Medido.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22331

Source
NTR

Brief title
Medido

Health condition

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

Sponsors and support

Primary sponsor: Mw. L. ter Brake-Berning, nurse practitioner Parkinson en Mw L. Vree Egberts, researcher
Source(s) of monetary or material Support: Innospense BV

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Does the use of Medido improve the Quality of life of Parkinson’s patients compared with the current method of medication distribution to Parkinson’s patients after a follow-up period of 3 months, as measured by the PDQ39 questionnaire;

2. What is the cost effectiveness ratio expressed in Cost per QALY of the Medido for Parkinson’s patients relative to current treatment for Parkinson’s patients, as measured by the Euroqol 5D (EQ5D);

3. What is the Quality of life for personal care givers for Parkinson’s patients for care givers in the Medido group versus regular care group, as measured by the PDQ carer questionnaire;

4. What is the patient experience of motor symptoms in the Medido group versus regular care group, as measured by the Visual Analog Scale (VAS);

5. How many times do you have a off-period during the day, as measured by the MDS-UPDRS.

Study description

Background summary

Medido versus regular care on physical disabilities.

Study objective

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.

Study design

Baseline en after 3 months.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

Patients:

1. Not capable of completing the questionnaires;

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2013
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-03-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40139
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
N/A