Queen Mary
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An investigation of the early effects of fixed orthodontic treatment on dietary intake and body weight in adolescent patients

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AN INVESTIGATION OF THE EARLY EFFECTS OF FIXED ORTHODONTIC TREATMENT ON DIETARY INTAKE AND BODY WEIGHT IN ADOLESCENT PATIENTS

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A thesis submitted for the degree of Doctor of Philosophy

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2011

Declaration

This thesis contains no materials that have been accepted for the award of any other degree or diploma in any university. To the best of the candidate's knowledge and belief, the thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

Signed: .....

Feras Abed Al Jawad

Date: .....

Abstract

Aim: To investigate the effects of fixed orthodontic treatment on dietary intake and body weight.

Methods: A hospital-based prospective cohort design undertaken in two distinctive parts:

An initial qualitative study in which semi-structured one-to-one interviews using a topic guide, with 10 adolescent patients (4 male; 6 female) with a mean age of 13.21 (SD 0.71) years, were used to identify changes in dietary behaviour and intake in response to fixed appliance treatment. The topic guide was tested, in 4 pilot interviews (1 male; 3 female) with a mean age of 12.5 (SD 0.98), before using it in the final test sample. A framework analysis method was used for data analysis. A supplementary questionnaire was developed to assess dietary behaviour based on the main themes and subthemes identified.

The second part was a quantitative study in which a total of 124 adolescent patients (41.9% male; 58.1% female) aged 11-14 (mean 13.1, SD 0.91) years were consecutively recruited and allocated to test and control groups. Both groups completed a socio-demographic questionnaire, food frequency questionnaire (FFQ) and child perception questionnaire (CPQ11-14) at baseline, 4-6 weeks and 3 month follow-up periods. On each occasion body mass index (BMI) and body fat percentage were measured. Patients completed a pain diary during the study period. In addition, the test group completed the supplementary questionnaire at both the 4-6 week and 3 month follow-up periods.

Results: Qualitative study: All patients reported varying degrees of pain levels which declined within the first 2 weeks. All patients reported that their diet changed in response to pain, inability to bite and chew and in response to the dietary instructions given to them by their orthodontist. Patients felt that their eating habits had become healthier during treatment.

Quantitative study: The response rate was 96.8% and the drop out was 12.1%. Both groups were comparable in relation to socio-demographic characteristics and baseline measurements. Patients adapted to pain by days 3 and 2 during the first and second follow-up periods, respectively ($P<0.001$), with pain intensity during the first period being the greatest. There was no significant difference between both

groups with respect to changes in energy, macro-nutrient intakes and BMI. Changes in fat percentage were significant between both groups (P<0.001). However, after adjusting for BMI status at baseline, changes in fat percentage between both groups were not significant. The impact on dietary behaviour was significantly higher at 4-6 weeks compared to 3 months (P<0.002). Only the oral symptoms domain of the CPQ11-14 worsened significantly during the first period of follow-up (P<0.001). BMI status at baseline appeared to be the only marginally significant moderator of change in fat percentage and impacts on dietary behaviour (P<0.05 and P<0.049, respectively) at follow-up.

Conclusion: There were no significant statistical or clinical changes in dietary intake and behaviour, BMI and fat percentage during the first 3 months of fixed orthodontic treatment.

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List of abbreviations

ANCOVA: Analysis of Covariance

BIA: Bioelectrical Impedance Analysis

BMI: Body Mass Index

BMR: Basal Metabolic Rate

CI: Confidence Interval

CPQ 11-14: Child Perception Questionnaire 11-14

CPQ ISF-16: the 16 Item Short Form of the Child Perception Questionnaire

DXA: Dual X-ray Absorbtiometry

EWB: Emotional Well-Being

FFQ: Food Frequency Questionnaire

FFM: Fat Free Mass

FL: Functional Limitation

FM: Fat Mass

HRQL: Health Related Quality of Life

IASP: International Association for the Study of Pain

ICC: Intra-class Correlation Coefficient

MPQ: McGill Pain Questionnaire

N: Number

NHS: National Health Service

NRS: Numerical Rating Scale

OASIS: Oral Aesthetic Subjective Impact Scores

OHIP-14: Oral Health Impacts Profile 14

OH-QoL: Oral Health-related Quality of Life

OIDP: Oral Impacts on Daily Performances

OS: Oral Symptoms

PHV: Peak Height Velocity

QoL: Quality of Life

RCT: Randomized Clinical Trial

SD: Standard Deviation

SPR: Specialist Orthodontist Registrar

SPSS: Statistical Package for the Social Sciences

SWB: Social Well-Being

TBF: Total Body Fat

TBW: Total Body Water

TO: Take Off

VAS: Visual Analogue Scale

VRS: Verbal Rating Scale

WHO: World Health Organisation

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Chapter 1

Introduction

In 1997, the Department of Health introduced the concept of Clinical Governance which aimed to improve the quality of care for patients in all health care settings, in particular, strengthening the partnership between patients and professionals and understanding issues related to quality of care from the patient's perspectives (Department of Health, 1997).

Since that time, an extensive body of literature has emerged advocating the use of patient-centred care in medical and dental healthcare settings rather than focusing on the more traditionally applied biomedical model (Mead and Bower, 2000). The advent of patient-centred care meant taking into account patients' perspectives and the way they perceive their impairments and the associated physical, psychological and social experiences and meanings attached to any disease or condition. Therefore, assessing patients' expectations and experiences are central to understanding health needs, patient satisfaction with treatment and the perceived overall quality of health systems (McGrath and Bedi, 1999; Locker, 2004; Newsome and McGrath, 2006).

In addition to having effective treatment methods for successful orthodontic treatment, it is also necessary to investigate how well patients accept the treatment and whether they experience any side effects. As with any treatment, fixed orthodontic treatment is not without side effects. Among the frequent complaints that patients raise during orthodontic treatment is the amount of discomfort that occurs which may include pain and pressure from teeth (Scheurer *et al.*, 1996; Sergl *et al*. 1998; Firestone *et al.*, 1999; Bergius *et al*., 2002; Bartlett *et al*, 2005), oral ulcerations and tongue soreness (Sinclair *et al*., 1986; Kvam *et al*., 1987, 1989), functional limitations, oral constraints, impaired swallowing (Goldreich *et al*., 1994; Doll *et al*., 2000; Sergl *et al*., 2000; Zhang *et al*., 2007) and negative impact on daily living and quality of life (Stewart *et al*., 1997; Mandall *et al*., 2006; Zhang *et al*., 2007; Miller *et al*., 2007; Chen *et al*., 2010).

However, it is also important to investigate and explore potential negative consequences of such side effects as part of researchers' commitment to produce evidence of the quality of care orthodontists deliver. Understanding patient experiences during treatment may facilitate adherence to treatment, improves patient attitudes towards that treatment and allow patients to cope and adapt to potential side effects (Robinson *et al*., 2008).

The relationship between oral health status and diet is well documented since good oral health is important for chewing and eating without causing dietary restrictions. For instance, Acs *et al* (1992) found that growth and body weight in children, with high nursing caries, were negatively affected compared to those with less nursing caries. Edentulous elderly patients with deficient masticatory performance may develop gastrointestinal disorders, due to reduced consumption of high-fiber foods (Brodeur *et al*., 1993).

In orthodontics, a very limited number of studies have assessed the impact of fixed orthodontic treatment on dietary intake and behaviour. Unfortunately, the nature of evidence seems to be inadequate and deficient as these studies are limited by their ill-defined methodological designs, inadequate sample sizes and the lack of comprehensive evaluation on how fixed orthodontic treatment may affect dietary intake and behaviour, body weight and body fat percentage (Cheraskin and Ringdorf, 1969a, b; Riordan, 1997).

As a result, an investigation of the effects of fixed orthodontic treatment on dietary intake, body weight and fat composition would be a welcomed addition to our further understanding of the effects of undergoing orthodontic treatment. It will also help shape the process of informed consent and provide patients with realistic expectations on what they may experience during the course of treatment. If changes occur it will be a significant consideration for patients undergoing orthodontic treatment and may necessitate special nutritional advice being required.

Therefore, the current research project aimed to investigate the early effects of fixed orthodontic treatment on dietary intake, body weight and fat percentage in a group of adolescent patients.

Chapter 2

Literature review

This review of the literature will address the following issues:

- The importance of physiological growth changes during adolescence.
- Factors affecting dietary intake and assessment methods will be discussed, with a specific focus on adolescents.
- The use of qualitative methods in research and their importance will be considered.
- Patient experiences during fixed orthodontic treatment will be reviewed, in particular, in relation to pain and their impact on quality of life.
- The literature in relation to oral health status and its relationship to dietary intake will be presented, leading to the question 'Does fixed orthodontic treatment affect dietary intake and body fat composition?'

2.1 Growth Dynamics during Adolescence

The human life span is comprised of several phases, in which each phase has its own unique physiology. These phases include pre-natal, neonatal, infancy, childhood, juvenile, puberty, adolescence, prime and senescence (Cameron, 2002).

The adolescence phase is a time when tremendous changes in height, weight, tissues and body composition take place. In addition, development of primary and secondary sexual characteristics is also observed. It is characterized by the adolescent growth spurt which occurs at 11-18 years of age (Thompson, 1942; Hauspie and Wachholder, 1986). While other growth spurts that take place during prenatal, post-natal and juvenile stages of human development seem to occur at roughly the same age, both within and between the genders, the adolescent growth spurt varies in magnitude and timing within and between genders (Cameron, 2002). The latter makes it difficult to estimate the exact age at which the adolescent growth spurt takes place between different individuals. However, there is a characterized sequence of growth events that each individual undergoes from the onset of the growth spurt to complete maturity, which is different between genders. Therefore, in studies assessing changes in anthropometric measurements in adolescent subjects, as a result of any clinical intervention, these events need to be taken into consideration.

2.1.1 Change in height

The adolescent growth spurt 'normally' starts at about 9-11 years in girls and 10-11 years in boys (Tanner *et al*., 1975; Sinclair and Dangerfield, 1998, Malina *et al*., 2004), during which an increase in height velocity, referred to as Take Off (TO) marks the onset of the growth spurt (Hauspie *et al*., 2004; Malina *et al*., 2004). The age at peak height velocity (PHV), during which the maximum rate of growth in stature during the adolescent spurt occurs, is usually reached within 2-3.5 years after the onset of puberty (Sinclair and Dangerfield, 1998; Hauspie *et al*., 2004). The estimated ages at TO and PHV vary between individuals and populations with an estimated standard deviation of about 1 year. It also varies between genders, boys being on average 2 years later than girls in the start of their adolescent spurt

(Marshall and Tanner, 1968; Hauspie *et al*, 2004; Malina *et al*., 2004). The mean PHV (cm/year) ranges between 7.1-9.1 cm/year in girls and 8.2-10.3 cm/year in boys and it varies between European and North American populations (Malina *et al*., 2004).

After reaching PHV, the growth velocity decreases rapidly shifting towards the end of the growth spurt in which girls and boys reach most of their final height around 16-17 and 18-19 years of age, respectively (Hauspie *et al*., 2004). In females, the most dramatic changes that occur after PHV stage is the onset of menarche which usually starts at least one year following the attainment of PHV (Tanner and Davis, 1985; Malina *et al*., 2004). The growth potential after the onset of menarche is limited and declines in the following years compared to the age of PHV, ranging from 5.1-7.6 cm until attaining complete maturity (Strasburger and Brown, 1991). The average age of menarche onset in studies conducted in western countries has ranged between 12.1-13.5 years (Malina *et al*., 2004).

2.1.2 Change in weight

In addition to growth in height, adolescents experience growth in weight and changes in body composition. Fifty percent of adult body weight is gained during the adolescent period. In girls, it is estimated that peak weight gain lags behind PHV by approximately six months, while in boys the difference is less (Lindgren, 1978). The amount of weight gain can reach up to 7.3 kg/year in girls, and 9 kg/year in boys (Lindgren, 1976). The rate of weight gain decelerates in the same manner as height velocity at later stages in puberty. It slows around menarche, but will continue into late adolescence. Females may gain 6.3 Kg during the latter half of adolescence (Barnes, 1975).

2.1.3 Changes in body fat composition

The general pattern of change in total body fat (TBF) increases throughout the adolescent stage, but velocity declines when reaching the final stages of maturity. Girls have larger values of TBF than males. The velocity in body fat gain percentage may decrease to a minimum at about 15 years in girls. In contrast to TBF, the patterns in fat free mass (FFM) are reversed. Boys have larger FFM values than

girls. In females, FFM declines continuously until reaching the final stages of puberty, while it continues post-pubertal in males (Guo *et al*., 1997).

2.1.4 Controlling for physiological changes in weight and height in adolescents

Based on the above dynamic changes of growth and maturation that occur during the adolescence stage, anthropometric measurements, such as body mass index (BMI), should be used with caution, as differences in age or sexual development during this stage are a major factor that might influence BMI. For example; subjects of the same age but at different stages of pubertal maturation will have different BMI values (O'Dea and Abraham, 1995; Bini *et al*., 2000).

Gender should also be taken into account, since differences in growth and body composition exist between males and females during pubertal development. Girls start their growth spurt two years earlier than boys and attain final maturity at 16-17 years compared to 18-19 years in boys (Malina *et al*., 2004).

Such physiological events and changes have led investigators to use specific methods to control for these changes when measuring weight in adolescents and highlight the importance of comparing an individual child with others of the same age. This is highly important in studies assessing nutritional status in children over time (Ebbeling *et al*., 2006).

Among the popular methods of measuring body fatness is the Body Mass Index (BMI) which is a useful proxy measure. BMI can be converted to centiles or z scores (standard deviations) adjusted for age and sex using growth reference data specific to the population of interest (Kuczmarski *et al*, 2000). BMI can also be used directly after adjusting for age and gender. Although BMI z scores have been widely used in cross sectional studies when comparing between populations and individuals, it is not the method of choice in studies assessing changes in adiposity in growing children over time. A recent report has found that the use of BMI directly adjusted for age and gender is superior to z scores or centiles in studies that involve following adolescent subjects for a short period of time, as the former is associated with less

variability (Cole *et al*., 2005). This finding was further supported by Berkey and Colditz (2006). Cole *et al* (2005) recommended the use of BMI directly, adjusted for age and gender by subtracting from each child's observed BMI the change in sex – age specific median BMI for the same period.

2.2 Dietary assessment

Medical research and a number of epidemiological studies have increasingly focused on the effects of diet on health and disease. Numerous studies have demonstrated that strong links exist between dietary intake and major diseases, such as coronary heart disease, cancer, diabetes and obesity (Todd *et al.*, 1999; Harding *et al.*, 2004; Key *et al.*, 2004). Furthermore, under-nutrition continues to be a significant health problem in many countries.

The purpose of dietary assessment is to estimate food consumption or nutrient intake in individuals or groups of people. Assessments may range from precise estimation of nutrient intake to broad estimates of the amounts of food available and the pattern and frequency of consumption. Therefore, before undertaking dietary assessment, it is highly important to know the purpose of dietary assessment, in whom and for how long it can be measured, and what is to be measured.

2.2.1 Factors affecting food choice, preference and behaviors

Dietary intake fulfills human biological needs for the maintenance of energy. However, the selection and manner of eating food is not determined entirely by physiology or nutritional needs. It is also dependent on agricultural, political, educational, cultural and social organizations in which the person lives. Food choice depends on many inter-relating factors which may influence behaviour, resulting in accepting or rejecting food products. This makes dietary assessment a challenging and complex process. Many models have described factors affecting food choice (Khan, 1981; Randall and Sanjur, 1981; Booth and Shepherd, 1988). The model summarized by Khan (1981) was used as a basis for classifying these factors:

1. Psychological and personal factors: psychological factors influence dietary choice via their influence on attitudes, beliefs, and meanings attached to foods, which may mediate the relationship between the determinants of food choice and other external influences (Conner, 1993; Steptoe *et al*., 2003). Personality factors such as moods and emotions can interact to influence food choice through physiological effects that change appetite or by changing other behaviour that constrains or alters food

availability (Gibson, 2006). Other personality traits such as, the extent to which individuals are reluctant to try novel foods (food products, dishes, cuisines) and the level of food importance in a persons' life and to what extent people enjoy food are important variables that affect food choice and dietary quantity (Pliner *et al*., 1998; Bell and Marshall, 2003).

2. Socio-economic factors: social class and material resources can affect food choice at both societal and individual level. The higher the social class and income, the healthier the diet (Friel *et al.*, 2003; Giskes *et al.*, 2004). Living in low-income households and conditions of relative poverty can influence life circumstances and individual health behaviors (such as dietary intake). In a school based survey, the Research with East London Adolescents: Community Health Survey), Stansfeld *et al.* (2003), reported that one third of the sample lived in households with neither parent employed and nearly half of the sample were eligible for free school meals. It was found that more than twice the proportions of pupils from year 7 never or hardly ever ate breakfast compared with another sample of year 7 pupils, from a longitudinal study in South London evaluating independent and fee-paying schools, the Health and Behaviors in Teenagers study, (Wardle *et al*., 1998). Steptoe *et al*. (2003), has found that the average number of portions of fruit and vegetables consumed per day in people living in a low income urban neighborhood in South London was 3.64, which is below the recommended target of five portions a day. Only 24 per cent of participants were eating five or more servings per day.

Cost of food is a major factor that influences dietary intake and food choice in lower socioeconomic groups. Cade *et al*. (1999) found a healthy diet, following dietary guidelines, was more expensive in monetary terms in a group of UK women.

3. Biological and physiological factors: gender differences and their relationship with healthy food choice is another factor that influences food preferences. The diet of women is usually of higher quality than men and they usually follow the recommended nutritional guidelines (Millen *et al*., 1997). Wardle *et al*., (2004) tested gender differences in dietary intake, in a large sample of young adults from 23

countries, and found that women were more likely than men to report avoiding high fat foods, eating fruit and fiber and limiting salt.

Age is also a strong determinant of food choice. Childhood and adolescence are considered to be important periods in life span for the development of dietary behaviors (Birch, 1999). Children's dietary habits and preferences develop as they grow and their preferences predict their food consumption. At the adolescent stage, the physiological demands of growth necessitate dietary requirements that are adequately adjusted to meet physiological growth needs.

Medical problems, medication, and medical interventions in health care systems, may have a major impact on dietary habits. Loss of appetite and pleasure of eating, eating and swallowing difficulties due to medical conditions or dental health status and mental health can influence dietary intake choices (Ayhan *et al*., 1996; Marcenes *et al*., 2003).

4. Educational factors: People who are better educated move into higher status and more highly paid professions which affect their food choice and patterns. Le Clerc and Thornbury (1983) found that the higher the general educational attainment of a subject, the greater their nutritional knowledge. Wardle *et al*. (2000) showed that nutritional knowledge was a partial mediator of the socio-demographic variation in food intake, especially for fruit and vegetables. The authors recommended inclusion of nutritional knowledge as part of health education, in promoting healthy eating patterns (Wardle *et al*., 2000). Parents' level of education also has a positive effect on the child's nutritional and eating behaviors adopted in later life (Moestue and Huttly, 2008).

5. Cultural, religious and regional factors: culture and religion have an enormous influence on food consumption. Some of the largest variations in food choice are due to boundaries imposed by cultures and traditions (which food is considered acceptable, when they may be eaten, who should prepare and cook, cooking methods, slaughter and food etiquette). Racial and geographic influences (i.e.

differences in nutrient intakes, variation in nutrient intake, beliefs about food, and meal patterns) are significant factors affecting dietary habits between different cultures and races (Herne, 1995). Even within the same culture there are still many differences in food choice, likes, and dislikes. Whichelow *et al*. (1991) demonstrated these phenomena by comparing frequency of consumption in 11 regions of Great Britain. For example, consumption of high-fat foods was more common in Scotland, Wales and Northern England.

6. Extrinsic factors: The quality expected of food is a function of where it is eaten and the circumstances under which it is to be consumed. Many factors such as atmosphere, the table, mood and presence of people are important aspects of the pleasure gained from eating occasions (Westenhoefer and Pudel, 1993).

Changes in season, temperature and weekday are important factors that can cause variations in food habits. Some food types are purchased and consumed more in specific periods of the year than other times (e.g. fruit, salad, cheese and yoghurt consumption increase in the summer time; Zifferblatt *et al*., 1980).

The advertising industry plays a major role in affecting people's choices and preferences. It informs consumers of what is deemed appropriate and inappropriate to eat by simple conditioning through repetition of the same advertisement or through sophisticated learning processes. It also gives visual, oral and written details of when and with whom various foods should be eaten (Warshaw and Davis, 1985). In the UK, television, radio, magazines, and newspapers are widely used to promote healthy eating patterns.

In summary, the greatest influences on choice and dietary quality appear to be a combination of the following biological factors: physical and mental health, social class, income and environmental factors, and as such should be considered when assessing dietary intake in any subject. These factors shape human food choice, intake, and eating behaviors by influencing the range and quantities of foods available to human populations. As a result, assessing dietary intake seems to be a

challenging task given the aforementioned factors and taking these factors into consideration is highly important in exploring subjects' eating habits and behaviours. Unfortunately, methods of dietary assessments cannot address all these factors comprehensively and misreporting appears to be the most daunting problem (Beaton *et al*., 1997; Kipnis *et al*., 2002).

2.2.2 Methods of Dietary assessment

2.2.2.1 The 24-Hour recall

The 24-Hour recall is one of the most commonly used methods for obtaining quantitative dietary data (Bingham *et al*., 1994; Subar *et al*., 2001; Hjårtaker *et al*., 2002). It is conducted by means of an interview in which the respondent is asked to provide a recall of all food and beverages consumed over the past 24 hours. The method depends on well-trained interviewers specialized in health, nutrition or home economics, who are skilful in identifying foods, to be able to get detailed and complete answers to ensure accuracy of the data (Subar *et al*., 2001). The interviewer should be familiar with the nutritional habits of different ethnic groups. The interview might be carried out face to face, over the telephone (Holmes *et al*., 2008), or by a computerized 24-Hour diet recall program (Slimani and Valsta, 2002).
The 24-Hour recall method provides detail about the types and amounts of food consumed by focusing on a single day. However, because of intra-individual variability in food consumption, a single 24-Hour recall does not represent the usual individual daily intake due to day-to-day variation. In addition, some reports have suggested that 24-Hour recalls are biased and that persons may systematically differ in reporting accuracy, when using biomarkers as a reference (Kipnis *et al*., 2003; Subar *et al*., 2003). The trend in these studies was towards under-reporting. Attempts to compensate for this limitation have included applying an averaging multiple 24-Hour recalls over a period of few days (Montgomery *et al*., 2005) or using the Multiple Pass 24-Hour recall. The latter method is based on a quick list of foods and drinks consumed; detailed description and a review with the interviewer probing for information on time/occasion, forgotten food and food details (Subar *et al*., 2003; Montgomery *et al*., 2005). The interviews can be a combination of face to face and telephone (Reilly *et al*., 2001). However, the Multiple Pass 24-Hour recall has not

shown significant reduction in the level of respondent bias reported in the single 24-Hour recall method (Subar *et al*., 2003; Montgomery *et al*., 2005).

The main advantages of the 24-Hour recall method are: it can capture and provide detailed information on food intake due to the personal contact between the respondent and the interviewer; there are no literacy requirements; it is suitable for use face to face, or by telephone and computer assisted interviews and has a relatively low respondent burden. The principle disadvantage is that the method does not provide information on habitual intake, unless the multiple pass 24-Hour method is used, which itself sometimes provides low quality and inconsistently reported information due to the increased respondents' burden with multiple administrations (Subar *et al*., 2003). Other limitations include that respondents' recall depends on memory; portion size is difficult to estimate and the method requires highly skilled interviewers.

2.2.2.2 Dietary records

Dietary records can be of several types:

2.2.2.2.1 Menu record

This is the simplest form of dietary record. The method records only the types of food consumed and the frequency with which they are consumed, without quantities. It requires little input from the respondent and it is possible for such a record to be kept for longer periods of time. The main advantage of this method is that it is useful for determining food intake patterns and behaviors over time to assess compliance to dietary guidelines (Pfau, 1999). The principle disadvantage is that it can not be used to estimate quantities of nutrient intake.

2.2.2.2.2 Estimated records

Estimated records require the respondent to record all food consumed over a specific period of time, generally between 1 and 7 days (Noble and Emmett, 1993; Brunner *et al*., 2001; Welch *et al*., 2001). The food and beverages consumed must be described in sufficient detail to allow the investigator to select an appropriate food from tables of food composition or for laboratory analysis. The record must also

provide information on the amounts of foods that have been consumed by using household measures (i.e. jugs, cups, spoons). Alternative approaches for the estimation of quantities include the use of photographs of foods with portion choices for a common food item or the use of food models (Brunner *et al*., 2001; McKeown *et al*., 2001). The investigator converts these estimates into weights that can be used to calculate food and nutrient intake.

The advantages of estimated records are that they appear to be accurate with respect to foods consumed, they do not rely on respondent memory and involve less disruption to normal eating patterns when compared to weighed records (Bonifacj *et al*., 1997; Chinnock, 2006). The disadvantages are that the method requires high cooperation on the part of the respondent, who should be motivated and literate. The time needed to code food type for nutrient analysis is also a burden and respondents get fatigued when estimating food for several days which will increase the rate of drop out in the study (Bingham *et al*., 1994). Furthermore, the cost of conducting this method is expensive (e.g. using food models and photographs; Bingham *et al*., 2003).

2.2.2.2.3 Weighed records

In this method the individual weighs each and every item of food and drink prior to consumption using special scales. A detailed description of the food and its weight is recorded in a specially designed booklet. Weighed records can be kept for 3 to 7 days (Bingham *et al*., 1997; Green *et al*., 1998; Holmes *et al*., 2008). Importantly, reporting must be done at the time of consumption. The person being investigated is trained by a skilled nutritionist in terms of describing their diet regarding the specification of foods, amounts and cooking methods (Bingham *et al*., 1997).

The weighed records method is often used as a reference or Gold Standard, against which other methods are compared to assess their validity (Leitz *et al.*, 2002; Pufulete *et al*., 2002).

The main advantage of weighed food records is that they have the potential to provide the most accurate description of the types and amounts of foods actually

consumed over a specified period of time, due to precise portion size recording. However, weighing all foods consumed each day is time consuming can cause respondent burden and requires high levels of cooperation and training (weighing each individual food item and then recording a description of each food onto a cassette tape; Black *et al*., 2000). The burden of keeping a diet record may influence the respondent to change their usual eating patterns in order to simplify record keeping and in most studies respondents tend to drop out, which will affect the required sample size in the population of interest (Bingham *et al*., 1994; Brown *et al*., 1996). Another important limitation of this method is that respondents tend to show lower food intake than the usual daily pattern, which in turn will bias the results. This systematic bias has been reported in many studies involving biomarkers (Martin *et al*., 1996; Black *et al*., 1997). In the National Diet and Nutrition Survey of British adults, 7-day weighed records were used. Levels of under-reporting were 46% for women and 29% for men (Pryer *et al*., 1997).

This method is expensive to conduct and requires highly skilled personnel to monitor all steps of the process, including respondent training and guiding (Bingham *et al*., 1997). Kristal *et al*. (2005) estimated that the cost of dietary assessment in this form, conducted during the Women's Health Initiative for a population of 160,000 women, using 3-day records was $23.2 million, while for another method such as the food frequency questionnaire (FFQ) the cost was only $1.2 million.

2.2.2.3 Diet history

The dietary history method is any assessment in which the respondent reports their past diet. This method collects information about the frequency of intake of various foods and the make up of all meals consumed in the past month, several months or a year.

The diet history includes several steps: the first step includes a detailed interview about usual pattern of eating, most frequently from a 24-Hour recall. The second step is the administration of a food list asking for the amount and frequency usually eaten, and the final step is a 3-day dietary record. During the interview the investigator attempts to construct the respondent’s pattern of intake over a period of

time, usually from a recall of intake of the previous day as a starting point for elaborating the usual variations in meal pattern and food intake (Jackson *et al*., 1990). Information on the usual size of food portions is obtained with the aid of food models or photographs (Hankin *et al*., 1983). The 3-day record is now seldom used as a regular step (Jackson *et al*., 1990).

The major strength of the diet history method is that it assesses usual meal patterns and details of food intake rather than intakes for a short period of time (as in records and 24-Hour recalls). However, the principle disadvantage of this method is that it is susceptible to recall bias and underestimation of both energy and nutrient intakes (Rothenberg *et al*., 1998; Martin *et al*., 2002). Other limitations of this method include the time and skills required by both interviewers and respondents (Tapsell *et al*., 1999; Martin *et al*., 2002). The respondents are asked to make judgments both about the usual foods and the amount of foods eaten. The interview usually takes at least 1 hour and the subject is asked to recall all their diet consumed over a long period of time (Black *et al*., 2000). These subjective tasks are difficult for respondents and require high levels of compliance. The interviewers should be well trained dieticians.

2.2.2.4 Food frequency questionnaires (FFQ)

A food frequency questionnaire (FFQ) is a list of foods with a selection of options for reporting how often each food is consumed in categorized frequencies, for certain periods mostly last month(s) or year, to obtain information about the usual food consumption patterns.

2.2.2.4.1 Utilization of FFQ

FFQs have been used in a large number of epidemiological studies to assess dietary intake in a wide range of situations. They have been used in: cross- sectional studies to provide group comparisons; ranking of individuals; assessment of usual dietary intake and patterns (Bolton-Smith *et al*., 1991; Osler *et al*., 1997); in case-control studies to provide support for a causal link between diet and disease (Potischman *et al*., 1998; Tzonou *et al*., 1998); in cohort studies where sample sizes are larger and differences in dietary habits and patterns between subjects is associated with disease occurrence (Bostick *et al*., 1993; Jacques *et al*., 1997); in

intervention studies where they may be used to track changes in diet as a response to some form of intervention (Kristal *et al*., 1994) and in dietary screening in clinical settings to discriminate between high and low consumers of certain foods or nutrients (Martin *et al*., 1997).

When compared to other self-reporting methods they are easy to administer, inexpensive, can evaluate dietary intake over longer periods and are the method of choice for large-scale epidemiological studies (at least more than 100 subjects; Cade *et al*., 2002).

In most validation studies, either weighed records or 24h-Hour recalls have been used to test validity of the FFQs (Martin *et al*., 1997; Mouratidou *et al*., 2006). FFQs were found to have acceptable validity and good correlations with these methods. Correlations most investigators consider to be good enough ranged from 0.4 to 0.7 (Willett *et al*., 1985; Bonifacj *et al*., 1997; Martin *et al*., 1997; Subar *et al*., 2001; Mouratidou *et al*., 2006; Molag *et al*., 2007). However, due to the great deal of evidence based on the use of biomarkers that suggested that these reference methods have significant bias, generally in the direction of under-reporting (Black *et al*., 1991; Preyer *et al*., 1997), the use of these reference methods has raised concerns about their ability to calibrate FFQs and whether they underestimate the performance of FFQs (Robinson *et al*., 1999).

Errors in FFQs and other self-reporting methods may include both random and systematic components (Willett, 1998). Random and systematic errors may occur at two levels: within a person and between persons. Random within-person error is due to day-to-day variation in food intake. Random between-person error may be caused by using only a few measurements per subject in the presence of random within-person error. Systematic within-person error is due to under-reporting or over-reporting of intake. Systematic between-person error results from systematic within-person error that affects subjects non-randomly.

In deciding among options for dietary assessment, Willett and Hu (2007) stated that the ability to assess intakes of foods as well as nutrients is highly desirable for a full understanding of disease relationships. In this respect, diet records perform relatively less well than FFQs for foods, because of greater day to day variability (Hunter *et al*., 1988). Furthermore, the ability to collect repeated measurements over time is important because the food supply and diets of individuals are constantly evolving; in this case, the FFQ has a major advantage because of the low burden on participants and cost. FFQs are highly informative in epidemiological applications and have a proven record of construct and predictive validity (Kabagambe *et al*., 2001; Shai *et al*., 2005).

2.2.2.4.2 The use of FFQ in assessing dietary changes

The use of the FFQ to detect dietary changes has been tested in studies designed to evaluate diet intervention trials. Most of these studies were conducted in an effort to: reduce risk of cancer or cancer recurrence (Kristal *et al*., 1994; Martinez *et al*., 1999; Thomson *et al*., 2003); promote healthy dietary changes (Patterson *et al*., 2003; Segovia-Siapco *et al*., 2007) or to detect the effect of pregnancy on dietary change (Brown *et al*., 1996).

In two randomized dietary-intervention trials, Kristal *et al* (1994) illustrated a measure called responsiveness to test the sensitivity of FFQ compared to a 4-day records. The FFQ in both trials showed acceptable sensitivity and responsiveness compared to the reference method. However, the results of this study were not supported or adjusted with a reliable objective measure to detect changes in fat consumption.

The work of Thomson *et al*. (2003) in the Women's Healthy Eating and Living (WHEL) diet intervention trial has shown better results using the responsiveness concept proposed by Kristal *et al*. (1994) as a measure of an evaluation of the sensitivity of the instrument to change. The intervention group was provided daily dietary goals of five servings of vegetables, three servings of fruit, 16 fluid ounces of vegetable juice, 30g of fibre, and from 15% to 20% of energy from fat. The comparison group in this trial was advised to consume a daily diet recommended for cancer prevention (five servings of vegetables and fruit per day, 20g of fiber and not

more than 30% of energy from fat). Both groups were asked to complete the FFQ and 24-Hour recalls, at baseline and at 1 year follow-up. Both dietary instruments demonstrated minimal change in diet among participants in the comparison group. However, the FFQ in the intervention group supported the increased intake of vegetables over 12 months through the increase of α and β-carotene and folate intake, although the recalls were slightly more responsive than FFQ.

Other intervention studies have assessed the performance of FFQ in detecting dietary changes, but with different time frames and modes of administration of both the FFQ and the reference method. Segovia-Siapco *et al* (2007) randomly assigned 'free-living' adults to either an intervention group (walnut supplemented) or a control diet. Subjects in the intervention and control groups were prescribed ≥ 28g of walnuts and ≤ 2g of walnuts per day, respectively. The intervention period was 6 months and the subjects in both groups were asked to complete an FFQ and at least six 24-Hour dietary recalls at the end of the trial period. Significant positive correlation (r=0.79) was found between the FFQ and the recalls method for α-linolenic acid, which is an excellent biomarker of walnut supplementation.

Patterson *et al*. (2003) assessed the ability of FFQ to detect changes in food intake in randomly assigned women who received intensive intervention to adopt a low-fat eating pattern. The FFQ showed good sensitivity in demonstrating changes observed in the intervention group who followed a low-fat diet when compared to the comparison group. This ability was also observed in other intervention studies (White *et al*., 1992; Brown *et al*., 1996).

