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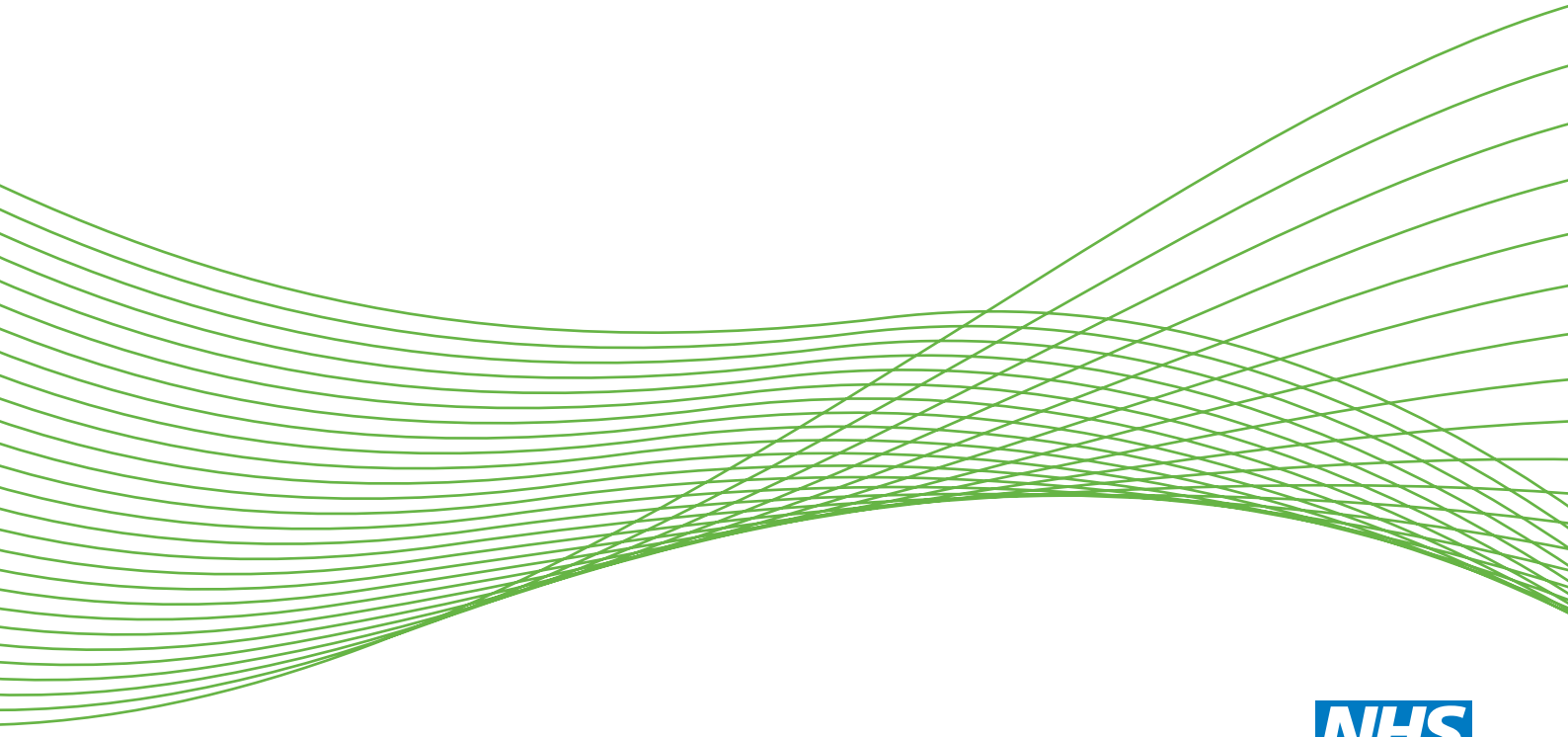
A manual-based intervention for carers of people with dementia and sleep disturbances: an acceptability and feasibility RCT

Kirsi M Kinnunen, Penny Rapaport, Lucy Webster, Julie Barber, Simon D Kyle, Brendan Hallam, Claudia Cooper, Rossana Horsley, James A Pickett, Anastasia Vikhanova, Colin A Espie and Gill Livingston



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A manual-based intervention for carers of people with dementia and sleep disturbances: an acceptability and feasibility RCT

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Abstract

A manual-based intervention for carers of people with dementia and sleep disturbances: an acceptability and feasibility RCT

Kirsi M Kinnunen,[1] Penny Rapaport,[1] Lucy Webster,[1] Julie Barber,[2] Simon D Kyle,[3] Brendan Hallam,[1] Claudia Cooper,[1,4] Rossana Horsley,[5] James A Pickett,[6] Anastasia Vikhanova,[1] Colin A Espie[3] and Gill Livingston[1,4]*

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Background: It has been estimated that between 25% and 40% of people living with dementia suffer from sleep disturbances, and there are currently no known effective treatments. Sleep disturbances may be the direct result of dementia or due to other comorbidities, such as pain and limited mobility. If carers' sleep is also disturbed, carers too can become tired and stressed, and this sometimes results in the breakdown of care in the home.

Objectives: To design an evidence-based manualised non-pharmacological therapy for sleep disturbances and test it for feasibility and acceptability.

Design: A single-blind, randomised, parallel-group feasibility trial, with participants randomised 2 : 1 to intervention or treatment as usual (TAU).

Setting: Five memory services in two London NHS trusts and Join Dementia Research (JDR).

Participants: The study recruited people with dementia and sleep disturbances (who scored ≥ 4 on at least one question on the Sleep Disorders Inventory) and their primary family carers.

Intervention: All participants were given an Actiwatch (CamNtech Ltd, Cambridge, UK) to wear to record their sleep patterns for 2 weeks before randomisation. The intervention group received Dementia RElAted Manual for Sleep; STrAtegies for RelaTives (DREAMS START). This was designed as a six-session, manual-based intervention for carers of people with dementia, delivered by trained and clinically supervised psychology graduates, based on evidence about managing sleep disturbance in people with dementia. It uses the structure of a previous manual-based treatment, STrAtegies for RelaTives (START). Family carers were consulted about structure, content and design. Sessions were interactive, and each involved techniques, tasks to practise between sessions, relaxation and a recapitulation on the previous session. The sessions covered understanding sleep and dementia, making a plan (incorporating information from Actiwatch read-outs and a light box to

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increase light), daytime activity and routine, difficult night-time behaviours, taking care of your own (carer's) sleep and using the strategies in the future. Carers kept their own manual, light box and relaxation recordings post intervention.

Randomisation and blinding: A statistician created an electronic randomisation list, stratified by site, using random permuted blocks. Those assessing the outcome were blinded to allocation; participants were not blinded.

Main outcome measures: Outcomes were assessed at 3 months. (1) Feasibility, defined as the percentage of eligible people who consented to the study recruitment, with an expected value of 50% [95% confidence interval (CI) 41% to 59%]. (2) Acceptability, defined as the percentage of intervention group participants attending ≥ 4 intervention sessions, with an expected value of 75% (95% CI 59% to 87%). The predetermined criterion for progression to the main trial was acceptability of ≥ 70%.

Results: Of 95 eligible patients referred, 63 (66%, 95% CI 56% to 76%) consented between 4 August 2016 and 24 March 2017: 61 from memory clinics and two from JDR. Of these, 62 participants (65%, 95% CI 55% to 75%) were randomised: 42 to the intervention arm and 20 to the TAU arm. Thirty-seven out of 42 participants (88%, 95% CI 75% to 96%) adhered to the intervention.

Conclusions: The results show that the randomised controlled trial is feasible and that the intervention is acceptable. A higher than expected proportion of eligible patients referred consented to the study and adhered to the intervention.

Limitations: Participants were not blinded and were recruited only in London.

Future work: The results of this trial indicate that a future efficacy trial is warranted.

Trial registration: Current Controlled Trials ISCTRN36983298.

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List of abbreviations

A	assessor
AD	Alzheimer's disease
ASRN	Alzheimer's Society Research Network
C	carer
CD	compact disc
CDR	Clinical Dementia Rating
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials
CSRI	Client Service Receipt Inventory
DEMQoL-Proxy	Dementia Quality of Life – Proxy
DREAMS START	Dementia RElAted Manual for Sleep; STrAtegies for RelaTives
ESS	Epworth Sleepiness Scale
HADS	Hospital Anxiety and Depression Scale
HSQ-12	Health Status Questionnaire-12
IAPT	Improving Access to Psychological Therapies
ICC	intracluster correlation coefficient
ID	identification
IQR	interquartile range
JDR	Join Dementia Research
MARQUE	Managing Agitation and Raising Quality of Life
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NPCRA	non-parametric circadian rhythm analysis
NPI	Neuropsychiatric Inventory
PPI	patient and public involvement
PSQI	Pittsburgh Sleep Quality Index
Q	question
RCT	randomised controlled trial
SCI	Sleep Condition Indicator
SCN	suprachiasmatic nucleus
SD	standard deviation
SDI	Sleep Disorders Inventory
START	STrAtegies for RelaTives
T	Therapist
TAU	treatment as usual
UCL	University College London
ZBI	Zarit Burden Interview

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Plain English summary

Sleep disturbances are common in dementia, and include reduced night-time sleep, night-time wandering and excessive daytime sleepiness. There are currently no known effective treatments. Family carers are often woken by their relatives, and so may become exhausted, stressed and unhappy, and feel unable to continue caring at home. In consultation with people affected by dementia and based on what was already known, a new six-session, manual-based sleep intervention, delivered to carers, was developed. It was called DREAMS START (Dementia RElATed Manual for Sleep; STrATegies for RelaTives). It uses strategies tailored to the needs of an individual, such as increasing light, activity, comfort, routine and relaxation. Participants with dementia wore a special wristwatch that monitored sleep, activity and light for 2 weeks before they started the intervention, and it was worn again for 2 weeks, 3 months later. Feasibility (whether or not enough people could be recruited to obtain meaningful results) and acceptability (the proportion of those receiving the intervention who completed it) were studied. About two-thirds of people who were asked agreed to take part in the study: 63 people with dementia and carers mainly from memory services consented and 62 were randomised (one quickly changed their mind). It was therefore feasible to recruit people. Twenty people continued with their usual treatment and 42 received the additional intervention (this was decided at random by computer). Nearly 90% of people completed four or more sessions, which meant that the intervention was considered acceptable. Carers answered questions about the person with dementia (sleep, behaviour, mood, quality of life and medication use), and their own sleep, mood and quality of life, at the beginning and end of the study. However, some of the people with dementia did not wear the watch at follow-up. The results suggest that the research was feasible and that the sleep intervention was acceptable. The next step will be to test the intervention in a larger study to see if it helps with sleep problems.

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Scientific summary

Background

Sleep affects all aspects of mental and physical life, including function and quality of life. People with dementia experience the same problems as other older people, such as pain and multiple health conditions, which impair sleep. In addition, sleep disturbances related to the dementia itself are common. People with dementia may wake during the night and be unaware of the time, or be frightened as they do not know what is happening. Dementia may also lead to impaired production of the hormone melatonin through structural and functional alterations to the suprachiasmatic nucleus. The circadian rhythm of melatonin production, high levels at night and low levels during the day, helps control the sleep–wake cycle. Dementia can therefore lead to decreased regularity of sleep, impaired sleep initiation, reduced sleep at night, difficulty maintaining sleep, increased night-time wandering and excessive daytime sleepiness. Sleep disturbances in dementia mean that the family members may be woken by the person with dementia and may be unable to leave them during the night because of safety concerns. There is no conclusive evidence that any medication for sleep problems in dementia is clinically effective, and such medications may cause harm. Non-pharmacological treatment should therefore be the first-line treatment for sleep management. However, most evidence to date comes from small-scale and often methodologically weak studies, and current treatment strategies are extrapolated from other illnesses, or are based on insufficient, or conflicting, evidence. Our team has previously successfully shown short-term and long-term clinical effectiveness and cost-effectiveness of a coping strategy-based manual for family carers of people with dementia, delivered by supervised graduate psychologists, and of delivering sleep cognitive–behavioural therapy to people who do not have dementia. The present study builds on this, encompassing the design of a complex manualised sleep intervention, followed by a pragmatic randomised controlled trial (RCT) to test it and, finally, a qualitative study to assess its acceptability and identify any needs for refinement.

Objectives

- To develop a manualised intervention for sleep disturbances in dementia: Dementia RElAted Manual for Sleep; STrAtegies for RelaTives (DREAMS START).
- To assess feasibility of recruitment and adherence to the intervention.
- To obtain estimates required for a full-scale trial in relation to potential primary outcomes (completion rates, standard deviations, correlation between baseline and follow-up measurements).
- To assess, from qualitative interviews, the acceptability of the intervention and instruments.

Design

A randomised, parallel-group, feasibility trial with blinded assessment. Participants were randomised 2 : 1 to intervention or treatment as usual (TAU).

Setting

Five UK memory services in two London NHS trusts and Join Dementia Research (JDR).

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Participants

People with dementia and sleep difficulties [defined as scoring ≥ 4 points on any of the Sleep Disorders Inventory (SDI) questions] and their primary caregivers.

DREAMS START intervention

A six-session, manual-based psychoeducational intervention was devised, which participants received in addition to TAU, and which was delivered by trained, clinically supervised psychology graduates to family carers of people with dementia. It is based on evidence about managing sleep disturbances in dementia and uses the structure of a previous manual-based treatment, STrAtegies for RelaTives (START). Family carers were consulted about structure and content. It is written in plain English, with vignettes and illustrations to clarify the messages. As the causes of sleep disturbances differ, the intervention is tailored to each individual's problems. Sessions are interactive and each session involves techniques, tasks to be practised between sessions, relaxation and, after session 1, a recapitulation on the previous session. The sessions covered understanding sleep and dementia, making a plan (incorporating information from Actiwatch read-outs and a light box to increase light), daytime activity and routine, difficult night-time behaviours, taking care of your own (carer's) sleep and using the strategies in the future. Carers kept their own manual, light box and relaxation recordings.

Training and fidelity

Four psychology graduates were trained and clinically supervised to deliver the intervention. They worked in teams of two therapists. For each intervention participant, the therapists recorded one randomly selected manual session. Another therapist then rated the fidelity to intervention delivery using a fidelity checklist.

Treatment as usual

Treatment as usual varies, in accordance with the practices of the trust in which the person with dementia is treated and their individual needs, but incorporates the National Institute for Health and Care Excellence (NICE) pathways guidelines for dementia and consists of assessment, diagnosis, symptomatic interventions, risk assessment and management and information.

Randomisation

A computer-generated randomisation list was used, stratified by site using random permuted blocks.

Blinding

Three researchers carried out the baseline and follow-up assessments, each assessing outcomes and blinded to randomisation status.

Assessments

Carers were interviewed at baseline and after 3 months and all randomised participants were asked to wear the Actiwatch for 2 weeks after each interview. Qualitative interviews were used to find out the opinions of those in the intervention group on all aspects of the study.

Primary outcome measures

- Feasibility of recruitment: agreement to take part in the trial, and randomisation.
- Treatment adherence (attending a predetermined number of sessions – intervention group only).

Secondary outcome measures

The secondary outcomes that were assessed were referral rates, follow-up rates, the difference in psychotropic medication prescription between groups, and reported side effects; choice of outcome for main trial by completion rates of validated instruments and Actiwatch wear (≥ 7 out of 14 days); acceptability of tools from qualitative interviews; estimates of statistical power and sample requirements based on detecting significant differences in outcomes; and qualitative assessment of intervention (in intervention group only).

Instruments: person with dementia

The instruments collecting information on the person with dementia were all completed with the family carer. Sociodemographic details and Clinical Dementia Rating™ (CDR) score were collected at baseline. The SDI was administered at screening and at 3 months. All other measures were collected at baseline and 3 months.

The CDR has six domains: (1) memory, (2) orientation, (3) judgement and problem-solving, (4) community affairs, (5) home and hobbies and (6) personal care. The global CDR, based on the domain scores, has four categories for people with dementia: 0.5, very mild; 1, mild; 2, moderate; 3, severe.

The SDI is validated for measuring sleep disorders in people with dementia. Its seven items describe specific sleep-disturbed behaviours according to frequency (0–4) and severity (0–3). Mean frequency and severity across the seven items are multiplied to derive the SDI global score.

The Neuropsychiatric Inventory (NPI) assesses the presence, frequency and severity of 12 neuropsychiatric symptoms. Multiplying the frequency (0–4) and severity (0–4) ratings for each symptom gives a domain score; summing all domain scores gives a total NPI score.

The Epworth Sleepiness Scale (ESS) assesses daytime somnolence (tendency to sleep/doze in specific daily situations). Each of the eight items is scored 0–3 and the total score (0–24) is the sum of item scores. A score of > 10 indicates excessive sleepiness.

Dementia Quality of Life – Proxy (DEMQoL-Proxy) is a 32-item questionnaire. Items 1–31 are scored 1–4 ('a lot' to 'not at all') and item 32 is scored 1–4 ('very good' to 'poor'). The total score is calculated as the sum across items 1–31 and ranges from 31 to 124, with higher scores indicating a better quality of life.

The Client Service Receipt Inventory (CSRI) was used to record patient service use and medication prescription and is used for estimating cost-effectiveness.

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The Safety and Tolerability Assessment was used to measure side effects (falls and comorbidities: gastrointestinal symptoms, neurological symptoms, infections) and whether these were mild, moderate or severe. The presence of other side effects (yes/no) and their type were recorded. Chronic comorbidities and significant life events affecting sleep or daytime functioning were recorded under 'Other comments'.

MotionWatch 8 (CamNtech Ltd, Cambridge, UK) watches (herein referred to as 'Actiwatches') were used over 14 days to monitor movement and light, and estimate sleep and circadian phase. Average values of the following measures were calculated for those participants for whom there were ≥ 7 days of data (in the following list, L refers to 'least active' and M refers to 'most active'):

- Sleep efficiency (%) – capturing both initiation and maintenance of sleep, reflecting the proportion of time in bed spent asleep.
- Sleep time (minutes).
- Wake time (minutes).
- Time of lights out.
- Time of falling asleep.
- Time of waking up.
- Time of getting up.
- Time in bed (hours).
- Fragmentation index – the degree of fragmentation of the sleep period, expressed as the sum of time moving (%) and time lying still for ≤ 1 minute (%).
- Relative amplitude – the amplitude of circadian rhythm (range 0–1), calculated by dividing the difference between average activity in the most active (M10) and most restful (L5) periods by the sum of M10 and L5.
- Interdaily stability – the degree of regularity in the activity–rest pattern, ranging from a total lack of rhythm (0) to a perfectly stable rhythm (1).
- Intradaily variability – the degree of fragmentation of activity–rest periods (range 0–2), from prolonged periods of activity and rest over 24 hours to multiple short periods.
- L5 – activity count for the five most restful hours.
- L5 start hour (of the 5 most restful hours).
- M10 – activity count for the 10 most active hours.
- M10 start hour (of the 10 most active hours).
- Core night-time (00.00 to 06.00) sleep efficiency.
- Core night-time (00.00 to 06.00) sleep time (minutes).
- Core night-time (00.00 to 06.00) wake time (minutes).

Instruments: carer

The Pittsburgh Sleep Quality Index (PSQI) is a self-report measure of sleep quality. It has nine items and seven component scores (0–3). The global PSQI score (0–21) is calculated as the sum of the component scores. A global score of ≥ 5 is indicative of poor sleep quality.

The Sleep Condition Indicator (SCI) is an eight-item scale characterising sleep dimensionally and against criteria for insomnia disorder. Each item is scored 0–4 and the total score (0–32) is calculated as the sum of item scores. A higher score means better sleep.

The Hospital Anxiety and Depression Scale (HADS) is a 14-item self-report scale measuring depression and anxiety using separate subscales of seven items, rated on a four-point scale (0–3). Three scores can be calculated: HADS-Depression (0–21), HADS-Anxiety (0–21) and HADS-Total (0–42). HADS-Total is calculated as the sum of the subscale totals. Higher scores mean higher levels of mood disturbance.

The Zarit Burden Interview (ZBI) is a 22-item self-report questionnaire measuring the impact of caring on the carer. Each item is scored 0–4, resulting in an accumulated score from 0 (no burden) to 88 (severe burden).

The Caregiver Health Status Questionnaire (HSQ-12) has 12 items, which produce a score on eight domains reflecting health and its impact on social, emotional and physical functioning. The items have a different number of responses (items 1 and 5–7: 1–5 responses; items 2–4: 1–3 responses; and items 8–12: 1–6 responses) and must be recoded before being summarised into the domain scores, which range from 0 (negative attribute) to 100 (positive attribute).

Qualitative interviews

A purposive sample of carers (randomised to the intervention group and chosen to cover a wide range of sociodemographic characteristics, including family and paid carers and those who did and did not complete the intervention) were interviewed about their views on the acceptability and practicality of the intervention and the assessment instruments, as well as to gain suggestions for refining the trial procedures. A semistructured interview guide of open-ended questions was developed and iteratively revised, adding further themes from the interviewees. All interviews were audio-recorded and professionally transcribed; recordings were destroyed after analysis. Interviewing continued until theoretical saturation was reached.

Results

Primary outcomes

Sixty-three (65%, 95% CI 55% to 75%) eligible referrals consented between 4 August 2016 and 24 March 2017, two from JDR and 61 from memory clinics; 62 out of 95 (65%, 95% CI 55% to 75%) participants were randomised and 37 out of 42 (88%, exact 95% CI 75% to 96%) adhered to the intervention.

Secondary outcomes

Four potential participants were referred per week from memory clinics. Of those participants randomised, 57 out of 62 (92%) were followed up at 3 months. Loss to follow-up was 4 out of 42 (9.5%, 95% CI 3% to 23%) in the intervention group and 1 out of 20 (5%, exact 95% CI 0.1% to 25%) in the TAU group. The Actiwatch was worn by 61 out of 62 participants randomised for seven or more nights at baseline, and 50 (81%) carers provided bedtimes and rise times in the sleep diary or used event markers (to aid the actigraphy analysis). However, at follow-up, 49 (79%) participants randomised wore the watch for ≥ 7 days, and 42 (68%) of those randomised recorded the bedtimes and rise times. Use of 'rescue medication' was not higher in the intervention group than the TAU group (odds ratio 0.51, 95% CI 0.06 to 4.01; $n = 55$ participants who had data collected about their medication use at 3 months). There was no indication of important harms in either group. At baseline, each sleep report measure, patient quality-of-life report and measure of carer mental health or burden was completed by the 62 participants randomised. The Neuropsychiatric Inventory and the SCI were completed by 61 participants. At 3 months, the SDI was completed by 56 (90%) of those randomised. All other structured instruments relating to the person with dementia were completed by 54 or 55 participants. Carer mental health and burden instruments were completed by all those in the study, and the carer sleep instruments by 55 or 56 participants. The preferred primary outcome measure for the main trial is, therefore, SDI. To calculate the sample size required for the main study, we used feasibility estimates of the standard deviation of baseline SDI scores (2.24) and the correlation between baseline and 3-month measurements (0.57). For an analysis of covariance to detect a 0.8-point difference in SDI scores will require between 230 and 296 participants in the intervention arm and 115–148 participants in the TAU arm (assuming an intracluster correlation coefficient of between 0 and 0.08, an average of 15 people per therapist, 2 : 1 randomisation, $\leq 15\%$ drop out and including an inflation for the case of non-normality). In qualitative interviews, it was discovered that most carers felt that the assessments were satisfactory but long. They liked the intervention and used differing components. Many wanted changes

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in the sleep diary, and would have liked the option to have the flexibility of either 1 or 2 weeks between the intervention sessions.

Conclusions

The results show that this intervention is feasible and acceptable. The next step is an efficacy trial. Actigraphy data for ≥ 1 week were available at follow-up for 79% of participants randomised, but only 68% of them had given event marker data for interpretation. Actigraphy measures may be unsatisfactory as primary outcomes. SDI was completed at follow-up by 90% of those randomised to the trial. SDI appeared to be the most practical way to measure sleep disorders in the person with dementia and would be our chosen primary outcome. Qualitative assessment showed that the manual was regarded positively, but requires minor changes: improving the sleep diary and offering greater flexibility in the timing between sessions.

Trial registration

This trial is registered as ISCTRN36983298.

Funding

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Chapter 1 Introduction

Scientific background

The prevalence of dementia and its impact, on both an individual level and a societal level, continue to increase. In 2015, there were 47 million people living with dementia worldwide.[1] It is estimated to cost US$818B and projected to become a trillion-dollar disease in 2018.[2] In the UK specifically, 850,000 people are living with dementia, a figure expected to rise to 1 million by 2021, and to double to 1.7 million over the next 30 years.[3] Currently, dementia care costs in the UK amount to approximately £26B, with the majority (£17.4B) falling on the people with dementia and their families.[3,4] Two-thirds of people with dementia live at home, where family members and informal carers provide most of the care.[3]

Sleep disturbances are common in older people without dementia, as sleep may be adversely affected by physical health state and pain. In dementia, there are additional factors that cause poor sleep. The prevalence of sleep disturbances in those with neurodegenerative dementias is estimated to be 25–40%,[5,6] with one meta-analysis of the prevalence of sleep disturbances in people with Alzheimer's disease (AD) finding a pooled prevalence of 39%.[7]

Sleep disturbances include reduced night-time sleep, fragmented sleep and wandering,[8,9] and are correlated with excessive daytime sleepiness and depression.[10] They may be both caused by and worsen AD and other dementias. Recent research has suggested a correlation between sleep disturbances and amyloid beta (Aβ) deposits.[11] Dementia may also lead to impaired production of the hormone melatonin through structural and functional alterations to the suprachiasmatic nucleus (SCN).[12,13] The circadian rhythm of melatonin production, high levels at night and low levels during the day, helps control the sleep–wake cycle.[14] People with dementia may wake during the night and not be aware of the time, or be frightened because they do not know what is happening. Dementia can therefore lead to decreased regularity of sleep, impaired sleep initiation and difficulty maintaining sleep at night, and wakefulness during daylight hours.[15]

Sleep acts as a restorative process for the brain and supports all aspects of mental and physical life, being a major determinant of day-to-day function and quality of life.[16] In turn, sleep disturbances reduce quality of life and are distressing for family members, whose sleep is often affected. Sleep disturbances in dementia increase family carer burden, predict their depressive symptoms and lead to care home admissions, elevating the individual, societal and economic costs associated with dementia.[10,17,18] Importantly, paid night-time care can be unaffordable or unfeasible for people who wish to continue caring at home.

Explanation of rationale

The causes of sleep disruption in individuals with dementia are multifactorial, and include physiological dementia-related changes, pain, environmental and behavioural factors, and medication side effects. There are currently no known effective treatments. Health teams use a mixture of sleep hygiene measures and psychotropic medication, extrapolated from other conditions. These confer limited benefit, and sedative medications may cause harm. A Cochrane review[19] of studies examining the effects on actigraphy sleep measures of drugs found no definitive effectiveness evidence. These conclusions are supported by recent investigations[20–23] (mostly in people with AD) that similarly found no efficacy evidence for any drugs or melatonin. Cholinesterase inhibitors and glutamate receptor antagonists, given particularly to people with AD or dementia with Lewy bodies, may increase wakefulness, but may hypothetically also support sleep through improved cognition.[24,25] However, there is no evidence of their efficacy. Overall, there is no conclusive evidence to suggest efficacy for any of these pharmacological options in the treatment of sleep disturbances in dementia.

