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Original Research Article

Validation of a pregnancy-adapted Mediterranean Diet Adherence Screener (preg-MEDAS): a validation study nested in the Improving Mothers for a better PrenAtal Care Trial BarCeloNa (IMPACT BCN) trial

Sara Castro-Barquero [1,2,3,†], Francesca Crovetto [1,4,5,†], Ramon Estruch [2,3,6,7,*], Ana María Ruiz-León [2,3,6,7], Marta Larroya [1,7], Emilio Sacanella [2,6,7], Francesc Casanovas-Garriga [3,6], Irene Casas [1], Ayako Nakaki [1,7], Lina Youssef [1,7,8], Alejandra Trejo-Domínguez [1], Leticia Benitez [1,7], Mariona Genero [1,4], Eduard Vieta [7,9], Eduard Gratacós [1,7,10], Fàtima Crispi [1,7,10,‡], Rosa Casas [2,3,6,7,**]

[1] *BCNatal | Barcelona Center for Maternal and Fetal Medicine (Hospital Clínic and Hospital Sant Joan de Déu), University of Barcelona, Barcelona, Spain;* [2] *Centro de Investigación Biomédica en Red de Fisiopatología de la Obesidad y Nutrición (CIBEROBN), Madrid, Spain;* [3] *Institut de Recerca en Nutrició i Seguretat Alimentaria (INSA-UB), University of Barcelona, Barcelona, Spain;* [4] *Institut de Recerca Sant Joan de Déu, Barcelona, Spain;* [5] *Primary Care Interventions to Prevent Maternal and Child Chronic Diseases of Perinatal and Development Origin, RD21/0012/0001, Instituto de Salud Carlos III, Barcelona, Spain;* [6] *Department of Internal Medicine Hospital Clinic, University of Barcelona, Barcelona, Spain;* [7] *Institut de Recerca August Pi Sunyer (IDIBAPS), Barcelona, Spain;* [8] *Josep Carreras Leukemia Research Institute, Hospital Clinic/University of Barcelona Campus, Barcelona, Spain;* [9] *Department of Psychiatry and Psychology, Hospital Clinic, Neuroscience Institute, University of Barcelona, CIBERSAM, Barcelona, Spain;* [10] *Centre for Biomedical Research on Rare Diseases (CIBER-ER), Madrid, Spain*

A B S T R A C T

Background: Non-time-consuming and easy-to-administer dietary assessment tools specific for pregnancy are needed.
Objectives: The aim of this validation study nested in the IMPACT BCN (Improving Mothers for a better PrenAtal Care Trial BarCeloNa) trial is to determine the concurrent validity of the 17-item pregnancy-adapted Mediterranean diet score (preg-MEDAS) and to analyze whether changes in the preg-MEDAS score were associated with maternal favorable dietary and cardiometabolic changes after 3 mo of intervention in pregnant women.
Methods: Dietary data was collected in 812 participants using the preg-MEDAS and a 151-item validated food frequency questionnaire (FFQ) at baseline (19–23 wk gestation) and final visit (31–34 wk gestation). Concurrent preg-MEDAS validity was evaluated by Pearson and intraclass correlation coefficients, κ statistic, and Bland-Altman methods.
Results: The preg-MEDAS had a good correlation with the FFQ ($r = 0.76$ and intraclass correlation coefficient 0.75). The agreement of each of the preg-MEDAS items ranged from 40.9% to 93.8% with a substantial agreement mean concordance ($\kappa = 0.61$). A 2-point increase in preg-MEDAS was associated with a decrease in maternal mean and systolic blood pressure (β: −0.51 mmHg; 95% confidence interval [CI]: −0.97, −0.04 mmHg and −0.87 mmHg; 95% CI: −1.48, −0.26 mmHg, respectively).
Conclusions: The preg-MEDAS displays good validity for assessing adherence to the Mediterranean diet, allowing detection of dietary changes over time. In addition, changes observed in preg-MEDAS are significantly associated with a decrease in maternal blood pressure. Therefore, we propose preg-MEDAS as a rapid and simple dietary assessment tool during pregnancy.
This trial was registered at clinicaltrials.gov as NCT03166332.

Keywords: validity, diet, Mediterranean diet, pregnancy, screener

Abbreviations: CI, confidence interval; er-MEDAS, energy-restricted Mediterranean Diet Adherence Screener; FFQ, food frequency questionnaire; ICC, intraclass correlation coefficient; IMPACT BCN, Improving Mothers for a better PrenAtal Care Trial BarCeloNa; MEDAS, Mediterranean Diet Adherence Screener; MedDiet, Mediterranean diet; preg-MEDAS, pregnancy-adapted Mediterranean Diet Adherence Screener; PREDIMED, PREvención con Dieta Mediterránea; SGA, small for gestational age.

* Corresponding author.
** Corresponding author.
E-mail addresses: restruch@clinic.cat (R. Estruch), rcasas1@recerca.clinic.cat (R. Casas).
† SC-B and FCrovetto contributed equally to this work.
‡ FCrispi and RC contributed equally to this work.

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Introduction

Maternal diet plays a crucial role in fetal development, influencing the risk of developing some complications during pregnancy, adverse outcomes for both the mother and fetus, as well as the development of chronic diseases in the long term, including adulthood [1,2]. It is widely acknowledged worldwide that the Mediterranean diet (MedDiet) is a healthy, easy-to-follow dietary pattern that has demonstrated numerous health benefits [3] in preventing many noncommunicable diseases such as diabetes, obesity, cancer, and cardiovascular diseases [3,4]. Furthermore, the MedDiet has also a protective role during the preconception period and pregnancy, with a positive association with maternal and offspring health [5]. Recently, in the IMPACT BCN (Improving Mothers for a better PrenAtal Care Trial BarCeloNa) randomized clinical trial [6], we first demonstrated that a MedDiet adapted to pregnancy or a Mindfulness-Based Stress Reduction program significantly reduces the incidence of newborns born small for gestational age (SGA) and other perinatal complications in pregnant women at high risk. Given the proven importance of maternal diet during pregnancy, it is essential to design non-time-consuming and easy-to-administer dietary assessment tools specific to this population to allow measuring and monitoring food consumption during this period of life, as well as to evaluate the adherence to the MedDiet. However, the dietary information collected in short dietary assessment tools is limited to a few items, without measuring absolute or relative intake of specific foods, energy, or nutrients. Therefore, alternative quantitative dietary assessment tools, such as food frequency questionnaires (FFQs) or food registries, may be needed to estimate energy intake or energy-adjusted intake of crucial nutrients or foods during pregnancy. Most dietary assessment tools rely on participants' memory, but particularly long dietary assessment tools may be difficult or confusing for participants to complete [7].

