AMERICAN UNIVERSITY OF BEIRUT

THE ASSOCIATION BETWEEN ORTHODONTIC TREATMENT AND DIETARY INTAKE IN ADOLESCENT PATIENTS

by
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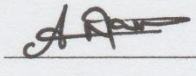

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AN ABSTRACT OF THE THESIS OF

Nancy Georges Abdo for Master of Science
Major: Orthodontics

Title: The Association between Orthodontic Treatment and Dietary Intake in Adolescent Patients

Background and Aims: Fixed appliances have been reported to cause dietary restrictions, however available literature carries many caveats, and there's lack of knowledge about whether dietary changes fall within normal ranges and whether they affect tooth movement. Therefore we aimed to assess acute and long term effect of fixed appliances and palatal expansion on dietary intake in adolescent patients; explore the healthiness of the reported dietary changes and their effect on tooth movement rate.

Methods: Patients (11-21yr) were recruited from the Orthodontics Clinics of AUBMC: 95 requiring treatment with fixed appliances, and 20 to be treated with palatal expansion. BMI and dietary intake were evaluated at baseline, 1, 5 and 13 weeks after treatment initiation to detect changes in nutrients and food categories. Participants completed a pain diary during the study period, and cephalometric measurements were performed on the initial lateral cephalometric X-ray to evaluate the influence of pain and initial severity of the malocclusion on dietary changes. Those changes were correlated with the rate of tooth movement computed by measuring the Little's irregularity index on sequential dental casts. Changes in dietary intake across time and across categorical variables were tested through analyses of variance; Pearson correlation product moment was employed for associations among different variables.

Results: In the fixed appliances group, BMI did not differ along the study period although total energy and absolute food intakes significantly decreased at 5weeks of treatment and further decreased at 13weeks. Adolescents adopted unhealthy dietary habits initially reflected by inadequate fiber (g/d) potassium (mg/d) and calcium (mg/d) intakes and high fat intake (%EI) especially saturated fat (%EI). These habits deteriorated during treatment due to decreased intakes of fruits-dried fruits (g/d), starchy vegetables (g/d) and dairy products (g/d) and increased intakes of pizzas-pies (%EI) and oils (%EI). Dietary changes were similar in the expansion subgroup except for a greater decrease in omega3 intake levels. Pain intensity and malocclusion severity were not associated with the observed dietary changes, however when the second arch was bonded early in treatment more prominent changes were detected. A decrease in vitamin C intake showed a weak but significant correlation with slower rate of tooth movement.

Conclusion: The orthodontist should refer patients to dieticians before treatment initiation to identify those with nutritional inadequacies necessitating personalized dietary guidance. In addition, he shall promote improvement of unhealthy dietary habits by advising on food selection and preparation during treatment; including softer food of high nutritional value for comfortable chewing and reinforcement of optimal growth, general health and periodontal tissues health during orthodontic tooth movement.

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ILLUSTRATIONS

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ABBREVIATIONS

%EI	Percent contribution to total Energy Intake
Δ	Difference
1wkE	First week of expansion
24-h	24 hours
a1	First arch
a2	Second arch
ADA	American Dental Association
AI	Adequate Intake
AMDR	Acceptable Macronutrient Distribution Range
AMPM	Automated Multiple-Pass Method
ANOVA	Analysis of Variance
AUB (MC)	American University of Beirut (Medical Center)
B	Baseline
BMI	Body Mass Index
BMI	Body Mass Index
DI	Dietary intake
DRI	Dietary Reference Intakes
Ex	Expansion subgroup
FA	Fixed Appliances group
FAO	Food and Agriculture Organization of the United Nations
FFQ	Food Frequency Questionnaire
g/d	Grams per day
IOM	Institute of Medicine
Kcal/d	Kilocalories per day
Kg	Kilograms
LII	Little's Irregularity Index
LPSG	Lebanese Portion Size Guide
M1	First month of treatment
M3	Third month of treatment
m	Meters
mcg/d	Micrograms per day
md	Mandibular arch
mg/d	Milligrams per day
mm	Millimeters
Mx	Maxillary arch
NFSC	Nutrition and Food Sciences Department
OB	Overbite
OJ	Overjet
SD	Standard Deviation
SES	Socioeconomic Status

SPSS	Statistical Package of the Social Sciences
U.S.	United States
USDA	United States Department of Agriculture
VAS	Visual Analogue Scale
WHO	World Health Organization
wk	Week
$\tilde{x}$	Median

CHAPTER I

INTRODUCTION

A. Background

During the last decades, guidelines for accreditation of dental schools by the American Dental Association (ADA) required that "the graduate must be competent to provide dietary counseling and nutritional education relevant to oral health". Accordingly, study of diet and nutrition has become a mandatory part of curriculum in many dental schools (Paul, Paul, & Paul, 2011; Riordan, 1997; Sharma, Mittal, Singla, & Grover, 2011) . With nutritional issues in the spot light, the concern of how orthodontic treatment affects patients' diet started to develop.

The nutritional needs of adolescents, which is the age of a typical orthodontic patient, are stressed by growth and development as well as the emotional stress of puberty. Moreover, the orthodontic treatment creates physical, physiologic and emotional stresses increasing nutrients' mobilization and utilization, thus raising the regular nutritional requirements of the patient. Therefore, maintenance of a well-balanced diet is of great importance to prevent infection, promote growth and development and allow healing of the periodontal tissues during orthodontic treatment (Paul et al., 2011; Sharma et al., 2011; Singh, Tripathi, Rai, & Gupta, 2017).

Orthodontists advise their patients to eat soft food to prevent appliance breakage, and to accommodate pressure sensitivity experienced with tooth movement. However, very few give clear cut instructions or provide diet charts. In absence of the latter, patients generally switchover to convenient food, that is easier to eat, without any

special attention to the nutritional value of the consumed food (Riordan, 1997; Sandeep et al., 2016; Sharma et al., 2011). Consequently, suboptimal levels of certain nutrients are common, and have an effect on the biologic response of the tissues influenced by orthodontic treatment (Ajmera, Tarvade, & Patni, 2015; Hickory & Nanda, 1981; Paul et al., 2011). In addition, occlusal changes during treatment may impair mastication and patients may cope by altering their diet or by swallowing coarse particles leading to digestive disorders. In both circumstances, impaired dietary intake may increase nutrition-induced disease risks (Shirazi, Mobarhan, Nik, Kerayechian, & Ferns, 2011).

B. The Role of the Orthodontist in Nutrition

Prior to initiation of orthodontic treatment, patients may have unrealistic expectations on whether eating habits will be affected. Indeed, patients may indicate that they did not think orthodontic treatment would affect what they eat and drink (Carter et al., 2015). This shows the importance of ensuring that patients are more aware of the challenges likely to be experienced and the changes they may need to make.

Being aware that nutrition, oral health and general health are linked, orthodontists should be able to screen for dietary issues and provide dietary advice as good nutrition maximizes orthodontic outcomes (Schindler & Palmer, 2011).

Furthermore, and given that orthodontic appliances increase the available surfaces for plaque accumulation, the orthodontist occupies an important position in educating patients about diet and dental caries. Recommendations should include reducing cariogenic food rich in sugar, and stressing the importance of non-cariogenic food as protein and fibers. In addition, the orthodontist is responsible of detecting and reporting any clinical manifestations of nutritional deficiencies or toxicities, through

careful examination of the oral cavity, before it appears in other body sites (Schindler & Palmer, 2011).

C. Research Question and Rationale

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 (Acs, Lodolini, Kaminsky, & Cisneros, 1992; Brodeur, Laurin, Vallee, & Lachapelle, 1993). Conversely nutrition play an important role in oral tissues' health promotion and caries prevention (Schindler & Palmer, 2011). However, a limited number of orthodontic studies have assessed the impact of treatment on dietary intake, and most importantly the effect of possible dietary changes on tooth movement during treatment. In addition, and to the best of our knowledge, no previous study have explored the effect of orthodontic appliances other than fixed appliances, for instance maxillary expanders, on dietary intake. In fact the prevalence of anterior and posterior crossbite malocclusion necessitating treatment with maxillary expansion is 9.5 and 23.3% respectively in the mixed dentition (Shalish, Gal, Brin, Zini, & Ben-Bassat, 2012), and can reach 51% in the early permanent dentition (Gungor, Taner, & Kaygisiz, 2016) which reflects the popularity of this treatment. And if dietary changes occur simultaneously, it will be a significant consideration for patients undergoing orthodontic treatment with fixed appliances and rapid maxillary expansion, as they may necessitate special nutritional advice depending on the nature of changes. Therefore, the current research question inquire about the association between orthodontic treatment, including fixed appliances therapy and rapid maxillary expansion, on dietary intake and body mass index in a group of Lebanese adolescent patients.

CHAPTER II

LITERATURE REVIEW

A. Dietary Assessment

1. Dietary Behavior in Adolescents

Adolescence is the developmental stage between childhood and adulthood. It ranges from the onset of puberty characterized by the appearance of secondary sexual characteristics, usually between the ages of 11 and 13 years, to the attainment of adulthood (Coleman, 2006). It is divided into three stages: early adolescence, ages eleven to fourteen; middle adolescence, ages fifteen to seventeen; and late adolescence, ages eighteen to twenty-one as defined by the American Academy of Pediatrics.

Adolescence is considered a nutritionally vulnerable period. During this phase there is a sudden acceleration of the velocity of growth altering the relatively uniform growth of childhood and increasing nutrients' demand. This sudden spurt is also associated with variety of biological and lifestyle changes and dramatic transitions in the physical, social, sexual, emotional and intellectual spheres affecting food habits, nutrients' intake and needs (Coleman, 2006; Spear, 2002).

Dietary patterns are generally poor among adolescents. Starting this phase, more food is consumed away from home, and teens begin to make their own food choices. Parental control on food choice is likely to decrease, food may be used to establish an independent identity, and peer influence affects significantly food choices (Carter et al., 2015; Schindler & Palmer, 2011). Irregular meals, snacking, meal skipping, vending machine use, fast food purchases, high sugar-sweetened, carbonated,

and/or caffeinated beverage intake, and mindless eating are the most frequent patterns observed (Casamassimo, Fields, & Mctigue, 2005). Furthermore, the sociodemographic characteristics of the family, parents' employment, education and economic status as well as the adolescents' lifestyle influence their dietary patterns. For instance snacking behavior and the consumption of processed meat, refined sugars and fast food is greater in those with a higher socioeconomic status, maternal employment, sedentary lifestyle and lower mother's educational level increasing the odds of overweight and obesity (Naja, Hwalla, Itani, Karam, et al., 2015; Nasreddine et al., 2014). Practical factors such as price, time available for food shopping and the preparation and cooking of food are also likely to impact on food choice (Carter et al., 2015). Psychological maturation also influences nutritional patterns especially in girls who, at this time of life, have increased bodily awareness and concern with social acceptance. Females are more likely to adhere to healthier diet rich in fruits, vegetables, fish, breads and cereals, with lower intakes of fat and sugar (Naja, Hwalla, Itani, Karam, et al., 2015). However young girls may go to extremes to maintain a slim figure at a time when biological demands require optimal food intake. The attempt to stay slim may result in nibbling, undereating, and lack of a good, varied diet. This may explain the repeated observation that teenage girls tend to be deficient in iron and certain vitamins ("Nutritional Assessment of Adolescents," 1973).

2. Dietary Assessment Tools

The purpose of dietary assessment is to estimate food consumption or nutrient intake in individuals or groups of people. 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 to be able to choose the dietary assessment method which best corresponds to the type of study conducted (Lee & Nieman, 2013) .

a. The Dietary Records

The dietary records rely on the patient recoding his daily dietary intake in a specially designed booklet. Dietary records can be of several types:

i. 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. The principle disadvantage is that it cannot be used to estimate quantities of nutrient intake (Pfau, 1999).

ii. Estimated Records

Estimated records require the respondent to record all food and beverages consumed over a specific period of time, generally between 1 and 7 days, and describe them in detail to allow the investigator to select an appropriate food from tables of food composition or for laboratory analysis. He must also provide information on the amounts of food consumed by using household measures (i.e. jugs, cups, spoons), or by estimation of quantities using photographs of food with portion choices, or using food models. The investigator converts these estimates into weights to calculate food and

nutrient intake. The advantages of estimated records are that they are accurate with respect to food consumed; they do not rely on respondent memory and involve less disruption to normal eating patterns when compared to weighed records. The disadvantages are that the method requires high cooperation on the part of the respondent, who should be motivated and literate. The amount of detail recorded can be manipulated by the patient especially if he knows that his diet will be analyzed. He may adjust what he ate (or what he recorded as eaten) to what he considers healthy or average. This way the actual intake may have been underreported. 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. Furthermore, the cost of conducting this method is expensive (e.g. using food models and photographs) (Riordan, 1997; Thompson & Subar, 2008; van Staveren & Ocké, 2006).

iii. Weighed Records

In this method the individual weighs each 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 at the time of consumption. The person being investigated should be trained by a skilled nutritionist to accurately specify the food, amounts and cooking methods. 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 food actually consumed over a specified period of time, due to precise portion size recording. However, weighing all food consumed each day can cause respondent burden because it requires high levels of cooperation and training. This might cause the

respondents to change their usual eating patterns by reducing the number of food and snacks eaten and to decrease the complexity of their diets to simplify the recording process. Thus, the food record may significantly underreport energy and nutrient intakes. Furthermore, respondents may drop out, which will affect the required sample size in the population of interest. This method is expensive to conduct and requires highly skilled personnel to monitor all steps of the process, including respondent training and guiding (Thompson & Subar, 2008; van Staveren & Ocké, 2006).

b. The One-to-One Interview

The one-to-one interview is a detailed interview in which the investigator attempts to construct the respondent‘s pattern of intake over a period of time, elaborating the usual variations in meals and the usual size of food portions. This method is susceptible to recall bias and underestimation of nutrient intakes. Time and skills is required by both interviewers and respondents (Jackson, Little, & Wilson, 1990; Martin, Tapsell, Batterham, & Russell, 2002).

c. The 24-Hour Recall Method

The 24-hour recall method is conducted by means of an interview (face to face, over the telephone or by a computerized 24-hour diet recall program) in which the respondent is asked to provide a recall of all food and beverages consumed over the past 24 hours. This method requires highly skilled interviewers or else it will be subjected to interviewer bias leading to an overestimation of the studied association. Furthermore, there is an intra-individual variability in food consumption which makes a single 24-hour recall not representing the usual individual daily intake due to day-to-day

variation. In addition to that, the respondent may not remember or report accurately all food and beverages consumed; there is a trend towards under- reporting and the portion size is difficult to estimate (Mahan, Escott-Stump, & Krause, 2007; Miresmaili, 2016). Attempts to compensate for these limitations have included applying an averaging of multiple 24-hour recalls over a period of few days and using the Multiple Pass 24-hour recall. The latter method consists of 5-step dietary interview that includes multiple passes through the 24 hours of the previous day, during which respondents receive cues to help them remember and describe food they consumed. It is based on a quick list of the food and drinks consumed; followed by a detailed description and a review to probe for information on time and occasion, forgotten food and food details. It was developed by the United States Department of Agriculture (USDA) in 1999. Initially, a pencil-and-paper version of the method was used, until a computer-assisted version of this 5-step method, the Automated Multiple-Pass Method (AMPM), was developed. It navigates the interviewer through the recall, posing standardized questions and providing response options for different food and beverages. It has been used since 2002 to collect dietary recalls in many nutritional surveys (Table 2.1) (Moshfegh et al., 2008).

Table 2.1: Outline of the 5 steps in the USDA Automated Multiple-Pass Method (AMPM) for collecting 24-h dietary recalls (Moshfegh et al., 2008).

Step	Purpose
Quick list	• To collect a list of food consumed by the respondent in a 24 hours period on the day before the interview. • Gives cues to think about the day's events to help remember the food eaten. • Respondent uses own recall strategies.
Forgotten food list	To elicit additional recall of food by focusing respondent's attention on 9 categories of food often forgotten: non-alcoholic beverages, alcoholic beverages, sweets, savory snacks, fruits, vegetables, cheeses, breads and rolls, and any other food.
Time and occasion	• To collect information on the time at which the respondent ate each food and the name of the eating occasion. • Sorts food into chronological order and groups them by eating occasion for the detail and review pass.
Detail and review	• To collect a detailed description of each food reported (including additions to the food), amount eaten, its source (e.g., store or restaurant), and whether it was eaten at home. • To review each eating occasion and the intervals between eating occasions to elicit additional recall.
Final probe	• To provide a final opportunity to recall food. • Gives cues about non-salient situations when food may be eaten and easily forgotten. • Encourages reporting of small amounts of food that may have been regarded as not worth mentioning.

To help estimating portion size many ways have been developed:

- Usage of photographs of actual food illustrating three different serving sizes on a plate (Figure 2.1),
- Life-size two dimensional (2-D) images representing different shapes and sizes of food, including life-size images of plates, bowls, cups, and glasses (Figure 2.2).
- A grid superimposed on the dinner plate to estimate the length and width of square or rectangular food, such as lasagna, meat, or cake (Figure 2.3) (Lee & Nieman, 2013).

Two-dimensional food models and photographs or digital images have been shown to be as effective as three-dimensional models for estimating portion size in nutritional research (Posner et al., 1992).

During the course of a 24-hour recall, a notebook including an assortment of snack food wrappers (for candy, chips, and chewing gum of various brands and sizes), real photographs of various food and supermarket food cases, pictures cut from magazine advertisements or actual food labels can be helpful in collecting accurate intake data. Lifelike food models (Figure 2.4) and glasses, bowls, and cups of various sizes; household spoons; measuring spoons; and measuring cups (Figure 2.5) can be also used to estimate portion size (Lee & Nieman, 2013).

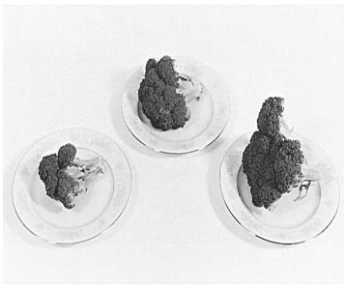

Figure 2.1: Food photographs of different portion size (Lee & Nieman, 2013)

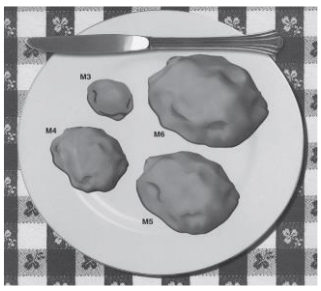

Figure 2.2: 2-D image of a life-size plate with four portion sizes. The knife lying across the top of the plate provides a size reference (Lee & Nieman, 2013).

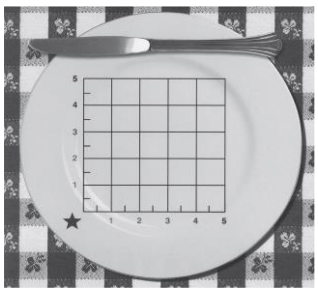

Figure 2.3: The grid superimposed on the plate assists in estimating the length and width of square or rectangular foods (Lee & Nieman, 2013).

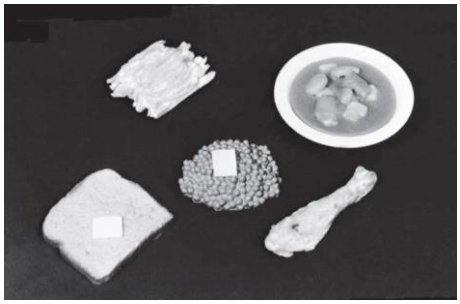

Figure 2.4: Lifelike food models (Lee & Nieman, 2013).

Figure 2.5: Serving size aids (Lee & Nieman, 2013).

d. The Food Frequency Questionnaire

A food frequency questionnaire (FFQ) is a list of food 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. When compared to other self-reporting methods it is easy to administer, inexpensive, practical, can evaluate dietary intake over longer periods. It is the method of choice in large-scale nutritional epidemiology studies, and in intervention studies where it may be used to track changes in diet as a response to a certain intervention (Cade, Thompson, Burley, & Warm, 2002; Kristal, Beresford, & Lazovich, 1994), or when aiming to assess the relation between food and related long-latent diseases (Moghames et al., 2016). The questionnaire consists of a list of food groups that are important contributors to the population's intake of energy and nutrients. Failure to include foods commonly eaten by groups with unique dietary habits may result in underestimation of nutrients' intake. Respondents indicate how many times a day, week, month, or year they usually consume the food. When a choice of portion size is not given, this is referred to as a simple or non-quantitative food frequency questionnaire format. However, a semi quantitative food frequency questionnaire gives

respondents an idea of portion size; and a quantitative food frequency questionnaire asks the respondent to describe the size of the usual serving as small, medium, or large relative to a standard serving (Figure 2.6) (Lee & Nieman, 2013).

A

Food Item	Average Use During Past Year					
	< 1 month	1–3 month	1–4 week	5–7 week	2–4 day	5+ day
coffee						
dark bread						
ice cream						

B

Food Item	Average Use During Past Year								
	< 1 month	1–3 month	1 week	2–4 week	5–6 week	1 day	2–3 day	4–5 day	6+ day
coffee (1 cup)									
dark bread (1 slice)									
ice cream (1/2 cup)									

C

Food Item	Medium Serving	Your Serving Size			How Often?				
		S	M	L	Day	Week	Month	Year	Never
coffee	(1 cup)								
dark bread	(1 slice)								
ice cream	(1/2 cup)								

Figure 2.6: Examples of three food frequency questionnaire formats: (A) the simple, or non-quantitative, format; (B) the semi-quantitative format; (C) the quantitative format (Lee & Nieman, 2013).

The accuracy of dietary intake information generated by an FFQ depends on the validity and reproducibility of this FFQ in the population it is intended to be used for. In Lebanon, Moghames et al. designed the first FFQ to assess dietary intake among school-aged children. It includes three sections: a food list of 112 food items, the portion size estimation and the frequency response. When tested against a 24-hour recall, this FFQ proved to be valid and reproducible in evaluating the dietary intake in Arabic speaking children (Moghames et al., 2016).

e. The 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 food and the makeup of all meals consumed in the past month, several months or a year. The diet history includes several steps: the first step consists of a detailed interview, which usually takes at least 1 hour, about usual pattern of eating and its variations, most frequently from a 24-hour recall. The second step is the administration of a food list asking for the frequency usually eaten and size of food portions with the aid of food models or photographs, and the final step is a 3-day dietary record. 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. However, the principle disadvantage of this method is that it is susceptible to recall bias and underestimation of both energy and nutrient intakes. Other limitations include the time and skills required by both interviewers and respondents who are asked to make judgments about the usual food and the amount eaten. These subjective tasks are difficult for respondents and require high levels of compliance. Furthermore, the interviewers should be well trained dieticians (Burke, 1947; Thompson & Subar, 2008; van Staveren & Ocké, 2006).

3. Dietary Assessment in Adolescents

Dietary patterns of this age group make dietary intake assessment in adolescents a challenging procedure. Plus there is lack of dietary assessment methods that address the teens' environment, attitudes, mentality, eating environments and patterns (M. B. E. Livingstone, Robson, & Wallace, 2004). Livingstone et al. found that

the mean energy intake using food records in 12-year old adolescents and 15-18 year olds was underestimated by 14% and 24%, respectively (M. B. Livingstone et al., 1992). 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, Schoeller, Cyr, & Dietz, 1990). The 24-Hour recall method in adolescents has also shown poor accuracy at the individual level and demonstrated positive bias in energy and nutrient intake (Reilly, Montgomery, Jackson, MacRitchie, & Armstrong, 2001). However at the population level it may provide accurate estimates of energy intake (M. Livingstone & Robson, 2000). Food Frequency Questionnaires (FFQ's) have shown acceptable validity and reproducibility in ranking adolescent consumers (Lietz, Barton, Longbottom, & Anderson, 2002). In conclusion, using a simple and less burdensome dietary assessment method may represent one way to obtain meaningful dietary information from a wide variety of adolescents, accepting the inherent limitations of the method (Robinson, Skelton, Barker, & Wilman, 1999).

B. Relationship between Orthodontics and Nutrition

1. The Effect of Nutrition on Orthodontic Tooth Movement

Nutrition plays an important role in facilitating or complicating the tissue reaction to orthodontic forces applied to the periodontal ligaments and alveolar bone. Those forces induce inflammation to encourage the bone modeling and remodeling process leading to tooth movement. In its turn, efficient tooth movement requires healthy biological response from the alveolar bone and periodontal ligament which relies on adequate nutrition. Any nutrient abnormalities (deficiencies or toxicities) can influence this proper biological response to applied orthodontic forces and undermine

the orthodontic outcomes. Studies delineating the role of nutrition and specific nutrients during orthodontic treatment are sparse, and many conclusions have been extrapolated from animal studies (Nimeri, Kau, Abou-Kheir, & Corona, 2013; Schindler & Palmer, 2011).

Litton studied the effect of ascorbic acid deficiency in guinea pigs during lateral movement of mandibular incisors with light continuous forces. He detected, on histological cuts, cessation of osteogenesis and disorganization of the periodontal ligament in animals receiving vitamin C deficient diet compared to controls. As ascorbic acid hinder the breakdown and reformation of collagen necessary for tooth movement, its deficiency slows down orthodontic tooth movement by decreasing the body's ability to heal (Litton, 1974). This finding was validated by Miresmaeili et al. who evaluated histologically the effect of dietary vitamin C administration in daily water on lateral movement of maxillary incisor in Wistar rats, 17 days after continuous application of 30 grams of opening force. A greater tooth movement was noted in presence of vitamin C with significantly higher osteoclast count indicating a faster movement (Miresmaeili, Mollaei, Azar, Farhadian, & Kashani, 2015).

Further research was done on biological methods (nutrients, vitamins, etc.) for accelerating tooth movement. Collins and Sinclair studied, in a split mouth technique, the effect of repeated intraligamentary injections of 50 picograms per milliliter of vitamin D, for several weeks during canine retraction with light forces (80g) in cats, knowing that systemic vitamin D is capable of activating osteoclastic activity. After 21 days, teeth receiving weekly injections of vitamin D had moved 60% further than their matched controls, and histological cuts showed a greater number of active osteoclasts, indicating more alveolar bone resorption on the pressure side of the periodontal

ligament in the experimental teeth. It should be noted that this article evaluated only initial response to local vitamin D application and therefore should not be considered as demonstrating a magic means of speeding up tooth movement (Collins & Sinclair, 1988). This finding was supported by Kale et al. who observed that repeated local applications of vitamin D for one week, during lateral movement of the maxillary incisors in rats, enhanced the rate of tooth movement due to the well-balanced bone turnover. A greater tooth movement was observed relative to the control group with higher number of osteoblast and Howship's lacunae (criterion of bone resorption) (Kale, Kocadereli, Atilla, & Aşan, 2004).

Besides vitamins, the effect of some minerals on tooth movement was tested. Akhoundi et al. investigated the effect of different amounts of dietary zinc on mesial movement of the molar using continuous force of 60 grams in rats. Although zinc is known as having osteogenic potential, it did not affect the rate of orthodontic tooth movement neither bone resorption. It should be noted that zinc was given 40 days prior to the orthodontic force activation which will diminish its effect on osteogenesis at the time of force application (Akhoundi et al., 2016).

Some other nutrients have been suggested to slow down orthodontic tooth movement. Kokkinos et al. demonstrated that Prostaglandin E2 (PGE2) responsible of alveolar bone resorption and orthodontic tooth movement can be affected by the type of dietary fat. He studied the effect of two types of dietary lipids, n-6 (corn oil) and n-3 fatty acids (fish oil), on distal movement of maxillary incisors with 56 grams of force in rats. Less tooth movement and lower concentrations of PGE2 were observed in the group fed in n-3 fatty acid relative to the group fed in n-6 fatty acid (Kokkinos, Shaye, Alam, & Alam, 1993). This result was in agreement with that of Iwami-Morimoto et al.

who found that fish oil enriched diet reduces osteoclastic activity and the subsequent bone resorption essential for tooth movement. In his experiment, the buccal movement of maxillary first molars with 20 grams of force in rats fed fish oil was 80% of that of rats fed corn oil, with the indicators of bone resorption being significantly lower in the fish oil group (Iwami-Morimoto, Yamaguchi, & Tanne, 1999). Carbonated soft drinks have been shown to slow down tooth movement as well. Aghili et al. showed that mesial movement of the first molar using 60 grams of force in rats was significantly lower in the groups receiving carbonated soft drink relative to the control group. In fact when calcium consumption is deficient, drinks high in phosphate have negative affect on bone metabolism. Furthermore, the high amount of sugar contained in those drinks led to statistically significant decrease in bone formation and resorption markers. The acidic components of those drinks also play a role in altering bone metabolism by influencing the bone remodeling process. Heavy carbonated soft drink consumption is a problem in orthodontic patients: besides reducing orthodontic tooth movement, it reduces the shear bond strength of orthodontic brackets; decreases enamel micro hardness and calcium release from the enamel surface specially in patients with salivary gland dysfunction or decreased salivary flow; and increase the risk of dental caries (Aghili, Hoseini, & Yassaei, 2014).

2. The Effect of Nutrition on Maxillary Expansion

Few studies investigated the effect of nutrients on the stability and time frame of maxillary expansion and they were conducted in animals. Uysal et al. evaluated the effect vitamin D on bone regeneration in response to expansion of mid-palatal suture, in rats. The intermaxillary suture was expanded for 5 days in a control and an experimental

groups. The latter received a local injection of vitamin D, 24 hours after the start of the expansion. The distance between the mesial corners of the maxillary incisors measured at the beginning and on the fifth-day of the expansion revealed no difference in the amount of expansion between experimental and control groups. However the quantitative bone histomorphometric examination in vitamin D administration group revealed more new bone formation, suggesting a positive effect of vitamin D on early phase of bone regeneration during the retention period after maxillary expansion (Uysal, Amasyali, Enhos, Sonmez, & Sagdic, 2009).

Uysal et al. also assessed bone formation after 5 days of maxillary expansion and 10 days of retention period in correlation with various doses of vitamin E injection into the premaxillary suture, 24 hours after the start of the expansion. The amount of expansion was not affected by the dose injected, nevertheless the amount of newly formed bone observed in the histomorphometric examination increased in a dose-dependent manner, suggesting that vitamin E, during the early stages to orthopedically expanded inter-premaxillary suture areas, may stimulate bone formation and shorten the retention period (Uysal, Amasyali, Olmez, Karslioglu, & Gunhan, 2009).

The effect of dietary boron on maxillary expansion in rabbits was also studied by Uysal et al. Expansion was undertaken for 5 days using helical springs delivering 250 grams of force between the maxillary incisors, and retention period ranged between 10 and 20 days. In the experimental groups dietary boron was added to the water during the expansion and retention period. Distance between the mesial corners of the incisors measured at the end of expansion was not different between experimental and control groups. However mineralized bone area and number of osteoblasts at the midpalatal suture, detected on histomorphometric cuts of the premaxillae, have increased in the

experimental group, with higher values at 20 days of retention compared to the 10 days. Therefore Boron had a positive effect on the early phase of bone regeneration in the midpalatal suture during expansion and retention periods (Uysal, Ustdal, Sonmez, & Ozturk, 2009).

Uysal et al. used the same expansion appliance in Wistar rats where one group was injected with vitamin C into the inter-premaxillary suture 24 h after appliance placement, and a second group with intramuscular injection of vitamin C after the first day of the experiment. He observed a larger bone area and higher percentage of newly formed bone on histological cuts, after 5 days of expansion and 15 days of retention period in both experimental groups relative to controls, but more significant in the group receiving the intramuscular injection. He concluded that systemic administration of vitamin C in conjunction with rapid maxillary expansion may shorten the time frame of the procedure and increase the quality of regenerated bone (Uysal et al., 2011). On the other hand, Farhadian et al. showed that continuous administration of dietary vitamin C doesn't have a positive effect on bone formation and retention of the expanded midpalatal suture in rats. In his experiment vitamin C was added to the water seven days prior to starting the expansion and continued until sacrificing the animals (17 days after the expansion that lasted 9 days). The experimental sample showed significantly lower number of osteoblasts compared to controls due to possible adverse effects of prolonged intake of vitamin C in rats which induces copper deficiency and causes iron overload that decrease osteogenesis. In contrast to animals, those effects do not apply to human beings (Farhadian et al., 2015).

In a more recent study, the effect of energy drinks on bone formation in expanded mid-palatal sutures of rats was examined. The energy drink was administered

via orogastric tubes after the expansion period (5 days) and throughout the retention period (12 days); the control group received the same volume of water. Histomorphometric evaluation of the dissected maxillae revealed a significantly greater percentage of newly formed bone and bone areas in the experimental group thus decreasing the time needed for retention. This positive effect was attributed to taurine (amino acid) and B-vitamins that are present in the energy drink (Birlik, Kazancioglu, Aydin, Aksakalli, & Ezirganli, 2017).

3. The Effect of Orthodontic Treatment on Nutrition

Cheraskin and Ringsdorf were the first to assess nutritional deficiencies during orthodontic treatment. They examined the extent of deficiency in ascorbic acid, known to have a role in bone metabolism essential for teeth movement, in a sample of 139 children between 9 and 17.6 years old undergoing orthodontic treatment. Plasma ascorbic acid levels obtained two hours after breakfast revealed a wide percentage of patients (17 to 53%) having suboptimal levels of vitamin C during orthodontic treatment. This deficiency may affect the connective tissue of the periodontal ligament and the formation of osteoid (Cheraskin & Ringsdorf Jr, 1969). In a second part of the same study vitamin C state was reexamined in the same group of patients using the lingual vitamin C test. 72% of the subjects showed suboptimal levels (Cheraskin & Ringdorf Jr, 1969). This result might not be valid as other studies demonstrated that lingual vitamin C test does not reflect changes in vitamin C intake and is not correlated the vitamin C levels in plasma or white cells (Leggott, Robertson, Rothman, Murray, & Jacob, 1986; Randolph, Wilson, Roth, & Young, 1974; Stults, Sapiro, Clemens, & Adams, 1987).

Other studies, did not concentrate on a specific nutrient, but compared all nutrients' intake levels before and after orthodontic adjustment that was expected to produce post-appointment sensitivity in patients between 12 and 16 years, undergoing orthodontic treatment with fixed appliances. Diet was recorded on a diet journal 3 days before and 3 days after the treatment (Riordan, 1997; Sharma et al., 2011). Riordan, whose study sample was limited to 10 participants, found that the mean intake of manganese (mg/d) and copper (mg/d); two important nutrients for bone metabolism and healing; decreased significantly after orthodontic adjustment. This was attributed to a decrease in intake of nuts, whole grains, fruits and vegetables that can cause discomfort to pressure-sensitive teeth (Riordan, 1997). In general, participants chose high fat (%EI) low carbohydrate (%EI) soft food diet. The same trends were observed in the Sharma et al. study that included 50 patients (Sharma et al., 2011)

The previous studies evaluated dietary intake of one group of orthodontic patients at different time points, however Shirazi et al. compared dietary intake of a control group to that of 90 patients, 15 to 17 years of age, on their sixth month of treatment with fixed appliances. Dietary intake was assessed through face-to-face interview using the 24-hour dietary recall method. Significant lower intakes of chromium (mg/d) and beta-carotene (mcg/d) were observed in the orthodontic group in comparison with the control group attributed to low consumption of hard vegetables (Shirazi et al., 2011). The validity of this result is questionable because of the large standard deviations detected in both groups for the majority of the micronutrients, which makes it harder to find statistical significant differences. Other results in this study revealed that orthodontic patients had significantly higher intakes of total fat (g/d) and cholesterol (g/d) and lower intake of fiber (g/d).

These dietary alterations were reported over a short term, precipitated by pain generated by the insertion and/or activation of orthodontic appliances, on the second and third days before adaptation (Ama Johal, Al Jawad, Marcenes, & Croft, 2013). Patients usually experience pain four hours after appliance insertion, reaching the peak between twelve hours and three days, and decrease gradually for up to seven days (A Johal, Fleming, & Al Jawad, 2014; Polat, 2007). However, pain duration can range from one day to two weeks, leading some patients to eat less than before treatment (Abed Al Jawad, Cunningham, Croft, & Johal, 2011). Accordingly, the length of time needed for patients to adapt to pain is not precisely known, nor is the extent to which pain can modify dietary behaviors because it is subjective response with large individual variations depending on age, gender, individual pain threshold, the magnitude of the force applied, emotional state stress, cultural differences and past pain experiences (Krishnan, 2007) . Some patients reported that pain during fixed orthodontic treatment caused moderate to extreme difficulty in chewing and biting food of firm consistency (Abed Al Jawad et al., 2011). Johal et al. who conducted a longer term study did not support the assumption that pain during treatment was a strong predictor of changes in dietary behavior. He used a 10-cm visual analogue scale (VAS) to record pain intensity at 4 to 6 weeks and 3 months over 7 days in 53 test patients aged 11–14 years undergoing orthodontic treatment with fixed appliances. His results showed that in 66% of the patients, pain had caused difficulty in eating and chewing only on the second and third days in the first and second follow up period, which declined significantly after that indicating adaptation (Ama Johal et al., 2013).

Besides avoiding pressure sensitivity, a restricted food choice can be due to tooth mobility, fear of breaking the appliance, embarrassment from food stuck in the

appliance, and the difficulty in maintaining good oral hygiene (Abed Al Jawad et al., 2011; Carter et al., 2015). Therefore patients reported eating less snacks compared to before treatment, cutting their food into pieces or cooking it in a different way, and eating less sticky and hard food types (Ama Johal et al., 2013). Some patients have been influenced as well by the dietary advice of the orthodontist in avoiding sweets, fizzy drinks, hard and sticky food. Accordingly the most avoided food items were apples, carrots, crisps, chocolate bars, meat dishes, nuts, toffees, chewing gum, crackers, and corncob. Food items that were consumed in greater frequency were mashed dishes, rice, pasta, bananas, soups, cheese, water, juices, boiled vegetables, and milk (Abed Al Jawad et al., 2011). Although changes might reduce with familiarity, the reduction of portion size may be the most alarming issue. Patients with fixed appliances reported taking longer time to eat which made them feel different to their peers, and modified their behaviors in order to finish at the same time by reducing the portion size eaten. This potentially affects school work and causes lack of concentration because nutritional requirements are not met (Carter et al., 2015).

A number of caveats may be raised regarding the available literature:

- Previous studies do not reflect the duration of the post-treatment nutritional changes, thus dietary patterns observed during orthodontic treatment might be transient.
- Dietary patterns in growing patients might be poor before treatment; consequently analyzing baseline diet is critical.

A more recent study has tried to overcome those caveats by comparing adolescents' dietary intake over 3 months of orthodontic treatment versus baseline. It showed that intakes of vitamin C (mg/d), vitamin B12 (mcg/d), potassium (mg/d) and phosphorus (mg/d) was significantly lower at the end of the third month with no change

in macronutrients' intake. Furthermore the consumption of bread, fizzy drinks and seed food (olive, date) decreased while consumption of soup increased between the initial and the last follow up time points. However this study was conducted on 17 patients only, therefore results may differ by increasing the sample size (Ilhan, Ozdemir, Coskuner, Taner, & Bilgic, 2018; Ozdemir, Ilhan, Coskuner, Taner, & Bilgic, 2018).

It remains to point out that in this entire literature, dietary assessment tools were used to estimate mean intakes. Given individual differences in dietary requirements, specific details on individual food intake is needed to personalize dietary guidance, and advice on food selection when others are avoided to prevent development of non-balanced unhealthy dietary habits

C. Research Objectives

The aims of the present study are to:

- Assess the short and intermediate-term effects of orthodontic treatment on dietary intake and body mass index in adolescent patients treated with fixed appliances or palatal expansion.
- Assess the effects of dietary changes on the rate of tooth movement during the leveling and aligning phase.
- Evaluate the relationship between treatment-generated pain and dietary intake changes during orthodontic treatment.
- Evaluate the relationship between baseline weight status and dietary intake changes during orthodontic treatment.
- Evaluate the relationship between baseline dento-skeletal components of the malocclusion and dietary intake changes during orthodontic treatment.

D. Hypotheses

Our hypotheses are that:

- Orthodontic treatment induces lower absolute intake levels and changes in the diet composition, especially during the first weeks, after which patients adapt and start to revert to their original dietary habits.
- Patients experiencing more dietary inadequacies (nutrients below norms) and unhealthy dietary changes during treatment have slower rate of tooth movement.
- Pain is not a strongly associated with dietary changes since pain levels decline after the first few days.
- Obese and overweight patients are more prone to dietary changes during orthodontic treatment.
- Dietary changes are more prominent in patients with higher initial malocclusion severity.

E. Clinical Significance

Because nutrition affects growth in adolescents and oral tissues health, this study targets growing patients undergoing orthodontic treatment with fixed appliances or rapid maxillary expansion to determine potential risk of nutritional imbalance over the immediate and intermediate term. The effect of maxillary expansion on dietary intake was not explored in previous studies. Dietary alteration would be expected with this treatment given the quick modification in occlusion and associated discomfort resulting from impaired mastication, retention of food under the appliance, inability to proper cleaning and possible taste alteration because of the position of the expansion screw in the palate.

The correlation of dietary changes with pain levels shall help orthodontists better titrate the forces used for tooth movement, and at least predict the duration of discomfort and means to alleviate the pain. Moreover, by recognizing nutritional habits adopted by patients during treatment, orthodontists could provide patients with realistic expectations of possible dietary alterations, especially if specific dietary changes might occur with certain treatments or even in relation to BMI weight status. Therefore orthodontists could be able to advise patients for more targeted dietary guidance and increase their awareness about changes required to maintain healthy eating habits during treatment.

Healthier nutrition should enhance biological functioning of periodontal tissues during tooth movement, as suboptimal levels of certain nutrients have been demonstrated to slow down the movement in animals. This study does not explore this aspect, however, the results should indicate which nutrients are usually altered with treatment. In turn, the effect of such nutrients on tooth movement would be the target of future investigation.

CHAPTER III

MATERIAL AND METHODS

The recruitment process, measures utilized, data collection procedures and statistical analysis methods are described in this chapter.

A. Research Design

This is a prospective longitudinal study conducted during the first 3 months of orthodontic treatment in patients with fixed appliances and others treated with palatal expansion. Data were collected at baseline (before treatment start), one week, 5 weeks and 13 weeks of treatment by means of dietary questionnaires, anthropometric and dental measurements, and self-administered pain diaries.

B. Participants

1. Target Population

The target population consisted of adolescent patients (age: 11-21 years as defined by the American Academy of Pediatrics) seeking orthodontic treatment with fixed appliances or palatal expansion prior to fixed appliances. Most of our patients seek orthodontic treatment during adolescence, a period in which a well-balanced diet should be maintained for optimal development and to support bone remodeling during tooth movement.

2. Inclusion Criteria

- Age: 11-21 years old.
- Planned orthodontic treatment using maxillary and/or mandibular fixed appliances or starting with rapid palatal expansion followed by fixed appliances.
- Late mixed or permanent dentition
- Patient able to assent and having parental consent.

3. Exclusion Criteria

- Congenital disorders such as cleft lip/palate, or syndromic conditions that will require multidisciplinary care and surgical intervention.
- Previous orthodontic treatment.
- Medical conditions (chronic disease or chronic medication) affecting dietary intake and body weight (anorexia nervosa, hormonal disturbances, diabetes, kidney disease, inborn error of metabolism, malabsorption problems).
- Subjects on therapeutic diet.
- Siblings (because they usually share same food consumption patterns).

4. Sample Selection and Recruitment

Ethical approval was sought before initiation of the study from the Social and Behavioral Sciences section of the Institutional Review Board (IRB) at the American University of Beirut (AUB) (The Proposal was submitted on August 14, 2017; amendments were requested on October 23 and November 9, 2017; the final approval letter was received on November 10, 2017).

Patients presenting at the Division of Orthodontics and Dentofacial Orthopedics of the American University of Beirut Medical Center (AUBMC) seeking orthodontic treatment, and necessitating treatment with fixed orthodontic appliances to correct their dental crowding and malocclusion, or palatal expansion to widen the maxillary arch and correct the crossbite, were invited to join the study.

Once the primary providers (resident and attending) identified a candidate for the study based on the inclusion criteria, they informed the coordinator that they may have a potential recruit. During the appointment that preceded insertion of the appliances, the primary physician sought initial approval from the patient and guardian to be contacted regarding the proposed research study by the research coordinator (NA). If they accepted, the study coordinator was called over and explained thoroughly the research project to the patient and parent(s) and asked them if they would be willing to participate.

If they accepted to participate, and prior to study initiation, a signed parental consent document and age-corresponding assent or consent document was required for each respondent (Appendix I). The recruitment period took place between November 2017 and April 2018; and between September 2018 and March 2019. Patients were assessed at baseline prior to treatment, and followed at one, 5 and 13 weeks of treatment. The subgroup of adolescent patients undergoing rapid maxillary expansion before fixed appliances was recruited in the same time period and assessed before and at 1 week after expansion procedure, and at the following 5 and 13 weeks with fixed appliances.

As incentive, participants were informed that at the termination of the study they will be offered a booklet instructing them about healthy eating habits. English and Arabic

versions of this booklet entitled “Healthy Eating Guidelines among Adolescents” were prepared by the Nutrition and Food Sciences Department (NFSC) at the American University of Beirut (AUB) (Appendix II). Participants who decided to withdraw from the study could still receive the specified compensation.

5. Sample Size

The target group of patients undergoing treatment with fixed appliances (braces) constituted the bulk of the sample, and those undergoing treatment with palatal expansion were in a smaller subgroup (exploratory arm).

The fixed appliances group sample size was calculated by using the sample size calculation formula for two dependent means (paired). The recommended alpha probability level of 0.05 and a statistical power level of 0.8 were used. The effect size was calculated based on the dietary fiber intake, because it was found in a previous study (Shirazi et al., 2011) to be statistically significantly different between the treatment group and the control group (p-value=0.007).

The Effect size was calculated by using the groups’ parameters, including:

- Mean of group 1= 12.7; SD: 9.37
- Mean of group 2= 9.47; SD 7.04 (Table 3.1).

Table 3.1: Sample size calculation

1- t test	Means	Difference between two dependent means (matched pairs)
2- Analysis	A priori	Compute required sample size
3- Input	• Tail(s)	Two
	• Effect size:	dz = 0.3
	• α error probability	α= 0.05
	• Power	1-β error probability= 0.8
4- Output	• Non centrality parameter	δ= 2.846
	• Critical t	t = 1.986
	• Df	Df= 89
	• Total sample size	**90**
	• Actual power	power= 0.803

The sample size calculation yielded a projected total sample of at least 90 subjects in the fixed appliances group.

In the palatal expansion subgroup we aimed to include at least 15 patients. This sample size was chosen based on our clinical statistics, the projected number of patients needing palatal expansion within the planned period of study (which was initially 9 months). The calculated sample size for both groups was not met during this period; therefore this period was extended until reaching an oversampling to account for potential loss to follow up.

Over 13 months, a total of 109 patients were recruited in the fixed appliance (FA) group and 22 in the palatal expansion (PE) subgroup. However 14 in the FA group (12.84%) and 2 in the PE subgroup (9.1%) were lost to follow up and dropped out of the study for the following reasons:

- Subjects withdrawing after completing the baseline assessment due to lack of time to commit to the long term follow-up time points of the study (FA group: n=10, percent=9.17%; PE subgroup: n=1, percent=4.55%).
- Subjects withdrawn by the study coordinator:
    - After completing the baseline assessment due to Patient/ guardian decision to delay the start of the treatment (FA group: n=3, percent=2.75%).
    - After completing the baseline and one week assessment due to no show at follow-up appointments coinciding with the planned time points for data collection (FA group: n=1, percent=0.92%; PE subgroup: n=1, percent=4.55%).

The final sample of patients who completed the study consisted of 95 in the main FA group and 20 in the PE subgroup (Table 3.2). Only data collected on this sample were analyzed.

Table 3.2: Diagram illustrating the flow of participants through the study

Main fixed appliance group	Expansion subgroup
n=109 Recruited Signed assent/consent Completed baseline assessment ↓ **13 dropped (11.92%)**	**n=22** Recruited Signed assent/consent Completed baseline assessment ↓ **1 dropped (4.55%)**
n=96 Completed 1 week post-fixed appliances bonding assessment ↓ **1 dropped (0.92%)**	**n=21** Completed 1 week post-expansion assessment ↓ **1 dropped (4.55%)**
n=95 Completed 5 weeks assessment	**n=20** Completed 5 weeks assessment
n=95 Completed 13 weeks assessment	**n=20** Completed 13 week assessment

C. Measures

The indices and instruments used in this study were selected to assess 3 main outcomes and their inter-relation: body mass index (BMI), dietary intake (DI), and tooth movement. Other measures including pain during treatment, and initial severity of the malocclusion were evaluated to assess their implication in dietary changes.

1. Sample's Characteristics Assessment

Before the start of treatment in both groups information about participant's health, sociodemographic status and lifestyle was collected to determine the sample's

baseline characteristics and evaluate their implication in possible dietary changes during treatment. To this end, the following questionnaires were used:

a. The Medical History Questionnaire

Designed specifically for this study, the Medical History questionnaire included questions about the general medical history (including sexual maturity, presence of congenial disorders, previous orthodontic treatment), presence of pathologic conditions that might affect dietary intake, and nutritional supplements intake (Appendix III). Accordingly patients were excluded if one or more of the exclusion criteria were applicable.

Information about puberty was necessary because dietary intake at this time might be altered by the biological and psychosocial changes of puberty and not necessarily because of orthodontic treatment (Spear, 2002). Male patients were asked about voice changes and facial hair growth, and female patients were asked about menarche. Accordingly patients were classified in pre-pubertal or post-pubertal stage of growth. This self-reported information has been widely used in epidemiological studies to determine the pubertal development (K. K. Ong et al., 2012). One investigator (N.A.) was responsible for filling the questionnaire for each patient in the presence of the parents/guardians.

Participants and their parents were informed in the assent, consent, and parental permission forms that some questions will trigger sensitive topics like puberty, and answering them may cause embarrassment or upset. However it was clarified that their answers were confidential and used only for research purposes without disclosure of names.

b. The Demographic and Socio-Economic Questionnaire

Built on previously used questionnaires (Moghames et al., 2016; Nasreddine, Hwalla, Saliba, Akl, & Naja, 2017) , this instrument included questions about the demographic and socio-economic status (SES) of the participants and their parents divided into two sections (Appendix III).

