Evaluation of the intervention SCIN (Scleroderma Interdisciplinary).

Gepubliceerd: 28-09-2010 Laatst bijgewerkt: 15-05-2024

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

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

Samenvatting

ID

NL-OMON23309

Bron
NTR

Verkorte titel
SCIN

Aandoening

Scleroderma, Depression.

Ondersteuning

Primaire sponsor: Reumacentrum Sint Maartenskliniek Nijmegen
Overige ondersteuning: Reumacentrum Sint Maartenskliniek Nijmegen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-11-2010
Aantal proefpersonen:	12
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	28-09-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33104
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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.