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In addition, people with dementia are often frail with multiple comorbidities, and non-pharmacological treatment options should therefore be the first line for sleep management. However, most evidence about non-pharmacological treatments comes from small-scale studies often lacking in methodological rigour, leading to insufficient, conflicting evidence.[26] The need for better research into such treatments for sleep disorders is mentioned specifically in the National Dementia Strategy,[27] and the outputs of the 2010 Ministerial Dementia Research Summit and 2011 National Institute for Health Research (NIHR) Dementia Research Workshop, summarised in the Ministerial Advisory Group for Dementia Research (MAGDR) final report[28] *Priority Topics in Dementia Research* in February 2011. As with many other problems, studies consistently indicate that patients and their doctors would prefer non-drug approaches for sleep problems.[29]

One approach with suggested potential to improve sleep disturbances is bright light therapy. A systematic review and meta-analysis[30] and a separate case series[31] found that light therapy had small to medium effects on sleep disturbances in the general population.

There have also been recent small pilots of non-pharmacological interventions aiming to reduce sleep disturbances in people living with dementia. In one study, 7 out of 14 (50%) people with dementia and carer dyads completed a sleep education programme, which was delivered to the carers in a group setting.[32] In another pilot study, by Gibson *et al.*,[33] 9 out of 15 (60%) dyads completed a programme incorporating light therapy, exercise and sleep education. Both studies were methodologically limited, with unsatisfactory completion rates, but the interventions showed some promise in alleviating sleep disturbances.

Neurodegenerative dementias are commonly characterised by circadian rhythm disruption attributable to progressive loss of SCN neurons.[34] Thus, strengthening circadian rhythmicity through bright light therapy is theoretically appealing. However, light therapy administered in a non-individualised way, for example on the wrong side of the phase–response curve, may exacerbate sleep disruption.

In the current study, the vision was to build on this contradictory, and as yet incomplete, evidence by bringing together expertise in clinical interventions in dementia and sleep, statistics and input from family carers, and to deliver the intervention individually to fit the specific problems of each participant in the study. The aim was to develop and test a manual to improve sleep and, therefore, quality of life for those with dementia and their families. Through our previous work with STrAtegies for RelaTives (START), a coping strategy-based manual for family carers of people with dementia, short-term and long-term clinical effectiveness and cost-effectiveness have successfully been demonstrated.[35,36] This provided an ideal platform on which to build our new manual: Dementia RElAted Manual for Sleep; STrAtegies for RelaTives (DREAMS START). It was planned that DREAMS START would be a manualised multicomponent intervention, delivered to carers by clinically supervised psychology graduates, comprising a cognitive–behavioural component, light therapy, behavioural activation, relaxation and coping skills for families. Details of its development and content are below.

Sleep disturbances are complex and their causes and best management strategies differ between individuals. It can also be difficult for family carers to attend a group at a specific or fixed time. Thus, our intervention was individually tailored. It used natural dusk and daylight (whenever feasible) as well as other light sources to manage endogenous melatonin production. In addition to bright light therapy and strategies to increase daytime activity, we planned the intervention to include cognitive–behavioural techniques for sleep management, which a Cochrane review had found effective in older adults without dementia and in family carers of people with dementia.[37,38] A collaborative, non-prescriptive model was central when this intervention was delivered. Family carers were encouraged to try different strategies and note in their manual what worked for them. Psychology graduates were trained as sleep therapists. The therapists had a similar skillset to Improving Access to Psychological Therapies (IAPT) practitioners, and psychology assistants in memory and mental health services. The intervention was designed to be delivered by therapists with this skill level so that it could be delivered by IAPT-based psychological well-being practitioners and secondary care psychology practitioners in the future. This research has the potential to improve sleep and quality of life of people with dementia and their family carers, in a feasible

and scalable intervention without the side effects of medication. If found to be clinically effective in a future full-scale trial, this intervention should also be cost-effective: it is cheap and may delay care home admission.

Specific objectives

Our research question was: how feasible is a pragmatic, randomised study to investigate the clinical effectiveness and cost-effectiveness of a manualised intervention (DREAMS START) to manage NHS patients with dementia and significant sleep disturbance living in their own homes?

Aims

The aims were to develop a manualised behavioural intervention for sleep disturbances in dementia and examine the feasibility of a full-scale trial.

Objectives

The objectives were to:

- obtain estimates of acceptability and feasibility that will inform continuation to the main trial, specifically to estimate [with 95% confidence intervals (CIs)] the proportion of eligible participants who agreed to participate in the trial and the proportion of participants offered the intervention that adhered to it
- obtain estimates required for the main trial's sample size calculation in relation to potential primary outcomes [standard deviations (SD); correlation between baseline and follow-up measurements and drop-out rate]
- use qualitative interviews to assess acceptability of the intervention and to detail any required refinements.

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Chapter 2 Methods

Ethics

The trial was approved by the London – Queen Square Research Ethics Committee (reference number 16/LO/0670; see *Appendix 1*).

Trial design

This was a cluster-randomised, parallel-group superiority trial, with blinded outcome assessment. Participants were allocated 2 : 1 to the intervention or treatment-as-usual (TAU) arm.

Participants: eligibility criteria

People with dementia and their family carer were included, and the inclusion criteria for such dyads are laid out in the feasibility study below. To help determine feasibility for a full trial, people with a range of types of dementia and living situations were included. We wanted to find out if there were obstacles in such wide inclusion criteria, to enable us to consider criteria for a full trial. In particular, people who had an alcohol-related dementia or lived alone or were looked after by paid carer were not excluded, although it was uncertain how this would affect delivery of the therapy.

People with dementia

Adults with dementia (any type and severity) and clinically significant sleep difficulties [Sleep Disorders Inventory (SDI)[39] item score of ≥ 4 on screening] that were judged a problem by the person with dementia or their family were included. If the person with dementia did not have capacity to give consent, a consultee's declaration was sought. Patients living in a care home were excluded. Those with a primary sleep disorder diagnosis (e.g. sleep apnoea), rather than dementia-related sleep problems, were also excluded.

Carers

Primary family carers of the person with dementia were included for quantitative assessment interviews and intervention delivery. When the carer who spent most time with the person with dementia was not a family carer, then the paid carer was able to participate in the intervention. The family carer, however, completed the carer assessment measures. All carers provided emotional or practical support to the person with dementia at least weekly. Carers who were unable to give informed consent, or with probable dementia, were excluded.

Study settings

NHS trusts

Participants were primarily recruited from two NHS trusts in London: Camden and Islington NHS Foundation Trust (site 1) and Barnet, Enfield and Haringey Mental Health NHS Trust (site 2). Both trusts provided funding to cover the excess costs resulting from training, intervention delivery and clinical supervision. Clinicians approached people with dementia and their family carers who were attending one of the five memory services: (1) Camden, (2) Islington, (3) Barnet, (4) Enfield or (5) Haringey. Those interested in the study were asked to give permission for the research team to approach them, and were given an information sheet. Following contact by our team, an appointment was arranged to obtain informed consent in the potential

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participants' homes (or in the research team's office if preferred). A baseline assessment was carried out after this. Intervention delivery and follow-up assessments also took place in the participants' homes.

Join Dementia Research

In addition, the research team approached potential 'matches' through Join Dementia Research (JDR). This is an online and telephone service developed and launched in 2014/15 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 the potential suitability of studies. To recruit from this site [site 3, University College London (UCL)/JDR], potential matches with any dementia diagnosis listed on JDR were identified. We ticked 'yes' to 'Has next of kin?', chose 'Include empty or NULL values', ticked 'yes' to 'Has a carer?', ticked 'no' to 'Volunteer is a carer?', ticked 'no' to 'Volunteer cares/supports a person with dementia?', and selected 'More than 3 times per week' for 'Contact with carer' ('Include empty or NULL values'), and selected 'Private Residence' and 'Assisted Living Accommodation' for 'Accommodation Type' ('Include empty or NULL values'). Owing to limited resources, we defined our search area based on proximity to UCL.

Data collection

Family carers were interviewed at screening/baseline (pre randomisation) and at the 3-month follow-up to collect data on the person with dementia and the carer. For around one-third of the participant dyads (22/62 randomised), each value entered into the participant database was double-checked; no systematic errors were found.

Patient measures

Demographic and clinical characteristics

1. Sociodemographic details (i.e. sex, date of birth, type of dementia diagnosed, age when left education, last occupation, current marital status, ethnicity) were collected at baseline. We had information on all potential participants' sex, including those who did not provide consent to be screened, those who were not eligible and those who were not randomised.
2. Type of dementia was recorded from clinical information.
3. Severity of dementia was measured using Clinical Dementia Rating™ (CDR)[40,41] through informant information at baseline. This is a reliable and valid instrument for rating the severity of dementia.[42] It is used to rate performance in memory, orientation, judgement and problem-solving, community affairs, home and hobbies, and personal care. This information was used to classify dementia severity of clinically diagnosed patients or those on JDR into very mild (0.5), mild (1), moderate (2) or severe (3).
4. Rescue medication's role: all prescribed psychotropic medication and melatonin was measured at baseline and 3 months by completing the Client Service Receipt Inventory (CSRI),[43] which incorporates a list of all medications in the previous 3 months. Use of the following was recorded:

    - anxiolytics and hypnotics
    - antipsychotics
    - antidepressants
    - other psychotropics.

5. Reported side effects: side effects were measured using a study-specific Safety and Tolerability Assessment (see *Appendix 2*) to record the occurrence of falls, dizziness, headaches and gastrointestinal symptoms (appetite or bowel symptoms) and any other side effects at baseline and 3 months.

Potential outcomes for the main trial

1. Sleep disturbance in the person with dementia was measured using the SDI[39] at screening and 3 months. The SDI is a standalone tool for assessing sleep disorder symptoms in people with dementia, developed for use to measure outcomes in original melatonin trials. It has been used in pharmacological and non-pharmacological studies and validated against actigraphy and clinical variables. The SDI consists of the seven sleep subquestions of the sleep and night-time domain of the Neuropsychiatric Inventory (NPI).[44] These are: (1) difficulty falling asleep, (2) getting up at night, (3) wandering, pacing or conducting inappropriate activities at night, (4) awakening the carer at night, (5) awakening at night, dressing, planning to go out, thinking that it is morning, (6) awakening too early in the morning and (7) excessive daytime sleepiness. SDI item scores are based on the carer's ratings on each of the seven symptoms separately. Each item is rated according to frequency (scale 0–4) and severity (scale 0–3) of sleep-disturbed behaviours and, when frequency and severity are multiplied, possible item scores range from 0–12. Those who scored ≥ 4 on any individual item were judged to have clinically significant sleep disturbance and were eligible for the study. The SDI mean global score, which is often reported, is the total frequency multiplied by severity, divided by 7.
2. Neuropsychiatric symptoms were measured using the NPI[44] at baseline and 3 months. This is a validated instrument with 12 domains of neuropsychiatric symptoms. A single frequency and severity rating is given for all behaviour subquestions within a domain, with each domain scoring between 0 and 12; higher scores mean increasing severity. A summed score out of 144 captures total neuropsychiatric symptoms.
3. Daytime sleepiness was measured from the Epworth Sleepiness Scale (ESS)[45] at baseline and 3 months. This is an eight-item measure assessing the tendency to sleep/doze in specific daily situations (possible score range 0–24; a score of > 10 indicates excessive sleepiness).
4. Quality of life was measured using the Dementia Quality of Life – Proxy (DEMQoL-Proxy)[46] at baseline and 3 months. It 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 with satisfactory psychometric properties.[47]
5. Services use was measured using the CSRI at baseline and 3 months. It is widely used for dementia trials and will delineate treatment as usual (TAU) as well as treatment for those in the active arm of the study.

Wrist-worn Actiwatches, worn 24 hours a day for 2 weeks at baseline pre randomisation and again 3 months after randomisation, provided estimates of rest–activity rhythms, light exposure and sleep. Actigraphy has theoretical advantages for patients who may not be able to remember well enough to accurately fill in questionnaires or sleep diaries. It has been validated against polysomnography (PSG) in populations including older adults without dementia (one study[48] of 77 people, with a mean age of 35 years) for its accuracy at correctly detecting sleep, wakefulness and wakefulness after sleep onset. The Actiwatch detected sleep in the whole population with 96.5% accuracy, but was not as good at detecting wakefulness (32.9% accuracy), and this became worse with increasing age. Another study of older women without dementia (with a mean age of 69 years) found that wrist actigraphy detected sleep less accurately in this age group and was unacceptable for those with low measures of sleep efficiency.[49] However, it has been used in 10 nursing home residents with severe dementia to estimate sleep during night-time, and the measures significantly correlated with total sleep time from electroencephalographic recordings.[50] We used the MotionWatch 8 (herein referred to as 'the Actiwatch'), a Conformité Européenne (CE)-marked class 1 (low-risk) medical device (CamNtech Ltd, Cambridge, UK). Such non-intrusive, reusable Actiwatches have been used successfully in previous trials of people with dementia and sleep disturbance.[51] The aim was to use a minimum of 1 week's worth of data. The participants were given written instructions (see *Appendix 3*). It was ensured that that the person with dementia and their carer between them understood the instructions and had the opportunity to ask questions. Whenever possible, the watch was placed on the wrist of the

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participant's non-dominant hand, and variability was controlled among the watches by ensuring that the participants wore the same watch at baseline and follow-up. The data were recorded in MotionWatch Mode 1, which uses a single-axis algorithm and peak detection, sampled at 50 Hz, and processed into 60-second epochs. Each recording was started in the evening on the day of the baseline or follow-up assessment (preferably at 17:00) and continued for a minimum of 14 days, after which the watch was collected. Carers were asked to use a sleep diary (see *Appendix 3*) to keep a record of the bedtimes and rise times of the person with dementia, or, as an alternative, to indicate these times by pressing the Actiwatch's 'event marker' button. These were used to define each participant's sleep analysis window. We also asked the carers to write down (e.g. in the sleep diary) any occurrences when the watch was not worn for > 1 hour. Participants were encouraged to contact the research team if they had any further questions about the watch.

- Sleep measures:
  - Sleep efficiency – sleep time expressed as a percentage of time in bed. This captures both initiation and maintenance of sleep, reflecting the proportion of time in bed spent asleep, and has been found to be reliably impaired in actigraphy studies of people with dementia and sleep problems.
  - Sleep time (minutes) – the total time spent in sleep according to the epoch-by-epoch wake/sleep categorisation. As the Actiwatch infers, time asleep is not 'actual sleep time'.
  - Wake time (minutes) – the total time spent awake according to the epoch-by-epoch wake/sleep categorisation. As the Actiwatch infers, time awake is not 'actual wake time' but it is the label used.
  - Time of 'lights out' or going to bed.
  - Time of falling asleep.
  - Time of waking up.
  - Time of getting up.
  - Time in bed (hours) – the total time between 'lights out' and getting up.
  - Fragmentation index – the degree of fragmentation of the sleep period, calculated by summing mobile time (%) and immobile bouts of ≤ 1 minute (%).
- Circadian rest–activity rhythm metrics/non-parametric circadian rhythm analysis (NPCRA) measures to assess the timing, amplitude and stability of rest–activity rhythms:
  - Relative amplitude – the amplitude of circadian rhythm (range 0–1), calculated by dividing the difference between average activity in the most active (M10) and most restful (L5) periods by the sum of M10 and L5.
  - Interdaily stability – the degree of regularity in the activity–rest pattern, ranging from a total lack of rhythm (0) to a perfectly stable rhythm (1).
  - Intradaily variability – the degree of fragmentation of activity–rest periods (range 0–2), from prolonged periods of activity and rest over 24 hours to multiple short periods.
  - L5 – activity count for the 5 most restful hours.
  - L5 – start hour (of the 5 most restful hours).
  - M10 – activity count for the 10 most active hours.
  - M10 – start hour (of the 10 most active hours).
- Core night-time analysis sleep measures:
  - Core night-time (00.00 to 06.00) sleep efficiency.
  - Core night-time (00.00 to 06.00) sleep time (minutes).
  - Core night-time (00.00 to 06.00) wake time (minutes).

Carer measures

Demographic characteristics

Sociodemographic details [sex, date of birth, current or last occupation, carer relationship to person with dementia, co-resident carer (yes/no), average number of visits per month (non-resident carer) and ethnicity] were collected at baseline. The details of a carer's sex and relationship to the person with dementia were available for all potential participants referred to the study, including those who did not provide consent to be screened, those who were not eligible and those not randomised.

Potential outcomes for the main trial

- Carer sleep quality was measured using the following:
  - The Pittsburgh Sleep Quality Index (PSQI)[52] at baseline and 3 months. It is a validated, reliable instrument to measure the carer's sleep (since it is commonly disrupted by sleep–wake patterns of the person with dementia).
  - The Sleep Condition Indicator (SCI)[53] at baseline and 3 months (a new eight-item scale developed in the UK with data on tens of thousands of people of all ages). It characterises sleep both dimensionally (like PSQI) and against insomnia disorder criteria (which PSQI does not).
- Mood disturbance was measured using the Hospital Anxiety and Depression Scale (HADS) at baseline and 3 months.[54,55] It is a validated, reliable measure of mood in carers throughout the age groups.
- Subjective burden for carers was measured using the Zarit Burden Interview (ZBI) at baseline and 3 months.[56] It is the most commonly used and well-validated measure of burden for carers of people with dementia and was used in this report to indicate whether or not burden may be changed by the intervention.
- A carer's health-related quality of life was measured using the Health Status Questionnaire-12 (HSQ-12) at baseline and 3 months.[57] It is a 12-item quality-of-life scale validated throughout the age group.

Interventions

DREAMS START intervention development

Conceptualisation of manual elements

The DREAMS START intervention was developed using an iterative and collaborative coproduction process with the team that developed the START and Managing Agitation and Raising Quality of Life (MARQUE) manualised interventions for carers of people with dementia (GL, PR, CC), experts in manualised cognitive–behavioural interventions for sleep disorders (CAE, SDK), our collaborators from the Alzheimer's Society (JAP, RH) and carers of people with dementia who have experienced sleep disturbances, and through practice sessions as part of therapist training. *Figure 1* summarises the manual development process.

Development of the intervention began in February 2016 when the project management team met and agreed that DREAMS START would be a six-session, multicomponent intervention, based on the best existing evidence at the time,[26,35,37,38,58–61] comprising a cognitive–behavioural component (including psychoeducation, coping skills for families, and activities for people living with dementia) and light therapy. *Figure 1* provides an overview of this process.

The first stage of intervention development was to share the existing StrAtegies for RelaTives (START)[35] and Oxford's manuals on cognitive–behavioural therapy for insomnia[62] within the team and to consider which elements to build into the DREAMS manual. One month later, Gill Livingston, Simon D Kyle and Penny Rapaport met face to face and, joined by Colin A Espie on the telephone, agreed the main initial

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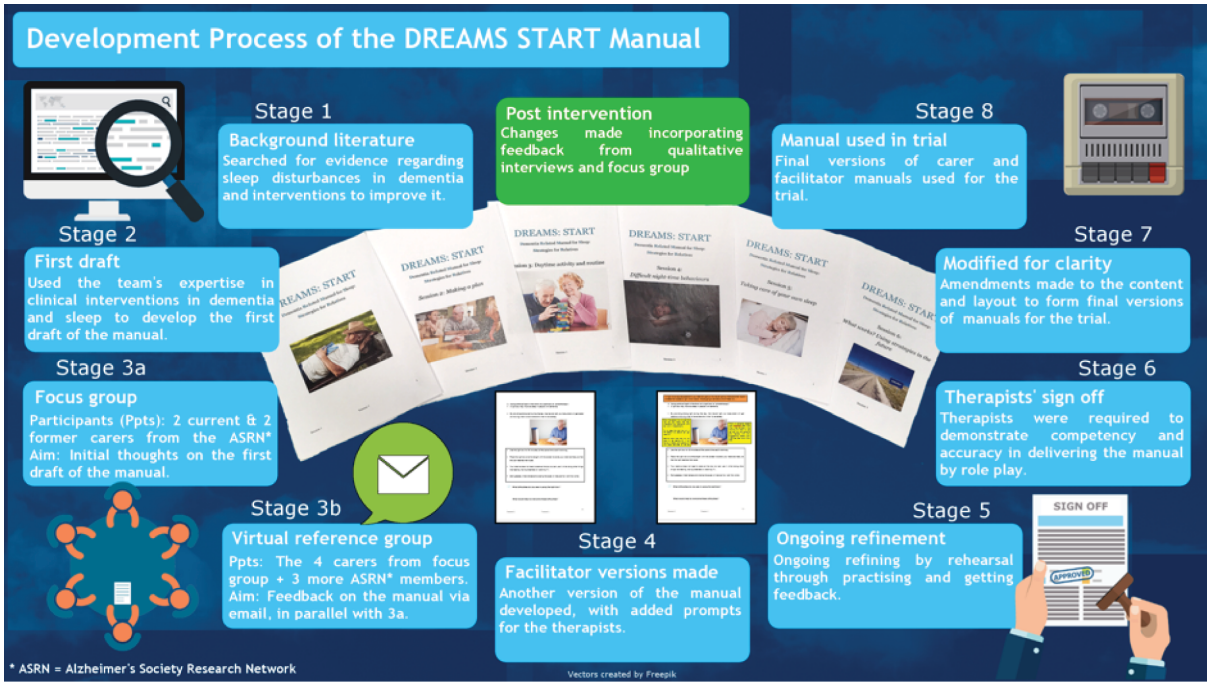

FIGURE 1 Development process of the DREAMS START manual.

structure and content of the six sessions. At this stage, it was agreed that the intervention would be both interactive and individualised, using the actigraphy data collected at baseline to inform a shared understanding of the person with dementia's night-time settling and waking problems, and their daytime sleepiness/fatigue and to help generate an optimal 'sleep window'. As in the team's previous work, a collaborative, non-prescriptive model was adopted, explicitly encouraging family carers to build on their own experience of what they have found works and to develop and use new techniques and behavioural strategies, recording what works in their manual, and continuing to use successful strategies. A specific focus was incorporated within sessions on identifying and overcoming barriers to changing behaviours and routines of people with dementia and considering how to minimise the risk of harm when people with dementia are awake at night. In line with the form of the START intervention, each session included a stress reduction exercise, a between-session practice task, a recapitulation on the previous session and troubleshooting around putting strategies into practice. Five of the same stress reduction techniques from the START intervention were used in the DREAMS START manuals (sessions 1–5). All manuals from the START intervention are available freely online.[36,60]

Session structure

Penny Rapaport and Simon D Kyle developed initial drafts of the six manual sessions (for further details, see *Intervention content*). These were as follows:

1. understanding sleep and dementia
2. making a plan
3. daytime activity and routine
4. difficult night-time behaviours
5. taking care of your own sleep
6. what works? Using strategies in the future.

Each session, after the first one, followed a similar structure. It began with a recapitulation of the previous week's session and a discussion about what the carer had achieved since then. The new topic was then introduced, and the carer and therapist generated relevant, individually tailored, plans that the carer could implement in the coming week. At the end of the session, the therapist talked the carer through a new relaxation exercise.

Drafts of the manuals were initially circulated within the project management team and revised based on feedback on both form and content. The goal was for the manuals to present comprehensive information succinctly and in plain English, without jargon, in an interactive format that encouraged carers to actively engage in sessions. This was done by including both theoretical components and practical exercises that called on the carers' own experiences and were discussed during the session. In addition, vignettes were used to involve the carer and to illustrate points, and to display diagrams and graphical information simply and clearly. We tried to maintain a balance between information provision and interactive exercises, to ensure that the carer participated in, rather than was lectured about, the manual. Large chunks of overly technical information were avoided and information was presented in a clear and engaging manner.

Patient and public involvement in the intervention development

After making initial revisions, family carers were invited, via the Alzheimer's Society Research Network (ASRN), to attend a focus group (in May 2016) to provide feedback on the drafts and to share their experiences of what strategies they did and did not find useful in caring for a relative with sleep difficulties. The group was facilitated by Penny Rapaport and Kirsi M Kinnunen, based on a semistructured topic guide (see *Appendix 4*). All carers consented to the discussion being audio-recorded, and discussions were then externally transcribed and the data were entered into NVivo 11 software (QSR International, Warrington, UK) and analysed using thematic analysis.[63,64] Two researchers (BH and LW) independently coded the transcript for the main themes that occurred and each labelled the themes and generated a thematic framework. They then met with Penny Rapaport to discuss and agree a consensus on their coding and generate the final framework, according to which the data were organised. Two current and two former carers of people with dementia attended the focus group and, having further revised the manual based on this initial feedback, a virtual reference group of family carers and people living with dementia was consulted by e-mail to obtain further feedback on the draft manuals. The virtual reference group included the four focus group participants and three additional members of the ASRN, including one person living with dementia, one current carer and one former carer.

The key themes elicited from the focus group related to the sleep disturbances that people with dementia experienced and the explanations carers had for these difficulties, the effects that sleep disturbances had on the carers, what they found helpful, and suggestions that they had for the DREAMS START intervention.

The main difficulty that the carers described was their relative waking repeatedly in the night and getting out of bed. This often increased the risk of coming to harm, for example by falling down the stairs or by using electrical appliances unsafely. Carers attributed this night-time waking to a number of causes, mainly confusion, worrying about their symptoms, and dementia type and severity. Confusion meant their relative with dementia mixing up night and day, which one carer felt was exacerbated by being indoors and inactive during the day.

All four of the carers in the focus group spoke of the emotional, physical and practical effects that their relative's sleep disturbance had on themselves, their relatives and other family members. The main effect on carers was that they themselves became sleep deprived. This happened because they were woken up directly by their relative, and also because they were kept awake by the worry that their relative might awaken, get up and come to harm. Carers described how the lack of sleep over time had negative physical effects on their health and affected their ability to work and function during the day. Carers highlighted various successful and unsuccessful strategies that they had used. Gentle touch and physical comfort had a relaxing effect on their relatives at bedtime and during the night, and keeping the evenings calm and winding down before bed was helpful. They also highlighted the importance of carers finding ways to manage their own stress and sleep problems. There was a common consensus between the carers that using medication to manage sleep problems in their relatives was not helpful. Some also found that there sometimes did not seem to be any pattern to the sleep problems and no helpful strategies.

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These findings were used to further refine the manual, ensuring that the emergent themes were included and, in particular, that there was a greater focus on carers finding ways to minimise the impact of sleep disturbances on their own well-being and ensure that the person with dementia was physically and emotionally comfortable. At this point, direct quotations from the carers about their experiences were added to the manual to situate the content and privilege the experiences of family carers. In addition, both the focus group participants and the virtual reference group participants gave feedback and made suggestions about different aspects of the manual sessions. These are summarised in *Table 1*.

