Medido.

Gepubliceerd: 19-03-2013 Laatst bijgewerkt: 15-05-2024

The expectation is that the use of Medido is a substantial improvement in the treatment and that physical disabilities will decrease. Also the cost effectiveness of Medido will be taken into account.

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

Samenvatting

ID

NL-OMON22331

Bron
NTR

Verkorte titel
Medido

Aandoening

Parkinson's Disease
Therapy adherence
Medication
Ziekte van Parkinson
Therapietrouw
Medicatie

Ondersteuning

Primaire sponsor: Mw. L. ter Brake-Berning, nurse practitioner Parkinson en Mw L. Vree Egberts, researcher
Overige ondersteuning: Innospense BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary parameter of this study is the physical disability of Parkinson’s patients. To measure the physical disability, the AMC Linear Disability Score (ALDS) will be used. The ALDS checks the activities in daily life of the patient. The ALDS is a flexible, validated and clinimetrically sound and flexible instrument to assess the level of disability in patients with Parkinson’s disease.

Toelichting onderzoek

Achtergrond van het onderzoek

Medido versus regular care on physical disabilities.

Doel van het onderzoek

The expectation is that the use of Medido is a substantial improvement in the treatment and that physical disabilities will decrease. Also the cost effectiveness of Medido will be taken into account.

Onderzoeksopzet

Baseline en after 3 months.

Onderzoeksproduct en/of interventie

This study is a prospective randomized controlled trial (RCT) with a follow up of 3 months. The interventions, Medido versus usual care, are randomly assigned to the patients and will be stratified by hospital (MST and ZGT). Measurements will take place at baseline, and after three months. At the end of the study it will be determined if there is a significant difference in ALDS between the two groups of patients.

The Medido is a medication dispenser with a CE characteristic and is used to make medication intake easier for patients. Patients are reminded to intake their medication, including non-Parkinson medication, by means of sound and light signals. Patients have to press a button to make the Medido dispense the next baxtered medication. Also the baxtered medication bag will be automatically opened by the Medido. If it is not possible to Baxter a specific medication (e.g. inhaled medication), the medication has to be taken apart from the Baxter. For half tablets a solution will be found; possibly a capsule will be used. Changes in

medication use during the study are passed on to the pharmacist, which is regular care. Subsequently, the baxtered medication can be changed. When is it needed, the time of intake can also be changed. This can be done remotely.
Patient take home the Medido and the pharmacist will fill the Medido at the patients home. Every pharmacist can fill the Medido. Depending upon the amount of medication, this can be done for a maximum of two weeks. The pharmacist calls the company that controls the Medido (Innospense) to upload the specific week schedule for the patient.
Thereafter, the patient can use the device and the patient will be reminded to take the medication. When this does not happen, a signal is sent to the call centre of Innospense and this will be recorded. The patient receives a short text message from the call centre. When this happens again within the same programmed time frame, the call centre will call the patient. When this happens two times a day a day, the investigator will call the patient.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

The patient:

1. Is older than forty years;

2. Has four or more medication intake moments a day, including non-parkinson medication;

3. Has on-off fluctuations when Parkinson medication is not taken;

4. Has given consent to participate in the study;

5. Is diagnosed with Parkinson’s disease;

6. Will be treated at Medisch Spectrum Twente at Enschede or ZiekenhuisGroep Twente at Hengelo or Almelo;

7. May receive personal at-home care.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients:

1. Not capable of completing the questionnaires;

2. Whose medication is administered by other persons, excluding patients with personal at-home care givers.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2013

Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-03-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40139
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3753
NTR-old	NTR3917
CCMO	NL43868.044.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40139

Resultaten

Samenvatting resultaten
N/A