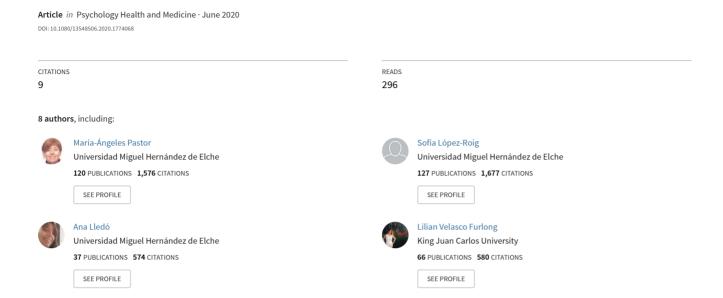
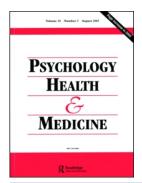
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Promoting unsupervised walking in women with fibromyalgia: a randomized controlled trial

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ABSTRACT

The objective of this study is to test the efficacy of a group motivational plus implementation intentions intervention in promoting adherence to an unsupervised walking program recommended for fibromyalgia, compared to an implementation intentions condition and to an active control condition. A triple-blind, randomized, longitudinal study with measures at baseline, short (seven weeks postintervention), mid (12 weeks) and long-term (36 weeks) is performed. Data are analyzed using multilevel longitudinal growth curve twolevel modelling. Participants are 157 women with fibromyalgia. In the short-term, adherence to the minimum and to the standard walking program (primary outcome measures) is explained by time (both p <.001), motivational plus implementation intentions intervention (both p < .001) and by their interaction (both p < .001). Regarding the secondary outcomes, only physical function is explained by time (p < .001), motivational plus implementation intentions intervention (p < .05) and by their interaction (p < .05). Motivational plus implementation intentions intervention achieve the promotion of walking as an exercise in the short-term; furthermore, physical function of the women in this condition is better than in the other two intervention groups, which is a relevant outcome from a rehabilitation point of view. However, more studies are needed to maintain the exercise at mid and long-term.

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KEYWORDS

Fibromyalgia; chronic pain; walking; group intervention; behavioral intention

Introduction

Fibromyalgia is a chronic condition, characterized by widespread musculoskeletal pain, with no well-established etiology, which also includes symptoms such as fatigue, sleep problems and cognitive and emotional disorders. Patients often report high functional impact, negative consequences in their daily life and negative effects on mood (Janssens et al., 2015; Tesio et al., 2018). Fibromyalgia is associated with a high socio-sanitary burden, with a prevalence of 3.4% for women and 0.5% in men (Queiroz, 2013). Exercise is one of the more commonly recommended non-pharmacological therapies (Macfarlane et al., 2017) and improves health-related quality of life, pain, physical function and global

well-being in this specific chronic pain problem (Bidonde et al., 2017; Häuser et al., 2010; Kelley & Kelley, 2011). Therefore, implementing exercise becomes a clinical goal in these patients. Walking is an easy and accessible form of exercise, with low musculoskeletal impact and positive health outcomes (O'Connor et al., 2015). However, among fibromyalgia patients, reported practice of walking is low (López-Roig et al., 2016) and this can limit the benefits on health outcomes. In other populations, interventions to increase walking combining motivational and post-motivational strategies have shown good results (French et al., 2012). Motivational interventions encourage people to create or strengthen goal intentions whilst post-motivational strategies help people to act according to these intentions. Implementation intentions are one of the strategies of the latter. Implementation intentions are if-then plans that link external or internal cues (if component) with behaviors that will be performed (then component) to attain goals (Gollwitzer, 1999). They are used for enabling people to manage potential selfregulatory difficulties for performing a target behavior (Gollwitzer & Sheeran, 2006). This is relevant in fibromyalgia, where pain, fatigue and 'to be having a bad day sicknesswise' have been identified as important obstacles for walking (Pastor-Mira et al., 2015). In other populations, interventions to increase walking combining motivational and postmotivational or volitional strategies have shown good results (Darker et al., 2010; French et al., 2012). Motivational interventions have been carried out to increase exercise in fibromyalgia (Ang et al., 2013). However, to the best of our knowledge, there are no interventions with implementation intentions as stand-alone strategy or combined with motivational strategies to promote walking in this problem.

