

DISC-studie.

No registrations found.

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

Summary

ID

NL-OMON29182

Source

NTR

Brief title

DISC-studie

Health condition

Type 2 Diabetes Mellitus

Sponsors and support

Primary sponsor: Academic Medical Centre (AMC)

Dept. of Social Medicine

Source(s) of monetary or material Support: Zonmw. The Netherlands Organization for Health Research and Development.

Intervention

Outcome measures

Primary outcome

The primary outcome measure is HbA1c at 16 months.

Secondary outcome

Secondary outcome measures are health related outcome measures (lipid profile, blood

pressure, BMI, weight, waist circumference, blood glucose values), diabetes related behaviour (nutrition, physical activity, medication adherence) and psycho social outcomes (quality of life, depression).

Study description

Background summary

Background:

Compared to those in higher socioeconomic groups, diabetic patients in lower socioeconomic groups have less favourable metabolic control and experience more diabetes-related complications. They encounter specific barriers that hinder optimal diabetes self-management, including a lack of social support and other psychosocial mechanisms in their immediate social environments. Powerful Together with Diabetes is a culturally sensitive social network intervention specifically targeted to ethnic Dutch, Moroccan, Turkish, and Surinamese diabetic patients in lower socioeconomic groups. For ten months, patients will participate in peer support groups in which they will share experiences, support each other in maintaining healthy lifestyles, and learn skills to resist social pressure. At the same time, their significant others will also receive an intervention, aimed at maximizing support for and minimizing the negative social influences on diabetes self-management.

Methods:

This study aims to test the effectiveness of Powerful Together with Diabetes. We will use a quasi-experimental design with an intervention group (Group 1) and two comparison groups (Groups 2 and 3), N=128 in each group. Group 1 will receive Powerful Together with Diabetes. Group 2 will receive Know your Sugar, a six-week group intervention that does not focus on the participants' social environments. Group 3 will receive standard care only. Assessment: participants in Groups 1 and 2 will be interviewed and physically examined at baseline, 3, 10, and 16 months. We will compare their haemoglobin A1C levels with the haemoglobin A1C levels of Group 3. Main outcome measures: haemoglobin A1C, diabetes-related quality of life, diabetes self-management, health-related, and intermediate outcome measures. We will conduct a process evaluation and a qualitative study to gain more insights into the intervention fidelity, feasibility, and changes in the psychosocial mechanism in the participants' immediate social environments.

Conclusion:

With this study, we will assess the feasibility and effectiveness of a culturally sensitive social

network intervention for lower socioeconomic groups. Furthermore, we will study how to enable these patients to optimally manage their diabetes.

Study objective

A social network intervention ('Powerful Together with Diabetes') will enable diabetic patients in lower socioeconomic groups to effectively manage their type 2 diabetes and optimize their metabolic control, health related outcomes, diabetes related behaviour and psycho-social outcomes.

Study design

Measurements will take place at baseline, 3, 10 and 16 months.

Intervention

Powerful Together with Diabetes is a culturally sensitive social network intervention specifically targeted to ethnic Dutch, Moroccan, Turkish, and Surinamese diabetic patients in lower socioeconomic groups. For ten months, patients will participate in peer support groups in which they will share experiences, support each other in maintaining healthy lifestyles, and learn skills to resist social pressure. At the same time, their significant others will also receive an intervention, aimed at maximizing support for and minimizing the negative social influences on diabetes self-management. Know your Sugar is a six-week group intervention that does not focus on the participants' social environments.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnosed with type 2 diabetes;
2. One year under treatment for diabetes;
3. Older than 30 years;
4. Living in a deprived neighbourhood.

Exclusion criteria

1. Their General Practitioner objects against participation;
2. The patient has severe psychiatric disorders;
3. The patient can't come to the location of the intervention independently;
4. The patient is planning to stay abroad for a longer period of time;
5. The patient is participating in other interventions aimed at improving his/her lifestyle.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending

Start date (anticipated):	01-10-2009
Enrollment:	256
Type:	Anticipated

Ethics review

Positive opinion	
Date:	29-06-2009
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	NL1776
NTR-old	NTR1886
Other	Zonmw : 76500003
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A