

# BMJ Open Design, development and validation of Food Frequency Questionnaires for the diabetic population: protocol for a systematic review and meta-analysis

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## ABSTRACT

**Introduction** The Food Frequency Questionnaire is one of the most widely used tools for estimating nutritional intake in epidemiological studies. No study has been systematically performed to comprehensively explore Food Frequency Questionnaires designed, developed and validated specifically for the diabetic population (FFQs-DDV-DiaP). Therefore, a systematic review and meta-analysis will be carried out in order to identify and describe FFQs-DDV-DiaP; to examine their design, development, validity and reproducibility; as well as to estimate the overall degree of correlation and agreement; and to evaluate the factors that affect them.

**Methods and analysis** A systematic literature review will be performed in PubMed/MEDLINE, Scopus and Web of Science to find potentially relevant studies. Original studies related to the design, development, as well as the assessment of the validity and reproducibility of FFQs-DDV-DiaP; reported in English or Romance languages will be selected. Independent reviewers will select studies, extract relevant data and assess FFQs-DDV-DiaP quality. Data will be pooled using the generic inverse-variance method with random-effects models and expressed as correlation coefficients or mean differences with 95% CIs to examine the global validity and reproducibility of FFQs-DDV-DiaP. Heterogeneity will be evaluated by the Cochran Q-statistic and quantified by the I<sup>2</sup> statistic. Stratified analyses and random-effects meta-regressions will be performed to explore heterogeneity and whether any covariate influences the effect sizes. Finally, publication bias will be assessed through the Begg's and Egger's tests.

**Ethics and dissemination** This systematic review and meta-analysis will not use confidential personal data. Therefore, the requirement of ethical approval or informed consent is not necessary. The results of this review will be disseminated only in peer-reviewed publications or at relevant scientific conferences.

**PROSPERO registration number** CRD42021268575.

## INTRODUCTION

Diabetes mellitus (DM) is a group of metabolic diseases characterised by elevated levels of glucose that occur due to defects in insulin secretion, insulin action or both at the same time.<sup>1</sup> According to the aetiology and pathology, DM could be classified as

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This systematic review and meta-analysis will include Food Frequency Questionnaires designed, developed and validated for the diabetic population without geographical or temporal restrictions.
- ⇒ Meta-analysis statistical techniques will be used to evaluate the influence of different factors on the validity and reproducibility of the Food Frequency Questionnaires specifically generated for the diabetic population.
- ⇒ A possible weakness of this meta-analysis may be that the degree of correlation and agreement of food, energy and nutrients could not be controlled by all the confounding factors due to the observational nature of the data of interest.

type 1 DM, which accounts for 5%–10% of all DM; type 2 DM, which represents 90%–95% of all DM; and gestational DM, which occurs during pregnancy, among others.<sup>1</sup> Epidemiological studies have associated certain dietary components with the risk of developing DM<sup>2</sup> and its complications.<sup>3</sup> An accurate dietary assessment is essential to know how nutrition is related to this disease. Various methods exist for estimating nutritional intake in free-living individuals, such as 24-hour dietary recalls (24-HDR), dietary records (DR) and Food Frequency Questionnaires (FFQs). Nevertheless, the dietary assessment to investigate associations between dietary components and diabetic complications should include a prolonged period, as occurs with FFQs. Likewise, in comparison with short-term methods, FFQs provide a better approximation of the habitual diet and allow researchers to categorise individuals according to their dietary intake. In addition, this tool enables the estimation of long-term dietary intake in a relatively simple, time-efficient and cost-effective way. Thus, it is one of the most widely used in epidemiological studies since the 1990s.<sup>4</sup>

