 2002, Povey et al., 1999). Shepherd suggests the application of the stage of change model to dietary change may be problematic and due note needs to be taken of the differences between addictive behaviours, such as smoking, for which the model was originally developed and nutrition related behaviours (Shepherd, 2002). Future studies are needed to fully determine the most accurate method to measure stage of change in relation to dietary behaviour (Ma et al., 2001).

To summarise, studies to date have shown healthy eating behaviours to be more positively associated with the action stage than the pre-action stages of change. These studies have also suggested there are difficulties associated with the application of the stage of change theories
to health related behaviour change, and more specifically to diet. It is therefore important when employing the stage of change model within different health contexts to be fully aware of the limitations to the model and its application. It is crucial when considering a behaviour change programme, to assess the stage of a patient’s readiness for change prior to commencing the programme.

It has been determined that efficient self-change of behaviours depends on doing the right thing at the right time (Prochaska et al., 1992). Therefore probably the most obvious and direct implication of this study is that, as we know knowledge alone does not necessarily bring about behaviour change, we need to assess the stage of a subject’s readiness for change and tailor interventions accordingly. A study by Campbell et al demonstrated that messages individually tailored to a person’s stage of change generated a significantly greater reduction in dietary fat than non tailored messages based on dietary guidelines (Campbell et al., 1994). More recently a Dutch study demonstrated that stage matched nutrition counselling promoted movement through stages of change resulting in a reduced fat intake. The authors suggest the stages of change is a useful tool for behaviour change (Verheijden et al., 2004). Matching treatment or intervention strategies to the needs of the patient according to their readiness to change also has important economic ramifications. Studies have shown that if individuals are not in the action stage, action – oriented programmes are likely to be inappropriate. For example, an intensive action and maintenance-oriented programme directed at cardiac subjects to quit smoking was very successful for subjects who were either in action or preparing for action, but the programme was ineffective for those individuals who were at the earlier stages of pre-contemplation and contemplation (Ockene, 1988).

The results of the stage of change assessment in this current study have the potential to assist in providing us with useful information for the future applicability of the intervention programme. Specifically in terms of selection of subjects and timing. This may more effectively utilize specialist dietetic time by segmenting the population into groups in terms of readiness to change. Then providing the “Eat Well with CF” programme to target groups of subjects when they are in a preparation or action phase. The stage of change model is a way of matching interventions to the stage at which subjects are, rather than expecting subjects to commence action orientated programmes when they are neither motivated nor prepared to do
so. This strategy should prevent wasteful use of time and resources trying to educate subjects
and change behaviour when they are not ready to consider change.

Following on from the interpretation of the results of this study, the next section will
concentrate on the strengths of the “Eat Well with CF” education programme and the lessons
learnt as a consequence of the study.

3.5.3 The programme

The home based nature of the “Eat Well with CF” programme offered flexibility to
accommodate different lifestyles, learning styles and medical needs. It allowed the subjects to
determine the best time of the week for them to complete the challenges. The flexibility of the
programme also allowed subjects to take extra time to complete the programme if there were
delays caused by illness or other commitments.

The benefits of the modular nature of the programme include the ability to re-refer to relevant
sections. For example if a patient develops diabetes they can refer back to the diabetes
section. It was also perceived as being useful to educate partners or parents. This observation
became evident when partners or parents attending workshops commented on how much their
knowledge had improved following their partners/childs participation in the programme.

An interesting finding as a result of the study was the poor reading ability of some subjects. It
was assumed the majority of subjects would have the appropriate reading skills to partake in
the programme, particularly as the programme had been reading age critiqued. It became
obvious that for many subjects their reading ability was extremely poor and the volume of
written material proved far too challenging. These subjects were therefore reluctant to take
part in the study. The assumption that the written programme would be applicable to most
subjects was inaccurate and highlighted the need for an alternative medium for presenting the
education programme. An audio tape and CD version was considered the most suitable
method. In addition to enabling subjects with poor reading ability to partake in the programme
it provided an additional/ alternative resource for all participants, thus expanding the scope of
applicability of the “Eat Well with CF” programme. The process evaluation in the final cohort of the study revealed the advantages of having an additional vehicle of learning in addition to the written programme, with many subjects using a combination of the written and audio versions (see chapter 5).

Three CF nutrition related behaviour programmes which were based on the SCT constructs include a parent training approach developed by Stark et al (Stark et al., 1990) counselling strategies developed by Luder (Luder and Gilbride, 1989) and Bartholomew’s family education programme (Bartholomew et al., 1997).

The limitations of these studies and therefore the generalisability of the findings will be discussed in further detail. The work undertaken by Stark and colleagues would prove very time intensive for the health care provider if the implementation was to be clinic wide. These studies only involved very small numbers of subjects who receive intensive behavioural management education. The weight increases were significant but the numbers were small. Bartholomew’s home based family education programme included a nutrition section, however this only included two SCT constructs, those of observational learning through modelling and social reinforcement. Experts recommend that the behavioural constructs should be used simultaneously to explain and address complex food and diet related behaviours as their affects are markedly reduced when used alone (AbuSabha and Achterberg, 1997).

The work conducted by Luder and colleagues involved 37 subjects, aged 4-29 years at the start of the study, subjects were followed up for 4 years. The subjects were given nutritional counselling and self-efficacy was applied to guide subjects how to change their pattern of thought and to lead them to the conviction that they can manage their own treatment programmes effectively. The model focuses on learnable skills or processes to influence a specific behaviour. It fosters a personal goal setting approach in participation and self-evaluation. The attainable (physical) rewards were very important in a behaviour change programme for children; this programme did not provide comprehensive information or small incremental changes to intake.

Stapleton (1998) developed a children’s home based behavioural nutrition education programme entitled “Go and Grow with CF”. This work in Australia was based on the SCT constructs of behavioural change and aimed to address the deficiencies identified in the three
previous programmes. Features identified as being essential for achieving health related behaviours in children were included.

These are:

1. Provide clear information in developmentally appropriate ways.
2. Encourage parental reinforcement of the advice provided.
3. Involve the family unit.
4. Establish concrete behavioural goals.
5. Allow the child to determine and participate in appropriate aspects of treatment.
7. Introduce record keeping in order for the child to self-monitor adherence, to assume more self-responsibility.
8. Provide interim follow up through telephone calls.
9. Implement a structured reward system.
10. Develop problem solving skills.
11. Provide opportunities for actual experience and participation.

"Go and Grow with CF" consisted of group sessions and home based learning. Other SCT characteristics of "Go and Grow with CF" that were incorporated in order to maximise knowledge and behavioural change in children were:

1. Provision of comprehensive nutrition and pancreatic enzyme dose adjustment information (behavioural capability).
2. Guidance through incremental steps (self-efficacy).
3. Use of a structured reward system (re-enforcement).

Fifty eight children (2-11yrs) and carers participated in a clinical trial which was designed to assess the effects of the programme on knowledge, self-management, behaviour, dietary intake and body composition using anthropometry.

Process evaluation was conducted, and 100% of carers indicated they would recommend "Go and Grow with CF" to other families. The limitations of this study include that the objective assessment of knowledge indicated significant short term improvement but there were no statistically significant improvements in other parameters assessed. The lack of significant improvement may suggest that the programme had no effect or that the parameters assessed or the instruments used were not sufficiently sensitive, the sample size was too small or the duration of the intervention and follow up too short.
Stapleton concluded that the carer's unanimous recommendation of the programme together with high levels of perceived learning, reported increase in confidence and improvement in children's knowledge short term, indicate the benefits of the programme. The absence of a long term effect of a single exposure to the programme on knowledge suggests regular ongoing education and counselling was required by families to reinforce aspects related to the child's current stage of development and disease status.

A simple framework has been proposed by O'Donnell which suggests that to be successful a programme needs to include: efforts to motivate, build skills and provide opportunities for the desired behaviour (O'Donnell, 2005). The self-management aspect of the "Eat Well with CF" programme, which included subjects setting their own goals and deciding on attainable rewards, was important to encourage patient's active participation at every stage of dietary modification. The use of tangible rewards as a method of reinforcement that helps motivate subjects to continue to participate in the programme was perhaps less important in our adult subjects than has been shown in the previous studies using children. Subjects were asked to choose their own rewards. For many, the reward was not tangible but was based on a feeling of personal achievement and satisfaction at gaining weight. Similarly the use of the supporter was demonstrated to be useful for some subjects but not for others. In an adult population it has become clear it is important that these aspects of the education programme remain flexible. Giving subjects the option of having a supporter and the option of whether they use tangible or intangible rewards for active programme participation. This adds to the flexibility of the programme and offers various options for each individual.

Active participation in a nutrition education programme has been shown to make it more likely that a truly long term change will occur (Evans and Hall, 1978).

The use of SCT frameworks in nutrition education programmes for children with CF has been previously discussed. Recent work investigating dietetic management in overweight children has utilised a behavioural approach based on the SCT constructs (Stewart et al., 2005). There are no similar studies utilising SCT in nutrition interventions for adults with CF. However SCT has been recently used as the theory on which many adult education programmes have been based. Examples of programmes using SCT include: a dietary intervention to reduce hypertension in an African-American population (Rankins et al., 2005), and an e-mail intervention for the promotion of physical activity and nutrition behaviour in the workplace (Plotnikoff et al., 2005). Numerous behavioural interventions for reduction of sexually
transmitted diseases and HIV transmission (Smith et al., 1996, Thompson et al., 1997, Ford et al., 1996) have found SCT an appropriate framework for adolescents and adults.

The next section will discuss the implications of this method of nutrition education on dietetic practice.

3.5.4 Dietetic intervention, how is this different?

Traditional dietetic consultations versus a patient centered philosophy

This novel method of nutrition education involves subjects learning in their home environment, setting their own goals and completing challenges to reinforce behaviour change. This is very different to the traditional model of one-to-one patient consultation in a hospital setting that dietitians have previously followed. Dietitians have traditionally functioned as nutritional advice givers rather than behaviour change agents. Over the last 20 years there has been a shift from the dietitian acting as a technician delivering advice to a consultant with expertise in all aspects of nutrition and dietetics (Judd, 1997). As a consequence there is need for competency in counselling skills in the dietetic practitioner. However the process of facilitating behaviour change has remained in the domain of applied psychology, as dietitians have not been taught the necessary skills. This implies dietitians need to review and re-think the traditional way participants are seen. Practically this involves considering how to utilise Social Cognitive Theory within dietetic practice.

The aim of dietary counselling is to increase subjects’ readiness to affect dietary changes and to encourage them to engage in self-management by providing them with the tools to solve problems in implementing recommended dietary behaviour (Rapoport, 1998).

A questionnaire survey undertaken in dietitians in the UK aimed to investigate their perceived adequacy of training in behaviour change techniques. The results of this study demonstrated that although facilitating dietary behaviour change is a key dietetic role, respondents felt that they had not received adequate training in behaviour change skills in their pre-registration dietetic training. Training was perceived as particularly poor in; applying theories of cognitive and behavioural therapy motivational techniques, group work skills and in both the theory and skills of relapse prevention. The authors suggest that in the current health service climate where evidence - based practice is crucial for all practitioners with the emphasis on improved quality of care with measurable outcomes, research must be funded and undertaken
to support attempts to improve dietitians effectiveness as behaviour change agents (Rapoport, 2000). Similar work in America highlighted the relatively little time devoted to behaviour modification and behaviour counselling skills in formal dietetic training (Rosal et al., 2001). The authors argue that nutritionists need to increase their knowledge of practical intervention strategies based on Cognitive Behavioural Theory. They suggest a patient centred counselling approach. The objectives of which include:

a) Increasing the patient’s awareness of their diet related risks.
b) Providing the patient with nutrition knowledge.
c) Increase the patient’s confidence in their ability to make dietary changes.
d) Enhance the skills needed for long-term adherence to dietary change.

