Group training for patients with Unexplained Physical Symptoms.

No registrations found.

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

Summary

ID

NL-OMON25959

Source
Nationaal Trial Register

Brief title
TOLK (Training Onverklaarde Lichamelijke Klachten)

Health condition

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

Onverklaarde Lichamelijke Klachten
Ongedifferentieerde Somatoforme Stoornis
Pijnstoornis
Somatoforme Stoornissen

Sponsors and support

Primary 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
The Netherlands
Source(s) of monetary or material Support: self-financing research

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The secondary outcomes are:

1. cost-effectiveness;

2. overall psychological distress.

1. Cost-effectiveness consists of direct costs due to health care utilization and indirect costs due to productivity loss. Cost-effectiveness is measured with the Trimbos/iMTA Questionnaire for Costs associatied with Psychiatric Illness (TiC-P). The TiC-P is administered at baseline, after the group therapy/waiting list, 3 months after the group training and one year after the group training.

2. Overall psychological distress consists of a broad range of physical and psychological symptoms and theirs intensity. Overall psychological distress is measured by the Symptom Checklist Revised (SCL-90-R). The SCL-90-R is administered at baseline, after the group therapy/waiting list, 3 months after group training and one year after the group training.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

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):	17-02-2005
Enrollment:	140

Type: Actual

Ethics review

Positive opinion
Date: 01-01-2009

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	NL1538
NTR-old	NTR1609
Other	METC Erasmus MC : MEC-2004-191
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A