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Effectiveness of physical activity prescription by primary care nurses using health assets: A randomized controlled trial

Running head:

Physical activity health assets prescription

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Conflict of Interest

No conflict of interest has been declared by the authors.

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•substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;

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ABSTRACT

Aim: To evaluate the effectiveness of a 12-month multifactorial intervention by primary care nurses using health assets in increasing adherence to physical activity prescription (150 minutes/week) in patients with two or more cardiovascular risk factors.

Background: Physical activity promotion is a priority and helps to decrease mortality risk due to cardiovascular diseases. However, adherence to the habitual physical activity prescription in primary health care settings is low.

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

Methods: 263 participants from 20 primary health care centres in Mallorca completed the randomized controlled trial study (intervention group N=128, control group N=135). The intervention consisted in four visits and included a motivational interview and an individualized prescription of physical activity using health assets. Primary outcome measure was the number of participants performing at least 150 minutes of weekly physical activity. Secondary outcomes included physical activity level and physical fitness, Sense of Coherence, cardiovascular risk, sociodemographic data, trans-theoretical stage of change, sleep quality and depression.

Results: Adherence to the recommendation of at least 150 min of physical activity was higher in the intervention than in the control group (χ^2=3.951, p=0.047). However, this higher adherence did not suppose higher physical activity levels because no differences between groups were found in the total physical activity performed after intervention (t=-0.915, p=0.361). At the end of the intervention participants randomized to the intervention group spent more time walking than participants in the control group (t=2.260, p=0.025).

Conclusion: The multifactorial intervention performed by primary care nurses induced a higher adherence to the 150-minute of weekly physical activity recommendation.

Impact: Adherence to the usual physical activity prescription in primary care is low. Physical activity prescription performed by primary care nurses and based on health assets and motivational interview can help to increase physical activity levels of patients. The main finding of the present study was that prescription using this approach was shown to be effective, leading to a higher adherence in the intervention group. This intervention is feasible in the nurse's primary health care setting, thus it could be implemented as the main tool when exercise is prescribed.

Trial Registration: International Standard Randomized Controlled Trial Number: ISRCTN76069254.

KEYWORDS

Nurse prescribing; Primary care; Randomized controlled trials

1 INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of death worldwide and in Europe (Roth et al., 2018). Each year CVD causes 3.9 million deaths in Europe (45% of all deaths) and is responsible for the loss of more than 64 million disability-adjusted life years (23%). CVD is the main cause of death in women in all but two European countries (Wilkins et al., 2017). In Spain, CVD is responsible for 29.8% of deaths (INE, 2017). Moreover, the burden of CVD deaths is not only associated to the disease itself but also to the significant personal, social and economic hardships imposed as a result of the disabilities they generate, with the latest data indicating that in 2015, CVD cost the European Union 210 billion of euros (Wilkins et al., 2017).

Physical activity (PA) guidelines from the WHO, the US Department of Health and Human Services and an increasing number of national governments worldwide recommend performing at least 150 min of weekly moderate PA (Arem et al., 2015; Davies, 2012; de Souto Barreto, 2015; Kahlmeier et al., 2015; Thompson et al., 2007). However, it has been reported that most of the population in developed countries is insufficiently active (Guthold, Stevens, Riley, & Bull, 2018; Haskell, Lee, Pate, Powell, Blair, Franklin, Macera, et al., 2007; Martinez-Gonzalez et al., 2001). Indeed, the 2017 survey from the European Commission reported that almost half of Europeans (46%) never exercise or play sports and the same figure is also true for the Spanish population (European Comission, 2018). A lack of PA has been associated with several chronic diseases (Department of Health & Human Services, 2018), premature mortality (Lacombe, Armstrong, Wright, & Foster, 2019) and economic burden (Ding et al., 2016). Furthermore, recent evidence suggest that sedentary behaviours are also related to increased risk of chronic diseases and mortality (Biswas et al., 2015; Charansonney, Vanhees, & Cohen-Solal, 2014; Patterson et al., 2018). A recent systematic review and

harmonised meta-analysis, with PA objectively measured with accelerometers, concluded that higher levels of total PA, performed at any intensity and with less time spent in sedentary activities, are associated with reduced risk for premature mortality (Ekelund et al., 2019). This study also suggested a non-linear dose-response relation between PA and the beneficial effects in adults. Following the main idea of the positive effects of PA, it has been particularly shown that regular PA is related to a reduced risk of fatal and non-fatal coronary events both in healthy individuals and subjects with coronary risk factors, with this effect following a dose-response relationship (I.-M. Lee, 2007). This beneficial effect is mainly induced by the positive effects of PA on risk factors for CVDs (Nystoriak & Bhatnagar, 2018), such as preventing or delaying development of hypertension and reducing blood pressure (BP) in hypertensive patients, increasing HDL cholesterol levels, helping to control body weight and lowering the risk of developing type 2 diabetes. (Lacombe et al., 2019). PA could also exert its beneficial effects enhancing cardiovascular function (Hambrecht et al., 2000).

1.1 Background

The 2012 European Guidelines on CVD prevention in clinical practice suggested that a large gap exists in Europe between required and actual primary and secondary cardiovascular prevention exercise-based interventions (Perk et al., 2012). More recently, it has been reported that the adequate implementation of the promotion of a healthy lifestyle and the results regarding the effectiveness of primary care intervention in increasing PA levels are still not clear (Canadian Agency for Drugs and Technologies in Health, 2014). The WHO has suggested that 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 capable of providing a broad range of lifestyle counselling should be at the core of the sector (World Health Organization, 1997). European

Guidelines on CVD Prevention in Clinical Practice has highlighted the role of nurses and primary care medical doctors in promoting a healthy lifestyle, based on increasing PA (Graham et al., 2007) and that the nurse-coordinated prevention programmes should be well integrated into healthcare systems (Perk et al., 2012; Piepoli et al., 2016).

