

BMJ Open Effectiveness of a multifactorial intervention based on an application for smartphones, heart-healthy walks and a nutritional workshop in patients with type 2 diabetes mellitus in primary care (EMID): study protocol for a randomised controlled trial

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To cite: Alonso-Domínguez R, Gómez-Marcos MA, Patino-Alonso MC, *et al.* Effectiveness of a multifactorial intervention based on an application for smartphones, heart-healthy walks and a nutritional workshop in patients with type 2 diabetes mellitus in primary care (EMID): study protocol for a randomised controlled trial. *BMJ Open* 2017;**7**:e016191. doi:10.1136/bmjopen-2017-016191

► Prepublication history for this paper is available online. To view these files please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2017-016191>).

Received 31 January 2017
Revised 12 July 2017
Accepted 10 August 2017



CrossMark

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ABSTRACT

Introduction New information and communication technologies (ICTs) may promote lifestyle changes, but no adequate evidence is available on their combined effect of ICTs with multifactorial interventions aimed at improving diet and increasing physical activity in patients with type 2 diabetes mellitus (DM2). The primary objective of this study is to assess the effect of a multifactorial intervention to increase physical activity and adherence to Mediterranean diet in DM2.

Methods and analysis *Study scope and population:* The study will be conducted at 'La Alamedilla' primary care research unit in Salamanca (Spain). 200 patients with DM2 of both sexes, aged 25–70 years and who meet the inclusion criteria and sign the informed consent will be recruited. Each participant will attend the clinic at baseline and 3 and 12 months after intervention.

Intervention Both groups will be given short advice on diet and physical activity. The intervention group will also take five heart-healthy walks and attend a group session on diet education and will be trained on use of an application for smartphone (EVIDENT II) for 3 months.

Variables and measurement instruments The main study endpoints will be changes in physical activity, as assessed by a pedometer and the International Physical Activity Questionnaire, and adherence to the Mediterranean diet, as evaluated by an adherence questionnaire and the Diet Quality Index. Anthropometric parameters and laboratory values, lifestyles and quality of life will also be assessed.

Ethics and dissemination It was approved by the Clinical Research Ethics Committee of Salamanca on 28/11/2016.

Trial registration NCT02991079; Pre-results.

INTRODUCTION

Diabetes mellitus is one of the diseases with greatest impact on health not only because of its high prevalence but also because of its

Strengths and limitations of this study

- This study uses multifactorial intervention, including new technologies, to improve glycaemic control in the diabetic population and increase physical activity and adherence to a Mediterranean diet. This is important since new cost-effective interventions in the management of type 2 diabetes are needed in primary care.
- The study complies with all Consolidated Standards of Reporting Trials recommendations. Due to the nature of the intervention, the participating subjects cannot be blinded, but the researcher who will analyse the data.
- The analysis of the adherence to the Mediterranean diet will be carried out using the data reported by the subjects themselves using a validated tool.
- Physical activity will be assessed objectively using a pedometer.
- The design of this multifactorial intervention does not allow conclusions to be drawn about the separate parts of the intervention

chronic complications and high mortality.¹ The WHO estimates that interventions on healthy lifestyles reduce the incidence by 35%–58% in people at high risk.²

Benefits of physical activity and dietary patterns for control of diabetes mellitus and chronic diseases.

Physical activity and diet are essential mainstays in the management of DM2. They are more effective for adequate weight loss and better metabolic control when used combined than alone.³

Benefits of physical activity

One of the acute effects of physical activity in DM2 is a decrease in blood glucose levels which is related to exercise duration and intensity. Thus, Motahari *et al* showed that physical activity increases central and peripheral insulin sensitivity and that the effect is maintained for 12–24 hours.⁴ Regular physical activity has also been related to a less atherogenic lipid profile, which may translate into a positive effect on cardiovascular mortality.⁵ In addition, several studies related increased physical activity to improvements in quality of life in the dimensions of sensory function, general health, vitality and physical function.^{6–8}

Benefits of diet

Dietary patterns have an impact on cardiovascular and metabolic risk factors, including weight, lipoprotein levels, blood pressure (BP) and endothelial health, among others. Esposito *et al*⁹ concluded in their meta-analysis that some types of healthy diets are associated to a 20% lower risk of developing DM2. Specifically, the Mediterranean diet,¹⁰ characterised by a high intake of vegetables, legumes, fruits and nuts and unrefined cereals, a high consumption of olive oil, but a low intake of saturated lipids, a moderately high intake of fish, low consumption of meat and poultry and a moderate intake of ethanol, mainly in the form of wine and generally during meals, decreased glycosylated haemoglobin levels by 0.30%–0.47% and cardiovascular events by 28%–30%.¹¹ On the other hand, Ruano *et al*¹² showed that adherence to the Mediterranean diet was associated to higher self-perceived health scores, while subjects with greater consumption of saturated fat perceived themselves as more tired and with greater social limitations.

