

CHAPTER 3: METHODOLOGY

3.1 Study design

This study has three phases. In Phase One, a cross sectional study was conducted to establish proxy baseline data on early childhood caries, nutritional status, dietary habits among preschool children aged 5 to 6 years old in Tumpat and Pasir Mas districts and also the knowledge, attitude, practice related to ECC among their mothers. The purpose of the proxy data was to estimate the extent of ECC prevalence and severity if the current toddler's health program was not modified or improved.

Following this, Phase Two and Phase Three of the study which was designed as an intervention prospective study, was done to assess the effectiveness of a health promotion intervention program in controlling ECC, its impact on nutritional status and dietary habits among toddlers aged 2 to 3 years old and also in improving the knowledge, attitude, practice related to ECC among their mothers. Phase Two was the pre-intervention while Phase Three involved the post-intervention part of the study. Toddlers in Tumpat District were identified as the intervention group which received a special health promotion intervention package named "Toddler Intervention Package for Total Oral Health or TIPTOP program"; while toddlers in Pasir Mas District acted as the control group which received the existing oral health education program for toddlers conducted by the Ministry of Health.

3.2 Sample size estimation

3.2.1 Phase One (A cross sectional study)

For the cross sectional study, sample size was estimated based on the first objective. Using the single proportion formula (Naing, 2007), the sample size was calculated as below:

$$n = \left[\frac{Z}{\Delta} \right]^2 P (1 - P)$$

P = anticipated population proportion = 87.1% (NOHSS, 1998).

Δ = absolute precision ($\pm 5\%$)

Z = 1.96 (constant)

Level of significance = 0.05

Therefore ;

$$n = \left[\frac{1.96}{0.05} \right]^2 0.87 (1 - 0.87)$$

$$n = 173.8 \text{ subjects}$$

After taking into account an estimated non-response rate of 10% and also the design effect of 2, the estimated sample size for Phase One was $(174 + 17) \times 2 = \mathbf{382 \text{ subjects}}$

3.2.2 Phase Two and Three (An intervention prospective study)

For the intervention prospective study, sample size was estimated based on the second and third objective of the study. By using Power and Sample Size (PS) software (Dupont and Plummer, 1998), a level of significance (α) as 0.05, 80% power of study, 99 % prevalence of ECC in control group (Badariah, 2005), 15% difference in the prevalence of ECC to be detected between control and intervention group and also 10%

drop out rate had been taken into account during the sample size estimation. Finally, the total sample size needed for Phase Two and Three of the study was **64 toddlers** for each group (intervention (n=64) and control (n=64)).

3.3 Population and Sample

3.3.1 Phase One (A cross sectional study)

In Phase One, the reference population to whom the results would be inferred to was all preschoolers aged 5 – 6 years in Tumpat and Pasir Mas districts. The source population where the samples were recruited from was all toddlers attending TABIKA/TADIKAKEMAS in both districts. The total numbers of TABIKA/TADIKAKEMAS were 50 in Tumpat and 47 in Pasir Mas, with the total enrolment was 1243 and 1172 respectively. From each district the estimated sample size needed was 191 subjects. Thus from the total TABIKA/TADIKAKEMAS, only 22 were randomly selected and involved in Phase One. All of the TABIKA/TADIKAKEMAS involved in this study was under the care of Government Dental Services preschool oral health program.

Within the TABIKA/TADIKAKEMAS selected, the inclusion criteria was that only preschoolers aged 5 – 6 years who resided in either district for most of their lives (defined as more than half of their lifetime). Preschoolers aged less than 5 years or more than 6 years were excluded. Data to establish the proxy baseline on early childhood caries, nutritional status, dietary habits among preschool children aged 5 to 6 years old in Tumpat and Pasir Mas districts and also the knowledge, attitude, practices related to ECC among their mothers was then collected, entered and analyzed using SPSS Version 18.0. Flowchart of the Phase One of this study was simplified in Figure 3.1.

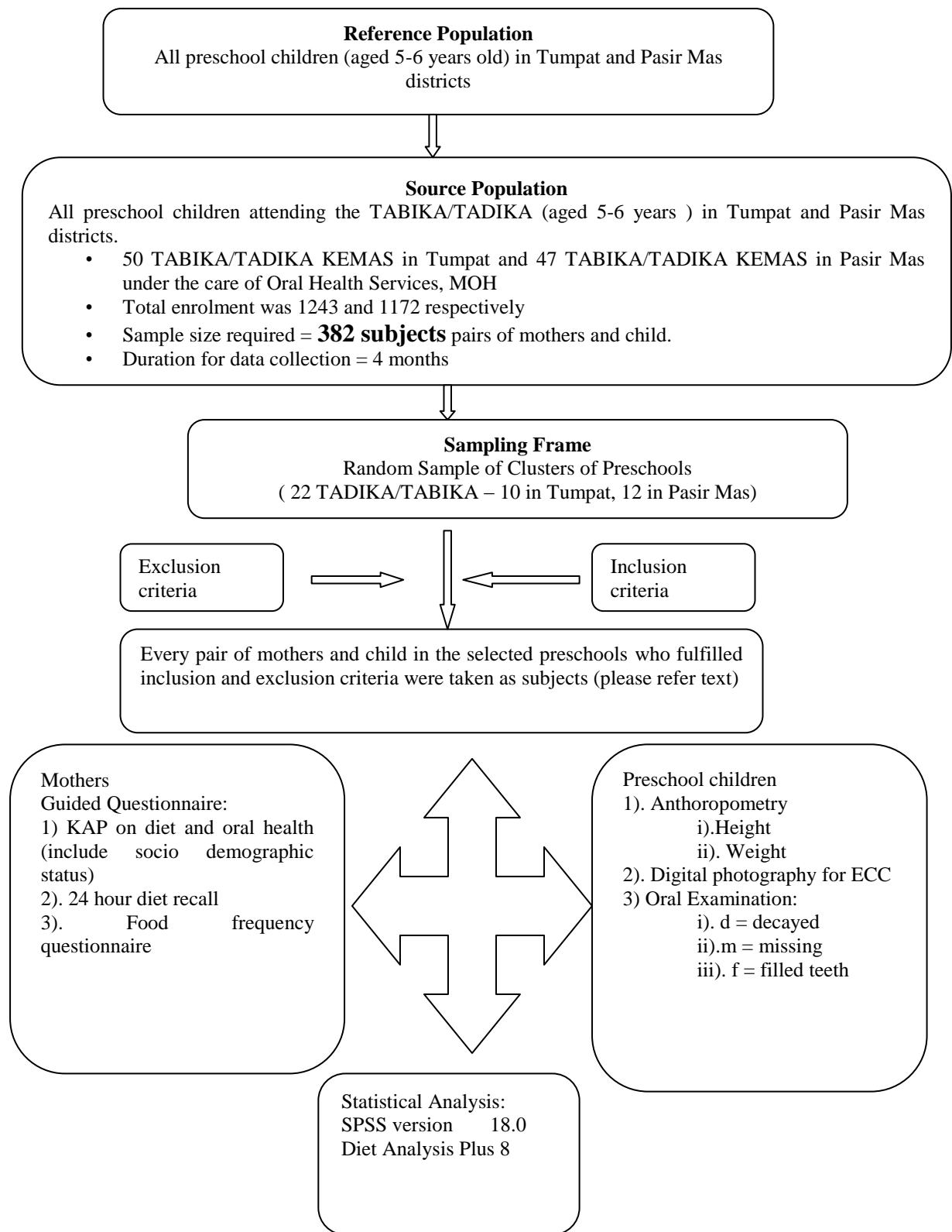


Figure 3.1 Flow Chart of Phase One.

