

'Powerful together against diabetes'. A Social network intervention for type 2 diabetics with a low socioeconomic status.

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Ethical review	-
Status	Pending
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON33159

Source

ToetsingOnline

Brief title

'Powerful together against diabetes'.

Condition

- Diabetic complications
- Lifestyle issues

Synonym

'Diabetes Mellitus' & 'Sugar Disease'

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Zorgonderzoek Nederland (Zonmw)

Intervention

Keyword: Diabetes self-management, Family intervention, Social network intervention, Social Support

Outcome measures

Primary outcome

The primary outcome measure is HbA1c at 24 months.

Secondary outcome

Secondary outcome measures are health related outcome measures, diabetes related behaviour, psycho-social outcome measures and motivational outcome measures.

Study description

Background summary

The prevalence of type 2 diabetes is higher among people with a lower socio-economic status, including migrants. This group has a poorer metabolic control and experiences more diabetes-related complications than diabetics with a higher socio-economic status. The amount of social support, diabetics receive from their direct social environment has a major influence on the way they manage their diabetes. However, interventions aimed at increasing social support for diabetics often have limited effects on diabetes self-management. This can be explained by the temporary nature of the social support offered in these interventions. After the end of these interventions, there is usually no further contact between the participants: the newly acquired social support comes to an end. Without permanent social support, it seems difficult for most diabetics to maintain an optimal diabetes self-management. A second explanation could be the limited focus of these interventions. These interventions often offer the participants social support from other diabetics (peer support), but disregard the participants* existing social environment. Providing patients with social support without addressing existing social influences on their

diabetes self-management seems less effective. In this project we study the effectiveness of an intervention for low socio-economic groups (*Powerful Together against Diabetes*) which aims to create permanent social support. The focus of this intervention is the participants' whole social network, including the participants' existing social environment and the influences this environment exerts on their diabetes self-management.

Study objective

The aim of this study is to evaluate the effect of the intervention *Powerful Together against Diabetes* on metabolic control, health related outcome measures, diabetes related behaviour, psycho-social outcome measures and intermediate outcome measures of diabetics with a low socio-economic status.

Study design

This study is a randomised controlled trial. We compare 300 patients that participated in the intervention with 300 patients that participated in the control group. Measurements will take place at baseline, 6, 12 and 24 months.

Intervention

Powerful Together against Diabetes is a group intervention that consists of three parts. Firstly group meetings will be organised consisting of 10 diabetics. These groups will meet frequently for a period of two years. The participants will exchange experiences about coping with diabetes, support each other in maintaining a healthy lifestyle and undertake activities to improve their lifestyle. A part of these group meetings is a social learning intervention in which the participants will be stimulated to mobilize social support within their direct social environment and at the same time learn to deal with social influences from their direct social environment that negatively influence their diabetes self-management. Thirdly we will organize a social network intervention in which we invite the direct social environment of the participants to learn about diabetes and discuss obstacles with the diabetic patient in order to stimulate their social support.

Study burden and risks

As far as we know, there are no risks associated with participation in this study.

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

Inclusion criteria:

- Diagnosed with type 2 diabetes
- One year under treatment for diabetes
- Older than 30 years
- Living in a deprived neighbourhood

Exclusion criteria

Patients will be excluded when:

- Their General Practitioner objects against participation
- The patient has severe psychiatric disorders
- The patient can't come to the location of the intervention independently
- The patient is planning to stay abroad for a longer period of time

- the patient is participating in other interventions aimed at improving his/her lifestyle.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	19-08-2010
Enrollment:	600
Type:	Anticipated

Ethics review

Not available

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	NL28802.018.09
Other	Wel ingediend, nog niet afgehandeld