

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

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin vascular abnormalities
Study type	Interventional

Summary

ID

NL-OMON49780

Source

ToetsingOnline

Brief title

Psychological intervention in patients with diabetic foot ulcer

Condition

- Skin vascular abnormalities
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

diabetic foot ulcer, foot wound

Research involving

Human

Sponsors and support

Primary sponsor: Noordwest Ziekenhuisgroep

Source(s) of monetary or material Support: Geen

Intervention

Keyword: cognitive behavior therapy, diabetic foot ulcer, quality of life, wound healing

Outcome measures

Primary outcome

The primary endpoint is the score on the Short form 36 (SF-36) measured at the second follow-up moment (6 months (+/- 2 months) after therapy for the intervention group and 12 months (+/- 2 months) after randomization for the control group).

Secondary outcome

Secondary endpoints are:

1. SF-36 results at the first follow up moment (at the end of therapy for the intervention group and 6 months after randomization for the control group)
2. Diabetic Foot Ulcer scale short form (DFS-SF) results at the first follow-up moment.
3. DFS-SF results at the second follow-up moment.
4. Occurrence of wound healing at the second follow-up moment.
5. minor amputation rate
6. major amputation rate

Study description

Background summary

Research has shown a significant association with diabetic foot ulcer and mental health symptoms. When the quality of life in patients with diabetic foot ulcer are measured, an equally low score on both role limitations due to physical health and role limitations due to emotional problems is found. To

help patients physical functioning there exist several medical devices, such as orthopedic shoes, shoe lifts and walking aids. However, there is no mental health care for the emotional problems associated with diabetic foot ulcer

Study objective

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

Study design

A randomized, parallel group controlled trial

Intervention

A medical psychologist will perform 8 therapy sessions for 45 minutes once every 2 weeks.

The therapy will include identifying and treatment of avoidance coping, coping behavior therapy, lifestyle management and processing traumatic experiences.

After therapy, patients will complete the DFS-SF and SF-36 survey again.

Study burden and risks

Patients are asked to complete 2 questionnaires 3 times. In addition, once will be asked to complete a short questionnaire on sociodemographic factors. The patients in the intervention group are asked about wound healing status by phone or at the hospital and to fill in the DFS-SF and SF-36 by phone, e-mail or at the hospital after the psychological therapy has ended (+/- 2 months, first follow-up moment) and 6 months (+/- 2 months) after the psychological therapy has ended (second follow-up moment).

The patients in the control group are asked about wound healing status by phone or at the hospital and to fill in the DFS-SF and SF-36 by phone, e-mail or at the hospital at 6 months (+/- 2 months) after randomization (first follow-up moment) and 12 months (+/- 2 months) after randomization (second follow-up moment).

The 8 therapy sessions lasts 45 minutes and will take place once every 2 weeks

Contacts

Public

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Scientific

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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 18-70 years
- Signed informed consent
- Diagnosed with diabetes mellitus
- * 1 neuropathic foot ulcer (toe pressure > 70 mmHg or the presence of pulsatile foot arteries as checked by palpation) on or below the malleolus
- Able to read, write, speak and understand Dutch
- Attending outpatient diabetic foot clinic
- The foot ulcer exists > 6 weeks

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)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	20-06-2019
Enrollment:	42
Type:	Actual

Ethics review

Approved WMO	
Date:	27-03-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	29-05-2020

Application type: Amendment
Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27954

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL66883.029.18
OMON	NL-OMON27954