

Study Protocol

PEaters Choice™: Randomized Control Trial to Improve Picky Eating Behaviour Among Children Aged 3-5 Years

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1. Background and Significance

Picky eating (PE) is one of the feeding difficulty spectrum (Kerzner et al. 2014). However, the definition of a PE is too broad and diverse, and the selection of this definition depends on the study conducted (Lafraire et al. 2016). Although there are various definitions of PE, most researchers use lack of diversity in food intake, fear of trying new foods (neophobia), and refusal to eat commonly eaten foods. As a result, mealtimes become longer, disrupting children's daily routines, and making life difficult for both the children and the parents (Taylor et al. 2015).

The prevalence of PE children varies by age (Li et al. 2017; Machado et al. 2016). The majority of PE increased with age and peaked at three years (Cardona Cano et al. 2015; Taylor et al. 2015). However, there are limitations to the prevalence of PE studies conducted in Malaysia. In one study, the prevalence of PE in children aged 5-6 years was reported to be 31.8 percent (Mohd Hanapi et al. 2022), while in another study, the prevalence of PE in children aged 5-10 years was reported to be 53.4 percent (Joseph-Louise et al. 2020). However, both studies were conducted on a small scale (n = 172 and 192) and only focused on a small region, thus do not represent the entire Malaysian population. When looking at studies from abroad, the prevalence of PE children has a broad range of between 20 to 55% (Chao 2018; Li et al. 2017; Machado et al. 2016). On another note, each of these studies had different definitions of PE, and screening tools are different from each other.

Several other studies have reported that picky eaters also contribute to malnutrition (Antoniou et al. 2016; Xue et al. 2015) as the nutritional status (weight-for-age, height-for-age, weight-for-height, and BMI for age) for PE children are commonly below the median line and significantly different from non-PE children (Chao 2018; Hassan et al. 2020; Kwon et al. 2017). In addition, children of picky eaters (PE) are more likely to be underweight and shorter than non-PE children (De Barse et al. 2015; Taylor et al. 2018; Tharner et al. 2014). This may be due to generally less caloric intake, insufficient protein, and vegetable intake, affecting the children's growth (Van Der Horst et al. 2016). Previous research also reported that PE children had a lower intake of micronutrients such as thiamine and dietary fiber than normal children, especially those eating small amounts and limited variety characteristics (Kwon et al. 2017).

There are two major aspects that determine PE eating behaviour: 1) cognitive factors and 2) social and environmental influences. (Lafraire et al. 2016) Taste and sensory preferences are one of the components of cognitive factors. At the early stages of age, smell and taste help infants initiate metabolic pathways and initiate infant digestive systems. The smell of breast milk prepares a baby for the digestive process, which is vital to their survival (Bloomfield et al. 2017). It is

natural for infants to accept and reject food according to its taste (Domínguez 2014). However, this is also influenced by exposure to food tastes during prenatal, postnatal, and weaning practices (Uwaezuoke 2015). This changes their taste preferences, and as they get older, children become choosy (Nicklaus et al. 2019). It has been reported in a few other studies that PE children commonly avoid eating vegetables, meat, fish, eggs, and sauces. There are several possible reasons for this rejection, including the bitter or sour taste, the aroma, and the mushy or slippery texture of the food (Boquin et al. 2014; Werthmann et al. 2015). In addition to the characteristics mentioned above, disgust and sensory sensitivity, texture and visual, also contribute to PE behavior and food neophobia (Kutbi et al. 2019). However, repeated exposure will help increase acceptance of the food (Barnhill et al. 2016; Garcia et al. 2020; Kutbi et al. 2019).

One of the elements of the social and environmental factors is parenting strategies. (Lafraire et al. 2016). Parenting strategies refer to parental behavior during children feeding time or, in other words, are feeding practice or feeding style. Parenting styles can be classified into three styles of parenting; 1) the authoritative style characterized by warm and support, reasoning and democratic participation; (2) the authoritarian style characterized by physical coercion, verbal hostility and punitive; and (3) the permissive style characterized by indulgence (Robinson et al. 2001). PE children are often associated with authoritarian style parenting (Power et al. 2018) possibly because parents force children to eat as one way to satisfy their demands (Fries et al. 2017; Van Der Horst et al. 2017). Another study categorizes feeding-related aspects into 12 categories: 1) monitoring 2) emotion regulation 3) food as rewards 4) child control 5) modeling 6) restriction for weight 7) restriction for health 8) teaching nutrition 9) encourage balance/ variety 10) pressure to eat 11) healthy environment, and 12) involvement (Musher-Eizenman et al. 2007). Pressuring children to eat, role modeling, restrictions, rewards, and food as a soothing medium significantly impact children's eating behaviors (Kutbi et al. 2019; Mitchell et al. 2013). It has been found that eating under pressure and using rewards affects the enjoyment of food and leads to picky eating (Ek et al. 2016; Finnane et al. 2017). Parents of children with picky eating behaviors were also less likely to practise autonomy-supportive prompts such as positive or neutral tone of voice, giving examples and explaining reasons for the food intake (Fries et al. 2017). Besides that, peer modeling has shown a negative relationship between food neophobia and PE. Children are easily influenced by peers and will imitate behaviors, including food choices, which result in disliking food avoided by peers (Kutbi et al. 2019).