The authors propose that this approach enables the nutritionist to tailor the intervention to the patient.

The authors recommend that formal education in behavioural strategies for promoting dietary change needs to be emphasised more in dietetic training. They advocate that nutritionists need to master counselling skills to assist their subjects in acquiring knowledge, attitudes and skills needed to move through the process of change and ultimately, adopt diets consistent with favourable health outcomes (Rosal et al., 2001).

In a typical dietetic consultation, a summary of the nutrition information required is provided, written or videotape information is also given. The dietitian may end the consultation believing she/he has provided adequate patient education. However the dietitian may subsequently feel frustrated when a lack of motivation to change in response to these efforts is detected. The dietitian may personalise this lack of motivation and attribute it to the lack of time available for sufficient patient teaching. The problem however stems not from lack of time but from the use of incomplete intervention; that is, imparting information is rarely sufficient to motivate behaviour change (Saarmann et al., 2000). Imparting information serves a purpose; it increases the knowledge base of the recipient. However as we have previously discussed increasing knowledge is not synonymous with encouraging change.

Without acknowledging a person’s stage of change regarding a particular issue and approaching teaching in a respectful manner shown to motivate change, patient education is often a waste of time and energy to both the patient and the health professional. It is important to dispel the notion that the patient must be taught everything they need to know in one session. An article describing the research on which effective nurse - patient teaching should
be based (Saarmann et al., 2000), makes a pertinent point which is also relevant to dietetic practice, "Significant progress would be made if the language of nursing evolved to reflect the research instead of the tradition".

The studies undertaken in this thesis have focused on moving dietetic practice from the traditional consultation towards a more patient focused, self-management approach. A patient centered philosophy requires the dietitian to have an understanding of the patient’s situation and involves working together to find solutions, the patient creates their own plan of action and the dietitian supports the subjects’ self-esteem, confidence and motivation.

The potential benefits of this patient focused approach to the health service are improved patient outcomes and potential reduction in costs by encouraging subjects to take an active self-management approach to their treatment. This type of intervention may enhance dietetic service quality by more effective use of specialist dietetic expertise in out patient clinics. This may lead to a reduction in dietetic hours in the long term as the demands of ad hoc problem solving may decrease. These benefits align with the Department of Health’s current ‘Improving Chronic Disease Management’ Programme (Colin-Thorne, 2004).

The implementation of such a programme would only require minimal additional training for dietitians in behaviour change skills and motivational interviewing techniques meaning that the initial outlay costs would be small.

3.5.5 Limitation of the study

In addition to the specific limitations discussed in the relevant sections, there are a number of additional general limitations of this study.

A limitation of any study requiring participant consent is selection bias. Subjects most interested or concerned with their weight/nutritional status are more likely to volunteer to take part in a study that has the potential to improve these parameters.

The bias in the type of analysis undertaken should be taken into account. Analysis by intention-to-treat is not free of bias, as this analysis considers the way in which we intended to treat subjects not the way in which they were actually treated, to account for drop outs. The difference we have shown may be therefore smaller than it actually should be. The Completers analysis on the other hand, is also biased in favour of showing a difference
whether one exists or not, as this analysis only includes those subjects who complete the study.

It is also important to consider the limitations of the RCT design. The randomization process produced study groups comparable in unknown as well as known factors likely to influence outcome apart from the actual treatment itself. Randomisation also guaranteed that the probabilities obtained from the statistical tests would be valid. Studies have shown participants in RCT’s of clinical treatment interventions to be less affluent, less educated and more seriously ill than non-participants (Britton et al., 1999).

The study was designed as an RCT based on the “true experiment” model which is the paradigm of medical methods. This type of study investigates “hard” clinical outcomes and may overlook other “softer” outcomes which may be important in this population. For example, the outcomes did not demonstrate how the intervention made subjects feel, if it made the subjects feel more supported, whether it encouraged a better rapport with the dietitian, whether the subjects felt the dietitian was more accessible as a consequence of the intervention. The concept of consumer satisfaction was investigated further by means of a process evaluation of the programme, which is discussed in more detail in Chapter 4.

Blinding was not possible in this study as the dietitian needed to know who was in the intervention and control groups. It must be considered that the same professional providing the control and intervention treatments could have the potential for group contamination, in addition the subjects in the intervention group had access to standard care. These should be considered as potential sources of bias.

The recruitment difficulties encountered during the study period meant the recruitment process took longer than was originally planned. We experienced difficulties in recruiting an already well studied population with a high burden of self-care. A further study was carried out specifically investigating reasons for non participation in the trial, see Chapter 5.

In addition the changing microbiological segregation restrictions for CF subjects during the study period limited the final numbers recruited. Pseudomonas Aeruginosa (PA) infection (Littlewood, 2004), is the most frequent and important pathogen responsible for chronic infection in people with CF (Lyczak et al., 2002). It is now well established that the clinical state can worsen when chronic PA infection becomes established. Chronic infection with PA can be associated with decline in pulmonary function and a worse prognosis. PA can be acquired from other people with CF. This document (Littlewood, 2004) describes precautions
that need to be taken in specialist centres and CF Clinics where there is a possibility of spread of transmissible strains of PA between subjects. The document stipulates that all CF Centres should have a policy on cross infection that addresses PA and considers the issues of surveillance, hygiene and segregation.

As a consequence of these restrictions, recruitment ceased at 74 subjects, although the original planned sample size was 100. At this time the local centre segregation was due to be instigated, which involved subjects with different strains of pseudomonas being segregated at all times, (in hospital and out patient clinics). It would therefore have been impossible to continue this study as per the original protocol, in particular the workshop aspect of the programme.

3.5.5.1 Sample size calculation required to achieve significant difference

The following table illustrates the required sample size needed to achieve a significant difference in each factor using the mean results and standard deviations found in the present investigation and provides information for further studies which was not available at the time this study was commenced.
Table 3-46 Power calculations using the means achieved in the present investigation to establish the required sample size of each group to achieve a significant difference of $p<0.05$ between the independent groups (with an 80% power) at 12 months following the intervention.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Difference in means</th>
<th>Common standard deviation</th>
<th>Predicted sample size for each group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>0.71</td>
<td>2.2</td>
<td>151</td>
</tr>
<tr>
<td>BMI</td>
<td>0.49</td>
<td>1.4</td>
<td>317</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>3.5</td>
<td>5.2</td>
<td>32</td>
</tr>
<tr>
<td>Reported fat intake</td>
<td>2.73</td>
<td>5.4</td>
<td>62</td>
</tr>
<tr>
<td>Specific nutrition knowledge</td>
<td>4.39</td>
<td>3.8</td>
<td>12</td>
</tr>
<tr>
<td>General nutrition knowledge</td>
<td>1.14</td>
<td>3.5</td>
<td>146</td>
</tr>
</tbody>
</table>

Table 3-46 includes the parameters where the intervention group achieved more favourable results than the control group. It shows that for the specific nutrition knowledge outcome only 12 subjects would have been required per group to achieve significance. It also illustrates that for the reported fat intake outcome to show significance a moderately increased sample size (62 in each group) would be necessary. However with regards to the weight parameters and general nutrition knowledge much larger sample sizes would be required.

3.5.6 The future of the intervention

Following the positive results of the randomised trial of “Eat Well with CF” it is crucial to consider the future applicability of the education programme.
The formal data collected as part of the trial and informal patient, medical, nursing, dietetic staff and carer comments noted throughout the period of all these studies, indicate the successful and beneficial nature of the programme. In this respect it is proposed that the written and audio versions of the "Eat Well with CF" programme could become the new standard practice and replace traditional standard dietetic practice.

The "Eat Well with CF" programme was developed several years ago, therefore the most important initial task would be to review, restructure and update the programme. The next step would involve considering how the delivery of the programme could be improved from the lessons learned during the studies undertaken. In addition the very practical aspects of how it could be applied to the clinical population with current NHS staffing and resources available needs to be assessed.

3.5.6.1 Proposed future programme structure

It is proposed that all subjects will be assessed on admission to the adult CF centre for general and specific nutrition knowledge and self-efficacy. The results of these questionnaires will be used as a measure of baseline knowledge and confidence. A one to one motivational interviewing approach will be used to measure the patient's stage of change. A specific questionnaire will be developed based on the self-report questionnaire used in the study. The subjects will then be segmented into groups depending on their readiness to change dietary behaviour. Those in the action stage will be provided with the 10 week home based programme and will be given weekly telephone calls from the dietitian and twice weekly newsletters, to monitor progress and offer advice and reassurance. The flexibility of the home based modular nature the programme offered was considered particularly important by the subjects. In addition this will reduce the amount of dietetic time spent on basic nutrition education at time restricted clinic appointments. The workshop aspect of the programme is no longer applicable due to the new microbiological segregation rules for subjects with CF. We could consider e-mail contact and support as suggested by the study investigating reasons for non participation (Chapter 5). The workshop aspect was one of the reasons cited for non participation in the study, due to the distances involved in travelling to and from the hospital. Subjects suggested telephone or e-mail contact would be preferable.

Those subjects in the pre- contemplation/contemplation stage will be re-assessed at each appointment and motivational interviewing techniques will be used to encourage movement
through the stages of change. These subjects will not undertake the education programme until they are in the action phase. Those receiving the education programme will be followed up every 3 months in the clinic setting, unless they have specific queries, in which case they will have access to the dietitian. The dietitian will provide regular, ongoing education and counselling. Goals and achievements will be reviewed and encouragement for continuation of the changes already made will be provided.

Additional modules may be added to the “Eat Well with CF” programme as research highlights new areas for consideration or as treatment modalities change. In addition update sessions with the dietitian may be necessary to act as a revision of education and/or to encourage or maintain motivation.

The first priority with respect to future applicability of the programme is to enable the control group participants of the trial to undertake the programme. Many of these subjects expressed a wish to undertake the programme during the period of the study; in addition they did not acquire any benefit from being involved in the study as controls. We would subsequently aim to provide the “Eat Well with CF” programme to all subjects who attend our centre. The results of all stages of the development and testing of this programme have been presented at European CF conferences and interest has been shown from other dietitians from both UK and European adult CF centres, we aim to promote the use of the programme in other CF centres both nationally and internationally.

It is important that in order to assess true treatment efficacy, long term success must be measured. Taking into consideration the behavioural aspect of the programme aims to change behaviour in the long term, it would be prudent to complete a longer term follow up. These subjects could be followed up annually to assess the longer term impact of the education programme on nutritional status.

