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A nurse-led intervention to reduce dopamine dysregulation syndrome in Parkinson's disease patients and their carers

Submission date
04/08/2008

Recruitment status
No longer recruiting

Registration date
18/09/2008

Overall study status
Completed

Last Edited
03/02/2016

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Parkinson’s disease (PD) is a long-term medical condition which is caused by the gradual loss of nerve cells (neurons) in a part of the brain called the substantia nigra. These neurons are normally responsible for producing dopamine, a chemical messenger (neurotransmitter) which carries signals around the brain that help to coordinate movement. In people suffering from PD, these neurons gradually die over time, causing the level of dopamine in the brain to gradually fall. As the levels of dopamine become lower, the brain is unable to coordinate movement as effectively, causing abnormal movements such as stiffness, tremor (uncontrollable shaking) and slowness of movement (bradykinesia). Dopamine dysregulation syndrome (DDS) is a rare but distressing complication of Parkinson's disease (PD). In a small minority of PD patients, the desire to take their medication becomes irresistible and leads to overuse of medication. These patients may try to obtain drugs from other sources and may show extreme reluctance to reduce medication when advised to by their doctors. This drug use is linked with a number of behavioural changes including gambling, increased and inappropriate sexual activities and other risky, anti-social behaviours (known collectively as impulse control disorders, ICD’s). ICD’s are thought to be the result of dopamine-sensitive reward pathways in the brain being activated, enforcing the inappropriate behaviours. The aim of this study is to find out whether cognitive behavioural therapy (a type of talking therapy aiming to change thought patterns and behaviours) given by nurses can be an effective treatment for PD patients with ICD’s.

Who can participate?
Adults suffering from Parkinson’s disease who are suspected of having DDS or ICD’s and their carers.

What does the study involve?
Patients are randomly allocated to one of two groups. Those in the first group take part in six fortnightly sessions of cognitive behavioural therapy (CBT) with a nurse over 12-16 weeks. The sessions are individually tailored to the patient and their current situation and aim to help patients to improve understanding of their condition, strengthening relationships between patients and their carer and learning problem-solving strategies to help them to take part in less

risky behaviour. After each session, participants are given written information and homework tasks to reinforce what they have covered in the sessions. Those in the second group are placed on a waiting-list for the CBT, and have no additional treatment in the study period. At the start of the study, after the treatment (12-16 weeks) and again at 24 weeks, patients and their carers in both groups are asked to complete a number of questionnaires in order to find out if the CBT has caused any change to the patients' behaviour.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Section of Cognitive Neuropsychiatry, Kings College London (UK)

When is the study starting and how long is it expected to run for?
January 2009 to January 2011

Who is funding the study?
The Parkinson's Disease Society (UK)

Who is the main contact?
Professor Tony David

Contact information

Type(s)
Scientific

Contact name
Prof Tony David

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Additional identifiers

Protocol serial number
J-0705

Study information

Scientific Title
Development and evaluation of a nurse-led intervention to reduce behavioural complications of dopamine dysregulation syndrome for Parkinson's patients and their caregivers

Acronym

ICaDDS

Study objectives
The aim of the study is to try to develop and evaluate a brief (12 - 16 week) PD nurse-led intervention with the aim of reducing the psychological and social problems caused by DDS in patients and their carers. The main outcome measure will be carer burden as rated on a standardised self-report scale and distress in relation to symptoms from a carer interview.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Joint South London and Maudsley and The Institute of Psychiatry NHS Research Ethics Committee, 20/02/2008, ref: 08/H0807/1

Study design
Multicentre randomised controlled unblinded crossover trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
The trial will be a psychosocial intervention versus waiting list controls.

The intervention will be a psychosocial intervention and will consist of six planned, fortnightly sessions. The sessions will take place over 12 - 16 weeks. Each session will be supported by literature and homework tasks. The precise agenda for each of the sessions will be individually tailored to the particular patient and caregiver, but will follow a common framework with the following themes:
1. Building insight and understanding
2. Interpersonal communication techniques to strengthen the patient-carer relationship
3. Problem solving and behavioural strategies for management and risk minimisation

The case manager element of the PD research nurse's role will comprise liaising between medical and social care agencies.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Assessments will take place at randomisation (week 0), at 12 - 16 weeks (end of treatment for the treatment group) and 24 weeks.

Caregiver:
1. The Zarit Carer Burden scale
2. The General Health Questionnaire (GHQ-12)
3. The Neuropsychiatric Inventory (given at 0 and repeated at 24 weeks)

Patients:
Individualised and standard scales to rate the frequency/severity/impact of the problem behaviour (e.g., Voon scales for gambling/hypersexuality). These will be recorded during the course of the trial as an aid to the individual intervention and to serve as a target for change (pre-treatment versus end of treatment scores).

Key secondary outcome(s))
Assessments will take place at randomisation (week 0), at 12 - 16 weeks (end of treatment for the treatment group) and 24 weeks.

1. Neuropsychiatric Inventory symptoms-cluster scores
2. The Golombok Rust Inventory Marital Status
3. Changes in medication, added psychotropic drugs and resource use (e.g. emergency doctor services; hospital admission)

It will not be feasible to rate outcome blind to treatment allocation since any carer interview is bound to reveal this. Observer bias will be minimised by the use of self-report measures.

Completion date
01/01/2011

Eligibility

Key inclusion criteria
1. Patients and caregiver dyads, male and female aged 18 years and older
2. Participants must have clinical diagnosis of Parkinson's disease
3. Participants must be suspected of having dopamine dysregulation syndrome or impulse control disorders
4. Both members of the dyad must be able to consent to the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Participant cannot speak English
2. Participant has a Mini Mental State Examimation (MMSE) Score of less than 19
3. Participant does not have an identifiable carer

Date of first enrolment
01/01/2009

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Section of Cognitive Neuropsychiatry
King's College London
Denmark Hill
London
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Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
The Parkinson's Disease Society (UK) (ref: J-0705)

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	26/02/2013		Yes	No