Treatment of functional neurological symptoms.

Gepubliceerd: 19-06-2009 Laatst bijgewerkt: 13-12-2022

The primary aim of this study is to investigate whether patients with neurological functional somatic symptoms have less limitations in daily activities 12 months after short-term educational treatment by neurologists, when compared to the current...

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

Samenvatting

ID

NL-OMON21971

Bron
NTR

Verkorte titel
FIT

Aandoening

functional neurological symptoms; functional somatic symptoms;
treatment functional symptoms;
randomised controlled trial;
Outcome functional neurological symptoms;

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum
Postbus 22660
1100 DD Amsterdam
The Netherlands

Overige ondersteuning: Achmea

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the patient’s health related quality of life 12 months after randomisation. Health related quality of life will be assessed with using the 'Short Form-36' health survey(SF-36).The primary outcome will be assessed 3, 6 and 12 months after randomisation.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Patients who present with functional somatic neurological symptoms form a non-ignorable part of the total neurological population, because of both the extent of the population and the severity of these symptoms. Nevertheless the symptoms of these patients are often regarded as not “real” neurological and the content of, and the most appropriate doctor responsible for medical treatment remains subject of debate. In the current approach at the outpatient department of the AMC Amsterdam, after the functional label is justified by thorough examinations, patients are referred to either a psychiatrist, or the general practitioner.

Objective:

The primary aim of this study is to investigate whether patients with neurological functional somatic symptoms have less limitations in daily activities 12 months after short-term educational treatment by neurologists, when compared to the current approach in which patients are informed about the diagnosis by the neurologist and referred to their general practitioners for further treatment.

The secondary aim is to investigate the predictors of successful outcome.

Study design:

In this randomised controlled trial patients who have been diagnosed with functional somatic neurological symptoms and informed about this diagnosis at the outpatient department or

day clinic of the department of Neurology at the AMC Amsterdam, will be randomised to either standard treatment by a general practitioner or to educational treatment using techniques from cognitive behavioural therapy by a neurologist. Patients are masked for their treatment allocation using a postponed consent procedure. Primary and secondary outcomes will be assessed at 3, 6 and 12 months after randomisation. The study duration is 2 years; 1 year recruitment, 1 year follow-up.

Intervention:

After information on the diagnosis, baseline assessment and randomisation, patients will receive either standard treatment by their general practitioner (control group) or educational treatment by a neurologist (intervention group).

Main study parameters endpoints:

The primary outcome is the patient's level of activities of daily living 12 months after randomisation. Physical disability will be assessed with the AMC linear disability scale (ALDS). Secondary outcomes are psychological symptoms assessed with the 'hospital anxiety and depression scale' (HADS), the physical symptom score, absence of work, medical consumption and quality of life (SF-36).

Power-analysis:

A total of 200 patients (100 patients per treatment arm) will be needed using at least 20 ALDS items (primary outcome parameter) to statistically detect (power 80%, two-sided alpha of 5%) a moderate effect size (difference between mean scores of both groups divided by pooled SD); or d = 0.50 as benchmark for assessing the relative magnitude of score differences on the ALDS scale.
Burden, benefits and risks associated with participation
All patients participating in this study will be interviewed by a neurologist at baseline and receive questionnaires concerning somatic and psychological symptoms, disabilities and quality of life, at baseline, and after 3, 6 and 12 months. This will take at most 30 minutes each time. Patients in the intervention group will receive educational treament by a trained neurologist, which is additional to standard medical care. Furthermore patients are asked to allow a single withdrawal of 14 mL of blood. This sample is stored fur possible future DNA analysis with regard to genes related to functional complaints.

Doel van het onderzoek

The primary aim of this study is to investigate whether patients with neurological functional somatic symptoms have less limitations in daily activities 12 months after short-term

educational treatment by neurologists, when compared to the current approach in which patients are informed about the diagnosis by the neurologist and referred to their general practitioners for further treatment.

Onderzoeksopzet

Baseline, 3, 6 and 12 months.

Onderzoeksproduct en/of interventie

Intervention group: Educational treatment by neurologists:

At the (outpatient) department of Neurology the patient is informed that he or she has functional symptoms. For further treatment these patients are referred to one of the neurologists trained in eductional therapy. This neurologist explains what functional symptoms are and that it is common, that symptoms are reversible and that self-help is a key part of getting better. The neurologist also explaines what the patient does not have and that the patient is not imaging or putting on the symptoms. The neurologist tries to find out what the thoughts of the patients on the cause of the symptoms are. At the first encounter and the two thereafter the neurologist tries to alter the patients' cognition of the complaints using simple counselling techniques derived from the studies by Stone et al (2005) and Blankenstein et al (2002), who constructed and tested an abridged reattribution model in Dutch distracted from the work of Goldberg et al (1989) and Gask et al (1989). The neurologists all had the same training and will during the study have regular meetings in which experience with patients is discussed. If the neurologist expects further improvement with physiotherapy, he will refer the patient, but the educational treatment programma by the neurologist remains unchanged.

Control group:

Standard treatment by a general practitioner.

Contactpersonen

Publiek

Academic Medical Center (AMC), Department of Neurology, H2
P.O. Box 22660.
Y.B.W.E.M. Roos
Meibergdreef 9
Amsterdam 1100 DD

The Netherlands
+31 (0)20 5663842

Wetenschappelijk

Academic Medical Center (AMC), Department of Neurology, H2
P.O. Box 22660.
Y.B.W.E.M. Roos
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663842

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Tension type headache: Headache without alarming symptoms, not consistent with one of the headache syndromes (migraine, cluster headache or analgesic abuse) and at least one other functional symptom;

2. Back and neck pain: Pain not considered to be caused by spinal pathology (fractures, spondylitis, metastases), myelopathy, radiculopathy, plexopathy or neuropathy and at least one other functional symptom;

3. Pseudo movement disorders: Movement disorders not consistent with one of the known movement disorders;

4. Mainly sensory disturbances: These disturbances cannot be explained by central of peripheral nervous system disorders;

5. Mainly motor disturbances other than movement disorders: These disturbances cannot be explained by central of peripheral nervous system disorders;

6. Pseudo-epilepsy ¡V atypical seizures without evidence for epilepsy on electroencephalographic investigations.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients under 18 years old;

2. Patients known prior to assessment to have psychiatric disorders other than somatoform, depressive, or anxiety disorders;

3. Patients with a primary diagnosis of a severe mood, anxiety, or psychotic disorders requiring psychiatric treatment;

4. Patient in psychotherapy at the time of the study;

5. Patients who obviously simulate their complaints;

6. Patients who are in dispute about financial or social benefit.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2009
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-06-2009
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	NL2454
NTR-old	NTR2570
Ander register	MEC AMC : 08/134
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A