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Development and Validation of Food Frequency Questionnaire (FFQ) for Ultra-processed Food Consumption among Adults in Malaysia: A protocol study

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Abstract

This study aims to develop and validate a food frequency questionnaire for ultra-processed food (FFQ-UPF) among Malaysian adults and will utilise a cross-sectional study design. Ultra-processed food items will be identified from the subjects' three days 24-hour dietary recalls and a primary ultra-processed food checklist. Frequency options and portion sizes will be determined from the literature review. Expert panels will validate the items' validity and relevancy and the newly developed FFQ-UPF will be pilot tested to the target population. It will also be validated against three days of 24-hour diet recall and will be retested two weeks after criterion validation.

Keywords: development; FFQ-UPF; Malaysia; ultra-processed food

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1.0 Introduction

The global food system has undergone marked alteration resulting from the advancement in food processing and technology in recent years, which have modified the food structure, taste, and nutritional content. NOVA Food Classification system developed by Monteiro et al. (2019) has defined ultra-processed food as formulated food substances with little if any, whole food and which habitually contain added flavours, colours, and other cosmetic additives, making the food hyper-palatable and affordable. As the food companies' primary focus is profit-based, the nutrient content and quality of the food products are "abandoned". Studies showed that increases in the intake of ultra-processed food in daily diet were associated with a surge in energy density, carbohydrates, free sugars, total and saturated fats, sodium, and reduction in protein, vitamins, and other minerals required by the body (Martini et al., 2021).

Research revealed that ingestion of ultra-processed food might lead to weight gain and other health complications (Pagliai et al., 2021). As a result, a proper assessment tool is required to assess the consumption of ultra-processed food, specifically among the Malaysian population. However, the majority of data on ultra-processed food consumption have been derived from 24-hour dietary recall, general food frequency questionnaires (FFQs), and food diaries, which have not been validated explicitly for assessing ultra-processed food. In this circumstance, tools specifically validated to assess ultra-processed food consumption levels can be helpful to avoid

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misinterpretation, mainly when used to examine the relationship with health status and to help in planning and making strategies to manage the intake of ultra-processed food in a particular population.

It is suggested to use FFQ in epidemiological studies to assess dietary intake as it helps provide information on the overall intake of the individuals, is cost-effective, and is time-saving. Even though multiple 24-hour diet recall and food diaries may outperform FFQ in assessing food intake and estimating nutrient intakes, traditional 24-hour recall or food diaries were impractical in extensive observational studies. The issues may arise due to feasibility concerns and costs associated with scheduling, training interviewers or respondents, and data coding (Park et al., 2018). To the best of our knowledge, limited FFQs are available to assess and evaluate the consumption of ultra-processed food among adults in Malaysia. Currently, the general FFQ for Malaysians consisted of food items including the overall consumption of the Malaysian diet that are not focused on the intake of ultra-processed food. Therefore, this study aims to develop and validate a food frequency questionnaire for ultra-processed foods consumption (FFQ-UPF) among adults in Malaysia.