FFQs should be developed specifically for the purpose of the research, assessing the foods, beverages, energy and/or nutrients of interest in the target group. FFQs should also take into account the population target in their design and development since diet may be influenced by factors such as ethnicity, sex, culture or economic status.<sup>5</sup> In addition to these factors, some medical conditions, such as DM, require appropriate dietary and nutritional approaches for their correct management. In this sense, it has been reported that the dietary habits of patients with diabetes may differ largely from that of the general population.<sup>6</sup> Therefore, dietary aspects such as the foods most commonly consumed or the portion size of these foods, two central elements in the design and development of FFQs,<sup>7</sup> may be substantially different between patients with DM and the general population. Notwithstanding, Cade *et al* reported that more than half of FFQs used in epidemiological studies were a modified version of existing questionnaires.<sup>5</sup> Many of these adapted questionnaires have also been applied in the diabetic population.<sup>8–10</sup> Nevertheless, it is currently unknown how many have been specifically designed, developed and validated for the diabetic population. Other crucial elements in the design and development of FFQs are the list of food items, the frequency response section and the measure of portion size.<sup>7</sup> The development of the list of food items is essential to the success of a FFQ since this should reflect the food habits of the target population at the time the data are collected.<sup>5</sup> Several approaches have been used to compile a list of food items, for instance, based on food composition tables, on a list of foods potentially relevant for the nutrient of interest, or using stepwise regression analysis with the data of food habits collected previously in the target population.<sup>7</sup> Once the list of food items is compiled, questions, typically close-ended, on the frequency of consumption of each food item are required. Frequency categories must be mutually exclusive and have adequately narrow time intervals to capture the between-person variations in food consumption or nutrient intake.<sup>11</sup> A wide variety of frequency options are habitually used in FFQs,<sup>5</sup> including those administered to the diabetic population.<sup>8–10</sup> In addition, these instruments allow estimating food and beverages consumption as well as energy and nutrient intakes by including portion size as part of frequency. In semiquantitative FFQs, a reference portion size, which reflects known consumption patterns in the target population, is provided. Quantitative FFQs request information on the portion size, while qualitative FFQs do not include this section on the questionnaire. Other characteristics related to the design and development of FFQs are the number of food items, method of administration (self-administered or interviewer-administered), use of visual support material or food models, among others.

Once the FFQ is generated, validation of the questionnaire is necessary to assess the overall correlation and agreement between the FFQs and the reference assessment method used. Most FFQs are validated against

another dietary assessment method, such as 24-HDR or DR, although other methods, such as biomarkers, are also used.<sup>5</sup> Meanwhile, reproducibility reflects reliability and is assessed by administering the same FFQ at different time points to the same group of subjects and analysing the agreement of responses. According to Cade *et al*, reproducibility has been assessed in less than half of FFQs.<sup>5</sup> Similarly, reproducibility has been studied in some<sup>12</sup> but not all Food Frequency Questionnaires designed, developed and validated for the diabetic population (FFQs-DDV-DiaP).<sup>10</sup> Correlation coefficients are the most common statistical method for evaluating the validity and reproducibility of FFQs.<sup>13,14</sup> Some of the characteristics related to the design and development of FFQs mentioned above may have a relevant impact on the validity and reproducibility of these instruments. Thus, higher correlation coefficients have been found in validity and reproducibility studies when subjects are allowed to specify the portion size<sup>13</sup> and when the number of food items in FFQs is higher.<sup>13,15,16</sup> Correlation coefficients for validity and reproducibility are also superior for interviewer-administered compared with self-administered questionnaires for energy, fat and vitamin A, but worse for vitamin C.<sup>5</sup> Most of the validated FFQs have been designed to be used by the general population, but around one-third of the FFQs have been specifically developed and validated for use in populations with or at risk of a particular disease, such as DM.<sup>12,17</sup> Despite that, no study has been systematically carried out to comprehensively explore the characteristics related to the design and development of FFQs-DDV-DiaP, and the effect of these factors on their validity and reproducibility. Knowing these factors will be of great use for the design and development of future FFQs for the diabetic population. Therefore, a systematic review and meta-analysis will be carried out in order to answer these questions: Which FFQs have been specifically designed, developed and validated for the diabetic population and what are their characteristics? What methods have been used to design, develop, and validate FFQs specific for the diabetic population? What are the pooled effect sizes for the correlation coefficients, as well as for the mean difference, of food, energy and nutrients obtained in the assessment of the validity and reproducibility of each food frequency questionnaire designed, developed and validated for the diabetic population (FFQ-DDV-DiaP)? What factors influence these pooled effect sizes obtained based on the results generated in the assessment of the validity and reproducibility of each FFQs-DDV-DiaP?