Currently, dietary assessment in intervention studies and dietary advice in clinical practice is usually assessed using dietary records, 24-h food registries, and FFQs [8]. However, these tools are sometimes impractical, time-consuming, and prone to errors due to subjective estimation of serving sizes. To ensure optimal monitoring of dietary compliance in the IMPACT BCN trial, we developed the pregnancy-adapted Mediterranean Diet Adherence Screener (preg-MEDAS). This screener was adapted from Mediterranean Diet Adherence Screener (MEDAS) from the PREvención con Dieta Mediterránea (PREDIMED) [9] and PREDIMED-Plus trials [10], including 3 additional items. These modifications aimed to adapt the traditional MedDiet to the specific nutritional requirements of pregnancy [11]. Particularly, diet during pregnancy should focus on nutritional quality rather than quantity [11]. The preg-MEDAS score ranges from 0 to 17 points, with 0 points indicating no adherence and 17 points indicating maximum adherence.

The present study aimed to determine the concurrent validity of the preg-MEDAS in participants of the IMPACT BCN trial. Additionally, we aimed to analyze whether an increase in adherence to the MedDiet, as measured by the preg-MEDAS score, was associated with favorable maternal dietary and cardiometabolic changes after 3 mo of intervention in pregnant women.

Methods

Study population

This is a validation study nested in the IMPACT BCN trial, a randomized clinical trial with parallel groups conducted at BCNatal, Spain. Pregnant women ($n = 1221$) at high risk for SGA were randomly assigned at 19 to 23 wk gestation to 3 interventions with a 1:1:1 allocation as per computerized random number generator: *1*) a MedDiet intervention; *2*) a stress reduction program based on mindfulness techniques; or *3*) usual care. Recruitment took place from February 2017 to October 2019, with follow-up until delivery (1 March, 2020). Additionally, 4 postnatal follow-up visits at 1 to 3 mo, 12 mo, 24 mo, and 6 y will be performed. The study protocol has been published elsewhere [12], and the main outcomes of the trial have also been reported [6]. The trial was registered at clinicaltrials.gov with identifier NCT03166332. The Institutional Review Board of the Hospital Clínic of Barcelona approved the study (HCB-2016-0830). All pregnant women provided written informed consent. For the present analysis, from the total sample of 1221 randomly assigned participants, 322 participants were excluded because of missing data on dietary information at baseline and/or final visit, 50 participants because of extreme energy intake outside predefined limits [13], 10 due to fetal/neonatal malformations, and 27 withdrew consent. Finally, 812 participants were included in the analysis (Figure 1).

Dietary assessment

A preg-MEDAS and a 151-item semiquantitative FFQ validated for the present study population [14] were collected from all participants by trained dietitians in face-to-face interviews at trial enrollment (19–23 wk) and final visit (34–36 wk).

Preg-MEDAS

The preg-MEDAS was based on the previous validated MEDAS [10] and modified as follows (Supplemental Table 1):

a) 9 items from the MEDAS were maintained without modification:

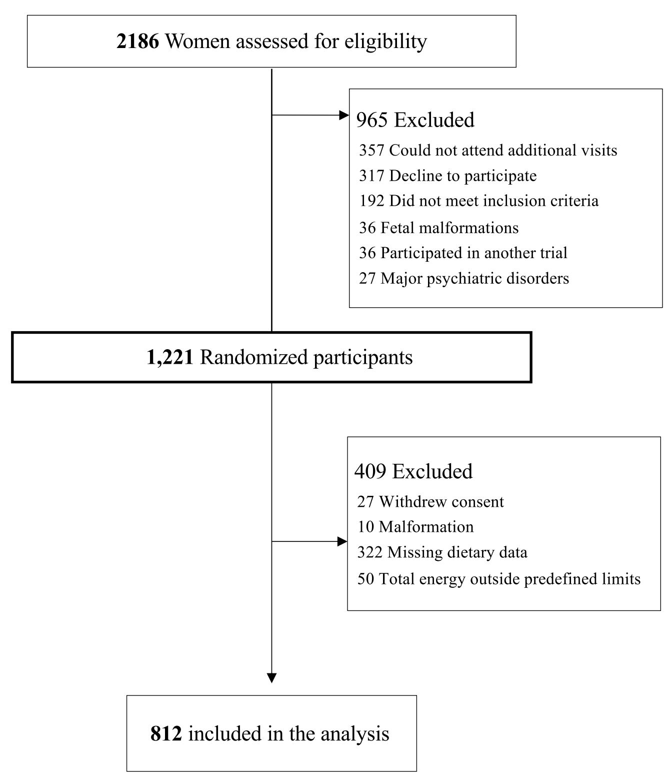

FIGURE 1. Flowchart of the study participants.