Finalising the intervention

Having further revised the manual based on feedback from family carers, Penny Rapaport drafted a therapist version of the manual that included additional prompts and guidance for the therapists. At this point, the team also checked the manuals for readability using the Flesch Reading Ease test,[65] and all sessions were rated to be within the categories of 'fairly easy' or 'easy' to read. The research assistants who were going to be delivering the intervention then spent time practising each session in pairs, with Gill Livingston, Penny Rapaport, Claudia Cooper and Kirsi M Kinnunen making further revisions to timing, content and structure whenever it did not flow or was unclear, too long or repetitive. The research assistants also met in groups, practised delivering the sessions and provided oral and written feedback on how to improve the sessions and increase the accessibility and clarity of the session content. This process was repeated until it was agreed by the researchers and therapists that the sessions were ready for use. *Box 1* shows the derivation of the final manual, including where each element of the intervention came from. Final versions of both the therapist and carer versions of the manual were then produced for use within the study (see *Appendix 5*).

TABLE 1 Suggested changes to the manual from focus group and virtual reference group

Topic	Suggestions
Content	To include more on the impact of different dementia types on sleep
	To make session 1 less didactic
	To explain the actigraphy data very simply
	To include a discussion of becoming more agitated or confused in the evening
	To include more on the physical causes of sleep problems, including medication
	To focus on increasing activities at times that the person is most likely to nap
	To mention the impact of nutrition on sleep
Design	To reduce the number of words per page and overall
	To include more pictures to make the manual more readable
	To ensure that any instruction to carers is very detailed and clear
	To simplify the diagrams delineating sleep processes
	To change specific pictures that were not felt to fit
	Formatting and typographical errors were identified
Session delivery	To emphasise potential benefits of the intervention and how the intervention could help and make life easier
	To ensure that the tone of this was as a partnership, working together with the carer rather than teaching them
	To respect the carer's existing knowledge and experience
	To allocate more time for session 1 or reduce the content

BOX 1 Derivation of DREAMS START manual

Session 1

Sleep and dementia – material provided by Simon D Kyle.

What is sleep? – material provided by Simon D Kyle.

What causes sleep problems in dementia? – written by Penny Rapaport, Simon D Kyle and Gill Livingston for DREAMS.

Making changes to improve sleep (lifestyle and bedroom factors) – adapted from CBT work by Colin A Espie.

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

Recapitulation on understanding sleep and dementia.

Light and sleep – material provided by Simon D Kyle.

Light, dementia and the body clock – material provided by Simon D Kyle.

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 work on sleep efficiency by Colin A Espie and Simon D Kyle.

Managing stress 2: focused breathing – adapted from START.

Summary – adapted from START.

Putting it into practice – adapted from START.

Session 3

Recapitulation 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 Penny Rapaport, Gill Livingston and Simon D Kyle.

Establishing a good day and night routine – adapted from CBT work by Colin A Espie.

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.[66]

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Session 4

Recapitulation 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

Recapitulation 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 CBT work by Colin A Espie.

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 Simon D Kyle for DREAMS.

What works? The importance of daytime activity – from START.

What works? Making a new sleep routine – based on the sleep manual by Colin A Espie and Simon D Kyle.

What works? Making changes to improve sleep – based on the sleep manual by Colin A Espie and Simon D Kyle.

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

What works? Challenging unhelpful thoughts and feelings – based on START and CBT work by Colin A Espie.

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 – developed for DREAMS.

CBT, cognitive–behavioural therapy.

Adherence to the manual

To inform the calculation of adherence to the intervention, the number of sessions that would count as adherence was discussed in a project management meeting. It was agreed that this was a matter of clinical judgement. Penny Rapaport (psychologist) and Gill Livingston (psychiatrist) judged that, as this was a group of people who often had comorbidities, those who attended most of the sessions, that is four or more, could be judged as adhering to the manual. This was specified in the analytical plan before analysis.

Intervention delivery

The six-session DREAMS START intervention is manual based and was delivered by trained and clinically supervised psychology graduates to carers. They were sometimes accompanied by people with dementia who were able to participate or whom chose to be there. Each carer was given part of the manual specific to each session at the beginning of each meeting, for them to write in and keep. Generally, the sessions took place in the home of the carer or the home of the person with dementia for whom they were caring. Occasionally, carers chose to have sessions elsewhere (the team base, the premises of the memory service from which the participant had been referred to the trial) because it was easier for them to attend. Each session lasted ≈1 hour and took place approximately weekly, at a time convenient to the carer, including evenings. The intervention sessions were generally delivered to the family carer who had been recruited to the study. However, sometimes paid carers participated in the sessions if, for example, they were with the person around the clock who would be most likely to implement strategies. Generally, the carers were encouraged to have the sessions without the person with dementia in the room, so that they could talk freely about any difficulties and to reduce any potential distress to the person with dementia. If the person with dementia wanted to participate in the sessions, either alone or with their main carer, they were included in the sessions. However, carers were encouraged to also participate in the sessions to maximise the potential for new strategies to be developed and used.

Intervention content

The DREAMS START manual used in the trial was designed to optimise both the individual's sleep at night and his/her wakefulness during the day. To optimise night-time sleep pressure and the circadian regulation of sleep, the intervention focused on supporting carers to use practical zeitgebers (cues that influence a person's biological rhythms, e.g. regular timing of bed and rising, morning wake-up light, standardised mealtimes) and to establish adaptive stimulus control (e.g. pre-bed settling routine, management of wakeful episodes). The intervention introduces strategies to promote de-arousal at night (e.g. relaxation, bedroom comfort, no caffeine or alcohol intake before bed, no activities in bedroom) and behavioural activation during the day to maintain alertness, reduce daytime naps and increase engagement to strengthen both central and peripheral clock timing. The intervention also focuses on helping carers to develop coping strategies to manage concerns about their own sleep health.

Sessions 1–5 all included one or two key topics for discussion, a specific plan or goal to try out between sessions, a stress reduction exercise with an accompanying compact disc (CD)/MPEG-1 Audio Layer III (MP3) file and a sleep diary for the carer to fill in for monitoring progress between sessions. Although manualised, during each session the participants would develop specific goals, which were combined to make an individualised plan.

The six intervention sessions covered the following:

1. Understanding sleep and dementia – psychoeducation on the importance of sleep, sleep process, the impact of dementia on sleep and what causes sleep problems in people with dementia. This session also discussed lifestyle and bedroom environment factors that can affect sleep, and carers were encouraged to identify potential changes that they could try out before the next session. In addition, the impact that sleep problems can have on the person with dementia and their relative was discussed.

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2. Making a plan – psychoeducation on the importance of light for sleep and the relationship between light, sleep and dementia. This session was built around the light and activity data collected by actigraphy at baseline, with the individual's data inserted into the manual in advance of the session and an explanation given. The carers were given a 'light box' (Lumie Arabica SAD Light, Lumie, Cambridge, UK) to keep and it was switched on and left on during the sessions to encourage people to understand that they habituated to the bright light (10,000 lux at 25 cm). A time switch was provided if carers wanted it, so that it could be switched on when they were otherwise engaged. It was recommended that the light box be used for 30 minutes at the same time every morning. During the session, the participants made an individual plan for increasing natural and artificial light for the person with dementia. Based on the individual's sleep data, a 'sleep efficiency' score (time asleep/time in bed) was calculated, and any suggested changes to an individual's time to bed and rise and for reducing daytime naps was integrated into their individual action plan.
3. Daytime activity and routine – this session highlighted the importance of daytime activity and routine and focused on building pleasant activities and exercise/physical activity into the day. This session included a seated exercise video for less physically able individuals. It also included the importance of establishing a good day and night routine and ways to strengthen the link between bed and sleep. In addition, an exercise and activity plan were built into the individual plan.
4. Difficult night-time behaviours – this session began with troubleshooting around putting the individual plan into action and identifying potential solutions to any barriers. The rest of the session focused on describing and investigating difficult night-time behaviours that were specific to the individual with dementia.
5. Taking care of your own sleep – this session included using the information collected on difficult night-time behaviours to create strategies for managing these difficulties. The rest of the session focused on the carer managing their own sleep, including ways to challenge unhelpful thoughts and feelings and make time for themselves.
6. What works? Using strategies in the future – this session recapitulated on earlier sessions and focused on what carers found useful and what worked. From this, an individualised sleep action plan was finalised, which included strategies for both the person with dementia and the carer.

Treatment as usual

Participants received TAU for 6 weeks, delineated by the CSRI. This was expected to vary between trusts, and also according to individual patient needs, but was expected to be in line with the National Institute for Health and Care Excellence (NICE) pathways guidelines for dementia.[67] TAU varies according to the practices of the trust in which the person with dementia is treated and the person's individual needs, but incorporates the NICE pathways guidelines[67] for dementia and consists of assessment, diagnosis, symptomatic interventions, risk assessment and management and information.

The volunteers from JDR may not have been currently receiving professional care, but details of any services they were receiving were gathered. Services are based around the person with dementia. Treatment is medical, psychological and social. Thus, TAU consisted of assessment, diagnosis, risk assessment and information. These included referral to dementia navigators; medication; cognitive stimulation therapy; START (in some trusts); practical support (social services provided); risk plans, for example telecare, treatment of neuropsychiatric symptoms, driving information to the Driver and Vehicle Registry Agency, medical identification (ID) bracelets and advice regarding power of attorney and capacity assessment; and social services referral for personal care, day centre and financial advice, and carer support.

After the follow-up data had been collected (including the 2 weeks of follow-up actigraphy), the participants in the control group received a summary of the baseline Actiwatch data, with advice on improving sleep (see *Appendix 6*). To maintain the follow-up assessor's blinding until the follow-up Actiwatch data had been analysed, the unblinded team posted this information to the participants once the follow-up actigraphy was complete (of which the assessor informed the unblinded team).

Both groups

After the follow-up assessor's unblinding, the assessor sent the participants an end-of-involvement letter (see *Appendix 7*), enclosing a summary of the follow-up Actiwatch data. The referring clinician was sent a copy of the letter.

Details of how the interventions were standardised

The intervention was standardised primarily through being manualised. This allowed the research team to maintain tight control over how the intervention was delivered, and provided a clear and detailed structure for the graduate psychologist therapists to adhere to. It also meant that the carers could keep the manual and refer back to notes, plans and information between and after the sessions. Variation came with the introduction of personalised goals and strategies, and the use of individual actigraphy data. Delivery of the interventions as intended and in a standardised way was assured by training the therapists and ensuring that they were 'signed off' as individually competent in each session, and by offering regular and structured clinical supervision, as detailed in the following section.

Training the therapists

Four research assistants who were psychology graduates with no clinical training were employed to deliver the intervention and received in-depth training prior to delivering the intervention. The research assistants participated in five knowledge and skills-based sessions on the following topics:

1. Dementia (CC)
2. Sleep (SK)
3. Introducing DREAMS START (GL)
4. Clinical skills for delivering the intervention part 1 (PR)
5. Clinical skills for delivering the intervention part 2 (PR).

Training was delivered through a combination of seminars, discussion, reflective learning and guided reading. Skills-based competencies were learnt through role-play, small-group exercises and clinical simulation in pairs. Training drew on the curriculum for psychological therapists devised by the Department of Health and Social Care for its IAPT programme, and the successful training programme developed for the START intervention. There was a strong practical focus in the training programme on how to deliver the therapy, potential clinical dilemmas, collaborative goal-setting, managing sessions with more than one participant, working with interpreters, empathic listening skills, effective use of supervision, safe working practice, and when to ask for help. Throughout the training, an emphasis was placed on the researchers facilitating carers to develop and practise using their own strategies and finding their own solutions rather than feeling the need to instruct carers and provide solutions within the session. In addition to the knowledge and skills-based training, therapists were trained to adhere to the manual by practising repeatedly in pairs, and required to demonstrate, by role playing the entire intervention for one of the clinical members of the research team, competence in delivering each session of the intervention to an agreed standard.

Supervising the therapists

The process of formal clinical supervision of the therapists began at the start of the intervention delivery period and continued until the final sessions had been delivered. The clinical psychologist, Penny Rapaport, met with each of the two teams (two therapists in each team) for 1.5 hours of group supervision per fortnight. In addition to this group supervision, she was available for individual supervision, which was either requested by the psychology graduates on an ad hoc basis, or (on occasion) was initiated by the investigators. If they had any urgent clinical or procedural concerns or questions relating to their clients, the therapists could approach Penny Rapaport, Claudia Cooper or Gill Livingston at any time, for example if risk issues arose during a session.

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The group supervision format was seen as the most effective use of available resources, with psychology graduates benefiting from both the professional expertise of their supervisor and the clinical experiences of their peers; it was successfully applied in the START randomised controlled trial (RCT). It was expected that the supervision format would also maximise peer support within and outside the supervision sessions, and facilitate effective teamworking. The format was tailored to reflect the specific needs of the present research study. During the course of the project, supervision performed a number of functions including case management, clinical skills development, ensuring safe practice with clients, and staff support. Each of these functions is explored in turn in the following sections.

Case management

An important function of supervision was to ensure that all of these interventions were being managed consistently, effectively and appropriately. Therefore, in every group supervision session, each therapist provided a brief overview of their caseload, ensuring that clients and any related issues or concerns did not get overlooked. This encouraged the therapists to be transparent about their work and to recognise when apparently simple or straightforward cases were more complex than initially perceived. As the cases for intervention were allocated and managed within the team, it was useful for the therapists to be aware of who their colleagues were seeing and who had space to take on new clients, developing a sense of shared responsibility.[61]

Clinical skills development

Group and individual supervision sessions provided the therapist with the opportunity to develop their clinical skills via a range of approaches. In addition to giving a brief summary of their caseloads at the start of every supervision session, the therapists would identify a clinical challenge or dilemma that they wished to explore in more detail.[61] Although the intervention was manualised and psychology graduates were expected to adhere strictly to the manual, there was great variety in the dilemmas that they encountered in delivering the intervention. Various issues tended to emerge within supervision, for example how to keep carers focused on the manual and engaged in the process, and how to manage sessions when the person with dementia and the carer were both contributing. Using a combination of role play and reflection on extracts of the fidelity recordings, the therapists were able to enhance their skills in delivering the intervention in a safe environment.

Ensuring safe practice with clients

There was a written policy about lone working and safeguarding, to which the therapists were trained to adhere. The clinical team provided the therapists with specific training in how to respond to any risks either disclosed by carers or witnessed in interactions, in relation to harm to either themselves or the person for whom they were caring. If concerns were raised, a plan was made with one of the lead investigators about how to manage the risk, and information was shared with the local clinical teams. By ensuring that there was an opportunity for individual supervision on request, and that a senior member of the team was always available, a culture of transparency developed whereby the therapists felt comfortable raising concerns about clients with the clinical academics in the team. Time was also taken within supervision to highlight the importance of behaving ethically and safely in all aspects of clinical work, for example how to practise safely when working alone in people's homes.

Staff support

Many of those receiving the intervention were experiencing high levels of emotional distress, often in the context of challenging social situations and physical environments. An important dimension of clinical supervision was to give the therapists an opportunity for self-reflection, making sense of their own responses to the people with whom, and situations in which, they were working. The combination of group and individual supervision meant that the psychology graduates benefited from the support of their peers and felt that their experiences were validated by their shared experiences.

Details of how adherence of care providers to the protocol was assessed or enhanced

Monitoring fidelity to the intervention

In addition to the close supervision and training identified in the previous section, a formal process for monitoring the fidelity of the therapists to the manualised intervention was instigated. Following a similar process to that used in the START RCT,[35,61] therapists audio-recorded one session per participant. The session to be recorded was selected at random by the trial manager using a Microsoft Excel® (Microsoft Corporation, Redmond, WA, USA) formula, before any interventions were carried out. Penny Rapaport devised a fidelity checklist for each session by considering the most important components of each session (see *Appendix 8*). To maintain the follow-up assessor's blinding, this session was rated for fidelity to the manual by the other therapist in the same team (who was not involved in that participant's intervention), using the checklist. For each recorded session, a fidelity score for four process factors was given by the rater, considering whether the therapist was (1) keeping the session to time, (2) keeping the carer focused on the manual, (3) keeping the carer engaged in the session and (4) managing the concerns of the carer. Possible scores ranged from 1, meaning 'not at all', to 5, meaning 'very focused', for each item. Ratings were out of a possible 5 points.

Outcomes

Primary outcomes

1. Feasibility of recruitment: this was assessed by (1) the proportion of participants consented out of those meeting the eligibility criteria at screening and (2) the proportion randomised after baseline assessment.
2. Feasibility of the intervention: this was assessed by recording the proportion of participants randomised into the intervention group who by the end of the trial had attended four or more of the six sessions.
3. Acceptability of the intervention: this was assessed through qualitative interviews with up to 20 intervention group participants after follow-up, post unblinding.

Therapist

Secondary outcomes

1. Referral rates from the recruitment period were measured from records about all and eligible referrals at the end of the recruitment period.
2. Follow-up rates were measured after the last follow-up visit, from records indicating which participants completed follow-up assessments at 3 months.
3. Reported side effects (patient falls and comorbid physical illnesses) were recorded using a study-specific DREAMS side-effects questionnaire at baseline and 3 months.

Acceptability of outcome measures for a future trial of clinical effectiveness and cost-effectiveness was assessed through recording the completion rates of instruments (see below) at baseline and 3 months, the acceptability of tools from the qualitative interviews post unblinding, and calculating the sample size that would be required to detect a clinically important difference in outcome.

Qualitative interviews

Sample recruitment and procedure

A purposive sample of carers who had received the intervention for qualitative interviews was recruited in order to assess acceptability of the intervention and whether or not there were groups that the intervention

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was unsuitable for, and to detail any required refinements in the intervention or the assessment procedure. They were invited to participate in the interview after follow-up assessment and unblinding.

Purposive sampling was used to ensure that people from a range of sociodemographic backgrounds were interviewed.[68] Included were people of differing ages and relationships to the person with dementia, family and paid carers, those living with the person with dementia and those living separately, people from varying ethnic backgrounds, those who had finished the intervention and one carer who had not finished the intervention. Carers were recruited until theoretical saturation was reached.

After this, Penny Rapaport and Lucy Webster met with the ASRN members who had been part of the development of the manual for a focus group to consider any changes post trial.

Qualitative interview content

A semistructured interview guide was developed for the carers who had been participants in the trial (see *Appendix 9*) of open-ended questions based on our study objectives. These explored the acceptability and practicality of both the intervention and the assessment measures, to gain suggestions for refining the trial. The interview guide was revised iteratively during the interview phase, adding themes as they were brought up by interviewees. All interviews were audio-recorded and recordings were destroyed after analysis.

After completing the trial and gaining qualitative feedback from the participants, the family carers that had contributed to the intervention development were invited to attend a focus group at the Alzheimer's Society premises in September 2017. The aim of this focus group was to hear group members' thoughts on the qualitative findings, the final version of the manual used in the trial and the materials being presented, and any suggestions for further refinement of the intervention.

Analysing actigraphy data

The actigraphy data were analysed using MotionWare Software 1.1.25 (CamNtech Ltd, Cambridge, UK), in accordance with a standard operating procedure (see *Appendix 10*). The analyses were performed as described below; baseline and follow-up measures were produced in the same way.

Sleep and non-parametric circadian rhythm analysis measures

The sleep analysis function of MotionWare was used to produce sleep measures from overnight actigraphy data. The NPCRA analysis in MotionWare is based on an approach that does not assume that the data fit any predefined distribution.[69] First, the whole recording period was highlighted, and the editing tool was used to remove recordings exceeding 14 days and periods of missing data (when the watch was off the wrist based on notes in the sleep diary or the carer's verbal report on Actiwatch data collection, or the recording indicated no data). The maximum recording period used for the analysis was 14 days (in the majority of cases from 17.00 on the first day to 17.00 on day 14, but in some from 18.00/19.00 on the first day to 18.00/19.00 on day 14). Second, using the edited data, each sleep period was defined, choosing as the start and end points the bedtimes and rise times recorded in the sleep diary or by using event markers (showing as blue lines in the data). If the carer did not complete the sleep diary or use the event maker button, the bedtimes and rise times were defined based on the carer's verbal report on Actiwatch data collection. In addition, the activity and light data were used as guidance for editing the sleep periods. When unsure, two researchers edited a sleep period and reached a consensus. Each sleep period was saved. The edited recording period was also saved to derive the NPCRA measures, and the summary option used to record average light (lux) over the same period. Finally, a report was produced, including all the sleep analyses and NPCRA measures evaluated in the feasibility trial as possible outcomes for the main trial. In the statistical analysis, sleep data based on fewer than seven nights were excluded. To produce NPCRA measures used in the statistical analysis, copies were made of each previously saved edited recording. The length of each missing data period was then checked, and any 24-hour periods with

≥ 3 hours of missing data were excluded.[70] Having saved the NPCRA period, a new report was produced containing the non-parametric measures only.

Core night-time measures

To produce sleep measures for what the research team defined as core night-time (0.00 to 06.00), a copy was created of the edited recordings previously saved. The existing sleep periods were removed and then the sleep summary table option was used to limit each new sleep period to start at 0.00 and end at 06.00. Having saved these periods, a report was produced containing the new sleep measures.

Sensitivity analysis

In a sensitivity analysis, only participants who lived with a family carer at baseline were included on the sleep and NPCRA measures. The sleep data that were based on seven or more nights and the NPCRA data without ≥ 3 hours of missing data for each 24-hour period were used.

Quantitative analysis

The flow of participants through the trial is described using a Consolidated Standards of Reporting Trials (CONSORT) diagram (see *Figure 3*). A patient's recruitment site, sex of the person with dementia, sex of the carer and a carer's relationship to the person with dementia were summarised as counts and proportions. Eligible patients and carers who consented were compared with those who were screened and did not consent. The following, with 95% CIs, were calculated:

- proportion of screened patients who were eligible for the trial
- proportion of eligible patients referred who consented to the trial
- proportion of participants in each randomised group who dropped out or were lost to follow-up by 3 months (when available, reasons for losses will be summarised)
- proportion of participants in the intervention group who adhered to the intervention (i.e. attended at least four of the six sessions)
- median number of sessions attended by those in the intervention group.

Summary of baseline data

Baseline data (sociodemographic characteristics, actigraphy measures and other scores) for participants and carers were summarised by treatment group using means (with SDs), medians [with interquartile ranges (IQRs)], counts and proportions, as appropriate, to gauge the balance in characteristics between the randomised groups.

Three-month follow-up

Follow-up scores, actigraphy measures and other scores at 3 months were summarised using means (with SDs), medians (IQRs) and counts (%) as appropriate. For continuous measures, correlations between baseline and follow-up measurements were calculated. The number of participants with completed values was summarised for each outcome.

Measurements were compared between randomised groups using appropriate regression models to provide estimates of the effect of the intervention with 95% CIs (e.g. difference in means), adjusted for baseline score and site. For actigraphy data analyses, the following were focused on: sleep efficiency, relative amplitude, sleep fragmentation index, start hour of most restful hours, activity count for most restful hours, start hour of most active hours and activity count for most active hours for those with ≥ 7 days of data. Core sleep data between 0.00 and 06.00 were measured and a sensitivity analysis excluding participants who did not live with a carer at baseline was carried out.

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Use of psychotropic medication

The frequency (%) of participants in each randomised group who had taken each type of medication (anxiolytics and hypnotics, antipsychotics, antidepressants, other psychotropics and melatonin) during the 3-month period prior to both the baseline and follow-up assessment was calculated.

Side effects

The frequencies (%) of comorbid physical illnesses and participant falls were summarised by randomised group at baseline and 3 months.

Qualitative analysis

Each interview with a carer who had participated in the trial was transcribed verbatim, with the transcription checked for accuracy by listening to the recording, and then anonymised. The transcribed interviews were entered into a software package for qualitative data analysis (NVivo 11). A thematic framework for analysis[64] was created by displaying coding in matrices and diagrams until a comprehensive picture of all the phenomena was obtained, a standard, recommended method to ensure rigour.[71] This constant comparison method was used to identify similarities and differences in the data. To create the initial coding framework, trial manager Kirsi M Kinnunen and research assistants Brendan Hallam and Lucy Webster independently coded the first three interviews, identifying the main themes that occurred in line with the study's objectives. They then met with investigators Gill Livingston and Penny Rapaport to discuss the themes and decide on a coding framework. If any discrepancies were identified, they met with Penny Rapaport and reached a consensus.

Using the initial framework, different pairs of researchers then independently coded all of the interviews and, as emerging themes and subthemes were identified, iteratively revised the framework. Each pair of researchers met to discuss discrepancies and agreed a consensus.

Similarly, in the focus groups of ASRN members, the carers consented to the discussion being audio-recorded. The recording was then externally transcribed and the data entered into NVivo 11 software and analysed using thematic analysis.[63,64]

Sample size

It was estimated that with 40 intervention participants (a larger group than the control group, to allow a more precise estimate of the proportion adhering to the intervention) and 20 control participants, the following 95% CIs would be achieved for the expected adherence and participation estimates:

- proportion of participants adhering to intervention – expected value 75%, 95% CI 59% to 87%
- proportion of appropriate referrals consenting to the trial – expected value 50%, 95% CI 41% to 59%.

This sample size was also judged sufficient for estimating the SD required for the sample size calculation in the main trial.[72,73] The estimated recruitment referral rate was approximately six potential participants per week. Two out of these were expected to be suitable and agree to participate. The expected follow-up rate was approximately 80%.

It was anticipated that the 95% CI for the expected adherence and participation estimates would provide acceptable ranges to inform continuation to the main trial. Overall, it was expected that the 'stop–go' measures would be related to the proportion adhering:

- ≥ 70% – go to main trial
- 60–69% – consider a modified trial design to increase adherence
- < 60% do not progress to main trial using this model.

Randomisation

Computer-generated randomisation lists were produced in Stata® Version 14 (StataCorp LP, College Station, TX, USA) by an independent statistician (not involved in data analysis). Randomisation was stratified by site and based on random permuted blocks of sizes three and six to allow 2 : 1 allocation to the intervention and TAU groups. The three site-specific lists produced were password protected, and could be accessed only by two members of a separate study team (randomisation allocator, as seen in *Figure 2*).

Blinding

Figure 2 shows the process from screening/baseline assessments (pre randomisation) through intervention delivery to blinded follow-up assessments. Three researchers [Assessors (A) 1 to 3 in *Figure 2*] screened the participants and carried out baseline assessments. The two researchers who were also therapists [Therapist (T) 1/A1 and T2/A2] asked for allocations from the randomisation allocators. They worked in two separate teams of two therapists each (Team A: T2 and T4; Team B: T1 and T3), and assessed outcomes only for those participants to whom the opposite team had delivered the intervention. The teams had their clinical supervision separately. Researcher A3 did not deliver any interventions and was kept blind to all participants' allocations. The follow-up assessments were arranged by T1/A1 and T2/A2, for those participants they were unblinded to. Owing to the nature of the intervention, it was not possible to blind the trial participants. When arranging the appointment, participants were reminded that they should not disclose their allocation group to the assessor, and should hide anything related to the intervention from view (e.g. light box, manual). On arrival for the outcome assessment, the assessor also asked participants not to disclose their group. Two baseline assessments and one follow-up assessment took place in our team base at UCL; all others took place in the homes of the participants.