As this study was completed in a relatively small group, to expand the scope of applicability of the findings, further investigation in a larger sample is needed to determine the full effects of the programme. A multicentre study would be appropriate.
3.5.7 Conclusion

The “Eat Well with CF” programme improved weight outcomes, significantly improved reported fat intake and specific nutrition knowledge and produced greater self-efficacy in adults with CF. Subjects in an “action” stage of change were more likely to have improved outcomes than those who were in a pre-contemplation or contemplation stage. The strengths of the programme include the theory based, flexible nature offering home learning with the option of both audio and written format. We have shown this to be a more effective way of providing nutrition education and encouraging behaviour change in CF subjects; therefore practice needs to change to accommodate this novel approach. The future applicability of the “Eat Well with CF” programme involves adapting dietetic practice to incorporate motivational interviewing to assess the subjects’ stage of change and to tailor the “Eat Well with CF” intervention accordingly. This new dietetic practice may more effectively promote life long dietary change and subsequently improve nutritional status and survival.
4. An investigation to examine the reasons for non-participation in the randomised controlled trial of “Eat Well with CF”.

4.1 Aims
The main aims of the study were:

1. To investigate reasons for non-participation in a RCT of the new nutrition education programme “Eat Well with CF”.
2. To examine ways in which the programme could be improved/enhanced to encourage more subjects to take part.

4.2 Methods

Huntingdon Local Research Ethics committee granted ethical approval for the RCT in 2000. The slow rate of recruitment led to the request for permission to investigate reasons for non-participation further. Ethical approval was granted only to ask subjects specific standard questions conditional to the subject firstly agreeing to take part.

Due to the conditions set by Huntingdon Local Research Ethics committee, subjects could not be randomly selected, as they had to agree to be interviewed. For this reason all subjects were asked for their permission to be interviewed about their reasons for not participating in the trial.

Subjects were either interviewed during clinic visits or via the telephone. Subjects were asked about the reasons behind not participating and were shown a 2 page excerpt from the programme. They were questioned about the possible ways the programme could be improved to enable them to participate. The questions the subjects were asked were:

1. Do you find it easy to read this page of the education programme?
2. Do you find the language difficult to understand?
3. If the programme were available as a written booklet, or an audiocassette or on video, which format do you think would appeal to the most subjects and why?
4.3 Results

Table 4-1 details the subject demographics

Table 4-1 Subject demographics for the study examining reasons for non-participation.

<table>
<thead>
<tr>
<th>Interview Method</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face to Face interview</td>
<td>5</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Telephone interview</td>
<td>6</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td>11</td>
<td>10</td>
<td>21</td>
</tr>
</tbody>
</table>

4.3.1 Reasons for non-participation

A total of 21 subjects were recruited for this study. Several reasons were given for non-participation. Two subjects (9.5%) suffered from dyslexia, which meant they felt they would have been unable to read and understand the programme. Eighteen subjects (86%) stated work or college commitments prevented them participating. Distance the subjects lived from the hospital also contributed to them declining to take part. Just under half the subjects (n=10, 47.6%) lived at least 45 minutes away from the hospital. This was confirmed by subjects not wanting to attend the hospital for the workshops, which featured as part of the programme. These factors are illustrated by the following patient quotes:

"I already have to take time off to come to the hospital and I don't want to give up any more of my annual leave for my CF treatment"
"I have to take half a day's annual leave just to attend clinics already and I want to use my annual leave for me things, not clinic visits."

"I live nearly one and a half hours away from the hospital, so that is a journey I don't want to do more than I have to"

The combination of poor reading ability, work/college commitments, lack of time, the workshops taking place during the week, and distance to the hospital was the most commonly cited reasons for non-participation.

Two subjects n=2 (9.5%) were excluded from the study as they were already involved in drug trials at Papworth Hospital at the time of recruitment. The other reasons subjects gave for not participating in the study were varied; many were social and personal, ranging from the subject going through a divorce, to others who were simply not interested. One subject also suggested a 10 week course was too long for him to remain interested. He would have taken part had the programme been shorter.

Three subjects (14.3 %) considered their weight and nutritional knowledge to be good. They all felt they had managed to achieve optimal nutritional intake and maintain their weight. One of these subjects said:

"I have managed to sort my weight and food out now. I don't want to make an issue out of it in case I make more of an issue out of it. I feel I know what I am doing now and I am happy with where I am at."

4.3.2 Improving participation in “Eat Well with CF”

Nine subjects (42.8%) suggested a way to improve the programme and increase participation was to introduce an audio-version. Subjects who showed any form of reduced reading ability agreed that having the choice of either an audio or a written version of the programme was the best way to ensure optimal enrolment rates.

Several subjects (n=3, 14.3%) stated that if it were a distance-learning programme that could be supported via the internet, or by telephone rather than workshops at the hospital, they would be more interested in taking part.
All subjects were asked what could be done to encourage them to take part in the programme. The majority of the subjects \( n=19 \) (90.5\%) said that the time scale of the programme and the attendance of workshops at the hospital were the main problems. Several subjects said that by making the programme a distance learning programme without workshops would result in better participation. This was an extremely popular suggestion with 42.9 \% \( (n=9) \) of the subjects agreeing that this would make them reconsider their non-participation.

4.4 Discussion

Factors which contributed to non-participation in the study included; poor reading ability, work or college commitments, lack of time, and involvement in other studies, workshops being held at the hospital during the week and the distance from home to hospital. In addition a variety of social and personal circumstances were cited as reasons for non participation. This reinforced the previously discussed issues surrounding a well studied population with a high burden of self care, to whom nutrition may not be a priority.

The production of an audio-version of the programme or an internet or telephone supported distance learning programme and adapting the workshop aspect of the programme were all suggested ways to broaden the appeal and encourage more subjects to be involved.

This study highlighted the limitations of the written programme and suggests that providing the programme in an additional /alternative format may enhance recruitment. In addition by expanding the learning environment it may encourage motivation in participants to complete the programme.
5. Process Evaluation

5.1 Introduction

Process evaluation was used to complement the outcomes evaluation; it is a means of gathering data to describe how the programme was implemented, to whom the services are delivered. Process data can yield important information to help better understand how, why and among which segments of the target population changes were or were not achieved. This information is essential for understanding why the programme was or was not successful and which components of the programme had the greatest impact on the outcomes.

5.1.1 Aims

The aims of this study were:

1. To assess the extent to which the programme suited the target population, (i.e. adults with cystic fibrosis)
2. To assess how well the programme fitted the original design.

5.2 Methodology

Following the final workshop at the end of the behavioural intervention, the process was evaluated using a 16 point questionnaire developed specifically for this programme but based on principles of a physical activity self-management programme (Marcoux et al., 1999) (Appendix 4).

The aim of the questionnaire was to provide information on the views of the subjects on the programme overall, whether the weekly goals and tasks had been achieved and to assess the effectiveness of the workshops, newsletters and weekly telephone calls from the dietitian. The subjects were given a programme evaluation questionnaire following the intervention and asked to return it by a specified date.
The final group to complete the programme (group C) had the additional audio-version, therefore the process evaluation for this group differed slightly from the first two groups, hence the methods and results have been summarised separately.

5.3 Results of Process evaluation for groups A and B

Nineteen out of twenty five (76%) questionnaires were returned completed. (8/10 in group A, 11/15 in group B). A summary of the results are provided.

Subjects were asked their views of the programme as a whole. Seventeen out of nineteen (89%) subjects made very similar comments based around the following positive themes: Good, great, very educational, useful, straightforward, and learned a lot. Other comments included the following participant quotes:

| “Good for the younger patient - maybe leaving home/going to University.” |
| “Didn’t necessarily apply to me, but could understand why it would be useful to others” |

Subjects were asked to give their views on the education pack as a whole.

Twelve out of sixteen (75%) subjects made comparable remarks. These included: good, great, very well laid out, excellent, well put together, lots of interesting facts, straightforward, to the point, easy to understand. Some selected quotes illustrate these points:

| “Handy to keep referring to on a regular basis rather than at the clinic.” |
| “Well crafted and easy to follow” |

Seventeen out of eighteen (94%) subjects considered the method of a home-based programme to be suitable for adults with cystic fibrosis. Additional useful comments included:

| “Very much so. It gives the patient control through gaining knowledge of how to combat cystic fibrosis problems” |
| “Yes, as it is handy to keep coming back to every time weight drops, for ideas to gain weight.” |
Subjects were asked to give examples of the goals they set themselves at the beginning of the programme. Some examples of goals were:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>To achieve a good balanced diet and lots of snacks</td>
<td></td>
</tr>
<tr>
<td>To learn more about food</td>
<td></td>
</tr>
<tr>
<td>Better nutritional understanding</td>
<td></td>
</tr>
<tr>
<td>To be more aware of what I am eating</td>
<td></td>
</tr>
</tbody>
</table>

Subjects were asked if they achieved their goals and if not, to give reasons why not. Some of the reasons given included:

<table>
<thead>
<tr>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circumstances beyond my control</td>
</tr>
<tr>
<td>You have to be in the right frame of mind and put 100% into your goals and I didn't</td>
</tr>
<tr>
<td>It’s hard to concentrate on eating more when you feel unwell</td>
</tr>
<tr>
<td>Chest infections and stress</td>
</tr>
</tbody>
</table>

Subjects were questioned about what was the most significant thing they learned from being involved in the study. Most subjects stated learning more about the calories in foods. Other participant comments included:

<table>
<thead>
<tr>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fat content</td>
</tr>
<tr>
<td>Foods to fortify meals</td>
</tr>
<tr>
<td>Calorie cost of exercise</td>
</tr>
<tr>
<td>Calorie content of foods</td>
</tr>
<tr>
<td>Nutrition and exercise</td>
</tr>
<tr>
<td>A combination of facts not one single thing</td>
</tr>
<tr>
<td>1g fat 9 calories, 1g CHO 4 calories, 1g Protein 4 calories</td>
</tr>
</tbody>
</table>
It was considered relevant to investigate whether subjects enjoyed the programme. Many did and they cited the main reasons for enjoying the programme as learning new information and gaining valuable knowledge about nutrition and cystic fibrosis.

The subjects considered the programme was a useful resource, which could be referred back to when required. It was considered fun, not too demanding or time consuming and flexible, the subjects being able to proceed at their own pace. When questioned about which particular parts of the programme they found most and least enjoyable, the workshops were cited as fun and inspirational and encouraged subjects to try harder.

Additional representative quotes are given:

<table>
<thead>
<tr>
<th>I gained more knowledge than I ever have in clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>It was a good layout and a good teacher</td>
</tr>
</tbody>
</table>

Subjects motivation was also questioned, (see table 5-1), As would be expected, motivation varied significantly between subjects including some being extremely motivated to achieve their goals. Several subjects commented that they were motivated at the start of the programme but this dipped during the middle and towards the end. It was remarked upon that the most important and interesting information was at the beginning of the programme. This comment was made by several subjects in various parts of the process evaluation questionnaire and is therefore discussed further in the potential programme improvement section.

Subjects observed that there were a lot of reminders to aid motivation. They were asked to rate how effective the different motivation methods were, including workshops, newsletters and weekly telephone contact by the dietitian. The results are given in Table 5-1.
Table 5-1 Participant rating of motivational factors such as telephone, workshops and newsletter contact that encouraged them to continue participating in the intervention study.