## RESEARCH AIMS

The main objectives are to identify and describe FFQs-DDV-DiaP; to examine their design and development, and the methodology used to assess their validity and reproducibility; as well as to estimate the overall degree of correlation and agreement of food, energy and nutrients obtained in the assessment of both the validity and the reproducibility of these FFQs-DDV-DiaP; and to

evaluate the influence of different factors on the pooled effect sizes obtained based on the results generated in the assessment of the validity and reproducibility of each FFQ-DDV-DiaP.

## METHODS AND ANALYSIS

This systematic review and meta-analysis protocol is developed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) guidelines<sup>18</sup> (online supplemental table S1). In addition, the protocol was previously registered in the International Prospective Register of Systematic Reviews (PROSPERO) on 8 August 2021 (CRD42021268575) and can be consulted online at: [https://www.crd.york.ac.uk/prospero/display\\_record.php?RecordID=268575](https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=268575). The implementation of the systematic review and meta-analysis will be conducted in compliance with the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) statement.<sup>19</sup> The project is expected to start at the end of 2021 and be completed and published in 2023.

### Eligibility criteria

Studies will be considered eligible whether they meet the criteria described below.

### Study designs

This systematic review and meta-analysis will include original studies related to the design, development, as well as the assessment of the validity and reproducibility of FFQs-DDV-DiaP, regardless of their study design. Secondary studies, such as reviews, systematic reviews and meta-analyses, will be excluded.

### Participants

FFQs-DDV-DiaP, regardless of the type of diabetes, sex, age or any other condition, from any region will be selected. Otherwise, FFQs designed, developed and validated for a population without DM and those whose participants suffer from other severe non-communicable diseases, such as cancer, will be discarded.

### Intervention/exposure

This study will not evaluate an intervention or exposure itself. Nevertheless, the evaluation of the validity of the identified FFQs will involve a comparison between the results obtained after administering the FFQs-DDV-DiaP and the reference dietary assessment method (24-HDR, diet history or DR) among the subjects of each selected study. Similarly, the assessment of the reproducibility of the identified FFQs will comprise a comparison between the data obtained from the initial administration of the FFQs-DDV-DiaP and those applied subsequently. Therefore, the FFQs-DDV-DiaP to estimate food consumption, energy or nutrient intake will be the instrument of interest in this systematic review and meta-analysis. Studies focusing on dietary assessment methods other than FFQs will be rejected.

### Comparators

In accordance with the aforementioned, a reference dietary assessment method, such as 24-HDR, diet history or DR, will be the comparator in the evaluation of the validity of the FFQs-DDV-DiaP; as well as the FFQs administered second, in the case of the assessment of the reproducibility of the FFQs-DDV-DiaP. Studies that have used other reference assessment methods against which to assess the validity of the FFQs-DDV-DiaP, such as biomarker measurements, doubly labelled water, energy expenditure studies or interviews, will be excluded.

### Outcomes

Primary outcomes will include data related to the design, development and assessment of the validity and reproducibility of the FFQs-DDV-DiaP and their characteristics. Thus, original studies reporting information by which the list of food items and the portion sizes of the FFQs-DDV-DiaP were defined, as well as the number of intake frequency response categories and administration mode of the questionnaires, the number of food items, the type of FFQs, the use of visual support material or food models, food, energy and nutrients analysed, the period evaluated, the type of diabetes, the study design for which the FFQs was generated, the reference dietary assessment method for the FFQs validation and their number of days of administration, the time interval between repeated FFQs during the evaluation of the reproducibility, sample sizes and the food composition table used will be included. Furthermore, original studies with data on the raw, deattenuated, and adjusted Pearson's, Spearman's or intraclass correlation coefficients, and/or means and SD will also be included, in order to assess the overall correlation and agreement between the FFQs-DDV-DiaP and the reference dietary assessment method (validity), as well as between the repeated FFQs (reproducibility), for the food, energy and nutrients analysed.

