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DREAMS START (Dementia related manual for sleep; strategies for relatives)

Submission date
02/11/2016

Recruitment status
No longer recruiting

Registration date
10/11/2016

Overall study status
Completed

Last Edited
10/08/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
There are expected to be 850000 people in the UK in 2015 living with dementia, two-thirds in the community. UK dementia care costs £26.3 billion. Many people living with dementia have problems with sleeping. Reduced night time sleep, night time wandering, and excessive daytime napping are common. Sleep problems can also disrupt the sleep of other members of the family. As there are currently no known effective treatments, health professionals use treatments which work in people who do not have dementia. They are often ineffective or have unacceptable side effects. This study is looking at a new manual-based sleep programme called DREAMS START (Dementia Related Manual for Sleep; Strategies for Relatives). It is made up of a combination of various strategies, which include increasing light, activity, comfort, routine and relaxation, tailored to the problems of each person. This study aims to test out the programme on people with dementia living at home and their family, to see if it is feasible and acceptable and seems to help.

Who can participate?
Adults with dementia who are experiencing sleep problems and have a family carer.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive treatment as usual, which may vary according to the practices of the Trust in which they are treated and their individual needs. Those in the second group receive treatment as usual as well as taking part in six hour-long weekly sessions of the DREAMS START programme. The treatment is tailored to each patient, as the family member fills in their own experiences and agreed strategies to try out between sessions. All participants are asked to wear an acti-watch (a watch-like device that measures sleep, movement and light) for two weeks and then again three months later, to compare the sleep patterns. Carers also complete questionnaires that ask about the person with dementia (sleep, behaviour, mood and quality of life), and about the carer's own sleep, mood and quality of life at the start of the study and after three months.

What are the possible benefits and risks of participating?
There are no guaranteed benefits of taking part but there is a chance that the sleep programme may help participants improve their sleep. There are no risks associated with participating.

Where is the study run from?
Memory services in Camden and Islington NHS Foundation Trust and Barnet, Enfield And Haringey Mental Health NHS Trust (UK)

When is the study starting and how long is it expected to run for?
February 2016 to October 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Dr Kirsi Kinnunen (scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
199820

Protocol serial number
CPMS 32467, IRAS 199820

Study information

Scientific Title
DREAMS START: Dementia RElATed Manual for Sleep; STrATegies for RelaTives

Acronym
DREAMS START

Study objectives
The aim of this study is to:
1. Develop a manualised programme (DREAMS START) for the management of sleep difficulties in people living with dementia.
2. Examine feasibility of a pragmatic randomised study to investigate the clinical and cost-effectiveness of this new programme.

Hypothesis:
The DREAMS START intervention will be acceptable as measured by the proportion of participants adhering to intervention: expected value 75%, (95% Confidence Interval= 59-87%).

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Queen Square Research Ethics Committee, 29/04/2016, ref: 16/LO/0670

Study design
Randomised controlled single-blind feasibility and acceptability trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Dementias and neurodegeneration, Primary sub-specialty: Dementia; UKCRC code/ Disease: Neurological/ Other degenerative diseases of the nervous system

Interventions
Participants are randomised to one of two groups with an allocation ratio of 2:1 (intervention: TAU) using an electronic randomisation list which has been computer generated by a statistician independent from the research team, using a programme written in STATA. The list is stratified by site using random permuted blocks. The lists are password-protected, and can only be accessed (and allocations provided) by two team members from an unrelated study.

Intervention arm: The six-session DREAMS START intervention is manual-based and delivered to carers by trained and clinically supervised psychology graduates in the participants' own homes. Each session lasts about one hour and takes place approximately weekly. The carer fills in their own experiences and agreed strategies to try out between sessions, and keeps the personalised manual. The last session will summarise what worked and which strategies the carer intends to continue using in the future. The manual includes:
1. Information about sleep and circadian processes and how sleep and brain function change with ageing and dementia

2. Analyses of the person with dementia's reading from the acti-watch
3. A plan for increasing light and activity
4. Relaxation exercises

Control arm: Participants receive treatment as usual (TAU) for six weeks which is delineated by the Client Service Receipt Inventory. This is expected to vary between trusts and also according to individual patient needs, but to be in line with the NICE pathways guidelines for dementia. Services are based around the person with dementia. Treatment is medical, psychological and social. Thus, it consists of assessment, diagnosis, risk assessment and information. These include referral to dementia navigators, medication, cognitive stimulation therapy, START (in some trusts), practical support (social services provided); risk plans, for example telecare, driving information to the Driver and Vehicle Registry Agency (DVLA), medical identification (ID) bracelets, advice regarding power of attorney and capacity assessment; and social services referral for personal care, day centre and financial advice, treatment of neuropsychiatric symptoms and carer support.

