Full title: Physical activity prescription by primary care nurses using health assets: study design of a randomised controlled trial in patients with cardiovascular risk factors

Running Head: Exercise prescription based on health assets

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Conflict of interest

The authors declare they have no conflict of interests.

Author contributions

All authors have agreed on the final version and meet at least one of the following criteria:

- substantial contributions to conception and design, acquisition of data or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

Abstract

Aim. To analyse the efficacy of a 12-month multifactorial intervention by primary care nurses in increasing adherence to physical activity prescription (150 min/week) in patients with two or more cardiovascular risk factors and with cardiovascular risk up to 15% determined by the REGICOR equation.

Background. In Spain cardiovascular diseases are responsible for 30.5% of deaths. Regular physical activity decreases mortality risk due to cardiovascular diseases but the effectiveness of physical activity prescription in routine in primary care settings has been shown to be low.

Design. Multicentre, single-blind, parallel randomized (in two different branches) clinical trial.

Methods. At least 368 participants will be recruited (184 control and 184 intervention), to show an 8% increase in adherence to the physical activity prescription (1.2% control group and 9.2% intervention group). Participants will be patients aged 35-75 years with at least two cardiovascular risk factors and with a cardiovascular risk of up to 15% measured using the Framingham-REGICOR equation. Intervention will be performed throughout baseline and three follow-up visits. A motivational interview, the trans-theoretical stages of changes of Prochaska and DiClemente and an individualized prescription of physical exercise using physical activity assets will be used in the intervention. Data will be collected at baseline and after the one-year intervention.

Discussion. The present study will allow us to find out whether this brief multifactorial intervention induces greater adherence to physical activity prescription than usual practice, improving the quality of patient care.

Trial Registration. International Standard Randomized Controlled Trial Number (ISRCTN): ISRCTN76069254. Protocol version 1.1, 6 July 2015.

Why is this research needed?

- Regular physical activity decreases mortality risk due to cardiovascular diseases but the effectiveness of exercise prescription in primary care consultancies is low.
- Physical activity promotion is a priority, but contribution of primary care nurses is unclear.
- Physical activity prescription based on the health assets model is a non-pharmacological alternative, focused on people, which can help to increase physical activity levels of patients.

Keywords: cardiovascular risk, primary care, physical activity, nursing, protocol, randomized controlled trial.

Introduction

Cardiovascular diseases (CVD) cause 47% of all deaths in Europe and are the main cause of death in women in all countries in Europe and the main cause of death in men in all but six countries (Nichols *et al.* 2012). Furthermore, in Spain CVD are responsible for 30.5% of deaths (Amor *et al.* 2015). One of the most important reasons explaining the impact on the burden of CVD and mortality is demographic evolution. A relative increase in life expectancy at birth has been produced, allowing a greater number of people to get old enough to develop CVD. Considering the expected trends of global population aging, it is estimated that the current global population aged 60 years and above will rise from 10% to 16.6% by 2030 and up to 21.4% by 2050.

It is noteworthy that the burden of CVD deaths is associated not only to the disease itself but also to a significant personal, social and economic burden due to the disability they generate. It is expected that the total burden of CVD, measured in years of life lost due to premature death or disability, will reach 178 million years worldwide by 2030, including 26 million years of life lost considering only Europe (WHO, 2008). Furthermore, it should be considered that in most countries the cost associated with cardiovascular diseases is continuously increasing (Hulme, 2013). The latest data indicate that in 2007 CVD cost the European Union 196,000 million (British Heart Foundation and European Network, 2008).

The World Health Organization (WHO) estimates that 80% of CVD-related premature deaths could be avoided if primary CVD causative factors (smoking, dyslipidaemia, hypertension, diabetes and obesity) were reduced through adoption of a healthier diet, exercising and smoking habit cessation (Yusuf *et al.* 2004). Among these modifiable risk factors, the prevalence of physical inactivity (approximately 34% of adults in Spain) has been shown to be higher than that of all other modifiable risk factors.

Furthermore, the majority of the population in developed countries has been shown to be insufficiently active (Haskell *et al.* 2007; Martínez-González *et al.* 2001; United States Department of Health and Human Services, 2000).