"How many servings of cooked vegetables, pasta, rice, or other dishes seasoned with *sofrito* (tomato, garlic, onion, or leek sauce made with extra virgin olive oil and low heat) do you consume per week?"; "How many servings of whole grain cereals, bread, pasta, or rice do you consume per week?"; "How many servings of refined cereals, bread, pasta, or rice do you consume per week?"; "How many servings of legumes do you consume per week?"; "How many servings of fish/seafood do you consume per week?"; "How many servings of red meat, including beef, lamb, non-lean pork, or duck, do you consume per week?"; "How many carbonated and/or sugar-sweetened beverages do you consume per week?"; "How many servings of nuts, including walnut, hazelnut, almond, peanut, or pistachio, do you consume per week?"; and "How many servings of butter, margarine, or cream do you consume per week?"

b) 4 items were slightly modified, mainly by modifying frequencies:

"Do you use extra virgin olive oil as the principal source of fat for cooking?" was changed to "How many tablespoons of extra virgin olive oil do you consume per day (for cooking, dressing, at restaurants, etc.)?". "How many servings of vegetables do you consume per day?" was modified to ≥3 servings per day, while "How many pieces of fruit do you consume per day?" was modified to ≥2 servings per day. Additionally, "How many times do you consume pastries such as cookies, custard, sweets, or cake per week?" was modified to <2 servings per week.

c) 4 new items were included:

"How many servings of fatty fish do you consume per week?"; "How many servings of processed meat, including hamburgers or sausages, do you consume per week?"; "How many servings of chicken, turkey, rabbit, or lean pork do you consume per week?"; and "How many servings of dairy, including milk, yogurt, cheese, or calcium-fortified vegetable milk, do you consume per day?"

d) 3 items were deleted from the screener:

"Do you drink wine? How much do you consume per week?"; "Do you add sugar to your beverages (coffee, tea)?"; and "How many servings of white bread do you consume per day?".

Compliance with each of the 17 items was scored with 1 point, with a total score ranging from 0 to 17.

151-item semiquantitative FFQ

Food consumption derived from the FFQ was converted into energy and nutrient intake with the Centro de Enseñanza Superior de Nutrición y Dietética (CESNID) and Moreiras composition tables using traditional recipes [15,16]. Details of the FFQ validations were described elsewhere [14]. Briefly, participants indicated their usual and frequent consumption of listed food items in the FFQ, based on 9 frequency categories (ranging from never or <1 time/mo to ≥6 times/d) and using common units or portion sizes. A total of 14 food groups were listed: milk and dairy products, cereals and whole grains, vegetables, legumes, sausages, oils and fats, eggs, meat and fish, fast food, canned products, fruit, nuts, sweets and desserts and others (salt and sugar), and alcoholic and nonalcoholic beverages.

Food intakes assessed with the FFQ were grouped into the food components of the preg-MEDAS for analysis. The relative validity of the 17-item preg-MEDAS was assessed by comparing the dietary information collected from the preg-MEDAS with the data obtained from the validated 151-item FFQ.

Biological and anthropometric measurements

Trained personnel measured pregnant participants' body weight, height, BMI, and blood pressure at recruitment (19–23 wk gestation) and final visit (34–36 wk gestation). Body weight was measured with an electronic scale with a precision of 100 g with participants wearing light clothing. Height was measured to the nearest 0.1 cm using a wall-mounted stadiometer. BMI was calculated by dividing body weight (kilograms) by height in meters squared. Blood pressure, including both diastolic and systolic, was measured in each forearm at heart level with a validated semiautomatic oscillometer (Omron HEM-705CP) at 3 time points separated by 2 min while the participant was in a seated position after 5 min of rest. The average of the 3 measurements was recorded in the data collection form. Mean arterial pressure was defined as diastolic blood pressure + 1/3 × (systolic blood pressure − diastolic blood pressure). Blood samples were drawn in the morning (after a minimum of 10 h of fasting) and analyses were performed at the CORE laboratory of the Hospital Clinic of Barcelona. Several prespecified biomarkers were evaluated in a subsample of randomly selected participants (30%) to assess the biological effects of the interventions. In 188 participants, Hb1Ac, vitamin B12, and folic acid were measured, while in 197 participants, transferrin was measured.

Birthweight percentile was calculated with birthweight adjusted by gestational age at delivery and sex, according to standards for the Spanish population [17].

Covariates

Maternal characteristics were obtained from different questionnaires and interviews administered to study participants, and details of the questionnaires and data collection are described elsewhere [12]. Data included maternal age (years), ethnicity (Asian/Black/Latin American/Maghreb/White), socioeconomic status (low/medium/high; defined as low if participants reported having never worked or being unemployed for >2 y and having a partner with unqualified work or who was unemployed; high if they reported university studies regardless of whether they were working; and medium if any other situation), educational level (primary/secondary/university), prepregnancy body weight (kilograms) and BMI (kilograms per meters squared), parity (multiparous/nulliparous), use of assisted reproductive technologies (yes/no), and smoking during pregnancy (no/stop during pregnancy/yes).

Statistical analysis

Continuous variables are expressed as mean ± SD. Categorical variables are expressed as number (*n*) and percentage (%). Comparisons among quartiles of the 17-item preg-MEDAS used the Pearson chi square test (χ^2) for categorical variables or 1-way analysis of variance for continuous variables. According to the statistical analysis plan of the trial [12], for the analyses of the secondary end points or covariates, no imputations of missing data were required.

The relative validity of the preg-MEDAS was assessed by several measurements. The absolute agreement of categorical variables between the 2 measurements was assessed by cross-classification and κ statistic. According to Landis et al. [18], values of κ >0.8 signify almost perfect agreement, 0.61 to 0.80 substantial agreement, 0.41 to 0.60 moderate agreement, 0.21 to 0.40 fair agreement, and ≤0.20 slight agreement.

Additionally, a mean proportional ratio of means of 100% [(preg-MEDAS / 151-item FFQ) × 100] and a mean difference (preg-MEDAS – 151-item FFQ) were also estimated. In addition, a linear regression model with the mean instrument differences of the scores derived from the preg-MEDAS and 151-item FFQ [(preg-MEDAS – 151-item FFQ)] as the dependent variable and the mean score of both [(preg-MEDAS + 151-item FFQ)/2)] as the independent variable was

TABLE 1
Baseline characteristics of the study population according to the 17-item preg-MEDAS derived from the 151-item FFQ.

