Full title of trial	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
Short title	DREAMS START RCT
Version and date of protocol	Version 1.3, 31-JUL-2021
Sponsor:	Camden and Islington NHS Foundation Trust Nicholas Portman Senior Regulatory Compliance Officer Email: sponsor.noclor.nhs.net
Sponsor protocol number	R-1484
Funder (s):	National Institute for Health Research – Health Technology Assessment (HTA)
ISRCTN no:	[Insert ISRCTN or Clinicaltrials.gov reference no]
Intervention(s):	National Institute for Health Research – Health Technology Assessment (HTA)
Standard/Control/Treatment as usual:	Treatment as usual
Phase of trial	N/A
Sites(s)	Multi-site

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PROTOCOL VERSION HISTORY

Version Number	Date	Protocol Update Finalised By (insert name of person):	Reasons for Update
1.0	04.06.20	Final version finalised by Penny Rapaport	Not applicable as first final version.
1.1	20.12.2020	Finalised by Penny Rapaport	Minor Amendement 1
1.2	23-JUN-2021	Finalised by TM	Minor Amendement 3
1.3	31-JUL-2021	Finalised by TM	Minor Amendment 5

SIGNATURES

The Chief Investigator and Priment have discussed this protocol. The investigator agrees to perform the investigations and to abide by this protocol.

The investigator agrees to conduct the trial in compliance with the approved protocol, GCP, the UK Data Protection Act (2018), any applicable EU/UK amended acts to the Data Protection regulation, the Trust Information Governance Policy (or other local equivalent), the UK Policy Framework for Health and Social Care Research , Priment's SOPs, and other regulatory requirements as amended.

Chief investigator
Penny Rapaport

12 June 2020

Signature | Date

Sponsor Representative
Anne Marie Downey
Trial Operations manger, Priment CTU

12 June 2020

Signature | Date

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2 LIST OF ABBREVIATIONS

Term	Definition
AD	Alzheimer's Disease
AE	Adverse Event
APR	annual progress report
AR	Adverse Reaction
BAME	Black, Asian and Minority Ethic
CBT	Cognitive Behavioural Therapy
CI	Chief Investigator
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CRN	Clinical Research Networks
CSRI	Client Service Receipt Inventory
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
DEMQOL-Proxy	Dementia Quality of Life measure reported by a carer
DI	Designated Individual
DMEC	Data Monitoring and Ethics Committee
DSMB	Data Safety and Monitoring Board
DSUR	Development Safety Update Report
EQ-5D-5L	Descriptive system of health-related quality of life states consisting of five dimensions
ESS	Epworth Sleepiness Scale
EU	European Union
GAfREC	Governance Arrangements for NHS Research Ethics
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GP	General Practitioner
HADS	Hospital Depression and Anxiety Scale

HRA	Health Research Authority
HSQ-12	Health Status Questionnaire
HTA	Health Technology Assessment
IAPT	Improving Access to Psychological Therapies
ICC	Intercluster correlation coefficient
ICF	Informed Consent Form
ICH	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ID	Identification
ISF	Investigator Site File
iVICQ	Valuation of Informal Care Questionnaire
ISRCTN	International Standard Randomised
ITT	Intention to treat
JDR	Join Dementia Research
NHS R&D	National Health Service Research & Development
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
Non- CTIMP	Non- Clinical Trial of an Investigational Medicinal Product
NPI	Neuropsychiatric Inventory
MHRA	The Medicines and Healthcare Products Regulatory Agency
PI	Principal Investigator
PIS	Participant Information Sheet
PPI	Patient Public Invovlement
QALYs	Quality Adjusted Life Year
QC	Quality Control
RA	Research assistant
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAR	Serious Adverse Reaction
SAE	Serious Adverse Event

SCI	Sleep Condition Indicator
SCN	Suprachiasmatic Nucleus
SDI	Sleep Disturbances Inventory
SDV	Source Document Verification
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
TAU	Treatment As Usual
TMG	Trial Management Group
TSC	Trial Steering Committee
UK	United Kingdom
USD	United States Dollar
WPAI	Work Productivity and Activity Impairment
ZBI	Zarit Burden interview

3 TRIAL PERSONNEL

See protocol cover page for Chief Investigator and Sponsor contact details.

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SUMMARY

Objectives:	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. Secondary objectives are to determine (i) whether DREAMS START is effective at 4 months; (ii) whether it increases people with dementia's quality of life; (iii) whether it increases family carer's quality of life; (iv) whether it is cost-effective; (v) whether it improves family carers' sleep and decreases their affective symptoms and burden; (vi) the mechanisms of change; and (vii) strategies for implementation if effective.
Type of trial:	Randomised controlled trial with process evaluation in people living with dementia and family carers.
Trial design and methods:	Multi-centre, parallel group, superiority randomised controlled trial (RCT) with masked outcome assessment in people living with dementia and family carers. Primary objective outcome assessment: Sleep Disturbances Inventory (SDI) (person with dementia) at 8 months Secondary objective outcome assessments: Quality of life: DEMQOL-Proxy (person with dementia), Health Status Questionnaire, HSQ-12 (Carer); daytime sleepiness: Epworth Sleepiness scale, ESS; Cost effectiveness: Client Service Receipt Inventory (CSRI) and EQ-5D 5-level proxy (EQ-5D-5L), Quality Adjusted Life Years (QALYs) from DEMQOL-Proxy and EQ-5D-5L; Neuropsychiatric symptoms –NPI; Carer's sleep: Sleep Condition Indicator SCI; Carer Mood: Hospital Depression and Anxiety Scale HADS ; Carer Burden: Zarit Burden interview ZBI
Trial duration per participant:	8 months
Estimated total trial duration:	31 months from first participant enrolled to last follow up (33 months including process evaluation qualitative interviews)
Planned trial sites:	multi-site, n=7
Total number of participants planned:	370 participants of whom 15-20 will participate in process evaluation
Main inclusion/exclusion criteria:	We defined inclusion/exclusion criteria based on the feasibility trial. The inclusion criteria (all to be satisfied): 1. People with dementia (any type/ severity) except those currently drinking alcohol heavily (See exclusion criteria). 2. 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. This is a pragmatic study and if the patient and family are

	unconcerned, treatment is unnecessary, as in normal clinical practice. 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 at the beginning of the study with someone present at night. Exclusion criteria (any): 1. Known primary sleep disorder diagnosis preceding dementing illness (e.g. sleep apnoea) 2. Current known heavy alcohol use (Alcohol Use Disorders Identification Test – Consumption (AUDIT C) Score ≥8). 3. People unavailable for >3 weeks (e.g. planned holiday or hospital admission) of intervention and follow-up. 4. Currently enrolled in another non pharmacological dementia RCT.
Statistical methodology and analysis:	Participants' baseline characteristics will be described by treatment group using summary statistics. We will use a mixed effects multiple regression model to compare SDI score between randomised groups at eight months, adjusting for baseline scores and site and allowing for facilitator clustering in the intervention arm. We will use similar models for the secondary clinical outcomes. Process evaluation qualitative interviews will be thematically analysed.

4 BACKGROUND AND RATIONALE

The 47 million people living with dementia worldwide is projected to increase to 131 million by 2050; at an estimated trillion United States Dollar (USD) cost[1]. Sleep disturbance affects 25-40% of people with dementia[2 3 4 5] with a meta-analysis finding a pooled prevalence of 39% in Alzheimer's disease (AD)[6]. Sleep disturbance affects all aspects of mental and physical functioning and quality of life[7] and may lead to or worsen AD[8]. People with dementia may wake during the night and be unaware of the time, or be distressed or disorientated. Family members provide most of the care for the two-thirds of people with dementia living at home[9]. Family carers find it difficult to cope with persistently disturbed sleep without paid night carers, who can be unaffordable[10]. Sleep disturbances also predict family carer depressive symptoms, burden and care home admission, elevating the individual, societal and economic impact of dementia[11-13]. Currently, annual dementia care costs in the UK are about £26 billion with people with dementia and their families paying most of the costs (£17.4 billion)[9 14].

As with other older people, most people with dementia have other illnesses and over 90% have at least one long-term health condition and may experience pain, discomfort or mood disturbances[15] which can

all contribute to sleep disturbance[16]. Additionally, dementia, specifically impairs the sleep–wake cycle through degeneration of the suprachiasmatic nucleus (SCN), leading to impaired melatonin production, disrupting circadian rhythms[8]. The circadian rhythm of melatonin production – high levels at night and low levels during the day – helps control the sleep-wake cycle[17]. Dementia can therefore lead to impaired sleep initiation, reduced night-time sleep, difficulty maintaining sleep, increased night-time wandering, and excessive daytime sleepiness[2 3 18].

The Lancet Commission on dementia and our systematic review of evidence up to June 2017 found no conclusive evidence that any therapy to treat sleep disorders is effective[10 19]. A Cochrane review of pharmacotherapies found no conclusive randomised controlled trial (RCT) evidence for people with dementia[20]. Hypnotic drugs can have adverse effects, including increased daytime sedation, falls[21] and mortality in older adults[22]. Pharmacological interventions, including melatonin, are not recommended as treatments[23] and studies consistently indicate that patients and their doctors prefer non-drug approaches for sleep problems[24]. Dementias are often characterised by circadian rhythm disruption that is at least partly due to progressive loss of SCN neurons[25]. Strengthening circadian rhythmicity through bright light therapy is theoretically appealing, but light therapy delivered to everyone at a standard time, whether they require extra light or not may exacerbate sleep disruption and agitation[26]. A Cochrane review found insufficient evidence for light therapy alone in dementia[27]. As sleep disturbances in people with dementia have mixed causes, it makes sense that promising interventions are multi-component. Two pilot studies in community-dwelling people with dementia, and our DREAMS START (Dementia RElAted Manual for Sleep; STrAtegies for RelaTives) feasibility RCT, found potential benefits of combining light with other components, including sleep education and hygiene, exercise, daytime activities and cognitive behavioural therapy (CBT)[28-30]. However, the other pilot studies had higher drop-out rates (40-50%)[29 30] than our feasibility RCT (8%). Currently, there is no conclusive evidence of any effective non-pharmacological treatment for sleep disturbances in people with dementia[31].