Regarding the secondary outcomes, the characteristics of the sample involved in the assessment of the validity and reproducibility of the FFQs-DDV-DiaP, such as diabetes duration, age, body mass index (BMI), glycosylated hemoglobin (HbA1c) and sex of the participants, will be selected. Data about the included studies (first author, year of publication, region or country) will also be collected. Other information on the assessment of the validity and reproducibility of the FFQs-DDV-DiaP, such as kappa coefficients of agreement, ability to rank subjects according to food, energy and nutrient levels, mean and limits of agreement estimated through the Bland-Altman method, will also be recorded.

### Setting characteristics

There will be no restrictions on the kind of setting or geographical location.

### Language

It will be selected publications reported in English, Spanish, Portuguese or other Romance languages. In the

case of studies published in a language other than those indicated above, an attempt will be made to obtain the information of interest, provided that it can be translated with sufficient guarantees. However, studies that use an alphabet other than Latin, which makes its translation difficult, will be ruled out.

### Information sources

The search strategy will include a comprehensive electronic search in PubMed/MEDLINE, Scopus and Web of Science (WOS) to find potentially relevant studies from their inception to December 2022. In addition, the reference lists of manuscripts selected for inclusion in the review will be hand-searched to identify other pertinent studies with information on FFQs-DDV-DiaP. Searches will be updated before the final analyses, and any further studies identified will be retrieved for inclusion.

### Search strategy

As mentioned above, the literature search strategy will implement in three different electronic bibliographic databases (MEDLINE, WOS and Scopus). The search strategy is developed first for MEDLINE, including Medical Subject Headings (MeSH) terms and free-text terms related to the four concepts of interest in this systematic review and meta-analysis: diet, food questionnaires, validity and reproducibility, and DM. Boolean operators ('AND' and 'OR') are used to combine all the free-text and MeSH terms. Then, the literature search strategy is adapted for Scopus and WOS. A dietitian and researcher with experience in systematic reviews (JF-C) developed the search strategy. The detailed search strategy for PubMed/MEDLINE is provided in online supplemental table S2.

After applying the search strategy and completing the selection process, the reference lists of eligible studies, relevant reviews and conference proceedings will be reviewed to identify additional sources of information. In addition, corresponding authors of potentially eligible publications, as well as those selected, will be contacted to request relevant data if necessary.

### Study records

#### Data management

The records retrieved will be imported into the EndNote reference management program, and duplicates will be removed. At least two reviewers will independently undertake the selection and extraction processes of the records. Divergences in these stages will be resolved by discussion until consensus is reached. Excluded records will have a justification by which they are discarded, according to the eligibility criteria described above. When two or more publications describe and provide relevant information of the same FFQs-DDV-DiaP, all these publications will be included in the review. The extraction process of the selected studies will be carried out using a standard Excel form (online supplemental table S3).

### Selection process

At least two reviewers will independently screen the records found for eligibility. Initial screening of the records will be based on the information contained in their titles and abstracts. During the second screening, assessment of the full text will determine whether studies will be included in the review. Disagreements will be resolved through discussion until a consensus among the reviewers is reached. Finally, any study not meeting the inclusion criteria will be removed, and the reasons for exclusion will be recorded in order to elaborate the subsequent flow chart. The reviewers will not be blinded to the journal name in which the studies have been published, nor to the authors, nor the institutions involved.

### Data collection process

A standard Excel form (online supplemental table S3) will be used to perform the data collection. Two investigators will extract data independently, and the results will be compared to avoid inaccuracies. This standard form includes information on the design, development, and study of the validity and reproducibility of FFQs-DDV-DiaP, and the characteristics and published years of the selected studies. The authors will be contacted to request additional information or clarification when the reported data are missing, insufficient or ambiguous.

Some strategies will be applied to avoid the inclusion of FFQs-DDV-DiaP in duplicate: the list of authors and the characteristics of FFQs-DDV-DiaP suspected of matching will be contrasted. In the event that duplicate FFQs-DDV-DiaP are detected, the information will be combined.

