# Group training for patients with Unexplained Physical Symptoms.

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The cognitive behavioural group training: 1. increases quality of life; 2. decreases direct costs due to health care utilization; 3. decreases indirect costs due to productivity loss; 4. decreases overall psychological distress.

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

## Samenvatting

### ID

NL-OMON25959

**Bron**
Nationaal Trial Register

**Verkorte titel**
TOLK (Training Onverklaarde Lichamelijke Klachten)

**Aandoening**

1. Unexplained Physical Symptoms
2. Undifferentiatied Somatoform Disorder
3. Chronic Pain Disorder
4. Somatoform Disorders

Onverklaarde Lichamelijke Klachten
Ongedifferentieerde Somatoforme Stoornis
Pijnstoornis
Somatoforme Stoornissen

### Ondersteuning

**Primaire sponsor:** drs. J. Lamé, Board of Directors
Riagg Rijnmond
Westhavenkade 85
3133 AV Vlaardingen

The Netherlands

Prof. dr. J. Passchier, supervisor of the Ph.D.student
Erasmus MC
Department of Medical Psychology and Psychotherapy
PO Box 2040
3000 CA Rotterdam
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**Overige ondersteuning:** self-financing research

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

The primary outcome is effectiveness of the group training. This effectiveness is operationalised with quality of life. Quality of life is measured with the 36-item Short Form Health Survey (SF-36), which is administered at baseline, after the group therapy/waiting list, 3 months after the group training and one year after the group training.

# Toelichting onderzoek

### Achtergrond van het onderzoek

After medical examination, physicians classify 20 to 74% of patients' symptoms as Unexplained Physical Symptoms (UPS). When UPS persists, cognitive-behavioural therapy may be considered. The cognitive-behavioural therapy based on the consequences model, in which various forms of psychosocial stress are labelled as consequences rather than causes of UPS, has shown to be more acceptable for patients than a therapy based on a causal model. Eighty percent of the patients with UPS accepted an individual therapy based on this model and effectiveness has been shown when applied in secondary medical care, while only 10% of the mental health referrals leads to treatment. However, when the applicability of this model is examined in primary medical care, the high acceptance showed a drastic drop. We modified the implementation of the consequences model into a standardized training program conducted by Riagg Rijnmond, a mental health institution. In this modified program, we standardised the protocol for the individual therapy suitable for patients' personal needs into a group training, in which the consequences model is used bottom-up instead of top-down. We assume that this innovative implementation is acceptable to patients, as it legitimates the existence of consequences, in other words, the patients are exonerated. The objective of this randomised controlled study is to assess applicability and (cost-)effectiveness of this particular cognitive behavioural group training. If we show that this group training is applicable and (cost-)effective, more patients with UPS could be served on a

(cost-)effective basis.

**Doel van het onderzoek**

The cognitive behavioural group training:

1. increases quality of life;

2. decreases direct costs due to health care utilization;

3. decreases indirect costs due to productivity loss;

4. decreases overall psychological distress.

**Onderzoeksopzet**

T1: baseline assessment;

(inclusion: up to September 2008);

T2: assessment after training/waiting list;

T3: assessment three month after training;

T4: assessement one year after training.

**Onderzoeksproduct en/of interventie**

The experimental condition is a cognitive behavioural group training consisting of thirteen ad verbatim protocollised weekly sessions of two hours each.

The control condition is a waiting list.

# Contactpersonen

## Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age between 18 and 65 years;

2. being able to speak, read and write Dutch;

3. at least 6 months duration of the Unexplained Physical Symptoms (UPS);

4. UPS can be classified as DSM-IV-TR Undifferentiated Somatoform Disorder or Pain Disorder;

5. written informed consent.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Undifferentiated Somatoform Disorder or Chronic Pain Disorder is not the principal DSM-IV-

TR classification;

2. UPS is not the principal somatic disease;

3. handicaps like cognitive mental impairment and blindness hinder the patient to participate in the training.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Actieve controle groep |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 17-02-2005 |
| Aantal proefpersonen: | 140 |
| Type: | Werkelijke startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 01-01-2009 |
| 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 | NL1538 |
| NTR-old | NTR1609 |
| Ander register | METC Erasmus MC : MEC-2004-191 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

## Resultaten

**Samenvatting resultaten**
N/A