	Adherence to the 17-item preg-MEDAS			
	First quartile	Second quartile	Third quartile	Fourth quartile
preg-MEDAS, unit	<5	5–7	8–9	>9
N	218	229	215	150
Maternal age, y	36.7 (4.80)	36.9 (4.45)	37.7 (4.64)	37.9 (4.31)
Intervention arm, *n* (%)				
Mediterranean diet	76 (34.9)	74 (32.3)	78 (36.3)	62 (41.3)
Stress reduction	65 (29.8)	73 (31.9)	64 (29.8)	48 (32.0)
Usual care	77 (35.3)	82 (35.8)	73 (34.0)	40 (26.7)
Ethnicity, *n* (%)				
White	174 (79.8)	190 (83.0)	184 (85.6)	125 (83.3)
Latin	34 (15.6)	31 (13.5)	21 (9.77)	17 (11.3)
Asian	4 (1.83)	6 (2.62)	0 (0)	2 (1.33)
Black	5 (2.29)	0 (0)	4 (1.86)	1 (0.67)
Other	1 (0.46)	2 (0.87)	6 (2.79)	5 (3.33)
Smoking habit, *n* (%)				
No	173 (79.4)	181 (79.0)	176 (81.9)	128 (85.3)
Stop during pregnancy	24 (11.0)	32 (14.0)	29 (13.5)	17 (11.3)
Yes	21 (9.63)	16 (6.99)	10 (4.65)	5 (3.33)
Educational level, n (%)				
Primary school	10 (4.59)	6 (2.62)	10 (4.65)	7 (4.67)
Secondary school	72 (33.0)	63 (27.5)	46 (21.4)	40 (26.7)
University	136 (62.4)	160 (69.9)	159 (73.9)	103 (68.7)
Marital status, n (%)				
Married	113 (51.8)	87 (38.0)	102 (47.4)	66 (44.0)
Not married couple	73 (33.5)	103 (45.0)	82 (38.1)	62 (41.3)
Divorced	8 (3.67)	7 (3.06)	5 (2.33)	3 (2.00)
Single	24 (11.0)	32 (14.0)	26 (12.1)	19 (12.7)
Employment status, *n* (%)				
Employed	179 (82.1)	190 (83.0)	174 (80.9)	126 (84.0)
Student	3 (1.38)	2 (0.87)	2 (0.93)	0 (0)
Autonomous	11 (5.05)	14 (6.11)	22 (10.2)	13 (8.67)
Housekeeper	5 (2.29)	6 (2.62)	8 (3.72)	4 (2.67)
Unemployed	20 (9.17)	17 (7.42)	9 (4.19)	7 (4.67)
Nulliparity, *n* (%)	120 (55.0)	144 (62.9)	126 (58.6)	88 (58.7)
Use of assisted reproductive technologies, *n* (%)	62 (28.4)	49 (21.4)	63 (29.3)	43 (28.7)
Body weight preconception, kg	64.2 (12.9)	62.9 (12.6)	63.8 (12.7)	63.0 (12.9)
BMI preconception, kg/m^2	24.4 (4.63)	23.3 (4.42)	23.8 (4.64)	23.5 (4.91)

Abbreviations: BMI, body mass index; FFQ, food frequency questionnaire; preg-MEDAS, 17-item pregnancy-adapted Mediterranean Diet Adherence Screener; SD, standard deviation.
Values are presented as means (SD) for continuous variables and *n* (%) for categorical variables. Pearson's χ^2 test was performed for categorical variables and Student t test for continuous variables.

also fitted. The related validity was also assessed by calculating Pearson product-moment correlation coefficients to compare the MedDiet adherence scores derived by the preg-MEDAS (test method) and by the 151-item FFQ (reference method). We further assessed the agreement between the scores obtained with the preg-MEDAS and the 151-item FFQ using the intraclass correlation coefficient (ICC). Moreover, we further assessed the agreement using the Bland-Altman method [19], which determines the agreement between the 151-item FFQ and preg-MEDAS by calculating the mean of their differences and the average score obtained with the 2 methods.

For changes in dietary intake, the general linear model approach to analysis of covariance was used to determine the changes in energy intake and key food consumption after 3 mo (dependent variables) for changes (final compared with baseline visit) in preg-MEDAS scores (decreased ≤ -1 points, stable 0–1 points, and increased ≥ 2 points, with stable score as the reference category) using the baseline intake, intervention arm, age, educational level (primary, secondary, university), and prepregnancy BMI ($<30/\geq 30$ km/m^2) as covariates.

The associations between changes in preg-MEDAS score (2 points increase at final compared with baseline visit) and cardiometabolic parameters of the mother and newborn data were analyzed by linear regression models. The results of the regression models are expressed as unstandardized β coefficients and 95% confidence intervals (CIs). For regression models, changes in preg-MEDAS were expressed as a 2-point increase. All regression models were adjusted for potential confounders. Model 1 was adjusted for age and intervention arm. Model 2 was additionally adjusted for educational levels status (primary, secondary, University), prepregnancy BMI ($<30/\geq 30$ km/m^2), and smoking status (yes, no, stop during pregnancy). For newborn data, model 2 was further adjusted for nulliparity (yes/no).

All analyses were performed using Statistical Package for the Social Sciences (SPSS) statistical software package version 27.0 (SPSS Inc). $P < 0.05$ was considered statistically significant.

Results

Baseline characteristics of the study population

Table 1 shows the baseline characteristics of our study population according to quartiles of baseline values of the preg-MEDAS estimated using the reference method (FFQ). Participants with higher adherence

TABLE 2
Absolute agreement between frequency and dietary food intake measured with the 17-item preg-MEDAS and the 151-item FFQ.