Statistical methods

The co-applicant statistician led and supervised the analysis, planned and conducted according to International Conference on Harmonisation (ICH) E9[74] and following the standard operating procedures of the PRIMENT Clinical Trials Unit. A predefined statistical analysis plan described the analysis fully; the following sections are a summary of the methods used to assess the primary and secondary outcomes.

Primary outcomes

Feasibility of recruitment

The proportion of eligible patients consenting to the trial and the proportion randomised were calculated with exact 95% CIs. The characteristics of eligible patients and carers who consented and those who did not consent were summarised in terms of site, patient sex, carer sex and carer's relationship to person with dementia. Comparisons between groups were made using chi-squared tests.

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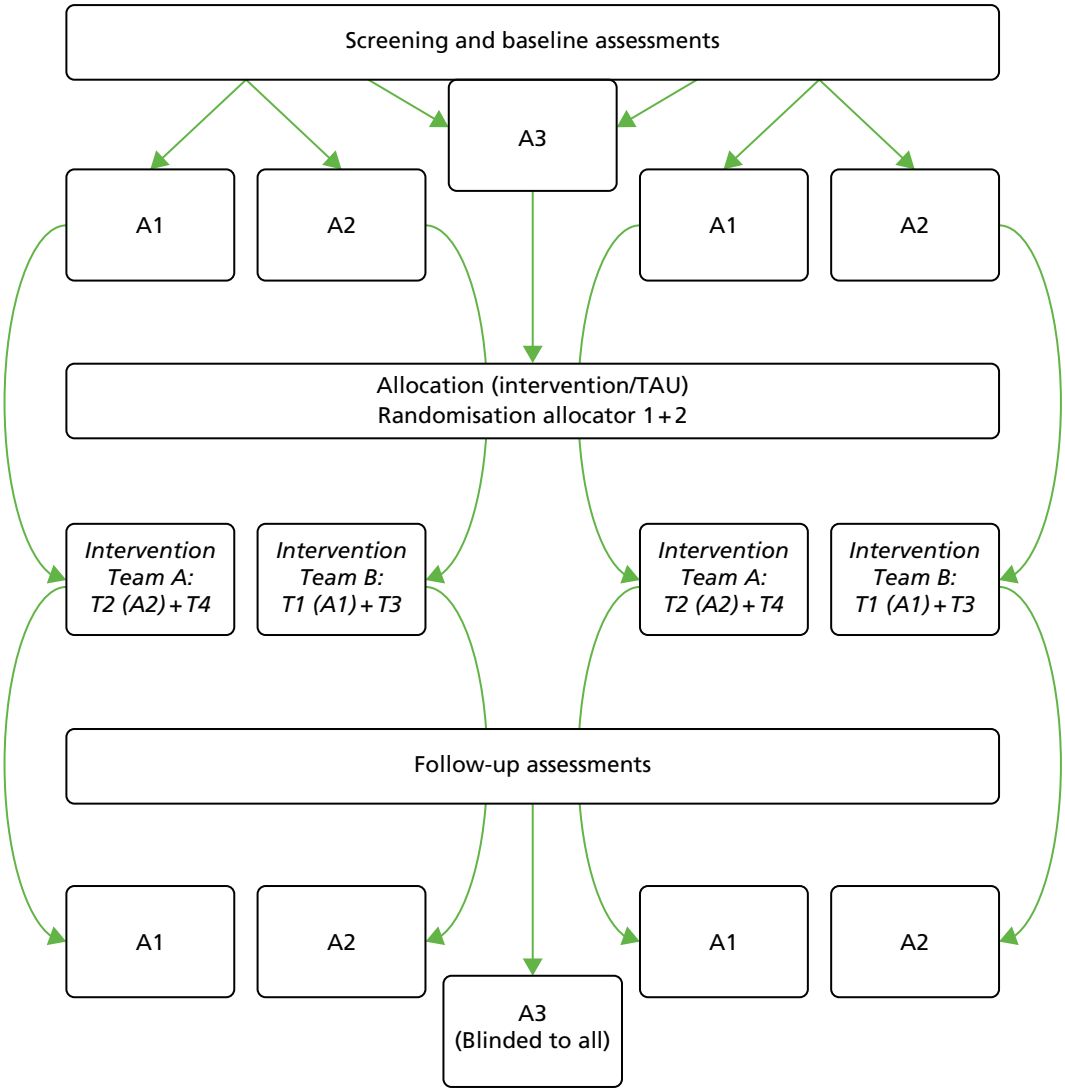

FIGURE 2 Assessments, randomisation and intervention delivery. A, assessor; T, therapist.

Treatment adherence

The proportion of participants in the intervention group that adhered to the treatment (i.e. attended at least four of the six sessions) was calculated with an exact 95% CI. The median number of sessions attended was also calculated.

Secondary outcomes

Referral rates

Weekly referral numbers were summarised from records kept over the 8 months of recruitment.

Follow-up rates

The proportion of participants lost to follow-up at 3 months in each randomised group was calculated with exact 95% CIs.

All psychotropic medication prescription

The proportion of participants receiving prescription for psychotropic medication was summarised by randomised group at baseline and follow-up. Logistic regression was used to compare prescription of psychotropic medication between the intervention and TAU groups, adjusting for site and baseline use.

Reported side effects: falls and comorbid physical illnesses

The frequency (%) of falls and comorbid physical illnesses are summarised by randomised group, at baseline and follow-up.

Potential outcomes for the main trial

Baseline data

Patient and carer sleep questionnaire scores and actigraphy measures at baseline and follow-up were summarised, by randomised group, using means (with SDs), medians (with IQRs), counts and proportions, as appropriate.

Follow-up data

Measurements were compared between randomised groups using appropriate regression models adjusted for baseline score and site. When normality assumptions of an ordinary least squares regression were met, these models were used to provide adjusted differences in means with 95% CIs. When distributional assumptions were violated, quantile regression was used to provide estimates of the adjusted median difference with a 95% CI. For continuous measures, Pearson correlation coefficients between baseline and follow-up measurements were calculated.

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Chapter 3 Results: randomised controlled trial

Participant recruitment and flow

The flow of participants through each stage of the trial is shown in the CONSORT flow diagram[75–78] (*Figure 3*). Four referrals per week were received, on average, and 123 people were referred through memory clinics from 4 August 2016 to 3 April 2017.

The study was open on JDR to recruitment from 22 November 2016 to 24 March 2017. The first search for potential matches (22 November 2016) found 49 people. The search was then expanded, using all of the JDR eligibility criteria, but increasing distance from UCL from 5 miles to 10 miles, and found 140 people.

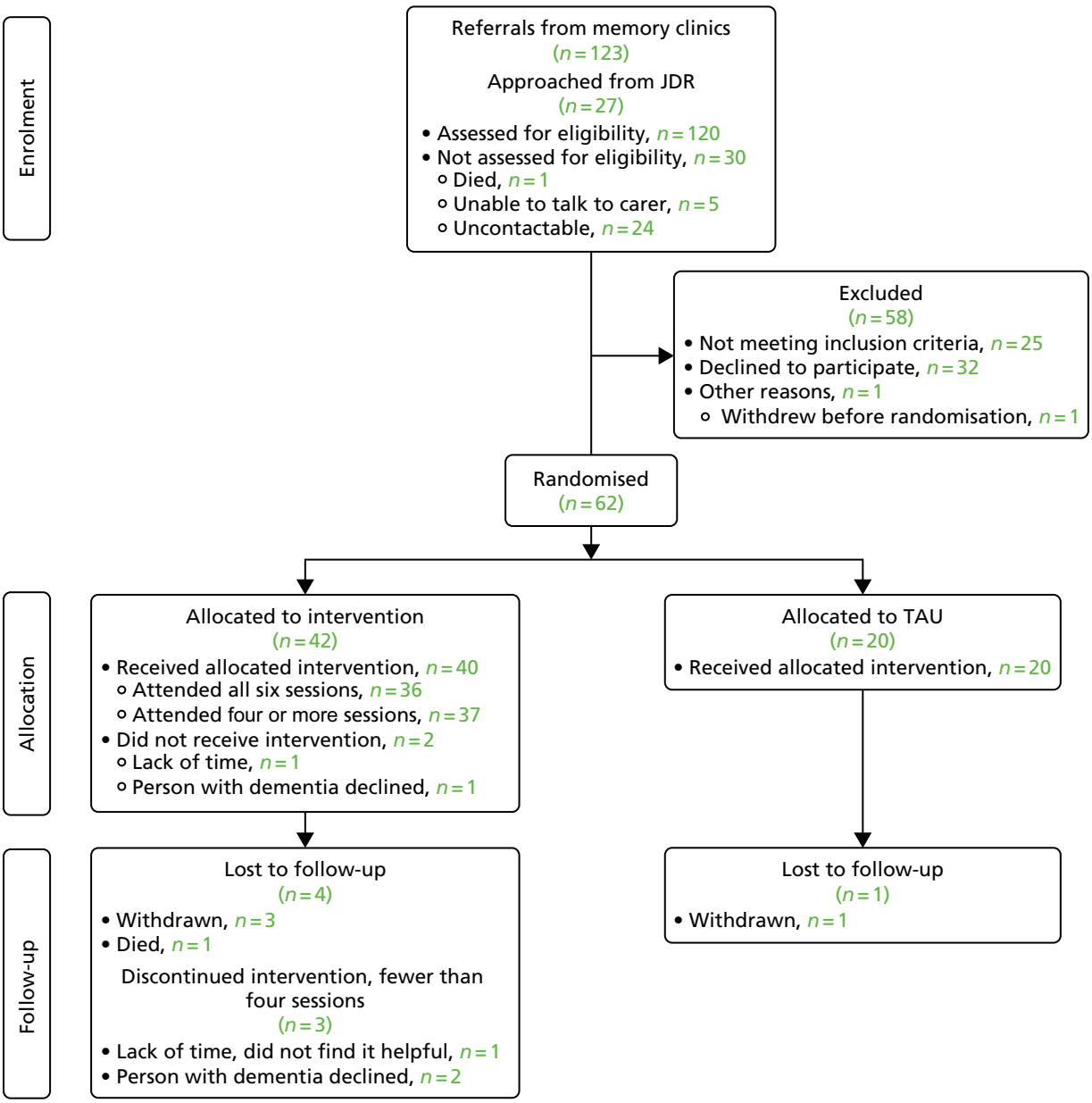

FIGURE 3 The CONSORT flow diagram: summary of recruitment and follow-up.

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The research team began to contact JDR volunteers on 5 December 2016 and stopped on 21 March 2017. Twenty-seven people were contacted using their preferred means of contact: e-mail ($n = 25$; mostly their carer's e-mail) or telephone ($n = 2$). E-mails were followed up by telephone calls. Nineteen volunteers did not respond to contact from the research team; three were not eligible for the study (two carers reported that the person they cared for had no sleep problems and one carer reported that the person they cared for was moving out of London); in one case, only the person with dementia could be spoken to and so their eligibility could not be determined. Of the 120 people assessed for eligibility, 95 were eligible (79%, 95% CI 70% to 86%) and 25 did not meet inclusion criteria.

Comparison of those who consented with those who did not

Table 2 compares the known demographic details of those who consented with those who did not, and shows that the study sample had good external validity. The care recipients who did not consent were, however, more likely to be male.

Baseline demographic and diagnostic data

Table 3 compares the demographic and diagnostic details of the randomised groups. Overall, there was a good demographic mix, with recruitment from a range of ethnicities and age groups and a variety of relationships between the people with dementia and the carers. There was a range of diagnoses, but the majority of people had AD or a mixed dementia. Most ($n = 45$, 73%) of the primary carers lived with the person with dementia. Four had another member of the family living with them, so 49 out of 62 (79%) had family members living with them; six (10%) had paid carers living with them, and seven (11%) had

TABLE 2 Characteristics of those eligible but did not consent vs. those who consented and were randomised

Characteristics	Participants, *n* (%)		
	Not consented ($N = 33$)	Randomised ($N = 62$)	*p*-value (χ^2 test)
Person with dementia			
Site			
Camden and Islington	24 (73)	40 (65)	
Barnet, Enfield and Haringey	7 (21)	20 (32)	
UCL/JDR	2 (6)	2 (3)	0.460
Sex			
Male	20 (61)	19 (31)	
Female	13 (39)	43 (69)	0.005
Carer			
Sex			
Male	11 (33)	18 (29)	
Female	22 (67)	44 (71)	0.665
Relationship to person with dementia			
Spouse	9 (28)	19 (31)	
Child/child-in-law	22 (69)	41 (66)	(Spouse vs. other)
Other	1 (3)	2 (3)	0.800

TABLE 3 Baseline demographic data and diagnostic characteristics by randomised group

Characteristics	Trial group	
	Intervention ($N = 42$)	TAU ($N = 20$)
Person with dementia		
Site, *n* (%)		
Camden and Islington	27 (64)	13 (65)
Barnet, Enfield and Haringey	14 (33)	6 (30)
UCL/JDR	1 (2)	1 (5)
Sex, *n* (%)		
Male	9 (21)	10 (50)
Female	33 (79)	10 (50)
Age (years)		
Mean (SD)	80.4 (9.0)	79.6 (7.0)
Lived with/alone, *n* (%)		
Family carer	28 (67)	17 (85)
Another family member	3 (7)	1 (5)
Paid carer	5 (12)	1 (5)
Alone	6 (14)	1 (5)
Diagnosis, *n* (%)		
Alzheimer's disease	22 (52)	7 (35)
Dementia with Lewy bodies	2 (5)	3 (15)
Mixed	8 (19)	4 (20)
Vascular dementia	8 (19)	6 (30)
Alcohol-related dementia	1 (2)	0 (0)
Unspecified	1 (2)	0 (0)
Age left education (years)		
Mean (SD)	15.7 (3.7) ($n = 40$)	16.4 (4.9) ($n = 19$)
Marital status, *n* (%)		
Single	1 (2)	1 (5)
Married	17 (40)	11 (55)
Divorced	1 (2)	0 (0)
Widowed	23 (55)	8 (40)
Ethnic group, *n* (%)		
White	27 (64)	13 (65)
Asian	3 (7)	3 (15)
Black	7 (17)	2 (10)
Other	5 (12)	2 (10)

continued

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TABLE 3 Baseline demographic data and diagnostic characteristics by randomised group (*continued*)

Characteristics	Trial group	
	Intervention (*N* = 42)	TAU (*N* = 20)
CDR global, *n* (%)		
Very mild	5 (12)	3 (15)
Mild	16 (38)	6 (30)
Moderate	18 (43)	9 (45)
Severe	3 (7)	2 (10)
Carer		
Carer sex, *n* (%)		
Male	10 (24)	8 (40)
Female	32 (76)	12 (60)
Carer age (years)		
Mean (SD)	56.15 (13.54)	59.09 (12.22)
Carer co-resident, *n* (%)		
Yes	28 (67)	17 (85)
Relationship to person with dementia, *n* (%)		
Spouse	10 (24)	9 (45)
Child/child-in-law	30 (72)	11 (55)
Grandchild	1 (2)	0 (0)
Friend	1 (2)	0 (0)
Carer ethnicity, *n* (%)		
White	29 (69)	14 (70)
Asian	3 (7)	3 (15)
Black	7 (17)	1 (5)
Other	3 (7)	2 (10)

family carers but lived alone. The intervention group included more women carers and carers were younger and less likely to be co-residents or spouses. The people with dementia in the intervention group were more likely to be women, and more had a diagnosis of AD than in the TAU group.

Primary outcomes

Of the eligible patients referred, 63 (65%, 95% CI 55% to 75%) consented: two from JDR and 61 from memory clinics. A total of 62 out of 95 eligible patients referred (65%, 95% CI 55% to 75%) were randomised. In eight cases, two carers were consented who were involved in the intervention (three people had two family carers; five had one family and one paid carer). A total of 42 people were randomised to the intervention. The median number of sessions attended was six; 37 participants (88%, 95% CI 75% to 96%) attended four or more sessions.

Secondary outcomes

Referral rates

An average of four potential participants were referred by the memory clinics weekly.

Follow-up rates

Of the 62 randomised participants, 57 (92%) were followed up at 3 months. The number lost to follow-up was 4 out of 42 participants (9.5%; exact 95% CI 3% to 23%) in the intervention group and 1 out of 20 (5%; exact 95% CI 0.1% to 25%) in the TAU group. Two people with dementia withdrew consent, two carers were uncontactable and one person with dementia died (see *Figure 3*).

All psychotropic medication prescription

Table 4 shows the number and frequency of psychotropic medication at baseline and 3 months, with 45% of each group receiving at least one psychotropic medication.

Table 5 shows the number of patients in each group who at the 3-month follow-up had a prescription for psychotropic medication or melatonin that had not been prescribed at baseline. The odds ratio of being prescribed at least one of these medications in the intervention group compared with the TAU group was 0.51 (95% CI 0.06 to 4.01; $n = 55$).

TABLE 4 Psychotropic medication prescription at baseline by randomised group

	Trial group, *n* (%)	
Medication prescription at baseline	Intervention (*N* = 42)	TAU (*N* = 20)
Anxiolytics and hypnotics	5 (12)	2 (10)
Antipsychotics	4 (10)	1 (5)
Antidepressants	14 (33)	7 (35)
Melatonin	0 (0)	0 (0)
Other psychotropic	1 (2)	0 (0)
At least one prescription of above medications	19 (45)	9 (45)

TABLE 5 Psychotropic medication prescription at 3-month follow-up by randomised group

	Trial group, *n* (%)	
Medication prescription at 3-month follow-up	Intervention (*N* = 37)	TAU (*N* = 18)
Anxiolytics and hypnotics	2 (5)	1 (6)
Antipsychotics	3 (8)	1 (6)
Antidepressants	12 (32)	7 (39)
Melatonin	2 (5)	1 (6)
Other psychotropic	1 (3)	0 (0)
At least one prescription of above medications	16 (43)	8 (44)

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Reported comorbid physical illnesses and side effects

Table 6 shows comorbid illnesses at baseline and comorbid illness and possible side effects at 3 months. At baseline, both groups reported similar rates of all symptoms. There is no clear pattern of difference in change over time between the two groups.

Intervention delivery

Forty dyads started the intervention. Two dropped out after randomisation but before commencement of the intervention, because the carer cited lack of time or the person with dementia declined. Three (7%) attended one to three sessions. The median duration of intervention delivery was 49.5 days (IQR 43.0–64.5 days).

The intervention was delivered by four clinically trained and supervised psychology graduates, two women and two men, who were ethnically white British ($n = 3$) and white Asian British ($n = 1$). Their ages ranged from 23 to 33 years. The therapists visited most participants in their homes. Two were seen elsewhere: one for a single session at UCL and another for all six sessions at Islington Memory Service.

Twenty-one of the carers in the intervention group had sessions without the person with dementia. The sessions were delivered to family or paid carers. This included 18 interventions with the family carer alone, two interventions solely with paid carers (one with one paid carer and one with three paid carers), and one intervention delivered to a family carer and a paid carer together. For five of these interventions delivered to carers, the person with dementia was present in the same room, but did not participate as they could not do so (owing to auditory impairment or the severity of their dementia) or did not want to. In six cases, there was an additional carer or family member present in the room, who observed one session of the intervention.

For 13 dyads, the person with dementia and their carer attended every session together. For others, the person with dementia participated in some sessions, but the family carer also had sessions without them. This included one intervention with the person with dementia, their family carer and their paid carer, and 12 interventions with the person with dementia and their family carer. One person with dementia participated in all six sessions, although their family carer participated in only three sessions.

TABLE 6 Summary of comorbid illness and side effects by randomised group

	Trial group, *n* (%)	
Comorbid illness or side effect	Intervention	TAU
Baseline	***(N = 42)***	***(N = 20)***
Falls	17 (40)	7 (35)
Gastrointestinal	21 (50)	9 (45)
Neurological	19 (45)	10 (50)
Infections	14 (34)	6 (30)
Other	6 (14)	2 (11)
3 months	***(N = 38)***	***(N = 18)***
Falls	16 (42)	7 (39)
Gastrointestinal	16 (42)	4 (22)
Neurological	15 (39)	10 (56)
Infections	18 (47)	5 (28)
Other	9 (24)	9 (50)

Altogether, this totalled 138 individual sessions just with carers (12 sessions with paid carers, six sessions with a paid carer and a family carer, and 120 sessions with family carers), 84 sessions with the person with dementia and their carer(s) (78 sessions with people with dementia and the family carer, and six sessions with the person with dementia and their family and paid carers) and three sessions with a person with dementia alone.

The therapists were flexible with timings and often met people in the evening or early morning to fit in with their work and other commitments. On average, each session took 69 minutes (means: session 1, 75 minutes; session 2, 71 minutes; session 3, 74 minutes; session 4, 66 minutes; session 5, 70 minutes; and session 6, 60 minutes).

Fidelity

One randomly selected intervention session was recorded for 34 out of 40 (85%) participants who started the intervention. Three participants refused the audio-recording, two did not continue the intervention up to the session randomised to be recorded and one recording was partial and could not be scored. Across all sessions (*Figure 4*), managing the carer's concerns and keeping the carer engaged in the session was rated 5/5 (IQRs 4.00–5.00 and 4.25–5.00, respectively), while keeping the carer focused on the manual and keeping the session to time was rated 4.00 out of 5.00 (IQRs 4.00–5.00 and 3.25–5.00, respectively).

Table 7 shows the strategies that the 37 carers who attended session 6 wrote down as their plan to use in future. Most of them intended to use several strategies.

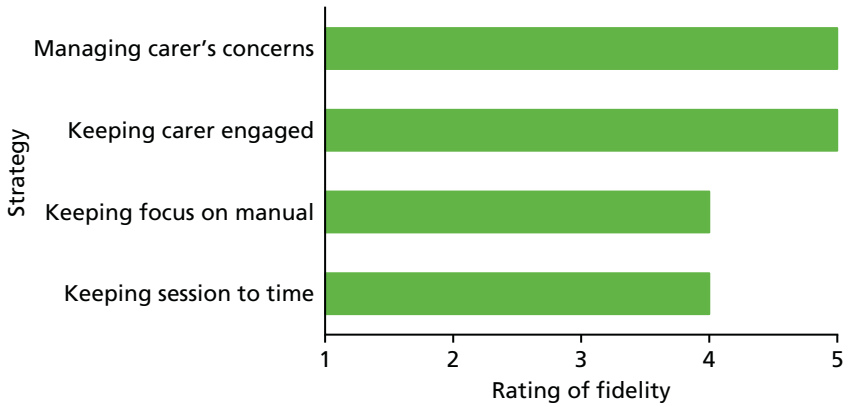

FIGURE 4 Median scores from fidelity monitoring of all sessions of intervention delivery.

TABLE 7 Number of carers planning to keep using each strategy at session 6

Strategies that the carers intended to keep using	*n* (%) (*N* = 37)
Increasing natural light or using light box	37 (100)
Increasing daytime activity or physical exercise	37 (100)
Making a new routine or strengthening the bed–sleep link	32 (86)
Bedroom and lifestyle changes to improve sleep	28 (76)
Managing night-time behaviours	26 (70)
Carer looking after her/himself and challenging unhelpful thoughts	32 (86)
Relaxation	28 (75)

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Potential outcomes for the main trial

Completion rate and results of validated interviews at baseline and 3 months' follow-up

Table 8 summarises completion rates and scores of patient- and carer-validated questionnaire scores at baseline. The NPI, PSQI, SCI and HSQ-12 were completed for 61 out of 62 (98.4%) participants. All other measures were completed for everyone. Summary scores are similar between the two groups, although carers in the intervention group had consistently better scores than carers in the TAU group.

TABLE 8 Completion rates and scores of baseline patient and carer validated interview measures by randomised group

Interview measures at baseline	Trial group	
	Intervention ($N = 42$)	TAU ($N = 20$)
Person with dementia		
SDI global score		
Median (IQR)	2.57 (1.35 to 3.67)	2.98 (1.85 to 3.96)
ESS total score		
Mean (SD)	9.95 (6.02)	8.85 (6.31)
NPI total score		
Mean (SD)	42.02 (23.17) ($n = 41$)	46.90 (23.48)
DEMQoL-Proxy		
Mean (SD)	87.57 (10.73)	88.51 (10.14)
Carer		
PSQI global score		
Mean (SD)	9.22 (4.08) ($n = 41$)	10.40 (4.52)
SCI total score		
Mean (SD)	15.32 (8.22) ($n = 41$)	13.50 (5.92)
HADS scores, mean (SD)		
Anxiety	8.17 (4.66)	9.30 (3.80)
Depression	5.24 (4.33)	7.65 (4.60)
ZBI score		
Mean (SD)	37.69 (18.39)	38.30 (19.27)
HSQ scores, mean (SD)		
Physical health	67.89 (32.79) ($n = 41$)	52.50 (39.47)
Mental health	60.95 (23.17)	52.33 (24.02)

Table 9 summarises the patient- and carer-validated questionnaire scores at 3 months. More than 90% of those who were randomised at baseline completed the SDI, HADS, ZBI, SCI and HSQ-12. Over 85% completed the other questionnaires. Summary data indicate generally better scores for the intervention group for both patient and carer measures. After adjusting for site and baseline score, significant improvements due to the intervention are evident for ESS total score, DEMQoL-Proxy and ZBI score.

Analysis of actigraphy data

Table 10 shows the baseline sleep data for those who wore the Actiwatches for seven or more nights and had complete NPCRA data, that is not including 24-hour periods with ≥ 3 hours of missing data. Only one of the 62 randomised participants with dementia did not wear the watch for seven or more nights at baseline. The sleep diary or event markers were used by 50 out of 62 (81%) randomised participants to record the person with dementia's bedtimes and rise times for actigraphy. Of the remaining 12 participants, eight (13%) gave a verbal report of sleep pattern, including any atypical bed or rise times (e.g. due to medical appointments), whereas four (6%) did not.

TABLE 9 Summary of patient and carer questionnaire outcomes at 3 months

Interview measures at 3 months	Trial group, mean (SD) [*n*]		Adjusted treatment effect (I – TAU)[a] (95% CI)[b] [*n*]
	Intervention (*N* = 42)	TAU (*N* = 20)	
Person with dementia			
SDI global score, median (IQR)	0.92 (0.49–2.94)	2.43 (0.82–3.88)	–0.30 (–1.42 to 0.82)[c]
ESS total score	7.17 (5.87) [36]	9.00 (7.55) [18]	–2.86 (–5.54 to –0.17) [54]
DEMQoL-Proxy	93.52 (10.12) [37]	87.07 (10.22) [18]	7.08 (2.25 to 11.91) [55]
NPI total score	38.69 (23.57) [36]	44.72 (23.22) [18]	–1.99 (–11.66 to 7.68) [54]
Carer			
PSQI global score	9.37 (4.16) [38]	9.5 (4.49) [18]	1.03 (–1.05 to 3.11) [55]
SCI total score	15.45 (7.45) [38]	14.53 (8.54) [19]	–0.41 (–3.75 to 2.93) [56]
HADS scores			
Anxiety	8.76 (5.57)	9.05 (4.22)	1.13 (–0.31 to 2.56)
Depression	5.71 (4.43)	8.79 (4.88)	–1.05 (–3.01 to 0.91)
Total	14.47 (9.20) [38]	17.84 (8.43) [19]	0.51 (–2.39 to 3.42) [57]
ZBI score	36.5 (17.07) [38]	42.16 (16.45) [19]	–5.32 (–9.83 to –0.82) [57]
HSQ scores			
Physical health	68.42 (32.60) [38]	54.39 (35.94) [19]	3.12 (–12.27 to 18.52) [57]
Mental health	55.96 (26.19) [38]	48.07 (21.15) [19]	1.25 (–9.52 to 12.02) [57]

a Mean of intervention group minus the mean of TAU group.
b Estimates are from models adjusted for baseline score and site. Regression is ordinary least squares unless otherwise indicated.
c Quantile regression.