In the participant section, the questions inquire about the date of birth for age calculation; and the number of rooms and living individuals per household. This information was used to determine the household crowding index calculated by dividing the total number of co-residents per household excluding the newborn infant, by the total number of rooms, excluding the kitchen, the hall, the balconies and bathrooms. It is assigned to 'no crowding' if the number is less than 1 person/room therefore a high SES, and 'crowding' if the number is 1 or more person/room therefore a low SES (Ama Johal et al., 2013; Moghames et al., 2016).

In the parents section, the question relates to the mother educational level. For the analysis, it was classified into 4 categories according to the highest level achieved (primary school or less, attained intermediate school, attained high school, attained university degree) (Moghames et al., 2016; Nasreddine et al., 2017).

This questionnaire was administered by the same investigator (N.A.) who interviewed the participant and the parents. For each question the option of "refuse to answer" was possible to avoid embarrassment.

c. The Lifestyle Questionnaire

Built on previously used questionnaires (Naja, Hwalla, Itani, Karam, et al., 2015; Nasreddine et al., 2014), the lifestyle questionnaire included questions on the

participants' physical activity, and the parent who is the most attentive to their diet (Appendix III).

Physical activity assessment inquired about the weekly frequency of various activities taking place outside the school setting, including moderate intensity activities such as playground activities, walking, dancing, bicycle or horse riding, as well as higher-intensity activities such as ball games, active games involving running, swimming. Based on the weekly frequency, study participants were categorized into three levels of physical activity: low (never), moderate (1-2 times/ week) and high (>2 times/ week) (Naja, Hwalla, Itani, Karam, et al., 2015; Nasreddine et al., 2014).

In addition, participants were asked to specify who of their parents is the most attentive to their diet. Four options were given as possible answers (my mother, my father, both of them, myself), and if none was applicable, the participant was asked to answer freely. Investigator N.A. interviewed the participants at baseline to collect the answers.

The above used questionnaires were reviewed by an associate professor-nutritionist at AUB (L.N.) and a professor- physician in internal medicine at AUBMC (K.B.) before being submitted to the IRB.

2. Anthropometric Assessment

Standard techniques and calibrated equipment were used for anthropometric measurements: height and weight to calculate the Body Mass Index (BMI). Measurements were duplicated at each time point and the average used in the analysis.

The body weight was measured using a mechanical column type weighing scale (DETECTO, model n◦ 3P7044; USA). Before stepping on the scale, participants

were asked to empty their pockets, remove the shoes, and any heavy clothing and to stand in the center of the scale platform with every effort to ensure the body weight was equally distributed on both feet. The weight was recorded in pounds and then converted to kilograms for BMI calculation (Moghames et al., 2016).

The body height was measured using the height rod associated to the weighing scale following the same institutional norms (no shoes, light clothing). The subject was asked to stand with the heels together, arms to the side, legs straight, shoulders relaxed, and the head oriented according to the natural head position. The headboard was lowered against the head with enough pressure to compress the hair. The measurement was read at the investigator‘s eye level with the headboard to avoid recording errors. The height was recorded in centimeters and then converted to meters for BMI calculation (Cogill, 2003).

Before the second reading, the patient was asked to step down off the scale’s platform and the first recordings were zeroed. Height and weight were then remeasured following the aforementioned standards. All collected data was recorded on the anthropometric assessment form (Appendix IV).

The Body Mass Index (BMI) was calculated as the weight in kilograms over the height in meters squared. Using the World Health Organization (WHO) growth charts and criteria, BMI-for-age z-scores were used to classify the participants as normal weight (between −2 SD and +1 SD), overweight (> +1 SD), underweight (< -2 SD), and obese (> +2 SD) relative to the WHO growth standard median of reference population of the same age and sex (Onis et al., 2007). Tables of reference data for children aged 5-19 years old are shown for both genders at the WHO website (http://www.who.int/growthref/who2007_bmi_for_age/en/index.html).

3. Dietary Intake Assessment

The dietary intake (DI) was evaluated using two different types of dietary assessment tools:

- The 24-hour (24-h) recall method to detect short term (acute) dietary changes during the first week of treatment relative to pre-treatment.
- The food frequency questionnaire (FFQ) to detect intermediate term dietary changes during the first 3 months of treatment relative to pre-treatment.

a. <u>The 24-h Dietary Recall</u>

The 24-h dietary recalls were carried using the 5 steps approach of the multiple pass food recall developed by the United States Department of Agriculture (USDA) (Table 2.1). This approach has consistently showed attenuation in the 24-h limitations including interviewer bias and participant's recall bias (Moshfegh et al., 2008). It consists of:

- A quick food list recall
- A forgotten food list probe
- The time and occasion at which foods were consumed
- A detailed overall cycle
- A final probe review of the foods consumed

At each time point, three 24-h reports were collected by phone from the subject him/herself in the presence of the parent (usually mother) to help report, when needed, specific details of the food that was consumed and that the subject did not recall. The three 24-h reports cover two week days (regular school days) and one weekend day (Saturday or Sunday) to account for differences in dietary habits between normal school

days and weekend days. The calls, conducted by the investigator N.A. followed a well-structured script (Appendix V) to ensure consistency and collection of all needed information through the developed check list. The patient and his/her parents were not informed in advance of the contact day in order to maintain regular eating habits, and the calls were not conducted on consecutive days to avoid response bias.

For each 24-hour recall, the gathered information included: food consumed by the participant in the previous day (the past 24 hours), time of intake of each meal and its portion, preparation methods; food brand and beverages consumed, if applicable. At the end of the recall, the participant was asked if the previous day was a usual day. In case he/she was fasting, ill, or having an atypical day (e.g. birthday, party, lunch invitation), the call was repeated on a another day to record the usual patterns (Moghames et al., 2016).

A pencil and paper version of the multiple pass 24-h recall method was used; (Appendix V). Mothers (or fathers, depending on more attentive guardian to child's nutrition) were allowed to assist in reporting the portion size and cooking method. Participants were given at the beginning of the study a two-dimensional (2D) food portion visual chart, and trained on using it to assist them in estimating the portion size of the eaten meal (Figure 3.1). This chart developed by Nutrition Consulting Enterprises and validated for the use in telephone dietary interviewing (Posner et al., 1992) consists of a two sided poster:

- Side A includes different size models of spoons (A1,A2,A3), glasses (A4,A6,A8), wine glass (A5), shot (A7), cups (A9, A10), bowls (A11, A15), mounds (A12,A13,A16), scoop (A17), and wedges (A14,A18,A19). It is used to estimate

portions of the foods that are typically measured in volumes such as condiments, beverages, fruits, vegetables, grains, cereals, and mixed meals.

- Side B includes different shapes and sizes of models (B1, B2, B3, B4, B5, B6) used to estimate the size of protein rich food like meats, fish, and cheese. The thickness of the meal is estimated by using the scale on the left side of the poster illustrating variable thickness measures ranging from 1 to 50. All the illustrated shapes represent real life size models.

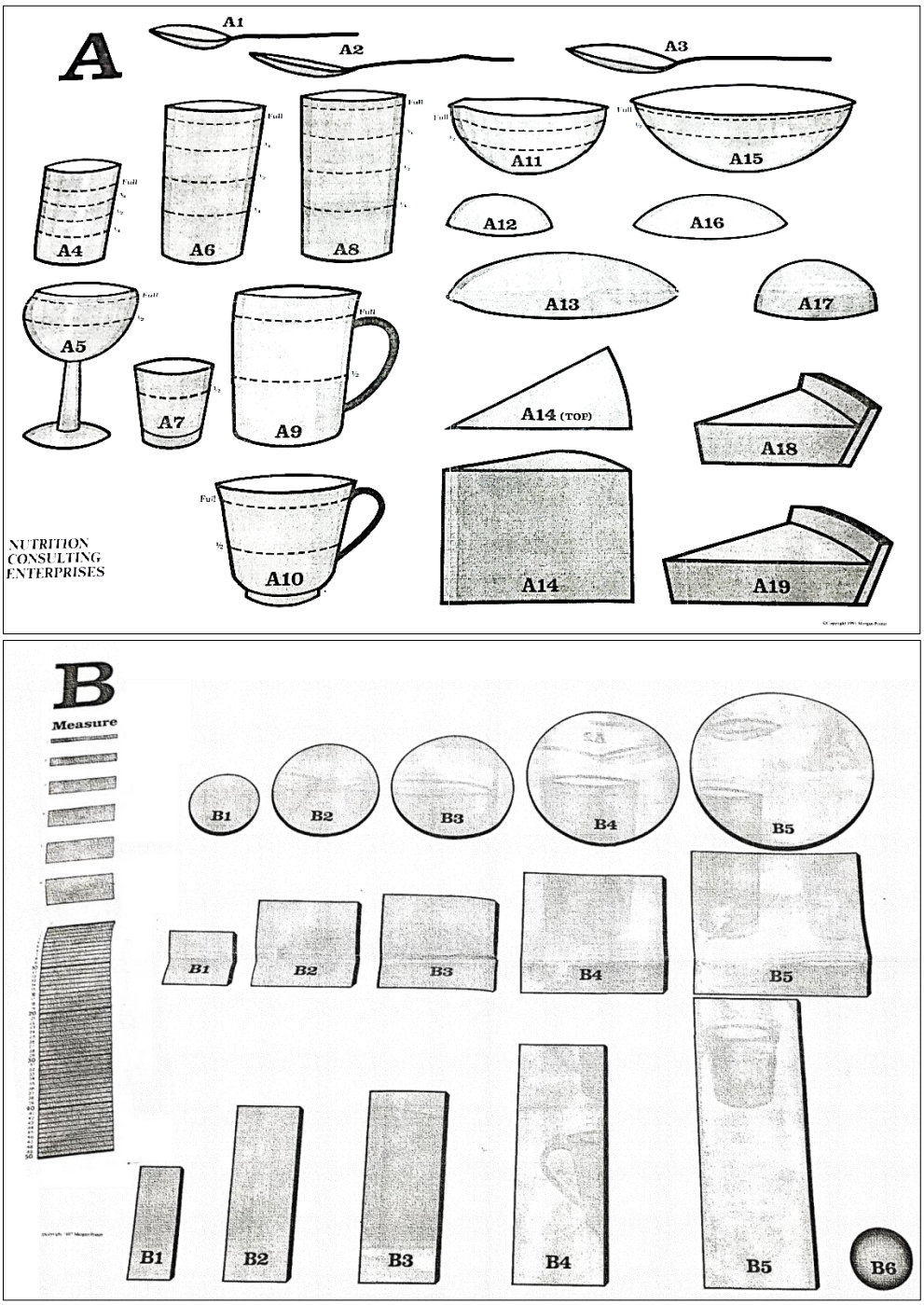

Figure 3.1: Food portion size illustration (Millen & Morgan, 1996).

To analyze the dietary intake data and estimate daily energy, macro and micronutrients' intakes, the Nutritionist Pro™ software (Axxya Systems Stafford, TX, USA, version 7.1.0, 2019) was used. The 24 hours dietary recalls were entered in the

"Diet Records" section after determining the sex and age range of the participant. The reported portion sizes were entered using the Lebanese Portion Size Guide (LPSG) available at the Nutrition and Food Sciences Department (NFSC), the 2D food portion visual, and the standard portion sizes available in the USDA database in order to maintain standardized nutrient analysis. The LPSG is a compilation of portion size estimates of food commonly consumed by the Lebanese population. It also includes standard portion size of food available in the USDA database. The use of LPSG is an approach to standardize dietary data entry and to minimize the inter- and intra-enterer variability. Portion size estimates reported from side A of the 2D food portion visual were entered by converting the shapes into household equivalents (cups and spoons). Those reported from side B were entered by converting the shapes into a weight in grams following the weight matrix where the reported size and thickness intersect (e.g. size B2, thickness 3 is equivalent to 42.51 grams).

b. The Food Frequency Questionnaire

A semi-quantitative Food Frequency Questionnaire (FFQ) was administered by investigator N.A. to assess participants' dietary intake over the previous month (Appendix V). The used questionnaire was developed by the department of NFSC at AUB in 2016 and validated to assess dietary intake among school-aged children in Lebanon (Moghames et al., 2016). Questionnaire completion required a 20-30 minutes interview with the participant in presence of the mother. It includes 3 sections: a list of 112 food items, portion size for which the 2D food portion visual chart is used, and the frequency of food intake (how many times per day, week or month the participant has

consumed the food). The FFQ also includes an open-ended section to provide information on unlisted additional food/ beverages consumed on a regular basis.

Data collected in the FFQ were entered using a previously developed Microsoft access database that includes food composition data for each food item included in the FFQ. The devised analysis module permitted to group food items into 45 categories and to determine mean consumption values per food item and per food group (g/day), average daily intake per individual, per sex group (g/day) and per age group (g/day). Energy, proteins, fat and carbohydrates per gram were calculated for each food item on the FFQ list. Individual daily energy intake was computed by summation of respective products of the quantity consumed and the energy per gram value for each food item. The same procedure was used to determine the daily intake of each macro and micronutrient.

Data entry of both the 24-h recalls and the FFQs was performed by the study coordinator N.A. Once completed, a research associate at the department of Nutrition and Food Sciences (NFSC) at AUB (N.Ad.) accomplished the data extraction and generated excel sheets including daily energy, macronutrients (protein, fat and carbohydrate) and micronutrients (vitamins and minerals) composition for each food item consumed.

Furthermore, for each participant, the consumed food items were grouped into 45 food categories based on the food groups classification conducted in other studies (Nasreddine et al., 2019; Nasreddine et al., 2017; Nasreddine et al., 2014).

The baseline and treatment results of the 24-hour recall and FFQ were compared, separately, for each subject to detect the individual changes in food groups consumed and in macro and micronutrients as a result of orthodontic treatment. In

addition, to have an idea about the healthiness of the reported diet, macronutrients percentage contribution to total energy and micronutrients' intakes were compared to Dietary Reference Intakes (DRI) representing norms by age and gender (National Academies of Sciences, 2004).

4. Rate of Tooth Movement Assessment

Little's irregularity index (LII) was used to assess the rate of tooth movement in both arches upon the start of movement during the initial leveling and aligning phase, which ranged between 3 and 6 months depending on the initial severity of deviation of contact points (Pandis, Polychronopoulou, & Eliades, 2007, 2010; Papageorgiou, Konstantinidis, Papadopoulou, Jäger, & Bourauel, 2014). LII is a quantitative score used originally to assess mandibular anterior incisors irregularity (Little, 1975). Later on it was also used to assess crowding of the maxillary anterior dentition. Reliability and validity of the method were tested with favorable results (Bernabé & Flores-Mir, 2006; Pandis et al., 2010).

The initial severity of maxillary and mandibular anterior irregularity was assessed on pretreatment dental casts, which are an integral part of the baseline pre-treatment records taken for each patient. Linear displacement of the five adjacent anatomic contact points of the incisors was measured in millimeters with digital calipers (Mitutoyo Digimatic Point Calipers with Absolute Encoder, series 573, Japan), and the five measurements were summed to calculate the LII score (Figure 3.2). Proper positioning of the caliper is important for consistent accuracy. The cast was stabilized on a horizontal plane and viewed from above sighting down onto the incisal edges of the anterior teeth. The caliper was held parallel to the occlusal plane to ensure recording

of the horizontal displacement disregarding the vertical discrepancies. The beaks of the caliper were lined up with the contact points in such a way to measure from contact point to contact point rather than only in a purely labiolingual direction, because rotations and labiolingual displacements were often accompanied by various amounts of mesiodistal overlap of the contact points. In case mesiodistal spaces were present, they were disregarded when the teeth in question were in proper arch form; however if spaces, rotation, or displacement were present, only the labiolingual displacement from the proper arch form was recorded (Little, 1975).

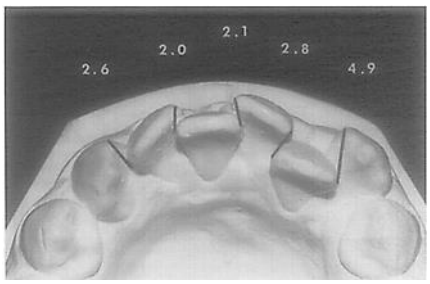

Figure 3.2: The linear distance from anatomic contact point to adjacent anatomic contact point of mandibular anterior teeth (Little, 1975).

During the first 13 weeks of treatment, alginate impressions of the dental arches were taken after removal of the archwires on the appointments coinciding with the monthly regular orthodontic visits. Impressions were poured into working plaster models on the same day to avoid material distortion. Measurements of the anterior contact points' displacement and calculation of LII were carried by one investigator (N.A.) as described above. On every model each measurement was repeated twice and recorded on the LII data sheet (Appendix VI). The average LII score was considered for the analysis and used for the classification of the malalignment severity (Table 3.3) at each time point (Little, 1975).

Table 3.3: Classification of the anterior malalignment severity based on LII score (Little, 1975)

LII score	**Malalignment severity**
0	Perfect alignment
1-3	Minimal irregularity
4-6	Moderate irregularity
7-9	Severe irregularity
10	Very severe irregularity

In the expansion subgroup and in addition to the above-described measurements, the initial inter-molar, inter-premolar and inter-incisal (distance between the two maxillary central incisors in case of a midline diastema) distances were assessed on pretreatment dental casts with the same digital caliper held parallel to the occlusal plane (Figure 3.3). Measurements were made on the most lingual point at the free gingival margins of the teeth to minimize the error that could result from buccal crown tipping during the expansion procedure (Adkins, Nanda, & Currier, 1990; Ngan et al., 1998).

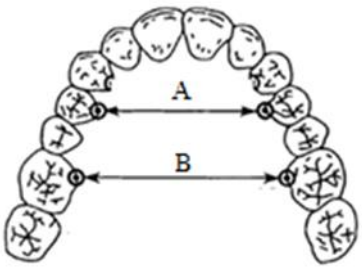

Figure 3.3: Arch width measurement: A is the interpremolar width, B is the intermolar width. All points are the most lingual points at the gingival margin (Adkins et al., 1990; Ngan et al., 1998).

An additional alginate impression of the maxillary arch was taken at the end of the first week of expansion. Inter-molar, inter-premolar and inter-incisal distances were measured directly after expansion and during the following 13 weeks of treatment with fixed appliances along with the LII. Arch width measurements were duplicated at each time point, recorded on the LII and arch width measurements sheet (Appendix VI), and the averages used for the analysis.

5. Pain Assessment

After insertion of the orthodontic appliances, each patient was given a pain diary, designed specifically for this study, to record pain intensity from teeth when eating and biting on a daily basis (Appendix VII). Recordings were made on a visual analogue scale (VAS) which is an unmarked (without numbers) continuous 100 millimeters 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 (Abed Al Jawad et al., 2011). The Visual Analogue Scale (VAS) is the most common method for assessing orthodontic pain (Seymour, Simpson, Charlton, & Phillips, 1985). It has been described as being simple, sensitive and reliable (Bergius, Berggren, & Kiliaridis, 2002; Sergl, Klages, & Zentner, 1998), and patients over 5 years of age are able to use it in a valid manner to rate pain intensity, regardless of sex or health status (Bergius, Kiliaridis, & Berggren, 2000). Other scales used for assessing pain include the Verbal Rating Scale which consists of a list of adjectives describing different levels of pain intensity (Jones, 1984), and the Numerical Rating Scale which is a discontinuous and segmented scale marked with whole numbers from 0 to 10 (Johnson, 2005). However, methods that rely on verbal rating have been criticized for their vocabulary

limitations which may cause confusion and be difficult to apply in younger age groups (Curro, 1990). Furthermore, the advantage of the visual analogue scale over the numerical rating scale is that the former provides freedom to choose the exact intensity of pain and gives maximum opportunity for expression in an individual personal response style (Krishnan, 2007).

The respondent placed a mark on the line that corresponds to the amount of experienced pain. The study coordinator (N.A.) measured the distance from the left margin to the recorded mark with a ruler and reported the value in millimeters (Figure 3.4). The weekly pain intensity was calculated as the average pain of the seven week days measurements. A question related to the use of analgesics for pain relief was added at the bottom of each page of the diary (Abed Al Jawad et al., 2011). The patient was asked to return the pain diary at the next appointment, scheduled 5 weeks after appliance insertion, and another diary was given at the following appointment.

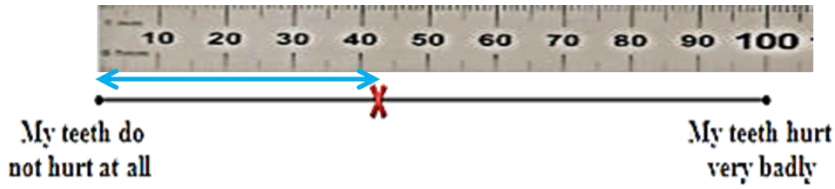

Figure 3.4: The VAS with a mark made at 42 millimeters (Abed Al Jawad et al., 2011).

In the expansion subgroup, patients were asked to fill an additional pain diary along the first week of expansion. After bonding of fixed appliances we followed the same schedule as for the main group.

6. Malocclusion Severity Assessment

The initial severity of the malocclusion was assessed on the pretreatment lateral cephalometric radiographs taken routinely at the department of Orthodontics at AUBMC before the start of orthodontic treatment. The cephalographs were obtained using the same digital cephalostat (GE, Instrumentarium, Tuusula, Finland) in a standardized method: the patient was positioned in natural head position with the jaws in centric occlusion and lips in gentle touch (Genno, Nemer, Eddine, Macari, & Ghafari, 2019; Macari & Hanna, 2013). The cephalograms were digitized by one investigator (N.A.) using the Dolphin Imaging Software (version 11.5; La Jolla, Calif). Angular and linear measurements (Figure 3.5) gauged the jaws' sagittal and vertical skeletal and dento-alveolar relationships (Table 3.4). The severity of the malocclusion was further categorized into different levels for each of the measurements (Table 3.5).

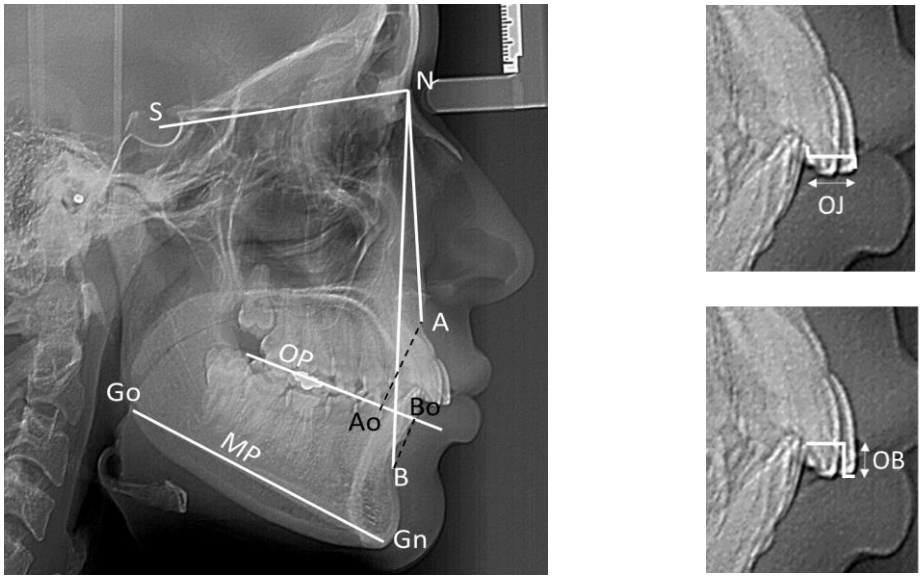

Figure 3.5: Cephalometric analysis including angular measurements: ANB, MP/SN; and linear measurements: AoBo, overjet (OJ), overbite (OB)

Table 3.4: Cephalometric measurements of vertical and sagittal relationships

Measurement	Definition	Category
ANB	Angle between points A, N and B (Steiner, 1953)	Sagittal relationship between the jaws
AoBo	Distance between the perpendiculars drawn from A and B points to the occlusal plane passing through the region of maximum cuspal interdigitation (Jacobson, 1975)	
MP/SN	Angle between cranial base cant (SN) and mandibular plane (MP) defined by gonion (Go) & gnathion (GN) points (Steiner, 1953)	Vertical relationship between the jaws (facial divergence)
OJ	Horizontal distance between the lingual incisal edge of the most forwardly positioned maxillary incisor to the labial incisal edge of the most forwardly positioned mandibular incisor (Cangialosi et al., 2004)	Dento-alveolar relationships
OB	Vertical distance between the incisal edges of the most forwardly positioned maxillary and mandibular incisors (Cangialosi et al., 2004)	

Table 3.5: Severity levels of the malocclusion

Category	Levels	Measurement range	Reference
Sagittal jaws relation	Skeletal class III Skeletal class I Skeletal class II	ANB≤0° 0°<ANB<4° ANB≥4°	Steiner analysis (Steiner, 1953)
Facial divergence	Hypodivergent pattern Normodivergent pattern Hyperdivergent pattern	MP/SN≤27° 27°<ANB<37° ANB≥37°	Steiner analysis (Macari & Hanna, 2013; Steiner, 1953)
Sagittal anterior dental relation	Edge to edge/crossbite Normal overjet Increased overjet	OJ<1mm 1mm≤OJ≤3mm OJ>3mm	ABO DI score (Cangialosi et al., 2004)
Vertical Anterior dental relation	Shallow/ openbite Normal overbite Deepbite	OB<1mm 1mm≤OJ≤3mm OJ>3mm	ABO DI score (Cangialosi et al., 2004)

The outcome measurements along with the measurement tools and units are summarized in Table 3.6.

Table 3.6: Summary table of the outcome measurements, tools and units

Outcome	Measurement tool	Measurement	Unit
Sample baseline characteristics	• Medical questionnaire	- Exclusion criteria - Pubertal stage	
	• Sociodemographic questionnaire	- Age of participant - Household crowding index - Mother education level	
	• Life style questionnaire	- Physical activity level - Parent attentive to patient's diet	
BMI	• Height rod	Body height	Meters
	• Mechanical scale	Body weight	Kilograms
Dietary intake	• 24h recall for short term dietary changes	- Macronutrients	Grams
		- Micronutrients	Milligrams/ micrograms
	• FFQ for intermediate term dietary changes	- Food groups	Grams
Rate of tooth movement	Dental casts	LII	Millimeters
Arch width changes (only in expansion subgroup)	Dental casts	- Interincisal distance - Interpremolar distance - Intermolar distance	Millimeters
Dental pain	Pain diary	Visual analogue scale	Millimeters
Initial severity of malocclusion	Lateral cephalometric radiographs	- Angular: ANB, MP/SN	Degrees
		- Linear: AoBo, OJ,OB	Millimeters

D. Procedures

In the main (fixed appliances) group, eligible patients underwent specific stages of treatment with fixed appliances placed on maxillary and/or mandibular teeth (Figure 3.6). The study covers only the first of usually 3 stages of therapy, commonly consisting of leveling and aligning crowded and rotated teeth. Depending on the severity of malalignment, a series of archwires is used with gradation from softer to

harder wires. The flow chart of data collection prior and during the first 13 weeks of treatment with fixed appliances is represented in Table 3.7.

Figure 3.6: Maxillary and mandibular fixed appliances with bands around molars and brackets on rest of teeth

Table 3.7: Flowchart of data collection in the fixed appliances group

Baseline assessment: before appliances insertion	
• Sample characteristics	- Medical questionnaire (MQ) - Demographic & socioeconomic questionnaire (DSQ) - Life style questionnaire (LSQ)
• Anthropometrics	Weight & Height → BMI
• Dietary intake	- Multiple Pass 24 hour Recall (MPR 24h) - Food Frequency Questionnaire (FFQ)
• Tooth irregularity	Little's irregularity index (LII)
• Malocclusion severity	Cephalometric measurements (Ceph Meas: ANB, AoBo, MP/SN, OJ, OB)
1st follow up assessment: during the first week after appliances insertion	
• Dietary intake	Multiple Pass 24 hour Recall (MPR 24h)
2nd follow up assessment: five weeks after appliances insertion	
• Anthropometrics	Weight & Height → BMI
• Dietary intake	Food Frequency Questionnaire (FFQ)
• Rate of tooth movement	Little's irregularity index (LII)
• Pain	Pain diary (PD) filled by patient over the past 5 weeks
3rd follow up assessment: thirteen weeks after appliances insertion	
• Anthropometrics	Weight & Height → BMI
• Dietary intake	Food Frequency Questionnaire (FFQ)
• Rate of tooth movement	Little's irregularity index (FFQ)
• Pain	Pain diary (PD) filled by patient over the past 5 weeks
N.B: Whenever the second arch was bonded during the study period an additional 24h recall was collected during the 1st week after bonding	

In the expansion subgroup, eligible patients had rapid palatal expansion using the Hyrax expander. The expander was placed in the maxillary arch and activated by the patient/parent for one or two weeks depending on the needed amount of expansion and the rate of maxillary suture opening, which translates into the development of a midline diastema anteriorly and crossbite correction posteriorly (Figure3.7). When the desired amount of expansion was achieved (palatal cusp of the maxillary molar touching the lingual plane of the buccal cusp of the mandibular molar), the patient/guardian was asked to stop activation of the expansion screw and the maxillary arch was bonded using fixed appliances to align the teeth and maintain the expanded arch circumference.

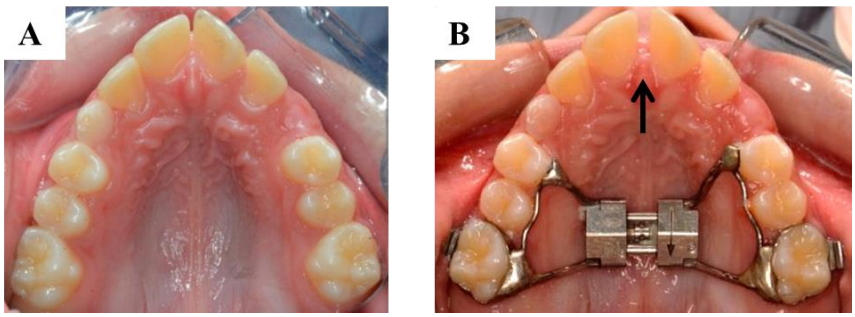

Figure 3.7: A. Maxillary arch requiring expansion; **B.** Midline diastema developed after expansion

In this subgroup, data were collected prior to and during the first week of expansion, and over the next 13 weeks after fixed orthodontic appliances insertion. The collection timetable was similar to that of the fixed appliances group during the first 13 weeks of the leveling and aligning phase (Table 3.8). The data collection timetables of both groups are summarized in Figure 3.8.

Table 3.8: Flowchart of data collection in the expansion subgroup

Baseline assessment: before expansion	
• Sample characteristics	- Medical questionnaire (MQ) - Demographic & socioeconomic questionnaire (DSQ) - Life style questionnaire (LSQ)
• Anthropometrics	Weight & Height → BMI
• Dietary intake	- Multiple Pass 24 hour Recall (MPR 24h) - Food Frequency Questionnaire (FFQ)
• Tooth irregularity & arch width	- Little's irregularity index (LII) - Interpremolar (IPm) & intermolar (IM) distances
• Malocclusion severity	Cephalometric measurements (Ceph Meas: ANB, AoBo, MP/SN, OJ, OB)
1st follow up assessment: during the first week after expansion	
• Dietary intake	Multiple Pass 24 hour Recall (MPR 24h)
• Arch width	Interincisal (II), interpremolar & intermolar distances
• Pain	Pain diary filled by patient over the expansion week
2nd follow up assessment: five weeks after fixed appliances insertion	
• Anthropometrics	Weight & Height → BMI
• Dietary intake	Food Frequency Questionnaire (FFQ)
• Rate of tooth movement & arch width	- Little's irregularity index (LII) - Interincisal (II), interpremolar & intermolar distances
• Pain	Pain diary (PD) filled by patient over the past 5 weeks
3rd follow up assessment: thirteen weeks after fixed appliances insertion	
• Anthropometrics	Weight & Height → BMI
• Dietary intake	Food Frequency Questionnaire (FFQ)
• Rate of tooth movement & arch width	- Little's irregularity index (LII) - Interincisal (II), interpremolar & intermolar distances
• Pain	Pain diary (PD) filled by patient over the past 5 weeks

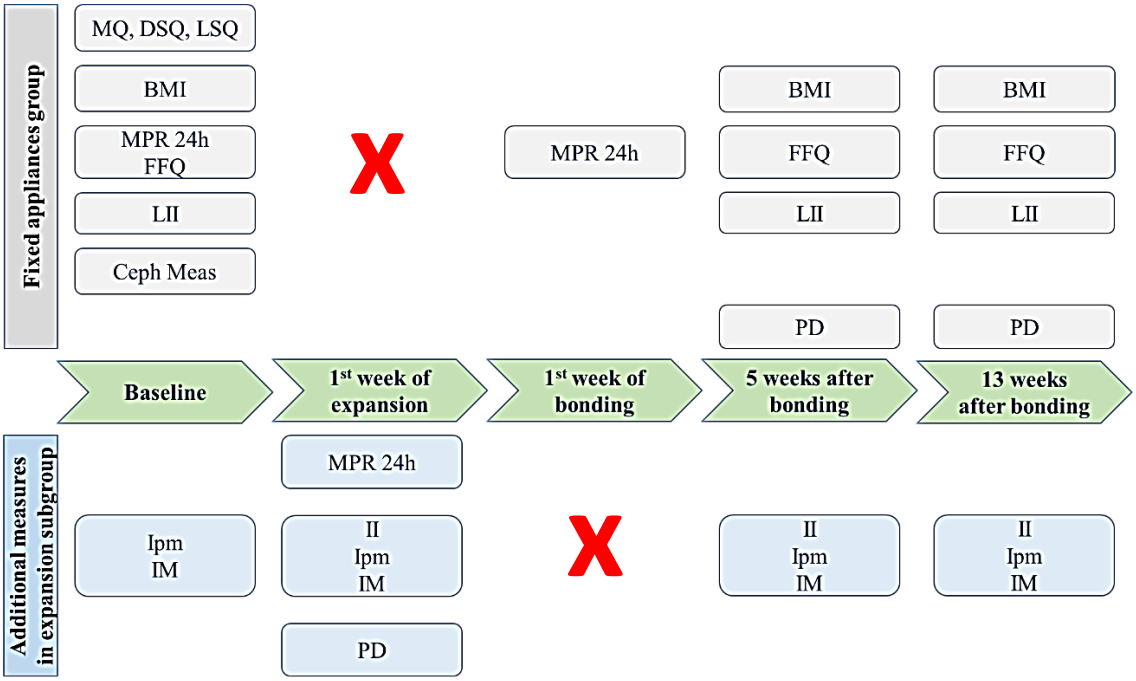

Figure 3.8: Summary timetable of data collection in the main fixed appliances group and the expansion subgroup

E. Ethical Considerations

Rules and regulations of confidentiality were followed according to AUB Institutional Review Board protocols. IRB approval was obtained before staring data collection.

1. Respect for Persons

Respect of autonomy was ensured by obtaining an informed consent from participants aged 18 till 21 or an age corresponding assent from minor adolescents along with a parental permission for participation in the study (Appendix I). Details about the purpose of the study, the procedures of data collection and the benefits were explained first orally by the study coordinator who clarified as well that participation is voluntary, and that later withdrawal from the study is always possible even after signing the

consent. If oral approval is attained, then parents and eligible participants were invited to read the information written in the assent/consent and parental permission forms and ask for any explanation before signing. English and Arabic versions of the forms were available. Illiterate legal guardians had the possibility of consenting orally and the signature is obtained from a witnessing person. Once parental signature is secured, the adolescent signed or wrote his/her name and date on the assent form before initiation of data collection. Enrollment of minor participants in the study required agreement of both parent/legal guardian and participant, if one of them is not secured participation is not considered. The contact information of the study coordinator (N.A.) was provided to the parent and participant in case of later arising questions, concerns or complaints about the study.

To protect privacy, it was highlighted that:

- Parent and child have the right not to answer any question that might cause discomfort since some questions trigger sensitive topics like puberty, and answering some of them may cause embarrassment. Questionnaires were collected at the department of Orthodontics of the AUBMC in a private setting.

- Some of the patient's records (initial dental study model and lateral cephalogram) will be accessed by the study coordinator. However all collected information will remain confidential and used solely for research purposes.

- Data will be secured in a locked drawer and a password protected computer at the department of Orthodontics of AUBMC and the NFSC department of AUB and accessed only by the study coordinator.

- Data will only be reported in the aggregate without disclosure of participants' names in any reports or presentations of the research. To this end all

questionnaires, data recording sheets, dental casts, pain diaries, and cephalograms were coded using one serial number for each participant.

2. Beneficence and Non-Maleficence

Enrolment in this study does not entail any risks. Possible side effects are related to the routine orthodontic treatment and not to the study itself, and were explained to the participant upon initiation of orthodontic treatment. During the session of fixed appliances or palatal expander insertion, the physician mentions the potential temporary feeling of pressure/pain from tooth movement and discomfort at speech and eating. Participants and parents were informed that should there be any problem encountered during the regular orthodontic practice, it will be dealt with accordingly.

In order to track tooth movement, impressions of the dental arches were taken by trained orthodontists during regular orthodontic visits to the clinic. For this procedure, the adequate amount of impression material is placed into a sized dental tray, and held over the teeth for 30 to 45 seconds. The physician was giving specific instructions while the tray is in the mouth to avoid discomfort.

Every effort was made to make the data collection process smooth and not consuming extra time from the participant. Although recording pain level in the pain diary was required on a daily basis, the process takes less than one minute to be completed. Furthermore before collecting the dietary questionnaires over the phone, parents were asked to provide the best time to call their children without undue intrusion in their home activities. In addition the call followed a standardized script to avoid deviation from the specific discourse agreed upon during the consent process.

The benefits of the study outweigh the unforeseen risks. The findings will increase the general knowledge about the association between orthodontic treatment and dietary intake, and help the orthodontists improve and redirect the dietary guidelines given to their patients in such a way to ensure a balanced dietary intake in order to maintain healthy growth and environment for tooth movement. In the absence of dietary guidance, growing patients generally switch to soft diet without attention to the nutritional value of the consumed food, therefore patients may benefit from findings to improve their diet habits. Furthermore, a potential correlation may exist between tooth movement and certain nutrients, which may have an impact on the speed of orthodontic treatment.

Patients who agreed to participate in this research were offered an instructive booklet about healthy eating habits (Appendix II) at the termination of the study. Refusal to participate or withdraw from the study involves no penalty or loss of benefits to which the subjects are otherwise entitled and does not affect their relationship with their physician, the level of care being received and neither affects their relationship with AUB/AUBMC.

3. Justice

The selection and recruitment procedures were equitable and just. There was no exclusion of any group based on sex, religion, socio-economic factors or age other than what specified for inclusion criteria.

It was important to include vulnerable groups such as minors and students because most of our patients seek orthodontic treatment during their adolescence, a period at which maintenance of a well-balanced diet is mandatory to promote patients

development and support bone remodeling necessary for teeth movement during orthodontic treatment. Therefore, investigating whether this group of patients is at risk of nutritional imbalance during their treatment is important. When an eligible minor patient was not accompanied by the parent at the appointment preceding insertion of fixed appliances or palatal expander, the study coordinator made sure to contact the parents and explained the study over the phone to ensure the adolescent's chance to be part of the study. Upon oral agreement, the parent was invited to come to the department of Orthodontics to sign the parental permission, or else the forms were sent with the patient to be signed at home and brought back before the start of data collection.

The extension of the recruitment period from 9 to 13 months as a consequence of the slow recruitment rate gave the chance to 26 patients (19 in the fixed appliance group and 7 in the expansion group) above the required sample size to be enrolled in the study. Those who decided to withdraw later and those who were withdrew by the study coordinator, for multiple missing appointments or after their decision to delay the start of the treatment, received the specified compensation as the rest of the subjects who completed the study.

F. Data Management

For each subject enrolled in the study, one unique serial number was assigned. Data of the sample's characteristics assessment questionnaires, anthropometric, pain, dental and cephalometric measurements were entered into Microsoft Excel. Data of the 24h recall questionnaire and the FFQ were entered into a specialized nutrition software

(Nutritionist Pro and Microsoft Access). After extraction the resulting datasets were merged into the final dataset along with the rest of the data.

Data cleaning was first performed by ensuring the linking of the questionnaires and data recording sheets according to the serial number, and if present, the participant's name. Following the confirmation of serial number entries and correct linking, data was de-identified by dropping all names and keeping only serial numbers. Additionally the data were overviewed to detect any missing or duplicated entries and inconsistencies were investigated and corrected.

Frequency distribution were finally generated for all variables to assess data distribution and the presence of outliers. Decision on the need to regroup variables were taken when needed.

G. Statistical Analyses

Descriptive statistics for fixed appliances and expansion groups were generated for all socio-demographic, dental and dietary intake variables. The Shapiro-Wilk normality test was run to check if the outcome variables have a normal distribution. Since some of the variables were not normally distributed because of the presence of some outliers, the mean and standard deviation might be distorted. Median ($\tilde{x}$) and range: minimum and maximum [min, max] were reported instead for better representation of the data.

For short-term comparison of dietary intake (between baseline and one week), the two-tailed paired t-test was used for normally distributed data, or its equivalent non-parametric test, the Wilcoxon signed-rank test was used when the data were not normally distributed.

Analysis of variance (Repeated measures ANOVA) followed by the Bonferroni Post-Hok analysis for multiple comparisons (for normally distributed data), and its equivalent the Friedman test followed by the Wilcoxon signed-rank test (for non-parametric data) were used for comparisons of dietary intake, anthropometric/dental measurements and pain levels among more than two time points for both fixed appliances and expansion groups:

- Dietary intake among baseline, 1st week of bonding 1st arch and 1st week of bonding 2nd arch
- Anthropometric measurements, dietary intake, irregularity index, arch width measurements and tooth movement among baseline, 5 and 13 weeks
- Pain levels among the different weeks of each month

The change in dietary intake between 1st month of bonding and baseline was compared across different categorical data: gender, pubertal stage, socio-economic status, mother education level, physical activity, parent who is more attentive to patient's diet, baseline BMI, number of bonded arches, the need for pain relief, sagittal and vertical jaws relationship, dental overjet and overbite.

For variables with 2 categories, the independent samples t-test (for normally distributed data) or the Mann-Whitney U test (for non-parametric data) were used for comparisons. For variables with more than 2 categories, the one-way ANOVA analysis of variance followed by the Bonferroni Post-Hoc multiple comparisons test (for normally distributed data) or the Kruskal-Wallis one way analysis of variance followed by a pairwise comparison (for non-parametric data) were employed for comparisons.

The change in dietary intake and pain levels were as well compared between the expansion subgroup and a matched sample from the fixed appliances group using

the two-tailed paired t-test (for normally distributed data) or the Wilcoxon signed-rank test (for non-parametric data).

The Pearson product moment correlation coefficient (and its equivalent non-parametric Spearman correlation coefficient) was performed to test correlations between the following variables:

- Changes in dietary intake and tooth movement
- Changes in dietary intake and pain levels
- Tooth movement and pain levels

Intra-examiner reliability of measurements was tested for the variables: height, weight, body mass index, Little's Irregularity index, visual analogue scale pain scores, and cephalometric measures, using the Pearson correlation product moment.

All statistical analyses were performed using SPSS and the level of significance was considered at 0.05.

CHAPTER IV

RESULTS

This chapter includes:

- A description of the fixed appliances group and expansion subgroups characteristics
- The comparison of anthropometric measurements, dietary intake, tooth movement and pain levels between the study timelines in each of the fixed appliances group and the expansion subgroup
- A comparison of the dietary intake changes across the categorical variables in the fixed appliances group
- A comparison of the dietary intake changes and pain levels between the expansion subgroup and a matched sample from the fixed appliances group
- The association between dietary changes, tooth movement and pain levels

A. Intra-examiner reliability of the measurements

The Pearson correlation product moment was used to test the intra-examiner reliability of measurements. High correlation existed between the duplicated measures of height, weight, body mass index, Little's Irregularity index, visual analogue scale pain scores, and cephalometric measures. The intra-class correlation coefficient was r= 0.99 with a p-value= 0.000. For measurements unique to the expansion subgroup, r= 0.98 with a p-value= 0.000.

B. Description of the Sample

1. Fixed Appliances Group

a. Sociodemographic, Lifestyle and Anthropometric Baseline Characteristics

The sample included 95 participants who completed the study: 44 males and 51 females, with a mean age of 14.71 years (SD: 2.83). 29.5% (n= 28) were classified in the prepubertal stage versus 66.3% (n=63) in the postpubertal stage. In four subjects, the pubertal stage could not be identified because they refused to answer on the puberty determination section of the medical questionnaire (Figure 4.1).

Almost 62% (n= 59) had a household crowding index greater than one (1.23 ± 0.29) revealing a lower socio-economic status. 60% of the participants' mothers had a university degree, 21.1% attained high school, and the rest attained intermediate school or less (Figure 4.1).

Almost half (50.5%) of the subjects had a moderate physical activity (1-2 times per week), 21 % had a high physical activity (>2 times/week), and the rest (28.5%) did not do any physical activity. The mother was the most attentive to the participant's diet (68.4%), and in 22.1% of the cases both parents were (Figure 4.1).

The mean BMI of the sample at baseline was 22.799kg/m^2 (SD: 3.877), with a mean body weight of 59.06kg (SD: 14.694) and a mean body height of 1.601m (SD: 0.11) (Table 4.3). The BMI classification showed that 2.1% were underweight; 45.3% normal weight, 38.9% overweight and 13.7% obese.

b. Treatment Approach and Baseline Occlusal Characteristics

All participants had at least one arch bonded starting, for the majority, with the maxillary arch (76.8%). During the study period that ranged over 13 weeks, 40 patients

out of the 95 (44.1%) got the second arch bonded, which was mainly the mandibular arch (82.5%). The pre-treatment analysis and the adopted treatment plan dictated the decision whether to start with bonding of the maxillary or mandibular arch and the time frame for bonding the second arch. The latter was categorized according to the periods defined for data collection: between the 1st and 5th week (before the 2nd follow up assessment: 32.5%), at the 5th week (at the 2nd follow up assessment: 35%) or at the 9th week (before the 3rd follow up assessment: 32.5%) (Figure 4.2).

The median Little's irregularity index (LII) was $\tilde{x}$= 3.245mm (range: [0, 11.96]) in the maxillary arch and $\tilde{x}$= 2.77mm (range: [0, 15.065]) in the mandibular arch (Table 4.15). The classification of LII in the maxillary arch revealed that 15.8% had a perfect alignment of the six anterior teeth. The majority of the participants (48.4%) had a minimal crowding, 23.2% had a moderate irregularity, 9.5% had a severe crowding, and the remaining 3.1% had a very severe irregularity. In the mandibular arch the LII was classified as follows: 16.8% perfect alignment, 57.9% minimal irregularity, 14.7 % moderate irregularity, 9.5% severe irregularity, and 1.1% very severe irregularity.

The measurements performed on the lateral cephalometric X-rays, allowed the determination of the initial severity of the malocclusion related to:

- The sagittal jaws relationship (ANB: 3.799 $\pm$ 2.807; AoBo: $\tilde{x}$= -0.7, [-16.7, 9.1]) distributed into: 36.8% class I malocclusion (ANB: 2.511 $\pm$ 1.062), 54.7% class II malocclusion (ANB: 5.648 $\pm$ 1.398), 8.4% class III malocclusion (ANB: -2.588 $\pm$ 2.403).
- The vertical jaws relationship (MP/SN: 32.247 $\pm$ 4.922) distributed into: 70.5% normodivergent pattern (MP/SN: 32.085 $\pm$ 2.785), 14.7% hypodivergent pattern (MP/SN: 25.029 $\pm$ 1.657), 14.7% hyperdivergent pattern (MP/SN: 40.243 $\pm$ 2.818).

- The overjet (OJ: 3.95 ± 2.091) distributed into: 16.8% normal overjet (OJ: 2.522 ± 0.554), 77.9% increased overjet (OJ: 4.593 ± 1.651), 5.3% anterior crossbite (OJ: $\tilde{x}$= -0.1, [-5.15, 0.7]).

- The overbite (OB: 2.603 ± 2.125) distributed into: 34.7% normal overbite (OB: 2.189 ± 0.564), 43.2% deep bite (OB: 4.455 ± 1.208), 22.1% anterior openbite (OB: $\tilde{x}$= -0.362, [-2.55, 0.85]) (Table 4.1).

2. Expansion Subgroup

a- Sociodemographic, Lifestyle and Anthropometric Baseline Characteristics

The sample included 20 participants who completed the study: 7 males and 13 females, with a mean age of 12.13 years (SD: 1.2), equally distributed between the prepubertal and postpubertal stages of growth (Figure 4.3).

Around 65% had a household crowding index greater than one (1.75 ± 1.33) indicating a lower socio-economic status. The majority of the mothers had a university degree (75%) and the other 25% had a high school degree (Figure 4.3).

The intensity of the physical activity was distributed as follows: 45% low activity, 35% moderate activity, 20% high activity. The mother was the most attentive to the participant's diet (60%), followed by both parents (30%), and the father alone (5%) (Figure 4.3).

The mean BMI of the sample was 20.883kg/m^2 (SD: 4.628), with a mean body weight of 46.975kg (SD: 13.751) and a mean body height of 1.492m (SD: 0.101) (Table 4.4). According to the BMI, 60% had their weight within normal range, 20% overweight, and 20% obese.

b- Treatment Approach and Occlusal Baseline Characteristics

The expansion screw was activated at a rate of two turns per day. The maxillary arch was the only bonded arch during the study period in the expansion subgroup.

The median LII in the maxillary arch was $\tilde{x}$= 4.463mm (range: [1.26mm, 17.33mm]) (Table 4.17). The severity of the anterior dental crowding was classified into: 40% minimal; 40% moderate, 20% severe, and 20% very severe (Figure 4.11). At baseline, the mean inter-premolar distance was 24.86mm (SD: 1.805mm), the mean inter-molar distance was 31.49mm (SD: 2.972mm), and the median inter-incisal distance was $\tilde{x}$= 0.222mm (range: [0, 0.9mm]) (Table 4.18).

The median ANB angle was $\tilde{x}$= 3.25° (range: [-5.9°, 7.8°]), and a mean MP/SN angle of 33.475° (SD: 4.368°). The linear cephalometric measurements were for AoBo $\tilde{x}$= -2.55mm (range: [-12.1mm, 6.3mm]), for the overjet 3.303mm (SD: 2.419mm), and for the overbite $\tilde{x}$= 0.875mm (range: [-2.85mm, 4.7mm]).