Although there is extensive documented evidence on the PE problems, no comprehensive intervention modules or mobile applications have focused on this group of the population across all age ranges. Intervention programs with

specialists such as pediatricians, occupational therapists, speech therapists, and dietitians are ideal. Still, it is less practical, especially to gather them at one time, one venue. In addition to this, most PE problems, both for typical and atypical development children, could be managed at the primary health care setting provided the staffs are sensitive to signs or red flags of PE (Milano et al. 2019). According to the Comprehensive Implementation Plan on Maternal, Infant, and Young Child Nutrition under action two (Who 2014), nutritional intervention programs currently in the health care setting are proposed to focus more on behavior change, which will also be the focus of this module. Therefore, this paper aims to describe the protocol of Randomized Controlled Trials by considering the limitations and suggestions gathered, to evaluate the effectiveness of the PEaters Choice™ module among picky eaters aged 3 to 5 years.

2. Objective

2.1 Main Objective

To evaluate the effectiveness of PEaters Choice™ for picky eaters in the age group of three to five years.

2.2 Specific Objective

1. To compare food repertoire, nutritional status and child eating behavior between intervention and control group.

2.3 Study Outcome

The primary outcome variable for this study is the list of foods eaten (food repertoire) by PE children. An increase in this list will demonstrate the effectiveness of this module in expanding the diversity of foods consumed. Secondary outcomes are children's eating behaviors, and nutritional status assessed through a WHO Anthro Software of weight-for-age, height-for-age, weight-for-height, and BMI-for-age.

3.Methodology

3.1 Study Type and Design

This study is single-blinded, with balance randomization (1:1) and parallel-group design (figure 1). The dyads will be recruit from chosen nurseries and kindergartens. Mothers, fathers or guardians of children who meet the inclusion and exclusion criteria will be invited to attend a briefing session led by the head researcher and concern form will be distributed. The objectives of this study and the intervention procedure will be described in detail in this session. Following that, the dyads will be randomly assigned to either intervention group or controlled group by using Microsoft Excel Random Number Generator. Dyads, will then fills out the sociodemographic information form, the Child Eating Behavior Questionnaires (CEBQ) and food intake form. The research team will also measure the children's weight and height using standard methods. Next, the nutritional status of each child is assessed by using WHO Anthro Software version 3.2.2.

Data collection will be conducted three times throughout the intervention program. In the sixth and 12th weeks, the data to be collected are CEBQ, anthropometry, and a list of commonly eaten foods. Follow-up sessions in the eighth and tenth weeks are used to assess progress and discuss any issues that may arise. Table 2 shows the data acquisition time for the parameter.