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TABLE 10 Baseline sleep and NPCRA measures by randomised group

Baseline actigraphy measures	Trial group	
	Intervention	TAU
Sleep measures	***(n = 41)***	***(n = 20)***
Sleep efficiency (%), median (IQR)	76.90 (66.60–83.00)	80.68 (70.75–86.30)
Average duration of sleep time (minutes), median (IQR)	448.00 (376–503)	442.00 (388–568.50)
Average duration of wake time (minutes), median (IQR)	111 (77–152)	114 (58.5–147.5)
Average time of lights out/bedtime,[a] median (IQR)	22:26 (22:07–23:08)	22:25 (21:37–23:25)
Average time of falling asleep,[a] median (IQR)	22:43 (22:07–23:40)	22:45 (22:04–00:16)
Average time of waking up, median (IQR)	08:10 (07:41–08:54)	08:20 (07:48–08:46)
Average time of getting up, median (IQR)	08:14 (07:52–09:00)	08:23 (07:56–08:56)
Average duration of time in bed (hours), mean (SD)	9.91 (1.35)	10.01 (1.80)
NPCRA measures	***(n = 42)***	***(n = 20)***
Relative amplitude, median (IQR)	0.71 (0.48–0.82)	0.78 (0.56–0.90)
Interdaily stability, mean (SD)	0.38 (0.16)	0.43 (0.17)
Intradaily variability, mean (SD)	1.11 (0.40)	1.03 (0.32)
L5 – average activity count for 5 most restful hours, median (IQR)	1381 (572–1919)	761 (358.5–1616)
Start hour of 5 most restful hours,[a] median (IQR)	01:00 (00:00–03:00)	01:00 (00:00–02:00)
M10 – average activity count for 10 most active hours, median (IQR)	8155 (5127–12,281)	8212.0 (3730.5–14,545.5)
Start hour of 10 most active hours, median (IQR)	10:00 (8:00–12:00)	8:30 (8:00–11:00)
Core night-time sleep measures	***(n = 41)***	***(n = 20)***
Sleep efficiency (%), median (IQR)	76.4 (68.1–83.9)	81.3 (67.15–91.05)
Average duration of sleep time (minutes), median (IQR) [*n*]	278 (245–303) [39]	300 (246–331) [19]
Average duration of wake time (minutes), median (IQR) [*n*]	57 (47–75) [39]	52 (26–76) [19]

a To calculate summaries, times have been ordered from 00.00 on one day until 00.00 the next day.

Notes

Sleep and core night-time measures are for those who had ≥ 7 nights of data available. NPCRA data are those calculated with all 24-hour periods with ≥ 3 hours of missing data excluded.

Table 11 shows the sleep data at follow-up for those who wore the watch for seven or more nights and NPCRA data with all 24-hour periods with ≥ 3 hours of missing data excluded. Of the 57 people with dementia who were randomised and still in the trial at follow-up, six refused to wear the watch again; 49 out of 51 (96%) of those who did wear it had actigraphy data for seven or more nights. Carers of 42 (82%) of these participants provided their relative's bedtimes and rise times via the sleep diary or event markers. Of the remaining 11, eight (16%) provided a verbal report of their relative's sleep pattern; three (6%) did not.

TABLE 11 Three-month sleep and NPCRA measures by randomised group

Actigraphy measures at 3 months	Trial arm		Adjusted treatment effect (I – TAU)[a] (95% CI)[b]
	Intervention	TAU	
Sleep measures	***(n = 32)***	***(n = 17)***	***(n = 49)***
Sleep efficiency (%), median (IQR)	76.05 (65.0–81.9)	78.6 (72.1–82.3)	0.39 (–4.89 to 5.68)[c]
Average duration of sleep time (minutes), median (IQR)	418.5 (383.5–506)	475 (396–534)	
Average duration of wake time (minutes), median (IQR)	112.5 (94.5–157.5)	105 (88–133)	
Average time of lights out/bedtime,[d] median (IQR)	22:15 (21:36–22:50)	22:03 (21:21–23:28)	
Average time of falling asleep,[d] median (IQR)	22:49 (21:59–23:23)	22:22 (21:39–23:55)	
Average time of waking up, median (IQR)	08:04 (07:16–08:38)	08:09 (07:38–08:41)	
Average time of getting up, median (IQR)	08:06 (07:20–08:44)	08:17 (07:48–08:43)	
Average duration of time in bed (hours), mean (SD)	9.89 (1.83)	10.05 (1.83)	
NPCRA measures	***(n = 34)***	***(n = 17)***	***(n = 51)***
Relative amplitude, median (IQR)	0.71 (0.49–0.87)	0.76 (0.51–0.90)	–0.02 (–0.10 to 0.06)[c]
Interdaily stability, mean (SD)	0.38 (0.18)	0.47 (0.19)	
Intradaily variability, mean (SD)	1.04 (0.38)	0.98 (0.40)	
L5 – average activity count for 5 most restful hours, median (IQR)	1067 (621–2003)	981 (493–1940)	76.88 (–521.40 to 675.16)[c]
Start hour of 5 most restful hours,[d] median (IQR)	01:00 (00:00–03:00)	01:00 (01:00–02:00)	
M10 – average activity count for 10 most active hours, median (IQR)	8247 (4258–12,155)	8132 (5960–17,158)	–198.29 (–1717.83 to 1321.25)[c]
Start hour of 10 most active hours, median (IQR)	10:00 (8:00–11:00)	9:00 (8:00–10:00)	
Core night-time sleep measures	***(n = 32)***	***(n = 17)***	***(n = 49)***
Sleep efficiency (%), median (IQR)	79.0 (63.75–82.6)	80.9 (69.8–86.5)	
Average duration of sleep time (minutes), median (IQR) [*n*]	285 (243–303) [30]	291 (251–311) [17]	
Average duration of wake time (minutes), median (IQR) [*n*]	62 (43–80) [30]	49 (39–70) [17]	

a Mean of intervention group minus the mean of TAU group.
b Estimates are from models adjusted for baseline score and site. Regression is ordinary least squares unless indicated.
c Quantile regression.
d To calculate summaries, times have been ordered as night-time, i.e. from 12.00 to 00.00 the following day.

Notes
Sleep and core night-time measures are only for those with ≥ 7 nights of data available. NPCRA data are those calculated with all 24-hour periods with ≥ 3 hours of missing data excluded.

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Sensitivity analysis of actigraphy estimates including only those co-resident with a carer

Table 12 shows the follow-up actigraphy data for the people living with a family carer.

Table 13 shows the correlation between scores on the baseline and follow-up questionnaire and actigraphy measures to contribute to power analysis for a full trial.

TABLE 12 Sensitivity analysis: 3-month sleep and NPCRA measures by randomised group, for those living with family carer at baseline

Actigraphy measures at 3 months	Trial group		Adjusted treatment effect (I – TAU)[a] (95% CI)[b] (*N* = 40)
	Intervention (*N* = 25)	TAU (*N* = 15)	
Sleep measures			
Sleep efficiency (%), median (IQR)	77.10 (67.6–85)	78.6 (71.8–85.6)	2.32 (–3.48 to 8.13)[b]
Average sleep duration (minutes), median (IQR)	439 (393–504)	488 (396–578)	
Average wake duration (minutes), median (IQR)	111 (96–149)	105 (88–138)	
Average time of lights out/ bedtime,[b] median (IQR)	22:17 (21:36–23:02)	21:53 (21:16–22:25)	
Average time of falling asleep,[b] median (IQR)	22:50 (21:54–23:25)	22:08 (21:32–23:30)	
Average time of waking up, median (IQR)	08:03 (07:12–08:35)	08:07 (07:30–08:41)	
Average time of getting up, median (IQR)	08:06 (07:16–08:44)	08:17 (07:37–08:43)	
Average duration of time in bed (hours), mean (SD)	9.80 (1.98)	10.22 (1.89)	
Fragmentation index, median (IQR)	46.4 (35.4–61.1)	41.9 (34.3–45.9)	0.77 (–9.91 to 8.37)[b]
NPCRA measures			
Relative amplitude, median (IQR)	0.69 (0.49–0.83)	0.76 (0.49–0.90)	–0.02 (–0.14 to 0.11)[b]
Interdaily stability, mean (SD)	0.37 (0.18)	0.46 (0.19)	
Intradaily variability, mean (SD)	1.07 (0.33)	1.05 (0.40)	
L5 – average activity count for 5 most restful hours, median (IQR)	1176 (544–1814)	981 (474–2314)	81.58 (–723.94 to 887.10)[b]
Start hour of 5 most restful hours (24 hour),[a] median (IQR)	01:00 (11:00–02:00)	01:00 (01:00–03:00)	
M10 – average activity count for 10 most active hours, median (IQR)	7632 (4048–11,251)	8132 (4392–17,886)	–869.46 (–2189.40 to 450.48)[b]
Start hour of 10 most active hours (24 hour), median (IQR)	10:00 (8:00–12:00)	9:00 (8:00–11:00)	
Core night-time sleep measures			
Sleep efficiency (%), median (IQR)	78.8 (65.3–89.0)	80.9 (69.8–87)	
Average sleep duration (minutes), median (IQR)	284 (240.5–308.5) (*n* = 24)	291 (251–313)	
Average wake duration (minutes), median (IQR)	64.5 (42–83.5) (*n* = 24)	49 (36–73)	

a Mean of intervention group minus the mean of TAU group.
b To calculate summaries, times have been ordered as night-time, i.e. from 12.00 to 00.00 the following day; this includes those with missing data.

Note
Thirteen excluded.

TABLE 13 Correlation between baseline and follow-up scores

Measure	Correlation
Person with dementia	
NPI total score	0.73
ESS total score	0.66
DEMQoL-Proxy	0.55
SDI total score	0.57
Sleep measures	
Sleep efficiency (%)	0.85
Average sleep time (minutes)	0.65
NPCRA measures	
Fragmentation index	0.82
Relative amplitude	0.78
L5 activity count – least active 5 hours	0.86
M10 activity count – most active 10 hours	0.90
Carer	
PSQI global score	0.58
SCI total score	0.69
HADS	
Anxiety	0.87
Depression	0.73
Total	0.84
ZBI score, mean (SD)	0.87
HSQ	
Physical health	0.67
Mental health	0.68

Assumptions and sample size calculation

It is envisaged that the main DREAMS trial will retain the same basic characteristics as the feasibility study. It will be a parallel, multicentre trial with two arms and 2 : 1 randomisation to the DREAMS intervention versus TAU and randomisation at the individual level. The primary outcome will be SDI score at 6 months (to allow more flexibility in intervention delivery time). As the intervention is delivered by therapists (with each therapist likely to see approximately 15 people), it is expected that there could be therapist clustering in the intervention group. Analysis will compare groups allowing for this clustering and making adjustment for baseline SDI score. *Table 14* shows calculated estimates of the required sample size based on variance and correlation of SDI scores observed from the feasibility work, and plausible ranges for other unknown parameters.

The analysis would compare groups allowing for clustering with adjustment for baseline SDI. We wanted to detect a difference in mean SDI (on the SDI 0–12 scale) scores of 0.6 (effect size 0.3) or 0.8 (effect size 0.4) because a mean difference of 0.8 was observed in the feasibility study, although there was a much larger difference in medians as data are skewed. SD estimated from baseline feasibility data was 2.24. Correlation between baseline and follow-up measurements was assumed to be 0.57 from feasibility study estimates.

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TABLE 14 Sample size required per group

ICC assumed	0		0.03		0.05		0.08	
Design effect	**1**		**1.33**		**1.55**		**1.88**	
Estimates of sample size	***I***	***TAU***	***I***	***TAU***	***I***	***TAU***	***I***	***TAU***
Difference in mean SDI score = 0.8 (effect size 0.4)								
N	168	84	188	94	200	100	218	109
N with dropout	198	991	220	110	233	118	255	128
N with inflation if non-normal	230	115	254	127	272	136	296	148
Difference in mean SDI score = 0.6 (effect size 0.3)								
N	297	149	330	165	352	176	386	193
N with dropout	349	175	388	194	414	207	454	228
N with inflation if non-normal	406	203	450	225	480	240	528	264

I, intervention; ICC, intracluster correlation coefficient.

Intracluster correlation (ICC) could be between 0 and 0.08 (0.08 indicated by upper confidence limit from START trial. This was used as the feasibility study was too small to provide a useful estimate.

We will aim for 2 : 1 randomisation (achieved by calculating unequal sample sizes before adjusting for clustering and inflated by the design effect to achieve a 2 : 1 ratio), with 90% power and significance of 0.05. Inflation for a non-parametric analysis is included for the case of data being non-normal (feasibility study data indicate that this may be the case for SDI). This calculation should provide a conservative estimate of the sample size needed in the case when analyses are based on transformed data (e.g. log or square-root transformation, which may be appropriate).[79]

Chapter 4 Results: qualitative study

Post-intervention qualitative interviews: intervention refinement

Demographics

Sixteen carers who received the DREAMS START intervention were interviewed, 15 of whom had completed all six sessions and one who had completed only two. The demographic characteristics of the carers are displayed in *Table 15*. The 16 carers included two paid carers and 14 family carers. The majority of carers were women and they were from a diverse range of ethnicities. Most spoke English as a first

TABLE 15 Demographics of qualitative interview participants

Characteristics	*n* (%)
Sex	
Female	12 (75)
Age (years)	
< 25	1 (6.25)
40–49	4 (25)
50–59	5 (31.25)
60–69	5 (31.25)
≥ 80	1 (6.25)
Ethnicity	
White British	5 (31.25)
White Irish	1 (6.25)
White Other	6 (37.5)
Spanish	2 (12.5)
Polish or German	1 (6.25)
Greek Cypriot	2 (12.5)
Turkish/Greek Cypriot	1 (6.25)
Black British Caribbean	1 (6.25)
Black British African	1 (6.25)
Asian Indian British	1 (6.25)
South American (Brazilian)	1 (6.25)
Relationship to person with dementia	
Husband	2 (12.5)
Wife	2 (12.5)
Son	2 (12.5)
Daughter	6 (37.5)
Daughter-in-law	1 (6.25)
Granddaughter	1 (6.25)
Paid carer	2 (12.5)

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language ($n = 11$). Their ages ranged from 22 to 87 years (median 53.5 years, IQR 48.5–64.0 years). Thirteen carers lived with the person with dementia, one of whom was a paid live-in carer Monday–Friday; the other three carers comprised two family carers who were non-resident and a paid carer who worked shifts as part of a team of carers. The qualitative findings are presented in three main headings: (1) the acceptability of the assessment tools and intervention, (2) aspects of the intervention that the carers found helpful and (3) the acceptability and practicality of the intervention.

Acceptability of the assessment tools and intervention

Questionnaires

Carers highlighted the lengthy and repetitive nature of the assessment questionnaires but recognised that this was important for the research:

> *But whether you, you know, prior to starting the questionnaire you say, look . . . they will seem really repetitive but it's just we really need this information because it's going to be really helpful in our, putting together the study.*
>
> *Carer (C)1; co-resident daughter*

One carer spoke of the difficulty in completing the SDI for the previous 2 weeks, as these may not be typical weeks in terms of the sleep disturbance:

> *I have a, you know, a slight question about that because things keep changing, so the last 2 weeks may not actually be typical.*
>
> *C2; co-resident wife*

Two participants spoke about their dislike of the PSQI measure; they did not see how measuring their sleep was relevant, had difficulty in averaging times or how long it takes to fall asleep and thought that it was long:

> *I think Pittsburgh is a bit long winded.*
>
> *C3; co-resident husband*

Both participants preferred the SCI over the PSQI, although one of them found it difficult to come up with an average time of how long it takes them to fall asleep and how long they are awake for during the night for the SCI.

One carer thought that there should be more options in possible answers to the HADS, as they felt that their answer did not reflect how they felt, and another carer did not think that it was relevant to their situation:

> *I think I found this one quite difficult . . . there seems to be a big jump from time to time, occasionally, to a lot of the time. I think it needs a bit more subtlety . . . Because, I mean, for instance, you know, I still enjoy the things I used to enjoy, yes, definitely as much, but there are times if I'm feeling very stressed that I don't, you know.*
>
> *C2; co-resident wife*

Three participants disliked the ZBI, considering it to be invasive, repetitive and subjective:

> *I remember thinking this is incredibly subjective . . . I think the day I filled it in I was feeling quite stressed, so I was emphasising the, you know, the more, you know, the stronger responses.*
>
> *C2; co-resident wife*

Two carers discussed how they had recently had operations, which affected their health-related quality-of-life answers.

One individual with dementia, who was present during the interview, suggested that there should be a question about whether or not the person with dementia and carer sleep separately, as this can affect how the sleep questions about the person with dementia are answered:

> *[Speaking to the person with dementia] So, you're saying there should be a question about do you sleep with your relative or your person you're caring for?*
>
> *C2; co-resident wife*

Actigraphy

Carers discussed both the person with dementia's experience of wearing the watch and the feedback they received about the person with dementia's sleep during the intervention sessions and after completion of the trial.

Wearing the Actiwatch

Many of the carers reported no problems with the person they care for wearing the watch, with the person with dementia either enjoying the experience or seeming to be unaware of it once it was on. The absence of problems wearing the watch was surprising to some of the carers:

> *Even after her shower if the carer forgot to put it back on her she used to tell her 'the watch, the watch'.*
>
> *C4; co-resident daughter-in-law*

> *And she kept it on for 2 weeks, which I was really impressed . . . Which I wasn't expecting, I have to be honest.*
>
> *C5; co-resident daughter*

There were some issues with the watch being taken off by either the person with dementia or the carers, whether paid or family, owing to either the person with dementia forgetting what the watch was or practical reasons, such as having a wash. Only one carer was unable to find the watch for an extended period of time:

> *It did come off one day, didn't it, we didn't find it for a day . . . but we found it. I think the carer had taken it off.*
>
> *C2; co-resident wife*

Ensuring that the watch was worn and kept safe was a cause for concern for some carers, as this carer described:

> *She'd taken it off once and had left it, they found it; another day someone else was wearing it during the course of the day, so quite how mum had managed that I don't know.*
>
> *C6; co-resident son*

Other minor problems with wearing the Actiwatch were reported by one carer each and included not liking its appearance, skin irritation and clothing covering the light sensor on the watch. Two participants commented on the event marker button on the face of the watch, which can be pressed to signal bedtimes or wake-up times. Both found that the person they cared for liked pressing the button themselves. In one case it was pressed repeatedly by the person with dementia, frequently at the wrong times:

> *As I say, I used to press it and she used to press it.*
>
> *C4; co-resident daughter-in-law*

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Actiwatch feedback

Many of the carers liked receiving the baseline Actiwatch data in session 2 of the intervention, especially when it confirmed their own impression of their relative's sleep pattern:

> *It sort of correlated with my own diary, and it correlated with my own experience, of the amount of activity that mum has, and the amount of light.*
>
> *C1; co-resident daughter*

Carers also discussed how the watch gave them new information, like how often the person with dementia woke in the night, especially if they lived separately, and how active they were during the day if the carer was absent:

> *It's good to know what happens in the day with her. Because I'm not here and it's interesting to see the sleeping, the movement and just generally what's going on and I think that's a really clever little watch.*
>
> *C11; co-resident daughter*

> *The watch where, you know, making a note of how many times she woke up in the night and that sort of thing. Because I'm sure she wakes up and gets up in the night many times without me even knowing.*
>
> *C8; co-resident husband*

Carers discussed the feedback participants received at study completion from the analysis of the Actiwatch worn at the 3-month follow-up. This feedback often did not accord with the carer's judgement of changes that had occurred, and one carer described disappointment at the lack of change on actigraph, but also thought this was because the follow-up Actiwatch recording was too soon to notice any changes:

> *I was quite disappointed that there was not much of a change, it was exactly the same as last time, and I was saying to myself; how come? . . . There wasn't much change to her routine and structure. It's only now that it's starting to pick up, so it could be that time it was early stages to ask for a good review.*
>
> *C12; co-resident granddaughter*

Intervention overall

Almost all the carers interviewed spoke positively about the intervention overall:

> *I found it really quite empowering. And with someone who suffers with dementia, or a family member of someone [who suffers with dementia], everything is just so bleak and, sort of, grey. And you're dealing with so much that actually having some idea of clarity and putting things into perspective and knowing that you can, [that] there are some things that you can do rather than all being completely unmanageable.*
>
> *C7; live-out daughter*

Only one participant, who dropped out of the intervention, reported that it was not helpful for her relative:

> *I have been on a course [about] how to deal with dementia in the past . . . So in a way I didn't find that very beneficial to be honest with you.*
>
> *C5; co-resident daughter*

The positive feedback mentioned how the intervention was enlightening, interesting, well-designed and provided a new perspective. Six of the interviewees planned to use the manual in the future:

> *It was really enlightening; it was, on a personal level, it was very, very . . . I found it to be really useful because there were things that I would overlook that I didn't realise were that important.*
>
> *C7; live-out daughter*

No, I think, really, it was just the total thing . . . was just interesting for us because we'd never have even thought about any of these things before.

C8; co-resident husband

Look, I got nearly 25 or 30 certificates. And I think this was the most complete. The most useful, the easiest. And compared to the others, I think there's nothing to add to this one . . . very well designed.

C9; paid carer

The relevance of the intervention was discussed, and participants highlighted how the relevance varied according to the individual presentation of their relative. Even when participants did not find some parts of the intervention relevant, they found other parts useful and judged the overall intervention to be interesting and useful:

But anyway, we were slightly difficult in our case because we're both quite active, you know, and we were already doing a lot of the things . . . so some of it didn't mean an awful lot to us. But, I mean, overall, somebody's done an awful lot of work, putting all this together and, you know, this package is quite useful, I think.

C8; co-resident husband

I think the DREAMS programme was quite interesting. Even though some of it didn't apply to my mum. A lot of the things were for the ones that move about, you know, are more mobile and everything. But some of the points were quite useful, you know, for me to use on my mum.

C10; co-resident daughter

Manual design

Participants found the manual layout user-friendly and easy to read, considered the balance of pictures, vignettes and text appropriate and felt the direct quotations from carers to be important. Two people wanted more examples and quotations:

It was well explained, it was in plain English, it was all understandable.

C13; live-out daughter

Pictures are always good . . . but I think more importantly is the case studies, you know, and anecdotes, yes, that's more important.

C1; co-resident daughter

One carer would have liked an electronic version of the manual and two would have liked to be able to use it on their mobile telephone:

It would've been better if the paperwork was more electronic, that way it doesn't get lost.

C12; live-in granddaughter

It might've been easier for me to just talk into my phone at the end of the day or, you know, to keep an audio diary.

C2; co-resident wife

Some application could be developed that would send you a message.

C5; co-resident daughter

Another carer suggested organising the manuals with tabs for reference to make it easier to find things.

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Content of the manuals

Participants found the content of the manual relevant and useful:

> *In my mind, there isn't anything that I think you've missed or anything different or that could be improved on. I think you covered an extensive range [of] matters in terms of relaxation, breathing, sleep, and understanding, all of those things.*
>
> *C11; co-resident daughter*

> *I found it very good, I didn't find anything boring about it; it was well calculated, and well put down on paper. I found every part of it very imaginative.*
>
> *C3; co-resident husband*

Participants also liked receiving information about caring for someone with dementia, the biological processes of sleep and how dementia can affect an individual's sleep. The diagrams used in the manual to describe circadian rhythms and sleep pressure were described as easy to understand for carers, but not for people with dementia. Having this specific information clearly explained helped the carers to make sense of sleep difficulties in dementia and justified making behavioural changes, such as increasing natural light:

> *The sleep cycle, REM [rapid eye movement] and all of this, and that it's in cycles, it isn't just one cycle that lasts the entire night . . . I think it's useful to know that, actually, if I, you know, if I do this it affects this and that's why then it has a knock-on effect.*
>
> *C1; co-resident daughter*

> *I really liked the fact that how sleep and dementia are correlating with each other, I found it very helpful. Because with people that have dementia, as their mind is slowly becoming less integrated, they're very more sensitive as to how it can impact their sleeping. Because if you have dementia . . . you don't have a tough shell against having a routine which can change dramatically, like myself.*
>
> *C12; co-resident granddaughter*

> *Now I'm really aware that being out in the conservatory is really good for her because of the light. Whereas before I thought, 'oh, it's better because it's a bit oppressive in the front of the house, a bit dark' . . . But now I know that there is a physical reason for it, it's not just, you know, a hunch.*
>
> *C7; live-out daughter*

Sleep diary and record forms

One aspect of the manual that received mixed feedback was the sleep diary, designed for participants to use between sessions to record sleep patterns and strategies tried. Completing a sleep diary was described as useful both for understanding the sleep patterns of the person with dementia and in enabling carers to provide further details to others, such as health professionals:

> *The diary, the timesheet, everything you know because it helps me to learn, it helped me to be able to see exactly what's going on. And I can give exact times to people now as to when she's awake whereas before I might've missed it.*
>
> *C11; co-resident daughter*

Although some carers found the sleep diary easy to complete, a number of carers spoke about the difficulties of completing it. They attributed this to the design of the diary and the added stress of record-keeping, especially when the person with dementia awoke in the night:

> *But it was a nightmare because of the ways, yes, because it goes from noon . . . sometimes if you forget also to do it you can think, 'oh, you know what we didn't . . . let's leave yesterday, let's just do today' . . . but by the time the next day came it just got really, yes, really confusing so we just left it.*
>
> *C7; live-out daughter*

But it was crazy because when you try to sleep and she's woken up you have to memorise the time, or otherwise you have to leave the bed and go and write it. Next day you think, what time was she awake? It was 3? It was 2?

C9; paid carer

One suggestion was to change the timings of the sleep diary to start recording at an earlier time of day, instead of noon, and to use day and night symbols:

I don't know what time would be good, maybe 6 a.m., you know, so you definitely knew that that was Tuesday, all that line.

C2; live-in wife

Other record forms within the manuals were described as easy to use and useful.

Process of intervention delivery

Carers valued a number of aspects of the process of intervention delivery. These included, first, having the space to talk; second, developing individualised strategies; and, third, being flexibly guided through the intervention.

Having the space to talk

Many carers simply appreciated the chance to talk through challenges with the therapist, something that had not always been available to them:

It was good that someone else had some ideas; it's always good to talk to people who have any vague idea of what you're going on about . . . It's rare to come up against someone with some understanding, even professionals.

