Cognitive-behavioural intervention in primary care for undifferentiated somatoform disorder

Gepubliceerd: 14-07-2014 Laatst bijgewerkt: 18-08-2022

We expect that the intervention will improve physical functioning, will be more cost-effective, and will reduce somatisation, depression and anxiety symptoms.

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

Samenvatting

ID

NL-OMON24561

Bron
NTR

Verkorte titel
CIPRUS

Aandoening

medically unexplained physical symptoms (MUPS), undifferentiated somatoform disorder (USD)

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary clinical outcome is the development in physical functioning along the total follow-up period as measured by the physical component summary (PCS) of the RAND-36.

The primary outcome measure for the economic evaluation is quality of life as measured by the EuroQol/EQ-5D. Direct and indirect costs will be assessed with the TIC-P 20 and data on health care use extracted from the electronic medical records of the GPs. Direct costs will be based on the Dutch standard cost prices and the indirect costs will be estimated based on the average of the population.

Toelichting onderzoek

Achtergrond van het onderzoek

Cognitive-behavioural (CB) interventions decrease undifferentiated somatoform disorder (USD) symptoms and improve functioning in secondary care. To date it is, however, unknown whether a short-term CB intervention for USD, provided by a primary care mental health care practitioner (MHNP) is (cost-)effective compared to usual care.

In a cluster randomised controlled trial, with randomisation on MHNP level, 212 adult USD patients will be assigned to either the intervention or control group. The intervention group will be offered a short-term CB intervention in addition to usual GP care. The treatment rationale is the consequences model focusing on the consequences or problems that arise due to the USD. In 6 sessions patients will receive psycho-education, problem solving techniques, activity scheduling and relaxation techniques, to learn to cope with identified problems. The control group will receive usual GP care. The intervention aims to enhance physical (role) functioning as measured by the physical component summary of the RAND-36. An economic evaluation will also be conducted with quality of life as a primary outcome measure, assessed by the EQ-5D. Direct and indirect costs will be assessed with the TIC-P. Secondary outcomes include somatisation (PHQ-15) and symptoms of depression and anxiety (HADS). Assessments will be taken at 0, 2, 4 and 12 months.

Recruitment started in August 2015 and was completed March 2017. Follow-up measurements were completed in April 2018.
For main results see PubMed: PMID: 31285038

Doel van het onderzoek

We expect that the intervention will improve physical functioning, will be more cost-effective, and will reduce somatisation, depression and anxiety symptoms.

Onderzoeksopzet

0, 2, 4 and 12 months after baseline

Onderzoeksproduct en/of interventie

Mental health nurse practitioners (MHNP) will offer intervention patients a short structured intervention based on cognitive-behavioural (CB) principles, in addition to usual GP care, to teach participants how to cope with the consequences of their symptoms. In up to 6 sessions patients will be provided with psycho-education, problem solving techniques, relaxation techniques, and activity scheduling. The consequences model of somatoform complaints has successfully been used in previous Dutch intervention studies and focuses on the consequences or problems that arise due to somatoform complaints and on their aggravating effects, rather than on causes of somatoform complaints. This model will be used as the treatment rationale. The focus is not so much on treating the symptoms, but rather on producing beneficial changes in (physical) functional outcome and quality of life. The MHNPs provide the CB approach of problem solving treatment (PST) as a means to learn to tackle and cope with the identified consequences. PST teaches problem-solving styles and skills. Several steps to problem solving have been described which will be practised during the sessions: 1) explanation of treatment rationale and ‘contracting’, 2) identification and clarification of problems, 3) the setting of clear goals, 4) formulation of alternative solutions, 5) selection of preferred solutions, 6) clarification of the necessary steps to implement solutions, and 7) evaluation of progress. In addition, activity scheduling and progressive relaxation techniques will be provided as these are important general features of CBT for somatoform complaints.

Patients in the control group will not be offered a specific additional intervention other than the care they would usually receive from the GP.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) Being 18 years of age or older

2) Meeting the criteria for undifferentiated somatoform disorder according to DSM IV:

a) The presence of 1 or more medically unexplained physical symptoms

b) The symptoms last at least 6 months

c) The symptoms significantly impair functioning/quality of life

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Having a medical disorder that explains the symptoms

2) Having a severe psychiatric disorder (i.e. psychosis-related disorders, dementia and bipolar disorder)

3) Having a handicap such as cognitive mental impairment and/or blindness

4) Being unable to speak or read Dutch

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2014
Aantal proefpersonen:	212
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	14-07-2014
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	NL4543
NTR-old	NTR4686
Ander register	ZonMw Programma Doelmatigheid : ZonMw dossier number 80-83700-98-42070

Resultaten

Samenvatting resultaten
Design paper: Sitnikova K, Leone SS, Zonneveld LNL, van Marwijk HWJ, Bosmans JE, van der Wouden JC, van der Horst HE. The CIPRUS study, a nurse-led psychological treatment for patients with undifferentiated somatoform disorder in primary care: study protocol for a randomised controlled trial. Trials. 2017;18(1):206.

Main results: Sitnikova K, Leone SS, van Marwijk HWJ, Twisk J, van der Horst HE, van der Wouden JC. Effectiveness of a cognitive behavioural intervention for patients with undifferentiated somatoform disorder: Results from the CIPRUS cluster randomized controlled trial in primary care. J Psychosom Res. 2019 Jun 24:109745.

Economic evaluation: Forthcoming.