This research builds on our successful feasibility RCT (NIHR/HTA 14/220/06)[28 32]. Our vision was to synthesise and add to incomplete evidence, co-produce a multi-component non-pharmacological intervention, and deliver it individually to fit each patient's needs. We co-produced DREAMS START using the best available evidence, patient and public involvement (PPI) and our clinical and research expertise[33]. The intervention is delivered to family carers, who implement strategies to reduce the person with dementia's sleep disturbances. It uses natural daylight (where feasible) and if necessary, timed phototherapy to strengthen and stabilise sleep-wake timing. Additionally, it, alerts carers to consider pain, uses strategies to increase comfort, reduce anxiety, increase daytime activity and CBT for sleep management, which Cochrane reviews found effective for older adults and family carers of people with dementia[34 35]. Our feasibility RCT found that the design and the intervention were feasible and acceptable; 63/95 (65%; 95% CI 55% to 75%) eligible referrals consented, 62/95 (65%; 95% CI 55% to 75%) were randomised, and 37/42 (88%; 95% CI 75% to 96%) randomised to the intervention adhered to it. Qualitative interviews indicated that it was acceptable. We will now aim to evaluate the intervention's effectiveness and process in a well-designed fully powered trial and use the data generated to make evidence-based clinical practice recommendations on managing sleep disturbance in dementia.

We need clinically and cost-effective ways to improve disrupted sleep for people with dementia, their families, health and social care systems, society and global economies. There are currently no treatments known to be effective. There is urgency, because of the increasing number of people with dementia, the effect of sleep disturbance on their families who may become depressed, and economically, as this leads to care home admissions[11-13]. Treating sleep problems effectively may not only improve wellbeing, daytime functioning and quality of life of those living with dementia, but, as insomnia is thought to increase amyloid deposition, treatment may slow disease progression[36]. People with dementia are particularly vulnerable to side-effects because of multiple morbidities, and pharmacological treatments are ineffective and harmful[19 24]. Non-pharmacological treatment options should be first line sleep management; however, evidence of efficacy is lacking[10]. Our team developed and delivered DREAMS START, showing that it is a feasible and acceptable intervention, with high adherence to treatment and indications of effectiveness[28 32].

Our team has a proven track record in developing, testing and implementing non-pharmacological sleep[37 38] and dementia care[39-41] interventions across a range of NHS settings, including primary (Improving Access to Psychological Therapies (IAPT)) and secondary care (memory services). In our previous work with START (STrAtegies for RelaTives), an intervention for family carers of people with dementia, we demonstrated short and long-term clinical and cost-effectiveness[40], providing an ideal platform on which to build DREAMS START. We are now implementing START for Black, Asian and Minority Ethnic (BAME) groups and through the voluntary sector. This proposed research has the potential to improve sleep and quality of life for people with dementia and their family carers, in a feasible and scalable intervention, without medication side effects, and to elucidate the mechanisms of impact. If clinically effective, our intervention should be cost effective: it is cheap and potentially will reduce health and social care burden, particularly if it delays care home admission.

Using a randomised controlled trial study design, we will answer the research question: is the DREAMS START intervention effective at improving sleep disturbance in people living with dementia at home at 8 months compared to usual NHS treatment? Outcome assessors will be blinded to randomisation status, but it will not be possible to blind study participants. Assessors will ask participants at the beginning of each interview not to disclose their allocation group. All assessments will take place in the home of the person with dementia or carer. Outcome assesors will be asked will be asked whether they have been unblinded at each follow up, to test unblinding. Where an assessor indicates that they have been unblinded corrective/preventative measures will be put into place and documented.

4.1 ASSESSMENT AND MANAGEMENT OF RISK

We do not think there are significant risks associated with the intervention for people in the intervention arm of the trial. We did not identify any harms associated with the intervention during our feasibility RCT, so it is unlikely that there will be a significant risk to participants or that the study will be discontinued on safety grounds. We will collect possible side effects from both arms. The study personnel and co-investigators will ensure that the study is conducted in line with NHS and professional ethical and research governance guidelines. Training and regular supervision will be provided to researchers on study procedures and intervention delivery by the chief investigator, site based primary investigators, and programme manager working on the study.

The table below summarises the risks, frequencies and mitigations of the Intervention:

Name of Intervention/ Assessments/ design and Methods/ trial Population	**Potential risk**	**Risk Management**
	Researcher safety	Researchers will follow the UCL lone working policy which can be found on the UCL website: http://www.ucl.ac.uk/estates/safetynet/guidance/lone_working/lone_working.pdf Researchers will carry mobile phones and they will be able to contact the chief investigator, the programme manager or local site primary investigator working on the team during work hours and out of hours when delivering the study intervention. Researchers will contact a member of the study team if they are not returning to the office after an assessment or intervention session. The study team will have addresses, phone numbers and next of kin details of all research assistants.
	Psychological distress of intervention participants	Where this occurs it will be mitigated by asking the participant if they wish to continue with the session, suggesting a break in the intervention session, moving on from the topic or the researcher terminating the intervention session. The researcher will then discuss this in clinical supervision and make a plan going forwards.

	Failure to protect privacy	All members of the research team will have undergone GCP, information governance and data protection training. No personal information will be sent to the research team prior to receiving 'consent to contact' from either self-referral or passed on by the recruiting organisation after consent from the participant. Contact details will be entered into password protected spreadsheets, stored on password protected computers that are only accessible to the research team. If information is disclosed by a participant that leads us to believe that any person is at significant risk, the researcher will discuss this with their supervisor. If the harm is to the family carer, we would consider whether that person had capacity to decide whether they wanted the abuse to be reported. If appropriate they will approach the participant and seek their consent for disclosure to the referrer or the participant's GP. Information would only be disclosed without a participant's consent if they lacked capacity to decide whether to consent to this disclosure and disclosure was considered to be in their best interests, or the information indicated that a person(s) other than the index participant was at significant risk of harm. The decision about whether disclosure of information without a participant's consent is warranted will be made by the Chief Investigator, Dr Penny Rapaport (Clinical psychologist) or by the Co-Chief Investigator, Professor Gill Livingston (Consultant Psychiatrist). Both have many years' clinical experience working in older people's mental health services. Decisions will abide by the Mental Capacity Act (2005, England and Wales).
	Researcher does not support the intervention effectively	The facilitators will be trained to deliver the intervention and will be supervised by experienced clinical psychologists. Researchers will receive guidance in the form of intervention protocols and manuals and will audio-record a random group-intervention session from each cohort to assess researcher fidelity to the manual using a standard checklist. Throughout the trial there will be close contact between the researcher and the study team to ensure adherence to the protocol.

	Trial conduct	There are good management procedures in place, including oversight committees such as TSC/DMEC and TMG. The trial is also supported by Priment CTU which is overseeing study management, providing SOPs and keeping track of training logs for research teams and the staff at research sites. There are appropriate regular team meetings in place with communication via telephone or email where necessary. The research team will keep in regular contact with the sites. All sites and researchers will be trained on the research process. As this is a single-blind study, there is a small risk that assessors may become unmasked. We will minimise this risk by asking the assessors to remind participants at each stage that they must not reveal their treatment arm allocation to their assessor and those arranging assessment appointments that any study materials must be placed out of site. Details of treatment arm allocation are stored to a section in Sealed envelope database, which assessors do not have access to. If an assessor does become unmasked, the study team will record this and ask an alternative assessor to complete future outcome measures for that participant.
	Contamination between arms	We will take steps to mitigate contamination in the TAU arm against this by ensuring that the trained facilitators at each site are not delivering interventions or working therapeutically on sleep with participants in the trial within their local clinical services. We will use the information from the CSRI, a measure of service utilisation, to record other forms of non-pharmacological therapy and pharmacotherapy for sleep or dementia symptoms received outside of the study. If control group participants report receiving any non-pharmacological intervention for sleep this will trigger a call from the research team who will collect information in a standardised way to determine if contamination has occurred and we will report on this. We will use this data to consider the extent of any contamination and its potential impact on the trial results. As assessments will be masked, there is a small risk that assessors may become unmasked accidentally by the participant or carer. We will minimise this risk by the following: assessors will remind participants at each stage that they must not discuss their intervention with their assessor and remind participants to hide any study related materials or equipment; if an assessor does become unmasked we will make a note of this and ask an alternative assessor to complete future outcome measures for this participant.

	COVID 19 impact	Delays are likely to trial set up due to COVID 19 impacting: Staffing resources (staff falling ill); staff recruitment to conduct research due to restrictions on non COVID 19 related activities and restrictions on non COVID 19 related research and prioritising of clinical non research activities in NHS sites. Study will be recruiting people living with dementia (including those without capacity) and family carers and conducting face to face assessments, also the intervention includes six sessions therapy delivered to family carers in their homes which currently would not be possible. We have agreed with the funder, the trial management group, the sponsor and the CTU to delay the start date of the project which should mean that by the end of the set up phase we are hopeful that we will be able to continue with face to face assessment and intervention with participants as planned. We believe this will allow us to conduct the trial and test the intervention in a rigorous and consistent way. We will continue with our set up phase as planned and will only open sites when it is safe to do so and when we are likely to recruit to target. However we have included in our protocol that we will, if necessary be able to conduct assessments and face to face visits over the telephone or by video calling and that we can also take verbal as well as written consent if necessary. This means that if there is a second wave of the pandemic, or restrictions are not lifted for certain vulnerable groups, or if people are unable to meet face to face for other reasons, we will be able to proceed.

5 OBJECTIVES

This study aims to determine whether our manualized, multi-component, non-pharmacological treatment package delivered by supervised non-clinically qualified psychology graduates, will deliver significant benefits for people living with dementia and their family carers. Additional aims are to assess the process and fidelity of delivery of the intervention, and explore the experiences of family carers receiving the intervention

Primary objective: 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.

Secondary objectives: To determine:

1. Whether the DREAMS START intervention improves sleep disturbance in people living with dementia at home at 4 months.
2. Whether it reduces daytime sleepiness
3. Whether it increases people with dementia's quality of life.
4. Whether it is cost-effective.
5. The role of psychotropic medication and melatonin in any change
6. Whether it increases family carers' quality of life
7. Whether it improves family carers' sleep and decreases their affective symptoms and burden.
8. What are the mechanisms of change?
9. If effective, how can we optimise the intervention for implementation at scale in the NHS?