In the sagittal dimension: 70% had a class I malocclusion (ANB: 2.307° ± 1.204°), 25% had a class II malocclusion (ANB: 6.06° ± 1.403°), and 5% had a class III malocclusion (ANB: -5.9°).

In the vertical dimension: 70% had a normodivergent pattern (MP/SN: 33.557° ± 2.561°), 15% had a hypodivergent pattern (MP/SN: 26.567° ± 0.666°), and 15% had a hyperdivergent pattern (MP/SN: 40° ± 1.646°).

35% had a normal overjet (OJ: 2.036mm ± 0.731mm); 55% had an increased overjet exceeding 3mm (OJ: 5.009mm ± 1.142mm), and 10% had a crossbite (OJ: -1.65mm ± 1.626mm).

25% had a normal overbite (OB: 1.77mm ± 0.765mm); 25% had a deep bite (OB: 3.89mm ± 0.677mm), and 50% had an open bite (OB: x̃= -0.35mm, [-2.85mm, 0.75mm]) (Table 4.2).

C. Intermediate Term Comparison of Anthropometric Measurements

1. Fixed Appliances Group

The body weight increased significantly (p=0.000) mainly between baseline (B) and 5 weeks (5wk) (B: 59.06 kg ± 14.694, 5wk: 59.743kg ± 15.201, p=0.002), and between baseline and 13 weeks (13wk) (13wk: 60.273kg ± 15.098, B vs 13wk: p=0.000), with no significant increase between 5 and 13 weeks (5wk vs 13wk: p=0.076). Similarly, the body height increased significantly across the study period (B: 1.601m ± 0.11, 5wk: 1.609m ± 0.108, 13wk: 1.616m ± 1.106, p=0.000). However the BMI did not change significantly (B: 22.799 ± 3.877, 5wk: 22.827 ± 3.999, 13wk: 22.812 ± 3.903, p=0.947) indicating a proportional increase in weight and height (Table 4.3).

The percentage of overweight and obese participants decreased at 5 weeks with a greater decrease in the obese category (Overweight: B: 38.9%; 5wk: 37.9%; Obese: B: 13.7%, 5wk: 10.5%). At 13 weeks, the percentage of overweight participants kept decreasing (34.7%). However, that of obese increased back to almost baseline percentage (12.6%) (Figure 4.4).

2. Expansion Subgroup

The body height increased significantly across the study period (B: 1.492m ± 0.101, 5wk: 1.497m ± 0.099, 13wk: 1.507m ± 0.098, p=0.000). However, there was

neither significant change in the body weight (B: 46.975kg ± 13.751, 5wk: 46.398kg ± 13.869, 13wk: 46.379kg ± 12.755, p=0.152), nor in the BMI (B: 20.883 ± 4.628, 5wk: 20.471 ± 4.732, 13wk: 20.182 ± 4.094, p=0.074) indicating that the increase in height did not affect significantly the BMI (Table 4.4).

At 5 weeks, 10% of overweight participants at baseline moved to the normal weight category, and 10% of the obese participants at baseline shifted to the overweight category. A 13 weeks, the % of obese participants was maintained, however 5% of the normal weight participants moved back to the overweight category (Figure 4.5).

D. Short Term comparison of Dietary Intake

1. Fixed Appliances Group

a. Comparison between Baseline and 1st Week of Bonding the First Arch (n=95)

There was a significant decrease in the quantity of total food intake (g/d) (B: 2337.209 ± 985.676, 1wk: 2189.377 ± 898.236, p=0.021) and total energy (kcal/d) (B: 1604.05 ± 573.71, 1wk: 1341.46 ± 667.404, p=0.000) (Table 4.5).

Macronutrients' intake (g/d) decreased significantly at one week with significant difference (p=0.000) in the intake of protein (g/d) (B: 60.718 ± 26.513, 1wk: 51.467 ± 34.603), carbohydrate (g/d) (B: 175.272 ± 64.154, 1wk: 143.886 ± 55.554), total fat (g/d) (B: 75.478 ± 29.103, 1wk: 62.542 ± 42.439) and dietary fiber (g/d) (B: 12.609 ± 7.197, 1wk: 9.42 ± 5.274). However, the diet composition (represented by the percentage of contribution of macronutrients to total energy intake- %EI) did not change significantly from baseline (Table 4.5).

The intakes of the majority of micronutrients decreased significantly at one week except for vitamins C, D and E levels which did not differ from baseline. The

most significant decreases (p=0.000) were observed for the intake of potassium, iron, magnesium, phosphorus, zinc, copper, chromium and B vitamins (Table 4.5).

b. Comparison among Baseline, 1st Week of Bonding the First Arch and 1st Week of Bonding the Second Arch (n=40)

The acute differences in total food consumption (g/d) and total energy intake (kcal/d) between baseline, 1st week of bonding 1st arch (a1), and 1st week of bonding 2nd arch (a2) were statistically significant (p=0.002 for total food intake; p=0.000 for total energy intake). They decreased significantly at one week after bonding the first arch (B: 2312.1 ± 869.311, a1: 2136.79 ± 934.749, p= 0.048 for total food intake; B: 1695.5 ± 631.3, a1: 1314.58 ± 865.915, p=0.000 for total energy intake); further decreased relative to baseline after bonding the second arch (a2: 1888.54 ± 641.85, B vs a2: p=0.004 for total intake; a2: 1202.49 ± 489.188, B vs a2: p=0.000 for total energy) was observed. However, the differences between one arch and two arches were not statistically significant (Table 4.6).

The same trend of change was observed for the majority of macro and micro nutrients, whereby levels were lower than baseline after bonding the 1st and 2nd arches (but not different between the two arches). The most significant decrease between the three time points (p=000) for macronutrients was in the absolute intake of sugar (g/d) (B: 62.051 ± 30.014, a1: 44.172 ± 28.657, a2: 42.032 ± 20.923, B vs a1: p=0.000, B vs a2: p=0.000) and dietary fiber (g/d) (B: 14.69 ± 9.566, a1: 10.023 ± 7.015, a2: 8.988 ± 3.865, B vs a1: p=0.000, B vs a2: p=0.000). On the other hand, the percent of contribution of the different macronutrients to the total energy did not change

significantly indicating a maintained diet composition whether one or two arches were bonded (Table 4.6).

For the micronutrients, the most significant decrease (p=0.000) between the three time points was in the intake of iron (mg/d) (B vs a1: p=0.002, B vs a2: p=0.000), magnesium (mg/d) (B vs a1: p=0.000, B vs a2: p=0.000), manganese (mg/d) (B vs a1: p=0.000, B vs a2: p=0.000), chromium (mg/d) (B vs a1: p=0.000, B vs a2: p=0.000), vitamin B1 (mg/d) (B vs a1: p=0.001, B vs a2: p=0.000) and vitamin B3 (mg/d) (B vs a1: p=0.000, B vs a2: p=0.000) (Table 4.6).

2. Expansion Subgroup

a. Comparison between Baseline and 1st Week of Maxillary Expansion (n=20)

During the first week of expansion (1wkE), total energy intake decreased significantly (kcal/d) (B: 1649.695 ± 579.357, 1wkE: 1259.381 ± 654.061, p=0.003). However, the decrease in the quantity of total food intake (g/d) was marginally significant (B: 2420.256 ± 914.025, 1wkE: 2110.672 ± 1000.314, p=0.051) (Table 4.7).

Intake of macronutrients (g/d) have decreased significantly at one week of expansion including protein (g/d) (B: 56.685 ± 26.11, 1wkE: 41.608 ± 21.682, p=0.006), carbohydrates (g/d) (B: 183.687 ± 63.076, 1wkE: 150.012 ± 75.999, p=0.037), sugar (g/d) (B: 60.654 ± 36.762, 1wkE: 46.376 ± 33.129, p=0.003), and total fat (g/d) (B: 78.014 ± 32.413, 1wkE: 55.889 ± 33.12, p=0.005). Unexpectedly the intake of fiber (g/d) during expansion did not differ significantly from baseline although it decreased. Furthermore, the percentage contribution of macronutrients' to total energy intake did not change significantly (Table 4.7).

There was a significant decrease in the intake of micronutrients including iron (mg/d) (p=0.011), calcium (mg/d) (p=0.03), magnesium (mg/d) (p=0.019), zinc (mg/d) (p=0.03), vitamin A (mcg/d) (p=0.037), riboflavin (mg/d) (p=0.012), niacin (mg/d) (p=0.002), pyridoxine (mg/d) (p=0.004), cobalamin (mcg/d) (p=0.044) and pantothenic acid or vitamin B5 (mg/d) (p=0.048) (Table 4.7).

E. Intermediate Term comparison of Dietary Intake among Baseline, 5 and 13 Weeks of Bonding

1. Fixed Appliances Group

The total food intake (g/d) and total energy intake (kcal/d) decreased significantly at 5 weeks (5wk), and further more at 13 weeks (13wk) of treatment (B: 3128.75 $\pm$ 1204.16, 5wk: 2784.9 $\pm$ 1000.83, 13wk: 2701.85 $\pm$ 994.583, B vs 5wk: p=0.003, B vs 13wk: p=0.000 for total food intake; B: 2977.49 $\pm$ 1447.92, 5wk: 2375.37 $\pm$ 1163.39, 13wk: 2343.15 $\pm$ 1050.78, B vs 5wk: p=0.000, B vs 13wk: p=0.000 for total energy intake), but with no statistical significance between 5 and 13 weeks (Table 4.8).

The same trend of change was observed for the majority of macro and micro nutrients, where absolute intake levels decreased significantly at 5weeks, and remained low relative to baseline at 13 weeks with no significant differences between 5 and 13 weeks. For macronutrients, the most significant difference among the three time points ($p \leq 0.001$) including between baseline and 5 weeks (p=0.000) and baseline and 13 weeks (p=0.000) was the decrease in the intake of protein (g/d) (B: 95.078 $\pm$ 42.1, 5wk: 77.165 $\pm$ 38.327; 13wk: 76.932 $\pm$ 35.774), carbohydrate (g/d) (B: 381.016 $\pm$ 196.007, 5wk: 293.116 $\pm$ 168.461, 13wk: 288.776 $\pm$ 154.537) and dietary fiber (g/d) (B: 27.139 $\pm$ 16.258, 5wk: 20.199 $\pm$ 9.737, 13wk: 20.337 $\pm$ 8.965). On the other side, the diet

composition (%EI) showed a significant increase in the percent of contribution of fat to total energy intake mainly at 5 weeks (B: 37.91 $\pm$ 7.516, 5wk: 39.886 $\pm$ 7.399, 13wk: 39.61 $\pm$ 6.786, B vs 5wk: p=0.013, B vs 13wk: p=0.033), at the expense of a decrease in carbohydrates (%EI) (B: 51.154 $\pm$ 7.258, 5wk: 48.917 $\pm$ 7.814, 13wk: 49.076 $\pm$ 6.897, B vs 5wk: p=0.012, B vs 13wk: p=0.007) (Table 4.8). Moreover, the classification of macronutrients intake relative to the norms set by the Institute of Medicine (2004) showed that at baseline 65.3% of the participants had a fat intake (especially saturated fats) exceeding the acceptable macronutrient distribution range (AMDR) of 35%. The proportion of participants following this pattern increased during the treatment (5wks: 75.8%, 13wks: 74.7%) in parallel with an increase in the percentage of participants consuming less than two-thirds of the dietary fiber adequate intake (AI) reaching more than 50% of the sample at 5 and 13 weeks (Figure 4.6) .

The significant differences in the intake of micronutrients during the treatment included a decrease in the levels of sodium (mg/d) (p=0.000), potassium (mg/d) (p=0.000), iron (mg/d) (p=0.001), calcium (mg/d) (p=0.003), magnesium (mg/d) (p=0.000), phosphorus (mg/d) (p=0.001), zinc (mg/d) (p=0.000), copper (mg/d) (p=0.000), manganese (mg/d) (p=0.004), chromium (mg/d) (p=0.001), vitamin A (mcg/d) (p=0.002), the B vitamins ($p<0.01$), and vitamins C (mg/d) (p=0.03) and D (mcg/d) (p=0.01) (Table 4.8). Furthermore the percentage of participants consuming less than two-thirds of the potassium, calcium and vitamin D dietary reference intake (DRI) exceeded 50% during the treatment (Figure 4.7).

For several food groups, the intake at 5 weeks of treatment decreased significantly, and remained low relative to baseline at 13 weeks without significant difference between 5 and 13 weeks. These food groups included breads (g/d) (B vs 5wk:

p=0.000, B vs 13wk: p=0.001), cereals (g/d) (B vs 5wk: p=0.001, B vs 13wk: p=0.004), biscuits-wafers-chocolate (g/d) (B vs 5wk: p=0.022, B vs 13wk: p=0.000); salty snacks (g/d) (B vs 5wk: p=0.001, B vs 13wk: p=0.004), eggs (g/d) (B vs 5wk: p=0.008, B vs 13wk: p=0.036), fruits and dried fruits (g/d) (B vs 5wk: p=0.000, B vs 13wk: p=0.038), and starchy vegetables (g/d) (B vs 5wk: p=0.047, B vs 13wk: p=0.019). The decrease in the intake of dairy products (g/d) was only noted at 5weeks (B vs 5wk: p=0.001), then increased back to baseline level at 13 weeks (B vs 13wk: p=0.518)., The decrease in the intake of candies (g/d) was not significant until 13 weeks (B vs 13wk: p=0.009), and there was a marginal decrease in the intake of nuts and seeds (g/d) (B vs 13wk: p=0.05). On the other hand, intake of fatty food categories (%EI) increased significantly at 5 weeks, remaining high relative to baseline at 13 weeks. This included the intake of pizzas and pies (%EI) (B vs 5wk: p=0.002, B vs 13wk: p=0.012), olive oil, olives and avocado (%EI) (B vs 5wk: p= 0.018, B vs 13wk: p=0.000), oils and salads dressing (%EI) (B vs 5wk: p=0.011, B vs 13wk: p=0.019) (Table 4.9).

2. Expansion Subgroup

The total energy intake (kcal/d) decreased significantly at 5 weeks and further more at 13 weeks (B: 2598.43 $\pm$ 1187.7, 5wk: 1983.88 $\pm$ 986.8, 13wk: 1950.99 $\pm$ 717.183, B vs 5wk: p=0.042, B vs 13wk: p=0.015). However, the decrease in total food intake (g/d) was only significant at 5 weeks (B: 3176.23 $\pm$ 1180.39, 5wk: 2384.5 $\pm$ 1061.04, 13wk: 2511.32 $\pm$ 908.059, B vs 5wk: p=0.011, B vs 13wk: p=0.084) (Table 4.13).

Macronutrients (g/d) decreased significantly at 5 weeks, and further more at 13 weeks relative to baseline, without significant difference between 5 and 13 weeks.

These macronutrients included protein (g/d) (B: 91.887 ± 51.129, 5wk: 60.463 ± 31.355, 13wk: 60.098 ± 25.269, B vs 5wk: p=0.023, B vs 13wk: p=0.007), carbohydrate (g/d) (B: 348.326 ± 168.649, 5wk: 263.314 ± 158.532, 13wk: 247.824 ± 115.356, B vs 5wk: p=0.03, B vs 13wk: p= 0.003), and dietary fiber (g/d) (B: 23.397 ± 11.321, 5wk: 17.963 ± 11.814, 13wk: 17.486 ± 7.364, B vs 5wk: p=0.021, B vs 13wk: p=0.012). However, the intake of total fat (g/d) and sugar (g/d) and percent of macronutrients contribution to total energy intake did not change significantly across the study timelines (Table 4.10). Regardless of the lack of change in fat intake (%EI), the latter (especially saturated fat %EI) was greater than the AMDR of 35% at baseline in 45% of the participants. The proportion of participants following this pattern increased during the treatment (5wks: 60%, 13wks: 65%), and in parallel the percentage of participants consuming less than two third of fiber's AI exceeded half of the sample at 5 weeks and reached the double at 13 weeks compared to baseline (Figure 4.8).

For micronutrients, the significant decrease after bonding was in the intake of sodium (mg/d) (p=0.043), potassium (mg/d) (p=0.008), iron (mg/d) (p=0.043), calcium (mg/d) ($p_{B/5wk}$=0.017, $p_{B/13wk}$=0.04), magnesium (mg/d) (p=0.01), phosphorus (mg/d) (p=0.043), zinc (mg/d) (p=0.021), manganese (mg/d) (p=0.011), vitamin A (mcg/d) (p=0.015), vitamin B1 (mg/d) (p=0.005), B3 (mg/d) (p=0.019), B5 (mg/d) (p=0.022), and vitamin D (mcg/d) (p=0.041) (Table 4.10). In addition, the percentage of participants consuming less than two thirds of potassium, calcium and vitamin D DRI was already high at baseline and got worse during treatment in more than 50% of the sample (Figure 4.9).

Analysis of the food categories showed that the intake of sea food (g/d) and fruits and dried fruits (g/d) significantly decreased at 5 and 13 weeks relative to baseline

(B vs 5wk: p=0.008, B vs 13wk: p=0.04 for sea food; B vs 5wk: p=0.006; B vs 13wk: p= 0.014 for fruits and dried fruits). The decrease in the intake of bread (g/d) was not significant until 13 weeks (B vs 13wk: p=0.006) as opposed to the intake of ice cream (g/d) that increased significantly at 13 weeks (B vs 13wk: p=0.041) as well as olive oil, olives and avocado (g/d) (B vs 13wk: p=0.000) (Table 4.11).

F. Comparison of the Tooth Movement among the Study Timelines

1. Fixed Appliances Group

The little's irregularity index (LII) have decreased significantly at 5 and 13 weeks (p=0.000) in the maxillary (Mx) (B: $\tilde{x}$=3.245, [0, 11.96]; 5wk: $\tilde{x}$= 1.95, [0, 12.78]; 13wk: $\tilde{x}$= 0.93, [0, 10.125]) and mandibular (md) (B: $\tilde{x}$= 2.77, [0, 15.065]; 5wk: $\tilde{x}$= 1.925, [0, 15.065]; 13wk: $\tilde{x}$= 1.075, [0, 15.065]) arches (Table 4.12). Consequently, the percentage of participants classified in the higher severity categories of the LII decreased during treatment and therefore the percentage of participants with perfect alignment increased (B: 15.8%, 5wk: 26.3%, 13wk: 52.6% in the Mx arch; B: 16.8%, 5wk: 33.7%, 13wk: 48.4% in the md arch) (Figure 4.10).

The tooth movement, calculated as the difference in LII (ΔLII) between two time points, was significantly greater in the first period of treatment (B-5wk) relative to the second period (5-13wk) in the maxillary arch (ΔMx $LII_{B\text{-}5wk}$: 1.257, [-1.035, 7.17]; ΔMx $LII_{5\text{-}13wk}$: 0.726, [-1.92, 3.635]; p=0.01). In both arches, the total movement (B-13wk) was significantly greater than the movement at each period of the treatment (B-13wk vs B-5wk: p=0.000; B-13wk vs 5wk-13wk: p=0.000) (Table 4.13).

2. Expansion Subgroup

The LII in the maxillary arch decreased significantly at 5, and further more at 13 weeks (B: $\tilde{x}$= 4.463, [1.26, 17.33]; 5wk: $\tilde{x}$= 2.148, [0.235, 16.24]; $\tilde{x}$= 13wk: 1.46, [0, 14.715]; p=0.000) (Table 4.14). In parallel, the percentage of participants with perfect alignment increased during the treatment (B: 0%, 5wk: 25%, 13wk: 45%) (Figure 4.11).

The tooth movement of the six maxillary anterior teeth was significantly greater during the first 5weeks after bonding (B-5wk) relative to the later between 5 and 13wk; and the total movement (B-13wk) was greater than in both periods (ΔMx $LII_{B\text{-}5wk}$: $\tilde{x}$= 2.123, [-0.4, 6.265]; ΔMx $LII_{5\text{-}13wk}$: $\tilde{x}$= 0.638, [-1.215, 3.095]; ΔMx $LII_{B\text{-}13wk}$: 3.08, [0.645, 8.17]; p=0.000) (Table 4.14)

The inter-premolar distance increased significantly one week after expansion (1wkE), continued to increase at 5weeks of bonding, and remained stable at 13 weeks (B: 24.86 $\pm$ 1.805, 1wkE: 28.49 $\pm$ 1.733, 5wk: 30.02 $\pm$ 2.25, 13wk: 29.99 $\pm$ 2.098, B vs 1wkE: p=0.000, 1wkE vs 5wk: p=0.002, 5wk vs 13wk: p=0.681). The inter-molar distance increased significantly after expansion with no significant increase after bonding (B: 31.49 $\pm$ 2.972, 1wkE: 36.96 $\pm$ 4.927, 5wk: 38.49 $\pm$ 4.15, 13wk: 38.96 $\pm$ 3.649, B vs 1wkE: p=0.000; 1wkE vs 5wk: p=0.641; 5wk vs 13wk: p=1). The inter-incisal distance increased significantly after expansion, remaining unchanged after 5 weeks, then decreased significantly at 13 weeks to approach baseline measurement (B: 0.222, [0, 0.9]; 1wkE: 1.37, [0, 3.28]; 5wk: 1.572, [0, 3.46]; 13wk: 0.391, [0, 2.09]; B vs 1wkE: p=0.000; 1wkE vs 5wk: p=0.601; 5wk vs 13wk: p=0.002; B vs 13wk: p=0.49) (Table 4.15).

G. Comparison of Pain Levels and Need for Pain Relief between 1st and 3rd Month of Treatment

1. Fixed Appliances Group

During the first (M1: week 1 to week 5) and third month (M3: week 1 to week 4) of treatment, pain levels decreased significantly (p=0.000) and progressively across the weeks of the month. The mean pain level at M1 was significantly higher than M3 (M1: 11.515, [0, 47.086]; M3: 8.253, [0, 98.823]; p=0.000). The same applies on the pain intensity at each week of M1, which was significantly greater than the corresponding week at M3 (M1wk1 vs M3wk1: p=0.000; M1wk2 vs M3wk2: p=0.01; M1wk3 vs M3wk3: p=0.008; M1wk4 vs M3wk4: p=0.001) (Table 4.16) explaining the higher need for pain relief at M1 in almost half of the sample (M1: 53.7%; M3: 19%). Pain medications were taken mainly in the first week after bonding (53.7%) (specifically at the first day= 42.1%); and to a lesser extent in the first week after the adjustment visit in the 3rd month of treatment (17.9%) (specifically one day after the appointment= 12.6%) (Figure 4.12).

2. Expansion Subgroup

During the expansion week, pain level was the highest at the first day (D1) of expansion (D1: 40.05, [0, 100]). It remained high at the 2nd (D2) and 3rd day (D3) (D1 vs D2: p=0.433; D1 vs D3: p=0.629) and decreased significantly starting the fourth day (D4) of expansion (D4: 25.45, [0, 100]; D1 vs D4: p=0.009). The mean pain level during the expansion week (Ewk) did not differ significantly during the first week after bonding (M1wk1), however it was higher than at the first week of the 3rd month

(M3wk1) (Ewk: 29.075, [0, 80.571]; M1wk1: 26.25, [0, 93.71]; M3wk1: 13.786, [0, 71.3]; Ewk vs M1wk1: p=0.204; Ewk vs M3wk1: p=0.03) (Tables 4.17 & 4.18).

After bonding pain levels decreased gradually across the weeks in each of M1 and M3 (p=0.000). The mean pain level at M1 was significantly higher than at M3 (M1: 11.256, [0, 36.226]; M3: 4.94, [0, 21.925]; p=0.022) (Table 4.18) with greater need for pain relief (M1: 15%, M3: 10%) (Figure 4.13). At each week of M1 pain intensity was significantly greater than the corresponding week at M3 except for the 1st week, and with a marginal significance at the 4th week (M1wk1 vs M3wk1: p=0.076; M1wk2 vs M3wk2: p=0.013; M1wk3 vs M3wk3: p=0.019; M1wk4 vs M3wk4: p=0.05) (Table 4.18).

The percentage of participants taking pain medications at the first week of expansion was the double of that in the first week of bonding and the triple of that in the first week of M3 follow up appointment (Ewk: 30%, M1wk1: 15%, M3wk1: 10%). Pain relief was needed the most at the first day of expansion (20%), the 1st 3 days after bonding (15%), and the 1st day after the follow up appointment at M3 (10%) (Figure 4.13).

H. Comparison of the Dietary Intake Changes across Categories of the Fixed Appliances Group Characteristics

The previous analysis revealed that at 5 weeks after bonding there was a significant increase in fat intake (%EI), and a significant decrease in the rest of the nutrients and food groups compared to baseline. At 13 weeks the intake was not significantly different from that at 5 weeks, therefore we concentrated on the change in the intake between 5 weeks and baseline (Δ_{5wk-B}). This change was calculated by subtracting the intake at 5 weeks from that at baseline. Consequently a negative sign

indicates a decrease in the intake and a positive sign indicates an increase in the intake at 5 weeks.

1. Comparison of Dietary Intake Changes in Males vs Females

Males experienced a greater decrease in total energy intake (kcal/d), intake of dietary fiber (g/d), calcium (mg/d), vitamin C (mg/d), dairy products (g/d), and fruits (g/d); as opposed to the increase in fat intake (%EI) which was greater in females. However, all the changes were not statistically significantly different between males and females (Table 4.19). In addition, females had a greater increase in BMI ($\Delta BMI_{5wk\text{-}B}$) without reaching statistical significance relative to males (M: $\tilde{x}$= 0.049, [-1.31, 1.977], F: $\tilde{x}$= 0.148, [-2.017, 1.69], p=0.532).

2. Comparison of Dietary Intake Changes in Prepubertal vs Postpubertal Patients

Postpubertal patients experienced a greater decrease in total energy intake (kcal/d), intake of fiber (g/d), and dairy products (g/d), and a greater increase in fat intake (% EI). On the other side, prepubertal patients experienced a greater decrease in the intake of calcium (mg/d), vitamin C (mg/d) and fruits (g/d). However, all the changes were not statistically significantly different between prepubertal and postpubertal patients (Table 4.19). In addition, postpubertal patients had a greater increase in BMI ($\Delta BMI_{5wk\text{-}B}$) without reaching statistical significance relative to prepubertal patients (prepub: $\tilde{x}$= 0.079, [-1.214, 1.977], postpub: $\tilde{x}$= 0.169, [-2.017, 1.722], p=0.794).

3. Comparison of Dietary Intake Changes in Participants with Lower vs Higher Socio-Economic Status (SES)

Participants with higher SES had more changes in dietary intake including a greater decrease in total energy intake (kcal/d), intake of dietary fiber (g/d), calcium (mg/d), vitamin C (mg/d), dairy products (g/d) and fruits (g/d) at the expense of a greater increase in fat intake (%EI). However, all the changes were not statistically significantly different between participants having a lower SES and those with a higher SES (Table 4.19).

4. Comparison of Dietary Intake Changes in Participants whose Mothers Attained School vs University Degree

Participants whose mother's education level was classified as 'primary school', 'intermediate school', and 'high school' were grouped into one category: 'attained school degree' and compared to those whose mother's education level was classified as 'attained university degree'.

Participants whose mothers attained university had a greater decrease in total energy intake (kcal/d), intake of dietary fiber (g/d), calcium (mg/d), and fruits (g/d) at the expense of a greater increase in fat intake (%EI), but they has less decrease in the intake of dairy products (g/d). Nevertheless, the changes were not statistically significantly different between participants whose mothers attained school and those whose mothers attained university (Table 4.19).

5. Comparison of Dietary Intake Changes in Participants with Low vs Moderate vs High Physical Activity

Participants having a high physical activity had the greatest decrease in total energy intake (kcal/d), dietary fiber (g/d), calcium (mg/d), vitamin C (mg/d) and fruits

(g/d), the greatest increase in fat intake (%EI). On the other side, participants with low physical activity experienced the greatest decrease in the intake of dairy products (g/d). Despite that, all the changes were not statistically significantly different among participants who have a low, moderate or high physical activity (Table 4.19).

6. Comparison of Dietary Intake Changes in Participants whose Mothers vs Other Members Being Attentive to their Diet

Participants whose either 'both parents', 'father', 'patient himself' or 'other' were attentive to their diet were grouped into one category: 'other members' and compared to those whose 'mother only' was attentive to their diet.

When mothers were attentive to their children' diet, there was less decrease in total energy intake (kcal/d), intake of dietary fiber (g/d) and vitamin C (mg/d), and less increase in fat intake (%EI), but a greater decrease in the intake of calcium (mg/d), dairy products (g/d) and fruits (g/d). However, the changes were not statistically significantly different between participants whom mothers were attentive to their diet versus those whom other members were attentive to their diet (Table 4.19).

7. Comparison of Dietary Intake Changes in Normal Weight vs Overweight vs Obese

Obese patients had the greatest decrease in total energy intake (kcal/d) and calcium (mg/d) intake and the greatest increase in fat intake (%EI). Overweight participants had the greatest decrease in fiber (mg/d) and dairy products (g/d) intake. Normal weight patients experienced the greatest decrease in the intake of vitamin C (mg/d) and fruits (g/d). Nevertheless, the changes were not statistically significantly different among normal weight, overweight and obese participants (Table 4.19).

8. Comparison of Dietary Intake Changes in Participants with One vs Two Bonded Arches

At the 5th week after bonding, patients with two bonded arches experienced a statistically significant greater decrease in total energy intake (kcal/d) (2arches: $\tilde{x}$= -1010, [-5680.187, 1026.818]; 1arch: $\tilde{x}$= -361.7, [-4798.565, 1685.652]; p=0.006), fiber (g/d) (2arches: $\tilde{x}$= -11.585, [-58.139, 8.771]; 1arch: $\tilde{x}$= -3.104, [-66.455, 14.705]; p=0.024) and vitamin C (mg/d) intake (2arches: $\tilde{x}$= -106.7, [-543.541, 71.769]; 1arch: $\tilde{x}$= -15.08, [-227.135, 107.119]; p=0.045). The decrease in the intake of calcium (mg/d), dairy products (mg/d), and fruits (mg/d) were as well greater in patients with two bonded arches but not significantly different from those with one bonded arch (Table 4.19).

9. Comparison of Dietary Intake Changes in Participants who Needed vs Did Not Need Pain Relief

Participants who needed pain relief during the 1st 5weeks after bonding had a greater decrease in total energy intake (Kcal/d), calcium (g/d), dairy products (g/d) and fruits (g/d) intake. However, the changes were comparable to those observed in patients who didn't need pain relief (Table 4.19).

10. Comparison of Dietary Intake Changes with respect to the Cephalometric Components of the Malocclusion

a. <u>Comparison of Dietary Intake Changes in Participants with Class I vs Class II Malocclusion</u>

Participants with class II malocclusion experienced a greater decrease in total energy intake (kcal/d), intake of dietary fiber (kcal/d), dairy products (g/d) and fruits (g/d), a greater increase in fat intake (%EI), and less decrease in calcium (mg/d) and

vitamin C (mg/d). However, the difference in dietary changes between class I and class II participants was not significant (Table 4.19).

b. Comparison of Dietary Intake Changes in Participants with Hypo vs Hyperdivergent Pattern of Growth

Participants with a hyperdivergent pattern experienced a greater decrease in total energy intake (kcal/d), fiber (g/d) and fruits (g/d), a greater increase in fat intake (%EI), and less decrease in the intake of calcium (mg/d), vitamin C (mg/d) and dairy products (g/d). Nevertheless, the changes in dietary intake were not significantly different between hypo and hyperdivergent patients (Table 4.19).

c. Comparison of Dietary Intake Changes in Participants with Normal vs Increased Overjet

Participants with an increased overjet exceeding 3mm had less decrease in total energy (kcal/d) and fiber (g/d) intake, less increase in fat intake (%EI), but more decrease in calcium (mg/d), vitamin C (mg/d), dairy products (g/d) and fruits (g/d) intake. Nevertheless, these changes were not significantly different from those observed in patients with normal overjet (Table 4.19).

d. Comparison of Dietary Intake Changes in Participants with Open vs Normal vs Deep Bite

Participants with a deep bite experienced the greatest decrease in total energy intake (kcal/d), fiber (g/d), calcium (mg/d), vitamin C (mg/d) and dairy products (g/d) intake and the least increase in fat intake (%EI). On the other hand, patients with open bite had the greatest decrease in fruits (g/d) intake. Despite that, the changes did not differ significantly among open bite, normal bite and deep bite patients (Table 4.19).

I. Comparison of Dietary Changes and Pain Levels between the Expansion Subgroup and a Matched Sample from the Fixed Appliances Group

Twenty participants from the fixed appliances group (FA) were matched with the twenty participants of the expansion subgroup (Ex) on sex and age (sex: 7 males, 13 females; age: FA: 12.436 $\pm$ 1.239, Ex: 12.13 $\pm$ 1.203; p=0.308) to compare the differences in dietary changes (including changes in total intake (kcal/d), macronutrients (g/d and %EI), and micronutrients' intake) on the short and intermediate term, and pain levels in the 1st (M1) and 3rd months (M3) after bonding between the two treatment modalities. The short term dietary change was calculated by subtracting the intake at 1 week after expansion for the Ex subgroup and 1 week after bonding for the matched FA group from that at baseline (Δ_{1wkE-B} for the Ex subgroup; Δ_{1wk-B} for the matched FA group). The intermediate term dietary change was calculated by subtracting the intake at 5 and 13 weeks after bonding from that at baseline (Δ_{5wk-B} and Δ_{13wk-B}) in the expansion subgroup and the matched FA group. Consequently, a negative sign indicates a decrease in the intake and a positive sign indicates an increase in the intake.

1. Comparison of Dietary Changes

The changes between baseline and one week, and between baseline and 5 weeks in total intake (kcal/d) and the macro (g/d and %EI) and micronutrients were not significantly different between the FA and Ex groups. On the other hand, looking at the changes in dietary intake between baseline and 13 weeks after bonding (Δ_{13wk-B}) some significant differences were observed: a decrease in intake levels of Omega 3 (g/d) in the Ex subgroup versus no change in the matched FA group (FA: $\tilde{x}$= 0, [-0.008, 0.018]; Ex: $\tilde{x}$= -0.002, [-0.257, 0.003]; p=0.011), and an increase in intake of soluble fiber (g/d)

in the Ex subgroup versus a decrease in the matched FA group (FA: $\tilde{x}$= -0.21, [-1.36, 0.612]; Ex: $\tilde{x}$= 0.076, [-1.195, 1.059]; p=0.037).

2. Comparison of Pain Levels

Although pain level at the first week of expansion in the Ex subgroup was higher than at the first week of bonding in the matched FA group, the difference was not statistically significant (p=0.724). The same applies on pain level at the first month of bonding between both groups (p=0.97). However, at the 3rd month, pain intensity was significantly higher in the matched FA group relative to the Ex subgroup (FA: $\tilde{x}$= 4.249, [0, 36.178]; Ex: $\tilde{x}$= 1.286, [0, 21.925]; p=0.044).

J. Associations between Dietary Changes, Tooth Movement and Pain Levels in the Fixed Appliances Group

In this section, we considered the following variables for the correlation analysis:

- The change in total energy intake (kcal/d), fat intake (%EI), dietary fiber (g/d), calcium (mg/d), vitamin C (mg/d), dairy products (g/d) and fruits (g/d) between baseline and 5 weeks (Δ_{5wk-B}), and the total change between baseline and 13 weeks (Δ_{13wk-B}).
- The tooth movement in the maxillary (Mx) and mandibular (md) arches between baseline and 5 weeks (ΔMx LII_{B-5wk} and Δmd LII_{B-5wk}), and the total movement between baseline and 13 weeks (ΔMx LII_{B-13wk} and Δmd LII_{B-13wk}).
- Pain levels during the 1st (M1) and 3rd months (M3) of treatment.

1. Association between Dietary Changes and Tooth Movement

The association between dietary changes (Δ_{5wk-B}) and tooth movement between baseline to 5 weeks (ΔMx LII_{B-5wk} and Δmd LII_{B-5wk}) showed a significant negative correlation between ΔMx LII_{B-5wk} and $\Delta Fruits_{5wk-B}$ intake (g/d) (r= -0.221, p=0.031).

The association between dietary changes (Δ_{13wk-B}) and tooth movement between baseline and 13 weeks (ΔMx LII_{B-13wk} and Δmd LII_{B-13wk}) showed a significant negative correlation between ΔMx LII_{B-13wk} and $\Delta Vitamin\ C_{13wk-B}$ intake (mg/d) (r= -0.228, p=0.026).

Despite the significance of these associations, the correlation coefficients revealed a weak relationship between dietary changes and tooth movement.

2. Association between Dietary Changes and Pain Levels

The association between dietary changes between baseline and 5 weeks (Δ_{5wk-B}) and pain levels at the 1st month after bonding (M1) revealed a significant negative correlation between pain at M1 and $\Delta Fiber_{5wk-B}$ intake (g/d) (r= -0.209, p=0.042), and between pain at M1 and $\Delta Fruits_{5wk-B}$ intake (g/d) (r= -0.271, p=0.008).

The association between dietary changes from baseline to 13 weeks (Δ_{13wk-B}) and pain levels at the 3rd month after bonding (M3) revealed a significant negative correlation between pain at M3 and $\Delta Energy_{13wk-B}$ intake (kcal/d) (r= -0.255, p=0.013), between pain at M3 and $\Delta Fiber_{13wk-B}$ intake (g/d) (r= -0.235, p=0.022), and between pain at M3 and $\Delta Vitamin\ C_{13wk-B}$ intake (mg/d) (r= -0.234, p=0.022).

Regardless of the significance of these associations, the correlation coefficients show a weak relationship between dietary changes and pain levels.

3. Association between Tooth Movement and Pain Levels

Pain at the 1st month of treatment was significantly positively correlated with the mandibular tooth movement from baseline to 5weeks (Δmd $LII_{B\text{-}5wk}$) (r= 0.304; p= 0.003).

Pain at the 3rd month of treatment was significantly positively correlated with the tooth movement from baseline to 13 weeks in the maxillary (ΔMx $LII_{B\text{-}13wk}$) (r= 0.294; p=0.004) and mandibular arches (Δmd $LII_{B\text{-}13wk}$) (r= 0.217; p=0.035).

However, the association between pain levels and tooth movement is weak as shown by the low correlation coefficients.

CHAPTER V

DISCUSSION

A. Introduction

Whilst orthodontic treatment is known to achieve optimal correction of the malocclusion, this research was needed to further understand its impact on dietary intake in adolescents given that earlier studies targeting adolescent population have inspected the short term dietary changes due to treatment (Riordan, 1997; Sharma et al., 2011); and those inspecting the longer term changes included a small sample sizes (<18 patients) (Abed Al Jawad et al., 2011; Ilhan et al., 2018; Ozdemir et al., 2018). The present prospective longitudinal design, targeted the effect of orthodontic treatment on dietary intake and body mass index in adolescents (11-21 years old) at the 1st week after treatment initiation to detect the acute dietary changes, and at 5 and 13 weeks of treatment to detect the intermediate term dietary changes. In addition, possible explanatory factors that might influence dietary changes during treatment were explored, including the socio demographic factors, patient's lifestyle, baseline BMI weight status, number of bonded arches, pain levels and need pain relief, and the initial severity of the malocclusion.

Furthermore, in a new perspective, the association between dietary changes and tooth movement was analyzed along with the comparison of fixed orthodontic therapy with rapid maxillary expansion, which yields faster tooth movement and potentially more acute pain.

B. Discussion of the Major Findings

1. Changes in BMI

The lack of significant difference in BMI during the study period suggests that it was not affected by the orthodontic treatment and the consequent dietary changes. This finding is in line with prior results (Ama Johal et al., 2013) of non-significant changes in BMI among baseline, 4-6 weeks and 3 months between 53 British adolescent patients (age 11-14 years old) and controls. However, our results were not concordant with those of Sandeep et al. (2016) who showed a significant decrease in BMI after the first month of treatment in 68 Indian patients relative to controls. This discrepancy may be related to the conduct of this study on adult patients (18-25 years) who lost weight. Older patients are more prone to dietary restrictions during orthodontic treatment than children and adolescents because it is harder for them to adapt and to tolerate changes in their oral cavity, and thus they are more likely to lose weight than younger patients (Negrutiu, Todor, Moca, Vaida, & Pusta, 2019). In adolescents, weight change corresponds to that of the height spurt (Spear, 2002), and both the weight and height of our growing patients were subject to significant changes. Nevertheless the maintained proportional relationship between these two variables over time could explain the absence of significant change in BMI.

It is important to note that our study covered only the first three months of treatment which is a relatively a short period to be able to observe a significant change in BMI. In fact, BMI can be affected by many factors other than height and weight, such as health status, basal metabolism, physical exercise, hormonal balance, race, heredity and diet (Kılınç & Sayar, 2019) including total energy intake and percent of fat contribution to total energy intake. Fat intake (%EI) was found to increase in our study,

however total energy intake (kcal/d) decreased, possibly explaining why BMI did not increase significantly. Moreover, some studies have demonstrated that BMI status at baseline mediates changes in BMI; more precisely overweight and obese are more likely to be affected by environmental factors such as the effect orthodontic treatment and therefore more prone to BMI changes (Ama Johal et al., 2013; Rosenbaum & Leibel, 1998). Since the majority of our study population were classified as having normal weight at baseline, and since their proportion increased during the study period, possible significant changes in BMI could be attenuated. Yet, considering both the fixed appliances and the expansion subgroup together (n=115), the baseline percentage of overweight (35.6%) and obesity (14.7%) was relatively high, comparable to estimates reported for the Lebanese adolescent population (34.8% overweight, and 13.2% obese (Nasreddine et al., 2014).

2. Changes in Dietary Intake

a. Short Term Changes

i. Changes in Nutrients

At one week of treatment (whether bonding fixed appliances or expansion of the maxillary arch), there was a significant decrease in macronutrients' intake (g/d) (protein, carbohydrates, fat, and fiber) consequent to the decrease in total food (g/d) and energy (kcal/d) intakes, and further decrease at one week after bonding the second arch; however the diet composition did not change. These findings differ from the short term changes reported by Riordan (1997) on 10 patients treated in the State University of New York and by Sharma et al. (2011) on 50 Iranian patients, aged 12-16 years old, showing no significant change in total intakes of macronutrients (g/d), most probably

because in these studies patients recorded their own diet, which may have led to recording bias. The finding in both studies of an increase in fat (%EI) intake and a decrease in carbohydrate (%EI) intake was similar to our findings at the 5th, but not in 1st week of treatment. This difference could be related to the fact that in these studies orthodontic appliances have been already in place for a certain undefined period of time, and dietary intake was compared at three days of appliance activation to that before activation, and not to baseline levels before appliances insertion as in our study.

The significant decrease in micronutrients' intake in our study, more specifically copper (mg/d) and manganese (mg/d), were in line with the findings of Riordan (1997) who attributed this decrease to the limited intake of nuts, fruits and vegetables.

The same trend of changes was observed at one week of bonding the second arch, however more severe, because in the majority of the patients the second arch was bonded at the 5th or 9th week of treatment, a time point at which it is usually accompanied by upgrading the orthodontic wire in the previously bonded arch which adds up to the discomfort and pain/pressure.

Acute changes in dietary intake are usually expected on the short term, after appliances insertion or adjustment, concomitant with the report by patients of eating less because of pain and discomfort, difficulty in chewing, food getting stuck in the appliances, and longer time needed to finish meals (Carter et al., 2015). Regardless of the clinical significance of the changes, more precisely the decrease in fiber intake by 3g/d, it was most important to determine if dietary modifications during the first week are temporary or sustained for a longer period in treatment, whereby consequences on general and oral tissues health and effect on optimal growth are of a concern.

b. Intermediate Term Changes

i. Changes in Nutrients

Our results did not support the expected premise that acute changes would start to decrease (Carter et al., 2015) after the first week of treatment and to reverse after the first month. In the fixed appliances group, at 5 and 13 weeks after bonding, total food intake (g/d) continued to decrease relative to baseline including total energy intake (Kcal/d), resulting in a decrease in the absolute intake of all macronutrients (g/d): protein, carbohydrates, sugar, total fat, and dietary fiber. The percent of fat contribution to total energy has significantly increased at the expense of a significant decrease in carbohydrates' intake (%EI). Although the 2% decrease in carbohydrates intake (%EI) is not clinically significant, the fact that sugar intake (%EI) -a type of carbohydrates- did not change means that this decrease affected the sources of carbohydrates with high nutritional value. This finding was validated after analyzing the food categories whereby intake of breads (g/d), cereals (g/d) and starchy vegetables (g/d) decreased significantly. However carbohydrates intake (%EI) was within the acceptable macronutrient distribution range of 45-65% along the study period (Table 5.1).

Therefore our major concern related to the changes in fat (%EI) and fiber (g/d) intakes, which deviated from norms (Figures 5.1-a & 5.2-a), reflecting unhealthy dietary habits among fixed appliances group participants. The increase in fat intake (%EI) (B: 37.91%; 5wk: 39.886%; 13wk: 39.61%) which was initially high relative to the upper limit of the AMDR (35%) (Figure 5.2-a), went in parallel with a decrease in dietary fiber intake (g/d) which was low at baseline in males (27.86g/d), and at the limit in females (26.52g/d) relative to the AI (males: 38g/d; females: 26g/d) (Figures 5.1- b & c).

In the absence of dietary recommendation for the Lebanese population, the AMDR and the AI to which we compared our findings on fat (%EI) and fiber (g/d) intakes respectively represent dietary recommendations for the U.S. and Canadian adolescent population as reported by the Food and Nutrition Board, Institute of Medicine (IOM) (National Academies of Sciences, 2004). When compared with the recommendations of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) for fat (30%EI) (World Health Organization, 2003; Smit, Mozaffarian, & Willett, 2009) and fiber (25g/day) (Kanauchi & Kanauchi, 2018; World Health Organization, 2003), our findings at baseline and follow up periods were even more alarming for fat intake (%EI) (Figure 5.2-a); fiber intake (g/d) was adequate at baseline but worsened after bonding (B: 27.139g/d; 5wk: 20.199g/d; 13wk: 20.337g/d) (Figure 5.1-a). Fat intake (%EI) at baseline was close to that reported in the Lebanese adolescent population (36.24%) (Nasreddine et al., 2014), which is a concern given that high fat intake increases the risk of obesity and its consequent health problems, notably when associated with lower intakes of fiber (g/d), fruits (g/d), vegetables (g/d) and dairy products (g/d) (Nasreddine et al., 2014; Niemeier, Raynor, Lloyd-Richardson, Rogers, & Wing, 2006; Powell & Nguyen, 2013).

These findings highlight the need to reconsider the dietary guidelines given to orthodontic patients in general and to provide individual follow up to patients in whom the intake of fiber is inadequate, especially that their proportion have increased during treatment, affecting more than half of the study sample. In addition the intake of high fat food should be limited most importantly those rich in saturated fat as almost 90% of the sample had intakes exceeding the recommendation even before the start of the treatment. Accordingly dietary intake should be analyzed before the start of orthodontic

treatment to detect patients who are more vulnerable to nutritional imbalances, and promote healthy dietary behavior to prevent further disparities during treatment. Azaripour et al. (2016) have shown that despite intensive dietary advice in 67 German adolescent patients (12-18 years old) with fixed orthodontic appliances, there was no improvement in dietary habits after 12 months in treatment compared with controls; hence nutritional guidelines should be adequately enforced and frequent recalls should be scheduled to ensure close monitoring of patients and repeated reinforcement to strengthen compliance.

The high fat/ low fiber intake seems to be a trend among adolescents worldwide, commonly reported in Western European countries (England, Scotland, France, Switzerland, and Germany (Rolland-Cachera, Bellisle, & Deheeger, 2000), Nordic countries (Denmark, Finland, Norway and Sweden (Samuelson, 2000), developing countries (Bahrain (Gharib & Rasheed, 2011), Libya, and Mexico (Ochola & Masibo, 2014), Arab countries (Kuwait (Zaghloul et al., 2013) and KSA (Washi & Ageib, 2010), South Africa (MacKeown, Pedro, & Norris, 2007), Australia (Huybrechts et al., 2017), Ireland (Hurson & Corish, 1997), Brazil (de Carvalho et al., 2006), Iran (Doustmohammadian, Keshavarz, Doustmohammadian, Abtahi, & Shahani, 2013), Greece, Canada, Portugal, Turkey, USA (Klimis-Zacas et al., 2007), Korea (Park, Na, Kim, Kim, & Sohn, 2012), Spain (Grosso & Galvano, 2016) and Pakistan (Rifat-uz-Zaman & Ali, 2013). However the intake of fiber (g/d) in our sample at baseline was better than in most of the countries. Adequate fiber intake was as well reported in Tunisia (Aounallah-Skhiri et al., 2011) and Cameroon (Ochola & Masibo, 2014) (Figures 5.1-d & 5.2-b).

Our findings on changes in macronutrients intake on the longer term during orthodontic treatment were not in line with the study of Ozdemir et al. (2018) who did not find significant differences in total energy (kcal/d) and macronutrients intakes (g/d) between baseline and the first 3 months of treatment in 17 Turkish adolescent patients (mean age: 13,76±2,01). This discrepancy could be related to the small sample size in their study, which did not allow to detect statistically significant differences, in addition to the use of the 24h dietary recall method for the long term dietary assessment, which is inadequate because this method is usually used for short term assessment. Also it was not clear if the recalls where repeated over several days and how they were distributed at each time point to represent the usual dietary intake (T Baranowski, 2012; Rutishauser, 2005) . On the other hand, Johal et al. (2013) in 53 British adolescent patients (aged 11-14 years) revealed a decrease in total energy intake (kcal/d), protein (g/d), carbohydrates (g/d) and fat (g/d) intakes during the first 4 to 6 weeks after bonding, being more severe relative to the second period that lasted until the 3rd month of treatment. These results were concordant with our findings of the major change occurring in the first 5 weeks, and remaining constant until 13 weeks of treatment.

Concerning intakes of micronutrients, the findings of a cross-sectional study by Shirazi et al. (2011) of 90 Iranian adolescent patients (15-17 years old) showing a significant lower intake of chromium (mg/d) at 6 month of treatment relative to a control group were similar to our findings at the 5th and 13th weeks of treatment. However, this reduction in our sample is not of a concern because only 1.1% of the adolescents had a chromium intake (g/d) below the level recommended by the IOM.

