



## Development and Validation of a Dish-Based Iranian Food Frequency Questionnaire: A Protocol Study

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### ABSTRACT

**Background:** The relation between long-term dietary intake and diseases is well known. There are several methods to determine long-term dietary intake. The food frequency questionnaire (FFQ) is used in studies to assess habitual dietary intake over a long term period. Dietary intake varies according to cultural differences, so an FFQ must be designed and validated for the target population. This protocol study aims to explain the development and validation of a semi-quantitative FFQ for the Iranian population that includes mixed dishes and single food items. **Methods:** The initial list of food items were extracted from interviews and expert opinion. An expert panel of ten nutritionists calculated the content validity ratio (CVR) and content validity index (CVI) of food items to finalize the FFQ. One hundred twenty eligible participants were included in the study. They completed the FFQ two times, with a ten month interval. They recorded their food intake for three days in the 2<sup>nd</sup> and 10<sup>th</sup> months of the study. In the 4<sup>th</sup> and 10<sup>th</sup> months, serum retinol and alpha-tocopherol, and 24-hour urinary potassium and nitrogen were measured. **Result:** Covering typical Iranian mixed dishes is the main advantage of this study. Given that the questionnaire is valid and reproducible, it can be used in epidemiologic studies. **Conclusion:** The current study developed a dish-based Iranian FFQ based on mixed food.

**Keywords:** Protocol; Food frequency questionnaire; Validity; Reproducibility; Questionnaire design; Iranian; Mixed dishes

### Introduction

Nutritional intake is an important modifiable risk factor in many non-communicable

diseases and has an important role in chronic disease management (Bijani *et al.*, 2018). Several

nutritional tools assess nutritional intakes including food record, 24-hours dietary recall, food diary, diet history questionnaire, and food frequency questionnaire (FFQ). The FFQ is the preferred tool in nutritional epidemiology due to the low cost and simplicity of administration (Moghames *et al.*, 2015). Given that it assesses long-term dietary intake, the FFQ is preferred in studies of chronic diseases (Dehghan *et al.*, 2012a).

FFQ ranks individual dietary intake instead of their absolute intake (Dehghan *et al.*, 2012a). A FFQ must be developed and evaluated in terms of validity and reproducibility in the population, since there are cultural differences in food intakes (Mirmiran *et al.*, 2010, Pakseresht and Sharma, 2010). If these differences are not considered, there may be false associations between dietary intakes and diseases (Dehghan *et al.*, 2012a).

The validity of a tool refers to the degree that the questionnaire measures aspects of the dietary intake (Willett, 2013). In validation studies, the FFQ is compared with a method considered to be superior to the FFQ (Willett, 2013). The FFQ is usually validated using several methods, such as comparison with other dietary reference methods (food record or 24-hours dietary recall) and comparison with biomarkers as an objective method of dietary assessment. Reproducibility refers to the FFQ consistency on more than one administration of the same individual at different times (Willett, 2013).

Many FFQs have been developed and validated in the Iranian population, but there is limited comprehensive FFQ consisting of mixed dishes. Mixed dishes constitute a major part of the Iranian diet and must be included in FFQs (Keshteli *et al.*, 2014). Most of the previous Iranian FFQs have evaluated simple food items (ingredients), so that the participants must convert their mixed-dish intake to the ingredients (Esfahani *et al.*, 2010, Malekshah *et al.*, 2006, Omidvar *et al.*, 2002, Pirouzpanah *et al.*, 2012), which could be confusing to them. According to the literature review, just one study was conducted in Iran which focused on mixed dishes and single food items

(Amini *et al.*, 2020). This study aims to design and validate a semi-quantitative FFQ consisting of mixed dishes along with food items for the Iranian population.

## Materials and Methods

*Study design:* Study time points are summarized in **Table 1** and **figure 1**. The participants completed the FFQ at baseline and month 10. At month 2 and month 10, they were asked to record their food intake for three days at months 2 and 10. Blood samples and 24-hour urine samples were taken at months 4 and 10.

### Questionnaire design

*First step; Developing the questionnaire:* To develop a new culturally adapted FFQ, in four cities in different areas in Iran, frequently consumed food types were recorded by a face-to-face interview with ten residents in each city. The selected cities have rich and diverse food options and recipes and are geographically located all over Iran. The food items were extracted from interviews. Further items were added to the initial FFQ list based on comments of expert nutritionists.