6 TRIAL DESIGN

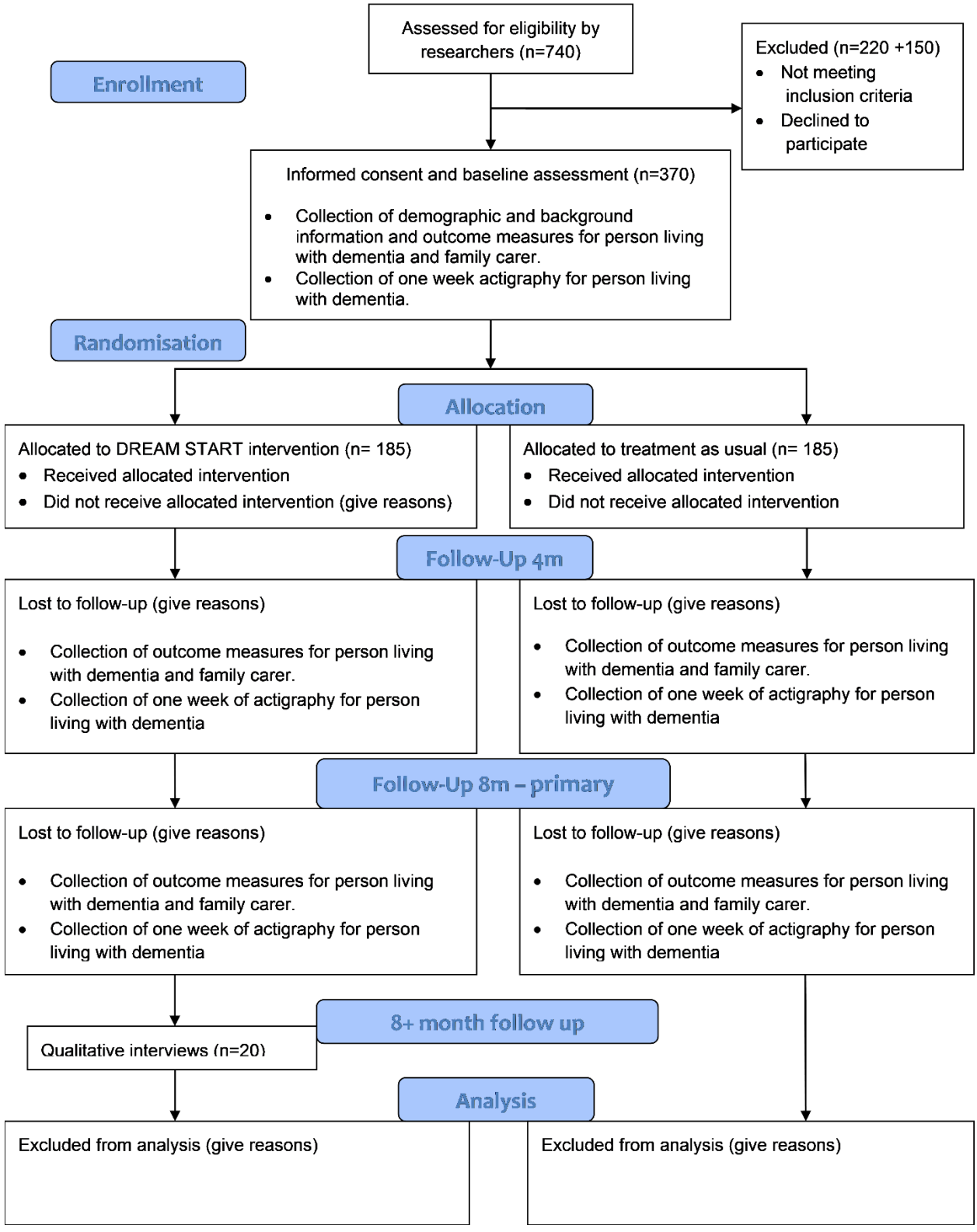
6.1 OVERALL DESIGN

Multi-centre, parallel group, superiority randomised controlled trial (RCT) with masked outcome assessment. Participants will be enrolled in the trial over an eight month period. Potential participants (both family carers and people living with dementia) will be identified by health and social care professionals who are already in contact with them or by Clinical Research Networks (CRNs) staff (if they have already given permission to be contacted about research) or they will self-identify through the research site Join Dementia Research (JDR). JDR is a free to use secure online and telephone service developed and launched in 2014/2015 by the NIHR. It aims to make it easier for people with dementia and other interested members of the public to participate in dementia studies. People register their interest, providing basic or more detailed demographic and clinical information and their contact details (including their preferred means of contact). The registrant or a named representative can then be contacted by researchers to discuss potential suitability of studies. Researchers will ensure participants have the information sheets at least 24 hours before making initial telephone contact. Eligibility will be checked by researchers on the initial screening call to potential participants. If potential participants meet the eligibility criteria, the researchers will offer either a baseline visit or if necessary offer an appointment via telephone or video call. At thisappointment, if potential participants are willing, researchers will obtain written informed consent or where necessary (audio-recorded) verbal 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 appointment (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 provided with (or sent by post) an actigraph to wear 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 purposive 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.

Figure 1 DREAMS START RCT flow diagram



7 INTERVENTION AND STANDARD/CONTROL/TREATMENT AS USUAL

Intervention: DREAMS START is a six-session manual-based intervention for carers of people with dementia to make changes to improve their relatives' sleep[32]. 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 (see Appendix 1 for the derivation of intervention components). The intervention provides information about sleep and dementia, supports carers to use practical *zeitgebers* (cues that influence the person's biological rhythms e.g. regular timing of bed and rising, morning wake-up light, regular meal times) and to establish adaptive stimulus control (e.g. pre-bed settling routine, management of wakeful episodes). 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 aim to deliver the sessions weekly or fortnightly depending on the availability of the carer but will be flexible to maximize adherence.

The sessions cover:

1. Understanding sleep and dementia;
2. Making a plan (using actigraph watches to generate information on activity patterns and timed phototherapy – using light boxes);
3. Daytime activity and routine;
4. Difficult night-time behaviours;
5. Taking care of your own (carer's) sleep;
6. What works? Using strategies in the future.

Training and supervising facilitators: We have already developed intervention delivery training for psychology graduates. To ensure treatment integrity, they will be required to demonstrate competence in delivering the intervention by role-play before we begin recruitment. Co-applicants from UCL and University of Oxford, with clinical and academic expertise in sleep and dementia and our study PPI co-applicant will deliver the short (2 days) training, which we will document, to ensure the intervention is replicable and costable. Training will focus on dementia and sleep-wake regulation, using actigraphs, empathic listening skills, facilitating behaviour change, using supervision effectively and working collaboratively with family carers and people living with dementia. It will emphasise the need to operate from an inclusive values base and to respect diversity and the existing knowledge and skills of family carers. Trained graduates aka "facilitators" will learn through a combination of seminars, discussion, reflective learning, and guided reading.

Facilitators will have fortnightly group supervision with a clinical psychologist with additional individual supervision as requested by facilitators or the study team. The group supervision format makes most effective use of available resources and enables the facilitators to benefit from the professional

expertise of their supervisor and the experiences of their peers. Supervision will include case management, skills development, risk management and safe practice and staff support.

Usual treatment: We are comparing the new treatment with treatment as usual (TAU). Participants randomised to the new treatment will also receive usual care. TAU varies according to where the person with dementia is treated and their individual needs, but incorporates National Institute for Health and care Excellence (NICE) guidelines for dementia and consists of assessment, diagnosis, symptomatic interventions, risk assessment and management, advice and information. There is currently no consistent approach to the treatment of sleep difficulties in dementia. We expect usual treatment to reflect that identified during our feasibility trial, where interventions were medical, psychological and social. This included referral to dementia navigators; medication; cognitive stimulation therapy; START (in some Trusts); risk plans, telecare, treatment of neuropsychiatric symptoms, driving information, medical identification (ID) bracelets, assessment for and advice regarding power of attorney and capacity assessment; and social services referral for personal care, day centre and financial advice, and carer support. Primarily, these interventions are what we would expect as part of general dementia care and support, rather than specifically focusing on sleep difficulties. During our feasibility trial, 45% of participants were prescribed one or more psychotropic medications, with 11% prescribed anxiolytic or hypnotic medication. We will not exclude those taking medication for sleep or stipulate what should happen during the study but will note psychotropic medication prescribed and taken.

8.1 CONCOMITANT MEDICATION

This is a trial of a psychological intervention. We will record all prescribed medications as part of the CSRI data collection for the study.

8.2 POST-TRIAL INTERVENTION ARRANGEMENTS

No arrangements in place.

9 SELECTION OF PARTICIPANTS

9.1 ELIGIBILITY OF TRIAL PARTICIPANTS

9.1.1 TRIAL PARTICIPANT INCLUSION CRITERIA

1. People with dementia (any type/ severity/ on any or no medication) except those currently drinking alcohol heavily (See exclusion criteria). In our feasibility study recruitment, retention and adherence to the intervention were good across type and dementia severity and we would anticipate that in a full trial the individualised nature of the intervention has potentially wide-ranging benefits.
2. 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. This is a pragmatic study and if the patient and family are unconcerned, treatment is unnecessary, as in normal clinical practice.
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. During our feasibility trial when no one else was there at night, carers (family or paid) were unable to implement strategies, like, a scheduled bedtime or wind down routine. It was also difficult to gain reliable information about the sleep patterns of people with dementia living alone.

9.1.2 TRIAL PARTICIPANT EXCLUSION CRITERIA

Any of:

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). During our feasibility trial two participants drank alcohol during the intervention sessions. These people were unable to work with a plan to change their sleep, which involved reducing alcohol, and we were concerned for the safety of our facilitators visiting the homes alone. The participants dropped out.
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.

9.2 RECRUITMENT

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. Information on posters and websites will be approved by REC before hand.

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 contacted by the research team. If they agree to be approached they will be given (or sent by post or electronically) an information sheet. Some prospective participants may have agreed to be contacted for research (as Trusts may have a register) but we will ask a clinician initially to ensure there have been no changes and ask, if possible, if they can make contact. Our experience is that this group of patients may not remember consenting and be cautious of calls from strangers. 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 referral will give the name, sex and relationship of the patient and carer (this will allow testing for external validity by comparing the sample recruited with those who were referred but refused). The researcher will then follow-up with the person with dementia and their family carer by phone 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 an appointment with those who express interest, to obtain their informed consent and complete the baseline assessment.

In addition, we will approach potential 'matches' through JDR. To recruit from JDR we will limit our search to locations where we have a research assistant (RA), identify people listed with dementia diagnosis, who live in their own home and have a carer. We will then contact them using their stated preferred means, screen for eligibility and follow the procedures outlined above. Participants who self-identify via contacting a researcher whose contact details will be on posters in NHS site reception areas or on the DREAMS START study website will be sent the PIS following a telephone discussion with a researcher about the study, they will be screened for eligibility and we will follow the procedures outlined above. For participants identified through JDR or self-identified, we will ensure that we access their GP details and if they consent to participate we will copy consent forms and inform GP of participation in the study.

People living with dementia considered to lack capacity: Staff working in the services from which we are recruiting will approach family carers of people with dementia who they think unlikely to have capacity to decide to take part. All potential participants will be given or sent the study leaflet, PIS for personal consultees and the PIS for family carers, and asked for their permission for a researcher to contact them. The same procedures described above for people with dementia with capacity to consent will be followed, however the approach will be to the family carer and they will be sent the personal consultee PIS and family carer PIS.

Researchers will complete screening logs containing information on all participants that agreed to be contacted by a researcher, the number who refused participation and the number who were not eligible and the reasons why they were not eligible/refused participation.

Participant recruitment at a site will only commence when the trial has

1. Been initiated by the Sponsor (or its delegated representative), and
2. Issued with the 'Open to Recruitment' letter or Green Light letter from the Sponsor.