The highest percentages of participants having inadequate minerals intake at baseline were for potassium (mg/d), followed by calcium (mg/d) and phosphorus

(mg/d). Those percentages increased during treatment to affect more than half of the sample for calcium and potassium intakes. Our findings were similar to those of Ozdemir et al. (2018) in 17 Turkish patients (mean age: 13,76±2,01) showing a significant reduction in intake levels of potassium (g/d) and phosphorus (g/d) by the end of the 3rd month of treatment, however their study did not show a significant reduction in the intake of calcium (g/d) like ours.

Suboptimal levels of potassium intake have been more common recently due to the transition towards modern diets compared with traditional food habits based on green leafy vegetables, fruits, legumes, cereals, whole grain products and dairy products. Our study revealed deficient intake of potassium (mg/d) in 53% of the sample at baseline increasing to 72% during treatment. The importance of potassium during growth relates to its role in bone formation, promoting an alkaline environment that reduces the mobilization of calcium to maintain normal pH after consumption of acid producing food, therefore preserving calcium in bone (Demigné, Sabboh, Rémésy, & Meneton, 2004; Palacios, 2006).

Moreover an initial calcium intake (mg/d) below recommended AI was observed in 45% of the patients and reached 64% of the patients during treatment. This higher percentage is in accordance with previous reports on calcium intake in different populations (Klimis-Zacas et al., 2007; Lutfiyya, Garcia, Dankwa, Young, & Lipsky, 2008; Rifat-uz-Zaman & Ali, 2013). Inadequate calcium intake in adolescents has been related to increased risk of osteoporosis (Abudayya, Stigum, Shi, Abed, & Holmboe-Ottesen, 2009), delayed pubertal development, lower circulating adrenal androgens and significantly higher parathyroid hormone levels (Annweiler et al., 2009), indicating a link between calcium intake, the hormonal milieu and skeletal maturation (Rifat-uz-

Zaman & Ali, 2013). Calcium is the main element of which bone is constructed, while also regulating bone remodeling process. It must be absorbed in sufficient quantities to build bone structure during growth and maintain it in maturity (Roberts, Epker, Burr, Hartsfield Jr, & Roberts, 2006; Schindler & Palmer, 2011).

The proportion of participants with low phosphorus intake (mg/d) were not as high as with calcium intake (mg/d), increasing from 21% initially to 36% during treatment. However since phosphorus plays a role in bone mineralization during growth, adolescents with inadequate intakes warrant attention. Nevertheless healthy individuals can adjust to a wide range of phosphorus consumption especially that it is a common element in diet, whereas the ability to adapt to low calcium intakes appears to be limited; accordingly the ratio of phosphorus to calcium intake seems to be more important in bone health than the absolute intake of phosphorus (Eastell & Lambert, 2002; Palacios, 2006).

Regarding vitamins, inadequate vitamin D intake (mcg/d) at baseline affected the highest percentage of the patients (89.5%), and its intake levels (mcg/d) significantly decreased during treatment affecting more than 90% of the sample. Also 57.9% of participants had initial intake of vitamin E (mg/d) below recommended levels, increasing to more than 95% at 13 weeks of treatment, despite the fact that vitamin E intake (mcg/d) did not show any significant change across time. Vitamins D and E play a role in bone formation and mineralization. Although the major source of vitamin D is not dietary, since it is mainly produced in the skin during exposure to sunlight, it is more important in the diet than cutaneous synthesis in winter and is present mainly in sea food and fortified dairy products.

Vitamin D maintains calcium homeostasis by acting on intestinal cells to increase absorption of dietary calcium or acting on bone cells to mobilize calcium stores when serum levels are low (Eastell & Lambert, 2002; Palacios, 2006). Inadequate consumption of vitamin D during adolescence can decrease calcium absorption and consequently its availability for bone mineralization during a stage where 50% of adult bone mass is being acquired (Klimis-Zacas et al., 2007). Vitamin D receptors have been demonstrated not only in osteoblasts but also in osteoclast precursors and in active osteoclasts. This vitamin accelerates the rate of tooth movement in rats by inducing a well-balanced bone turn over, and its stimulatory action on osteoblasts can help stabilizing tooth movement by increasing bone apposition on the pressure side of the periodontal ligament after application of orthodontic forces (Diravidamani, Sivalingam, & Agarwal, 2012).

Vitamin E is needed during adolescence for new cell' growth and development (Breidenassel et al., 2011; Spear, 2002). Furthermore, since vitamin E is an antioxidant (Ahmadieh & Arabi, 2011; Breidenassel et al., 2011), inadequate levels in the diet implies its inability to protect lipids from peroxidation, a process intimately involved in the development of atherosclerotic plaques increasing the risk of coronary artery disease. This effect is amplified when associated with high intake of saturated fats and low intake of polyunsaturated fat (De Lorgeril & Salen, 2004; Monge-Rojas, 2001). In our sample where 86% of patients had intakes of saturated fats (%EI) exceeding the AMDR and 83% had intakes of α-linolenic (omega-3) polyunsaturated fat (%EI) below the AMDR, the percentages were worse during treatment.

In the expansion subgroup, inadequate intakes of fiber (g/d), potassium (mg/d), calcium (mg/d), phosphorus (mg/d), vitamins D (mcg/d) and E (mg/d) were observed at

baseline and during treatment in a high proportion of patients, similar to proportions observed in the fixed appliances group. Because it was not totally adequate to make conclusions based on the comparison of the dietary intake between the fixed appliances group and the expansion subgroup due to the difference in sample size, we matched 20 participants from the fixed appliances group on age and sex with the 20 participants of the expansion subgroup to better understand whether any of the two treatment modalities can induce more drastic dietary changes in the first week of treatment, and whether the physical presence of the expander, even if not activated after bonding, would be a cause for greater dietary changes in the expansion subgroup. In the first week, the dietary changes were similar between the two groups, indicating that orthodontic appliances whether acting from inside (maxillary expander) or outside (labial fixed appliances), the subsequent tooth movement and resultant pain caused dietary changes rather than the appliance type itself. After stopping the expansion screw activation and bonding fixed appliances in the expansion subgroup, the observed dietary changes at the 5^{th} week were also similar to the fixed appliance group, indicating that by that time patients had already adapted to the presence of the expander in their palate. On the other hand, at 13 weeks of treatment, a statistically significant decrease in the intake of soluble fiber (g/d) in the fixed appliances group was likely due to a decrease in starchy vegetables consumption (g/d), and a statistically significant decrease in the levels of Omega-3 (g/d) in the expansion subgroup, related to a decrease in sea food consumption (g/d). Nevertheless the differences between the two groups in regards to the change in these two nutrients' intakes were not clinically significant. It should be noted that seafood consumption is already low in the Lebanese population and countries of the region (Naja, Hwalla, Itani, Baalbaki, et al., 2015).

In absence of a proper dietary counseling, the shift towards a westernized type of a diet lacking the essential nutrients might sustain along the orthodontic treatment that lasts on average two and a half years. This long term decrease in the intake of fiber and essential vitamins and minerals will potentially have a negative effect on growth by inducing bone disorders like osteomalacia, and lead to serious health issues that could be initiated even at a young age for instance cardiovascular disease, metabolic syndrome, diabetes, anemia, hypertension, cancer (Dahl & Stewart, 2015; Washi & Ageib, 2010).

ii. Changes in Food Groups

The previously described significant changes in the macro and micronutrients' intake levels were attributed to changes in intakes of food categories rich in those nutrients. In the fixed appliances group lower protein (g/d) and vitamin D (mcg/d) intake levels were associated with a decrease in the intake of eggs (g/d) and dairy products (g/d); the decrease in the intake of carbohydrates (g/d) was the consequence of a decrease in the intake of breads (g/d), cereals (g/d) and starchy vegetables (g/d); the decrease in fiber (g/d) and potassium (mg/d) intakes was the resultant of a decrease in fruits (g/d), dried fruits (g/d) and starchy vegetables (g/d) intakes; the decrease in the intake of calcium (mg/d) followed the decrease in consumption of dairy products (g/d); and the lower intake levels of phosphorus (mg/d) was due to the decreased intake of dairy products (g/d) and starchy vegetables (g/d) (Eastell & Lambert, 2002; Palacios, 2006). All of these food groups of high nutritional value showed a significant decrease at both periods of treatment (5 and 13 weeks) relative to baseline. Findings related to the significant decrease in the intake of breads (g/d) and fruits (g/d) were in line with those

reported in other studies (Azaripour et al., 2016; Ilhan et al., 2018). Therefore even after a longer period in treatment, when pain is expected to have subsided, patients still ate less and avoided fruits and vegetables most probably the hard ones (apples, carrots, corn on the cob) because of difficulty in chewing and biting, and discomfort from food getting stuck in the appliances (Abed Al Jawad et al., 2011; Carter et al., 2015). Ilhan et al. (2018) showed as well, in a sample of 17 Turkish adolescents (mean age: 13,76±2,01), a significant reduction in the intake of soft drinks (g/d) and an increased consumption of soups (g/d) at the 3rd month of treatment similar to our results in what relates to the direction of change; whereas in our study the change in the intake of these two food groups was not significant compared to baseline.

Intakes of other food categories of low nutritional value including biscuits (g/d), wafers (g/d), chocolate (g/d), candies (g/d), and salty snacks (g/d) have decreased significantly during treatment, in agreement with a qualitative study (Abed Al Jawad et al., 2011) conducted on 10 British adolescent patients (11-14 years old) at their 4-6 weeks of treatment with fixed appliances. This decrease may explain the lower levels of sugar intake (g/d) which accompanied the decrease in total food intake (g/d); the percent contribution of sugary food groups to total energy intake did not differ significantly from baseline; accordingly sugar intake (%EI) did not change. This finding reinforces the report by Azaripour et al. (Azaripour et al., 2016) on the high percentage of adolescent patients (12-18 years old), who have been in treatment for one year, consuming sweets at least once a day similarly to controls, indicating that eating habits are rarely modified with treatment.

The WHO issued guidelines in 2003 that recommended intake of free sugars should provide ≤10% of energy intake, and suggested in 2015 further reduction to <5%

of energy to protect dental health throughout life (Erickson & Slavin, 2015; Mela & Woolner, 2018; Moynihan, 2016). Adolescents satisfy a large part of their energy needs through the consumption of sweetened snacks, however when patients undergo orthodontic treatment, reduction of the intake of food containing sugar is critical to prevent decalcification (Carter et al., 2015; Schindler & Palmer, 2011). Moreover, our study revealed significant increase in the consumption of pizzas & pies (%EI); avocados, olives & olive oil (%EI); and oils & salad dressing (%EI) during treatment, which have contributed to the elevation of total fat intake (%EI).

In the expansion subgroup, in addition to the significant decrease in the intake of breads (g/d), fruits and dried fruits (g/d) and the significant increase in intakes of olives, olive oil and avocado (%EI), there was a significant decrease in the intake of sea food (g/d), which was reflected by significantly lower levels of Omega-3 (g/d) during treatment. In addition the intake of ice-cream (g/d) was increased significantly without leading to change in sugar intake levels (g/d) because it was compensated by decreases in chocolate, biscuits and candies consumption (g/d).

The adopted dietary habits in the present study reflect patterns adopted by Lebanese adolescents in general, whereby a shift was observed towards a Western type of a diet associated with low fiber- high fat and saturated fat intakes, characterized by increased consumption of processed meat, pizza, pies, mayonnaise, fast food and refined sugars; and moving away from the traditional Lebanese pattern that is rich in bread, cereals, dairy products, fruits, vegetables and legumes (Naja, Hwalla, Itani, Baalbaki, et al., 2015; Naja, Hwalla, Itani, Karam, et al., 2015). Knowing that many food habits acquired during adolescence are sustained later in life, interventions aiming at altering dietary behaviors should be implemented in the early adolescent years

because they have the potential of affecting the individual's lifetime risk for diet-related diseases (Laska, Larson, Neumark-Sztainer, & Story, 2012). Therefore promoting the adherence to the healthy dietary pattern is of a great importance before the start of the treatment followed by reinforcement during the treatment. However since some of the foods could be hard to chew with braces, changes in the way of food preparation should be advised. Overweight and obese patients who are at a higher risk for health problems should be advised to see specialized dietitians. In this general perspective, the intervention of orthodontic appliances could be seen as an opportunity to introduce healthier eating patterns.

3. Tooth Movement

In both fixed appliances group and expansion subgroup, maxillary tooth movement was significantly higher in the first period of assessment (between baseline and 5 weeks) after bonding relative to the second period (between 5 and 13 weeks). This finding was concordant with other studies that revealed the initial rate of incisors alignment to be always higher at the beginning of the treatment up to 4-5 weeks before declining gradually (Abdelrahman, Al-Nimri, & Al Maaitah, 2014; Evans, Jones, & Newcombe, 1998; E. Ong, Ho, & Miles, 2011). This rate was attributed to the higher Little's initial irregularity index, which positively correlates with the rate of tooth movement (Scott, DiBiase, Sherriff, & Cobourne, 2008). This trend applied to our findings whereby the Little's irregularity index was significantly higher at baseline relative to that at 5 weeks, and the latter was significantly higher relative to LII at 13 weeks. These changes explain the decrease in percentage of participants classified in higher incisor's irregularity severity groups of the LII throughout the treatment periods.

However, in the mandibular arch, tooth movement was similar between the two treatment periods, despite the significant decrease in LII across the study time points. This result could be related to the fact that the majority of patients started treatment with one bonded arch, the maxillary arch; the mandibular arch having been bonded at a later period of treatment.

In the expansion subgroup, the major increase in interpremolar, intermolar and interincisal distances was seen at one week of expansion, with less changes after fixed appliances insertion. This finding was in accordance with other studies where the total increase in arch width measurements at the end of treatment resulted mainly from the active expansion, followed by a slight decrease at the end of the fixed appliances therapy (Gurel, Memili, Erkan, & Sukurica, 2010; Lima, Lima Filho, & Bolognese, 2005). The intericisal distance showed a significant decrease that started after 5 weeks of fixed appliances insertion and regained baseline measure by 13 weeks of treatment. This closure was due to the active ligation forces placed on the maxillary central incisors early in treatment to close the midline diastema that opened consequent to the orthopedic midpalatal sutural split in young patients (Ghoneima et al., 2011).

4. Pain Levels and Need for Pain Relief

Our findings on pain levels after the insertion of fixed orthodontic appliances were in agreement with other studies (Ertan Erdinç & Dinçer, 2004; Ama Johal et al., 2013; Polat, 2007; Wiedel & Bondemark, 2015). The highest pain levels were observed during the first week after bonding, justifying the greater reported need for pain relief in the first three days. Pain intensity decreased significantly thereafter, probably because of the nature of applied mechanics, whereby 5 weeks post-orthodontic treatment wires

were less or inactive. Furthermore pain intensity dropped significantly at the 3rd month relative to the 1st month of treatment with lessened need for pain relief. This finding indicates that patients adapted faster to pain in the second period of treatment; or that there was change in mechanics. After bonding, fixed appliances were directly loaded with the initial orthodontic wires for fresh tooth alignment; however at the 3rd month the fixed appliances were not necessarily reactivated or upgraded to heavier ones if existing wires were still active.

In the expansion subgroup, findings on pain intensity during the expansion period was similar to other studies (Baldini et al., 2015; Gecgelen et al., 2012; Needleman, Hoang, Allred, Hertzberg, & Berde, 2000). Pain levels started to decrease significantly at the 4th day of expansion however the ingestion of pain relief was very random. At the first week after bonding, pain intensity was similar to that reported during expansion. This pattern applied when participants in the expansion subgroup were compared to themselves during the expansion week and at the 1st week after bonding; and when pain levels where compared between the expansion week in the expansion subgroup and the 1st week of bonding in a matched sample from the fixed appliances group. Although one could expect higher levels of pain during expansion relative to fixed orthodontic therapy, rapid maxillary expansion in young patients, who are at earlier stages of skeletal maturity, has an orthopedic effect leading to sutural split and therefore exerting less pressure on the teeth themselves (Baldini et al., 2015; Needleman et al., 2000). Matched samples showed as well similar pain levels during the 1st month of fixed orthodontic therapy. This finding is anticipated because the expander was not activated during this period and therefore it is not adding to the pain arising from braces activation. However at the 3rd month of treatment pain levels were

significantly higher in the fixed appliances group probably because more patients had the second arch bonded during the second period of treatment (67.5% after the 5th wk vs 32.5% before 5wks) as opposed to the expansion group where only the maxillary arch was bonded during the study period.

5. Changes in Dietary Intake across the Sample Characteristics

The present study revealed that the only characteristic that had a significant impact on intermediate dietary changes was the sequence of treatment more precisely the number of bonded arches at 5 weeks. The investigated dietary changes included potential factors affecting the increase in fat intake (%EI), and the decrease in total energy (kcal/d), fiber (g/d), calcium (mg/d), vitamin C (mg/d), dairy products (g/d) and fruits (g/d) intakes reflecting unhealthy dietary habits that might impact optimal growth, general health and bone remodeling necessary for tooth movement.

a. <u>Dietary Changes across Socio-Demographic Characteristics and BMI Categories</u>

Similar dietary changes were observed in prepubertal and postpubertal patients, probably because pre and post-pubescent consume the same absolute food amount because of the greater food energy required for their relatively high rate of growth (de Castro & Goldstein, 1995).

Furthermore dietary intake changes were not significantly different between higher and lower SES patients, which was in line with the results of Johal et al. (Ama Johal et al., 2013) but contrary to other studies (Buttriss, 2000; Roos, Karvonen, & Rahkonen, 2004) depicting healthier diet in higher social classes.

In addition participants whose mothers attained university degree experienced similar dietary changes during treatment relative to patients whose mothers reached school degree. Although less dietary changes (healthier diet) were expected in patients with highly educated mothers (Naja, Hwalla, Itani, Karam, et al., 2015), the higher likelihood of employment might distract mothers from following up on their children's diet (Nasreddine et al., 2014).

Dietary changes were also similar among patients with different baseline BMI status. This finding was not in line with Johal et al. (2013) who found that overweight/obese patients had significantly higher impact on their diet during treatment.

b. Dietary Changes in Patients with One versus Two Bonded Arches

At the 5th week of treatment patients with two bonded arches before that time point (i.e. 2nd arch being bonded between the 1st and 5th week of treatment) experienced a significantly greater decrease in total energy intake (kcal/d), fiber (g/d) and vitamin C (mg/d) intakes relative to patients with one bonded arch. However when the second arch was bonded later in treatment (at the 5th or the 9th week), dietary changes were similar in patients with one and those with two bonded arches. No previous study has explored the effect of time of orthodontic appliances insertion on dietary changes. Our findings highlight the importance of sequential bonding of the dental arches: 'one arch at a time', to give the patient a reasonable period (at least 5 weeks according to the present study) to adapt to the presence of the appliance and resultant pain/discomfort, before bonding the second arch. This sequencing apparently increases compliance and adherence to dietary advice.

c. Dietary Changes in Patients who Did or Did Not Need Pain Analgesics

The fact that intermediate dietary changes were not significantly different between patients who consumed pain analgesics and those who did not, most probably was related to the decrease of pain levels after the first week of treatment. This finding was not in accordance with the study of Johal et al. (2013) who found significantly higher impact on dietary habits in patients consuming pain relief medication, although the level of reported significance was marginal.

d. Dietary Changes in Patients with Different Malocclusion Severity

In the literature several associations were reported between malocclusions and malnutrition. Malnutrition was associated with the reduction of skull base length, jaw height, maxillomandibular width and lower facial height (Singh et al., 2017). Vitamin D deficiency causes rickets disease, maxillary dysplasia, and disturbed closure of facial sutures leading to open bite and transverse hypodimension (Zambrano et al., 2003). Vitamin C deficiency may alter collagen formation and bone and jaws development (Schindler & Palmer, 2011). A positive correlation was observed between non-consumption of coarse and fibrous foods and increased incidence of class II malocclusion (Singh et al., 2017).

The effect of the initial malocclusion on dietary changes during orthodontic treatment was not investigated before. This study hypothesis that dietary changes are more prominent in patients with higher initial malocclusion severity was not supported because dietary changes were similar regardless of the skeletal and dental malocclusion severity in the sagittal and vertical dimensions. This finding could be related to the functional adaptability of the malocclusion to the higher demands of nutrition

particularly that skeletal jaws discrepancies in the sagittal and vertical dimensions tend to be naturally compensated by teeth position and inclination favoring adequate mastication. Indeed, patients classified in the higher severity groups showed mean dental overjet and overbite that deviated from patients with normal bite by 2mm on average, arguably not a clinically significant disparity able to induce more differential dietary changes. Our study covered only the first 13 weeks of the leveling and alignment phase of the orthodontic treatment. Given that occlusal corrections such as incisors retraction to reduce the overjet or molar intrusion to close the anterior openbite are done at a later stage of treatment, more pronounced dietary changes might be seen later when the position of the anterior teeth is being normalized providing better abilities of chewing and biting and supporting our original hypothesis.

6. Associations among Dietary Changes, Tooth Movement and Pain Levels

a. Association between Dietary Changes and Tooth Movement

Nutritional deficiencies during most intensive bone remodeling, as occurs during orthodontic force application and subsequent tooth movement, can greatly influence final outcome (Schindler & Palmer, 2011). Our results indicate a significant negative correlation between the decrease in fruits (g/d) and vitamin C (mg/d) intake and maxillary tooth movement, indicating that the more severe this decrease, the lower is the rate of tooth movement. To our knowledge there are no previous reports on the effect of nutrients' intake on tooth movement during orthodontic treatment in humans, and many conclusions have been extrapolated from animal studies. Although the correlation coefficient revealed a weak association of 23% between the decrease in vitamin C intake and tooth movement, its significance should not be neglected. In fact

tooth movement requires simultaneous synchronous functioning of collagen metabolism that depends on adequate supply of vitamin C for the production of mature collagen. Therefore vitamin C deficiency disturbs the integrity of the PDL and formation of osteoid (Hickory & Nanda, 1981; Khatri & Kolhe, 2018). Animal studies have shown that orthodontic forces applied on teeth of pigs whose diet is deficient in vitamin C resulted in alteration of the periodontal ligament and supporting alveolar bone as compared to non-deficient controls (Litton, 1974). Large resorption lacunae and increased osteoclastic activity were secondary to vitamin C deficiency jeopardizing bone remodeling and slowing orthodontic tooth movement (McCanlies, Alexander, Robnett, & Magness, 1961). On the other hand oral vitamin C administration increased orthodontic tooth movement in rats with more osteoclast lacunae around the root in the pressure area (Miresmaeili et al., 2015).

Our hypothesis that patients experiencing more dietary inadequacies (nutrients below norms) and unhealthy dietary changes during treatment have slower rate of tooth movement warrants further research, including a larger sample size and a well-tailored protocol to consolidate the weak, although significant, association detected in the present study; and possibly explore the potential of other nutrients to affect tooth movement in orthodontic patients.

b. Association between Dietary Changes and Pain Levels

In support of our hypothesis was that pain is not strongly associated with dietary changes since pain levels decline after the first few days, a week correlation was observed between pain levels and intermediate term dietary changes. This finding is

also in accordance with another study conducted in 11-14 years old British patients (Ama Johal et al., 2013).

In contrast several studies have reported that pain from orthodontic treatment resulted in difficulty in eating and chewing, in particular, foods of firm or hard consistency (Carter et al., 2015; Kılınç & Sayar, 2019; Krishnan, 2007; Sandeep et al., 2016). It is plausible that impact of pain on dietary intake occurs during the early days of treatment. Nevertheless the sustained dietary changes at 5 and 13 weeks of treatment in our study despite the decrease in pain levels, suggests the presence of factors different than pain contributing to the intermediate term changes in dietary intake. These factors might relate to the physical aspect of the fixed orthodontic appliances including difficulty in chewing and biting (Abed Al Jawad et al., 2011; Negrutiu et al., 2019), fear of appliance breakage, embarrassment or discomfort from food getting stuck in the appliances, and difficulty in cleaning them (Azaripour et al., 2016; Carter et al., 2015) . Without proper dietary advice these factors would still affect dietary intake as long as the fixed appliances are present (Schindler & Palmer, 2011). Other factors may relate to the functional aspect of the appliance including the use of Nickel Titanium wires during the leveling and alignment phase inducing occlusal changes while leveling the marginal ridges of posterior teeth. These wires exert continuous forces on the teeth for physiological and efficient tooth movement (Airoldi, Riva, & Vanelli, 1995) and their action is accompanied by an increase in physiological tooth mobility (Konermann et al., 2017), which in turn might impair the masticatory function leading to dietary changes with preference for softer food (Shirazi et al., 2011).

c. Association between Tooth Movement and Pain Levels

Pain levels were positively correlated with tooth movement in both arches indicating that with higher rate of tooth movement pain levels increase. As discussed, the earlier higher rate of tooth movement is associated with more severe crowding. As crowding decreased in the second period of treatment, a simultaneous significant decrease in pain levels occurred. Therefore, higher pain levels are expected when incisors irregularity is more severe. Accordingly the use of light forces during orthodontic treatment is advised as heavier forces induce more pain during the 1st week of treatment especially upon mastication (Bergius et al., 2000; Ogura et al., 2008), thus explaining the observed acute dietary changes. However, heavier forces do not produce faster tooth movement (Gonzales et al., 2008; Yee, Türk, Elekdağ-Türk, Cheng, & Darendeliler, 2009), increase the risk of root resorption (Chan & Darendeliler, 2005; Kurol & Owman-Moll, 1998; Weltman, Vig, Fields, Shanker, & Kaizar, 2010), and undermine alveolar bone resorption limiting biological tooth movement (Thilander B, 2005; Tomizuka et al., 2007; Von Böhl, Maltha, Von den Hoff, & Kuijpers-Jagtman, 2004).

C. Strengths and Limitations

Several strengths and limitations of the present study have been illustrated in their relevant contexts throughout this chapter. This section will serve as a concise summary.

1. Strengths

The prospective cohort design of this study avoided the usual bias related to cross-sectional and case-control designs of previous studies, providing therefore a higher quality of evidence relative to the available literature in addition to the inclusion of a bigger sample size. The long term follow up was necessary because an acute dietary change by itself is not alarming unless sustained for a longer period whereby its impact on general health and growth is to be considered. Also, the follow-up of same participants from baseline till completion of the study, rather than being compared to controls, allowed the detection of individual changes in dietary intake. This outcome paves the way towards personalizing dietary advice to orthodontic patients. Moreover the analysis of BMI and dietary intake at baseline revealed that the percentage of overweight/obesity and nutrients and food intake habits in our sample were comparable to those reported in nutritional studies in Lebanese adolescents in general (Naja, Hwalla, Itani, Karam, et al., 2015; Nasreddine et al., 2014; Nasreddine et al., 2012), a finding that adds credibility to our findings.

This study has shed light on novel topics, which to our knowledge, were never discussed in the orthodontic literature including:

- Comparison of nutrient intake at baseline and during treatment to the Dietary Reference Intake in patients undergoing orthodontic treatment (Table 5.1). This comparison helped understand whether the unhealthy diet reflected by the significant increase in fat (%EI) and the decrease in carbohydrates (%EI), fiber (g/d) and several micronutrients was initiated by treatment, or was a habit acquired prior to treatment (as for low fiber (g/d)- high fat (%EI) baseline intakes) and deteriorated with treatment. In addition, classifying nutrients intakes relative to norms for each participant in the study

sample (Figures 4.6 and 4.7) allowed the identification of individuals at risk of nutritional inadequacy (i.e. patients whose intake deviated from norms) and highlighted the importance of implementing a personalized dietary guidance and ensuring patient's commitment before inserting orthodontic appliance if baseline intake levels do not conform to dietary reference intakes.

- Investigation of dietary intake changes in patients undergoing rapid maxillary expansion.
- Comparison of dietary intake changes and pain levels between two treatment modalities: the rapid maxillary expansion and the fixed orthodontic therapy.
- Assessment of the bonding sequence effect on dietary intake changes.
- Exploration of the association between dietary intake changes and rate of tooth movement in humans.
- Evaluation of the relationship between the original cephalometric components of the malocclusion and dietary intake changes during orthodontic treatment.

Furthermore, the tools used to measure the outcome variables were adequately chosen and manipulated:

- All baseline questionnaires were based on previous ones used in nutritional studies at the NFSC department at AUB (Moghames et al., 2015; Naja, Hwalla, Itani, Karam, et al., 2015; Nasreddine et al., 2014; Nasreddine et al., 2012), and were reviewed by a panel of experts including a nutritionist and a physician in internal medicine before initiation of data collection.
- Dietary assessment was conducted by the same researcher to ensure consistency. The researcher went through extensive training prior to data collection to

minimize interviewer errors. For the short term dietary intake assessment the multiple pass 24-h recall approach was used as it was shown to provide accurate estimates of dietary intake in children and adolescents by reducing patient recall bias (Burrows, Martin, & Collins, 2010). In addition 3 recalls were taken from every patient at each time point to enable individual representation of the usual dietary habits (T Baranowski, 2012). For the intermediate term dietary intake assessment a previously validated FFQ was used as it was shown to be valid and reliable in Lebanese children and adolescents (Moghames et al., 2015).

- Anthropometric assessment was undertaken by one researcher using a standardized protocol, and at each time point every measurement was taken twice to reduce measurement errors.
- Dental measurements were performed twice on dental casts poured on the same day of impression taking to reduce the risk of impression material deformation.

2. Limitations

Ideally, following up on patients until the end of their treatment could have yielded a greater insight into the overall effects of fixed orthodontic treatment on dietary intake and body mass index. Furthermore an assessment after debonding orthodontic appliances could have shown if the changes in dietary intake caused by the orthodontic treatment would be retained afterwards. However administering the questionnaires used in the present study for a longer period would have resulted in a higher withdrawal rate and may have proven to be burdensome to patients. In addition, a longer term follow up might not show a shift in the dietary habits adopted during the initial stage of orthodontic treatment whereby the cycling of pain would be a factor in retaining these

habits along the treatment duration. Moreover, in absence of proper dietary guidance, these habits are expected to sustain even after treatment because dietary habits that are acquired during adolescence are more likely to be retained in adulthood (Naja, Hwalla, Itani, Karam, et al., 2015).

Another limitation relates to the questionnaires used for dietary intake assessment as they rely on the respondents' memory. In the 24h dietary recall questionnaire, recalling food intake in younger age groups may be associated with under-reporting (missing foods), over-reporting, as well as incorrect identification of food because of the youngster's lower knowledge of food type and preparation (Nasreddine et al., 2014). Despite the well-known limitations of the 24-h recall questionnaire such reliance on memory and day-to-day variation, the questionnaire provides accurate estimates of energy intake at the population level (M. Livingstone & Robson, 2000). In addition the use of the Multiple Pass Recall approach and the parents' assistance during the recall in younger patients helped increasing the validity of reporting. The recall bias could be more important in the FFQ as respondents should recall what they had eaten in the past month. However the detailed food list provided in this questionnaire reduced the odds of the recall bias especially in children at 10 years and onwards who were reported to give accurate dietary information and are aware of the frequency of consumed food (Tom Baranowski & Domel, 1994).

Dietary assessment 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 (Booth & Shepherd, 1988; Khan & Hackler, 1981; Randall & Sanjur, 1981), including a combination of psychological, personal, social, economic, and cultural factors that might complicate dietary assessment and could confound findings.

Although the sample size of the fixed appliances group was based on a sample size calculation, when participants were distributed across the different categories (pubertal stage, SES, mother education level, baseline BMI status, number of bonded arches, need for pain relief and cephalometric components of the malocclusion), the sample size in each category was smaller and sometimes unbalanced between categories of the same independent variable. This factor might have influenced the ability of the proposed explanatory variables to reflect significant differences in dietary changes across their respective categories. In addition, the sample size of the expansion subgroup was small, although it properly represented an exploratory arm of the initial research question. Acute and intermediate term dietary changes were close to these observed in the fixed appliances groups nevertheless more conclusive findings on the association between rapid maxillary expansion and dietary intake should be drawn from larger samples.

CHAPTER VI

CONCLUSIONS AND RECOMMENDATIONS

A. Conclusions

1- Fixed orthodontic appliances are a trend setter: dietary intake changes were set at one week and sustained until 13 weeks of treatment.

2- At baseline, before treatment, adolescents had unhealthy dietary habits:

- Fiber intake (g/d) in females was at the limit of adequate intake, and 26% below adequate intake in males
- Fat intake (%EI) was 3% above the acceptable macronutrient distribution range
- A high intake of saturated fats and low intakes of α-linolenic Omega 3 fat and vitamin E, which were maintained during treatment

3- The initially adopted unhealthy dietary habits deteriorated at 1 & 5 weeks of treatment relative to baseline and exacerbated at 13 weeks of treatment along with an increase in number of participants adopting these unhealthy habits:

- Fiber intake (g/d) significantly decreased by 26%, relative to baseline (↓fruits-dried fruits & starchy vegetables intake)
- Fat intake (%EI) significantly increased in by 2% relative to baseline (↑pizzas-pies & oils intake) at the expense of a significant decrease in carbohydrates (↓breads & cereals intake)
- Other unhealthy dietary changes included a decrease below Dietary Reference Intake of potassium (initially low), calcium (↓dairy products intake), phosphorus, and vitamin D (↓seafood & eggs intake).

4- BMI did not differ significantly during the study period and baseline BMI weight status apparently did not affect treatment generated dietary changes.

5- The rate of tooth movement was significantly higher in the first 5 weeks of treatment and decreased thereafter in parallel with the decrease in the initial incisors irregularity. The decrease in vitamin C intake showed a significant but low correlation with slower tooth movement warranting further investigation.

6- Pain levels and the need for pain relief medication have significantly decreased by the 1st week of treatment and therefore were not implicated in intermediate term dietary changes. However higher pain intensity was associated with the initial higher rate of tooth movement.

7- The initial severity of the malocclusion determined through cephalometric analysis was not incriminated in the observed dietary changes, however when the second arch was bonded early in treatment (prior to 5 weeks) dietary changes were more severe.

8- Patients treated with fixed appliances and those treated with rapid palatal expansion experienced almost similar dietary intake changes and pain levels.

B. Recommendations

Orthodontists usually see patients in childhood or early adolescence, ages that should allow for early screening and intervention for dietary problems. Therefore, ideally orthodontists could refer or recommend to patients referral to specialized dieticians prior to treatment. The purpose would be to help identifying patients with nutritional inadequacies necessitating personalized dietary guidance to improve on unhealthy dietary habits before further deterioration during treatment.

More directly, the orthodontist should assist in promoting change in the dietary behavior and dietary recommendations.

1- Orthodontic procedures:

a. Using light forces and bonding dental arches sequentially to give the patient enough time to adapt, which in turn would increase patient compliance with the dietary advice.

b. Providing patients with realistic expectations about pain experience, difficulties in chewing, discomfort from food getting stuck in the fixed appliances. In addition to incorporating the concept of healthy eating necessity in the treatment plan session.

c. Monitoring problems in appliances (poking wires, debonded brackets) that cause pain/discomfort and consequently prevent adequate dietary intake.

2- Dietary guidance:

a. Educating patients about the importance of maintaining good oral hygiene and reducing the intake of added sugars to avoid demineralization of teeth becoming more vulnerable with brackets and bands in place.

b. Reinforcing the individualized dietary guidance implemented by the dietician and strengthen compliance. However, given that some healthy food are hard to chew or bite on with braces, and can cause discomfort and appliance breakage, the orthodontist should suggest methods of hard food preparation or substitution with softer/healthier food.

c. Changing practices when addressing the dietary advice to the patient by adopting a positive attitude; for instance instead of saying “Do not

bite into a carrot", say "Bite carefully into carrots after cutting them into thin slices". This change in practice is an essential step to improve dietary guidelines for orthodontic patients.

d. Do not stop eating fruits and vegetables. Cut them instead into small pieces or thinner slices, shred them and eat them on the back teeth. When in pain, choose softer kinds of fruits and vegetables, or boil and mash the harder kinds to become softer.

e. Substitute crunchy or chewy breads with healthier and softer sources of carbohydrates such as soft whole grain bread, pasta, rice, barley and legumes. Whole grain cereals such as breakfast cereals and oatmeal can be consumed with milk to become softer.

f. Increase calcium intakes through the consumption of commonly soft milk and dairy products. Choose the non-fat or low fat dairy products. In addition to its importance in bone health, calcium has a buffering effect due to its ability to neutralize acids and therefore reduce the vulnerability of the dentition towards dental caries during treatment (Singh et al., 2017)

g. Limit the intake of saturated and trans fatty acids by avoiding fried food, commercially prepared bakery goods (pies, pizzas, donuts), processed food such as frozen meals or partially prepared box meals; and consume homemade meals instead. Substitute lard or butter with vegetable oils. Consume healthier unsaturated sources of fat such as fatty fish rich in omega 3 and vitamin D, avocados, and nut butters which can substitute for the hard nuts.

The recommendations should be addressed in the presence of the parents, to involve them in having better control over their children dietary habits as agents of

change. They would take part in motivating their child to improve diet and support him to change food behavior such as spending more time in preparing a healthy lunch or dinner in a way that can be easily eaten with braces, and offering healthy and soft homemade snacks to be taken to school instead of the fatty and sugary processed snacks.

Being oriented mechanically should not distract the orthodontist from maintaining a biologic perspective and to continue to think in terms of support of the biologic process and incorporating dietary counseling and referral in his routine therapy. If the clinician starts out with the idea of expecting favorable change over a period of time with nutritional control, the orthodontist will be "on the way to being a complete physician of the oral cavity, the face and the total health" (Ricketts, 1989).

This research has revealed poor dietary habits in orthodontic patients before the start of treatment potentially reflecting the nutritional patterns in the community. Consequently, the increased risks for diet related diseases cause a great public health concern which highlights the need from public health services to institute programs for dietary assessment, counseling and education in schools.

C. Directions for future research

Future research should include:

1- The follow-up of patients until the end of active treatment to explore the consistency of the current findings.

2- Recruit other populations from other resources than in the current study to assess the generalizability of the findings.

3- Use accurate and precise methods to measure nutrient intake such as biomarkers and blood tests, although the justification for their use might be controversial.

4- Investigate changes in dietary intake and body composition in adults to assess whether they differ from adolescents as patient adaptation to fixed orthodontic treatment may differ depending on age.

5- Recruit a larger sample of patients based on the type of malocclusion and compare baseline dietary intake among the different severity groups and to norms. Ideally, the patient should be followed until after occlusal correction to evaluate dietary changes compared to pre-occlusal correction and/or to patients with normal occlusion.

6- Evaluate the effect of some nutritional supplements (e.g. vitamin C or D) on the rate of tooth movement and bone remodeling markers if such research is justified.

7- Evaluate the effect of the explanatory factors on dietary changes in a larger sample of patients undergoing rapid maxillary expansion, in addition to the association between dietary changes and nutrient intake levels with the rate of maxillary expansion and arch width changes.

8- Compare dietary intake between patients undergoing fixed appliances therapy and other types of fixed or removable orthodontic appliances, for instance lingual braces or clear aligners that might induce more pain.

TABLES

Table 4.1: Baseline cephalometric measurements in the fixed appliances group (n=95)

	n	%	Mean	SD
Sagittal jaws relationship				
ANB angle (◦)	95	100	3.799	2.807
AoBo (mm) $^{\tilde{x},R}$			-0.7	[-16.7, 9.1]
Class I	35	36.8	2.511	1.062
Class II	52	54.7	5.648	1.398
Class III	8	8.4	-2.588	2.403
Vertical jaws relationship				
MP/SN angle (◦)	95	100	32.247	4.922
Normodivergent	67	70.5	32.085	2.785
Hypodivergent	14	14.7	25.029	1.657
Hyperdivergent	14	14.7	40.243	2.818
Dental anterior overjet (OJ)				
Overjet (mm)	95	100	3.95	2.091
Normal OJ	16	16.8	2.522	0.554
Increased OJ	74	77.9	4.593	1.651
Crossbite $^{\tilde{x},R}$	5	5.3	-0.1	[-5.15, 0.7]
Dental anterior overbite (OB)				
Overbite (mm)	95	100	2.603	2.125
Normal OB	33	34.7	2.189	0.564
Deep bite	41	43.2	4.455	1.208
Open bite $^{\tilde{x},R}$	21	22.1	-0.362	[-2.55, 0.85]

$^{\tilde{x},R}$ For this variable the median is reported instead of the mean, and the range [min, max] instead of the standard deviation (SD)

Table 4.2: Baseline cephalometric measurements in the expansion subgroup (n=20)

	n	%	Mean	SD
Sagittal jaws relationship				
ANB angle (◦) $^{\tilde{x},R}$	20	100	3.25	[-5.9, 7.8]
AoBo (mm) $^{\tilde{x},R}$			-2.55	[-12.1, 6.3]
Class I	14	70	2.307	1.204
Class II	5	25	6.06	1.403
Class III	1	5	-5.9	—
Vertical jaws relationship				
MP/SN angle (◦)	20	100	33.475	4.368
Normodivergent	14	70	33.557	2.561
Hypodivergent	3	15	26.567	0.666
Hyperdivergent	3	15	40	1.646
Dental anterior overjet (OJ)				
Overjet (mm)	20	100	3.303	2.419
Normal	7	35	2.036	0.731
Increased	11	55	5.009	1.142
Crossbite	2	10	-1.65	1.626
Dental anterior overbite (OB)				
Overbite (mm) $^{\tilde{x},R}$	20	100	0.875	[-2.85, 4.7]
Normal	5	25	1.77	0.765
Deep bite	5	25	3.89	0.677
Open bite $^{\tilde{x},R}$	10	50	-0.35	[-2.85, 0.75]

$^{\tilde{x},R}$ For this variable the median is reported instead of the mean, and the range [min, max] instead of the standard deviation (SD)

Table 4.3: Intermediate term comparison of anthropometric measurements in the fixed appliances group (n=95)

	Baseline (B)		5 weeks (5wk)		13 weeks (13wk)		p-value[1]
	Mean	SD	Mean	SD	Mean	SD	
Weight kg	59.06	14.694	59.743	15.201	60.273	15.098	0.000*
Height m	1.601	0.11	1.609	0.108	1.616	0.106	0.000*
BMI kg/m^2	22.799	3.877	22.827	3.999	22.812	3.903	0.947

	p-value[2]		
	B/5wk	B/13wk	5wk/13wk
Weight kg	0.002*	0.000*	0.076
Height m	0.007*	0.000*	0.000*

* p-value <0.05
[1] Refers to the p-value of repeated measures ANOVA/ Friedman test
[2] Refers to the p-value of Bonferroni Post-Hok/ Wilcoxon test

Table 4.4: Intermediate term comparison of anthropometric measurements in the expansion subgroup (n=20)

	Baseline (B)		5 weeks (5wk)		13 weeks (13wk)		p-value[1]
	Mean	SD	Mean	SD	Mean	SD	
Weight kg	46.975	13.751	46.398	13.869	46.379	12.755	0.152
Height m	1.492	0.101	1.497	0.099	1.507	0.098	0.000*
BMI kg/m^2	20.883	4.628	20.471	4.732	20.182	4.094	0.074

	p-value[2]		
	B/5wk	B/13wk	5wk/13wk
Height m	0.046*	0.000*	0.000*

* p-value <0.05
[1] Refers to the p-value of repeated measures ANOVA/ Friedman test
[2] Refers to the p-value of Bonferroni Post-Hok/ Wilcoxon test

Table 4.5: Comparison of total and nutrients intake between baseline and one week after bonding the 1st arch in the fixed appliances group (n=95)

	Baseline (B)		Week 1 (1wk)		p-value
	Mean	**SD**	**Mean**	**SD**	
Total intake[1]					
Weight	2337.209	985.676	2189.377	898.236	0.021*
Energy	1604.05	573.71	1341.46	667.404	0.000*
Macronutrients intake (g/d)					
Protein	60.718	26.513	51.467	34.603	0.000*
Carbohydrate	175.272	64.154	143.886	55.554	0.000*
Sugar	56.137	28.585	46.926	27.229	0.003*
Glucose	10.077	7.389	7.906	6.235	0.025*
Galactose $\tilde{x}^{,R}$	0.037	[0, 5.56]	0.052	[0, 3.945]	0.452
Total Fat	75.478	29.103	62.542	42.439	0.000*
Cholesterol	175.211	98.793	145.577	93.83	0.014*
Saturated Fat	21.88	10.117	18.163	10.485	0.001*
MFA	25.558	11.532	19.665	10.207	0.000*
PFA	16.205	7.632	13.084	6.445	0.001*
Oleic Fat	22.911	10.977	17.132	9.333	0.000*
Linoleic Fat	14.653	7.012	11.603	6.058	0.001*
Linolenic Fat	0.86	0.626	0.668	0.361	0.000*
EPA-Omega3 $\tilde{x}^{,R}$	0.003	[0, 0.078]	0.002	[0, 0.187]	0.492
DHA-Omega3 $\tilde{x}^{,R}$	0.017	[0, 0.223]	0.011	[0, 0.656]	0.077
Dietary Fiber	12.609	7.197	9.42	5.274	0.000*
Soluble Fiber $\tilde{x}^{,R}$	0.115	[0, 1.77]	0.042	[0, 1.2]	0.119
Insoluble Fiber	1.128	1.112	0.947	0.93	0.091
Crude Fiber $\tilde{x}^{,R}$	2.076	[0.391, 85.498]	1.582	[0.014, 41.696]	0.000*
Macronutrients intake (%EI)					
Protein	15.088	3.189	15.316	3.719	0.664
Carbohydrate	44.116	6.941	44.538	8.756	0.624
Sugar	14.082	5.261	14.596	7.303	0.667
Total Fat	42.116	5.843	40.587	7.305	0.083
Saturated Fat	12.189	3.354	12.067	4.101	0.635
Linoleic Fat	8.148	2.48	7.973	2.665	0.864
Linolenic Fat	0.48	0.215	0.46	0.153	0.516

Table 4.5: Comparison of total and nutrients intake between baseline and one week after bonding the 1st arch in the fixed appliances group (n=95) *(Continued)*

	Baseline (B)		Week 1 (1wk)		p-value
	Mean	**SD**	**Mean**	**SD**	
Micronutrients intake[2]					
Sodium	2167.711	967.525	1783.298	883.255	0.001*
Potassium	1864.258	810.657	1503.56	654.91	0.000*
Iron $^{\tilde{x},R}$	9.252	[3.619, 126.861]	7.316	[0.633, 17.547]	0.000*
Calcium $^{\tilde{x},R}$	693.829	[168.977, 2651.925]	564.237	[157.794, 7155.467]	0.008*
Magnesium	209.979	97.404	172.4	69.628	0.000*
Phosphorus	798.579	357.987	705.551	559.399	0.000*
Zinc mg	6.966	3.3	5.706	2.526	0.000*
Copper mg	0.922	0.425	0.766	0.323	0.000*
Manganese $^{\tilde{x},R}$	2.018	[0.339, 16.135]	1.567	[0.362, 25.936]	0.001*
Chromium	0.042	0.025	0.028	0.019	0.000*
Vitamin A	369.73	292.6	292.594	230.056	0.02*
β-Carotene $^{\tilde{x},R}$	1457.92	[29.288, 7127.473]	1196.735	[11.62, 9853.22]	0.003*
Thiamin (B1)	1.017	0.387	0.799	0.31	0.000*
Riboflavin (B2)	1.092	0.512	0.93	0.64	0.000*
Niacin (B3)	15.038	6.656	11.462	5.063	0.000*
Pyridoxine (B6)	1.238	0.619	0.973	0.439	0.000*
Folate (B9)	235.85	146.622	186.374	89.704	0.000*
Cobalamin (B12)	2.537	1.977	2.244	2.212	0.043*
Vitamin B5	3.086	1.331	2.594	1.127	0.000*
Vitamin C	60.535	55.516	56.19	46.641	0.719
Vitamin D $^{\tilde{x},R}$	0.939	[0, 11.561]	0.502	[0, 21.33]	0.208
Vitamin E $^{\tilde{x},R}$	0.107	[0, 12.031]	0.282	[0, 10.161]	0.088
Vitamin K $^{\tilde{x},R}$	82.22	[7.483, 552.703]	56.996	[1.626, 737.524]	0.016*

* p-value <0.05

$^{\tilde{x},R}$ For this variable the median is reported instead of the mean, and the range [min, max] instead of the standard deviation (SD)

[1] For the total intake: weight is reported in grams/day, energy in kilocalories/day

[2] Micronutrients are reported in milligrams/day except for vit A, βcarotene, vit B9, vit B12, vit D and vit k in micrograms/day

Table 4.6: Comparison of total and nutrients intake among baseline, one week of bonding the 1st arch and one week of bonding the 2nd arch in the fixed appliances group (n=40)

	Baseline (B)		Week1-1st arch (a1)		Week1-2nd arch (a2)		p-value[3]
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	
Total intake[1]							
Weight	2312.1	869.311	2136.79	934.749	1888.54	641.85	0.002*
Energy	1695.5	631.3	1314.58	865.915	1202.49	489.188	0.000*
Macronutrients intake (g/d)							
Protein	61.532	28.991	51.954	49.048	46.07	21.728	0.004*
Carbs	188.26	71.518	135.626	58.532	133.035	50.864	0.001*
Sugar	62.051	30.014	44.172	28.657	42.032	20.923	0.000*
Glucose	11.459	8.286	7.447	6.192	6.753	5.285	0.001*
Galac-tose $\tilde{x},R$	0.066	[0, 3.146]	0.043	[0, 3.945]	0.107	[0, 4.321]	0.77
Total Fat	79.881	31.611	62.616	57.724	54.833	27.852	0.002*
Cholest.	170.217	91.498	146.016	106.402	152.008	113.256	0.207
Saturated Fat	22.016	10.192	16.238	9.672	17.066	11.352	0.001*
MFA	27.453	12.754	18.759	11.318	17.192	9.357	0.001*
PFA	17.731	7.59	12.824	6.517	11.081	5.418	0.002*
Oleic Fat	24.976	12.531	15.955	9.946	15.063	8.639	0.001*
Linoleic Fat	16.191	6.974	11.125	5.627	9.898	4.833	0.001*
Linolenic Fat	0.952	0.896	0.64	0.431	0.676	0.523	0.007*
EPA Om-ega3 $\tilde{x},R$	0.003	[0, 0.078]	0.002	[0, 0.024]	0.003	[0, 0.144]	0.012*
DHA O-mega3 $\tilde{x},R$	0.019	[0, 0.223]	0.012	[0, 0.088]	0.008	[0, 0.417]	0.02*
Dietary Fiber	14.69	9.566	10.023	7.015	8.988	3.865	0.000*
Soluble Fiber $\tilde{x},R$	0.128	[0, 1.77]	0.063	[0, 1.188]	0.048	[0, 1.738]	0.14
Insoluble Fiber $\tilde{x},R$	0.966	[0, 5.461]	0.572	[0, 4.051]	0.595	[0, 4.429]	0.037*
Crude Fiber $\tilde{x},R$	2.714	[0.639, 85.498]	1.669	[0.014, 41.696]	1.601	[0.038, 103.897]	0.000*
Macronutrients intake (%EI)							
Protein	14.463	3.074	15.224	4.243	15.431	4.549	0.461
Carbs	44.659	6.038	44.445	10.199	45.236	10.086	0.914
Sugar	14.834	4.579	14.781	8.135	14.334	6.126	0.294
Total Fat	42.297	5.775	40.627	8.116	40.136	7.395	0.245
Sat. Fat	11.674	3.03	11.506	4.037	12.106	4.899	0.592

