

Effectiveness of a diabetes education and counseling program for Turkish, Moroccan and Hindustani patients by bicultural educators embedded in a multidisciplinary setting.

Published: 11-12-2006

Last updated: 14-05-2024

The main question is: does an ethnic specific cultural approach, including an ethnic specific education programme and individual guidance by a bicultural educator as part of the multidisciplinary team, has a beneficial effect on glycaemic control in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON30418

Source

ToetsingOnline

Brief title

Effectiviteit cultureel competente diabeteseducatie

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

diabetec, type 2 diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden

Source(s) of monetary or material Support: De personele kosten van de onderzoeker worden uit eigen middelen betaald; voor de overige kosten van het onderzoek is sponsorgeld van enkele farmaceutische bedrijven verkregen, GlaxoSmithKline, Novo Nordisk, Sanofi-aventis

Intervention

Keyword: Diabetes, education, ethnic, minority

Outcome measures

Primary outcome

The main effect parameter is change in HbA1c in favour of the intervention group

Secondary outcome

Diabetes related knowledge

Reported behaviour of following diabetes related advices

Behavioural determinants (attitude, self efficacy, intention)

Blood lipids (total cholesterol, HDL-cholesterol, triglyceride)

Blood pressure

Weight

Waist

Study description

Background summary

The prevalence of type 2 diabetes (DM2) has increased significantly in the past ten years. Compared to the indigenous Dutch population, diabetes is two to five times more common in non-western ethnic minority groups. Most of the older immigrants live in a relatively traditional manner and their proficiency in the

Dutch language is limited. As a result of communication problems Dutch physicians experience more difficulty in delivery of optimal diabetes care to patients of ethnic minority groups. A former study showed a poorer glycaemic control in Turkish DM2 patients compared to their Dutch counterparts, although a similar diabetes care was provided. DM2 is a complex disease and treatment usually demands for behavioural changes, and can only succeed in well cooperative patients. Therefore a good understanding of the illness by the patient is essential. Furthermore advice as well as behavioural rules should be in line with the culture and social environment of the patients. We expect that a cultural competent education (education in the native language with respect to the patients' culture) can improve the diabetes care to DM2 patients from non-western ethnic minority groups, and by that improve the patients' compliance and the glycaemic control.

Study objective

The main question is: does an ethnic specific cultural approach, including an ethnic specific education programme and individual guidance by a bicultural educator as part of the multidisciplinary team, have a beneficial effect on glycaemic control in Turkish Moroccan and Hindustani type 2 diabetes patients

Secondary the effect on weight, diabetes related knowledge, quality of life, determinants of behavioural change attitude, self efficacy, compliance towards behavioural advice, and medication will be assessed.

Study design

waiting list controlled design. After informed consent the patients are randomly assigned to either the intervention group or the waiting list (control) group. All patients will receive usual care.

Intervention

Patients from the intervention group receive six educational group sessions given by bicultural health educators. The health educators will make use of a diabetes education manual developed by the public health service Rotterdam for the education of Turkish type 2 diabetes patients. Apart from the group education, the health educators will counsel the diabetes patients during the course of the study.

Study burden and risks

All patients are interviewed before and after the study. This will take about for hours of the patients' time. The frequency of taking a venous blood sample and of the physical examinations is once every 3 months and does not differ from the frequency in usual care, although the investigator will see to

more carefully that the examinations will take place.

The burden for patients from the intervention will be approximately 15 hours of extra education and time for counseling.

In our opinion participation to this study will not create an extra risk for the patients

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

Turkish, Moroccan or (Surinamese) South Asian Indians patients known with type 2 diabetes. Patients must be over 18 years and under treatment of the diabetes centre "Diabetes Zorg Haaglanden"

Exclusion criteria

The physician in attendance objects participation

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2006
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO	
Date:	11-12-2006
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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

CCMO

ID

NL14541.098.06