9.3 INFORMED CONSENT PROCEDURE

It is the responsibility of the researcher delegated by the Investigator to obtain written or (audio-recorded) verbal informed consent from each participant prior to participation in the trial, following adequate explanation of the aims, methods, anticipated benefits and potential hazards of the trial.

The person taking consent will be GCP trained, suitably qualified and experienced in taking consent and assessing capacity, and will have been delegated this duty by the CI/ PI on the Staff Signature and Delegation of Tasks.

"Adequate time" must be given for consideration by the patient before taking part. Consent will be sought at least 24 hours after potential participants have been given the study documentation. The designee will explain that participants are under no obligation to enter the trial and that they can withdraw at any time during the trial, without having to give a reason. No clinical trial procedures will be conducted prior to the participant giving consent by signing the Consent form. Consent will not denote enrolment into the trial.

When obtaining verbal consent we shall send the relevant information sheet in advance and shall then contact the person by telephone in order to gain their consent to participate. The verbal consent process will be audio recorded and the recordings will be securely stored. Researchers will be given additional training in taking consent verbally and follow a trial specific SOP.

A copy of the signed Informed Consent form will be given to the participant. The original signed form will be retained in the trial file at site a copy will be sent to staff to place in the medical notes/case notes/source documents.

The PIS and consent form will be reviewed and updated if necessary throughout the trial (e.g. where additional assessments will be done or where new safety information becomes available) and participants will be re-consented as appropriate.

We will include people living with dementia who lack capacity to decide to take part, because we will not be able to evaluate how the intervention works for people with more severe dementia if we only recruit people living with dementia who have capacity. We will abide by the Mental Capacity Act (England and Wales) (2005) throughout. We will ensure potential participants are assisted to understand studies and to give informed consent, and use consultees if they are unable to. The consent process, including capacity assessment will be documented in the source document/medical notes.

People with dementia who have capacity to consent and their family carer: If the patient's clinician, who is approaching the potential participant, believes that the client is eligible for the study and has capacity to consent to participate in the study, they will ask if they can be approached and if researchers can be told about them.

1. They will inform them either verbally or by letter that they are being asked to participate in a project evaluating a new intervention to help people who have dementia and sleep problems and their family carers. They will be given or sent an information sheet by the researchers informing them about the study, and given at least 24 hours to consider this (or 72 hours if the PIS is posted to them). They will be informed that they do not have to decide immediately and will have a week to decide whether they want to participate, and time to discuss the study further if they wish, with family carers or research staff. They will also be informed that if they decide not to take part that this will not adversely affect their care in any way. If they indicate either physically or verbally that they do not wish to participate or become distressed by this approach they will not be assessed further.

2. The researcher will contact the person with dementia and/or their family member who would like to take part in the study, answer any questions they might have and if they would like to proceed, arrange a time to speak. The researcher will either visit or phone the potential participant and ask that their relative be present if possible. If it is not possible to speak with the person with dementia and family carer at the same time, the researcher will arrange a separate discussion to elicit written or (audio-recorded) verbal informed consent.

3. If the person with dementia agrees to take part, the researcher, who will be trained to assess capacity (both in person and over the phone), will conduct a brief test of capacity, as assessment

of capacity is an on-going process. If the person has capacity they will then be given a consent form to sign. If the person no longer has capacity to consent to participate, the stages below will be followed.

4. For people who self-identify (via JDR, recruitment posters or website) the researcher will assess eligibility over the telephone and then send out the PIS to eligible participants. They will be informed that they do not have to decide immediately and will have a week to decide whether they want to participate, and time to discuss the study further if they wish, with family carers or research staff. They will also be informed that if they decide not to take part that this will not adversely affect their care in any way.

People with dementia who lack capacity to consent and their family carer: When a member of staff working in the service we are recruiting from decides that a person does not have capacity to consent for themselves, the following steps will be taken.

1. On our behalf, the member of staff in the recruiting organisation who knows the potential participant will contact their next of kin, family carer or someone close to the person (who does not receive remuneration for this role) who will act as a "personal consultee". In almost all cases we would expect that this would also be the person invited to take part in the study as a family carer. The approach will either be at a face-to-face consultation or over the telephone. Potential family carer participants will be sent or given a study leaflet, a PIS for their own participation in the study and the personal Consultee PIS, a letter asking them to express their interest in participating in the study and a reply slip by the identifying clinician. The information given will explain that the study will not involve any change in the care that the person is going to receive. They will be encouraged to consider the person's prior wishes or thoughts regarding taking part in research. They will be asked to give permission (verbally to the clinician, or by completing a reply slip to be contacted by the research team and will have the information sheet for at least 24 hours before they are contacted by the researcher to answer any questions they may have, and if they would like to, to make an appointment to meet with them or proceed with telephone consent.

2. Family carers of people who lack capacity to consent will be asked to complete a consultee declaration form on behalf of their relative with dementia, and sign a written written or audio-record a verbal informed consent form for their own participation in the study..

Procedure to be used if a patient loses capacity during the study or if a patient who originally did not have capacity regains capacity: All people living with dementia who have capacity to consent at the start of the study will be asked to identify someone who they would wish for us to approach to act as a personal consultee in the event that they lose capacity during the life of the research study. If the researcher working with the participant, who would be trained to review capacity as an ongoing process on each appointment had reason to believe they had lost capacity, they would liaise with the referring professional team or the participant's GP. They would seek to understand whether this loss of capacity was likely to be temporary, in which case the study could be delayed, or permanent. If the latter they

would proceed as described for potential participants with dementia believed to lack capacity to decide whether to take part. The consent form will include a statement to say that, if the participant loses capacity to give consent during the course of the study, they would /would not be willing for their caregiver to act as a personal legal representative and give consent on their behalf.

It is possible that a participant who lacked capacity at the commencement of the study might regain it. If the researcher observing them, who would be trained to review capacity as an ongoing process on each appointment had reason to believe they had regained capacity, they would discuss this with the consultee. They would proceed as described for potential participants with dementia believed to have capacity to decide whether to take part, in order to elicit their written or recorded verbal informed consent before continuing with the study.

10 TRIAL PROCEDURES

10.1 PRE-TREATMENT ASSESSMENTS

We will keep careful records about eligible referrals and consent to participate, these will inform intervention adherence and acceptability measures. We will document these in a CONSORT flow diagram. We will collect all interview data from the carer, to reduce patient burden and ensure that data is comparable if the degree of impairment of the patient prevents them completing questionnaires. We know from our feasibility study that this interview is acceptable to families. We will ask study participants to consent to long-term follow-up beyond the study, using routinely collected data from GP and secondary care including electronic health records and if we can approach them again after the study has ended. Baseline appointments will take place in the participant's home or at the researcher's work place whichever the participant prefers if necessary we will conduct appointments remotely via telephone or video call. At the baseline appointment, 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 complete primary and secondary outcome assessments and ask the person living with dementia to wear an actigraph for a week. We will collect one week actigraphy for the person with dementia (Axivity AX3[42] from baseline and before 4 and 8 month follow-ups) to collect data on activity. We will also use the data collected to inform plans for increasing activity for participants in the treatment group and understandings of the mechanism of change of the intervention, exploring changes in activity patterns and how this relates to other outcomes. We will also collect information on any planned hospitalizations during the trial period.

All pre-treatment procedures will be carried out as specified in the schedule of assessments as specified in Appendix 1.

10.2 REGISTRATION / RANDOMISATION PROCEDURES

The Trial Manager will perform the randomisation procedure, after consent and baseline data collection are completed and the actigraphs have been worn for a week. Randomisation will be conducted by the Trial Manager, or if the Trial Manager is not available, by a member of the research team who is not

involved in participant recruitment or follow-up. Randomisation will be provided by a web based system using the company Sealed Envelope. It will be set up, tested and validated following Priment SOPs. Randomisation will occur at the level of the patient and will be blocked and stratified by site using a 1:1 intervention: treatment as usual ratio. Participants will be assigned to treatment groups through consecutive allocation of participant numbers and the use of a Trial Participant Log. The researcher facilitating the intervention will be different from the researcher conducting the follow-up assessments for each participant to enable masking of outcome assessment. The Trial Manager will notify the researcher of allocation, who will either arrange the intervention sessions or inform the participant that they have been randomised to the control arm of the trial. The researchers collecting data will be masked to group allocations. The person delivering the intervention will be independent of the person who would be carrying out the follow up assessments, who will be blinded to the intervention allocation. Clinical supervision will be conducted in separate groups to avoid unmasking during discussions.

10.3 SUBSEQUENT ASSESSMENTS AND PROCEDURES

10.3.1 VISIT SCHEDULE AND ASSESSMENTS

Four and eight month follow up appointments will take place at the participant's home or the researcher's work place or if necessary remotely via telephone or video call. All subsequent assessments and procedures will be carried out as specified in the schedule of assessments (Appendix 1)

Process evaluation

Intervention only measures:

1. Attendance at each intervention session including who attended sessions and reasons for non-attendance/cancellation (We define attending ≥4 sessions as adherence; median number of sessions attended was 6 in feasibility with 88% attending≥4).
2. Fidelity recording and checklist completed for one session for each intervention participant. This will be picked by the trial mananger using randomisation.
3. RAs will conduct qualitative interviews with 15-20 participants and all staff delivering the intervention about their experiences of receiving or delivering the intervention and how participants have used the intervention and implemented changes. This will inform the process evaluation.

A schedule of all trial assessments and procedures is set out in Appendix 1.

10.4 CLINICAL PROCEDURES

Section 13 describes all the questionnaires and measures to be used to assess the efficacy of the DREAMS START intervention. All questionnaires will be carried out by researchers and the intervention will be delivered by trained facilitators.

The process for training and supervising facilitators is described above in section 7.

10.5 ASSESSMENT OF TRIAL INTERVENTION COMPLIANCE

Measuring fidelity to the intervention: We will collect information on trial adherence and attendance as outlined below. In addition to supervision and training, we will formally monitor fidelity to the intervention. Following a similar process to that used in the feasibility study and the START RCT, facilitators will, with the carer/patient's permission, record one intervention session per participant, decided by the trial manager randomly generating session numbers. A researcher not involved in the therapy will independently rate fidelity to the manual, using our existing checklist incorporating the key content of each session and four process factors ("keeping the session to time", "keeping the carer focused on the manual", "keeping the carer engaged in the session" and "managing the concerns of the carer").

10.6 DISCONTINUATION/WITHDRAWAL OF PARTICIPANTS

In consenting to participate in the trial, participants are consenting to intervention, assessments, follow-up and data collection. Participants may discontinue the intervention sessions or withdraw from the project at any time. Participants who withdraw from the intervention will be asked if they would still agree to meet with the researchers completing outcome assessments but not take part in the intervention. Therefore, although we will stress that participants can withdraw at any time without giving a reason, we shall retain any assessments that have been collected to that point and we shall maintain contact unless told otherwise. All contacts with participants and reasons for withdrawing from the intervention or study will be documented on the study database hosted by Sealed Envelope.

