

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

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27954

Source

Nationaal Trial Register

Health condition

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

Sponsors and support

Primary sponsor: Northwest Clinics

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary outcomes are:

1. SF-36 results measured 2 months after randomization
2. Diabetic Foot Ulcer scale short form (DFS-SF) results measured 2 months after randomization
3. DFS-SF results measured 8 months after randomization
4. occurrence of wound healing
5. minor amputation rate
6. major amputation rate

Study description

Background summary

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.

Study objective

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

Study design

8 months after randomization

Intervention

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.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Other
Start date (anticipated):	01-01-2019
Enrollment:	40
Type:	Unknown

Ethics review

Not applicable	
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 49780
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results