Evaluation of the intervention SCIN (Scleroderma Interdisciplinary).

No registrations found.

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

Summary

ID

NL-OMON23309

Source
NTR

Brief title
SCIN

Health condition

Scleroderma, Depression.

Sponsors and support

Primary sponsor: Reumacentrum Sint Maartenskliniek Nijmegen
Source(s) of monetary or material Support: Reumacentrum Sint Maartenskliniek Nijmegen

Intervention

Outcome measures

Primary outcome

The primary outcome measure is depression. This is measured using a combined score (mean) of two VAS questionnaires measuring depression. These measures will be completed twice a week before, during and after the intervention to assess whether this variable change over time.

Secondary outcome

Data will be collected in two different manners:

1. 8 Visual Analogue Scales;

2. A set of questionnaires.

The secondary outcome measures are visual analogue scales of Appearance Self Esteem (ASE), Fear of Progression (FoP), pain and fatigue.

The set of questionnaires consists of 9 questionnaires on coping, physical functioning, depression, anxiety, ASE and FoP.

Study description

Background summary

Scleroderma 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. Recently it became clear that Appearance Self Esteem and Fear of Progression are important stressors in scleroderma. The aim of this study is to evaluate the efficacy of a protocol for cognitive behavioral treatment (CBT) of psychological distress as a component of multidisciplinary treatment in scleroderma on psychological distress. This will be evaluated using a multiple-baseline single-case design.

Study objective

After receiving the intervention (SCIN), the depressive symptoms in the scleroderma patients will be decreased.

Study design

The 8 VAS questionnaires will be completed twice a week, starting after the intake. In total the VAS questionnaires will be completed 47 times.

The set of questionnaires will be completed at timepoints T0 (before intervention), T1 (after intervention) and T2 (6 months after intervention).

Intervention

The intervention consists of 10 CBT sessions in 14 weeks. The overall goal is decreasing

depression. Furthermore the psychological intervention will be individual, modular and tailored to the patients' most important stressor (ASE or FoP). In addition, individual physical therapy, occupational therapy and/or specialized nurse care will be given using evidence-based methods and best practice guidelines.

Contacts

Public
Postbus 9011
Linda Kwakkenbos
Nijmegen 6500 GM
The Netherlands
+31 (0)24 3528123
Scientific
Postbus 9011
Linda Kwakkenbos
Nijmegen 6500 GM
The Netherlands
+31 (0)24 3528123

Eligibility criteria

Inclusion criteria

1. Scleroderma, diagnosed by a rheumatologist following the ACR criteria;

2. High distress at two consecutive assessments (6 months between assessments): Cut-off: CES-D >= 16;

3. High score (> 0.5 SD above average of cohort) on at least one of the following questionnaires: Appearance Self Esteem (ASE), Fear of Progression (FoP);

4. One-way travel time to Sint Maartenskliniek Nijmegen less than 1 hour.

Exclusion criteria

1. Life expectancy less than 1 year;

2. Acute serious complications;

3. Serious psychiatric co-morbidities;

4. Other serious co-morbidities;

5. Insufficient knowledge of the Dutch language;

6. Major organ failure.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2010
Enrollment:	12
Type:	Actual

Ethics review

Positive opinion

Date:	28-09-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33104
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2427
NTR-old	NTR2536
CCMO	NL28603.091.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33104

Study results

Summary results
Kwakkenbos L, Willems LM, van den Hoogen FHJ, van Lankveld WGJM, Beenackers H, van Helmond TF, Becker ES, van den Ende CHM. Cognitive-behavioural therapy targeting fear of progression in an interdisciplinary care program: a case study in systemic sclerosis. J Clin Psychol Med Settings. In press.