3.3.2 Phase Two and Three (An intervention prospective study)

Phase Two was the pre-intervention study and the Phase Three was the follow up of post intervention where the reference population consisted of all toddlers (2 – 3 years old) in Tumpat and Pasir Mas districts. The source population was all toddlers attending the post natal assessment program in the Health Clinics in both districts. Toddlers from Tumpat were identified as the intervention group and toddlers from Pasir Mas was selected as the control group. The selection of intervention and control group was based on both being in a poor district in Kelantan and the prevalence of early childhood caries was high (according to NOHPS 2005 - National Oral Health Survey of Preschool Children; proxy baseline ECC prevalence of Tumpat= 97% and Pasir Mas=99%). In addition both districts have the same socioeconomic characteristics.

The inclusion criteria was that at baseline: (a) all toddlers recruited in this study must be caries-free (dmft=0), (b) aged between 2 – 3 years old, and (c) their mothers gave consent and must be willing to be involved in the subsequent intervention study for a period of 18 months. (d) In addition, to control for other confounding social factors, both toddlers and mothers must reside in either Tumpat and Pasir Mas districts only. Therefore, those who resided in other districts were excluded. This was very important because we would like to assess the effectiveness of a long term community based health promotion package in controlling ECC and measure other indirect impacts on nutritional status, dietary habits of the toddlers and KAP related to ECC of the mothers.

The screening phase involved all toddlers aged 2 to 3 years who were registered with the postnatal clinics in Pasir Mas Health District and Tumpat Health District. They were examined for ECC at the *Pusat Kesihatan* dan *Klinik Desa* in Tumpat and Pasir Mas. The total numbers of toddlers screened were 519. However, at the end of screening, only 15.8% (n=82) toddlers were found to be caries free and fulfilled all the

other inclusion and exclusion criteria. This comprised of 41 toddlers from Tumpat district in the intervention group and 41 toddlers from Pasir Mas in the control group. However during the intervention, one of toddlers from Tumpat district dropped out when the parents moved to another district. So the final sample consisted of 40 from Tumpat and 41 toddlers from Pasir Mas who participated until the end of study period.

Baseline data for both intervention and control group was collected during pre-intervention in Phase Two of the study. Baseline measurements were taken for both general and oral health status. General health measures include nutritional status, dietary habits and KAP related to ECC among the mothers. Oral health measures include ECC assessment among the toddlers. The intervention group then received a packaged intervention program called ‘Toddler Intervention Package for Total Oral Health’ or TIPTOP program which included at least four times intervention visit by the principal researcher, once in six months within a period of 18 month. The same set of data at baseline was collected at every visit to monitor progress.

The control group however, followed the usual “Toddlers and Postnatal Program” at all Health Clinic and *Klinik Desa* in Pasir Mas. After 18 months, the post intervention data collection or Phase Three of the study commenced. Measurements for general health and oral health were repeated. All data was then entered and analyzed using SPSS Version 18. Details of data collection procedure will be explained in the following sections. The flowchart of Phase Two and Three of the study is illustrated in Figure 3.2.

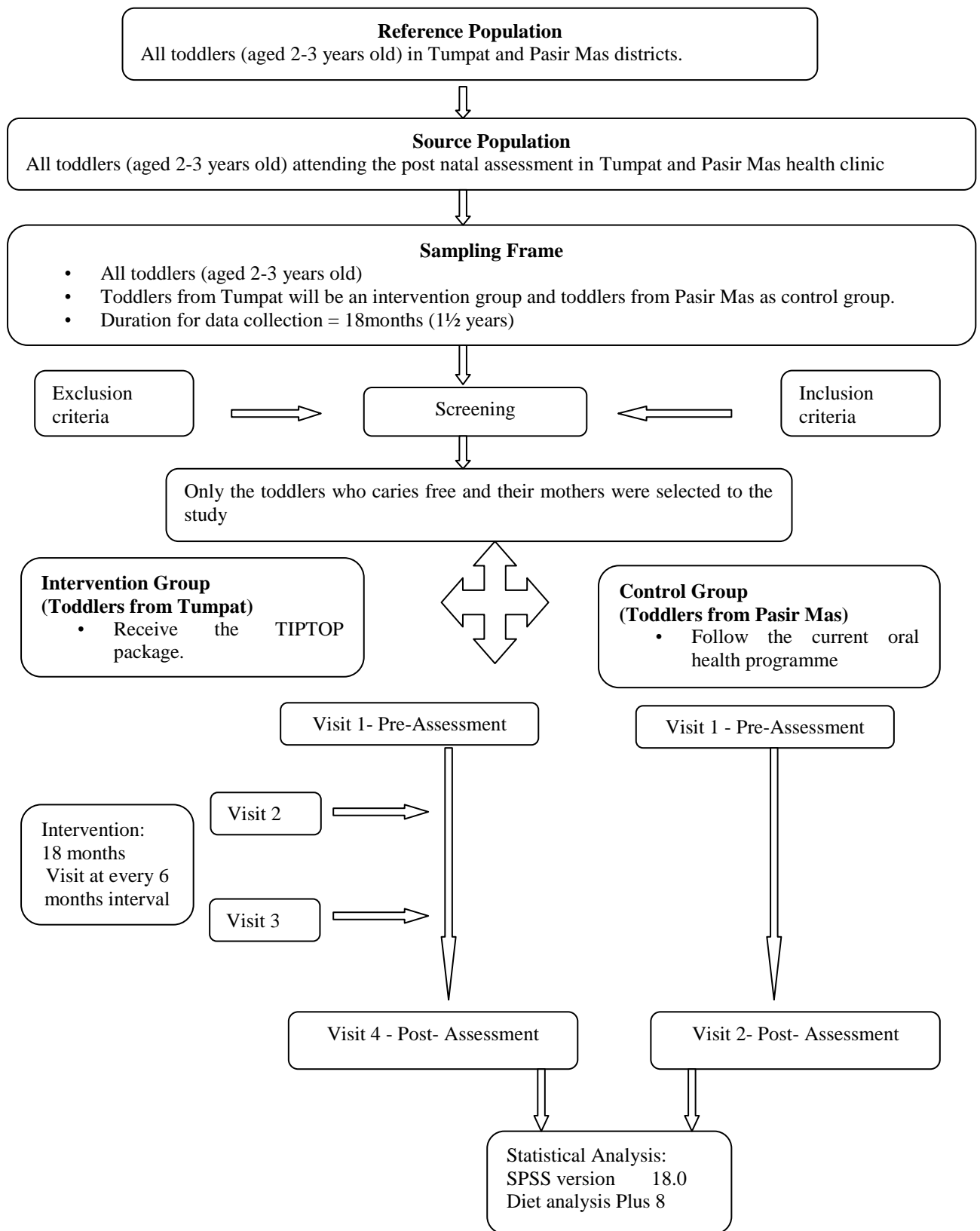


Figure 3.2 Flow Chart of Phase Two and Three.