Physical inactivity is a modifiable risk factor not only for cardiovascular disease but also for many other chronic diseases such as diabetes mellitus, colon and breast cancer, obesity, hypertension, osteoporosis, osteoarthritis and depression (revised by Warburton *et al.* 2006). People performing reasonable physical activity (PA) levels, especially during adult ages and when they are elderly, show lower odds of suffering from a chronic disease or a sudden death (Knoops *et al.* 2004); and adopting a more active lifestyle has been associated with lower risk of several diseases such as HTA, ischemic cardiomyopathy, osteoporosis, obesity, diabetes, anxiety and depression (Chobanian *et al.* 2003).

Regarding CVD, regular physical activity reduces the risk of death from these diseases and observational studies have shown a decrease in the incidence of cardiovascular events in people regularly performing physical activity (Yusuf *et al.* 2004), with this effect following a dose-response relationship (Lee, 2007). The relative risk of suffering a cardiovascular event in inactive individuals is twice as much as in active ones. The Framingham study, after 14 years of cohort follow-up, showed that cardiovascular morbidity and mortality was inversely proportional to the physical activity level. However, other studies have shown that a weekly energy expenditure of 500-2,000 Kcal of weekly physical activity induced cardiovascular benefits that were not improved when physical activity levels were increased. In this regard, a recent study shows that performing 15 minutes a day, or 90 minutes a week, of physical activity causes a reduction in all causes of death, including all cancers and increases life expectancy by three years (Wen *et al.* 2011). However, the PA guidelines from WHO (the World

Health Organization, 2006), the US Department of Health and Human Services (Thompson *et al.* 2007) and the United Kingdom Chief Medical Officer (Chief Medical Officers, 2011) recommend performing at least 150 minutes of weekly moderate physical activity.

The decreased incidence of cardiovascular events in patients performing physical activity could be explained by an improvement in lipid profile and glycaemic control, prevention of HTA and obesity, decrease in heart rate, increased volume of heart cavities and heart wall thickness, increased systolic volume and increased myocardial capillary density and capillary dilation capability. Furthermore, in patients with CVD, physical activity improves the endothelial function of the epicardial coronary vessels and resistance blood vessels (Hambrecht *et al.* 2000).

Background

The primary care sector seems to be a proper environment for promoting increased physical activity levels, mainly in patients with low physical activity levels. However, the adequate implementation of this lifestyle promotion as well as results regarding the effectiveness of primary care interventions in increasing physical activity levels are not clear (Bott, 2014). In 1998 WHO suggested that in many Member States, a more integrated health sector is needed, with a much stronger emphasis on primary care. Furthermore, it was indicated that a well-trained family health nurse, providing a broad range of lifestyle counselling, should be at the core of the sector (WHO, 1997). In 2007 the European Guidelines on Cardiovascular Disease Prevention in Clinical Practice highlighted the role of nurses, as well as primary care medical doctors, in promoting a healthy lifestyle, based on increasing physical activity (Graham *et al.* 2007) and the

2012 update reported that nurse-coordinated prevention programs should be well integrated into healthcare systems (Perk *et al.* 2012).

In addition to analysing the effectiveness of primary care physical activity promoting programs, some randomized controlled trials also compare the effectiveness of interventions performed by nurses and by primary care medical doctors. While in a systematic review Fleming & Godwin did not find any difference between results obtained after nurse and medical doctor interventions (Fleming & Godwin, 2008), many other studies have reported improved results when the promoting program was performed by nurses rather than by medical doctors, with the authors suggesting that these differences could be attributed to the longer time nurses could spend with patients (Grimstvedt *et al.* 2012; Klemenc-Ketise *et al.* 2015; ter Bogt *et al.* 2011; Whittemore *et al.* 2010).

In fact, lack of time, together with a lack of reimbursement for health promotion activities, inadequate practice capacity and lack of clinical guides, are some of the barriers encountered when implementing PA interventions in primary care settings (Josyula & Lyle, 2013; Patel *et al.* 2013). Furthermore, the efficacy of PA prescription in routine in primary care settings is low (1.2%) (Grandes *et al.* 2009). However, it is noteworthy that when brief counselling has been used, small improvements in the adherence to the prescription have been observed (Hillsdon, 2013), with the percentage of participants accomplishing the goal of at least 150 minutes of weekly PA increasing to 3.9% in a study performed in Spain (Grandes *et al.* 2009). Furthermore, it has been reported that introducing motivational strategies such as a more intensive program of prescription or the use of PA records, (giving this information to the patients) could lead to an improvement not only in adherence to the PA program prescribed but also in the prescription procedure per se (Hillsdon, 2013; Josyula & Lyle, 2013). Following these

suggestions, the present study will analyse the effectiveness of a brief PA prescription using a motivational interview, the trans-theoretical stages of change of Prochaska and DiClemente and the PA assets from the health care area.