<table>
<thead>
<tr>
<th>Motivational factor</th>
<th>Poor motivator N (% of responders)</th>
<th>Good motivator N (% of responders)</th>
<th>Excellent motivator N (% of responders)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workshops</td>
<td>3 (19%)</td>
<td>2 (13%)</td>
<td>11(69%)</td>
</tr>
<tr>
<td>Telephone</td>
<td>1(6%)</td>
<td>11(69%)</td>
<td>4(25%)</td>
</tr>
<tr>
<td>Newsletter</td>
<td>2(25%)</td>
<td>9(50%)</td>
<td>7(39%)</td>
</tr>
</tbody>
</table>

Additional external motivating factors were also explored. Selected participant quotes illustrate some of these motivators:

- Wanting to achieve my goals
- I started to gain weight through using ideas given in the booklet and workshops - this was a real motivator
- My own wish to learn new things
- It has given me something to do

The following tables 5-2 and 5-3 illustrate participant ratings of various aspects of the “Eat Well with CF” programme, including content, appearance, age appropriateness, overall structure and participant enjoyment.
Table 5-2  Groups A and B (n = 19) participant rating of content, appearance and age appropriateness of “Eat Well with CF”

<table>
<thead>
<tr>
<th>Programme section</th>
<th>Rating</th>
<th>Content N (%)</th>
<th>Appearance N (%)</th>
<th>Age appropriate N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy &amp; fat</td>
<td>Poor</td>
<td>0 (0%)</td>
<td>1 (5%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>Good</td>
<td>1 (5%)</td>
<td>2 (11%)</td>
<td>3 (16%)</td>
</tr>
<tr>
<td></td>
<td>Very good</td>
<td>6 (32%)</td>
<td>6 (32%)</td>
<td>7 (37%)</td>
</tr>
<tr>
<td></td>
<td>Excellent</td>
<td>11 (58%)</td>
<td>9 (47%)</td>
<td>7 (37%)</td>
</tr>
<tr>
<td>Digestion</td>
<td>Good</td>
<td>2 (11%)</td>
<td>2 (11%)</td>
<td>2 (11%)</td>
</tr>
<tr>
<td></td>
<td>Very good</td>
<td>5 (26%)</td>
<td>8 (42%)</td>
<td>5 (26%)</td>
</tr>
<tr>
<td></td>
<td>Excellent</td>
<td>11 (58%)</td>
<td>8 (42%)</td>
<td>10 (53%)</td>
</tr>
<tr>
<td>Body image</td>
<td>Satisfactory</td>
<td>2 (11%)</td>
<td>0 (0%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td></td>
<td>Good</td>
<td>3 (16%)</td>
<td>3 (16%)</td>
<td>3 (16%)</td>
</tr>
<tr>
<td></td>
<td>Very good</td>
<td>3 (16%)</td>
<td>6 (32%)</td>
<td>6 (32%)</td>
</tr>
<tr>
<td></td>
<td>Excellent</td>
<td>10 (53%)</td>
<td>9 (47%)</td>
<td>9 (47%)</td>
</tr>
<tr>
<td>Food labelling</td>
<td>Good</td>
<td>4 (21%)</td>
<td>2 (11%)</td>
<td>3 (16%)</td>
</tr>
<tr>
<td></td>
<td>Very good</td>
<td>7 (37%)</td>
<td>7 (37%)</td>
<td>6 (32%)</td>
</tr>
<tr>
<td></td>
<td>Excellent</td>
<td>6 (32%)</td>
<td>8 (42%)</td>
<td>9 (47%)</td>
</tr>
<tr>
<td>Nutrition &amp; exercise</td>
<td>Good</td>
<td>2 (11%)</td>
<td>3 (16%)</td>
<td>2 (11%)</td>
</tr>
<tr>
<td></td>
<td>Very good</td>
<td>6 (32%)</td>
<td>5 (26%)</td>
<td>6 (32%)</td>
</tr>
<tr>
<td></td>
<td>Excellent</td>
<td>10 (53%)</td>
<td>10 (53%)</td>
<td>9 (47%)</td>
</tr>
<tr>
<td>Fibre</td>
<td>Good</td>
<td>2 (11%)</td>
<td>2 (11%)</td>
<td>2 (11%)</td>
</tr>
<tr>
<td></td>
<td>Very good</td>
<td>8 (42%)</td>
<td>7 (37%)</td>
<td>8 (42%)</td>
</tr>
<tr>
<td></td>
<td>Excellent</td>
<td>8 (42%)</td>
<td>8 (42%)</td>
<td>7 (37%)</td>
</tr>
<tr>
<td>Appetite &amp; Diabetes</td>
<td>Good</td>
<td>1 (5%)</td>
<td>2 (11%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td></td>
<td>Very good</td>
<td>8 (42%)</td>
<td>7 (37%)</td>
<td>7 (37%)</td>
</tr>
<tr>
<td></td>
<td>Excellent</td>
<td>9 (47%)</td>
<td>9 (47%)</td>
<td>9 (47%)</td>
</tr>
</tbody>
</table>
Table 5-3 Summary table of Group A and B (n =19) participant rating of various aspects of the “Eat Well with CF” education programme.

<table>
<thead>
<tr>
<th>Programme section</th>
<th>Patient rating N (%)</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EXCELLENT</td>
<td>GOOD</td>
<td>FAIR</td>
<td>POOR</td>
</tr>
<tr>
<td>Overall programme</td>
<td>0/19(0%)</td>
<td>17/19(89%)</td>
<td>2/19 (11%)</td>
<td>0/19(0%)</td>
</tr>
<tr>
<td>Education pack</td>
<td>0/16(0%)</td>
<td>12/16(75%)</td>
<td>4/16(25%)</td>
<td>0/16(0%)</td>
</tr>
<tr>
<td>Home based learning, is it suitable for adults?</td>
<td>17/18(94%)</td>
<td>0(0%)</td>
<td>1/18 (6%)</td>
<td></td>
</tr>
<tr>
<td>Did you achieve your goals?</td>
<td>7/8(87%)</td>
<td>1/8 (13%)</td>
<td>0/8(0%)</td>
<td></td>
</tr>
<tr>
<td>Did you enjoy participating?</td>
<td>12/19(63%)</td>
<td>0/19(0%)</td>
<td>7/19(37%)</td>
<td></td>
</tr>
<tr>
<td>How much did you learn from the programme?</td>
<td>12/19(63%)</td>
<td>6/19(32%)</td>
<td>17/19(89%)</td>
<td></td>
</tr>
</tbody>
</table>

5.4 Process evaluation of the “Eat Well with CF” programme and Audio Version, Group C

The previous study investigating recruitment difficulties for the RCT of the behavioural nutritional education programme for cystic fibrosis subjects demonstrated some subjects were reluctant to take part in the study due to poor reading skills. It is likely that due to chronic illness, many adults with CF have missed a great deal of education and may have difficulties with reading and comprehending written information. Therefore, an audio version of “Eat Well with CF” was produced to enable participation of subjects who may have difficulties
with the written version or who wish to supplement their learning with an audio version. This section discusses the process evaluation of the final group, group C, who received both the written and audio versions of the programme.

5.4.1 Aims

The main aims of the study were:
1. To assess the relative benefits of the use of the audio version of the “Eat Well with CF” programme and to make recommendations as to whether this version should form part of the standard package.

5.4.2 Methods

A process evaluation questionnaire was developed to provide information on the views of the subjects on the programme overall, whether the weekly goals and tasks had been achieved and to assess the effectiveness of the workshops, newsletters and weekly telephone calls from the dietitian. It was also designed to provide feedback on the effectiveness of the audio version and to assess consumer acceptability of the audio version.

12 subjects were recruited from those taking part in the main RCT.
5.4.3 Results

The baseline characteristics of participating subjects are illustrated in table 5-4.

Table 5-4 Baseline characteristics of participating subjects in the study examining the relative benefits of the audio version of eat well with CF showing age, BMI, presence of CF related diabetes, infection and pancreatic status.

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>Male subjects</th>
<th>Female subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=8 (67%)</td>
<td>N=4 (33%)</td>
</tr>
<tr>
<td>Mean Age (years)</td>
<td>23</td>
<td>28</td>
</tr>
<tr>
<td>Range</td>
<td>17-27</td>
<td>18-40</td>
</tr>
<tr>
<td>BMI Kg/m2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;17</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>18-20</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>21-24</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Presence of CF related Diabetes</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Infection states</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not infected</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Pancreatic insufficient</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Pancreatic sufficient</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Group C was comprised of 12 subjects. Unfortunately 2 subjects withdrew from the study prior to commencing the intervention and 1 participant left the country without informing us. Therefore the actual numbers of subjects involved in Group C were 9.
Six out of nine subjects returned the process evaluation questionnaires. Table 5-5 provides a summary of participant ratings.
Table 5-5 Group C (n = 6) participant rating of content, appearance and age appropriateness of “Eat Well with CF”

<table>
<thead>
<tr>
<th>Programme section</th>
<th>Rating</th>
<th>Tape clarity, Easy to understand $N$</th>
<th>Suitable for adults with CF $N$</th>
<th>Useful addition to written version $N$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>Satisfactory</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Good</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Very good</td>
<td>3</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Excellent</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Energy and fat</td>
<td>Satisfactory</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Good</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Very good</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Excellent</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Digestion, Enzymes and malabsorption</td>
<td>Satisfactory</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Good</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Very good</td>
<td>3</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Excellent</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Adult issues</td>
<td>Satisfactory</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Good</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Very good</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Excellent</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Appetite</td>
<td>Satisfactory</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Good</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Very good</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Excellent</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Good</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Very good</td>
<td>4</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>NA</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>How did I do? Review and reflection</td>
<td>Satisfactory</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Good</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Very good</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Excellent</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
Subjects were questioned about their views of the programme overall and most considered it to be very useful. The groups views on the usefulness of the tape were varied some thought the tape was very useful, while others much preferred the written version. Several selected quotes to illustrate these points are given:

**The written programme**

| I have learnt about things that never occurred to me before and have improved my eating habits in ways I didn’t expect |
| A helpful motivation |

**The audio-version of the programme**

| It was definitely useful, more convenient to listen to and the more long-winded sections were easier to digest. |
| A bit boring, droned on a bit – better if you read the book first |
| It was OK, a CD might be better as you could easily skip to each section |

Subjects were questioned about whether the tape was a good alternative to the written programme for people with reading difficulties. Six out of six (100%) said they thought it was, that it had all the information contained in the programme and was clearly presented. Interestingly they all also suggested it was as useful to those without reading difficulties as an alternative or additional medium for obtaining the information. Two out of six (33%) subjects remarked that they could listen to the tape whilst in the car and two out of six (33%) stated they could do other jobs whilst listening.

Two out of six (33%) subjects found it was easy to listen to the tape without reading the pack, two out of six (33%) found it better to do the two together, one out of six (17%) preferred to listen to the tape before reading the programme, and commented that the activities seemed easier when written down.
Most subjects remarked that they did learn from the programme, and two out of six (33%) thought that perhaps the tape had a role to play in the learning, although two out of six (33%) said it definitely did not have a role to play in the learning.

Selected participant quotes to illustrate this point are given:

<table>
<thead>
<tr>
<th>Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>“I didn’t really like the tape, I found it sank in better when reading”</td>
</tr>
<tr>
<td>“Some info I had read in the pack seemed to stick in the mind when I listened to it on the tape”</td>
</tr>
<tr>
<td>“Maybe the tape helped, but it wasn’t essential, could have managed without”</td>
</tr>
</tbody>
</table>

Three out of six (50%) subjects really enjoyed the programme and three out of six (50%) thought the programme was OK.

Workshops and weekly phone calls were once again cited as helpful motivators.

