The efficacy and feasibility of the use of motivational interviewing to improve adherence to wearing prescribed footwear in diabetic foot patients

Published: 26-11-2012
Last updated: 26-04-2024

The primary objective of this study is to assess the efficacy of the use of motivational interviewing to improve adherence to wearing prescribed footwear in diabetic foot patients. Secondary objectives are to assess the feasibility of applying…

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

Summary

ID

NL-OMON43895

Source
ToetsingOnline

Brief title
Motivational interviewing and adherence in diabetic foot patients

Condition

- Diabetic complications

Synonym
diabetic foot, diabetic neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Adherence, Diabetes, Interviewing, Motivational

Outcome measures

Primary outcome

Short-term (1 wk) and long-term (3 months) adherence in wearing prescribed

footwear.

Secondary outcome

Feasibility of motivational interviewing in diabetic foot patients

Normal variability in adherence over time (3, 6, 9, 12 months)

Factors of non-adherence in wearing prescribed footwear

In-shoe peak pressure in the footwear worn at home

Study description

Background summary

Foot ulceration is a severe complication of diabetes that is an important precursor to infection and amputation. Therefore, prevention of ulceration is of paramount importance in this patient group. Treatment often includes the use of prescribed orthopaedic footwear. To be effective in prevention, prescribed footwear should be worn by the patient, in particular when being ambulant. However, adherence to wearing prescription footwear is known to be low in diabetic patients with foot complications. Furthermore, ulcer recurrence is prevalent in this patient group. Therefore, ways should be found to improve adherence in order to improve clinical outcome. Motivational interviewing has been shown to be an effective evidence-based patient education method to change behaviour of patients, including those with diabetes. The technique is a directive, client-centred counselling style for eliciting behavioural change by helping clients to explore and resolve ambivalence. We hypothesize that motivational interviewing is also effective in changing behaviour of diabetic foot patients to wear prescribed footwear since these patients are generally reluctant to change or are ambivalent about changing their behaviour, two

domains where motivational interviewing is being considered as particularly useful.

Study objective

The primary objective of this study is to assess the efficacy of the use of motivational interviewing to improve adherence to wearing prescribed footwear in diabetic foot patients. Secondary objectives are to assess the feasibility of applying motivational interviewing to improve adherence in patients with a diabetic foot, to assess normal variability in adherence over time, to explore causes of non-adherence in wearing prescribed footwear in diabetic patients, and to assess in-shoe plantar pressures in the footwear that patients wear while they are at home.

Study design

A pilot RCT and an observational study of a cohort

Intervention

The control group receives usual care, while the intervention group additionally receives 2 sessions of motivational interviewing.

Study burden and risks

The risks associated with this study are negligible. A small sensor is placed in the patients* shoe, and a step activity monitor is worn around the ankle, both causing no adverse events in the many measurements that we have performed to date. Both will be worn for 7 consecutive days. Depending on the study group, patients require 3 to 6 extra visits to the outpatient clinic. A benefit may be that adherence increases as a result of the intervention. Previous research from our group has shown that if adherence can be assured in combination with adequate pressure relief in the shoe, risk for ulceration can be substantially reduced.

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 yrs, diabetes type 1 or 2, (history of) foot ulceration, prescription therapeutic footwear worn >3 months

Exclusion criteria

-Inability to walk
-Participation in another study that may influence the outcomes of this study.
-Concomitant severe physical or mental conditions that limit the ability to follow instructions for the study.
- Inability to read and understand the Dutch language and follow the study instructions

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2013
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO Date:	26-11-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-01-2014
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

No registrations found.

In other registers

Register	ID
CCMO	NL42112.018.12