Interventions effective for increasing physical activity and changing dietary patterns in patients with DM2

While associated to increased costs, interventions effective for increasing physical activity and changing dietary patterns in patients with DM2 have been shown to be cost-effective as compared with conventional management, as they decrease long-term complications in those subjects.¹³

In their study, Lim *et al* sent personalised messages of exercise, diet and glucose through a clinical decision support system, which worked from the data received from the patients, at the hospital server, of their physical activity and their glycaemic control. They found that their multifactorial intervention decreased fasting blood glucose levels, body mass index (BMI), waist circumference and BP, improved the lipid profile and albuminuria and decreased the need for oral antidiabetic drug by 11.6%.¹⁴

De Greef *et al* used an intervention consisting of pedometers for objective measurement and physical activity and reinforcement by phone calls, which resulted in reduction of daily sitting time of patients by 23 min.¹⁵ Yu *et al* carried out a study where individualised exercise

prescriptions were performed from an accelerometer data carried by each patient showed a significant increase in physical activity and a reduction in daily energy intake total.¹⁶ Similarly, the Fukuoka *et al*'s study¹⁷ achieved an increase of 2551 steps in the group receiving the educational intervention.

On the other hand, Monlezun *et al*¹⁸ conducted a study focused on improvement of diet. The intervention group achieved decreases in glycosylated haemoglobin (–0.4% vs –0.3%, $p=0.575$), diastolic BP (–4 vs 7 mm Hg, $p=0.037$) and total cholesterol (–14 vs 17 mg/dL, $p=0.044$) as compared with the control group.

Use of information and communication technologies (ICTs) in health

Healthcare, as demanded by society today, requires incorporation of ICTs. As in other fields, ICTs are becoming increasingly present in the field of health and should therefore be incorporated into health-promoting interventions. A meta-analysis by Jeon *et al*¹⁹ showed that the mobile applications most commonly used by nurses are those for self-management of chronic diseases, while physicians promote use of applications on symptom management and treatment of diseases.

There is an increasing number of clinical trials in chronic diseases using mobile phones to support control. Liang *et al*, in a meta-analysis on interventions with new technologies for diabetes control, concluded that, after interventions using mobile, glycosylated haemoglobin was decreased by 0.5%. Significantly greater decreases were reported in patients with DM2 as compared with type 1 DM.²⁰

In the EVIDENT II study²¹ (PI13/00618), an application (app) for smartphones was developed (record entry no. 00/2014/2207) and used in the general population to improve dietary pattern and increase physical activity. The present project is intended to adapt this app and to extend assessment of its effects to patients with DM2.

Objectives

The main objective of this study is to evaluate the impact of a multifactorial intervention (application for smartphones, healthy walks for the heart and dietary workshop) on the increase of physical activity to meet the international recommendations and on increased adherence to the Mediterranean diet in patients with DM2. Secondary objectives will include assessment of the impact of intervention on improvement of dietary patterns, cardiovascular risk factors and metabolic control.

METHODS AND ANALYSIS

Design and setting

Randomised, controlled clinical trial with two parallel groups aimed at assessing the effects of adding an ICT tool and group activities on diet and heart-healthy walks (intervention group) as support to behavioural and



education advice (attention-control group) on physical activity increase and improvement of dietary patterns.

Study setting

The study will be conducted in the setting of primary healthcare in Salamanca, at 'La Alamedilla' research unit, which belongs to the Network for Research on Preventive Activities and Health Promotion (REDIAPP) and to the Biomedical Research Institute of Salamanca (IBSAL).

Study population

Subjects will be selected through age stratification random sampling from the 1361 patients with DM2 attending the 'La Alamedilla' healthcare centre in Salamanca, Spain who meet the inclusion criteria. The population will be divided into three groups according to age: 25–35 years, 36–50 years and 51–70 years.