<table>
<thead>
<tr>
<th>Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Workshops - as you get to talk to others about what you have done”</td>
</tr>
<tr>
<td>“The one workshop I did attend was brilliant, the chance to ask questions and discuss issues made it so much more stimulating and relevant.”</td>
</tr>
</tbody>
</table>

5.5 **Discussion**

From the results of the process evaluation, the subjects concluded that “Eat Well with CF” was interesting, well structured, easy to understand and suitable for their peer group. They enjoyed participating and gained valuable knowledge about nutrition and CF. One of the aims of this thesis was to evaluate participant satisfaction by conducting a process evaluation study. This qualitative process evaluation has illustrated that the programme was suitable for the target group and fitted the original design.

5.5.1 **Potential programme improvements**

Following the formal comments collated from the process evaluation questionnaires and informal patient comments at the workshops and during the weekly contact with the dietitian,
some suggestions were provided to improve the content or format of the education programme.

Many subjects commented that they did not need to gain weight and therefore the emphasis on how to improve weight was somewhat out of place. These subjects suggested, less emphasis on how to gain weight but the addition of a general healthy eating section.

It was also suggested by several subjects that the educational content of the programme was very intensive some weeks (e.g. week 7) and much less intensive other weeks (e.g. week 5). The structure of the programme was also commented upon, several subjects pointing out that the first part of the programme was more interesting than the second. It therefore appears evident that the education programme needs an element of restructuring.

Another example of this can be seen in a subjects comment about the diabetes section; “Restructure the diabetes section to be more relevant to those who do not have diabetes, to encourage them to read it”

It was suggested that at the half way workshop there should be a formal review of goals and to motivate people to be more involved in personalising the challenges to personalise the challenges to fit an individual’s lifestyle and situation.

The final group commented on the audio version of the programme and a couple of subjects suggested the use of different voices on the tape and to try to make the tape less monotone and more interesting.

5.5.2 Summary

The main recommendations from this process evaluation were to provide the audio version of the programme as an addition to the written programme, to reduce the length of the intervention to maintain subject’s interest, to try to spread the sections more evenly over each week and to run workshops on a Saturday, to enable easier participation of subjects in employment.
6. Overall Conclusions

This thesis describes the use of psychological models combined with nutritional science. Our data demonstrates that a nutrition education programme enables peer motivation, increased self efficacy and the subject being able to gain more control over their treatment and becoming more confident in providing their prescribed dietary regimen.

We hypothesized that adults with CF completing a home based behavioural nutrition education programme would have an improved nutritional status, an improvement in specific nutrition knowledge and self efficacy regarding their ability to cope with a special diet, compared with those receiving standard care.

The tendency towards an increase in weight, despite a decline in lung function, the significant improvement in self-efficacy and specific nutrition knowledge, and the short term improvement in reported fat intake in those subjects who completed the "Eat Well with CF" programme substantiate these hypotheses and suggest the effectiveness of this novel approach to nutrition education in adults with CF. The strengths of the programme include the theory based flexible nature offering home learning with the option of both audio and written format. In addition, the positive results of the process evaluation highlight the significant personal enjoyment and benefit received by the participants.

The studies in this thesis contribute to the evidence base for both the use of behavioural nutrition education programmes in adults with CF and for dietetic practice. This new model of practice utilises the dietitian as a group facilitator as opposed to the traditional medical model. It has the potential to enhance dietetic practice by providing the education programme to subjects who are in the action stage of change, assisting others to move towards an action orientated stage, enabling them to achieve maximum benefit from their dietitian.

Implementation of nutrition related behavioural programmes at several stages in the lifespan of someone with CF may require health care providers to make adjustments in their approach to practice. Periodic participation in behavioural based education programmes may result in the achievement and life-long maintenance of optimal nutritional status for people with CF, which has to be the focus for all dietetic practitioners.
Appendices

Appendix 1  Peer Review Questionnaire

'Eat Well with CF'

1. What are your views of the package as a whole?

........................................................................................................................................
........................................................................................................................................

2. Do you think that this method of a home based programme is suitable for adults with CF?

........................................................................................................................................
........................................................................................................................................

3. Please rank each section of the pack 1-5 based on the following criteria:

1 = poor
2 = satisfactory
3 = good
4 = very good
5 = excellent
<table>
<thead>
<tr>
<th>CONTENT</th>
<th>APPEARANCE</th>
<th>AGE APPROPRIATENESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTRODUCTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIGESTION &amp; ENZYMES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADULT ISSUES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>APPETITE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIABETES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>APPENDIX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OVERALL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If you rank any section as 'Poor' or 'Satisfactory', please provide some feedback on how this section could be improved.

<table>
<thead>
<tr>
<th>CONTENT</th>
<th>APPEARANCE</th>
<th>AGE APPROPRIATENESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTRODUCTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIGESTION &amp; ENZYMES</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
ADULT ISSUES

APPETITE

DIABETES

APPENDIX

OVERALL

Any other comments:

..........................................................

..........................................................

..........................................................

Are there any major gaps/omissions that should be covered?

..........................................................

..........................................................

..........................................................

Thank you for your time.

Please return the questionnaire (you can keep hold of the pack) by .30th March 2001

Dr Helen Truby, School of Biomedical and Life Sciences, University of Surrey, Guildford

GU2 7HX. This analysis forms part of an undergraduate student project so your assistance in

returning the questionnaire promptly is appreciated.
Appendix 2  Formic questionnaires
EVALUATION OF A HOME BASED NUTRITION EDUCATION PROGRAMME FOR ADULTS WITH CYSTIC FIBROSIS

Patients Initials

Patients Number

Date of Completion

Time Period

Baseline

3 Months

6 Months

12 Months
Stages of Change Questionnaire

In order to help us individualise your treatment, please answer the following questions

1. Please cross [X] one box which best describes how you feel about changing your diet / improving your weight.

  - I haven't given the matter of changing my diet / improving my weight any thought at all.
  - I think about changing my diet / improving my weight from time to time and then put the matter out of my mind.
  - I keep meaning to change my diet / improve my weight but don't get around to it.
  - From time to time I try to improve my weight but at other times I go back to my usual eating habits.
  - I have consciously trying to change my diet / improve my weight, for the last six weeks.
  - I have been consciously trying to change my diet / improve my weight, for longer than the last six weeks

Please cross [X] one box for each of the following two statements:

2. It would be difficult for me to change my diet / improve my weight, in the next month.

  - Strongly agree
  - Agree
  - Uncertain
  - Disagree
  - Strongly disagree

3. I intend to change my diet / improve my weight in the next month.

  - Strongly agree
  - Agree
  - Uncertain
  - Disagree
  - Strongly disagree
Self-Efficacy Questionnaire:

Meal provision for yourself

Below are some questions regarding meal provision and in particular, the extent to which you are confident (or not) in your ability to meet your various dietary needs.

Please respond by marking the scale according to the statement that most reflects your own beliefs.

'0' indicates that you have no confidence in your ability to perform the task, and '3' indicates high confidence in your ability to perform the task.

How confident are you in your ability to provide:

<table>
<thead>
<tr>
<th>(Not at all confident)</th>
<th>(Extremely confident)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meals that meet your specific needs?</td>
<td>0</td>
</tr>
<tr>
<td>A high energy diet?</td>
<td>0</td>
</tr>
<tr>
<td>A high fat diet?</td>
<td>0</td>
</tr>
<tr>
<td>Meals with adequate vitamins?</td>
<td>0</td>
</tr>
<tr>
<td>Diet supplements (such as milkshakes)?</td>
<td>0</td>
</tr>
<tr>
<td>A high-calorie snack once a day?</td>
<td>0</td>
</tr>
</tbody>
</table>

How confident are you in your ability to ensure:

<table>
<thead>
<tr>
<th>(Not at all confident)</th>
<th>(Extremely confident)</th>
</tr>
</thead>
<tbody>
<tr>
<td>You eat a high-energy lunch at school / college / work?</td>
<td>0</td>
</tr>
<tr>
<td>You have a suitable diet when away from home?</td>
<td>0</td>
</tr>
<tr>
<td>You finish a meal you prepare?</td>
<td>0</td>
</tr>
</tbody>
</table>
The Short Fat Questionnaire

Please cross ☐ only one box for each question (Cross the box which applies to your diet)

1. How often do you eat fried food with a batter or breadcrumb coating?
   - Six or more times a week □
   - Three to Five times a week □
   - Once or Twice a week □
   - Less than once a week □
   - Never □

2. How often do you eat gravy, cream sauces or cheese sauces?
   - Six or more times a week □
   - Three to Five times a week □
   - Once or Twice a week □
   - Less than once a week □
   - Never □

3. How often do you add butter, margarine, oil or sour cream to vegetables, cooked rice or spaghetti?
   - Six or more times a week □
   - Three to Five times a week □
   - Once or Twice a week □
   - Less than once a week □
   - Never □

4. How often do you eat vegetables that are fried or roasted with fat or oil?
   - Six or more times a week □
   - Three to Five times a week □
   - Once or Twice a week □
   - Less than once a week □
   - Never □

5. How is your meat usually cooked?
   - Fried □
   - Stewed or goulash □
   - Grilled or roasted with added oil or fat □
   - Grilled or roasted without added oil or fat □
   - Eat meat occasionally or never □

6. How many times a week do you eat sausages, salamis, meat pies, hamburgers or bacon?
   - Six or more times a week □
   - Three to Five times a week □
   - Once or Twice a week □
   - Less than once a week □
   - Never □

7. How do you spread butter / margarine on your bread?
   - Thickly □
   - Medium □
   - Thinly □
   - Don't use butter or margarine □
8. How many times a week do you eat chips or French fries?
   - Six or more times a week □
   - Three to Five times a week □
   - Once or Twice a week □
   - Less than once a week □
   - Never □

9. How often do you eat pastries, cakes, sweet biscuits or croissants?
   - Six or more times a week □
   - Three to Five times a week □
   - Once or Twice a week □
   - Less than once a week □
   - Never □

10. How many times a week do you eat chocolate, chocolate biscuits or sweet snack bars?
    - Six or more times a week □
    - Three to Five times a week □
    - Once or Twice a week □
    - Less than once a week □
    - Never □

11. How many times a week do you eat potato crisps, corn chips or nuts?
    - Six or more times a week □
    - Three to Five times a week □
    - Once or Twice a week □
    - Less than once a week □
    - Never □

12. How often do you eat cream?
    - Six or more times a week □
    - Three to Five times a week □
    - Once or Twice a week □
    - Less than once a week □
    - Never □

13. How often do you eat ice-cream?
    - Six or more times a week □
    - Three to Five times a week □
    - Once or Twice a week □
    - Less than once a week □
    - Never □

14. How many times a week do you eat cheddar, edam or other hard cheese, cream cheese or cheese like camembert?
    - Six or more times a week □
    - Three to Five times a week □
    - Once or Twice a week □
    - Less than once a week □
    - Never □

15. What type of milk do you drink or use in cooking or tea and coffee?
    - Condensed □
    - Full-cream □
    - Full-cream and reduced fat □
    - Reduced fat □
    - Skim or none □
16. How much of the skin on your chicken do you eat?
   Most or all of the skin □  Some of the skin □  None of the skin / I am a vegetarian □

17. How much of the fat on your meat do you eat?
   Most or all of the fat □  Some of the fat □  None of the fat / I am a vegetarian □
Nutritional Knowledge Questionnaire

Test your nutritional knowledge

This questionnaire consists of 20 questions. Each question consists of 5 statements. Please cross the statement you think is correct or most correct.