Routine PA prescription in primary care settings has a low efficacy level (1.2%) (Grandes et al., 2009). However, when brief counselling was used, small improvements in the adherence to the prescription were observed (Hillsdon, 2013) and in a study performed in Spain, the percentage of participants accomplishing the goal of at least 150 min of weekly PA increased to 3.9% (Grandes, Sanchez, Montoya, Sanchez-Pinilla, & Torcal, 2011). Furthermore, it has been reported that introducing motivational strategies such as a more intensive programme of prescription, or the use of PA records and then passing this information along to the patients, could lead not just to an improvement in adherence to the PA programme prescribed, but also in the prescription procedure per se (Hillsdon, 2013; Josyula & Lyle, 2013). In addition, improvements have been observed when the prescription was performed by nurses rather than by medical doctors, suggesting that the longer time nurses were able to spend with patients was the main reason for this (Grimstvedt et al., 2012; Klemenc-Ketis, Terbovc, Gomiscek, & Kersnik, 2015; ter Bogt et al., 2011; Whittemore et al., 2010).

The motivational interview has been revealed to be 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 healthcare provider (W. W. M. Lee, Choi, Yum, Yu, & Chair, 2016; Rubak, Sandbaek, Lauritzen, & Christensen, 2005). Actually, one of the main goals of motivational interview is to increase patient's empowerment. Furthermore, this type of

clinical interview already has turned out to be effective in the treatment of alcohol problems, drug addiction, giving up smoking, losing weight and increasing PA levels (Hardcastle, Taylor, Bailey, Harley, & Hagger, 2013).

The trans-theoretical model of change (J. O. Prochaska, DiClemente, & Norcross, 1992) suggests that any behavioural change follows a process. The change model consists of five progressive stages showing where individuals are in the process of changing their attitudes and behaviours: pre-contemplation, contemplation, preparation, action and maintenance. This model has been used to help people adopt healthy behaviours and to dispense with unhealthy ones, where the characteristics of intervention depend on the particular stage each patient is allocated (J. J. Prochaska & Prochaska, 2011).

Getting people to adopt an active lifestyle is a complex process that is influenced by several factors, including personal, social and environmental factors (Calogiuri & Chroni, 2014). Following the salutogenic model (Antonovsky, 1996), the sense of coherence (SOC) has been used as an assessment tool for modifying lifestyles based on the enhancement of health assets (Morgan & Ziglio, 2007). SOC has been considered as an adaptive dispositional orientation that enables coping with adverse experience (Antonovsky, 1996). SOC integrates the meaningfulness, comprehensibility and manageability of a situation (Antonovsky, 1996). Some studies have shown that positive health outcomes, such as higher levels of PA (Hassmén, Koivula, & Uutela, 2000), a healthier diet and a lower prevalence of alcohol and snuff consumption (Lindström & Eriksson, 2006), can be predicted by using the SOC questionnaire. In this regard, Nilsen et al, in a study developed with subjects at risk of type 2 diabetes concluded that high SOC values were also good predictors of successful lifestyle changes (Nilsen, Bakke, Rohde, & Gallefoss, 2015). Thus, SOC could be a useful tool for clinicians to identify

patients who are more likely to benefit from a healthy lifestyle promotion program (Nilsen et al., 2015; Wainwright et al., 2007).

Health assets could be defined as an individual's internal or external strengths or accessible resources which enhance ability to optimise health (Van Bortel, Wickramasinghe, Morgan, & Martin, 2019). According to the salutogenic model, locating health assets in the community can promote patients to perform the prescribed PA (Botello et al., 2013). This paradigm is focused on problem solving and the ability to use the resources available (Lindström & Eriksson, 2006), thus determining the indicators of both the patients themselves and the social context that improves health (Antonovsky, 1996). Furthermore, this paradigm identifies generalized resistance 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, Ramos Valverde, Moreno Rodríguez, & Hernán García, 2011). Using this paradigm, it is possible to change and revitalize health promotion towards action models based on health assets (Morgan & Ziglio, 2007). Information strategies are the initial component for understanding programmes of PA, motivating and encouraging people to become active and providing advice about how barriers to increasing PA could be overcome (C L Craig, Bauman, & Reger-Nash, 2010).

2 THE STUDY

2.1 Aims

The primary aim of this study was to examine the effectiveness of a 12-month multifactorial intervention by primary care nurses in increasing adherence to PA prescription (150 min/week) in patients with two or more cardiovascular risk factors. This multifactorial intervention included the motivational interview, the trans-theoretical

stages of changes of Prochaska and DiClemente and an individualized prescription of PA using health assets.

Specifically, we aimed to analyse the effectiveness of the intervention for:

(i). Increasing PA performed.

(ii). Decreasing the number of cardiovascular risk factors and the overall cardiovascular risk score.

(iii). Increasing the number of participants moving through the change process in the model of the trans-theoretical stages of change of Prochaska and DiClemente.

(iv). Increasing adherence to PA prescription depending on the SOC value.

In addition, changes in several health-related variables such as BMI, blood pressure, depression, diet quality, physical fitness, sleep quality and self-perceived quality of life and health were evaluated.

The hypothesis of the study was that the multifactorial intervention induces higher adherence to the recommended PA (at least 150 min per week) than using standard care in patients with at least two cardiovascular risk factors. Furthermore, the intervention was expected to:

1. Increase PA levels.
2. Decrease cardiovascular risk.
3. Allow patients in pre-contemplative or contemplative stages to progress in the trans-theoretical stages of change of Prochaska and DiClemente towards PA practice.
4. Be more effective in participants with a higher SOC.

2.2 Design

A parallel, two arm, multicentre, single-blind randomized controlled trial was developed. A detailed research study protocol was previously published (Riera-Sampol et al., 2017).

2.3 Participants and randomization

Between January 2015 and January 2017, a random sample was recruited by 38 primary care nurses from 20 primary health care centres in Mallorca (6 urban and 14 rural). Inclusion criteria were: patients aged 35-75 years with at least two cardiovascular risk factors (men older than 55 or women older than 65 years, diabetes, hypertension, BMI >30 kg/m^2, smoking, dyslipidaemia and family history of CVD). Exclusion criteria were: institutionalized patients, a Barthel index below 60, terminal illness, dementia or cognitive impairment, presence of myocardial infarction, bypass or coronary angioplasty in the previous 3 months, unstable coronary heart disease or untreated heart failure-patients living outside the healthcare area and current participation in another research study. The Barthel index is an ordinal scale that measures functional independence in the domains of personal care and mobility (Mahoney & Barthel, 1965). Lower values indicate dependence in activities of daily living.

A sample size determination was performed as it was detailed in the study protocol (Riera-Sampol et al., 2017). Parameters considered were: difference of 8%, or higher, between groups in the final percentage of participants performing at least 150 min of weekly PA (χ^2 test), follow-up loss rate of 15%, two-sided level of significance $\alpha = 5\%$, $\beta = 20\%$, a maximum of 20% of participants in the control group following the instructions given to participants in the intervention group (contamination). This calculation showed that a final number of 128 participants in each group are required.