Subjects eligible will be those of both sexes with DM2 routinely monitored at the healthcare centre aged 25–70 years who, after receiving information about the study, agree to take part and sign the informed consent. To be considered a patient as DM2 must meet the criteria of the American Diabetes Association: fasting plasma glucose ≥ 126 mg/dL (7.0 mmol/L) or 2 hour plasma glucose ≥ 200 mg/dL (11.1 mmol/L) during an oral glucose tolerance testing using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water or glycosylated haemoglobin $\geq 6.5\%$ (48 mmol/mol); in all these cases, in the absence of unequivocal hyperglycaemia, the results should be confirmed by repeat testing. In addition, will be considered as DM2, patients with classic symptoms of hyperglycaemia or hyperglycaemic crisis, a random plasma glucose ≥ 200 mg/dL (11.1 mmol/L).²²

Exclusion criteria include age over 70 years, because of the difficulty to use ICTs; history of cardiovascular events (acute myocardial infarction, stroke, etc); musculoskeletal disease that prevents walking; clinically documented neurological and/or neuropsychological that prevents attendance to the healthcare centre; participation in an interventional trial or any other condition that may interfere with the study procedures as assessed by the investigators.

Sample size

The final sample will consist of 200 subjects selected by simple random sampling from among patients with DM2 seen at the healthcare centre. Such subjects will subsequently be randomised in a 1:1 ratio to an intervention group and an attention-control group using Epidat 4.0 software (figure 1).

Sample size has been estimated for the primary study variables. With regard to physical activity increase (daily number of steps), assuming an alpha risk of 0.05 and a beta risk of 0.20, with a SD of 4500 steps/day, 98 subjects would be required in each group (196 in total) to detect an increase by 1850 steps/day in the intervention versus the attention-control group, assuming a 5%

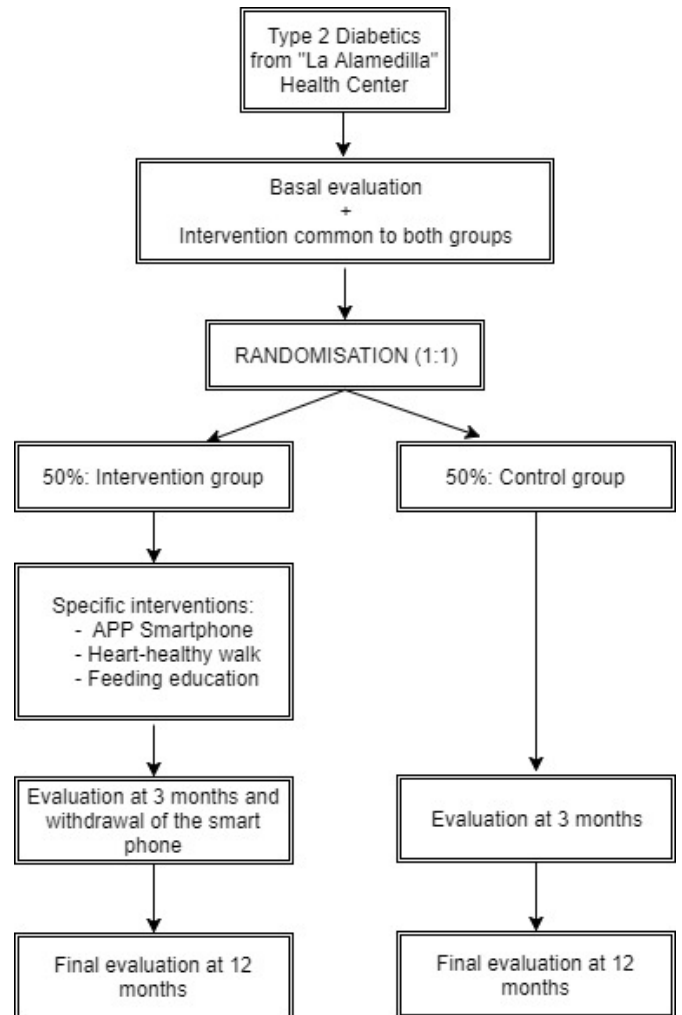


Figure 1 Flow chart of EMID study.

dropout rate. As regards adherence to the Mediterranean diet, assuming an alpha risk of 0.05 and a beta risk of 0.20, with a SD of two points,²³ with expected losses of 10%, 70 subjects would be required in each group (140 in total) to detect an increase by one point in the total questionnaire score in the intervention as compared with the attention-control group. Therefore, the sample of 200 subjects, 100 per group, that will be recruited, is considered sufficient to test the hypotheses of the project.