*Second step: Validity evaluation Qualitative assessment of face and content validity:* An expert panel of ten nutritionists qualitatively assessed the face and content validity of the questionnaire.

Content validity ratio (CVR) in three options (i.e. 'essential', 'useful but not essential', 'not essential') was assessed by the experts. According to their choice, the CVR was calculated as follows:

$$CVR = (N_e - N/2)/(N/2)$$

*N:* total number of experts, *N<sub>e</sub>:* number of experts choosing essential

With ten expert panel members, according to Lawshe table, a CVR of 0.62 is necessary to maintain a food item in the FFQ (Lawshe, 1975).

The relevancy of items to the aim of questionnaire design was assessed by four choices questions ('very relevant', 'relevant but needs minor revision', 'the item needs some revision', 'not relevant'). According to the choices, content validity index (CVI) was calculated as follows:

$$CVI = (N_1 + N_2)/N$$

*N:* total number of experts, *N<sub>1</sub>:* very relevant, *N<sub>2</sub>:*

*relevant but need minor revision*

The CVI equal to 0.8 is acceptable, in the range of 0.7-0.8 the items need revision, and lower than 0.7 are unacceptable (Zamanzadeh *et al.*, 2015).

The initial questionnaire includes 150 food items. The final questionnaire will consist of single and mixed items (food in which some ingredients are mixed according to the recipe, like Ghormeh-Sabzi stew which consists of meat, onion, chopped greens, and beans). The frequency of intake is a multiple-choice question ranging from never to more than six times a day. The portion size was recorded with the household plates and utensils. The questionnaire was filled based on food consumption in the past year. A short food album of household utensils and some food was added to the beginning of the questionnaire helping the participants in remembering portion sizes.

*Study population:* This descriptive correlation study was carried out among healthy adults covered by Mashhad health centers affiliated with Mashhad University of Medical Sciences, Mashhad, Iran. The sample size was calculated based on data from a previous study in which retinol was measured as a biomarker of dietary intake (Mirmiran *et al.*, 2010). Retinol is an important dependent variable; type one error and the power of the study were considered 0.05 and 80% respectively. The correlation coefficient between biomarkers and recalls was 0.18. According to the formula suggested for cross-sectional studies computing the Pearson correlation coefficient, the calculated sample size was 46. The study considered a two-fold sample size because of male and female inclusion. Thirty percent was added for the possible drop out, so the final sample size was 120.

The study participants were selected according to a stratified random sampling of ten health centers of Mashhad. In every health center, based on a block selected randomly from the map, 12 people (6 men and 6 women) were selected. Due to possibly similar food intake, one member of every family was selected. The participants were invited to the health centers.

*Inclusion criteria:* The participants were

healthy adults aged 18-65 years, without a history of chronic metabolic diseases, such as dyslipidemia, hypertension, diabetes, and chronic liver or kidney disease, without a history of neoplasia, non-pregnant and non-lactating. They must have an ordinary dietary intake and not adhered to a special diet at the time of participation. Finally, they must reside in Mashhad and stay there for six months before participation in the study and until the end of the study.

*Exclusion criteria:* Participants were excluded if they did not complete one of the two FFQs or if they were diagnosed with a chronic disease during the study.

*FFQ completion:* The designed FFQ was introduced to the participants and they were trained on how to fill the frequency and portion size options, then they completed the questionnaire themselves. In case of any question or ambiguity, an expert nutritionist was available. It was estimated that it would take forty min to complete the questionnaire.

*Food record:* The participants were asked to keep a 3-day food record at months 2 and 10 and were reminded by phone calls. They were asked to write down everything they eat from the time they wake up in the morning until they go to bed at night for 3 consecutive days (two week-days and one weekend). To this end, they had a face to face training session by a nutritionist and received an instruction booklet, a short food album, and pictures of household utensils in order to record portion sizes of food intakes.

*Reproducibility assessment:* Ten months after the onset of the study, the participants were asked to return to the health center and fill the FFQ again under the supervision of a nutritionist.