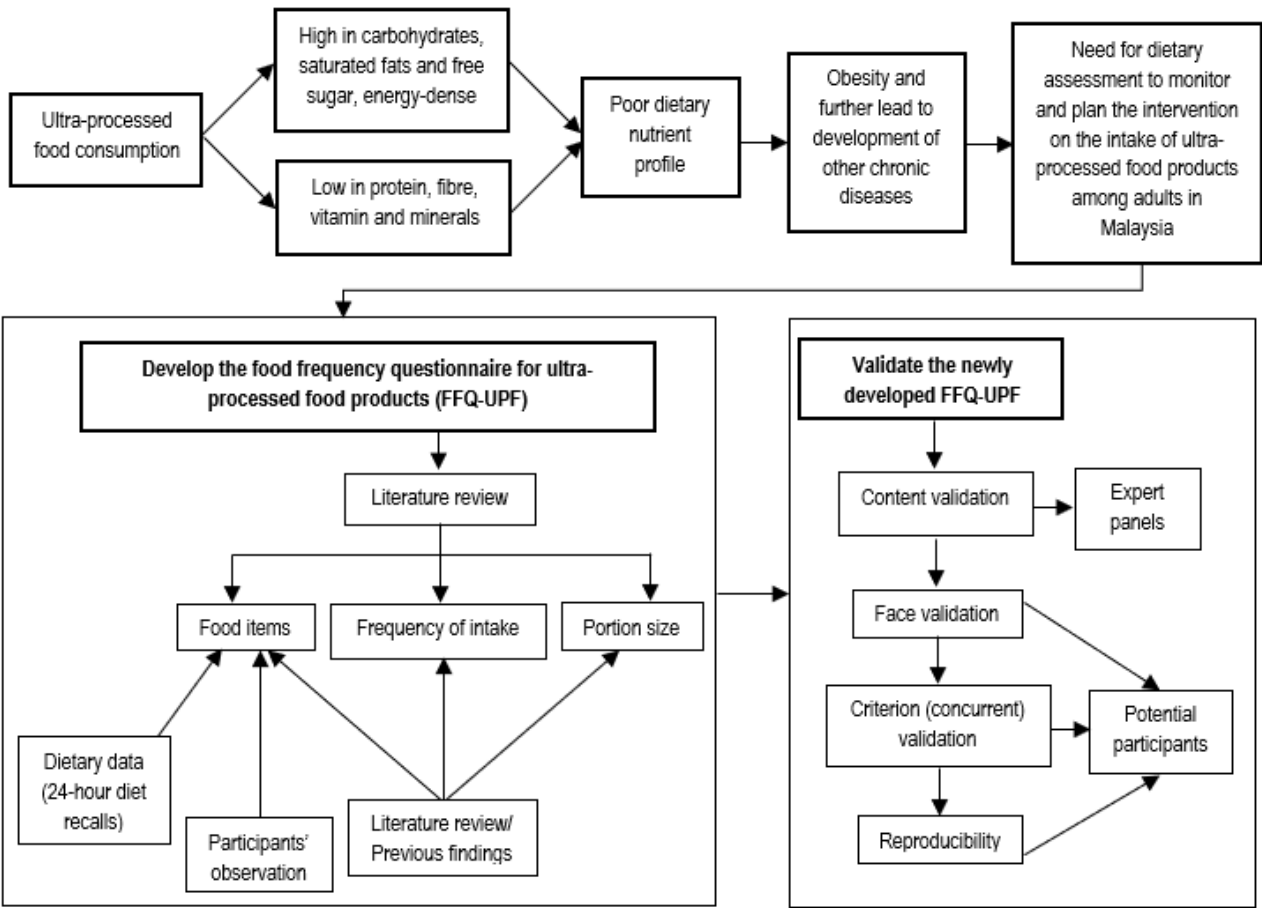


Fig. 1: Illustration of conceptual framework of the research

2.0 Literature Review

Multiple classification systems have been proposed resulting from the requisite to characterize foods based on their processing level. The common standard classification system used in nutrition research produced by NOVA, the International Agency for Research on Cancer (IARC), the International Food Information Council (IFIC), and the University of North Carolina (UNC) systems (Martinez-Perez et al., 2021). Comparing these four classification methods, only NOVA used the term “ultra-processed food” whilst other method used the term “highly processed food” to classify the food according to the level of processing. NOVA Food Classification system defined ultra-processed foods as formulations of ingredients that undergo a series of industrial processes and are primarily exclusive for industrial use with the addition of colours, flavours, emulsifiers, and other additives are commonly added to make the finished product edible or hyper-palatable (Monteiro et al., 2019). It was found that a fraction of ultra-processed food intake had higher energy density, higher overall fat content, saturated and trans-fat, and higher levels of free sugar with lower fibre, protein, vitamins, and potassium when compared to the fraction of intake of natural or minimally processed food (Martini et al., 2021).

Ultra-processed foods have become dominant components in the diets of people all over the world, accounting for up to 50% of energy intake in high-income countries, including Canada, U.S and U.K and up to 30% in middle-income countries, such as, Chile and Mexico with consumption volumes rapidly increasing (Elizabeth et al., 2021). Meanwhile, China, Korea, and Indonesia showed relatively

low intake of ultra-processed food (Setyowati, Andarwulan & Giriwono, 2018; Li & Shi et al., 2021; Shim et al., 2021). However, China and Korea showed a slight increase in the consumption of this food group by 2.6% from 1997 – 2011 and 3% from 2010 – 2018, respectively. In Malaysia, there were two studies assessed the intake of ultra-processed food among adults in Terengganu. It was found 40.38% of the total energy intake among Terengganu adults contributed by ultra-processed food (Asma' et al., 2019). However, a later study showed that the intake of this food group decreased to 23% of total energy intake (Asma' et al., 2020).

