Graded Exposure in patients with Painful Diabetic Neuropathy

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To investigate the effects of the cognitive behavioural intervention GEXP on physical activity and quality of life, hereby targeting specific fears in patients with PDN.Hypothesis: GEXP, as addition to usual care, increases the levels of physical...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON47289

Source
ToetsingOnline

Brief title
PDN & GEXP

Condition

- Diabetic complications
- Peripheral neuropathies
- Lifestyle issues

Synonym
Nerve pain in the feet caused by diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Adelante Zorggroep
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic Pain, Graded Exposure, Painful Diabetic Neuropathy, Rehabilitation

Outcome measures

Primary outcome

The purpose of this project is to develop and test a cognitive behavioural intervention targeting specific fears in patients with PDN, in order to increase physical activity and improve QOL.

To check whether the interventions modify pain-related fear, diabetes related fear, pain catastrophizing, pain experience patients fill in questions on an electronic diary. The daily measures consist of 1 question concerning pain intensity (VAS 0-10), 10 questions derived from the PART-Q30 questionnaire and 2 personalized open answer questions based on the Photograph-series Of Daily Activities (PHODA) and Canadian Occupational Performance Measure (COPM) taken at baseline.

Physical activity and perceived activity decline: The level of activity will be determined using an accelerometer and a questionnaire consisting of two concepts: physical activity and perceived activity decline (PAD). Anamnestic physical activity will be measured using the Physical Activity Rating Scale (PARS).

Secondary outcome

- Blood samples will be taken to assess glucose regulation. These samples include glucose, HbA1c and insulin (in order to calculate the HOMA2-IR score).

All questionnaires are described in more detail in the research protocol.

- Rehabilitation goals. The Canadian Occupational Performance Measure (COPM)

will be used to assess perceived limitations in activities an participation and to aid the goal formulation process.

- Disability. Disability will be measured using the Pain Disability Index (PDI).

- Quality of Life. Quality of life (QoL) will be measured using the 33-item Norfolk Quality of Life Questionnaire, Diabetic Neuropathy Version (Norfolk-QOL-DN).

- Overall PDN related fear will be measured using Painful Diabetic Neuropathy (PDN) Anxiety Rasch-Transformed 30-item questionnaire (PART-Q30).

- Overall Anxiety and Depression will be measured using the Hospital Anxiety and Depression Scale (HADS).

Study description

Background summary

Painful Diabetic Neuropathy (PDN) affects up to 20% of the people with diabetes and is associated with considerable morbidity, mortality and diminished health related quality of life (QOL). Unfortunately, pain treatment in PDN is frequently not or only partially successful. Patients with PDN often suffer from enhanced levels of anxiety, fears, and other negative feelings, such as depression, as well as loss of mobility and unsteadiness, resulting in further social isolation. Recent qualitative research confirms the existence of various fears and beliefs that can contribute to diminished physical activity, mobility and QOL. We propose an explanatory model for disability in PDN that states that fear of falling and fear of hypoglycaemia both have a disruptive and negative effect on physical functioning in patients with PDN. Avoidance of physical activity can be a result of these fears, which may further lead to disability, depression and overall lower QOL. In addition, suboptimal glycaemic control can further influence the experience of pain by leading to hypervigilance. Especially in patients with irrational and incorrect cognitions, fear will have a disabling effect. Several pain populations, in whom fear indeed lead to disability, have been treated successfully with graded exposure in vivo,

targeting fear of movement/pain, with an increase in physical activity and QOL.

Study objective

To investigate the effects of the cognitive behavioural intervention GEXP on physical activity and quality of life, hereby targeting specific fears in patients with PDN.

Hypothesis: GEXP, as addition to usual care, increases the levels of physical activity, thereby optimizing glucose regulation, reduce pain and disability and increase QOL.

Novelty and importance of this work: So far studies have mainly concentrated on conservative treatment methods for PDN. This project has a unique multidimensional approach on disability in PDN. It includes a combination of methods from psychological and medical sciences that cover a bio-psychosocial perspective on pain related disability. The studies as proposed in the project contain methods derived from research in medicine, movement sciences and psychology. The results of the project will improve our understanding of disability in patients with PDN. In case of proven effectiveness of the proposed treatment program, the project will improve quality of life of patients with PDN and can improve the care of DM in the Netherlands and abroad.

Study design

This study will be performed in a randomized replicated sequential single-case experimental ABC-design with multiple measurements. After a > 3-week no-treatment baseline measurement period (period A) patients are randomly assigned to the treatment (GEXP; period B). The starting point of the interventions will be determined at random by a computer system providing allocations in a locked, unreadable file that will be assessed only by an independent research administrator. At 6-months after baseline there will be a follow-up period of 2 weeks (FU; period C) (Figure 2). Each outcome variable will be measured systematically over time in each phase and on at least twenty percent of the data points in each condition (periods A, B and C). The study will include at least three attempts to demonstrate an intervention effect at three different points in time.

Intervention

Graded Exposure in vivo (GEXP) is a second-generation cognitive-behavioural intervention, and is characterized by systematic and repeated exposure to feared movements, activities and/or sensations in order to activate fear. The GEXP that was developed for patients with chronic pain who report substantial pain-related fear, and fear of movement/(re)injury in particular, is highly structured, protocolled, individually tailored, and aims to restore a normal

pattern of daily function.
After a > 3-week no-treatment baseline measurement period (period A) patients are randomly assigned to the treatment (GEXP; period B). At 6-months after baseline there will be a follow-up period of 2 weeks (FU; period C).

Period A (>3 weeks):
• 1x blood sample.
• 1x questionnaires.
• 10 days of accelerometry.
• Daily registration in diary.

Intervention: GEXP during 8 weeks
• 1x blood sample.
• 2x 1 hour therapy, during 8 weeks.
• 8 weeks digital diary.
• 10 days of accelerometry.
• 2x questionnaire.
• 1x blood sample.

Follow-up:
• 1x blood sample..
• 1x questionnaire
• 2 digital diary,
• 10 days of accelerometry.

Study burden and risks

Graded Exposure in vivo (GEXP) is a second generation cognitive-behavioural intervention in which fearful activities are being challenged. It is expected that the risks associated with participation to the study are negligible and that the burden will be minimal. The measurements that will be conducted during the study consist of questionnaires and are not invasive or risk full.
In this study, blood samples at T1, T2, T3 and T4. Blood sampling itself can cause bruises. Infections or continued bleeding are very rare.
Diabetes Mellitus type II is a disease that can adverse events such as muscle injuries or periods of hypoglycaemia. The entire research team including therapists, will be trained to recognize DM related complications and to know which further actions are required.
In the case that an adverse event occurs, there is always a physician available for consultation. All adverse events reported spontaneously by the subject or observed by the investigator or his staff will be recorded.

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

- Age > 18 years
- Diabetes mellitus type II
- Clinical neurological examination, CNE > 5
- Diabetic Neuropathy Symptom Score, DNS >= 1
- Douleur Neuropathique 4 Questions, DN4 >= 3

Exclusion criteria

Patients with lower limb morbidities other than PDN such as peripheral arterial disease, severe osteoarthritis, any other neurological disease than PNP or any other disease that may cause pain in the feet and/or damage to the peripheral nervous system. Furthermore patients who have received any form of cognitive behavioural therapy in the last 6 months will be excluded.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-06-2017
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	28-12-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL57919.068.16