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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

Registration date
21/09/2011

Overall study status
Completed

Last Edited
12/10/2018

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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/carer 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/carer 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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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/carer 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, 7June 2011, ref: 11/EE/0179

Primary study design
Interventional

Study design
Prospective parallel-group single centre blinded randomised controlled trial

Study type(s)
Treatment

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 persons 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 patients 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 patients 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 patients PD.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
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)

Key secondary outcome(s)
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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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
United Kingdom

England

Study participating centre
Norwich School of Medicine
Norwich
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Sponsor information

Organisation
University of East Angia (UK)

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
University/education

Funder Name
University of East Anglia (UK)

Alternative Name(s)
UEA University of East Anglia, UEA

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

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?
Results article	results	01/08/2014		Yes	No
Protocol article	study protocol	28/11/2011		Yes	No