Table 3.1 Differences between TIPTOP Program verses Existing Toddler Program by Ministry of Health (Oral Health Division, MOH, 2006).

TIPTOP Package Components for toddlers: INTERVENTION GROUP	Existing Toddler / Preschool program (MOH): CONTROL GROUP
<p><u>1. NUMBER OF VISITS AT HEALTH CENTER</u></p> <p>FOUR VISITS AT ONE VISIT EVERY SIX MONTHS WITH 1 HOUR PER VISIT AT HEALTH CLINIC</p> <ul style="list-style-type: none"> - For toddlers with early signs of ECC on the central incisors, they will be visited (home visit) more often than once every 6 months (maximum of once every month). - For this special group ie identified as “high risk” group, their diet counseling was individualized and performed at home. 	<p>TWO VISITS AT ONE VISIT PER YEAR AT HEALTH CLINIC</p> <ul style="list-style-type: none"> - this is the normal standard operating procedure (SOP) ie, to visit each clinic or preschool at least once a year. - home visit is not specified and for which child it should be targeted.
<p><u>2. NUTRITION AND DIET EDUCATION COMPONENT</u></p> <p>Standardized Nutrition education and resources to mothers (in group setting)</p> <p>a). PAMPHLET</p> <p>This was distributed at the beginning of the session to the mothers</p> <p>The topics are:</p> <ul style="list-style-type: none"> Topic 1 : Early Childhood Caries Topic 2 : The daily oral care Topic 3 : Cariostatic Food Topic 4 : A balanced diet for 2 to 6 years old children <p>b) CD ON NUTRITION AND ORAL HYGIENE</p> <p>This session will start by playing a CD after the mothers receive the leaflet and pamphlet.</p> <p>The topics covered in the CD are:</p> <ul style="list-style-type: none"> • Early childhood caries among children • Guidelines on children oral care • Nutrients in food • Food pyramid for children • Nutritious food for children • The types of cariogenic food • Nutrition guidelines as a caries prevention 	<p>Nutrition education and resources to mothers (in group)</p> <ul style="list-style-type: none"> - following the current syllabus of MOH, Oral Health Division. (Oral Health Division, 2006)

<p>c) <u>ORAL HEALTH EDUCATION (OHE) AND MAINTENANCE SKILL COMPONENT : FOR CHILD AND MOTHER TOGETHER</u></p> <ul style="list-style-type: none"> • All the toddlers were given a free toothbrush and toothpaste at each intervention session. • The practical session was conducted by trained nurses. • Mothers must be present and encouraged to participate. • The duration of this session is about 10 minutes. 	<p>Oral Health Education (OHE) and maintenance skill for child.</p> <ul style="list-style-type: none"> • All the toddlers were given a toothbrush and toothpaste for a toothbrushing drill • The practical session was conducted by trained nurses. • Mothers are present when these toothbrushing drills are carried out. • The duration of this session is about 10 minute.
<p>d) POSITIVE REINFORCEMENT COMPONENT: WITH DIGITAL PHOTO RECORDS</p> <ul style="list-style-type: none"> • Four (4) digital macro photos of the front teeth which are clear enough to show caries status are taken at every visit in digital record format • One printed photo is given to the mother as a visual record for reinforcement and comparison at the next visit. • One is kept in the patients file/folder for reference and discussion with the mothers to monitor the caries status of the front teeth at every visit. 	<p>No photo records are done by MOH in the current SOP guidelines.</p> <p>(Note: The present study took digital photos to record the status of the front teeth at baseline and at end of the study period for comparison purposes in the control group)</p>
<p>e) POSITIVE REINFORCEMENT COMPONENT: WITH TOKEN AND TRAVELLING ALLOWANCE</p> <p>Token and travelling allowance was given 4 times ie at every visit to facilitate and encourage attendance because most of the subjects were poor and could not afford to travel regularly to clinic.</p>	<p>The MOH does not give tokens or travel allowance to patients as a matter of policy.</p> <p>(Note: However we gave positive reinforcement in the form of similar token and travelling allowances for the 2 visits to encourage them to come for the regular sessions and to reduce non-response bias)</p>
<p>f) POSITIVE REINFORCEMENT COMPONENT: WITH SMS REMINDER SERVICES</p> <p>A personal reminder service in the form of SMS was sent to all the mothers mobile phones to remind them to implement daily oral hygiene, control sugar intake and eat balanced diet once every 2 weeks.</p>	<ul style="list-style-type: none"> • No SMS reminder service in MOH program. • No mail reminder service in MOH program.

<p>Note: SMS is the cheapest and most economical form of mass communication (at 20 cents per SMS) as compared to face-to-face talk or via postal communication. Although these respondents were supposedly from the low socio-economic group, it was observed that almost all households had at least one accessible mobile phone belonging to a family member. The personal feedback received was very positive and encouraging. In fact the mobile phone was the most useful form of communication between the researcher and the respondents.</p>	
<p>g) POSITIVE REINFORCEMENT COMPONENT: BY INDIVIDUALIZED DIET COUNSELING DURING HOME VISITS FOR HIGH-RISK CHILDREN ONLY.</p> <ul style="list-style-type: none"> • Aims to support mothers to change their attitudes and daily practices affecting children’s dietary behaviors so that they choose and prepare diets with low or non-cariogenic snacks, limit sweet foods to mealtimes and perform tooth brushing after sugar exposures. • The timing of diet counseling is about 15 minutes per house visit. <p>Although the visit is short, the personalized counseling, taking into consideration each individual’s needs and circumstances was greatly appreciated and created a personal bond of friendship and trust between the researcher and the respondents.</p>	<ul style="list-style-type: none"> • The MOH encourages home visits for oral health education but these are at the discretion of state dental health department. Most states do not have SOP policies for home visits for toddlers. • More often the implementation is occasional and not systematically applied to those at high risk.