Since the inception of NOVA, nutrition researchers all over the world have significantly linked ultra-processed foods to poor dietary quality as well as negative metabolic and health outcomes in a variety of populations and countries (Elizabeth et al., 2021). Several studies have reported on the effect of ultra-processed food consumption on health outcomes. A systematic review of cross-sectional and cohort studies performed by Pagliai et al. (2021) summarized that ultra-processed food consumption was associated with a significant increase in the risk of overweight/obesity and high waist circumference, reduced HDL-cholesterol, and increased risk of metabolic syndrome. High consumption of ultra-processed foods was also associated with an increased risk of all-cause mortality, prevalent cardiovascular disease, coronary heart disease, cerebrovascular disease, hypertension, type 2 diabetes mellitus, metabolic syndrome, overweight and obesity, depression, irritable bowel syndrome, overall cancer, postmenopausal breast cancer, gestational obesity, adolescent asthma and wheezing, and frailty (Chen et al., 2020).

Various tools have been developed to assess and evaluate individuals' dietary intake, including 24-hour diet recall, dietary record (DR), diet history, and food frequency questionnaire (FFQ). Majority of the previous studies assessing the consumption of ultra-processed food via multiple-pass and automated multiple-pass 24-hour diet recall. The researchers also used food diaries and general FFQ in collecting the data on ultra-processed food intake. 24-hour diet recall and dietary record are open-ended assessment tools that gather a variety of detailed information on food consumption, including the food preparation methods, ingredients used in the mixed dishes, and the brand name of commercial products over a specific period. However, both methods only focus on short-term intake, and some respondents may intentionally under-reporting their diet. Besides, diet analysis from these methods may be time-consuming, laborious, and expensive to implement (Park et al., 2018).

Another strategy to assess and evaluate dietary intake is the FFQ. FFQ is an advanced food checklist in the dietary method that queries the respondents about how often and how much food they consume over a specific period (Cade et al., 2002). Compared to other methods, FFQ enables the long-term dietary intake assessment to be performed in a relatively simple, cost-effective, and time-efficient manner. FFQs allow the characterisation of dietary patterns and intake, the exploration of diet-disease connections, intervention evaluation, the assessment of nutrient-gene interaction, cross-population comparison, and worldwide nutrition monitoring (Sharma et al., 2011).

It is asserted that the FFQ should be developed specifically for the population to accomplish the objectives or purposes of the study (Cade et al., 2002). As there are differences in the individuals' sociodemographic and cultural backgrounds that influence their diet, FFQ should be constructed uniquely for each study group and research objective. However, the recently developed questionnaires are not explicitly designed to assess the intake of ultra-processed food intake among adults in Malaysia. Plus, the developed questionnaires are based on the population's usual food intake, which may not be relevant to other countries' use. Hence, developing a new food frequency questionnaire, specifically for ultra-processed food, may help future research on ultra-processed food among Malaysians.

There are three vital components of FFQ: food items, frequency of intake, and portion sizes (Cade et al., 2002). The development of a food list is crucial as it is the core to the success of the FFQ. The total variability of the population's diet, which includes various foods, brands, and preparation, cannot be captured fully with a finite food list (Thompson & Subar, 2017). Hence, gathering and developing a specific food list is essential in analysing the intake of ultra-processed food intake for the specific population. The food items included in the developed FFQ for Malaysians are not focused on ultra-processed food and are not classified based on the food processing level. In FFQ, frequency of intake is used to assess the rate or regularity of consumption of particular food based on the time frame of interest and the purpose of the study (Cade et al., 2002). It is recommended that the frequency should be closed rather than open-ended questions to help reduce coding time and transcription errors and reduce the number of questionnaires that must be rejected due to incomplete responses or cannot be adequately interpreted. Portion size refers to the amount of food and beverages that are typically served and is essential if the weight of the food (in grams) or nutrient intake is required in the study. Portion size should reflect known consumption patterns in the population. Plus, the questionnaire should allow for a wide range of portion size expression to distinguish subjects with similar frequency of consumption but different portion sizes (Cade et al., 2002). The respondents may be asked to describe their usual intake as small, medium, and large servings with the medium servings being specified. Alternatively, portion sizes can also be presented in a photo booklet or estimated using common household utensils.

