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Validation of Modified Dietary Habits Instrument in Cardiovascular Diseases Study

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Abstract. The association between dietary habits and cardiovascular diseases (CVDs) has been established. However, the dietary habits vary among countries, therefore, there is scarcity in the literature for a standardized instrument to assess the dietary habits. This paper is aimed to evaluate the psychometric properties of modified dietary habits instrument, originally based on a food frequency questionnaire (FFQ). In this case-control study, it was used to find the most prevalent dietary habits in CVDs patients and their corresponding controls. The modified instrument consisted of 13 items representing thirteen food groups identified from CVDs related studies and FFQ. A sample of 180 (90 cases and 90 controls) was selected from the largest cardiac hospital of Pakistan through systematic sampling. Data was collected through modified instrument using direct investigation method. Twelve food groups were validated which further constituted two main factors labelled; healthy and unhealthy dietary habits. Exploratory factor analysis explained 70% and 68% variation through these two main identified dietary habits in cases and control, respectively. Internal consistency reliability for healthy and unhealthy dietary habits in cases were 0.905 and 0.879 and almost similar coefficient of reliability was recorded in the control group. Further, the mean score of healthy dietary habits was significantly less than unhealthy dietary habits ($p < 0.001$) in the cases and vice versa in controls. This study concludes that the modified instrument is valid and reliable and should be used to assess the dietary habits in CVDs related studies. Further, mean score of unhealthy dietary habits can help in disease prediction models and early diagnosis of cardiac problems.

INTRODUCTION

Validity of data collection instruments is the most important process in applied research for generalisation of study findings. Sensitivity, specificity and acceptable predictive strength are the anticipated outcomes of valid and reliable instruments [1]. The reliability and validity of the instruments, tests and observer judgements are assessed through psychometric evaluation especially in the field of health sciences [2]. Health researchers are specifically trying to design lifestyle measurement instruments which would possibly help in the reduction of disease burden. Currently, cardiovascular diseases (CVDs), leading cause of mortality in the world, have grasped the attention of these researchers for disease reduction solutions [3]. Literature highlighted that huge burden of CVDs is directly linked with unhealthy lifestyle which mainly constituted by dietary habits [4, 5]. These dietary habits are strongly linked with the majority of CVDs related risk factors. Therefore, it is essential to explore and quantify the prevalence of different dietary habits through valid instrument/questionnaire to control the upsurge of CVDs.

Dietary habits are closely linked with cultural values, socio-economic factors, regional traditions and religious beliefs [6]. Like meat and its products consumption are directly influenced by these factors. Further, alcohol consumption and its intake were also discussed in the dietary habits of European and American regions as component but it is

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not common in pre-dominantly muslims regions of the world [7, 8]. The regional and environmental needs also affect the dietary habits of the residents [9]. Like, Pakistani and Indian cuisine usually contains more curry and extensive deep frying that is a source of saturated and trans fats [10]. Usage of processed foods especially vegetables and meat is high in European region but in Pakistan it is still in dormant stage due to pre-dominantly agricultural nature of the country and easy access to natural products [11]. This regional disparity in dietary habits indicated that measurement of dietary habits should be measured at country level for better understanding of linkage between diet and health.

Food frequency questionnaire (FFQ) is the general term which is used for the dietary habits assessment questionnaires and mainly used in epidemiological population-based studies[12]. It is used to establish the link between dietary habits and health outcomes [13]. The FFQ assess the dietary habits of studied population in terms of identification of most prevalent food groups, their frequency and proportion of usage in routine. Past CVDs related researches used, European dietary patterns [14], Mediterranean-type diet [14], diet according to healthy eating recommendations [15], Prudent-pattern diet and western-pattern diet [16] to establish the link between these diets and CVDs outcome. It indicates that researches of different regions are using modified FFQs for the measurement of dietary habits for their particular regions. Further, previous FFQs are having large number of items (ranges from 44 to 350 items) to ask about dietary habits of respondents in last 6 months to one year which can create the recall bias in the findings [12]. It generates the need of quick, short, cost-effective and simple FFQ. Therefore, the main aim of this paper is to identify the most prevalent food groups in CVDs patients and their controls. These identified food groups will provide directions to develop a valid and reliable modified short FFQ which can be used as a baseline dietary habits assessment questionnaire, especially in Pakistan. Further, this modified FFQ will be helpful in determining the potential differences in dietary habits between CVDs patients and their controls which will guide the practitioners in reducing the potential burden of CVDs.