Participants recruited by each nurse were randomly allocated by an external researcher to the intervention or the control group using the Research Randomizer program (www.randomizer.org/).

2.4 Intervention

A 12-month multifactorial intervention performed by primary care nurses was tested. Each nurse treated participants randomized to both intervention and control groups. A Template for Intervention Description and Replication (TIDieR) of the intervention is shown in the "Supporting Information". Intervention was conducted between March 2015 and January 2018 and was performed over four visits (baseline and follow-up visits 1, 2 and 3, which took place 2, 6 and 9 months after the baseline one respectively). Motivational interview, information regarding the beneficial effects of PA and an individualized prescription of PA using the health assets were used as the main tools. Specific contents were mainly determined depending on the participant's trans-theoretical stage of changes of Prochaska and DiClemente and on the self-reported weekly time spent performing PA (whether participants perform at least 150 minutes of PA per week or not) (Figure 1). Essentially, participants, for any visit, in the action/maintenance state received PA prescription using the local health assets. In the follow-up visits of these participants, the accomplishment of the 150 minutes of PA goal was also considered to determine intervention contents. In this regard, participants accomplishing the goal of 150 minutes of weekly PA received congratulatory messages and positive reinforcement. Furthermore, whether prescription should be modified (changing activities, increasing exercise duration and/or intensity, etc.) was checked in agreement with the participant. On the other hand, participants who did not achieve this goal were asked about the reasons for not doing so and about the about the convenience of changing the exercise prescribed. The motivational interview was used for participants in the Preparation/Contemplation

and Pre-contemplation stages. However, while PA prescription was performed in participants in the Preparation/Contemplation stages, this prescription was not completed when participants were in the Pre-contemplation stage.

To allow this PA prescription, mapping of local PA assets was performed following the methodology previously suggested (Botello et al., 2013). Briefly, a group consisting of: a community leader (well-known and involved in the community activities), a nurse from the health centre and a researcher belonging to the research group, collected all relevant data through individual and group interviews of inhabitants in the area and asked about the facilities and resources to perform PA.

After checking for its usefulness and validity in terms of PA prescription, this information was included in a PA assets booklet that was the main tool for this intervention and it was used for performing the PA prescription to the participants from the intervention group. Therefore, each booklet included PA assets from its own area, suggested activities related to each asset and characteristics of these assets, such as: address and/or location in a map of the area, contact details, availability of asset information in social networks and the time schedule of the suggested activities. The booklet also included templates for recording the detailed individualized PA prescription. When PA prescription using this booklet was performed, participants were asked to choose three of the available activities depending on their own preferences. Intensity, duration and frequency for the selected physical activities were determined by taking into account the participant's physical fitness. This information was also recorded in the booklet.

Participants in the control group received standard care PA prescription during the baseline visit. It was a general, non-customized prescription and following WHO recommendations (de Souto Barreto, 2015), 30-60 minutes of PA at least 4-5 days per

week were suggested. No follow-up visits were scheduled for participants randomized to control group.

All nurses involved were provided with specific training before the beginning of the study. In this training, they were provided with the necessary knowledge and skills to deliver both the PA promotion counselling using motivational interviewing techniques and stages of change model as well as the PA prescription using the PA assets. As each nurse was treating participants randomized to both study groups, specific reminders aimed at preventing the contamination of the intervention and control groups were given.

2.5 Outcome measures and data collection

The primary outcome was the number of participants performing at least 150 min of weekly PA. Secondary outcomes included: PA level, SOC, cardiovascular risk factors and cardiovascular risk, physical fitness, sociodemographic data, anthropometrical measurements, trans-theoretical stage of change, sleep quality and depression. Data were collected from January 2015 to May 2017, using previously validated standard procedures. At baseline, the following data were collected from participants:

- PA levels: the standard short form of the International Physical Activity Questionnaire (IPAQ) (Cora L Craig et al., 2003) was used to determine participants' PA levels and the weekly time of PA performed to determine the number of participants performing at least 150 min of PA.
- Cardiovascular risk and cardiovascular risk factors. Cardiovascular risk was determined using the Framingham-REGICOR equation which entails a calibration of the Framingham score for the Spanish population (Marrugat et al., 2011). Age, gender, smoking habits, the presence or absence of diabetes, blood total cholesterol and HDL-cholesterol levels and systolic and diastolic BP were needed to determine

the cardiovascular risk. Serum concentrations of total cholesterol, HDL-cholesterol, LDL-cholesterol and triacylglycerides were measured using an autoanalyser (SYNCHRON CXH9 PRO; Beckman Coulter, Brea, CA, USA). Systolic and diastolic BP was taken with an automatic and calibrated sphygmomanometer (OMRON M3; OMRON Healthcare Europe, Spain). Self-reported smoking status was also recorded.

- Sociodemographic variables: age, gender, marital status, education level and employment status.
- Anthropometric measurements (body weight, height, BMI and abdominal waist circumference) according to the recommendations of the International Standards for Anthropometric Assessment (Stewart, Marfell-Jones, Olds, & De Ridder, 2011).
- Diet quality, measured as the adherence to the Mediterranean diet, using the simplified assessment of adherence to the Mediterranean Diet 14-item questionnaire, previously developed and validated for the Spanish population (Estruch et al., 2018).
- Sleep quality using the MOS Sleep Scale (Hays, Martin, Sesti, & Spritzer, 2005).
- Depression using the Patient Health Questionnaire (Diez-Quevedo, Rangil, Sanchez-Planell, Kroenke, & Spitzer; Haddad et al., 2013; Kroenke, Spitzer, & Williams, 2001).
- Self-perceived quality of life and health status using questions with five possible responses: very good, good, fair, bad and very bad.
- SOC. The 13 item form for the orientation to life questionnaire was used to assess the SOC values reflecting the ability to perceive life as comprehensible, manageable and meaningful (Alsén & Eriksson, 2016).

- Physical fitness was measured using the chair stand test (Millor, Lecumberri, Gómez, Martínez-Ramírez, & Izquierdo, 2013).
- Trans-theoretical stage of change (J. O. Prochaska et al., 1992) was ascertained considering the following stages and their main characteristics: pre-contemplation (people who are not thinking about changing their sedentary behaviour), contemplation (dissonant sedentary patients beginning to be disgusted with their sedentary life and thinking about performing PA), preparation (people starting the process of change and willing to start doing PA) and action-maintenance (people doing PA).