The validation stage is critical for ensuring the questionnaire's psychometric soundness accurately measures its aim. Content validity, or logical validity, is a more methodical way of assessing a measure's content validity, which entails a panel of experts reviewing specific criteria and is typically performed during the test design process or to validate the translation and standardisation of an instrument for use in a different culture (Salkind, 2010). Face validity is the extent to which a test appears to measure what is intended and involves service users or potential participants in all the development stages of an instrument to improve the acceptability, relevance, and quality of the tools and related research (Wiering, Boer & Delnoij, 2017). Next, criterion validity (or criterion-related validity) assesses how well a test measures the outcome for which it was designed. As there is no "gold standard" or "standard of procedure" estimating dietary intake, FFQs are generally validated by comparing their results with reference methods, for instance, 24-hour dietary recall or dietary records in some studies (Fatimah et al., 2015). Reproducibility demonstrates reliability and refers to the comparability of the same method at distinct time points (Cui et al., 2021). Generally, reproducibility is determined by administering the same FFQ to the same group of subjects twice and analysing the relationship between the two responses.

3.0 Methodology

3.1 Research Design

This study will utilise a cross-sectional study design to develop and validate FFQ, specifically on ultra-processed food. This study is adapted from a study conducted by Fatimah et al. (2015). Figure 2 shows the phases involved in developing and validating the food frequency questionnaire for ultra-processed food (FFQ-UPF). The sample size for the development of FFQ-UPF will be divided based on the six zones in Malaysia and three main ethnicities, including Malay, Chinese, and Indian. The expected start date is on 01/05/2023 and the estimated enrolment of the last subjects is 30/09/2023.

3.1.1 Development of FFQ-UPF

The purpose of FFQ-UPF development is to identify the ultra-processed food items consumed by adults in Selangor, portion size, and frequency of intake by conducting three days of 24-hour diet recall and literature review. This study will use Cronbach's alpha formula in sample size estimation, using a sample size calculator (Ariffin, 2023). The estimated number of subjects for this step is **162**. Adults aged 19 – 59 years old, Malaysian citizens and have good literacy in Bahasa Melayu or English will be included in this study. However, adults who are diagnosed with chronic diseases, or require special diets or dietary needs will be excluded. Next, the ultra-processed food which contributed to the subject's dietary recall will be identified, and the number of items to be included in the FFQ-UPF will be determined from three days of 24-hour dietary recall and a primary food checklist based on the literature review search for potential ultra-processed foods consumed by Malaysian adults. Food items accounting for up to 90% of total energy and macronutrient intake and appearing more than 20 times in 24-hour diet recalls will be chosen to be included in the FFQ (Fatimah et al., 2015). A comprehensive literature review search will be conducted to determine suitable frequency options and portion sizes in assessing and estimating ultra-processed food intake for a specific time frame. The portion size for ultra-processed food will be determined from the food packaging, MyFCD database, and the Food Atlas.

3.1.2 Content Validation of FFQ-UPF

This step aims to validate the content of the newly developed FFQ-UPF via content validation by the expert panels. According to Yusoff (2019), the number of experts for content validation should be at least six and not exceed ten based on the recommendations and experience. Therefore, **six** expert panels will be reviewing the newly developed FFQ. Inclusion: an individual is currently working as a healthcare professional with expertise in food and nutrition, including dietitians, nutritionists, dietetics clinical instructors, and dietetics/nutrition lecturers. These expert panels will validate the content for its validity and relevancy for each food item using the content validity index (CVI), content validity ratio (CVR), and Kappa statistics. Experts will evaluate the items to determine whether the items included are relevant, clear, and essential.

