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Combining motivational and volitional strategies to promote unsupervised walking in patients with fibromyalgia

Submission date
28/11/2013

Recruitment status
No longer recruiting

Registration date
09/12/2013

Overall study status
Completed

Last Edited
24/04/2014

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Fibromyalgia is a condition that involves widespread and diffuse chronic pain. For such patients, moderate aerobic exercises have shown positive health outcomes. Adherence to physical activity in the medium and long term is an important problem. This study addresses an important need: to increase adherence to a unsupervised walking program. Behavioral theories suggest that a combination of motivational aspects (to develop or strengthen a behavioral intention: theory of planned behavior) and volitional aspects (engagement of intention in behavior: implementation intentions) work better than a single intervention. This study aims to identify the motivational processes involved in adherence to walking and to test how well a intervention that combines motivational and volitional elements will work.

Who can participate?
Patients diagnosed of Fibromyalgia attending patients associations in Alicante, Elche, Madrid and Talavera de la Reina in Spain.

What does the study involve?
Participants will be randomly allocated to one of three groups: motivational and volitional, volitional only, posture advice. The three groups will receive the same information on the benefits of physical exercise and walking. The motivational intervention enhances self-efficacy and personal positive consequences of walking. The volitional intervention includes the formulation of goals and of if then plans to carry out the personal goals related to the walking program.
Over a period of three years participants will come five times to the University for measures and intervention. When the intervention starts, patients will fill a daily logs and use a pedometer.

What are the possible benefits and risks of participating?
There will be no any risk and immediate direct benefit to those taking part. But there should be benefits in the future because results are expected to show that the intervention under consideration works well and this can be incorporated into routine clinical practice in the future.

Where is the study run from?
The study has been set up by the Universities of Miguel Hernandez (Elche) and Rey Juan Carlos (Madrid) in collaboration with Fibromyalgia patients associations from Alicante, Elche, Madrid and Talavera de la Reina (Spain).

When is the study starting and how long is it expected to run for?
Recruitment started mid-2012 and it will be finished at the end of 2014. Participants will be enrolled on the study for a period of three years.

Who is funding the study?
Funding has been provided by a competitive grant from the Spanish Ministry of Economy and Competitiveness.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Combining motivational and volitional strategies to promote unsupervised walking in patients with fibromyalgia: a randomised controlled trial

Study objectives
Fibromyalgia is a complex chronic condition characterized by widespread musculoskeletal pain, fatigue, sleeping problems and other symptoms with no well-established etiology.

Our main hypothesis is that a combined intervention (both motivational and volitional) will significantly increase walking behavior in fibromyalgia patients. This effect will be higher than in a merely volitional intervention in the short term and will be stable in the medium and long term.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Research Ethics Board of the Miguel Hernández University, 21/01/2011, ID: DPS-MPM-001-11

Study design
Multicentre experimental randomized triple-blinded study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Fibromyalgia

Interventions
The intervention is based on two well-established theories for predicting behavior. One group will receive a motivational plus implementation intention intervention, a second group will receive only an implementation intention intervention and the control group will be given a neutral task related to postural hygiene. The three groups will receive the same information on the benefits of physical exercise in fibromyalgia. The motivational intervention will be based on the predictors of behavioral intention, in order to create or strengthen the behavioral intention during the experimental study. Implementation intentions are 'if-then' plans that specify when, where and how a goal will be achieved, linking a critical situation ('if' component) with a goal-directed behavior ('then' component).

Longitudinal measures: baseline, 7 weeks, 3 and 9 months post experimental intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Two primary outcomes will be assessed as an indicator of the intervention effect on exercise adherence:

1. Proportion of participants who perform the full minimum walking criteria at the end of the period of 6 weeks, and the proportion of participants who maintain it at 3 and 9 months
2. Among participants who perform the full minimum walking criteria, we will focus on the proportion who reaches the recommended pattern for fibromyalgia patients at week 6

We will use self-reported measurements, self-reported items and daily logs, and a pedometer.

Secondary outcome measures
1. 6-minute Walk Test (6-MWT): the 6-MWT is a clinically relevant measure of the physical function that the Spanish Rheumatology Society recommends using with fibromyalgia patients
2. The short self-administered Spanish version of the International Physical Activity Questionnaire (s-IPAQ)
3. Fibromyalgia impact: Spanish adaptation of the Fibromyalgia Impact Questionnaire (FIQ)
4. Pain: total score of an 11-point numerical rating scale (NRS) (0 = 'no pain at all' and 10 = 'the worst pain you can imagine')
5. Emotional status: Spanish adaptation of the Hospital Anxiety and Depression Scale (HAD)

s-IPAQ , FIQ , NRS and HAD will be assessed in the first, second and third year

Overall study start date
01/09/2012

Completion date
01/09/2014

Eligibility

Key inclusion criteria
1. Women aged between 18-70 years old
2. Fit London-4 criteria for fibromyalgia (London Fibromyalgia Epidemiology Study Screening Questionnaire: White et al., 1999; Branco et al., 2010)
3. Medical recommendation to walk

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Upper age limit
70 Years

Sex
Female

Target number of participants
582

Key exclusion criteria
Comorbidity which impedes walking

Date of first enrolment
01/09/2012

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
Spain

Study participating centre
Departamento de Psicología de la Salud
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Sponsor information

Organisation
Spanish Ministry of Science and Innovation (Spain)

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Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Spanish Ministry of Economy and Competitiveness (Spain) (PSI 2011-25132)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/04/2014		Yes	No