C6; co-resident son

And actually it was nice knowing that I had an hour . . . to just speak about problems and try to find out answers, work it through because nobody in the . . . national health system, you know, has that time.

C7; live-out daughter

Often carers related this to the specific qualities of the therapists, who were seen to both listen and give space while gently guiding carers through the sessions, facilitating the process:

I used to look forward to my sessions with [T1]. He's very professional and also a gentle man . . . He's softly spoken but he puts the point across.

C11; co-resident daughter

[T2] was very understanding, she was engaged and patient and she was dealing with my quirkiness every time I randomly asked her a random question out of the blue.

C12; co-resident granddaughter

Developing individualised strategies

Carers valued how the therapists and the manual supported them to both build on existing strategies and develop new ones. In particular, they valued that they were encouraged to make specific plans and try new strategies out:

Quite often I was doing something similar, or I was just on the edge of it or doing parallel but not quite achieving, and he, sort of, fine-tuned it.

C6; co-resident son

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> *She knew my tendency of being slightly forgetful and being all over the place. So she tried to give me a plan that was realistic and not overambitious.*
>
> *C12; co-resident granddaughter*

Realising that they already had strategies to build on and being encouraged to try things out and notice changes was validating and reinforcing:

> *There was a lot of positive reinforcement, which I think was very helpful, actually, because I think it's very easy in this sort of situation to become depressed and, you know, kind of overwhelmed by a kind of inertia.*
>
> *C2; co-resident wife*

> *It just made me aware that I was already doing stuff, whereas before I was, like, 'oh, I'm not doing enough' and, you know . . . reaffirming, reassurance and also reminding.*
>
> *C1; co-resident daughter*

One carer discussed the manual using real-life examples as validating their own experiences of caring:

> *Well, I think what made it easier was looking at examples of people with dementia and how their family and carers dealt with it. And it made it easier for me knowing that I'm not the only one who finds it hard, you know. Because sometimes you can question yourself and say, 'well, I'm just not doing this right.'*
>
> *C11; co-resident daughter*

Being guided through the intervention

Participants found it useful to have the therapist guide them through the manual, rather than a more self-help style intervention. This process increased motivation to try to practise new strategies:

> *She talked through the manual, rather than just letting me, on my own time, read it, which really helped . . . it gave a lot of insight into what the manual was about, because her talking through it gave a lot more understanding.*
>
> *C12; co-resident granddaughter*

> *In the beginning, I said, 'no I'll do that [relaxation and exercise] when I'm on my own', but she made us do it. Well, not forcefully, but, you know, she had a nice way to get around you. So we did it with her . . . I realised it was easy to do it so we did it when she wasn't here, yes.*
>
> *C14; co-resident wife*

Carers valued the flexible pacing of the sessions, including being given the manuals one at a time and each session having a different focus:

> *Yes it was because each week T1 would give me, like, a new session of paperwork to look through and I found that easy . . . Because it wasn't given to you all in one big bulk . . . And each session covered a different thing.*
>
> *C11; co-resident daughter*

In general, carers felt that the number of sessions was appropriate. Some highlighted that fitting in weekly sessions could be challenging. Some suggested more flexibility around both the number (e.g. having four longer sessions instead of six) and spacing of the sessions (e.g. having up to 2 weeks between them). Having time between the sessions was also valued as an opportunity to try out new strategies, without losing momentum:

> *They did vary sometimes, they weren't as . . . slightly as long. So it was, yes, it met the needs of that particular subject.*
>
> *C13; live-out daughter*

At the time I was thinking, 'oh, that's come round quite quickly' . . . However, the times where we did wait for 2 weeks, yes, I wouldn't want to go over longer than that because then you forget about stuff . . . Yes, I think between 1 and 2 weeks is ideal, yes, absolutely.

C7; live-out daughter

Which aspects of the intervention did carers find useful?

Strategies from the intervention included using the light box; increasing natural light, exercise and daytime activity; practising the relaxation exercises; carers looking after themselves; changes to the bedroom environment; changes to the bedtime routine; managing night-time behaviours; lifestyle changes; and reducing daytime naps. Carers spoke about what strategies they did and did not use and what effects they noticed on themselves and their relatives. How relevant certain strategies were to carers varied in relation to the specific circumstances or presentation of their relative; for example, if a person with dementia went out every day, increasing natural light or activity was not as relevant.

Using the light box

Of the 16 participants interviewed, 14 had tried to use the light box to increase their relative's light during the intervention. Only three of them were using the light box every day at the time of the interview:

Every morning he asks me to switch on the light, you know . . . he totally seems to count on the light.

C14; co-resident wife

However, five of those not using it every day spoke about using the light box again, particularly in the autumn or/winter when there is less light:

Well, we didn't use it after, sort of end of March really, mid-March because she was out so much then and the nights were getting lighter. But certainly I think it was February time for a period of about 3 weeks or 4 weeks that we did we just put it on while she was in the room . . . It probably did help; it did because she wasn't going to sleep so much during the day.

C7; live out daughter

The others spoke of their relative disliking the light because of its brightness or because it did not seem to be working:

She didn't want it on a lot of the time; she said it was too bright.

C13; live-out daughter

My son said, you know, it's making their nan sleep more.

C10; co-resident daughter

Increasing natural light

Five people spoke about trying to increase natural light, often indoors, by sitting nearer to windows or opening curtains, or spending more time outdoors:

We changed the furniture, so she was near the window. So she has more light.

C9; paid carer

What we still try and do is take my mother out daily. So still trying to give her some exercise. Still to get her out into the sunlight for at least half an hour.

C15; co-resident son

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Carers had mixed opinions on the effects of increasing natural light; some felt that it aided sleep, whereas others felt that it had no effect:

> *Yes, she's more settled when she goes out and she got more light. And then she becomes more tired and she sleeps better.*
>
> *C9; paid carer*

> *Getting my mom up in the morning, lots of daylight, it didn't really seem to have that much effect.*
>
> *C6; co-resident son*

Increasing exercise

Increasing walking

Four carers spoke about increasing exercise by walking outdoors, which also increased exposure to natural light, and had continued using this strategy beyond the intervention. One carer increased their relative's exercise by parking farther away from places they were visiting:

> *Well, also now she goes back out walking the dog with [other family carer] because she's got now the walker . . . I know it's, you know, getting dark by then.*
>
> *C4; co-resident daughter-in-law*

> *What we still try and do is take my mother out daily. So still trying to give her some exercise.*
>
> *C15; co-resident son*

Using seated exercises

The seated exercise routine was meant for people who could not go out with ease or exercise standing. It was discussed by five of the interviewees. Four people enjoyed the exercises and were still continuing to use them beyond the intervention (three people with dementia and one carer). Another carer was trying the exercises with their relative, but was considering stopping, because they were too tired as they were sleeping very badly:

> *And he joins in which is brilliant. Because it's very hard to get him to do his exercises for his joints but he loves this.*
>
> *C14; co-resident wife*

> *Yes, there was the one I thought was quite good because my mum doesn't do a lot of activity, walking around. There was one with your feet, moving your feet up and down as an exercise. She'd be sitting down but still moving her feet and her arms.*
>
> *C13; live-out daughter*

> *I was doing exercise with her before but I sort of tailed off because then, you know, her sleep's been so bad, and she's so tired.*
>
> *C1; co-resident daughter*

Increasing daytime activity

The majority of the interviewees discussed small things they had tried in order to increase daytime activity in the person with dementia, including listening to audiobooks, music and the radio, looking through photographs, watching television programmes and videos, playing bingo, reading newspapers and playing with sensory objects. Carers appreciated the focus on daytime activities and on the things that they could try, especially when it built on what they were already doing:

> *It just made me aware that I was already doing stuff, whereas before I was, like, 'oh, I'm not doing enough' and, you know.*
>
> *C1; co-resident daughter*

> *I did like the reminders of the importance of going out every day. I mean, I sort of do, but there were lots of reminders of sensible things to do . . . but I was thinking about it, you know, trying to do fun things together.*
>
> *C2; co-resident wife*

Some valued how the sessions had guided them to adapt existing activities or the environment where the activities took place to make it easier for the person with dementia to participate:

> *We worked out headphones for the TV for her because she has to have it so, so loud, so she can enjoy TV more without trying to read the subtitles. So she's enjoying TV a lot more and programmes that she used to like to watch.*
>
> *C4; co-resident daughter-in-law*

For carers whose relatives were already very active, the focus on activities was less relevant.

Practising the relaxation exercises

Although many of the interviewees enjoyed the relaxation exercises within the sessions, some felt that the exercises were not for them and struggled to practise between sessions. Carers were more likely to use elements of the exercises that did not require the CD, such as the breathing exercises, or used it as a reminder to take a moment to relax and notice when they were feeling stressed:

> *I try and incorporate the breathing when I'm feeling a bit, like today I thought, 'ugh, God, I just haven't got the patience today to deal with mum's agitation' . . . but it's, like, you do it, for that moment of time you're relaxed and then it's, like, you have to go back into it.*
>
> *C1; co-resident daughter*

One carer also described using the imagery relaxation exercises with their relative, adapting it to make it more relevant and briefer for use over the telephone:

> *I did try and get my mum using that kind of technique. Imaging herself in a particular environment. I changed it sometimes to the Caribbean. To somewhere that she is familiar with . . . Sometimes I'd speak to her over the phone and try to describe . . . an imagery to think of that she'd like that made her feel happy.*
>
> *C13; live-out daughter*

Carer looking after themselves

Carers spoke about how the session around looking after themselves was important, but that they needed more in-depth opportunity to address more long-standing patterns and habits:

> *What it did do was it stopped you and it said, 'hang on a minute, you know, this is a management programme it's not just about the person, it's about the family member and looking after . . .' but actually the fundamentals of looking after yourself, you know, when it comes to practice it's difficult.*
>
> *C7; live-out daughter*

> *I think it's absolutely key, you know, it's probably the most important aspect of the whole thing, but also very, very difficult because if one's spent, you know, nearly 70 years of one's life practising, you know, all the buzzing.*
>
> *C2; co-resident wife*

Changes to the bedroom environment

Changes to the bedroom environment covered a range of topics, from making the room more comfortable to adding more personal objects so that, when the person living with dementia woke up, they recognised

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that they were at home. Mostly carers felt the bedroom was too warm, which some confirmed using the thermometer provided:

> *I think that is part of this really just to try and keep things in order in her bedroom, so when she goes to bed she doesn't have to go to bed in chaos.*
>
> *C7; live-out daughter*

> *And I did put the heating, central heating, on the timer. So it came off a bit earlier, so that it was slightly cooler. And yes, she was saying she was freezing . . . You know, and it was just mild.*
>
> *C13; live-out daughter*

Some participants had, before the intervention, thought about changes that they could make to improve the bedroom environment, such as blackout curtains, either themselves or with help from their memory service. For others, changes to the bedroom environment were not possible: for example, one person with dementia had never liked having their bedroom curtains closed at night, and their carer felt that this was impossible to change:

> *Just before we started this I actually got blackout curtains, which had already helped a bit to make her sleep a bit.*
>
> *C6; co-resident son*

Changes to bedtime routine

The changes made to the bedtime routine encompassed making the wind-down period start earlier, trying to decrease stimulating activities before bedtime and changing the time the person with dementia went to bed, which seemed to improve sleep:

> *I would phone my mum sometimes about 10 o'clock just to say goodnight and I've just put that a bit more forward now so I phone her at 9 o'clock. And then that 9 to 10 o'clock is a sort of period of winding down.*
>
> *C7; live-out daughter*

> *Trying to keep her up as long as possible so she'll sleep better through the night. All those sort of things, they did help, because obviously when she goes to bed early she will get up early.*
>
> *C15; co-resident son*

Some discussed how the bedtime routine was fixed because their relative lived alone and depended on paid carers, or because they thought changing the routine may be too confusing for their relative.

Managing night-time behaviours

Strategies for managing night-time behaviours included thinking more about the causes of behaviours and carers reacting differently to being disturbed in the night:

> *I've now figured out, look, she's not going back to bed because it's not right, she doesn't know what to say and what to do. And she's actually started coming into my room and at first I couldn't understand why. Now I know she's trying to tell me something's wrong . . . So I know now to just go in and, I have a spare, and I can have mom's bed changed so that she's back in bed and asleep in 15 minutes flat.*
>
> *C6; co-resident son*

One carer also adapted the home environment by putting signs on bathroom and bedroom doors, which helped their relative find their way to and from the bathroom in the night, and prevented them wandering around the house in the night.

Lifestyle changes

The main lifestyle change mentioned was reducing the consumption of caffeine from the late afternoon onwards, and especially before bed, which most people did. However, this was not always successful. Another carer discussed how her relative drank caffeine at night but did not think that had any impact on his sleep:

> *We talked about having a snack before bed and cutting out caffeine, which I tried, again, for a little while, but we seem to have slid back to . . . Well, P does have, does actually drink decaffeinated tea now, which he didn't before . . . But he likes a particular form of coffee, which is very sweet and has caffeine, and I haven't been able to wean him off that.*
>
> *C2; co-resident wife*

Reducing daytime naps

Carers used a number of the strategies, such as going out and increased activity, to try to reduce daytime napping in the person with dementia. Some of the carers had some success with these strategies, but other carers discussed finding it an ongoing struggle to reduce naps:

> *But a couple of, like, past photos, family photos and everything, you know, like we recorded and had on a CD . . . A few other videos, places that she was familiar with, like her village, where she comes from, that kept her awake a few times.*
>
> *C10; co-resident daughter*

> *If you wake her up she'll get really angry, so my dad phones me and he says, 'she's been asleep for about 45 minutes, can you phone?'. So, he'll put the phone right next to her to wake her. So I'll phone up, she'll pick it, I'll say, 'hi Mum, how are you? What you doing?' you know, and I'll try.*
>
> *C7; live-out daughter*

> *And it's impossible if she wants to go to sleep, she will go to sleep, no matter what you do. Napping, you know.*
>
> *C4; co-resident daughter-in-law*

Overall benefits for carer and person with dementia

Overall, nine of the carers interviewed spoke about their relative sleeping better after taking part in the intervention, but five of them were unsure whether or not it was due to the intervention or other reasons, such as medication or progression of dementia over 3 months:

> *You've created a miracle, because it really did work.*
>
> *C11; co-resident daughter*

> *For years, she's been very bad at sleeping and it seems to have improved quite a bit, but whether that's anything to do with this course, I don't know.*
>
> *C8; co-resident husband*

> *Mum was put on mirtazapine and we started the research. So, it is very difficult to say what . . . where the benefit came from . . . And again I don't know whether it's the mirtazapine. She's actually gone down on her mirtazapine from 30 to 15 [mg] and her sleep is still OK.*
>
> *C7; live out daughter*

Some attributed the improvements to a changed routine:

> *She definitely stays upstairs in her room during the night for longer. She came less times downstairs to eat or just listen to the radio, as she used to . . . Yes, it's a better routine.*
>
> *C9; paid carer*

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One carer described how the intervention improved not only the sleep but also the mood of the person she cared for; this person with dementia had taken part in the sessions with the carer:

> *But I have to say he enjoyed it every week, he looked forward to it. And he seemed to think it was making him better. And his mood, everything changed and, touch wood, he's still the same.*
>
> *C14; co-resident wife*

In terms of benefits for carers, two described how the intervention had also improved their own sleep and two spoke about feeling calmer from the skills that they had learnt from the intervention:

> *I really was and even people at work noticed a difference with me. It was like, you seem full of life. I'd say it's because I'm sleeping at night now . . . The programme as I saw it for us, for my mum and for me, worked really well.*
>
> *C11; co-resident daughter*

> *I've learnt to be calmer though and more patient by sort of . . . To stop thinking about it and think of something else.*
>
> *C10; co-resident daughter*

One carer also mentioned the feeling of altruism she felt from taking part in the research:

> *And I think there's something, it sounds a bit weird, but there is something comforting about having done this, having been involved in something that is hopefully going to lead to some helpful outcomes for a lot of people, so I think that in itself is good.*
>
> *C2; live-in wife*

One carer of a relative with very severe dementia felt that the intervention had a limited effect:

> *I'm not saying don't offer it to them [people with severe dementia] . . . but if you find that, actually, it's more helpful in people with mild to moderate dementia, you might feel that it'll be of more benefit and you'll be able to reach more people within those categories, and help more people as a result.*
>
> *C1; co-resident daughter*

Acceptability and practicality of the intervention

What made it easier to put strategies into practice?

Carers described various factors that made it easier to overcome challenges and put strategies into practice.

Support from others

Having additional care and support from others, including other family members and paid carers who could try out strategies and encourage their relatives to make changes, was described as helpful:

> *When my cousin came, it did help make sense of ways we could give a change to my nan's well-being. Because he's the only one who convinced my nan, I could not convince her.*
>
> *C12; co-resident granddaughter*

> *I made the point of asking, when the carer was at home with her all day, get her out as well. So it just made me think of it, that, to do, rather than leave everything for me to do when I come in from work, so, good ideas.*
>
> *C6; co-resident son*

Routine and organisation

A number of carers discussed how building activities into an existing routine and planning ahead made it easier to increase daytime activities, particularly if their relative was a person who liked to go out anyway:

> *And I had suggested about taking out her clothes in advance for . . . To encourage her to go to church on the Sunday. So on the Saturday I would come, and I have done that a few times . . . And probably half of the time she has taken it up. So that's kind of encouraged her because her clothes are all ready, she knows what she's going to wear.*
>
> *C13; live-out daughter*

> *My mother is the sort of person who likes to go out, so that was quite easy.*
>
> *C15; co-resident son*

Indirect changes rather than confrontation

The carers described how coming up with creative solutions, which could involve distracting relatives, rather than trying to directly get them to change a behaviour, worked well:

> *We'll park a little bit further away from where we're going for a destination, she's got to walk to get there . . . She has done a bit more walking herself, so I think it's helped her. That does tire her . . . Helps her sleep.*
>
> *C15; co-resident son*

Support and suggestions from the therapist

The manner and approach of the therapists was seen to facilitate and motivate the carers to make changes:

> *[Regarding the relaxation exercises] In the beginning I said, 'no I'll do that when I'm on my own' . . . but you know, she had a nice way to get around you. So we did it with her. No, I realised it was easy to do it so we did it when she wasn't here, yes.*
>
> *C14; co-resident wife*

What made it harder to put strategies into practice?

The barriers to making use of the intervention have been organised into three subthemes: (1) factors related to the person with dementia, (2) factors related to the carer and (3) practical issues.

Difficulties relating to dementia and comorbid physical illness

Most carers described the impact of the dementia itself on their ability to make changes or try out new strategies. They often attributed this to the unpredictability of the condition and fluctuation in their relative's wishes, for example the person with dementia not understanding something, or it not being possible to leave things lying around as the person with dementia would destroy them:

> *The only difficulty I found was if I made arrangements, or I wanted to make arrangements, I'll ask [her] first, if she says yes, then we go . . . Once we got there, I am afraid it was no, I don't want to go in, I don't like it, don't like this place.*
>
> *C3; co-resident husband*

> *I can't leave stuff like this out and about, I have to lock everything away, so you then get a situation of it's all locked away, I've finally got mum to bed, I'm doing this, I'm doing that and I don't remember to go back and do it . . . if I want to keep anything safe, complete, stop it being ripped apart . . . everything's got be hidden. That's the big thing for me personally.*
>
> *C6; co-resident son*

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Carers found inflexibility in their relatives particularly challenging, especially when strategies involved making changes to long-standing routines, such as having the room a certain temperature or having the curtains closed during the day:

> *Every suggestion that I gave her, she threw it out of the window. So, I knew that even if I did put my 100% into it, I was not going to get anything out of it, because my nan is reluctant.*
>
> *C12; co-resident granddaughter*

> *We discussed the room temperature, how she likes the room so hot and . . . [paid carer] keeps trying cooling it down and my mum would then go mad having a go at her, 'why are you doing that? Are you trying to get me to catch a cold?'.*
>
> *C7; live-out daughter*

One man caring for his mother with dementia described how having the therapist in their home affected his mother, as she did not understand who the therapist was and why they were talking to him:

> *She didn't quite know who [T2] was and she got . . . She started getting this jealous rage thinking that [T2]'s going to take me away.*
>
> *C15; co-resident son*

One carer spoke about being unable to stop her relative from daytime napping, including the difficulties arising from the hangover effects of sleep medication taken the night before, which prevented her from being able to practise strategies with her relative:

> *If she does sleep, she's completely out of it, I think I've said this before, and she doesn't rouse at all for an entire day, so it's like she's accumulated all these hours of not sleeping and just making up for it, and that can last 2 days, even.*
>
> *C1; co-resident daughter*

The impact of comorbid physical health problems were frequently highlighted, for example infections increasing confusion, continence issues at night waking a relative or mobility issues making it harder to increase activity:

> *When she had the urine infection in between so that can affect her sleep. You know, like going into a deeper sleep.*
>
> *C10; co-resident daughter*

> *I think with Parkinson's [disease], which means that he needs to get up and go to the loo several times during the night, that kind of thing is not able to be influenced by taking part in this kind of project.*
>
> *C2; co-resident wife*

> *There's not a lot he can do . . . It's the mobility that's holding him back.*
>
> *C14; co-resident wife*

Carers' tiredness, competing demands and relationship with the care recipient

Carers spoke about their own stress, health problems and tiredness affecting their motivation. The carer we interviewed who did not complete the intervention spoke about the added stress of the intervention being part of why they dropped out:

> *That made it harder? . . . it's just a vicious circle, isn't it, because if you're tired, you're less hopeful and you don't have the patience and then you start thinking about yourself and how unfair things are.*
>
> *C7; live-out daughter*

It would've put more of a stress for myself and I didn't want any more.

C5; co-resident daughter

The relationship between either family carers or paid carers with the person with dementia was also discussed as something that made it harder to try strategies:

I mean, some of the things, I think what may make it a bit harder for me is that she's not my mother, she's my mother-in-law, you know.

C4; co-resident daughter-in-law

One carer also discussed having additional caring responsibility for another parent who also had dementia and how that made it harder to try strategies with their parent who was taking part in DREAMS:

Yes, because it's not just my mother. I look after my dad as well, so when you're not looking after one, you're looking after the other one.

C15; co-resident son

Sometimes, carers spoke in more general terms about multiple competing demands on their time, stressful life events and feeling overwhelmed or hopeless. This affected their ability to engage with the intervention and make changes:

When the sessions were going to start with T2, I was very much disorganised and scattered and I had a lot of things that I was thinking, and that was going over my mind . . . It was not the right time for me to focus on it.

C12; co-resident granddaughter

I don't know. You read a section and think, 'yes, yes, yes, I've got it, I can do that', we'll do that and it doesn't work out. It just doesn't work out. So you leave it, and if you try it again another day and it will, but most of the times it doesn't.

C4; co-resident daughter-in-law

Well, I actually, I had a bit of a breakdown when she was in a state . . . all night she stayed awake one night, she was awake every 10 to 20 minutes, she's knocking on my door, calling me, you know, quite angry and it carried on until the next afternoon, into the evening. I just had enough, I couldn't take it any more. I just slept for like 36 hours. I had to get my sister to come here to look after them for about 2 or 3 days.

C15; co-resident son

But I have so many things to think about, what with finding things for her to do, doing the cooking, the housework and all. I don't want any more things to think about.

C8; co-resident husband

Practical issues

There were various practical issues that made it harder for carers to make use of the intervention. This included being at work during the day or at night, which resulted in them being unable to try out strategies with their relative:

If I was here to increase daytime activity, it would be a lot easier . . . But the fact that I'm not here and I'm at work, it's just hard.

C11; co-resident daughter

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In addition, when the carer did not live with their relative or if they slept separately, it was difficult to try new strategies or to see any effects:

> *Sometimes I'd . . . Yes, that was one thing, sometimes I didn't think there was enough time to try things out, because by the following week, you know, you either haven't had time, or it didn't work so well . . . and based on the fact as well that I'm not living with my mum.*
>
> *C13; live-out daughter*

> *And the other thing, it was suggested to try to keep her up a bit later. And that wasn't quite working at all, me not living with her.*
>
> *C13; live-out daughter*

> *Because P sleeps down here and I sleep upstairs, so I wasn't checking whether the temperature was optimal for sleep.*
>
> *C2; live-in wife*

Carers also described the lack of flexibility available in paid care, especially for working carers who were not with their relative during the day:

> *Very hard. I said to T1 that, for me, that's almost going to be impossible unless we change the whole package for mummy with the carers, created more time per session with them and getting them to do other things with her, other than just feed her and take her to the toilet.*
>
> *C11; live-in daughter*

Another barrier raised by carers related to the time of year the interventions took place. Participants spoke about how it was harder to get their relative to leave the house when the weather was bad in the winter months, which affected both activity and light levels:

> *But the middle of winter, you come home at 4 in the afternoon and it's pitch black, cold, damp and horrible, and I don't particularly want to start dragging her out.*
>
> *C6; live-in son*

Post-intervention patient and public involvement focus group's views about further improvements to the manual

The post-intervention patient and public involvement (PPI) focus group was facilitated by Penny Rapaport and Lucy Webster and was hosted by James A Pickett of the Alzheimer's Society. Five carers who had not had the intervention attended the focus group, all of whom had contributed to the earlier intervention development process.

The key themes elicited from the focus group related to what the carers liked about the intervention, what they felt should be added or enhanced in future versions, what they felt were barriers to delivery and effectiveness of the intervention and general suggestions for a future trial of DREAMS START.

The focus group participants highlighted aspects of both the content and process of intervention delivery that they thought were useful and important. In terms of content, they felt that a focus on behavioural activation and physical activity was important for both carers and people with dementia, and could lead to a reduction in daytime napping and night-time wakening. In terms of process, the carers highlighted how combining a methodical, manualised and structured approach with support from a therapist to put strategies into practice and troubleshoot difficulties was beneficial. They also appreciated the flexible and personalised delivery of the intervention and felt that the manual was easy to read and follow.

One of the main challenges that they perceived was that increasing activity or making daytime changes, especially if the person with dementia lives alone, relies on adequate local services being available, which in their experiences was rarely the case. They also perceived the intervention to be harder both to deliver and put into practice if the person with dementia did not recognise that they had a sleep problem or had a different understanding of how they slept than their relative.

The main suggestions made by the focus group participants related to building technology into any future iterations of the intervention. Carers suggested having application-based technology both to remind carers to try a particular strategy at a set time and to facilitate real-time recording. Some acknowledged the importance of having simple paper-recording available as an alternative. They felt that using telecare and other assistive technology (which was often part of plans) could be further explored in a future trial, as this would be useful for those people with dementia who are alone during the day and could help manage difficult or risky behaviours at night. The carers also suggested that future versions of the manual should be even more personalised, with more detailed instructions for therapists on how to deliver the intervention flexibly based on the particular presentation of the person with dementia and the specific impact on family carers. They suggested including more detailed vignettes of the sleep difficulties people with dementia may experience, based on the data collected in this feasibility study. Focus group participants also felt that having a peer support component in which participants could either directly or virtually connect with others participating in the intervention would be beneficial to carers.