Overall, these studies show that the FFQ can be used to detect dietary changes specific to an intervention effect, but with various degrees of sensitivity and performance. These variations are due to differences in the sample size, study design and objectives, and the reference method (recalls/records) used for comparison. It is also important to note that the use of a reference method in most studies to validate the ability of FFQ is due to the fact that modifications of the original version of FFQ were made specific to the nutrient or population of interest (i.e. fat intake; Kristal *et al*., 1994; Martinez *et al*., 1999; Segovia-Siapco *et al*., 2007).

Any modifications to the validated FFQ will require re-validating the new version with another reference method (Cade *et al*., 2002).

2.2.3 Dietary assessment in adolescents

Accurate assessment of dietary intake in adolescents is highly important for monitoring the health status of this age group and necessary for conducting clinical research designed to evaluate the diet-disease relationship. However, measuring dietary intake in adolescents is a challenging procedure and not an easy task when compared to adults (Livingstone *et al*., 2004). These challenges are due to a number of factors which characterize the eating habits of adolescents. These include irregular meals, snacking and meal skipping, peer influence, overweight and obese subjects under-reporting their intake. In addition to the aforementioned, there are also difficulties with dietary assessment research in school settings and a lack of dietary assessment methods that address eating environments and patterns of teens and their capabilities and motivations at different stages of adolescence (Bandini *et al*., 1990; Livingstone *et al*., 1992; Frank, 1994; Samuelson, 2000).

Due to these factors, studies of dietary intake and habits in adolescents face a number of unique respondent and observer considerations that differ from dietary assessment in adults (Livingstone et al., 2004). Validation studies of energy and nutrient intake in children and adolescents have led to the recognition that much of the dietary intake in this age group is prone to reporting error, mostly through under-reporting (Livingstone et al., 1992). Reporting error does not only occur systematically due to differences in dietary methods, but is also influenced by the body weight status (Bandini *et al*., 1990). Whilst some dietary methods for adults are considered superior to other methods (i.e. weighed food records are considered the Gold Standard method), this might not be the case for adolescents.

Dietary assessment methods used for adolescents have shown behavioral alterations in actual and reported food intake. The nature and extent of these constraints are difficult to quantify. Therefore, the true validity of different dietary survey methods is unknown. Most studies that have used diet records (weighed and estimated) have shown bias towards under-reporting in recording energy and

nutrient intake. Livingstone *et al* (1992) found that the mean energy intake using weighed food records in 12-year old adolescents and 15-18 year olds was underestimated by 14% and 24%, respectively. Similar results were found when estimated food records were used in another group of adolescents, with negative bias being particularly explicit in obese subjects (Bandini *et al*., 1990). The 24-Hour recall method has also shown poor accuracy at the individual level and demonstrated positive bias in energy and nutrient intake (Fisher *et al*., 2000; Reilly *et al*., 2001). In addition to these reported limitations, repeated dietary recording over a prolonged period of time using weighed or estimated records is inaccurate as these methods are considered to be a burden and associated with incomplete recording (Bratteby *et al*., 1998).

FFQs have been used in the dietary assessment of adolescents because of their ease of administration and low cost. Furthermore, FFQs have shown acceptable validity and reproducibility in ranking adolescent consumers (Robinson *et al*., 1999; Lietz *et al*., 2002).

In the United States, Rockett *et al.* (1997) have shown that a simple self-administrated FFQ used in older children and adolescents (9-18 years old) could provide nutritional information about this age group. The validity was tested by comparing average value of the FFQ, administrated twice, to the average of three 24-hour recalls. The correlation coefficient between the two methods was 0.54, regarded as an acceptable outcome and similar to that found in adults (Rimm *et al*., 1992).

In the United Kingdom, dietary assessment in adolescents has received limited investigation, in particular the use of FFQs when compared to studies in adult populations. Lietz *et al* (2002) assessed the validity of an FFQ that was used in the European Prospective Investigation of Cancer against a 7-day weighed dietary record. The median correlation coefficient between both methods, when adjusting for energy intake, was 0.48. The FFQ was found to adequately classify subjects into low, medium and high consumers (Lietz *et al*., 2002). However, it was not judged to

be an appropriate method to estimate absolute intake in this age group, due to the small sample size of the study (n=50) and the use of 7-day food records as a reference method, which in themselves underestimate energy and nutrient intake (Livingstone *et al*., 1992).

Robinson *et al*. (1999) developed an FFQ which can be used to estimate energy and macronutrient intake over the previous month in a group of adolescents. Although the study assessed both sexes, the data published was in relation to female adolescents only. The validity of the FFQ was tested against a 7-day weighed record. Energy and macronutrient intake determined by the FFQ were higher than those recorded by the 7-day weighed records. Except for protein intake, there was a reasonable agreement between FFQ and 7-day records (correlation coefficient range of 0.28 for energy to 0.33 for carbohydrate). However, despite the compliant nature of the girls, energy intakes assessed by the weighed records were low in relation to their basal metabolic rate. This was reported as perhaps not representing habitual diet and might have underestimated the ability of FFQ to describe energy and macronutrient intake in this population. The FFQ used in this study was found to work well in terms of compliance and estimates of energy intakes were compatible with predicted energy needs (Robinson *et al*., 1999). Furthermore, it was found to be reproducible. Although weighed dietary records are considered to be the Gold Standard in adult populations, this study showed that FFQ may represent a better dietary tool for use with adolescents. Weighed records or diet history methods require highly motivated and compliant subjects, due to the burden associated with these methods which may lead to incomplete or inaccurate recording (Bratteby *et al*., 1998).

In summary, dietary assessment in adolescents appears to be a challenging process, due to a number of unique problems and factors related to the unstructured dietary intake of this age group and the lack of proper dietary methods that address the teen's environment, attitudes and mentality. Research into these aspects has been limited, and little progress has been made in understanding the variables associated with mis-reporting and biases in estimating nutrient intakes (Livingstone

et al., 2004). Therefore, using a simple and less burdensome dietary assessment method, such as FFQ, may represent one way to obtain meaningful dietary information from a wide variety of individuals, including those who are unwilling to provide good prospective records (Robinson *et al*., 1999), accepting the inherent limitation of this method itself.

2.3 Qualitative approaches in research

Qualitative methodologies in research have become increasingly accepted as methods used in public health and nutrition to understand the complexity of human behaviour and the interaction between disease and society. In contrast to quantitative research, qualitative research is concerned with the quality or nature of human experiences and the meanings of phenomena to individuals. It starts with ‘what’, ‘how’ and ‘why’ type questions rather than 'how much'. It is also concerned with examining these questions in the context of everyday life and from the individual’s point of view (Draper, 2004).

The introduction of the qualitative approach into the health care field began in the late 1960s’ when proponents of qualitative research argued that scientific methods as applied in health care systems were not an appropriate model for studying people (Schutz, 1962; Cicourel, 1964). The last two decades have seen an increased use of qualitative approaches to research, and they have become widely accepted methods across different disciplines. If the study is explanatory in nature and seeks to unearth an understanding about an area in which little is known, or if the research is attempting to find the meaning of, or understand the experience of a given situation by a group of individuals, qualitative methodologies are an appropriate choice. Bower and Scambler (2007) stated that qualitative research can broaden the evidence base for Dental Public Health and practice because it allows researchers to answer important research questions that are difficult to address satisfactorily using quantitative methods alone. Hence, qualitative methods can bridge the gap between scientific evidence and clinical practice (Green and Britten, 1998).

2.3.1 Reliability, validity and generalisability of qualitative research

It is well known that qualitative research is different from quantitative research in aspects related to the nature of reality and knowledge, the relationship between the researcher and participant, approaches adopted, sampling procedures, validity, analysis techniques and generalisability. However, many researchers have questioned the value of qualitative research. One criticism which has leveled at qualitative research is that it allegedly lacks the ‘scientific’ rigor and credibility

associated with traditionally accepted quantitative methods. For example, Morse (1999) states that if qualitative research is not considered to be generalisable, then it is arguably of little use.

Quality in qualitative research has received a great deal of attention and scrutiny, in particular adopting a set of criteria that would be used to assess the reliability and validity of findings and theories generated. Unfortunately, there has been disagreement and the controversy seems to be unresolved, mainly due to many researchers embracing a set of generic criteria, in the context of methods used in quantitative research, rather than those relevant to the particular qualitative approach proposed or reported. In this respect, qualitative research seems not to be unified yet (Cohen and Crabtree, 2008).

The notion of adopting a format identical to that used in quantitative research to assess quality in qualitative research has lead some researchers to develop and identify a formalized framework that can be used to evaluate qualitative research (Horsburgh, 2003). Whilst reliability in quantitative research is important, it is an equally important issue in qualitative research but assessed in a different way. Reliability in qualitative research does not focus on obtaining exactly the same results, but rather on achieving consistent similarity in the quality of the results (Collingridge and Gantt, 2008). One way of demonstrating reliability is by the researcher reporting information about the research process, and adopting a rigorous methodology, data collection, and interpretation, and producing results that enrich the understanding of the meanings that people attach to a specific phenomena (Cohen and Crabtree, 2008; Collingridge and Gantt, 2008).

The validity concept is applied in a similar fashion in qualitative research, by selecting an appropriate method, applied in a coherent and rigorous manner, which will answer the research question. There are many popular methods used to assess validity in qualitative research (Mays and Pope, 2000). Respondent validity, which is used in many qualitative research studies, involves returning the data and findings to participants in order to obtain their validation. Although commonly used, some

researchers questioned its value and found it to be problematic in terms of what the participants recall and the quality of data (Koch and Harrington, 1998). Reflexivity is another method adopted in evaluating validity. It assesses whether the findings of the study might have been influenced by personal and/or intellectual bias. Triangulation is a method that has been associated with robust qualitative research. Triangulation may include multiple methods of data collection and data analysis, but does not suggest a fixed method for all the researches (Golafshani, 2003). Other methods include peer review/debriefing and external auditing, which involves having a researcher not involved in the research process evaluate the accuracy of methods, interpretations and findings (Cohen and Crabtree, 2008).

With respect to generalisability, it is not the purpose of qualitative research to be generalisable in the traditional sense used in quantitative research, yet qualitative research has its own redeeming qualities that set it above that requirement. Quantitative research is statistical and numerical. In qualitative research it is situational representativeness that is sought (Horsburgh, 2003). According to Adelman *et al* (1980), the knowledge generated by qualitative research is significant in its own right. That is, qualitative methods focus on selected contemporary phenomena that large quantitative studies would not probe or identify. Hence, qualitative research can explain and describe more detailed aspects which would give more personal understanding of a specific phenomenon, and that would contribute valuable insight to the community (Myers, 2000). An alternative approach to generalisability in qualitative research is to use what is known as the analytical generalization (Collingridge and Gantt, 2008). This involves a reasoned judgment about the extent to which findings of one study can be used as a base and guide in another relevant situation provided that the study follows a coherent and rigorous approach and is well executed.

2.3.2 The use of qualitative methods in developing patient centered measures and nutritional epidemiology

Qualitative techniques have been used in many studies aimed at developing questionnaires in health sciences that take into account patients' and/or clinicians' perspectives. The use of qualitative methods in developing questionnaires can elicit

patients' perspectives rather than depending on clinicians' decisions and opinions, and are considered to be one of the best sources of item generation for any tool or scale (Williams, 2003).

The idea of patient-centeredness stemmed from the introduction of Clinical Governance in health care systems to assess the quality and effectiveness of care in the National Health Service (NHS), as part of the commitment to deliver high quality at the heart of everyday clinical practice (Department of Health, 1997). These issues have led to a need to develop measures that reflect patients' experiences in health care settings rather than only focusing on the treatment outcomes from the clinician's point of view or relying on traditional objective measures. For example, a recent report explored the face and content validity of the 16 item short form of the Child Perceptions Questionnaire (CPQ ISF-16) using a qualitative approach with 10 adolescent patients. The report found that young children with malocclusion expressed concerns about the face and content validity of CPQ ISF-16 in relation to its wording, absence of some relevant questions and response format (Marshman *et al*., 2010). This emphasizes the need to use qualitative approaches when considering developing patient – centered measures.

In orthodontics, measures have been introduced to assess different aspects of patients' experiences during the course of treatment, using qualitative approaches such as measures of patient satisfaction and quality of life (Bennett *et al*., 1997; Travess *et al.*, 2004; Sayers and Newton, 2006; Bernabé *et al*., 2008; McNaire *et al*., 2009; Ryan *et al*., 2009).

Jokovic *et a*l (2002) developed a questionnaire to assess the impact of oral status on quality of life in adolescents, in which interviews were conducted with 10 patients in the generation process for the questionnaire items. The questionnaire has shown acceptable validity in assessing OH-QoL in different populations of adolescents (Johal *et al*., 2007; O'Brien *et al*., 2007). Bernabé *et al* (2008) used face to face interviews to assess the validity of a questionnaire that measures daily impacts of wearing orthodontic appliances (OIDP). Ryan *et al* (2000) used in-depth interviews

with both clinicians and patients to develop a questionnaire to assess orthognathic patients' perceptions of referral to a mental health professional. They found that the majority of patients felt positive about being referred to mental health professionals before commencing treatment. McNaire *et al* (2009) designed a questionnaire to assess patient satisfaction with the process of orthodontic treatment based on qualitative techniques.

In nutritional epidemiology, qualitative studies have been used in various aspects of dietary assessment methods. They have been used to show how current food choices are shaped by experiences throughout certain occasion or events (Falk *et al*., 1996). They have also been used to enhance the development of dietary assessment tools to reduce the amount of potential errors associated with dietary assessment methods or to complement quantitative methods (Carbone *et al*., 2002; Coates *et al*., 2006). Such methods have also helped in understanding dietary assessment data, in judging whether dietary assessment methods are capturing habitual regimen that reflect long term patterns or diet-disease associations (Maynard and Blane, 2009).

2.4 Patients' experiences during fixed orthodontic treatment

2.4.1 The experience of pain

In orthodontics, the experience of pain and discomfort in relation to fixed orthodontic treatment is a frequent complaint (Stewart *et al*., 1997; Sergl *et al*., 1998). Furthermore, studies have shown that pain during orthodontics is a key deterrent and a major reason for discontinuing treatment (Patel, 1989; Brown and Moerenhout, 1991). Therefore, orthodontists should inform their patients about the possible side effects of undergoing orthodontic treatment, specifically the amount of pain/discomfort they might experience, throughout the course of the treatment, along with possible consequences.

2.4.1.1 The mechanism of orthodontic pain/discomfort

According to the International Association for the Study of Pain (IASP), pain is an unpleasant sensory and emotional experience associated with actual or potential damage or described in terms of such damage (Bonica, 1979). Pain in orthodontics is always recognized and accepted as a subjective response which shows large individual variations. It depends on multiple factors such as age, gender, individual pain threshold, the magnitude of the force applied, emotional state stress, cultural differences and past pain experiences (Brown and Moerenhout, 1991; Scheurer *et al.*, 1996; Sergl *et al*. 1998; Firestone *et al.*, 1999; Bergius *et al*., 2002). The subjective perception of pain makes it difficult to measure, as there is a wide range of individual response even with similar forces being applied to teeth (Burston, 1964).

The mechanisms whereby the application of orthodontic forces results in pain/discomfort are not fully understood. It is reported that orthodontic procedures can create tension and compression zones in the periodontal ligament space. This in turn will reduce the proprioceptive and discriminating abilities of the patients, resulting in a lowering of the pain threshold and disruption of the normal mechanisms associated with proprioception input from nerve endings in the periodontal ligaments. In addition, pressure, ischemia, and oedema in the periodontal ligament space will take place. All these changes are correlated with the presence of prostaglandins,

substance P and other substances which will cause sensitivity and activate inflammatory reaction (Burston, 1964). Hence, orthodontists often prescribe analgesics to patients, especially during the early stages of the treatment (Polat *et al*., 2005).

2.4.1.2 The prevalence and duration of pain related to fixed orthodontic treatment

When compared to other orthodontic treatment approaches, fixed orthodontic treatment is reported to cause significant pain. The severity of pain and discomfort in patients undergoing fixed orthodontic treatment was significantly higher than patients undergoing removable appliance therapy (Stewart *et al*., 1997; Sergl *et al*., 1998).

The prevalence, magnitude and time course of orthodontic pain has been reported in many studies that included different age groups, in particular, adolescent groups. Studies showed varied results in relation to the effect of age on pain perception. Brown and Moerenhout (1991) found that fixed orthodontic treatment caused more pain and negative impact on well being in adolescents compared to adults and preadolescents, whereas Jones and Chan (1992) showed more pain is experienced by adults. Negan *et al*. (1989), showed no significant difference between adults and adolescents. Critical comparisons between these conflicting results are difficult, perhaps due to: differences in study designs and methodologies used; cultural differences in pain perception as pain was investigated in different populations; personality and psychological factors perhaps being more important than age and sex in pain perception; adults rating their pain levels more reliably than children and adolescents and the fact that pain is a subjective response and is measured indirectly.

The majority of studies evaluating pain due to fixed appliances have shown that patients reported pain during the first week after appliance placement, which then declines. Tecco *et al* (2009) reported that 90% of patients reported pain during the first day, which declined gradually over the following 7-9 days. Scheurer *et al.* (1996) found that 95% of patients reported pain after 24 hours and 25% after 1 week. Fleming *et al*. (2009) reported that more than 60% of adolescent patients relied on

analgesics for symptomatic relief of pain in first the week, following placement of their appliance, whilst Oliver and Knapman (1985) reported that only 16% consumed analgesics.

Although the majority of studies have reported that pain intensity is highest during the first week after placement of the appliances and then declines, it is not precisely known how much time is needed for patients to adapt to this pain, as other reports found that pain can last longer. This may be due to the fact that pain itself is measured indirectly and studies have used different approaches to measure it, or that the majority of studies have followed up patients during the first week of treatment. Few studies followed up patients for longer periods. Brown and Moerenhout (1991) reported that patients needed up to 14 days to adapt to discomfort and pain experiences. Sergl *et al*. (1998) found that patients experience discomfort throughout the treatment although the intensity of pain after 3 months is much lower than the first week of treatment. Other studies reported that pain may be periodic throughout the treatment (Kvam *et al*., 1987).

2.4.1.3 Potential negative impacts of orthodontic pain on patients

2.4.1.3.1 Impact on compliance and acceptance

Patient compliance during orthodontic treatment has been associated with the amount of pain and discomfort experienced throughout the course of the treatment. Sergl *et al*. (1998) reported that acceptance of the treatment and compliance can be predicted by the amount of pain and discomfort during the first 6 month period after appliance placement. Another study reported that 8% of a study population discontinued treatment because of pain (Patel, 1989). Some studies reported that the level of pre-treatment explanations to patients and their parents seems to be unsatisfactory, which may have resulted in poor compliance with treatment (Oliver and Knapman, 1985). Krishnan (2007) stated that patients' initial attitude towards orthodontic treatment should be understood during the diagnosis phase, and should be discussed with the patient to help prepare them to encounter discomfort during the active treatment stage. However, although these studies suggest a link between pain experience and patient compliance, they fail to explain how this association

occurs and whether other factors are more related to patients' compliance and adherence to treatment. For example, a recent study showed that psychosocial factors such as social class and maternity support predicted patients' adherence to fixed orthodontic treatment during the first year of active treatment in a group of adolescent patients (Joury *et al*., 2010).

2.4.1.3.2 Impact on daily activities and diet

The literature supports the view that pain from fixed orthodontic treatment has a definite impact on the daily activities of patients. However, what is not clear is the extent of such an impact due to the use of simple, unspecific and generic measures. Brown and Moerenhout (1991) reported that pain from fixed orthodontic treatment in adolescents caused wakeful nights and consumption of analgesics. According to Scheurer *et al* (1996), pain from fixed appliances resulted in a negative impact on daily life. This impact was reported to be significantly greater in girls. However, the authors used only dichotomized questions and the visual analogue scale (VAS).

In addition, a number of studies have reported that pain during fixed orthodontic treatment caused moderate to extreme difficulty in chewing and biting foods of firm consistency. Otasevic *et al*. (2006) found that in a cohort of adolescent patients undergoing fixed orthodontic treatment the most common complaint was difficulty in eating and chewing. Oral ulcers were the second most common complaint. Bergius *et al*. (2002) reported the same effects and showed that patients had difficulty in chewing hard food. Firestone *et al* (1999) found that patients significantly underestimated changes they would need to make in their diet as a response to pain after insertion of initial archwires. Patients reported that they ate less than they used to before the treatment. However, the authors used only a single VAS question to measure the patients' change of their diet.

Although studies have reported that orthodontic pain caused dietary restriction, no study has identified or evaluated what specific dietary changes occur, or what type of food items are most affected. All studies have reported generic impacts on dietary intake such as difficulty in eating, without a clear explanation of dietary habit changes. Furthermore, the majority of studies have evaluated impacts on dietary

restriction during the first week of treatment only, without any evaluation of the effects over continued treatment.

2.4.1.4 Pain measurement

Since pain is a complex perceptual phenomena and a subjective experience, pain assessment is a challenging procedure. Orthodontic pain can only be measured indirectly. Therefore, a number of approaches have been used to assess and evaluate pain.

The most common method for assessing orthodontic pain is the Visual Analogue Scale (VAS). This method is designed to present the respondent with a rating scale, with minimum constraints (Seymour *et al*., 1985). The respondent marks a location on the 100 mm line corresponding to the amount of experienced pain. This will provide freedom to choose the exact intensity of pain and will give maximum opportunity for expression in an individual personal response style (Krishnan, 2007). The VAS has been described as being simple, sensitive and reliable (Sergl *et al*., 1998, Bergius *et al*., 2002; Bartlett *et al*, 2005). Furthermore, children over 5 years of age are able to use VAS in a reliable and valid manner to rate their pain intensity, regardless of their sex or health status (Bergius *et al*., 2000).

Other methods of assessing pain include the Verbal Rating Scale (VRS) which consists of a list of adjectives describing different levels of pain intensity (Jones, 1984), the Numerical Rating Scale (NRS) and an algometer. This is a device that contains two input systems, one a metal strip attached to orthodontic brackets, the other a 5V signal from a remote control television unit that the patient activates when beginning to feel pain. Questionnaires such as the McGill Pain Questionnaire (MPQ) and patient interviews have been also used in pain assessment in which the patient rates responses on a specific scale (Sergl *et al*., 1998). However, methods that rely on verbal rating such as VRS and MPQ have been criticized for their vocabulary limitations (Curro, 1990). Furthermore, they may cause confusion and be difficult to apply in younger age groups.

2.4.2 The effect of fixed orthodontic treatment on quality of life (QoL)

2.4.2.1 The QoL concept

In 1946, the World Health Organization broadened its definition of health to include physical, emotional, and social wellbeing. Subsequently, the Department of Health in England defined Oral Health as “the standard of oral and related tissue health that enables individuals to eat, speak, and socialize without active disease, discomfort, or embarrassment, and that contributes to general wellbeing” (Department of Health, 1994). This broadened concept of health meant that biological measures of disease needed to be supplemented with subjective health measures evaluating the individual's perspective. As a result, health related quality of life (HRQL) measures were introduced and have become popular over the last four decades.

In theory, HRQL measures combine information about health status and the value attached to that status by the individual (Guyatt, 1997). Since health conditions may affect the physical, psychological, and social functioning of the individual, these impacts may compromise the individual's QoL. In addition to prolonging survival and relieving clinical symptoms, the main underlying assumption of HRQL is that the primary objective of any intervention is to improve quality of life and well being (Berzon, 1998).

Over the past two decades, the impact of oral health and disease, dental appearance, malocclusion and treatment for these conditions on psychological and functional well-being has drawn increasing attention (Cushing *et al*., 1986; Slade and Spencer, 1994; Leao and Sheiham, 1996; Jokovic *et al*., 2002; Johal *et al*., 2007; O’Brein *et al*., 2007; Taylor *et al*., 2009; Benson *et al*., 2010; Laing *et al*., 2010).

Oral health related quality of life (OH-QoL) as a multidimensional construct refers to the extent to which oral disease disrupts an individual’s normal functioning. Much development of OH-QoL measures have been based on Locker’s (1988) conceptual model of oral health. This model states that there are five consequences of oral disease: impairment, functional limitation, pain/discomfort, disability, and handicap. These consequences are sequentially related and can lead to psychological and

social impairment. Since then, researchers have stressed the need to conceptualize oral health as an integral part of general health, as oral health can affect general heath and vise versa (Gift and Atchison, 1995).

Measures of OH-QoL in Dentistry have been developed to take into account patients' perceptions and how oral problems affect physical, psychological and social well being (Cunningham and Hunt, 2001). These measures can be used as complementary measures to objective clinical measures and normative needs to assess health needs, outcomes and the effectiveness of health care given (Mandall *et al*., 2001; O'Brien *et al*., 2007). Although clinical indicators are still of importance, they require supplementation with OH-QoL measures for two main reasons: first, the OH-QoL outcome does not necessarily correlate with objective findings, and patients' ratings of outcome may not correlate with those of clinicians (Bennett and Phillips, 1999; Kok *et al*., 2004; Tsakos *et al*., 2006; O'Brien *et al*., 2007).

2.4.2.2 The impact of orthodontic treatment on OH-QoL

As part of evaluating dental care in health care systems, assessing the effectiveness and the provision of orthodontic treatment beyond clinician parameters is important to determine if treatment is appropriate and the pre-treatment goals are met. Understanding patients' experiences during the course of treatment is highly important as such patients may experience pain, discomfort and functional limitations (Stewart *et al*., 1997; Sergl *et al*., 1998).

Few OH-QoL measures have been developed for children and specifically for use in orthodontics. The most commonly used and validated OH-QoL measure for children appears to be the Child Perception Questionnaire (CPQ11-14) (Jokovic *et al*., 2002). This instrument was developed for use as an outcome measure in clinical trials and in the evaluation of studies which assess change at the group level (Locker and Allen, 2007). The measure has been shown to be sensitive to clinical and self-perceived variations in orthodontic status (Locker *et al*., 2007) and has been validated in the UK (Marshman *et al*., 2005). In the UK, it was used in studies assessing the impact of malocclusion on QoL (Johal *et al*., 2007; O'Brien *et al*., 2007). In both studies, the measure seemed to be valid and was able to differentiate

OH-QoL between malocclusion and non-malocclusion groups. In other populations, it has been used to assess changes in OH-QoL during orthodontic treatment (Zhang *et al*., 2008). In addition to (CPQ11-14), other OH-QoL measures have been used with children in orthodontics. These include: the Oral Impacts on Daily Performance (OIDP; Gherunpong *et al*., 2004), a shortened version of Oral Health Impacts Profile (OHIP-14; Goes, 2001), the English version of the Child-OIDP index (Yusuf *et al*., 2006) and the oral aesthetic subjective impact scores (OASIS; Mandall *et al*., 1999). However, these measures were either validated in specific populations or measured OH-QoL in children not in the adolescence stage.

The impact of fixed orthodontic treatment on OH-QoL has only received limited attention (de Oliveira and Sheiham, 2004; Mandall *et al*., 2006, Zhang *et al*., 2007, 2008; Bernabé *et al*., 2008; Chen *et al*., 2010). These studies have shown that patients may experience negative physical, psychological and social impacts during the course of orthodontic treatment.

Mandall *et al* (2006) developed a questionnaire to assess the impact of fixed appliance treatment on daily life. The questionnaire was piloted on 66 patients at the first, second and third visits after their fixed appliance had been placed. The questionnaire was said to have face and content validity because it was based on a qualitative approach. In addition, it had an acceptable internal consistency and test-retest reliabilities. However, criterion and construct validities were not tested. Furthermore, although the questionnaire had a dietary impact sub-scale, it was generic in which other irrelevant conceptual sub-scales were included. Finally, the questionnaire was not tested in other populations to evaluate its sensitivity and reliability when compared to other OH-QoL measures such as the CPQ11-14.

de Oliveira and Sheiham (2004), found that in a sample of 1675 randomly selected Brazilian adolescents, those who were either undergoing or had never undergone orthodontic treatment were more likely than those who had completed treatment to report negative impacts on daily living using two oral health-related quality of life

measures: the Oral Impacts on Daily Performance (OIDP) and a shortened version of Oral health Impacts Profile (OHIP-14). Fifty one per cent of adolescents who had an oral health-related impact reported that dental pain related to eating was the most frequent cause.

Zhang *et al*. (2008) reported on the changes in OH-QoL during the first six months of fixed appliance treatment, in a sample of 217. Each subject completed a Child Perception Questionnaire (CPQ11-14) before treatment, 1 week after the start of treatment, and 1, 3 and 6 months thereafter. There were significant negative changes in overall CPQ scores during the study period, and consistently with respect to oral symptoms compared to before treatment ($P<0.05$). The period of greatest change occurred during the first month of treatment. Similar findings, applying the CPQ11-14, were also found in another group of adolescents wearing fixed orthodontic appliances (Zhang *et al*., 2007).

Bernabé *et al* (2008) assessed the prevalence and intensity of impacts on daily performance related to wearing different types of orthodontic appliances in 357 Brazilian adolescents. Ninety per cent of subjects reported impacts on one daily living performance, commonly eating or speaking. Such impacts were higher among adolescents wearing fixed rather than removable or a combination of fixed and removable orthodontic appliances.

The above studies have found negative impacts and compromised OH-QoL during the course of orthodontic treatment. In particular, domains relating to oral symptoms and functional limitations (i.e. eating, chewing and biting difficulties) appear to be affected. No previous studies have explored how dietary intake and frequencies are affected and whether body composition changes occur as a result of orthodontic treatment. Furthermore, a number of studies have been cross sectional in design rather than longitudinal, and have not included a control group in relation to OH-QoL and experiences during fixed appliance treatment.

2.5 Oral health status and dietary intake

The literature suggests that dental health status can have a major impact on quality of life (QoL) (Slade and Spencer, 1994; Sheiham *et al*., 1999, 2001; Tsakos *et al*., 2006). However, the impacts of impaired oral health on dietary intake, food choices and body composition have received limited investigation and exploration. Few reports in this field have shown that good oral health is important for chewing and eating efficiently without causing dietary restriction. Acs *et al* (1992) found that growth and body weight in children with high nursing caries, was negatively affected compared to those with less nursing caries. This finding was also supported by Ayhan *et al* (1996). Oral health status has also been found to be an important factor for the nutrition of older people. Marcenes *et al* (2003) reported that specific nutrient intakes were lower in edentulous compared to dentate subjects. Brodeur *et al* (1993) found that edentulous elderly patients with deficient masticatory performance may develop gastrointestinal disorders, due to reduced consumption of high-fibre foods.

In orthodontics, many studies have reported that pain and discomfort are the most frequent complaints during fixed orthodontic treatment (Scheurer *et al.*, 1996; Sergl *et al*. 1998; Firestone *et al.*, 1999; Bergius *et al*., 2002; Bartlett *et al*, 2005). However, few studies have explored the physical, social, or psychological effects and impacts of orthodontic treatment (de Oliveira and Sheiham, 2004; Mandall *et al*., 2006, Feldmann *et al*., 2007; Zhang *et al*., 2007, 2008; Chen *et al*., 2010). Most of these studies have found that oral health related QoL during orthodontic treatment was worse when compared with pre-treatment. These findings were only used to identify areas where patients may be pre-warned of specific potential problems during the course of treatment to give them realistic expectations of the treatment and to help overcome problems associated with non-compliance. Other aspects such as nutritional intake and effects on body weight were not investigated, although specific domains of OH-QoL measures such as oral symptoms and functional limitations were found to be significantly worse during the first six months of treatment (Zhang *et al*., 2008).

The main limitations of these studies were: firstly, a number used measures that lacked construct, face and content validity which in turn may lead to inaccurate

results (Mandall *et al*., 2006, Feldmann *et al*., 2007; Marshman *et al*., 2010). Secondly, most measures used were generic and not specific to the attribute of interest, which means that some items are irrelevant (O'Brien *et al*., 2007). Thirdly, no control subjects with malocclusion traits were recruited to compare their experiences and OH-QoL with those undergoing orthodontic treatment. Fourthly, most measures introduced are cumbersome, that is, they can only be used for research purposes rather in clinical settings. Therefore, there should be means of translating what is found in research to all health care systems and applying patient-centred measures in combination with traditional objective measures. Finally, although studies showed that pain is the most common complaint patients raise during treatment and that OH-QoL during treatment is worsened, there was no explanation of possible consequences of these impacts on other aspects of patients' life such as the effect on their diet. At present this aspect is unclear and requires further investigation as part of broadening our understanding of patient experiences during fixed orthodontic treatment and to aid in reliably informing patients what they would possibly face as a result of undergoing orthodontic treatment.

2.5.1 Does fixed orthodontic treatment affect dietary intake and body composition?

Orthodontists often recommend their patients to eat soft food and avoid food of hard consistency due to the anticipated chewing difficulties, risk of appliance breakage and discomfort. Furthermore, orthodontic patients are instructed to follow a strict oral hygiene protocol after eating to prevent periodontal disease, caries and staining of their teeth, which in turn may affect the amount and frequency of food consumption.

In addition to these factors, many studies as previously discussed (See section 2.4.1) have shown that pain is the most common problem that patients experience during the course of treatment. A few studies have proposed, without any strong evidence, that pain may result in difficulty in eating. However, it is not clear what changes occur in diet and how patients change their eating behaviours. This is mainly due to using generic or simple measures such as dichotomized questions or VAS without incorporating specific subjective and/or objective measures (Firestone *et al*., 1999; Erdinç and Dinçer, 2004).

It is well known that inadequate food intake, which in turn will influence energy levels, will result in a series of physiological and behavioural responses. The principle response is a reduction in body size, lower body weight and reduced muscle mass and fat stores (Shetty, 1999).

A limited number of investigators have attempted to specifically investigate the potential impact of fixed orthodontic treatment on dietary intake. Cheraskin and Ringsdorf (1969a) found that between 17% and 53% of orthodontic patients demonstrated suboptimal vitamin C status as measured by plasma ascorbic acid in blood. In further study up to 72% of patients demonstrated suboptimal vitamin C status when using the lingual vitamin C test (Cheraskin and Ringsdorf, 1969b). Unfortunately, in both studies the design, sampling procedures and methodology were poorly defined.

Riordan (1997) reported changes in nutrient intake following placement of fixed appliances although the only statistically significant differences were found in relation to copper ($P<0.0018$) and manganese ($P<0.016$) levels. However, the study was limited to the assessment of nutritional changes 3 days after orthodontic adjustment, in a very small sample ($n=10$), and the absence of a control group. Furthermore, this study did not include any objective measures such as measuring body fat composition.