Additional data such as presence of illness and current medication were recorded during the baseline visit. On the other hand, excluding the SOC, which was not determined again, data collected from participants during the final visit (at 12 months) were the same as in the baseline one.

During the follow-up visits, only the variables needed to determine intervention contents (duration and frequency of physical activities performed and the trans-theoretical stage of change), as well as changes in parameters such as medication and incidence of illness in the previous months, were collected (data not shown).

2.6 Data analysis

Descriptive statistics were presented as mean and standard deviation (SD) or number and percentage for categorical variables. The significance of differences between the control and the intervention groups in baseline and in final characteristics were tested using the Student's t-test for unpaired data (continuous variables) or the χ^2 test (categorical variables). The primary outcome was determined by means of the comparison between the percentage of participants form each group achieving the goal of 150 minutes of

weekly PA at the end of the study (final visit). Baseline data analyses involve intention-to-treat populations. However, due to study design, randomized patients who did not attend the baseline visit could not be included in the baseline data analyses. Patients were included in these analyses regardless of participation in any follow-up or in the final visit and they were analysed in the group into which they were randomized. To test whether the intervention was more effective in patients with a higher SOC value, participants from the intervention group were divided into tertiles according to their SOC scores. All analyses were performed on Statistical Package for Social Science (SPSS) version 25.0 (IBM, New York, USA). In all cases, a p value below 0.05 was considered statistically significant.

2.7 Validity and reliability

The study design, procedures and reporting followed the CONSORT statement recommendations on randomized controlled trials (Schulz, Altman, & Moher, 2010). All questionnaires and instruments used for data collection have been demonstrated to have psychometric adequacy.

The survey at 12 months (the last visit) was conducted by an external researcher who was blinded to participants' allocation. The data analysis, including all statistical analysis, was performed by a researcher of the study who was also blinded to allocation.

2.8 Ethical considerations

Ethics approval was obtained from the Health Service Ethics Committee. Participation was voluntary and confidentiality was protected. Participants were assured that their participation in the study was voluntary and that they could withdraw from the study at any point without any negative consequences. Participants' written consent was obtained and all data collected were kept anonymous and confidential.

3 RESULTS

The flow of participants through each stage is shown in Figure 2. Initially, 760 participants were assessed for eligibility and, among them, 370 were randomized (48.7%). Thirty-one of the 181 participants initially randomized to the control group (17.1%) did not receive intervention because they decided to withdraw from the study before the baseline visit or due to withdraw of the nurse on account of illness. Fifteen more participants from the control group (8.3%) did not attend the final visit due to different reasons (recent cancer diagnosis, sepsis and voluntarily withdraw from the study without any reported reason). On the other hand, in the intervention group, of the 189 subjects initially allocated, 29 (15.3%) didn't receive intervention due to: their job (work schedule), withdraw of the nurse on account of illness, or because they reported, during the baseline visit, participation in another research study. During the one-year intervention and follow-up, 32 additional participants from the intervention group (16.9%) withdrew from the study because of the following reasons: cancer diagnosis, angina, stroke, knee surgical intervention, spur surgical intervention, pancreas cancer diagnosis, familiar problems and voluntary withdraw. Among participants completing the study, 23 (18%) did not attend at least one of the follow up visits due to lack of availability.

The final number of participants, 135 randomized to the control group and 128 randomized to the intervention group, fits with the sample size calculation indicated above. The baseline characteristics of participants from each group are shown in Table 1. No significant differences were found at baseline between participants in the control and in the intervention groups.

Figure 3 shows the adherence to the weekly 150 minutes of PA recommendation. It is noteworthy that after intervention, adherence to the at least 150 min of PA

recommendation was higher in the intervention than in the control group (χ^2=3.951, p=0.047). Regarding the effectiveness of the intervention in patients with a higher SOC, among the 14 subjects who achieved success at the end of the study (gained adherence), five were in the lowest tertile, three in the medium tertile and six in the highest tertile, with no significant effect of the SOC value.

Table 2 shows the PA performed by participants in the study as well as their physical fitness measured using the chair test. The higher adherence indicated above did not suppose higher PA levels because no differences between groups were found in the total PA performed before and after intervention. At the end of the study, participants in the intervention group spent more time walking than participants in the control group (t=2.260, p=0.025).

Table 3 shows changes during the study in several outcome measures: sleep quality, depression, adherence to the Mediterranean diet and percentage of participants reporting good quality of live and good health perception. No significant differences between groups were found at baseline and after intervention.

Table 4 shows values for different parameters after intervention. No differences between groups were found after intervention for parameters such as BMI, blood pressure, cholesterol levels, cardiovascular risk (Framingham-REGICOR equation) or number of cardiovascular risk factors. Furthermore, the intervention did not induce changes in lifestyle patterns such as: the adherence to the Mediterranean diet, smoking status and alcohol consumption.

4 DISCUSSION

The main finding of the present study was that the intervention induced a greater adherence to the 150-minute of weekly PA recommendation. Furthermore, the

intervention induced an increase in the time the participants in the intervention group spent walking.

Regarding the protocols tested for exercise prescription, previous studies have shown that when brief counselling was used for the PA prescription, small improvements in the adherence to the prescription were observed (Hillsdon, 2013), with the percentage of participants accomplishing the goal of at least 150 min of weekly PA increasing to 3.9% in a study performed in Spain (Grandes et al., 2011). Thus, results from these studies as well as from the present one, suggest that these prescription strategies could lead to an improved adherence to the main PA recommendation.