3.4 Variables in the study

The dependent variables in this study were anthropometric measurements to reflect the nutritional status, frequency of taking sugary foods and drinks and 24 hour diet recall to reflect the dietary habits and also the prevalence of ECC. All the dependent variables were measured among the preschoolers (proxy population) and the toddlers (intervention study population). Another dependent variable was the KAP related to ECC among mothers of the preschoolers in Phase One and mothers of the toddlers in Phase Two and Three of the study. The independent variable was time.

3.5 Intervention tool

The intervention tool was a health promotion intervention program which was specially designed in this study and given the acronym “TIPTOP program” which stands for ‘Toddler Intervention Package for Total Oral Health Program’. The TIPTOP is a comprehensive package covering the following aspects of health promotion:

- i) **Cognitive component:** ie basic knowledge on good nutrition and oral health / hygiene (through group face-to-face education, Video CD-LCD presentation, leaflet and pamphlet distribution), as well as a free CD to take home.
- ii) **Psychomotor component:** ie. Basic skill with hands-on practical on tooth brushing using fluoride toothpaste for both mother and child, together.
- iii) **Attitude component:** ie. which include individualized diet counseling depending on the persons socio-economic circumstances and lifestyle, positive reinforcement and digital photo record of the decay status of the primary maxillary incisors as a means to reinforce their beliefs and attitudes that their preventive actions is successful or otherwise.

3.5.1 Contents of “TIPTOP” program.

3.5.1.1 Knowledge: Nutrition and oral health education in group setting.

The first session was in a group setting to get all the mothers to know each other and be supportive of one another. All mothers from the intervention group in Tumpat received 4 different topics at every visit. Each topic was conducted every 6 months interval during the intervention period in the Health clinic. It was aimed at informing the mothers about general nutrition as well as the importance of reducing dietary exposures to sweet foods and hidden sugars and how it impacts on general and oral health. The duration of nutrition and oral health education was about 15 minutes followed by group activities and discussion session (Table 3.1).

Topics included in the education component were:

- i) Topic 1 : Nursing Bottle Caries
- ii) Topic 2 : Daily care for teeth (“*Penjagaan gigi harian*”)
- iii) Topic 3 : Cariogenic foods and beverages
- iv) Topic 4 : Food pyramid for toddlers aged 2 to 6 years old.

3.5.1.2 Knowledge: Leaflet and pamphlet distribution

Leaflets and pamphlets were also distributed at the beginning of the session to the mothers to reinforce the verbal messages and instructions and to be read at home. The topics covered were:

- i) Deciduous teeth: Diet and Care
- ii) Breast feeding and bottle feeding
- iii) Sugary drinks and snacks consumption
- iv) Early Childhood Caries (ECC) and it’s prevention

3.5.1.3 CD on nutrition and oral hygiene

This session was started after the mothers had received the leaflet and pamphlet.

The duration of the CD session was about 5 minutes (Table 3.1).

3.5.1.4 Skill: Practical on tooth brushing

All toddlers were given a toothbrush and toothpaste each. The practical session was conducted by trained dental nurses (Dental Therapist). The duration of this session was about 10 minutes. (Table 3.1)

3.5.1.5 Attitude: Diet counseling (Individualized)

The counseling was aimed at facilitating mothers to change their own attitudes and to influence their children's dietary behaviors and eventually they are able to choose diets with low or non-cariogenic alternatives, limit sweet foods to mealtimes and perform effective tooth brushing with fluoridated toothpaste after sugar exposures. The timing of diet counseling was about 15 minutes (Table 3.1). For toddlers who were detected with early sign of caries at any time during the scheduled visits, the frequency of individualized diet counseling was increased to once every month during home visits.

3.5.1.6 Attitude: A digital photo record of decay status involving the primary maxillary incisors.

A digital photo of the primary maxillary incisors of all the toddlers in the intervention group and control group was taken using an SLR camera in macro shooting mode. The duration of this session was about 10 minutes. This served as a permanent record for periodic monitoring of ECC status for both the researcher and the parents of toddlers.

3.5.1.7 Attitude: Positive reinforcement

The digital photo of the anterior teeth of the toddler was printed and given to the mothers to keep as a record for future reference. The mothers were encouraged to pin the photos in a prominent place in their home as a means of reminder and reinforcement to take care of the child's diet and practice strict daily oral hygiene. Tokens (eg. toothbrush, toothpaste, *keropok* snacks etc.) and travelling allowance was given at every visit to the health center in order to enable respondents to take part in the toddler program activities. The photo session took about 5 minutes.

3.5.1.8 Periodic Reminders

All of the mothers in the intervention group received periodic reminder services (every week) to remind them to implement the given information. Two types of reminders were:

1. Phone SMS reminder – the researcher sent a short message service or “SMS” reminder once every week. A sample of the SMS messages were: “*Jangan lupa gosok gigi anak anda setiap hari*”, “ *Jangan beri makanan manis kepada anak anda*”, “*Buah-buahan baik untuk kesehatan, beri pada anak anda*”, “*Kacang, susu, keju, yogurt bagus untuk gigi, beri pada anak anda*”.
2. Email reminder – the mothers who were computer literate, have access to computers and have email addresses received email reminders to remind them to implement the given messages.

Table 3.2 Total Timing of the TIPTOP Program

	Method	Duration of Time In Minutes (Maximum)
1.	Nutrition and oral health education	15
2.	Individualized diet counseling	15
3.	CD on nutrition and oral hygiene	5
4.	Practical on tooth brushing	10
5.	A digital photo record of decay status involving primary maxillary incisors	10
6.	Positive reinforcement	5
	Total time of TIP-TOP Program	60 minutes (1 hour)

3.6 Measurement Tools

Several types of research tools were used in this study to measure different outcomes. Basically, the tools used to measure the child's general health were nutritional status (anthropometric measurements), dietary habits, and KAP of the mothers. The tool used to assess oral health was dmft status (ie ECC) among the preschoolers in Phase One and toddlers in Phase Two and Three of the study. Other oral health status measures such as periodontal status, fluorosis, clefts, oral pathological conditions, and clefts were not assessed.

3.6.1 Nutritional status - Anthropometry Measurements

Anthropometry is the measurement of body size, weight and proportions. Measures obtained from anthropometry can be sensitive indicators of health, development and growth in infants and children (Moore and Roche, 1983). The measures can be used to evaluate nutritional status, for example whether the obesity is caused by over nutrition or emaciation resulting from protein-energy malnutrition. They are valuable in monitoring the effects of nutritional intervention for disease, trauma, surgery or malnutrition (Chumlea and Roche, 1987; Brodie, 1988).

3.6.1.1 Height measurement

In this study, height was measured using SECA Stadiometer (Model 220, Germany), accurate to the nearest 0.1 cm. The procedure of taking height measurement using this tool was as follows. During the measurement, the subjects were barefoot and wear minimal clothing to facilitate correct positioning of the body. The subjects stood with heels together, arms to the side, legs straight, shoulders relaxed and head in the Frankfort horizontal plane (look straight ahead). Heels, buttocks, scapulae (shoulder

blades) and back of the head was against the vertical surface of the Stadiometer (Robert DL and David CN, 2007).