The motivational interview has been revealed as a useful tool for promoting behaviour and lifestyle changes and a useful intervention strategy in the treatment of lifestyle disorders and disease (Miller & Rollnick, 2014). Motivation for changing will be greater if the patient makes their own decision after discussing the pros and cons of the suggested change together with the health care provider (Rubak *et al.* 2005). The motivational interview also improves the degree to which the patient feels responsible for their own circumstances (locus of control). This type of clinical interview has turned out to be effective in the treatment of alcohol problems, drug addiction, giving up smoking, losing weight and increasing physical activity levels (Hardcastle *et al.* 2008).

The trans-theoretical model of change, suggested by Prochaska and DiClemente (Prochaska *et al.* 1992) will also be used. With this model, behaviour change is viewed as a process. The Stages of Change model has been used to help people adopt new healthy behaviours and dispense with unhealthy behaviours. The Stages of Change model consists of five stages, which, in the present study, can help determine where individuals are in the process of changing their attitudes and behaviours in terms of increasing physical activity:

- Pre-contemplation: People in this stage are not thinking about changing their inactive behaviour and are not aware of their problem.
- Contemplation: People in this stage can identify that they are inactive and have devoted some thought to changing.

- Preparation: People in this stage have begun the process of change by examining possibilities and options (considering a pool membership, looking for a social or local cycling group, etc.).
- Action: People in this stage have taken steps to overcome their inactive lifestyle by changing their behaviour form an inactive to an active lifestyle. Action involves the most overt behavioural changes, requiring a commitment of time and energy.
- Maintenance: People in this stage consolidate the gains attained as a result of initial action through sustained involvement in the new active lifestyle and/or avoidance of the old inactive lifestyle.

In this regard, it is widely recognized that the 5 A's model created by the US Preventive Service Task Force (US Preventive Task Force, 2012) is the most feasible and effective. Therefore, this strategy for implementing behavioural interventions and brief advice will be used. This model includes five steps: ask, advise, assess, assist and arrange. We must also bear in mind that primary care health professionals play an important role in motivating and helping change risky behaviours because they entail the first level of care. Furthermore, they have multiple opportunities for advising and intervening over time to address the risk factors and behaviours of large groups of the population.

However, getting people to adopt an active lifestyle is a complex process that is influenced by several factors, including personal, social and environmental factors (Pan *et al.* 2009). In this sense and following the salutogenic model (Antonovsky, 1996), the 'sense of coherence' (SOC) scale has been used as an assessment tool for modifying lifestyles based on the enhancement of health assets. In fact, a positive relationship between having a strong SOC and taking up healthy behaviours (Lindström & Eriksson,

2006) has been reported. In this regard, some studies have shown that a strong SOC is related to higher levels of physical activity (Hassmén *et al.* 2000), a healthier diet and a lower prevalence of alcohol and snuff consumption (Lindström & Eriksson, 2006).

To do this, community health assets will be located to allow patients to perform the exercise scheduled following the salutogenic model (Botello *et al.* 2013). This paradigm is focused on problem solving and the ability to use the resources available (Lindström & Eriksson, 2006), thus determining indicators of both the subject themselves and the social context that improves health (Antonovsky, 1996). Furthermore, this paradigm identifies Resistance General Resources such as biological, material and psychosocial factors that make people perceive their life as coherent, structured and understandable in an easier way (Rivera de los Santos *et al.* 2011). They help people to move towards a healthy status due, at least in part, to one of the strengths of the salutogenic model, which is its practical applicability. Furthermore, the salutogenic model is a good approach to be applied in policy and public health programs development. In this sense, using this paradigm it is possible to change and revitalize health promotion toward action models based on health assets (Craig *et al.* 2010; Rivera de los Santos *et al.* 2011). Nowadays, public health research suggests the use of a socio-ecological approach for improving adherence to physical activity (Thompson *et al.* 2007). Information strategies are the initial component for understanding programs of physical activity, motivating and encouraging people to become active, as well as providing advice about how barriers to increasing physical activity could be overcome (Craig *et al.* 2010).