Interestingly, all of the carers asked questions or expressed frustration that the manual would not be widely available until a full RCT had been completed. What they felt was the most important outcome for a future trial was discussed and the participants felt that there needs to be a continued focus on improving carers' sleep as well as the sleep of people with dementia. One carer suggested testing the manual in a self-help format for carers alongside testing in individual, facilitated sessions.

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Chapter 5 Discussion

Main findings

The study fulfilled the primary outcomes for feasibility and acceptability to continue to a full-scale trial. The expected recruitment rate to indicate feasibility stipulated in the protocol of potentially eligible participants was 50%, but the actual percentage of eligible referrals recruited exceeded this at 65%. Those who were recruited were, in the main, demographically similar to those who were not. However, family carers who cared for men with dementia were more likely to refuse to participate than those who cared for women with dementia. The research team are unsure why this should be. There was no difference in the sex of the carer who consented to the study or refused to participate, or whether carers were the care recipient's spouse or child. The proportion of men recruited also reflects the proportion of men with dementia in the older population.

In terms of acceptability, the percentage of participants randomised to the intervention group attending four or more of six sessions was 88%, exceeding the expected value of 75%. The median number of sessions attended was six, with two people dropping out before they began the sessions (one because of lack of time and one because the person with dementia refused), but only three of those who started did not adhere to the intervention. Thus, most of those in the intervention group appeared to find it acceptable to attend all sessions once they had started.

Recruitment and follow-up

The referral rates were four potential participants per week from two memory clinics, which informs the number of trusts required for a full trial. We used JDR and recruited two people over the recruitment period. There was clearly more potential, but 19 out of 25 (76%) of those registered on the list did not respond to contact and only two of those we contacted consented. Thus, it seems that JDR is most useful as a supplementary method to recruit people rather than as the sole or main method. Generally, $\geq$ 80% follow-up is regarded as satisfactory, and this trial achieved 92%.

Completion of outcome measures

Very high completion rates of the validated questionnaire measures were achieved, using carers as informants. At baseline, all but one person with dementia wore the watch and 50 (81%) carers completed the sleep diary or event markers to record the person with dementia's bedtimes and rise times. However, at follow-up 49 (79%) of the 62 people with dementia in the randomised group had $\geq$ 7 days of actigraphy data and 42 (82%) of their carers provided the bedtimes and rise times on the sleep diary or by using event markers to aid interpretation.

Primary and secondary outcomes for a full trial

Actigraphy as outcome and tool

It was originally envisaged that actigraphy data would be the primary outcome in a full trial. However, in the feasibility study, it was available for only 79% of randomised participants at follow-up (for $\geq$ 7 days; the usual 'gold' standard). In addition, the sleep diary or event markers, which give times of going to bed or getting up, are required to interpret the data. Only 68% of people randomised provided this, so data interpretation was difficult for some of those with records, as it relied solely on verbal reports or the researchers' supposition. Therefore, our feasibility study indicates that we are unlikely to have the level of reliable data required to use actigraphy as a primary outcome. The research team suggest that it would be helpful to validate the use of Actiwatches in this population before considering actigraphy measures as a primary outcome in any efficacy trial.

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There is, in addition, a paucity of validation data about actigraphy in this population. Although sleep efficiency is often taken as a good summary sleep measure from actigraphy in younger people, it appears not to be as well measured in older people possibly because sleep in actigraphy is inferred from time in bed and movement. Movement is, in contrast, directly measured. According to the actigraphy data, both groups were still spending a long time in bed after the intervention and it did not look as if the intervention changed this sleep behaviour in any substantial way. There was an indication from our actigraphy results that the intervention participants were more active during the day and less active during the night. These findings accord with the qualitative feedback from the carers in the study as well as the results of the validated instruments. The carers in the study and the PPI group judged the important outcomes to be that the person with dementia was less restless during the night, more awake during the day, disturbed them less during the night-time and seemed happier (which are measured in the SDI). In these circumstances, they were unsure that these measurements of sleep added additional outcome information, or were accurate.

In contrast to their disappointment with actigraphy as feedback, the carers and therapists found the information from actigraphy valuable to use at baseline to consider the rest–activity pattern and help make a plan and this would continue to be incorporated in the manual as part of the intervention in a full trial.

Overall, the place of actigraphy in a full study would, therefore, be to measure changes in daytime and night-time activity as a secondary outcome and as part of the intervention.

Validated interview measures

In the qualitative assessment participants commented on the combined length of the questionnaires, and felt that this was acceptable if participants need to be reassured that this information is being collected for the purposes of the research and will be useful. The completion rate for all validated instruments at baseline was very high, ranging from 98% to 100%.

Instruments for the person with dementia

The validated instruments to measure sleep disorder had a high rate of completion at follow-up, and the SDI was completed at follow-up by 90% of those initially recruited to the trial. This appeared to be the most practical way to measure sleep. The qualitative feedback from carers participating in the trial and PPI indicated that they felt that it reflected their experience of sleep as well and had relevance. Therefore, it is proposed as the outcome in a main trial.

Summary data for the carer-reported instruments indicated generally better scores for the intervention group and, after adjusting for site and baseline problems, there was significant improvement in daytime sleepiness and in quality of life of people with dementia, despite the small numbers in the study. There was also no increase and a possible reduction in the numbers of people who were prescribed at least one medication for sleep. These may be related to each other. Although power for these results had not been considered, the consistency in the direction of all the results suggests that they may be real. It is important that the intervention may reduce daytime sleepiness, whereas sedative medication sometimes increases it. Similarly, it is always important to consider quality of life for someone with dementia, as an intervention may improve a specific domain while reducing overall quality of life. We would therefore conclude that the DEMQoL-Proxy and ESS should be measured in a full trial. We also administered the CSRI, to assess the feasibility of its use, and suggest that it too should be included in a full trial, as this would enable the cost-effectiveness of an intervention to be calculated.

Harms

There was no clear increase or difference between groups in the use of psychotropic medication and melatonin, with the intervention group possibly being prescribed slightly fewer medications afterwards, taking into account baseline measures. This suggests that any effects were not due to psychotropics being used as rescue medication in the intervention group. There was no indication of important harms in terms of side effects in either group.

Carer outcomes

The carers in the intervention group reported significant improvements in ZBI-measured burden, and the direction of results suggested that there may be an improvement in depressive symptoms (HADS). It is important to consider the effect of sleeplessness on carers' stress levels and mental health, and we would conclude that these measurements should be retained for a full trial. A few of the carers disliked the questionnaires used to measure carer sleep as they found it difficult to report averages. It is possible that they might be willing to record their own sleep using a sleep diary, attributing any sleep disturbance to disturbance of their relative's sleep or any other cause. However, this was not tested and the carers were not very positive about sleep diaries for their relatives.

As carer sleep is often disturbed by the person with dementia, it seems worthwhile to measure it. In order to select one measure for future trials, two instruments were used: the PSQI and the SCI. The rate of carers who filled in these questionnaires was satisfactory, with 61 (98%) of the randomised carers completing both at baseline. Fifty-six (90%) completed the PSQI at follow-up and 57 (92%) completed the SCI. The SCI gives the information to consider whether or not criteria for insomnia have been fulfilled, whereas the PSQI does not. Overall, more than half of the carers fulfilled the SCI criteria for poor sleep at baseline. In the qualitative interviews, two carers were of the opinion that the PSQI did not measure relevant features of sleep and that it was too long. They preferred the SCI to the PSQI, and we will go with their preferences.

Additional data

One individual with dementia present during the interview also suggested that it may be important to record whether or not carers and the person they care for share a bed or bedroom as part of the assessments, as this can affect how the questionnaire is answered. This would be added to an assessment for a full trial.

Power for a full trial

To calculate the sample size required for the main study, feasibility estimates were used by calculating the SD of baseline SDI scores (2.24) and the correlation between baseline and 3-month measurements (0.57). As there is no estimate of clinically significant difference, a SD of 0.4 was used, different sizes were calculated considering the CI for ICC from the earlier START study. A full study with 2 : 1 randomisation (which is feasible from the results above) will require 230–296 participants in the intervention arm and 115–148 participants in the TAU arm (assuming an average of 15 participants per therapist, 2 : 1 randomisation and a drop-out rate of $\leq$ 15%, and including an inflation for the case of non-normality).

Where to recruit participants for a full trial

It was found that memory clinics (four referrals per week from two trusts) were a better source of referrals than JDR (two consented in total). JDR would be used as an adjunct rather than as the main source of referrals for a trial.

Changes to those recruited for a full trial

Participants from a range of dementia diagnoses and living situations were recruited. It had been expected that the intervention would be delivered mainly to family carers, but consenting participants chose a complex variety of methods of delivery. Slightly fewer than half were to family members by themselves. The intervention was thus delivered to family carers, paid carers and sometimes to both. Frequently the person with dementia was also included and, in one case, half of the sessions were delivered to a person with dementia alone. Delivering the intervention with the person with dementia present, although not always problematic, did present challenges for the therapists that were addressed in clinical supervision. In a few cases, the person with dementia and the family member presented conflicting views of their sleep

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difficulties and the potential solutions and strategies. This was especially the case when the person with dementia denied that they had any difficulties with sleep and, therefore, did not see the need for making any changes. It became clear during and after the first session for the one person with dementia who had some sessions alone that they could not retain or recall the information being discussed and, therefore, were unable to make use of the sessions. In a future trial, people with dementia would not be excluded from jointly participating in the intervention sessions; however, additional training would be built in for the therapists on delivering sessions with people with dementia present and how to manage any conflict and interpersonal challenges that arose.

It was envisaged that someone with sleep disturbance and dementia would have a paid carer or family member with them at night to ensure safety. This was not always the case. When people lived alone, the carers (whether family or paid) were unable to implement strategies, for example 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. Therefore, people without a night-time carer would be excluded in a full trial. In addition, the intervention would be delivered only to people with dementia who have a carer also participating.

Families also found that making changes during the day was difficult if the person with dementia was alone during the day. This led to them being offered time switches for the light boxes. They found increasing activity if there was no one at home depended on the availability of services, such as going to a centre or having someone to take the person with dementia out. It is important to discuss this explicitly and consider the options available.

When paid carers attended the intervention, they were also able to implement strategies. Working with them may be important to allow people to remain living at home, as care agencies insist on full-day rates and two carers if the carer is disturbed frequently during the night. This may become financially non-viable and make it harder for someone with dementia to stay at home. Since it appeared feasible and is potentially useful, paid carers would be included in a full trial if people with dementia and their families wished.

People with a diagnosis of alcohol-related dementia or who were currently drinking were not excluded from the study. 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 there was also concern for the safety of our therapists visiting the homes by themselves, if the family were often absent. The participants then dropped out. Therefore, in future, anyone with current heavy drinking habits would be excluded.

It was not considered that people who were leaving the country for months or forever would be referred to the study. However, one person was leaving the UK and, although they did not fufil inclusion criteria in other ways, being in the UK for the trial and follow-up would be specified as a criterion. This would not exclude those going on holiday, only those who would be away for a period that prevented them from receiving the intervention or being assessed after the intervention.

The intervention content and delivery

Manual design and delivery

Generally carers felt that the number of sessions was appropriate and liked the balance of pictures, vignettes and text. They appreciated the direct quotations from carers. Some thought that they would continue to use the manual itself as well as strategies within it. To make it easier for participants to use the manuals in between the sessions and after the intervention, one participant's suggestion of tabs will be used.

Topics

Carers liked the information about caring for someone with dementia, the biological processes of sleep and how dementia can affect an individual's sleep, and found the diagrams helped them to understand why they should make changes, such as increasing natural light and activity, including exercise. They tried different components depending on individual needs. Many of them asked for specific help from relatives, which would continue after the study. They often made adaptations to the environment, for example putting signs on the bathroom door. Some realised that their relative got up during the night for a reason that they were able to address, which helped improve their relative's comfort and reduce their own sleep disturbance.

At session 6, all carers made a plan for the future and clearly appreciated a multimodal intervention as they wanted to continue using a range of strategies. All intended to persevere with the light box (although not necessarily in the summer) and continue to increase activity or physical exercise. Many intended to carry on with a later bedtime routine, usually going to bed around half-an-hour later than before, and continued to be aware that a comfortable bedroom is important. Most carers became more aware of looking after themselves by giving themselves time, challenging negative thoughts or using relaxation. They felt that this had improved their own quality of life and made them a better carer, and so they would continue with these self-care strategies.

The carers interviewed wanted to ensure that, in future, therapists did not go through all the content of the manual on topics that were not relevant to them, for example sections about increasing activity if the person with dementia was very active. For a full trial, it will be stated at the beginning of the sessions that not all of the topics will be relevant, and, if they are irrelevant, they will be omitted, but participants will still have the information within their manual should it later become relevant (e.g. if their relative's sleep disturbance or physical health changes, or as their dementia progresses).

The carers felt that using telecare and other assistive technology (which was often part of plans) could be further emphasised in a future trial, as this would be useful for those people with dementia alone during the day and could help manage difficult or risky behaviours.

Some carers mentioned in the qualitative interviews that they would have preferred electronic versions of the sleep diaries that were used for the actigraphy and in the intervention, and found that it was difficult to complete the next day when they had to remember when someone had been awake in the night. They suggested that the timings of the sleep diary be changed to start recording from 06:00 instead of 12:00, and day and night symbols be used to make it a lot clearer; this will be done. The research team believe that it is worth investigating the possibility of, for example, sending an automated message to prompt a carer to report information, such as bedtimes or rise times. This could be done by simply replying to the text or by writing the information in the diary.

Delivery by therapists

The therapists were clinically supervised psychology graduates who were delivering the intervention to varying combinations of carers and people with dementia. Both the participants and the PPI group felt that the therapists were taking a facilitative and supportive approach. This was essential to the therapeutic process, as it was complex for participants to overcome the barriers to helping relatives who were often unable to formulate and remember plans themselves. They valued face-to-face contact and that the strategies were delivered to them and tailored to their individual needs.

Complexity

The intervention was complex and could be individually tailored, but took only six sessions. As sleep problems are complex and diverse, this allowed it to be appropriately individualised.

Fidelity

Fidelity ratings were high, suggesting that different therapists were able to deliver the intervention consistently.

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Flexibility

The intervention was offered weekly; the median time taken to deliver the intervention was 7 weeks. Most participants thought it was ideal to have 1–2 weeks between sessions, rather than necessarily aiming for weekly sessions. Therefore, a degree of flexibility in timing would be offered for an intervention in future, allowing for the intervention to take up to 3 months.

Strengths and limitations

The trial recruited people from urban and suburban environments in London only, which is a limitation to the external validity. Although there were both male and female care recipients, men were more likely to refuse. However, people from a range of age groups and with varying types and severity of dementia, relationships to the care recipient, marital status and educational backgrounds were successfully recruited. In particular, it is often the case that ethnic minorities are under-represented in studies; this study recruited ≈35% of people of ethnic minority status. In general, the findings should have good external validity.

Although one carer commented that sleep patterns in the last 2 weeks may be atypical, the analysis of such data at a group level should eliminate any systematic bias.

A very high proportion of carers remained in the study. Although the outcome assessors were blinded to outcome, the participants were not. It is possible that there was some bias in the ratings, as some carers might have felt that they had to report a positive result to please the researcher interviewing them, who was not the therapist, but in most cases had met them for screening and baseline assessment. However, the instruments are validated, and in other studies carers have frequently reported no beneficial effect in quantitative interviews.[80] In addition, those in the intervention group were prescribed slightly less medication for sleep, suggesting that independent doctors, using family reports, may have felt that sleep had improved.

All participants who were interviewed and had completed the intervention liked it. Of the three carers who had started the intervention but not completed at least four sessions, only one could be recruited for a post-intervention qualitative interview. The researchers were trained in qualitative interview techniques, including how to make the interviewee feel comfortable and avoid leading questions. During the interviews, they emphasised to the carer that they wanted to hear suggestions for changes and what had not worked, as that would be very useful to inform further development of the intervention and the research programme. The slight reduction in the prescription of psychotropic medication also suggests that the participants were reporting some improvement to their doctors.

If the person with dementia lived alone, the sleep pattern was reported by the person with dementia, who may have had difficulties remembering it, although their ability to live alone may indicate that they were less impaired. The carer would, therefore, have been likely to report their relative's assessment and this assessment may be less reliable.

Data were gathered to enable the design of a full trial, in terms of both a power calculation and primary and secondary outcomes. The primary outcome is SDI rather than actigraphy, as had been envisaged. The results were used to calculate the numbers needed for a full trial. The clinically relevant difference in SDI score is not known, but an effect size > 0.2 is usually accepted as such.[81]

Participants were asked to wear the Actiwatch on the same wrist (most often on the non-dominant side) at baseline and follow-up, to help consistency of interpretation of results. Actigraphy interprets sleep from movement rather than measures sleep. Detection of 'sleep' is made by inference from lack of activity. The accuracy of this may vary with the population, device and circumstances. The validated sleep estimation algorithms all assume the intention to sleep, so are for people in bed around their habitual bedtime.[82] There is little validation in people with dementia, who may frequently be quite still while awake,

move around during sleep or may sleep during the day. The families thought that the person whom they looked after was sleeping better, but the actigraphy results did not support this. They also felt that the person with dementia was less sleepy during the day, but the Actiwatch may not pick this up, because the algorithms are not expected to do so.

Interpretation

A manual was coproduced in this study that shows acceptability and feasibility. Minor changes to the manual content and delivery would be made in a full trial. These comprise adding more flexibility in timing; stating at the beginning of the sessions that not all of the topics will be relevant and omitting those that are not; discussing how to get help to increase activity early on for those who are alone during the day; emphasising interventions for safety, including telecare; and adding tabs to the manual to make it easier to use. The diary design would also be improved and the possibility of sending an automated message would also be investigated, to prompt a carer to report information, such as bedtimes or rise times, by replying to the text or by writing the information in the diary.

Changes can be made to the inclusion and exclusion criteria, such as excluding those without a family or paid carer at night, those who are not staying in the UK for the period of the study or those who are currently drinking. The primary outcome (SDI) can be stated, a full trial can be powered and appropriate secondary outcomes can be chosen.

Conclusions

This acceptability and feasibility study fulfilled its primary outcomes and indicated that the SDI, which is a questionnaire measuring sleep and completed using carer information, would be a satisfactory primary outcome.

Implications for health care

There is now a feasible and acceptable manual that can be used in a future trial, and the information to design such a trial.

Recommendations for future research

The study was not powered for efficacy, but the evidence from the validated questionnaires suggested that there was potential for efficacy. However, as it cannot be certain from this indication, this is something that could be tested in a full trial. It may be appropriate to evaluate a comprehensive intervention first, with options to see how it might be delivered more cheaply after the efficacy trial. This encompasses both improving sleep disturbance and increasing the quality of life of the person with dementia, and reducing the stress on their family carer. The recruitment and retention reflect the salience and potential benefits of the intervention, which augurs well for the next step, that is, a full trial.

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The research was designed, conducted, analysed and interpreted by the authors, entirely independently of the funding sources.

Contributions of authors

Kirsi M Kinnunen (DREAMS START Study Manager and Postdoctoral Researcher specialising in dementia) assisted with the editing of the manual, trained the staff for the interviews and use of the manuals, finalised the document changes made for ethics approval, developed the Trial Master File and Case Report Form, submitted the study for Health Research Authority approval and trial registration. Kirsi M Kinnunen also prepared site information packs, wrote the standard operating procedures and policies, set up databases, liaised with research and development, Local Clinical Research Networks and the sponsor for site setup, was responsible for the day-to-day management of the trial and screened the participants for eligibility and consented them. She also gathered baseline and follow-up quantitative data, analysed the actigraphy data, contributed to the quantitative analytic plan, carried out the qualitative interviews, identified themes for the initial coding framework and wrote initial parts of the report.

Penny Rapaport (Principal Clinical Psychologist in Older People) contributed to the conception and design of the study, designed and revised the manual, trained the staff for the interviews and use of the manuals, supervised the intervention delivery, devised the qualitative interview, identified themes for the initial coding framework, supervised the qualitative analysis and wrote initial parts of the report.

Lucy Webster (DREAMS START and MARQUE Research Assistant in the Division of Psychiatry) assisted with the editing of the manual, screened the participants for eligibility and consented them, gathered baseline and follow-up quantitative data, analysed the actigraphy data, delivered the intervention, carried out the qualitative interviews, identified themes for the initial coding framework, coded the majority of the qualitative interviews and wrote initial parts of the report.

Julie Barber (Senior Lecturer in Medical Statistics) contributed to the conception and design of the study, drafted the quantitative analytic plan, analysed the quantitative data and wrote initial parts of the report.

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Simon D Kyle (Senior Research Fellow in Sleep Disorders) contributed to the conception and design of the study, designed and revised the manual and contributed to the quantitative analytic plan.

Brendan Hallam (DREAMS START Research Assistant in the Division of Psychiatry) assisted with the editing of the manual, screened the participants for eligibility and consented them, gathered baseline and follow-up quantitative data, analysed the actigraphy data, delivered the intervention, carried out the qualitative interviews and identified themes for the initial coding framework.

Claudia Cooper (Clinical Reader in Psychiatry) contributed to the conception and design of the study, designed and revised the manual, trained the staff for the interviews and use of the manuals and contributed to the quantitative analytic plan.

Rossana Horsley (Alzheimer's Society Research Network Member) contributed to the conception and design of the study, commented on the manual and led the PPI contribution.

James A Pickett (Head of Research at Alzheimer's Society) commented on the manual and co-ordinated the PPI contribution.

Anastasia Vikhanova (DREAMS START Research Intern) coded the majority of the qualitative interviews.

Colin A Espie (Professor of Sleep Medicine) contributed to the conception and design of the study.

Gill Livingston (Professor of Psychiatry of Older People) wrote the application and protocol, acted as chief investigator, contributed to the conception and design of the study, designed and revised the manual, trained the staff for the interviews and use of the manuals, wrote the ethics application and submitted it, contributed to the quantitative analytic plan, devised the qualitative interview, identified themes for the initial coding framework, wrote initial parts of the report and acts as guarantor.

All authors revised the report critically for important intellectual content and gave final approval of the version to be published.

Publications

Kinnunen KM, Vikhanova A, Livingston G. The management of sleep disorders in dementia: an update. *Curr Opin Psychiatry* 2017;**30**:491–7.

Livingston G, Barber JA, Kinnunen KM, Webster L, Kyle SD, Cooper C, *et al.* DREAMS-START (Dementia RElAted Manual for Sleep; STrAtegies for RelaTives) for people with dementia and sleep disturbances: a single-blind feasibility and acceptability randomised controlled trial. *Int Psychogeriatric* 2018;**17**:1–15.

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

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Appendix 1 Ethics approval

NHS
Health Research Authority

National Research Ethics Service

London - Queen Square Research Ethics Committee

[redacted]

29 April 2016

Professor Gill
Livingston UCL

Division of psychiatry

[redacted]

Dear Professor Livingston

Study title:	**DREAMS START (Dementia Related Manual for Sleep; Strategies for Relatives)**
REC reference:	**16/LO/0670**
Protocol number:	**1**
IRAS project ID:	**199820**

The Research Ethics Committee reviewed the above application at the meeting held on 21 April 2016.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Rachel Heron, nrescommittee.londonqueensquare@nhs.net Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

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Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Mental Capacity Act 2005

I confirm that the Committee has approved this research project for the purposes of the Mental Capacity Act 2005. The Committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

A Research Ethics Committee established by the Health Research Authority

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

1. Participant Information Sheets

    a) The block of text under 'what is the purpose of the study' should be broken up with space between paragraphs and possibly a sub-heading (ie 'Outline of Procedures') to make it easier to read.

    b) Please check the grammar in the following sentences: 'If you agree, you or your relative will be asked to sign a consent' (form?) and 'you can ask o move' (under the heading 'What are the possible disadvantages to taking part?')

    c) Please provide complete contact telephone number for Professor Livingstone.

    d) Please ensure that all information sheets contain information about the destruction of audio recordings.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

Clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

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Non NHS sites

The Committee has not yet completed any site-specific assessment(s) (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Summary of discussion at the meeting

Dr Claudia Cooper was welcomed to the meeting. She was advised that an observer was present, and raised no objection.

Social or scientific value; scientific design and conduct of the study

Relevance of the research to the impairing condition

The Committee agreed the research is connected with an impairing condition affecting persons lacking capacity or with the treatment of the condition.

Justification for including adults lacking capacity to meet the research objectives

The Committee agreed the research could not be carried out as effectively if it was confined to participants able to give consent.

was agreed that a representative sample could not be achieved without including those patients with dementia who had lost capacity

The Committee noted that the intervention manual was not yet developed and asked about the progress of this. *Dr Cooper advised that it was 80% complete but would be 'tweaked' as the study progressed. On request, she had provided a draft version of the manual for review.*

The Committee asked about randomisation of participants, or whether they would be matched for any characteristics.

Dr Cooper stated that allocation to study groups would be random, as befitted a pilot study.

She had a query for the Committee, which was whether it would be acceptable to provide the actigraph data to the Control group (as they had worn it for the trial and it would seem unfair not to provide the data). She advised that they would provide simple feedback with a contact number in case the participant wished to discuss them.

In discussion after Dr Cooper had left the meeting the Committee agreed that this would be acceptable.

The Committee discussed whether there was enough information in the Draft manual and in the information sheets to approve the study, and agreed that there was.

Recruitment arrangements and access to health information, and fair participant selection

The Committee raised the possibility that carers would potentially benefit from this research, and therefore may allow their own interests to over-ride those of their relatives. The Committee asked Dr Cooper her view on whether the carer was the most appropriate consultee in this situation.

Dr Cooper stated that the carer would have a vested interest in the health of their relative, and was emphatic that she did not consider this to be a problem.

Arrangements for appointing consultees

The Committee considered the arrangements set out in the application for appointing consultees under Section 32 of the Mental Capacity Act to advise on whether participants lacking capacity should take part and on what their wishes and feelings would be likely to be if they had capacity.

After discussion the Committee agreed that reasonable arrangements were in place for identifying personal consultees and for nominated consultees independent of the project where no person can be identified to act as a personal consultee.

The Committee agreed that procedures in place were adequate and that the procedures were not burdensome for the person lacking capacity

Favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future)

The Committee asked for a description of the intervention, as this had not been clear in the application*. Dr Cooper explained that the intervention involved a psychology graduate meeting with the family carer, to take them through the manual. This would involve completing exercises, talking about the background to the sleep problems, and the additional reasons ie melatonin production in dementia. The difficulties caused for the carer by the sleep disturbance would be discussed. Homework would be given in between this and the second session, which would use CBT principles in taking to the carer. The data from the Actigraph would be used in this session. This process was still under development.*

Dr Cooper explained that although the CBT intervention was not delivered by experts, the graduates would be supervised by experts. Other tactics would be used such as daylight and engaging the person in activities they enjoyed. This was part of the manual which was still under development.

