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4-STEPS: a physical activity program for unexplained chronic fatigue

Submission date
21/09/2011

Recruitment status
No longer recruiting

Registration date
25/01/2012

Overall study status
Completed

Last Edited
09/03/2015

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Unexplained Chronic Fatigue is a serious medical condition, mainly characterized by severe unexplained fatigue, leading to impaired functioning and lower quality of life. Patients with CF often report that the fatigue is made worse by exercise, but avoiding physical activity in turn perpetuates fatigue and physical disability. It has therefore been recommended that CF patients engage in physical activity instead of refraining from it to manage their symptoms. We have developed a brief physical activity program for patients suffering from unexplained chronic fatigue, the '4-Steps to control your fatigue' (4-STEPS) program. The main aim of this study is to evaluate the effectiveness of the 4-STEPS program in promoting physical activity and in reducing fatigue.

Who can participate?
To take part you need to be aged 18-65, diagnosed with idiopathic chronic fatigue or chronic fatigue syndrome, and be fluent in spoken Portuguese.

What does the study involve?
If you take part, you will be invited to an individual interview, in which we will ask you to fill out a set of questionnaires. We will then randomly allocate you to receive either the physical activity program or standard care. If you are allocated to the physical activity group, in addition to standard care you will also receive:
1. Two face-to-face individual motivational interviews
2. A booklet to help you pursue their physical activity goal
3. Two brief telephone counseling sessions aimed at relapse prevention
4. A pedometer to register your physical activity (steps taken) on a daily basis
Three months and 12 months after the start of the study, we will invite all participants (both groups) for a follow-up interview. Again, we will ask you to fill out a set of questionnaires. Moreover, we will ask you to answer some questions about your personal goal and the processes involved in achieving your goal. If you are allocated to the physical activity group we will ask you to fill a questionnaire about your satisfaction with the program that will be delivered. If you allocated to the standard care group, once the study has finished we can send you the booklet, if you wish to receive this information.

What are the possible benefits and risks of participating?
There are no known risks to participants.

Where is the study run from?
The study takes place at several health care institutions and the Portuguese Fibromyalgia and Chronic Fatigue Syndrome Patients Association.

When is the study starting and how long is it expected to run?
Patients will be enrolled in the study between January 2011 and January 2012. Follow-up examinations will run until January 2013.

Who is funding the study?
This study is partly funded by the Portuguese Foundation for Science and Technology, by the Research Unit on Psychology and Health, ISPA-University Institute (Portugal) and by the Health Psychology Department, Leiden University (The Netherlands).

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
Four steps (4-STEPS): a self-regulation based intervention for physical activity adherence in chronic fatigue patients - a randomized controlled trial

Acronym
4-STEPS

Study objectives
To evaluate the efficacy of a self-regulation based intervention for physical activity adherence in chronic fatigue patients.

On 31/01/2012 the overall trial end date was changed from 30/01/2013 to 28/02/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee, North Regional Health Admnistration, December 2009, ref: 27.09

Study design
Multi-centre randomized controlled trial

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
Idiopathic chronic fatigue/chronic fatigue syndrome

Interventions
The control condition receives usual care.

The experimental condition receives the self-regulation based physical activity intervention. The intervention consists of:
1. Two face-to-face individual motivational interviews, aimed at exploring important health and life goals, increase participants motivation and confidence to be physically active and set a specific physical activity goal. These sessions have a 2 weeks interval and the duration of the sessions is approximately 1 hour.
2. A self-regulation booklet to help patients pursue their physical activity goal. The booklet contains information and activities related to the main self-regulation skills, such as goal efficacy, goal planning, goal setting, self-monitoring, emotional control, cope with problems and relapse prevention.

3. Two monthly brief telephone counseling sessions aimed at relapse prevention.
4. A pedometer to register physical activity (steps taken) on a daily basis.

Intervention Type
Behavioural

Primary outcome measure
Fatigue severity (CIS-R) measured at baseline, time 2 (3 months later) and time 3 (12 months later)

Secondary outcome measures
1. Self-regulation skills (SRSB questionnaire)
2. Autonomous/controlled motivation (TSRQ)
3. Self-efficacy (goal efficacy from the SRSB and barriers efficacy from Barriers efficacy scale)
4. Behavioral responses to illness (BRIQ)
5. Psychological symptoms (depression and anxiety subscales of the BSI)
6. Somatic symptoms (PHQ-15)
7. Quality of sleep
8. Social support
9. Physical activity (Yamax SW-200 pedometer and self-report)
10. Physical and mental functioning (SF-12 v.2)
11. ICF and CFS diagnosis (CDS-CFS symptom inventory)
12. Fatigue impact (adapted sub-scale of BPI); need for recovery (NFR scale)
13. Use of healthcare resources
Measured at baseline, time 2 (3 months later) and time 3 (12 months later)

Overall study start date
01/01/2011

Completion date
28/02/2013

Eligibility

Key inclusion criteria
1. Meeting the operationalised criteria for [idiopathic chronic fatigue/chronic fatigue syndrome (ICF/CFS) (CDC criteria)]
2. Aged between 18 and 65
3. Fluent in spoken Portuguese

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
82 (41 per group)

Key exclusion criteria
1. Presence of concurrent somatic condition which in the judgment of the physician could explain the fatigue symptoms
2. Presence of severe psychiatric disorder (e.g. psychotic illness)

Date of first enrolment
01/01/2011

Date of final enrolment
28/02/2013

Locations

Countries of recruitment
Netherlands

Portugal

Study participating centre
PO Box 9555
Leiden
Netherlands
2300 RB

Sponsor information

Organisation
Foundation for Science and Technology (Fundação para a Ciência e Tecnologia) (Portugal)

Sponsor details
Av. D. Carlos I
126
Lisboa
Portugal
1249-074

Sponsor type
Government

ROR

https://ror.org/00snfqn58

Funder(s)

Funder type
Government

Funder Name
Foundation for Science and Technology (Fundação para a Ciência e Tecnologia) (Portugal) (SFRH /BD/47579/2008)

Alternative Name(s)
Foundation for Science and Technology, Portuguese Science and Technology Foundation, Fundacao para a Ciencia e a Tecnologia, FCT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Portugal

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?
Results article	results	01/04/2015		Yes	No