The study

Aim

To analyse the efficacy of a 12-month multifactorial intervention by primary care nurses in increasing adherence to physical activity prescription (150 min/week) in patients with two or more cardiovascular risk factors and with a cardiovascular risk, determined using the Framingham-REGICOR equation, of up to 15%.

Objectives

1. To analyse the efficacy of the intervention in:

- Increasing physical activity performed.
- Decreasing cardiovascular risk determined by the Framingham-REGICOR equation.
- Increasing the number of participants moving through the change process in the model of the trans-theoretical stages of change of Prochaska and DiClemente.
- Increasing adherence to physical activity prescription depending on the SOC value.

2. To evaluate changes in several health-related variables such as blood pressure, body mass index (BMI), depression, diet quality, physical fitness and sleep quality.

Hypotheses

A brief multifactorial intervention based on a motivational interview, the trans-theoretical stages of changes of Prochaska and DiClemente and an individualized prescription of physical exercise (patients will choose from several activities that can be adapted to their day to day living) improves adherence to the minimum recommended physical activity (150 minute per week) by 7.8% in the absolute percentage in patients

with at least two cardiovascular risk factors and with a cardiovascular risk of up to 15% measured using the Framingham-REGICOR equation.

The intervention will:

- Increase physical activity levels.
- Decrease BMI and cardiovascular risk.
- Allow patients in pre-contemplative or contemplative stages to progress in the trans-theoretical stages of change of Prochaska and DiClemente.
- Be more effective in patients with a higher value of SOC.

Design

Randomized, multicentre, single blind clinical trial.

Participants

Participants will be recruited from primary care centres in Mallorca, including both urban and rural centres. The inclusion criteria used for recruiting participants for this study are: patients aged 35-75 years with at least two cardiovascular risk factors and with a cardiovascular risk of up to 15% measured using the Framingham-REGICOR equation. Exclusion criteria include: (1) institutionalized patients, with a Barthel index below 60, terminal illness, dementia or cognitive impairment, or participating in another research study; (2) presence of myocardial infarction, bypass or coronary angioplasty in the previous 3 months, unstable coronary heart disease or untreated heart failure; (3) patients living outside the health care area; and (4) patients participating in another research study.

Cardiovascular risk factors considered are: age (men older than 55 and women older than 65), presence of diabetes, hypertension, obesity (BMI>30 $kg \cdot m^2$), smokers, dyslipidaemia and family history and age of onset of CVD.

Sample size determination

Sample size calculation is based on the primary outcome and primary analysis for the intention-to-treat population. We estimate 1.2% of patient participants performing at least 150 minutes of weekly physical activity in the placebo group (Grandes *et al.* 2009) and 9% in the intervention group.

Sample size is adjusted for an estimated follow-up loss rate of 15%, a two-sided level of significance of α=5%, which determines that 128 patients in each group will be required to detect a difference of at least 8% in the percentage of patients performing at least 150 minutes of weekly physical activity in the active and control groups. We assume that a percentage (a maximum of 20%) of patients in the control group will follow the instructions given to intervention patients (study contamination). By applying the corresponding correction taking into account this contamination effect, the final calculated sample size is 368 patients.

Randomization

After recruitment, participants recruited by each nurse will be randomly allocated either to the intervention or control group. Research Randomizer (www.randomizer.org/) will be used to perform the randomization.

Physical activity assets mapping and physical activity assets booklet

Mapping of physical activity assets at a local level will be performed following the methodology previously described (Botello *et al.* 2013). This mapping will be conducted by a group consisting, at least, of a community leader (well-known and involved in the community activities), a nurse from the health centre and a researcher from the university research group. This group will be responsible for collecting data through individual and group interviews of inhabitants in the area and asking about facilities or resources in the community to perform physical activity.

All the information about physical activity assets from each health area will be included in the physical activity assets booklet that will be used as the main tool for performing the physical activity prescription. In addition to the physical activity assets, this booklet will include the activities related to each asset, as well as additional information about these assets, such as the address and/or location in a map of the area, contact details, availability of asset information in social networks, as well as the time schedule of the suggested activities when necessary. Finally, the booklet will include some templates for writing down each visit physical activity prescription as indicated below.

