

Implementation of a nurse-led self-management support in primary care for type 2 diabetes patients with emotional distress with problems with daily functioning.

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25250

Bron

Nationaal Trial Register

Verkorte titel

SMS

Aandoening

emotional distress / emotionele klachten

implementation / implementatie

type 2 diabetes mellitus

primary care / eerstelijnszorg

practice nurse / praktijkondersteuner

minimal psychological intervention / minimale psychologische interventie

daily functioning / dagelijks functioneren

Ondersteuning

Primaire sponsor: Maastricht University, CAPHRI School for public health and primary care

Overige ondersteuning: Diabetes Fonds, Stem van de Patient

Zorgverzekeraar CZ

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Daily functioning as measured by means of the Daily Functioning Thermometer (DFT), a visual analogue scale;
2. Distress Scale of the 4DSQ to assess changes in distress symptoms.

Toelichting onderzoek

Achtergrond van het onderzoek

Emotional distress is prevalent among type 2 diabetes patients. It may lead to a downward spiral caused by poor adherence, deterioration of the condition and a further decline in daily functioning, which in turn aggravates the emotional problems. A nurse-led minimal psychological intervention for chronically ill appeared to be (cost) effective. For implementation in regular care, adaptations are needed. The adapted Self management Support (SMS) program facilitates practice nurses (PNs) to incorporate a stepped care approach of early detection and treatment of emotional distress accompanied by problems with daily functioning. A pragmatic cluster randomised controlled trial will be carried out with a baseline measurement and follow-ups after 4 and 12 months. The population consists of 46 practice nurses and their eligible diabetic patients (N=460; 10 per practice nurse). Practice nurses of the intervention group receive SMS training. They learn to detect emotional distress and problems with daily functioning, and to provide self management support to eligible patients. Patients with severe problems will be referred to the GP. The study involves an effect evaluation and process evaluation of SMS. Primary outcome measure is daily functioning. Secondary measures include emotional health status, participation and autonomy, control over the disease, self-efficacy, quality of life, patient reported assessment of care, and health care use. Process parameters measured by means of questionnaires and interviews explore the facilitators and barriers regarding successful implementation of SMS.

Onderzoeksopzet

T0: Baseline;

T4: 4 months after baseline;

T12: A year after baseline.

Onderzoeksproduct en/of interventie

PNs of the intervention arm will apply SMS in addition to usual care, i.e. 3-monthly diabetes check-ups according to the current guidelines. They will be trained during three 8-hours educational meetings to carry out SMS. The PNs learn to detect emotional distress and problems with daily functioning during regular consultations. Patients with severe problems will be referred to the GP. Patients with mild to moderate emotional problems (according to the 4DSQ) accompanied by problems with daily functioning (according to the Daily Functioning Thermometer) receive self management support from the PN in max. 2 extra consultations. The self-management support is based on principles of Problem Solving and/or Reattribution.

PNs of the control arm are instructed to provide usual care. They receive SMS training after follow-up.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients are eligible if they have a clinically established diagnosis of diabetes type II, are treated in primary care by a practice nurse, experience emotional distress and encounter problems with daily functioning.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients that are not able to read and write Dutch.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2011
Aantal proefpersonen:	460
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	14-02-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34709

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2636
NTR-old	NTR2764
CCMO	NL31235.068.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34709

Resultaten

Samenvatting resultaten

Van Dijk – de Vries A, Van Bokhoven MA, De Jong S, Metsemakers JFM, Verhaak PFM, Van der Weijden T Van Eijk JTM. Patients' readiness to receive psychosocial care during nurse-led routine diabetes consultations in primary care: A mixed methods study. International Journal of Nursing studies 2016; 63, 58-64. doi: <http://dx.doi.org/10.1016/j.ijnurstu.2016.08.018>

Van Dijk – de Vries, A. Het dagelijks functioneren centraal in een diabetesconsult. Implementatie van zelfmanagementondersteuning in de eerstelijns diabeteszorg. Verpleegkundige 2016; 2, 24-27.

Van Dijk – de Vries A, Van Bokhoven MA, Winkens B, Terluin B, Knottnerus JA, Van der Weijden T, Van Eijk JTM. Lessons learnt from a cluster-randomised trial evaluating the effectiveness of Self-Management Support (SMS) delivered by practice nurses in routine diabetes care. BMJ Open 2015; 5(6).

Van Dijk – de Vries A, Van Bokhoven M, Terluin B, Van der Weijden T Van Eijk JTM. Integrating nurse-led Self-Management Support (SMS) in routine primary care: design of a hybrid effectiveness-implementation study among type 2 diabetes patients with problems of daily

functioning and emotional distress: a study protocol. BMC Fam Pract 2013; 14:77.