At present, it would appear that the effect of fixed orthodontic treatment on nutritional intake, body weight and body fat percentage is not clear from the literature. Probably orthodontists do not perceive that such impacts can take place or maybe the idea of patient-centeredness needs to be promoted more extensively. As a result, there is a need to explore this aspect and investigate whether patients undergoing fixed orthodontic treatment are potentially at risk of dietary/nutritional restriction. This in turn, would allow us to reliably inform patients of what they could expect in terms of their dietary intake and behaviour during treatment and possibly provide them with dietary guidelines if changes are proven to occur.

Chapter 3

Aims, objectives and null hypothesis

3.1 Aims

The aims of this study were to assess and explore the effects of fixed orthodontic treatment on dietary intake and habits, body mass index (BMI), body fat percentage and quality of life in a group of adolescent patients.

3.2 Specific objectives

1. To assess quantitative and qualitative changes in dietary habits and intake due to fixed orthodontic treatment in adolescent patients, during the first 3 months of fixed orthodontic treatment.

2. To assess changes in adolescents' BMI and body fat percentages due to fixed orthodontic treatment during the first 3 months of fixed orthodontic treatment.

3. To assess the intensity of pain experienced due to fixed orthodontic treatment during the first 3 months of fixed orthodontic treatment.

4. To investigate whether experiencing pain and taking analgesics during fixed orthodontic treatment are correlated with changes in dietary intake, BMI, body fat percentages and QoL.

5. To investigate whether dietary instructions given to patients by their orthodontist are correlated with changes in dietary intake, BMI, body fat percentages and QoL.

6. To investigate whether BMI status at baseline is a moderator for changes in dietary intake, BMI, body fat percentage and QoL.

7. To assess the changes in adolescents' quality of life during the first 3 months of fixed orthodontic treatment, in particular, changes in oral symptoms and functional limitations domains.

3.3 Null hypothesis

Fixed orthodontic treatment will not result in:

1. Change in energy or macro-nutrient intake and dietary habits.
2. Change in body mass index (BMI) and fat percentage.
3. Change in quality of life.

3.4 Theoretical framework

The present study adopted a combination of two proposed models in which related aspects of both model's pathways have been adopted in the present study to explain the changes in the main outcome variables namely: dietary intake and behaviour, BMI, fat percentage and OH-QoL (Khan, 1981; Wilson and Cleary, 1995).

According to Khan (1981), dietary intake and choices can be influenced by multiple factors namely; biological (i.e. physical impairment), environmental and personality factors.

Wilson and Cleary (1995), explained the link between health, disease and health related quality of life (HRQoL) by proposing a model which encompasses both biological and physiological variables (e.g. pain) at one end and total HRQoL at the other end. Symptom status and functioning problems of disease (functional, psychological and social experiences) serve as a link between both ends. In addition, the model identifies the mediating role that personal and environmental factors have on this causal sequence.

The present study assessed a combination of biological (pain) and environmental factors (socio-demographic factors, the influence of dietary instructions given to patients by their orthodontists and BMI status at baseline) in explaining changes observed in the outcome variables. However, personality factors were not evaluated in the present study as introducing more measures to the study's subjects might

have resulted in causing fatigue to subjects which in turn may have lead to an increased attrition rate. Furthermore, the fourth and fifth levels in the Wlison and Cleary (1995) model namely: general health perceptions and overall quality of life, were not measured. Therefore, only biological and environmental factors were tested to assess their relationship with the outcome variables (Figure 3.1).

Several studies have reported that dental pain such as pain from caries can cause dietary restrictions to a child's eating abilities, which may decrease their nutrient intake (Acs *et al*., 1992, Clarke *et al*., 2006). It is well documented that fixed orthodontic treatment causes pain and discomfort. This in turn, might cause dietary restrictions and changes in dietary behaviour (Firestone *et al*., 1999; Bergius *et al*., 2002; Erdinç and Dinçer, 2004; Otasevic *et al*., 2006). In addition, dental pain from caries has been reported to affect children's OH-QoL (Kijakazi *et al*., 2009). Evidence suggests that OH-QoL of patients undergoing fixed orthodontic treatment is worsened, in particular, domains related to oral symptoms and functional limitations (Mandall *et al*., 2006; Bernabé *et al*., 2008; Zhang *et al*., 2008). This may be due to the amount of pain and discomfort patients experience during the course of the treatment.

Socio-economic status and material resources can affect food choice at both a society and an individual level. The higher the social class and income, the healthier the diet (Friel *et al.*, 2003; Giskes *et al.*, 2004). Living in low-income households and conditions of relative poverty can influence life circumstances and individual health behaviors (such as dietary intake). Furthermore, socio-economic status is an environmental contributor to an adolescents' OH-QoL (Donaldson *et al*., 2008).

The medical literature suggests that BMI status can be an important moderator to changes in dietary intake and habits in interventions directed to prevent obesity, with overweight and obese subjects being more likely to be responsive to such interventions and drop weight compared to normal weight subjects (Rosenbaum and Leibel, 1998; Raben *et al*., 2002; Ebbeling *et al*., 2006). Although fixed orthodontic treatment is not a treatment directed to prevent obesity or cause weight loss, this

factor was examined to assess whether it could influence changes in dietary intake and body fat composition. BMI status has been reported to be an environmental factor that might affect QoL. For example, Hlakty *et al* (2010) reported that obese subjects with medical conditions such as, diabetes and coronary artery disease had significantly worsened QoL compared to normal weight subjects.

Finally, orthodontists often recommend their patients avoid eating food of a hard consistency and high sugar content. Such instructions may result in patients changing the amount and type of foods eaten which may lead to changes in BMI and fat percentage.

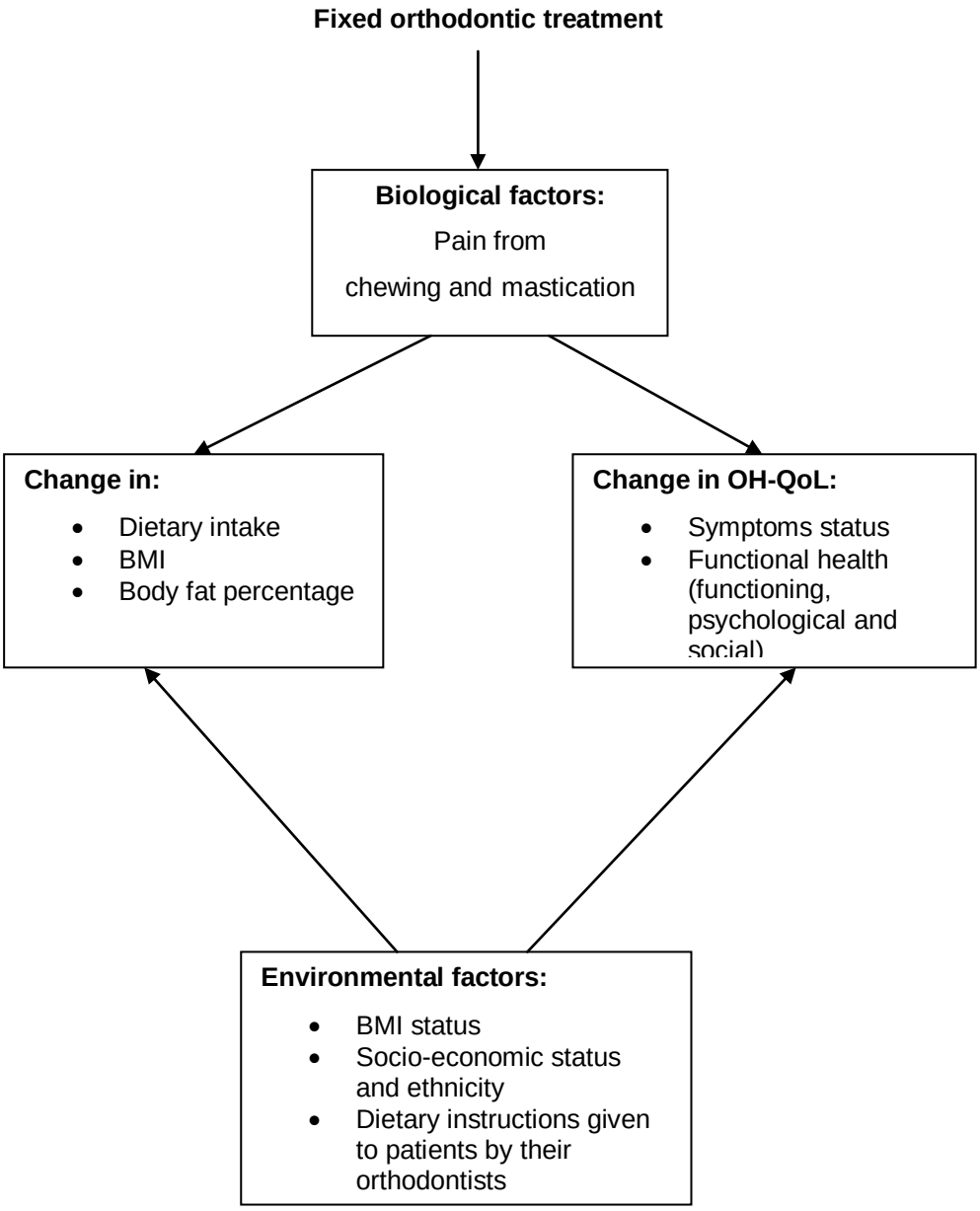

Figure 3.1 The proposed theoretical framework

Chapter 4

Subjects and Methods

This chapter will be divided into 2 parts.

The first will discuss the qualitative approach that was adopted to develop a supplementary questionnaire which was to be used in the main study, to assess the effects of fixed orthodontic treatment on dietary intake and behaviour.

The second part will explain the methodology that was adopted in the main quantitative study.

4.1 Qualitative approach

4.1.1 Aims of qualitative study

Due to the lack of previously reported data exploring, in particular, the type of food items that are most affected and how patients shift their habitual dietary intake due to fixed orthodontic treatment, a qualitative approach was carried out in addition to the quantitative data to answer the following questions:

1. How and why does fixed orthodontic treatment affect dietary intake?
2. What food items are most likely to be restricted due to the treatment?
3. What food items are most likely to be consumed due to the treatment?

Therefore, the specific aims of this qualitative study were:

1. To identify changes in dietary intake.
2. To identify causes of dietary intake change.
3. To identify changes in dietary behaviours.
4. To identify shifts in dietary intake and the food items most commonly affected.
5. To develop a questionnaire that will assess changes in dietary intake and behaviour.

4.1.2 Subjects and methods

The study adopted a qualitative approach to assess changes in dietary intake and behaviour and was approved by the East London and The City Ethics Committee (08/H0703/50; Appendix 1). Figure 4.1 shows the steps involved in conducting the qualitative study.

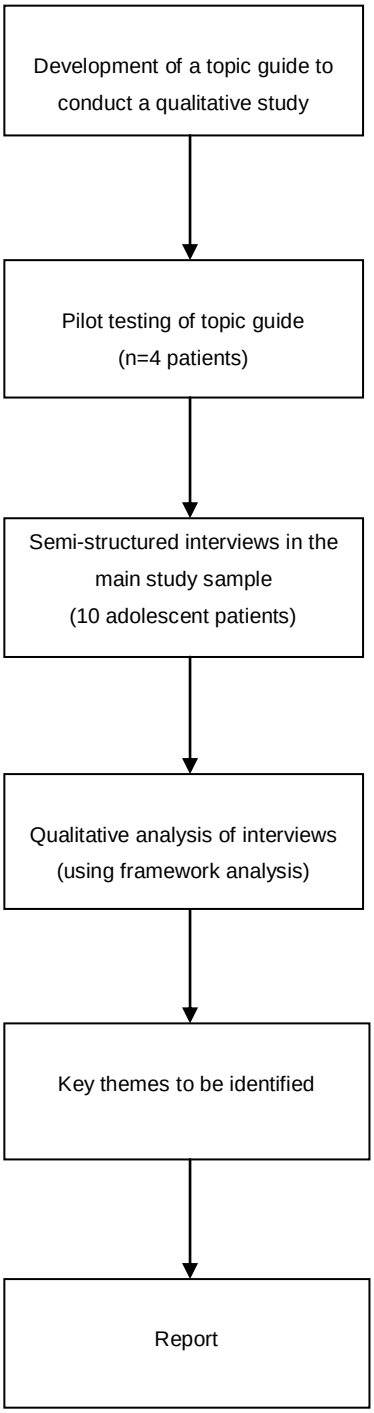

Figure 4.1 Steps involved in conducting the qualitative study

4.1.2.1 Training and calibration

The researcher attended 4 training courses which covered; qualitative research methods and techniques, analysis of qualitative data and appraising qualitative studies. The courses were organized by the Guy's and St Thomas' NHS Foundation Trust and King's College, London (Appendix 2). In addition, the researcher gained a clinical insight into undertaking dietary assessments in children with the Nutrition and Dietetic Department, Paediatric Dietetic Clinic, The Royal London Hospital (Appendix 3).

4.1.2.2 Participants

Patients who were due to undergo fixed appliance treatment in the Orthodontic department at the Dental Institute, Barts and The London Hospital were identified and recruited on the basis of the following selection criteria.

The inclusion criteria were: patients aged 11-14 years who required upper and lower fixed appliances and were medically fit and well. Patients were excluded from the study if there was a history of chronic disease or medication which might influence nutritional habits, those with syndromic conditions, undergoing orthognathic surgery or having adjunctive removable appliance therapy and patients who were likely to be fasting at any point during the study.

Unlike quantitative studies, statistical representation based on sample size calculation is not sought in qualitative studies. Patients were selected using the principles of purposive sampling in order to provide as wide a range of experiences as possible in terms of dietary intake and behaviour. Thus, the sample included patients of different genders, ages and ethnic backgrounds to reflect the diversity of dietary intakes in the population being treated. All patients were to be interviewed at their first review appointment (4-6 weeks), following placement of their fixed appliances. The reason for interviewing patients at their first review appointment (4-6 weeks) was the fact that patients in the quantitative study were to be followed-up during the first 3 months of treatment. Thus, understanding patients' experiences within the first 3 months was assumed to be more reflective to patients in the

quantitative study, as patients' experiences and their adaptation to treatment may change as the treatment progresses in later stages.

Patients and their parent/guardian(s) were given an invitation letter to participate in the study at the placement of their fixed appliances appointment (Appendix 4). This gave them 4-6 weeks to consider participation in the study. Patients and their parent/guardian(s) who agreed to participate were asked to sign a consent form before conducting the interviews (Appendix 5). Appointments were arranged with the Specialist Registrar providing the patient's treatment to minimize inconvenience.

4.1.2.3 Methodology

4.1.2.3.1 The topic guide

Semi-structured, one-to-one interviews were undertaken, with no time constraints, in a non-clinical setting to assure privacy. Interviews were based on a topic guide (Appendix 6), which was a list of key questions to be asked, to help to define areas to be explored in relation to the research objectives. This approach is considered appropriate for children and provides them with some guidance on what to talk about (Gill *et al*., 2008). Furthermore, it allows divergence and follow-up questioning, whereby new information raised by individual patients is, in turn, included in future interviews. Questions for the topic guide in the current study were developed by the research team, taking into account the opinions and suggestions of Specialist Practitioners in the orthodontic department at Barts and The London Hospital. The topic guide was tested, in 4 pilot interviews, before using it in the final test sample. This was to help ensure that it would generate constructive data by examining and comparing emerging themes from the interviews in terms of their consistency and frequency. This also enabled testing of the recruitment strategy and allowed the investigator (F.A.) to fully develop their interview skills.

4.1.2.3.2 The interviews

Interviews for the final test sample of the study were conducted by a single investigator (F.A.) who interviewed them, based on the topic guide, in a neutral and non-judgmental manner. Patient recruitment for the final test sample was carried out until the point was reached when no further new themes or data emerged, in terms

of the effect of orthodontic treatment on dietary intake and behaviour. This point was reached after 10 interviews had been undertaken. All interviews were recorded and immediately transcribed verbatim by a transcription agency (Transcript Divas, Middlesex, UK). All interviews were tape-recorded using a small, high quality, portable battery powered cassette recorder. The duration of each interview was 15-20 minutes depending on the information and experiences reported by each patient. The interviews were conducted during the period (July 2009-September 2009).

4.1.3 Data analysis

Unlike quantitative analysis, qualitative data analysis occurs concurrently with data collection. Data analysis in the current study adopted the principles of framework analysis. Ritchie and Spencer (1994) describe framework analysis as 'an analytical process which involves a number of distinct though highly interconnected stages'. The basic principles of this method are adopted from other qualitative techniques such as the grounded theory and/or the thematic approaches (Ritchie and Spencer, 1994). However, this method is appropriate to research that has a specific research question with a limited time frame. Furthermore, this method allows themes to develop both from the research questions and from the narratives of research participants (Rabiee, 2004). Emerging data throughout the data collection stage were compared and characterized until a point was reached where no new themes emerged and all responses were repetitive. Data analysis was divided into 5 stages (Ritchie and Spencer, 1994):

The *first stage* involved familiarization with the data by listening to the tapes and reading the transcripts entirely, several times. The goal was to get a general sense of the data and break the interview into general themes.

The *second stage* involved identification of a thematic framework by writing memos in the margin of the text in the form of short phrases, ideas or concepts to develop categories. Memos were also made on a Word document for each interview.

The *third stage* was indexing, which involved sifting the data and highlighting quotes and making comparisons between and within cases.

The *fourth stage* involved 'lifting' the quotes from the original context and placing them under the newly developed appropriate thematic content and categories for these themes. Each quote was read and checked to identify if it was answering the research question(s) and whether it was adding something new of great importance or merely repeating existing responses.

The *final stage* was interpretation of the data, in which the relationship between quotes, themes and data were examined to generate meaning. In this stage, consideration of the actual words used and their meanings were assessed along with the context in which they were used. Frequencies of comments and ideas along with their intensities were also analyzed. Deciding on specific outcomes and concepts is the final stage in generating the whole picture of the study.

All data from the interviews were analyzed, checked and coded by 2 independent investigators (F.A. and S.C.) to ensure that all themes and concepts extracted were similar, and to minimize the risk of bias in interpreting the data. The resultant coded category system proposed by both researchers was similar and, following discussion, two main themes were identified: pain experience and dietary behaviour change. These findings were subsequently assessed for comprehensiveness and validity by inviting a further four 4 adolescent patients, who were also undergoing fixed appliance treatment, to be interviewed in relation to their experiences.

4.1.4 Questionnaire development

The aims of this questionnaire were to help assess the effects of fixed orthodontic treatment on dietary behaviour, and to identify shifts and changes in any food items consumed during treatment. This questionnaire was to complement the dietary assessment method used in the main quantitative study and to provide a greater insight into the dietary behaviour of adolescents undergoing fixed orthodontic treatment.

4.1.4.1 Items generation

Items for the questionnaire were derived from analysis of the interviews; in which the 2 major themes identified were used as a baseline and information derived from the

interviews was used to develop the potential questions. The questionnaire format adopted a combination of Likert scales and dichotomized responses (Steiner and Norman, 2003). Dichotomized responses were used to ask patients about their consumption of specific food items which were likely to be affected as a result of treatment and were scored '0' for no impact and '1' for an impact. The responses included *'ate as usual'* or *'ate with difficulty/couldn't eat'* for food items that were difficult to eat or *'ate as usual'*, *'ate more'* for food items which were easier to eat. Responses for the 5-point Likert scale ranged from '*strongly agree'* to *'strongly disagree'* to assess changes in dietary behaviour and habits due to the fixed appliances (Appendix 7).

Scores for all items would be summed, with higher scores reflecting more dietary behaviour changes.

Questionnaire items covered the following aspects of fixed orthodontic treatment:

1. Dietary restriction related to orthodontic pain.
2. Pain experience in the last month
3. The influence of dietary instructions given by the orthodontist.
4. Habitual dietary changes related to the treatment, such as decrease in consumption of hard food, increased consumption of other foods, reduced number of meals eaten compared to before treatment and changes in food preparation.
5. Shifting and changing intakes of specific food and drink items.
6. The influence of treatment on adopting healthy eating habits.

The final questionnaire comprised a total of 32 items (12 Likert format and 20 dichotomized questions). The questionnaire was divided into 3 parts:

1. The experience of pain and various impacts of fixed orthodontic treatment on dietary behaviour (12 Likert questions).

2. Food and drink items anticipated to be difficult to consume (11 dichotomized questions).
3. Food and drink items anticipated to be eaten more often (9 dichotomized questions).

4.1.4.2 Pre-testing and piloting process

Four school children (3 males, 1 female), aged between 11-14 years, and a secondary school teacher were invited to assess the readability and clarity of the questionnaire. Minor wording amendments were undertaken following queries highlighted in relation to the wording of the questionnaire.

Following this step, the amended questionnaire was further piloted on five patients undergoing fixed appliance treatment in the orthodontic department, Barts and The London Hospital. These patients completed the questionnaire without any difficulty requiring an average of 3 minutes and thought that the questionnaire items reflected their experiences.

4.1.4.3 Validity of the questionnaire

In developing the questionnaire, criterion validity could not be assessed, as this is the first study to assess the effects of fixed appliances on dietary intake and there is no 'Gold Standard' against which to measure. In addition, construct validity for the questionnaire was not assessed or tested, as the definition of the construct of interest (dietary behaviour) was not established. However, content and face validity were tested by a panel of experts and patients from the pilot study. It was not possible to test reproducibility of the questionnaire as impacts related to treatment in relation to dietary intake would change with time depending on the amount of pain experienced and levels of their adaptation during the various stages of treatment.

4.2 The main quantitative study

4.2.1 Study design

This study adopted a hospital-based prospective consecutive design that followed up subjects undergoing orthodontic treatment for a 3 month period. A group of patients who had yet to start their fixed appliance treatment were also consecutively recruited and followed up for a 3 month period.

In the current study, a control group was consecutively recruited from patients ready to start treatment during their preparatory period of assessment prior to placement of their fixed appliances and were thus excluded from further analysis.

4.2.2 Subjects

4.2.2.1 Sample size calculation

A pilot study was carried out, after obtaining ethical approval, on 32 patients awaiting fixed appliance placement, during their preparatory period. The patients were followed up for 3 months during which time: body weight, height, BMI, fat percentages, dietary intake and quality of life (QoL) were measured at baseline, 4-6 weeks and 3 months. This pilot study was carried out between (October 2008 and January 2009).

The purpose of the pilot study was:

- To calculate the required sample size for the present study as there was no previous study that has described body weight and dietary changes during fixed orthodontic treatment.
- To check for any content and language difficulties with the study questionnaires.
- To test the practicality of all measurements.
- To measure the time required for the clinical measurements and the administration of all questionnaires.
- To become familiar with the study protocol.

The pilot study was carried out by a single examiner (F.A.) and showed that the study protocol was feasible and all anthropometric measurements and questionnaires were carried out without any difficulties. The subjects did not face any difficulties in completing the questionnaires, nor did they fail to comply with the anthropometric measurement procedures. The average time needed for each subject to complete both questionnaires and recording anthropometric measurements was between 25 and 30 minutes.

Sample size calculation was performed using Power and Sample size Calculation software version 3.0.2 (Nashville, TN, USA).

After 3 months, BMI increased 0.24 Kg/m^2 and the standard deviation for this change was 0.6. To detect a 0.24 Kg/m^2 reduction in BMI in the test group applying a standard deviation of 0.6, at an alpha value of 5 per cent and 80 % power, required 51 subjects in each group (test and control). To allow a loss to follow up of 20 per cent, recruitment was inflated to 62 subjects in each group. Therefore, the total sample size for the proposed study was estimated to be 124 subjects. A similar sample size was found using changes in QoL outcomes in the same group.

4.2.2.2 Selection Criteria

A hundred and twenty four subjects were consecutively recruited from the orthodontic clinic at the Dental Institute, Barts and The London Hospital. The records of subjects who were due to undergo orthodontic treatment were reviewed applying the study's selection criteria.

The inclusion criteria for both test and control groups were as follows:

1. Adolescent patients aged between 11-14 years old. This age range accounts for the majority of patients seeking fixed orthodontic treatment. As patients were being followed up for 3 months only, normal physiological changes that might affect the results of this study, as a confounding factor, are likely to be minimal. This is because it is common practice in studies measuring growth changes from childhood to adulthood to calculate increments of height and

weight measurements at intervals of not less than 0.85 years and no greater than 1.15 years (Tanner and Davis, 1985). Increments calculated over shorter periods of time are more relatively affected by measurement error or seasonal changes (Tanner and Davis, 1985). In the present study a control group of the same age group was recruited. This was to help ensure that any changes observed in the test group were most likely to be due to the treatment effect, rather than any other factor. Also, to adjust for normal physiological growth changes, BMI changes in each patient were adjusted for sex-age specific median BMI for the same period applying the World Health Organization reference data (WHO; de Onis *et al*., 2007). This was undertaken by subtracting from each patient's observed BMI change score the change in sex–age specific median BMI for the same period and then comparing between both test and control groups.

2. Subjects requiring fixed orthodontic treatment only, in one or both jaws.
3. Subjects who were fit and well.

The exclusion criteria for both test and control groups were the following:

1. A history of chronic disease or chronic medication that might influence nutritional habits or body weight. This refers specifically to any medical condition that necessitates special dietary requirements or may influence healthy dietary intake (e.g. anorexia nervosa, diabetes, anaemia, hormonal disturbances).
2. Subjects with syndromic conditions such as facial deformities (i.e. cleft lip and palate). This reflects the need for multidisciplinary care, with surgical intervention.
3. Subjects who require surgical dentistry or orthognathic surgery.
4. Subjects who require removable appliances, including functional appliances.
5. Subjects who will be fasting at any point of the study.

In the present study, it was assumed that patients exhibited similar malocclusion characteristics, as only patients who required fixed appliance treatment were

recruited. In addition, only patients who were eligible for orthodontic treatment on the basis of need. That is grades 4 and 5 of the dental health component (DHC) of the Index of Treatment Need (IOTN) were accepted for treatment. Other forms of simple malocclusion are not accepted for treatment. Therefore, the sample was assumed to be homogenous with respect to malocclusion severity.

The present study followed-up patients for the first 3 months after placement of fixed appliance treatment. This resulted in patients being in initial stages of treatment with NiTi archwires in place. The department protocol for initial archwire sequence includes placement of either a 0.014 or 0.016 NiTi archwire. Erdinç and Dinçer (2004) reported that there was no significant difference in perceived pain in a group of patients who were on 0.014 inch NiTi compared to another group who were on 0.016 inch NiTo archwires.

4.2.3 The study groups

Subjects were allocated to test and control groups based on the following criteria.

4.2.3.1 The test group

Subjects for the test group constituted those who would undergo placement of fixed appliance after being called off from the waiting list and have completed their preliminary investigations. A total of 62 subjects were recruited to the test group. Baseline assessment was performed, just prior to placement of their fixed appliance, with follow-up outcome measures being performed at 4-6 weeks and 3 months.

4.2.3.2 The control group

Subjects for the control group constituted those awaiting placement of fixed appliances. Sixty two subjects were recruited to the control group from those who had been called off the waiting list and were undergoing preliminary investigations prior to receiving active fixed appliance therapy. The mean period for these preliminary investigations is 3 months. Thus, baseline and follow-up measures at 4-6 weeks and 3 months were undertaken prior to the subject receiving active fixed appliance treatment.

4.2.4 Methods

4.2.4.1 Ethics Approval

The study obtained ethics approval from the East London and The City Ethics Committee (08/H0703/50) (Appendix 1).

4.2.4.2 Study Conduct

The medical and dental history was reviewed. Subjects who met the selection criteria were invited to participate in the current study. The researcher (F.A.) was introduced to the patient by their Specialist Orthodontic Registrar (SPR's), to whom the patient's care had been assigned. Patients and their parent/guardian(s) were then approached before their appointment. The researcher explained the project objectives to the patient and their parent/guardian(s) in a separate room to assure privacy. The patient and parent/guardian(s) were given an invitation letter inviting them to participate in the study (Appendix 8). Confidentiality was assured. Informed consent was then obtained from both the patient and their parent/guardian(s) who agreed to participate (Appendix 5). The same protocol was applied to subjects in the control group. The researcher (F.A.) went to the clinic on a daily basis during the data collection period and by collaborating with the SPR's, patient recruitment was undertaken. The data collection period was between (December 2009 and May 2010). Figure 4.2 illustrates the study protocol adopted in this study.

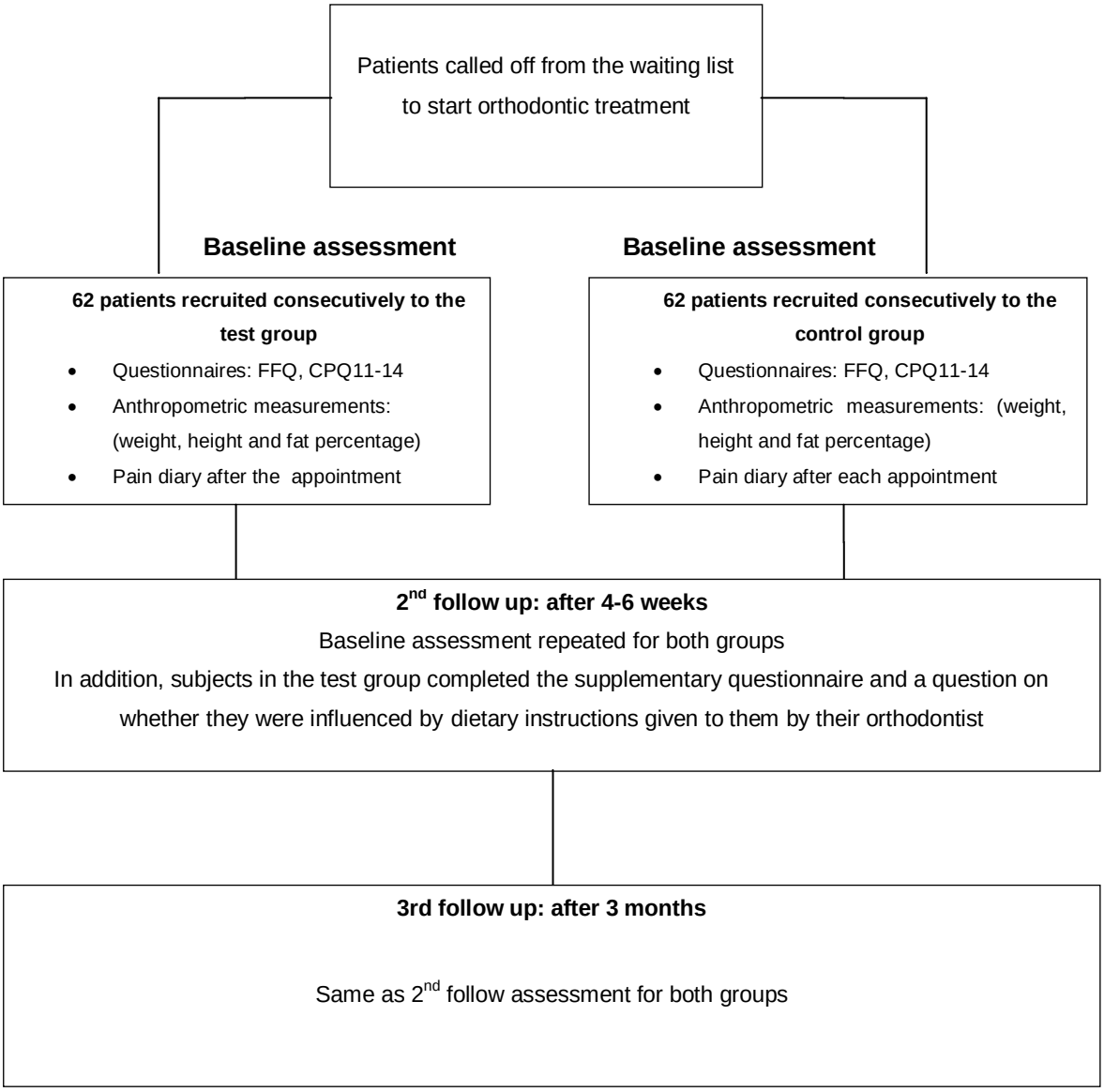

Figure 4.2 The quantitative study protocol

4.2.4.3 Baseline assessment

Once informed consent was obtained, and prior to the placement of the fixed appliance (test group), and prior to the initial clinical examination after call off from the waiting list (control group), age, gender and socio-demographic data were obtained using a questionnaire (Appendix 9). Socio-economic status for patients was obtained using socio-economic indicators which included: which adult the patient was living with, parental employment, household crowding, car ownership, house ownership and access to Internet (Rogers *et al*., 1995; Health Education Authority,

1997). The variable of ethnicity was categorized into 5 groups: White, Asian, Black, Mixed and Others based on the recommendations of the UK Census (2001).

Subjects in both test and control groups were asked to complete two further questionnaires, the Food Frequency Questionnaire (FFQ) and the Child Perception Questionnaire (CPQ11-14) (Appendices 10 and 11, respectively). The FFQ is a validated dietary measure (83 items) for use in adolescent females in the UK (Robinson *et al.*, 1999). The CPQ11-14 provides a validated measure of the impact of oral health status on quality of life in adolescents aged 11-14 years old (Jokovic *et al*., 2002). Clear instructions were provided on how to complete each questionnaire. In addition, an example was given on how to fill the FFQ to avoid any confusion.

After completing the questionnaires, the subject's height and weight were measured to calculate their Body Mass Index (BMI) along with body fat percentage. The height was measured using a stadiometer and the body weight and fat percentage was measured using a digital scale (Tanita Corp., Tokyo, Japan).

At the end of their appointment with the SPR, each subject was given a pain diary to be completed at home and returned at their next appointment. Subjects were asked to record their perceived pain intensity from their teeth and perceived pain levels from chewing and biting over the following 7 days and one time at the end of every following week after their initial first visit. At each time point, patients were asked whether they consumed analgesics. Patients were asked to record their responses one time at each time point (Appendix 12). For the control group the word 'braces' was removed from the questions in the pain diary.

4.2.4.4 Follow-up assessment

After 4-6 weeks and at 3 months, each subject from both test and control groups was asked to complete follow-up FFQ and CPQ11-14. In addition, subjects in the test group were asked to complete the supplementary questionnaire (Appendix 7) that assessed the impact of fixed orthodontic treatment on dietary behaviours and on specific food items (see section 4.1). They were also asked whether they were influenced by dietary instructions given to them by their orthodontist (Appendix 13).