Before the measurements were taken, the subjects were asked to inhale deeply, hold the breath and maintain an erect posture (stand up tall) while the headboard is lowered on the highest point of the head with enough pressure to compress the hair (Chumlea and Roche, 1987; Moore and Roche, 1983; and Gordon et al. 1988). The measurement was read to the nearest 0.1 cm with the eye level with the headboard to avoid errors caused by parallax. In order to ensure a reliable standard of measurement, the intra examiner reliability test was performed by taking twice repeated height measurements of 60 subjects and reliability tests using intra class correlation coefficient, which showed a score of 0.98 indicating high intra examiner reliability. In the actual study, the measurements were taken three times and the average was calculated and recorded.

The value of height was then referred to height-for-age to get z-score and was categorized according to WHO classification (2006). Low of height-for-age was used as an indicator of stunting, an index of chronic malnutrition. The classification of height-for-age (HAZ) was as follows:

Table 3.3 Height-for-age classification

Z-score	WHO Classification
Above median	Normal
< - 2.0 sd	Stunting
-2.0 sd to -3sd	Moderate stunting
<-3.0sd	Severe stunting

3.6.1.2 Weight measurement

The subjects were weighed in minimum clothing, without shoes and measured using a weighing scale (Model TANITA HD319, Japan), recorded to the nearest 0.1 kg. The SECA weighing scale has been calibrated periodically. During measurement, the subjects stood still in the middle of the scale's platform without touching anything and with the body weight equally distributed on both feet. The weight was read to the nearest 0.1 kg and recorded (Robert and David, 2007). The intra examiner reliability test again was performed by taking twice repeated weight measurements of 60 subjects and reliability tests using intra class correlation coefficient which showed a score of 0.96 indicating high intra examiner reliability. In the actual study, the measurement was taken three times and the average was calculated and recorded. The value of weight was referred to weight-for-age (WAZ) to get the z-score and was categorized according to WHO Classification (2006). Low weight-for-age (WAZ) is used as an indicator of wasting, an acute condition of current malnutrition.

The WAZ classification as follow:

Table 3.4 Weight-for-age classification

Z-score	Classification
>2sd	Overweight
median to <2sd	Normal
< - 2.0 sd	Underweight
-2.0 sd to -3 sd	Moderate underweight
<-3.0 sd	Severe underweight

(WHO, 2006)

3.6.1.3 Body Mass Index (BMI-for-age) Calculation

Body mass index was calculated based on the formula as follows:

$$\text{BMI} = \frac{\text{Weight (kg)}}{\{(\text{Height (m)})^2\}}$$

Age of the toddlers was changed to age in months. After calculating the BMI, the values were referred to BMI-for-age to get the Z-scores. The value of Z-score was different between boys and girls. The preschool children aged 5 to 6 years was referred to WHO classification (2007) reference and the toddler's age 0 to 5 years old referred to WHO classification (2006).

The classification of BMI-for-age as follow:

Table 3.5 BMI-for-age classification (Preschool aged 5-6 years old)

Z-score	Classification
> +2sd	Obesity
>+1sd	Overweight
Median to -1sd	Normal
< -2sd	Thinness
< -3sd	Severe thinness

(WHO, 2007)

Table 3.6 BMI-for-age classification (Toddlers 0 to <5 years)

Z-score	Classification
> +2sd	Overweight
>+1sd	At risk of overweight
Median to -1sd	Normal
< -2sd	Thinness
< -3sd	Severe thinness

(WHO, 2006).

3.6.2 Dietary Habits

In order to reflect the dietary habits, frequency of taking sugary food and drinks and type of food and beverages consumed in a period of 24 hours was assessed. Frequency of taking sugary food and drinks was determined using the Food Frequency Questionnaire or FFQ, while food and beverage consumed in the last 24 hours was assessed using 24 hours diet recall.

3.6.2.1 Food frequency of sugary foods and drinks questionnaire

The FFQ was a tool used to assess nutrient intake by determining how frequent a respondent consumes sugary foods and beverages. The questionnaire consists of a list of sugary foods and beverages that are important contributors to the intake of energy and nutrients. According to Boeing *et al.* (1989), FFQ is a suitable method in evaluating food intake in epidemiology studies because it is simple, easy to answer and not pose a burden to the respondent. The FFQ data was transferred and analyzed using SPSS Version 18.0.

In our study, initially the food frequency list was developed based on the list of sugary food and drinks by (Habibian *et al.*, (2001) and Palmer (2003). The list was then modified to include Malaysian foods according to the Nutrient Composition of Malaysian Foods (Tee E.S *et al.*, 1997) and Atlas of Food Exchanges & Portion Sizes (Suzana *et al.*, 2002). The contents of the FFQ were validated by nutrition experts consisting of two lecturers in Community Nutrition and Clinical Nutrition in University Science of Malaysia.

The respondents were asked to mention how many times a day, week, month or year that they usually consume the foods. The food intake frequency was categorized into a 7-point scale rating, that is 1 = never/rarely, 2 = once a month, 3 = 2–3 times a month, 4 = once a week, 5 = 2–3 times a week, 6 = once daily, and 7 = 2–3 times daily.

Information on the frequency of intake of each food item in the FFQ was used to calculate the food consumption frequency score of the food item consumed by respondents. The formula used was based on Chee *et al.* (1996) who adapted it from Reaburn, Kronl & Lau (1979).

Food consumption frequency score =

$$\frac{R_1 S_1 + R_2 S_2 + R_3 S_3 + \dots + R_7 S_7}{7}$$

$S_1 - S_7$ = the scale ratings

$R_1 - R_7$ = percentage of respondents selecting a rating

7 = the maximum scale rating

The higher the score, the more frequent the specific food was consumed. A pilot study was carried out on 60 mothers with similar characteristics as the study sample and analysis of reliability test conducted showed a Cronbach Alpha of 0.95 which indicate excellent internal consistency reliability. Therefore, this FFQ method was used as our measurement tool in the present study to reflect the dietary habits of the preschoolers in the proxy cross-sectional study and toddlers in the longitudinal intervention study.

3.6.2.2 24 Hour Diet Recall

The 24 hour diet recall was a tool used to record the food and beverage consumed by the respondents in last the 24 hours. By using the standardized form (from *Kajian Pengambilan Makanan, Malaysia* (2002/2003), the 24 hour recall nutritional intake was conducted to provide information on the subject's exact food intake whereby a trained interviewer would ask the respondent to recall in detail all the food and

beverages consumed during the previous 24 hours. It was conducted in four stages, based on the format of the forms. Firstly, a complete list of all foods and beverages consumed during the previous 24 hour were recorded. Secondly, detailed descriptions of all foods and beverages were recorded (e.g. cooking method). Thirdly, estimated amounts of all food and beverages consumed were obtained and finally, the recall was reviewed to ensure all items have been recorded correctly. All the information was analyzed using the nutrient calculation system “Diet Analysis Plus 8 - Version 2”. The Diet Analysis Plus 8 software was based on Excel, accessibility and flexible-hours use of a ‘2-in-1’ food composition database and a calculator of nutrient intake.