	Frequency[1]	preg-MEDAS[2]	FFQ[3]	κ (95% CI)	Absolute agreement (%)
1. How many tablespoons of extra virgin olive oil do you consume per day (for cooking, dressing, at restaurants, etc.)?	≥4	70.8	70.4	0.73 (0.68, 0.78)	88.8
2. How many servings of vegetables do you consume per day? Count garnish and side serving as 0.5 point. 1 serving = 200 g	≥3	25.1	51.0	0.18 (0.12, 0.23)	58.4
3. How many pieces of fruit do you consume per day?	≥2	58.1	54.6	0.55 (0.49, 0.61)	78.0
4. How many servings of cooked vegetables, pasta, rice or other dishes seasoned with *sofrito* (tomato, garlic, onion, or leek sauce made with extra virgin olive oil and low heat) do you consume per week?	≥2	44.5	37.6	0.78 (0.74, 0.82)	89.4
5. How many servings of whole grain cereals, bread, pasta, or rice do you consume per week?	≥5	39.0	57.0	0.76 (0.70, 0.81)	80.0
6. How many servings of refined cereals, bread, pasta, or rice do you consume per week?	<3	23.5	20.6	0.78 (0.73, 0.83)	91.6
7. How many servings of legumes do you consume per week? 1 serving =150 g	≥3	19.1	20.9	0.78 (0.73, 0.83)	93.0
8. How many servings of fish/seafood do you consume per week? 1 serving = 100–150 g fish; 4–5 pieces or 200 g of seafood)	≥3	26.5	40.3	0.63 (0.58, 0.68)	83.3
9. How many servings of fatty fish do you consume per week? 1 serving = 100–150 g	1	44.6	45.8	0.86 (0.82, 0.89)	92.9
10. How many servings of red meat, including beef, lamb, non-lean pork, or duck, do you consume per week? 1 serving = 100–150 g	≤1	72.4	17.0	0.13 (0.10, 0.16)	43.6
11. How many servings of processed meat, including hamburgers or sausages, do you consume per week? 1 serving = 100–150 g	≤1	72.4	14.8	0.10 (0.07, 0.13)	40.9
12. How many servings of chicken, turkey, rabbit, or lean pork do you consume per week? 1 serving = 100–150 g	≥3	53.8	67.9	0.64 (0.59, 0.69)	82.5
13. How many carbonated and/or sugar-sweetened beverages do you consume per week?	<1	55.0	62.2	0.74 (0.70, 0.79)	87.4
14. How many servings of nuts, including walnut, hazelnut, almond, peanut, or pistachio, do you consume per week? 1 serving = 30 g	≥3	43.1	54.7	0.69 (0.65, 0.74)	84.5
15. How many times do you consume pastries such as cookies, custard, sweets, or cake per week?	<2	40.6	16.7	0.42 (0.36, 0.48)	74.6
16. How many servings of dairy, including milk, yogurt, cheese, or calcium-fortified vegetable milk, do you consume per day?	≥3	21.3	27.2	0.67 (0.61, 0.73)	87.7
17. How many servings of butter, margarine, or cream do you consume per week?	<1	62.4	59.0	0.87 (0.84, 0.91)	93.8

Abbreviations: CI, confidence interval; FFQ, food frequency questionnaire; preg-MEDAS, pregnancy-adapted Mediterranean Diet Adherence Screener.
[1] Criterion to score 1 point.
[2] Percentage of participants scoring 1 on the 17-item preg-MEDAS.
[3] Percentage of participants scoring 1 on the 151-item FFQ.

to the MedDiet were older and had lower preconception body weight and BMI. Pregnant women allocated in the highest adherence score also showed a higher percentage of nulliparity and use of assisted reproductive technologies (40.2% in both cases). Baseline characteristics of the study population according to the 17-item preg-MEDAS categories (low <6 points; medium 7–11 points; high ≥12 points) are shown in Supplemental Table 2.

Absolute agreement and correlation of preg-MEDAS and FFQ

We measured by cross-classification the absolute agreement between FFQ items and habits of dietary food intake (preg-MEDAS) (Table 2). Ranks varied from 41% for consumption of processed meat per week to 94% for consumption of butter, margarine, or cream per week. We estimated a mean of 79.3% for all items. In relation to the degree of agreement, we used the κ statistic. The κ statistic ranged from slight agreement (κ = 0.10 for processed meat) to almost perfect agreement (κ = 0.87 for butter, margarine, or cream) concordance. The mean κ for all items was 0.61, or substantial agreement.

In contrast, the Pearson coefficient (Table 3) was 0.76 (95% CI: 0.73, 0.79), which revealed a strong correlation between the preg-MEDAS score and the FFQ. In addition, the ICC showed the same degree of correlation (ICC: 0.75; 95% CI: 0.68, 0.80).

Table 3 and Figure 2 also show that the mean of the preg-MEDAS score was 7.18 ± 2.49 for the FFQ and 7.73 ± 2.52 for preg-MEDAS (mean difference: 0.55; 95% CI: 0.43, 0.67). The preg-MEDAS score overestimated by 8% the scoring in comparison with the score obtained by FFQ. Additionally, the β coefficient was 0.52 (95% CI: 0.43, 0.62), which means that the discrepancies are observed in higher score ranking. The Bland-Altman plot (Figure 2) also shows a small regression coefficient; therefore, this bias is negligible.

Maternal dietary and cardiometabolic risk factors after 3 mo of intervention according to the preg-MEDAS scores

Energy and nutritional intake and food consumption was derived from the preg-MEDAS score and the FFQ after 3 mo of intervention. Table 4 shows that pregnant women who improved their preg-MEDAS score (increased ≥2 points) compared to those with a stable score showed a daily increase of energy intake. Furthermore, participants who increased their preg-MEDAS score showed a higher daily intake of vegetables, fruits, legumes, whole grain cereals, fish and fatty fish, nuts, extra virgin olive oil, and dairy products and lower daily intake of refined cereals and sweets and pastries.

Table 5 shows the association between 2-point change in the preg-MEDAS score after 3 mo and cardiovascular disease risk factors in pregnant women. Changes in the preg-MEDAS score were inversely associated with mean blood pressure (β: −0.48 mmHg; 95% CI: -0.96, −0.00 mmHg) and systolic blood pressure (β: −0.84 mmHg; 95% CI: −1.46, −0.21 mmHg) in the minimally adjusted model. In the fully adjusted model, mean and systolic blood pressure were β: −0.51 mmHg; 95% CI: −0.97, −0.04 mmHg and β: −0.87 mmHg; 95% CI: −1.48, −0.26 mmHg, respectively. No significant associations were found between 2-point changes in the preg-MEDAS and body weight gain during pregnancy, BMI change during pregnancy, diastolic blood pressure, and levels of hemoglobin, ferritin, albumin, total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, transferrin, HbA1c, vitamin B12, and folic acid. (Table 5).