Discontinuation of Trial Treatment for clinical reasons

A participant may be withdrawn from trial treatment whenever continued participation is no longer in the participant's best interests, and the reasons for doing so will be recorded. Reasons for discontinuing treatment may include:

1. disease progression whilst on therapy
2. unacceptable side effects or safety events
3. intercurrent illness which prevents further treatment
4. participants withdrawing consent to further trial treatment
5. Any alterations in the participant's condition which justifies the discontinuation of treatment in the site investigator's opinion.
6. Persistent non-compliance to protocol requirements.

The decision to withdraw a participant from treatment will be recorded in the CRF and medical/case notes/source documents.

In these cases participants remain within the trial for the purposes of follow-up for safety and or data analysis according to the treatment option to which they have been allocated.

Participant withdrawal from trial treatment

If a participant expresses their wish to withdraw from trial treatment, we explain the importance of remaining on trial follow-up and seek permission to allow use of routine follow-up data to be used for

trial purposes. The importance of safety follow-up will be emphasised to the participant in the Participant Information Sheet.

The decision of the participant to withdraw from treatment will be recorded in the CRF and medical/case notes/source documents.

The participant may withhold their reason for withdrawal however, if the participant gives a reason for their withdrawal, this will be recorded.

Withdrawal of Consent to Data Collection
If a participant explicitly states they do not wish to contribute further data to the trial their decision must be respected and recorded in the CRF and medical/case notes/source documents. Only data collected to the point of their withdrawl will be used, unless the participant specifically requests otherwise. This will be explained to the participant and it will be in the participant information sheet.

Loss to follow-up
If a participant moves from the area, every effort should be made for the participant to be followed up at another participating trial site and for this new site to take over the responsibility for the participant. We will also try to complete assessments by phone if the patient has moved to somewhere where this is not possible.

10.7 REPLACEMENTS
Withdrawn participants will not be replaced.

10.8 STOPPING RULES
The trial may be stopped before completion for the following reasons:

- On the recommendation of the TSC or DMEC
- On the recommendation of the sponsor and CI, or funder

10.9 DEFINITION OF END OF TRIAL
The expected duration of the trial is 33 months from recruitment of the first participant. The end of trial is the date of the last participant final follow up.

11 RECORDING AND REPORTING OF ADVERSE EVENTS AND REACTIONS
Collection, recording and reporting of adverse events (including serious and non-serious events and reactions) to the sponsor will be completed according to Priment pharmacovigilance SOPs.

11.1 DEFINITIONS for AE

Term	Definition

Adverse Event (AE)	Any untoward medical occurrence in a participant administered a treatment/intervetnion and which does not necessarily have a causal relationship with the treatment/intervention. *Therefore an AE can be any unfavourable or unintended change in the structure (signs), function (symptoms) or chemistry (laboratory data) in a participant to whom a procedural intervention has been administered, including occurrences which are not necessarily caused by or related to that intervention.*
Serious Adverse Event (SAE), Serious Adverse Reaction (SAR) or Unexpected Serious Adverse Reaction	Any adverse event that: results in death, is life-threatening*, 3. requires hospitalisation or prolongation of existing hospitalisation**, results in persistent or significant disability or incapacity, or consists of a congenital anomaly or birth defect
Serious Adverse Reaction	Any SAE that is 1. Related to the trial intervention AND 2. Expected (listed in the protocol as an expected side effect of the intervention)
*A life- threatening event, this refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. ** Hospitalisation is defined as an inpatient admission, regardless of length of stay. **Hospitalisation for pre-existing conditions, including elective procedures do not constitute an SAE.**	
Suspected Unexpected Serious Adverse Reaction (SUSAR)	Any SAE that is deemed to be 1. Related to the trial intervention AND 2. Unexpected (not listed in the protocol as an expected side effect of the intervention)
Important Medical Event	These events may jeopardise the participant or may require an intervention to prevent one of the above characteristics/consequences. Such events should also be considered 'serious'.

11.2 RECORDING ADVERSE EVENTS

All adverse events will be recorded in the medical records/case notes/source data in the first instance following consent and will be recorded with clinical symptoms and accompanied with a simple, brief description of the event, including dates as appropriate. All adverse events will be recorded until the participant has completed the intervention.

Only Serious adverse events will be recorded in the CRF and SAE log. This is because the intervention is not invasive/already has a well-known safety profile and therefore, collection of AE data is not going to

add any value to the safety profile of the intervention. We will collect information on any planned hospitalization at baseline and these will not be considered as adverse events.

11.3 EXPECTED SIDE EFFECTS

Based on our feasibility work we expect few side effects specific to the intervention. The following events listed below describe expected procedural/disease related AEs: List all expected procedural and or disease related events.

- Possible emotional distress or discomfort as a result of the questionnaires or intervention
- Potential for falls as a result of increased physical activity or getting out and about more or because of other age related conditions
- For those with more severe dementia; death, hospitalisation due to common causes related to the condition (e.g. UTIs, delirium, common infections) or transition to a care home as a result of progression of illness

11.4 ASSESSMENTS OF SERIOUS ADVERSE EVENTS

Each serious adverse event will be assessed to determine if the event is related to the intervention and if the event is expected.

11.5 RELATED EVENTS

The assessment of the relationship between adverse events and the administration of the intervention is a decision based on all available information at the time of the completion of the case report form. If the event is a result of the administration of any of the research procedures then it will be classed as related and the REC will be informed (see Section 11.7).

11.6 EXPECTED EVENTS

If the event has been listed in the protocol (section 11.3) as an expected side effect of the intervention then the event will be classed as expected. If the event is not listed then it will be classed as unexpected.

11.7 PROCEDURES FOR RECORDING AND REPORTING SERIOUS ADVERSE EVENTS AND SUSPECTED UNEXPECTED SERIOUS ADVERSE EVENTS

All serious adverse events (SAEs/SARs/SUSARs) will be recorded in the medical records and the CRF, and Priment SAE log. The SAE log will be reported to the sponsor at least once a year.

All SAEs will be recorded from randomisation until end of the intervention.

All SAEs (except those specified in section 11.3 as not requiring reporting to the Sponsor), must be recorded on a serious adverse event (SAE) form. The CI/PI or designated individual will complete the sponsor's SAE form and the form will be preferably emailed to the Sponsor primentsafety@ucl.ac.uk and to the sponsor representatives at sponsor.noclor@nhs.net, within 24 h of his / her becoming aware of the event. The Chief or Principal Investigator will respond to any SAE queries raised by the sponsor as soon as possible.

Completed SAE forms must be sent within 24 hours of becoming aware of the event to Priment CTU

Email forms to primentsafetyreport@ucl.ac.uk and sponsor.noclor@nhs.net

The reporting of adverse events to the ethics committee and sponsor will be completed according to Priment non-CTIMP safety management SOP or to any other specific requirements of the Sponsor of the trial is not UCL.

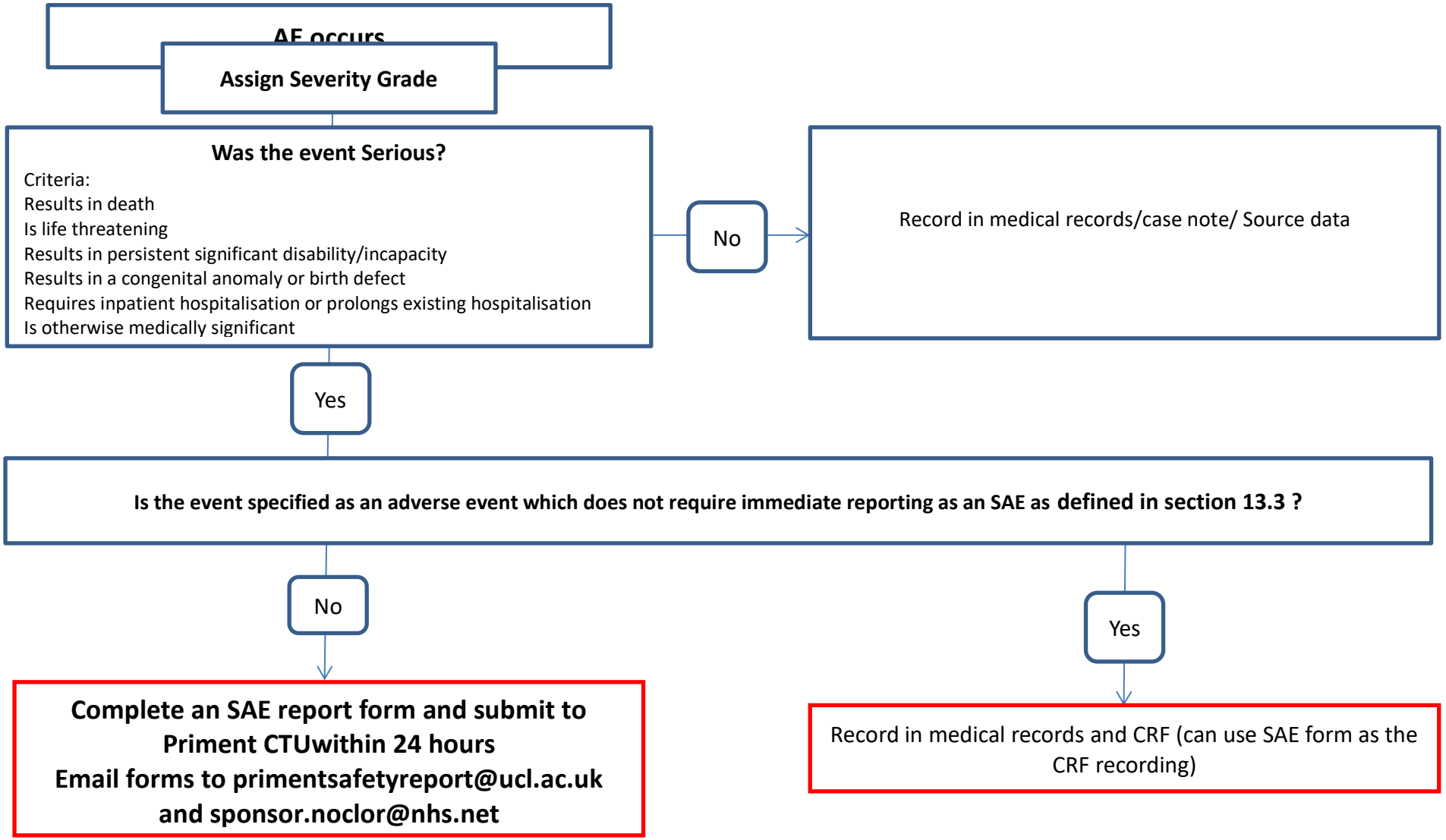
The reporting of adverse events to the ethics committee and sponsor will be completed according to Priment non-CTIMP safety management SOP. All serious adverse events will be recorded on the online database hosted by Sealed Envelope. All SAEs will be recorded on a serious adverse event (SAE) form. The CI/PI or designated researcher will complete the SAE form and the form will be preferably emailed to the Sponsor within 24 hours of becoming aware of the event by the trial manager. The Chief or Principal Investigator will respond to any SAE queries raised by the sponsor as soon as possible.