Responses to this question were dichotomized to yes/no. Repeat BMI and body fat percentage measurements were also undertaken at these same time points for both groups. The reason for asking patients to complete their first follow-up at 4-6 weeks is that appointments in the orthodontic clinic are usually given to patients within this period depending on availability and the treatment being received. It was not possible to standardize the duration of follow up periods as this is considered unethical, inconvenient and would interfere with the care given to patients.

4.2.5 Measurements

4.2.5.1 Questionnaires

Four types of self administered questionnaires were used in this study: the socio-demographic questionnaire, the Food Frequency Questionnaire (FFQ), the Child Perception Questionnaire (CPQ11-14) for both groups and a supplementary questionnaire to assess dietary behaviours in the test group.

4.2.5.1.1 Food Frequency Questionnaire (FFQ)

This is a self-administered questionnaire designed to assess energy and macro-nutrient intake in adolescents. The FFQ is a validated measure for use in adolescent females in the UK (data for males remains unpublished) and was shown to yield reproducible responses which can be used to describe broad dietary patterns (Robinson *et al*., 1999). It consists of a list of 83 foods and a selection of options relating to the frequency of their consumption over the past month. The frequency of consumption options are categorised into eight frequencies ranging from 'never' to 'more than 5 times a day'. There are no portion size options for each food item in the questionnaire, since average portion sizes specific to adolescents were used. Average portion sizes for each food item were derived from published values specific for the UK population developed by the Royal Society of Chemistry (Davies and Dickerson, 1991). These average portion sizes have been provided by the author (Robinson *et al*., 1999). Molag *et al* (2007) showed from the results of the meta-regression analysis that inclusion of portion sizes options did not consistently affect the ranking of different nutrients and that average portion sizes were superior, compared to studies using FFQs with portion size options.

4.2.5.1.1.1 Computation of food and nutrient intakes

Conversion of frequency estimates of food intake into energy and nutrients measures requires appropriate nutrient database or food composition tables that can be used to provide nutrient values for each frequency estimate of a specific food. Food composition databases provide detailed information on the concentrations of nutrients and nutritionally important components in foods. Food composition tables vary between each country. In the UK, comprehensive tables of the composition of British foods were brought together to become The Composition of Foods. Several editions were published to include new and evolving foods. The latest (sixth) edition was used in the present study (Food Standards Agency, 2002). The tables provide the energy and nutrient contents of every 100 gm of food consumed.

This FFQ is used to calculate an approximate daily energy and macro-nutrient intake (carbohydrates, proteins and fats; Robinson *et al*., 1999). Nutrient and energy intakes were calculated by multiplying the weight of the average portion for any frequency selected by its nutrient and energy content from the UK food tables (Food Standards Agency, 2002). Total nutrient intakes were calculated from the sum of the products of the nutrient content of the portion of each food. Because the FFQ measures average daily intake of energy and macro-nutrients, each frequency option of the questionnaire was mapped to calculate daily intake as follows: every frequency option was converted to daily intake by dividing the median range of the frequency by the number of days for the period of interest (dividing by 7 for a week and by 30 for a month) daily intakes were mapped as follows: never [= 0/day], 1-3 times a month [=2 times (2/30=0.07/day)], once a week [=1/7=0.14/day], 2-3 times a week [= 2.5 times (2.5/7=0.36/day)], 4-6 times a week [= 5 times (5/7=0.7/day)], once a day [=1/day], 2-4 times a day [= 3/day] and 5 or more times a day [= 5/day].

Example:

The following example illustrates how energy and macro-nutrient intake were calculated. A subject was asked how often he/she has eaten white bread in the last month that responded '2-3 times a week', their energy and macro-nutrient content for this response would be calculated as follows:

According to the Royal Society of Chemistry, the average portion size for white bread eaten by adolescents is 60 gm. According to the food composition tables in the UK (Food Agency Standards, 2002), 100 gm of white bread contains 219 kcal, 46.1 gm of carbohydrates, 7.9 gm of protein and 1.6 gm of fat. The frequency of daily intake based on the subject's response (2-3 times a week) is 0.36 times/day. Therefore, the average energy and macro-nutrient intake per day based on the subject's response would be:

Energy intake/day = 0.36 * 60/100 * 219 kcal = 47.3 kcal/day
Carbohydrate intake/day = 0.36 * 60/100 * 46.1 gm = 9.9 gm/day
Protein intake/day = 0.36 * 60/100 * 7.9 gm = 1.7 gm/day
Fat intake/day = 0.36 * 60/100 * 1.6 = 0.34 gm/day

4.2.5.1.2 Child Perceptions Questionnaire (CPQ11-14)

The CPQ11-14 was designed to measure the impact of oral health status on quality of life (QoL) in children aged between 11-14 years. The aim was to produce a measure which conformed to contemporary concepts of child health and had discriminative and evaluative properties, and is applicable to children with various dental, oral, and oro-facial disorders (Jokovic *et al*., 2002). This questionnaire is one of a battery of measures developed to assess children's quality of life which include a questionnaire for children aged 8-10 years, a questionnaire for parents that captures their perceptions of their child's oral health-related quality of life and a scale to assess the effects of oral disorders on family functioning. The CPQ11-14 is a 37 item validated questionnaire and includes 4 domain subscales: oral symptoms, functional limitations, emotional well being and social well being (Jokovic *et al*., 2002). The CPQ11-14 was developed using the item-impact method proposed by Juniper *et al* (1996) which is based on the frequency and the perceived importance of the items selected by adolescents. The preliminary list of items was developed after interviewing parents and experts dealing with children affected by oro/craniofacial conditions. The items were then reduced using the item-impact method. Finally the measure was tested for validity and reliability. It was shown to have a good construct validity by showing significant positive correlations between scale scores and children's rating of their oral health and the extent to which the

condition of mouth and teeth affected their life overall. It has also demonstrated excellent test-retest reliability and internal consistency exceeding 0.8.

The CPQ11-14 was assessed in the UK and has shown acceptable reliability, criterion and construct (Marshman *et al*., 2005; Johal *et al*., 2007; O'Brien *et al*., 2007). It has also shown to be sensitive to clinical and self-perceived variations in orthodontic status (Locker *et al*., 2007).

Each item of the CPQ11-14 (Appendix 10) is scored on a 5-point Likert scale to rate the impact of their oral health status on the particular aspect of QoL, with responses ranging from 'never' (score = 0) to 'every day or almost every day' (score = 4). Possible score ranges for oral symptoms, functional limitations, emotional well being and social well being may range from 0-24, 0-36, 0-36 and 0-52, respectively.

4.2.5.1.3 The supplementary questionnaire

The aim of this questionnaire was to assess the impact of fixed orthodontic treatment on dietary behaviours, and specifically food items that might be affected due to treatment. This questionnaire was developed based on a qualitative study (see section 4.1).

4.2.5.2 Anthropometric Measurements

Anthropometric measurements comprised assessment of the subject's height, weight and body fat percentage. An assessment form was used to record the data (Appendix 14).

4.2.5.2.1 Body Mass Index (BMI)

The patients' height and weight was measured to calculate the Body Mass Index (BMI). It is determined from the subject's body weight in kilograms [Kg] divided by their height in metres squared [m^2]. Height and weight was measured according to the Food and Nutrition Anthropometric Indicators Measurement Guide (Cogill, 2003). The measurements for height and weight were taken to the nearest 0.1 centimetres and 0.1 Kg, respectively. Three readings for both height and weight were recorded, and the median of these was used. The majority of patients were measured at the

same time of the day during the study follow-up periods as patients are given appointments to match the schedule of the SPR's treating the patient. This attempted to control for variations in body weight and height during the day.

The body weight was measured using a digital scale (Tanita TBF-300, Tanita Corp., Tokyo, Japan). The patient was asked to remove their shoes and any heavy clothing and to stand still in the centre of the scale's platform with every effort to ensure the body weight was equally distributed on both feet (Figure 4.3).

The height was measured using a stadiometer (Chasmors Limited, London, UK). The subject was asked to remove their shoes and was asked to stand with their heels together, arms to the side, legs straight, shoulders relaxed, and positioned with their head in Frankfort horizontal plane. Heels, buttocks, scapula, and the back of the head were in light contact with the vertical surface of the stadiometer. just before the measurement was taken. The head board was lowered against the head with enough pressure to compress the hair. The measurement was read with the investigator's eye level with the headboard, to avoid errors in recording.

BMI changes across the study periods in both groups were adjusted for age and sex by subtracting from each patient's observed BMI the change in sex–age specific median BMI for the same period using the WHO reference data (de Onis *et al*., 2007). Tables of reference data for children aged 5-19 years old are presented for both genders at the WHO website (http://www.who.int/growthref/who2007_bmi_for_age/en/index.html). From these tables the normal physiological growth of BMI were tracked for subjects from the reference population who were the same age and sex as the current study's subjects. These tables provide monthly changes of BMI at any age for subjects who are at the median of the growth curve. Changes in median BMI were obtained from the tables and then subtracted from observed BMI changes of the study's subjects who were the same age and sex.

In order to assess whether BMI at baseline predicted changes in outcome variables, in particular, overweight and obese patients who are more likely to lose weight in intervention programs (Ebbeling *et al*., 2006), patients were classified into either normal or overweight/obese based on the international cut-off points developed by Cole *et al*. (2000). These cut-off points were based on an international survey that used six large nationally representative cross sectional growth studies. Great Britain was one of the countries. These curves were averaged to be used internationally and age-sex specific cut-off points for overweight and obesity were defined for each age (Cole *et al*., 2000).

4.2.5.2.2 Bioelectrical Impedance Analysis (BIA)

BIA is a commonly used method in clinical settings to estimate body composition, including body fat percentage. It measures the impedance or resistance to the electrical signal as it travels through the water found in the muscle and fat tissues of the body. The greater the body fat content, the greater the resistance to current flow. The impedance value is combined with anthropometric data (height and weight) into a prediction equation to give body compartment measures, depending on age and gender.

The Tanita body-fat analyzer (Tanita TBF-300, Tanita Corp., Tokyo, Japan) is a novel system which is commonly used in the UK to estimate body fat percentage, based on the BIA principle (Figure 4.3). The Tanita system used in the current study measured voltage drop when a small alternating current was applied through contact with the two metal foot plates. Body weight will be recorded automatically. The device is small, portable, simple and rapid for measuring body composition. The impedance scale used in the present study has been used in children and found to be highly correlated with the whole-body dual X-ray absorptiometry (DXA), a commonly used reference method for calibrating body fat analyzers (Tyrrell *et al*., 2001). Furthermore, the Tanita system has been used in the UK and was found to be valid and acceptable when compared to reference methods (Jebb *et al*., 2000). To eliminate bias in estimating fat percentage between different ethnic groups, equations specific to the population of interest were developed that take into account ethnic variability. These equations were based on a recent study that validated the

same fat analyzer (Tanita TBF-300) used in the current study (Haroun *et al*., 2010). This equation took into account the variations between ethnic backgrounds in estimating fat percentage in a sample of adolescent subjects aged 11-15 years living in East London. The equations applied were as follows:

For females:
TBW= 1.814 + (0.603 × HT2/*Z*) + (0.846 × Black) + (1.664 × Asian).

For males:
TBW= −3.249 + (0.695 × HT2/*Z*) + (0.748 × Black) + (1.564 × Asian).

Where TBW = total body water, HT= height and Z= the impedance value obtained from the fat analyzer.

When the above values were used in the White population, both terms 'Black' and 'Asian' are 0. Black and Asian adolescents are ascribed 1 for their respective ethnic groups and 0 for the dummy variable as appropriate.

To measure fat mass (FM) and fat percentage, the fat free mass (FFM) should be measured. FFM was calculated as TBW/hydration value (constant). The hydration values used in this study were based on sex-specific equations. The equations were as follows:
For females: hydration value = 79.797 − (0.385 × age) and for males hydration value = 78.176 − (0.237 × age).

After that, FM is measured by subtracting FFM from body weight. Fat percentage was calculated by dividing FM by weight.

All measurements were made after a period of at least 5 minutes of the subject standing to minimize potential errors from acute shifts in fluid distribution. The subject was then asked to stand barefoot on two metal plates of the platform, one foot on each metal plate. Fat percentages and weight readings automatically

appeared on a small screen and all measurements were printed out. The procedure was repeated and the average of both readings recorded. Details of the prediction equations were provided by the manufacturer (Tanita Corp., Tokyo, Japan), and the scale specifications were designed for use in the UK.

Figure 4.3 The Tanita scale

4.2.5.2.3 Training and Calibration

The principle researcher (F.A.) was trained to measure height and weight, along with gaining a clinical insight into undertaking dietary assessments in children, by the Nutrition and Dietetic Department, Paediatric Dietetic Clinic, The Royal London Hospital (Appendix 3).

4.2.5.3 Measuring pain

Patients in the test and control groups were given pain diaries to record their pain levels and experiences. The diary asked patients to rate their pain intensity from their teeth and how much the braces hurt them during eating and biting on a Visual Analogue Scale (VAS). In addition, there was a specific question relating to the use

of analgesics for pain relief (Appendix 12). The VAS included an unmarked 100 mm horizontal line, weighted at both ends by the descriptive terminology '*'my teeth don't hurt me at all*'' on the left and '*'my teeth hurt me very badly*'' on the right. The patient was asked to place a mark on the line that best corresponded to the level of pain experienced. Subsequently, measurements were made of the distance from the left margin to the recorded mark on the line, using a ruler.

4.2.6 Outcome Measures

The outcomes measures being applied in the current study were the following:

1. Quantitative changes in energy and macro-nutrient intake.
2. Impacts on dietary behaviours and habits.
3. Changes in BMI and fat percentage.
4. Changes in quality of life during the initial treatment period.

4.2.7 Error study

4.2.7.1 Questionnaires

To assess reproducibility (test-retest reliability) of the questionnaires, 10 patients who were assigned randomly, completed the FFQ and CPQ11-14, during the same day, after they had finished their appointments with the SPR's.

4.2.7.2 Anthropometric measurements

The Tanita scale used in the present study has been found to have high correlation (r=0.89) with the whole-body dual X-ray absorptiometry (DXA), a reference method commonly used to calibrate body fat analyzers (Nunez *et al*., 1999). In addition, to eliminate bias in relation to variability in estimating fat percentage between different ethnic groups, equations specific to the population of interest were developed that took into account ethnic variability (Haroun *et al*., 2010; See section 4.2.5.2.2)

Reproducibility of anthropometric data was checked by repeating measurements in 20 patients, who were randomly selected. The repeat measurements were taken at the end of their SPR appointment. Reproducibility was tested using t-paired test to

detect if there were any systematic errors. Measurement error for the VAS scores was evaluated by re-measuring 20 randomly selected pain diaries.

The Tanita scale was calibrated every 2 weeks, as recommended by the manufacturer, to ensure its accuracy in measuring body weight, using an object of known weight. This was also repeated in relation to the stadiometer using a known height of an object (one meter long stick). The height measurement was read with the examiner's eye level with the headboard, to avoid errors in recording.

4.2.8 Data analysis plan

Data analysis was carried out using the Statistical Package for the Social Sciences software (SPSS), version 16.0 (Chicago, ILL, USA). Data was checked for entry errors. The researcher (F.A.) identified any unclear or missing data and checked it with the subject during the data collection period. At baseline, the test and control groups were compared with respect to the frequency of the range of socio-demographic data to test for similarity of both groups.

In the present study, data analysis was carried out in two stages, in line with the proposed theoretical framework (see section 3.4).

The first stage compared both groups with respect to outcome variables (dependant variables) namely; BMI, fat percentage, dietary intake (FFQ) and QoL. This step is to ensure that if there were any differences between the groups they are due to the treatment effect.

The second stage helped identify changes in outcome variables in the test group which were significantly different from the control group. In addition, it explained dietary behaviour scores in the test group. This was undertaken by assessing the effect of the study's related independent variables namely; pain levels for chewing and biting, consumption of analgesics and dietary instructions given to patient by their orthodontists In addition, the effect of the study's non-related variables was assessed namely; socioeconomic indicators, BMI at baseline and treatment approach (extraction vs. non-extraction). After that, a multiple regression model was

built for each dependant variable that was significantly different from the control group and for dietary behaviour variables. This step was to identify which independent variable influenced and contributed most to changes in the dependant variable(s) (Figure 4.4).

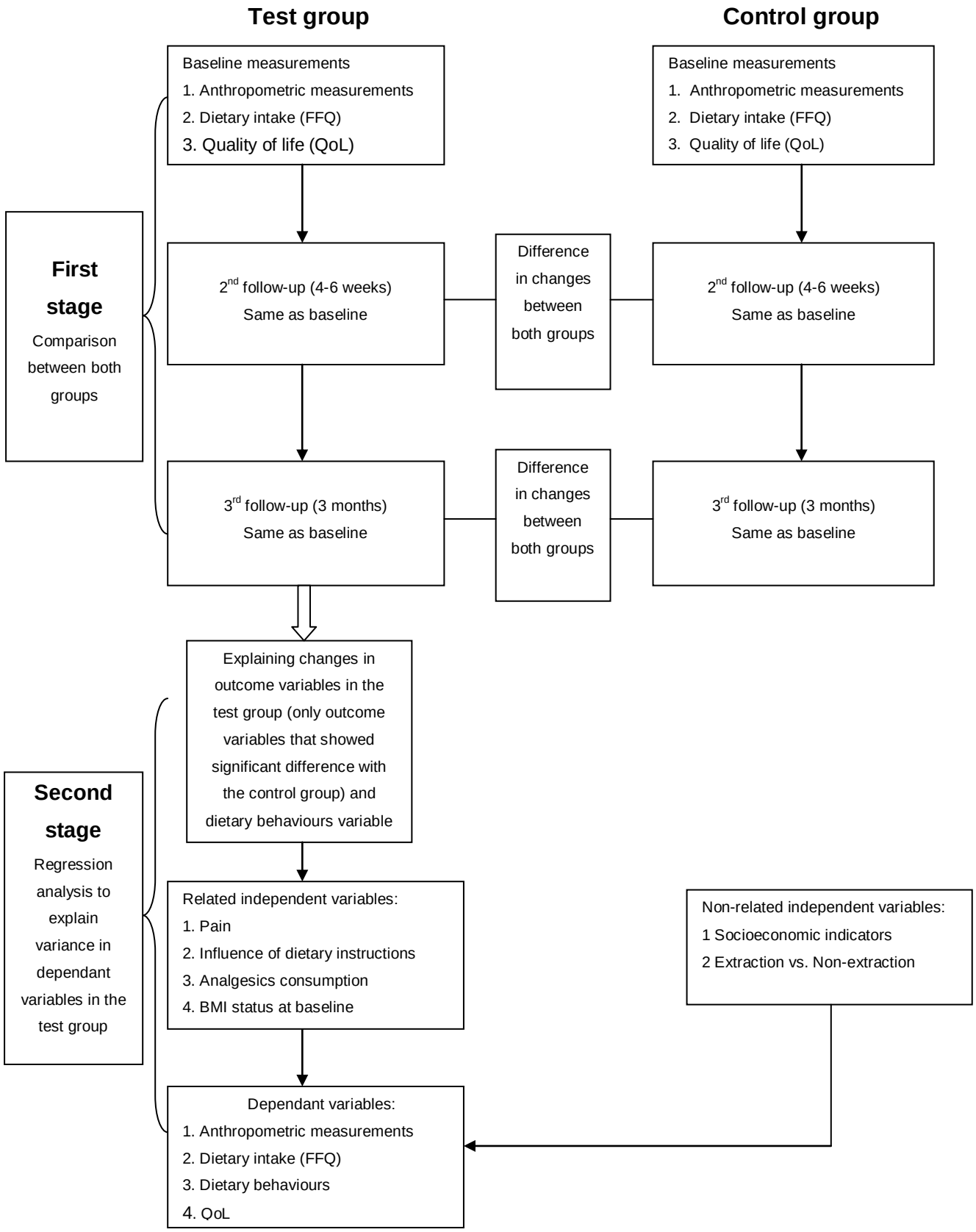

Figure 4.4 Stages of the analysis

Data analysis was conducted on the following variables: gender; ethnicity; age; socio-economic status (represented by parental employment status, which adult(s) the child lives with; crowding status of the house; car and house ownership; and access to the Internet); pain levels; use of analgesics, anthropometric measurements (body weight, height, BMI and fat percentages); dietary intake (FFQ); dietary behaviours (supplementary questionnaire); the influence of dietary instructions given by orthodontists, treatment approach (extraction vs. non-extraction), BMI at baseline and quality of life measures (CPQ11-14).

The variables related to socio-economic indicators were categorized as follows: Parental employment status was categorized into 4 groups: 'both parents employed'; 'only father employed'; 'only mother employed'; and 'both parents unemployed'. The variable, which adult the child lived with, was categorized into 4 groups: 'with both parents'; 'single-parent father'; 'single-parent mother'; 'doesn't live with parents'. The variable of ethnicity was collapsed into 5 groups, based on the recommendations of the UK Census (2001): 'White', 'Asian', 'Black', 'Mixed' and 'Others'. Crowding of the house was calculated by dividing the number of persons by the number of the rooms in the house and assigned to: ‘no crowding’ (if the number is less than 1.5 person/room), and ‘crowding’ (if the number is 1.5 or more person/room). Car ownership was categorized into: 'no car'; 'one car'; and '2 or more cars'. House ownership was categorized into: 'rented', 'own it' or 'I don’t know'. The difference between date of measurement and date of birth was employed to calculate age.

Data relating to pain intensities from teeth; pain from chewing; anthropometric measurements (adjusted BMI and fat percentages); FFQ; supplementary questionnaire and QoL were numerical. Scoring of these variables was described earlier. For pain levels from teeth and chewing, the average of measurements based on the first 7 days and the value recorded at the end of each following week throughout the first (baseline to 4-6 weeks following) and the second period (4-6 weeks to 3 months) were calculated to be used in further analysis in relation to outcome measures. In addition, changes in pain intensity, at each time point, were assessed by comparing pain scores in each time point to first day score (the control).

This was performed by undertaking a Wilcoxon test, as data were not normally distributed. Responses to the item asking the patient whether dietary instructions given by the orthodontist affected dietary intake were dichotomized into 'yes' or 'no'. Treatment approach variable was dichotomized into 'extraction' and 'non-extraction'. BMI status at baseline was dichotomized into 'normal' or 'overweight/obese'.

The scoring of the supplementary questionnaire (dietary behaviours) was described earlier (See section 4.1.4.1). In addition, the frequencies of responses for each item in the supplementary questionnaire were presented at 4-6 weeks and 3 months.

Data analysis included the following steps:

The first step tested the reliability of scales used in the study. The internal consistency reliability of the Supplementary questionnaire and the (CPQ11-14) was tested using Cronbach's alpha. Test-retest reliability for questionnaires, anthropometric data and VAS scores was tested by intra-class correlation coefficients (ICC). In addition, paired t test was employed for anthropometric data to investigate for any systematic errors.

The second step included describing and comparing the characteristics of both groups by performing a frequency distribution and Chi square test for categorical variables. For numerical variables, descriptive statistics and independent t-test were performed. The mean and 95% confidence interval (CI) were used for variables with normal distributions and the median (range) were used for variables with skewed distributions. For normally distributed variables, parametric tests were employed whilst non-parametric tests were employed for variables which were not normally distributed (skewed).

The third step compared both groups with respect to the study's dependent variables, namely; anthropometric measurements (BMI and fat percentage), dietary intake (FFQ) and QoL. This was done by comparing changes in each dependent variable in the following periods: baseline to 4-6 weeks following, baseline to 3

months following and 4-6 weeks to 3 months. A one-way between group analysis of covariance was conducted (ANCOVA). Measurements at baseline were treated as a covariate in the analysis to control for differences between both groups. Effect sizes were presented to assess the magnitude of differences between both groups. The widely accepted thresholds of 0.2, 0.5 and 0.8 described by Cohen (1988) were used to define 'small'; 'moderate' and 'large' effect sizes, respectively. The reason for using ANCOVA was because this test is considered an appropriate method when subjects are not randomly assigned in different groups. The model will adjust for socio-demographic variables if there is a significant difference between both groups in these variables at baseline. In addition, within group changes during the study periods were assessed by employing paired t or Wilcoxon tests where appropriate. For dietary behaviour scores in the test group, the Wilcoxon test was employed to assess changes in scores between 4-6 weeks and 3 months.

The fourth step tested the effects of each independent variable (explanatory variables) on changes in each outcome (dependent) variable in the test group during the study's follow-up periods. Only dependent variables that were significantly different at the 0.05 level between both groups were tested in the test group. In addition, the effects of each independent variable on dietary behaviours scores were tested. For the univariate analysis, simple linear regression, independent t-test (or Mann-Whitney U test if data were not normally distributed) and ANOVA test (or Kruskal-Wallis test if data were not normally distributed) were employed where appropriate. The aim of this step was to select independent variables that would be entered into the multivariable linear regression to explain changes in each outcome variable and dietary behaviour scores. Based on the study's proposed theoretical framework, the independent variables were divided into 2 groups: non-related variables that are not the focus of the current study, which included socio-demographic variables and treatment approach and related variables, which included pain levels, consumption of analgesics, BMI status at baseline and the influence of dietary instructions given by orthodontists. The independent variable was selected if its relationship with changes in each dependent variable at 4-6 weeks

and 3 months was significant at the 0.2 level based on Altman's (1991) recommendations. The same was done for dietary behaviour scores.

The fifth step tested the changes in dependant variables in the test group that were significantly different between both groups as well as dietary behaviour scores. This was done by running a multiple regression model for each dependant variable by entering the independent variables that were statistically significant at the 0.2 level, in the univariate analysis. The aim of this step was to test which independent variable contributed greatest to changes in each outcome variable during the period of the study.

The sixth and final step tested the associations of all of the dependent variables with each other by employing the Pearson correlation coefficient test.

Chapter 5

Results

This chapter will be divided into 2 parts.

The first will present the results of the qualitative study followed by the second part which will present the results of the quantitative study.

5.1 The qualitative study

Two major themes were identified from the interviews: pain experience and dietary behaviour changes. In addition, a number of sub-themes were introduced, on the basis of the information generated from the interviews. This permitted further exploration of each theme in terms of frequency of occurrence and severity of effect thus providing a greater insight into the effects of appliance treatment (Table 5.1).

Ten patients (4 males) were recruited, with a mean (standard deviation, SD) age of 13.21 (SD 0.71) years. Four patients were Caucasian, 4 were Asian and 2 were of Afro-Caribbean origin.

The following sections include the main themes and sub-themes identified along with direct quotations from the interviews for each theme followed by a letter and a number to identify each coded participant (indicated by a ‘P’).

Table 5.1 Main themes (related to pain and dietary change) and sub-themes from the interview analysis

1. Issues related to pain experience	2. Issues related to dietary change
The experience of pain	Difficulties in eating and chewing
Duration of pain	The amount of food eaten
Use of analgesics	Food items couldn't be eaten
Time of the day	Food items eaten more
Site of pain	Dietary changes due to orthodontist advice
	Eating healthier diet

5.1.1 Patient experiences relating to pain

This theme was subdivided into: pain experience, duration, intensity, site, use of analgesics and time of day.

In response to questions related to these sub-themes, all patients reported pain and discomfort during the first few days after appliance placement, after which it lessened and patients got used to it.

"In the first 3 days it was hurting my cheeks because it kept on scratching on them, but then after a while I got used to it and it was alright" **(P8).**

Pain duration ranged from a day up to 2 weeks. However, seven patients reported that pain levels decreased during the first few days and only three patients reported a longer duration of pain.

"Yeah, on the first day it really hurt, on the 2nd, 3rd and 4th day started to get used to it but you still can feel little aches and pains now and again" **(P2).**

Patients reported varying degrees of pain level ranging from mild to severe. In some cases the pain was intolerable and frustrating.

"Hurtful. I get like swelling in, you know, my gums. It just a lot so, I feel like, you know, really like angry because I can't do anything about the pain and stuff" **(P9).**

The site of the pain in the mouth was variable but mainly localized to the teeth. A few patients reported pain in the soft tissues (cheeks and gums).

"The very back teeth as the wire that goes through the base has kept on scratching at my cheeks. Yeah, that's the only part mostly" **(P8).**

Three patients used pain control.

"Yeah I had to take Nurofen because it was hurting me" **(P4).**

Generally, patients reported the pain was most severe in the mornings although three patients reported pain throughout the whole day or when eating hard food types.

"After you get the braces you get the pain early in the morning when you wake up, yeah your jaw really hurts in the morning" **(P4).**

5.1.2 Patient experiences relating to dietary changes

This theme was divided into: difficulties in eating and chewing, amount of food eaten, food items that could not be eaten or were eaten more, changes in dietary behaviour due to their orthodontist's advice and eating healthier diet.

In response to questions related to these sub-themes, nine patients reported difficulty in eating hard foods, particularly in relation to biting and chewing. Three patients reported difficulties due to food getting stuck in their brace which was then uncomfortable for them.

"Like I can't eat any hard foods. I can only have soft foods" **(P3)**

The majority of patients reported that their diet had changed and they were eating less, changing what they ate or changed the method of preparation of food (i.e. cutting food into smaller pieces).

"Yeah, a lot, because I can't chew properly and stuff. I can't swallow. It affects my diet and stuff" **(P9).**

The most common food items patients reported avoiding were apples, carrots, crisps, chocolate bars, meat dishes, nuts, toffees, gums, crackers and corn on the cob. The majority of patients moved to soft diet because it was easier to chew and less painful.

"Chip potatoes, crisp hard crunchy stuff and like hard vegetables that have to be boiled and chewy stuff you can't eat" "Corn on cob and chewing gum" **(P4)**.

The most common food items which were consumed in greater quantity/frequency were mashed dishes, rice, pasta, bananas, soups, cheese, water, juices, boiled vegetables and milk.

"Soups and stuff like that. I never used to like them, but now I feel hungry and grab a soup, yeah" **(P8).**

Eight patients reported that they were influenced by dietary instructions given to them by their orthodontist and avoided eating certain food types, in particular, sweet foods, toffee, chewing gum, 'junk' and fizzy drinks.

"Yeah. She gave me a list of things and 'do's and 'don't's and I stick to them because I don't want to have messed up teeth once they're sorted, like stains and stuff so I have to stick to them" **(P8).**

Interestingly, seven patients reported that their diet was healthier due to eating fewer snacks, eating healthier food and maintaining good oral hygiene by avoiding high sugar content foods.

"Yeah it's changed because I have to eat softer foods and that, but it's better. I don't eat a lot of junk because it gets stuck in my mouth" **(P4).**

5.2 The quantitative study

This part will be divided into the following sections:

5.2.1 Response rate, dropouts and final sample size

5.2.2 Validation of the study scales

5.2.3 Description of the sample

5.2.4 Comparison between both groups with respect to changes in outcome variables at follow-up periods

5.2.5 Dietary behaviours in the test group

5.2.6 Pain levels in the test group during the study periods

5.2.7 Relationship between independent variables and changes in the dependent variables in the test group

5.2.8 Multivariable analysis

5.2.9 Correlations between the study's outcome variables

5.2.10 Summary of the findings

5.2.1 Response rate, dropouts and final sample size

The present study invited 128 patients to participate. Only 4 refused to take part, giving a 96.8% response rate. One hundred and twenty four patients were therefore recruited to the study. However, a further 15 patients (12.1%) dropped out or were excluded from further analysis (9 from the test group and 6 from the control group).The reasons for this were: patients giving incomplete records during the study period or missing their appointments (11 patients), patients who were given appointments beyond the study's follow up periods (long appointments; 3 patients) and unknown reasons (1 patient).

The final sample size comprised 109 patients (53 in the test group; 56 in the control group). There were no missing data at the study's follow-up periods as the researcher checked each questionnaire completed immediately and identified any missing or unclear data with the patient. With respect to the pain diary, patients who gave incomplete diaries were excluded from further analysis.

The mean (SD) duration of time until the first follow up (4-6 weeks) for the test and control groups was 39.45 (SD 5.5) and 36.25 (SD 6) days; respectively. The mean duration of time until the second follow up (at 3 months) was 87.60 (SD 6.7) and 86.47 (SD 6.4) days, respectively. There was no significant difference in the duration of follow up times between both groups (Table 5.2).

Table 5.2 Mean duration of the study follow up periods in the test (n=53) and control (n=56) groups.

	Mean (SD) (Days)	95% CI	P Value
Time until 1st follow-up			
Test group	39.45 (5.52)	-0.5-7.9	0.112
Control group	36.25 (5.96)		
Time until 2nd follow-up			
Test group	87.60 (6.7)	-3.5-5.9	0.616
Control group	86.47 (6.4)		

5.2.2 Validation of the study scales

The validation methods used in this study for questionnaires included internal consistency and intraclass reliability (test-re-test reliability). Internal consistency was performed on the supplementary questionnaire and the Child Perception Questionnaire (CPQ11-14) whilst intraclass reliability was performed on CPQ11-14 and FFQ. Internal consistency for the supplementary questionnaire and CPQ11-14 was 0.77 and 0.84, respectively. Intraclass reliability coefficients for CPQ11-14 and FFQ were 0.96 and 0.93, respectively.

Intra-examiner reliability for measuring height, weight and fat percentage revealed to be very good. Intraclass reliability coefficients for height, weight, fat percentage and VAS scores were 0.98, 1, 0.97 and 1 respectively. In addition, the results of paired t

tests showed no significant differences (P>0.05) between any set of repeated measurements, indicating no evidence of systematic effects.

5.2.3 Description of the sample

5.2.3.1 Socio-demographic characteristics

The sample included 109 patients (53 in the test group and 56 in the control group). The majority were females 65 (59.6%). The mean age of the sample was 13.1 (SD 0.91) and included patients of diverse ethnic backgrounds. According to the recommendations of the UK Census (2001), ethnicity was collapsed into 5 major groups: namely, White, Asian, Black, Mixed and Other ethnic background. In the present study, Asians and Whites were the most ethnic backgrounds followed by the Blacks 40.4%, 39.4% and 14.7%, respectively.

Almost 82% of patients lived with both parents, 20% lived with unemployed parents and 83% lived in non crowded houses. Eighty per cent of patients' parents owned one car or more, 60% of patients lived in owned houses and all patients had access to internet.

Except for house ownership (socio-economic indicator), both groups had similar socio-demographic characteristics with no significant difference in any variable, indicating almost comparable groups (Table 5.3). Therefore, socio-demographic variables were excluded from further analysis except for house ownership indicator.

Table 5.3 Socio-demographic characteristics of the sample (n=109).