Neonatal birthweight and gestational age according to the preg-MEDAS score

Table 5 shows the association between 2-point changes in the preg-MEDAS score and newborn data. No significant associations were observed in newborn birthweight, percentile, or gestational age.

Discussion

This study validates a short novel questionnaire to assess the adherence to the MedDiet in pregnant women, whose nutritional requirements are slightly different compared to the nonpregnant general population.

Given the utmost importance of maternal diet for an optimal pregnancy and offspring development [20,21], the development of easy-to-follow dietary assessment tools is needed to facilitate a simple and rapid evaluation of dietary patterns with clear guidance on how to address dietary inadequacies. For this purpose, we modified the original MEDAS according to pregnancy nutritional requirements. Maternal requirements vary by individual characteristics, and in addition to considering dietary quality before pregnancy, several factors such as preconception maternal body weight, age, gestational age, multiple gestation, physical activity level, and medical conditions should be considered [11]. According to Marshall et al. [11], a balanced maternal diet including fish twice a week for docosahexaenoic acid and whole grains for folate, vitamin B12, iron, and choline is recommended. In the IMPACT BCN trial, the dietary intervention was based on the results derived from the PREDIMED study [22], and the aim of the dietary intervention was to change the dietary pattern instead of focusing on changes in single foods or macronutrients. Thus, preg-MEDAS was specifically designed considering pregnancy needs. To construct this new screener, we used the 17-item energy-restricted MEDAS (er-MEDAS) [10]. From the original er-MEDAS, 3 items were removed. The first is related to wine consumption and the second is related to the quantity of sugar added to tea or coffee. Furthermore, the original question related to red meat and processed meat was split into 2 independent questions, and we removed fresh-squeezed juice from the question about daily fruit consumption. Finally, 2 new items also were added: *1*) quantity of fatty fish consumed; and *2*) dairy product intake.

TABLE 3
Correlation coefficients and between method agreement measurements of the 17-item preg-MEDAS and the reference method (151-item FFQ).

Parameter	Value
Mean score (SD)	
According to FFQ	7.18 (2.49)
According to preg-MEDAS	7.73 (2.52)
Difference of means[1] (95% CI)	0.55 (0.43, 0.67)
Ratio of means[2], % (95% CI)	113.5 (111.1, 115.8)
Regression coefficient[3] (95% CI)	0.52 (0.43, 0.62)
Pearson correlation coefficient (95% CI)	0.76 (0.73, 0.79)
Intraclass correlation coefficient (95% CI)	0.75 (0.68, 0.80)

Abbreviations: CI, confidence interval; FFQ, food frequency questionnaire; preg-MEDAS, 17-item pregnancy-adapted Mediterranean Diet Adherence Screener.
[1] Calculated as: preg-MEDAS – FFQ.
[2] Calculated as: [preg-MEDAS / FFQ] × 100.
[3] Regression coefficients (β) between mean of the preg-MEDAS and mean differences (independent variable) between the preg-MEDAS and the preg-MEDAS obtained by the reference method.

Our findings disclosed a strong correlation between the preg-MEDAS score and the reference method (FFQ), showing the effectiveness of the preg-MEDAS score to classify participants according to the preg-MEDAS score rating. κ statistics or agreement between the 17-item preg-MEDAS and the 151-item FFQ ranged from slight agreement (κ = 0.10 for processed meat) to almost perfect agreement (κ = 0.87 for butter, margarine, or cream) concordance. The average concordance across the 17-items preg-MEDAS score (κ = 0.61) was defined as substantial agreement, and its magnitude was higher than shown for the 17-item er-MEDAS score [10]. Additionally, κ values of modified questions on dietary consumption and behavior in the preg-MEDAS were similar or higher to those reported in the MEDAS validation study. In addition, absolute agreement between frequency and dietary food intake measured with the 17-item preg-MEDAS score and the 151-item FFQ was very good for some food groups, such as butter, margarine, or cream, refined cereals, legumes, and fatty fish (all >91%), dairy products and carbonated and/or sugar-sweetened beverages (all >87%), *sofrito* and extra virgin olive oil (>88%); good for whole grain cereals, nuts, fish and seafood, and lean meat (all ≥80%), and fresh fruit and pastries (>74%); and lower agreement for fresh vegetables (58.4%), red meat (43.6%), and processed meat (40.9%). The agreement obtained in our validation study is higher or similar to the values observed in other studies with similar methodology [9,10,23,24]. Therefore, the good agreement between the preg-MEDAS and the 151-item FFQ indicates the validity of preg-MEDAS score to measure the adherence to the MedDiet. To our knowledge, this is the first time that a validation of a MEDAS adapted to pregnancy has been carried out.

Our analysis also showed a strong correlation (r = 0.76) between the preg-MEDAS score and the FFQ, which was higher compared to the er-MEDAS score, which had a correlation of 0.60 [10]. In this sense, the present study showed similar or higher correlation values for specific foods and nutrients compared to other short dietary assessment questionaries with FFQ as the reference method [25–30]. The ICC for 1 to 4 mo duration reported by Rice et al. [31] was 0.72, which is similar to our ICC value (0.75). However, although our ICC was considerably higher than those reported in other studies at medium and long term (1–10 y), compared to other studies at short-term (1–2 wk intervention), our ICC was lower [32,33].

