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A parallel multi-centre randomised controlled trial to determine the clinical and cost-effectiveness of DREAMS START (Dementia RElAted Manual for Sleep; STrAtegies for RelaTives) for people living with dementia and their carers

Submission date
12/08/2020

Recruitment status
No longer recruiting

Registration date
30/09/2020

Overall study status
Completed

Last Edited
27/05/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Background and study aims
Dementia is a syndrome (a group of related symptoms) associated with an ongoing decline of brain functioning.
Many people living with dementia have disturbed sleep, including reduced night-time sleep, night-time wandering and daytime sleepiness. They often wake family members, who may become exhausted, stressed and unhappy. Night-time paid care may be unaffordable and care at home may break down. The primary objective of this trial is to determine whether the DREAMS START intervention improves sleep disturbance in people living with dementia at home at 8 months compared to usual NHS treatment.

Who can participate?
People with dementia with a clinically significant sleep disorder that the patient or their family judge as problematic, and who live in their own home with someone present at night, and a family carer that supports the person with dementia emotionally or practically at least weekly.

What does the study involve?
We will recruit from five varied NHS sites for a randomised trial. Randomised means a computer decides who has DREAMS START and who only has the treatment they would get anyway. We will make small changes to DREAMS START (e.g. offering it either weekly or two weekly, rather than only weekly; and using a text reminder service) based on advice from our earlier study. We will ask family carers to rate their relatives' sleep on a widely used well-tested questionnaire (Sleep Disorders Inventory) which family carers found clear and relevant in our earlier study.

What are the possible benefits and risks of participating?
In our feasibility study participants reported the intervention to be acceptable and qualitatively described finding it beneficial. We do not yet know whether the intervention will be clinically and cost-effective and therefore will be potentially beneficial to both people with dementia and their family carers and this will be explained to them during the consent process. Informed by our pilot work, we do not anticipate any risk to participants. It may be mildly burdensome for carers to keep to weekly appointments but we have added more flexibility into the trial following what we learned at the pilot stage and will adjust the timing to fit around the carer's schedule. To reduce the burden on the people living with dementia participating in the study we will be collecting all information on them by proxy. The researcher delivering the intervention will be trained to manage situations in which the family carer or person with dementia becomes distressed and the researcher will receive regular clinical supervision from a trained clinical psychologist to help them to manage these situations.

Where is the study run from?
University College London & Camden and Islington NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2020 to April 2024

Who is funding the study?
National Institute for Health Research Health Technology Assessment (NIHR128761)

Who is the main contact?
Dr Penny Rapaport, p.rapaport@ucl.ac.uk

Study website
https://fundingawards.nihr.ac.uk/award/NIHR128761

Contact information

Type(s)
Scientific

Contact name
Dr Penny Rapaport

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
272935

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 46209, NIHR128761, IRAS 272935

Study information

Scientific Title
A parallel multi-centre randomised controlled trial to determine the clinical and cost-effectiveness of DREAMS START (Dementia RElAted Manual for Sleep; STrAtegies for RelaTives) for people living with dementia and their carers

Acronym
DREAMS START

Study objectives
To determine whether the DREAMS START intervention improves sleep disturbance in people living with dementia at home at 8 months compared to usual NHS treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/08/2020, London – Camden & Kings Cross Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0) 2071048086; CamdenandKingsCross.REC@hra.nhs.uk), ref: 20/LO/0894

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)

Treatment

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

Health condition(s) or problem(s) studied
Sleep disturbance in people with dementia

Interventions
Current interventions as of 16/01/2024:

Design
A multi-centre randomised controlled trial, with qualitative process evaluation. Participants (both family carers and people living with dementia) will be enrolled in the trial over an eight month period. Half of these people will receive the DREAMS START intervention in addition to usual treatment and the other half will continue to receive usual treatment alone.

Study population
We will recruit 370 dyads of people living with dementia living at home and experiencing sleep difficulties and their family carers.

Planned Intervention
Researchers will deliver six sessions over approximately three months (with sessions offered flexibly weekly to fortnightly) for those randomised to the intervention. Sessions will be delivered to family carers alone or where appropriate to the family carer and the person living with dementia together.

DREAMS START is a six-session manual-based intervention for carers of people with dementia to make changes to improve their relatives' sleep. We co-designed the intervention based on evidence, academic expertise from UCL and the University of Oxford collaborators based on published trials in insomnia in adults and dementia care, and PPI and clinician expertise, to optimise both the person with dementia's sleep at night and daytime wakefulness. The intervention provides information about sleep and dementia, supports carers to use practical strategies to regulate their relatives sleep and daytime activity. It uses strategies to promote de-arousal at night (e.g. relaxation, bedroom comfort, no caffeine or alcohol pre-bed, relaxation) and daytime behavioural activation to maintain alertness and reduce daytime naps. The intervention also focuses on helping carers to look after their own (sleep) health. Each session teaches different relaxation strategies. We will use text messaging reminders to carers to encourage them to put strategies into practice and complete diaries and record forms. We will aim to deliver the sessions weekly or fortnightly depending on the availability of the carer but will be flexible to maximize adherence. We will deliver the sessions in the participant's home or at the researcher's place of work if this is preferred by the participant, where necessary we will offer to deliver the sessions over the phone or by video call.