Where the event is unexpected and thought to be related to the intervention, the event is classified as a SUSAR and this must be reported to the Health Research Authority within 15 days. SUSARs that are fatal or life-threatening must be notified to REC within 7 days after the Chief Investigator has learned of them. The Chief Investigator (or their delegate) is responsible for reporting SUSARs to the ethics committee that approved the study.

Participants must be followed up until clinical recovery is complete and any test results have returned to normal or baseline values, or until the event has stabilised. Follow-up should continue after completion of protocol treatment and/or trial follow-up if necessary.

Follow-up SAE forms (clearly marked as follow-up) should be completed and emailed to Priment as further information becomes available.

Flow Chart for SAE reporting



11.8 NOTIFICATION OF DEATHS

Only deaths that are assessed to be related to the Intervention will be reported to the sponsor. This report will be immediate.

11.9 REPORTING URGENT SAFETY MEASURES AND OTHER SAFETY EVENTS

If any urgent safety measures are taken, the CI/ PI shall immediately notify Priment and the sponsor representative at sponsor.noclor@nhs.net of this measures, and in any event no later than 3 calendar days from the date the measures are taken. Written notification will be submitted within 3 calendar days to the MHRA and relevant REC as in line with Priment SOP on Urgent Safety Measures.

11.10 NOTIFICATION OF SERIOUS BREACHES TO GCP AND/OR THE PROTOCOL

A "serious breach" is a breach which is likely to effect to a significant degree –

1. the safety or physical or mental integrity of the participants of the trial; or
2. the scientific value of the trial.

The sponsor of a clinical trial shall notify the licensing authority in writing of any serious breach of –

1. the conditions and principles of GCP in connection with that trial; or
2. the protocol relating to that trial, as amended from time to time, within 7 days of becoming aware of the breach.

PRM-SOP-006 Non Compliance To Study Protocol, Regulatory Requirements and Serious breaches of GCP or trial protocol will be followed.

12 DATA MANAGEMENT

12.1 DATA COLLECTION TOOLS AND SOURCE DOCUMENT IDENTIFICATION

A data management plan will be created which will include details of the data collection tools, methods of completing case report forms, sign off of completed CRFs, source document identification and methods to maximise completeness of data collection.

It will be the responsibility of the investigator to ensure the accuracy of all data entered in the CRFs. The delegation log will identify all those personnel with responsibilities for data collection and handling, including those who have access to the trial database.

Data collected for the study will be entered into the paper case report forms (pCRFs) and then entered into the online data base/electronic case report forms (eCRFs).

12.2 DATA COLLECTION AND HANDLING

All data will be collected and handled in accordance with Priment SOP Data Handling and the trial specific arrangements will be detailed in the data management plan.

Data protection and data confidentiality
All investigators and study site staff will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

All data will be pseudonymised by removing all direct and indirect identifiers, and storing the key file separately from pseudomymised data.

The key file will be stored on a secure university drive with password protection, and access limited to the minimum number of individuals necessary to undertake the research.

Data transfer
Any letters containing patient identifiable information will be sent via recorded mail.

Electronic data containing patient identifiable information will be transfered between sites through (i) electronic documents sent via secure email (i.e. NHS email) or (ii) password protected electronic documents sent via email, with passwords sent separately via text message.

Patient identifiable data shared with third party organisations including interview recordings shared with a UCL-approved transcription service which may contain personal and sensitive information, will be transferred via secure platforms secure platform hosted by the transcription service).

Raw anonymised data from data loggers will be sent to co-applicants at the University of Oxord via (ii) password protected electronic documents sent via email, with passwords sent separately via text message.

Data storage
Patient contact details for initial contact and arranging research appointments, will be stored on a secure university drive with password protection, and access limited to the minimum number of individuals necessary to undertake the research.

Data containing direct identifiers (i.e. voice recordings) will be stored in a password protected file on a secure university server. Interview recordings will be stored until interviews have been transcribed and then permanently deleted from the University server. Data will be stored and deleted from UCL-approved supplier servers in accordance with supplier policies that comply with UCL's Terms and Conditions and Data Privacy Regulations. Outside of the transcription operations team, the only person who would have access is the TM.

Raw anonymised data from data loggers will be stored on a secure university drives with password protection, and access limited to the minimum number of individuals necessary to undertake the research.

12.3 TRIAL DATABASE

The CRFs will be entered into a web-based clinical data management system, Red Pill, provided by Sealed Envelope through Priment. Sealed Envelope has been assessed by Priment to ensure that adequate processes are in place and are being followed for quality management, software development and security. There will be an agreement in place between the sponsor and Sealed Envelope to ensure compliance and agreement with clinical trial regulations and data protection laws.

12.4 DATA OWNERSHIP

At the end of the trial the data belongs to Camden and Islington NHS Foundation Trust.

13 STATISTICAL CONSIDERATIONS

13.1 OUTCOMES

13.1.1 PRIMARY OUTCOMES

The primary outcome is resident sleep at 8 months and will be measured using the SDI, a validated instrument. The SDI is validated for measuring sleep disorder in people with dementia and describes the frequency and severity of sleep-disturbed behaviours. It is a standalone tool for sleep disorder symptoms in people with dementia. Used in pharmacological and non-pharmacological studies, it is validated against clinical variables and was used in recent promising pilot studies of non-pharmacological interventions[28-30 43]. SDI [44] has the seven sleep sub-questions of the sleep and night-time domain of the Neuropsychiatric Inventory (NPI)[45]. These are: difficulty falling asleep; getting up during the night (not scored as positive if someone gets up once or twice per night to pass urine and quickly falls back to sleep); wandering, pacing or getting involved in inappropriate activities at night; awakening the carer during the night; awakening at night, dressing, and planning to go out, thinking that it is morning and time to start the day; awakening too early in the morning (earlier than is his/her habit); and sleeping excessively during the day. Each item is rated according to frequency (scale 0 (Not present in the last two weeks) – 4 (once or more per day (every night)) and severity (scale 1 (mild) -3 (marked)) of sleep-disturbed behaviours and, when multiplied, possible item scores range from 0-12. Data will be treated as continuous. This instrument will be used at baseline, 4 month follow up, and 8 month follow up (with 8 months as the primary timepoint).

13.1.2 SECONDARY OUTCOMES

All secondary outcome measures will be taken at baseline, 4 month and 8 month follow ups and are detailed in the schedule of assessments (Appendix 1). Any licences needed for use will be in place prior to data collection beginning.

Person living with dementia (all proxy measures):

1. Neuropsychiatric symptoms (Neuropsychiatric Inventory, NPI)[45], a validated instrument with 12 domains. This will enable assessment and consideration of whether other neuropsychiatric symptoms, for example depression and anxiety, or total neuropsychiatric symptoms, are changed by the intervention.
2. Epworth sleepiness scale (ESS)[46] is an eight item measure assessing tendency to sleep/doze in specific daytime situations (possible score range 0-24; a score of >10 indicating excessive sleepiness).
3. DEMQOL-Proxy[47] is a 31 item interviewer-administered questionnaire answered by a carer. It is a responsive, valid and reliable measure of quality of life in people with dementia. It has psychometric properties at least as good as other dementia-specific quality of life instruments. 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)[48] 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)[49] 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 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[42] from baseline and before 4 and 8 month follow-up). Although we did not find actigraphy to be valid or acceptable as an outcome measure during our feasibility trial, carers and facilitators found information from actigraphy valuable in informing plans for increasingactivity. Therefore, we will continue to incorporate this into the intervention in the full trial. We will also use the data collected to inform understandings of the mechanism of change of the intervention, exploring changes in activity patterns and how this relates to other outcomes.

Family carer:

1. Sleep Condition Indicator (SCI)[50] is an eight item scale to assess sleep disturbance. It characterises sleep both dimensionally and against insomnia disorder criteria.
2. The hospital anxiety and depression scale (HADS)[51] is a validated, reliable instrument to measure mood throughout age groups.
3. Zarit Burden Interview (ZBI)[52] the most commonly used and well validated measure of burden for carers of people with dementia.

4. Health Status Questionnaire (HSQ-12)[53] a 12-item health-related quality of life scale validated throughout age group.
5. Modified Client Service Receipt Inventory (CSRI)[48] 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)[49] is a generic measure of health related quality of life.

13.2 SAMPLE SIZE AND RECRUITMENT

13.2.1 SAMPLE SIZE CALCULATION

We used the standard deviation (SD) of baseline SDI scores (15.74) and the correlation between baseline and follow-up measurements (0.57) observed in our feasibility trial. There is no published SDI minimum clinically important difference. We aim to detect a difference of ≥5.5 points, consistent with important differences identified through our survey of experts. This corresponds to a small-medium effect size of 0.35, and is realistic (an average difference of 5.6 was observed in feasibility work). To account for potential facilitator clustering in the intervention arm, we assumed an intercluster correlation coefficient (ICC) as observed in the START and MARQUE studies (0.03). A full study with 1:1 randomisation to detect a difference of 5.5 on SDI (effect size 0.35) between intervention and TAU with power 90% and 5% significance requires 370 participants; 185 in each arm (assuming an average of 15 people per facilitator, up to 15% drop out and with inflation for non-normality). This calculation should provide a conservative estimate of the sample size needed in the case where analyses are based on transformed data (e.g. log or square root transformation may be appropriate)[54]. Calculation of sample size was carried out using STATA version 14.

13.2.2 PLANNED RECRUITMENT RATE

In our feasibility study, 63 (65%; 95% Confidence Interval 55% to 75%) eligible referrals consented to participate, with four referrals received per week from memory clinics. 92% of those randomised were followed up at 3 months, indicating a high level of retention. To recruit 370 participants, we plan to recruit 50 participants a quarter, or around 8-10 a quarter from each of 7 centres. (In our feasibility study we recruited 11 participants/quarter/centre and in the START RCT 10 participants/quarter/centre). We will conduct an internal pilot to ensure that we are able to recruit to time and target across sites.

13.3 STATISTICAL ANALYSIS PLAN

SUMMARY OF BASELINE DATA AND FLOW OF PARTICIPANTS

Our co-applicant statistician (JB) will lead and supervise the analysis. The statistical analyses will be described in a predefined statistical analysis plan, and planned and conducted according to ICH E9 and

following the standard operating procedures of Priment CTU. All analyses will be carried out using STATA version 15. A summary of the main analyses are given here.