3.1.3 Face Validation of FFQ-UPF

Following the content validation, the objective of this step is to validate the content of newly developed FFQ-UPF among the target population by face validity. A minimum number of 25 to 75 respondents is recommended to evaluate the face validity, administration process, data entry preparation, and descriptive statistics. Yusoff, Ariffin & Hadie (2021) suggested a sample of 30 respondents should be sufficient. Hence, this study will involve another group of **50** subjects in these steps, considering the 20% dropouts. The inclusion criteria for this step are adults aged 19 to 59 years old, Malaysian citizens, have good literacy in Bahasa Melayu or English, and do not take part in the first step (development of FFQ-UPF). Adults who are diagnosed with chronic disease or require special diets or dietary needs will also be excluded. The newly developed FFQ-UPF will be pilot tested to the target population based on the sample size recommended. The subjects will answer the newly developed FFQ by themselves and will be observed if they have any confusion or misunderstandings about the components or terms including the selection of food items, information on food items, wording of food items, placement of food items, portion size, various formats of frequency of consumptions used in the FFQ. The researchers or dietitians will facilitate the process of face validation. Modifications for FFQ-UPF will be made from the subjects' feedback.

3.1.4 Criterion (concurrent) validation of FFQ-UPF

Next, the purpose of criterion (concurrent) validation of FFQ-UPF is to validate the items and reliability of FFQ-UPF with reference method by criterion (concurrent) validity among the target population. The sample for these steps will be calculated using Pearson's correlation coefficient for hypothesis testing using a sample size calculator (Ariffin, 2023). Hence, the estimated sample size for these steps is **105**. The subjects in this will be adults aged 19 to 59 years old, Malaysian citizens, have good literacy in Bahasa Melayu or English, and do not take part in the first step (development of FFQ-UPF). The exclusion criteria for the subjects in this step are adults who are diagnosed with chronic diseases or require special diets or dietary needs. After face validation, the FFQ-UPF will be validated by criterion (concurrent) validity to determine the performance of this newly developed questionnaire. The newly developed FFQ-UPF will be validated with three days 24-hour diet recall.

3.1.5 Reproducibility of FFQ-UPF

The fifth step aims to determine the reliability and comparability of the newly developed FFQ-UPF by reproducibility. This step will involve the same subjects who take part in criterion (concurrent) validation will take part in this step. Reproducibility of FFQ measures the consistency of the same subjects in answering the FFQ at different time points. In this study, the newly developed FFQ-UPF (FFQ-

UPF2) will be administered again to the subjects after two weeks of completing the first FFQ-UPF (FFQ-UPF1) during face validation. The same subjects who take part in criterion (concurrent) validation will take part in this step.