Intervention

Intervention will be performed by primary care nurses over four visits: baseline visit and follow-up visits 1, 2 and 3, which will take place 2, 6 and 9 months after the baseline one, respectively. The intervention will include a motivational interview, the trans-theoretical stages of changes of Prochaska and DiClemente and an individualized prescription of physical exercise using the physical activity assets. The content of this intervention will mainly depend on the participant's trans-theoretical stage of changes of Prochaska and DiClemente, but also on the self-reported weekly time spent performing physical activity, as shown in Table 1. Furthermore, physical condition will

also be considered to decide intensity, duration and frequency of the exercise prescribed.

Participants belonging to the control group will receive the routine physical activity prescription during the baseline visit. No follow-up visits will be scheduled for participants belonging to control participants.

All nurses involved will be provided with a specific training workshop prior to the commencement of the study. They will be equipped with the necessary knowledge and skills to deliver both the physical activity promotion counselling using motivational interviewing techniques and stages of change model as well as the physical activity prescription. Since the same nurses working in the setting would contact patients in both the intervention and control group, specific reminders aimed at preventing the contamination of the intervention and control groups will be given.

Outcome measures

The primary outcome is the number of participants performing at least 150 minutes of weekly physical activity. Secondary outcomes include physical activity level, sense of coherence (SOC), blood pressure and blood biochemical parameters, cardiovascular risk factors, physical fitness, socio-demographic data, anthropometrical measurements and trans-theoretical stage of change of Prochaska and DiClemente. Furthermore, the number of physical activity assets from each health area as well as the main characteristics of the health care centre (urban or rural, number of inhabitants from the area, etc.) will be collected.

Physical activity levels

The standard short form of the International Physical Activity Questionnaire (IPAQ) (Craig *et al.* 2003) will be used to determine participants' physical activity levels as well as the weekly time of physical activity performed to determine the number of participants performing at least 150 minutes of physical activity. IPAQ comprises 4 simple questions on physical activity, which will be included in the study questionnaire. The IPAQ results will be expressed as metabolic equivalents (MET)-minutes per week.

Physical fitness

Physical fitness will be measured using the chair stand test (Millor, Lecumberri, Gómez, Martínez-Ramírez, & Izquierdo, 2013). This test consists of standing up and sitting down from a chair as many times as possible within 30 seconds. A standard chair (with a seat height of 40 cm) without a backrest but with armrests will be used. Initially, subjects will be seated on the chair with their back in an upright position. They will be instructed to look straight forward and to rise after the '1, 2, 3, go' command at their own preferred speed with their arms folded across their chest. Physical fitness level will be classified as low, sufficient or good depending on the times the participant stands up within the 30-second test.

Cardiovascular risk factors

Cardiovascular risk will be determined using the Framingham-REGICOR equation which entails a calibration of the Framingham score for the Spanish population (Marrugat *et al.* 2007, 2011). The necessary parameters for determining the Framingham-REGICOR value are: age, gender, smoking habits, presence or absence of diabetes, blood total cholesterol and HDL-cholesterol levels and systolic and diastolic blood pressure.

Serum concentrations of total cholesterol, HDL-cholesterol, LDL-cholesterol and triacylglycerides will be measured by using an autoanalyser (SYNCHRON CXH9 PRO, Beckman Coulter, Brea, CA, USA). Blood pressure will be measured three times with a five-minute gap between each measurement after a resting period of 10 minutes in the supine position using an automatic and calibrated sphygmomanometer (OMRON M3, OMRON Healthcare Europe, Spain). Self-reported smoking status will also be recorded.

Sense of Coherence

Sense of coherence will be measured using the 'SOC questionnaire' which involves the instruments for measuring this parameter at individual level in the Salutogenic model of Antonovsky. The 13-item form of the Orientation to Life Questionnaire (SOC-13) will be used to assess a global life orientation reflecting the ability to perceive life as comprehensible, manageable and meaningful (Alsén & Eriksson, 2016). A total sum score will be calculated, ranging from 13–91. To measure SOC at different levels, the total SOC will be divided into tertiles. The short form of the SOC scale has been validated in a Swedish context (Virués-Ortega, Martínez-Martín, del Barrio, & Lozano, 2007).