Variables and measurement instruments

The primary outcome of this study will be to assess the impact of adding to standard care a multifactorial intervention (app for smartphones, heart-healthy walks and dietary workshop) on the increase of physical activity and adherence to the Mediterranean diet in patients with DM2. Secondary outcomes will include assessment of the impact of intervention on improvement of dietary patterns, cardiovascular risk factors, metabolic control and health-related quality of life (HRQL).

Sociodemographic variables

At the time of study entry and before the first intervention visit, data on age, sex, marital status, educational level and occupation will be collected.

All other variables will be collected at baseline and 3 and 12 months after intervention. If a subject does not attend the 3-month follow-up visit, we will contact him again at the 12-month visit.

Anthropometric variables

These will be recorded with the subject in light clothes and without shoes. Body weight will be measured twice using an adequately calibrated (precision ± 0.1 kg) certified electronic scale (Scale 7830; Soehnle Professional GmbH & Co, Backnang, Germany). Height will be measured using a portable system (Seca 222; Medical scale and Measurement systems, Birmingham, UK), with the subject standing, recording the average of two measurements and rounding to the nearest centimetre. BMI will be calculated using the formula: weight in kg divided by height in m^2 . Waist circumference and hip circumference will be measured using a flexible measuring tape parallel to the floor, following the recommendations of the SEEDO.²⁴

BP measurement

Three measurements will be done of systolic and diastolic BP, using the average of the last two values, with a validated *OMRON M10-IT* sphygmomanometer (Omron Healthcare, Kyoto, Japan), following the recommendations of the European Society of Hypertension.²⁵

Measurement of blood glucose profile

This will be determined during a full day, before and 2 hours after each meal, following the criteria of the American Diabetes Association²² with a certified glucometer *Glucomen LX PLUS* (A. Menarini GmbH).²⁶

Lifestyle-related variables

Smoking

This will be measured using a questionnaire on smoking history and pattern.

Alcohol consumption

This will be assessed using a questionnaire to assess consumption in the past 7 days, detailing the drinks and their volume.

Laboratory variables

Venous blood sampling will be performed between 08:00 and 09:00 after participants have fasted and abstained from smoking and consumption of alcohol and caffeinated beverages for 12 hours. Fasting plasma glucose, creatinine, serum total cholesterol, high-density lipoprotein and triglyceride levels will be measured using standard enzymatic automated methods. Low-density lipoprotein cholesterol will be estimated by the Friedewald equation when the direct parameter is not available. Glycated

haemoglobin will be measured with an immune turbidimetric assay.

Blood samples will be collected in the primary care centre and will be analysed at the University Hospital of Salamanca in external quality assurance programmes of the Spanish Society of Clinical Chemistry and Molecular Pathology.

Physical activity variables

Regular physical activity will be recorded using the International Physical Activity Questionnaire (IPAQ),²⁷ in its short version validated in Spanish, which assesses activity in the past 7 days and differentiates it into three types (walk, moderate and intense physical activity) and by energy expenditure estimated for each of them (3.3, 4.0 and 8.0 Metabolic Equivalents of Task (METs), respectively). This allows for calculating the METs-min/week and for stratifying subjects by three activity levels (low, intermediate and high). Activity will also be objectively measured for seven consecutive days using a previously validated digital pedometer (Omron HJ-321 Tri-Axial) with 3D sensor and clock²⁸ that will be placed on the right side of the waist. The pedometer records total steps, aerobic steps,²⁹ distance walked and calories consumed and memorises the results of the last 7 days. Aerobic steps are those counted separately when walking more than 60 steps by minute and more than 10 consecutive minutes.