For the diet analysis, all Malaysian foods based on the “Nutrient Composition of Malaysian Foods” book compiled by Tee, *et al.*, (1997) must be entered to the Diet Analysis Plus 8, because Malaysian foods were not included in the original program. The recipe for certain foods which were not in the book was created before entering the dietary data to the program. Next, all the nutrients data obtained were transferred to SPSS Version 18 for the calculation of dietary adequacy, based on the “Recommended Nutrient Intakes for Malaysia 2005” (NCCFN, 2005).

3.6.3 Knowledge, Attitude and Practice (K/A/P) on diet and oral health

The questionnaire for KAP on diet and oral health was adapted from Oral Health Promotion: Evaluation Toolkit proposed by Watt, (2004). This questionnaire was translated from English to Bahasa Melayu by a lecturer in *Pusat Bahasa*, University Science of Malaysia. It was back translated from Bahasa to English by another language expert for validation purpose. A pilot study was carried out on 60 mothers of similar characteristics with the study sample and the reliability test performed revealed a Cronbach Alpha of 0.70 which reflects good internal consistency of the KAP questionnaire.

The questionnaire consists of two sections. First section was to retrieve the socio demographic information while the second section was on KAP on diet and oral health.

Details are as follows:

Table 3.7 Section 1: Socio demographic status questionnaire

	Child Information		Parents Information(Mother/Father)
1.	Registration number	1.	Name
2.	TBK/Clinic	2.	Age
3.	Name	3.	Race
4.	Age (years/month)	4.	Level of education
5.	Sex	5.	Occupation
6.	Weight (kg)	6.	Family members
7.	Height (cm)	7.	Monthly total family income
8.	BMI	8.	Monthly expenditure for food
9.	dmf Index	9.	Water supply: Well, Well (with motorised pump) and Kelantan piped water supply)

Table 3.8 Section 2: KAP on diet and oral health

	Domain	Total questions
1.	Parents/carers knowledge: bottle use	3
2.	Parents/carers knowledge: caries prevention	2
3.	Parents/carers knowledge: sugar	8
4.	Parents/carers knowledge: tooth brushing	5
5.	Parents/carers knowledge: Fluoride	2
6.	Attitude outcome measures: caries	3
7.	Attitude outcome measures: deciduous teeth	3
10.	Breastfeeding: practices	2
11.	Bottle-feeding: parents/carers practices	2
12.	Children's sugary drinks and snacks consumption: sugary drinks	9
13.	Children's sugary drinks and snacks consumption: snacks	1
	Total questions	40

Knowledge was assessed through 20-items. Respondents were asked whether the statements given were correct. Answer options provided for each statement were "Agree" "Disagree," or "Not sure." Each positive statement with the correct "Agree" answer was given one point, while each negative statement with the correct "Disagree" answer was given one point. For every "not sure" and wrong answer a zero point was given. Scoring was based on the assumption that the higher the score, the better the

knowledge. The total score was divided into poor, moderate and high respondents' knowledge. A score less than one third of total score was categorized as poor knowledge, a score from one third to two third was categorized as moderate and a score more than two third was considered as having high knowledge.

For assessing attitude, six statements on attitude towards diet and oral health were formulated. Respondents were asked whether "Agree", "Disagree" or "Not Sure" for every item. One point was given to every positive statement with "agree" answer which reflects a positive attitude. One point was given to every negative statement with "disagree" answer which also reflects a positive attitude. The higher the scoring showed more positive attitude on diet and oral health. The total score was divided into poor, moderate and high respondents' attitude. A score less than one third of total score was categorized as poor attitude, a score from one third to two third was categorized as moderate and a score more than two third was considered as having high attitude.

Assessment of practice was done through 14-items. For item 27, 30 and 31, the respondents were asked to answer "Yes" or "No" to given statements and one point was given for the correct answers. For item 28, based on a scale of 1 to 4, respondents were asked to indicate the duration of breastfeeding practice and one point was given for the correct answer. For domain 29, the respondents were asked about the practice of bottle feeding and one point was given for every correct answer. A higher score indicates a more positive practice on diet and oral health. The total score was divided into poor, moderate and high respondents' practice. A score less than one third of total score was categorized as poor practice, a score from one third to two third was categorized as moderate and a score more than two third was considered as having high practice. The questionnaire is attached in the Appendix.

3.6.4 Oral Health Measures – Early Childhood Caries

The index of dental caries used in this study was the dmft index (WHO, 1997). The index was chosen primarily because the subjects in this study were below 6 years old. At this age all deciduous teeth would have normally erupted. So, any missing deciduous tooth was considered more likely to be due to caries unless other reason such as trauma was being implicated. The criterion used for ECC in the present study was “decay involving primary maxillary incisors”. This was based on the definition of ECC as “the occurrence of any sign of dental caries on any tooth surface during the first three years of life”. It must be noted that the all toddlers included in the study sample must be caries-free (dmft 0) at the beginning of the study (ie at baseline).

3.7 Data Collection and Quality Control

3.7.1 Phase one (Cross sectional study)

In Phase One, the data collected in the proxy population of preschool children aged 5 to 6 years old in Tumpat and Pasir Mas districts were caries (dmft), nutritional status, dietary habits and also the knowledge, attitude, practices (KAP) related to ECC among their mothers. After consent was obtained, both general health and oral health status of the preschoolers were measured.

To control the quality of data for nutritional status, a SECA stadiometer was used to measure height, where the subjects wear minimal clothing and were required to take off their shoes. They were asked to inhale deeply, hold their breath and maintain an erect posture while the headboard is lowered on to the highest point of their head. With the eye level with the headboard, the measurement was then read to the nearest 0.1 cm. For weight measurements, the subjects were required to stand still in the middle of the TANITA HD 319 weighing scale’s platform without touching anything and with the body weight equally distributed on both feet. The weight was read to the nearest 0.1 kg

and recorded. All measures were done at least twice and the average taken. Based on the weight and height measurements, BMI was calculated to reflect their nutritional status. Measurements were compared to the reference values of the National Centre for Health Statistics (NCHS), and classification of the nutritional status was done based on the WHO recommendations (2006) and (2007).