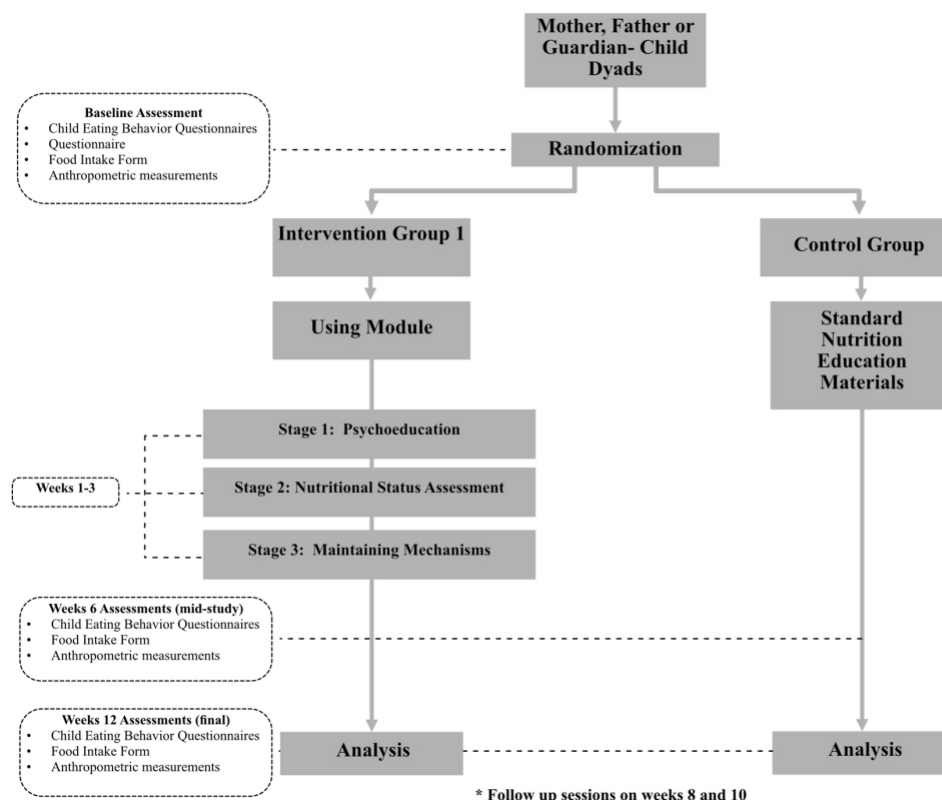


Figure 1. PEaters Choice™ study flow

Table 1. Data acquisition time for the parameter.

| Parameters | Baseline | Week 6 | Week 12 |
|--------------------------------------------------------|----------|--------|---------|
| CEBQ | X | X | X |
| Number of food consumed by the subject | X | X | X |
| Anthropometry (weight, height, and nutritional status) | X | X | X |

3.2 Study Intervention

There will be nine sessions conducted throughout the intervention period, which are three module activity sessions (10 activities), three assessment sessions (baseline, mid-study assessment and final assessment), two follow-up sessions to be completed in the eighth and tenth weeks. Then the subjects will be divided randomly into two groups using Microsoft Excel random number generator: intervention group and control group. Intervention group will use the modules developed at the beginning of the project, while the control group will be given standard nutrition education materials. This module will have four primary sub modules (SM): SM1- An overview of picky eaters, SM2-Healthy eating for children, SM3-Parental Strategies and SM4- Sensory perception. This module will use

behavioral approach with gradual exposure as the basis for implementation of each activity (Hesley 2019).

There are three stages in implementing this module (adaptation from (Thomas et al. 2019)). The first stage is Psychoeducation in which mother, father, or caregiver of a PE child will be briefly described on the PE problems and the three SM. At this stage, mother, father or guardian are encouraged to maintain current dietary practices. The second stage is Nutritional Status Assessment, in which a greater emphasis on the nutritional component, including anthropometric assessment, food intake, and serving sizes for all food groups will be implemented. The third stage is the Maintaining Mechanism. At this stage, the mother, father or guardian of the PC child will follow the intervention-type activities from SM2, SM3 and SM4. All these intervention activities are intended to support the changes made in the second stage. Figure 1 shows the flow chart for this module along with the related sub -modules.