### Data items

Information on the selected studies, data related to the design, development, and assessment of the validity and reproducibility of the FFQs-DDV-DiaP and their characteristics, and the statistical methods employed to assess validity and reproducibility of the FFQs-DDV-DiaP will be registered. The following section will more specifically detail the information that will be collected. The extraction form (online supplemental table S3) includes all these variables and their definitions, with particular details about the planned outcomes. Any modification for these outcomes will be documented and considered when conducting the systematic review and meta-analyses.

### Outcomes and prioritisation

The primary outcomes of this systematic review and meta-analysis include descriptive data related to the design, development, and assessment of the validity and reproducibility of the FFQs-DDV-DiaP. Thus, information by which the list of food items (national health surveys, food composition tables,...) and the portion sizes (national health surveys, food composition tables, household measures, ...) of the questionnaires were defined, as well as the number of intake frequency response categories (1, 2, 3, ...) and administration mode (self-administered, interviewer-administered, ...) of the FFQs-DDV-DiaP, the

number of food items, the type of FFQs (quantitative, semiquantitative, qualitative), the use of visual support material or food models (yes/no), food, energy and nutrients analysed, the period evaluated (weeks, months, years), the type of diabetes (type 1DM, type 2DM, or gestational DM), the study design for which the FFQs was generated (prospective cohort studies, clinical trial, ...), the reference dietary assessment method for the FFQs validation (24-HDR, diet history or DR) and their number of days of administration (1 day, 3 days, 7 days, ...), the time interval between repeated FFQs during the evaluation of the reproducibility (weeks, months, years), sample sizes and the food composition table used (food composition data from the US Department of Agriculture, FAO/INFOODS Food Composition Databases, ...) will be included. Furthermore, original studies with data on the raw, deattenuated, and adjusted Pearson's, Spearman's or intraclass correlation coefficients, and/or means and SD for food, energy, and nutrients will also be included in order to assess the overall correlation and agreement between the FFQs-DDV-DiaP and the reference dietary assessment method in the validation, as well as between the repeated FFQs to evaluate the reproducibility.

The secondary outcomes will include characteristics of the population evaluated during the assessment of the validity and reproducibility of the FFQs-DDV-DiaP, such as diabetes duration, age, BMI, HbA1c and sex; and information on the selected studies (first author, year of publication, region or country), will also be collected. Additional information regarding the assessment of the validity and reproducibility of the FFQs-DDV-DiaP, such as kappa coefficients of agreement, ability to rank subjects according to food, energy and nutrient levels, mean and limits of agreement estimated through the Bland-Altman method, will be recorded.

### Risk of bias individual studies

The quality of the included studies will not be examined since the interest of this systematic review and meta-analysis will be the FFQs-DDV-DiaP. Nevertheless, FFQs identified will be assessed for quality using the summary score by Dennis *et al.*<sup>20</sup> This score assesses the quality of nutritional information from FFQs. Thus, each FFQ will be ranked according to a score range from 0 to 15. FFQs with a count of 7 or more will be classified as 'high quality'. Those FFQs with a score of 6 or less will be categorised as 'low quality'. Two independent reviewers will conduct the quality appraisal, with discrepancies being resolved by discussion.

### Data synthesis

Data on the outcomes of interest mentioned above will be presented in tabular and/or narrative form to provide an overview of this information. Kappa values will be extracted and used as a measure of agreement between FFQs-DDV-DiaP and the reference dietary assessment method and between the repeated FFQs. The agreement will be classified according to the following thresholds

established by Landis and Koch<sup>21</sup>: slight if  $\kappa=0.01-0.20$ , fair if  $\kappa=0.21-0.40$ , moderate if  $\kappa=0.41-0.60$ , substantial if  $\kappa=0.61-0.80$ , almost perfect if  $\kappa=0.81-0.99$ .