Approach and consent
Researchers will recruit 370 family carer-people with dementia dyads from memory services, older adult mental health services and primary care in NHS Trusts supported by local Clinical Research Networks (CRNs) and from JDR. We will advertise the study through a poster to be displayed in the reception area of participating NHS sites, the DREAMS START study website and via the research organisation JDR.

CRN staff and clinicians at trial sites will identify potential participants, who, unless they have given permission to be approached for research, will be initially approached by a clinician for agreement to be approached. If they agree to be approached they will be given (or sent by post or electronically) an information sheet. Verbal permission will be sought from the person with dementia and the family carer (if present) from the identifying clinician, and the clinician will contact the researcher either by telephone or secure email to inform them of any interested participants. Those interested in participating will be referred to the research team.

The researcher will then follow-up with the person with dementia and their family carer at least 24 hours after the PIS has been given in person or at least 72 hours if it has been sent in the post. They will answer any questions, check eligibility and then arrange to meet either face to face or if necessary via telephone or video call those who express interest, to obtain their informed consent and complete the baseline assessment. Researchers will take written informed consent or where necessary (audio-recorded) verbal consent from family carers and their relative with dementia if they have capacity to consent. If the person with dementia does not have capacity to consent, the family member will be asked to complete a personal consultee form.

Procedures
At the initial meeting, if potential participants are willing, researchers will obtain written or (audio-recorded) verbal informed consent to take part in the study from family carers and people living with dementia who have capacity (or a personal consultee will sign for people living with dementia who lack capacity to consent). They will then complete the baseline assessments. If necessary, the researcher will leave the self-complete questionnaires with the participant to complete and return to the researcher by post within two weeks of the baseline assessment (they will be given a freepost envelope with the researchers address). Alternatively, participants will be offered the opportunity to complete the secondary outcome measures with a researcher over the telephone. At the initial appointment the participants living with dementia will be asked to wear an actigraph for one week from baseline and with support from their family carer to return the actigraph by post after one week (they will be given a freepost envelope which the researchers address or the researcher will pick it up). An actigraph is a small, non-invasive device that is worn on the wrist like a watch that measures movement. We used them during our feasibility DREAMS START study and found that they were acceptable to people living with dementia. We will use the data collected to inform understandings of the mechanism of change of the intervention, exploring changes in activity and how this relates to other outcomes.

Once consent has been obtained, all measures collected, and the actigraphs worn for a week, participants will then be randomised to receive the DREAMS START intervention or routine care. Researchers will deliver six sessions over approximately three months (with sessions offered flexibly weekly to fortnightly) for those randomised to the intervention. We will audio-record intervention sessions to assess researcher fidelity to the manual. All participants will be followed up at four and eight months from randomisation to complete primary and secondary outcome measures by researchers masked to intervention status. When the appointments are made, the participants will be asked to hide any materials they may have from view and reminded not to disclose whether they received the intervention. A week before the four and eight month follow ups all people living with dementia will be sent an actigraph in the post and they and their carer will also be phoned and asked to wear this for a week before the four and the eight month follow up assessment. After the eight month follow up a sample of 15-20 participants randomised to the intervention will also be contacted to take part in an optional qualitative interview to explore their experiences of receiving the intervention. We will ensure that they cover the range of participants - spouses and non-spouse carers; men and women;

those completing and not completing the intervention; differing ethnic groups and differing sites. We will also ask the DREAMS START facilitators to provide structured feedback on the intervention.

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Previous interventions:

Design
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Intervention Type
Behavioural

Primary outcome measure
Resident sleep at 8 months measured using the SDI

Secondary outcome measures
At baseline, 4 month and 8 month follow ups:
Person living with dementia (all proxy measures):
1. Neuropsychiatric symptoms (Neuropsychiatric Inventory, NPI)
2. Tendency to sleep/doze in specific daytime situations (Epworth sleepiness scale (ESS))
3. Quality of life (DEMQOL-Proxy) answered by a carer. This will also be used in the cost-effectiveness analysis to calculate Quality of life Adjusted Life Years (QALY)
4. Modified Client Service Receipt Inventory (CSRI) a proxy questionnaire asking about health and social care service use information in the past 4 months for the patient (including care home admission, extra patient care during therapy)
5. EQ-5D 5 level (EQ-5D-5L) proxy is a generic measure of health-related quality of life. Carer proxy responses will be used to calculate QALYs and incremental cost per QALY gained
6. Medication- psychotropic medication to delineate the role of rescue medication and any effect of the intervention on prescribing. This data will be collected as part of the CSRI
7. Side effects measure for fall and comorbidities at baseline. Using a Safety, and Tolerability Assessment to record the occurrence of falls, dizziness, headaches and gastrointestinal symptoms (appetite or bowel symptoms) and other side effects and whether these were mild, moderate or severe. This will allow us to assess potential harms
8. One-week actigraphy for person with dementia (Axivity AX3 from baseline and before 4 and 8-month follow-up)