Participants in both groups are followed up for three months.

Intervention Type
Other

Primary outcome(s)
1. Feasibility of the intervention is assessed by recording the proportion of participants adhering to intervention (attending predetermined session numbers) and by the proportion of appropriate referrals consenting to the trial at baseline
2. Acceptability of the intervention is assessed through qualitative interviews after follow-up, post-unblinding

Key secondary outcome(s))
1. Referral rates from the recruitment period are measured from records about eligible referrals at the end of the recruitment period
2. Follow-up rates are measured after the last follow-up, from records indicating which participants completed assessments at three months
3. All psychotropic medication prescribed is assessed by completing the Client Service Receipt Inventory (incorporating a list of medications in the last 3 months) at baseline and three months
4. Reported side effects are recorded using a study-specific questionnaire at baseline and three months
5. Acceptability of outcome measures for a future trial of clinical and cost-effectiveness is assessed through recording the completion rates of instruments (see below) at baseline and three months, the acceptability of tools from the qualitative interviews post-unblinding, and estimating the statistical power and sample requirements based on detecting significant differences in outcomes in statistical analysis

Patient measures (data collected by interviewing the carer):
1. Socio-demographic details (sex, age, age when left education, last occupation, current marital status, ethnicity) are collected at baseline
2. Medication use is measured by completing a list at baseline and three months
3. Type of dementia is recorded from the referral information at baseline
4. Severity of dementia is measured using Clinical Dementia Rating at baseline
5. Sleep disorder is measured using the Sleep Disorders Inventory at baseline and three months
6. Actigraphy variables (sleep efficiency, sleep time, wake time, relative amplitude, interdaily

stability, light) are obtained from acti-watches worn at baseline and three months
7. Neuropsychiatric symptoms are measured using the Neuropsychiatric Inventory at baseline and three months
8. Daytime sleepiness is measured using the Epworth Sleepiness Scale at baseline and three months
9. Quality of life is measured using the DEMQOL-Proxy at baseline and three months
10. Services use is measured using the Client Service Receipt Inventory at baseline and three months
11. Side effects are measured using a study-specific questionnaire (falls and co-morbid physical illnesses) at baseline and three months

Carer measures:
1. Socio-demographic details (sex, age, relationship with patient, co-residency or the average no. of visits/month, last or current occupation, ethnicity) are collected at baseline
2. To consider which measure is better in this population, carer sleep quality is measured using the Pittsburgh Sleep Quality Index and the Sleep Condition Indicator at baseline and three months
3. Mood disturbance is measured using the Hospital Anxiety and Depression Scale at baseline and three months
4. Subjective burden for carers is measured using the Zarit Burden Interview at baseline and three months
5. Health-related quality of life is measured using the Health Status Questionnaire (HSQ-12) at baseline and three months

Completion date
31/10/2017

Eligibility

Key inclusion criteria
1. Adults with dementia (any type, any severity)
2. Sleep Disorders Inventory item score ≥4 (a reliable and valid measure of sleep in dementia)
3. Sleep that patient and their family judge is a problem
4. Person with dementia gives consent if has capacity OR consultee provides declaration if the person with dementia is not able to give informed consent (but is not unwilling)
5. Family carer able and willing to give informed consent
6. Family carer gives emotional or practical support at least weekly to the person with dementia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment

Key exclusion criteria
1. Person with dementia living in a care home
2. Person with dementia has other primary sleep disorder diagnosis (e.g. sleep apnoea)
3. Family carer not willing or able to give informed consent

Date of first enrolment
04/08/2016

Date of final enrolment
30/04/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Camden Memory Service
The Peckwater Centre
6 Peckwater Street
London
United Kingdom
NW5 2TX

Study participating centre
Islington Memory Service
Units 8-10 Blenheim Court
62 Brewery Road
London
United Kingdom
N7 9NY

Study participating centre
Barnet Memory Service
The Springwell Centre
Barnet Hospital
Wellhouse Lane
Barnet
United Kingdom
EN5 3DJ

Study participating centre
Enfield Memory Service
Avon Villa
Chase Farm Hospital
127 The Ridgeway
Enfield
United Kingdom
EN2 8JL

Study participating centre
Haringey Memory Service
St. Ann's General Hospital
St. Ann's Road
London
United Kingdom
N15 3TH

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2018		Yes	No
Results article	results	01/02/2019	24/01/2020	Yes	No
Basic results		18/10/2018	18/10/2018	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1	20/01/2016	10/08/2022	No	No