Question 1
a. There is no malnutrition in the United Kingdom
b. School tuck shops always illustrate sound health practices
c. Diet is one of the factors which leads to coronary heart disease, obesity and dental caries
d. Overweight babies seldom become overweight adults
e. Yoghurt should be substituted for milk in a weight reducing diet

Question 2
a. To reduce weight, it is advisable to eat two meals daily instead of three
b. Overweight young children should not be prescribed weight control diets
c. To reduce weight it is advisable to substitute honey for sugar
d. Raw sugar is a much "better" food than white sugar
e. There is a relationship between sugar intake and the incidence of dental caries

Question 3
a. A lactating woman requires more calories than a pregnant woman of the same age and height and undertaking similar activity
b. Individual adults undertaking similar activities, have identical calorie requirements
c. Calorie requirements increase with age
d. Mental activity increases calorie requirement
e. Calories from alcohol are more fattening than calories from other sources

Question 4
a. All red meats are rich in calcium
b. Calcium is used in the synthesis of haemoglobin
c. Iron requirements are reduced in pregnancy
d. Seafoods contain more iodine than meat or poultry
e. All seafoods are rich in fat
Question 5
a. Calories are provided by the protein, fat and carbohydrates in our diet
b. Carbohydrate in the form of sugar yields significantly more calories than carbohydrate in the form of starch
c. Alcohol calories are not significant in the United Kingdom diet
d. The "drinking man's" diet which promises weight reduction while following a high fat and high alcohol diet is nutritionally sound
e. Lengthy periods of fasting are a sound health practice for weight control

Question 6
a. Butter is a rich source of animal protein
b. Safflower oil and coconut oil are rich in polyunsaturated fatty acids
c. Polyunsaturated margarines are always spreadable immediately after removal from the refrigerator
d. The repeated use of polyunsaturated oils for deep frying does not reduce the level of polyunsaturated fatty acids
e. Increasing the amount of polyunsaturated fatty acids in the diet always results in a lowering of the level of cholesterol in the blood

Question 7
a. Vegetable fibre and meat fibre are similar in composition and structure
b. Raw carrots are a richer source of carotene than cooked carrots
c. Baked potatoes contain less vitamin C than boiled potatoes
d. Boiled vegetables should be cooked by adding them to a small amount of boiling water and cooked in a receptacle with a well fitting lid
e. Cooked legumes contain as much protein as meat

Question 8
a. Freezing compartments in single door domestic refrigerators are suitable for the long term storage of frozen food
b. Freezing destroys all bacteria in food
c. Foods should not be refrozen after thawing
d. Freezing reduces the protein content in meat
e. Canned foods last indefinitely
Question 9
a. An extreme lack of vitamin A in the diet will lead to scurvy
b. Yellow peaches, apricots and carrots contain carotene which is converted to vitamin A in the body
c. Fruits and vegetables are a rich source of vitamin D
d. All vitamins are destroyed when fruits are dried
e. Fleshy foods (meats, fish, poultry) are rich in vitamin C

Question 10
a. All insecticides and pesticides are a health hazard and they should be banned
b. The addition of iodine to salt reduces the risk of tooth decay
c. Organically grown vegetables are richer in vitamins and minerals than conventionally grown vegetables
d. Controlled fluoridation of community water supplies reduces the incidence of dental caries
e. Vegans include milk and cheese in their diet

Question 11
a. Textured vegetable proteins are being developed as meat substitutes but they contain less fat than meat
b. Textured vegetable protein should not be substituted for meat in a child's diet
c. Textured vegetable proteins are being developed as meat substitutes but they contain significantly less protein than meat
d. Textured vegetable protein is an expensive meat substitute
e. A lactovo vegetarian does not eat any animal products

Question 12
a. Protein is essential for body building
b. Protein is a good source of polyunsaturated fatty acids
c. Vegetables do not contain protein
d. The protein in eggs is less nutritious than the protein in cows' milk
e. Protein yields more calories than an equal quantity of fat
Question 13
a. An orange should be included in a child's diet each day
b. Canned "fruit drinks" are suitable substitutes for fresh orange juice
c. Canned orange juice and frozen juice are suitable substitutes for fresh orange juice
d. If a child is allergic to oranges it must be given vitamin C tablets
e. Frozen peas do not contain vitamin C

Question 14
a. A wholegrain fortified cereal with milk forms a good basis for an adult's breakfast
b. All children need a cooked breakfast
c. Grilled meat is more nutritious than meat cooked in a casserole
d. White rice is as nutritious as potatoes
e. The nutritional value of our diet is closely related to the cost

Question 15
a. It is impossible to take "too many" vitamins
b. Cheese at the end of a meal aids digestion
c. Beer is rich in vitamin B
d. Reconstituted powdered milk is a good substitute for fresh milk
e. Meat provides roughage in our diet

Question 16
a. Yoghurt has important health properties and is much more nutritious than milk
b. Whole milk, skim milk, yoghurt and cheese are all rich sources of calcium
c. Children of all ages need less calcium than adults because they have smaller skeletons
d. Eggs provide almost as much calcium as milk
e. Whole milk, skim milk, low fat yoghurt and cheese are rich sources of vitamin A
Question 17
a. Wholemeal bread contains more fibre and vitamin B than white bread
b. White bread is a poor quality food
c. Brown bread is only "coloured" white bread
d. White bread and biscuits lead to dental decay
e. Wholemeal bread is an excellent source of vitamin C

Question 18
a. Bread should be eliminated from reducing diets.
b. The purpose of a reducing diet is to reduce the calorie intake to achieve rapid weight loss
c. The purpose of most reducing diets is to provide nutritious meals and reduce the calorie intake below the calorie output in order to achieve loss from 500g to 1kg weekly.
d. Sugar is essential for energy.
e. Honey may be substituted for sugar in a reducing diet

Question 19
a. Skim milk contains the same amount of vitamin A as whole milk.
b. Table margarine is not a good source of vitamin A.
c. Most of vitamin A is produced by the action of ultra-violet on a chemical substance in our skin.
d. Potatoes are "fattening".
e. Skim milk contains less calories but approximately the same amount of calcium as whole milk.

Question 20
a. Milk is an excellent source of calcium and iron.
b. Human milk contains more vitamin C than cow's milk.
c. Physical activity greatly increases our protein requirements
d. Men need more calories than women because they work harder.
e. The iron in prunes is destroyed when they are stewed.

Question 21
a. The entire responsibility for the nutrition standards of the family should rest with the mother
b. Cider vinegar is beneficial in the treatment of arthritis.
c. Aluminium saucepans are harmful.
d. Grapefruit is slimming.
e. Margarine provides approximately the same calories as butter.
Thank you for being involved in this study.
The questions are not a test.
I want you to try and answer as best you can.

I'm going to ask you some questions about food enzymes. When I use the word enzyme I mean Pancrease or Creon.

1. What do enzymes do? ________________________________________________________

Please answer yes, no or don't know. Remember this is not a test. Please do not guess. If you don't know the answer it's OK to say, don't know.

2. Are enzymes needed when eating a biscuit? □ Yes □ No □ Don't know

3. Are enzymes needed when drinking milk? □ Yes □ No □ Don't know

4. Are enzymes needed when eating a apple? □ Yes □ No □ Don't know

5. Are enzymes needed when eating cake? □ Yes □ No □ Don't know

6. Do enzymes work better if taken after eating? □ Yes □ No □ Don't know

7. When you eat a fatty meal should you take more enzymes? □ Yes □ No □ Don't know

8. Could you get a tummy ache if you forgot to take your enzymes with a meal? □ Yes □ No □ Don't know

9. Does a breakfast of toast and juice need more enzymes than a breakfast of bacon and egg? □ Yes □ No □ Don't know

10. Is it best to take enzymes before and during a meal? □ Yes □ No □ Don't know

From these foods, of each pair which has the most fat?

11. Which has the most fat - a boiled egg □ Yes □ No □ Don't know
   a banana □

12. Which has the most fat - a slice of toast □ Yes □ No □ Don't know
   a slice of cheese □

13. Which has the most fat - a bowl of jelly □ Yes □ No □ Don't know
   a bowl of custard □

14. Which has the most fat - a glass of milk □ Yes □ No □ Don't know
   a glass of juice □

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Scanning by R&D Unit, Papworth Hospital NHS Trust, 01480 830541 ext 4147
Here are some questions about energy you get from the food you eat.

From this list of foods. Of each pair which has the most energy?

15. Which has the most energy - a glass of lemonade □ a glass of milk □ Don't know □
16. Which has the most energy - a cheese sandwich □ a jam sandwich □ Don't know □
17. Which has the most energy - a carton of chips □ a boiled potato □ Don't know □
18. Which has the most energy - a tomato □ a sausage □ Don't know □

Answer yes, no or don't know to the following questions.

19. Does a child with CF need less energy than a child who does not have CF? □ □ □

If a child with CF needed to increase their energy intake which of the following would help?

20. Would drinking milkshakes give you more energy? □ □ □
21. Would adding cream to fruit and vegetables give you more energy? □ □ □
22. Would drinking more water give you more energy? □ □ □
23. Would eating meals and between meal snacks give you more energy? □ □ □
24. Would adding more margarine or butter to hot food give you more energy? □ □ □
25. Would sprinkling cheese on vegetables give you more energy? □ □ □
26. Should people with CF stop eating salty foods? □ □ □
27. Do people with CF sweat more than people who do not have CF? □ □ □
28. Is the sweat of people with CF more salty than the sweat of people who do not have CF? □ □ □

Which of the following food and drinks have lots of salt in them? Does

29. Lemonade? □
30. Cheese? □
31. Packet Soup? □
32. Yoghurt? □
33. Pizza? □
From this list of foods. Of each pair which has the most salt?

34. Which has the most salt - a packet of crisp □ a bag of jelly beans □ Don't know □

35. Which has the most salt - a sausage □ a slice of bread □ Don't know □

36. Which has the most salt - a bowl of custard □ a bowl of soup □ Don't know □

37. Which has the most salt - a slice of tomato □ a slice of cheese □ Don't know □

Words to describe what you pass in the toilet are poo, jobs, stools, bowel movement which of the following has happened to you in the past year.

In the past year

38. Have you had firm or hard poo? □ □

39. Have you had very bad smelling poo? □ □

40. Have you had oily or greasy poo? □ □

41. Has your tummy been bloated or hard poo? □ □

42. Have you done a poo less often than usual? □ □

43. Have you had pale, light brown or yellow poo? □ □

44. Have you had tummy cramps or pains? □ □

45. Have you had loose or runny poo? □ □

46. Have you done poo more often than usual? □ □

47. Has your poo not gone away the first time you pushed the button to flush the toilet? □ □
The next set of questions ask what you would do in certain situations. You can have more than one answer for most questions.