Due to the well-established benefits of PA on the prevention of CVD (Alves et al., 2016), increasing adherence to the minimum PA levels recommended as a preventive tool has become one of the main goals in the primary care, as any improvement, even the modest one observed in the present study, is an important contribution to one's health status. In this sense and regarding the primary outcome of this study, it is striking that the higher adherence to the at least 150-minute of weekly PA recommendation was mainly due to a decrease in the adherence in the control group (decreasing from 79.4% to 72.4%) rather than to an increase in the intervention group (80.5% vs. 82.8%). We suggest the main reason leading to this pattern of change was the initial high adherence to the PA recommendations in both groups. This initial high adherence could have prevented a further increase in the adherence to the PA recommendation in the intervention group. In spite of this, it is a positive finding, because it involves that the prescription induces people to keep PA levels, it is not in the line of the hypothesis suggested, which expects an increase in the adherence to the prescription and a general increase in PA levels. Results of the present study suggest that in populations with high adherence, the prescription protocol used is more useful to prevent people from decreasing PA levels

and, thus, the adherence of current PA levels, rather than for increasing this adherence. It is also worth mentioning that, contrary to findings of previous studies, no increase in PA in the control group was observed, a result that has been found in other studies (Grandes et al., 2011; Müller-Riemenschneider, Reinhold, Nocon, & Willich, 2008), probably because of the initial high PA level indicated above. In contrast with previous results (Nilsen et al., 2015), no association was found in the present study between high SOC values and healthy lifestyle changes (increased PA adherence). It should be considered that not all studies have found these positive associations between SOC values and healthy outcomes (Nilsen et al., 2015). In this regard, results from a systematic review suggested that SOC should be used as an orientation tool rather than as a screening instrument (Eriksson & Lindström, 2006). On the other hand, the high initial adherence of participants could also be one of the reasons for this result, as it has been suggested above.

As it has been indicated above, in the study performed by Grandes et al. the adherence to the PA recommendation increased after intervention (Grandes et al., 2011). However, in the present study, participants meeting the minimum recommended PA levels were excluded. Actually, most of participants were in the pre-contemplation to preparation stages, while in the present study most of the participants were initially in the action and maintenance stages. These differences in participants considered could explain the different results obtained. In fact, decreases in cardiovascular risk associated with as little as 45 to 60 minutes of walking per week or 2.6 to 3.9 MET-h/week (Haskell, Lee, Pate, Powell, Blair, Franklin, MacEra, et al., 2007) have been reported, with these figures being accomplished, on average, by all participants in the present study. However, it is striking that the intervention induced differences in the time spent walking because while participants from the intervention group seemed to increase this time, while participants

from the control group showed a slightly shorter time walking. The tendency of an increase in the intervention group could be related to the PA prescription in this group because one of the main and most common PA assets included in the PA assets booklet used as the main tool for the prescription were the adequate and recommended walking routes for the participants to walk. These routes were allocated within each one of the healthcare areas and presented essential characteristics such as mainly flat terrain and with the entire course being adequate for pedestrians.

One of the characteristics of participants in the present study was their employment status, with only a third of them being active workers. Thus, the high PA levels reported could not be attributed to the PA performed in workplaces. This observation could be of interest because there is strong evidence showing that the role of occupational PA in CVD prevention is questionable, supporting the notion of primary prevention of CVD through engagement during leisure time PA (Li, Loerbroks, & Angerer, 2013).

The slight changes observed in the adherence, together with the high initial PA levels, could be the responsible of the lack of changes found in cardiovascular risk factors such as obesity, cholesterol levels and BP. This lack of changes could be interpreted as a positive result in terms of maintaining levels of cardiovascular risk factors. However, it seems that the PA levels accomplished by participants were not enough to improve their cardiometabolic profile. This result should be more attributable to intensity rather than to the duration of PA performed. On average, participants in the study spent around three times the minimum level of PA recommended, although they mainly walk (around 95% of the whole time spend doing PA). In spite of a dose response curve for PA and healthy effects of PA has been suggested (as it has been indicated above), some studies have revealed that intensity could be essential when significant improvement are to be achieved (Füzéki & Banzer, 2018). Therefore, while walking could be adequate for maintenance

of cardiometabolic health, a higher intensity could be needed for improving the cardiometabolic profile.

4.1 Limitations

Although the present study was conducted under mostly real clinical practice conditions, several limitations should be acknowledged. A possible contamination is that all the prescribed activities were available to the whole community, thus they could also have been used by participants in the control group. However, the intervention included not only the prescription of community assets to practice PA but also the individualized prescription of PA (intensity and duration), which could, at least in part, prevent this contamination. In addition, nurses were previously advised to prevent this contamination during the visit. Furthermore, participating in an intervention study on the prescription of PA can be associated with a greater interest and motivation not only of the participants to perform PA but also of the nurses to perform and to prescribe PA. This greater interest could have resulted in that most of participants had already initially accomplished the recommended 150 minutes of weekly PA.

It should be kept in mind that this intervention has been implemented within a research project fashion. However, it should be highlighted that the intervention per se does not take too much time. In fact, the mapping of the PA local assets and the continuous actualization of the assets' details, could be considered as the limiting factors of the strategy in terms of the time this process takes. Therefore, we consider that the intervention tested could be implemented in a feasible and sustainable way into routinely real practice conditions in primary care and without the participation of additional professionals such as PA professionals.

5 CONCLUSIONS

A multifactorial intervention using social prescription of health/PA assets by primary care nurses in patients with cardiovascular risk factors induced higher adherence to the 150-minute of weekly PA recommendation at 12 months. More studies are needed to test whether this multifactorial intervention increases adherence to the PA recommendations in participants with lower adherence or lower PA levels than the ones in the present study. It would be also interesting to determine whether the positive effects of the intervention are maintained in the long-term. We consider that this intervention is feasible in a nurse's primary health care setting, thus it could be implemented as the main tool when exercise is prescribed. However, more studies aiming to determine this issue should be conducted.

CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

AUTHOR CONTRIBUTIONS

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (http://www.icmje.org/recommendations/)]:

•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.