Table 4.6: Comparison of total and nutrients intake among baseline, one week of bonding the 1st arch and one week of bonding the 2nd arch in the fixed appliances group (n=40) *(Continued)*

	Baseline (B)		Week1-1st arch (a1)		Week1-2nd arch (a2)		p-value[3]
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	
Macronutrients intake (%EI)							
Linoleic Fat	8.701	2.333	8.256	2.874	7.484	2.658	0.099
Linolenic Fat	0.495	0.302	0.463	0.181	0.509	0.322	0.905
Micronutrients intake[2]							
Na	2210.29	1102.38	1682.54	1053.35	1570.77	786.248	0.088
K	2022.08	893.199	1457.25	726.953	1341.64	526.272	0.001*
Fe	10.28	5.329	7.552	4.097	6.671	2.894	0.000*
Ca $\tilde{x}^{,R}$	590.02	[292.53, 2651.93]	524.588	[231.15, 7155.47]	427.497	[181.5, 1544.83]	0.007*
Mg	235.048	122.655	173.445	83.835	153.219	59.333	0.000*
P $\tilde{x}^{,R}$	740.131	[331.79, 2346.66]	546.618	[209.87, 5397.66]	519.161	[197.83, 1407.77]	0.003*
Zn	7.025	3.817	5.55	2.929	5.518	2.941	0.028*
Cu	1.043	0.539	0.766	0.369	0.808	0.8	0.001*
Mn $\tilde{x}^{,R}$	2.312	[0.947, 11.155]	1.554	[0.362, 19.139]	1.51	[0.354, 3.561]	0.000*
Cr	0.048	0.026	0.027	0.018	0.027	0.025	0.000*
Vit A	358.977	319.124	280.957	210.687	337.168	420.505	0.535
βcaro-tene $\tilde{x}^{,R}$	1596.08	[110.28, 7127.47]	1122.07	[11.62, 8621.89]	851.536	[14.196, 8273.59]	0.15
Vit B1	1.024	0.443	0.755	0.355	0.737	0.303	0.000*
Vit B2	1.054	0.52	0.948	0.858	0.85	0.383	0.067
Vit B3	15.996	6.667	11.264	6.564	10.623	5.03	0.000*
Vit B6	1.305	0.607	0.983	0.539	1.01	0.803	0.001*
Vit B9	247.766	177.39	181.318	108.047	172.033	82.787	0.004*
Vit B12 $\tilde{x}^{,R}$	2.078	1.823	1.551	[0.125, 18.758]	1.765	[0, 28.072]	0.557
Vit.B5	3.099	1.173	2.436	1.09	2.429	0.996	0.011*
Vit C	68.388	51.583	56.344	47.487	50.628	41.392	0.218
Vit D $\tilde{x}^{,R}$	0.777	[0.024, 6.216]	0.407	[0, 21.33]	0.72	[0, 7.051]	0.799
Vit E $\tilde{x}^{,R}$	1.105	[0, 12.031]	0.266	[0, 10.161]	0.038	[0, 4.644]	0.129
Vit K $\tilde{x}^{,R}$	103.514	[13.931, 552.703]	58.866	[1.626, 737.524]	48.146	[8.66, 466.477]	0.068

Table 4.6: Comparison of total and nutrients intake among baseline, one week of bonding the 1st arch and one week of bonding the 2nd arch in the fixed appliances group (n=40) *(Continued)*

		p-value[4]		
		B/a1	**B/a2**	**a1/a2**
Tot int-ake	Weight	0.048*	0.004*	0.276
	Energy	0.000*	0.000*	0.809
Macronutrients intake	Protein	0.002*	0.001*	0.788
	Carbs	0.000*	0.000*	0.946
	Sugar	0.000*	0.000*	0.619
	Glucose	0.009*	0.000*	0.791
	Total Fat	0.001*	0.000*	0.861
	Saturated Fat	0.000*	0.011*	0.989
	MFA	0.001*	0.000*	0.259
	PFA	0.002*	0.000*	0.179
	Oleic Fat	0.000*	0.000*	0.468
	Linoleic Fat	0.000*	0.000*	0.502
	Linolenic Fat	0.002*	0.005*	0.657
	EPA-Omega3	0.027*	0.192	0.915
	DHA-Omega3	0.162	0.011*	0.451
	Dietary Fiber	0.000*	0.000*	0.582
	Insoluble Fiber	0.02*	0.017*	0.605
	Crude Fiber	0.001*	0.001*	0.925
Micronutrients intake	K	0.000*	0.000*	0.638
	Fe	0.002*	0.000*	0.452
	Ca	0.013*	0.068	0.638
	Mg	0.000*	0.000*	0.211
	P	0.005*	0.001*	0.405
	Zn	0.012*	0.023*	0.638
	Cu	0.000*	0.000*	0.390
	Mn	0.000*	0.000*	0.867
	Cr	0.000*	0.000*	0.727
	Vit B1	0.001*	0.000*	0.979
	Vit B3	0.000*	0.000*	0.476
	Vit B6	0.001*	0.002*	0.468
	Vit B9	0.004*	0.007*	0.737
	Vit B5	0.001*	0.001*	0.936

* p-value <0.05

$\tilde{x}$,R For this variable the median is reported instead of the mean, and the range [min, max] instead of the standard deviation (SD)

1 For the total intake: weight is reported in grams/day, energy in kilocalories/day

2 Micronutrients are reported in milligrams/day except for vit A, βcarotene, vit B9, vit B12, vit D and vit k in micrograms/day

3 Refers to the p-value of repeated measures ANOVA/ Friedman test

4 Refers to the p-value of Bonferroni Post-Hok/ Wilcoxon test

Table 4.7: Comparison of total and nutrients intake between baseline and 1st week of maxillary expansion in the expansion subgroup (n=20)

	Baseline (B)		Week1 expansion (1wkE)		p-value
	Mean	**SD**	**Mean**	**SD**	
Total intake[1]					
Weight	2420.256	914.025	2110.672	1000.314	0.051
Energy	1649.695	579.357	1259.381	654.061	0.003*
Macronutrients intake (g/d)					
Protein	56.685	26.11	41.608	21.682	0.006*
Carbohydrate	183.687	63.076	150.012	75.999	0.037*
Sugar	60.654	36.762	46.376	33.129	0.003*
Glucose	9.594	6.666	6.802	5.353	0.006*
Galactose $\tilde{x}^{,R}$	0.022	[0, 2.373]	0.04	[0, 2.308]	0.658
Total Fat	78.014	32.413	55.889	33.12	0.005*
Cholesterol	153.75	106.98	103.292	59.722	0.045
Saturated Fat	22.345	12.65	16.720	10.314	0.028*
MFA	25.955	10.076	19.605	14.424	0.052*
PFA	18.205	7.487	12.813	8.876	0.012*
Oleic Fat	23.153	9.692	17.533	13.041	0.048*
Linoleic Fat	16.905	7.287	11.783	8.540	0.012*
Linolenic Fat	0.914	0.351	0.71	0.46	0.057
EPA-Omega3 $\tilde{x}^{,R}$	0.002	[0, 0.059]	0.002	[0, 0.006]	0.365
DHA-Omega3 $\tilde{x}^{,R}$	0.015	[0, 0.203]	0.003	[0, 0.024]	0.005*
Dietary Fiber	11.989	3.875	9.532	5.358	0.081
Soluble Fiber $\tilde{x}^{,R}$	0.06	[0.008, 0.227]	0.037	[0, 0.223]	0.55
Insoluble Fiber $\tilde{x}^{,R}$	0.617	[0.114, 2.436]	0.456	[0, 2.509]	0.765
Crude Fiber $\tilde{x}^{,R}$	2.527	[0.726, 5.025]	1.631	[0.2, 13.476]	0.117
Macronutrients intake (%EI)					
Protein	13.525	3.312	13.642	3.383	0.874
Carbohydrate	45.473	7.76	48.122	6.316	0.154
Sugar	14.757	6.663	14.916	7.927	0.859
Total Fat	41.958	6.239	38.949	5.609	0.114
Saturated Fat	11.655	3.269	11.572	3.333	0.97
Linoleic Fat	9.115	2.295	8.267	2.994	0.196
Linolenic Fat	0.502	0.094	0.494	0.13	0.851

Table 4.7: Comparison of total and nutrients intake between baseline and 1st week of maxillary expansion in the expansion subgroup (n=20) *(Continued)*

	Baseline (B)		Week1 expansion (1wkE)		p-value
	Mean	SD	Mean	SD	
Micronutrients intake[2]					
Sodium	2014.597	896.998	1645.075	888.304	0.078
Potassium	1786.462	663.945	1520.582	868.286	0.086
Iron	10.622	4.028	7.361	4.969	0.011*
Calcium	738.953	362.898	587.075	384.764	0.03*
Magnesium	202.473	65.129	168.405	80.635	0.019*
Phosphorus	764.668	318.683	644.929	373.159	0.093
Zinc mg	7.021	2.886	5.395	3.814	0.03*
Copper mg	0.926	0.312	0.775	0.407	0.073
Manganese	2.253	0.902	1.791	0.912	0.068
Chromium	0.041	0.023	0.031	0.028	0.171
Vitamin A	396.583	226.532	293.773	249.564	0.037*
β-Carotene	2301.741	1937.249	1528.202	1371.736	0.313
Thiamin (B1)	0.925	0.326	0.801	0.373	0.063
Riboflavin (B2)	1.031	0.457	0.815	0.498	0.012*
Niacin (B3)	14.017	4.953	10.085	5.584	0.002*
Pyridoxine (B5)	1.126	0.346	0.866	0.458	0.004*
Folate (B9)	212.888	101.776	186.9	104.368	0.191
Cobalamin (B12)	2.526	1.573	1.826	1.678	0.044*
Vitamin B5	3.114	1.341	2.575	1.502	0.048*
Vitamin C $^{\tilde{x},R}$	36.822	[8.012, 207.478]	47.223	[2.135, 261.189]	0.852
Vitamin D $^{\tilde{x},R}$	1.292	[0.02, 10.633]	1.010	[0.077, 12.498]	0.191
Vitamin E $^{\tilde{x},R}$	0.093	[0, 1.681]	0.625	[0, 5.551]	0.093
Vitamin K	92.492	65.885	73.501	72.601	0.263

* p-value <0.05

$^{\tilde{x},R}$ For this variable the median is reported instead of the mean, and the range [min, max] instead of the standard deviation (SD)

1 For the total intake: weight is reported in grams/day, energy in kilocalories/day

2 Micronutrients are reported in milligrams/day except for vit A, βcarotene, vit B9, vit B12, vit D and vit k in micrograms/day

Table 4.8: Intermediate term comparison of total and nutrients intake in the fixed appliances group (n=95)

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[3]
	Mean	SD	Mean	SD	Mean	SD	
Total intake[1]							
Weight	3128.75	1204.16	2784.9	1000.83	2701.85	994.583	0.003*
Energy	2977.49	1447.92	2375.37	1163.39	2343.15	1050.78	0.000*
Macronutrients intake (g/d)							
Protein	95.078	42.1	77.165	38.327	76.932	35.774	0.000*
Carbs	381.016	196.007	293.116	168.461	288.776	154.537	0.000*
Sugar	119.343	88.931	98.891	86.18	94.757	84.476	0.022*
Glucose	22.035	12.56	16.552	10.54	18.74	12.001	0.000*
Galactose $\tilde{x},R$	0.534	[0.017, 9.936]	0.423	[0.003, 4.942]	0.52	[0.019, 3.359]	0.1
Total Fat	126.861	77.521	104.672	51.765	102.979	45.605	0.015*
Cholest.	258.948	138.602	214.609	131.982	218.606	134.074	0.000*
Saturated Fat	38.033	21.773	32.881	22.062	31.739	20.942	0.01*
MFA	44.147	25.61	37.414	18.963	37.753	17.633	0.083
PFA	30.635	28.707	23.232	13.565	22.566	9.966	0.009*
Oleic Fat	41.357	24.679	35.139	17.913	35.385	16.544	0.127
Linoleic Fat	28.541	27.33	21.586	12.923	20.945	9.351	0.02*
Linolenic Fat	1.592	1.263	1.238	0.645	1.215	0.551	0.02*
EPA Omega3 $\tilde{x},R$	0.005	[0, 0.039]	0.005	[0, 0.129]	0.005	[0, 0.071]	0.515
DHA Omega3 $\tilde{x},R$	0.033	[0, 417.299]	0.022	[0, 120.051]	0.02	[0, 120.037]	0.213
Dietary Fiber	27.139	16.258	20.199	9.737	20.337	8.965	0.001*
Soluble Fiber	0.792	0.594	0.594	0.580	0.605	0.501	0.003*
Insoluble Fiber $\tilde{x},R$	1.192	[0.072, 20.618]	0.774	[0.023, 6.485]	0.928	[0, 5.855]	0.074
Crude Fiber $\tilde{x},R$	7.041	[0.759, 96.647]	4.79	[0.611, 119.772]	5.522	[0.548, 97.154]	0.137
Macronutrients intake (%EI)							
Protein	13.143	3.029	13.317	3.258	13.264	3.112	0.745
Carbs	51.154	7.258	48.917	7.814	49.076	6.897	0.056
Sugar	15.691	6.368	15.74	5.97	15.199	5.699	0.959
Total Fat	37.91	7.516	39.886	7.399	39.61	6.786	0.029*
Sat. Fat	11.44	2.72	11.907	3.037	11.705	2.849	0.597
Linoleic	8.229	3.859	8.474	3.186	8.373	2.791	0.032*
Linolenic	0.467	0.175	0.485	0.165	0.474	0.126	0.435

Table 4.8: Intermediate term comparison of total and nutrients intake in the fixed appliances group (n=95) *(Continued)*

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[3]
	Mean	SD	Mean	SD	Mean	SD	
Micronutrients intake[2]							
Na	3263.68	1822.59	2380.65	1134.87	2371.45	1039.39	0.000*
K	3212.15	1512.95	2594.27	1200.14	2616.78	1204.94	0.000*
Fe	25.617	20.673	17.07	10.864	17.242	10.335	0.001*
Ca	1410.15	610.753	1223.69	587.863	1206.27	570.134	0.003*
Mg	490.964	207.219	408.782	156.108	397.637	150.265	0.000*
P	1405.05	648.5	1123.12	549.082	1111.15	545.357	0.001*
Zn	12.295	6.18	9.696	4.675	9.467	4.059	0.000*
Cu	1.867	0.842	1.483	0.797	1.483	0.675	0.000*
Mn $^{\tilde{x},R}$	4.792	[1.173, 72.672]	3.819	[1.1, 21.769]	3.474	[0.783, 23.293]	0.004*
Cr $^{\tilde{x},R}$	0.395	[0.014, 2.633]	0.265	[0.004, 2.628]	0.281	[0.003, 2.64]	0.001*
Vit A $^{\tilde{x},R}$	2170.22	[115.92, 47034.1]	1478.53	[101.37, 13348.3]	1228.18	[177.4, 10697.5]	0.002*
βcaro-tene $^{\tilde{x},R}$	2828.96	[442.44 29617.8]	2602.47	[55.667, 33143.7]	3227.02	[78.336, 16270.6]	0.039*
Vit B1	2.758	2.096	1.862	1.02	1.881	1.063	0.000*
Vit B2	2.716	1.898	1.886	1.156	1.878	1.121	0.000*
Vit B3	32.837	21.818	23.187	13.538	23.504	12.357	0.000*
Vit B6 $^{\tilde{x},R}$	11.744	[0.472, 423.434]	6.393	[0.826, 213.267]	8.257	[0.519, 364.068]	0.003*
Vit B9	626.723	469.767	449.87	261.471	446.115	253.214	0.003*
Vit B12	8.591	7.36	6.199	5.269	5.931	4.841	0.000*
Vit.B5	5.844	2.638	4.779	2.263	4.795	2.221	0.000*
Vit C	122.718	95.187	89.002	65.235	95.806	83.185	0.03*
Vit D $^{\tilde{x},R}$	3.571	[0.201, 44.803]	2.604	[0.052, 17.789]	2.177	[0.088, 16.093]	0.01*
Vit E	3.688	3.425	3.649	3.077	3.427	2.436	0.745
Vit K	187.504	151.998	158.504	121.001	152.46	89.976	0.192

		p-value[4]		
		B/5wk	B/13wk	5wk/13wk
Tot int-ake	Weight	0.003*	0.000*	0.669
	Energy	0.000*	0.000*	0.73
Macron-utrients intake	Protein	0.000*	0.000*	0.908
	Carbs	0.000*	0.000*	0.741
	Sugar	0.003*	0.002*	0.841
	Glucose	0.000*	0.013*	0.168

Table 4.8: Intermediate term comparison of total and nutrients intake in the fixed appliances group (n=95) *(Continued)*

		p-value[4]		
		B/5wk	**B/13wk**	**5wk/13wk**
Macronutrients intake	Total Fat	0.005*	0.001*	0.844
	Cholesterol	0.000*	0.001*	0.629
	Saturated Fat	0.002	0.001	0.944
	PFA	0.015*	0.004*	0.938
	Linoleic Fat	0.016*	0.005*	0.932
	Linolenic Fat	0.008*	0.002*	0.821
	Dietary Fiber	0.000*	0.000*	0.664
	Soluble Fiber	0.001*	0.007*	0.521
	Carbs %EI	0.012*	0.007*	0.991
	Total Fat %EI	0.013*	0.033*	0.859
	Linoleic Fat %EI	0.165	0.299	0.471
Micronutrients intake	Na	0.000*	0.000*	0.864
	K	0.000*	0.000*	0.923
	Fe	0.000*	0.000*	0.935
	Ca	0.001*	0.001*	0.818
	Mg	0.000*	0.000*	0.651
	P	0.000*	0.000*	0.938
	Zn	0.000*	0.000*	0.832
	Cu	0.000*	0.000*	0.697
	Mn	0.011*	0.002*	0.166
	Cr	0.005*	0.017*	0.864
	Vit A	0.001*	0.000*	0.41
	βcarotene	0.062	0.767	0.439
	Vit B1	0.000*	0.000*	0.962
	Vit B2	0.000*	0.000*	0.767
	Vit B3	0.000*	0.000*	0.876
	Vit B6	0.011*	0.061	0.738
	Vit B9	0.000*	0.000*	0.982
	Vit B12	0.000*	0.000*	0.772
	Vit B5	0.000*	0.000*	0.973
	Vit C	0.001*	0.008*	0.885
	Vit D	0.004*	0.015*	0.506

* p-value <0.05

$\tilde{x}$,R For this variable the median is reported instead of the mean, and the range [min, max] instead of the standard deviation (SD)

[1] For the total intake: weight is reported in grams/day, energy in kilocalories/day

[2] Micronutrients are reported in milligrams/day except for vit A, βcarotene, vit B9, vit B12, vit D and vit k in micrograms/day

[3] Refers to the p-value of repeated measures ANOVA/ Friedman test

[4] Refers to the p-value of Bonferroni Post-Hok/ Wilcoxon test

Table 4.9: Intermediate term comparison of food groups intake in the fixed appliances group (n=95)

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[1]
	Mean	SD	Mean	SD	Mean	SD	
Food groups (g/d)							
Breads	118.652	77.056	88.508	56.283	91.346	60.996	0.001*
Cereals $^{\tilde{x},R}$	13.981	[0, 453.6]	10.449	[0, 298.26]	5.592	[0, 229.04]	0.029*
Rice	74.136	63.119	66.652	64.741	70.083	57.832	0.692
Pasta/ noodles $^{\tilde{x},R}$	29.826	[0, 270.39]	22.369	[0, 159.43]	16.777	[0, 194.4]	0.14
Bulgur/ wheat ^{R}	9.044	[0, 259.2]	6.45	[0, 129.6]	8.484	[0, 129.6]	0.065
Pastries $^{\tilde{x},R}$	5.589	[0, 70]	4.274	[0, 62.589]	4.668	[0, 94.143]	0.074
Sugar/ jams $^{\tilde{x},R}$	3.107	[0, 42.525]	4.039	[0, 40.5]	2.7	[0, 71.186]	0.531
Biscuit/Ch-ocolate $^{\tilde{x},R}$	34.796	[0, 377.98]	25.647	[0, 313.17]	23.724	[0, 255.15]	0.004*
Traditional sweets ^{R}	5.464	[0, 105.71]	5.753	[0, 96]	6.395	[0, 105.73]	0.83
Ice-cream ^{R}	12.102	[0, 205.71]	9.46	[0, 157.81]	12.345	[0, 145.8]	0.094
Pizzas/pies	39.885	36.153	45.033	43.382	42.593	32.976	0.484
Salty snacks $^{\tilde{x},R}$	18.858	[0, 777.6]	12.822	[0, 268.71]	11.402	[0, 149.75]	0.018*
Fast foods	75.084	66.831	66.39	55.603	70.938	62.153	0.487
Legum-es $^{\tilde{x},R}$	24.3	[0, 169.63]	19.573	[0, 196.26]	24.3	[0, 185.01]	0.569
Poultry/ organs $^{\tilde{x},R}$	16.2	[0, 334.35]	16.777	[0, 250.77]	13.422	[0, 194.4]	0.366
Meat/organ meat $^{\tilde{x},R}$	35.979	[0, 233.32]	24.625	[0, 304.22]	28.577	[0, 140.94]	0.072
Sea food $^{\tilde{x},R}$	9.125	[0, 97.143]	5.918	[0, 81.252]	4.474	[0, 113.95]	0.083
Eggs $^{\tilde{x},R}$	11.836	[0, 96.429]	8.877	[0, 96.429]	8.877	[0, 96.429]	0.011*
Processed meat $^{\tilde{x},R}$	7.728	[0, 145.8]	4.286	[0, 169.634]	4.659	[0, 56.571]	0.47
Milk unsweet $^{\tilde{x},R}$	41.01	[0, 1020.6]	36.45	[0, 623.7]	24.3	[0, 623.7]	0.235
Dairy products $^{\tilde{x},R}$	72.975	[1.512, 699.84]	52.687	[0, 521.10]	68.177	[0, 454.6]	0.023*

Table 4.9: Intermediate term comparison of food groups intake in the fixed appliances group (n=95) *(Continued)*

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[1]
	Mean	SD	Mean	SD	Mean	SD	
Food groups (g/d)							
Sweet dairy prod.[x̃,R]	6.906	[0, 243.23]	5.592	[0, 125.93]	4.194	[0, 101.16]	0.282
Fruits/dried fruits [x̃,R]	122.025	[0, 734.23]	84.401	[0, 616.22]	89.84	[0, 506.47]	0.005*
Fresh fruit juices [x̃,R]	16.777	[0, 500]	10.253	[0, 340.2]	12.583	[0, 935.55]	0.293
Canned juice/fruits [x̃,R]	19.726	[0, 1020.6]	6.575	[0, 255.15]	6.575	[0, 340.2]	0.167
Reg. soft drink [x̃,R]	12.15	[0, 660]	12.15	[0, 510.3]	8.388	[0, 330]	0.161
Diet soft drinks [R]	13.82	[0, 330]	14.469	[0, 330]	11.743	[0, 162.74]	0.585
Olive-oil/ avocado [x̃,R]	8.322	[0, 111.89]	6.075	[0, 152.11]	8.1	[0, 162.49]	0.75
Oil/salad dressings	6.608	6.191	6.555	5.288	6.1	[0, 4.403	0.831
Salad/vegetables [x̃,R]	121.611	[0, 1310.1]	116.829	[0, 1293]	126.257	[1.512, 702.98]	0.129
Cooked vegetables [x̃,R]	47.956	[0, 518.4]	35.196	[0, 202.93]	41.077	[0, 297.19]	0.137
Mahashi [x̃,R]	9.074	[0, 69.254]	5.592	[0, 76.471]	9.074	[0, 112.64]	0.29
Starchy vegetables [R]	14.145	[0, 259.2]	9.336	[0, 240]	8.288	[0, 54.247]	0.009*
Nuts/ seeds [R]	14.415	[0, 170.1]	11.153	[0, 170.1]	8.743	[0, 170.1]	0.042*
Pickles/condiment [x̃,R]	2.025	[0, 76.95]	2.025	[0, 72.9]	2.646	[0, 78.975]	0.789
Alcoholic beverage [R]	1.136	[0, 30.758]	0.662	[0, 33.554]	1.026	[0, 41.096]	0.867
Coffee/ creamer [R]	41.271	[0, 1020.6]	48.83	[0, 1020.6]	37.263	[0, 1020.6]	0.678
Energy drinks [R]	5.063	[0, 133.65]	2.297	[0, 44.55]	3.561	[0, 145.8]	0.162
Tea [x̃,R]	48.6	[0, 340.2]	42.525	[0, 434.37]	45.999	[0, 765.45]	0.528
Soups/ broth [R]	11.02	[0, 64.8]	11.4	[0, 97.2]	15.196	[0, 121.5]	0.912

Table 4.9: Intermediate term comparison of food groups intake in the fixed appliances group (n=95) *(Continued)*

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[1]
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	
Food groups (g/d)							
Cakes/ desserts $^{\tilde{x},R}$	7.562	[0, 125.5]	6.51	[0, 85.403]	3.781	[0, 85.714]	0.147
Animal based fat ^{R}	1.203	[0, 24.3]	0.968	[0, 8.1]	1.178	[0, 20.25]	0.608
Canned vegetables ^{R}	0.693	[0, 36.45]	0.825	[0, 41.942]	3.087	[0, 72.9]	0.027*
Candies ^{R}	3.429	[0, 51.72]	3.416	[0, 29.826]	2.105	[0, 64.8]	0.012*
Water	1365.19	748.54	1331.57	681.636	1261.18	706.906	0.353
Food groups (%EI)							
Breads	11.906	7.356	11.301	6.817	11.817	7.789	0.99
Cereals $^{\tilde{x},R}$	2.721	[0, 42.986]	1.753	[0, 32.095]	1.297	[0, 37.246]	0.05
Rice $^{\tilde{x},R}$	2.888	[0, 18.023]	2.821	[0, 35.995]	3.444	[0, 21.147]	0.374
Pasta/ noodles $^{\tilde{x},R}$	1.625	[0, 11.021]	1.454	[0, 9.565]	1.508	[0, 16.235]	0.855
Bulgur/ wheat ^{R}	0.287	[0, 6.027]	0.254	[0, 6.566]	0.258	[0, 2.253]	0.183
Pastries $^{\tilde{x},R}$	0.639	[0, 7.813]	0.689	[0, 10.049]	0.537	[0, 8.513]	0.445
Sugar/ jams $^{\tilde{x},R}$	0.496	[0, 7.35]	0.603	[0, 10.078]	0.496	[0, 8.969]	0.575
Biscuit/Chocolate	6.464	4.935	5.475	4.087	5.218	4.473	0.104
Traditional sweets ^{R}	0.665	[0, 4.369]	0.788	[0, 10.374]	0.985	[0, 9.832]	0.996
Ice-cream ^{R}	1.089	[0, 14.806]	1.083	[0, 15.443]	1.206	[0, 10.653]	0.115
Pizzas/ pies $^{\tilde{x},R}$	3.363	[0, 21.928]	4.083	[0, 33.69]	5.023	[0, 27.233]	0.012*
Salty snacks $^{\tilde{x},R}$	4.651	[0, 52.871]	3.048	[0, 42.658]	3.462	[0, 48.552]	0.095
Fast foods	7.704	5.057	8.425	6.607	8.829	6.448	0.449
Legumes $^{\tilde{x},R}$	3.363	[0, 7.029]	1.248	[0, 27.443]	1.526	[0, 11.277]	0.469
Poultry/ organs $^{\tilde{x},R}$	0.861	[0, 15.248]	1.388	[0, 11.713]	1.289	[0, 18.087]	0.026*
Meat/organ meat	4.091	3.993	4.234	3.781	4.325	3.954	0.844

Table 4.9: Intermediate term comparison of food groups intake in the fixed appliances group (n=95) *(Continued)*

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[1]
	Mean	SD	Mean	SD	Mean	SD	
Food groups (%EI)							
Sea food $^{\tilde{x},R}$	0.555	[0, 6.165]	0.935	[0, 5.958]	0.354	[0, 4.986]	0.371
Eggs $^{\tilde{x},R}$	0.753	[0, 5.722]	1.024	[0, 7.226]	0.655	[0, 7.893]	0.26
Processed meat $^{\tilde{x},R}$	0.369	[0, 5.083]	0.689	[0, 8.666]	0.423	[0, 2.871]	0.516
Milk unsweet $^{\tilde{x},R}$	0.611	[0, 13.95]	2.168	[0, 19.512]	0.47	[0, 9.951]	0.485
Dairy products	5.541	4.111	5.085	5.023	5.609	4.669	0.102
Sweet dairy prod.$^{\tilde{x},R}$	0.315	[0, 6.28]	0.263	[0, 4.533]	0.266	[0, 4.744]	0.834
Fruits/dried fruits	3.649	3.327	3.298	2.993	3.931	3.526	0.088
Fresh fruit juices $^{\tilde{x},R}$	0.343	[0, 6.916]	0.257	[0, 10.917]	0.303	[0, 10.812]	0.665
Canned juice/fruits $^{\tilde{x},R}$	0.377	[0, 11.963]	0.21	[0, 5.304]	0.323	[0, 9.997]	0.448
Reg. soft drink $^{\tilde{x},R}$	0.239	[0, 5.715]	0.243	[0, 8.754]	0.12	[0, 7.64]	0.838
Diet soft drinks ^{R}	0.011	[0, 0.216]	0.013	[0, 0.329	0.012	[0, 0.176]	0.547
Olive-oil/ avocado	2.184	1.818	2.692	2.512	3.44	3.241	0.000*
Oil/salad dressings	1.955	1.633	2.693	2.489	2.416	1.819	0.03*
Salad/vegetables $^{\tilde{x},R}$	1.417	[0, 14.947]	1.748	[0, 40.032]	1.99	[0.04, 14.254]	0.031*
Cooked vegetables $^{\tilde{x},R}$	1.065	[0, 14.982]	0.937	[0, 9.466]	1.533	[0, 16.63]	0.373
Mahashi $^{\tilde{x},R}$	0.313	[0, 3.289]	0.376	[0, 2.276]	0.403	[0, 4.886]	0.325
Starchy vegetables ^{R}	0.457	[0, 5.395]	0.344	[0, 6.781]	0.33	[0, 2.2]	0.236
Nuts/ seeds ^{R}	2.77	[0, 20.95]	2.231	[0, 24.462]	2.072	[0, 26.519]	0.219
Pickles/condiment $^{\tilde{x},R}$	0.091	[0, 3.537]	0.115	[0, 5.255]	0.163	[0, 9.543]	0.67

Table 4.9: Intermediate term comparison of food groups intake in the fixed appliances group (n=95) *(Continued)*

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[1]
	Mean	SD	Mean	SD	Mean	SD	
Food groups (%EI)							
Alcoholic beverage [R]	0.026	[0, 0.605]	0.014	[0, 0.661]	0.043	[0, 2.903]	0.565
Coffee/ creamer [R]	5.07	[0, 60.047]	6.054	[0, 64.6]	5.06	[0, 60.484]	0.805
Energy drinks [R]	0.065	[0, 1.255]	0.053	[0, 2.021]	0.058	[0, 2.612]	0.389
Tea [$\tilde{x}$,R]	0.042	[0, 3.787]	0.045	[0, 6.883]	0.034	[0, 5.183]	0.29
Soups/ broth [R]	0.133	[0, 1.575]	0.16	[0, 1.557]	0.261	[0, 2.851]	0.282
Cakes/ desserts [$\tilde{x}$,R]	0.785	[0, 20.826]	0.912	[0, 7.381]	0.723	[0, 16.238]	0.303
Animal based fat [R]	0.251	[0, 4.306]	0.298	[0, 3.201]	0.419	[0, 9.003]	0.475
Canned ve-getables [R]	0.006	[0, 0.294]	0.006	[0, 0.286]	0.026	[0, 0.629]	0.016*
Candies [R]	0.193	[0, 1.959]	0.175	[0, 1.493]	0.167	[0, 3.378]	0.061

		p-value[2]		
		B/5wk	B/13wk	5wk/13wk
Food groups (g/d)	Breads	0.000*	0.001*	0.844
	Cereals	0.001*	0.004*	0.642
	Biscuit/Wafer/Chocolate	0.022*	0.000*	0.161
	Salty snacks	0.001*	0.004*	0.429
	Eggs	0.008*	0.036*	0.699
	Dairy products	0.001*	0.518	0.035*
	Fruits/dried fruits	0.000*	0.038*	0.264
	Starchy vegetables	0.047*	0.019*	0.215
	Nuts/seeds	0.173	0.058	0.558
	Canned vegetables	0.893	0.013*	0.068
	Candies	0.752	0.009*	0.005

Table 4.9: Intermediate term comparison of food groups intake in the fixed appliances group (n=95) *(Continued)*

		p-value[2]		
		B/5wk	**B/13wk**	**5wk/13wk**
Food groups (% EI)	Cereals	0.005*	0.029*	0.682
	Pizzas and pies	0.002*	0.012*	0.46
	Poultry/organs	0.02*	0.057*	0.747
	Olive-oil/Avocado	0.018*	0.000*	0.005*
	Oil/salad dressings	0.011*	0.019*	0.614
	Salad/raw vegetables	0.022*	0.002*	0.818
	Canned vegetables	0.893	0.013*	0.038*

* p-value <0.05

$\tilde{x}$,R For this variable the median is reported instead of the mean, and the range [min, max] instead of the standard deviation (SD)

R For this variable the range [min, max] is reported instead of the standard deviation

1 Refers to the p-value of repeated measures ANOVA/ Friedman test

2 Refers to the p-value of Bonferroni Post-Hok/ Wilcoxon test

Table 4.10: Intermediate term comparison of total and nutrients intake in the expansion subgroup (n=20)

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[3]
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	
Total intake[1]							
Weight	3176.23	1180.39	2384.5	1061.04	2511.32	908.059	0.015*
Energy	2598.43	1187.7	1983.88	986.8	1950.99	717.183	0.017*
Macronutrients intake (g/d)							
Protein	91.887	51.129	60.463	31.355	60.098	25.269	0.011*
Carbs	348.326	168.649	263.314	158.532	247.824	115.356	0.006*
Sugar	103.542	73.598	72.857	46.99	70.579	53.986	0.086
Glucose	17.552	14.645	11.274	9.994	14.211	10.767	0.247
Galac-tose $^{\tilde{x},R}$	0.425	[0.038, 1.83]	0.276	[0.001, 1.235]	0.332	[0.014, 2.506]	0.638
Total Fat	99.202	42.385	80.393	37.446	84.171	32.265	0.186
Cholest.	240.484	173.862	148.167	96.628	152.877	98.693	0.047*
Saturated Fat	28.378	14.37	23.74	11.715	23.379	9.702	0.242
MFA	35.054	15.658	28.083	13.351	31.257	13.36	0.128
PFA	24.599	10.436	20.992	14.148	21.262	9.584	0.091
Oleic Fat	32.17	13.284	26.541	12.617	29.316	12.624	0.162
Linoleic	22.685	9.411	19.737	13.571	19.905	9.236	0.047*
Linolenic	1.255	0.677	1.015	0.645	1.041	0.39	0.212
EPA Om-ega3 $^{\tilde{x},R}$	0.009	[0, 0.259]	0.003	[0.001, 0.026]	0.003	[0, 0.015]	0.005*
DHA O-mega3 $^{\tilde{x},R}$	0.065	[0.004, 110.459]	0.012	[0.001, 69.599]	0.014	[0.002, 55.253]	0.006*
Dietary Fiber	23.397	11.321	17.963	11.814	17.486	7.364	0.043*
Soluble Fiber $^{\tilde{x},R}$	0.315	[0.008, 1.827]	0.306	[0.059, 2.409]	0.347	[0.028, 1.937]	0.819
Insoluble Fiber $^{\tilde{x},R}$	0.827	[0.132, 10.886]	0.722	[0.14, 3.801]	0.696	[0.101, 3.321]	0.157
Crude Fiber $^{\tilde{x},R}$	4.502	[0.618, 50.233]	4.125	[1.023, 42.763]	4.094	[0.929, 42.19]	0.951
Macronutrients intake (%EI)							
Protein	13.819	3.674	12.316	2.236	12.35	2.363	0.24
Carbs	53.522	5.931	51.112	8.695	49.891	9.199	0.338
Sugar	15.256	6.076	14.301	6.117	13.604	5.546	0.387
Total Fat	34.986	4.973	38.445	8.567	39.843	9.537	0.35
Sat. Fat	9.823	2.043	11.168	3.067	10.984	2.647	0.247
Linoleic	8.15	2.239	9.365	4.379	9.64	4.301	0.522
Linolenic	0.432	0.152	0.456	0.11	0.489	0.115	0.212

Table 4.10: Intermediate term comparison of total and nutrients intake in the expansion subgroup (n=20) *(Continued)*

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[3]
	Mean	SD	Mean	SD	Mean	SD	
Micronutrients intake[2]							
Na	3016.79	1539.91	2372.89	1497.08	2278.39	932.502	0.043*
K	2788.65	1345.73	2032.59	1125.27	2095.31	967.467	0.008*
Fe $^{\tilde{x},R}$	29.5	[1.797, 81.213]	13.283	[3.015, 100.863]	16.006	[3.896, 65.605]	0.043*
Ca	1408.15	651.684	1062.45	496.069	1120.68	419.054	0.058
Mg	464.196	177.912	349.847	164.853	366.554	120.216	0.01*
P	1283.08	699.365	901.345	510.799	917.63	384.896	0.043*
Zn	10.748	5.048	7.87	4.176	7.74	2.819	0.021*
Cu	1.606	0.873	1.144	0.683	1.165	0.571	0.086
Mn	5.889	5.31	3.45	2.718	3.611	2.915	0.011*
Cr $^{\tilde{x},R}$	0.168	[0.013, 2.563]	0.087	[0.01, 2.572]	0.149	[0.012, 2.534]	0.287
Vit A $^{\tilde{x},R}$	2962.46	[151.63, 12737.9]	901.163	[116.69, 9840.72]	1207.24	[237.28, 6554.81]	0.015*
βcaro-tene	4162.94	3757.12	2904.75	2237.22	3026.5	2605.83	0.35
Vit B1	3.038	1.915	2.086	1.814	2.031	1.273	0.005*
Vit B2	3.147	2.286	2.282	2.142	2.156	1.551	0.086
Vit B3	40.404	27.955	26.542	24.116	25.873	17.632	0.019*
Vit B6 $^{\tilde{x},R}$	4.949	[0.211, 160.027]	3.751	[0.435, 75.132]	4.256	[0.471, 145.028]	0.449
Vit B9	688.28	484.5	516.231	514.788	494.819	369.261	0.086
Vit B12 $^{\tilde{x},R}$	8.948	[0.335, 49.575]	4.282	[0.797, 28.387]	5.342	[1.137, 22.246]	0.091
Vit.B5	5.219	2.559	3.752	1.99	3.744	1.683	0.022*
Vit C	93.075	69.925	72.098	61.261	78.667	65.567	0.212
Vit D $^{\tilde{x},R}$	4.02	[0.059, 31.533]	2.24	[0.07, 21.789]	3.334	[0.293, 18.198]	0.041
Vit E $^{\tilde{x},R}$	2.258	[0.908, 9.28]	1.667	[0.517, 22.3]	2.337	[0.315, 9.093]	0.35
Vit K	152.567	76.535	113.861	71.216	124.667	72.29	0.065

Table 4.10: Intermediate term comparison of total and nutrients intake in the expansion subgroup (n=20) *(Continued)*

		p-value[4]		
		B/5wk	**B/13wk**	**5wk/13wk**
Tot int-ake	Weight	0.011*	0.084	0.788
	Energy	0.042*	0.015*	1
Macronutrients Intake g/d	Protein	0.023	0.007*	1
	Carbs	0.03*	0.003*	1
	Cholesterol	0.014*	0.011*	0.502
	Linoleic fat	0.167	0.048*	0.737
	EPA-Omega3	0.005*	0.003*	0.737
	DHA-Omega3	0.006*	0.023*	0.296
	Dietary Fiber	0.021*	0.012*	0.97
Micronutrients intake	Na	0.086	0.014*	0.478
	K	0.01*	0.014*	0.332
	Fe	0.025*	0.006*	0.881
	Ca	0.017*	0.04*	0.332
	Mg	0.008*	0.024*	1
	P	0.01*	0.017*	0.455
	Zn	0.049*	0.019*	1
	Mn	0.017*	0.01*	0.737
	Vit A	0.002*	0.017*	0.681
	Vit B1	0.008*	0.005*	0.654
	Vit B3	0.011*	0.001*	0.911
	Vit B5	0.015*	0.005*	0.709
	Vit D	0.044	0.145	0.433

* p-value <0.05

$\tilde{x}^{,R}$ For this variable the median is reported instead of the mean, and the range [min, max] instead of the standard deviation (SD)

[1] For the total intake: weight is reported in grams/day, energy in kilocalories/day

[2] Micronutrients are reported in milligrams/day except for vit A, βcarotene, vit B9, vit B12, vit D and vit k in micrograms/day

[3] Refers to the p-value of repeated measures ANOVA/ Friedman test

[4] Refers to the p-value of Bonferroni Post-Hok/ Wilcoxon test

Table 4.11: Intermediate term comparison of food groups intake in the expansion subgroup (n=20)

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[1]
	Mean	SD	Mean	SD	Mean	SD	
Food groups (g/d)							
Breads	99.275	40.278	84.333	61.805	66.722	39.57	0.001*
Cereals $^{\tilde{x},R}$	64.8	[0, 349.91]	20.132	[0, 487.6]	22.928	[0, 364.49]	0.164
Rice $^{\tilde{x},R}$	65.813	[10.125, 388.8]	48.6	[0, 194.4]	26.131	[11.185, 291.6]	0.244
Pasta/ noodles $^{\tilde{x},R}$	28.894	[0, 194.4]	15.845	[0, 64.8]	24.3	[0, 79.713]	0.297
Bulgur/ wheat ^{R}	3.355	[0, 29.826]	5.437	[0, 74.564]	3.341	[0, 14.913]	0.832
Pastries $^{\tilde{x},R}$	6.477	[0, 33.857]	4.899	[0, 32.857]	7.019	[0, 45]	0.618
Sugar/ jams $^{\tilde{x},R}$	0.804	[0, 37.848]	1.141	[0, 14.175]	0.804	[0, 28.35]	0.556
Biscuit/Ch-ocolate $^{\tilde{x},R}$	24.25	[0.986, 198.4]	13.434	[1.47, 102.41]	18.099	[0.311, 80.765]	0.142
Traditional sweets ^{R}	2.992	[0, 11.31]	2.928	[0, 18.58]	5.428	[0, 34.857]	0.086
Ice-cream $^{\tilde{x},R}$	5.918	[0, 81]	7.94	[0, 81]	9.731	[0, 120]	0.026*
Pizzas/ pies $^{\tilde{x},R}$	35.089	[3.945, 189.04]	20.499	[0, 108.88]	20.499	[3.288, 113.09]	0.196
Salty snacks $^{\tilde{x},R}$	29.962	[0.986, 90.514]	16.885	[0, 283.5]	27.634	[0, 131.57]	0.441
Fast foods	48.013	36.331	40.808	32.885	45.948	34.685	0.522
Legum-es $^{\tilde{x},R}$	22.45	[0, 88.545]	22.369	[0, 82.021]	20.505	[0, 100.29]	0.304
Poultry/ organs $^{\tilde{x},R}$	34.419	[0, 291.6]	7.548	[0, 72]	4.142	[0, 139.31]	0.12
Meat/organ meat $^{\tilde{x},R}$	15.635	[0, 121.02]	18.709	[0, 79.324]	15.862	[0.932, 78.07]	0.316
Sea food $^{\tilde{x},R}$	11.052	[0, 173.13]	3.535	[0, 54.257]	3.886	[0, 76.947]	0.043*
Eggs $^{\tilde{x},R}$	5.918	[0, 25.714]	2.959	[0, 38.571]	1.479	[0, 38.571]	0.079
Processed meat $^{\tilde{x},R}$	3.946	[0, 43.908]	3.551	[0, 40.5]	1.288	[0, 21.291]	0.235
Milk unsweet $^{\tilde{x},R}$	85.05	[0, 623.7]	78.975	[0, 330]	58.47	[0, 311.85]	0.637
Dairy prod.	73.998	63.3	49.097	32.466	56.628	56.061	0.157

Table 4.11: Intermediate term comparison of food groups intake in the expansion subgroup (n=20) *(Continued)*

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[1]
	Mean	SD	Mean	SD	Mean	SD	
Food groups (g/d)							
Sweet dairy prod.[x̃,R]	7.397	[0, 71.429]	4.436	[0, 67.857]	4.851	[0, 83.397]	0.672
Fruits/dried fruits [x̃,R]	153.062	[9.817, 813.35]	56.425	[0, 221.77]	54.393	[0, 225.82]	0.003*
Fresh fruit juices [x̃,R]	2.796	[0, 72.9]	2.097	[0, 178.2]	9.221	[0, 255.15]	0.528
Canned juice/fruits [x̃,R]	16.438	[0, 200]	1.398	[0, 200]	3.288	[0, 114.29]	0.343
Reg. soft drink [x̃,R]	9.321	[0, 330]	1.398	[0, 94.286]	4.194	[0, 109.35]	0.469
Diet soft drinks [R]	11.647	[0, 182.25]	1.692	[0, 21.699]	2.803	[0, 27.123]	0.174
Olive-oil/ avocado [x̃,R]	3.868	[0.675, 20.057]	4.725	[0.466, 53.454]	9.577	[0.675, 56.025]	0.005*
Oil/salad dressing [x̃,R]	4.621	[1.35, 14.796]	2.025	[0.675, 36.45]	4.621	[1.35, 18.225]	0.216
Salad/vegetables [x̃,R]	100.702	[13.585, 431.54]	78.922	[3.419, 485.7]	67.216	[10.359, 526.01]	0.387
Cooked vegetables	82.752	67.133	60.7	51.594	53.993	33.574	0.522
Mahashi [x̃,R]	10.932	[0, 59.143]	5.671	[0, 69.357]	6.199	[0, 34.027]	0.046*
Starchy vegetables [R]	6.455	[0, 54.012]	7.435	[0, 64.8]	6.2	[0, 60.75]	0.789
Nuts/ seeds [R]	8.334	[0, 72.9]	4.141	[0, 16.777]	5.95	[0, 48.6]	0.865
Pickles/condiment [x̃,R]	1.141	[0, 29.36]	2.103	[0, 13.5]	1.971	[0, 20.505]	0.674
Coffee/ creamer [R]	7.049	[0, 85.05]	16.251	[0, 191.36]	5.038	[0, 55.923]	0.717
Energy drinks [R]	1.678	[0, 25.165]	1.568	[0, 20.505]	0.419	[0, 8.388]	0.735
Tea [x̃,R]	11.367	[0, 434.49]	21.102	[0, 387.34]	20.129	[0, 434.49]	0.732
Soups/ broth [x̃,R]	8.388	[0, 129.6]	8.388	[0, 194.4]	9.321	[0, 170.1]	0.901

Table 4.11: Intermediate term comparison of food groups intake in the expansion subgroup (n=20) *(Continued)*

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[1]
	Mean	SD	Mean	SD	Mean	SD	
Food groups (g/d)							
Cakes/ desserts $^{\tilde{x},R}$	6.751	[0, 21.616]	4.701	[0, 11.704]	1.611	[0, 53.888]	0.086
Animal based fat ^{R}	0.726	[0, 14.175]	0.576	[0, 4.05]	0.503	[0, 2.796]	0.166
Canned ve-getables ^{R}	0		0.419	[0, 8.388]	0		0.368
Candies $^{\tilde{x},R}$	0.932	[0, 72.9]	0.164	[0, 13.981]	0.296	[0, 5.592]	0.202
Water	1578.42	1109.32	1223.43	745.904	1358.15	660.343	0.444
Food groups (%EI)							
Breads	13.306	11.028	11.75	5.392	10.037	6.034	0.705
Cereals $^{\tilde{x},R}$	11.528	[0, 31.817]	6.088	[0, 47.612]	6.777	[0, 44.069]	0.589
Rice $^{\tilde{x},R}$	3.423	[0.353, 18.232]	3.177	[0, 23.213]	2.808	[0.982, 14.499]	0.705
Pasta	2.158	1.87	1.721	1.426	2.385	1.576	0.241
Bulgur/ wheat ^{R}	0.129	[0, 0.893]	0.372	[0, 5.685]	0.131	[0, 0.564]	0.689
Pastries $^{\tilde{x},R}$	0.958	[0, 3.953]	0.878	[0, 5.401]	1.322	[0, 6.728]	0.987
Sugar/ jams $^{\tilde{x},R}$	0.17	[0, 5.561]	0.288	[0, 3.36]	0.277	[0, 5.095]	0.273
Biscuit/Ch-ocolate	4.226	2.476	5.053	4.173	4.801	4.508	0.522
Traditional sweets ^{R}	0.504	[0, 1.866]	0.787	[0, 5.602]	1.098	[0, 4.973]	0.205
Ice cream $^{\tilde{x},R}$	0.463	[0, 10.412]	1.069	[0, 9.173]	1.375	[0, 25.632]	0.004*
Pizzas/ pies $^{\tilde{x},R}$	3.816	[0.473, 22.373]	3.057	[0, 20.667]	3.446	[0.75, 14.051]	0.638
Salty snacks $^{\tilde{x},R}$	7.143	[0.507, 26.619]	4.678	[0, 45.061]	5.981	[0, 43.863]	0.729
Fast foods	5.843	3.945	6.731	4.463	7.341	4.537	0.638
Legum-es $^{\tilde{x},R}$	1.115	[0, 5.825]	1.472	[0, 4.812]	1.209	[0, 5.374]	0.704
Poultry/ organs $^{\tilde{x},R}$	2.075	[0, 17.826]	0.972	[0, 4.897]	0.426	[0, 9.131]	0.58
Meat/organ meat $^{\tilde{x},R}$	1.703	[0, 10.02]	1.886	[0, 11.24]	1.878	[0.127, 10.731]	0.449