To collect information on dietary habits of the preschoolers, a guided interview questionnaire were conducted on their mothers by trained dental nurses. The mothers were given FFQ to determine the frequency of taking sweet foods and sweet beverages among their children, a 24 hour diet recall sheet to determine the dietary intake of preschoolers according to the Malaysia recommended dietary allowances (RDA) standard (NCCFN, 2005). In addition, the KAP questionnaire to assess mothers' knowledge, attitude and practices related to ECC was also administered. The FFQ and KAP questionnaire were completed on the same day; whereas the 24-hour diet recall was interview to the mothers to record the diet intake for 2 weekdays and one weekend day to get the average of nutrient intake. All data was rechecked for completeness.

To control for data quality of dental caries, three dental officers involved in clinical examinations were trained and calibrated to use the dmft index of WHO (1997) and they were able to duplicate the examination accurately exceeding a percentage agreement of at least 80% (Kappa 0.93). While the intra-oral examinations were performed by the dentists, the clinical data was recorded by trained dental nurses.

To control for data quality of the digital photograph used to record anterior teeth caries, prior to data collection, an in-vitro artificial caries was photographed to establish a standardized protocol for digital photography that is clear, accurate and reproducible to record early childhood caries (ECC). The purpose of this protocol is to produce a digital image of sufficient quality that is able to show a frank cavity and differentiate a white spot lesion on the maxillary side of the central incisors when printed or shown in

a computer screen. The in-vitro artificial white spot lesion was created using phosphoric acid used for etching fissure sealants, between the proximal surfaces of two extracted maxillary incisors mounted on a plaster cast and fixed on to a phantom head. Several factors were varied such as dryness of the enamel, type of lighting (torch light and camera built-in / angled flash (with flash and without flash), angle of incident lighting (30, 45, 90 degree), duration of lens exposure-automatic, oral cleanliness (free from plaque deposit) and distance between the camera lens and tooth were controlled and tested. Digital photographs were taken using different setting to establish the best set-up. The best visual result was then used as the standard operating procedure for recording the progress of ECC on the maxillary incisors during the field survey. The established standard was tested in vivo on preschoolers. The digital photos were repeated until a clear soft and hard copy was obtained.

3.7.2 Phase Two and Three (An intervention prospective study)

These phases of study was conducted among toddlers aged 2 – 3 years and involved the pre intervention and post intervention assessment of both general and oral health status measurements. At pre intervention in Phase Two, the baseline data for both intervention and control group was collected for both general and oral health status. These include nutritional status (height, weight, BMI), dietary habits (FFQ and 24 hour diet recall) and KAP related to ECC among the mothers and also ECC assessment and digital photography among the toddlers.

The intervention group then received a packaged intervention program (TIPTOP program) which included at least four times intervention visit by the principal researcher, once in six months within a period of 18 month. The control group however followed the usual “Toddlers and Postnatal Program” at all Health Clinic and *Klinik Desa* in Pasir Mas and were visited twice by the principal researcher. The same set of

data at baseline was collected at every visit to monitor progress. This included the digital photography record of the current status and the progression of ECC of the primary maxillary incisors which was taken at every visit. One copy of the printed photo was given to the mother and another copy was kept in the children's file. For toddlers with early signs of ECC (eg. white spot lesion) on the central incisors at any visit, they were visited more than once during the 6 months (maximum of once every month) to control the seriousness. For this special group, their diet counseling was individualized at home. After 18 months, the post intervention data collection or Phase Three of the study commenced. Measurements for general health and oral health were repeated. Summary of data collection procedure is shown in figure 3.3 and figure 3.4.

To prevent possible bias in diagnosing ECC photo records between the intervention and control group, the examination of digital photos was done in a neutral district (Kota Bharu). Except for the principal investigator, the examiners were "blinded" ie. They did not know whether the photos came from intervention (Tumpat) or control district (Pasir Mas). Their task was just to state whether ECC was present or not, based totally on the digital photo record. This procedure complemented and confirmed the clinical examination (dmft diagnosis) which was done on site at the district health center.