Dietary pattern variables

Adherence to Mediterranean diet, the main outcome variable in the nutrition area, will be measured using a validated 14-item questionnaire called Mediterranean Diet Adherence Screener (MEDAS)³⁰ developed by the Prevention with the Mediterranean Diet (PREDIMED) group. MEDAS is a valid instrument for quick estimation of adherence to the Mediterranean diet. MEDAS includes 12 questions on food consumption frequency and two questions on intake habits of foods considered characteristic of the Spanish Mediterranean diet. Each question will be scored 0 or 1. One point will be assigned to use of olive oil as main cooking fat, preferential use of white rather than red meat, intake of four or more spoonfuls (one spoonful=13.5 g) of olive oil, two or more vegetable portions, three or more pieces of fruit, less than one portion of red meat or sausages, less than one portion of animal meat and less than one cup (100 mL) of carbonated and/or sugary drinks, as well as weekly consumption of seven or more glasses of red wine, three or more servings of fish, two or less servings of legumes, two or less portions of industrial (not homemade) pastry, three or more portions (one portion=30 g) of nuts and two or more dishes dressed with sauce of tomato, garlic, onion or leek, cooked slowly with olive oil. The final score will range from 0 and 14 points. A score of 9 or higher will be considered adequate adherence to the Mediterranean diet.³⁰ In addition, regular diet will be assessed using the Diet Quality Index.³¹ This is based on 18 groups of food items which are



classified into three categories based on their recommended frequency of use. The first category includes eight foods, the second category seven and the third category includes three foods. Frequency of consumption is organised into three types of response: in the first group, 'less than once daily', 'once daily' or 'more than once daily'; in the second group, 'less than four times weekly', 'four to six times weekly' or 'once daily' and in the last group, 'less than two times weekly', 'two to three times weekly' or 'four or more times weekly'. Total score will range from 18 to 54 points.

Analysis of motivation for change

Following the model of Prochaska and Diclemente,³² we will use a questionnaire to classify the patients according to the motivation for the change in diet, physical activity, consumption of alcohol and tobacco. (a) Precontemplation: subjects are aware that certain behaviours are a risk for their health or that they have a health problem; they are reluctant to accept changes in behaviour. (b) Contemplation: subjects are aware that certain behaviours are a risk for their health or that they have a health problem and agree to make changes within 6 months. (c) Preparation: subjects seriously consider the intention to change their behaviour in the near future (within 30 days). (d) Action: subjects are actively working in behavioural changes that affect their health. (e) Maintenance: subjects adopt the behaviours acquired as routine. Maintenance is considered if the new behaviour is sustained for more than 6 months.

Health-related quality of life

This will be assessed using the validated Spanish version of SF-12 V.2.^{33 34} SF-12 is a short version of the SF-36 questionnaire³⁵ that includes 12 items, with three to five categories of response in a Likert scale. The SF-12 questionnaire is self-administered and was developed for measuring eight dimensions of HRQL: physical functioning, physical role, bodily pain, general health, vitality, emotional role, social functioning and mental health. These eight dimensions may be pooled as two summary measures: the physical component summary (PCS-12) and the mental component summary (MCS-12). To estimate the summary components of the SF-12, the algebraic sum of the standardised scores of each of the eight dimensions weighted by their weights is calculated. The PCS-12 and MCS-12, obtained adding the scores of all 12 questions, range from 0 to 100, with a score of 0 indicating the lowest level and a score of 100 the highest level.

Intervention

Specific intervention and counselling appointment will be performed by three nurses at the health centre, who have previously been instructed in two 1 hour sessions on how to carry out each session. The sessions have been standardised, describing in each one what points should be treated, in what order and for how long.

Common to both groups

All participants (attention-control and intervention) prior to the random assignment will receive a 10 min individual physical activity and food counselling appointment.

Nutritional advice

Both the attention-control and intervention groups will be given nutritional advice aimed at adequate compliance with the Mediterranean diet. Advice, which will be standardised for both groups, will consist of an individual 5 min visit where a diptych with information about the session will also be given. The first part (2 min) will address the concept of the plate method already used in several studies as reference standard in nutrition^{36–39} and which allows for creating a variety of menus. This is a simple method that does not require measuring or weighting food portions. A plate approximately 23 cm in size is used to create the main menu for lunch or dinner. The plate is divided into four parts: half the plate for salad or vegetables, one-fourth for proteins (with white meat preferred to red meat) and the final fourth for carbohydrates. In addition to the above, a medium-sized piece of fruit and a skimmed dairy product should be taken as dessert. The second part of the session (2 min) will be focused on development of each particular recommendation to comply with the Mediterranean diet, using short, clear messages. The last part (1 min) will be used to answer any question.