Table 4.11: Intermediate term comparison of food groups intake in the expansion subgroup (n=20)) *(Continued)*

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[1]
	Mean	SD	Mean	SD	Mean	SD	
Food groups (%EI)							
Sea food $^{\tilde{x},R}$	0.654	[0, 8.539]	0.266	[0, 3.694]	0.521	[0, 5.453]	0.011*
Eggs $^{\tilde{x},R}$	0.48	[0, 2.01]	0.649	[0, 2.24]	0.38	[0, 2.618]	0.164
Processed meat $^{\tilde{x},R}$	0.334	[0, 2.278]	0.428	[0, 2.324]	0.14	[0, 1.486]	0.402
Milk unsweet $^{\tilde{x},R}$	1.179	[0, 11.648	1.851	[0, 8.462]	1.597	[0, 6.864]	0.443
Dairy prod.	3.925	2.721	4.165	2.705	4.156	3.176	0.951
Sweet dairy prod.$^{\tilde{x},R}$	0.36	[0, 2.411]	0.417	[0, 3.987]	0.313	[0, 3.34]	0.876
Fruits/dried fruits $^{\tilde{x},R}$	3.251	[0.627, 21.782]	2.421	[0, 14.383]	1.809	[0, 14.826]	0.212
Fresh fruit juices $^{\tilde{x},R}$	0.108	[0, 1.652]	0.087	[0, 3.567]	0.177	[0, 6.402]	0.641
Canned juice/fruits $^{\tilde{x},R}$	0.507	[0, 4.846]	0.048	[0, 4.96]	0.115	[0, 2.575]	0.522
Reg. soft drink $^{\tilde{x},R}$	0.145	[0, 4.17]	0.023	[0, 1.147]	0.125	[0, 1.429]	0.758
Diet soft drinks ^{R}	0.02	[0, 0.346]	0.004	[0, 0.042]	0.005	[0, 0.044]	0.395
Olive-oil/ avocado $^{\tilde{x},R}$	1.03	[0.189, 4.712]	1.926	[0.227, 14.798]	2.827	[0.812, 8.415]	0.006*
Oil/salad dressing $^{\tilde{x},R}$	1.466	[0.33, 12.235]	1.47	[0.35, 22.702]	2.279	[0.466, 8.543]	0.549
Salad/vegetables	2.56	2.364	2.168	2.078	2.591	2.544	0.819
Cooked vegetables $^{\tilde{x},R}$	1.56	[0.077, 11.133]	2.073	[0, 29.931]	2.213	[0.121, 9.132]	0.861
Mahashi $^{\tilde{x},R}$	0.626	[0, 1.589]	0.522	[0, 2.542]	0.505	[0, 1.968]	0.523
Starchy vegetables ^{R}	0.24	[0, 1.816]	0.299	[0, 1.71]	0.26	[0, 2.262]	0.982
Nuts/ seeds $^{\tilde{x},R}$	0.224	[0, 13.641]	0	[0, 5.488]	1.152	[0, 14.595]	0.717
Pickles/condiment $^{\tilde{x},R}$	0.069	[0, 0.912]	0.094	[0, 0.734]	0.111	[0, 1.101]	0.59

Table 4.11: Intermediate term comparison of food groups intake in the expansion subgroup (n=20) *(Continued)*

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[1]
	Mean	SD	Mean	SD	Mean	SD	
Food groups (%EI)							
Coffee/ creamer [R]	2.572	[0, 35.411]	4.172	[0, 46.055]	1.421	[0, 19.994]	0.832
Energy drinks [R]	0.031	[0, 0.36]	0.036	[0, 0.508]	0.007	[0, 0.15]	0.735
Tea [x̃,R]	0.008	[0, 1.576]	0.017	[0, 3.19]	0.013	[0, 1.734]	0.449
Soups/ broth [x̃,R]	0.151	[0, 1.537]	0.169	[0, 3.641]	0.244	[0, 3.323]	0.342
Cakes/ desserts [x̃,R]	0.77	[0, 2.301]	1.167	[0, 2.942]	0.206	[0, 8.379]	0.086
Animal based fat [R]	0.501	[0, 3.949]	0.22	[0, 1.552]	0.164	[0, 0.931]	0.516
Canned ve-getables [R]	0		0.002	[0, 0.038]	0		0.368
Candies [x̃,R]	0.158	[0, 1.428]	0.037	[0, 0.796]	0.049	[0, 0.506]	0.09

		p-value[2]		
		B/5wk	B/13wk	5wk/13wk
Food groups (g/d)	Breads	0.145	0.006*	0.391
	Ice cream	0.171	0.041*	0.896
	Sea food	0.008*	0.04*	0.327
	Fruits/dried fruits	0.006*	0.014*	0.218
	Olive-oil/Avocado	0.107	0.000*	0.26
	Mahashi	0.314	0.014*	0.554
Food grp (%EI)	Ice cream	0.108	0.028*	0.936
	Sea food	0.008*	0.107	0.277
	Olive-oil/Avocado	0.108	0.002*	0.158

* p-value <0.05

[x̃,R] For this variable the median is reported instead of the mean, and the range [min, max] instead of the standard deviation (SD)

[R] For this variable the range [min, max] is reported instead of the standard deviation

[1] Refers to the p-value of repeated measures ANOVA/ Friedman test

[2] Refers to the p-value of Bonferroni Post-Hok/ Wilcoxon test

Table 4.12: Comparison of maxillary (Mx) and mandibular (md) Little's Irregularity Index (LII) among the study timelines in the fixed appliances group (n=95)

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[2]
	Med[1]	Range	Med[1]	Range	Med[1]	Range	
Mx LII	3.245	[0, 11.96]	1.95	[0, 12.78]	0.93	[0, 10.125]	0.000*
md LII	2.77	[0, 15.065]	1.925	[0, 15.065]	1.075	[0, 15.065]	0.000*

	p-value[3]		
	B/5wk	B/13wk	5wk/13wk
Maxillary LII	0.000*	0.000*	0.000*
Mandibular LII	0.000*	0.000*	0.000*

* p-value <0.05
[1] Refers to the median
[2] Refers to the p-value of Friedman test
[3] Refers to the p-value of Wilcoxon test

Table 4.13: Comparison of maxillary (Mx) and mandibular (md) tooth movement (ΔLII) among the study timelines in the fixed appliances group (n=95)

	B-5wk		5-13wk		B-13wk		p-value[1]
	Mean	Range	Mean	Range	Mean	Range	
ΔMx LII	1.257	[-1.035, 7.17]	0.726	[-1.92, 3.635]	1.983	[-2.68, 7.41]	0.000*
Δmd LII	0.591	[-1.845, 7.075]	0.625	[-0.415, 6.725]	1.216	[-0.8, 7.665]	0.000*

	p-value[2]		
	B-5wk/5-13wk	B-5wk/B-13wk	5-13wk/B-13wk
ΔMaxillary LII	0.01*	0.000*	0.000*
ΔMandibular LII	0.704	0.000*	0.000*

* p-value <0.05
[1] Refers to the p-value of Friedman test
[2] Refers to the p-value of Wilcoxon test

Table 4.14: Comparison of maxillary Little's Irregularity Index (Mx LII) and tooth movement (ΔMx LII) among the study timelines in the expansion subgroup (n=20)

	Baseline (B)		5 Weeks (5wk)		13 Weeks (13wk)		p-value[2]
	Med[1]	Range	Med[1]	Range	Med[1]	Range	
Mx LII	4.463	[1.26, 17.33]	2.148	[0.235, 16.24]	1.46	[0, 14.715]	0.000*
	B-5wk		5-13wk		B-13wk		pvalue[2]
ΔMx LII	2.123	[-0.4, 6.265]	0.638	[-1.215, 3.095]	3.08	[0.645, 8.17]	0.000*

	p-value[3]		
	B/5wk	B/13wk	5wk/13wk
Maxillary LII	0.000*	0.000*	0.001*
	B-5wk/5-13wk	B-5wk/B-13wk	5-13wk/B-13wk
Δ Maxillary LII	0.005*	0.005*	0.000*

* p-value <0.05
[1] Refers to the median
[2] Refers to the p-value of Friedman test
[3] Refers to the p-value of Wilcoxon test

Table 4.15: Comparison of maxillary arch width measurements among the study timelines in the expansion subgroup (n=20)

	Baseline		1 wk expansion[4]		5 weeks		13 weeks		p-value[5]
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
IP[1]	24.86	1.805	28.49	1.733	30.02	2.25	29.99	2.098	0.000*
IM[2]	31.49	2.972	36.96	4.927	38.49	4.15	38.96	3.649	0.000*
II[3]	0.222	[0, 0.9][R]	1.37	[0, 3.28][R]	1.572	[0, 3.46][R]	0.391	[0, 2.09][R]	0.000*

	p-value[6]					
	B/1wkE[4]	B/5wk	B/13wk	1wkE/5wk	1wkE/13wk	5wk/13wk
IP	0.000*	0.000*	0.000*	0.002*	0.012*	0.681
IM	0.000*	0.000*	0.000*	0.641	0.134	1
II	0.000*	0.001*	0.49	0.601	0.002*	0.002*

* p-value <0.05
[R] The range is reported instead of the standard deviation (SD)
[1] Refers to the inter-premolar distance
[2] Refers to the inter-molar distance
[3] Refers to the inter-incisal diastema
[4] Refers to one week post-expansion (1wkE)
[5] Refers to the p-value of repeated measures ANOVA/ Friedman test
[6] Refers to the p-value of Bonferroni Post-Hok/ Wilcoxon test

Table 4.16: Comparison of pain levels in the 1st and 3rd months of treatment the fixed appliances group (n=95)

	Month 1(M1:wk1 to wk5)		Month 3(M1:wk1 to wk4)		p-value[2]
	Mean	Range	Mean	Range	
Mean	11.515	[0, 47.086]	8.253	[0, 98.823]	0.000*
Week 1 (wk1)	32.038	[0, 87.57]	18.815	[0, 97.86]	0.000*
Week 2 (wk2)	9.426	[0, 57.71]	6.43	[0, 99.57]	0.01*
Week 3 (wk3)	6.292	[0, 52]	4.712	[0, 99.43]	0.008*
Week 4 (wk4)	6.446	[0, 84.14]	3.055	[0, 98.43]	0.001*
Week 5 (wk5)	3.372	[0, 69.86]	0.000*		
p-value[1]	0.000*				

* p-value <0.05
[1] Refers to the p-value of Friedman test
[2] Refers to the p-value of Wilcoxon test

Table 4.17: Comparison of pain levels during the expansion week in the expansion subgroup (n=20)

	Expansion week (Ewk)		p-value[2]	
	Mean	Range	Ewk/M1wk1	Ewk/M3wk1
Mean Ewk	29.075	[0, 80.571]	0.204	0.03*
Day 1 (D1)	40.05	[0, 100]	D1/other days	
Day 2 (D2)	35.4	[0, 89]	0.433	
Day 3 (D3)	38.5	[0, 100]	0.629	
Day 4 (D4)	25.45	[0, 100]	0.009*	
Day 5 (D5)	26.525	[0, 100]	0.025*	
Day 6 (D6)	19.475	[0, 67]	0.006*	
Day 7 (D7)	18.125	[0, 70]	0.005*	
p-value[1]	0.000*			

* p-value <0.05
[1] Refers to the p-value of Friedman test
[2] Refers to the p-value of Wilcoxon test

Table 4.18: Comparison of pain levels in the 1st and 3rd months after bonding in the expansion subgroup (n=20)

	Month 1(M1:wk1 to wk5)		Month 3(M1:wk1 to wk4)		p-value[2]
	Mean	**Range**	**Mean**	**Range**	
Mean	11.256	[0, 36.226]	4.94	[0, 21.925]	0.022*
Week 1 (wk1)	26.25	[0, 93.71]	13.786	[0, 71.3]	0.076
Week 2 (wk2)	10.093	[0, 39.57]	3.227	[0, 21.28]	0.013*
Week 3 (wk3)	8.768	[0, 33.86]	1.126	[0, 8.57]	0.019*
Week 4 (wk4)	8.278	[0, 39.14]	1.623	[0, 14.86]	0.05
Week 5 (wk5)	2.893	[0, 35.71]	0.001*		
p-value[1]	0.000*				

* p-value <0.05
[1] Refers to the p-value of Friedman test
[2] Refers to the p-value of Wilcoxon test

Table 4.19: Comparison of dietary changes (Δ) between baseline & 5weeks after bonding across the categories of the fixed appliances group characteristics

	n	Median						
		ΔEn. Kcal/d	ΔFat %EI	ΔFiber g/d	ΔCa mg/d	ΔVit C mg/d	ΔDiary g/d	ΔFruits g/d
Gender								
Males	44	-556.1	1.309	-4.925	-214.6	-23.61	-23.93	-31.87
Females	51	-303.4	3.224	-2.677	-188.3	-7.667	-13.278	-25.2
p-value		0.244	0.44	0.279	0.545	0.374	0.474	0.66
Pubertal stage								
Prepubertal	28	-363.2	1.51	-2.433	-272.1	-24.01	-11.697	-39.08
Postpubertal	63	-579.2	2.202	-6.178	-107.7	-7.667	-16.87	-21.43
p-value		0.744	0.518	0.222	0.267	0.75	0.763	0.627
Socio Economic Status								
Lower SES	59	-399.7	1.048	-3.675	-107.7	-4.693	-15.914	-22.09
Higher SES	33	-507.3	3.847	-5.153	-267.7	-28.9	-32.855	-27.67
p-value		0.742	0.296	0.404	0.476	0.117	0.486	0.693
Mother education level								
School	36	-329.3	1.309	-2.205	-66.47	-7.309	-32.222	-13.61
University	57	-588.9	2.677	-6.223	-210.6	-23.55	-15.006	-35.88
p-value		0.421	0.74	0.256	0.458	0.682	0.508	0.48
Physical activity								
Low	27	-454.9	1.534	-3.013	-218.7	-20.7	-32.885	-25.2
Moderate	48	-326.2	1.818	-3.404	-58.79	-4.574	-15.971	-22.81
High	20	-775.5	3.686	-8.812	-358.9	-33.37	-16.152	-49.45
p-value		0.359	0.181	0.32	0.074	0.246	0.430	0.626
Parent attentive to patient's diet								
Mother	65	-399.7	1.534	-3.133	-197.9	-15.67	-22.107	-27.67
Other	30	-607.6	4.78	-9.017	-154.2	-19.72	-9.574	-26.87
p-value		0.283	0.265	0.061	0.713	0.457	0.532	0.692
Baseline Body Mass Index Weight Status								
Normal	43	-355.2	1.705	-4.698	-78.49	-32.73	-15.914	-31.18
Overweight	37	-588.9	1.048	-6.178	-197.9	-4.693	-28.507	-27.67
Obese	13	-702.7	7.106	-2.266	-218.7	-20.58	-16.937	2.73
p-value		0.78	0.655	0.732	0.957	0.499	0.911	0.277
Number of bonded arches at 5 weeks								
One arch	82	-361.7	2.663	-3.104	-184.1	-15.08	-15.46	-23.14
Two arches	13	-1010	0.355	-11.585	-218.7	-106.7	-70.301	-149.9
p-value		0.006*	0.587	0.024*	0.429	0.045*	0.081	0.06

Table 4.19: Comparison of dietary changes (Δ) between baseline & 5weeks after bonding across the categories of the fixed appliances group characteristics *(Cont'd)*

	n	Median						
		ΔEn. Kcal/d	ΔFat %EI	ΔFiber g/d	ΔCa mg/d	ΔVit C mg/d	ΔDiary g/d	ΔFruits g/d
Sagittal jaws relationship								
Class I	35	-399.7	0.355	-3.675	-210.56	-20.58	-5.476	-22.09
Class II	52	-416.9	3.325	-4.015	-193.12	-15.72	-17.827	-24.55
p-value		0.931	0.35	0.842	0.972	0.849	0.5	0.842
Vertical jaws relationship								
Hypodiv.	14	-407.6	-2.15	-2.95	-237.28	-45.75	-25.82	-35.85
Hyperdiv.	14	-671.5	3.507	-6.227	-159.13	-20.64	-22.384	-38.63
p-value		0.319	0.563	0.399	0.828	0.329	0.769	0.982
Dental overjet								
Normal	16	-785.9	2.96	-6.405	-102.31	-7.241	-10.241	-25.49
Increased	74	-389.3	1.291	-3.233	-201.82	-19.02	-17.827	-26.44
p-value		0.673	0.137	0.534	0.891	0.493	0.966	0.51
Dental overbite								
Open bite	21	-349.1	1.569	-3.133	-0.469	-6.952	2.025	-35.88
Normal bite	33	-371.2	3.224	-3.013	-203.6	-15.76	-6.434	-22.09
Deep bite	41	-523.4	1.534	-5.794	-210.57	-28.89	-33.21	-28.85
p-value		0.462	0.193	0.696	0.357	0.622	0.066	0.741
Need for pain relief during the 1st 5weeks after bonding								
No	44	-377.5	3.385	-4.925	-143.83	-16.47	-13.147	-26.44
Yes	51	-466.2	1.048	-3.075	-200.75	-14.49	-25.766	-28.85
p-value		0.976	0.217	0.852	0.958	0.649	0.244	0.303

* p-value <0.05

Table 5.1: Comparison of macronutrients intake to Dietary Reference Intake (DRI)

	Baseline	5wk	13wk	DRI (norms)
Macronutrients' mean intake %EI				**AMDR [1]**
Protein	13.143	13.317	13.264	10-30%EI
Carbohydrate	51.154	48.917*	49.076*	45-65%EI
Sugar	15.691	15.74	15.199	<25%EI
Total Fat	37.91 [N]	39.886* [N]	39.61* [N]	25-35%EI
Saturated Fat	11.44 [N]	11.907 [N]	11.705 [N]	<8%EI
n-6 PFA (linoleic)	8.229	8.474	8.373	5-10%EI
n-3 PFA (linolenic)	0.467 [N]	0.485 [N]	0.474 [N]	0.6-1.2%EI
Dietary Fiber mean intake g/d				**AI [2]**
Males	27.857 [N]	19.928* [N]	20.783* [N]	38g/d
Females	26.519	20.433* [N]	19.952* [N]	26g/d

* The mean intake is statistically significantly different from corresponding baseline
[N] The mean intake is different from corresponding DRI
[1] Refers to the Acceptable Macronutrient Distribution Range (Sciences, 2004)
[2] Refers to the Dietary Fiber Adequate Intake (Sciences, 2004)

ILLUSTRATIONS

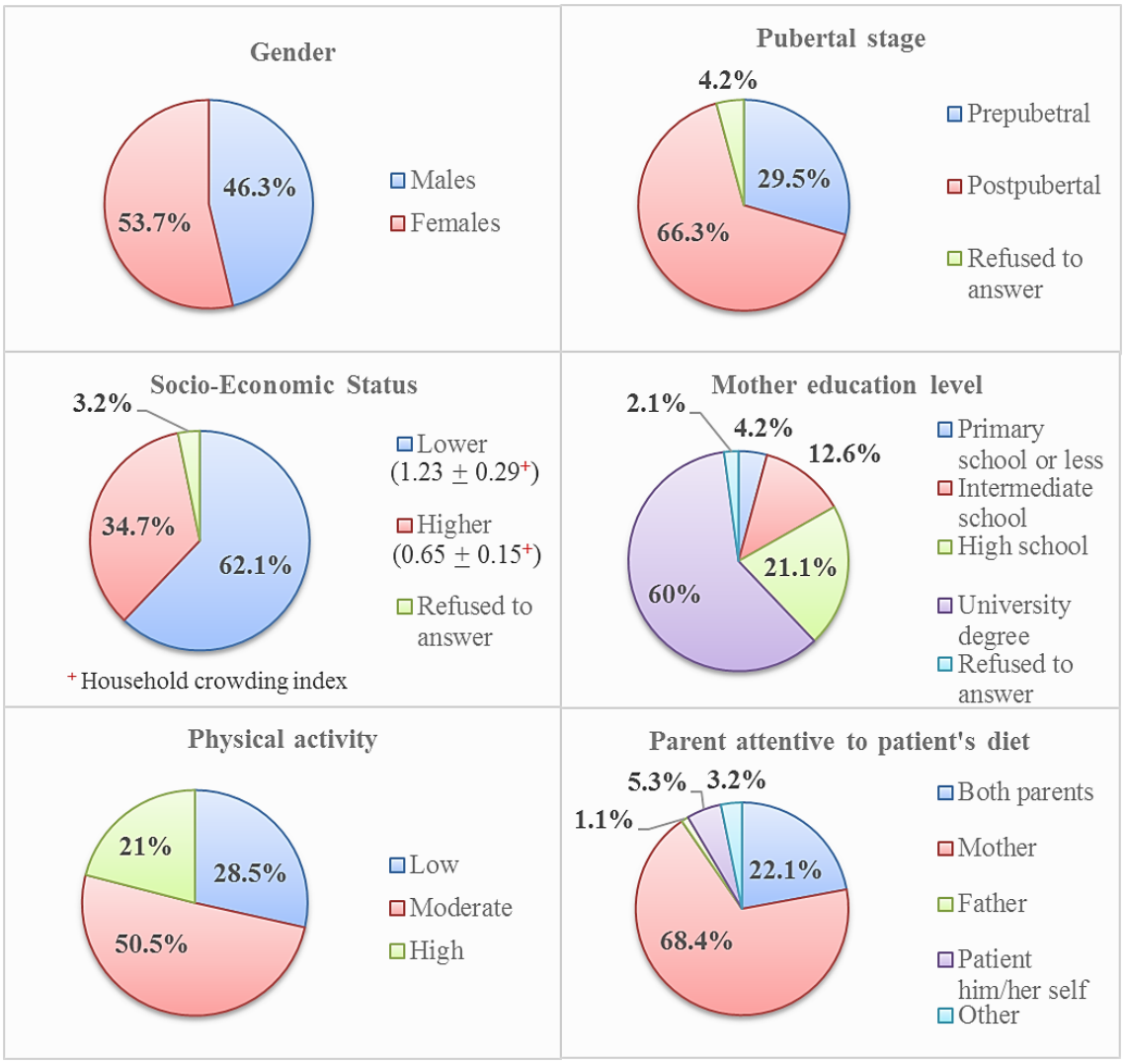

Figure 4.1: Sociodemographic and lifestyle baseline characteristics of the fixed appliances group (n=95; mean age= 14.71 ± 2.83)

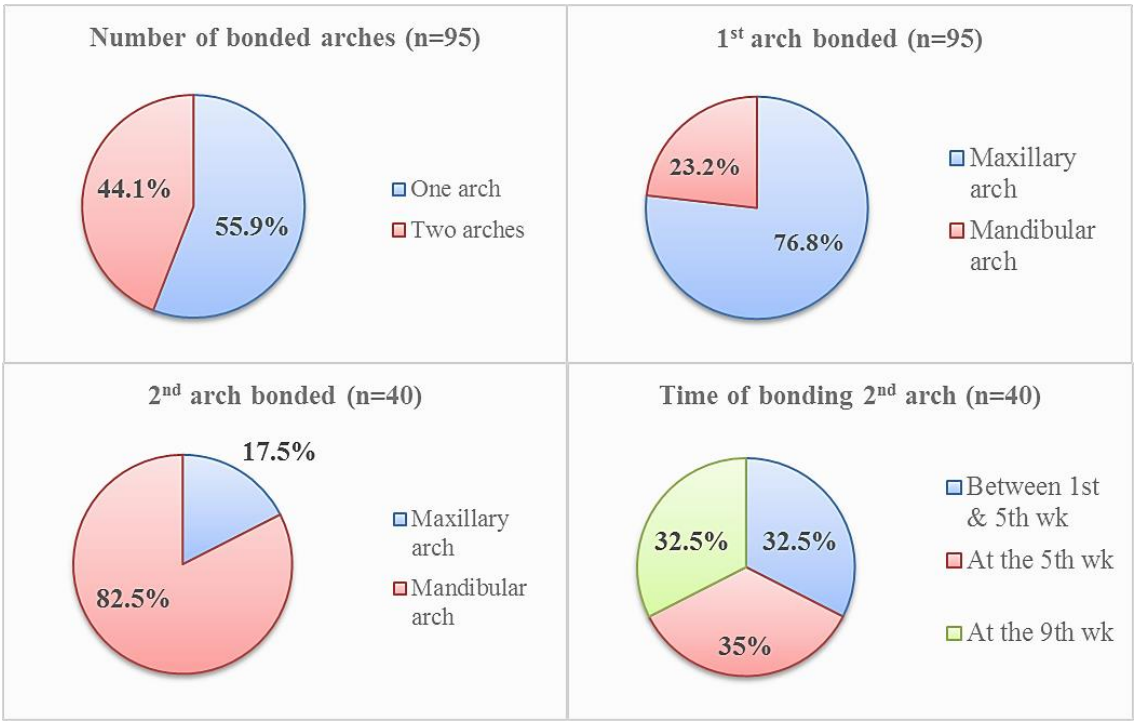

Figure 4.2: Treatment approach in the fixed appliance group

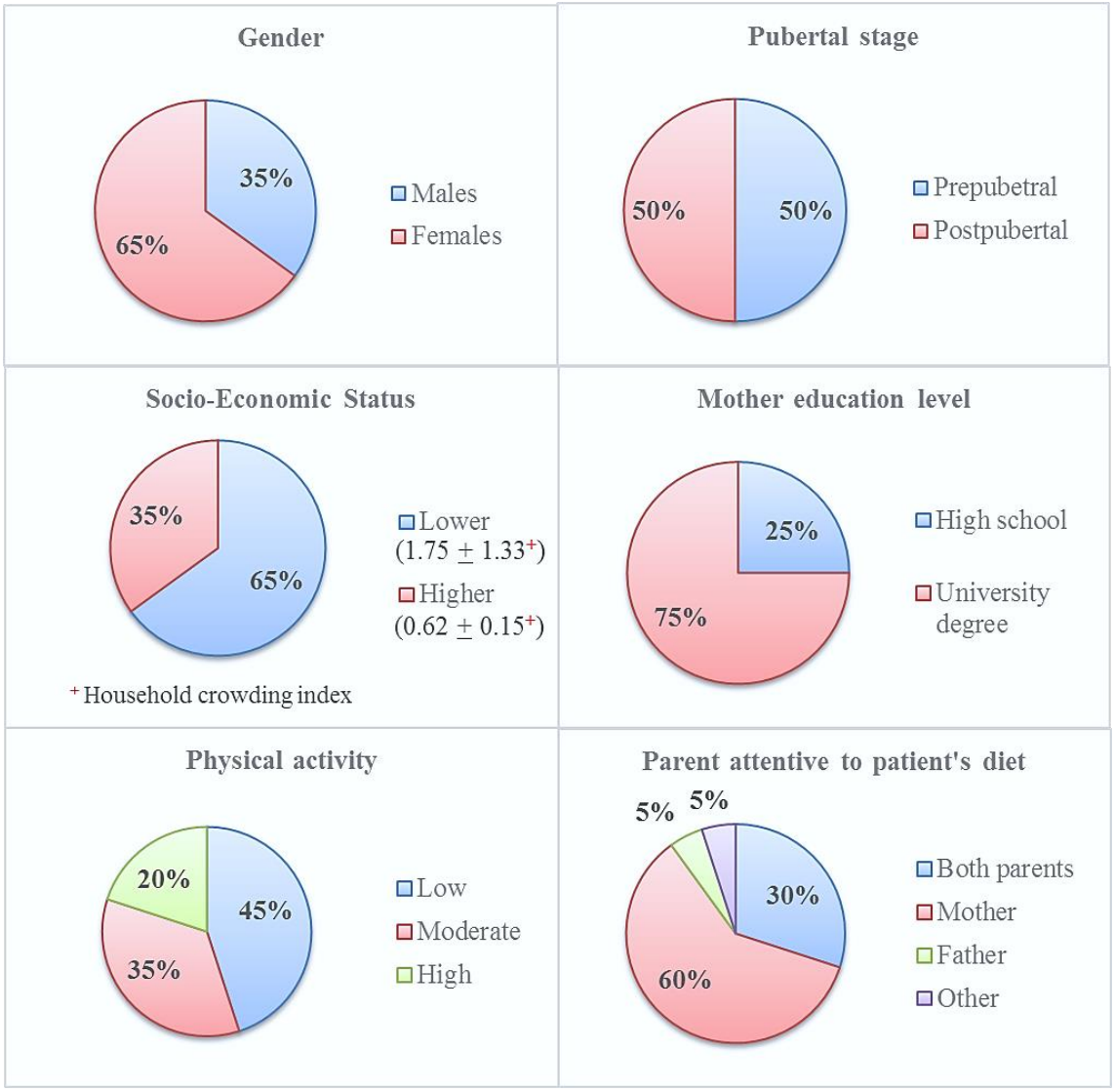

Figure 4.3: Sociodemographic and lifestyle baseline characteristics of the expansion subgroup (n=20; mean age= 12.13 ± 1.2)

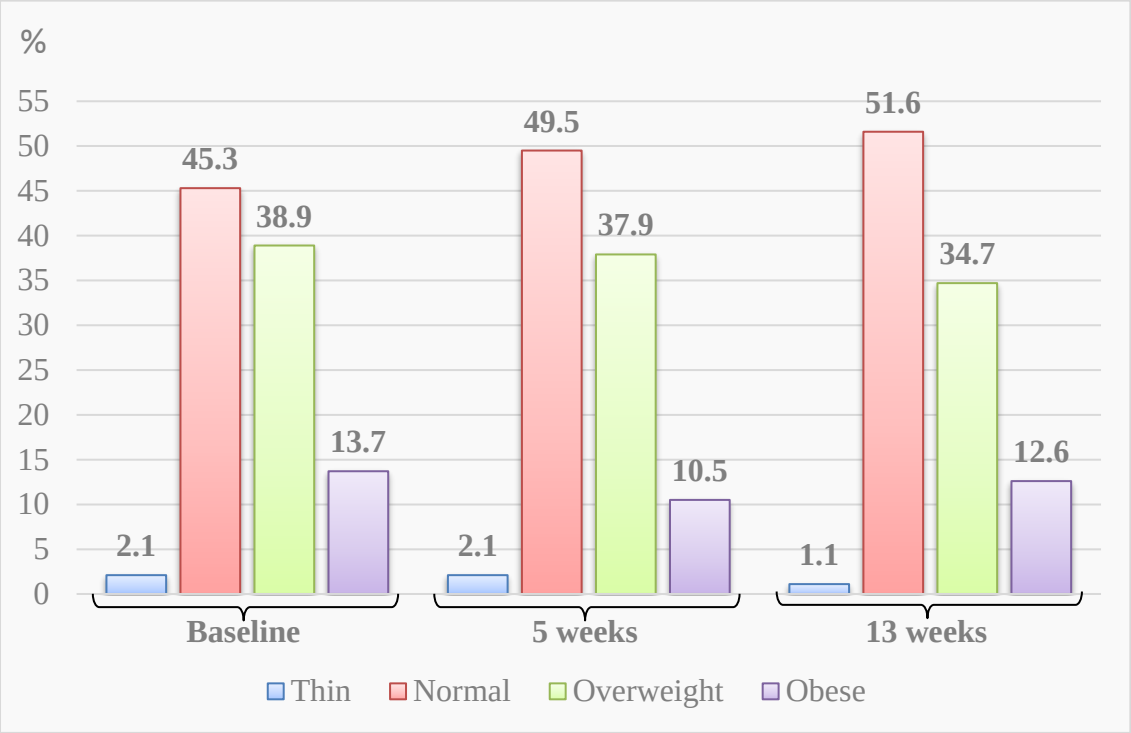

Figure 4.4: Body Mass Index classification across the study timelines in the fixed appliances group (n=95)

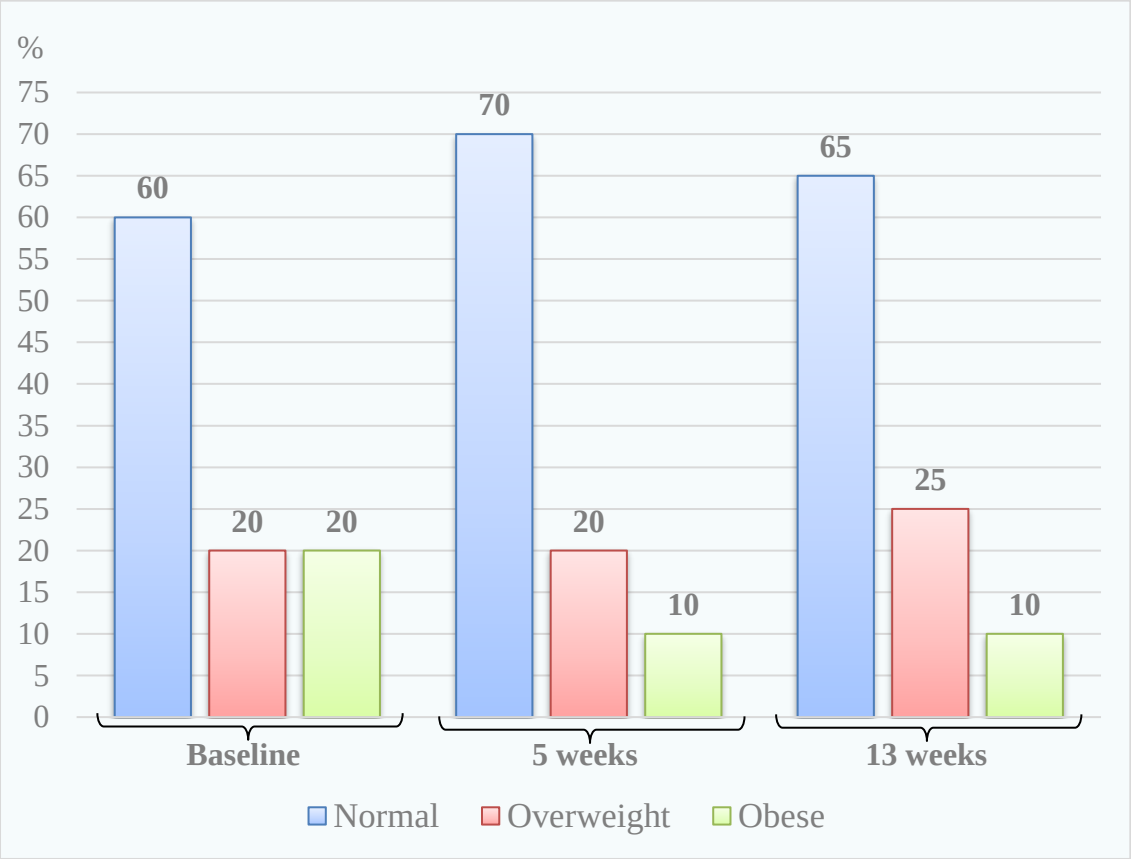

Figure 4.5: Body Mass Index classification across the study timelines in the expansion subgroup (n=20)

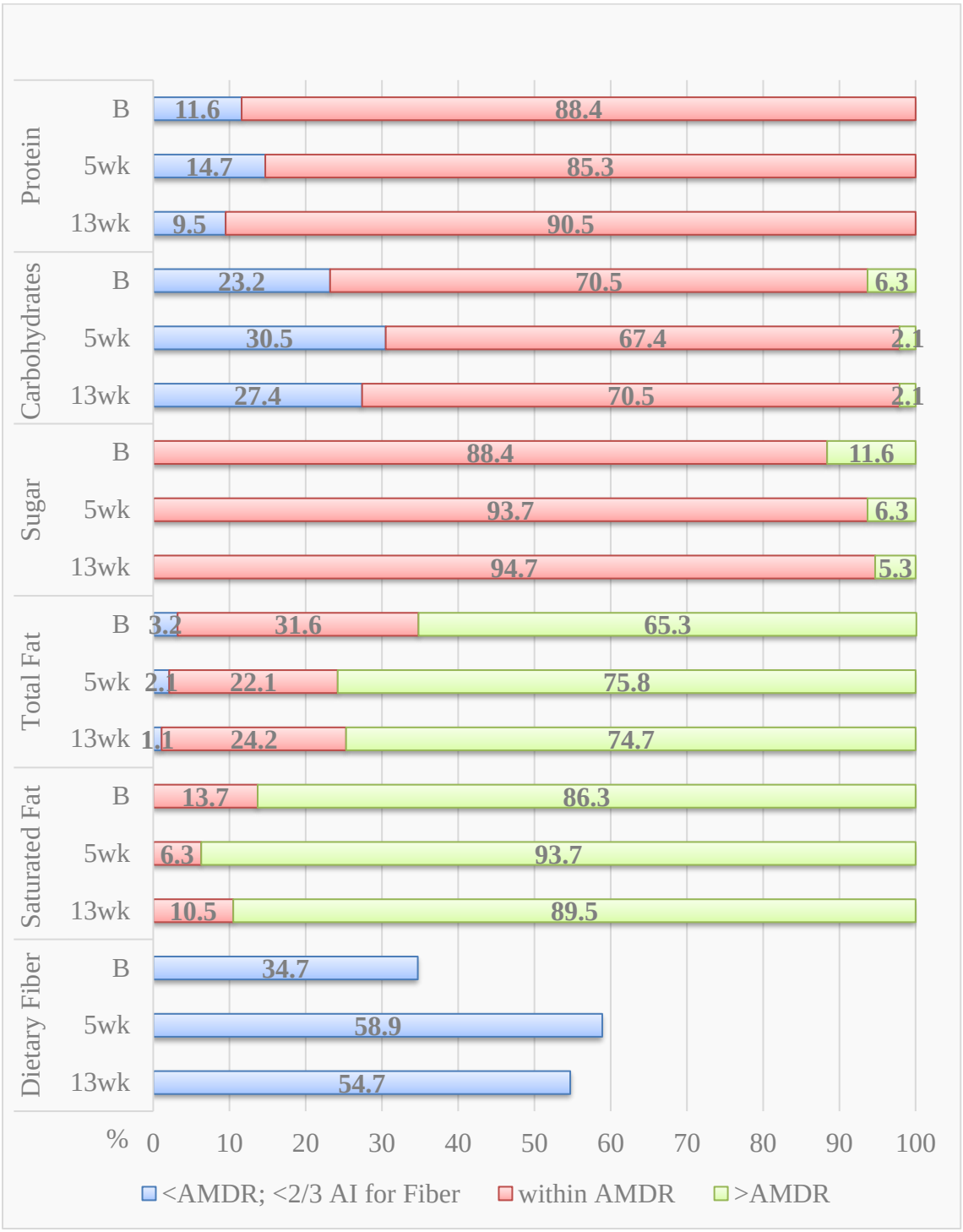

Figure 4.6: Distribution of participant's macronutrients intake relative to the norms (AMDR, and AI for Fiber) at baseline (B), 5 (5wk) and 13 weeks (13wk) in the fixed appliances group (n=95)

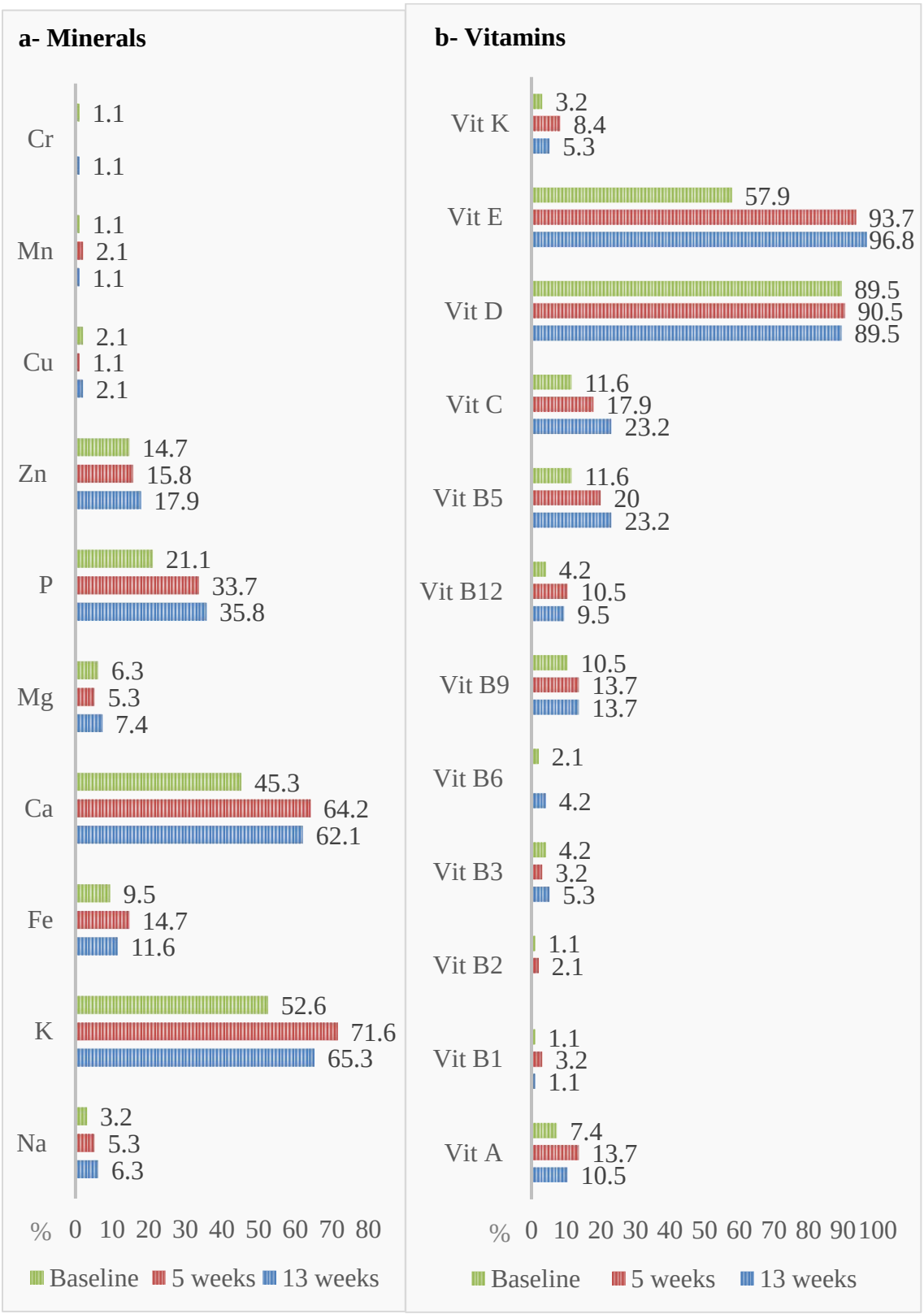

Figure 4.7: Percentage of participants consuming less than 2/3 of the micronutrients' Dietary Reference Intake (DRI) in the fixed appliances group (n=95)

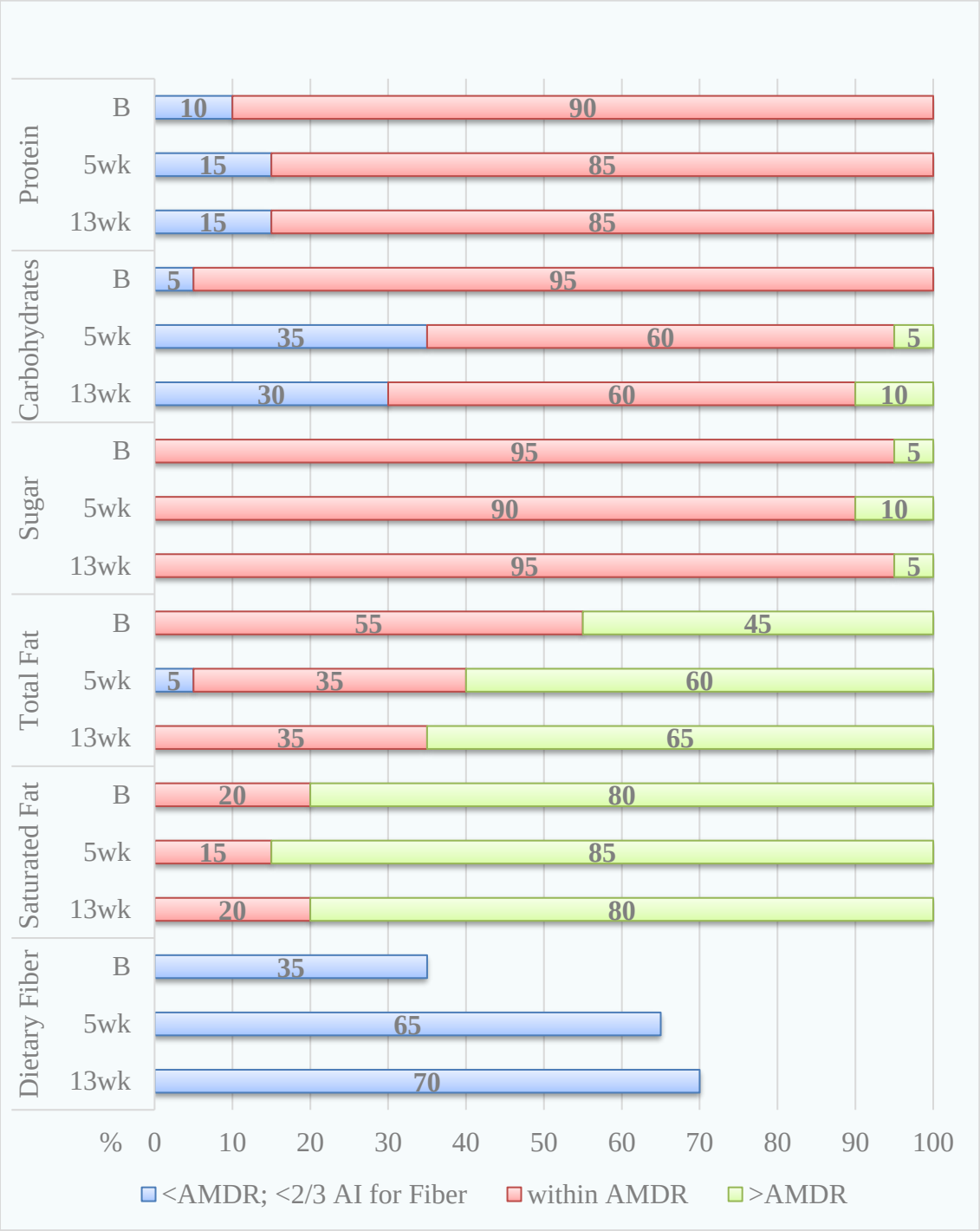

Figure 4.8: Distribution of participant's macronutrients intake relative to the norms (AMDR, and AI for Fiber) at baseline (B), 5 (5wk) and 13 weeks (13wk) in the expansion subgroup (n=20)

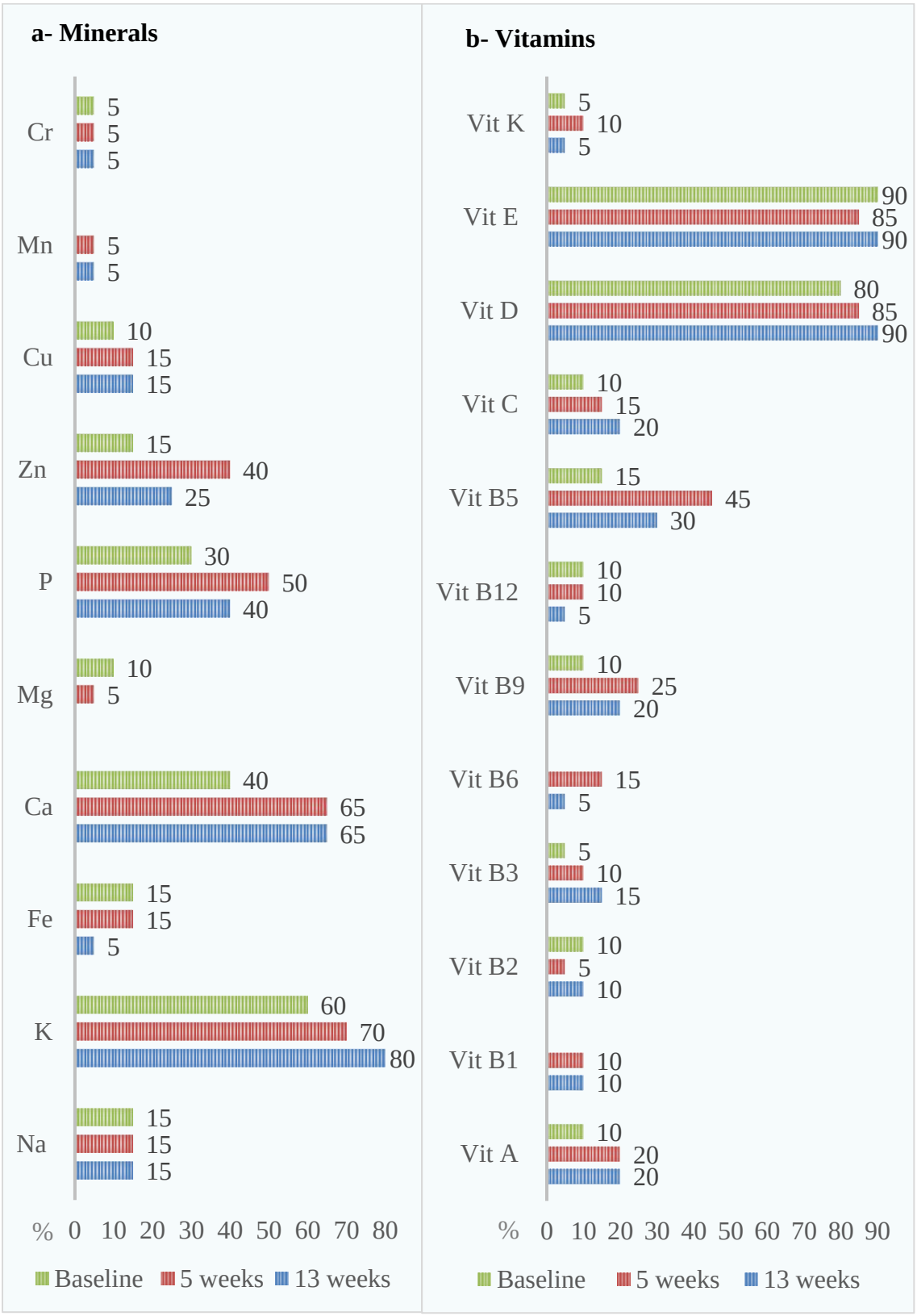

Figure 4.9: Percentage of participants consuming less than 2/3 of the micronutrients' Dietary Reference Intake (DRI) in the expansion subgroup (n=20)

