Web-based self-management of insulin titration in patients with type 2 diabetes: The Di@log Study

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

Samenvatting

ID

NL-OMON27433

Bron
NTR

Verkorte titel
Di@log Study

Aandoening

diabetes mellitus type 2 (DM type II)

Ondersteuning

Primaire sponsor: VU Universtity Medical Center, EMGO institute
Overige ondersteuning: Sanofi-aventis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Difference between intervention and control groups in glycaemic control measured by glycated haemoglobin concentration (HbA1c-level)

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND:

The disease management of DM2 needs to be improved, since a great part of the patients still doesn’t reach the target level of HbA1c (e.g. < 7.0%) . High HbA1c levels contribute to a higher risk to develop severe complications. One of the obstacles in the disease management is the transition to insulin therapy, because of reasons of both patient and health care providers. There is a need for innovative strategies to facilitate this. Making use of interactive behaviour change technology (IBCT) is one potential resource for improving the effectiveness of diabetes management programs by enhancing patient empowerment through feedback mechanisms, based on the theory of self-regulation. AIM: The primary objective of the study is to determine the effect on glycaemic control in terms of HbA1c of a patient-centered web-based insulin-titration programme in suboptimal controlled T2DM patients who have started insulin glargine.
Secondary objectives are to assess the effects of the programme, on frequency of hypoglycaemic episodes, illness perceptions, self-efficacy, treatment satisfaction, and quality of life.

STUDY DESIGN:

Open, parallel, randomized, controlled trial in patients with type 2 diabetes from general practices.

STUDY POPULATION:

DM2 patients with suboptimal controlled glucose (i.e. HbA1c > 7.0%), using maximal oral antidiabetic drugs and are eligible for starting insulin treatment. 248 patients will be recruited at general practices.

INTERVENTION:

The intervention group will titrate insulin by themselves, assisted by an internet programme with computerized algorithms responding on inserted fasting glucose values. De control group will be treated as usual: the health care provider will adjust the insulin dose according to national standards. The total intervention will take 12 months. Together with the inclusion

period of 12 months, the study time will be 24 months. Measures will be taken at baseline and after 3, 6 and 12 months.

PRIMARY OUTCOME MEASURES:

Difference between intervention and control groups in glycaemic control measured by glycated haemoglobin concentration (HbA1c-level).

Doel van het onderzoek

The internet programme promotes self-regulatory behaviour with a focus on insulin titration, facilitating effective self-monitoring and evaluation of self-care behaviours through feedback on input of the patients¡¯ glucose values (based on the self-regulation theory by Leventhal). This is expected to result in improved self-management skills, self-efficacy and subsequent glycaemic control. The self-regulation of diabetes and subsequent positive glycaemic outcomes are expected to translate into better quality of life and treatment satisfaction compared to the control group, where there is less emphasis on patients¡¯ self-management.

Onderzoeksopzet

baseline; t=0

t=1 = 3 months

t=2 = 6 months

t=3 = 12 months

Onderzoeksproduct en/of interventie

An open, parallel, cluster randomised, controlled trial among DM2 patients from general practices, with a HbA1c of above 7.0% , who are using maximal oral antidiabetic agents and are eligible for insulin treatment. General Practices (GP) will be randomly assigned to the intervention group or the control group. All patients eligible for the trial will use insulin glargine (Lantus). Patients from the GP’s in the intervention group will use a special designed internet programme to self-manage the insulin titration. The control group will receive care as usual, i.e. the insulin titration will be provided by their own health care provider. The intervention group will receive general education about diabetes and insulin therapy, and will be learned how to self-administer insuline injections and how to use a glucose monitor device Additionally they will be learned how to use the internet program. They will learn to know and understand the ranges of test results and what steps to take in response to high or low blood glucose. The intervention group will perform self-monitoring according to standard testing frequency instructions and use the internet program during one year. Both groups will receive computerized questionnaires by email at baseline and 3 months, 6 months and 12 months after initiating insulin treatment.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with type 2 diabetes mellitus from general practices

2. Age between 35 and 75 years

3. HbA1c > 7.0% in combination with maximal oral antidiabetic agents (i.e. the combination of two oral medicines, what cannot further be increased)

4. Capable of using a computer and the internet

5. Willingness to accept, and ability to inject insulin glargine (Lantus®)

6. Ability and willingness to perform self monitoring of blood glucose

7. Written informed consent

8. Understanding of Dutch language

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Serious mental impairment

2. Serious endocrine disorders

3. Serious disease with a life expectancy < 1 year

4. Corticosteroid use

5. Not capable to use a computer or not used to the internet.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2009
Aantal proefpersonen:	248
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-05-2008
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	NL1270
NTR-old	NTR1316
Ander register	Sanofi-Aventis the Netherlands B.V. : PO4700041309
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A