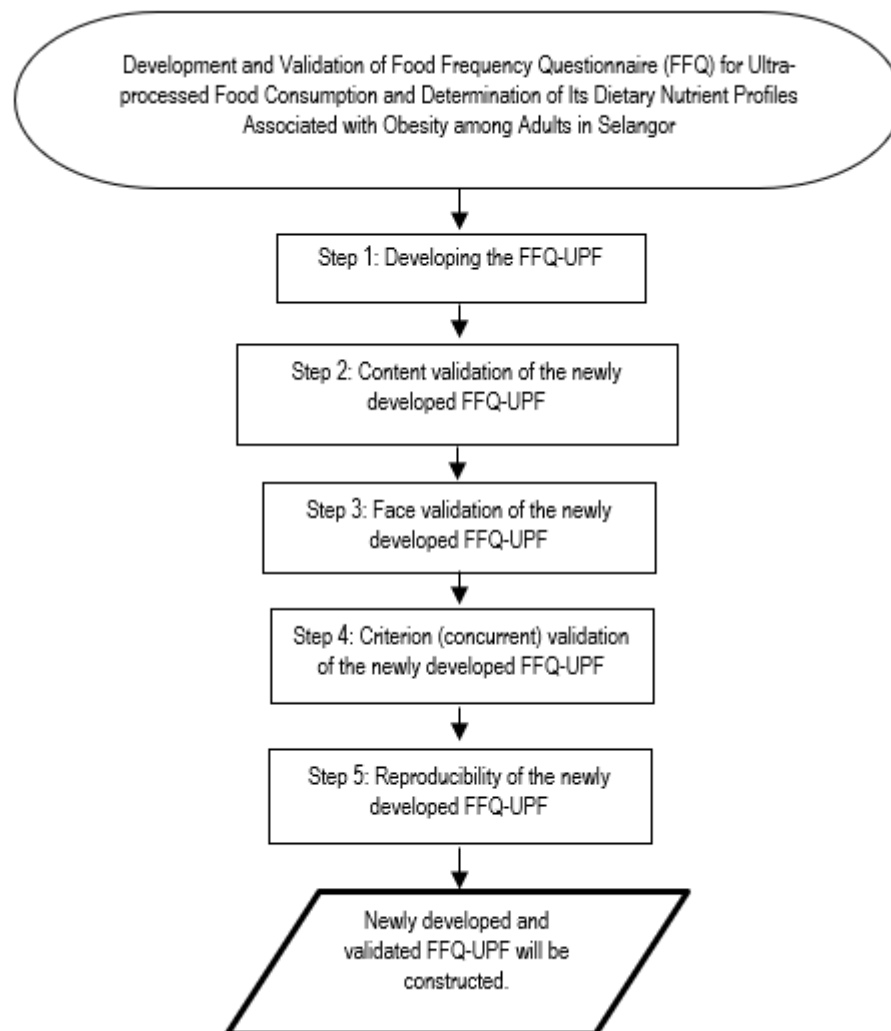


Fig. 2: Illustration of research design

3.2 Ethical consideration

Ethical clearance of this research will be obtained from UiTM Ethics Committees. All information about the research will be kept private and confidential throughout the research process. Subjects will fill in an informed consent form before participating in this study. The subjects involved in this study are voluntary. They can decline or withdraw from this study without external forces from the research team or any authorities involved.

3.3 Data analysis

Data that will be obtained from the participants will be analysed based on the objectives of this study. The subjects' age and nutrient intake will be analysed using Descriptive analysis and expressed as mean \pm standard deviation (SD). Frequency statistics will be computed for other descriptive characteristics of the participants. For the food items that will be included in the newly developed FFQ derived from the literature review and 24-hour diet recall, the data will be analysed using Microsoft Excel. The experts will validate the content of the newly developed FFQ based on several content validity measurements, including Items-Content Validity Index (I-CVI), Scale-level-Content Validity Index (S-CVI), and Content Validity Ratio (CVR) for the items' essentiality. Kappa statistics will be used as an interrater agreement index to guarantee the expert agreement without any random chance agreement.

The face validity index (FVI) will be calculated to determine the items' clarity and comprehensibility, using item level-FVI (I-FVI) and scale level-FVI (S-FVI). The normality of the data in the validation study will be analysed using the Kolmogorov-Smirnov test. Dietary data from the FFQ-UPF will according to the formula: frequency of intake (conversion factor) \times serving size \times total number of servings \times weight of food in one serving. The conversion factor used to estimate nutrient intake will be based on the frequency of intake of the FFQ. Correlation between the newly developed FFQ-UPF and three days of 24-hour diet recalls will be analysed using the correlation coefficient which is Pearson's r . The FFQ-UPF reproducibility will be tested using the Shapiro-Wilk test. Next, we will compute

Spearman's correlation coefficients to assess the strength of the relation between FFQ-UPF1 and FFQ-UPF2. The statistical analysis will be conducted using the Statistical Package for the Social Sciences (SPSS version 23).

4.0 Discussion

This study will focus on developing and validating a food frequency questionnaire for ultra-processed food intake based on their dietary intake for the past 24 hours. It will be conducted for three days, which include the intake on two weekdays and one weekend. The study will involve adults in Malaysia. However, this study will not determine the direct association of ultra-processed food with nutritional and health-related outcomes such as subjects' BMI status, non-communicable diseases, fasting blood sugar, and lipid profile. The study will also not collect data on the subjects' anthropometric status and blood profile.

5.0 Conclusion and Recommendations

This study will develop a food frequency questionnaire focusing on culturally specific ultra-processed food products consumed by adults, which can be used as a diet assessment tool to assess mainly ultra-processed food intake in epidemiological studies in Malaysia. Evaluating the consumption of ultra-processed food among Malaysian adults may help monitor and plan the intervention to reduce the rate of obesity in Malaysia. The results of this study may help policymakers and communities to be aware of the effects of consuming ultra-processed food in the long run on their health.

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Paper Contribution to Related Field of Study

This paper will help in providing the protocol for the development and validation of a food frequency questionnaire that is culturally specific for the Malaysian population and mainly focused on ultra-processed food, whereby, the food items included in the study will be determined based on their processing level. The developed and validated FFQ-UPF may be used in epidemiological studies performed among Malaysians which will help the policymakers to monitor, evaluate, and plan interventions in ultra-processed food consumption among Malaysians.

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