Ambulatory activity-based feedback (ABF)

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It is expected that the CFS patient gets more insight in his or her physical activity pattern, intentions develops to change the behaviour, and really changes the behaviour resulting in a reduction of the CFS complaints.

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

Samenvatting

ID

NL-OMON20820

Bron
NTR

Verkorte titel
Ambulatory activity-based feedback (ABF)

Aandoening

Chronic fatigue syndrome / myalgic encephalomyelitis chronische vermoeidheidssyndroom / myalgische encephalomyelitis

Ondersteuning

Primaire sponsor: ZonMw
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome parameters are:

- Experienced fatigue
- Physical functioning

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

The chronic fatigue syndrome (CFS) is characterized by chronic 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. The current treatment for CFS in rehabilitation centre 'Het Roessingh' consists of cognitive behavioural therapy (CBT). The aim of this study is to investigate the additional value of 'ambulant physical activity based feedback (ABF)' to the standard rehabilitation program for CFS. It is expected that the CFS patient gets more insight in his or her physical activity pattern, intentions develops to change the behaviour, and really changes the behaviour resulting in a reduction of the CFS complaints.

Objective of the study:

The primary goal is to investigate if CBT plus ABF has an additional reducing effect on experienced fatigue and an additional positive effect on physical functioning, in comparison to CBT alone. Secondary goals are to investigate if CBT plus ABF has additional reducing effects on experienced disabilities and social functioning, and an additional positive effect on psychological determinants in comparison to CBT alone. Furthermore, the influence of ABF on the awareness of the physical activity level of the CFS patient will be studied. Also, a change in the behavioural intention to achieve a balance in the physical activity level will be studied, and if ABF really is obeyed. Finally, the feedback system will be evaluated by means of usability satisfaction, usefulness and utility.

Study design:

The study design is a 'randomized controlled trial (RCT)' in which the intervention group receives the standard treatment (CBT) plus ABF and the control group the standard treatment (CGT) alone.

Study population:

The study population shall consist of CFS patients with an age of 18 years or older and be eligible for the group treatment of cognitive behavioural therapy in the pain division of 'Het Roessingh'.

Intervention:

The intervention will consist of the distribution of ambulant feedback on the physical activity level by using a microcomputer of pocket size and an accelerometer. The intervention on the physical activity level shall be given in 4 blocks of 9 days in the home situation, dispersed between the weeks of treatment with clinical admission in 'Het Roessingh'.

Primary study parameters:

The primary outcome parameters are experienced fatigue and physical functioning.

Secundary study parameters:

Secondary outcome parameters are:

- Outcome parameters which measure perceived limitations, social functioning, self efficacy and catastrophizing. These are measured by means of 'patient specific complaints (PSC), ‘self efficacy scale (SES)’ and the ‘Jacobsen fatigue catastrophising scale (J-FCS)’.

- Behavioural determinants, which could influence the actual compliance to the given feedback to achieve a balance in the physical activity pattern, will be evaluated by means of a self composed questionnaire.

- The physical activity level will be measured objectively and subjectively by means of an accelerometer and the Baecke questionnaire, respectively.

- The physical activity level, expectancies to and experiences with the feedback will be scored with a number between 1 till 10 on the PDA.

Usability satisfaction, usability and utility of the feedback system will be evaluated with a self composed questionnaire (only in the intervention group).

Other outcome measures are:

- Demographic characteristics of the participants (age, gender, work status, sick leave/disability pension, civilian status, duration of complaints, education level, and usage of medicines) will be obtained by means of the standard intake questionnaire in favour of the treatment.

- Psychological condition will be evaluated during the intake by means of the 'SCL90'.

- Causal attributions (CAL) will be evaluated during the intake by means of the 'causal attribution list (CAL)'.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The burden for CVS patients consists of the examination of extra questionnaires, the baseline measurement and (if allocated) the intervention with the feedback system. The potential advantage of the intervention is that CFS patients could achieve more balance in their daily physical activity pattern, resulting in a reduced experience of their CFS complaints. It is not possible to preclude the participation as aggravating. However, the potential disadvantages of the research do not counterbalance the potential advantages the research could bring.

Doel van het onderzoek

It is expected that the CFS patient gets more insight in his or her physical activity pattern, intentions develops to change the behaviour, and really changes the behaviour resulting in a reduction of the CFS complaints.

Onderzoeksopzet

T0 Intake (up to 3 months before start of treatment)

T1 Baseline (start treatment)

T2 End measure (9 weeks after start of treatment)

T3 Follow up (6 months after start of treatment)

Onderzoeksproduct en/of interventie

The intervention will consist of the distribution of ambulant feedback on the phyical activity level by using a microcomputer of pocket size and a accelerometer.
The intervention on the physical activity level shall be given in 4 bloks of 9 days in the home

situation, dispersed between the weeks of treatment with clinical admission in 'Het Roessingh'.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Referred by a physician with the diagnose CFS

2. CIS20 subscale fatigue >35

3. Age of 18 years or older

4. Willing to and capable, to participate in the clinical rehabilitation program

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Current alcohol or drug addiction

2. Enforced or negative motivation to participate in the rehabilitation program (for instance, focussed on the acquirement of facilities)

3. CVS patiënt is focussed on another diagnosis related to the complaints of fatigue

4. Current lawsuit which could hamper the revalidation proces

5. Dominant psychopathology (conversion, psychosis, anxiety, serious depression)

6. Insufficient control of the Dutch language

7. Extensive cognitive disturbances (diagnosed by a psychologist or rehabilitation physician)

8. Serious psychosocial problems with an acute nature (for instance; decease of a relative, divorce, etc.)

9. CFS patiënt is insufficient to instruct and/or not capable to participate in a group)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	10-11-2008
Aantal proefpersonen:	78
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-10-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 32464
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1452
NTR-old	NTR1513
CCMO	NL24984.044.08
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON32464

Resultaten

Samenvatting resultaten
N/A