

The effect of psychological intervention on the quality of life and wound healing in patients with diabetic foot ulcer.

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The quality of life and wound healing of patients with a diabetic foot ulcer will improve after undergoing a psychological intervention.

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27954

Bron

NTR

Aandoening

diabetic foot ulcer
quality of life
cognitive behavior therapy
wound healing
diabetische voetwond
kwaliteit van leven
psychologische interventie
wondheling

Ondersteuning

Primaire sponsor: Northwest Clinics

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the result of Short form 36 (SF-36) measured 8 months after randomization.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The quality of life of patients with a diabetic foot ulcer is poor. This is due to physical limitations and emotional problems. Medical devices help patients overcome their physical limitations. However, there is no mental help program for these patients yet.

Objective: The aim of this study is to evaluate the effect of psychological intervention for the quality of life and wound healing in patients with a diabetic foot ulcer.

Study design: A single-center, randomized, prospective cohort study.

Study population: Patients visiting the multidisciplinary outpatient diabetic foot clinic with ≥ 1 foot ulcer on or below the malleolus, who are diagnosed with diabetes mellitus and aged between 18 and 65 years are eligible for inclusion.

Intervention: One group of patients will receive therapy for 45 minutes once a week for 8 weeks. The therapy is including cognitive behavioral therapy, lifestyle and stress management, coping behavior therapy and treatment for depression. The other group will not receive psychological therapy.

Main endpoints: The primary outcome is the score on the Short form 36 (SF-36) 6 months after finishing psychological intervention. Secondary outcomes are the result of Diabetic Foot Ulcer scale short form (DFS-SF) after finishing therapy and after 6 months follow-up, the occurrence of wound healing and the occurrence of minor and major amputation.

Doel van het onderzoek

The quality of life and wound healing of patients with a diabetic foot ulcer will improve after undergoing a psychological intervention.

Onderzoeksopzet

8 months after randomization

Onderzoeksproduct en/of interventie

A medical psychologist will perform therapy for 45 minutes 2 times a week for 8 weeks. The therapy is including cognitive behavioral therapy, lifestyle and stress management, coping behavior therapy and treatment for depression. Hereafter, patients will complete the DFS-SF and SF-36 survey again.

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age 18-65 years

- Signed informed consent
- Diagnosed with diabetes mellitus
- ≥ 1 neuropathic foot ulcer (toe pressure > 70 mmHg) on or below the malleolus
- Able to read and write Dutch

- Attending outpatient diabetic foot clinic

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Living in a nursing home

- Diagnosed with alzheimer's disease
- Diagnosed with vascular dementia
- Diagnosed with lewy body dementia
- Diagnosed with frontotemporal dementia
- Diagnosed with amyotrophic lateral sclerosis
- Diagnosed with Parkinson's disease
- Life expectancy ≤ 1 year, in the investigator's opinion
- Diagnosed with schizophrenia
- Diagnosed with schizoaffective disorder
- Diagnosed with schizophreniform disorder
- Diagnosed with bipolar disorder
- Diagnosed with delusional disorder
- Diagnosed with brief psychotic disorder
- Diagnosed with folie à deux

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	40
Type:	Onbekend

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49780
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7406
NTR-old	NTR7622
CCMO	NL66883.029.18
OMON	NL-OMON49780

Resultaten