	Test group (N=53)	Control group (N=56)	Overall (N=109)	P Value
Age, Mean (SD)	13.14 (0.78)	12.91 (0.94)	13.10 (0.91)	0.290
Male, n (%) Female, n (%)	25 (47.2%) 28 (52.8%)	19 (33.9%) 37 (66.1%)	44 (40.4%) 65 (59.6%)	0.225
White, n (%) Asian, n (%) Black, n (%) Mixed, n (%) Other, n (%)	17 (32.1%) 21 (39.6%) 11 (20.8%) 3 (5.7%) 1 (1.9%)	26 (46.4%) 23 (41.1%) 5 (8.9%) 2 (3.6%) 0 (0%0	43 (39.4%) 44 (40.4%) 16 (14.7%) 5 (4.6%) 1 (0.9%)	0.225
Which adult they live with Living with both parents n (%) Only father, n (%) Only mother, n (%) Neither, n (%)	 39 (73.6%) 1 (1.9%) 12 (22.6%) 1 (1.9%)	 50 (89.3%) 1 (1.8%) 5 (8.9%) 0 (0)	 89 (81.7%) 22 (1.8%) 17 (15.6%) 1 (0.9%)	0.160
Parents employment Both employed, n (%) Only father, n (%) Only mother, n (%) Both not employed, n (%)	 23 (43%) 12 (22.6%) 6 (11.3%) 12 (22.6%)	 30 (53.6%) 11 (19.6%) 5 (8.9%) 10 (17.9%)	 53 (48.6%) 23 (21.1%) 11 (10.1%) 22 (20.2%)	0.763
Crowding Yes, n (%) No, n (%)	 8 (15.1%) 45 (84.9%)	 11 (19.6%) 45 (80.4%)	 19 (17.4%) 90 (82.6%)	0.532
Car ownership Own more than 2 cars, n (%) One car only, n (%) No cars, n (%)	 17 (32.1%) 24 (45.3%) 12 (22.6%)	 24 (42.9%) 21 (37.5%) 11 (19.6%)	 41 (37.6%) 45 (41.3%) 23 (21.1%)	0.507
Home ownership Own home, n (%) Rent home, n (%) Don't know, n (%)	 25 (47.2%) 22 (41.5%) 6 (11.3%)	 40 (71.4%) 14 (25%) 2 (3.6%)	 65 (59.6%) 36 (33%) 8 (7.3%)	0.03
Access to internet Yes, n (%) No, n (%)	 53 (100%) 0 (0%)	 56 (100%) 0 (0%)	 109 (100%) 0 (0%)	0.999
Total	53	56	109	

5.2.3.2 Baseline measurements of the sample

5.2.3.2.1 Anthropometric measurements

There was no significant difference between both groups with respect to BMI and fat percentage at baseline (Table 5.4).

Table 5.4 Baseline anthropometric measurements for the sample (test group n=53 and control group n=56)

	Mean (SD)	95% CI	P Value
BMI			
Overall sample Test group Control group	20.2 (3.3) 20.6 (3.8) 19.9 (2.8)	-0.58-1.9	0.290
Fat %			
Overall sample Test group Control group	23.5 (8.9) 22.8 (9.6) 23.2 (8.2)	-2.8-3.9	0.739

5.2.3.2.2 BMI status at baseline

There was no significant difference between both groups with respect to BMI status at baseline (Table 5.5).

Table 5.5 Baseline BMI status for the sample (test n=53 and control group n=56)

	Normal weight N (%)	Overweight/obese N (%)	P value
Test group	40 (75.5 %)	13 (24.5 %)	0.875
Control group	44 (78.6 %)	12 (21.4 %)	

5.2.3.2.3 Energy and macro-nutrient intake

Data for energy and macro-nutrient intakes were not normally distributed. Therefore, non-parametric tests were employed to assess differences between both groups.

The median was presented. Table 5.6 shows that there was no significant difference between both groups with respect to energy and macro-nutrient intakes at baseline.

Table 5.6 Baseline energy and macro-nutrient intakes for the sample (test group n=53 and control group n=56)

	Median	Inter-quartile range	P Value
Energy intake (kcal)			
Test group	2976	2129-3759	0.182
Control group	2615	1893-3235	
Carbohydrates intake (gm)			
Test group	365	253-484	0.712
Control group	318	236-497	
Protein intake (gm)			
Test group	116	83-157	0.175
Control group	95	70-138	
Fat intake (gm)			
Test group	110	76-145	0.254
Control group	91	70-130	

5.2.3.2.4 Quality of life (QoL) scores

Overall quality of life (QoL) and sub-domain scores, namely: social well being (SWB), emotional well being (EWB), oral symptoms (OS) and functional limitations (FL) were similar at baseline between both groups, with no significant differences observed. This indicates that the sample was homogeneous with respect to this measure (Table 5.7). The median is presented as data were not normally distributed.

Table 5.7 Baseline overall OH-QoL and sub-domains scores for the sample (test group n=53 and control group n=56)

	Median	Inter-quartile range	P Value
Overall score			
Test group	28	18-32	0.825
Control group	26	20-37	
SWB domain scores			
Test group	4	2-7	0.731
Control group	6	3-11	
EWB domain scores			
Test group	5	2-7	0.221
Control group	5	2-10	
OS domain scores			
Test group	7	3-8	0.08
Control group	5	3-7	
FL domain scores			
Test group	7	3-10	0.664
Control group	6	4-8	

5.2.4 Comparison between both groups with respect to changes in outcome variables at follow-up periods

5.2.4.1 Changes in anthropometric measurements

Table 5.8 shows that changes in BMI between baseline and 4-6 weeks and 3 months follow-up periods in both groups were insignificant. However, BMI in the test group dropped whilst an increase in the control group was seen. BMI decreased between baseline and 4-6 week follow-up period in the test group (-0.03) whilst it increased in the control group. Following this, in the second follow-up period (between 4-6 weeks and 3 months) BMI in the test group started to increase. This indicates that that the main drop in BMI during the study period occurred during the first month and after that the test group started to resume normal growth between the 4-6 weeks and 3 month follow-up period (Table 5.8).

With respect to fat percentage changes, there was significant difference between both groups at baseline and 4-6 weeks and baseline and 3 months ($P<0.001$; $P<0.001$, respectively). However, the corresponding size effects of differences between both groups at both periods were low (0.14 and 0.2, respectively). Fat percentage decreased in the test group significantly ($P<0.001$) whilst increased in the control group. However, the main decrease in fat percentage in the test group occurred during the first month (-2.4%) and little drop was observed after that (-0.3) (Table 5.8).

However, after controlling for BMI status at baseline (normal/overweight or obese), the difference in fat percentage changes between both groups was insignificant ($P<0.156$). This means that changes in fat between both groups were confounded by BMI status at baseline. There was no change in BMI statistics between both groups, after controlling for BMI status at baseline.

Overall, the decrease observed in BMI and fat percentage in the test group followed a similar trend. Most of the decrease in both parameters occurred during the first month of treatment.

Table 5.8 Changes in BMI and fat % in both groups during the study periods (test group n=53 and control group n=56)

Change	baseline and 4-6 weeks				baseline and 3 months				4-6weeks and 3 months			
	Mean	95%CI	P value	*Effect size*	Mean	95%CI	P value	*Effect size*	Mean	95%CI	P value	*Effect size*
BMI												
Test group	-0.03	-0.3-0.03	0.147	0.02	-0.01	-0.63-0.03	0.122	0.02	0.02	-0.02-0.08	0.624	.002
Control group	0.25				0.36				0.11			
Fat %												
Test group	-2.4*	-4.8- -1.5	0.001	0.14	-2.7*	-5.3- -2.4	0.001	0.2	-0.3	-2.3-0.3	0.116	0.02
Control group	0.4				1.1				0.7			

P value obtained from ANCOVA test to assess differences between groups adjusted for baseline measurements and physiological growth for BMI values
* Paired t statistics were significant, indicating within group changes over time

5.2.4.2 Changes in energy and macro-nutrient intakes (carbohydrates, protein and fat)

There was no significant difference between both groups with respect to energy and macronutrient intakes, although there was a greater reduction in dietary intake in the test group. However, changes after that were almost similar in both groups at 3 month follow-up period (Table 5.9).

Table 5.9 Changes in energy and macronutrient intakes in both groups during the study periods (test group n=53 and control group n=56)

Change	baseline and 4-6 weeks				baseline and 3 months				4-6weeks and 3 months			
	Mean	95%CI	P value	*Effect size*	Mean	95%CI	P value	*Effect size*	Mean	95%CI	P value	*Effect size*
Energy intake												
Test group	-442.2	-478-753	0.670	0.002	-510.5	-578-683	0.743	0.001	-68.3	-693-524	0.924	.000
Control group	-304.7				-457.7				-153			
Carbohydrate intake												
Test group	-120.6	-76-117	0.644	0.002	-124	-87-115	0.763	0.001	-3.6	-81-67	0.963	.000
Control group	-100				-110				-10.3			
Protein intake												
Test group	-24	-32-30	0.204	0.01	-36	-41-35	0.442	.006	-12	-39-35	0.432	0.006
Control group	-23.2				-33.3				-10.1			
Fat intake												
Test group	-28.7	-29-32	0.755	0.001	-35.9	-37-29	0.788	0.001	-7.2	-31-21	0.908	.000
Control group	-27.7				-31.1				-4.4			

P value obtained from ANCOVA test to assess differences between groups adjusted for baseline measurements

5.2.4.3 Changes in total QoL and sub-domain scores

There was significant difference in total QoL scores between both groups, at baseline and 4-6 weeks and baseline and 3 months ($P<0.012$; $P<0.015$, respectively). Total QoL scores in the control group decreased significantly at 4-6 weeks and 3 months whilst no significant changes in the test group were observed (Table 5.10). This indicates that QoL improved in the control group during the study period. In relation to the emotional well being (EWB) domain, there was no

significant difference between both groups at 4-6 weeks and 3 months. However, EWB scores increased significantly within each group at 4-6 weeks and 3 months. This indicates that EWB improved significantly in both the test and control groups during the treatment (Table 5.10). For the social well being (SWB) domain, there was no significant difference between both groups at 4-6 weeks but it was significant between baseline and 3 months mainly due to significant decrease in SWB scores in the control group (Table 5.10). For oral symptoms (OS) and functional limitation (FL) domains there was significant difference between both groups at 4-6 weeks and 3 months. OS scores in the test group increased significantly during the first month indicating worsening of this domain during this period. FL scores in the control group decreased significantly during the first month indicating improvement in this domain at this period. For other time points there was no significant change in OS and FL within each group (Table 5.10).

Table 5.10 Changes in total QoL and sub-domain scores in both groups during the study periods (test group n=53 and control group n=56)

Change	baseline and 4-6 weeks				baseline and 3 months				4-6weeks and 3 months			
	Mean	95%CI	P value	*Effect size*	Mean	95%CI	P value	*Effect size*	Mean	95%CI	P value	*Effect size*
Overall score												
Test group	0.4	1-9.1	0.012	0.06	0.2	1-9.5	0.015	0.055	-0.2	-2.8-3.36	0.588	0.003
Control group	-4.6*				-5.2*				-0.67			
EWB												
Test group	-1.54*	-1.3-1.8	0.855	0.00	-1.77*	-1.4-1.8	0.795	0.001	-0.23	-1.18-1.12	0.766	0.001
Control group	-1.78*				-1.98 *				-0.2			
SWB												
Test group	0.3	1.1-0.86	0.204	.01	0.02	0.13-3.4	0.035	0.041	-0.28	-1-1.9	0.304	0.01
Control group	-0.82				-1.57*				-0.75			
OS												
Test group	0.83*	0.52-2.6	0.001	0.125	0.88	0.05-2.3	0.005	0.072	0.05	-1.2-0.56	0.718	0.001
Control group	-0.73*				-0.32				0.41			
FL												
Test group	0.81	0.5-3.6	0.002	0.086	1.1	0.86-4.1	0.001	0.107	0.3	0.65-1.4	0.128	0.022
Control group	-1.26*				-1.37*				-0.11			

P value obtained from ANCOVA test to assess differences between groups adjusted for baseline measurements

* Paired t statistics were significant, indicating within group changes over time

5.2.5 Dietary behaviours in the test group

In this section, changes in dietary behaviour scores in the test group along with frequency distribution of responses to each item obtained from the supplementary questionnaire at 4-6 week and 3 month follow-up periods will be presented. Data were not normally distributed. Hence, median values and non-parametric tests were used to assess changes between both periods.

There was significant difference in dietary behaviour scores between both periods (P<0.002). Median scores decreased significantly in the second (3 month) period of follow-up. This indicates that there were less dietary behavioural impacts in the second period compared to the first (4-6 week) period of follow-up (Table 5.11).

Table 5.11 Changes in dietary behaviour in the test group (n=53) during the study periods

	Dietary behaviour score at 4-6 weeks (n=53)	Dietary behaviour score at 3 months (n=53)	P value (Difference between 2 periods)
Median score	32	29	0.002

P value obtained from Wilcoxon test

Frequency distribution of responses to items of the supplementary questionnaire was divided into three parts: Likert format items, items for foods that were difficult to eat and items for foods that were eaten more.

5.2.5.1 Frequency distribution of responses to items of the Likert format

Table 5.12 shows the frequency distribution of responses to Likert scale items. To simplify interpretation of results, responses for the Likert format items were collapsed into 3 options; strongly disagree/disagree, neutral and strongly agree/agree.

Two thirds of patients (66%) agreed that pain had caused them difficulty in eating and/or chewing during the first period (Question 1). Only 9 (17%) said that they

disagreed. However, the number of patients who agreed in the second period dropped to 29 (54.7%).

In both follow-up periods, the majority of patients agreed that the braces hurt during the first week (Question 2), 49 (92.4%) and 46 (86.8%), respectively. Twenty eight patients (52.9%) agreed that braces hurt during the second week (Question 3) in the first period and 21 (39.6%) in the second period. However, in the third and forth week, the majority of patients disagreed that braces has hurt them in both periods (Questions 4 and 5). Only 5 (9.4%) patients agreed that braces hurt in the third week and 2 (3.8%) in the fourth week during the first period. In the second period, 4 patients (7.6%) agreed that braces hurt in the third week and one patient (1.9%) in the fourth week.

Twenty nine patients (54.7%) agreed that they ate less snacks and ate less food compared to before treatment (Questions 6, 7). However, this number decrease to 21 (39.6%) for eating less snacks and 19 (35.9%) for eating less food compared to before treatment in the second period.

Almost half of the patients (49.1%) agreed that they had to cut their food into pieces or cooked in a different way during the first period and 22 (41.5%) in the second period (Question 8).

In both follow-up periods, the majority of patients agreed that they ate less sticky food because it gets stuck in their braces, 79.3% and 75.5%, respectively (Question 9). Two thirds of the patients in the first period and almost half of the patients in the second period agreed that they ate less sticky food/sweet because they were asked by their doctors (Questions 10). Thirty one patients (58.5%) in the first period agreed that they ate less hard food because they were to do so by their doctors and 29 (54.7%) agreed in the second period (Question 11).

Finally, almost two thirds of patients (64.2%) in the first period and more than half of the patients (56.6%) in the second period disagreed that the braces resulted in them

eating less healthy. Only 9 patients in the first period and 10 patients in the second period agreed that they ate less healthy (Question 12).

Table 5.12 Frequency distribution of responses to items of Likert format of the supplementary questionnaire in the test group (n=53) during the study periods

Item	At 4-6 weeks N, (%)	At 3 months N, (%)
Question 1		
Strongly disagree/disagree	9, (17%)	12, (22.7%)
Neutral	9, (17%)	12, (22.6%)
Strongly agree/agree	35, (66%)	29, (54.7%)
Question 2		
Strongly/disagree/disagree	2, (3.8%)	3, (5.7%)
Neutral	2, (3.8%)	4, (7.5%)
Strongly agree/agree	49, (92.4%)	46, (86.8%)
Question 3		
Strongly disagree/disagree	10, (18%.9)	12, (22.6%)
Neutral	15, (28.3%)	20, (37.7%)
Strongly agree/agree	28,(52.9%)	21, (39.6%)
Question 4		
Strongly disagree/disagree	38, (71.7%)	34, (64.2%)
Neutral	10, (18.9%)	15, (28.3%)
Strongly agree/agree	5, (9.4%)	4, (7.6%)
Question 5		
Strongly disagree/disagree	44, (83%)	45, (84.9%)
Neutral	7, (13.2%)	7, (13.2%)
Strongly agree/agree	2, (3.8%)	1, (1.9%)
Question 6		
Strongly disagree/disagree	9, (17%)	15, (28.3%)
Neutral	15, (28.3%)	17, (32.1%)
Strongly agree/agree	29, (54,7%)	21, (39.6%)
Question 7		
Strongly disagree/disagree	17, (32.1%)	19, (35.8%)
Neutral	7, (13.2%)	15, (28.3%)
Strongly agree/agree	29, (54.7%)	19, (35.9%)
Question 8		
Strongly disagree/disagree	18, (33.9%)	19, (35.8%)
Neutral	9, (17.0%)	12, (22.6%)
Strongly agree/agree	26, (49.1%)	22, (41.5%)
Question 9		
Strongly disagree/disagree	1, (1.9%)	8, (15.1%)
Neutral	10, (18.9%)	5, (9.4%)
Strongly agree/agree	42, (79.3%)	40, (75.5%)

Question 10		
Strongly disagree/disagree	9, (17%)	13, (24.5%)
Neutral	9, (17%)	14, (26.4%)
Strongly agree/agree	35, (66%)	26, (49.0%)
Question 11		
Strongly disagree/disagree	10, (18.9%)	16, (30.2%)
Neutral	12, (22.6%)	8, (151%)
Strongly agree/agree	31, (58.5%)	29, (54.7%)
Question 12		
Strongly disagree/disagree	34, (64.2%)	30, (56.6%)
Neutral	10, (18.9%)	13, (24.5%)
Strongly agree/agree	9, (17%)	10, (18.9%)

5.2.5.2 Frequency distribution of responses to items for foods/drinks that were anticipated to be difficult to eat

In the first period, the majority of patients reported that they ate with difficulty/couldn't eat apples, carrots, corn on cob and toffees/chewing gums, 71.7 %, 60.4 %, 62.3 % and 71.7 %, respectively (Questions 13, 14, 15 and 22). In the second period, these percentages dropped down to 64.2 %, 52.8 %, 56.6 % and 66 %, respectively (Table 5.13). For other foods, almost half of the patients (49.1 %) reported that they ate with difficulty/couldn't eat nuts in the first period and one third in the second period (Question 18). Twenty four patients (45.3 %) couldn't eat chocolates and sweets in the first period and 16 (30.2 %) in the second period (Question 21). Almost one third couldn't eat crackers in both periods (Question 16). For meat dishes, it was 17 (32.1 %) in the first and 15 (28.3 %) in the second period (Question 20). Almost one quarter of the patients (24.5 %) couldn't eat salads in the first period but this dropped to 6 patients (11.3%) in the second period (Question 17). Twelve patients (22.6 %) reported that they drank less pop/fizzy drinks in the first and 10 patients (18.9%) in the second period (Question 23; Table 5.13).

Table 5.13 Frequency distribution of responses to items for foods that were anticipated to be difficult to eat in the test group (n=53) during the study periods

Item	At 4-6 weeks N, (%)	At 3 months N, (%)
Question 13		
Ate as usual	15, (28.3%)	19, (35.8%)
Ate with difficulty/couldn't eat	38, (71.7%)	34, (64.2%)
Question 14		
Ate as usual	21, (39.6%)	25, (47.2%)
Ate with difficulty/couldn't eat	32, (60.4%)	28, (52.8%)
Question 15		
Ate as usual	20, (37.7%)	23, (43.4%)
Ate with difficulty/couldn't eat	33, (62.3%)	30, (56.6%)
Question 16		
Ate as usual	33, (62.3%)	36, (67.9%)
Ate with difficulty/couldn't eat	20, (37.7%)	17, (32.1%)
Question 17		
Ate as usual	40, (75.5%)	47, (88.7%)
Ate with difficulty/couldn't eat	13, (24.5%)	6, (11.3%)
Question 18		
Ate as usual	27, (50.9%)	36, (67.9%)
Ate with difficulty/couldn't eat	26, (49.1%)	17, (32.1%)
Question 19		
Ate as usual	44, (83.0%)	44, (83%)
Ate with difficulty/couldn't eat	9, (17.0%)	9, (17%)
Question 20		
Ate as usual	36, (67.9%)	38, (71.7%)
Ate with difficulty/couldn't eat	17, (32.1%)	15, (28.3%)
Question 21		
Ate as usual	29, (54.7%)	37, (69.8%)
Ate with difficulty/couldn't eat	24, (45.3%)	16, (30.2%)
Question 22		
Ate as usual	15, (28.3%)	18, (34%)
Ate with difficulty/couldn't eat	38, (71.7%)	35, (66%)
Question 23		
Drank as usual	12, (22.6%)	10, (18.9%)
Drank less	41, (77.4%)	43, (81.1%)

5.2.5.3 Frequency distribution of responses to items for foods/drinks that were anticipated to be eaten more

The majority of patients reported that they ate the following food items as usual: rice and pasta dishes, chips and burgers in both periods (Questions 24 and 26; Table 5.14). One third of the patients (34 %) reported that they drank water more than usual during the first period. This percentage dropped down to 28.3 % in the second period (Question 30). Almost one quarter of the patients reported that they ate/drank the following food/drink items more than usual during the first period: mashed dishes, bananas, soups and juices. This percentage dropped in the second period to 15.1 %, 3.8 %, 20.8 % and 15 %, respectively (Questions 25, 27, 29 and 31). Eleven patients (20.8 %) reported that they ate more soft and boiled vegetables during the first period. This percentage dropped to (9.4 %) during the second period (Question 28; Table 5.14).

Table 5.14 Frequency distribution of responses to items for foods/drinks that were anticipated to be eaten/drunk more in the test group (n=53) during the study periods

Item	At 4-6 weeks N (%)	At 3 months N (%)
Question 24		
Ate as usual	47, (88.7%)	47, (88.7%)
Ate more	6, (11.3%)	6, (11.3%)
Question 25		
Ate as usual	41, (77.4%)	45, (84.9%)
Ate more	12, (22.6%)	8, (15.1%)
Question 26		
Ate as usual	50, (94.3%)	47, (88.7%)
Ate more	3, (5.7%)	6, (11.3%)
Question 27		
Ate as usual	40, (75.5%)	51, (96.2%)
Ate more	13, (24.5%)	2, (3.8%)
Question 28		
Ate as usual	42, (79.2%)	48, (90.6%)
Ate more	11, (20.8%)	5, (9.4%)
Question 29		
Ate as usual	39, (73.6%)	42, (79.2%)
Ate more	14, (26.4%)	11, (20.8%)
Question 30		
Ate as usual	35, (66.0%)	38, (71.7%)
Ate more	18, (34.0%)	15, (28.3%)
Question 31		
Ate as usual	41, (77.4%)	45, (84.9%)
Drank more	12, (22.6%)	8, (15.1%)
Question 32		
Ate as usual	42, (79.2%)	46, (86.8%)
Drank more	11, (20.8%)	7, (13.2%)

5.2.6 Pain levels in the test group during the study periods

Because nearly all patients in the control group didn't experience pain or difficulty in chewing, results for the test group are presented only. Data for pain scores were not normally distributed. Therefore, the median is presented and non parametric tests were employed. Pain scores for the 2 periods in which patients were given pain

diaries are presented these were baseline to 4-6 weeks and 4-6 weeks to 3 months, respectively (Tables 5.15-16).

Pain intensities from teeth and pain from biting and chewing declined significantly on day 3 in the first period and on day 2 in the second period when compared to baseline (day 1; (P<0.001 and P<0.001, respectively). This decline continued in subsequent time points when compared to day 1.This indicates that adaptation to pain took place after 3 days in the first period and after 2 days in the second period. When comparing between the same individual time point in the 2 periods, pain levels in the second period declined. However, this decline was not significant in relation to pain intensities from the teeth but was significant in relation to pain intensities from biting and chewing except for Day 1. In the first period, pain was reported in all time points except the 3rd and 4th week whilst in the second period it was reported in all time points except the 2nd, 3rd and 4th week (Tables 5.15-16).

Table 5.15 Median pain intensities from teeth in the test group (n=53) during the study periods at all time points compared to day 1

Time points	First period (Between baseline and 4-6 weeks) Median	Second period (Between 4-6 weeks and 3 months) Median	P value (between both periods)
Day 1	54	51	0.204
Day 2	48	42 *	0.184
Day 3	34 *	30 *	0.156
Day 4	25 *	24 *	0.108
Day 5	15*	14 *	0.125
Day 6	9 *	7 *	0.132
Day 7	7 *	3 *	0.100
Week 2	4*	0	0.060
Week 3	0	0	-
Week 4	0	0	-

* (P < 0.001) obtained from Wilcoxon test between each individual time point in each period and Day 1.

Table 5.16 Median pain intensities from biting and chewing in the test group (53) during the study periods at all time points compared to day 1

Time points	First period (Between baseline and 4-6 weeks) Median	Second period (Between 4-6 weeks and 3 months) Median	P value (between both periods)
Day 1	65	62	0.124
Day 2	65	47 *	0.001
Day 3	53 *	35 *	0.001
Day 4	38 *	26 *	0.001
Day 5	23 *	17 *	0.001
Day 6	15 *	9 *	0.001
Day 7	11 *	4 *	0.001
Week 2	4 *	0	0.001
Week 3	0	0	-
Week 4	0	0	-

* ($P < 0.001$) obtained from Wilcoxon test between each individual time point in each period and Day 1.

5.2.6.1 Frequency of analgesic consumption in the test group during the study periods

The total number of patients who consumed analgesics at any point during the first and second periods was 33 and 15; respectively. In the first period, the number of patients who reported consuming analgesics in the first day was 28 (52.8%). However, this number decreased in the following days reaching 3 patients only in the second week (Table 5.17). In the second period, the number of patients who reported taking analgesics in the first day dropped to 14 (26.4%). This number decreased further in the following days (Table 5.17). The number of patients who consumed analgesics in both periods was 13 (24.5%).

Table 5.17 Frequency of analgesic consumption in the test group (n=53) during the study periods

Time points	First period (Between baseline and 4-6 weeks) N, (%)	Second period (Between 4-6 weeks and 3 months) N, (%)
Day 1	28, (52.8%)	14, (26.4%)
Day 2	22, (41.5%)	6, (11.3%)
Day 3	13, (24.5%)	4, (7.5%)
Day 4	7, (13.2%)	2, (3.8%)
Day 5	5, (9.4%)	1, (1.9%)
Day 6	4, (7.5%)	1, (1.9%)
Day 7	3, (5.7%)	-
Week 2	3, (5.7%)	-
Week 3	-	-
Week 4	-	-

5.2.7 Relationship between independent variables and changes in the dependant variables in the test group

Comparisons between both test and control groups revealed that there was significant difference between both test and control groups with respect to changes in fat percentage, unadjusted for BMI status at baseline, oral symptoms (OS) domain and functional limitation (FL) domain during the first period of the study (baseline- 4-6 weeks). Fat percentage decreased in the test group by 2.4% whilst OS and FL domains increased by 0.8 and 1.1, respectively. In the second period (4-6 weeks – 3 months), there was no significant difference between both groups with respect to changes in all outcome variables indicating that most of changes occurred during the first period. Therefore, this section will explore the effect of the study's explanatory variables: namely, pain from biting and chewing, analgesic consumption, dietary instructions given to patients by their orthodontist and BMI status at baseline on changes in fat percentage, OS and FL domains in the first period, in the test group. In addition, the effects of the aforementioned explanatory variables on dietary behaviour scores at 4-6 weeks will be explored. The aim was to identify independent variables to be entered in the multiple regression model to explain changes in the aforementioned outcome variables during the first period.

5.2.7.1 The relationship between related independent variables and changes in fat percentage

This section will examine the association between the related independent variables: namely, pain from biting and chewing, analgesic consumption, dietary instructions given to patients by their orthodontist and BMI status at baseline with changes in fat percentage. In addition, the association between the non-related independent variables: namely, treatment approach and house ownership socioeconomic indicator with changes in fat percentage will be examined.

5.2.7.1.1 The relationship between pain from biting and chewing and changes in fat percentage

Pain from biting and chewing was determined by calculating the average pain reported in all time points during the first period of the study. The result of univriate simple linear regression showed that there was a significant negative relationship between average pain and changes in fat % at the 0.2 level (P<0.106). The higher the pain the greater the drop in fat % (Table 5.18).

Table 5.18 Relationship between pain from chewing and biting and changes in fat % in the test group (n=53) during the first period

Independent variable	Dependant variable (changes in fat %)		
	B-value	(95%CI)	P value
Pain from biting and chewing	-0.006	(-0.013 - 0.001)	0.106

5.2.7.1.2 The relationship between analgesic consumption and changes in fat percentage

Independent t tests showed that there was no significant difference in changes in fat percentage between patients who consumed analgesics and those who did not, at the 0.2 level (P= 0.588; Table 5.19).

Table 5.19 Relationship between analgesic consumption and changes in fat % in the test (n=53) group during the first period

	Changes in fat %	P value
Consumed analgesic (n=33)	-2.37	0.588
Didn't consume analgesic (n=20)	-2.50	

5.2.7.1.3 The relationship between dietary instructions given by orthodontists to patients and changes in fat percentage

Independent t tests showed that there was no significant difference between patients who were influenced by dietary instructions given to them by their orthodontists and those patients who were not influenced (P = 0.524; Table 5.20).

Table 5.20 Relationship between dietary instructions and changes in fat % in the test group (n=53) during the first period

	Changes in fat %	P value
Influenced (n=33)	-2.15	0.524
Not influenced (n=20)	-2.86	

5.2.7.1.4 The relationship between BMI at baseline and changes in fat percentage

Mann Whitney U tests showed that there was a significant relationship between BMI status at baseline and changes in fat % at the 0.2 level (Table 5.21). Overweigh/obese patients dropped more fat percentage compared to normal weight patients (P = 0.107).

Table 5.21 Relationship between BMI status at baseline and changes in fat % in the test group (n=53) during the first period

BMI status at baseline	Changes in fat % Mean rank	P value
Normal (n=40)	29	0.107
Overweight/Obese (n=13)	21	

5.2.7.1.5 The relationship between house ownership and changes in fat percentage

House ownership was the only socioeconomic indicator that was significantly different between both groups (See Table 5.3). Therefore, it was included in the univariate analysis as an independent non-related variable. One-way analysis of variance (ANOVA) showed no significant difference between all categories of house ownership variable (P = 0.652; Table 5.22).

Table 5.22 Relationship between house ownership and changes in fat % in the test group (n=53) during the first period

	Changes in fat %	P value
Own it (n=25)	0.24	0.652
Rent it (n=22)	1.72	
Don't know (n=6)	-3.25	

5.2.7.1.6 The relationship between treatment approach and changes in fat percentage

Independent t test showed that there was no significant difference in changes in fat percentage between patients who had extraction treatment and non-extraction treatment (P = 0.749; Table 5.23).

Table 5.23 Relationship between treatment approach and changes fat % in the test group (n=53) during the first period

		Changes in fat %	P value
Extraction	(n=30)	-2.27	0.749
Non extraction	(n=23)	-2.62	

5.2.7.2 The relationship between independent variables and oral symptoms and functional limitations domains

Univariate analysis showed that there was no significant relationship between the study's independent variables and OS and FL domains, at the 0.2 level. Therefore, multiple regression analysis was not performed for both domains as it would appear that there are other factors that might influence both domains.

5.2.7.3 The relationship between independent variables and dietary behaviour scores

This section will examine the association between the related independent variables: namely, pain from biting and chewing, analgesic consumption, dietary instructions given to patients by their orthodontist and BMI status at baseline with dietary behaviour scores. In addition, the association between the non-related independent variables: namely, treatment approach and house ownership socioeconomic indicator with dietary behaviour scores will be examined.

5.2.7.3.1 The relationship between pain form biting and chewing and dietary behaviour scores

Simple linear regression showed that there was a significant positive relationship between pain from biting and chewing and dietary behaviour scores at 0.2 level (P = 0.049).The higher the pain the higher the dietary behaviour score (Table 5.24).

Table 5.24 Relationship between pain from biting and chewing and dietary behaviour in the test group (n = 53) during the first period

Independent variable	Dependant variable (dietary behaviour)		
	B-value	(95%CI)	P value
Pain from biting and chewing	0.14	(-0.001 - 0.295)	0.049

5.2.7.3.2 The relationship between analgesic consumption and dietary behaviour scores

Mann-Whitney U tests showed that there was a significant difference in dietary behaviour scores between patients who consumed analgesics and those that did not at 0.2 level (P = 0.049). Patients who consumed analgesics had higher dietary behaviour scores compared to patient who did not (Table 5.25).

Table 5.25 Relationship between analgesic consumption and dietary behaviour in the test group (n=53) during the first period

	Dietary behaviour Mean rank	P value
Consumed analgesic (n=33)	30.24	0.049
Didn't consume analgesic (n=20)	21.65	

5.2.7.3.3 The relationship between dietary instructions given by orthodontists to patients and dietary behaviour scores

Mann-Whitney U tests showed that there was a significant difference in dietary behaviour scores between patients who were influenced by dietary instructions given to them by their orthodontists and those who were not (P = 0.062). Patients who were influenced by their orthodontist had higher scores compared to those who weren't influenced (Table 5.26).

Table 5.26 Relationship between dietary instructions and dietary behaviour in the test group (n=53) during the first period

	Dietary behaviour (Mean rank)	P value
Influenced (n=33)	30.1	0.062
Not influenced (n=20)	22.0	

5.2.7.3.4 The relationship between BMI at baseline and dietary behaviour scores

Mann Whitney U tests showed that there was a significant relationship between BMI status at baseline and dietary behaviour scores at the 0.2 level (P = 0.02). Overweight/obese patients had higher dietary behaviour scores than normal weight patients (Table 5.27).

Table 5.27 Relationship between BMI status at baseline and dietary behaviour in the test group (n=53) during the first period

BMI status at baseline	Mean rank	P value
Normal (n=40)	24.2	0.025
Overweight/Obese (n=13)	35.3	

5.2.7.3.5 The relationship between home ownership and dietary behaviour scores

The Kruskal-Wallis test showed that there was no significant relationship between house ownership and dietary behaviour scores at the 0.2 level (P = 0.369; Table 5.28).

