

Is Carer Assisted Adherence Therapy beneficial for improving medication adherence and quality of life in people with PARKinson's disease?

Submission date 17/08/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/09/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/10/2018	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims?

Parkinsons disease (PD) is a disabling condition which reduces quality of life. The most effective treatment for PD is medication. Despite severe symptoms which affect peoples movements, studies have shown that many people with PD do not always stick to their medication schedule correctly. This can be for many reasons. We call this non- adherence. Non-adherence may lead to worsening symptoms which results in deterioration. A major challenge is therefore to help patients to take their medication correctly, thereby maximising the benefit of treatment.

Although PD people may be completely independent, later in the disease people often require support with routine daily tasks. These people may be supported by informal carers such as a spouse or family member and can include help with taking medication. For the caregiver this responsibility can often be burdensome.

There is a need for a treatment that helps people with PD to take their medications correctly. This new treatment may improve the correct taking of medications in PD, leading to reduced symptoms. As medication has been shown to be effective in PD, improved adherence to medication may improve a persons quality of life. Treatments aiming to improve adherence to medication have been shown to be effective in other conditions. However, there is little evidence of such treatments for PD. It is also acknowledged that in PD caregiver involvement in promoting medication taking is important. Therefore, caregivers need to be supported too in their role of encouraging medication taking. We anticipate that a treatment that targets both people with PD and their spouse/carers is likely to improve medication adherence and maximise quality of life. The main aim of this study is to test if people with PD and their spouses/carers who receive a new treatment, Carer Assisted Adherence Therapy in Parkinsons disease (CAAT-PARK), improve in medication adherence and quality of life, compared to people who do not receive the new treatment.

Who can participate?

People attending Medicine for the Elderly or Neurology outpatient appointments for diagnosed or probable PD. Spouse/carers will be invited to participate. To take part you need to be:

Prescribed one or more medications for your PD

English speaking and literate

On a stable medication regime i.e. not altered within the previous month
Not have dementia or significantly cognitive impairment
Not taking medication as prescribed

What does the study involve?

The treatment being tested in this study is Carer Assisted Adherence Therapy for people with PD (CAAT-PARK). The treatment is delivered over seven sessions in participants homes, each lasting around twenty minutes. While one group will receive CAAT-PARK, the other group will receive traditional care with no other support than what is usually provided. We call this treatment as usual. Both groups will receive medical treatment as usual but one will also receive CAAT-PARK.

What are the possible benefits and risks of participating?

We do not promise that the findings of this study will directly benefit participants. The findings will however be used to help improve treatments for people with PD. Participants randomly assigned to the group receiving the treatment may improve in how they take their medication as a result of the treatment. We do not predict any risks or distress directly resulting from CAAT-PARK.

Where is the study run from?

The study recruits participants from a secondary care university hospital in the East of England, UK. Two departments are participating in the enrolment (Medicine for the Elderly Movement Disorder Clinic and Neurology Out-patients).

When is the study starting and how long is it expected to run for?

Recruitment will be a rolling programme over 12 to 14 months until recruitment targets are achieved. Patients will be enrolled into the study starting September 2011.

Who is funding the study?

This research is supported through University of East Anglia Faculty of Medicine and Health Sciences Post-Graduate Research Studentship Funding.

Who is the main contact for the study?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

The use of Carer Assisted Adherence Therapy for people with PARKinsons disease and their carers (CAAT-PARK): study protocol for a randomised controlled trial

Acronym

CAAT-PARK

Study objectives

To investigate whether people with Parkinson's Disease (PD) and their spouses/carers who receive a programme of Carer Assisted Adherence Therapy in addition to Treatment as Usual (TAU) show significantly greater rates of medication adherence and improved quality of life from baseline to 12 week post randomisation compared to those who receive TAU only.

Secondary objectives are to investigate whether people who receive CAAT-PARK and those who receive TAU differ in terms of overall disease state, activities of daily living, beliefs about medication, generic health related quality of life, and levels of carer distress. We also aim to investigate the experience of those receiving the intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee East of England - Cambridge Central, 7 June 2011, ref: 11/EE/0179

Study design

Prospective parallel-group single centre blinded randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Medication adherence in people with Parkinson's disease

Interventions

CAAT-PARK is a brief cognitive-behavioural approach aimed at facilitating a process of shared decision making. CAAT-PARK is rooted in the observation that a person's beliefs impact on treatment adherence. The central theory is that when people make shared choices with a professional they are more likely to continue with those choices because they are personally owned and meaningful. Identification and amplification of the personally relevant benefits of treatment, modifying beliefs about medication and exploring ambivalence towards medication taking behaviour represent interrelated constructs that are central tenants of the therapy.