We will summarise family carer and person with dementia's baseline characteristics by randomised group using means (with standard deviations), medians (with interquartile ranges), counts and proportions, as appropriate. We will use this summary to gauge the balance in characteristics achieved between randomised groups. A CONSORT diagram will describe the flow of patients through the trial (http://www.consort-statement.org/).

13.3.2 PRIMARY OUTCOME ANALYSIS

For each randomised group we will summarise the primary outcome (SDI at 8 months) using means with standard deviations and medians with interquartile ranges. We will also graphically examine the distribution of the score. We will describe the effect of the intervention using the difference in mean SDI score calculated with a 95% confidence interval. This estimate will be obtained from a mixed effects multiple regression model adjusting for baseline SDI score and site and allowing for facilitator clustering in the intervention arm[55]. If assumptions of the regression model are violated, the SDI score will be analysed after appropriate transformation (e.g. a log transformation). We will calculate the intra-cluster correlation coefficient (with 95% confidence interval) to describe facilitator clustering.

In secondary analyses we will examine repeated measurements of outcome at 4 and 8 months by treatment group using summary statistics and profile plots. We will extend the mixed effects model to include these repeated measurements and allow consideration of the effect of the intervention over time. We will carry out all analyses by intention to treat (ITT), comparing randomised groups.

13.3.3 SECONDARY OUTCOME ANALYSIS

Analyses of secondary clinical outcomes will take a similar approach to the analysis described for the primary outcome, with models adjusting for the associated baseline measurement.

Health economics: Rachael Hunter our co-applicant health economist, will be responsible for all cost-effectiveness aspects of the trial from design through to analysis and dissemination. We will develop a full health economics analytic plan, signed off by the Principal Investigators (PI) and statistician, prior to data analysis. We will calculate the incremental cost per QALY gained of DREAMS START plus TAU compared to TAU only, over 8 months from a health and social care cost perspective using the EQ-5D-5L proxy to calculate QALYs in line with NICE guidance. Secondary analyses will calculate QALYs using the DEMQOL and relevant tariff, and include impact and cost of carers (paid as well as family and close others) out of pocket costs and relevant wider societal costs.

We will include the EQ-5D-5L (a generic measure of health related quality of life) for carers in the economic evaluation. We will not measure carer productivity loss alone, some carers will be retired, so measuring productivity loss, which focuses on absenteeism from paid employment and presenteeism

within paid employment, is not sufficient here. Instead we will capture the equivalent of "productivity loss" in our carer population by measuring days off and changes in employment such as moving from full-time to part-time employment and retirement. This will be costed using the human capital approach. The most important component of this analysis will be impact on carer time and health care resource use which will be measured using the Valuation of Informal Care Questionnaire and a modified CSRI respectively. We will also include the brief Work Productivity and Activity Impairment (WPAI) questionnaire for caregivers, to ensure we fully capture productivity losses in carers that are in employment.

We will use number of sessions attended, duration of the session and the profession and grade of the staff delivering the session to calculate participant level costs of the DREAMS START intervention, in addition to the training and supervision cost. We will modify the CSRI based on data from our feasibility data and will use costs from published sources.

Carers will complete the questionnaires about service use, time spent caring and productivity loss in the past 4 months at baseline, 4 months and 8 months. We will calculate QALYs as the area under the curve, adjusting for baseline, over 8 months using the EQ-5D-5L and DEMQOL-Proxy to calculate QALYs. We will report descriptive statistics for resource use, costs and QALYs for baseline, 4 and 8 months. We will calculate the mean incremental costs and QALYs of DREAMS START compared to usual care over 8 months using patient level data linear regression, adjusting for site and facilitator clustering in line with the statistical analysis plan, with 95% confidence intervals, cost-effectiveness planes and cost-effectiveness acceptability curves calculated using bootstrapping. We will conduct sensitivity analyses for any assumptions made. We will assess the level and type of missing data and in conjunction with the statistician determine the most appropriate method for accounting for missing data, which is likely to be multiple imputation using chained equations.

13.3.4 SENSITIVITY AND OTHER PLANNED ANALYSES

Missing Data: Where there is missing outcome data, analyses will be based on people with an available outcome and will therefore rely on an assumption that data is missing at random. We will describe the number (%) with missing outcome in each group, look at reasons for missingness and consider characteristics of the patients excluded from the ITT analysis.

In a sensitivity analysis, we will re-estimate the treatment effect, with additional adjustment for baseline predictors of missingness. Further analyses based on multiple imputation methods will be considered if appropriate.

Other analyses: We will carry out the following supportive analyses for the primary and secondary outcomes using the same modelling approaches as described previously:

- Estimation of an unadjusted treatment effect estimate
- Further adjusted analyses allowing for other predefined factors related to the outcome.
- Estimation of the treatment effect adjusting for any concerning imbalances in baseline characteristics.

Process evaluation:

Qualitative: We will purposively sample and conduct qualitative interviews after completing other outcomes with 15-20 participants (selected for maximum variation, men and women, completers and non-completers, spouses and non-spouse family carers and people with dementia, across sites) and 5 staff delivering the intervention. We will transcribe qualitative data verbatim. We will use a thematic analytic approach[56]. Researchers will check transcriptions against audio recordings (we will at the time of interview encourage participants not to use any personally identifying information in their interview but will check this after transcription and anonymise them and enter into NVivo software to familiarise themselves with data. Two researchers will independently, systematically code transcripts into meaningful fragments and label initial codes, discussing and resolving discrepancies[57]. The team will then organise data into preliminary themes. We will use the constant comparison method[58], iteratively identifying similarities and differences in the data. We will triangulate qualitative data with fidelity ratings, intervention adherence (session attendance; action plans, strategy tried) and quantitative outcomes (including patterns in activity from actigraphy).

Quantitative: In considering change mechanisms, analysis will focus on movement as a potentially important indicators. We will consider rest-activity amplitude, reflecting the relative difference between the least active five hours (L5) and the most active ten hours (M10) in the day. These will be recorded via the actigraphs worn for a week at baseline and a week prior to 4 and 8 month follow-up points. The mediating effect of these measures on our primary and secondary outcomes will be examined using the stepped approach described by Whittle et al[59]. This is a four-step process that:

1. Describes the change in the mediator variable between baseline and follow-up.
2. Uses linear regression to test for associations between the intervention and the potential mediator (test of the direct effect of intervention on mediator).
3. Fits a regression for the outcome with mediator and intervention as covariates, enabling calculation of the indirect mediating effect (as a ratio of coefficient estimates with bootstrap used to calculate confidence intervals).
4. Investigates whether the results hold after adjustment for potential confounding variables.

Models fitted in all steps will be mixed models that account for facilitator clustering.

Fidelity analysis: To analyse fidelity of delivery of DREAMS START, we will assess the number of appointments delivered across all intervention participants. Checklists will be applied independently of the facilitator to a random selection of one recorded intervention session for each participant a researcher. A mean fidelity score will be produced by dividing the number of items on the checklist identified as being delivered in the appointment, by the number of items on the checklist that should have been delivered per appointment, per researcher and across all appointments. We will adopt thresholds used in other intervention fidelity work: where 81–100% constitutes high fidelity, 51-80 is moderate fidelity and 50% or lower constitutes low fidelity.

13.4 INTERIM ANALYSIS

Internal Pilot

The internal pilot analysis will be carried out based on the data available after 9 months of recruitment. Recruitment and intervention attendance will be summerised overall and by site and assessed against

pre-specified stop/go criteria (see Tables 1 and 2 below) . At the end of this phase, a decision will be made by the funder, after recommendations by the TSC and data monitoring and ethics committee (DMEC), on whether or not to proceed with the trial. Recruitment will continue while data on the number of patients in the internal pilot are analysed and reviewed by the committees and a funder decision obtained. All internal pilot data collected will be included in the final trial analyses. We expect to recruit 150 participants within nine months of the first participant being recruited. The pilot analyses will not involve a formal comparison of primary and secondary outcomes between groups.

Table 1: Recruitment - Stop/Go [against target of 150 (30 per site) by the end of month 9]

Recruitment Criteria: % of Target n (n/site)	**Proposed Action**
>80% (>24)	Progress to main trial phase
70-80% (21-24)	Progress to main trial phase, implementing additional remedial strategies
50-69% (15-20)	Urgent measures required, discuss with TSC and HTA
<50% (<15)	Consider stopping trial, discuss with TSC and HTA

Table 2: Intervention attendance – Stop/Go [% intervention participants completing ≥4 sessions]

Intervention attendance Criteria (≥4 /6 sessions)	**Proposed Action**
>80% participants attend ≥4 sessions	Progress to main trial phase
60-79% participants attend ≥4 sessions	Progress to main trial phase, implementing strategies (e.g., retrain certain facilitators)
<60% participants attend ≥4 sessions	Consider stopping trial, discuss with TSC and HTA

13.5 OTHER STATISTICAL CONSIDERATIONS

Any deviation(s) from the original statistical plan will be described and justified in the protocol, statistical analysis plan and/or in the final report, as appropriate.

14 RECORD KEEPING AND ARCHIVING

At the end of the trial, all essential documentation will be archived securely by the CI and trial sites for a minimum of 20 years from the declaration of end of trial.

Essential documents are those which enable both the conduct of the trial and the quality of the data produced to be evaluated and show whether the site complied with the principles of Good Clinical Practice and all applicable regulatory requirements.

The sponsor will notify sites when trial documentation can be archived. All archived documents must continue to be available for inspection by appropriate authorities upon request.

15 OVERSIGHT COMMITTEES

As CIs, PR and GL will take responsibility for ensuring the project delivers high quality research and outputs to time and target. PR will lead the day-to-day running and project oversight with support from GL's and co-applicants. Most of the co-applicant group have previously collaborated successfully. SA project manager, will ensure training at all sites and will monitor the RAs. She will chair weekly project meetings (face to face or telephone) to manage day-to-day activities. PR/GL will attend to ensure continued progress and milestones. C&I NHS Foundation Trust will be sponsor. Research will commence after National Research Ethics Service (NRES) /Health Research Authority (HRA) approvals are in place.

15.1 TRIAL MANAGEMENT GROUP (TMG)

Trial Management Group (TMG) will consist of the programme manager, all co-applicants including our Patient Public Invovlement (PPI) co-applicant, with PR as chair. It will provide overall management and concentrate on progress. The TMG will be responsible for overseeing the trial. The group will meet biannually, quarterly in the first year, and will send updates to PIs. The TMG will review recruitment figures, SAEs and substantial amendments to the protocol prior to submission to the REC. All PIs will be kept informed of substantial amendments through their nominated responsible individuals.