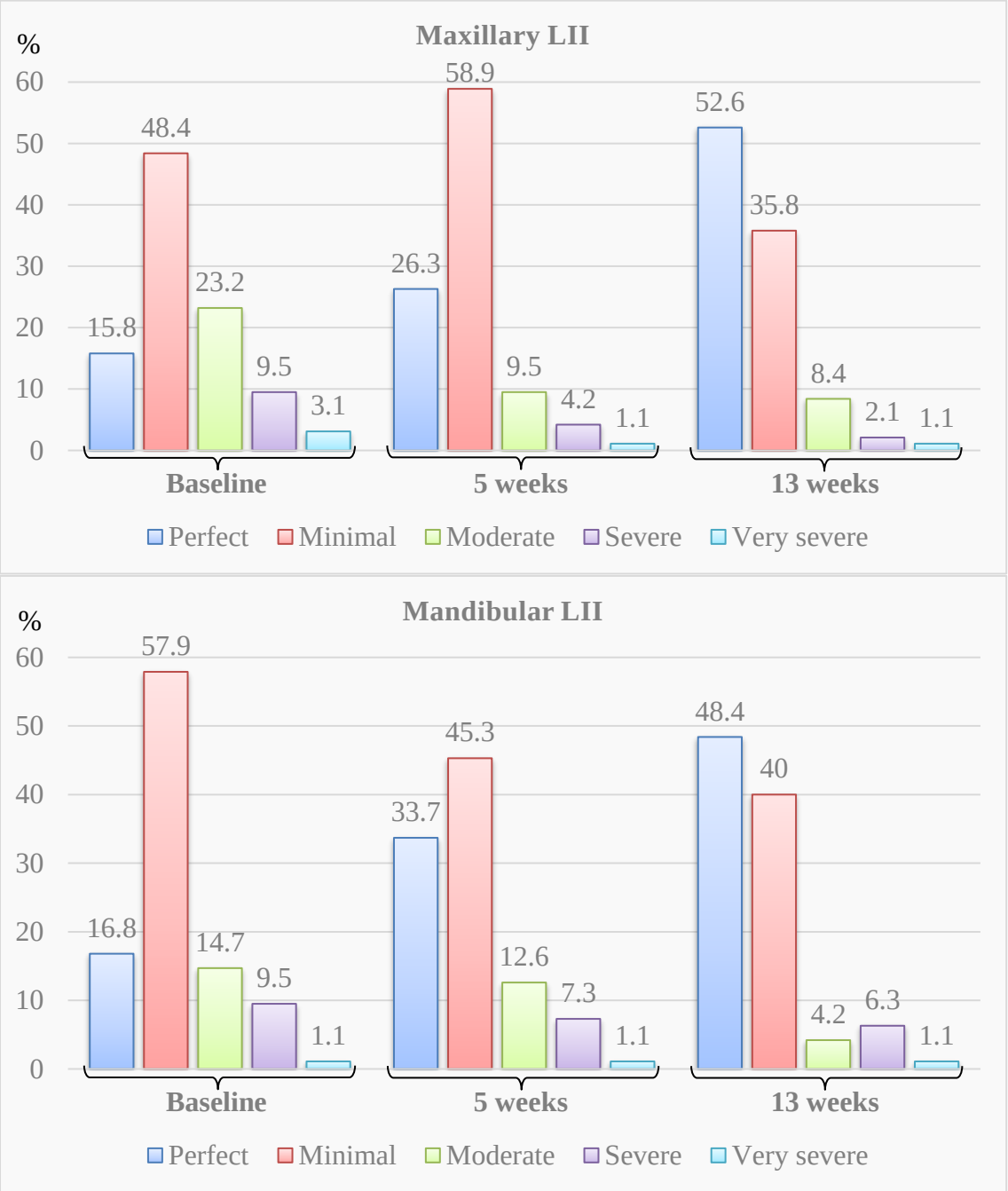

Figure 4.10: Distribution of participants' maxillary and mandibular Little's Irregularity Index (LII) across the LII categories in the fixed appliances group (n=95)

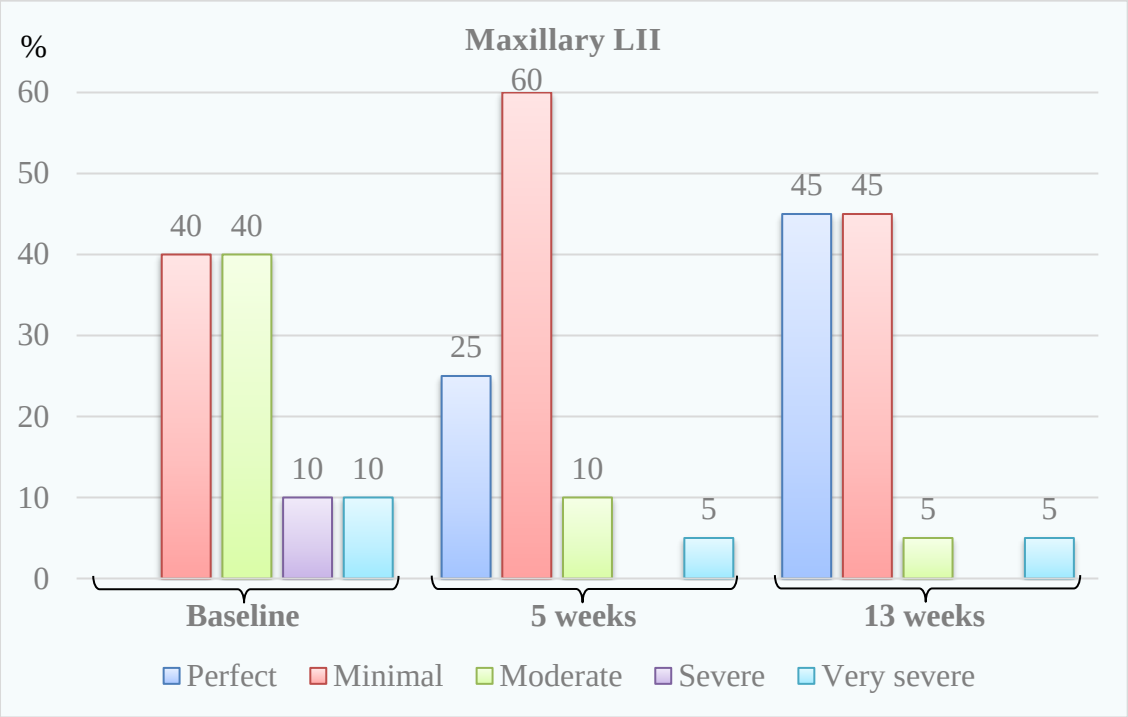

Figure 4.11: Distribution of participants' maxillary Little's Irregularity Index (LII) across the LII categories in the expansion subgroup (n=20)

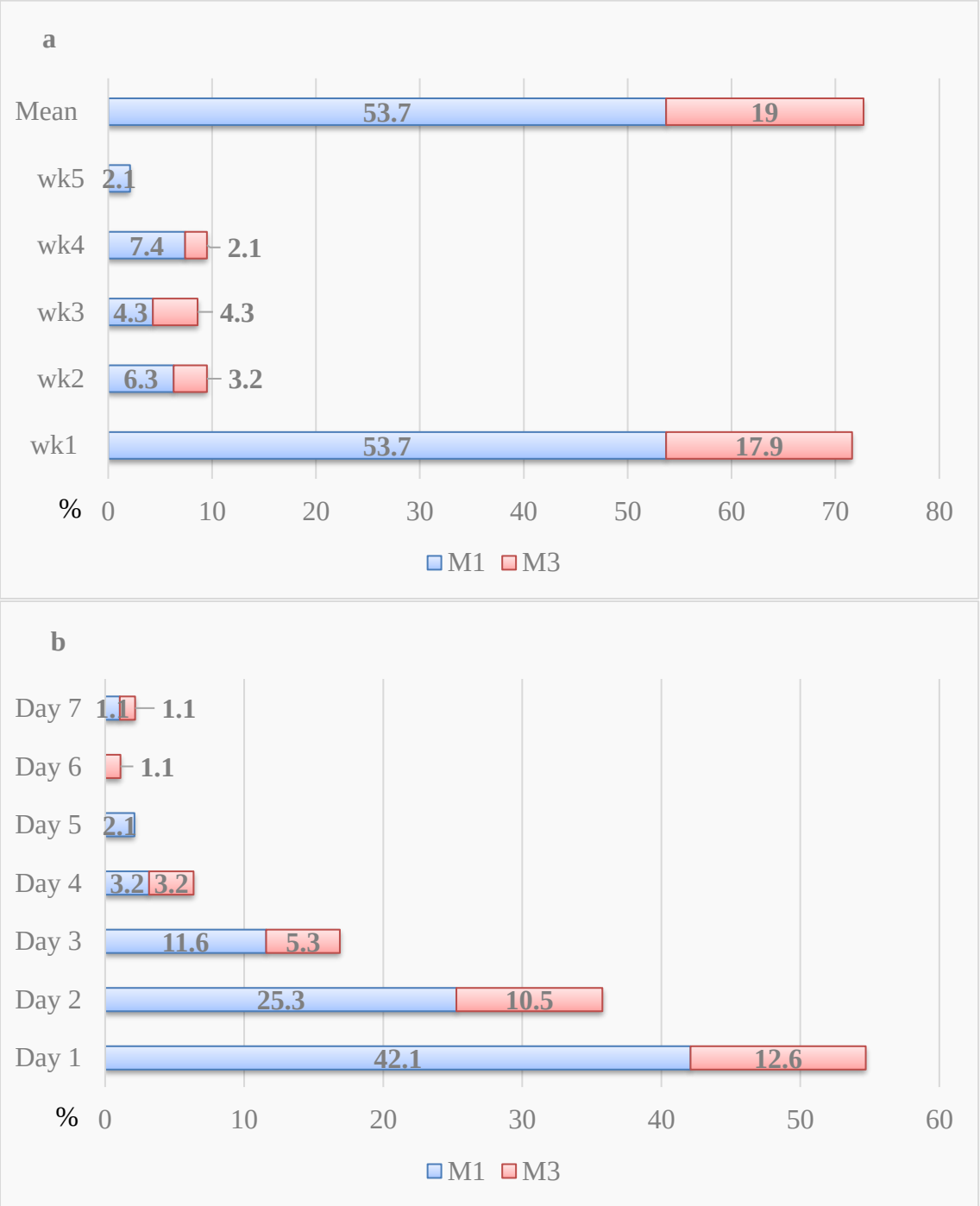

Figure 4.12: Percentage of participants needing pain relief**: a**-At each week (wk) during the 1st (M1) and 3rd month (M3) after bonding; **b**-In each day of the 1st week of M1 and M3 in the fixed appliances group (n=95)

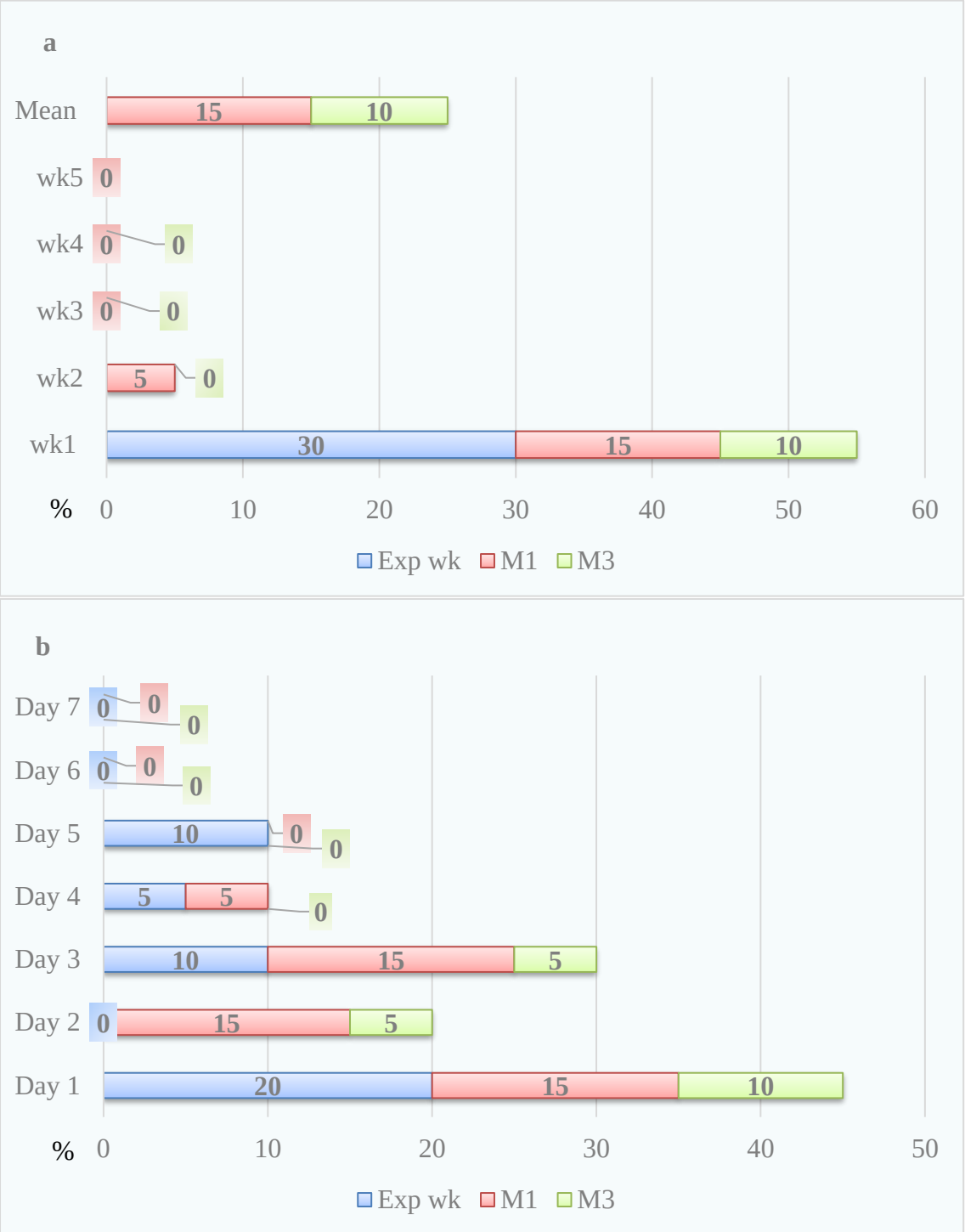

Figure 4.13: Percentage of participants needing pain relief**: a**-During the expansion week (Exp wk) and each week (wk) of the 1st (M1) and 3rd month (M3) after bonding; **b**-In each day of the Exp wk and 1st week of M1 and M3 in the expansion subgroup (n=20)

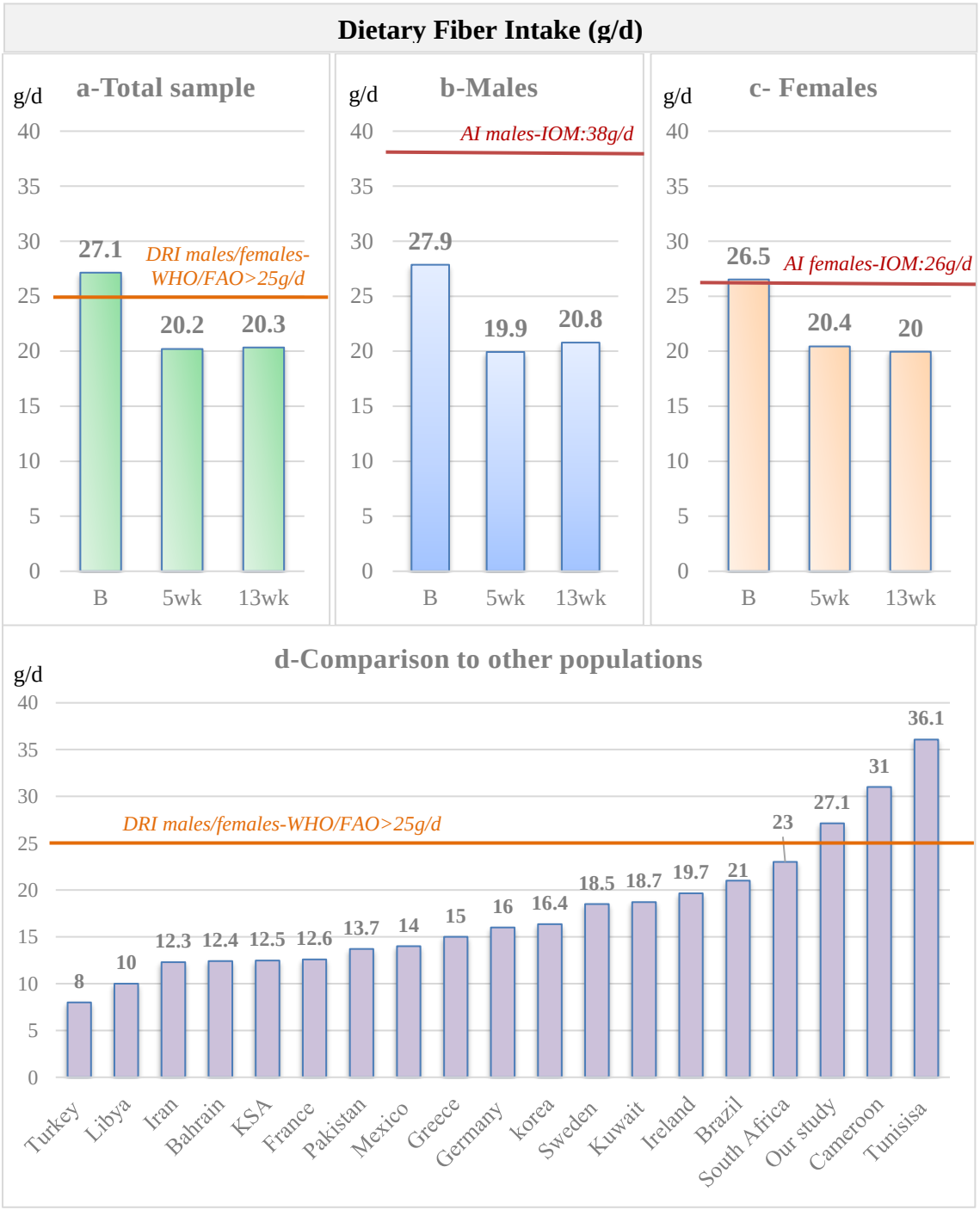

Figure 5.1: Comparison of dietary fiber intake a-Across the study timelines in the total sample to the Dietary Reference Intake (DRI) set by the WHO/FAO; b-Across the study timelines in males to the Adequate Intake (AI) for males set by the IOM; c- Across the study timelines in females to the AI for females set by the IOM; d-Among adolescents in our sample at baseline, neighboring countries and worldwide

Figure 5.2: Comparison total fat intake (%EI) a-Across the study timelines in the total sample to the Dietary Reference Intake (DRI) set by the WHO/FAO and the upper limit of the Acceptable Macronutrients Distribution Range (UL AMDR) set by the IOM; b-Among adolescents in our sample at baseline, Lebanon, neighboring countries and worldwide

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Appendix I

Minor's Initials _____

Institutional Review Board
American University of Beirut
Faculty of Medicine
Bliss Street
Beirut, Lebanon
Tel: (01) 350-000 ext. 5445

CHILD PARTICIPANT ASSENT FORM
(approximate ages 7-12)

Project Title: The association between orthodontic treatment and dietary intake in adolescent patients
Protocol Number: OTO.JG.11 / SBS-2017-0301
Principal Investigator(s): Joseph Ghafari
Co-principal investigator: Lara Nasreddine
Study coordinator: Nancy Abdo
Co-Investigator: Anthony Macari
Address: Division of Orthodontics and Dentofacial Orthopedics, Department of Otolaryngology Head and Neck Surgery, AUBMC, 6th floor, Beirut, Lebanon
Phone: 01/3500000; 5709 (Joseph Ghafari); 71/112603 (Nancy Abdo)
Site where the study will be conducted:
Clinics of the Division of Orthodontics and Dentofacial Orthopedics, Department of Otolaryngology Head and Neck Surgery, American University of Beirut Medical Center, 6th floor

We want to tell you about a research study we are doing. A research study is a special way to find out about something. We are trying to find out more about if the braces that we will receive to straighten your teeth will change the way you eat. You are being asked to join the study because you are still growing and the type of food you eat food influence your growth, health, and teeth alignment. Your participation is voluntary. Ethical approval was sought before initiation of the study from the Institutional Review Board at the American University of Beirut.

If you decide that you want to be in this study, this is what will happen

Once the primary providers (resident and attending) recognize that you are a candidate for the study, they inform the coordinator that you are a potential recruit. During the appointment that precedes placement of the orthodontic appliances or the palatal expander, the primary physician will seek initial approval from you and your guardian to be contacted in regards to the proposed research study by the research coordinator. If you accept, the study coordinator will be called over and will explain thoroughly the research project to you and your parent(s) and ask you if they would be willing to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of it.

To be able to participate in this study you should be:

- Aged between 11 and 21 years
- In need for orthodontic treatment requiring braces to correct your dental crowding and/or malocclusion or expansion to widen your upper jaw
- Having both primary and permanent teeth erupted

If you meet the above mentioned inclusion criteria, the study coordinator will explain the following to you:

- You will be in this study for 13 weeks.
- You will be asked to answer few questions about yourself, your health, family, home, and lifestyle. The questionnaire needs to be filled during your parent's presence as some questions might be difficult to answer by your own
- Before you receive your appliance (braces or expander), you will be called three times over the phone for 20 minutes and asked to state the food you ate the day before, and you will be asked to answer a food questionnaire to state the number of times you ate certain foods in the previous month. The calls will be repeated during the first week after you put the appliance, and the questionnaire will be repeated after 5 weeks and 13 weeks of your treatment. The phone call will start with your parents and then we ask them to give you the phone.
- Your height and weight will be measured before receiving the braces, then after 5 weeks and 13 weeks of treatment during your regular monthly visits to the clinics.
- At the initial appointment of braces placement, you will be given a booklet in which you will grade how much pain you feel from braces when you eat. This will take less than one minute per day. You will be asked to fill this booklet during the first five weeks of treatment, and between week 10 and week 13 of treatment. If your orthodontic treatment requires an expander before braces placement, you will be asked to fill an additional booklet during the first week of expansion.
- Molds of your teeth will be taken before you start with braces, then additional molds after five and thirteen weeks to measure how fast your teeth are moving. If you will have an expander before you start with braces, additional molds will be taken after the first week of expansion. The additional molds will be taken for research purposes by the resident treating you, and this will require an extra 5-7 minutes per session.
- Please note that some of your records taken at our department will be accessed to retrieve data for research purposes.
- When the research time is over, you will continue your treatment normally. There are around 120 other people who will take part in this study.

<u>Can anything bad happen to me?</u>

- Your enrolment in this study will not carry any risks.
- Some questions may cause embarrassment/ upset you. You have the right not to answer any question that might cause you discomfort. However your answers are confidential and used only for research purposes without your name being disclosed.

- The pain you will feel from the braces is normal because teeth are being moved from their original place, to align in a better way. Your doctor will explain that to you during the session of braces placement.
- In order to track the movement of your teeth, molds of your teeth will be taken during your regular visits to the clinic. During this procedure an adequate amount of dental impression material is filled in a tray adequate to the size of your mouth, and held over your teeth for 30 to 45 seconds. Your doctor will give you specific instructions while the tray is your mouth to avoid discomfort.

Can anything good happen to me?

- Depending on your current dental health status, we might be able to give you guidelines to improve oral health.
- We hope to learn something helping other kids at your age who are about to have braces to get good advice from their doctor about what to eat to maintain healthy growth and environment for tooth movement.

Do I have other choices?

You can choose not to be in this study

Will anyone know I am in the study?

- We will not tell anyone you took part in this study.
- When we are done with the study, we will write a report about what we found out. We will not use your name in the report.
- Records will be monitored and may be audited by the IRB while assuring confidentiality.

What happens if I get hurt?

- If there is any problem with your braces, you must tell your treating doctor directly, and he will deal with it accordingly after consulting the attending doctor.
- In case of any complaints or concerns about the study, your parents/legal guardians have been given information on what to do and whom to contact.
- Even if you decide not to be in this study, we will still take care of you.
- Before you say yes to be in this study; be sure to ask Dr. Nancy Abdo to tell you more about anything that you don't understand.

Will I get paid to be in this study?

No, but at the end of the study you will be offered a booklet informing you about healthy eating habits.

If you decide to withdraw from the study you can still receive the specified compensation.

What if I do not want to do this?

You don't have to be in this study. It's up to you. If you say yes now, but you change your mind later, that's okay too. All you have to do is tell us. In all cases we will still take care of you.

If you want to be in this study, please sign or print your name.

☐ Yes, I will be in this research study. ☐ No, I don't want to do this.

_____	_____	_____
Child's name	signature of the child	Date & Time

_____	_____	_____
Person obtaining Assent	signature	Date & Time

Minor's Initials _____

Institutional Review Board
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ADOLESCENT PARTICIPANT ASSENT FORM
(approximate ages 13-17)

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Principal Investigator(s): Joseph Ghafari
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Site where the study will be conducted:
Clinics of the Division of Orthodontics and Dentofacial Orthopedics, Department of Otolaryngology Head and Neck Surgery, American University of Beirut Medical Center, 6th floor

We want to tell you about a research study we are doing. A research study is a special way to find out about something. We are trying to find out more about if the braces that we will receive to straighten your teeth will change the way you eat. You are being asked to join the study because you are still growing and the type of food you eat food influence your growth, health, and teeth alignment. Your participation is voluntary. Ethical approval was sought before initiation of the study from the Institutional Review Board at the American University of Beirut.

WHAT IS INVOLVED IN THE STUDY?

Once the primary providers (resident and attending) recognize that you are a candidate for the study, they inform the coordinator that you are a potential recruit. During the appointment that precedes placement of the orthodontic appliances or the palatal expander, the primary physician will seek initial approval from you and your guardian to be contacted in regards to the proposed research study by the research coordinator. If you accept, the study coordinator will be called over and will explain thoroughly the research project to you and your parent(s) and ask you if they would be willing to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of it.

To be able to participate in this study you should be:

- Aged between 11 and 21 years
- In need for orthodontic treatment requiring braces to correct your dental crowding and/or malocclusion or expansion to widen your upper jaw
- Having both primary and permanent teeth erupted

If you meet the above mentioned inclusion criteria, the study coordinator will explain the following to you:

- You will be in this study for 13 weeks.
- You will be asked to answer few questions about yourself, your health, family, home, and lifestyle. The questionnaire needs to be filled during your parents' presence as some questions might be difficult to answer by your own.
- Before you receive your appliance (braces or expander), you will be called three times over the phone for 20 minutes and asked to state the food you ate the day before, and you will be asked to answer a food questionnaire to state the number of times you ate certain foods in the previous month. The calls will be repeated during the first week after you put the appliance, and the questionnaire will be repeated after 5 weeks and 13 weeks of your treatment. The phone call will start with your parents and then we ask them to give you the phone.
- Your height and weight will be measured before receiving braces, then after 5 weeks and 13 weeks of treatment during your regular monthly visits to the clinics.
- At the initial appointment of braces placement, you will be given a booklet in which you will grade how much pain you feel from braces when you eat. This will take less than one minute per day. You will be asked to fill this booklet during the first five weeks of treatment, and between week 10 and week 13 of treatment. If your orthodontic treatment requires an expander before you start with braces, you will be asked to fill an additional booklet during the first week of expansion.
- Molds of your teeth will be taken before you start with braces, then additional molds after five and thirteen weeks to measure how fast your teeth are moving. If you will have an expander before you start with braces, additional molds will be taken after the first week of expansion. The additional molds will be taken for research purposes by the resident treating you, and this will require an extra 5-7 minutes per session.
- Please note that some of your records taken at our department will be accessed to retrieve data for research purposes.
- When the research time is over, you will continue your treatment normally. There are around 120 other people who will take part in this study.

WHAT MAKES THIS DIFFERENT FROM THE USUAL TREATMENT?

- You will be receiving the usual treatment (braces or expansion) as discussed with your doctor to align your teeth.
- The experimental part of this study is analyzing the types of food you are eating during your treatment and check if this is different from what you used to eat before treatment. The molds that will be taken for your teeth will be used to evaluate if the speed of your teeth alignment is affected by what you are eating,

because previous studies on animals demonstrated that food lacking some types of vitamins slow down teeth alignment and consequently elongate the treatment duration.

WHAT ABOUT CONFIDENTIALITY?

Every reasonable effort will be made to keep your records confidential. The data will be stored in a locked file cabinet and on password protected computer in the Division of Orthodontics and Dentofacial Orthopedics. It will be only accessible to the study team. However, while you are in this study we do have to let some people look at your records. These people can see your records:

- The IRB (for the protection of human subjects in research): Records will be monitored and may be audited by the IRB while assuring confidentiality.

- The study coordinator and the research team.

We will keep your records confidential unless we are required by law to share any information.

WHAT IF YOU ARE INJURED IN THE STUDY?

- If there is any problem with your braces, you must tell your treating doctor directly, and he will deal with it accordingly after consulting the attending doctor.
- In case of any complaints or concerns about the study, your parents/legal guardians have been given information on what to do and whom to contact.

WHAT ARE THE COSTS?

There are no costs associated with your participation.

WILL YOU GET PAID TO BE IN THIS STUDY?

You will not get paid for participating in this study. However, at the end of the study you will be offered a booklet informing you about healthy eating habits.

If you decide to withdraw from the study you can still receive the specified compensation.

WHAT ARE YOUR RIGHTS AS A RESEARCH SUBJECT?

- Being in this study is voluntary. You don't have to be in this study if you don't want to or you can stop being in the study at any time. Your decision will not result in any penalty or loss of benefits that you have now, and will not affect the course of your orthodontic treatment.
- If you have questions about your rights you may call: Institutional Review Board on 01-350000 ext. 5445
- You will be told about any new information that may affect your health, welfare, or willingness to stay in this study.

AGREEMENT TO BE IN THE STUDY

Refusal to participate or withdraw from the study will involve no penalty of loss of benefits to which you are otherwise entitled and will not affect your relationship with your doctor, the level of care being received and neither will it affect your relationship with AUB/AUBMC.

Your signature below means that you have read the above information about the study and have had a chance to ask questions to help you understand what you will do in this study. Your signature also means that you have been told that you can change your mind later if you want to. You will be given a copy of this assent form. By signing this assent form you are not giving up any of your legal rights.

_____	_____
NAME OF SUBJECT	AGE
_____	_____
SIGNATURE OF SUBJECT	DATE & Time

_____	_____	_____
PERSON OBTAINING ASSENT	SIGNATURE	DATE & Time

Adult's initials _____

Institutional Review Board
American University of Beirut
Faculty of Medicine
Bliss Street
Beirut, Lebanon
Tel: (01) 350-000 ext. 5445

Consent to participate in a research study

Project Title: The association between orthodontic treatment and dietary intake in adolescent patients
Protocol Number: OTO.JG.11 / SBS-2017-0301
Principal Investigator(s): Joseph Ghafari
Co-principal investigator: Lara Nasreddine
Study coordinator: Nancy Abdo
Co-Investigator: Anthony Macari
Address: Division of Orthodontics and Dentofacial Orthopedics, Department of Otolaryngology Head and Neck Surgery, AUBMC, 6th floor, Beirut, Lebanon
Phone: 01/350000; 5709 (Joseph Ghafari); 71/112603 (Nancy Abdo)
Site where the study will be conducted:
Clinics of the Division of Orthodontics and Dentofacial Orthopedics, Department of Otolaryngology Head and Neck Surgery, American University of Beirut Medical Center, 6th floor

You are being asked to participate in a clinical research study conducted at the American University of Beirut. Please take time to read the following information carefully before you decide whether you want to take part in this study or not. Feel free to ask your doctor if you need more information or clarification about what is stated in this form and the study as a whole. Your participation is voluntary. Ethical approval was sought before initiation of the study from the Institutional Review Board at the American University of Beirut.

1) Purpose of the research study and overview of participation

Purpose: The purpose of this study is to check if the orthodontic appliance(s) (braces or expander) we are inserting on your teeth to align them and/or expand your upper jaw, will change your diet. It will serve for evaluating if you are prone to nutritional restriction during treatment and if this will affect the speed of your teeth movement.

Duration and overview of participation:
Once the primary providers (resident and attending) recognize that you are a candidate for the study, they inform the coordinator that you are a potential recruit. During the appointment that precedes placement of the orthodontic appliances or the palatal expander, the primary physician will seek initial approval from you and your guardian to

be contacted in regards to the proposed research study by the research coordinator. If you accept, the study coordinator will be called over and will explain thoroughly the research project to you and your parent(s) and ask you if they would be willing to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of it.

To be able to participate in this study you should be:

- Aged between 11 and 21 years
- In need for orthodontic treatment requiring braces to correct your dental crowding and/or malocclusion or expansion to widen your upper jaw.
- In a late mixed or permanent dentition.

If you meet the above mentioned inclusion criteria, the study coordinator will explain the following to you:

- You will be enrolled in this study for 13 weeks.
- During the visit that precedes the appliance placement, you will be asked to answer few questions about yourself, your health, family, home, and lifestyle. The questionnaire needs to be filled during your parents' presence as some questions might be difficult to answer by your own.
- Before receiving your appliance, your dietary intake will be assessed by calling you three times over the phone for 20 minutes to state the food you ate the day before, and you will be asked to answer a food questionnaire to state the number of times you ate certain foods in the previous month. The calls will be repeated during the first week after you put the appliance, and the food questionnaire will be repeated after 5 weeks and 13 weeks of your treatment. The phone call will start with your parents and then we ask them to give you the phone.
- Your height and weight will be measured before receiving the braces, then after 5 weeks and 13 weeks of treatment during your regular monthly visits to the clinics to determine the effect of your dietary behavior during treatment on your body weight.
- At the initial appointment for braces placement, you will be given a booklet in which you will grade how much pain you feel from braces when you eat. This will take you less than one minute per day. You will be asked to fill this booklet during the first five weeks of treatment, and between week 10 and week 13 of treatment to evaluate the association between pain generated during orthodontic treatment and nutritional intake. If your orthodontic treatment requires an expander before braces placement, you will be asked to fill an additional booklet during the first week of expansion.
- Molds of your teeth will be taken before receiving braces, then additional molds after 5 weeks and 13 weeks of treatment to measure how fast your teeth are moving in correlation with the nutritional intake. If you will have an expander before you start with braces, additional molds will be taken after the first week of expansion. The additional molds will be taken for research purposes by the resident treating you, and this will require an extra 5-7 minutes per session.
- Please note that some of your records taken at our department will be accessed to retrieve data for research purposes.

- When the research time is over, you will continue your treatment normally. There are around 120 other people who will take part in this study.

2) Any risks as a result of participating in the study

- Your enrolment in this study will not entail any risks.
- Some questions will trigger sensitive topics like puberty, and answering some of them may cause embarrassment/ upset you. You have the right not to answer any question that might cause you discomfort. However your answers are confidential and used only for research purposes without your name being disclosed.
- The regular orthodontic potential side effects are explained to you upon initiation of orthodontic treatment. Those possible side effects are related to the routine orthodontic treatment and not related to your enrollment in this study. The pain that you might be feeling from braces is normal because teeth are being moved from their original place, to align in a better way. Your doctor will explain that to you during the session of braces placement.
- In order to track the movement of your teeth, impressions of your teeth will be taken during your regular visits to the clinic. For this procedure, a minimal amount of dental impression material is filled in a tray adequate to the size of your mouth, and held over your teeth for 30 to 45 seconds. Your doctor will give you specific instructions while the tray is your mouth to avoid discomfort.

For more information about these risks and side effects, ask your doctor, or Dr. Joseph Ghafari or Dr. Nancy Abdo.

3) Any benefits as a result of participating in the study

- Depending on your current dental health status, we might be able to give you guidelines to improve oral health.
- The total data collected from your and other participants will increase the general knowledge about the association between orthodontic treatment and food intake, and help the orthodontists understand the importance of giving ~~personalized~~ dietary guidelines to their patients, following them up and motivating them to improve their dietary habits.

4) Any alternative treatment

This study does not test different alternatives of treating your teeth mal-alignment. You will be included in this study if you are receiving fixed braces or expansion. The only alternative is not to participate in this study.

5) Confidentiality

- If you agree to participate in this research study, the information will be kept confidential and used solely for research purposes.
- Records will be monitored and may be audited by the IRB while assuring confidentiality.
- When the study is concluded, the data will be stored in the Division of Orthodontics and Dentofacial Orthopedics.

- All data from this study will be maintained in a secure locked drawer in a locked office or on a password protected computer.
- Data will only be reported in the aggregate. No names of individual participant will be disclosed in any reports or presentations of this research.
- Your research data may be reviewed by the AUB Institutional Review Board or Office of Human Research Protections.

After the conclusion of the study, the Principal Investigator will retain all original study data in a secure location for at least three years to meet institutional archiving requirements. After this period, data will be responsibly destroyed.

6) Compensation & treatment available if injury

Should there be any problem usually encountered in the regular orthodontic practice, it will be dealt with accordingly.

7) Incentives:

If you agree to participate in this research, at the termination of the study you will be offered an instructive booklet about healthy eating habits.
If you decide to withdraw from the study you can still receive the specified compensation.

8) Participant rights

- Your participation in this study is voluntary and you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled. In addition, your decision will not affect your relationship with your physician, the level of care being received and neither will it affect your future relationship with AUB/AUBMC.
- By signing this form, you do not give up any personal legal rights you may have as a participant in this study.
- The Institutional Review Board responsible for human subjects research at AUB has reviewed this research project and found it to be acceptable, according to applicable Lebanese and U.S. federal regulations and AUB policies designed to protect the rights and welfare of participants in research.

9) Contacts and Questions

For questions, or clarifications about the study you may contact:

Dr. Joseph Ghafari
+961 3313252
jg03@aub.edu.lb

Nancy Abdo
+961 71 112603
na182@aub.edu.lb

For more questions about your rights as a participant in this study, or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the AUB Institutional Review Board on:
01-350000 – 5445; Fax: 000961 1 738025; irb@aub.edu.lb

Signature section

I have read (or someone has read to me) and understood all aspects of the research study form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study, and I know that I can contact **Dr. Nancy Abdo** at **+961 71 112603** or any of her designee involved in the study in case of any questions. If I feel that my questions have not been answered, I can contact the Institutional Review Board for human rights at **01-350000 – 5445**. I understand that I am free to withdraw this consent and discontinue my participation in this project at any time, even after signing this form, and it will not affect my care or benefits.
I am not giving up any legal rights by signing this form, and I know that I will receive a copy of this signed informed consent form.

Name of Patient or Legal Representative or Parent/Guardian	**Signature**
Date & Time	
Witness's Name (if patient, representative or parent does not read)	**Witness's Signature**
Date & Time	

Investigator's Statement:

I have reviewed, in detail, the informed consent document for this research study with _____ (name of patient, legal representative, or parent/guardian) the purpose of the study and its risks and benefits. I have answered to all the patient's questions clearly. I will inform the participant in case of any changes to the research study.
There are no blanks in this document. A copy of this form has been given to the participant/subject.

Name of Investigator or designee	**Signature**
Date & Time	

Parent's initials: _____

Institutional Review Board
American University of Beirut
Faculty of Medicine
Bliss Street
Beirut, Lebanon
Tel: (01) 350-000 ext. 5445

Permission for child to participate in a research study

Project Title: The association between orthodontic treatment and dietary intake in adolescent patients
Protocol Number: OTO.JG.11 / SBS-2017-0301
Principal Investigator(s): Joseph Ghafari
Co-principal investigator: Lara Nasreddine
Study coordinator: Nancy Abdo
Co-Investigator: Anthony Macari
Address: Division of Orthodontics and Dentofacial Orthopedics, Department of Otolaryngology Head and Neck Surgery, AUBMC, 6th floor, Beirut, Lebanon
Phone: 01/3500000; 5709 (Joseph Ghafari); 71/112603 (Nancy Abdo)
Site where the study will be conducted:
Clinics of the Division of Orthodontics and Dentofacial Orthopedics, Department of Otolaryngology Head and Neck Surgery, American University of Beirut Medical Center, 6th floor

- **This is a permission form for your child for whom you are legal guardian to participate in a research study conducted at the American University of Beirut**. It contains important information about this study and what to expect if you decide to permit your child to participate.
- **Your child's participation is voluntary.**
- Please take time to read the following information carefully before you decide whether you permit your child to take part in this study or not. Feel free to ask the study coordinator if you need more information or clarification about what is stated in this form and the study as a whole. Ethical approval was sought before initiation of the study from the Institutional Review Board at the American University of Beirut.

1) Purpose of the research study and overview of participation

Purpose: The purpose of this study is to check if the orthodontic appliance(s) (braces or expander) we are inserting on your child's teeth to align them and/or expand the upper jaw, will change his/her diet. It will serve for evaluating if your child is prone to nutritional restriction during treatment and if this will affect the speed of his/her teeth movement.

Duration and overview of participation:
Once the primary providers (resident and attending) recognize that your child is a candidate for the study, they inform the coordinator that he/she is a potential recruit. During the appointment that precedes placement of the orthodontic appliances or the palatal expander, the primary physician will seek initial approval from you and your child to be contacted in regards to the proposed research study by the research coordinator. If you accept, the study coordinator will be called over and will explain thoroughly the research project to you and your child and ask him/her if he/she would be willing to participate. If you decide to permit participation, you will be asked to sign this form and will receive a copy of it.
To be able to participate in this study your child should be:

- aged between 11 and 21 years
- In need for orthodontic treatment requiring braces to correct his/her dental crowding and/or malocclusion or expansion to widen your upper jaw.
- In a late mixed or permanent dentition.

If your child meet the above mentioned inclusion criteria, the study coordinator will explain the following to you and your child:

- Your child will be enrolled in this study for 13 weeks.
- During the visit that precedes the appliance placement, he/she will be asked to answer few questions about him/herself, health, family, home, and lifestyle. The questionnaire needs to be filled during your presence as some questions might be difficult to answer by his/her own.
- One of the questionnaires (The sociodemographic questionnaire- Parents section) includes a section that should be answered by you or your partner.
- Before receiving the appliance, his/her dietary intake will be assessed by calling him/her three times over the phone for 20 minutes to state the food he/she ate the day before, and he/she will be asked to answer a food questionnaire to state the number of times he/she ate certain foods in the previous month. The calls will be repeated during the first week after putting the appliance, and the food questionnaire will be repeated after 5 weeks and 13 weeks of the treatment. The phone call will start with you, and then you will be asked to give the phone to your child.
- Height and weight will be measured before receiving the braces, then after 5 weeks and 13 weeks of treatment during the regular monthly visits to the clinics to determine the effect of his/her dietary behavior during treatment on his/her body weight.
- At the initial appointment for braces placement, he/she will be given a booklet to grade how much pain he/she feels from braces when eating. This will take him/her less than one minute per day. He/she will be asked to fill this booklet during the first five weeks of treatment, and between week 10 and week 13 of treatment to evaluate the association between pain generated during orthodontic treatment and nutritional intake. If his/her orthodontic treatment requires an expander before braces placement, he/she will be asked to fill an additional booklet during the first week of expansion.
- Molds of his/her teeth will be taken before receiving braces, then additional molds after 5 weeks and 13 weeks of treatment to measure how fast your teeth

are moving in correlation with the nutritional intake. If he/she will have an expander before starting with braces, additional molds will be taken after the first week of expansion. The additional molds will be taken for research purposes by the resident treating your child, and this will require an extra 5-7 minutes per session.

- Please note that some of your child's records taken at our department will be accessed to retrieve data for research purposes.
- When the research time is over, he/she will continue the treatment normally. There are around 120 other people who will take part in this study.

2) Any risks from your child's participation in the study

- Your child enrolment in this study will not entail any risks.
- Some questions will trigger sensitive topics like puberty, and answering some of them may cause embarrassment/ upset you and/or your child. You and your child have the right not to answer any question that might cause you discomfort. However the answers are confidential and used only for research purposes without names being disclosed.
- The regular orthodontic potential side effects are explained to your child upon initiation of orthodontic treatment. Those possible side effects are related to the routine orthodontic treatment and not related to his/her enrollment in this study. The pain that he/she might be feeling from braces is normal because teeth are being moved from their original place, to align in a better way. His/her doctor will explain that during the session of braces placement.
- In order to track the movement of his/her teeth, impressions of the teeth will be taken during the regular visits to the clinic. For this procedure, a minimal amount of dental impression material is filled in a tray adequate to the size of his/her mouth, and held over your teeth for 30 to 45 seconds. His/her doctor will give him/her specific instructions while the tray is his/her mouth to avoid discomfort.

For more information about these risks and side effects, ask your doctor, or Dr. Joseph Ghafari or Dr. Nancy Abdo.

3) Any benefits from your child's participation in the study

- Depending on your child's current dental health status, we might be able to give him/her guidelines to improve oral health.
- The total data collected from your child and other participants will increase the general knowledge about the association between orthodontic treatment and food intake, and help the orthodontists understand the importance of giving dietary guidelines to their patients, following them up and motivating them to improve their dietary habits.

4) Any alternative treatment

This study does not test different alternatives of treating your child's teeth mal-alignment. He/she will be included in this study if he/she is receiving fixed braces or expansion. The only alternative is not to participate in this study.

5) Confidentiality

- If you agree on your child's participation in this research study, the information will be kept confidential and used solely for research purposes.
- Records will be monitored and may be audited by the IRB while assuring confidentiality.
- When the study is concluded, the data will be stored in the Division of Orthodontics and Dentofacial Orthopedics.
- All data from this study will be maintained in a secure locked drawer in a locked office or on a password protected computer.
- Data will only be reported in the aggregate. No names of individual participant will be disclosed in any reports or presentations of this research.
- The research data may be reviewed by the AUB Institutional Review Board or Office of Human Research Protections;

After the conclusion of the study, the Principal Investigator will retain all original study data in a secure location for at least three years to meet institutional archiving requirements. After this period, data will be responsibly destroyed.

6) Compensation & treatment available if injury

Should there be any problem usually encountered in the regular orthodontic practice, it will be dealt with accordingly.

7) Incentives:

If you agree on your child participation in this research, at the termination of the study your child will be offered an instructive booklet about healthy eating habits.
If your child decides to withdraw from the study he/she can still receive the specified compensation.

8) Participant rights

- Your child's participation in this study is voluntary and he/she may leave the study at any time. You may refuse to allow your child's participation, or withdraw at any time, without penalty or loss of benefits to which you are otherwise entitled. In addition, your decision will not affect your child's relationship with his physician, the level of care being received and neither will it affect your future relationship or that of your child with AUB/AUBMC.
- If you are a student or employee at AUB, your decision about whether or not you allow your child to participate in this research will not affect your grades or employment status.
- If you choose to allow your child to participate in the study, you may discontinue his/her participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you or your child may have as a participant in this study.
- The Institutional Review Board responsible for human subjects research at AUB has reviewed this research project and found it to be acceptable, according to applicable Lebanese and U.S. federal regulations and AUB policies designed to protect the rights and welfare of participants in research.

9) Contacts and Questions

For questions, or clarifications about the study you may contact:

Dr. Joseph Ghafari **Nancy Abdo**
+961 3 313252 **+961 71 112 603**
jg03@aub.edu.lb **na182@aub.edu.lb**

For more questions about your child's rights as a participant in this study, or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the AUB Institutional Review Board on:
01-350000 – 5445; Fax: 000961 1 738025; irb@aub.edu.lb

Signature section

I have read (or someone has read to me) and understood all aspects of the research study form, and I am aware that I am being asked to give permission for my minor child (or child under my guardianship) to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to give permission for my child/child under my guardianship to participate in this study, and I know that I can contact **Dr. Nancy Abdo** at **+961 71 112603** or any of her designee involved in the study in case of any questions. If I feel that my questions have not been answered, I can contact the Institutional Review Board for human rights at **01-350000 – 5445**. I understand that I am free to withdraw this permission and discontinue my child's participation in this project at any time, even after signing this form, and it will not affect my child's and my care or benefits. I am not giving up any legal rights by signing this form and I know that I will receive a copy of this signed parental permission form.

_____
Name of the minor participant

_____ _____
Name of Legal Representative or Parent/Guardian of the minor **Signature**

_____ _____
Date & Time **Relationship to the participant**

_____ _____
Witness's Name (if patient, representative or parent does not read) **Witness's Signature**

_____
Date & Time

Investigator's Statement:

I have reviewed, in detail, the parental permission document for this research study with _____ (name of legal representative, or parent/guardian) the purpose of the study and its risks and benefits before requesting the signature(s) above. I have answered to all the parent or legal guardian of the child subject/participant questions clearly. I will inform the participant and his parent or legal guardian in case of any changes to the research study.

There are no blanks in this document. A copy of this form has been given to the parent/legal guardian of the child participant/subject.

_____ _____

Name of Investigator or designee **Signature**

_____

Date & Time

Appendix II

Healthy Eating Guidelines among Adolescents

1. Enjoy a Variety of Nutritious Foods Every Day

Adolescence is a critical growth period where proper nutrition is crucial for normal physical and mental development, which will permanently shape adulthood years. The consumption of a variety of foods will help ensure appropriate intakes of essential nutrients such as antioxidants and fiber, as well as the needed vitamins and minerals which are protective against chronic diseases. This can be achieved by increasing the consumption of nutrient-dense foods (fruit, vegetables, legumes, whole grains, fish, and low-fat or fat-free milk and dairy products) and lowering the consumption of unhealthy foods that are high in calories and poor in nutrients (refined grains, fatty foods, and sweets). Presented below are the food groups (Box 1.1) and the recommended daily intakes for each food group by age (Table 1.1).