Development of modified FFQ

We used previous FFQs and identified the various food groups which had a strong connection with CVDs in the past researches as discussed in section 1. High frequency of fruits and vegetables [7, 8], whole grains or cereals [17], poultry, seafood and fish [15, 18], low fat or skimmed milk and its products [15] are considered the healthy food choices. Oil/saturated fats [8, 18], sweets and bakery items, soup and sauces [18, 19], energy and fizzy drinks [20], processed foods [19], more consumption of red meat [21] direct intake of salt and related items consumption [7] are considered the unhealthy habits in CVDs researches. Usage of multivitamins is also discussed in previous FFQs and recent study also reported its mixed link with CVDs as well [22]. Alcohol consumption and its intake were discussed in European and American regions [7, 8]. These identified food groups were also partially available in Pakistani literature[10, 11]. Pakistan is a Muslim country and alcohol consumption is legally prohibited activity, therefore this group of drinks was not included in the study.

In this paper, the finalized food groups were fruits, vegetables, cereals, white meat, dairy (skimmed milk) and its products,usage of vitamins, sweets, lipids and fats, soup and sauces, energy and fizzy drinks, processed foods,fresh red meat and salty foods. We measured the frequency of food groups through one single global item (one item for each food group) as recently used in short FFQ [23]. Further, routine frequency of usage of identified food groups would be asked in last one month to reduce the recall bias. Each question would be measured at closed ended nine point scale as per guideline of FFQ development [24] and also used in majority of previous FFQs [12]. The scale is defined as Never or less than 1 month = 0, 1-3 times per month = 1, once a week = 2, 2-4 times = 3, 5-6 times = 4, once a day =5, 2-3 time per day = 6, 4-5 times per day = 7 and 6 times and above per day = 8.

METHODOLOGY

Face and content validity of the modified FFQ

The modified short FFQ consisted of 13 items (food groups) based on the intensive review of literature. A sample of 30 subjects (15 cases and 15 controls) were selected for pre-testing of the study by following the guidelines regarding pre-testing procedure [**?**]. Face validity of modified FFQ was assessed through the selected 30 subjects. Further, its

content validity was assessed by four neutral experts who were not involved in the study. The experts were asked to assess the validity of the questionnaire in terms of clarity and representativeness of the questions at five point scale. Based on experts comments few changes were made in the items which had less than 0.80 content validity index (CVI) as suggested in the literature [25]. However, after suggested modifications acceptable value of CVI (0.94) was achieved for modified FFQ. Further, it was suggested by the experts that these 13 food groups can be bifurcated into healthy and unhealthy dietary habits sub-scales. However, this bifurcation needs confirmation through empirical approach which was performed in next phase of study.

Study design and selection of subjects

This was a case-control study and conducted in the duration of 25th September-24th October 2018 in Punjab Institute of Cardiology (PIC) which is the largest cardiovascular hospital in the country. In this study, people registered in the hospital emergency with first cardiac event, in their whole life, and confirmed by the on-duty physician was considered as case of the current study. It was a likelihood that chronic patients might have modified their dietary habits and lifestyle after the previous heart problem. Therefore, these chronic patients were excluded from the study. Further, participants with age over 30 years were recruited in the study to avoid possible congenital heart patients in younger ages. Then, hospital-based controls were chosen after the confirmation of the physician about the healthy status of controls. These controls were mainly the attendants of the selected cases who probably shared the same living environment as faced by the cases. This strategy of control selection will possibly provide better estimates about the exposures and provides satisfactory results [26]. A sample of 180 cases and controls were selected through systematic sampling by considering (1:1) age and gender-wise matching. Therefore, 90 cases and their 90 matched controls were recruited in the study. Direct investigation method was adopted to ask about the dietary habits through modified FFQ after inquiring some essential demographic information.

Data analysis techniques

The statistical analysis in this study was conducted for cases and controls separately. There are two main assessments of modified FFQ which are internal consistency reliability (ICR) and validity. ICR was measured using Cronbach alpha (α) with generally acceptable cut-off value > 0.70 [1, 27]. The computational formula is given in Equation 1.