*Blood and urine sampling:* At month 4, the participants were informed by telephone to attend the laboratory of Qhaem hospital in Mashhad in the morning between 7:00-9:00 in the fasting state for 12 hours prior to specimen collection. A 7 ml venous blood sample was drawn from the

antecubital vein and serum was extracted after centrifugation at 3000 rpm for 10 min. The serum was transferred to three microtubes. Two aliquots were kept at -70 °C. When all specimens were taken, they were sent to the Nutrition faculty laboratory at Tehran University of Medical Sciences in dry ice. The third serum aliquot was assessed enzymatically (spectrophotometry) with the Selectra auto-analyzer with Pars Azmoon kits to measure serum cholesterol and triglyceride (TG) concentration. Serum concentrations of cholesterol and TG were used to calculate the partial correlation between serum retinol and alpha-tocopherol. The serum concentration of retinol and alpha-tocopherol were measured using the HPLC method. The HPLC YL9100 instrument was used. The column used to calculate retinol and alfa-tocopherol is C18, the temperature of the column was 37 °C, and 50 µg was injected every time. The instrument flow was 1 ml/min, approximately 10 min was expected as the duration of every cycle, and 280 nm was the expected wavelength. The retinyl acetate is the internal standard for retinol measurement (Dulińska-Litewka *et al.*, 2009).

After getting the blood specimen a plastic container was given to every participant to collect their urine for 24-hours. If more than 50 ml urine is not collected, they should repeat the collection. The potassium content of 24-hour urine was assessed by flame photometry technique. The urinary urea nitrogen excretion was measured by spectrometry method and the value was converted to urea nitrogen excretion in g/day (Hristova, 2001). Daily total protein intake can be calculated via the formula:  $6.25 \times (24\text{-h Urinary nitrogen} + 2)$ . Also, 85% of nitrogen intake is disposed via urine (Isaksson, 1980). In the 10<sup>th</sup> month, biochemical sampling was repeated based on the mentioned method.

*Food item analysis:* The consumption of food items (mixed or single items) from food records and FFQs was calculated. Mixed items were converted to their ingredients, according to the existing data (Amini *et al.*, 2020). The method of

recipe calculation is mentioned in detail, elsewhere (Amini *et al.*, 2020). After considering yield factor, energy and nutrients were calculated according to the USDA (US Department of Agriculture) food composition table (USDA, 2019). To get daily consumption, based on FFQ data, the frequency of consumption was multiplied by the portion size (in grams). Nutrient intakes from FFQ were calculated based on the following formula:

$(\text{Frequency of intake in 1}^{\text{st}} \text{ day}) \times (\text{weight of portion size in gram}) \times (\text{nutrient content per gram})$

*Data analysis:* Statistical analysis was done by SPSS software version 16.0 (SPSS Inc., Chicago, IL, USA). The data were reported as mean  $\pm$  standard deviation ( $\pm$ SD). The normality of data distribution was assessed by the Shapiro-Wilk test. In the case of abnormal distribution of data, non-parametric tests were applied. To assess the validity of FFQ, the nutrient intake was compared with the nutrients of food records. Correlation coefficients were calculated. Correlation coefficients (between FFQ and records data) of  $< 0.3$ ,  $0.3\text{-}0.39$ ,  $0.4\text{-}0.59$ , and  $0.6 \leq$  showed poor, fair, moderate, and high validity, respectively (Wakai, 2009). Another method to assess the validity of the questionnaire is to compare with data of biochemical measurements as an objective method that overcome errors of other validity methods. Nutrient intake assessed by FFQ was compared with the biomarkers and correlation coefficients were calculated. Serum retinol and alpha-tocopherol were adjusted against serum cholesterol and TAG to calculate the partial correlation. The degree of quartiles agreement between nutrient intake of FFQ and food record was evaluated using cross-classifications and was reported as same, adjacent, and opposite quartiles. To assess reproducibility, nutrient intakes calculated from the first and second FFQ administrations were compared and intraclass correlation was calculated. The acceptable correlation coefficient was considered  $0.5 <$  (Willett, 2013).

*Ethical considerations:* This study has been approved by the Ethics Committee of Mashhad University of Medical Sciences

(o.IR.MUMS.fm.REC.1394.628). The study process was explained briefly to the participants and they were asked to read and sign the consent form.

