

Nurses' led home support for type 2 diabetes patients with an acute coronary syndrome.

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23055

Bron

NTR

Verkorte titel

Living with diabetes

Aandoening

Type 2 diabetes, acute coronary syndrome, self-management, self-efficacy
Primary care

Ondersteuning

Primaire sponsor: UMC Utrecht, Julius Center

Overige ondersteuning: Dutch Diabetes Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Health-related QOL, both generic and diabetes-specific. This will be measured as diabetes distress and well-being.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Type 2 diabetes (DM2) patients have an increased risk of cardiovascular complications. Both DM2 and cardiac disease are associated with a decreased quality of life (QOL) and combination of these diseases results in an even more decreased QOL. Self-management is an important part of diabetes care, and in addition has a positive impact on QOL; however for most patients it is difficult for to perform self-management tasks, because they lack self-efficacy. Therefore, self-management support in DM2 patients with an acute cardiac syndrome (ACS) is important for improving self-efficacy and QOL.

Objective:

To develop and evaluate the effectiveness of a tailored supportive intervention by a diabetes nurse to help people with DM2 to cope with the occurrence of an ACS that might influence their QOL.

Study design:

Randomised controlled trial. Patients will be randomised in an intervention group, receiving usual care and a tailored intervention, and in a control condition. The control condition receives usual care and a consultation by telephone.

Study population: DM2 patients with a myocardial infarction (MI) and/or revascularisation procedure within three weeks after discharge from the hospital.

Intervention:

A diabetes nurse, trained for this study, will visit the patients in the intervention group three times at home to discuss several subjects, including illness perceptions, diet, physical activity, pharmacotherapy, the role of DM2 in the cardiac event and the frequency of controls.

Main study parameters/endpoints:

Primary: Diabetes distress and health related QOL.

Secondary: Depression, self-management behaviour, HbA1c%, exercise, self-efficacy and illness perceptions. Other: biomedical and life style measures.

Doel van het onderzoek

The overall objective of this study is to develop and evaluate the effectiveness of a tailored supportive intervention by a diabetes nurse to help people with type 2 diabetes cope with the occurrence of an acute cardiac syndrome (ACS) that might influence their QOL considerably.

Primary Objective: To evaluate the effectiveness of home visits by a diabetes nurse on QOL in DM2 patients who recently suffered from an ACS.

Secondary objectives: To assess the effectiveness of the intervention on depression, self-management behaviour, self-efficacy, and illness perceptions.

Onderzoeksopzet

The baseline measurements T(0) will be conducted within three weeks after discharge from the hospital. The final measurements will be performed four to five months after discharge from the hospital (T1)

Onderzoeksproduct en/of interventie

A diabetes nurse, trained for this project, visits the patients three times at home:

1. Within three weeks after discharge from the hospital;
2. Two weeks after the first home visit;
3. Two months after the second home visit.

During the home visits, the following subjects will be discussed:

- A. Illness perception, guided by the completed IPQ-R (Revised Illness perception questionnaire). Discuss the extent to which patients think that DM2 is an extra burden in recovering from and coping with the consequences of the cardiac event;
- B. The role of DM2 in the aetiology of the cardiac event;
- C. Nutrition/diet;
- D. What to do and not to do regarding sexuality and other physical activity;

E. Pharmacotherapy. Treatment may be already very complicated in DM2 patients. When the disease is complicated by a cardiac event, pharmacotherapy may even become more complicated;

F. Agreements on the control scheme with different health care providers. After a cardiac event, DM2 patients sometimes skip their controls at the general practice because they think the controls at the cardiologist are sufficient.

Participants who will be randomised to the control group will receive usual care. In addition, they will receive a consultation by telephone to offer them personal attention.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. DM2 patients;
2. At time of inclusion in the hospital or very recently dismissed from the hospital after their first ACS;
3. Sufficient knowledge of the Dutch language.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Not speaking or understanding the Dutch language;
2. Not able to fill in questionnaires.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-10-2011
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 20-09-2011

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2929
NTR-old	NTR3076
Ander register	Diabetes Fonds : 2009.70
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A