$$\alpha = \frac{N.\bar{c}}{\bar{v} + (N-1).\bar{c}} \tag{1}$$

where N is the number of items, $\bar{c}$ is average covariance between item-pairs and $\bar{v}$ is average variance. In addition to Cronbach alpha corrected item-total correlation (CI-TC) was also used in this study. Its cut-off value is ≥ 0.30 which guides the researcher that this item should be retained for the inclusion of reliable item. Exploratory factor analysis (EFA) was used on this modified FFQ to explore the hidden significant factors from the identified food groups. The assumption of normality of data was also assessed before the application of EFA through one sample Kolmogrove Smirnove (KS) test. It tests the null hypothesis that data is normal against the alternative hypothesis that data is not normal. Kaiser-Meyer-Olkin (KMO) test determines sampling adequacy and its ideal value is ($\geq$ 0.60). Test of sphericity which tests the null hypothesis that correlation matrix is identity matrix. For the application of EFA this test should be significant at 0.05 level of significance. After these two pre-requisites tests (KMO and test of sphericity), individual contribution of each item (food group) was assessed through communalities(explained proportion of variance through each item). Its value should be greater than 0.40 otherwise item should be deleted and re-run the analysis. For the identification of number of significant factors scree plot was used which is plotted between number of factors and eigenvalues. The number of factors which produced eigenvalue $>$1.0 should be finalized. And these identified significant factors should explain more than 60% variation [27]. Further, varimax rotation was used to maximizes the variances of the squared loadings (squared correlations between factors and items). Further, it evenly distributes the amount of variation explained through identified factors in EFA. In the end, independent sample t-test was also used to see the significant difference between the mean score of the healthy and unhealthy dietary habits in cases and controls groups separately. These mean scores were computed for the confirmed food groups. For example, mean score for healthy dietary habits in cases = sum of frequency of usage of healthy dietary habits in last month /5 (number of confirmed healthy dietary habits). Similarly, other mean scores for unhealthy dietary habits (for cases and controls) and healthy dietary habits for controls were computed based on confirmed number of food groups. All the tests used in the study were tested at 0.05 level of significance.

RESULTS

Demographic analysis

The data were collected from total 180 subjects (90 cases and 90 controls). Mean ages of cases and controls were 49.02 $\pm$ 11.30 and 49.42 $\pm$ 11.05 years respectively. Majority of the cases and controls were males (n = 72; 80% in cases and controls) as compared to females (n = 18; 20%). Almost equal distribution was found in cases and controls with respect to rural (cases, n = 63; 70%; controls, n = 67; 74%) and urban background of the participants (cases, n = 27; 30%; controls, n = 23; 26%). Similarly, majority participant were literate in cases (n = 71; 78%) and (n = 69; 72%) in controls. However, 27% of cases were self employed or have their own business. But this percentage was almost half in the control group (n = 13, 14.4%). The socio-economic status (SES) of cases and controls was measured in four levels which are low, lower middle, upper middle and high SES. Majority, (40%) of cases were from low SES, however, same percentage of controls belongs to upper middle group. The remaining number of participants in cases and controls were having almost equal percentage in other three categories.

Internal consistency reliability

The reliability coefficient (using Cronbach alpha) was used to measure the internal consistency of the modified FFQ in cases and controls separately. Initially there were 13 questions in the modified FFQ which were bifurcated into two sub-scales (factors) which were healthy and unhealthy dietary habits after discussion with experts at content validity stage.

ICR for cases.

Initial ICR values of two sub-scales of healthy and unhealthy dietary habits in cases data were 0.801 and 0.879, respectively. However, one item from healthy dietary habits *usage of vitamins* had shown CI-TC (-0.158) due to its low prevalence in the data therefore, this item was deleted from healthy dietary habits group. The re-run of ICR analysis provided significant raise in the reliability coefficient from 0.801 to 0.905. These results showed that both sub-scales in the cases data had good acceptable ICR.

ICR for control.

The same item *usage of vitamins* from a group of healthy dietary habits had shown low CI-TC (-0.169) in controls dataset as identified in cases dataset. This item was deleted from 13 items data and re-run the analysis. The finalized Cronbach alpha for healthy and unhealthy dietary habits were 0.908 and 0.883 respectively. These findings had shown that these sub-scales were also reliable after deletion of one item (usage of vitamins).

Exploratory factor analysis

Exploratory factor analysis was performed on finalized 12 items or food groups which were confirmed in reliability analysis of cases and controls. One sample KS test for both data sets separately gave p-value (p = 0.11) and (p = 0.089) for cases and controls respectively. As p-values were greater than 0.05, therefore, we could not reject the null hypothesis and concluded that data is normal. This EFA provided two-factor solution through varimax rotation method in both groups (cases and controls) by using eigenvalue greater than 1 as an indicator of a significant number of factors.

EFA for Cases.