The aim of this study was to establish the efficacy of an intervention that combines both motivational and implementation intentions strategies to enhance the short, medium and long-term adherence to an unsupervised walking exercise program recommended for fibromyalgia (Gusi et al., 2009). It was hypothesized, first, that women with fibromyalgia assigned to a motivational plus implementation intentions condition (MIIC) would significantly increase unsupervised walking compared to an active control group (CC) and to a group with implementation intentions stand-alone intervention (IIC). Second, this effect should remain stable in the mid and long-term.

Materials and methods

Trial design

A triple-blind, randomized longitudinal study with two treatment groups and one active control group was performed (Trial registration: ISRCTN68584893). Multilevel statistical analyses were performed with a two-level design with repeated measures, in which the level-1 was set up from moments when dependent variables measures were taken; moments are nested at the person level, which is level-2. The study was approved by the Research Ethics Board of the Miguel Hernández University and corresponds to the second phase (intervention and follow-up study) of a broader research (Pastor et al., 2014). First, participants attended university labs for a baseline assessment session (time1, T1) and intervention. We used a computer program to randomize the number of participants in the three experimental groups and four fibromyalgia associations, taking into account the size of each center (Doménech & Granero, 2011). We applied another

computer program to generate random sequences to allocate in each center participants to the three experimental groups (Doménech, 2009). Second, all participants received a 15-minutes group information session all together. Afterwards, the interventions for each experimental condition were performed consecutive and simultaneously in different group sessions on the same day at different labs. Participants were guided by the person responsible for the day schedule to their randomly assigned intervention sessions. All participants received the same contact time (around 75 minutes) distributed in the different components of each intervention (see interventions section).

Follow-up measures were also taken at the university labs at a short-term (seven weeks post-intervention, time 2, T2), at a mid-term (12 weeks post-intervention, time 3, T3) and at long-term (36 weeks post-intervention, time 4, T4). Interventions and follow-up measures were conducted over two years (2013 and 2014).

Participants and recruitment

A total of 581 members from four Spanish fibromyalgia associations, which collectively comprise 2438 members with a clinical diagnosis of fibromyalgia (a compulsory requisite to join the association), satisfied the inclusion criteria for this study: women, aged between 18 and 69 years, without severe psychiatric comorbidity or other conditions preventing to walk, who met the London-4 criteria for fibromyalgia (White et al., 1999), who did not walk or who did so below the minimum walking time and amount we had established (see variable section). The London-4 criteria is a screening questionnaire and was introduced to ensure population homogeneity because of its optimal sensitivity. Recruitment was made via mail and phone. Out of the 581 eligible participants, we were unable to contact six and 122 refused to participate. Thus, our population was comprised by 453 women with fibromyalgia which were all contacted by ordinary mail, email and phone through the associations. Finally, 191 attended the first appointment (T1; 42.2%). In total, 157 finally participated, 51 were allocated to MIIC, 43 to IIC and 63 to CC (see Figure 1).

The mean age of the 157 women was 54.1 years (SD = 8.1). Out of 157, it was found that 81.5% (n = 128) were currently being treated medically for fibromyalgia. The mean time since diagnosis was 11.6 years (SD = 5.8).

Interventions (complete researcher's handbook is available upon request).

Information (15 minutes)

In order to create the goal intention, the contents were: 1) the benefits of walking as exercise in fibromyalgia, 2) how to walk properly taking into account a graded exercise strategy, 3) the walking program recommended by Gusi et al. (2009), and 4) the most frequent worries about walking previously identified in an elicitation study (Pastor-Mira et al., 2015) and how to deal with them.

Motivational intervention (30 minutes)

Participants assigned to the MIIC condition received a group motivational training session to strengthen their goal intention to walk as exercise by enhancing their control perception (using the previously identified facilitators for walking) and their positive attitude towards walking (increasing the accessibility of the previously identified positive behavioral beliefs) (Pastor-Mira et al., 2015; 2020).

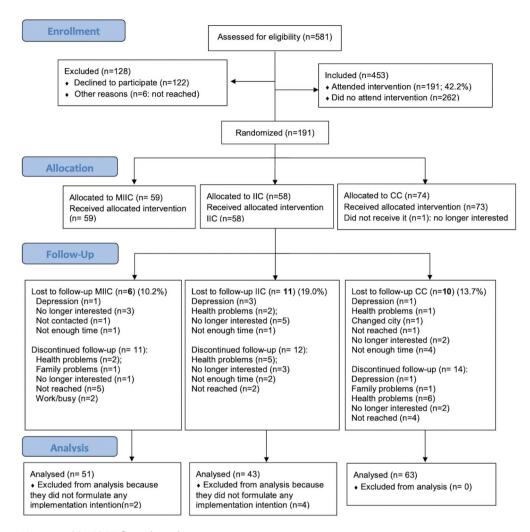


Figure 1. CONSORT flow chart diagram.