Advice on physical activity

Both groups will be given advice on physical activity aimed at compliance with the current international recommendations for the general population. Advice will be given in an individual 5 min appointment where the benefits for health of physical activity and recommendations to decrease sitting time and take at least 10 000 steps daily will be discussed.^{40 41} The first part (2 min) will address recommendations for physical activity related to cardiovascular health. The second part (2 min) will focus on understanding of the intensity of some specific activities such as walking, riding a bicycle or other activities. The last part (1 min) will be used to answer any questions. A diptych will finally be given.

Specific intervention for the study group

This is a multifactorial intervention based on an application for smartphones, healthy walks and a nutrition workshop, which will take place in groups of 10 participants. The training in the application and the nutrition workshop for diabetic subjects will be carried out during the same week and the walks will be done with a week of difference between them. For monitoring the adherence of subjects, how many of the sessions have attended will be assessed.

Application for smartphones (EVIDENT II)

The tool developed (intellectual property registry no. SA-81–14) is the result of an agreement between the company CGB and the GIAPCyL research group of

REDIAPP (RD12/0005/0004), through the Infosalud Foundation, to use it in the study entitled “Effectiveness of use of a mobile tool added to a standard intervention in lifestyle improvement in an adult population. A randomised clinical trial, the EVIDENT II Study”²¹ (PI: PI13/00618). This application for smartphones, easy to use for adult people, allows for rapid assessment of whether personal habits agree with the recommended healthy lifestyles as regards both nutrition and physical activity. Food intake is assessed in terms of amount and quality based on standardised patterns, adaptation to the Mediterranean diet and adequate proportion of the main nutrient classes, generating a customised recommendation. The application provides detailed information on nutritional deviations, both in diet composition and in calorie number, to allow for a change in habits. In addition, subjects must enter the physical activity performed during the day and its duration.

A workshop will be conducted to train participants in use of the device, which will be collected at 3 months, at the common visit, to download the information stored.

Heart-healthy walks

Subjects will take five heart-healthy walks consisting of 10 min of warming exercises, a circuit of 4 km walking and 10 min of stretching and relaxation. Groups of 10 people, accompanied by at least two nurses, will take the walk on a flat ground, which will start and end at the door of the healthcare centre. Once you have completed the five heart-healthy walks, the participants will already know the route and can continue doing them themselves without the need for the nurses to go with them. Subjects were instructed to have their healthy walk out aerobic (50%–70% of maximal heart rate), as recommended by the American Diabetes Association.⁴² The participants were divided into two groups depending on the intensity of their healthy walk. One group carried out the healthy walk at a moderate intensity (5 METs), with a speed of 6 km/hour. The other group performed at a low intensity (2.5 METs) carrying an average speed of 3–4 km/hour.⁴³ Walks will occur once weekly for five consecutive weeks.

Group sessions on nutritional education

A workshop lasting 1 hour and a half will be held. The workshop will be based on improving the Mediterranean diet, discussing in more detail the benefits of healthy nutrition, food groups, importance of labelling in diabetic patients, recommended cooking procedures use of the plate method, practical examples and their use will also be provided.

Blinding strategy

Because of the nature of interventions, participating subjects and research staff cannot be blinded. The person responsible for statistical analysis will, however, be blinded to the intervention.

Statistical analysis

Data entry will be done with a questionnaire designed for the study, using the Teleform system (Autonomy Cardiff Vista, California, USA). Data quality will be ensured using the range checks for data values. Data will be provided as mean and SD for quantitative variables and by frequency distribution for qualitative variables. Analysis of the results will be performed on an intent-to-treat basis. If data distribution is non-normal, parallel non-parametric tests will be used. A Kolmogorov-Smirnov test will be used to verify normal data distribution. A X^2 test will be used to analyse the association between independent qualitative variables and a McNemar test for paired samples. The means of two groups will be compared using a Student's t-test or Mann-Whitney's U test for independent samples, and change within the same group will be assessed using a Student's t-test or Wilcoxon's test for paired samples as appropriate. The relationship between quantitative variables will be analysed using a Pearson's or Spearman's correlation coefficient as appropriate. A multivariate analysis will be performed to explore the variables most determinant for changes in physical activity and dietary pattern. In order to identify whether changes in independent variables have significant effects on dependent variables as a whole, a multivariate analysis of variance will be performed. To analyse the effect of intervention, changes in the intervention and attention-control groups will be compared and Cohen's d will be estimated, adjusting for variables that may have an influence on the result, especially baseline data. A gender and age analysis will be conducted to evaluate the differences in the mid-term and long-term outcomes between men and women and according to the different age groups. The impact of intervention may be modified by age, sex, cultural and socioeconomical level, BMI and baseline lifestyles, as well as some conditions (hypertension, dyslipidaemia, etc). These variables will be controlled in the analysis. For two-sided tests, an alpha risk of 0.05 will be set as the limit of statistical significance. Data will be analysed using IBM SPSS Statistics for Windows V.23.0 (IBM, Armonk, New York, USA).