48. What would you do to check your growth and weight?
   a. Be weighed on the scale
   b. Notice how you fit into clothes (are they more tight or loose than usual)
   c. Look at your lung function test
   d. Measure your height
   e. Read your growth chart
   f. Others

   If Other please specify

49. What are the reasons why people with CF may have difficulty putting on weight.
   a. Not eating enough food or high energy food
   b. Not remembering to take enzymes at all necessary times
   c. Due to malabsorption, runny, oily poo
   d. Sleeping longer than people who do have CF
   e. Exercising/playing a lot
   f. Having a lung or chest infection
   g. Coughing a lot
   h. Have higher energy needs than people who do not have CF
   i. Others

   If Other please specify
50. What would you say or do if someone at school/college/work, teased/made fun/ or laughed at you taking enzymes.

a. Do nothing □
b. Get upset □
c. Stop or hide when taking enzymes □
d. Explain why you take them □
e. Tease them back □
f. Tell a teacher □
g. Tell your mum or dad □
h. Other □

If Other please specify ________________________________________________

51. Extra salt is needed by people with CF. When is extra salt needed?

a. When playing sport/exercising/running games that make you sweat □
b. When sick/have a chest infection/been coughing a lot □
c. When watching TV □
d. In hot weather/summer □
e. Other □

If Other please specify ________________________________________________

52. I'm going to tell you about a problem a boy has with CF has. Please tell what you think he should do. Jack had tummy pains the day after he and his family ate a meal of fish and chips. If Jack usually has 4 enzymes with his meal, how many enzymes should Jack have next time he eats a meal of fish and chips.

a. 4 or less □
b. 5 □
c. 5 or 6 □
d. 7 or more □
e. Don't know □
The Cystic Fibrosis Quality of Life Questionnaire

The following questionnaire is designed to find out how CF affects your life. Read each statement, and then indicate which response is closest to how you feel by crossing one of the boxes after each statement. Please try to answer all the questions, as honestly as you can.

SECTION ONE:

How often, over the past two weeks, do you feel that your CF has affected the following aspects of your physical functioning/mobility?

1. Because of my CF, during the last two weeks, I have had difficulty doing heavy physical jobs. For example; digging, moving furniture, washing the car, vacuuming etc.

   All of the time □  most of the time □  a good bit □  sometimes □  occasionally □  never □

2. During the last two weeks, my CF has prevented me from getting out of the house to run errands. For example; paying bills, posting a letter, doing light shopping etc.

   All of the time □  most of the time □  a good bit □  sometimes □  occasionally □  never □

3. Because of my CF, over the last two weeks, it has been difficult for me to do light tasks around the house. For example; preparing a light snack, washing up, doing light shopping etc.

   All of the time □  most of the time □  a good bit □  sometimes □  occasionally □  never □

4. Over the last two weeks, getting around the house has been difficult, because of my CF.

   All of the time □  most of the time □  a good bit □  sometimes □  occasionally □  never □

5. For the last two weeks, CF has made it difficult to move from my bed or my chair.

   All of the time □  most of the time □  a good bit □  sometimes □  occasionally □  never □

6. Despite CF, over the last two weeks, I have got around and done what I like.

   All of the time □  most of the time □  a good bit □  sometimes □  occasionally □  never □

7. During the last two weeks, there are places that I would like to have gone, but didn't because of my CF.

   All of the time □  most of the time □  a good bit □  sometimes □  occasionally □  never □

8. My CF has limited the type of sports and exercise I have been able to do over the last two weeks.

   All of the time □  most of the time □  a good bit □  sometimes □  occasionally □  never □
9. **During the last two weeks**, my CF has made me feel lacking in energy.

   All of the [ ] most of the [ ] a good bit [ ] sometimes [ ] occasionally [ ] never [ ]

10. **Over the last two weeks**, I have found that my physical functioning and mobility have affected my quality of life by making life less enjoyable.

   All of the [ ] most of the [ ] a good bit [ ] sometimes [ ] occasionally [ ] never [ ]

**SECTION TWO:**

Over the *past two weeks*, has CF affected your social life in any of the following ways?

11. When I have been out socialising, **over the last two weeks**, I have behaved more cautiously than I would like to because of my CF.

   All of the [ ] most of the [ ] a good bit [ ] sometimes [ ] occasionally [ ] never [ ]

12. Because of my CF, **during the last two weeks**, I have tended to avoid visiting friends.

   All of the [ ] most of the [ ] a good bit [ ] sometimes [ ] occasionally [ ] never [ ]

13. **For the last two weeks**, I have avoided going out and socialising because of my CF.

   All of the [ ] most of the [ ] a good bit [ ] sometimes [ ] occasionally [ ] never [ ]

14. I find that the way in which CF affects my socialising interferes with my overall enjoyment of life.

   All of the [ ] most of the [ ] a good bit [ ] sometimes [ ] occasionally [ ] never [ ]

**SECTION THREE:**

The following questions ask about your symptom and treatment aspects of your CF. **How have the following factors affected you over the last two weeks?**

15. **Over the last two weeks**, I have found my treatments (ie physio, enzymes etc) very time consuming.

   All of the [ ] most of the [ ] a good bit [ ] sometimes [ ] occasionally [ ] never [ ]

16. **During the last two weeks**, my treatments have interfere with other things that I have wanted to do.

   All of the [ ] most of the [ ] a good bit [ ] sometimes [ ] occasionally [ ] never [ ]
17. Over the last two weeks, I have found that my treatments have interfered with my enjoyment of life.

All of the time | most of the time | a good bit of the time | sometimes | occasionally | never |

18. I have found my breathlessness troublesome, during the last two weeks.

All of the time | most of the time | a good bit of the time | sometimes | occasionally | never |

19. Over the last two weeks, I have found my coughing troublesome.

All of the time | most of the time | a good bit of the time | sometimes | occasionally | never |

20. I have found my coughing embarrassing over the last two weeks.

All of the time | most of the time | a good bit of the time | sometimes | occasionally | never |

21. For me, over the past two weeks, breathlessness / coughing have made life less enjoyable.

All of the time | most of the time | a good bit of the time | sometimes | occasionally | never |

SECTION FOUR:

Over the past two weeks, I have found that my CF has made me feel:

22. Resentful:

All of the time | most of the time | a good bit of the time | sometimes | occasionally | never |

23. Angry:

All of the time | most of the time | a good bit of the time | sometimes | occasionally | never |

24. Embarrassed:

All of the time | most of the time | a good bit of the time | sometimes | occasionally | never |

25. Irritable:

All of the time | most of the time | a good bit of the time | sometimes | occasionally | never |

26. So fed up that nothing can cheer me up:

All of the time | most of the time | a good bit of the time | sometimes | occasionally | never |

27. Anxious:

All of the time | most of the time | a good bit of the time | sometimes | occasionally | never |
28. Fustrated:
All of the [square] most of the [square] a good bit [square] sometimes [square] occasionally [square] never [square]

29. The way that my CF makes me feel **emotionally** interferes with my quality of life:
All of the [square] most of the [square] a good bit [square] sometimes [square] occasionally [square] never [square]

**PLEASE NOTE** the remaining sections have a slightly different response scale, which asks you to indicate to what extent you either agree or disagree with each statement. Again, indicate which response is the closest to how you feel by crossing [X] one of the boxes after each statement. Please try to answer **ALL** questions as honestly as possible.

**SECTION FIVE:**

The next section asks you about any concerns that you may have for the future because of your CF:

30. It concerns me that I may not be able to have any/have more children.


31. I have concerns about being assessed for a heart-lung transplant.


32. The possibility of needed a heart-lung transplant worries me.


33. I worry about CF shortening my life.


34. In general thinking about the future makes me feel concerned/worried.


35. The worries that I have about the future makes life less enjoyable.


**SECTION SIX:**

In **general**, do you agree or disagree that your CF has affected your relationships with other people in any of the following ways

36. Establishing new relationships / friendships is difficult because of my CF.

37. I find that my friends don't always understand the limits that my CF places on me.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Slightly Agree</th>
<th>Slightly Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
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<td>Slightly Agree</td>
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38. My CF makes it difficult for me to establish intimate relationships.

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<td>Strongly Disagree</td>
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39. My CF makes it difficult for me to maintain intimate relationships.

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<th>Strongly Agree</th>
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<td>Slightly Agree</td>
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40. I find that my CF interferes with me having a satisfactory sex life.

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41. I find that CF makes me feel different from other people my own age.

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<tr>
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42. My CF makes me feel isolated from other people.

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<th>Strongly Agree</th>
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43. I am concerned that my CF is stressful for those who are close to me.

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44. I worry that, because of my CF, I will never be able to lead an independent life.

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45. The way in which CF affects my relationships with other people interes with my quality of life by making life less enjoyable.

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<th>Strongly Agree</th>
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<td>Strongly Disagree</td>
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SECTION SEVEN:

CF can affect your height/weight, in general how has this made you feel?

46. I believe that my CF has made me too small.

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<th>Strongly Agree</th>
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47. I feel that because of my CF I am too thin.

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<th>Strongly Agree</th>
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<tbody>
<tr>
<td>Strongly Agree</td>
<td>Agree</td>
<td>Slightly Agree</td>
<td>Slightly Disagree</td>
<td>Disagree</td>
<td>Strongly Disagree</td>
</tr>
</tbody>
</table>
48. The way that my CF has made me look because of my height/weight makes life less enjoyable.

- strongly [ ] agree [ ] slightly [ ] disagree [ ]
- strongly [ ] agree [ ] slightly [ ] disagree [ ]

**SECTION EIGHT:**

The next section asks you about problems you may experience at college, work or school as a result of your CF. If you are no longer working or at college, please answer the questions in relation to your past experiences.

49. CF makes / has made, finding a suitable college course/job difficult.

- strongly [ ] agree [ ] slightly [ ] disagree [ ]
- strongly [ ] agree [ ] slightly [ ] disagree [ ]

50. Holding down a job/college course is/has been difficult because of my CF.

- strongly [ ] agree [ ] slightly [ ] disagree [ ]
- strongly [ ] agree [ ] slightly [ ] disagree [ ]

51. I am now unable to work/go to college because of my CF.

- strongly [ ] agree [ ] slightly [ ] disagree [ ]
- strongly [ ] agree [ ] slightly [ ] disagree [ ]

52. I find that CF interferes with my career/college OR school life to such an extent that it makes life less enjoyable.

- strongly [ ] agree [ ] slightly [ ] disagree [ ]
- strongly [ ] agree [ ] slightly [ ] disagree [ ]

Thank you for completing the questionnaire.
Appendix 3  Measurement of Socio-Economic Status in Cystic Fibrosis

1. What is your occupation or job title?

........................................................................................................................................
........................................................................................................................................

2. What do you actually do?

........................................................................................................................................
........................................................................................................................................

3. If you are not currently employed

........................................................................................................................................
........................................................................................................................................

4. What is/was the title of your most recent occupation?

........................................................................................................................................
........................................................................................................................................

5. What is/was the title of your spouse/partners most recent occupation?

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........................................................................................................................................

6. What is/was the title of your father’s most recent occupation?

........................................................................................................................................
........................................................................................................................................
7. What is/was the title of your mother’s most recent occupation?

8. Why are you currently not working?
   Student/ full time education
   Unemployed
   Housewife/home maker
   Ill health

9. How old were you when you left school?

10. When you left school, how many of the following qualifications did you obtain?
    GCSE’S, CSE’S, O’Level, School Certificate or Scottish Certificate of Education
    GCE A’ Levels, Higher Scottish Certificate of Education, or Higher school certificate
    GNVQ

11. Have you studied for any qualifications since leaving school?

   If yes, what qualifications have you obtained? (Include those you are studying for now)
A first degree

A higher degree

A diploma, HND, OND

Professional qualification e.g. RGN

GNVQ

NVQ

City and Guilds

RSA

Other (specify)
1. What are your views of the programme as a whole?

