

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

<b>Submission date</b> 21/09/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 25/01/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/03/2015	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> 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?

Marta Marques

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## Contact information

### Type(s)

Scientific

### Contact name

Prof Stan Maes

### Contact details

PO Box 9555

Leiden

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## Additional identifiers

### Protocol serial number

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 Administration, December 2009, ref: 27.09

### **Study design**

Multi-centre randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

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)

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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)

**ROR**

<https://ror.org/00snfq58>

## 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)**

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

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Portugal

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2015		Yes	No