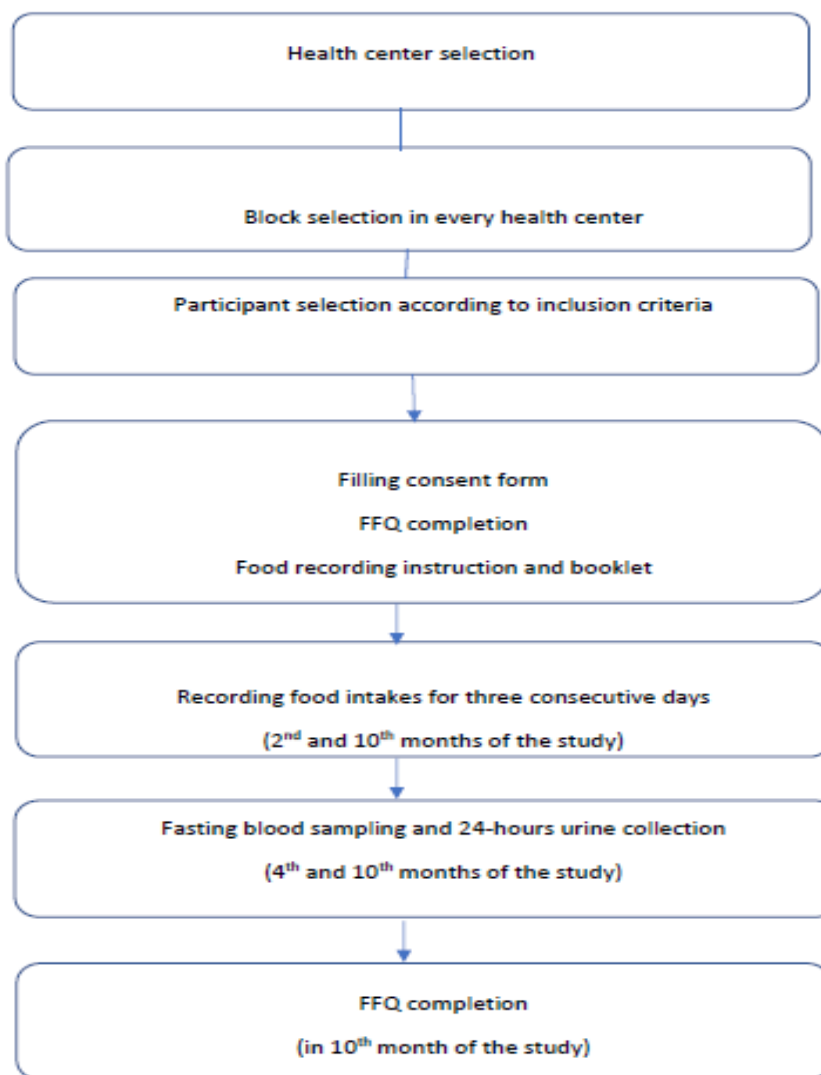


Figure 1. The study diagram.

Table 1. The study time points

<i>Study time point/ month of the study</i>	0	1	2	3	4	5	6	7	8	9	10
Participant selection and eligibility screen	*										
Informed consent	*										
FFQ completion	*										*
3-day food record			*								*
Blood and urine sampling					*						*

## Result

The correlation coefficients between nutrients intakes based on food records and FFQs, the correlation coefficients between nutrients intake of FFQ and biomarkers, and the intraclass correlation between nutrients intake of FFQs were calculated and reported. The percentile agreements between FFQ and record quartiles were calculated via cross classification method.

## Discussion

Nowadays, the impact of chronic dietary exposures on the incidence of non-communicable diseases is well known (Bijani *et al.*, 2018). The FFQ is an inexpensive and feasible tool to assess dietary exposure (Dehghan *et al.*, 2012c). Because of different food intakes in a specific population, FFQ validation studies must be done in the target population (Dehghan *et al.*, 2012b).

Although the Iranian dietary intake mostly consists of mixed food items, the majority of designed Iranian FFQs focused on single food. Thus, the inclusion of mixed food items in FFQs is necessary to improve accuracy and participants' cooperation in nutritional epidemiology studies. This study is the first study in the east of Iran where single and mixed dishes FFQ is developed and applied. It can be used to assess associations between chronic diseases and nutritional intake.

Covering both single and mixed food items, including participants from ordinary people, and using three ways to assess the validity of the FFQ are strengths of this study. This study has some limitations due to random sampling of participants and the limitation of financial supports in using biomarkers.

## Conclusion

The current study developed a dish-based Iranian FFQ based on mixed food that could both improve the current FFQs in Iran and simplify its usability to assess associations between chronic diseases and nutritional intake.

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## Competing interests

The authors declare that they have no competing interest.

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