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Table 1. General characteristics and SOC values of participants in the study

	All (n=310) n (%) / Mean (SD)	Control group (n=160) n (%) / Mean (SD)	Intervention group (n=150) n (%) / Mean (SD)	p
Male sex	157 (50.6%)	80 (50%)	77 (51.3%)	0.814
Age (years)	62.2 (8.8)	62.3 (8.8)	62.1 (8.7)	0.872
Weight (kg)	83.1 (16.8)	82.9 (16.8)	83.2 (16.9)	0.884
Height (cm)	162.6 (9.1)	162.5 (9.4)	162.7 (8.7)	0.840
BMI (kg/m²)	31.3 (5.6)	31.4 (5.7)	31.3 (5.5)	0.923
Systolic BP (mm Hg)	131.8 (16.9)	132.0 (19.8)	131.6 (13.2)	0.841
Diastolic BP (mm Hg)	79.1 (8.9)	79.2 (9.9)	79.0 (7.8)	0.822
Total cholesterol (mg/dl)	193.7 (38.7)	193.1 (34.2)	194.4 (42.9)	0.783
HDL cholesterol (mg/dl)	53.3 (23.9)	55.3 (27.2)	51.2 (19.8)	0.133
LDL cholesterol (mg/dl)	113.4 (38.2)	111.5 (36.5)	115.4 (40.0)	0.382
Triglycerides (mg/dl)	140.5 (78.6)	135.0 (63.1)	146.2 (91.9)	0.214
Cardiovascular risk factors (n)	3.2 (1.2)	3.2 (1.2)	3.3 (1.2)	0.670
Cardiovascular risk (%)	6.4 (4.0)	6.2 (3.9)	6.6 (4.0)	0.430
Adherence Mediterranean Diet				
Low adherence	119 (40.2%)	62 (40.8%)	57 (39.6%)	0.832
High adherence	177 (59.8%)	90 (59.2%)	87 (60.4%)	
Smoking status				
Non-smoker	125 (41.1%)	67 (42.9%)	58 (39.2%)	0.862
Ex-smoker	122 (40.1%)	62 (39.7%)	60 (40.5%)	
Smoker	57 (18.8%)	27 (17.4%)	30 (20.3%)	
SOC	68.8 (13.1)	68.3 (13.8)	69.3 (12.4)	0.495
Trans-theoretical stages of changes				
Pre-contemplation	11 (4.1%)	5 (3.3%)	6 (5.1%)	0.361
Contemplation	9 (3.3%)	3 (2.0%)	6 (5.1%)	
Preparation	33 (12.2%)	21 (13.7%)	12 (10.2%)	
Action-maintenance	218 (80.4%)	124 (81.0%)	94 (79.6%)	
Education level				
Primary school	161 (53.0%)	76 (48.7%)	85 (57.4%)	0.128
Secondary school	143 (47.0%)	80 (51.3%)	63 (42.6%)	
Employment status				

Worker	94 (31.2%)	49 (31.8%)	45 (30.6%)	0.683
Unemployed	34 (11.3%)	15 (9.7%)	19 (12.9%)	
Retiree	173 (57.5%)	90 (58.5%)	83 (56.5%)	

Results are expressed as mean (standard deviation) or as number and (percentage) of participants. p indicates the significance of the difference for the comparison between control and intervention groups, Student's t-test for independent samples (continuous variables) or χ^2 test (categorical variables). Cardiovascular risk is expressed as REGICOR value. SD: standard deviation; BMI: body mass index; BP: blood pressure; HDL: high-density lipoproteins; LDL: low-density lipoproteins; n: number; SOC: sense of coherence.

Table 2. Participants' physical activity levels, physical fitness and sitting time before and after intervention

	Before n (%) / Mean (SD)	After n (%) / Mean (SD)	P (before; after)
PHYSICAL FITNESS			
Control			
Bad	32 (20.6%)	26 (19.7%)	0.557; 0.473
Sufficient	74 (47.7%)	61 (46.2%)	
Good	49 (31.7%)	45 (34.1%)	
Intervention			
Bad	20 (16.9%)	32 (25.6%)	
Sufficient	54 (45.8%)	51 (40.8%)	
Good	44 (37.3%)	42 (33.6%)	
TOTAL PHYSICAL ACTIVITY			
Sessions/week			
Control	7.0 (5.5)	5.8 (3.6)	0.623; 0.888
Intervention	7.2 (3.2)	5.8 (2.8)	
Minutes/day			
Control	71.2 (65.3)	59.6 (54.2)	0.816; 0.361
Intervention	70.0 (69.8)	67.3 (61.4)	
Mets-hour/week			
Control	30.7 (30.6)	24.4 (23.1)	0.816; 0.361
Intervention	29.9 (30.3)	27.0 (24.6)	
WALKING			
Sessions/week			
Control	5.7 (4.9)	4.4 (2.7)	0.994; 0.186
Intervention	5.7 (2.1)	5.1 (2.2)	
Minutes/day			
Control	69.2 (60.4)	56.3 (42.2)	0.608; 0.025*
Intervention	65.6 (63.9)	71.5 (63.2) *	
Mets-hour/week			
Control	22.5 (22.2)	18.1 (16.6)	0.911; 0.059
Intervention	22.2 (24.2)	22.9 (20.3)	
SITTING TIME			
Hours/day			
Control	5.2 (2.9)	6.8 (4.1)	0.136; 0.824
Intervention	4.7 (2.5)	6.9 (3.6)	

Results are expressed as mean (standard deviation) or as number and (percentage) of participants. p values indicate the significance of the difference for the comparison between control and intervention groups at baseline and after intervention (before; after), Student's t-test for independent samples (continuous variables) or χ^2 test (categorical variables). * indicates a significant difference ($p<0.05$). Mets: metabolic equivalent of task.

Table 3. Effectiveness of intervention improving health related parameters

	Before n (%) / Mean (SD)	After n (%) / Mean (SD)	p (before; after)
Sleep quality			
Control	11.6 (4.2)	11.4 (5.1)	0.140; 0.514
Intervention	12.4 (5.0)	11.0 (4.4)	
Depression			
Control	4.9 (4.6)	5.1 (4.4)	0.674; 0.527
Intervention	5.2 (4.5)	4.7 (4.6)	
Quality of live (good and very good)			
Control	122 (76.3%)	91 (71.7%)	0.577; 0.371
Intervention	116 (78.9%)	98 (76.6%)	
Health status (good and very good)			
Control	98 (61.3%)	86 (67.7%)	0.343; 0.824
Intervention	99 (66.4%)	85 (66.4%)	

Results are expressed as mean (standard deviation) or as number and (percentage) of participants. p values indicate the significance of the difference for the comparison between control and intervention groups at baseline and after intervention (before; after), Student's t-test for independent samples (continuous variables) or χ^2 test (categorical variables).