Anthropometrical measurements

Body weight (electronic scale Seca 700; Seca, Hamburg, Germany), height (stadiometer Seca 220 CM Telescopic Height Rod for Column Scales, precision 0.5 cm; Seca) and abdominal waist circumference (flexible steel tape, Lufkin Executive Thinline W606, precision 1 mm) will be determined according to the recommendations of the International Standards for Anthropometric Assessment (ISAK, 2001) by well-trained researchers to minimize coefficients of variation. Each measurement will be made three

times and the average value calculated. Body mass index will be determined as weight (kg) divided by height (m) squared.

Socio-demographic characteristics

Sociodemographic data such as age, gender, marital status, education level, employment status and social class will be collected using the classification of the Spanish Society of Epidemiology (Domingo-Salvany *et al.* 2013).

Patient Health Questionnaire (PHQ-9)

The Patient Health Questionnaire is a self-administered version of the PRIME-MD diagnostic instrument for common mental disorders. The PHQ-9 is the depression module, which scores each of the 9 DSM-IV criteria as '0' (not at all) to '3' (nearly every day) leading to an overall score from 0 to 27. Determined values for sensitivity and specificity in adults is 61% and 94% respectively (Kroenke, Spitzer, & Williams, 2001). It also includes an additional question to go further into the influence of symptoms on daily life. The Spanish validated questionnaire has shown similar properties to the original version (Diez-Quevedo, Rangil, Sanchez-Planell, Kroenke, & Spitzer) and it has also been validated for primary care use (Haddad *et al.* 2013).

Adherence to the Mediterranean Diet

Diet quality will be measured using a simplified assessment of adherence to the Mediterranean Diet (14-item questionnaire), previously developed and validated for the Spanish population (Martínez-González, Fernández-Jarne, Serrano-Martínez, Wright, & Gomez-Gracia, 2004). Each item is scored as 0 or 1. A global score of 9 or higher indicates a good adherence to the Mediterranean Diet.

Sleep quality

The MOS Sleep Scale is a validated 6-item self-report questionnaire that measures six dimensions of sleep, including initiation, maintenance, quantity, adequacy, somnolence and respiratory impairments (including shortness of breath or snoring) (Hays, Martin, Sesti, & Spritzer, 2005).

Stages of change of Prochaska and DiClemente

Questions leading to ascertain the patient's stage of change towards physical activity will be included. The following stages will be considered in this model: pre-contemplation (people who are not thinking about changing their sedentary behaviour and are not aware of their problem), contemplation (dissonant sedentary patients beginning to be disgusted with their sedentary life and thinking about performing physical activity, e.g. in the next six months), preparation (people starting the process of change and willing to start doing physical activity e.g. in the following month) and action-maintenance (people doing physical activity).

Data collection

Data collection will mainly be performed during the baseline and final visits. During the follow-up visits, the variables needed to determine the intervention (duration and frequency of physical activities performed and the trans-theoretical stage of change of Prochaska and DiClemente) as well as changes in parameters such as medication and incidence of illness in the previous months will be collected.

During the baseline visit the following data will be collected from participants: sociodemographic variables, anthropometric measurements, serum concentrations of

total cholesterol, HDL-cholesterol, LDL-cholesterol and triacylglycerides, blood pressure, presence of illness, current medication, physical activity levels, sleep quality, depression, SOC, physical fitness, trans-theoretical stage of change of Prochaska and DiClemente and visit duration.

During the final visit the following data will be collected from participants: anthropometric measurements, serum concentrations of total cholesterol, HDL-cholesterol, LDL-cholesterol and triacylglycerides, blood pressure, presence of illness, medication, physical activity levels, sleep quality, depression, physical fitness, trans-theoretical stage of change of Prochaska and DiClemente and visit duration.

Data analysis

Statistical analysis will be performed using SPSS v.21 (IBM, New York, USA) and Stata v.10 (StataCorp, Texas, USA) programs:

- Descriptive analysis, labelling and data cleaning: rating atypical and extreme values, identification and labelling of missing and/or unenforceable values, description of variable distribution, normality tests, scatter plots.
- Comparative analysis: data from the two study groups will be analysed. Comparison of clinical characteristics between control and intervention groups will be performed by t-test and chi-square test depending on the nature of the variable. When the assumptions of normality would not be met, the test D Somer will be applied. The clinical relevance of the intervention will be determined by taking into account the number of patients achieving 150 min of weekly physical activity. Relative risk reduction (RRR), absolute risk reduction (ARR), and the number of patients needing treatment (NNT) will be determined. Crude and adjusted analyses will be performed for

baseline characteristics (through "Generalized estimating equation") to determine the effect of belonging to the control or intervention group.

