Ambulatory feedback on physical activity to CFS patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33092

Source
ToetsingOnline

Brief title
Ambulatory feedback on physical activity to CFS patients

Condition

- Other condition

Synonym
chronic fatigue syndrome, myalgic encephalomyelitis

Health condition

chronische vermoeidheidssyndroom

Research involving
Human

Sponsors and support

Primary sponsor: Roessingh Research and Development
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: chronic fatigue syndrome, comparison, feedback, physical activity

Outcome measures

Primary outcome

The primary outcome measure is the physical activity level measured with an accelerometer.

Firstly, it will be investigated if the average physical activity pattern through the day during the distribution of feedback will come closer to the stipulated norm. Secondly, it will be investigated if the distribution of feedback tips will lead to a changed physical activity level directly after the distributed feedback tip.

Secondary outcome

Secondary parameters are:

- On the PDA the physical activity level will be scored subjectively on a visual analog scale from 0 till 10, and the questions about the experience and expectation with the feedback tips will be answered with 'yes' or 'no'.

- The behavioral intention/motivation to follow the given feedback in order to get more balance in the physical activity pattern and determinants which are of influence on the behavioral intention/motivation will be evaluated by means of self drafted questionnaire with items scored on a 7 point scale.

- The physical activity level will be measured subjectively by means of the

Baecke questionnaire

- The users satisfaction and usability will be measured with an existing

questionnaire containing 9 items scored on a 5 point scale

- The extent of fatigue will be measured with the CIS20 questionnaire

- Demographical data will be obtained towards age, gender, work status, length

of complaints, diagnose of CFS and level of education.

Study description

Background summary

The chronic fatigue syndrome (CFS) is characterized by persistent or relapsing fatigue lasting for at least 6 months and other additional symptoms. CFS patients do often have a disturbed balance in their pattern of physical activities. To combat a disturbed balance, a feedback system has been developed which provides feedback on physical activities (ABF) carried out in the home situation of the CFS patient. The expectation is that use of the ABF system in combination with cognitive behavioral therapy will have additional therapeutic effect as measured in terms of fatigue and physical functioning. In the distribution of ambulatory feedback on physical activities, little research has been done in the most optimal form of feedback distribution. An important starting point is the way the feedback will be based on. This research will study if feedback based on a comparison with oneself in time (temporal comparison) will be act on more than feedback based on a comparison with a social norm group (social comparison).

Study objective

The primary goal is to explore if CFS patients will act on feedback by changing their physical activity pattern. Furthermore, differences in acting on feedback will be investigated between feedback based on 'temporal comparison' versus 'social comparison'.

Secondary will be investigated:
- Experiences and expectations about the feedback tips
- Evaluation of the feedback system by means of users satisfaction and usability.
- Changes in intention/motivation to achieve a balanced physical activity level by the distribution of ABF.

- Changes in awareness of the own physical activity level through the distribution of ABF

Study design

The study design is a randomized prognostic cohort. One group will receive feedback based on a comparison of their own actual physical activity level with a healthy norm (social comparison), and the other group will receive feedback based on a comparison of their own actual physical activity level with a norm based on their own baseline measurement (temporal comparison).

Intervention

The intervention will consist of the distribution of ambulatory feedback on the physical activity level by using of a microcomputer of pocket size (PDA) and an accelerometer. The intervention on the physical activity level shall be given during a 2 week period in the home situation.

Study burden and risks

The burden for CFS patients consists of the examination of questionnaires, a baseline measurement during a one week period and feedback on physical activities during a 2 week period. Participation in this study could be experienced as aggravating and therefore influence the CFS complaints negatively.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Persistent or relapsing unexplained chronic fatigue lasting 6 or more consecutive months (Fukuda et al, 1994);Age between 18-65 years

Exclusion criteria

In treatment with (pre)clinical hospitalisation for complaints of chronic fatigue during participation in the trial;Wheelchair bounded patients;Pathological disorder diagnosed by general practitioner or medical specialist, which could explain the complaints of chronic fatigue;Insufficient control of the Dutch language

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	11-01-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	16-09-2009
Application type:	First submission
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26523
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL29029.044.09
OMON	NL-OMON26523