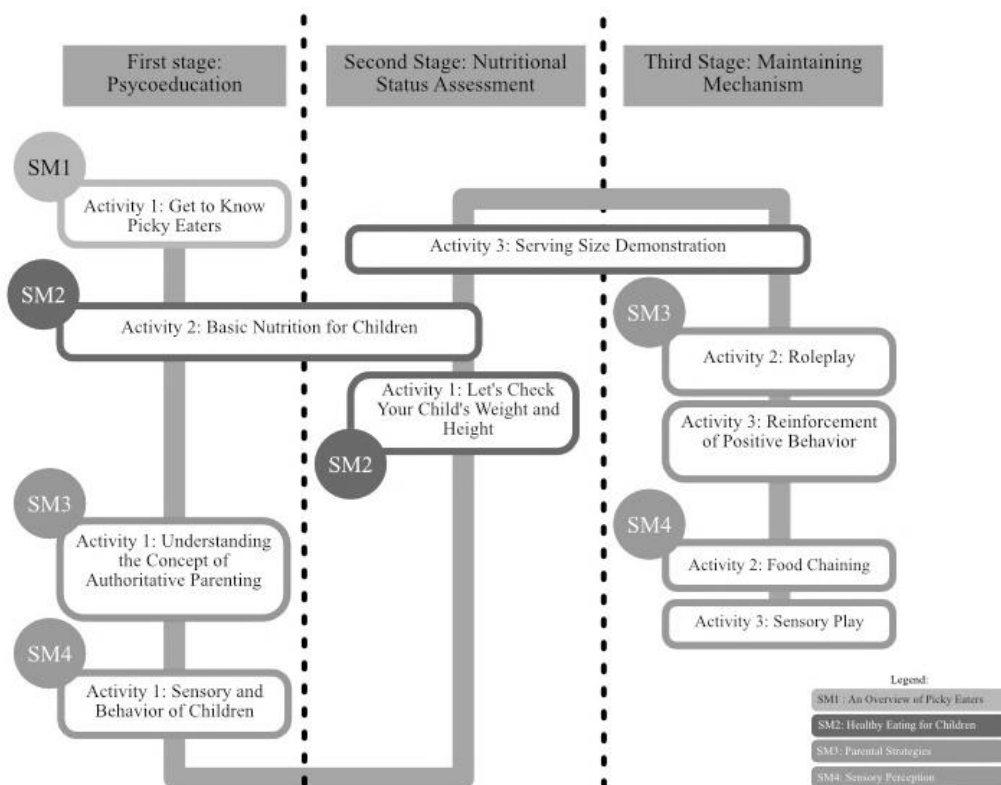


Figure 2. PEaters Choice™ sub-modules flow chart

3.3 Study Setting

The study will be conducted at the UKM Specialist Children's Hospital (HPKK UKM) in Kuala Lumpur to simulate real-life situations for this module. All briefings, therapies and activities will be conducted at this place. Considering several factors, especially the ability of the subject to commit to attending the prescribed session, the selected area to participate in the study is a 5 km radius from HPKK UKM.

3.4 Study Participant

The sampling method used is cluster sampling. A list of nurseries and kindergartens in the selected area will be obtained from government departments. Then, it will be grouped into four categories: government nurseries, private nurseries, government kindergartens, and private kindergartens.

3.5 Inclusion Criteria

Subject (Children):

1. Subjects are between three and five years old.
2. Subjects had PE problems (screened using the CEBQ).

Mother, Father or guardian:

1. Understanding the Malay language.
2. Knowing about the subject's nutrition and behaviour.

3.6 Exclusion Criteria

The dyads will be excluded if:

1. The subject has clinical health problems such as autism, down syndrome, global developmental delay, dyslexia, or any health problem interfering with eating habits.
2. Mother, father, or guardian is non-Malaysian.

3.7 Sample Size

Sample size calculation using the G-Power program (95% confidence interval, 80% power) found a minimum of 138 subjects required. The study sample was increased by 10%, considering the dropout factors to 154 subjects (77 people for each group).

3.8 Data Collection

3.8.1 Sociodemographic, Anthropometry and Nutritional Status

The sociodemographic information will be collected using the form provided at the beginning of the study. Mothers, fathers or guardians will fill out forms under the research team's supervision. Among the information requested are the personal information of the children and parents, parents' occupations, family income, and details about other siblings.

Weight and height measurements will be taken three times during the study period by the research team who have been trained. Weight measurements will use SECA Clara 803 scales. Subjects will be weighed with minimal and light clothing. Subjects were asked to stand in the center of the scales with their legs slightly open. The subject should also be in a state of silence and immobility. Readings were taken at the nearest 0.1 kg measure (Who 2008). As for height measurement, the measurement will use SECA 213 Stadiometer. Subjects should stand barefoot in the center of the height gauge site with feet slightly open. The back of the head, shoulders, buttocks, calves and back heels touch the back end of the stadiometer. Position the subject's head vertically with the eyes in the Frankfurt horizontal plane position. Then lower the horizontal bar up to the vertex of the head. Readings were taken from the front with measurements of the nearest 0.1 cm (Who 2008). Body Mass Index (BMI) is calculated from weight and height readings. Child growth was assessed by determining weight-for-age, height-for-age, weight-for-height, and BMI-for-age z scores using WHO Anthro software version 3.2.2 (Blössner et al. 2011). Classifications used for each growth indicator to determine a child's nutritional status were based on (Who 2006) (Table 2).

Table 2. Growth indicator classifications

| Category | Range |
|-------------------------------------------------|---------------------------|
| <u><i>Weight-for-age</i></u> | |
| Severe underweight | z score < -3 s.d |
| Moderate underweight | -3 s.d ≤ z score < -2 s.d |
| Normal | -2 s.d ≤ z score < 2 s.d |
| Growth Problem | z score > 2 s.d |
| <u><i>Height-for-age</i></u> | |
| Severe stunted | z score < -3 s.d |
| Moderate Stunted | -3 s.d ≤ z score < -2 s.d |
| Normal | score ≥ -2 s.d |
| <u><i>Weight-for-height and BMI-for-age</i></u> | |
| Severe Waisted | z score < -3 s.d |
| Waisted | -3 s.d ≤ z score < -2 s.d |
| Normal | -2 s.d ≤ z score < 2 s.d |
| Overweight | z score > 2 s.d |
| Obese | z score > 3 s.d |