2. What are your views on the evaluation pack as a whole?

3. Do you think this method of a home based programme is suitable for adults with cystic fibrosis?

4. Please rank each section of the pack 1 - 5 based on the following criteria:-
   1. Poor
   2. Satisfactory
   3. Good
   4. Very good
   5. Excellent
<table>
<thead>
<tr>
<th>Content</th>
<th>Appearance (including layout/format)</th>
<th>Age appropriateness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy &amp; fat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Digestion &amp; enzymes</td>
<td></td>
<td></td>
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<tr>
<td>malabsorption</td>
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<td>Body image</td>
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<tr>
<td>Food labelling</td>
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<tr>
<td>Nutrition &amp; exercise</td>
<td></td>
<td></td>
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<tr>
<td>Fibre</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appetite &amp; diabetes</td>
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</table>

If you rank any section as 'poor' or 'satisfactory' please provide some form of feedback on how you think this section could be improved.

................................................................................................................................................
................................................................................................................................................

5. What were your goals for the programme?
................................................................................................................................................
................................................................................................................................................

6. Have you achieved your goals?
7. if not, do you know why not?

8. To help to find out what you have learnt from the programme, please tick one of the following statements.
   - I have learnt nothing from the programme
   - I have learnt very little from the programme
   - I have learnt several things from the programme
   - I have learnt a lot from the programme

9. Please tick the statement which is most accurate.
   - I learnt more than I thought I would
   - I learnt less than I thought I would
   - I knew all the information anyway

10. What would you say is the most relevant and significant thing you have learned?

11. Please tick the statement which most closely reflects your enjoyment of the programme.
   - I did not enjoy participating in the programme
   - I neither enjoyed or disliked participating in the programme
   - I really enjoyed participating in the programme
12 (a) Please comment on why you liked or disliked participating in the programme

.................................................................................................................................

.................................................................................................................................

(b) ..................................... Which part did you find particularly enjoyable or not enjoyable
.................................................................................................................................

.................................................................................................................................

13. Were you motivated to complete the programme?
.................................................................................................................................

.................................................................................................................................

14. Please rank each of these motivational factors based on the following criteria

1.  = a poor motivator
2.  = a good motivator
3.  = an excellent motivator

<table>
<thead>
<tr>
<th>Attending workshops</th>
<th></th>
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<tr>
<td>Telephone calls from dietitian</td>
<td></td>
</tr>
<tr>
<td>Newsletters</td>
<td></td>
</tr>
</tbody>
</table>

Please give details of any other factors which helped to motivate you to complete the programme
.................................................................................................................................
.................................................................................................................................
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15. Has your enzyme dose changed as a result of the programme, if so how?
16. Do you have any suggestions to improve the programme?

Any other comments

Thank you for your time and thanks for completing the programme
Appendix 5  Workshop format

Workshop 1  Introductory workshop - 10 subjects, lunch and travel expenses provided.

9.00am  ARRIVE
Coffee, croissants, Danish pastries.

9.30 -10.15am  HAND OUT THE PROGRAMME AND CALORIE COUNTER
Explanation of the programme HW (explain about the patient quotes on each page, explain about needing to set aside 30-40 minutes per week to read the sections and complete the challenges, the prompt sections in the top right hand corner, summarising what has gone already)

A WORD FROM THE CONSULTANT DB
1. Setting your Goals - read case study James, Elizabeth
2. What is going to motivate me to complete this programme?
3. Supporter or no supporter, if so what are their goals?
4. Analyse your diet

10.15 am  COFFEE

10.30 am
Group weight (explain weighing as a group 3/3/4 mean values will be used as not even numbers, also link weight to aim weight for individuals, therefore not to penalise those who do not want to or need to gain any weight)
Prizes at the end of the programme, best weight gain in a group and best nutrition quiz score as a group

Team nutrition quiz (split subjects into 3x groups 3/3/4)

11.00 am VISITOR
Dr Liz Chapman, Clinical Psychologist
The importance of nutrition and body image - How to motivate myself

11.30 am THEORY HW
Introduction to CF Nutrition
Extra energy requirements.
Digestion and the role of enzymes what happens to enzymes once I've swallowed them?
Questions?

12.00 pm LUNCH

Finish
1. Margarine contains fewer calories and fat than butter.
   a. True
   b. False

2. Where is most of the fat found in chicken?
   a. Wings
   b. Thighs
   c. Skin
   d. a and b only
   e. None of the above

3. Which food group provides protein, calcium and vitamin D to help build strong bones, teeth and muscles?
   a. Milk, cheese and yoghurt
   b. Meat, chicken, fish, eggs, nuts and pulses
   c. Bread, cereals, rice and pasta
   d. Vegetables
   e. Fruit

4. How many servings of fruits and vegetables should you eat every day?
   a. 1
   b. 2
   c. 3
5. Broccoli has lots of vitamin C, carotenoids and folic acid
   a. True
   b. False

6. What does vitamin A do for you?
   a. Helps red blood cells absorb nutrients
   b. Helps maintain healthy skin and good eyesight
   c. Helps form strong muscles
   d. Helps build strong bones

7. Orange juice has a lot of which vitamin?
   a. A
   b. C
   c. B
   d. E

8. Bread, cereals, potatoes and spaghetti are all food source of what?

9. The absorption of iron from cereals is improved by
   a. Using only wholegrain cereal
   b. Using a reduced fat milk with the cereal
10. Which has the most dietary fibre?
   a. Brown bread
   b. White bread
   c. Wholemeal bread

11. Which of the following types of food offer healthy low fat choices?
   a. Chinese
   b. Italian
   c. Mexican

12. Which food group does beef come under?
   a. Fruit and vegetables
   b. Fats and oils
   c. Meat, poultry, fish, beans, eggs and nuts
   d. Bread, cereal, rice and pasta

13. Which of the following foods contains the most fat?
   a. 8oz fillet steak
   b. 8oz corned beef
   c. 8oz sausage

14. How many calories do you think a Big Mac and fries contains
   a. 650
b. 1,000  
c. 250  
d. 800  

15. Alcohol is a source of calories  
   a. True  
   b. False
Appendix 7  Workshop 2 Interim workshop, week 5 of the programme.

9.30am    ARRIVE
Coffee, croissants, Danish pastries

10.15am   INTRODUCTION
Aims of today's workshop

Review the programme so far
Review your goals so far
What do you think of the programme so far?
Have you learnt from the programme?
Any problems with the programme so far?
Which bits have been most useful, least useful.

10.30am   EXERCISE AND NUTRITION
Introduction to exercise, aerobic (with oxygen) and anaerobic (without oxygen) exercise, Anaerobic, sprinting, jumping, requires the body to produce energy very rapidly without the use of oxygen, the body can only keep up intense aerobic activity for short periods of time.

Aerobic exercise includes walking, jogging, swimming this is of lower intensity and longer duration, energy is produced in the presence of oxygen and the activity can therefore be kept up longer.

Good fluid intake dehydration,
Body composition rather than weight

Think about the calorie cost of exercise

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.00am</td>
<td>A WORD FROM THE PHYSIOTHERAPIST ON THE ENERGY COST</td>
</tr>
<tr>
<td></td>
<td>OF EXERCISE</td>
</tr>
<tr>
<td>11.30am</td>
<td>NUTRITION QUIZ 2 (GROUP QUIZ)</td>
</tr>
<tr>
<td></td>
<td>Questions?</td>
</tr>
<tr>
<td>12.00pm</td>
<td>LUNCH AND FINISH</td>
</tr>
</tbody>
</table>
Appendix 8  Nutrition Quiz 2

1. Put these snacks in order starting with the lowest calories first.
   1. Mars bar
   2. Packet of crisps
   3. Thick and creamy yoghurt

   1. Toasted cheese sandwich
   2. Sausage roll
   3. Doughnut

2. How many calories are in 1g fat?
   - 1g fat
   - 1g carbohydrate
   - 1g protein

3. Which of these drinks has the highest calories?
   1. Apple juice
   2. Red wine
   3. Beer

4. How many grams of fat are there in a MacDonald’s quarter pounder with cheese?
   1. 10g
   2. 30g
   3. 20g

5. To increase calories in mashed potato, what could you add?
6. To increase calories in Ready Brek or porridge, what could you add?

7. Give 3 examples of high calorie breakfasts
   1. ....................................................................................................................................................................................................................................
   2. ....................................................................................................................................................................................................................................
   3. ....................................................................................................................................................................................................................................

8. Give 3 brand names of different enzyme preparations
   1. ....................................................................................................................................................................................................................................
   2. ....................................................................................................................................................................................................................................
   3. ....................................................................................................................................................................................................................................

9. When should you take enzymes?

10. Why might you be prescribed an antacid with the enzymes?

11. Milk is a great source of
   1. Iron
   2. Calcium
   3. Carbohydrate
   4. All of the above
   5. 2 and 3 only
12. Bottled water is
   1. Safer than tap water
   2. Not as safe as home filtered tap water
   3. Probably safer than tap water as long as you buy 'spring water'
   4. None of the above

13. Which of the following beverages have no fat, sugar or oil in them?
   1. Milk
   2. Coffee with cream
   3. Lemonade
   4. Iced tea

14. Eggs are an excellent source of
   1. Good quality protein and vitamin B12
   2. Calcium and vitamin C
   3. Polyunsaturated fatty acids and iodine

15. When looking at a food label, the ingredients are listed in order with the ingredient contributing the highest quantity first.
   1. True
   2. False
Appendix 9  Final workshop, end of week 10 of the programme

9.30am – 12.00pm

This workshop is designed to finish off the programme

REVIEW AND REFLECTION

How did I do? Look at score before and after the programme,

So what did I get out of the programme. Look at this section in the

programme, what did you say.

GENERAL DISCUSSION

How did you feel the programme went?

Did you achieve your goals?

How did your achieve your goals?

Have your eating habits changed?

Did having a supporter help?

FINAL QUIZ

FORMAL PROCESS EVALUATION

i.e. How the subjects felt the intervention went, was it easy to

complete, well structured etc.

10.30am  COFFEE

Group weigh in

Prizes for group winners

236
Nutrition quizzes

11.00am HOW TO KEEP GOING
How to continue with the changes made
How to keep motivated

FINAL QUESTIONNAIRES

11.30am LUNCH & FINISH
Appendix 10  Final Nutrition Quiz

1. Why does someone with cystic fibrosis need more calories than someone who doesn't have cystic fibrosis?

2. How many calories in 1g fat

<table>
<thead>
<tr>
<th>Energy content</th>
<th>1g carbohydrate</th>
<th>1g protein</th>
</tr>
</thead>
</table>

3. Name two different types of fat.

4. How many calories do you need per day?

5. Which has the highest calories?
   a) Chicken Kiev and chips
   b) Lasagne

6. How would you fortify a bowl of soup?

7. When should enzymes be taken.
8. What happens to enzymes once you have swallowed them?

9. Name 4 foods you don't need to take enzymes with.

10. Give 2 symptoms of malabsorption.

11. What is the difference between aerobic and anaerobic exercise?

12. What effect does exercise have on energy balance?

13. What is fibre?

14. Which foods contain fibre?

15. If you increase the fibre in your diet, what else must you consider?
16. If someone with cystic fibrosis has a baby, can they breastfeed the baby?

17. Give 3 ways you can try to improve your appetite.

18. How many units of alcohol are recommended for a man per week?

19. What is diabetes?

20. What are the dietary recommendations for someone with cystic fibrosis and diabetes?
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