Methodological limitations

The study complies with all Consolidated Standards of Reporting Trials recommendations, but because of the nature of the intervention, participating subjects cannot be blinded. However, the researcher who analyses the data will be blinded. Analysis of one of the primary outcome measures, increased adherence to the Mediterranean diet, will be performed using data reported by subjects themselves; however, a validated tool will be used to assess this variable. The other primary outcome measure, physical activity, will be assessed using a pedometer, a device that provides objective data, and may serve as quality control. On the other hand, the design of this multifactorial intervention does not allow to draw conclusions about the separate parts of the intervention.



ETHICS AND DISSEMINATION

Ethics approval and consent to participate

The study was approved by the Clinical Research Ethics Committee of the Health Area of Salamanca on 28 November 2016.

The protocol was registered in ClinicalTrials.gov using the following identifier: NCT02991079. Registered 12 December 2016.

Participants will be asked to sign informed consent before being enrolled into the study, in compliance with the Declaration of Helsinki⁴⁴ and the WHO standards. Subjects will be informed of the study objectives and the risks and benefits of the tests they will undergo. The study includes collection of biological samples, of which study subjects will carefully be informed. None of the examinations involves life-threatening risks for the type of subjects to be included in the study. Because of the foregoing, confidentiality of subjects enrolled will be ensured at all times, in compliance with the provisions in the Spanish Organic Act on Personal Data Protection (15/1999, of December 13) and the conditions set down in Act 14/2007, on biomedical research.

Dissemination plan

We will use a variety of methods to ensure that our work will achieve maximum visibility. Publication of our study protocol provides an important first step towards this direction. In this paper, we have sought to offer a comprehensive overview of relevant literature, while underlining current research gaps that necessitated the design and implementation of the EMID study.

Similarly, the study results, given their applicability and implications for the general population, will be disseminated in investigator meetings and in articles published in scientific journals, specifically, one for each study objective. In addition, it has been proposed to perform a doctoral thesis based on this project.

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Acknowledgements We thank all professionals participated in the study: S Conde-Martín, MC Rodríguez-Martín, S Pascual-Sánchez, E Ruiz-Fernández, C Lugones-Sánchez, MD Muñoz-Jimenez, A Cabo-Laso, JA Maderuelo-Fernández and E Rodríguez-Sánchez.

Contributors RA-D, MAG-M and JIR-R conceived and designed the study. RA-D and JIR-R prepared the study protocol. MAG-M, MCP-A and LG-O provided methodological and statistical knowledge. JIR-R is responsible for study management, staff training and supervision. RA-D will be responsible for daily conduct of the study, including study monitoring. NS-A, CA-C and CC-S participated in data collection. RA-D and JIR-R prepared the manuscript. LG-O and JIR-R made the final review of the manuscript. All authors have read the protocol, made their contributions and approved the final text.

Funding This study is supported by research grants from the Regional Health Management of Castilla and León awarded in 2016 for research projects in biomedicine, health management and social and health care (GRS 1276/B/16) in the setting of the 2016 programme for promoting research activity of nurses (BOCYL-D-11022016-2) and the 2015 programme for motivating nurses who have completed their residency (ORDER SAN/360/2015), jointly funded by the European Union Institute for Health/European Regional Development Fund (ERDF).

Competing interests None declared.

Patient consent Obtained.

Ethics approval Clinical Research Ethics Committee of the Health Area of Salamanca.

Provenance and peer review Not commissioned; externally peer reviewed.

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BMJ Open 2017 7:

doi: 10.1136/bmjopen-2017-016191

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