Table 4. Comparisons between participants in control and in intervention groups after intervention

	Control group (n=135) n (%) / Mean (SD)	Intervention group (n=128) n (%) / Mean (SD)	p
Weight (kg)	82.2 (16.2)	82.7 (16.1)	0.804
BMI (kg/m²)	31.4 (5.7)	31.2 (4.9)	0.803
Systolic BP (mmHg)	137.7 (19.2)	134.4 (15.5)	0.128
Diastolic BP (mmHg)	80.5 (11.5)	80.8 (11.6)	0.861
Total cholesterol (mg/dl)	187.6 (37.7)	188.7 (40.1)	0.822
HDL cholesterol (mg/dl)	48.9 (10.9)	48.4 (15.5)	0.770
LDL cholesterol (mg/dl)	112.0 (32.9)	110.5 (37.5)	0.737
Triglycerides (mg/dl)	136.4 (67.5)	155.4 (98.7)	0.071
Cardiovascular risk factors (n)	2.7 (1.7)	2.8 (1.7)	0.645
Cardiovascular risk (%)	6.5 (3.6)	6.8 (3.4)	0.551
Adherence Mediterranean Diet			
Low adherence	56 (47.1%)	61 (50.8%)	0.559
High adherence	63 (52.9%)	59 (49.2%)	
Smoking status			
Non-smoker	53 (41.7%)	56 (43.8%)	0.321
Ex-smoker	50 (39.4%)	56 (43.8%)	
Smoker	24 (18.9%)	16 (12.4%)	
Trans-theoretical stages of changes			
Pre-contemplation	9 (6.9%)	5 (4.0%)	0.788
Contemplation	7 (5.3%)	7 (5.6%)	
Preparation	11 (8.4%)	10 (8.0%)	
Action-maintenance	104 (79.4%)	103 (82.4%)	

Results are expressed as mean (standard deviation) or as number and (percentage) of participants. p indicates the significance of the difference for the comparison between control and intervention groups, Student's t-test for independent samples (continuous variables) or χ^2 test (categorical variables). Cardiovascular risk is expressed as REGICOR value. SD: standard deviation; BMI: body mass index; BP: blood pressure; HDL: high-density lipoproteins; LDL: low-density lipoproteins; n: number.

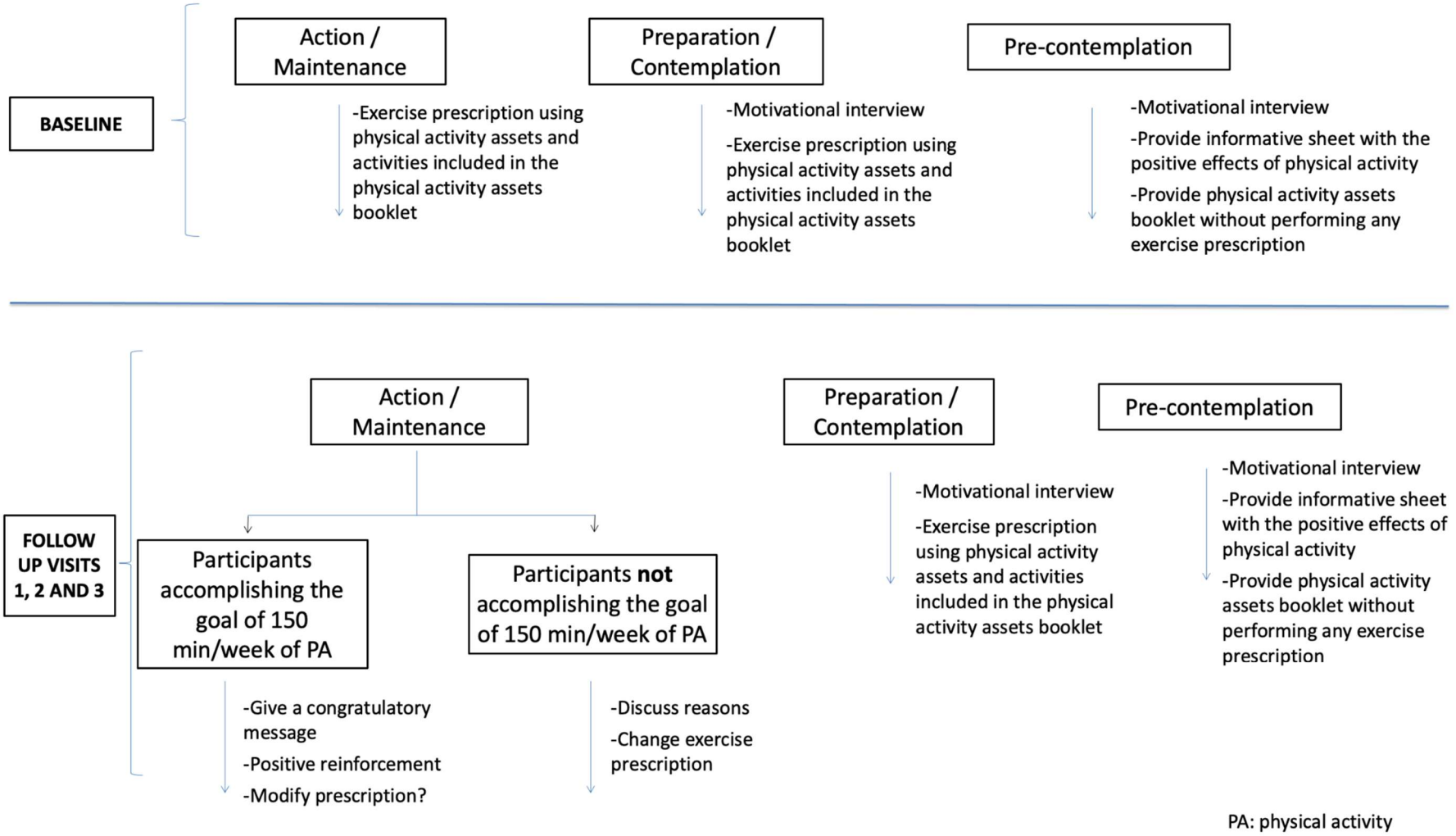

FIGURE 1. Intervention contents depending on the stage of change of Prochaska and DiClemente and on the achievement of the weekly 150 min of physical activity goal

