Evaluation of a tailored psychological intervention as component of multidisciplinary treatment for patients with Systemic Sclerosis and elevated levels of distress

Published: 03-02-2010
Last updated: 15-05-2024

The aim of the present study is to evaluate the efficacy of a protocol for cognitive behavioral treatment (CBT) of psychological distress as a component of multidisciplinary treatment in SSc on psychological distress.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Connective tissue disorders (excl congenital)
Study type	Interventional

Summary

ID

NL-OMON33104

Source
ToetsingOnline

Brief title
Psychological intervention for patients with Systemic Sclerosis

Condition

- Connective tissue disorders (excl congenital)
- Mood disorders and disturbances NEC

Synonym
Scleroderma, Systemic Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: interne onderzoeksgelden

Intervention

Keyword: Distress, Intervention, Psychology, Systemic Sclerosis

Outcome measures

Primary outcome

Primary outcome measure is the percentage of patients scoring above the cut-off score of psychological distress after the intervention, compared with controls.

Secondary outcome

Short measures of appearance self-esteem, fear of progression, pain and fatigue are completed before, during and after the intervention in addition to a short measure of depressed mood. Furthermore, after the intervention and at follow-up, measures of physical functioning, coping and cognitions will be completed.

Study description

Background summary

Systemic Sclerosis or scleroderma (SSc) has serious negative consequences for the patient. Elevated levels of depression are observed in 36 to 65% of the patients. There is a growing recognition that these psychological problems should be treated, in addition to regular and ongoing medical and paramedical treatment. Only recently it has become clear which stressors are most important in SSc, and which psychological mechanisms are related to psychological distress in SSc. Therefore, these new insights have cleared the way for the development of integrated, systematic multidisciplinairy interventions for SSc.

Study objective

The aim of the present study is to evaluate the efficacy of a protocol for cognitive behavioral treatment (CBT) of psychological distress as a component of multidisciplinary treatment in SSc on psychological distress.

Study design

The effect of the psychological component of multidisciplinary treatment will be evaluated in a controlled trial. In addition, a series of single-case experiments will be conducted.

Intervention

For the multidisciplinary intervention, available interventions are integrated and standardised into an individual, modular and tailored treatment programme. The psychological intervention consists of 11 individual sessions of cognitive behavioural therapy. Psychological treatment modules are developed for the most salient stressors in SSc. Together, patient and therapist will choose which modules are relevant for the individual patient. In addition, individual physical therapy, occupational therapy and/or specialized nurse care will bebe provided using evidence- based methods and best practice guidelines.

Study burden and risks

For this study, patients are invited to an integrated, multidisciplinary intervention. The burden of the study contains completing questionnaires (two questionnaires of 1 tot 1,5 hours per questionnaire and 45 short questionnaires of 2-5 minutes each). Questionnaires are used of which it is plausible that they are not experienced as insulting or incriminatory , so the burden of completing the questionnaires will only contain time.

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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. High distress at two consecutive assessments (6 months between assessments): CES-D >= 16.
2. High score (>0.5 SD above average of cohort) on at least one of the following questionnaires: Appearance Self Esteem, Fear of Progression, Pain or Fatigue.

Exclusion criteria

1. Serious psychiatric co-morbidity
2. Major organ failure: (chronic) organ insufficiency, that needs major intervention like dialysis or lung transplantation.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-10-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	03-02-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23309
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL28603.091.09
OMON	NL-OMON23309