CAAT-PARK is delivered in five phases that form the core of the therapy: assessment, medication problem-solving, a medication timeline (looking back), exploring ambivalence and discussing beliefs and concerns about medication. Key therapy skills incorporate exchanging information, developing discrepancy between the patient's thoughts and behaviours about medication and working with resistance to discussing medication and treatment. The aim of CAAT-PARK is to achieve a mutual decision about medication between the individual and therapist. A key concept is that where patients and therapists make choices about treatment mutually, adherence to that regimen will be enhanced.

Participants allocated to CAAT-PARK will receive seven 20 minute sessions at weekly intervals. Each weekly session will incorporate a separate theme, however, each session will be participant centred. Where a patient's carer has consented to the trial, the intervention will be delivered to the carer at the same time. Ten sessions over the course of the trial will be recorded to determine treatment fidelity against the CAAT-PARK manual.

Participants randomised to TAU will receive no additional information regarding medication adherence. Care will continue as usual according to routine practice. We will not provide any guidance to the clinical team as to the content of the usual care. Routinely usual care constitutes a clinic visit every 9-12 months to see the hospital consultant who is managing the patient's PD.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Change in adherence to medication determined by the Morisky Medication Adherence Scale (MMAS-4)

2. Change in quality of life (QoL) determined by the Parkinsons Disease Questionnaire-39 (PDQ-39)

Secondary outcome measures

People with PD:

1. Movement Disorder Society Unified Parkinsons Disease Rating Scale (MDS-UPDRS) Part I (non-motor experiences of daily living), Part II (motor experiences of daily living) and Part IV (motor complications)
2. Beliefs about Medication Questionnaire (BMQ)
3. EuroQol quality of life questionnaire (EQ-5D)

Spouse/Carer Outcomes:

1. Carer Distress Scale (CDS)
2. BMQ

Overall study start date

01/09/2011

Completion date

31/10/2012

Eligibility

Key inclusion criteria

Current inclusion criteria as of 20/12/2011

1. Adults diagnosed with, or with probable, Idiopathic PD (three out of four of the chief UK Brain Bank criteria)
2. Prescribed one or more anti-parkinsonian medications by a Consultant Neurologist or Consultant Physician with specialist knowledge of movement disorders
3. English speaking and literate (participants are required to actively engage in the therapy process)
4. Stable medication regime i.e. not altered within the previous month, and not expected to change during the period of the research project (12 weeks)
5. Not demented or significantly cognitively impaired as assessed either informally by the clinical team or formally using the Mini-Mental State Examination (MMSE) score of ≥ 24 (recent clinic score used where available)
6. Show poor adherence as determined by a Morisky Medication Adherence Scale (MMAS-4) score of 1 or above

Previous inclusion criteria

1. Adults diagnosed with, or with probable, Idiopathic PD (three out of four of the chief UK Brain Bank criteria)
2. Prescribed one or more anti-parkinsonian medications by a Consultant Neurologist or Consultant Physician with specialist knowledge of movement disorders
3. English speaking and literate (participants are required to actively engage in the therapy process)
4. Stable medication regime i.e. not altered within the previous month, and not expected to change during the period of the research project (12 weeks)
5. Not demented or significantly cognitively impaired as assessed either informally by the clinical team or formally using the Mini-Mental State Examination (MMSE) score of ≥ 24 (recent clinic score used where available)

6. Show poor adherence as determined by a Morisky Medication Adherence Scale (MMAS-4) score ≥ 2

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

We aim to recruit 40 couples (patient and spouse/carer) into each treatment group.

Key exclusion criteria

1. Suspected Parkinsonism due to other causes than idiopathic PD
2. Treated with anti-parkinsonian medications for a mental health complaint
3. Diagnosed with dementia
4. Life expectancy < 6 months

Date of first enrolment

01/09/2011

Date of final enrolment

31/10/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Norwich School of Medicine

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Sponsor information

Organisation

University of East Anglia (UK)

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Sponsor type

University/education

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ROR

<https://ror.org/026k5mg93>

Funder(s)**Funder type**

University/education

Funder Name

University of East Anglia (UK)

Alternative Name(s)

UEA

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications**Publication and dissemination plan**

Not provided at time of registration.

2013 results published in thesis <https://ueaeprints.uea.ac.uk/48397/>

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	study protocol	28/11/2011		Yes	No
Results article	results	01/08/2014		Yes	No