Post-motivational intervention: implementation intentions (30 minutes)

In the same session, participants in the MIIC and IIC were focused on elaborating *if-then* plans to deal with one of the three frequent obstacles of walking identified in the elicitation study (Pastor-Mira et al., 2015): pain, fatigue and 'to be having a bad day sickness-wise' (*if* component). For the *then* component, participants chose one of the three self-instructions related to chronic pain management strategies: acceptance and commitment (i.e. '... I accept that I have this difficulty, walking is good for me and I'll go out for a walk!'), task persistence (i.e. '... Walking is good for me and ... I'll go out for a walk!') and relaxation (i.e. '... I will breathe deeply, I will relax and tell myself: Walking is good for me ... !'). Participants received instructions to choose by themselves both obstacle and strategy, taking into account their personal circumstances and preferences. Participants in the IIC received previously the first postural hygiene session.



Control intervention (30 minutes + 30 minutes)

Participants in the control condition received two consecutive sessions about postural hygiene. In the first session, participants received information about the benefits of the postural hygiene norms. In the second session, they practiced some basic postures and though about the postures that can be incorporated into their daily lives.

Measures

Sociodemographic and clinical variables (T1)

With an 'ad hoc' questionnaire, we assessed sociodemographic variables such as age, marital status, educational level and work status together with other clinical data, such as time since fibromyalgia diagnosis, type of medical specialist who diagnosed, number of other chronic diseases, and if the participant was under medical treatment at the time of the study.

Intention to walk (T1-T4)

Intention to walk as exercise was measured according to the Theory of planned behavior recommendations (Fishbein & Ajzen, 2010). We used the mean score on six items answered on a previously tested seven-point scale with different wording anchors depending on each item ($\alpha = .90$) (Pastor-Mira et al., 2015). High scores indicate high intention (i.e.: 'intend to walk ...', 'I will walk ...').

Primary outcome measures (T1-T4)

- Logbooks with weekly sheets: Participants recorded days, minutes of walking and duration of rests during the activity. With this tool, the self-reported adherence to the minimum walking program measure (AMWP) was obtained (at least 30 minutes in bouts of 15 minutes, with a small rest between bouts, twice a week, over a minimum of six consecutive weeks) and the self-reported adherence to the standard walking program measure (ASWP) (at least 60 minutes in bouts of 20 minutes, with a small rest between bouts, four times a week, over a minimum of six consecutive weeks) (Gusi et al., 2009). In both measures, we considered the proportion of participants who reached at least 80% of the consecutive weeks carrying out the walking program in each period. The AMWP and ASWP variables were then categorized into binary, based on the completion or not of the minimum or standard programs.
- A pedometer step counter (Yamax EX5103D USB pedometer) to measure walking behavior. It was used the average steps per walking day for exercising.

Secondary outcome measures (T1, T2, T4)

- Fibromyalgia impact: Using the Spanish adaptation of the Revised Fibromyalgia Impact Questionnaire (FIQR) (Salgueiro et al., 2013). FIQR measures the perceived health impact of people with fibromyalgia, in terms of function (9 items), overall impact (2 items) and symptoms (10 items), scoring from 0 to 10, with different wording anchors depending on each item. It was calculated the total score (0–100), with the sum of the three domains. High scores represent high impact on quality of life ($\alpha = .93$).

- Pain intensity perception: Measured by the mean score of the maximum, minimum, and usual pain intensity during the last week and pain intensity at time of the assessment (Jensen et al., 1999), where 0 = 'no pain at all' and 10 = 'the worst pain you can imagine' ($\alpha = .82$). The scale has good psychometric properties in Spanish fibromyalgia samples.
- Distress: It was used the total score of the Spanish adaptation of the Hospital Anxiety and Depression Scale (Terol et al., 2007) (α = .88). The scale includes 14 items with different wording anchors. High scores indicate high distress. The use of total score (0 to 21) is recommended for pain chronic patients (LoMartire et al., 2020).
- Physical function: The Six-Minute Walk Test (6MWT) was used as a clinically relevant objective measure of the physical function (Rivera et al., 2006). It was recorded the distance that each participant can quickly walk on a flat surface in a period of 6 minutes.
- Treatment variables: At the end of each intervention the participants' expectations about treatment results and their satisfaction with the intervention they had received were assessed with four items scored from 0 (nothing) to 10 (totally). It was also asked if they would recommend the intervention to other people with fibromyalgia (yes/no). Finally, it was measured the commitment with their personal goal and with their plan to walk in the case of MIIC and IIC (1 = a little, 10 = a lot). For CC it was asked only for their commitment with their personal goal.