In Lebanon, nutritional deficiencies are highly prevalent among adolescents, including iron, calcium, zinc, potassium, vitamin D, folate, vitamin B12, and the two antioxidants: vitamin A and selenium. To help achieve the recommended daily intake of these nutrients, Tables 1.2, 1.3, 1.4, and 1.5 provide examples of foods rich in vitamin D, iron, vitamin B12, and folate, respectively. Additionally, Boxes 1.3, 1.4, and 1.5 provide guidelines and practical tips to help increase intake from these nutrients. Also presented are important recommendations for achieving an adequate diet for special population groups (Boxes 1.6 and 1.8).

BOX 1.1 Meet the Food Groups

THE FIVE FOOD GROUPS

Cereals*

Bread, cereals, rice, pasta, corn, barley, 'Burghul', noodles, etc.

Fruits

Apples, strawberries, bananas, prunes, oranges, apricots, etc.

Vegetables

Cucumbers, tomatoes, lettuce, onions, spinach, squash, carrots, green beans, etc.

Low-fat/Fat-free Milk and Dairy**

Milk, yogurt, cheeses, 'Labneh', ice cream, puddings and milk-based desserts
(such as 'Mhallbiyeh', custard, and 'Riz Bi Halib')

Protein-rich Foods***

Red meat, poultry, fish, eggs, nuts/seeds, and legumes (beans, lentils, chickpeas, etc.)

* Make sure you serve the teen with whole-grain cereals
** Make sure you choose for the teen low-fat/fat-free dairy products, as well as low-fat/fat-free and low-sugar puddings and milk-based desserts
*** Make sure you serve the teen with lean red meat, and poultry with no skin. Include fish at least 2 times a week in the teen's menu. Make sure he/she consumes legumes on a weekly basis

Table 1.1	Recommended Intakes and Examples of Serving Sizes of Each of the Five Food Groups by Age		
Food Group	**11-13 years**	**14-18 years**	**Examples of One Serving of Each of the Food Groups**
Cereals (with at least half of the servings consumed as whole grains)	5 - 6 servings/day	6 - 8 servings/day	•¼ big loaf Arabic whole-wheat pita bread • ½ cup cooked 'Burghul', whole wheat, brown rice, or whole wheat pasta/noodles • 1 cup whole-grain breakfast cereal (unsweetened)
Fruits	1.5 servings/day	1.5 - 2 servings/day	• 1 small apple • 1 large banana, orange, or peach • ½ cup dried fruit (dates, prunes, raisins, apricots) • 1 cup fresh fruit juice
Vegetables	2 - 2.5 servings/day	2.5 - 3 servings/day	• 1 cup raw vegetables • 2 cups raw green leafy vegetables • 1 cup cooked vegetables • 1 cup vegetable juice
Low-fat/fat-free milk and dairy	3 servings/day	3 servings/day	• 1 cup yogurt or liquid milk • 3 tablespoons powdered milk • 45 g white cheese • 8 tablespoons 'Labneh' • 1 cup milk-based dessert
Protein-rich foods	5 servings/day	5 - 6.5 servings/day	• 30 g cooked lean red meat, poultry, or fish • 1 whole egg or 1.5 egg whites • ¼ cup cooked legumes • 15 g unsalted nuts/seeds

Note:
- The cedar food guide at the beginning of this manual provides a graphic illustration of the above food groups and the recommended intake of each
- The recommended intakes from each of the five food groups and the serving equivalents for each group are adapted from recommendations of the United States Department of Agriculture (USDA MyPlate, 2011)

BOX 1.2 Key Recommendations to Help the Teen Choose a Variety of Nutritious Foods

• Stock your kitchen with easy and healthy nutrition. Keep a variety of nutritious food items in your kitchen to make snacking easy and healthy for the teen (dried fruit, unsalted nuts and seeds, washed ready-to-eat fruit and vegetables, etc.)

• Encourage the teen to choose nutrient-dense food items from each food group, such as:

- Whole-grain products as the basis of most meals
- A variety of fruit of different colors every day (such as fruit with pits citrus fruit, berries, and melons)
- A variety of vegetables of different colors every day (such as dark-green leafy vegetables, orange-colored vegetables, and starchy vegetables)
- A variety of legumes and unsalted nuts and seeds in his/her daily or weekly diet
- Low-fat/fat-free milk and dairy products (yogurt, cheese, and 'Labneh') every day

Box 1.3 Tips

To Increase Calcium Intake

Recommended daily intake of calcium:
11 - 18 years: 1300 mg
To achieve the recommended daily intake of calcium:

- Encourage the teen to consume low-fat/fat-free milk and dairy products (refer to Table 1.1 for the recommended daily intake of dairy products and examples of one serving)
- Prepare puddings and snacks made with reduced sugar and low-fat/fat-free milk such as 'Riz Bi Halib', 'Mhallbiyeh', and 'Creme Caramel'
- Offer sandwiches of low-fat/fat-free 'Labneh' or cheese
- Include other foods rich in calcium in the teen's diet:

- Dark-green leafy vegetables
- Canned fish with edible bones (such as sardines and anchovies)

Box 1.4 Tips

To Increase Vitamin D Intake

To achieve the recommended daily intake of vitamin D of 600 IU* per day, adolescents are encouraged to:

- Consume a variety of fish and seafood (salmon, sardines, and tuna)
- Consume vitamin D-fortified food products (such as fortified breakfast cereals and fortified milk), if available

Refer to Table 1.2 for examples of vitamin D-rich food items

Attention: Although the sun is important for vitamin D synthesis by the body, it is advised to limit the teen's exposure to sun due to risk of skin cancer. Using sunscreens of SPF greater than 15 can limit the skin's ability of synthesizing vitamin D. Refer to a health care provider to check if supplementation is needed.

*IU = International Units

Table 1.2	Vitamin D-Rich Food Items
Food Item	**Vitamin D (IU)**
Cod liver oil (1 tablespoon)	1,360
Salmon, cooked (100 g)	360
Sardines, canned in oil (½ can)	250
Tuna, canned in oil (½ can)	229
Tuna, light, canned in water (½ can)	154
Milk, vitamin-D fortified (1 cup)	98
Egg (1 whole)	20
Beef liver, cooked (100 g)	15
Note: 100 g meat equals to slightly more than the size of a deck of playing cards or the palm of a hand 1 cup = 240 ml	

Box 1.5 Tips

To Increase Iron Intake

Recommended daily intake of iron:

11 - 13 years: 8 mg
14 - 18 years, boys: 11 mg
14 - 18 years, girls: 15 mg

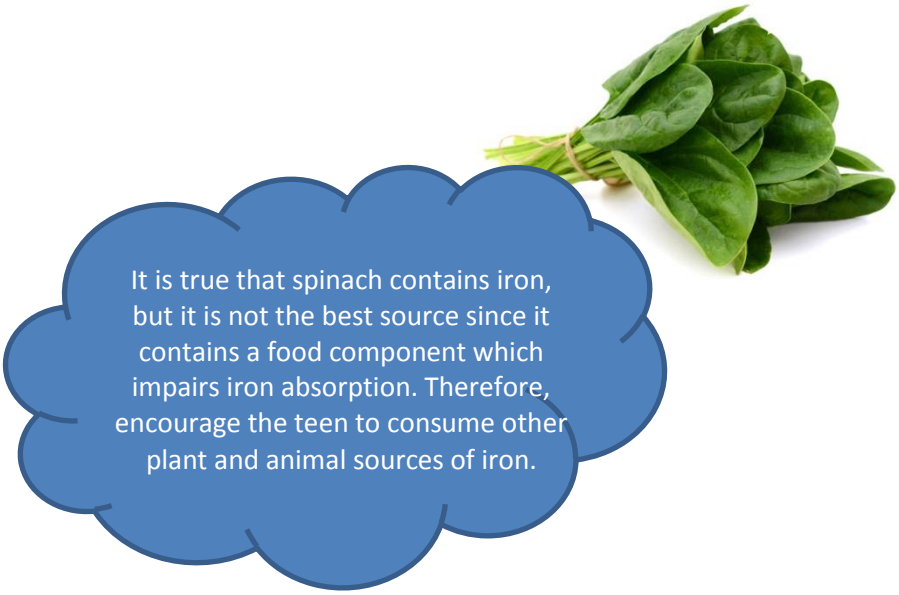
To achieve the recommended daily intake of iron:

- Encourage the teen to consume lean red meat and poultry since they are rich sources of iron that is well-absorbed by the body
- Prevent the teen from drinking tea, coffee, or caffeine-containing carbonated beverages with meals because they interfere with iron absorption in the body
- Encourage the teen to eat more dark-green vegetables (such as broccoli, 'Mlukhiyeh', celery, and Swiss chard), and to consume legumes (such as lentils, fava beans, and chickpeas) on a weekly basis. Make sure to include a source of vitamin C (such as lemon juice or orange juice) or some form of meat with these dishes to enhance the absorption of iron from plant-food items
- Encourage the teen to consume unsweetened iron-fortified breakfast cereals, raisins, and seeds (such as pumpkin seeds) as snacks

Refer to Table 1.3 for examples of iron-rich foods

Table 1.3	Iron-Rich Food Items
Food Item	**Iron (mg)**
Organ meat, cooked (90 g)	5.2 - 9.9
Cereals, iron-fortified (¾ cup)	4.5
Pumpkin seeds, roasted (2 tablespoons)	4.2
Lentils, cooked (½ cup)	3.3
Beef, tenderloin, cooked (90 g)	3
Kidney beans, cooked (½ cup)	2.6
Sardines, canned in oil, drained (1 can)	2.5
Lima* beans, boiled (½ cup)	2.3
Pinto** beans, boiled (½ cup)	1.8
Raisins (½ cup)	1.5
Chicken thigh, cooked (105 g)	1.3
Chicken breast, cooked (½ breast, 90 g)	1.1

Note:
90 g meat equals in size a deck of playing cards or the palm of a hand
*Lima beans: "Fasoulia Aa'reeda"
**Pinto beans: "Fasoulia Aysha Khanum"



BOX 1.6 Important Recommendations for Special Population Groups

Vegetarian Teens

Vegetarian teens are at risk of developing protein, iron, and vitamin B12 deficiency. Therefore, they are encouraged to:

- Include a variety of plant-based protein sources (such as legumes and nuts) in their diet to ensure an adequate intake of iron and protein
- Add vitamin C-rich food items (such as lemon or orange juice, kiwi, and green peppers) to their meals to increase the bioavailability of iron from plant sources
- Consume vitamin D and vitamin B12-enriched foods or supplements if they are strict vegetarians, since vitamin B12 is only found in animal products (refer to Table 1.4 for examples of vitamin B12-rich food items)

Box 1.7 Recommended Daily Intake of Vitamin B12

11 - 13 years:
1.8 µg
14 - 18 years:
2.4 µg

Note:
µg = micrograms

Table 1.4 Vitamin B12-Rich Food Items	
Food Item	**Vitamin B12 (µg)**
Beef liver, braised (1 slice)	47.9
Salmon, cooked (90 g)	4.9
Lean Beef, broiled (90 g)	2.4
Yogurt (1 cup)	1.4
White tuna, canned in water (½ can)	1
Milk (1 cup)	0.9
Egg, hard-boiled (1 whole)	0.6
Chicken breast, roasted (½ breast, 90 g)	0.3

Note:
90 g meat equals in size a deck of playing cards or the palm of a hand
1 cup = 240 ml

Box 1.8 Important Recommendations for Special Population Groups

Pregnant Teens

A daily intake of 600 µg per day of folic acid is necessary to reduce the risk of anemia and fetal malformation. Therefore, pregnant teens should take a folic acid supplement providing 400 µg per day before and during pregnancy, alongside consuming a folate-rich diet consisting of green leafy vegetables, fruit, beans, and peas (refer to Table 1.5 for examples of folate-rich food items)

Pregnant teens should also increase their intake of iron-rich foods from animal sources, and make sure to consume vitamin C-rich foods with plant-based meals (refer to Table 1.3 for examples of iron-rich food items)

Table 1.5	Folate-Rich Food Items
Food Item	**Folate (µg)**
Beef liver, braised (90 g)	185
Spinach, frozen, boiled (½ cup)	100
Asparagus, boiled (4 spears)	85
Spinach, raw (1 cup)	60
Green peas, frozen, boiled (½ cup)	50
Broccoli, frozen, cooked (½ cup)	50
Lettuce, Romaine, shredded (½ cup)	40
Cantaloupe (¼ medium)	25
Banana (1 medium)	20
Note: 90 g meat equals in size a deck of playing cards or the palm of a hand	

2. Eat Sensibly to Grow Normally and Have a Healthy Body Weight

Normal physical growth and development are crucial components during adolescence. Underweight in adolescents is associated with negative health effects, like anemia, nutrient deficiencies, bone disorders, and heart irregularities. On the other hand, overweight and obesity in adolescence are linked to increased risk of chronic diseases, such as type 2 diabetes, cardiovascular disease, hypertension, and dyslipidemia. Therefore, teens, whether overweight/obese or underweight, should achieve and maintain a healthy body weight (refer to Boxes 2.1 and 2.2 for selected practical recommendations).

In Lebanon, obesity rates have almost doubled among adolescents in the past decade, which paralleled the emergence of chronic diseases in this population. Lifestyle studies point to an increase in calorie consumption and a decrease in physical activity as underlying factors among Lebanese youth. Faulty dietary habits have been noticed in this population, characterized mainly by high intake of saturated fats and sugar, and low intake of fruit, vegetables, legumes, and whole-grain cereals. Therefore, the maintenance of a healthy body weight is to be considered a priority issue.

BOX 2.1 Key Recommendations for Overweight/Obese Teens

• Adolescence is a period of active growth and development. Thus, weight loss is not the best approach; the teen should aim at slowing or stopping weight gain rather than losing weight

• If weight loss is needed, 1 kg per month for adolescents between 12 and 18 years

• Ask for professional advice for proper evaluation of the teen's nutritional status and on guidance for weight management

• Weight management should be achieved through lifestyle changes that involve the whole family (family meal times and physical activity)

• Pay attention to portion sizes, and choose small plates to limit the teen's calorie intake

• Avoid labeling food as "good" or "bad", and do not give foods as rewards to the teen

• Limit screen time (watching TV, computer time, video games, and electronic media) for the teen to less than 2 hours per day. Do not encourage the teen to eat in front of the TV or the computer

BOX 2.1 Key Recommendations for Overweight/Obese Teens (Continued)

• Limit bringing into the house and offering the teen calorie-dense foods, such as high-fat sugary foods (Arabic sweets, pastries, chocolate, fried food, etc.)

• Limit bringing into the house and offering the teen calorie-dense beverages, such as commercial fruit juices and carbonated beverages

• Increase the teen's consumption of nutrient-dense and fiber-rich food items, such as fruit and vegetables, legumes, and whole grains

• Offer the teen a healthy breakfast every day since regular breakfast consumption helps to maintain a healthy body weight. Examples of healthy breakfast items include:
- Whole-grain breakfast cereal with low-fat/fat-free milk
- Whole-wheat bread with cheese (low-fat/fat-free, low-salt), 'Labneh'(low-fat/fat-free), or 'Zaatar'
- Hard-boiled eggs with fresh vegetables
- 'Foul Mdammas' or 'Baleela' with fresh vegetables

• Limit the teen's consumption of high-calories breakfast food items, such as 'Manaeesh', 'Knefeh', croissant, or crepes

• Make healthy low-calorie snack foods easily accessible to the teen (washed ready-to-eat fruit and vegetables, low-fat/fat-free yogurt, low-fat and low-sugar milk-based desserts, etc.)

• Limit eating out at restaurants, particularly fast-food restaurants. When eating out, help the teen choose small portions or low-calorie options, such as salads and grilled/baked foods instead of fried ones

BOX 2.2 Key Recommendations for Underweight Teens

• Encourage the teen to eat frequent small meals and snacks every day
• Increase the teen's calorie intake by offering him/her nutrient-dense and calorie-rich foods and beverages, such as:

- Fresh juice
- Full-fat milk or yogurt
- Milkshakes made from fresh fruit and full-fat milk
- Milk-based desserts and puddings

(custard, 'Riz Bi Halib', 'Mhallbiyeh', 'Mughli', etc.)

- Fresh fruit or fruit salad
- Popcorn or whole-wheat cereals
- Dried fruit or unsalted nuts added to meals and snacks
- High-protein foods (milk and dairy, eggs, red meat, fish, poultry, and beans)

3. Drink Plenty of Water

Water is required for digestion, absorption and transportation of nutrients, as well as for the elimination of waste products. Drinking water is also essential for preventing dehydration which can lead to impaired cognition, reduced cardiovascular function, mental and physical tiredness, as well as high risk of kidney stones on the long term. The amount of water and other fluids recommended for daily consumption is presented in Box 3.1.

In Lebanon, water intake among adolescents may be decreasing at the expense of other beverages, such as soft drinks and sweetened juices. Also, evidence in the country points to a possible mineral and microbial contamination of drinking water sources. As safe water is important for proper hydration and overall health, teens are advised to increase their intake of water, while making sure they have access to safe drinking water. Presented below are specific considerations on water consumption for special population groups (Boxes 3.2 and 3.3).

Box 3.1 Recommended Daily Intake of Water and Other Fluids

11 - 13 years: at least 2.1 - 2.4 L per day

14 - 18 years, boys: at least 3.3 L per day

14 - 18 years, girls: at least 2.3 L per day

Note: Water needs increase in hot and humid climates and when engaging in physical activity

Box 3.2 Key Recommendations for Water Consumption

• Get your home tap water checked for microbial and mineral contamination. If it is not safe for drinking, drink safe bottled-water
• Encourage the teen to drink the recommended amounts of water every day, distributed throughout the day (i.e. water breaks), even when he/she is not thirsty
• Encourage the teen to choose water as the main hydrating fluid over other types of beverages, such as coffee, tea, carbonated beverages, and sweetened juices
• Encourage the teen to drink more water when exposed to extreme temperatures (very cold or very hot weather), as well as before, during, and after any physical activity
• Always keep a bottle of water with the teen
• The following beverages also contribute to the daily intake of fluids in decreasing order of preference:
- Unsweetened herbal infusions
- Low-fat/fat-free milk
- Non-sugar sweetened beverages that contain some nutritional benefits (such as fruit and vegetable juices)

Attention: Energy drinks should not be consumed by children or teens because of the stimulants they contain and the potential health risks they may cause

Box 3.3	Important Recommendations for Special Population Groups
Physically Active Teens Encourage the teen to drink 1 - 1.5 cups of fluids 45 minutes before exercise, and at least 2/3 of fluids cup every 20 minutes during exercising. Advise the teen to avoid fruit juices or carbonated beverages during exercise, because these beverages may cause cramps, diarrhea, or nausea due to their sugar load.	Pregnant Teens An additional 1 cup of fluids above the basic requirements of at least 2.3 L per day are needed. Breastfeeding Teens 3 - 4 cups of fluids above the basic requirements of at least 2.3 L per day are needed in order to account for fluids lost in breast milk.

Appendix III

Subject ID Number: _____

Medical History Questionnaire

1. **Determination of puberty**

For boys: Did you notice recently voice changes and/or facial hair growth?
For girls: Did you get your period?

☐ No ☐ Yes, specify when: _____ ☐ Refused to answer

2. Do you have any medical/general health problem; or chronic disease?

☐ No ☐ Yes Specify: _____

3. Are you currently taking any medication: why and for how long?

☐ No ☐ Yes Specify: _____

4. Are you taking growth hormones?

☐ No ☐ Yes Specify: _____

5. Have you ever been hospitalized: when and why?

☐ No ☐ Yes Specify: _____

6. Do you have allergy to any kind of food/drugs?

☐ No ☐ Yes Specify: _____

7. Are you restricted by your physician from eating certain types of food, why?

☐ No ☐ Yes Specify: _____

8. Is there food that you don't eat at all?

☐ No ☐ Yes Specify: _____

9. Are you currently taking any nutritional supplements?

☐ No ☐ Yes Specify: _____

10. Are you on a therapeutic diet?

☐ No ☐ Yes Specify: _____

11. Are you complaining from dental pain or pain in other parts of your body preventing you from eating properly?

☐ No ☐ Yes Specify: _____

12. Do you have any of the following conditions:

N Y Congenital malformations
Specify ……...

N Y Hormonal disturbances
Specify…….....

N Y Diabetes

N Y Kidney problems

N Y Malabsorption problems
Specify ……

N Y Inborn error of metabolism
Specify …….

N Y Gastrointestinal disorders
Specify ……

N Y Digestion problems
Specify ……..

N Y Swallowing difficulties
Specify …….

N Y Food allergies
Specify …….

N Y Malnutrition problems
Specify …….

N Y Vitamins/minerals deficiency
Specify …….

N Y Iron deficiency

N Y Anemia

N Y Eating problems (difficulty in consuming adequate nutrition by mouth; or eating inappropriate items), specify …….

N Y Food intolerance (difficulty digesting certain foods and having an unpleasant physical reaction to them), specify …….

N Y Psychiatric problems, specify …….

13. Other comments that you would like to add: …….

Date: _____ / _____ / _____
Day Month Year

Subject ID Number: _____

Demographic and Socio-Economic Questionnaire

Participant's section

1. What is your date of birth? _____ / _____ / _____
   Day Month Year

2. In the house that you live in for the majority of the year, how many rooms does it have? (NTS: This excludes the kitchen, bathroom, garage, or open balconies)
   _____
   □ Refused to answer

3. What is the total number of individuals living in your household? (NTS: This includes helpers, relatives or family members that frequently live with you on a permanent or semi-permanent basis) _____
   □ Refused to answer

Parents section

1. You are:
   a. Father
   b. Mother

2. What was the highest educational level that you have achieved?
   a. Illiterate
   b. Read and write
   c. Primary school
   d. Intermediate school
   e. High school
   f. Technical diploma
   g. University degree
   h. Refused to answer

3. What was the highest educational level that your partner has achieved?
   a. Illiterate
   b. Read and write
   c. Primary school
   d. Intermediate school
   e. High school
   f. Technical diploma
   g. University degree
   h. Refused to answer

Date: _____ / _____ / _____
Day Month Year

Subject ID Number: _____

Life Style Questionnaire

The following questions are about your life style

1. Do you do physical activity?
- ☐ No
- ☐ Yes

If yes, what kind of sports? _____
How often? _____

2. Who of your parents is more attentive to your diet?
- ☐ Both my father and mother
- ☐ My mother
- ☐ My father
- ☐ Other; specify: _____

Date: _____ / _____ / _____
Day Month Year

Appendix IV

ANTHROPOMETRIC MEASUREMENTS

Division of Orthodontics and Dentofacial Orthopedics/
Study on orthodontic treatment and dietary intake

Subject ID number: _____

DATE OF BIRTH			AGE	GENDER	
Day	Month	Year	Years / Months	M	F

		Baseline	At 5 weeks of treatment	At 13 weeks of treatment
Date (D/M/Y)				
Weight (Kg)	1st			
	2nd			
	Average			
Height (m)	1st			
	2nd			
	Average			
BMI (Kg/m^2)	1st			
	2nd			
	Average			
BMI weight status				

Appendix V

SCRIPT FOR 24 HOURS RECALL INTERVIEW

CARRIED BY INVESITGATOR NANCY ABDO (NA)

***1* PART 1: Introduction and greetings**

		CHECK
A	Good morning/ evening	
B	This is Dr. Nancy Abdo, may I speak to (participant's name) please.	
C	Greetings	
D	Is this a good time to ask you the questions you agreed to answer?	

If ok, proceed. If not, ask for a convenient time to call back today

***2* PART 2: Explanation of process**

		CHECK
A	I will ask you the questions in a specific order.	
B	Please let me know if you don't understand any of the questions for me to repeat or explain.	
C	Before I start asking you about what you ate yesterday, I would like you to have the 2D visual poster that we gave you on your last visit by your side.	

When the participant confirms that he has the poster next to him/her start the 24 hours- recall.

***3* PART 3: Questionnaire**

		CHECK
A	MAIN QUESTION: **What did you eat and drink yesterday since you woke up until going back to bed**	
	FOLLOW-UP QUESTIONS	
1	Did you eat or drink additional things between the meals? (sweets, fruits, soft drinks …)	
2	Did you add any salt, sugar, pepper, oil, sauce to the eaten food?	
3	Would you please specify at what time did you eat each of the food you stated previously	
4	What activities did you do yesterday? Did you eat or drink anything before, during or after the activity (ies)?	
5	Now please look into the poster, I will restate each food you ate and you will tell me how much is the portion size you had and how it was prepared (fried, grilled, with added sugar/salt, eaten in a plate or as a sandwich …).	
	If you feel that you need mom or dad to help you answer this part there is no problem.	
6	Any other food that you recall eating yesterday?	
7	What time did you sleep yesterday? Did you eat or drink anything before sleeping?	
8	How much water did you drink yesterday?	
B	FINAL QUESTION: **Was yesterday a usual day? □ Yes □ No, specify**	

***4* PART 4: Thank you**

		CHECK
A	Is there anything else you would like me to know?	
B	Do you need anything regarding your braces?	
C	Thank you for your time and cooperation.	
D	Please don't forget to keep filling the pain booklet every night.	
E	Have a nice day/evening.	

COMMENT on how the phone session went:

24-hr Recall Form

Interviewer's Name: _____	**Date** (DD/MM/YYYY)**: ____/____/_____**
Subject ID Number: _____	**Day of the Week: _____**
Interview Start Time: _____	

1. **Please recall what you ate and drank the previous day from the time you woke up until the next morning.**

Time	Food eaten	Amount	Method of preparation

Time	Food eaten	Amount	Method of preparation

2. Was yesterday a usual day?

1.Yes

2.No, *please specify*: _____

Subject ID number: _____
Date (dd/mm/yy): _____

Food Frequency Questionnaire

Please think about your eating patterns during **the past month**. Please indicate your usual intake of each of the following food items **per day**, **week**, or **month.** Please be as precise as you can in your recall. The accuracy of the study results depends on the accuracy of your answers. Your parent is allowed to assist you.

Code	Food Item	Standard Portion Size	Usual Portion		Frequency of Consumption			
	Example: Burger Patty	Side B	2 x B 4	**Thickness** 3	□ D	□ W	□ M	□ Never
1	**Breads and Cereals**							
1.1	Bread, White, Arabic	1 large Arabic loaf/ 1 medium Arabic loaf			□ D	□ W	□ M	□ Never
1.2	Bread, Whole Wheat, Arabic	1 large Arabic loaf/ 1 medium Arabic loaf			□ D	□ W	□ M	□ Never
1.3	Markouk Bread	1 large loaf			□ D	□ W	□ M	□ Never
1.4	Kaak, big round soft (abou arab)	1 big round kaak			□ D	□ W	□ M	□ Never
1.5	Kaak fingers	1 finger sized			□ D	□ W	□ M	□ Never
1.6	Kaak round with anis	1 small round kaak			□ D	□ W	□ M	□ Never
1.7	Bread, White Baguette French	1 baguette			□ D	□ W	□ M	□ Never
1.8	Bread, Whole Wheat Baguette French	1 baguette			□ D	□ W	□ M	□ Never
1.9	Bread, Toast Bread/Pain de mie	1 medium toast			□ D	□ W	□ M	□ Never
1.10	Rice cakes / Cracottes	1 regular cracotte/cake			□ D	□ W	□ M	□ Never
1.11	Bread, Burger bun	1 bun			□ D	□ W	□ M	□ Never
1.12	Bread, Pain au lait	1 pain au lait			□ D	□ W	□ M	□ Never

1.13	Bread, Hotdog Bun	1 hotdog bun		□ D	□ W	□ M	□ Never
1.14	Breakfast Cereals, Plain	Side A/ 1 carton		□ D	□ W	□ M	□ Never
1.15	Breakfast Cereals, Bran	Side A/ 1 carton		□ D	□ W	□ M	□ Never
1.16	Breakfast Cereals, Sugar/chocolate coated	Side A /1 carton		□ D	□ W	□ M	□ Never
1.17	Rice, White	Side A		□ D	□ W	□ M	□ Never
1.18	Rice, Brown	Side A		□ D	□ W	□ M	□ Never
1.19	White Pasta, plain	Side A		□ D	□ W	□ M	□ Never
1.20	Plain Noodles	Side A		□ D	□ W	□ M	□ Never
1.21	Bulgur	Side A		□ D	□ W	□ M	□ Never
1.22	Whole Wheat	Side A		□ D	□ W	□ M	□ Never
1.23	Popcorn, popped with oil/ butter	Side A		□ D	□ W	□ M	□ Never
1.24	Popcorn, popped without oil	Side A		□ D	□ W	□ M	□ Never
1.25	Popcorn, with cheese	Side A		□ D	□ W	□ M	□ Never
1.26	Popcorn, with caramel	Side A		□ D	□ W	□ M	□ Never
2	**Dairy products**						
2.1	Milk Whole Fat	Side A		□ D	□ W	□ M	□ Never
2.2	Milk Low Fat (2%)	Side A		□ D	□ W	□ M	□ Never
2.3	Milk Skim (0-1%)	Side A		□ D	□ W	□ M	□ Never
2.4	Milk Condensed and Sweetened	Side A		□ D	□ W	□ M	□ Never
2.5	Kashta canned	Side A/ 1 can		□ D	□ W	□ M	□ Never
2.6	Milkshake	Side A/1 carton		□ D	□ W	□ M	□ Never
2.7	Yogurt Whole Fat (not including ayran)	Side A		□ D	□ W	□ M	□ Never
2.8	Yogurt Skim (0%)	Side A		□ D	□ W	□ M	□ Never

2.9	Yogurt Ayran	Side A/ 1 bottle			□ D □ W □ M □ Never
2.10	Yogurt Flavored (strawberry, fruit, chocolate, etc. flavored)	Side A/1pack			□ D □ W □ M □ Never
2.11	Yogurt flavored, Low Fat	Side A			□ D □ W □ M □ Never
2.12	Cheese, Yellow, Full Fat (cheddar, kashkawan, etc.)	1 square/triangles Side A or B			□ D □ W □ M □ Never
2.13	Cheese, Yellow, Low Fat (cheddar, kashkawan, etc.)	1 square/triangle Side A or B			□ D □ W □ M □ Never
2.14	Cheese, White, Full Fat (akkawi, feta, etc.)	1 square/triangles Side A or B			□ D □ W □ M □ Never
2.15	Cheese, White, Low Fat (akkawi, feta, etc.)	1 square/triangles Side A or B			□ D □ W □ M □ Never
2.16	Cheese Spread, Full Fat (kiri etc.)	1 square/triangles Side A or B			□ D □ W □ M □ Never
2.17	Cheese Spread, Low Fat (picon, Kraft, puck, etc.)	1 square/triangles Side A or B			□ D □ W □ M □ Never
2.18	Labne, Full fat	Side A (2 tbsp= 50g= 1 medium fat meat)			□ D □ W □ M □ Never
2.19	Labne, Low Fat or Skim	Side A			□ D □ W □ M □ Never
2.20	Shankleesh	Side A			□ D □ W □ M □ Never
2.21	Areeshi	Side A			□ D □ W □ M □ Never

3	**Fruits and Juices (seasonal, if any)**						
3.1	Apples □ seasonal	Side A/ 1 medium portion		□ D	□ W	□ M	□ Never
3.2	Banana □ seasonal	Side A/ 1 medium portion		□ D	□ W	□ M	□ Never
3.3	Orange □ seasonal	Side A/ 1 medium portion		□ D	□ W	□ M	□ Never
3.4	Grapefruit □ seasonal	Side A/ 1 medium portion		□ D	□ W	□ M	□ Never
3.5	Kiwi □ seasonal	Side A/ 1 medium portion		□ D	□ W	□ M	□ Never
3.6	Mango □ seasonal	Side A/1 medium portion		□ D	□ W	□ M	□ Never
3.7	Berries (strawberries, blueberries, raspberries) □ seasonal	Side A/ 1 medium portion		□ D	□ W	□ M	□ Never
3.8	Pears □ seasonal	Side A/ 1 medium portion		□ D	□ W	□ M	□ Never
3.9	Plums □ seasonal	Side A/ 1 medium portion		□ D	□ W	□ M	□ Never
3.10	Peach □ seasonal	Side A/ 1 medium portion		□ D	□ W	□ M	□ Never
3.11	Apricots □ seasonal	Side A/ 1 medium portion		□ D	□ W	□ M	□ Never
3.12	Cantaloupe (melon) □ seasonal	Side A/ 1 medium portion		□ D	□ W	□ M	□ Never
3.13	Watermelon □ seasonal	Side A/ 1 medium portion		□ D	□ W	□ M	□ Never
3.14	Grapes, fresh □ seasonal	Side A/ 1 medium portion		□ D	□ W	□ M	□ Never

3.15	Dried fruits: raisins, dates, apricots □ Ramadan	Side A		□ D □ W □ M □ Never
3.16	Canned fruits, unsweetened	Side A		□ D □ W □ M □ Never
3.17	Canned fruits, sweetened	Side A		□ D □ W □ M □ Never
3.18	Homemade fruit salad	Side A		□ D □ W □ M □ Never
3.19	Fruit juice **Fresh**	Side A		□ D □ W □ M □ Never
3.20	**Fresh** vegetable juices: tomato/other vegetables	Side A		□ D □ W □ M □ Never
3.21	Fruit juice **bottled without added sugar**	Side A/ 1 carton (240 mL)		□ D □ W □ M □ Never
3.22	Fruit juice **bottled / powder with added sugar**	Side A/ 1 carton (240 mL)		□ D □ W □ M □ Never
3.23	Vegetable drinks: **bottled** /canned	Side A/ 1 carton (240 mL)		□ D □ W □ M □ Never
4	**Vegetables (seasonal, if any)**			
4.1	Salad - green: lettuce, celery, green peppers, onions	Side A		□ D □ W □ M □ Never
4.2	Dark green vegetables (e.g.spinach, seleq, hindbeh, mouloukhiye)	Side A		□ D □ W □ M □ Never
4.3	Carrots, raw or cooked	Side A/ 1 medium portion		□ D □ W □ M □ Never
4.4	Tomatoes, fresh	Side A/ 1 medium portion		□ D □ W □ M □ Never
4.5	Cucumber	Side A/ 1 medium portion		□ D □ W □ M □ Never

4.6	Corn/ green peas, cooked	Side A			□ D □ W □ M □ Never
4.7	Corn on the cob □ seasonal	1 medium portion (1/2 regular cob)			□ D □ W □ M □ Never
4.8	White potatoes, baked/ boiled/ mashed	Side A/ 1 medium portion			□ D □ W □ M □ Never
4.9	French fries	Side A			□ D □ W □ M □ Never
4.10	Zucchini/eggplant, cooked (not stuffed)	Side A			□ D □ W □ M □ Never
4.11	Cauliflower/ Cabbage /Broccoli	Side A			□ D □ W □ M □ Never
5	**Meat and Alternatives**				
5.1	Legumes: white/ red/ fava beans, etc.: cooked	Side A			□ D □ W □ M □ Never
5.2	Chickpeas/ Lentils (not incl. hommus tahini)	Side A			□ D □ W □ M □ Never
5.3	Beef: steak, rib, roast, veal	Side B			□ D □ W □ M □ Never
5.4	Beef: ground, cooked	Side A/Side B			□ D □ W □ M □ Never
5.5	Lamb	Side A/Side B			□ D □ W □ M □ Never
5.6	Chicken/ Poultry without skin	Leg/thigh/breast/ Side B			□ D □ W □ M □ Never
5.7	Ham/Pork	Side B/ Regular slice			□ D □ W □ M □ Never
5.8	Fish, canned with oil (tuna/sardines)	1 small can/ 1 big can/ Side B			□ D □ W □ M □ Never
5.9	Fish, canned with water (tuna)	1 small can/ 1 big can/ Side B			□ D □ W □ M □ Never
5.10	Fish, fresh/frozen	Side B			□ D □ W □ M □ Never

5.11	Shellfish: shrimp, lobster, clams	Shrimp: 1 medium Calamari: 1 medium Crab stick: 1 stick			□ D	□ W	□ M	□ Never
5.12	Eggs, whole, large	1 medium			□ D	□ W	□ M	□ Never
5.13	Eggs, egg white	1 medium			□ D	□ W	□ M	□ Never
5.14	Organ meats (liver, kidneys, brains, tongues, etc.)	Side B/ Side A/ cups			□ D	□ W	□ M	□ Never
5.15	Smoked Turkey	Side B			□ D	□ W	□ M	□ Never
5.16	Luncheon meats: bologna, salami, mortadelle, etc.	Side B/ Regular slice			□ D	□ W	□ M	□ Never
5.17	Sausages, makanek, hot dogs	Side B/ Hotdog Size/ Makenek Size			□ D	□ W	□ M	□ Never
6	**Fats and Oils (in cooking, salads and sandwiches)**							
6.1	Vegetable oil: corn, sunflower, soy, canola	Side A			□ D	□ W	□ M	□ Never
6.2	Olive oil (excl. Zaatarwzeit)	Side A			□ D	□ W	□ M	□ Never
6.3	Olives	1 olive			□ D	□ W	□ M	□ Never
6.4	Vegetable ghee	Side A			□ D	□ W	□ M	□ Never
6.5	Butter	Side A			□ D	□ W	□ M	□ Never
6.6	Mayonnaise	Side A			□ D	□ W	□ M	□ Never
6.7	Salad dressing, honey mustard	Side A			□ D	□ W	□ M	□ Never
6.8	Salad dressing, Balsamic/ apple. Grape vinegar	Side A			□ D	□ W	□ M	□ Never

6.9	Lard/ animal ghee	Side A			□ D □ W □ M □ Never
6.10	Nuts and seeds, raw, peanuts, almonds, walnuts, etc.	Side A/ 1 small pre-packed bag			□ D □ W □ M □ Never
6.11	Nuts and seeds, roasted and **unsalted** peanuts, almonds, sunflower seeds	Side A/ 1 small pre-packed bag			□ D □ W □ M □ Never
6.12	Nuts and seeds, roasted and salted peanuts, almonds, sunflower seeds, etc.	Side A/ 1 small pre-packed bag			□ D □ W □ M □ Never
6.13	Avocado □ seasonal	Side A/ 1 medium portion			□ D □ W □ M □ Never
6.14	Peanut butter	Side A			□ D □ W □ M □ Never
7	**Sweets and Desserts**				
7.1	Cookies: chocolate chips, oatmeal, peanut butter, etc	1 medium portion/ Side B			□ D □ W □ M □ Never
7.2	Date roll	1 medium portion/ Side B			□ D □ W □ M □ Never
7.3	Muffin, cupcake, not frosted	1 medium portion/ Side B			□ D □ W □ M □ Never
7.4	Muffin, cupcake, frosted	1 medium portion/ Side B			□ D □ W □ M □ Never
7.5	Doughnuts, sugared with **no stuffing**	1 medium portion/ Side B			□ D □ W □ M □ Never

7.6	Doughnuts, sugared with chocolate / custard stuffing	1 medium portion/ Side B			□ D	□ W	□ M	□ Never
7.7	Eclaire	1 medium portion/ Side B			□ D	□ W	□ M	□ Never
7.8	Biscuits, stuffed crème (ex. Oreo, dabkeh)	1 medium portion/ Side B			□ D	□ W	□ M	□ Never
7.9	Biscuits, wafer (ex. Unica)	1 medium portion/ Side B			□ D	□ W	□ M	□ Never
7.10	Biscuits, plain (ex. Digestive)	1 medium portion/ Side B			□ D	□ W	□ M	□ Never
7.11	Cake, with icing	1 medium portion/ Side B			□ D	□ W	□ M	□ Never
7.12	Cake, **without icing**	1 medium portion/ Side B			□ D	□ W	□ M	□ Never
7.13	Pudding/ Custard/ Mhalabiya	Side A			□ D	□ W	□ M	□ Never
7.14	Jello	Side A			□ D	□ W	□ M	□ Never
7.15	Ice cream □ seasonal	1 scoop/ 1 stick/ Side A			□ D	□ W	□ M	□ Never
7.16	Chocolate spread	Side A			□ D	□ W	□ M	□ Never
7.17	Chocolate bar	1 medium bar/ Side B			□ D	□ W	□ M	□ Never
7.18	Cereal Bar	1 medium bar			□ D	□ W	□ M	□ Never
7.19	Sugar candies, lollipops	1 item			□ D	□ W	□ M	□ Never
7.20	Jelly beans	Side A/ 1 pre-packed bag			□ D	□ W	□ M	□ Never
7.21	Sugar - Added to foods and drinks	Side A			□ D	□ W	□ M	□ Never

7.22	Halawa	Side A		□ D □ W □ M □ Never
7.23	Molasses, honey, jam	Side A		□ D □ W □ M □ Never
7.24	Arabic sweets, Knafe	Side B/ 1 portion with kaak		□ D □ W □ M □ Never
7.25	Arabic sweets, baklava, maamoul	Side A/ 1 regular portion		□ D □ W □ M □ Never
8	**Beverages**			
8.1	Soft drinks, **caffeinated, diet**	Side A/ 1 can (330 mL)		□ D □ W □ M □ Never
8.2	Soft drinks, **caffeinated, regular**	Side A/ 1 can 330		□ D □ W □ M □ Never
8.3	Soft drinks, **without caffeine, regular**	Side A/ 1 can 330		□ D □ W □ M □ Never
8.4	Soft drinks, **without caffeine, diet**	Side A/ 1 can 330		□ D □ W □ M □ Never
8.5	Sports Drinks (ex. Gatorade)	Side A		□ D □ W □ M □ Never
8.6	Energy Drinks (ex. Red bull)	Side A		□ D □ W □ M □ Never
8.7	Nescafe/ Turkish/ American cofee	Side A		□ D □ W □ M □ Never
8.8	Tea □ seasonal	Side A		□ D □ W □ M □ Never
8.9	Herbal Tea (chamomile, anis, etc) □ seasonal	Side A		□ D □ W □ M □ Never
8.10	Coffee or tea, decaffeinated	Side A		□ D □ W □ M □ Never
8.11	Iced tea □ seasonal	Side A/ 1 can (330 mL)		□ D □ W □ M □ Never
8.12	Hot chocolate, cocoa, with milk, liquid □ seasonal	Side A		□ D □ W □ M □ Never
8.13	Bottled Water	Side A/ 1 Liter		□ D □ W □ M □ Never

8.14	Sparkling Water	Side A/ 1 Liter		□ D	□ W	□ M	□ Never
8.15	Tap Water	Side A		□ D	□ W	□ M	□ Never
9	**Miscellaneous**						
9.1	Manaeesh, zaatar	1 large/ 1 bouchee		□ D	□ W	□ M	□ Never
9.2	Manaeesh, cheese	1 large/ 1 bouchee		□ D	□ W	□ M	□ Never
9.3	Manaeesh, kechek	1 large/ 1 bouchee		□ D	□ W	□ M	□ Never
9.4	Fatayer, spinach	1 small portion		□ D	□ W	□ M	□ Never
9.5	Sambousek - meat/cheese	1 small portion		□ D	□ W	□ M	□ Never
9.6	Hummus be Tahini	Side A		□ D	□ W	□ M	□ Never
9.7	Stuffed zucchini koussa	Side A / 1 stuffed zucchini		□ D	□ W	□ M	□ Never
9.8	Stuffed grape leaves	Side A / 1 stuffed grape leaf		□ D	□ W	□ M	□ Never
9.9	Stew meal (excl. rice)	Side A		□ D	□ W	□ M	□ Never
9.10	Kebbe	Side B / 1 small kebbe		□ D	□ W	□ M	□ Never
9.11	Soup,Broth/ Vegetable □ seasonal □ Ramadan	Side A		□ D	□ W	□ M	□ Never
9.12	Soup, Cream □ seasonal □ Ramadan	Side A		□ D	□ W	□ M	□ Never
9.13	Chicken nuggets	Side B/ 1 nugget		□ D	□ W	□ M	□ Never
9.14	Fish fingers	Side B/ 1 finger		□ D	□ W	□ M	□ Never
9.15	Escalope (chicken or meat)	Side B		□ D	□ W	□ M	□ Never
9.16	Cordon Bleu	Side B		□ D	□ W	□ M	□ Never
9.17	Beef Burger	1 patty		□ D	□ W	□ M	□ Never
9.18	Chicken burger, fried	1 patty		□ D	□ W	□ M	□ Never

9.19	Chicken burger, grilled	1 patty		□ D □ W □ M □ Never
9.20	Cheese burger	1 patty + cheese		□ D □ W □ M □ Never
9.21	Fish burger	1 filet		□ D □ W □ M □ Never
9.22	Pizza	Side B/ 1 medium slice		□ D □ W □ M □ Never
9.23	Falafel, sandwich	1 sandwich/ 1 qors		□ D □ W □ M □ Never
9.24	Chawarma, sandwich	1 small sandwich		□ D □ W □ M □ Never
9.25	Crepes/ waffles - salty	1 medium		□ D □ W □ M □ Never
9.26	Crepes/ waffles - with sugar or chocolate	1 medium		□ D □ W □ M □ Never
9.27	Croissant - cheese, zaatar, chocolate	1 medium		□ D □ W □ M □ Never
9.28	Chips: potatoes, corn, tortilla, etc.	Side A/ 1 medium bag		□ D □ W □ M □ Never
9.29	Pretzels (baton sale)	Side A/ 1 medium bag		□ D □ W □ M □ Never
9.30	Crackers, salty (ex. Tuc)	Side A/ 1 medium bag		□ D □ W □ M □ Never
9.31	Zaatar (with oil, sesame and sumac)	Side A		□ D □ W □ M □ Never
9.32	Ketchup	Side A		□ D □ W □ M □ Never
10	**ALCOHOLIC BEVERAGES**			
10.1	Beer	Side A/ 1 bottle		□ D □ W □ M □ Never
10.2	Spirit drinks (e.g. Whiskey, Rum,Vodka.)	Side A		□ D □ W □ M □ Never
10.3	Wine	Side A		□ D □ W □ M □ Never

Are there any other foods NOT MENTIONED ABOVE that you usually eat at least once per week? **Examples: Fava beans, pâté, tahini, pickles, coconut, sushi, non-alcoholic beverages (freeze), alcoholic cocktails), etc.** **Do not include dry spices. Do not list foods that have listed in the previous section.** ***Include any supplement intake.**		
Other foods that you usually eat at least once / week	**Usual serving size**	**Serving/week**

Appendix VI

Little's Irregularity Index

Division of Orthodontics and Dentofacial Orthopedics/
Study on orthodontic treatment and dietary intake

Subject ID number: _____

Baseline	Date (D/M/Y)					
	Maxillary arch			Mandibular arch		
	1st	2nd	Average	1st	2nd	Average
Right canine-right lateral						
Right lateral-right central						
Right central-left central						
Left central-left lateral						
Left lateral-left canine						
Sum (irregularity index)						
Classification						

At 5 weeks of treatment	Date (D/M/Y)					
	Maxillary arch			Mandibular arch		
	1st	2nd	Average	1st	2nd	Average
Right canine-right lateral						
Right lateral-right central						
Right central-left central						
Left central-left lateral						
Left lateral-left canine						
Sum (irregularity index)						
Classification						

At 13 weeks of treatment	Date (D/M/Y)					
	Maxillary arch			Mandibular arch		
	1st	2nd	Average	1st	2nd	Average
Right canine-right lateral						
Right lateral-right central						
Right central-left central						
Left central-left lateral						
Left lateral-left canine						
Sum (irregularity index)						
Classification						

Little's Irregularity Index and arch width measurements

Division of Orthodontics and Dentofacial Orthopedics/
Study on orthodontic treatment and dietary intake
Subject ID number: _____

Baseline	Date (D/M/Y)					
	Maxillary arch			Mandibular arch		
	1st	2nd	Average	1st	2nd	Average
Right canine-right lateral						
Right lateral-right central						
Right central-left central						
Left central-left lateral						
Left lateral-left canine						
Sum (irregularity index)						
Classification						
Inter premolar distance						
Inter molar distance						

At 1 week of expansion	Date (D/M/Y)		
	Maxillary arch		
	1st	2nd	Average
Inter incisal distance			
Inter premolar distance			
Inter molar distance			

At 5 weeks of FA treatment	Date (D/M/Y)					
	Maxillary arch			Mandibular arch		
	1st	2nd	Average	1st	2nd	Average
Right canine-right lateral						
Right lateral-right central						
Right central-left central						
Left central-left lateral						
Left lateral-left canine						
Sum (irregularity index)						
Classification						
Inter incisal distance						
Inter premolar distance						
Inter molar distance						

At 13 weeks of FA treatment	Date (D/M/Y)					
	Maxillary arch			Mandibular arch		
	1st	2nd	Average	1st	2nd	Average
Right canine-right lateral						
Right lateral-right central						
Right central-left central						
Left central-left lateral						
Left lateral-left canine						
Sum (irregularity index)						
Classification						
Inter incisal distance						
Inter premolar distance						
Inter molar distance						

Appendix VII

In this pain diary, an example of pain assessment questionnaire is shown at the 1st day after treatment

Assessment over the rest of the days followed the same format

Pain Diary

Assessment during:

□ First week of expansion

□ First 5weeks of fixed appliances treatment

□ Third month of fixed appliances treatment

Subject ID number: ----------

Instructions:

- This pain dairy is made for you to record pain intensity from teeth while eating and biting

- Each page of this diary includes a scale made of a ten centimeters horizontal line marked at both ends by: “my teeth don’t hurt me at all” on the left and “my teeth hurt me very badly” on the right

- Your task is to place a line perpendicular to the horizontal scale line at the point that represents your pain intensity

- You will be also asked if you used any medication to help you calm down your pain

- This booklet should be kept proper and clean and filled every night for the following week/ month

- You should return this diary at your next appointment with your treating doctor

Your cooperation is appreciated

Week 1/ Day 1

Date of completion of these questions

_____ / _____ / _____
Day **Month** **Year**

How much did the braces hurt you from biting and chewing food?

Please put a vertical mark │ on the line below to show how much your teeth have hurt

My teeth do not hurt at all

My teeth very badly

<u>Pain killers</u>

Did you take any pain killers/ medicine to help your teeth hurt less?

Please put a cross (X) in the correct box

☐ **Yes** ☐ **No**