Family carer:
1. Sleep Condition Indicator (SCI) is an eight item scale to assess sleep disturbance
2. The hospital anxiety and depression scale (HADS) is a validated, reliable instrument to measure mood throughout age groups
3. Zarit Burden Interview (ZBI) the most commonly used and well validated measure of burden for carers of people with dementia
4. Health Status Questionnaire (HSQ-12) a 12-item health-related quality of life scale validated throughout age groups
5. Modified Client Service Receipt Inventory (CSRI) a questionnaire asking about health and social care service use information in the past 4 months. This will incorporate the Valuation of Informal Care Questionnaire (iVICQ) a measure of carer time and activity and the Brief Work Productivity and Activity Impairment (WPAI) a measure of productivity loss
6. EQ-5D 5 level (EQ-5D-5L) is a generic measure of health-related quality of life

Overall study start date
21/08/2020

Completion date
30/04/2024

Eligibility

Key inclusion criteria

1. People with dementia (any type/severity/on any or no medication)
2. Sleep Disorders Inventory (SDI) score >=4. The SDI is a valid and reliable standalone tool for sleep disorder in people with dementia. Those who score >=4 have clinically significant sleep disorder
3. Sleep that patient or their family judge as problematic
4. Patient with capacity gives consent, or if not capacitous, consultee gives consent and patient not unwilling
5. Family carer gives informed consent
6. Family carer supports the person with dementia emotionally or practically at least weekly
7. Person with dementia lives in their own home with someone present at night

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
370 dyads (740 people living with dementia and family carers)

Total final enrolment
740

Key exclusion criteria
Current exclusion criteria as of 18/12/2023:
1. Known primary sleep breathing disorder diagnosis preceding dementia (e.g. sleep apnoea) from self or proxy report
2. Current known heavy alcohol use from self or proxy report (AUDIT C Score >=8)
3. People unavailable for >3 weeks of intervention and follow-up (e.g. planned holiday or hospital admission
4. Currently enrolled in another non pharmacological dementia RCT

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Previous exclusion criteria:
1. Known primary sleep breathing disorder diagnosis preceding dementia (e.g. sleep apnoea) from self or proxy report
2. Current known heavy alcohol use from self or proxy report (AUDIT C Score >=5)
3. People unavailable for >3 weeks of intervention and follow-up (e.g. planned holiday or hospital admission
4. Currently enrolled in another non pharmacological dementia RCT

Date of first enrolment
01/02/2021

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Pancras Hospital
Camden and Islington NHS Foundation Trust
4 St Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre
Chapel Street Assessment and Treatment Centre
Sussex Partnership NHS Foundation Trust
Chapel Street
Chichester
United Kingdom
PO19 1BX

Study participating centre
Essex Partnership University NHS Foundation Trust
The Lodge
Runwell Chase
Runwell
Wickford
United Kingdom
SS11 7XX

Study participating centre
North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
United Kingdom
RM13 8GQ

Study participating centre
West Park Hospital
Tees, Esk and Wear Valleys NHS Foundation Trust
Edward Pease Way
Durham
United Kingdom
DL2 2TS

Sponsor information

Organisation
Camden and Islington NHS Foundation Trust

Sponsor details
St Pancras Hospital
4 St Pancras Way
London
England
United Kingdom
NW1 0PE
+44 (0)20 3317 3747
sponsor.noclor@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.candi.nhs.uk/

ROR
https://ror.org/03ekq2173

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR128761

Funder Name
National Institute for Health Research (NIHR) (UK)

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/04/2025

Individual participant data (IPD) sharing plan
The qualitative and quantitative datasets generated during and/or analysed during the current study will be available upon request from PRIMENT CTU Data Management Group on priment@ucl.ac.uk in collaboration with members of the DREAMS START Trial Team. Any request for data must come through to Priment CTU in the first instance and where the request is reasonable, anonymised datasets, stored on the publicly available UCL Research Data Repository https://rdr.ucl.ac.uk/ will be shared once analysis and publication of the trial findings have occurred.

IPD sharing plan summary
Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3	19/07/2022	13/12/2022	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 4.0	13/01/2023	07/09/2023	No	No
Statistical Analysis Plan	version 2.0	21/11/2023	22/11/2023	No	No
Other files	HEAP version 1.0	08/12/2023	18/12/2023	No	No
Protocol article		01/02/2024	09/02/2024	Yes	No
Results article		01/10/2024	07/10/2024	Yes	No
Protocol file	version 5.0	27/02/2024	21/10/2024	No	No

Other publications	a within-trial economic evaluation	21/05/2025	27/05/2025	Yes	No