# Behandeling van patiënten met chronisch vermoeidheidssyndroom met gedoseerde oefentherapie en/of cognitieve gedragstherapie.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON20281

**Source**
NTR

**Brief title**
CFS-ReAct

**Health condition**

Chronic fatigue syndrome
Chronisch vermoeidheidssyndroom

### Sponsors and support

**Primary sponsor:** Isala klinieken
**Source(s) of monetary or material Support:** Isala klinieken, afdeling sportgeneeskunde

### Intervention

### Outcome measures

**Primary outcome**

CIS-20 questionnaire (fatigue severity) at 6 months.

**Secondary outcome**

1. CIS-20 questionnaire (fatigue severity) at baseline and 3 months;

2. SCL-90-R questionnaire (psychiatric symptom) at baseline, 3 and 6 months;

3. RAND-36 questionnaire (functional impairment) at baseline, 3 and 6 months;

4. Maximal oxygen uptake capacity at baseline, 3 and 6 months;

5. EuroQol 5D (health outcome) at baseline, 3 and 6 months;

6. Healthcare consumption and economic costs questions at baseline, 3 and 6 months.

# Study description

**Background summary**

Both cognitive behaviour therapy and graded exercise therapy are proven effective therapies that can improve outcome, however both therapies are only moderately effective. The hypothesis is that a combination of graded exercise training and cognitive behavioural therapy is more effective than each of these therapies alone.

Study design:

Prospective intervention study.

Study population:

Patients with chronic fatigue syndrome, 18-65 yr old. An internal physician will refer patients eligable for this study to the investigator. All patients will be recruted in the Netherlands.

Intervention:

Group one receives graded exercise training by a sports physician, group two receives cognitive behavioural therapy by a clinical physchologist and group three receives both

cognitive behaviour therapy and graded exercise therapy by both a sports physician and a clinical psychologist.

Main study parameters/endpoints:

The main study parameter will be fatigue, the main symptom in chronic fatigue syndrome, measured by a validated questionnaire (CIS-20) at 6 months treatment. Secondary endpoints will be fatigue at 3 months treatment, psychiatric symptoms, functional impairment, physical condition, work participation and medical consumption at 3 and 6 months treatment.

**Study objective**

The hypothesis is that a combination of graded exercise training and cognitive behavioural therapy is more effective than each of these therapies alone.

**Study design**

Baseline, 3 and 6 months.

**Intervention**

Graded exercise therapy:

The duration is gradually increased to 3 times 30 minutes in 6 months. The treatment starts with an intake interview followed by 3 individual sessions of 1 hours in 6 months.

Cognitive behaviour therapy:

The treatment starts with an intake interview followed by 14 individual sessions of 2 hours in 6 months and 2 follow-up sessions.

Combined Graded exercise therapy and Cognitive behaviour therapy:

The treatment starts with an intake interview followed by 10 to 12 individual sessions of 2 hours and 2 follow-up sessions with the psychologist and 3 sessions with the sports physician of 1 hour in 6 months.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Meet CDC-94 CFS criteria;

2. Age: 18-65 yr;

3. CIS-20 score > 35 on subscale fatigue.

## Exclusion criteria

1. Not able to understand, speak, read or write Dutch sufficiently;

2. Severe mental disorder or severe physical co-morbidity, impeding physical exercise;

3. Patient is currently engaged in a legal procedure concerning disability-related financial benefits;

4. Previously treated with GET or CBT for CFS.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-12-2011 |
| Enrollment: | 90 |
| Type: | Actual |

## IPD sharing statement

**Plan to share IPD:** Undecided

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 14-12-2011 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL3066 |
| NTR-old | NTR3214 |
| CCMO | NL32433.075.11 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A