

The efficacy of cognitive behavior therapy and aerobic exercise training for decreasing experienced fatigue in patients with facioscapulohumeral dystrophy.

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Aerobic exercise therapy (AET) and cognitive behavioral therapy (CBT) are hypothesized to be both more effective in improving activity level and, with that, decreasing experienced fatigue of FSHD patients compared to the usual care. The maintenance...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23621

Bron

NTR

Verkorte titel

FACTS-2-NMD

Aandoening

facioscapulohumeral dystrophy, FSHD, facioscapulohumerale dystrofie, muscular dystrophy, muscle disease, spierziekten, spierdystrofie, neuromuscular disease, neuromusculaire aandoeningen

Ondersteuning

Primaire sponsor: Radboud University Medical Centre department of Rehabilitation

Overige ondersteuning: ZonMW/ Prinses Beatrix Fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Experienced fatigue

Toelichting onderzoek

Achtergrond van het onderzoek

In facioscapulohumeral dystrophy (FSHD) muscle function is impaired and declines over time. Currently there is no effective therapeutic treatment available for FSHD. Loss of muscle strength contributes to experienced fatigue through a lower level of physical activity. Fatigue and physical inactivity determine social dependency and loss of participation. Therefore, to decrease experienced fatigue and improve quality of life, two distinctly different therapeutic approaches can be followed: aerobic exercise training (AET) to maintain functional capacity or a cognitive-behavioral approach (CBT) to stimulate an active life-style yet avoiding excessive physical strain. There is preliminary evidence for the effectiveness of aerobic exercise in FSHD. CBT has been proven effective in chronic fatigue syndrome and post-cancer fatigue. AET and CBT are hypothesized to be both more effective in improving activity level and, with that, decreasing experienced fatigue of FSHD patients compared to the usual care. The maintenance of the beneficial effects of CBT may be longer than those of AET, because the changes in activity level are achieved more intrinsically.

Doel van het onderzoek

Aerobic exercise therapy (AET) and cognitive behavioral therapy (CBT) are hypothesized to be both more effective in improving activity level and, with that, decreasing experienced fatigue of FSHD patients compared to the usual care. The maintenance of the beneficial effects of CBT may be longer than those of AET, because the changes in activity level are achieved more intrinsically.

Onderzoeksopzet

- at baseline $t=0$
- after the treatment period $t = 4$ months
- after three months follow-up $t = 7$ months

- after 6 months follow-up t = 10 months

Onderzoeksproduct en/of interventie

Cognitive behavioral therapy, 1-hour session, once a week in the expert centre of chronic fatigue, during 16 weeks.

OR aerobic exercise therapy, 1-hour session, three times a week, one session at a rehabilitation centre, two sessions at home during 16 weeks.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

1. Age between 18 and 70 years
2. A life-expectancy longer than one year
3. Suffering from severe experienced fatigue (i.e. a score on the CIS-fatigue ≥ 35)
4. Ability to walk independently (ankle-foot orthoses and canes are accepted)
5. Being able to exercise on a bicycle ergometer
6. Being able to complete the intervention

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Cognitive impairment
2. Insufficient mastery of the Dutch language
3. Disabling co-morbidity interfering with the intervention programs or influencing outcome parameters
4. Pregnancy
5. Use of psychotropic drugs (except simple sleeping medication)
6. Severe cardiopulmonary disease (chest pain, arrhythmia, pacemaker, cardiac surgery, severe dyspnoea d' effort, emphysema)
7. Epileptic seizures
8. Poorly regulated diabetes mellitus or hypertension
9. Clinical depression, as diagnosed with Beck Depression Inventory for primary care (BDI-PC) (Arnau et al. 2001) (Beck et al. 1997)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2009
Aantal proefpersonen:	75
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	16-09-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1387

Register

NTR-old

Ander register

ISRCTN

ID

NTR1447

ZonMW : 89000003

ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A