Statistical analyses

Descriptive and internal consistency analyses were performed using the SPSS v. 24. Missing data were handled by the Longitudinal Data R package (Genolini, 2016).

Multilevel Modelling (MLM)

Data analyses were performed by the R Statistical Package (R. C.Team, 2019). The nlme R package (Pinheiro et al., 2016) and the lme4 R package (Bates et al., 2015) were used, to perform a multilevel longitudinal growth curve model. Model fit was assessed using chi-square tests on the log-likelihood values to compare different models, and by using the Akaike's information criterion (AIC) relative goodness of fit index. Predictors tested were: 1) time, 2) treatment with one component (IIC), 3) treatment with two components (MIIC) and 4) time x treatment interactions.

Results

No significant differences were found at baseline between participants' characteristics or in intention to walk or in any of the dependent variables in each experimental condition, with the exception of distress where participants in the CC scored higher than those in MIIC (F = 3.9, p = .02). Also, no significant differences were found between groups in the different treatment variables, like expectations or satisfaction, measured at the end of interventions (see Supplemental material 1-3).



Primary outcomes

Adherence to a minimum walking program (AMWP)

The fitted model showed that AMWP is explained by time (F(3) = 8.47, p < .001), by MIIC (F(1) = 3.72, p < .001) and by their interaction (F(3) = 5.95, p < .001) as fixed effects, and by time as a random effect. Tukey post-hoc contrasts showed significant differences (T = -2.24, p < .001).

Adherence to a standard walking program, ASWP

The fitted model showed that ASWP was explained by time (F(3) = 6.10, p < .001), by MIIC (F(1) = 5.54, p < .001) and by their interaction (F(3) = 3.48, p < .001) as fixed effects. Tukey post-hoc contrasts showed significant differences (T = -2.29, p < .001) in time 2 between the CC and the MIIC).

Walking behavior-steps

Neither time nor treatments were significant as fixed effects.

See Figure 2 for graphical representation of all primary outcomes. See Supplemental material 2 for modelling process of primary outcomes.

Secondary outcomes

No significant interaction effects were obtained for fibromyalgia impact, pain intensity, and distress. The fitted model showed that physical function is explained by time (F (1,296) = 20.07, p < .001, MIIC (F(1,147) = 5.87, p < .05), and their interaction (F(1,147) = 5.87, p < .05)(1,296) = 3.70, p < .05) as fixed effects (see Supplemental material 2 for modelling process of secondary outcomes, and Supplemental material 3 for graphic representation).

Discussion

In this study, a brief group intervention with motivational and implementation intention strategies achieved the incorporation of an unsupervised walking program in women with fibromyalgia. This outcome is in accordance with previous research (Milne et al., 2002; Prestwich & Kellar, 2014) and with the first hypothesis. However, in contrast to the expectations, the effects on promoting the walking program were not stable. In chronic pain, implementation intentions have also been applied together with other motivational strategies and cognitive behavioral therapy in chronic back pain, improving physical capacity at short and midterm (three months) (Christiansen et al., 2010). Differences in diagnosis, context (in this case, community) and the intervention (motivational plus implementation intentions alone and applied once in a group session, not individually) could explain the discrepancy.

