An RCT for the evaluation of the effects of Real Time Medication Monitoring (RTMM) on improving medication adherence in diabetes type 2 patients in the Netherlands.

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

Samenvatting

ID

NL-OMON19988

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Diabetes Mellitus type 2, medication adherence

Ondersteuning

Primaire sponsor: NIVEL Netherlands Institute for Health Services Research, Mediq Apotheken, Evalan BV
Overige ondersteuning: Zilveren Kruis Achmea

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Adherence to oral antidiabetic medication.

Toelichting onderzoek

Achtergrond van het onderzoek

Improving adherence is an issue that receives attention worldwide. The aim of this study is to evaluate the effects of Real Time Medication Event Monitoring (RTMM) on adherence to oral antidiabetics in patients with diabetes type 2 in the Netherlands. The RTMM system makes it possible to monitor patients' medication use real time through the internet and remind patients only when they forget to take their medication. This RCT, with pre- and posttest measurements, involves 210 diabetes type 2 patients with suboptimal levels of adherence (<80% based on pharmacy refill data). Patients are randomly appointed to two experimental groups and one control group. Patients in the first experimental group use the RTMM system including SMS-alerts and a personal webpage where they can monitor their medication use. Patients in the second experimental group use the RTMM system without SMS reminders or webpage access. Patients in the control group are not exposed to any intervention. The intervention lasts for 6 months. All participants complete two questionnaires, one before and one after the intervention. Pharmacy refill data of all patients will be extracted for the period before (12 months), during (six months) and after (six months) the intervention. Differences in adherence between the two experimental groups during the intervention will be studied (using real time registered data), as well as differences between the two experimental groups and the control group (using pharmacy refill data).

Doel van het onderzoek

Many patients, especially patients with a chronic illness, experience difficulties in following treatment recommendations. Adherence to long-term therapy for chronic illnesses in developed countries averages only 50%. As a result of poor adherence, patients do not receive optimal benefit from their drug therapy. Suboptimal treatment can lead to increased use of health care services (acute care and hospitalizations), reduction in patient's quality of life, and increased healthcare costs (e.g. drug costs and medical costs). Thus, improving adherence is an issue that receives attention worldwide. A Real Time Medication Event Monitoring (RTMM) system has been developed, which makes it possible to monitor patients' medication use real time through the internet and reminds patients only when they forget to take their medication. RTMM can provide opportunities to improve adherence, especially in patients who forget taking pills or are inaccurate in their timing (unintentional

nonadherence). The aim of this study is to evaluate the effects of RTMM+ (with SMS reminders), compared to RTMM– (no SMS reminders) and usual care, on the adherence to oral antidiabetic medication of diabetes type 2 patients with suboptimal adherence levels in the Netherlands.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

The intervention consists of providing RTMM with SMS reminders to non-adherent diabetes type 2 patients to improve their adherence to oral antidiabetics. Two experimental groups and one control group participate in the intervention for six months. Patients in the first experimental group (RTMM+ group) receive their medication in an electronic medication dispenser and receive SMS reminders when they forget to take their pill. Through this medication dispenser, the actual medication taking behaviour of patients is registered real time at a central database. For each patient the dispenser is programmed in line with the patient's prescribed medication regimen. Each time the patient does not open the dispenser during the agreed time period, an SMS reminder is sent to the patient at the end of this period. Patients, as well as their pharmacists, receive an internet account through which they can monitor their medication use. Patients in the second experimental group (RTMM– group) receive their medication in a similar medication dispenser, but without SMS reminders and internet account. The medication taking behaviour of these patients is also registered real time at the central database. Patients in the third group, the control group, receive care-as-usual. They are not exposed to any intervention and they are not approached during these six months.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Using oral antidiabetic medication for at least one year;

2. Having an adherence level of <80% according to pharmacy refill data from the year preceding the intervention;

3. Aged between 18 and 65 years;

4. Last prescription (theoretically) until at least two months before the start of the intervention;

5. Understanding/speaking the Dutch language;

6. Using a mobile telephone.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age <18 years or >65 years;

2. Not understanding/speaking Dutch.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2008
Aantal proefpersonen:	210
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-06-2009
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	NL1772
NTR-old	NTR1882
Ander register	METC UMC Utrecht : 08-165/C
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A