A TMG charter will be in place to detail arrangements and frequency of meetings.

15.2 TRIAL STEERING COMMITTEE (TSC)

The Independent Trial Steering committee (TSC) will meet biannually (or more if required) with PPI and NHS service contribution. It will monitor adherence to the protocol and advice through an independent chair. The role of the TSC is to provide overall supervision of the trial. The TSC will review the recommendations of the (Independent) Data Monitoring and Ethics Committee and, on consideration of this information, recommend any appropriate amendments/actions for the trial as necessary. The TSC acts on behalf of the funder(s) and Sponsor.

A TSC charter will be in place to detail arrangements and frequency of meetings.

15.3 DATA MONITORING AND ETHICS COMMITTEE (DMEC)

There will be a Data Monitoring Committee to provide independent advice on data and safety aspects of the trial. It will review and assess recruitment, interim monitoring of safety and effectiveness, trial conduct and external data. Meetings of the Committee will be held biannually to review interim analyses or as necessary to address any issues. The DMEC is advisory to the TSC and can recommend premature closure of the trial to the TSC.

The Patient and Public Involvement (PPI) group will be a virtual group. It will meet biannually and send representatives to the TMG, TMG and DMEC.

A DMEC charter will be in place to detail arrangements and frequency of meetings.

16 DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

The investigator(s)/ institution(s) will permit trial-related monitoring, audits, REC review, and regulatory inspection(s), providing direct access to source data/documents. Trial participants are informed of this during the informed consent discussion. Participants will consent to provide access to their medical/case notes/source documents.

17 ETHICS AND REGULATORY REQUIREMENTS

Priment will ensure that the trial protocol, participant information sheet, consent form, GP letter and submitted supporting documents have been approved by the appropriate research ethics committee, prior to any participant recruitment. The protocol, all other supporting documents including and agreed amendments, will be documented and submitted for ethical and regulatory approval as required. Amendments will not be implemented prior to receipt of the required approval(s).

Before any NHS site may be opened to recruit participants, the Chief Investigator/Principal Investigator or designee must receive written confirmation from the Trust Research & Development (R&D) Office of their capacity and capability to deliver the study. It is the responsibility of the CI/ PI or designee at each site to ensure that all subsequent amendments gain the necessary approvals, including confirmation from the Trust R&D of capacity and capability to deliver at the site. This does not affect the individual clinician's responsibility to take immediate action if thought necessary to protect the health and interest of individual participants (see section 9.6 for reporting urgent safety measures).

An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended. The chief investigator will prepare the APR.

Within 90 days after the end of the trial, Priment will ensure that the main REC is notified that the trial has finished. If the trial is terminated prematurely, those reports will be made within 15 days after the end of the trial.

The CI will supply Priment with a summary report of the trial, which will then be submitted to the REC within 1 year after the end of the trial.

Patient and public involvement (PPI): We judge the quality and success of our feasibility RCT and the acceptability of our co-produced intervention to be a direct result of the meaningful and ongoing contribution of those with lived experience of dementia during and beyond the project. Ongoing PPI has helped us to clarify our research questions, our outcome measures and our inclusion criteria, for the proposed study and will continue throughout. We are partnered by the Alzheimer's Society, who are leading PPI. James Pickett (Head of Research, Alzheimer's Society), will be our overall PPI lead and will

chair our Community of Interest. Rossana Horsley who has lived experience as a carer and is a member of the AS Volunteer Network, will continue her input, having contributed to our earlier feasibility study and development of the grant application for this RCT. Our PPI representatives will be on our TMG, TSC and DMEC to provide partnership, discuss with others in the AS, enhance the relevance, practicality and utility of our materials and be partners in dissemination. They will advise on the language and content of information sheets and contribute to the revision of the intervention and training of facilitators. We will follow INVOLVE guidance for researchers on involvement and payment of patients and the public and replacement carer time, incorporating costs into our proposal. The AS will provide training and support for our PPI and we will encourage attendance at the one-day PPI course at UCL and research network training.

18 MONITORING REQUIREMENT FOR THE TRIAL

The sponsor/Priment will determine the appropriate level and nature of monitoring required for the trial. Risk will be assessed on an ongoing basis and adjustments made accordingly.

The degree of monitoring will be proportionate to the objective, purpose, phase, design, size, complexity, blinding, endpoints and risks associated with the trial.

A trial specific oversight and monitoring plan will be established for studies. The trial will be monitored in accordance with the agreed plan.

19 FINANCE

The HTA NIHR funds this RCT. The study funding has been reviewed by the UCL/UCLH & C&I Research Office, and deemed sufficient to cover the requirements of the study. NHS costs will be supported via the Local Clinical Research Network.

20 INSURANCE

Camden and Islington NHS Foundation Trust will provide indemnity through a standard NHS insurance scheme should liability arise as a result of the study management, design or conduct. The NHS indemnity does not offer no-fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance, of NHS Research Ethics Service review and specific guidance, to pay compensation for non-negligent harm.

21 PUBLICATION POLICY

We will disseminate our findings in a peer reviewed journal and at an international conference. We will present findings in appropriate local forums for health and social care professionals; participants who have indicated they are interested in the results will be sent a summary of the findings. All NIHR-funded primary research studies are required to register in an appropriate registry. The NIHR's registry of choice is the International Standard Randomised Controlled Trial Number Register (ISRCTN). Registry information on ISCTRN will be updated regularly as appropriate and in line with instructions from the relevant NIHR secretariat/monitoring team and ISRCTN. Our publication policy is as follows:

Authorship for any paper or conference abstract will be agreed by completion of the first draft.

To be considered for publication it will be expected that authors have contributed to each of the following:
a. Conception and design of the study, or acquisition of data, or analysis and interpretation of data;
b. Drafting the article or revising it critically for important intellectual content;
c. Final approval of the version submitted.
The study co-applicants have all contributed to the conception and design of the study, thereby meeting criteria (a).

We will discuss the most useful form in which to disseminate our findings within the DREAMS START Trial Management Groups.

All research outputs and publications will include the following NIHR funding acknowledgment and disclaimer: "This study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme (HTA NIHR128761). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care".

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APPENDIX 1 – SCHEDULE OF ASSESSMENTS

	Screening (Pre-treatment assessment)	**Randomisation**	**Treatment Phase**						**Follow up**	**Final visit**	**Sub sample qualitative interview**
Visit No:	1		2	3	4	5	6	7	8	9	10
	Baseline		Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	4 month	8 month	+ 8month
Window of flexibility for timing of visits:		+/- 2 days							+/- 4 weeks	+/- 4 weeks	+/- 4 weeks
Screening-Informed Consent	X										
Screening-SDI (person with dementia)	X								X	X	
Screening -Dementia type (person with dementia)	X										
Dementia severity (CDR) (person with dementia)	X										
Screening – AUDIT C (person with dementia)	X										
Screening -Eligibility confirmation	X										

Demographics (person with dementia)	X										
NPI	X								X	X	
Epworth sleepiness scale	X								X	X	
DEMQOL-Proxy	X								X	X	
CSRI/medication (proxy, for person with dementia)	X								X	X	
EQ-5D-5L (proxy, for person with dementia)	X								X	X	
Side effects	X								X	X	
Actigraphy	X								X	X	
Demographics (carer)	X										
Sleep condition indicator (carer)	X										
HADS (carer)	X								X	X	
Zarit (carer)	X								X	X	
Health Status Questionnaire (12) (carer)	X								X	X	
CSRI/medication (carer)	X								X	X	
EQ-5D-5L (carer)	X								X	X	
Intervention acceptability									X	X	x

Randomisation		X				
Trial Intervention/Treatment			X			
Adverse Events review	X		X	X	X	X
Withdrawal	X		X	X	X	X
Follow-up				X	X	

APPENDIX 2

Derivation of DREAMS START manual

Session 1:

Sleep and dementia –material provided by SK

What is sleep? – Material provided by SK

What causes sleep problems in dementia – written by PR, SK and GL for DREAMS

Making changes to improve sleep (lifestyle & bedroom factors) Adapted from CE CBT work

Managing the stress that sleep problems can bring – Adapted from START

Managing stress: The signal breath – Adapted from START

Summary – Adapted from START

Putting it into practice- Adapted from START

Session 2:

Recap on understanding sleep and dementia

Light and sleep - material provided by SK

Light, dementia and the body clock - material provided by SK

Making a light therapy plan – developed for DREAMS

Your relative's sleep pattern – Developed for DREAMS

Making a new sleep routine: Your relative's plan – Developed for DREAMS based on CE and SK work on sleep efficiency

Managing stress 2: Focused Breathing – Adapted from START

Summary – Adapted from START

Putting it into practice – Adapted from START

Session 3:

Recap on making a plan

The importance of daytime activity and routine – Adapted from START

Planning daytime activity – Adapted from START

Sleep, exercise and physical activity – Developed for DREAMS by PR, GL, SK

Establishing a good day and night routine - Adapted from CE CBT work

Managing stress 3: Guided Imagery - Adapted from START

Summary - Adapted from START

Putting it into practice - Adapted from START

Seated exercises visual guide – From NHS Choices website

Session 4:

Recap on daytime activity and routine

Troubleshooting: putting plans into action – Developed for DREAMS

Managing night-time behaviour problems – Adapted from MARQUE / START

Describing and investigating behaviours Adapted from MARQUE / START

Managing stress 4: Stretching – Adapted from START

Summary – Adapted from START

Putting it into practice - Adapted from START

Session 5:

Recap on night-time behaviour problems

Creating strategies for managing behaviours – Adapted from MARQUE

Managing your own sleep – Developed for DREAMS

Managing thoughts and feelings - Adapted from CE CBT work

Challenging unhelpful thoughts and feelings - Adapted from START

Managing stress 5: Guided imagery – ocean escape-Adapted from START

Summary-Adapted from START

Putting it into practice- Adapted from START

Session 6:

Overall structure based on that developed in START and refined in MARQUE

Putting it all together

What works? Light, sleep and dementia – written by SK for DREAMS

What works? The importance of daytime activity – from START

What works? Making a new sleep routine – based on CE and SK sleep manual

What works? Making changes to improve sleep – based on CE and SK sleep manual

What works? Managing night-time behaviours – Based on MARQUE/START

What works? Challenging unhelpful thoughts and feelings – Based on START and CE CBT

What works? Relaxation – Based on START

Keeping it going – developing an action plan – Developed for DREAMS

Action plan for you and your relative – Developed for DREAMS

Summary – for DREAMS

SK = Simon Kyle (University of Oxford); CE = Colin Espie (University of Oxford); GL =Gill Livingston (UCL); PR = Penny Rapaport (UCL); CBT = Cognitive Behavioural Therapy; START = Strategies for Relatives; MARQUE = Managing Agitation and Raising Quality of Life.