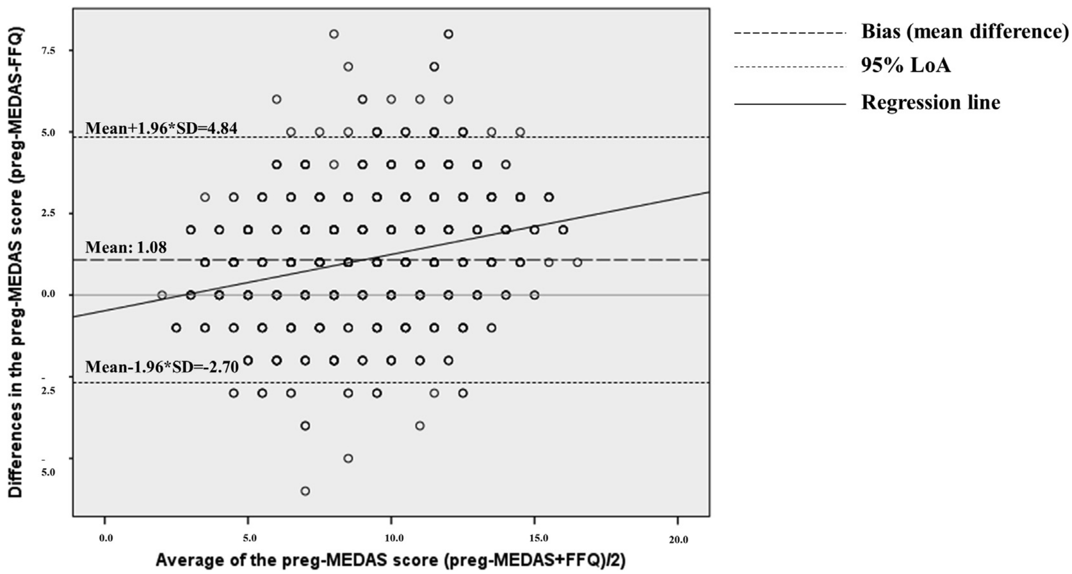

FIGURE 2. Bland-Altman plot for the agreement of the pregnancy-adapted Mediterranean Diet Adherence Screener (preg-MEDAS) score derived from the score and the food frequency questionnaire (FFQ). FFQ, food frequency questionnaire; LoA, limits of agreement; preg-MEDAS, 17-item pregnancy-adapted Mediterranean Diet Adherence Screener; SD, standard deviation.

To estimate if the preg-MEDAS over- or underestimated score ratings, we calculated the mean difference between the preg-MEDAS and the reference method (151-item FFQ). The preg-MEDAS overestimated the scores by 8% in comparison to the scores obtained from the FFQ.

TABLE 4

Three-month changes in daily intake and food consumption derived by the FFQ according to changes (decreased, stable, and increased score) in the preg-MEDAS.

	3-months changes in the preg-MEDAS		
	Decreased score (≤−1 point)	Stable score (0–1 point)	Increased score (≥2 points)
N	186	221	405
Energy, kcal/d	−65 (−138, 9)	Ref.	151 (89, 213)
Vegetables, g/d	−13 (−33, 6)	Ref.	41 (25, 57)
Fruits, g/d	1 (−27, 30)	Ref.	63 (39, 87)
Legumes (g/d)	−3 (−11, 4)	Ref.	18 (12, 24)
Refined cereals, g/d	12 (6, 19)	Ref.	−15 (−20, −9)
Whole grain cereals, g/d	−7 (−13, 0)	Ref.	20 (15, 26)
Processed meat, g/d	−0 (−4, 3)	Ref.	0 (−3, 3)
Fish, g/d	−11 (−18, −4)	Ref.	19 (13, 25)
Fatty fish, g/d	−6 (−9, −2)	Ref.	9 (6, 12)
Nuts, g/d	−3 (−6, 1)	Ref.	9 (6, 12)
Extra virgin olive oil, g/d	−3 (−5, −0)	Ref.	3 (1, 5)
Dairy products, g/d	−60 (−97, −23)	Ref.	95 (64, 125)
Sweets and pastries, g/d	2 (−4, 7)	Ref.	−7 (−11, −2)

Abbreviations: CI, confidence interval; FFQ, food frequency questionnaire; preg-MEDAS, 17-item pregnancy-adapted Mediterranean Diet Adherence Screener; Ref., reference.

Values are expressed as nonstandardized β-coefficients and 95% CI from general linear models. The model was adjusted by intervention arm, age, educational levels (primary, secondary, University), prepregnancy body mass index (<30/≥30 km/m^2), and baseline level of each nutritional parameter. preg-MEDAS denotes 17-item pregnancy-adapted Mediterranean Diet Adherence Screener.

To assess the relevance of the preg-MEDAS as a clinical and research tool, the association of the preg-MEDAS with maternal dietary and cardiovascular disease risk factors was assessed before and after a 3-mo intervention to promote the MedDiet during pregnancy. Interestingly, the preg-MEDAS score was significantly increased in those food items considered as "key foods" of the MedDiet after a 3-mo intervention. As expected, energy intake was also increased as participants increased their consumption of extra virgin olive oil, fatty fish, or nuts, which are all good sources of healthy fats (MUFAs and PUFAs). Notably, the increase in the preg-MEDAS score was significantly associated with favorable mean changes in blood pressure, specifically systolic blood pressure. Pregnancy is considered a stress test for women's cardiovascular health, with hypertensive disorders of pregnancy an important source of perinatal complications. Studies have reported that dietary patterns based on higher intake of vegetables, fruits, whole grains, nuts, legumes, fish, and vegetable oils, as well as lower intake of meat and refined grains, were associated with lower risk of hypertensive disorders of pregnancy by 30% to 42% and a lower risk of preeclampsia by 14% to 29% [34,35].

The major strengths of the present study are the large sample size of a well-phenotyped pregnant population, the dietary data collection was carried out by trained dietitians through face-to-face interviews using validated questionnaires, and the validation was conducted based on prospective data. In addition, the association of maternal dietary and cardiovascular disease risk factors was also studied. Finally, the preg-MEDAS is an easy and quick tool to assess diet that can be used both in clinical practice and epidemiological studies. We also acknowledge some limitations. First, the use of the FFQ as the reference method may have led to misclassification and bias due to self-reported information of food intake [36]. However, the use of other dietary assessment tools may report similar biases [37]; therefore, similar overestimation is to be expected to be observed for both instruments. Second, employing short dietary assessment tools may offer sufficient insights into dietary patterns during pregnancy, but this tool

TABLE 5
Multiple adjusted regression coefficients and 95% CIs for the association between 2-point change in the preg-MEDAS with maternal cardiovascular characteristics and nutritional parameters.

