

Improving care for sexual problems in persons with type 2 diabetes

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23632

Source

NTR

Brief title

DAX

Health condition

Type 2 diabetes mellitus, Sexual function, Quality of life, Primary care

Sponsors and support

Primary sponsor: VU University medical center, EMGO+ Institute

Source(s) of monetary or material Support: Dutch Diabetes Research Foundation

Intervention

Outcome measures

Primary outcome

Primary outcomes include sexual functioning, sexual satisfaction, and quality of life.

Secondary outcome

Secondary outcomes concern depressive symptoms, sexual distress, emotional well-being,

and treatment satisfaction.

Study description

Study objective

The overall aim of this study is to study the effectiveness of a PLISSIT-model intervention in men and women with type 2 diabetes in primary care.

Primary outcomes include sexual functioning, sexual satisfaction, and quality of life. Secondary outcomes concern depressive symptoms, sexual distress, emotional well-being, and treatment satisfaction.

Study design

All outcomes will be measured by means of self-report questionnaires at baseline, and after 3 and 12 months post-baseline. Treatment satisfaction will be assessed in telephone interviews.

Intervention

Patients in the intervention group will receive sexual counselling from their general practitioner based on the PLISSIT model. General practitioners in the intervention group will be trained by a sexologist to execute the PLISSIT model.

Patients in the control group will receive an information leaflet on Diabetes and Sexuality from their general practitioner, in addition to usual care.

Contacts

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Eligibility criteria

Inclusion criteria

1. Men and women with diagnosed type 2 diabetes mellitus
2. Patients aged between 40 and 75 years
3. Patients who indicate to be dissatisfied about their sexual function
4. Patients who indicate they want to talk about their sexual problem with their general practitioner.
5. Patients have to be able to read, write and understand the Dutch language.

Exclusion criteria

1. Participation in scientific research that aims to improve one or more of our outcome measures.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control: Active

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-12-2014
Enrollment: 200
Type: Anticipated

Ethics review

Positive opinion
Date: 23-09-2014
Application type: First submission

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
NTR-new	NL4638
NTR-old	NTR4807
Other	Dutch Diabetes Research Foundation : 2012.00.1554

Study results