Table 5.28 Relationship between house ownership and dietary behaviour in the test group (n=53) during the first period

		Dietary behaviour (Mean rank)	P value
Own it	(n=25)	30.08	0.369
Rent it	(n=22)	23.75	
Don't know	(n=6)	26.08	

5.2.7.3.6 The relationship between treatment approach and dietary behaviour scores

Mann-Whitney U tests showed that there was no significant difference in dietary behaviour scores between patients who had extraction and non extraction treatments at the 0.2 level (P = 0.907; Table 5.29).

Table 5.29 Relationship between treatment approach and dietary behaviour in the test group (n=53) during the first period

		Dietary behaviour (Mean rank)	P value
Extraction	(n=30)	27.22	0.907
Non extraction	(n=23)	26.72	

5.2.8 Multivariable analysis

5.2.8.1 Multivariable analysis between changes in fat percentage and independent variables

Univariate analysis between changes in fat percentage and the study's independent variables showed that pain from chewing and biting and BMI status at baseline were the only independent variables that were statistically significant at the 0.2 level (P<0.106, P<0.107; respectively). Therefore, both variables were entered into the final multiple regression model to explain changes in fat percentage.

Multiple regression analysis showed that both variables explained 12 per cent of the variance in changes of fat percentage (R^2 = 0.12). The overall significance of the model was P<0.04. However, when assessing the contribution of each independent variable individually to changes in fat percentage, BMI at baseline had a stronger contribution than pain from chewing and biting, with beta coefficient of -0.27 and -0.19, respectively. This means that BMI status at baseline was the strongest predictor of changes in fat percentage (P<0.05) compared to pain from chewing and biting (P<0.156). Overweight/obese patients dropped more fat percentage than normal weight patients (Table 5.30).

Table 5.30 Multiple regression analysis between independent variables and changes in fat % in the test group (n=53) during the first period

Model	Unstatndardised coefficients		Standardised coefficients	T	P value	Correlation	95.0 per cent confidence Interval for B	
	B	Standard Error	Beta			Part	Lower Bound	Upper Bound
Constant	4.67	2.928		1.598	0.116		-1.203	10.56
Pain	-0.049	0.034	-0.192	-1.440	0.156	-0.191	-0.117	0.019
BMI at baseline	-0.274	0.137	-0.268	-2.006	0.05	-0.266	-0.549	0.000

5.2.8.2 Multivariable analysis between dietary behaviour scores and independent variables

Univariate analysis between dietary behaviour scores and the study's independent variables showed that pain from chewing and biting, analgesics consumption, dietary instructions and BMI status at baseline were the only independent variables that were statistically significant at the 0.2 level ($P<0.049$, $P<0.049$, $P<0.062$ and $P<0.025$, respectively). Therefore, these independent variables were entered into the final multiple regression model.

Multiple regression analysis showed that the entered independent variables explained 47 per cent of the variance in dietary behaviour scores ($R^2 = 0.47$). The overall significance of the model was $P<0.016$. The model showed that the effect of the independent variables on dietary behaviour scores has decreased. However, BMI status at baseline remained significant ($P=0.049$) explaining 26 % of the variance. This means that BMI status at baseline was also an important predictor for dietary behaviour scores. Overweight/obese patient had higher dietary behaviour scores indicating more impact on their dietary behaviour due to treatment (Table 5.31).

Table 5.31 Multiple regression analysis between independent variables and dietary behaviour scores in the test group (n=53) during the first period

Model	Unstatndardised coefficients		Standardised coefficients	T	P value	Correlation	95.0 per cent confidence Interval for B	
	B	Standard Error	Beta			Part	Lower Bound	Upper Bound
Constant	26.32	2.645		9.95	0.001		21.01	31.64
Pain	0.096	0.072	0.177	1.33	0.188	0.170	-0.048	0.240
Consuming analgesics	2.34	2.31	0.137	1.01	0.317	0.129	-2.31	7.002
Dietary instructions	3.409	2.28	0.199	1.49	0.143	0.190	-1.19	8.01
BMI status at baseline	5.028	2.49	0.260	2.01	0.049	0.257	0.01	10.04

5.2.9 Correlations between the study's outcome variables

There was a significant positive correlation between changes in BMI and fat percentage ($R^2 = 0.31$, $P<0.024$). However, correlations between BMI changes and dietary intake, dietary behaviour scores, oral symptoms and functional limitation domains were weak ($R^2 = 0.07$, $R^2 = -0.16$, $R^2 = 0.01$ and $R^2 = 0.05$, respectively). In addition, correlations between fat percentage changes and dietary intake, dietary behaviour scores, oral symptoms and functional limitation were weak ($R^2 = 0.22$, $R^2 = 0.01$, $R^2 = 0.18$ and $R^2 = 0.16$, respectively). Finally, correlations between changes in dietary intake and changes in oral symptom and functional limitation domains were weak too ($R^2 = 0.2$ and $R^2 = 0.18$, respectively).

5.2.10 Summary of the findings

1. A hundred and twenty four patients were consecutively recruited into test and control groups. The response rate was 96.8 per cent and the drop out was 12.1 per cent. The total number of patients included for the analysis in the test and control groups was 53 and 56, respectively.
2. Except for house ownership, there were no significant differences between both groups in any baseline socio-demographic characteristics and baseline measurements, indicating comparable groups.
3. There were no significant differences between both groups with respect to changes in BMI in the follow-up periods. .
4. There were significant differences between both groups with respect to fat percentage changes between baseline and 4-6 weeks and 3 month-follow-up periods ($P<0.001$). However, after adjusting for BMI status at baseline, the difference was not statistically significant ($P<0.156$).
5. The decrease observed in BMI and fat percentage in the test group followed a similar trend. Most of the decrease in both variables occurred during the first period of follow-up (baseline to 4-6 weeks).
6. There were no significant differences between both groups with respect to changes in energy and macro-nutrient intakes in the follow-up periods.
7. There were a significant differences in changes in total OH-QoL scores between both groups between baseline and 4-6 weeks and 3 month-follow-up periods ($P<0.012$ and $P<0.015$; respectively). These differences were mainly due to the significant decrease in overall scores in the control group with no significant changes in the test group. For sub-domains scores, changes in oral symptoms and functional limitations domains were significant between both groups during the first period ($P<0.002$; $P<0.002$, respectively) and the second period of follow-up ($P<0.005$; $P<0.001$, respectively). Oral symptoms domain increased significantly in the test group between baseline and 4-6 weeks and 3 months. However, psychological well-being domain scores decreased significantly during the same periods. Most of the changes occurred during the first period of follow-up in the study.

8. Pain intensities from both the teeth and from biting and chewing declined significantly on day 3 in the first period and on day 2 in the second period of follow-up when compared to Day 1 ($P<0.001$ and $P<0.001$, respectively). This decline continued at subsequent time points when compared to day 1. There was a substantial decrease in the number of patients who consumed analgesics in the second period (15 patients) when compared to the first period (33 patients).
9. There were significant changes in dietary behaviour scores in the test group at 4-6 weeks and 3 months ($P<0.002$). The median score decreased significantly at 3 months when compared to scores at the 4-6 week-follow-up period.
10. Generally, the number of patients who reported having an impact on any dietary behaviour item in the supplementary questionnaire decreased at 3 months when compared to 4-6 weeks.
11. None of the study's independent variables had a significant relationship with oral symptoms and functional limitations domains at the 0.2 level.
12. Results of the multivariate analysis showed that BMI status at baseline was the only significant predictor of changes in fat percentage (%) and dietary behaviour scores ($P<0.05$; $P<0.049$, respectively). Overweight/obese patients were more likely to have high dietary scores and changes in fat percentage (%) compared to normal weight patients.
13. There was a significant positive relationship between changes in BMI and changes in fat percentage (%) ($R^2 = 0.31$, $P<0.024$). However, there was a weak correlation between the other outcome variables indicating that the majority of patients who were normal weight (n = 40) didn't experience any significant changes in their dietary intake, BMI and fat percentage (%). BMI status at baseline mediated the effect of treatment on these outcome variables.

Chapter 6

Discussion

6.1 Introduction

The present study aimed to investigate the early effects of fixed orthodontic treatment on dietary intake and behaviours, body fat, represented by body mass index (BMI) and fat percentage, and oral health quality of life (OH-QoL) by conducting qualitative and quantitative studies. In addition, the study explored possible explanatory factors that might influence dietary intake and body fat composition, namely, pain levels, dietary instructions given to patients by their orthodontists and BMI status at baseline.

6.2 Why is understanding patient experiences during orthodontic treatment important?

Medical and dental care has undergone profound changes. One of the most important changes was the advent of patient-centred care. This meant shifting from the traditional biomedical model that focuses on the identification and treatment of disease, to patients' feelings, experiences and what is involved in any intervention from the patients' perspectives. Therefore, assessing patients' expectations and experiences are central to understanding health needs, patient satisfaction with treatment and the perceived overall quality of health systems (McGrath and Bedi, 1999; Locker, 2004; Newsome and McGrath, 2006).

Whilst fixed appliance therapy is known to achieve optimal dental correction of malocclusion, further patient-centred research is needed to aid in understanding the impact of such treatment on the patient. The present study attempted to investigate and provide an insight into the effects of fixed orthodontic treatment on dietary intake and behaviour as research in this area is scarce, and limited by the recruitment of ill-defined samples; unclear methodological design; a lack of control groups and invalid dietary assessment techniques (Cheraskin and Ringdorf, 1969a, b; Riordan, 1997). Such knowledge would be a welcome addition that can help shape the process of informed consent, as well as providing patients with an insight into what they can

expect and how they can develop coping methods throughout the treatment period. These in turn may improve patient compliance with treatment and achieve more acceptable and positive treatment outcomes (Sergl *et al*., 2000; Chen *et al*., 2010). For example, several reports have suggested that informing patients about pain and discomfort during fixed orthodontic treatment may predict patients' compliance during treatment and may help them adapt to treatment procedures (Bartsch *et al.,* 1993; Sergl *et al*., 1998; Williams *et al*., 2004; Abu Alhaija *et al*., 2010). Therefore, the present study was undertaken, applying patient-centred approaches, to assess the potential impacts of fixed appliance treatment on dietary intake and behaviour. This will potentially broaden our understanding of patients' experiences and feelings which in turn, will improve the quality of care given and allow patients to be provided with reliable and realistic information about treatment as part of orthodontists' commitment to improving the overall quality of care given rather than focusing solely on clinical outcomes.

6.3 The benefits of using mixed methods in research

To expand on the discussion in the previous section, the present study used a combination of qualitative and quantitative research methods in an attempt to broaden our understanding of how and why fixed orthodontic treatment could influence dietary intake and behaviour. The use of mixed methods in research has been rapidly increasing and has shown itself to be useful in explaining many phenomena in a number of health care systems (Sinuff *et al*., 2007; Östlund *et al*., 2010). Qualitative methods are applied in situations where there is little information in relation to the phenomenon of interest in which in depth exploration and examining of subjects' "experiences and beliefs are identified in the context of everyday life from the subjects'' point of view to develop theories and hypotheses that can form a foundation for further research (Morse, 1995). A qualitative approach can also form a foundation for the later preparation of a quantitative study (Sinuff *et al*., 2007). Furthermore, qualitative approaches can elicit rich and valuable information when developing instruments and tools, such as questionnaires, to be used in quantitative studies helping to ensure that the tools are patient-centred and more relevant to subjects, rather than using traditional methods in developing tools and measures that are based on clinicians' opinions (Onwuegbuzie *et al*., 2010).

The following sections will be divided into 2 parts. The first part will discuss the findings of the qualitative study, followed by a discussion of the findings of the quantitative study.

6.3.1 The qualitative study

The aims of the present qualitative study were to explore in depth the effects of fixed orthodontic treatment on dietary intake and behaviour, identifying factors that might influence changes in dietary intake, identifying food items that are most likely to be restricted or consumed and developing a supplementary questionnaire that was used in the quantitative study to assess the impacts of treatment on dietary behaviour. This approach provided an insight into patients' experiences and attitudes and a preliminary understanding of how patients' dietary intake changes during the early stages of treatment. Furthermore, it formed a foundation to build on, in which a further quantitative study was carried out to supplement the findings of the present qualitative study.

One of the main themes identified in the present qualitative study was the experience of pain. Several previous reports have investigated the experience of pain during fixed orthodontic treatment, applying different quantitative methods in rating pain levels. However, this qualitative study is the first to explore in depth the nature and duration of pain and its association with dietary intake during the course of treatment. The majority of patients reported pain and discomfort during the first few days of treatment after which it started to decrease in intensity within the first week. This finding agrees with previous studies which reported that the highest peak of pain occurred during the first week (Sergl *et al*., 1998; Firestone *et al*., 1999; Bergius *et al*., 2002). Three patients reported that pain lasted for a longer period, up to 2 weeks Brown and Moerenhout (1991). The site of pain, based on patients' accounts, was variable but it was mainly localized to teeth. However, three patients reported pain in the soft tissue (cheeks and gums) as in a study which reported that the second most frequent problem patients experienced during fixed orthodontic treatment was oral ulcerations Ostavic *et al* (2006). Finally, patients reported that pain was most severe during the mornings; however, three patients reported that pain was present throughout the day. Overall, the aforementioned findings of the

present qualitative study seem to support and confirm previous quantitative studies in relation to pain experienced during treatment.

The second main theme identified aspects and experiences related to the effects of fixed appliance therapy on dietary intake, behaviours and choices. The present study showed that the majority of patients reported that they had difficulty in eating and chewing due to pain and that this resulted in eating a softer diet in preference to hard food types. This is in agreement with previous research (Brown and Moerenhout, 1991; Firestone *et al*., 1999). A further reason identified for dietary change was the fact that some food types became 'stuck' to the appliance with resultant difficulty in maintaining good oral hygiene being reported. Perhaps not surprisingly, one of the most frequently stated reasons for dietary change was the influence of dietary instructions given by their orthodontist. Among the main instructions given were to avoid eating hard and high sugar content foods to avoid appliance breakage and to reduce the risk of developing caries, respectively.

As a result, patients reported that they had to change the type and consistency of foods eaten during the treatment and the present study identified which food items were either difficult to eat or were consumed more. The most common food items which were reported as being difficult to eat were; apples, carrots, crisps, chocolate bars, meat, nuts, toffees, gums, crackers, and corn–on-the-cob. Patients reported changing to softer foods such as mashed dishes, rice, pasta, bananas, soups, cheese, water, juices, boiled vegetables and milk. Some patients reported that they had to change the method of preparation of some foods (i.e. cutting food into smaller pieces or changing the method of cooking). This is the first study to identify specific food items that might be difficult to eat or consumed more due to treatment. Such findings can be discussed and addressed with patients before placing the appliance to inform them about the possible impacts on their dietary intake in relation to treatment.

One of the most interesting findings of the present study was the fact that although patients reported difficulty in eating and chewing due to the amount of pain and

discomfort experienced, they felt that their eating habits were healthier compared with those pre-treatment. Patients reported eating fewer snacks, eating healthier food and avoiding high sugar content foods. On the face of it, this finding could be regarded as important in the context of public health, as obesity during adolescence is becoming a global problem and fixed orthodontic treatment seems to contribute to adopting a healthier eating style. However, such findings cannot be generalized due to the qualitative nature of the research, lack of statistical representation and the fact that a further study should be carried out in a larger population to thoroughly investigate this issue. Hence, a quantitative study was carried out to further evaluate this findings' impact.

Whilst validity and reliability in qualitative research are important, there are two opposing views. The first applies the concepts used in quantitative research, but with different methods to take into account the goals of qualitative research. The second argues that qualitative research should not be judged by the same conventional methods used in quantitative research (Mays and Pope, 2000; Collingridge and Gantt, 2008). The most popular methods used in qualitative research are: respondent validity, reflexivity and fair dealing (Mays and Pope, 2000). In the present study, respondent validity, i.e. comparing the investigator's findings with those of the research subjects, was achieved by discussing the findings of the main study with a separate group (n=4) of adolescents undergoing fixed appliance treatment and assessing whether they agreed that these findings reflected their own experiences.

Reflexivity assesses whether the findings of the study might have been influenced by personal and/or intellectual bias. This was addressed by the principal investigator conducting a number of patient interviews prior to commencing the current study, in order to familiarize himself with the interview process and to learn to ask standardized questions in an open and non-leading manner.

Fair dealing was achieved by recruiting patients of different ages, genders and ethnic backgrounds to take account of the diversity of dietary intake (Herne, 1995). Furthermore, an independent researcher (S.C.) was asked to analyse the data and

compare their findings with the findings of the present study in relation to themes and sub-themes identified, to ensure that there was no bias in the interpretation process of the interviews.

In summary, the findings of the present qualitative study reveal that patients undergoing fixed appliance treatment experience changes in their dietary intake that should not be underestimated and this necessitates further investigation in a large population study. However, these dietary changes appear to have potential benefits, as the majority of patients felt that they had adopted healthier eating habits, as a result of treatment. Another important advantage of the present study was the use of the themes and sub-themes identified in designing a supplementary questionnaire that was used in the quantitative study to give a greater insight of the effects of fixed orthodontic treatment on dietary intake and behaviours.

With respect to the qualitative approach adopted in this study, there are limitations. The results may have been influenced by the one-to-one contact between the patient and the researcher, and the alternative use of focus groups may have provided a more interactive and effective approach (Kennedy *et al*., 2001). However, an attempt to conduct focus group interviews proved too difficult logistically in terms of arranging follow-up appointments at the same time for patients being treated by a number of different clinicians. Whilst the number of patients interviewed in this study was small, recruitment continued up to the point when no new themes arose. This is a common approach in qualitative research (Travess *et al*., 2004; Ryan *et al*., 2009). Another potential limitation in the present study is the bias related to selecting the patients who were willing to talk about their experiences compared to other patients. These patients tend to be polarized in their views, either extremely happy or extremely unhappy (Travess *et al*., 2004). However, one of the most important aims of qualitative research is to provide a wide range of opinions and experiences within the population under study. To fulfill this requirement, patients were selected from different demographic groups to ensure as much as possible that a wide range of views had been examined and explored. Another possible limitation of the present qualitative study was the fact that patients were interviewed at their first review

appointment (4-6 weeks) rather than asking them at later stages to get a wider range of experiences. However, because the quantitative study aimed to follow-up patients for the first 3 months, it was more appropriate to interview patients within this period, as the supplementary questionnaire that was developed based on the qualitative study would be more reflective to patients' experiences in the quantitative study. Finally, one of the limitations of the qualitative study lies in the fact that all interviews and analyses were done by a single investigator (F.A.) which might have influenced the interviewing and the analytical process. Ideally, the presence of a facilitator would have eliminated this risk of bias. However, at the time of conducting the study, there were no additional funds to employ a trained independent facilitator to carry out the interviews. To overcome this problem, the principal investigator carried out pilot interviews before commencing the main study to get himself familiar with the interviewing process and asking questions in a standardized and neutral manner, that would not influence patients' responses to any questions.

6.3.2 The quantitative study

The present quantitative study aimed to further investigate the effects of fixed orthodontic treatment on dietary intake and behaviour, body fat composition and quality of life (QoL) in a representative group of adolescent patients, applying a combination of objective and subjective measures. This study allowed the findings of the qualitative study to be built on, quantifying changes in the aforementioned outcome variables through statistical means and drawing causality inferences.

6.3.2.1 Changes in BMI and fat percentage

In the present study, BMI and the bioelectrical impedance analysis (BIA) method were used to measure body fat changes during the study period. Although BMI is a widely used measure of body fat, in particular in adolescent populations, it is not sensitive to body fat distribution and can mis-classify subjects with high fat content (Reilly *et al*., 2000). Furthermore, BMI is unable to distinguish between fat mass gain or loss or fat-free gain or loss (Garn *et al*., 1986; Kuczmarski, 1993). Therefore, using another reliable measure such as the bioelectrical impedance analysis (BIA) method to estimate changes in fat content would provide greater insight into shifts in fat distribution during the early stages of fixed appliance treatment.

The findings of the present quantitative study showed that both BMI (after adjusting for physiological growth) and fat percentage decreased between baseline and 4-6 weeks and between baseline and 3 months in the test group and increased during the same periods in the control group. However, whilst there was no statistically significant difference between both groups with respect to changes in BMI, there was a significant difference in fat percentage changes ($P<0.001$). After adjusting for BMI status at baseline, neither BMI changes nor fat percentage changes were significant between both groups. This means that BMI status at baseline (normal or overweight/obese) moderated changes in fat percentage between both groups, with patients who were overweight or obese at baseline more likely to lose fat than 'normal' weight patients. This finding was further supported in the univariate and multivariate analyses to assess changes in fat percentage in the test group. There was a significant difference between patients who were normal weight and overweight/obese patients at the 0.2 level. In the multiple regression analysis, BMI status at baseline was the strongest predictor of change in fat percentage ($P<0.05$). Indeed, this finding is consistent with studies that introduced intervention programs to prevent obesity in adolescents (Robinson, 1999; Ebbeling *et al*., 2006). Ebbeling *et al* (2006) investigated the role of sugar-sweetened beverages (SSBs) in promoting obesity in 103 adolescent subjects, who were randomly assigned to either an intervention group who relied on home deliveries of zero calorie beverages or a control group who didn't change their consumption of SSBs. The study found that BMI differed significantly ($P<0.016$) between the intervention and control groups in subjects who were at the upper baseline-BMI tertile (overweight/obese) whereas no significant group difference was found in subjects in the middle and lower tertiles, indicating that BMI status at baseline mediated changes in BMI. A possible reason for this finding could be that the susceptibility of some individuals to gain or lose body fat involves complex interactions between genetic predispositions, psychological factors and environmental stimuli. Overweight and obese subjects are inherently more likely to be affected by environmental factors such as the effect of fixed orthodontic treatment (Rosenbaum and Leibel, 1998). However, the role and degree of influence of environmental factors in explaining the susceptibility of obese subjects to changes in their fat composition is not clear (Wardle *et al*., 2008;

Hebebrand and Hinney, 2009). It is important to note that the findings of the present study should be interpreted with caution, as the number of overweight/obese patients was only 14 when comparing them to 40 normal weight patients, which could reduce the power of the analysis, in particular the sensitivity of the multiple regression model as it is recommended to have more patients when running regression analysis (Pallant, 2007).

The fact that the present study showed that overweight/obese patients had a tendency to lose more fat compared to normal weight patients could be linked indirectly to the findings of the qualitative study that showed that the majority of patients interviewed thought that their eating habits were healthier (See section 6.3.1). Obesity is a serious public health problem and its alarming increase all over the world has led scientists to introduce interventional programs that focus on modifying dietary habits and adopting healthier eating styles (Campbell and Rössner, 2001). Perhaps this could be another possible explanation of overweight/obese patients being more likely to lose more body fat. In addition, the present study showed that just over two thirds of patients (64.2 %) in the test group reported that they disagreed with the statement that treatment resulted in eating in a less healthy manner during the first period of follow-up (4-6 weeks). This finding supports the findings of the qualitative study (See section 6.3.1).

The findings of the present study showed that the main drop in BMI and fat percentage in the test group occurred during the first period of follow-up (baseline – 4-6 weeks, 0.03 Kg/m² and 2.4%, respectively). During the subsequent follow-up period (4-6 weeks – 3 months), BMI increased by 0.02 and the drop in fat percentage was only 0.3 %. This implies that the main impact of fixed appliances occurred during the first follow-up period of the study and that patients appeared to adapt to the treatment. This finding could be linked with dietary behaviour scores at 4-6 weeks and 3 months. Patients at 4-6 week follow-up had significantly higher median scores (higher impact on their dietary behaviour) compared to the 3 months ($P<0.002$) follow-up period. This might have reflected their body fat composition where the main changes in BMI and fat percentage occurred during the first period

(Baseline – 4-6 weeks), which corresponded to the higher scores at 4-6 weeks. As expected, BMI and fat percentage increased in the control group. This was not a surprising finding, reflecting normal physiological changes that take place during adolescence (Rogol *et al*., 2000).

Although BMI and fat percentage decreased, in particular, during the first period of follow-up (baseline – 4-6 weeks), changes in BMI that are considered significant in studies introducing intervention programs, such as health diet regimens and weight loss programs, to prevent obesity in adolescent subjects consider a clinically relevant difference of 0.45 Kg/m² to 0.63 Kg/m² (Robinson, 1999; Ebbeling *et al*., 2006). Wabitsch *et al* (1996) reported that adolescents who followed a weight reduction program for 40 days lost 5.8 per cent of their fat content using the BIA method. Although fixed orthodontic treatment is not a treatment that is intended to promote or cause weight loss, these reported changes in the medical literature suggest that the observed change in BMI and fat percentage in the current study's test group are not clinically significant. The changes observed in BMI and fat percentage during the first period of the follow-up period (baseline-4-6 weeks) were only 0.03 Kg/m² or 2.4 per cent, respectively.

Finally, changes in BMI and fat percentage between baseline and 4-6 weeks follow-up were significantly correlated but the correlation coefficient value was not high (R^2 = 0.31). As mentioned earlier, BMI is not a sensitive index to distinguish between fat mass gains or loss and this might have attenuated the true changes in body fat. Eisenkölbl *et al* (2001) showed that the BIA method was superior to BMI in estimating body fat when both methods were validated against a reference method. Hence, the BIA method was used to estimate changes in fat percentage in combination with BMI in the current study. Furthermore, the body fat analyser (Tanita, TB 300) used in the present study has been validated to be used in the present study's population, applying specific equations for each ethnic background (Haroun *et al*., 2010). This in turn eliminated bias in estimating fat percentage associated with this method using the manufacturer's equations which do not take

into account gender and ethnic variations (Jebb *et al*., 2000; Dehghan and Merchant, 2008).

6.3.2.2 Changes in energy and macro-nutrient intake

The findings of the present study showed that there was no statistically significant difference between both groups in terms of changes in energy and macro-nutrient (carbohydrates, protein and fat) intakes. However, patients in the test group were observed to reduce more energy and macro-nutrient intake during the first follow-up period of the study compared to the control group. There were smaller changes in both groups between the 4-6 week and 3 month follow-up period, indicating that the dietary intake of patients in the test group returned to normal and that the main changes in dietary intake in the test group were limited to the first follow-up period of the study.

This finding reflects changes that were observed in relation to both BMI and fat percentage in the test group, in which the main drop in both measurements occurred during the first follow-up period after which patients started to resume normal physiological behaviour. This finding is consistent with the medical literature, in which lowering dietary intake will result in a series of physiological responses. The principal response is a reduction in body weight and reduced muscle mass and fat stores (Shetty, 1999).

In light with these findings, it would appear that fixed orthodontic treatment resulted in changes in dietary intake, in particular, during the first follow-up period of the study and the direction of the changes was towards reducing energy and macro-nutrient intake. However, this change was not statistically significant and such changes could be attributed to other factors such as the following:

Firstly, although the Food Frequency Questionnaire (FFQ) used in the present study was a validated measure to assess dietary intake in adolescents (Robinson *et al*., 1999), the questionnaire does not retrieve unique details of the individual's diet and respondents can misreport their dietary intake using this method (Subar *et al*., 2003, Kristal *et al*., 2005). The estimation tasks for an FFQ are complex and difficult and as

such may lead to considerable shift in nutrient estimation and yield inaccurate estimates of the average intake for a group (Smith, 1993). In children, this limitation has an additional dimension of difficulty due to the cognitive ability to remember their diets (Rockett and Colditz, 1997). This might explain the decrease in energy and macro-nutrient intake in patients in the control group at 4-6 weeks compared to their intake at baseline, although the decrease was less than that observed in the test group. In addition to these challenges, adolescents dietary behaviour is characterized by having irregular meals, snacking and meal skipping, peer influence and overweight and obese subjects under-reporting their intake (Livingstone *et al*., 1992; Frank, 1994; Samuelson, 2000).

Secondly, the full variability of an individual's daily diet, which includes many foods, brands and different preparation methods, cannot be fully captured by the FFQ. For example, obtaining accurate reports in relation to foods eaten, both as single items and in mixtures, can be problematic and challenging. This may lead to an inaccurate estimation and changes in the amount of food eaten on a daily basis (Breifel *et al*., 1992; Kristal *et al*., 2005).

Finally, it is reported that seasonal variation might also influence dietary intake, which could lead to changes in the amount and types of foods eaten. This could pose the possibility of a potential error in reporting dietary intake (Shahar *et al*., 2001) although other studies found that the effect of seasonal variation is of small magnitude (Ma *et al*., 2006). However, the influence of this factor in the present study was minimized by recruiting patients to both groups concurrently, with their resultant follow-up taking place during both the winter and spring seasons, with few patients followed up until early summer.

Despite the aforementioned limitations of FFQ in estimating energy and macro-nutrient intake, it was the most appropriate, convenient and practical method to be used in the sample being recruited when compared to other self-reported methods such as weighed or estimated records. Energy and macro-nutrient intake changes estimated using the FFQ in the present study appeared to follow the same trend of

changes observed with the objective measures (BMI and fat percentage) being applied, although the correlations were weak. The use of weighed or estimated records involves a great deal of patient compliance in terms of how burdensome these methods are to respondents, in particular, asking them to record their dietary intake on 3 different occasions. This in turn, could influence the response rate and lead patients to give incomplete records or drop out of the study (Bratteby *et al*., 1998). Furthermore, energy and macro-nutrient intake changes estimated using these methods are prone to mis-reporting and bias in this age group (Livingstone *et al*., 1992).

6.3.2.3 Impact on dietary behaviour

The present study investigated the impact of fixed orthodontic treatment on short-term dietary behaviour to further elucidate how patients' dietary habits are affected, and to explore specific shifts in their dietary intake that conventional self-reported dietary assessment methods would not capture. The questionnaire used to assess dietary behaviours was developed based on a qualitative approach in patients of the same population (See section 4.1.4). This approach is considered the best source for item generation for a questionnaire and ensured that the measure is truly patient-centred (Williams, 2003).

The findings of the present study showed that the median score at 4-6 weeks follow-up after placement of their fixed appliance for patients in the test group was significantly higher than the score at 3 months ($P<0.002$). This indicates that there were higher impacts on dietary behaviour during the first period of the follow-up in the study, after which they started to adapt as the impact lessened in the second period of the follow-up. This finding corresponds with the quantitative findings of the present study in relation to energy intake, macro-nutrients intake, BMI changes and fat percentage changes, in which the main changes in the test group occurred during the first period of follow-up, after which it appears that patients adapt to the treatment, with small changes being observed in the second period of follow-up.

The results of the univariate and multiple regression analyses showed that BMI status at baseline was the strongest moderator for dietary behaviour score at 4-6

week follow-up. Overweight/obese patients reported significantly higher impact compared to normal weight patients (P<0.025) in the univariate analysis. In addition, BMI status at baseline was the only significant variable that remained significant in the multiple regression analysis and explained the variance in dietary behaviour score out of all the study's explanatory variables (P<0.049). Indeed, this finding supports the previously discussed finding in relation to changes in fat percentage during the first follow-up period of the study. BMI status was also the strongest moderator for changes in fat percentage in the test group. It also confirms the findings of other studies, which reported that patients at the upper end of the BMI distribution are more likely to respond to interventions that modify their dietary behaviours (Robinson, 1999; Ebbeling *et al*., 2006).

The present study showed that the frequency of patients in the test group who reported an impact for every item in the supplementary questionnaire was higher at 4-6 weeks compared to the 3 month follow-up period. Two thirds of patients agreed that pain resulted in difficulty with eating during the first follow-up period of the study. In the second period the percentage of patients who agreed dropped to 54 %. This finding has been reported in numerous studies (Firestone *et al*., 1999; Bergius *et al*., 2000; Otasevic *et al*., 2006). The fact that the percentage of patients who agreed that pain caused them difficulty in eating decreased in the second follow-up period of the study was an expected outcome, as patients adapt to pain as the treatment progresses and pain levels at later stages of the treatment tend to fall. Sergl *et al*. (1998) found that patients experience discomfort throughout the treatment, although the intensity of pain after 3 months is much lower than the first week of treatment. This finding is further supported in the present study (See section 6.3.2.5).

In both 4-6 week and 3 month follow-up periods of the study, the majority of patients reported that fixed appliances hurt during the first week (92.4 % and 86.8 %, respectively). This finding is consistent with previous studies which have reported that pain intensity is highest during the first week after placement of the appliances and then declines (Scheurer *et al*., 1996; Fleming *et al*., 2009; Tecco *et al*., 2009). Furthermore, the present finding supports the results of the current qualitative study

(see section 6.3.1). The percentage of patients who reported that fixed appliances hurt during the second week after placement was 53 % and this figure fell to 39.6 % in the second period. A similar finding was reported by Brown and Moerenhout (1991) who found that patients needed up to 14 days to adapt to discomfort and pain experiences. As expected, only a few patients in the current study reported that they experienced pain in the third and fourth weeks in both follow-up periods, which indicates that patients adapted to the pain in the later stages of the treatment.

The present study showed that over half of the patients agreed that they ate less snacks and food compared to before treatment, during the first follow-up period of the study. This percentage decreased to 39.6 % in the second follow-up period. Firestone *et al* (1999) found that patients underestimated significantly changes they would need to make in their diet as a response to pain after insertion of initial archwires. One reason for this finding might be related to the fact that the majority of patients reported pain, in particular during the first week. This pain might have affected their ability to eat, which in turn resulted in a reduction of their eating frequency, although results of the multiple regression analysis did not show that pain from chewing and biting was a significant contributor to changes in the fat percentage and dietary behaviour scores. This may be due to the fact that pain is experienced in the early stages of treatment and then declines in following weeks. Another possible reason could be due to the influence of dietary instructions given to them by their orthodontist. The majority of patients (56%) reported that they were influenced by instructions given to them by their orthodontist. This finding was further supported in two items of the supplementary questionnaire. Two thirds of patients reported that they ate less sticky/sweet foods and 58.5% reported that they ate less hard food because they were asked to refrain by their orthodontist during the first follow-up period shortly after placement of the fixed appliance. However, the results of the multiple regression analysis showed that dietary instruction given to patients was not significant in explaining changes in fat percentage and dietary behaviour scores.

Almost half of the patients reported that they had to cut their food into pieces or that it was cooked in a different way during the first follow-up period whilst 41.5% reported this finding in the second follow-up period. Although this finding is considered an impact as a result of the treatment, it could be argued that such an impact might have a protective effect for any dietary changes, as patients get around eating hard foods, for example, by cutting them into smaller pieces or eating foods which are less difficult to chew by cooking them in a different way, such as by boiling them. This finding could be linked indirectly to the insignificant changes observed in energy intake, macro-nutrient intake, BMI changes and adjusted fat percentage change.

One of the interesting findings reported by patients in the qualitative study was the fact that patients felt that their dietary intake and behaviour became healthier compared to pre-treatment (see section 6.3.1). This finding was further explored in the present study. Almost two thirds of patients in the test group disagreed that treatment resulted in eating less healthily during the first follow-up period. More than half reported the same during the second follow-up period. This is consistent with the previously mentioned findings, which includes eating less sweet and sticky foods and snacking less compared to pre-treatment.