Parameter	2-points increase Regression coefficient (95% CI)	
	Model 1	Model 2
Body weight gain during pregnancy, kg	−0.07 (−0.28, 0.14)	0.00 (−0.23, 0.24)
BMI change during pregnancy, kg/m^2	−0.09 (−0.25 , 0.08)	−0.08 (−0.25, 0.08)
Systolic blood pressure, mmHg	**−0.84 (−1.46, −0.21)**	**−0.87 (−1.48, −0.26)**
Diastolic blood pressure, mmHg	−0.30 (−0.76, 0.16)	−0.33 (−0.78, 0.12)
Mean blood pressure, mmHg	**−0.48 (−0.96, −0.00)**	**−0.51(−0.97, −0.04)**
Hemoglobin, g/L	−0.03 (−0.07, 0.01)	−0.04 (−0.08, 0.00)
Ferritin, ng/mL	−0.25 (−0.68, 0.18)	−0.24 (−0.67, 0.19)
Albumin, g/L	0.02 (−0.09, 0.13)	0.02 (−0.09, 0.12)
Cholesterol, mg/dL	1.90 (−0.30, 4.10)	1.83 (−0.38, 4.03)
HDL cholesterol, mg/dL	0.10 (−0.65, 0.84)	0.06 (−0.69, 0.81)
LDL cholesterol, mg/dL	1.10 (−1.30, 3.49)	0.93 (−1.48, 3.34)
Triglycerides, mg/dL	0.72 (−2.87, 4.30)	0.77 (−2.81, 4.35)
Transferrin, g/L	0.04 (−0.01, 0.09)	0.04 (−0.01, 0.09)
Hb1Ac, %	−0.25 (−1.11, 0.61)	−0.30 (−1.17, 0.56)
Vitamin B12, pg/mL	3.50 (−3.22, 10.2)	3.52 (−3.20, 10.2)
Folic acid, ng/mL	−0.16 (−0.78, 0.47)	−0.15 (−0.78, 0.48)
Newborn parameters		
Gestational age at delivery, wk	0.04 (−0.03, 0.11)	0.04 (−0.03, 0.11)
Percentile birth weight	−0.26 (−1.55, 1.04)	−0.29 (−1.58, 0.99)
Body weight newborn, g	6.16 (−15.7, 28.0)	4.19 (−17.6, 26.0)

Abbreviations: BMI, body mass index; HbA1c, glycated hemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein.
Values are expressed as nonstandardized β coefficients and 95% CIs from the regression models. Model 1 was adjusted by intervention arm and age. Model 2 was further adjusted by educational level (primary, secondary, University), prepregnancy BMI ($<30/\geq30$ km/m^2), and smoking status (yes, no, stop during pregnancy). For newborn parameters, model 2 was further adjusted by nulliparity (yes/no). Hemoglobin (n = 761); ferritin (n = 699); albumin (n = 711); total cholesterol (n = 718); HDL (n = 710); LDL (n = 590); triglycerides (n = 717); transferrin (n = 197); HbA1c, vitamin B12, folic acid (n = 188).

might not estimate nutrients and energy intake or detect deficiencies in specific nutrients. However, the FFQ used in the present study was validated using plasma and urinary biomarkers of specific key foods of the preg-MEDAS (extra virgin olive oil and nuts). Therefore, the use of alternative quantitative dietary assessment tools, such as FFQs or food registries, may be needed to estimate the energy intake or specific nutrients or foods consumption that may hold particular significance during pregnancy, such as ultra-processed foods. Third, the population of the present study does not represent the general pregnancy population due to the inclusion criteria of being at high risk for SGA. Additionally, the study was conducted in a high-resource setting and a low proportion of obesity and gestational diabetes population [6]. For this reason, the results of this study may not be replicable in other populations.

In conclusion, the preg-MEDAS disclosed a good validity for assessing the adherence to a pregnancy-adapted MedDiet, allowing to detect dietary changes over time. In addition, changes observed in the preg-MEDAS score after 3 mo were significantly associated with favorable changes in maternal dietary compounds and blood pressure. Therefore, we propose the preg-MEDAS as a rapid and simple dietary assessment tool during pregnancy.

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Author contributions

The authors' responsibilities were as follows – EG, FCrispi, FCrovetto, EV, RC, RE: designed research; SC-B, FCrispi, FCrovetto, RE, AMR-L, ML, AN, LY, LB, EV, EG, RC: conducted research; SC-B, FCrispi, FCrovetto, RC, RE: analyzed data; FCrispi, FCrovetto, RC, RE: had responsibility for the final content; SC-B, FCrispi, FCrovetto, RC, RE: writing-original draft preparation; and all authors: read and approved the final manuscript.

Conflict of interest

RE reports grants from the Fundación Dieta Mediterránea (Spain) and Cerveza y Salud (Spain), and speaking and lecture fees from Brewers of Europe (Belgium), the Fundación Cerveza y Salud (Spain), Pernaud-Ricard (Mexico), Instituto Cervantes (Alburquerque, United States), Instituto Cervantes (Milan, Italy), Instituto Cervantes (Tokyo, Japan), Lilly Laboratories (Spain), and the Wine and Culinary International Forum (Spain), as well as nonfinancial support for the organization of a National Congress on Nutrition and feeding trials with products from Grand Fountain and Uriach Laboratories (Spain). EV has received grants and served as consultant, advisor or CME speaker for the following entities: AB-Biotics, AbbVie, Adamed, Angelini, Biogen, Biohaven, Boehringer-Ingelheim, Celon Pharma, Compass, Dainippon Sumitomo Pharma, Ethypharm, Ferrer, Gedeon Richter, GH Research, Glaxo-Smith Kline, HMNC, Idorsia, Janssen, Lundbeck, Medincell, Merck, Novartis, Orion Corporation, Organon, Otsuka, Roche, Rovi, Sage, Sanofi-Aventis, Sunovion, Takeda, and Viatris, outside the submitted work. All other authors report no conflicts of interest.

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Data availability

Data described in the manuscript, code book, and analytic code will be made available from the corresponding author on reasonable request.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ajcnut.2024.05.025.

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