Ambulatory feedback on physical activity to CFS patients.

Gepubliceerd: 17-07-2009 Laatst bijgewerkt: 19-03-2025

CFS patient will act on feedback with temporal comparison more than feedback with social comparison.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26523

Bron
NTR

Verkorte titel
ABF in CFS

Aandoening

chronische vermoeidheidssyndroom, myalgische encephalomyelitis

chronic fatigue syndrome, myalgic encephalomyelitis

Ondersteuning

Primaire sponsor: Roessingh Research and Development b.v.
Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

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).

Objective of the study:

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:

1. Experiences and expectations about the feedback tips;

2. Evaluation of the feedback system by means of users satisfaction and usability;

3. Changes in intention/motivation to achieve a balanced physical activity level by the distribution of ABF;

4. 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).

Study population:

Patients between 18 and 65 years from the 1st and 2nd line in health care with complaints of chronic fatigue of at least 6 months will be approached to participate in the study.

Intervention (if applicable):

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.

Primary study parameters/outcome of the study:

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.

Secundary study parameters/outcome of the study (if applicable):

Secondary parameters are:

1. 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';

2. 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;

3. The physical activity level will be measured subjectively by means of the Baecke questionnaire;

4. The users satisfaction and usability will be measured with an existing questionnaire containing 9 items scored on a 5 point scale;

5. The extent of fatigue will be measured with the CIS20 questionnaire;

6. Demographical data will be obtained towards age, gender, work status, length of complaints, diagnose of CFS and level of education.

Doel van het onderzoek

CFS patient will act on feedback with temporal comparison more than feedback with social comparison.

Onderzoeksopzet

1. Intake;

2. Baseline measurement: 1 week period;

3. T1: questionnaires;

4. Intervention: 2 week period;

5. T2: questionnaires.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Persistent or relapsing unexplained chronic fatigue lasting 6 or more consecutive months (Fukuda et al, 1994);

2. Age between 18-65 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. In treatment with (pre)clinical hospitalisation for complaints of chronic fatigue during participation in the trial;

2. Wheelchair bounded patients;

3. Pathological disorder diagnosed by general practitioner or medical specialist, which could explain the complaints of chronic fatigue;

4. Insufficient control of the Dutch language.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2009
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-07-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33092
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1804
NTR-old	NTR1914
CCMO	NL29029.044.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33092

Resultaten

Samenvatting resultaten
N/A