When correlation coefficients, or means and SD for food, energy or nutrients obtained in the assessment of the validity and reproducibility of the FFQs-DDV-DiaP are available, meta-analyses will be implemented. Thus, to determine the overall degree of correlation between FFQs-DDV-DiaP and the reference dietary assessment method, as well as between the repeated FFQs, raw, deattenuated, or adjusted Pearson's, Spearman's or intraclass correlation coefficients will be combined separately. The correlation coefficients will not be transformed into Fisher's z scores since this change produces an upward bias in the mean estimation of the correlation coefficients. In addition, the negligible downward bias generated by untransformed correlations is usually lower than this upward bias.<sup>22</sup> Cohen's conventions for interpretation of the correlation coefficients will be followed. Thus, a value of 0.1 indicates a small effect size, a value of 0.3 indicates a medium effect size, and a value of 0.5 a large effect size.<sup>23</sup>

In order to estimate the overall agreement between FFQs-DDV-DiaP and the reference dietary assessment method, as well as between the repeated FFQs, means and SD will be used. In this case, pooled effect sizes will be expressed as (mean difference) MD and 95% CIs. Exceptionally, in the case of data with different measurement scales, we will use the standardised MD and 95% CI. Data in forms other than the mean and SD, such as median and the IQR, will be converted, when possible, using the estimation methods proposed by Wan *et al.*<sup>24</sup> These methods allow appropriate estimates for both normal and skewed data. Furthermore, whether a study provided the mean and SE, the SE will be converted into a SD by the following equation:  $SE \times \text{square root of the sample size}$ . Random-effects models and the generic inverse variance method will be used to define the respective effect sizes. Random-effects models give more conservative results than fixed-effects models<sup>25</sup> and take into account not only the between-study variability (heterogeneity) but also the within-study variability, expressed by the CI of each study's effect size.<sup>26</sup> Forest plots will be created to visualise individual and global estimates. Univariate and multivariate meta-regressions with Knapp-Hartung modification<sup>27</sup> will be conducted to examine the potential effect of some covariates on the effect sizes, and bubble plots will be generated when appropriate. Heterogeneity will be tested using the Cochran Q-statistic and quantified by the  $I^2$  statistic, which represents the percentage of variation attributable to between-study heterogeneity.<sup>28</sup> It will be considered low, medium and high heterogeneity  $I^2$  values of 25%, 50% and 75%, respectively.<sup>29</sup> Stratified analyses, sensitive analysis, and univariate and multivariate meta-regression models will be used to explore potential sources of heterogeneity, using covariates, such as the region or country, the type of diabetes, the type of FFQs, the administration mode, the period evaluated, the

number of food items, the reference dietary assessment method for the FFQs validation and their number of days of administration, the time interval between repeated FFQs during the evaluation of the reproducibility, sample sizes, among others. Heterogeneity will be examined even if any initial heterogeneity is non-significant, that is, when heterogeneity is low or moderate. In the case of obtaining high heterogeneity in any meta-analyses for any food, nutrient or energy assessed, and this cannot be explained by the abovementioned strategies, the overall pooled estimates will not be given, since it would not be a reliable result. In addition, the adjusted  $R^2$  will be calculated to examine how much of the heterogeneity is explained by these covariates.

Finally, stratified analyses and random-effects meta-regressions will be performed to explore whether any covariate aforementioned influences the effect sizes. Bubble plots will be created to show a relevant influence of a single continuous covariate on the effect size. In addition, sensitivity analysis will be conducted using the leave-one-out method to analyse the influence of each study on the overall pooled estimates.<sup>30</sup>

### Meta-bias

The tests of Egger<sup>31</sup> and Begg<sup>32</sup> and the funnel plot will be used to evaluate the presence of publication bias. Statistical analysis will be performed using the STATA software package (V.15.0, STATA Corp, College Station, Texas, USA). P values below 0.05 will indicate statistical significance, except for heterogeneity whose threshold will be 0.1.

### Patient and public involvement

No patient involved.

**Contributors** JF-C is the guarantor. JF-C conceived, designed and drafted the protocol, provided statistical expertise and developed the search strategy. EA contributed to the conception and the development of the protocol. All authors read, provided feedback and approved the final protocol.

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