One of the aims of the present study was to understand in depth how patients' dietary intake changed during fixed orthodontic treatment. This aspect has never been explored previously. In the present study, patients in the test group were asked about their consumption of specific food items that were chosen based on the findings of the qualitative study. In the first follow-up period (baseline-4-6 weeks), the majority of patients reported that they ate with difficulty/couldn't eat the following food types; apples, carrots, corn-on-the-cob and toffee/chewing gums. Almost half of patients ate with difficulty/couldn't eat nuts and sweets and one third ate with difficulty/couldn't eat meat dishes. More than one fifth of the patients reported that they consumed less pop/fizzy drinks. In the second follow-up period (4-6 weeks- 3 months), the percentage of patients who reported an impact in the aforementioned food and drink items decreased, which may again be due to adaptation to the

treatment as it progresses. The present study showed that almost two thirds of patients agreed that treatment caused them difficulty in eating, and this might have made them avoid eating hard foods. Another possible explanation based on the findings of this study may relate to the influence of dietary instructions given to patient at the start of the treatment. The present study showed that the majority of patients were influenced by their orthodontists' instructions. As reported earlier, two thirds of patients reported that they ate less sticky/sweet foods and 58.5% reported that they ate less hard food because they were asked to by their orthodontist during the first period. It would appear that instructions given by the patients' orthodontists after placement of their fixed appliance could affect patients' dietary habits, resulting in them avoiding certain food items such as hard foods, sweets and sticky food. The rationale for such advice from an orthodontist's point of view is to avoid appliance breakage and to prevent tooth decay and periodontal disease.

The present study showed that patients during their first follow-up period consumed certain food and drink items more than usual as compared with before the treatment. Again, the percentage of such patients decreased in the second follow-up period. One third of patients reported that they drank more water than usual and one quarter reported that they ate/drank more mashed dishes, bananas, soups and juices. This finding was expected as patients substituted food items that they couldn't eat, in particular hard foods, for soft consistency food items or drinking more, and is consistent with other findings that support the findings of the qualitative study (See section 6.31). This finding could also explain the insignificant changes observed between both groups in relation to changes in dietary intake, BMI and adjusted fat percentage. Energy intakes gained from food and drink items that were consumed more might have compensated for energy shortage from food items that couldn't be eaten. Hence, energy intake, BMI and fat percentage changes in the test group were not significant. For example, Riordan (1997) reported in a study that assessed the effects of orthodontic treatment on 10 adolescent patients that there was a trend in patients towards greater intake of total and saturated fat at the expense of carbohydrates. However, the study was limited to only assessing patients' dietary intake during the first three days after appliance placement.

Overall, it would appear that patients undergoing fixed orthodontic treatment could experience changes in their dietary behaviour that may result in changes in the amount and types of food eaten. This impact appears to decline as treatment progresses and patients adapt to their appliances. However, and in light of the findings of the present study, these impacts appear to be of little clinical significance for the following reasons:

1. The insignificant changes observed in the objective measures used in the present study (changes in BMI and fat percentage).
2. The insignificant changes observed in energy and macro-nutrient intakes.
3. The presence of potential proactive factors such as cutting foods into pieces or cooking food in a different way. Such factors may have attenuated the effect of treatment on dietary intake.
4. Shifting to other food and drink items that might compensate for food items that were difficult to eat.

6.3.2.4 Changes in quality of life (QoL)

This is the first longitudinal study to assess the OH-QoL of adolescent patients undergoing fixed orthodontic treatment when compared to an untreated control group exhibiting similar characteristics. QoL is a multi-dimensional concept and many aspects of life can have a major impact on QoL. Therefore, recruiting a control group was essential to isolate the treatment effect from any other external factor that might influence the perceived OH-QoL in the test sample. The present study assessed changes in OH-QoL as part of the general purposes of QoL measures, which can be used in many situations, one of which is regular monitoring of patients' care and the quality of treatment given to them (Jenkinson *et al*., 1993). Furthermore, a key aspect of the present study was to investigate ‘dietary intake’, this in turn being regarded as an important factor that influences QoL (Plaisted *et al*., 1999; Wayne *et al*., 2006; Gariballa and Forster, 2007).

The present study showed that there was a significant difference in the total OH-QoL scores between both groups, at baseline and 4-6 weeks and baseline and 3 months ($P<0.012$ and $P<0.015$, respectively). However, within group changes revealed that

the overall OH-QoL in the test group deteriorated between baseline and 4-6 week follow-up, although not significantly, whereas there was almost no change between baseline and 3 months. On the other hand, overall OH-QoL in the control group improved significantly at 4-6 weeks and 3 months. This indicates that the difference between both groups was mainly due to improved OH-QoL in the control group as changes in overall OH-QoL in the test group were small and insignificant. This finding supports the findings of Chen *et al* (2010) who didn't find any significant changes in overall OH-QoL in a group of Chinese patients after 1 month. However, Zhang *et al* (2008) reported significant changes after 1 month but no significant changes after 3 months using CPQ11-14. Bernabé *et al* (2008) reported that 90% of patients who were wearing fixed orthodontic treatment experienced at least one negative impact, as assessed by the Oral Impact on Daily performances (OIDP).

For sub-domains scores, the present study showed that there was a significant difference between both groups in oral symptoms (OS) and functional limitation (FL) domains at 4-6 weeks ($P<0.001$ and 0.002, respectively) and 3 months ($P<0.035$ and $P<0.002$, respectively). Both domains deteriorated in the test group at the 4-6 week and 3 month follow-up periods. However, it was only significant for changes in OS after 4-6 weeks, with no significant change at other time points in respect of both domains. This finding was expected for both domains as patients during treatment experience pain, discomfort and oral health problems such as bleeding gums, ulcerations and speech problems which may contribute to the deterioration observed in OS and FL domains. This finding is consistent with the findings of Zhang *et al* (2008) who reported that OS and FL domains significantly deteriorated after 1 month of fixed appliances treatment.

For the emotional well being (EWB) domain, there was no significant difference in the present study between both groups at 4-6 weeks and 3 months. However, EWB improved significantly within each group at the same time points. Zhang *et al* (2008) found in a group of adolescent patients undergoing fixed appliance treatment that the EMB domain improved after 1 month. Furthermore, they found that improvement in EWB continued as treatment progressed. They attributed this to the fact that patients

adapted to the treatment and that fixed appliances are popular and more accepted by the public (Sergl *et al*., 2000). In contrast to this finding, Chen *et al* (2010) reported that EWB deteriorated significantly. For the social well being score (SWB) domain, there was no significant difference between both groups at 4-6 weeks. However, there was a significant difference between both groups at 3 months ($P<0.035$) mainly due to significant improvement in SWB in the control group. SWB deteriorated in the test group but changes were not statistically significant. This finding may relate to the fact that adolescent patients feel shy or embarrassed because of the presence of the fixed appliance, which may influence their social interactions with their peers who are without fixed appliances. However, a recent study found that children do not make social judgements about other children purely on the basis of wearing fixed orthodontic appliance. Fixed appliance treatment was viewed by a group of children as part of the normal dental appearance in adolescence (Patel *et al*., 2010).

The findings of the present study showed unexpectedly that total OH-QoL scores and all sub-domain scores improved significantly at some points of the study in the control group, and that the main difference between both groups was mainly due to significant changes in the control group. It could be argued that such significant changes should not occur as it is assumed that the OH-QoL of this group should remain stable, as they were not under any intervention, and previous studies reported good reproducibility of the CPQ11-14 (Jokovic *et al*., 2002; O'Brien *et al*., 2007). A possible explanation could be that subjects, in particular adolescents, may not remember their baseline status, which may lead to changes in their responses in another occasion (Striener and Norman, 2008). This explanation was also supported by Kok *et al* (2004) who suggested that children may respond with better (OH-QoL) when a questionnaire is re-administered at a later time. Golembiewski *et al* (1975) defined response shift as changing internal standards, values and the conceptualization of QoL, which may complicate assessment of QoL. Such response shift in children may be compounded further by changes in cognitive and psychological awareness with time (Allison *et al*., 1997). Another explanation could be linked to an increase in awareness of patients in the control group of oral hygiene

protocols during the preparatory period of their treatment, as well as the positive impact of other forms of dental treatments that patients receive before placing fixed appliances, such as attention to periodontal problems. Such impacts may explain the decline in OH-QoL scores during the course of the study. Finally, the improved OH-QoL observed in the control group could have arisen from the clinical attention given to patients by their registrars and the relationship that is built during the preparatory period of the treatment, before placing fixed appliances. Such an effect has been reported in a recent review which showed that placebo interventions could have a therapeutic impact and can influence patient-reported outcomes such as the OH-QoL scale used in the current study (Hróbjartsson and Gøtzsche, 2010).

Overall, the findings of the present study showed that the main negative impact on OH-QoL in the test group occurred for all domains except the EWB domain during the first follow-up period (baseline – 4-6 weeks), after which patients started to adapt to the treatment. As expected, the OS domain was the only domain that deteriorated significantly in the test group during the first follow-up period.

Finally, although some researchers call for the use of condition-specific measures when assessing OH-QoL in orthodontic patients (Bernabé *et al*., 2008; Tsakos, 2008), generic measures such as the CPQ11-14 are more useful for making comparisons with general populations. This will make evaluation of relative impacts of therapies and healthcare programs more possible and helpful. Furthermore, it might capture unforeseen impacts that condition specific measures would overlook (Wolinskey *et al*., 1998). It is worth mentioning that CPQ11-14 has been shown to be sensitive to change in the context of orthodontic treatment (Agou *et al*., 2008).

6.3.2.5 Pain levels during the study period

This is the first study to investigate pain levels prospectively in two consecutive periods. The present study aimed to investigate the intensity and duration of pain following insertion of orthodontic appliances during the study periods, namely between baseline and 4-6 weeks and 4-6 weeks and 3 months. In addition, the study examined the interactions between pain from biting and chewing and the study's dependent variables. Several studies have reported that pain from orthodontic

treatment resulted in difficulty in eating and chewing, in particular, foods of firm or hard consistency (Sinclair *et al*., 1986; Scheurer *et al*., 1996; Firestone *et al*., 1999). However, these studies didn't explain or explore the extent to which dietary intake was influenced, and whether other factors were responsible for changes in dietary intake and/or behaviour. This is mainly due to the limitations of using simple and generic measures that are limited in sensitivity and in their ability to detect a wide range of variations in dietary intake.

The findings of the present study showed that patients in the test group started to adapt to pain from teeth and from biting and chewing by the third day during the first follow-up period (baseline – 4-6 weeks) and by the second day, during the second follow-up period of the study (4-6 weeks – 3 months). This indicates that patients adapt quicker to pain and discomfort after insertion of archwires in the second compared to the first follow-up period. This finding supports other studies which investigated pain intensity during fixed orthodontic treatment and reported that patients adapted to pain within the first week (Scheurer *et al*., 1996; Sregl *et al*., 1998; Bergius *et al*., 2002; Pringle *et al*., 2009; Tecco *et al*., 2009).

The present study showed pain levels from teeth and from biting and chewing in the second period declined. It was statistically significant for pain from chewing and biting. This finding further supports the previously discussed finding that patients adapted to fixed appliances as treatment progressed. Furthermore, the percentage of patients who consumed analgesics in the second follow-up period dropped to more than half the percentage of patients who reported consuming analgesics during the first period. This might explain the small changes observed in BMI, fat percentage and dietary intake as well as the significant drop of dietary behaviour scores at 3 months compared to 4-6 weeks. The decline in pain intensities observed during the study allowed the patients to resume their normal daily intake of foods. However, the findings of the present study showed that the impact of pain on changes in fat percentage and dietary behaviour scores at 4-6 weeks was not significant in the multiple regression analysis, although pain could be perceived as the strongest predictor based on the assumption that pain would result in difficulty in

chewing and mastication and the fact that the majority of patients reported that pain resulted in difficulty with eating hard foods. A possible explanation for this could be that the highest intensity of pain, as this study and other studies have shown, occurs during the first few days after appliance placement, after which pain declines. It could be that treatment impacts on dietary intake occur during the early days of treatment and because the pain declines in subsequent days, patients' normal eating habits are resumed. An attempt was made to ask the patients to fill in the supplementary questionnaire after one week and return it in a self-addressed envelope. The purpose of this was to explore in depth the impact of treatment on dietary behaviour during the first week and assess the correlation between pain levels and dietary behaviour scores as well as comparing scores at one week with the scores obtained at 4-6 weeks and 3 months. Unfortunately, the response rate was poor and only few patients returned the questionnaire, not enough to conduct a meaningful statistical analysis.

It would appear from the findings of the present study that patients adapted to pain after a few days of appliance placement and that patients' perceived pain levels after the second appointment declined in all time points compared to pain levels recorded after the first follow-up appointment. The effect of pain on dietary behaviour between appointments appears to be minimal as the highest peak of pain occurs during the first few days, after which it declines throughout the month.

6.3.2.6 The interaction of the study's independent variables with outcome variables based on the proposed theoretical framework

The present study proposed a theoretical framework to explain changes in outcome variables namely: dietary intake and behaviour, changes in BMI, fat percentage and in OH-QoL (See section 3.4). The theoretical framework was based on Khan's (1981) model which explained factors that affect dietary intake and behaviour and Wilson and Cleary's (1995) model which conceptualizes the relationship between clinical variables and HRQoL. Common factors in both models in relation to the aforementioned outcome variables were adopted. These factors included biological (pain) and environmental (socio-demographic indicators, BMI status at baseline and dietary instruction given to patients by their orthodontists) variables. Both models

included additional factors, which were not measured, such as personality that could mediate changes in dietary intake and OH-QoL. Ideally, testing for personality factors would have yielded a comprehensive understanding of changes in outcome variables. However, introducing more measures to the study's subjects might have affected the response rate which in turn may have led to loss of power of the study. Furthermore, personality factors, total HRQoL and overall patients' satisfaction were beyond the scope of the present study.

The present study aimed to explain the observed changes in outcome variables in the test group, which were significantly different from the control group. In addition, it explained dietary behaviour scores in the test group. The study found that there was a significant difference between the groups with respect to changes in the unadjusted fat percentage, oral symptoms (OS) and functional limitation (FL) domains of the OH-QoL scale, during the first follow-up period of the study (baseline-4-6 weeks). No significant changes were found between the two groups during the second follow-up period (4-6 weeks- 3 months). Hence, changes during the first period were explored.

The current study proposed a list of related explanatory variables (biological and environmental factors), namely: pain and analgesic consumption, socio-economic indicators, dietary instructions given to patients by their orthodontist and BMI status at baseline, that have been shown to be associated with changes in dietary intake, body fat and OH-QoL in other contexts and other disciplines in Dentistry. For example, Acs *et al* (1992) found that growth and body weight in children with high nursing caries was negatively affected compared to those with less nursing caries. The findings of the current qualitative study showed that patients were influenced by dietary instructions given to them by their orthodontist, after placement of fixed appliances. BMI status at baseline has been shown to be an important moderator of changes in dietary intake and BMI in interventions aimed to prevent obesity were overweight/obese subjects tend to lose more weight when compared to normal weight subjects (Ebbeling *et al*., 2006). Furthermore, BMI status is an important environmental factor that can affect HRQoL (Hlakty *et al*., 2010). Finally, socio-

demographic indicators can influence dietary intake and OH-QoL (Giskes *et al.*, 2004; Donaldson *et al*., 2008). Therefore, the effects of these variables were examined in the present study to assess their association with changes in fat percentage, dietary behaviour scores and OS and FL domains.

The present study showed that BMI status at baseline was the only explanatory environmental variable that moderated changes in fat percentage and dietary behaviour scores. That is, obese/overweight patients lost more fat percentage and had higher impact on their dietary behaviour when compared to normal weight changes. As mentioned earlier, this finding is consistent with the medical literature which reports that overweight and obese subjects respond more to interventions that are put in place to prevent obesity (Robinson, 1999; Ebbeling *et al*., 2006). However, this finding should be interpreted with caution as the P values for the effect of BMI status at baseline on changes in fat percentage and dietary behaviour scores were marginally significant ($P<0.049$ and $P<0.05$, respectively). Such an effect could be attributed to errors related to sampling procedure, the small number of subjects (n=53) analyzed in the multiple regression model and the presence of random errors.

The present study did not support the assumption that pain (biological factor) or analgesic consumption during treatment was a strong predictor of changes in fat percentage and dietary behaviour scores during the study period. However, pain from chewing and biting was statistically significant, with dietary behaviour scores at the 0.05 level in the univariate analysis. An explanation of this, as stated earlier, could be that the highest intensity of pain occurred during the first few days, after which it started to decline and patients resumed their normal daily dietary behaviours.

Although the qualitative study reported that patients were influenced by dietary instructions given to them, the quantitative study did not show that this variable influenced changes in fat percentage and dietary behaviour scores significantly in the final regression analysis. This might be due to the fact that patients shifted to

other food items of softer consistency or, as discussed earlier, patients changed the method and the manner of eating and/or the preparation of food.

The present study revealed that none of the independent variables were significantly associated with changes in oral symptoms (OS) and functional limitation domains (FL) of the OH-QoL scale being applied. This finding was not surprising as quality of life (QoL) is a broad and multidimensional concept (Locker, 1988). It is therefore unlikely that the study's independent variables would relate conceptually to the aforementioned domains. However, at a glance, it might be assumed that some of the study's independent variables may relate to both domains. For example, the experience of pain may have been perceived to be related to some items in both domains in view of the fact that pain has been reported to affect QoL (Wong *et al*., 2010). However, there are other items in both domains that might be irrelevant to the experience of pain, such as items related to bad breath or bleeding from 'gums', difficulty in sleeping or in opening the mouth widely which might have attenuated the correlation of both domains to pain. O'Brien *et al* (2007) addressed this issue but in the context of the impact of malocclusion on QoL. They concluded that the CPQ11-14 was comprised of items that were irrelevant to malocclusion such as the OS and FL domains. It has to be mentioned that CPQ11-14 is a generic measure which makes it able to capture other impacts of oral health apart from pain and discomfort. Finally, according to Wilson and Cleary (1995), personality factors such as sense of coherence, health locus control and self-esteem might have mediated the effects of the proposed independent variables on the study's outcome variables, although their effects were not tested in the present study.

6.3.2.7 Strengths and limitations of the study

The prospective and longitudinal design adopted was a strength of the present study. The present design avoided the usual bias related to cross-sectional and retrospective designs. That is, exposures and causes such as pain or BMI status at baseline were measured before changes in outcome variables, namely, dietary intake and behaviour, body fat percentage and QoL. This design allowed differentiation between a cause and an effect, which was one of the most important criteria proposed by Hill (1965).

Another important strength of the present study was the concurrent recruitment of a control group from the same clinic, which helped to ensure that if any differences were found they were more likely to be due to the treatment effect. In addition, the comparability and similarity of baseline characteristics (except for house ownership indicator) between both test and control groups helped the validity of the results by controlling for factors that are not the focus of the study and which might otherwise affect the outcome (Rothman and Greenland, 1998). Furthermore, the statistical test (ANCOVA) that was employed to compare both groups helped to control for any variability in baseline measurements that might otherwise influence changes in dietary intake, body fat and QoL.

The present study applied a combination of different objective and subjective measures that complemented each other, and explored in depth how changes occurred with respect to changes in dietary intake and body fat. Two objective measures of body fat were used and two subjective measures were used to assess dietary intake, one of which was developed based on a qualitative approach, which further ensured that the measure was patient-centred. This combination of measures contributed in helping to comprehensively explore and examine in depth the changes in outcome variables of interest, and revealed that the changes in dietary intake and body fat (applying objective and subjective measures) followed a similar trend in which the main changes occurred during the first period of the study (baseline-4-6 weeks).

The present study treated outcome variables, namely dietary intake and behaviour, BMI, body fat percentage and QoL as a continuum rather than dichotomizing them. This is consistent with recommendations that call for assessing any health outcome as a continuum rather than a dichotomized entity, as the latter may lead to loss of information and is considered less sensitive in statistical analyses (Antonovsky, 1987; Royston and Altman, 2006). For example, the use of linear regression, which is one of the most accurate methods in statistical analysis, gives stable parameter estimates with smaller confidence intervals that would not be affected by changes in sample size (Kleinbaum *et al*., 1998; Norris *et al*., 2006). The only downside of such

a method is the fact that translating statistical results into clinically meaningful interpretations may be challenging.

Despite the strengths of the present study, there are a number of limitations that exist. Adopting a non randomized clinical study was one. A randomized clinical trial (RCT), in accordance with the CONSORT statement, is superior to other study designs such as the present study as selection bias would be eliminated (Moher *et al*., 2001). Furthermore, it would ensure that both groups are comparable with respect to baseline characteristics, although this aspect was met in the present study as both groups were comparable. The main reasons for not adopting an RCT were the following:

1. It was considered unethical to deny patients treatment in the control group as they had to wait for patients in the test group to finish their follow-up period, before starting their own active treatment; particularly in view of the fact that there is no longer a waiting list.

2. It was not possible to know whether patients who met the selection criteria on the waiting list would require fixed orthodontic treatment alone or other forms of adjunctive treatment, as the final treatment plan is decided until the patient is removed off from the waiting list.

However, the generation of preliminary data evidence, in relation to a new topic which has not been investigated, is recommended before conducting an RCT (Rothman and Greenland, 1998; Sibbald and Roland, 1998).

Ideally, following up patients until the end of their treatment could have yielded a greater insight into the effects of fixed orthodontic treatment on dietary intake and body composition. For example, assessing pain levels at later stages of treatment when stainless steel archwires are inserted. The rigidity of stainless steel wires might cause excessive pressure on the periodontium when compared to initial NiTi archwires and this aspect would be tempting to investigate. At present, all studies

that have assessed pain, during fixed orthodontic treatment, are limited to the early stages of treatment. However, and in line with the findings of the present study, it is anticipated that significant changes were unlikely to occur during the later stages of the treatment as the present study showed that the main change in outcome variables occurred during the first period (4-6 weeks) of follow-up. Following this period it appears that patients adapted to pain and resumed normal dietary intake and behaviours. Furthermore, administering the questionnaires used in the present study for a longer period would have resulted in a higher attrition rate and may well have proven to be burdensome to patients.

The present study applied a validated questionnaire to estimate dietary intake during the two follow-up periods (Robinson *et al*., 1999). However, it has to be acknowledged that such a method is not without errors and biases, and patients may have misreported their dietary intake at baseline and at the study's follow-up periods (Livingstone *et al*., 1992; Frank, 1994; Samuelson, 2000). For example, patients in the control group reported less energy intake at 4-6 weeks compared to baseline, which is a common problem with food frequency questionnaires (FFQ) when used in adolescents (Livingstone *et al*., 2004). Furthermore, this method relies on respondents' memory which would make it difficult for children to remember what they had eaten in the past month. However, Baranowski and Domel (1994) reported that children at 10 years and onwards can give accurate dietary information and are aware of the foods they have eaten. Furthermore, and when compared to other self-reported methods that might be superior to FFQ in adults, FFQ is the method of choice in dietary assessment in adolescents, as studies have shown that adolescents misreported their dietary intake using other self-reported methods such as estimated or weighed records (Rockett *et al*., 1997; Rockett and Colditz, 1997; Berkey *et al*., 2000; Livingstone *et al*., 2004). One of the strengths of the present study was the use of a supplementary questionnaire that was designed based on a qualitative approach, to further elicit patients' dietary behaviours during the early stages of treatment. This complemented the FFQ applied to patients and expanded our understanding of the impacts of treatment on dietary intake and behaviours.

The present study developed a supplementary questionnaire to assess the impact of fixed orthodontic treatment on dietary behaviour and habits based on a qualitative approach. However, although qualitative approaches are considered to be the best source for items generation (Williams, 2003), it has to be acknowledged that the supplementary questionnaire lacked some important psychometric properties such as criterion and construct validities due to the lack of specific definition of the construct of interest and the fact that there was no 'Gold standard' method to test the questionnaire's criterion validity. Hence, this questionnaire may not be suitable to be applied in other populations. However, the questionnaire showed acceptable internal consistency when it was tested in the test group (Cronbach $\alpha = 0.77$).

A potential limitation pertained to the assessment of body fat, using body mass index (BMI). Although it is a popular measure of body fat, it is not an equivalent measure of percent body fat, for each race-sex group (Daniels *et al*., 1997). Furthermore, recent evidence shows that the stage of sexual maturation should be taken into account when assessing BMI in adolescents in different clinical settings. Subjects who are at same age and sex might be at different stage of sexual development which in turn may influence levels of body fat (Wang, 2002; Ribeiro *et al*., 2006; Kahl *et al*., 2007; Pinto *et al*., 2010). However, it was not possible to ask patients about their sexual maturation due to cultural constraints and the need to have training for methods of identifying sexual maturation of a subject. In order to overcome this shortcoming in using BMI, the present study applied another reliable and validated measure of body fat using the bioelectrical impedance analysis (BIA) method, applying specific equations that were developed to be used in the same population of adolescents as those recruited to the present study and took into account the variability of fat percentage between different ethnic groups (Haroun *et al*., 2010).

A further limitation of the present study is the fact that dietary assessment, in particular, in adolescents is a challenging and complex task. Many factors that are beyond the scope of this study can influence dietary intake on a daily basis (Khan, 1981; Randall and Sanjur, 1981; Booth and Shepherd, 1988). These factors are a combination of psychological, personal, social class, economic, agricultural and

cultural factors that might complicate dietary assessment. However, the present study recruited a control group exhibiting similar characteristics to patients in the test group. This, in turn, helped to reduce the effect of such factors as confounders although their impacts on results of the present study cannot be ruled out.

Although the sample size for the present study was based on a sample size calculation applying figures that were obtained from a pilot study of patients who were followed-up for 3 months from the same clinic, the multiple regression analysis was only employed in the test group (n = 53). This sample size (53) number is considered to be small when running regression analyses, which in turn can lead to loss of sensitivity for the regression test and may possibly lead to type II error (Pallant, 2007). This factor might have influenced the predictive ability of the study's proposed explanatory variables that were not significant in the regression model. For example, the present study showed that pain was significantly associated with dietary behaviour scores in the univariate analysis ($P<0.049$) but insignificant in the multiple regression analysis.

Chapter 7

Conclusions

Adolescent patients undergoing fixed appliance treatment and followed-up over a 3 month basis showed the following:

- There were no significant changes in energy and macro-nutrient intakes.
- There were no significant changes in body mass index and fat percentage.
- The greatest impact on dietary behaviour occurred at 4-6 weeks, after which the impact decreased significantly at 3 months.
- Overweight/obese patients were more likely to lose fat and have greater dietary behaviour impact when compared to normal weight patients. However, this finding was inconclusive.
- Patients adapted to pain after few days of appliance placement and that patients' perceived pain levels after the second appointment declined in all time points compared to pain levels recorded after the first follow-up appointment.
- Although patients with higher pain levels and those who were influenced by dietary instructions given to them by their orthodontist, lost more fat and had higher dietary behaviour scores, this relationship was not statistically significant.
- The presence of potential protective factors such as shifting to other food and drink items, cutting food into pieces and cooking food in a different way might have attenuated the effect of fixed orthodontic treatment on dietary intake and body fat composition.
- There was statistically significant difference between both groups in overall OH-QoL mainly due to improvement in OH-QoL in the control group. However, oral symptoms domain worsened significantly in patients in the test group during the first 4-6 weeks when compared to patients in the control group. The difference between both groups was unlikely to be of clinical significance.

In light with these findings, it would appear that fixed appliance treatment does not significantly affect energy or macro-nutrient intake, body mass index, body fat percentage and total quality of life. Therefore, the null hypothesis proposed by the present study is accepted.

Chapter 8

Recommendations for future research and interventions

8.1 Recommendation for future research

Based on the findings of the present study the following recommendations are suggested for future research:

1. Adopt a randomized clinical trial (RCT) design to provide a high quality evidence base and ascertain any causality inferences.
2. Follow-up patients until the end of their active treatment to ensure that the current findings of the study remain consistent.
3. Recruit another population different from that being investigated in the current study to assess the generalisability of the findings. Perhaps from a specialist practice.
4. Use accurate and precise methods to measure nutrient intake such as biomarkers and blood tests, although the justification for their use might be controversial.
5. Investigate changes in dietary intake and body composition in adult population to assess whether they differ from adolescents as patients' adaptation to fixed orthodontic treatment may vary and differ depending on age (Brown and Moerenhout, 1991).
6. Apply the Wilson and Cleary (1995) model comprehensively in explaining changes in OH-QoL to take into account personality factors which might mediate changes in OH-QoL.
7. Assess associations between ectomorph, mesomorph and endomorph bodily form and malocclusion traits.

8.2 Recommendation for interventions

The findings of the current study showed that fixed orthodontic treatment resulted in changes in dietary intake and body fat and the direction of the changes was towards reducing energy intake, macro-nutrient intake, BMI and body fat percentage. However, these changes appear not to be of clinical importance and that

overweight/obese patients are more likely to be influenced by the treatment. Furthermore, the main changes occurred during the first 4-6 weeks of treatment after which patients started to adapt to treatment.

At the clinical level, these findings can be regarded highly important for orthodontists and could be part of the informed consent process, as fixed orthodontic treatment does not cause serious dietary restriction or significant negative changes in body fat. In addition, based on the current findings of both the qualitative and quantitative studies, the majority of patients felt that their dietary intake became healthier compared to before the treatment. Therefore, patients who are asking about potential impacts of treatment on their dietary intake at the start of their active treatment could be assured that there is no risk of serious dietary restriction and that dietary changes appear to be minimal and only during the first month. Such information may help to improve patients' motivation and acceptance to treatment which may lead to better compliance and successful treatment outcomes.

At a policy level, the present study showed that fixed orthodontic treatment which is one of the most common forms of treatment for malocclusion is a safe treatment and poses no potential negative impact on dietary intake and body fat. This in turn, will help to further justify the need to fund and allocate resources to clinical settings at the national health services where fixed orthodontic treatment is provided.

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East London and the City Research Ethics Committee 1

LIST OF SITES WITH A FAVOURABLE ETHICAL OPINION

For all studies requiring site-specific assessment, this form is issued by the main REC to the Chief Investigator and sponsor with the favourable opinion letter and following subsequent notifications from site assessors. For issue 2 onwards, all sites with a favourable opinion are listed, adding the new sites approved.

REC reference number:	08/H0703/50	**Issue number:**	0	**Date of issue:**	18 July 2008
Chief Investigator:	Dr. Feras Abed Al Jawad				
Full title of study:	An Investigation of the effect of fixed orthodontic treatment on nutritional intake and body weight in adolescent female patients				

This study was given a favourable ethical opinion by East London and the City Research Ethics Committee 1 on 17 July 2008. The favourable opinion is extended to each of the sites listed below. The research may commence at each NHS site when management approval from the relevant NHS care organisation has been confirmed.

Principal Investigator	*Post*	*Research site*	*Site assessor*	*Date of favourable opinion for this site*	*Notes* [1]
Dr. Feras Abed Al Jawad	Full time PhD student in Orthodontics	Orthodontic consultant clinic, Department of Oral Growth and development, 3rd floor, Barts and the London, The Dental Institute, Turner Street, London, E1 2AD.	East London and the City Research Ethics Committee 1	18/07/2008	

Approved by the Chair on behalf of the REC:

..... (Signature of Co-ordinator) .....**Sandra Burke**..... (Name)

Appendix 2: Qualitative courses certificates

NHS
National Institute for
Health Research

Biomedical Research Centre
Guy's & St Thomas' NHS Foundation Trust and King's College
London

Certificate of Attendance

Feras Abed Al Jawad

Attended the following course

Qualitative Data Analysis
Dr Theresa Wiseman
20th April 2008

Dr Jo Armes
Research Fellow

Jo Armes

Continued (Appendix 2)

NHS
National Institute for Health Research

Biomedical Research Centre
Guy's & St Thomas' NHS Foundation Trust and King's College London

Certificate of Attendance

Feras Abed Al Jawad

Attended the following course

Introduction to Critical Appraisal of Qualitative Research
Ms S Lawson
29th April 2009

Dr Jo Armes
Research Fellow

Jo Armes

Appendix 3: Letter from the Nutrition and Dietetic Department

Barts and The London NHS
NHS Trust

Nutrition and Dietetic Department
Healthcare Governance Directorate
59 Philpot Street
The Royal London Hospital
Whitechapel
London
E1 1BB

Tel: 020 7377 7735
Main switchboard: 020 7377 7000
Fax: 020 7377 7737
Email: @bartsandthelondon.nhs.uk
www.bartsandthelondon.nhs.uk

19th May 2008

To whom it may concern

This is to acknowledge that Dr. Feras Abed Al Jawad has met with the Paediatric Dietetic Team to discuss his research project. He attended a paediatric dietetic outpatient clinic and gained clinical insight into undertaking dietary assessment in children. This included gathering information on dietary intake and eating habits by detailed questioning of patients and their carers.

Yours sincerely

L Collins

Lucy Collins BSc (Hons) RD
Principal Paediatric Dietitian

Appendix 4: Patient and parent/guardian information sheet for the qualitative study

An investigation of the effect of fixed orthodontic on nutritional intake and body weight in adolescent patients

Barts and The London

Queen Mary's School of Medicine and Dentistry

Date:

Version Number: 08/H0703/50

Part 1:

We would like to invite you to take part in this academic research project, which will form part of a higher academic qualification, to find the answer to the following question: **Does fixed braces affect your nutrition and body weight?** Before you decide if you want to join in, it's important to understand why the research is being done and what it will involve for you. So please consider this leaflet carefully. Talk about it with your family, friends, doctor or nurse if you want to and I will be delighted to answer any questions you may have.

We are interested in looking at the effect of fixed braces on your eating patterns and habits and understand how discomfort and pain from braces affect your diet. We think that it is an important aspect that could better help orthodontist to advise their patients when they are given fixed braces. Especially, as orthodontic treatment involves putting braces for long periods of time which might cause discomfort and difficulties in eating and swallowing compared to children without braces. We will carry out an interview with you which will be recorded. This interview will ask questions about your diet and whether it has changed.

You will be one of 10 patients who will help us to answer the above question.

It is up to you and your parent/guardian to decide if you want to be involved in this helpful research project. We will describe the study and go through this information sheet. If you do decide, your doctor will ask you to sign a form giving your consent. You will be given a copy of this information sheet and your signed form to keep. You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not in any way affect the care you receive.