3.8.2 Child Eating Behaviour Questionnaires (CEBQ)

The CEBQ will be self-administered by the parent or guardian with the assistance of the research team. CEBQ is an instrument used to identify eating behaviors for children. This instrument was chosen because it is a more sensitive and comprehensive instrument in assessing eating behaviour (51). The CEBQ (52) was translated into Malay and validated (53). This questionnaire has 35 questions with eight primary constructs divided into food approach behaviors that refer to positive responses during eating and food avoidance behaviors that refer to adverse reactions during eating. Food approach behaviors are food responsiveness (7 questions), enjoyment of food (3 questions), emotional-overeating (3 questions), and desire to drink (3 questions). In comparison, food avoidance behaviors are satiety responsiveness (5 questions), slowness in eating (4 questions), emotional under-eating (4 questions), and food fussiness (6 questions). Cronbach's Alpha coefficient value among Malaysian children is good between 0.75 to 0.85 (53).

Each question must be answered using a Likert scale with a choice of 5 answers, namely never (1), rarely (2), sometimes (3), often (4), and always (5). A high average score for each construct indicates a high intensity for the behaviour.

The construct used in the CEBQ is food fussiness, with six questions to assess PE behaviour. Children were categorized as PE if they obtained a mean value of three and above (54).

3.9 Statistical Analysis Plan

Data will be analyzed using the SPSS program. Using mixed ANOVA, we compared the list of foods eaten (food repertoire) before, during, and after the intervention between the two groups to evaluate the impact of the intervention. On the CEBQ, the comparison of eight primary constructs scores between the two groups was also accomplished with mixed ANOVA. A similar statistical analysis was used to assess the nutritional status of the intervention and control groups.

3.10 Data Management

The research team will manage all data. Data will be entered into the SPSS program by the researcher and reviewed by the head researcher. Questionable data will be confirmed with original forms or relevant sources. Outlier data that is deemed unreasonable will be removed and marked as missing.

Most of the questionnaires will be filled out by mothers, fathers or guardians, in ensuring they understand the questions correctly. To avoid data loss, each form will be carefully reviewed once completed by mothers, fathers or guardians. Weighing scales and stadiometers will always be calibrated using standard weights and rulers before weight and height measurements are taken. The head researcher will check 10% of the BMI calculation and nutritional status as a quality control measure.

3.11 Discontinuation Procedures and Stopping Rules

The procedure in this study did not involve any invasive process and provided only minimal risk to the subjects. Therefore, the subjects will continue participating in the study for 12 weeks. If the subject fails to attend two consecutive therapy/activity sessions and does not attend three sessions in total, the subject will be removed from the study. However, the final decision to discontinue the subject will be made after discussion with the research team members.

3.12 Ethics of Study

This study has obtained ethical approval from the Research Ethics Committee, Universiti Kebangsaan Malaysia (UKM PPI/111/8/JEP-2021-746, 11 January 2022).

3.13 Informed Consent/Assent Process

The dyads will be contacted through appropriate means and informed about this study using the study information form provided. If they agree to participate in the study, they will fill out a consent form to participate in the study.

3.14 Privacy

Privacy, confidentiality, and data/information that refers directly to the participant's identity will be strictly protected. However, data from this study will be used to make a report and may be published. Data will be reported collectively without reference to individuals.

3.15 Risk to study Participant

The risk was minimal in participating in this study.

3.16 Conflict of Interest

All researchers has no conflicts of interest in this study.

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INFORMED CONSENT FORM

Research Title: PEaters Choice™: Randomized Control Trial to Improve Picky Eating Behaviour Among Children Aged 3-5 Years

Researcher's Name:

I,, IC No:

- have read the information in the Patient Information Sheet, **including information regarding the risk in this study**
- have been given time to think about it, and all of my questions have been answered to my satisfaction.
- understand that I may freely choose to withdraw from this study at any time without reason and repercussion
- understand that my anonymity will be ensured in the write-up.

I voluntarily agree to be part of this research study, follow the study procedures, and provide necessary information to the researcher or other staff members, as requested.

.....
(Signature)

.....
(Date)

| | |
|---------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| <p>..... Witness (if any)</p> <p>..... (Signature)</p> <p>..... (IC Number)</p> <p>..... (Date)</p> | <p>..... Researcher</p> <p>..... (Signature)</p> <p>..... (IC Number)</p> <p>..... (Date)</p> |
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