Ethical considerations

Ethics approval has been obtained from the Institutional Review Board of the Balearic Islands Health Service (CEI-IB Ref No: IB 2341/14). The researcher will ensure that the ethics standards are adhered to during the study. Participation will be voluntary and confidentiality will be protected. Participants will be assured that their participation in the study is voluntary and that they can withdraw from the study at any point without any negative consequences. Participants' written consent will be obtained and all data collected will be kept anonymous and confidential.

Validity and reliability

The study design, procedures and reporting will follow the CONSORT statement recommendations on randomized controlled trials (WHO, 1997). Questionnaire and recruitment process will be evaluated in a pilot study in two primary care centres and quality of data will be guaranteed by a clinical trials monitor.

Due to study procedures, patients and nurses cannot be blind to patient allocation. After the one-year intervention, the main outcome will be assessed by an external evaluator not involved previously in the study and blind to patient allocation. The statistician will also be blind to patient allocation.

Discussion

An increasingly aging population along with an increased lifespan induce a high proportion of people who will suffer from a cardiovascular event in the next years. Such

increased CVD events will have a long-term impact not only on the burden of disease and mortality, but also on a social and economic level due to disability generated. These patients could benefit from the positive health effects provided by increased physical activity levels, therefore decreasing drug consumption and the risk of CVD complications and drug side effects (Naci & Ioannidis, 2013; Pedersen & Saltin, 2015).

In the present study we combine a brief multifactorial intervention based on motivational interviewing performed by primary care nurses together with prescribing social community health assets to promote physical activity. The intervention aims to increase patient motivation for physical activity and, thus, to increase adherence to the physical activity prescription. Accomplishing this aim will contribute to improving quality of patient care, as this will be more personalized and will, thereby, reduce the risk of cardiovascular disease incidence.

The proposed study is in line with the new trends in health promotion and in performance in evidence-based primary care consultation. If the intervention included in the present project results in enhanced physical activity levels and, thereby, in improved health markers, it could become a new and useful treatment at primary care level for patients with cardiovascular risk, or with a previous cardiovascular event, as well as for more health issues. The project can also contribute to a more efficient use of health resources, as well as reduce attendance time compared with primary care routine clinical practice or to hospital rehabilitation programs.

Limitations

It cannot be ruled out that since the prescribed activities will be available for the whole community, they could also be performed by participants belonging to the control group. Thus, this possible contamination should be considered. However, the

intervention includes not only the resources (community assets to practice physical activity) but also the prescription of physical exercise including intensity and duration, which could, at least in part, prevent this contamination. The decision to participate in an intervention study including exercise prescription may also be associated with subject and/or nurse increased motivation and interest for performing physical activity and for physical activity related issues.

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Table 1. Intervention contents depending on the stage of change of Prochaska and DiClemente

<table>
<tr><th>Stage
Visit</th><th colspan="3">Action / Maintenance</th><th>Preparation / Contemplation</th><th>Pre-contemplation</th></tr>
<tr><td>Baseline</td><td colspan="3">-Exercise prescription using physical activity assets and activities included in the physical activity assets booklet</td><td rowspan="3">-Motivational interview

-Exercise prescription using physical activity assets and activities included in the physical activity assets booklet</td><td rowspan="3">-Motivational interview

-Provide informative sheet with physical activity positive effects

-Provide physical activity assets booklet without performing any exercise prescription</td></tr>
<tr><td rowspan="2">Follow-up 1, 2 and 3</td><td rowspan="2">Has the participant accomplished the goal of 150 minutes of weekly physical activity?</td><td>YES</td><td>-Give a congratulatory message
-Positive reinforcement
-Check whether prescription should be modified (changing activities, increasing exercise duration and/or intensity, etc.)</td></tr>
<tr><td>NO</td><td>-Discuss reasons
-Change exercise prescription</td></tr>
</table>