You will not have to attend any extra visits other than the planned routine orthodontic visits. The interviewer will ask you and your parent/guardian some questions about how braces have affected your eating habits and how you have adjusted eating to cope with the brace. All information gathered will be dealt with confidentiality. We will ask your parent's/guardian's permission to access your

medical file from your doctor to help check your health. If you have a long standing illness or on a prescribed medication that will affect your eating habits, you will not be included in the study. This interview will take place in the first appointment that follows the appointment of fitting in the braces.
There are no risks or harms involved in taking part in this study and it will not change or affect your future treatment.

If further information is required, please feel free to contact at anytime to discuss your concerns or points to be clarified.

Name: Feras Abed Al Jawad
Address: Centre of oral Biometrics, The Dental Institute, 5th floor
Barts and The London
Turner Street
London E1 2AD, Tel: 020 7377 7632

Thank you for reading so far-if you are interested, please go to Part 2:

Part 2:

If we get any new information related to the study, the research doctor will tell you and discuss it with you. The outcomes of this study will be published in professional journals, to better inform patients of any effects of brace treatment. A summary of results will be sent to you.
You are free to drop out any anytime during the research period, and it will not affect or risk your brace treatment or dental care.

If there is a problem or you have any concerns about any aspect, you should ask to speak the researcher doctor who will do his best to answer your questions. If you remain unhappy and wish to complain formally, you do this through the NHS Complaints Procedure. Detail can be obtained from the hospital.

Bart's and The London NHS Trust Hospital has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of the study. Theses special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action.

Please contact Patient Advisory Liaison Service (PALS) if you have any concerns regarding the care you have received, or as an initial point of contact if you have a complaint. Please telephone 020

7377 6335, minicom 020 7943 1350, or email pals@bartsandthelondon.nhs.uk, you can also visit PALS by asking at any hospital reception.

If you have a complaint pleases contact:
The Complaints Officer
c/o Chief Operating Officer for the Barts and The London,
Queen Mary School of Medicine and Dentistry
Wardens Office
32 Newark Street
Whitechapel
London E1 2AA

All information which is collected about you during the course of the research will be kept strictly confidential. This means we will only tell those who have a need or right to know. Wherever possible, we will only send out information that has your name and address removed. We will send a letter to your doctor informing him your participation in the research. We will also ask him to confirm your medical condition and whether you are under current medication which might affect your dietary intake.

Before any research goes ahead it has to be checked by a research Ethics Committee. They make sure that the research is fair. Your project has been checked by the East London Research Ethics Committee. Project reference No: 08/H0703/50.

This study is funded by the orthodontic consultant clinic, Barts and The London, Queen Mary's School of Medicine and Dentistry

Thank you for this-please ask any questions if you need to.

Appendix 5: The parent/guardian consent form

Consent form

Parent/Guardian Written Consent Form

Study Number: 08/H0703/50

Patient Identification Number for this study:

Title of Project: An Investigation of the effect of fixed orthodontic treatment on nutritional intake and body weight in adolescents.

Name of Researcher: Feras Abed Al Jawad

I confirm that I have read and understand the information sheet dated……. (version 08/H0703/50) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. I have a copy of the leaflet to keep. ☐

I understand my child's part in the study. I know what procedures and measures he/she will go through and what is being asked of him/her. ☐

I understand that my child's participation is voluntary and that he/she is free to withdraw at any time without giving any reason, without her medical care or legal rights being affected. ☐

I understand that relevant sections of my child's medical notes and data collected during the study, may be looked at by individuals from the consultant orthodontic clinic, from regulatory authorities or from the NHS Trust, where it is relevant to my child's taking part in this research. I give permission for these individuals to have access to my child records. ☐

I agree to my child's GP being informed of my participation in the study, and that the principle investigator will contact the GP in relation to my child's medical health and to identify any known eating disorders or any medication taken by my child that might influence dietary intake. ☐

I know that the local East London and the City Ethics Committee has seen and agreed to this study. ☐

I agree that my child take part in the above study. ☐

…… …….. …….

Name of patient's parent/guardian **Date** **Signature**

Appendix 6: Topic guide for the qualitative study

Topic Guide

Questions about the pain:

1. How would you describe your experience with the braces in the last month?
2. How would you describe the pain? How did it hurt you?
3. How long did it last for?
4. How would you describe the intensity of the pain?
5. Which part of the day you had the most severe pain?
6. Which part of your mouth you had the pain?
7. Did you take any painkillers?

Questions about the diet:

1. Do you think that your eating and chewing abilities were affected?
2. Do you think that your diet or the amount of food you ate was less?
3. What food items you couldn't eat because of the braces?
4. What food items you ate more because of the braces?
5. Were you influenced by dietary instructions given to you by your doctor?
6. Do you think that your eating habits are better and healthier?
7. Do you think that your body weight has changed?

Appendix 7: The supplementary questionnaire to assess dietary behaviour

The following questions are being done to understand the effects of braces on your eating habits. By answering the following questions. You will help us learn more about your experiences.

Please remember

- **Answer as honestly as you can. Don't talk to anybody about the questions when you are answering.**
- **Your answers are strictly confidential. The people in the study team will take them away when you have finished.**
- **Before you answer, ask yourself: Does this happen to me because of the treatment?**

Code:

We would be grateful if you would answer the following questions relating to your eating habits following putting on your braces.

Please tick ONE box for each question:

1. **Pain from the braces has caused you difficulty in eating and/or chewing**
   - □ *Strongly agree*
   - □ *Agree*
   - □ *Neutral/no opinion*
   - □ *Disagree*
   - □ *Strongly disagree*

2. **The braces hurt most during the first week**
   - □ *Strongly agree*
   - □ *Agree*
   - □ *Neutral/no opinion*
   - □ *Disagree*
   - □ *Strongly disagree*

3. **The braces hurt most during the first 2 weeks**
   - □ *Strongly agree*
   - □ *Agree*
   - □ *Neutral/no opinion*
   - □ *Disagree*
   - □ *Strongly disagree*

4. **The braces hurt most during the third week**
   - □ *Strongly agree*
   - □ *Agree*
   - □ *Neutral/no opinion*
   - □ *Disagree*
   - □ *Strongly disagree*

5. **The braces hurt most during the fourth week**
   - □ *Strongly agree*
   - □ *Agree*
   - □ *Neutral/no opinion*
   - □ *Disagree*
   - □ *Strongly disagree*

6. **Because of the braces i now have less snacks between meals compared to before treatment**
   - □ *Strongly agree*
   - □ *Agree*
   - □ *Neutral/no opinion*
   - □ *Disagree*
   - □ *Strongly disagree*

7. **The braces resulted in me eating less food compared to before treatment**
   - □ *Strongly agree*
   - □ *Agree*
   - □ *Neutral/no opinion*
   - □ *Disagree*
   - □ *Strongly disagree*

8. **Because of the braces your food has had to be cut into smaller pieces cooked in a different way**
   - □ *Strongly agree*
   - □ *Agree*
   - □ *Neutral/no opinion*
   - □ *Disagree*
   - □ *Strongly disagree*

9. **You ate less sticky foods because it gets stuck in your braces**
   - □ *Strongly agree*
   - □ *Agree*
   - □ *Neutral/no opinion*
   - □ *Disagree*
   - □ *Strongly disagree*

10. **You ate less foods because you were asked to by your dentist**
   - □*Strongly agree*
   - □ *Agree*
   - □ *Neutral/no opinion*
   - □ *Disagree*
   - □ *Strongly disagree*

11. **You ate less hard food types because you were asked to by your dentist**
   - □ *Strongly agree*
   - □ *Agree*
   - □ *Neutral/no opinion*
   - □ *Disagree*
   - □ *Strongly disagree*

12. **The braces resulted in me eating less healthy**
   - □*Strongly agree*
   - □ *Agree*
   - □ *Neutral/no opinion*
   - □ *Disagree*
   - □*Strongly disagree*

Please choose from the following list of food and drinks whether you ***Ate/Drank* as usual** OR ***Ate with difficulty/couldn't eat/drink*** because of the braces. Tick **ONE** box only for each item.

Note: if you don't eat/drink anything from the following list anyways, **Tick** the *Ate/Drank* as usual box.

13. Apples	□ *Ate as usual*	□ *Ate with difficulty/couldn't eat*
14. Carrots	□ *Ate as usual*	□ *Ate with difficulty/couldn't eat*
15. Corn on cob	□ *Ate as usual*	□ *Ate with difficulty/couldn't eat*
16. Crackers	□ *Ate as usual*	□ *Ate with difficulty/couldn't eat*
17. Salads (i.e. Cucumbers, carrots)	□*Ate as usual*	□ *Ate with difficulty/couldn't eat*
18. Nuts (i.e. Pistachio, peanuts)	□ *Ate as usual*	□ *Ate with difficulty/couldn't eat*
19. Toasted bread	□*Ate as usual*	□ *Ate with difficulty/couldn't eat*
20. Meat dishes (i.e. Steaks, lamb chops)	□ *Ate as usual*	□ *Ate with difficulty/couldn't eat*
21. Chocolate bars, crisps and biscuits	□ *Ate as usual*	□ *Ate with difficulty/couldn't eat*
22. Toffee and Chewing gums	□ *Ate as usual*	□ *Ate with difficulty/couldn't eat*
23. Pop/fizzy drinks	□ *Ate as usual*	□ *Ate with difficulty/couldn't eat*

Please choose from the following list of foods and drinks whether you ***Ate/Drank as usual*** *OR* ***Ate/Drank more*** because of the braces. Tick **ONE** box only for each item.

Note: if you don't eat/drink anything from the following list anyways, **Tick** the *Ate/Drank as usual* box.

24. Rice and Pasta dishes	□ *Ate as usual*	□ *Ate more*
25. Mashed dishes (i.e. mashed potatoes)	□ *Ate as usual*	□ *Ate more*
26. Chips and burgers	□*Ate as usual*	□ *Ate more*
27. Bananas	□ *Ate as usual*	□ *Ate more*
28. Soft or boiled vegetables	□ *Ate as usual*	□ *Ate more*
29. Soups	□ *Ate as usual*	□ *Ate more*
30. Water	□ *Drank as usual*	□ *Drank more*
31. Juices	□ *Drank as usual*	□ *Drank more*
32. Milk	□ *Drank as usual*	□ *Drank more*

THANK YOU

Appendix 8: Patient and parent/guardian information sheet for the quantitative study

An investigation of the effect of fixed orthodontic on nutritional intake and body weight in adolescent patients
Barts and The London
Queen Mary's School of Medicine and Dentistry
Date:
Version Number: 08/H0703/50

Part 1:

We would like to invite you to take part in this academic research project, which will form part of a higher academic qualification, to find the answer to the following question: Does orthodontic treatment affect your nutrition and body weight? Before you decide if you want to join in, it's important to understand why the research is being done and what it will involve for you. So please consider this leaflet carefully. Talk about it with your family, friends, doctor or nurse if you want to and I will be delighted to answer any questions you may have.

We are interested in looking at the effect of fixed braces on your eating pattern, body weight, body fat composition and quality of life. We think that it is an important aspect that could better help orthodontist to advise their patients when they are given fixed braces. Especially, as orthodontic treatment involves putting braces for long periods of time which might cause discomfort and difficulties in eating and swallowing compared to children without braces. We will measure your height; weight and body fat composition and ask you to complete two questionnaires which look at food intake and quality of life during the first 3 months of your treatment. Some questions will ask about you and your home background.

You will be one of 140 patients who will help us to answer the above question.

It is up to you and your parent/guardian to decide if you want to be involved in this helpful research project. We will describe the study and go through this information sheet. If you do decide, your doctor will ask you to sign a form giving your consent. You will be given a copy of this information sheet and your signed form to keep. You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not in any way affect the care you receive.

You will not have to attend any extra visits other than the planned routine orthodontic visits. Your body weight, height and body fat composition will be measured just before the start of treatment, and then 1

month and 3 months after the start of treatment. We will use scales to measure your height, weight and body fat composition, which will take only few seconds. You will be asked to remove your shoes and socks during these measurements to improve the accuracy of the measurements. You will also be asked to fill in 2 questionnaires. The first one will ask about the number of times you eat and the type of food, the other one will ask about how the braces have affected your quality of life. There are few questions about you and your family background. Each routine visit will last for 45 minutes. We will ask your parent's/guardian's permission to access your medical file from your doctor to help check your health. If you have a long standing illness or on a prescribed medication that will affect your eating habits, you will not be included in the study.

There are no risks or harms involved in taking part in this study and it will not change or affect your future treatment.

If further information is required, please feel free to contact at anytime to discuss your concerns or points to be clarified.

Name: Feras Abed Al Jawad
Address: Centre of oral Biometrics, The Dental Institute, 5th floor
Barts and The London
Turner Street
London E1 2AD, Tel: 020 7377 7632

Thank you for reading so far-if you are interested, please go to Part 2:

Part 2:

If we get any new information related to the study, the research doctor will tell you and discuss it with you. The outcomes of this study will be published in professional journals, to better inform patients of any effects of brace treatment. A summary of results will be sent to you.

You are free to drop out any anytime during the research period, and it will not affect or risk your brace treatment or dental care.

If there is a problem or you have any concerns about any aspect, you should ask to speak the researcher doctor who will do his best to answer your questions. If you remain unhappy and wish to complain formally, you do this through the NHS Complaints Procedure. Detail can be obtained from the hospital.

Bart's and The London NHS Trust Hospital has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of the study. There is special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action.

Please contact Patient Advisory Liaison Service (PALS) if you have any concerns regarding the care you have received, or as an initial point of contact if you have a complaint. Please telephone 020 7377 6335, minicom 020 7943 1350, or email pals@bartsandthelondon.nhs.uk, you can also visit PALS by asking at any hospital reception.

If you have a complaint pleases contact:
The Complaints Officer
c/o Chief Operating Officer for the Barts and The London,
Queen Mary School of Medicine and Dentistry
Wardens Office
32Newark Street
Whitechapel
London E1 2AA

All information which is collected about you during the course of the research will be kept strictly confidential. This means we will only tell those who have a need or right to know. Wherever possible, we will only send out information that has your name and address removed. We will send a letter to your doctor informing him your participation in the research. We will also ask him to confirm your medical condition and whether you are under current medication which might affect your dietary intake.

Before any research goes ahead it has to be checked by a research Ethics Committee. They make sure that the research is fair. Your project has been checked by the East London Research Ethics Committee. Project reference No: 08/H0703/50.

This study is funded by the orthodontic consultant clinic, Barts and The London, Queen Mary's School of Medicine and Dentistry.

Thank you for this-please ask any questions if you need to.

Appendix 9: Socio-demographic questionnaire

The following questions are about you and your home

1. Are you a boy or a girl?

□Boy
□Girl

2. When were you born? ---------/----------/----------
Day Month Year

3. Write the number on the line below:
I live with ……. Other adults and children NOT including myself.
(e.g. If you live with mum, step-dad and two sisters write '4')

4. Which adults do you live with most of the time?

Tick a box for each adult who lives in your home now.

Mum □

Dad □

Step-dad/Mum's boyfriend/partner □

Step-mum/dad's girlfriend/partner □

dad's girlfriend/partner □

Mum's boyfriend/partner □

Grandfather □

Grandmother □

In care

Other ……..

5. Does your mum or step-mum have a job?

✔ one box only

☐ Mum or step-mum has a job/ is a student

☐ Mum or Step-mum does NOT have a job

☐ Don't live with mum

6. Does your dad or step-dad have a job?

☑ one box only

☐ Dad or step-dad has a job/ is a student

☐ Dad or Step-dad does NOT have a job

☐ Don't live with dad

7. How many rooms other than the kitchen, bathroom and hall does your home have?

Write the number on the line below:

My home has ……. rooms NOT including the kitchen, bathroom and hall.

8. Does anyone you live with have a car or van?

☐ No ☐ Yes, one ☐ Yes, two or more

9. Do your parents/ carers own or rent your home (If they have a mortgage , tick they own it)?

☐ They own it ☐ They rent it ☐ Don't know

10. Does your family have access to the internet at home?

☐ No ☐ Yes ☐ Don't know

11. Which category best describes you?

- This is your race or ethnic group

Please tick (✔) ONE box only

White
- □1 White: UK
- □2 White: Irish
- □3 White: Greek
- □4 White: Turkish
- □5 White: Orthodox Jewish
- □6 White: Kurdish
- □7 White: other (please write) ……..

Mixed
- □8 Mixed: White and Black Caribbean
- □9 Mixed: White and Black African
- □10 Mixed: White and Asian
- □11 Mixed: other (please write) ……

Asian
- □12 Asian: Indian
- □13 Asian: Pakistani
- □14 Asian: Bangladeshi
- □15 Asian: other (please write) ……..

Black
- □16 Black: Caribbean
- □17 Black: African
- □18 Black: Somali
- □19 Black: British
- □20 Black: other (please write): ……

Other ethnic group
- □21 Chinese
- □22 Vietnamese
- □23 Other (please write): ……

Appendix 10: Food Frequency Questionnaire (FFQ)

Instructions

The questions in this questionnaire either ask you to put a TICK in the box to indicate the answer that describes you best OR they ask you to write your answer on the dotted line.

The first set of questions asks you about how often you have eaten certain foods in the PAST MONTH. For each food, we would like you to tick the box that tells us how often you have eaten it. The boxes along the top and bottom of each page describe the number of times in a day or week you have eaten the food in the box on the left hand side of the page.

So if you ate the food occasionally, but not every week of the past month, you would tick under the box that says '1-3 times a month'.

If you ate it almost every day in the past month, you would tick under the box that says '4-6 times a week'.

If there is something that you have been eating several times a day in the past month, you would either tick under the box that says '2-4 times a day' or the box that says '5 or more times a day', depending on how often you usually ate it.

Example:

The following question is filled in as an example, and shows that in the past month, I ate two apples every day, on average. Some days I may have eaten more and some days I may have eaten less, but over the whole month I ate about two apples a day.

OVER THE PAST MONTH HOW OFTEN HAVE YOU EATEN THESE FOODS?

In the PAST MONTH....	5 or more times a day	2-4 times a day	once a day	4-6 times a week	2-3 times a week	once a week	1-3 times a month	never
FRESH FRUIT								
Apples		✓						

On the next page there is an practice question for you to answer.

Practice Page

Below are two example questions for you to fill in.

Example 1:
If, in the past month, I ate two slices of toast made with white bread for breakfast, and a sandwich made with brown bread for lunch every day which boxes would you tick?

OVER THE PAST MONTH HOW OFTEN HAVE YOU EATEN THESE FOODS?								
In the PAST MONTH....	5 or more times a day	2-4 times a day	once a day	4-6 times a week	2-3 times a week	once a week	1-3 times a month	never
BREADS AND CRACKERS								
White bread, toast or rolls								
Brown & wholemeal bread, toast or rolls								

Example 2:
If I ate butter or margarine on my toast at breakfast time, and butter or margarine on the bread that made up my sandwich, I would also have to tick the box for fat spreads, under the 'dairy foods' section. Which box would I tick to indicate how often I ate fat spreads in the past month if I had toast for breakfast every day and a sandwich at lunch every day?

OVER THE PAST MONTH HOW OFTEN HAVE YOU EATEN THESE FOODS?								
In the PAST MONTH.....	5 or more times a day	2-4 times a day	once a day	4-6 times a week	2-3 times a week	once a week	1-3 times a month	never
DAIRY FOODS								
Fat spreads - on bread etc eg butter, margarine, Gold								

Now please complete the rest of the questionnaire. If you have any problems answering the questions that begin over the page, please ask one of the people from the study team.

OVER THE PAST MONTH HOW OFTEN HAVE YOU EATEN THESE FOODS?								
In the PAST MONTH.....	5 or more times a day	2-4 times a day	once a day	4-6 times a week	2-3 times a week	once a week	1-3 times a month	never
BREADS & CRACKERS								
White bread, toast or rolls								
Brown & wholemeal bread, toast or rolls								
Other breads eg Pitta, Naan, Croissant								
Crackers & crispbread e.g ryvita, cream crackers								
BREAKFAST CEREALS								
Packet cereals e.g cornflakes, muesli								
Porridge, ready brek								
BISCUITS, CAKES, SWEETS & SNACKS								
Chocolate biscuits eg Penguins, chocolate digestives								
Other biscuits eg custard creams, Nice, gingernuts								
Cakes eg muffins, swiss roll, fruit cake								
Pastries & buns eg jam tarts, doughnuts, crumpets								
Chocolate & snack bars eg Mars, Twix, cereal bar								
Sweets eg toffees, mints, fruit gums, boiled sweets								
Crisps & snacks eg Frisps Hula Hoops								
In the PAST MONTH.....	5 or more times a day	2-4 times a day	once a day	4-6 times a week	2-3 times a week	once a week	1-3 times a month	never

OVER THE PAST MONTH HOW OFTEN HAVE YOU EATEN THESE FOODS?								
In the PAST MONTH.....	5 or more times a day	2-4 times a day	once a day	4-6 times a week	2-3 times a week	once a week	1-3 times a month	never
MEATS, MEAT DISHES & PIES								
Roast meats - pork, beef, chicken or lamb								
Beefburgers, hamburgers								
Chicken or turkey burgers & nuggets								
Mince dishes eg Chilli con carne, Lasagne, bolognaise sauce								
Stews & curries-pork, beef, lamb or chicken								
Liver, kidney & faggots								
Bacon & gammon								
Sausages								
Meat pies, pasties and sausage rolls, Scotch egg								
Cold meats eg. corned beef, ham, Spam								
FISH								
Fish fingers & fish cakes								
White fish eg Plaice, Cod including fish in batter								
Oily fish eg Mackerel, Sardines, Salmon, Tuna								
Prawns, crab, scampi, other shellfish								
PIZZAS & FLANS								
Pizza								
Quiche or savoury flan								
In the PAST MONTH.....	5 or more times a day	2-4 times a day	once a day	4-6 times a week	2-3 times a week	once a week	1-3 times a month	never

OVER THE PAST MONTH HOW OFTEN HAVE YOU EATEN THESE FOODS?								
In the PAST MONTH.....	5 or more times a day	2-4 times a day	once a day	4-6 times a week	2-3 times a week	once a week	1-3 times a month	never
PUDDINGS								
Sponge pudding, fruit crumbles, cheesecake								
Milk puddings e.g rice								
DAIRY FOODS								
Low fat yogurt, fromage frais								
Full fat yogurt e.g. Greek								
Dairy desserts, fruit fool, chocolate & fruit mousse								
Low fat & cottage cheese								
Cheese e.g. Cheddar, Brie cream cheese								
Milk in drinks, on cereal, milkshakes etc								
Eggs, boiled, fried, omelette								
Fat spreads - on bread etc eg butter, margarine, Gold								
MISCELLANEOUS FOODS & SAUCES								
Soup								
Jam, honey & marmalade								
Peanut butter								
Sugar -in drinks, on cereal								
Tomato ketchup & pickle								
Custard, cheese sauce, gravy								
Mayonnaise, salad cream								
Bovril & Marmite								
In the PAST MONTH.....	5 or more times a day	2-4 times a day	once a day	4-6 times a week	2-3 times a week	once a week	1-3 times a week	never

OVER THE PAST MONTH HOW OFTEN HAVE YOU EATEN THESE FOODS?								
In the PAST MONTH.....	5 or more times a day	2-4 times a day	once a day	4-6 times a week	2-3 times a week	once a week	1-3 times a month	never
BISCUITS, CAKES, SWEETS & SNACKS (continued)								
Ice creams & lollies								
Nuts eg peanuts, cashews								
Dried fruit eg raisins, dried apricots, dates								
FRESH FRUIT								
Apples								
Oranges, satsumas								
Grapefruit								
Bananas								
Grapes								
Peaches, nectarines								
Strawberries, raspberries								
Other tropical fruits eg. melon, pineapple, mango								
DRINKS								
Tea								
Coffee								
Hot chocolate, Horlicks								
Diet fizzy drinks eg Diet Coke, Diet Sprite								
Other fizzy drinks eg Lilt, 7-Up, Coke								
Still drinks, squash/cordial								
Pure fruit juice								
Alcoholic drinks e.g. wine, lager & spirits								
In the PAST MONTH.....	5 or more times a day	2-4 times a day	once a day	4-6 times a week	2-3 times a week	once a week	1-3 times a month	never

OVER THE PAST MONTH HOW OFTEN HAVE YOU EATEN THESE FOODS?								
In the PAST MONTH.....	5 or more times a day	2-4 times a day	once a day	4-6 times a week	2-3 times a week	once a week	1-3 times a month	never
VEGETARIAN FOODS								
Vegeburgers & bangers								
Vegetable dishes e.g. veg. curry,veg. lasagne								
Pulses e.g.lentils, chick peas, hummus,red kidney beans,INCLUDING BAKED BEANS								
Tofu, Quorn								
POTATOES, PASTA & RICE								
Boiled potatoes, jacket potato								
Chips, roast & fried potatoes								
Pasta - fresh & dried, tinned spaghetti in sauce								
Rice, boiled, fried								
VEGETABLES								
TINNED peas, mixed veg.								
Sweetcorn								
Cabbage & spring greens (fresh/frozen)								
Carrots (fresh/frozen)								
Peas & green beans (fresh/frozen)								
Broccoli/brussel sprouts (fresh/frozen)								
Cauliflower (fresh/frozen)								
Salad, lettuce, cucumber								
Tomatoes (fresh/tinned)								
In the PAST MONTH.....	5 or more times a day	2-4 times a day	once a day	4-6 times a week	2-3 times a week	once a week	1-3 times a month	never

Appendix 11: Child Perception Questionnaire (CPQ11-14)

QUESTIONS ABOUT ORAL PROBLEMS

In the <u>past 3 months</u>, how often have you had:

1. **Pain in your teeth, lips, jaws or mouth?**

   - ❑ Never
   - ❑ Once or twice
   - ❑ Sometimes
   - ❑ Often
   - ❑ Everyday or almost every day

2. **Bleeding gums?**

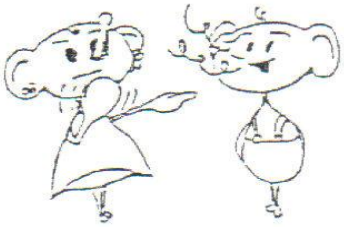
   - ❑ Never
   - ❑ Once or twice
   - ❑ Sometimes
   - ❑ Often
   - ❑ Everyday or almost every day

3. **Sores in your mouth?**

   - ❑ Never
   - ❑ Once or twice
   - ❑ Sometimes
   - ❑ Often
   - ❑ Everyday or almost every day

4. **Bad breath?**

   - ❑ Never
   - ❑ Once or twice
   - ❑ Sometimes
   - ❑ Often
   - ❑ Everyday or almost every day



5. **Food stuck in or between your teeth?**

   - ❑ Never
   - ❑ Once or twice
   - ❑ Sometimes
   - ❑ Often
   - ❑ Everyday or almost every day

In the past 3 months, because of your teeth, lips, mouth or jaws, how often has it been:

10. **Difficult to bite or chew food like apples, corn on the cob or steak?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

11. **Difficult to open your mouth wide?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

12. **Difficult to say any words?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

13. **Difficult to eat foods you would like to eat?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

14. **Difficult to drink with a straw?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

15. **Difficult to drink or eat hot or cold foods?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

QUESTIONS ABOUT FEELINGS

Have you had the feeling because of your teeth, lips, jaws or mouth?
If you felt this way for another reason, answer 'Never'.

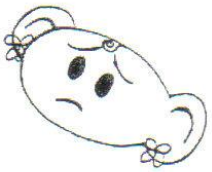
In the past 3 months, how often have you:

16. **Felt irritable or frustrated?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

17. **Felt unsure of yourself?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day



18. **Felt shy or embarrassed?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

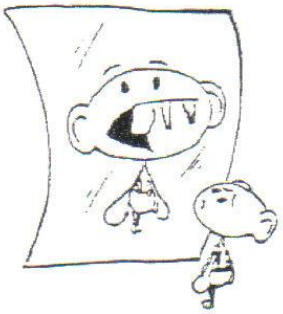
In the past 3 months, because of your teeth, lips, mouth or jaws, how often have you:

19. **Been concerned what other people think about your teeth, lips, mouth or jaws?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

20. **Worried that you are not as good-looking as others?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day



21. **Been upset?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

22. **Felt nervous or afraid?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

23. **Worried that you are not as healthy as others?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

24. **Worried that you are different than other people?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

QUESTIONS ABOUT SCHOOL

Have you had these experiences because of your teeth, lips, jaws or mouth? If it was for another reason, answer 'Never'.

In the past 3 months, how often have you:

25. **Missed school because of pain, appointments, or surgery?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

26. **Had a hard time paying attention in school?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

27. **Had difficulty doing your homework?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

28. **Not wanted to speak or read out loud in class?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

QUESTIONS ABOUT YOUR SPARE-TIME ACTIVITIES & BEING WITH OTHER PEOPLE

Have you had these experiences because of your teeth, lips, jaws or mouth? If it was for another reason, answer 'Never'.

In the past 3 months, how often have you:

29. **Avoided taking part in activities like sports, clubs, drama, music, school trips?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

30. **Not wanted to talk to other children?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

31. **Avoided smiling or laughing when around other children?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

32. **Had difficulty playing a musical instrument such as a recorder, flute, clarinet, trumpet?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

33. **Not wanted to spend time with other children?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

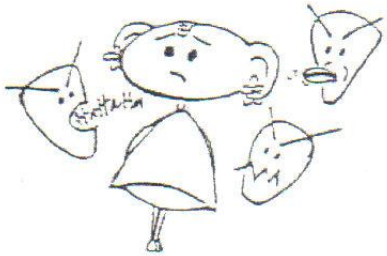
34. **Argued with other children or your family?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

In the past 3 months, because of your teeth, lips, mouth or jaws, how often have:

35. **Other children teased you or called you names?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day



36. **Other children made you feel left out?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

37. **Other children asked you questions about your teeth, lips, jaws or mouth?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

Appendix 12: Pain Dairy

DIARY

To complete everyday during the first 7 days and one time the second, third and fourth week

Code:

First day

Date of completion of these questions:

/ /

1- How much are your teeth hurting at the moment?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

2- How much braces is hurting you from biting and chewing food?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

Pain killers

Have you taken any pain killers/ medicine since your appointment with your orthodontist to help your teeth hurt less?

Please put a cross (X) in the correct box

Yes ☐ **No** ☐

Second day

Date of completion of these questions:

/ /

1- How much are your teeth hurting at the moment?

Please put a cross (X) on the line to show how much your teeth have hurt

My teeth do not hurt at all — **My teeth hurt very badly**

2- How much braces is hurting you from biting and chewing food?

Please put a cross (X) on the line to show how much your teeth have hurt

My teeth do not hurt at all — **My teeth hurt very badly**

Pain killers

Have you taken any pain killers/ medicine since your appointment with your orthodontist to help your teeth hurt less?

Please put a cross (X) in the correct box

Yes ☐ **No** ☐

Third day

Date of completion of these questions:

/ /

1- How much are your teeth hurting at the moment?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

2- How much braces is hurting you from biting and chewing food?

Please put a cross (X) on the line to show how much your teeth have hurt

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My teeth do not hurt at all — **My teeth hurt very badly**

Pain killers

Have you taken any pain killers/ medicine since your appointment with your orthodontist to help your teeth hurt less?

Please put a cross (X) in the correct box

Yes ☐ **No** ☐

Fourth day

Date of completion of these questions:

/ /

1- How much are your teeth hurting at the moment?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

2- How much braces is hurting you from biting and chewing food?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

Pain killers

Have you taken any pain killers/ medicine since your appointment with your orthodontist to help your teeth hurt less?

Please put a cross (X) in the correct box

Yes ☐ **No** ☐

Fifth day

Date of completion of these questions:

/ /

1- How much are your teeth hurting at the moment?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

2- How much braces is hurting you from biting and chewing food?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

Pain killers

Have you taken any pain killers/ medicine since your appointment with your orthodontist to help your teeth hurt less?

Please put a cross (X) in the correct box

Yes ☐ **No** ☐

Sixth day

Date of completion of these questions:

/ /

1- How much are your teeth hurting at the moment?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

2- How much braces is hurting you from biting and chewing food?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

Pain killers

Have you taken any pain killers/ medicine since your appointment with your orthodontist to help your teeth hurt less?

Please put a cross (X) in the correct box

Yes ☐ **No** ☐

Seventh day

Date of completion of these questions:

/ /

1- How much are your teeth hurting at the moment?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

2- How much braces is hurting you from biting and chewing food?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

Pain killers

Have you taken any pain killers/ medicine since your appointment with your orthodontist to help your teeth hurt less?

Please put a cross (X) in the correct box

Yes ☐ **No** ☐

Second week

Date of completion of these questions:

/ /

1- How much are your teeth hurting at the moment?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

2- How much braces is hurting you from biting and chewing food?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

Pain killers

Have you taken any pain killers/ medicine since your appointment with your orthodontist to help your teeth hurt less?

Please put a cross (X) in the correct box

Yes ☐ **No** ☐

Third week

Date of completion of these questions:

/ /

1- How much are your teeth hurting at the moment?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

2- How much braces is hurting you from biting and chewing food?

Please put a cross (X) on the line to show how much your teeth have hurt

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My teeth do not hurt at all — **My teeth hur very badly**

Pain killers

Have you taken any pain killers/ medicine since your appointment with your orthodontist to help your teeth hurt less?

Please put a cross (X) in the correct box

Yes ☐ **No** ☐

Fourth week

Date of completion of these questions:

/ /

1- How much are your teeth hurting at the moment?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

2- How much braces is hurting you from biting and chewing food?

Please put a cross (X) on the line to show how much your teeth have hurt

---

My teeth do not hurt at all — **My teeth hurt very badly**

Pain killers

Have you taken any pain killers/ medicine since your appointment with your orthodontist to help your teeth hurt less?

Please put a cross (X) in the correct box

Yes ☐ **No** ☐

Appendix 13: Question about the influence of dietary instructions given to patients by their orthodontist

Were you influenced by dietary instructions given to you by your dentist?

□ Yes

□ No

Appendix 14: Anthropometric form

Anthropometric form

Code:

Age: **Gender:**

1st visit

Body weight = 1st……., 2nd ……, 3rd……

Height: 1st……., 2nd ……, 3rd……

BMR= ……..,, Fat%= …….

2nd visit

Body weight = 1st……., 2nd ……, 3rd……

Height: 1st……., 2nd ……, 3rd……

BMR= ……..,, Fat%= …….

3rd visit

Body weight = 1st……., 2nd ……, 3rd……

Height: 1st……., 2nd ……, 3rd……

BMR= ……..,, Fat%= …….