The two-component intervention also increased physical function of participants in the MIIC which is a significant clinical outcome from a rehabilitation point of view. These findings are relevant taking into account the low physical activity and walking in women with fibromyalgia (López-Roig et al., 2016; McLoughlin et al., 2011), their chronic disabling symptoms and the reported benefits of this exercise in their health outcomes (Busch et al., 2011; Häuser et al., 2010). It is worthy to underline that the credibility of the different interventions for participants was high, without differences in



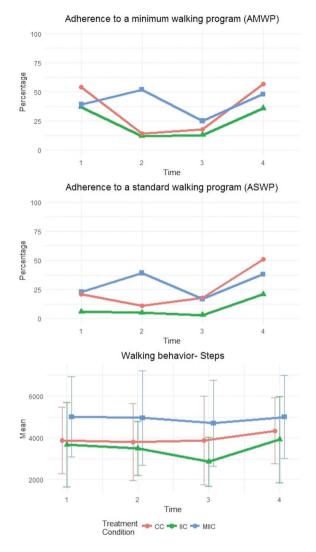


Figure 2. Bar stacked char and line plots of adherence to a minimum walking program (AMWP), adherence to a standard walking program (ASWP), and walking behavior (steps).

treatment expectations or satisfaction. Therefore, differences in effects between treatments were not due to those variables. The two-component intervention introduced the walking exercise in a sustained manner (over a minimum of six consecutive weeks).

In fibromyalgia, motivational interventions have been conducted to increase physical activity, with some positive results on pain intensity and self-reported physical activity in the immediate post-intervention (Ang et al., 2013). To the best of our knowledge, our study is the first in fibromyalgia with motivational and post-motivational strategies in an unsupervised context of exercise, promoting adherence to a walking program with a brief intervention. The ICC data and the spaghetti plots showed the positive effect of the MIIC as also dependent on personal bases. The individual variability was more remarkable for the adherence to the minimum walking program, which was the lowest goal of exercise

and the starting point of our program. These results are in agreement with the reported heterogeneity of people with fibromyalgia (Busch et al., 2011; Luciano et al., 2016) and underlined the importance of developing customized interventions for exercise. This issue can be relevant for the maintenance of walking at mid and long-term. In this sense, there could be other possible explanations for the lack of stability of our results. First, our participants were instructed to review their walking goal attainment every week and setting the exercise goal for the next week. In contrast, they were trained to use the same implementation intention to manage the obstacle they selected the day of the intervention. This obstacle could change along with the illness status or flare ups over follow-up. Therefore, they could have been dealing with a non-relevant inhibitor over this long time. In future research, we might train participants allowing changes in the if component over time. Second, there have been reports that program delivery affects adherence, with supervised being considered better than unsupervised programs or having improved adherence if participants are recruited and supervised by health personnel (Sanz-Baños et al., 2018). This was not our case, as our framework was a self-management context with women from community associations of fibromyalgia. Finally, no reminder strategies of the intervention were used, and no contact was had with the participants during follow-up until the day of the assessment, except for the last period (36 weeks postintervention) when participants were called to assure their attendance. Taking into account the positive effect of using plan reminders (Prestwich & Kellar, 2014; Prestwich et al., 2009), we should consider introducing them in future interventions.

It should be kept in mind some limitations. First, participants in the three conditions increased walking in the last follow up measure; this could be an unintended effect of our research design. Due to the length of the last period, it was reminded them via a phone call (on up to three occasions) the date of the assessment and confirmed their attendance. It could have been provoked participants to meet the experimenter's expectations or the aim of the intervention. Second, surprisingly, participants in the CC showed good walking results and they were also very satisfied with treatment. It is possible that postural hygiene training may have given skills to participants to handle their first main problem for walking reported previously (joint and muscular pain). Finally, it was found a baseline imbalance between experimental conditions in some dependent variables, such as those related to walking. This fact could be introducing some uncontrolled effect; however, there were no significant differences between groups, and the higher proportion of women walking in the CC at baseline than in the other conditions supports the better result in T2 for the participants in the MIIC.

In summary, despite the above-mentioned cautions, we present a promising, short and highly structured intervention which achieved getting sedentary women with fibromyalgia to start walking in a sustained manner (over a minimum of six weeks) which can be improved in future studies by achieving stability at mid and long-term. This intervention also increased physical function of participants in the MIIC, a relevant outcome in fibromyalgia. It is worth highlighting that we worked with a walking program which includes a complex behavior which refers to walking in a specific way over a specific time, for exercising. The goal was not to increase physical activity, it was to introduce a walking program as a self-management strategy in agreement with a recommended intervention for fibromyalgia. Our findings are also relevant taking into account the low physical activity and walking in fibromyalgia women, the reported benefits of this exercise



in their health outcomes and their chronic symptoms. The two-component intervention introduced the walking exercise, but further research should be conducted in order to achieve stability of this effect.

Disclosure statement

No potential conflict of interest was reported by the authors.

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