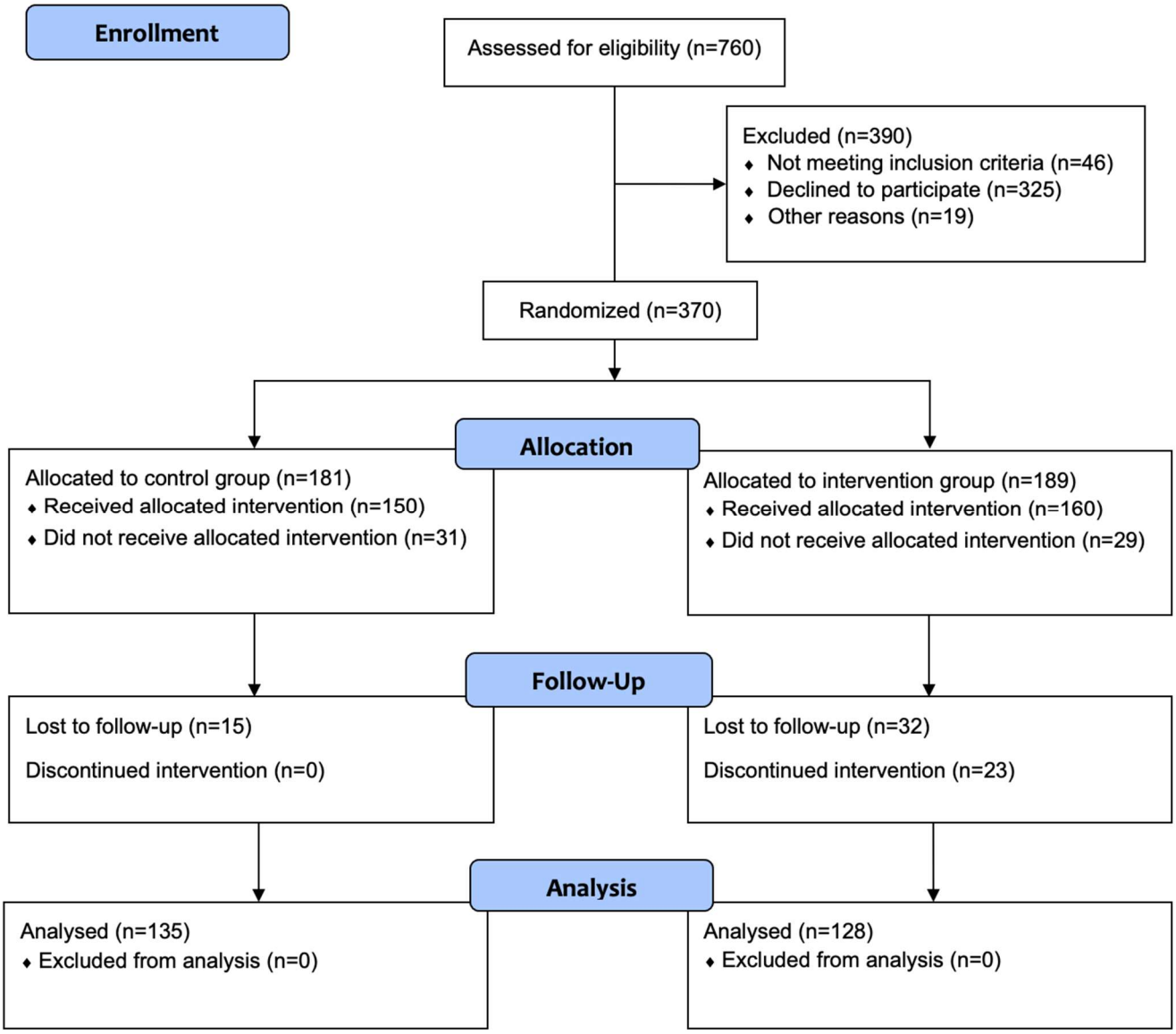

FIGURE 2. Participants' Flow Diagram

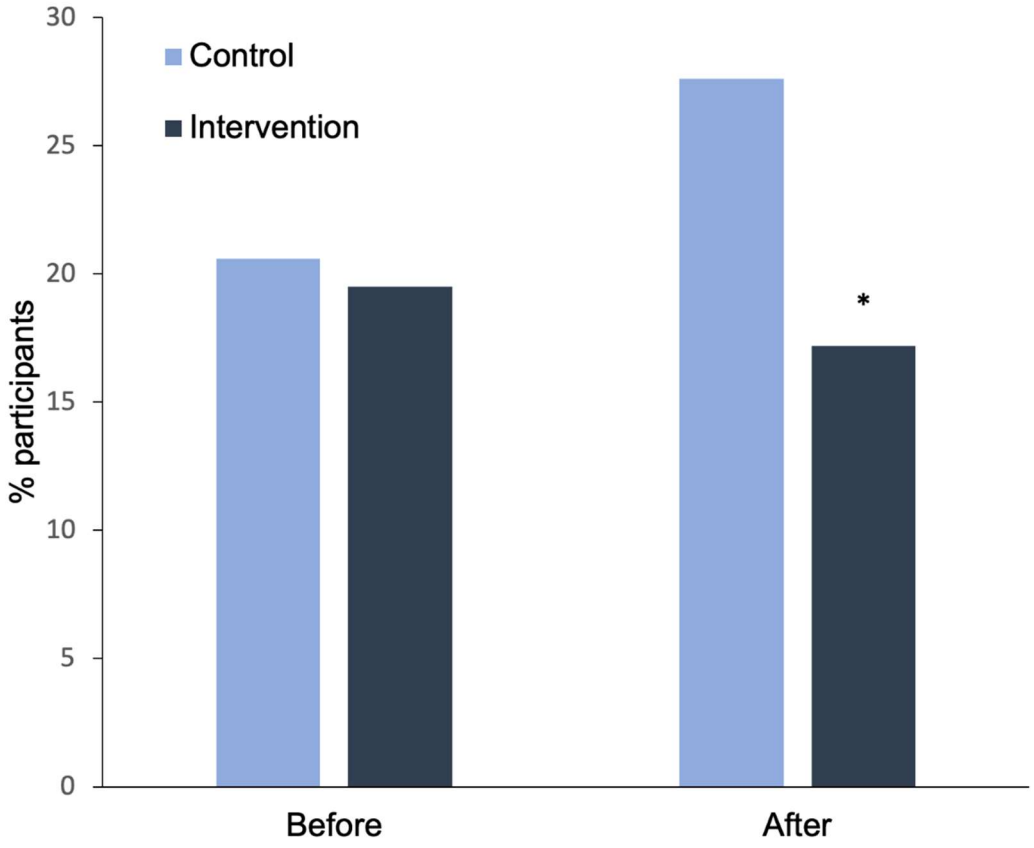

FIGURE 3. Percentage of participants not adhered to the weekly 150 min of PA recommendation in control and intervention groups