In the first step, sampling adequacy of the cases data was assessed through the KMO test that estimated a value of 0.804 (above than the cut-off value of 0.60). Test of sphericity was also significant at 0.05 level of significance ($p < 0.001$) that indicates data could be factorized for further analysis. Communalities values mentioned in Table 1 for these 12 items were also in the range of 0.537-0.889, which were greater than the 0.40 cut-off value. These values showed that all items were contributing more than 50% in this EFA to constitute new most likely independent factors. The EFA for cases data explained approximately 70% variation through these two identified factors (greater than the recommended value of 60%). The first factor explained 37.01% variation and other factor was explaining 33.57% variation. Table 1 shows that factor 1 was comprised of the first 5 items and the second factor consisted of 7 items.

TABLE 1. Exploratory factor analysis (EFA) for dietary habits instrument in cases and controls

	Cases Group			Control Group		
Items	Factor 1	Factor 2	Communalities	Factor 1	Factor 2	Communalities
Fruits	0.903		0.816	0.732		0.719
Vegetables	0.846		0.744	0.829		0.863
Cereals	0.780		0.608	0.741		0.680
White meat	0.849		0.722	0.907		0.840
Dairy products	0.848		0.721	0.746		0.619
Sweets		0.629	0.591		0.614	0.727
Lipids and fats		0.606	0.537		0.632	0.569
Soup and sauces		0.918	0.849		0.834	0.728
Fizzy drinks		0.942	0.889		0.558	0.511
Processed foods		0.871	0.761		0.789	0.650
Fresh red meat		0.776	0.607		0.639	0.521
Salty foods		0.925	0.857		0.692	0.612
Eigen values	4.441	4.029		4.212	3.827	
% variance	37.01	33.575	70.585	35.102	32.889	67.991

These two identified factors were labelled as healthy dietary habits and unhealthy dietary habits in the Table 1 and also discussed in face and content validity section.

EFA for Controls

Controls dataset showed better sampling adequacy (KMO = 0.871) as compared to cases dataset (KMO = 0.804). Bartlett test of sphericity was significant ($p < 0.001$) for factorization of control dataset. All communalities values in this dataset were in the range of 0.511-0.863 which were almost similar to cases dataset and also greater than the 0.40 cut-off value. However, Table 1 shows that EFA for controls dataset explained slightly less variation (approximately 68%) through these two identified factors but this explained variation was still above the recommended value of 60%. Similar to cases data factor 1 was comprised of first 5 items and the second factor was consisted of 7 items and were labelled with same name of healthy and unhealthy dietary habits as suggested in previous sections.

Mean score comparison of healthy and unhealthy dietary habits

Two independent sample t-test was performed on the mean scores of healthy and unhealthy dietary habits in cases and controls separately. In cases dataset, mean score of unhealthy dietary habits is (3.96) and significantly (t = 4.47, p-value = 0.001) greater than the mean score of healthy dietary habits (2.20). However, in control dataset, mean healthy dietary habits score (3.86) was significantly (t = 5.22, p-value = 0.001) higher than mean unhealthy dietary habits score (2.30). These findings highlighted that cases and controls showed very different food priorities which can determine their health status.

DISCUSSION

The main aim of this study is to develop the short FFQ and assess its psychometric properties in CVDs related study. Usually, in disease based studies dietary habits are evaluated in cases only. However, in this study both groups (cases and controls) were under consideration so that a significant difference in dietary habits could be observed in both groups of study. In Pakistan, CVDs have been increasing at gigantic pace, further there is deficiency of standardized questionnaire to assess the dietary habits in this multi-cultural and multi-ethnic country [10]. We tried to develop a short, valid and reliable FFQ for the assessment of healthy and unhealthy dietary habits in cases and controls of CVDs studies. Our study findings have shown that modified version of FFQ is reliable and valid in this case-control study and can be considered in CVDs related researches. Our study findings can be compared with previous studies which also reported that the modified versions of FFQ showed good reliability and validity in different regions of the world [28, 29]. Further, a study suggested that short FFQ (20- items scale) was the good replacement of detailed FFQ

[23]. Further, the mean difference of dietary habits scores is an important indications and can provide guidelines for practitioners in controlling the potential CVDs burden in the population. The usage of controls in addition to cases in this study would expand the scope and applicability of this modified FFQ on CVDs and healthy population as well. However, this modified FFQ has the limitation regarding nutrient intake which can be possible through detailed FFQ and need another study.

CONCLUSION

This study concludes that the modified version of FFQ developed for CVDs related studies is reliable and valid to be used in future studies especially in sub-continent where a particular type of dietary habits prevails. This questionnaire should be used at clinical level and also for the public health awareness to reduce the CVDs risk in the general population by computing their healthy and unhealthy dietary scores.

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