Figure 3.3 Diagrams of data collection in Intervention group

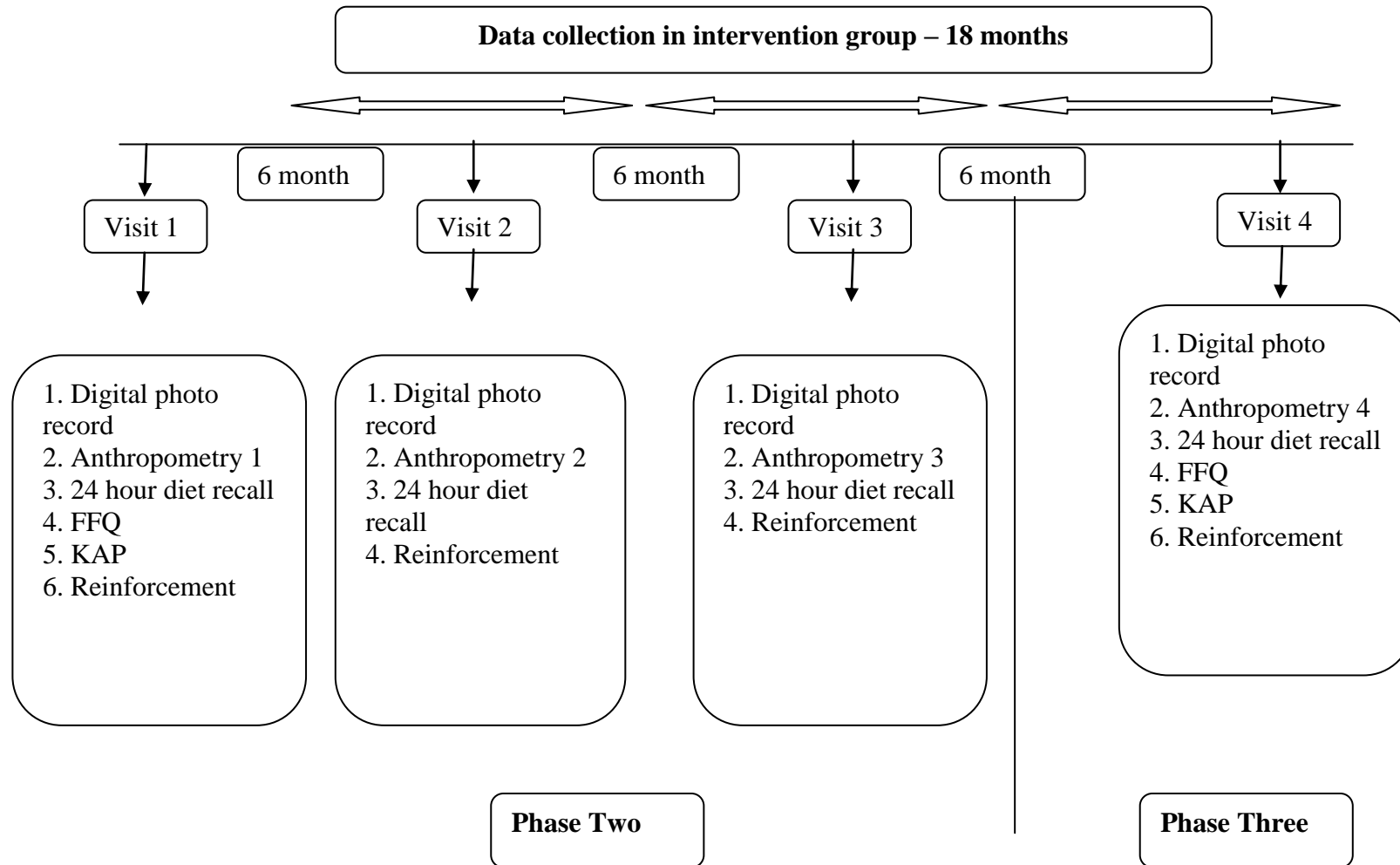
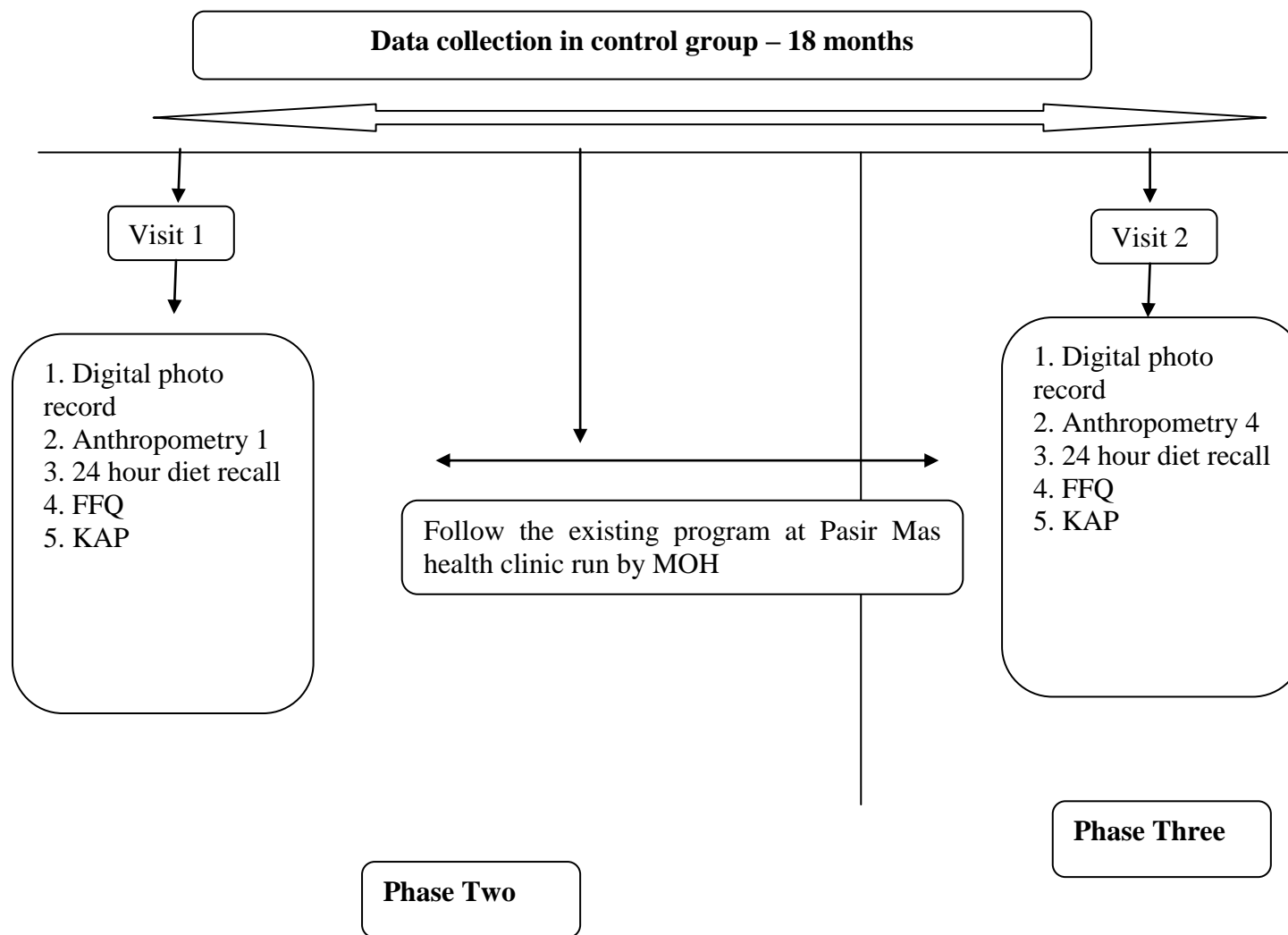


Figure 3.4 Diagrams of data collection in Control group



3.8 Data Analysis

Data was entered, cleaned and analyzed using SPSS Version 18 (SPSS, 2010). Descriptive statistics such as means and standard deviation (SD) for continuous variables, and the frequency and percentages for categorical variables was determined. Data were then analyzed based on the objectives of the study.

For the first objective of study, appropriate descriptive statistic analyses were performed to present the characteristics of subjects, nutritional status, dietary habits, KAP and prevalence of ECC. In order to achieve second and third objectives, several inferential statistic were employed based on either the outcome variables were continuous or categorical. It also depends on whether the comparison of outcome variables was within or between groups. If the outcomes were categorical such as nutritional status and prevalence of ECC, comparison between the pre and post assessment within each intervention and control group were done using Mc Nemar tests.

However, when pre and post assessments were compared within intervention and control group in terms of continuous outcomes such as dietary habits which comprise of FFQ and 24 hour diet recall and also KAP score and mean dmft, either paired t-tests or Wilcoxon tests were employed. In cases where the pre and post differences in nutritional status and prevalence of ECC between intervention and control groups were compared, Chi-square test was used. While, when continuous outcomes such as dietary habits and KAP on sugary foods and drinks between intervention and control were assessed, the independent t-test were used. Finally, in order to predict the early childhood caries (odds) univariately between intervention and control group, the simple logistic regressions was used. Level of significance was set at 0.05.

Diet and nutrition was analyzed using the nutrient calculation system software “Diet Analysis Plus 8” version 2. For data entry, all Malaysian foods based on the “Nutrient Composition of Malaysian Foods” books which were compiled by Tee et al.,

(1997), were entered into the Diet Analysis Plus 8, because Malaysian foods were not included in the original program. Thus the recipe for certain foods which are not in the book were created before entering the dietary data to the program. Subsequently, all of the nutrients data obtained were transferred to SPSS Version 18 for the calculation of dietary adequacy, based on the “Recommended Nutrient Intakes for Malaysia 2005” (NCCFN, 2005).