Balance between benefit and risk, burden and intrusion

The Committee noted that while the research would not benefit participants lacking capacity it is intended to provide knowledge of the causes or the treatment or care of sleep disturbance in dementia. After discussion, the Committee agreed that the risk to participants is likely to be negligible and the research will not significantly interfere with their freedom of action or privacy or be unduly invasive or restrictive.

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The Committee did note that the intervention would be likely to benefit carers of those with sleep disturbance in dementia, and that the benefit for the individual with dementia was less clear, however it was agreed that the research was not unduly invasive or restrictive and had the potential to benefit participants.

The Committee decided that the research did not require Site-Specific Assessment at non-NHS sites as it involves no clinical interventions and all study procedures at sites would be undertaken by the Chief Investigator's team and the Committee was satisfied that the risk to participants is likely to be negligible.

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

The Committee asked who was responsible for assessing capacity.

Dr Cooper responded that this would be the person taking consent. In response to another question from the Committee, she advised that it would be unusual for anyone to lose capacity during the 3 month trial, but if they did the MCA procedures would be followed and they would seek a consultee.

Additional safeguards

The Committee was satisfied that reasonable arrangements would be in place to comply with the additional safeguards set out in Section 33 of the Mental Capacity Act.

Informed consent process and the adequacy and completeness of participant information

Information for consultees

The Committee reviewed the information to be provided to consultees about the proposed research and their role and responsibilities as a consultee.

The Committee considered that the information was not adequate for the following reasons: and requested the following changes:

The Committee noted that the text was continual and this made it hard to read. The Committee agreed that the blocks of text needed to be broken up. The Committee also noted that only one of the information sheets explained the process for destroying audio recordings – this needed to be on all of the information sheets. Both of these points applied

to all information sheets, and not only the consultee information. The Committee agreed that the consultee information was otherwise satisfactory.

Other ethical issues were raised and resolved in preliminary discussion before her attendance at the meeting.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UCL Insurance certificate 2015-2016]	NA	13 July 2015
GP/consultant information sheets or letters [Letter to GP and trust health professional DREAMS]	1	01 February 2016
Interview schedules or topic guides for participants [Interview guide focus groups 1 DREAMS]	1	01 February 2016
Interview schedules or topic guides for participants [Individual interview guide DREAMS]	1	01 February 2016
IRAS Checklist XML [Checklist_04042016]		04 April 2016
Letter from funder [Agree to fund letter]		14 December 2015
Non-validated questionnaire [Patient demographics]	1	01 February 2016
Non-validated questionnaire [Family carer demographics]	1	01 February 2016
Non-validated questionnaire [DREAMS side effects]		
Other [Dreams session 1 draft manual]	1	30 March 2016
Other [Dreams draft manual session 2]	1	30 March 2016
Other [Dreams draft manual session 3]	1	30 March 2016
Participant consent form [Consent form DREAMS RCT focus groups]	1	01 February 2016
Participant consent form [Consent form DREAMSpatients]	1	01 February 2016
Participant consent form [Consultee declaration form DREAMS]	1	01 February 2016
Participant consent form [Consent form DREAMS RCT relatives]	1	01 February 2016
Participant information sheet (PIS) [PIS DREAMS patient v1 01.02.2016]	1	01 February 2016
Participant information sheet (PIS) [PIS DREAMS relatives v1]	1	01 February 2016
Participant information sheet (PIS) [PIS DREAMS consultee version1 01.02.2016]	1	01 February 2016
Participant information sheet (PIS) [PIS DREAMS AS focus groups v1 01.02.2016]	1	01 February 2016
REC Application Form [REC_Form_24032016]		24 March 2016
REC Application Form [REC_Form_04042016]		04 April 2016
Referee's report or other scientific critique report [referees comments shortlisting]		19 March 2015
Referee's report or other scientific critique report [referees from HTA full application]		
Research protocol or project proposal [DREAMS START (Dementia Related Manual for Sleep; Strategies for Relatives) feasibility and pilot study]	1	20 January 2016
Summary CV for Chief Investigator (CI) [Short CV GL 2016]	NA	23 March 2016
Validated questionnaire [caregiver HSQ]	NA	
Validated questionnaire [CSRI DREAMS]	1	23 March 2016
Validated questionnaire [DEMQOLproxy family carer]	NA	
Validated questionnaire [Zarit interview]	NA	
Validated questionnaire [Neuroepworth sleep scale]		

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Validated questionnaire [Neuropsychiatric Inventory]		
Validated questionnaire [HADS]		
Validated questionnaire [Pittsburgh Sleep quality Index]		
Validated questionnaire [Sleep disorders Inventory]		
Validated questionnaire [The sleep condition indicator]		

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting

requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

16/LO/0670	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project. Yours sincerely

[redacted]

Signed on behalf of

Dr Eamonn Walsh Chair

E-mail: nrescommittee.london-queensquare@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers" [SL-AR2 for other studies]

Copy to: *Smaragda Agathou*

Ms Lynis Lewis, NoCLoR

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London - Queen Square Research Ethics Committee

Attendance at Committee meeting on 21 April 2016

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Yogi Amin	Consultant in Neuroanaesthesia & Neurocritical Care	No	
Miriamtha Dahdal	Teaching Assistant	No	
Dr Simon Eaton	Senior Lecturer in Paediatric Surgery and Metabolic Biochemistry	Yes	
Miss Sarah Gregory	Clinical Research Officer	No	
Dr Katie Harron	Statistician	No	
Dr Khalil Hassanally	GP	No	
Mrs Jenny Johnson	Charity Trustee	Yes	
Eleanor Rose Lee-Millais	Nurse	Yes	
Dr Lorraine Ludman	Chartered Psychologist	Yes	
Mrs Claire Reynolds	Radiotherapy Radiographer	No	
Miss Sheetal Sumaria	Pharmacist	Yes	
Dr Eamonn Walsh	Lecturer	Yes	
Mr Jonathan Watkins	Social Worker	No	
Ms Danielle Wilson	Clinical Trials Facility Manager	Yes	
Miss Zalika Xavier	Vaccine Sales Representative	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Rachel Heron	REC Manager

NHS
Health Research Authority

National Research Ethics Service

London - Queen Square Research Ethics Committee

[redacted]

09 May 2016

Prof Gill Livingston

UCL

Division of psychiatry

[redacted]

Dear Prof Livingston

Study title:	**DREAMS START (Dementia Related Manual for Sleep; Strategies for Relatives)**
REC reference:	**16/LO/0670**
Protocol number:	**1**
IRAS project ID:	**199820**

Thank you for your letter of 9 May 2016. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 29 April 2016

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Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant information sheet (PIS) [PIS DREAMS patient v1.1 06.05.2016]	1.1	06 May 2016
Participant information sheet (PIS) [PIS DREAMS relatives v1.1 06.05.2016]	1.1	06 May 2016
Participant information sheet (PIS) [PIS DREAMS consultee v1.1 06.05.2016]	1.1	06 May 2016
Participant information sheet (PIS) [PIS DREAMS AS focus groups v1.1 06.05.2016]	1.1	06 May 2016

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors	NA	13 July 2015
only) [UCL Insurance certificate 2015-2016]		
GP/consultant information sheets or letters [Letter to GP and trust health professional DREAMS]	1	01 February 2016
Interview schedules or topic guides for participants [Interview guide focus groups 1 DREAMS]	1	01 February 2016
Interview schedules or topic guides for participants [Individual interview guide DREAMS]	1	01 February 2016
IRAS Checklist XML [Checklist_06052016]		06 May 2016
Letter from funder [Agree to fund letter]		14 December 2015
Non-validated questionnaire [Patient demographics]	1	01 February 2016
Non-validated questionnaire [Family carer demographics]	1	01 February 2016
Non-validated questionnaire [DREAMS side effects]		
Other [Dreams session 1 draft manual]	1	30 March 2016
Other [Dreams draft manual session 2]	1	30 March 2016
Other [Dreams draft manual session 3]	1	30 March 2016
Participant consent form [Consent form DREAMS RCT focus groups]	1	01 February 2016
Participant consent form [Consent form DREAMS patients]	1	01 February 2016
Participant consent form [Consultee declaration form DREAMS]	1	01 February 2016
Participant consent form [Consent form DREAMS RCT relatives]	1	01 February 2016
Participant information sheet (PIS) [PIS DREAMS patient v1.1 06.05.2016]	1.1	06 May 2016
Participant information sheet (PIS) [PIS DREAMS relatives v1.1 06.05.2016]	1.1	06 May 2016
Participant information sheet (PIS) [PIS DREAMS consultee v1.1 06.05.2016]	1.1	06 May 2016
Participant information sheet (PIS) [PIS DREAMS AS focus groups v1.1 06.05.2016]	1.1	06 May 2016
REC Application Form [REC_Form_24032016]		24 March 2016
REC Application Form [REC_Form_04042016]		04 April 2016
Referee's report or other scientific critique report [referees comments shortlisting]		19 March 2015

Referee's report or other scientific critique report [referees from HTA full application]		
Research protocol or project proposal [DREAMS START (Dementia Related Manual for Sleep; Strategies for Relatives) feasibility and pilot study]	1	20 January 2016
Summary CV for Chief Investigator (CI) [Short CV GL 2016]	NA	23 March 2016
Validated questionnaire [caregiver HSQ]	NA	
Validated questionnaire [CSRI DREAMS]	1	23 March 2016
Validated questionnaire [DEMQOLproxy family carer]	NA	
Validated questionnaire [Zarit interview]	NA	
Validated questionnaire [Neuroepworth sleep scale]		
Validated questionnaire [Neuropsychiatric Inventory]		
Validated questionnaire [HADS]		
Validated questionnaire [Pittsburgh Sleep quality Index]		
Validated questionnaire [Sleep disorders Inventory]		
Validated questionnaire [The sleep condition indicator]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

16/LO/0670 **Please quote this number on all correspondence**

Yours sincerely

[redacted]

Rachel Heron
REC Manager

E-mail: nrescommittee.london-queensquare@nhs.net

Copy to: *Smaragda Agathou*

Ms Lynis Lewis, NoCLoR

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Appendix 2 Safety and tolerability assessment

1

DREAMS SIDE EFFECTS

Has the patient had any of the following **in the past three months**? Please circle the appropriate answer and if the answer is **YES**, circle one of:

Mild: intervention not indicated

Moderate: intervention indicated

Severe: needs hospitalisation

1. Falls (P_SE1_B)

YES ☐ NO ☐

If YES (P_SE1s_B): Mild ☐ Moderate ☐ Severe ☐

2. Other comorbid physical illnesses

2a. Gastrointestinal (diarrhoea, nausea, sore mouth, vomiting) (P_SE2a_B)

YES ☐ NO ☐

If YES (P_SE2as_B): Mild ☐ Moderate ☐ Severe ☐

2b. Neurological (headache,visual/auditory disturbances, dizziness) (P_SE2b_B)

YES ☐ NO ☐

If YES (P_SE2bs_B): Mild ☐ Moderate ☐ Severe ☐

2c. Infections (P_SE2c_B)

YES ☐ NO ☐

If YES (P_SE2cs_B): Mild ☐ Moderate ☐ Severe ☐

2d. Has the patient developed any other side effects? (P_SE2d_B) YES ☐ NO ☐

If YES, what were these side-effects:_____
_____

_____

Any further comments_____
_____

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Appendix 3 Actiwatch instructions and sleep diary

The image of the Actigraph watch (MotionWatch8) has been reproduced with permission from CamNtech Ltd, Cambridge, UK.

Actigraph-Watch Instructions

(MotionWatch 8)



- We would like you to wear this watch-like device, called an **acti-watch**. The watch will measure your sleep-wake pattern by detecting movement.
- We would like you to wear the watch on the opposite wrist from the one you write with, **24 hours a day for the next 2 weeks**.
- The watch also contains a light sensor, which measures the light intensity wherever you are. It is ideal that the watch **is not covered by a sleeve or jacket**. (However, your personal comfort is more important especially during colder temperatures so do not worry if the watch gets covered).
- The **watch can be worn whilst showering and washing up** (and any other 'wet activities'), though you can take it off if you don't wish to get the watch wet. If you do take it off please remember to put your watch back on afterwards.
- If the watch has been off the wrist for more than an hour, then **please write down** when this happened.
- The **button** should be pressed in bed (before attempting to sleep) and when getting out of bed (no longer attempting to sleep). A **red light** should flash when you press this button.

If you have any problems using the acti-watch, please contact _____ who gave you the watch on: _____

Many thanks.

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NIHR Journals Library www.journalslibrary.nihr.ac.uk

Sleep Diary

Day	Got up (for the last time in the morning)	Bed time (for the first time in the evening)	Nap(s) during the day
Example: Sunday 3rd July	*7:45am*	*10:15pm*	*1pm to 1:30pm*

Appendix 4 Focus group interview schedules

DREAMS START (Dementia Related Manual for Sleep; Strategies for Relatives) feasibility and pilot study: focus group feedback on intervention manual for development

Introductions

Thank you for agreeing to take part in this group. My name is . . . . As you know, I am a researcher from UCL and I will conduct and record this focus group. Everything you say is confidential but I would like you to introduce yourselves so that the typist can identify you.

Description of the research

We are in the process of developing a manual, which, over the next year, we are going to be testing out with people with dementia and their family carers as part of a trial. It will be delivered to individuals at home, and we hope that it will help with sleep and lead to improvement in quality of life for people with dementia and their families. The intervention will be based on what we know works from research and practice with people who do not have dementia and on our specialist research and clinical knowledge of people with dementia and their families.

Before we finalise the intervention, we want to hear your views and opinions about what we have developed, and then make further changes to the intervention manual. We are asking you because we know that you have responded to the Alzheimer's Society invitation as this is something you are interested in and probably have experience of. We want to make use of your expertise.

Sleep difficulties/current understandings

Question (Q). Could you tell us about any sleep difficulties that your relative experiences?

- What do you notice happening at night and during the day?
- What effect do these problems have on you and your relative?
- How do you understand what may be causing these sleep difficulties for your relative?
- Which sleep difficulties do you find most difficult to manage?
- What has worked well in managing sleep difficulties?
- What have you tried?
- What has not worked well?

We are particularly interested in how to make the manual practical and to fit in with people's lives.

Introduce the manual

Show them the draft manual/structure and present an overall summary.

- People with dementia and their families will receive their own copy of the manual to write in and keep.
- They will wear an actigraph (special watch) to see how their sleep rhythms are.
- There will be practical suggestions to try out between sessions.
- There will be one member of staff working with the person with dementia and their family.
- The manual contains information about sleep and dementia.
- Each session will include a combination of information giving, discussion and making an individualised plan with practical exercises, including increasing light at particular times and increasing activity.
- There will be a relaxation exercise and people will be given a relaxation CD or MP3 files.
- Each session will be around 1 hour.
- The staff member delivering the intervention will be supervised by a clinical psychologist and their general practitioner (GP) and memory service team will know that they are in the study.

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The sessions of the DREAMS intervention comprise the following:

- Learning about sleep and dementia.
- Relaxation and bedroom comfort/pre-bed and mealtime routine.
- Using natural light, morning wake-up light.
- Pleasant activities.
- Management of daytime naps.
- Relaxation, especially at night.
- What works? Using skills and strategies in the future.

Give them a few minutes to look through and make any general comments. These prompts are only if not already covered. (Explain that this is only a draft/outline).

Q. What are your initial thoughts on the manual?

Q. What do you think about the design of the manual?

Prompts:

- How do you find the layout?
- Is it easy to read and follow, for example not too much text on each page/fonts/colours?
- What do you think of the pictures and images – more, less, different?
- How do you find the balance of information-giving and discussion?

Q. What do you think about the outline structure and content of the sessions?

Prompts:

- Do the topics and examples fit with what your experience is or has been?
- Is there anything important that you feel is missing?
- Does the order of the sessions make sense?
- Is it pitched at the right level for a range of people?
- Is it easy to understand?
- Do the key points stand out?

Q. Do you have any other feedback regarding layout, design, content, etc.?

Q. What do you think might make it harder for people to participate in the sessions and use the manual? (Prompt about wearing actigraph, using light box, increasing activities.)

Q. What do you think might make it easier for people to participate in the sessions and use the manual? (Prompt about wearing actigraph, using light box, increasing activities.)

Q. Before we finish, is there anything else you would like to mention that we have not already covered?

Thank you for taking part today.

DREAMS START virtual/e-mail reference group (July 2016)

- Seven participants.
- Each sent different sections (two) of the manual; two participants sent the full manual (Trial Steering Committee members).

- Four questions via e-mail:
  - What do you think about the design? For example, how do you find the layout? Is it easy to read and follow, for example not too much text on each page/fonts/colours? What do you think of the pictures and images – more, less, different?
  - What do you think about the content? For example, is it easy to understand? Do the key points stand out? Do the topics and examples fit with what your experience is or has been? Is there anything important that you feel is missing? Is it pitched at the right level for a range of people?
  - How do you find the balance of information-giving and discussion?
  - Any other feedback (layout, design, content, acceptability of intervention, etc.)?

DREAMS START feasibility and pilot study: focus group with family carers post intervention

Introductions

Thank you for agreeing to take part in this group. My name is . . . . As you know, I am a researcher from UCL and I will conduct and record this interview. Everything you say is confidential but I would like you to introduce yourselves so that the typist can identify you.

Description of the research

We have now completed the feasibility and pilot study of the DREAMS START intervention and wanted to meet with you all today to discuss our findings and any potential changes to the manual in the future. Before we begin talking, we will briefly tell you about the final version of the manual we used in the study and how we delivered it and then XXX will tell you about how the study has gone and what the people who received the intervention told us about how they found it.

Following our discussion today and based on the findings of the study so far, we will probably make further changes to the manual and how we deliver it, which we will hopefully test in a randomised controlled trial in the future. Therefore, we want to hear your views and opinions about what we have developed and tested and how it could be improved before further testing.

Revisiting the manual

Show them the manual used in the study and present an overall summary (present summary slides of content and process).

- People with dementia and their families received their own copy of the manual to write in and keep.
- They wore an actigraph (special watch) to see how their sleep rhythms were.
- There were practical suggestions to try out between sessions.
- There was one member of staff working with the person with dementia and their family.
- The manual contained some information about sleep in dementia.
- Each session included a combination of information-giving, discussion, looking at the results of the sleep actigraph from the week before and practical exercises, including increasing light at particular times and increasing activity.
- There were relaxation exercises and people were given relaxation CD or MP3 files.
- Each session was around 1 hour.
- The staff members delivering the intervention were supervised by a clinical psychologist, and the participant's GP and memory service team will know that they are in the study.

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The sessions of the DREAM intervention include the following:

- Learning about sleep and dementia.
- The importance of routine pre bed and at mealtimes.
- Relaxation and bedroom comfort.
- Using natural light, morning wake-up light.
- Pleasant activities.
- Management of daytime naps.
- Relaxation, especially at night.
- What works? Using skills and strategies in the future.

Give them a few minutes to look through and make any general comments. These prompts are only if not already covered.

Q. What are your initial thoughts on the manual we used?

What do you think about the design of the manual?

Prompts:

- How do you find the layout?
- Is it easy to read and follow, for example not too much text on each page/fonts/colours?
- How do you find the quotes? Prompts relevance, length.
- What do you think of the pictures and images – more, less, different?
- How do you find the balance of information-giving and discussion?

Q. What do you think about the content of the sessions?

Prompts:

- Do the topics and examples fit with what your experience is or has been?
- Is there anything important that you feel is missing?
- Is it pitched at the right level for a range of people?
- Is it easy to understand?
- Do the key points stand out?

Q. What do you think about the structure of the sessions?

Prompts:

- Does the order of sessions make sense?
- What do you think about the length of each session?
- Is there anything else we could do to make it easier to understand?
- What do you think about having relaxation and homework in each session?
- Do you think it is better to give out the manual session by session or all at once?

Brief presentation of findings to date:

- What are your first thoughts on the findings?
- Did anything surprise you that you heard?
- What do you think we could do to address some of the barriers raised? *(Put up slide about what made it harder?)*

- Do you have any suggestions about how to make it easier for people to make use of DREAMS START? *(Put up slide about what made it easier?)*
- Based on what you have heard today, do you have any other suggestions about changes we could make to the design/content/structure and process the sessions?

Q. Before we finish, is there anything else you would like to mention that we have not already covered?

Thank you for taking part today.

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Appendix 5 Final version of the DREAMS START manual: carer and facilitator versions

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DREAMS: START

Dementia Related Manual for Sleep:

Strategies for Relatives



Session 1 Version 1

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UCL Division of Psychiatry
6th Floor Maple House
149 Tottenham Court Road
London W1T 7NF
United Kingdom

Session 1 Version 1

Introduction

- This is your manual to use.
- These sessions are about you, your relative and how sleep problems affect you both.
- They are based on **what has been shown to work**, and **what we know about people with dementia and with sleep problems**.
- Over the next few weeks we will work together to:
    - Understand your relative's sleep pattern
    - Try out new strategies to help
    - Use information about sleep problems in dementia
    - Develop a regular sleep pattern for your relative and help you sleep too
- You may feel **'I have tried it all before'** and you are probably already using some of the strategies. We hope to build on what you do now and introduce new ideas, doing more of what works and less of what does not.

Key Point:
Although not all difficulties will change. Putting what you learn in DREAMS: START into practice should make things better.

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What to expect

- Our discussions will be based on **you and your relative's experiences**.
- We will make a plan together to improve sleep **based on** the particular challenges you and your relative face, as with sleep, it is not 'one size fits all'.
- You will **put strategies into practice** during, and between sessions.

There will be six sessions each lasting **one hour and each will include:**

- A new topic to discuss.
- Making a plan for you to try out between sessions.
- A new way of reducing stress for you and your relative.
- Ways to monitor progress between sessions.

DREAMS: START

Session 1: Understanding sleep and dementia
Session 2: Making a plan
Session 3: Daytime activity and routine
Session 4: Difficult night-time behaviours
Session 5: Taking care of your own sleep
Session 6: What works? Using strategies in the future

Session 1 Version 1

DREAMS: START

Session 1:

Understanding sleep and dementia



Session 1 Version 1

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Plan for today

Sleep and dementia	p. 7
What is sleep?	p. 8
What causes sleep problems in dementia?	p. 12
Making changes to improve sleep	p. 13
The impact of sleep problems on you and your relative	p. 20
Managing the stress that sleep problems can bring	p. 21
Managing stress: The signal breath	p. 22
Summary	p. 24
Putting it into practice	p. 25

Sleep and dementia

Talking point:

Tell me about your relative's sleep problems?

- Sleep disturbance is very common in dementia. 50-90% of people with dementia have disturbed sleep at some point.
- Sleep difficulties can often start several years before being diagnosed with dementia and worsen as dementia becomes more severe.
- Some of the difficulties that you may see happening include:

☐ Waking up several times during the night, often confused

☐ Waking up too early

☐ Being very sleepy or falling asleep during the day

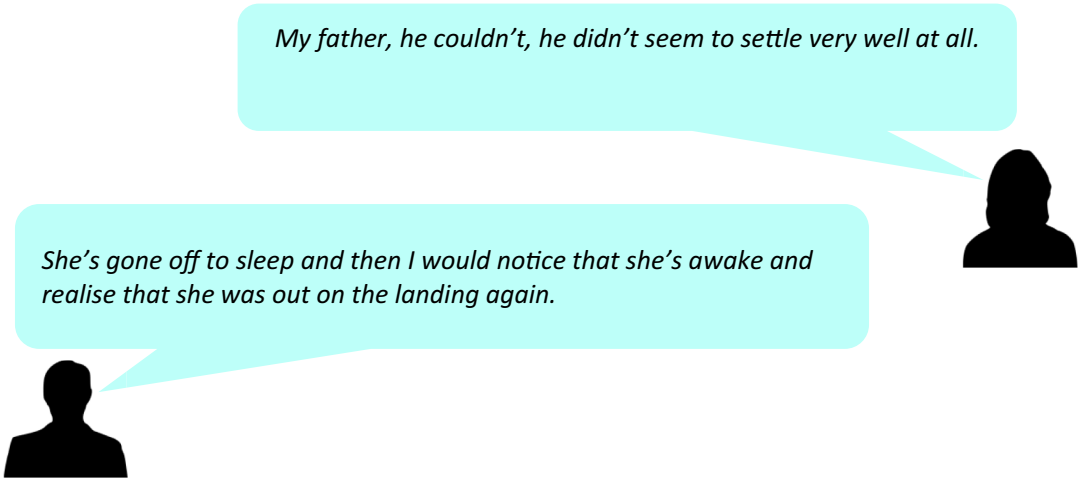
☐ Having a disturbed sleep pattern e.g. asleep during the day and awake at night

☐ Agitation or restlessness in the evening or at night

☐ Difficulty falling asleep

☐ Pacing or wandering

☐ Other_____



Session 1 Version 1

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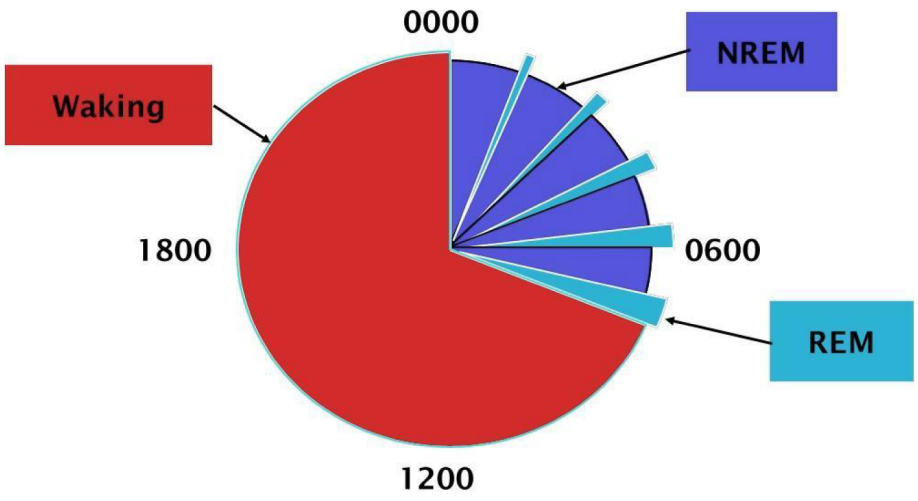
What is sleep?

Talking point:

What do you notice happening to you and your relative when you don't get a good night's sleep?

- Sleep is an important time for us to refresh our brain and body.
- The sleeping brain is not simply in "off-mode", but instead goes through various stages of sleep. Throughout the night we move between two types of sleep:
    - Non-REM (NREM) sleep happens more at the beginning of the night consisting of phases of light and deep sleep. When in the deepest sleep, we are harder to wake up.
    - REM (rapid-eye movement) sleep happens later in the night; here we experience brief bursts of eye movements and dream.
- The brain's 'sleep cycles' each last about 90 minutes, and move from NREM to REM sleep. Good sleepers typically have 4-5 sleep cycles each night.



A typical sleep-wake cycle for someone going to bed at midnight and getting up at 7am

How does sleep work?

- Sleep is automatic and controlled by two processes which work together so that we sleep well at night. These are:

    1. The Circadian Rhythm or 'the body clock'
    2. 'Sleep pressure'

Circadian rhythm

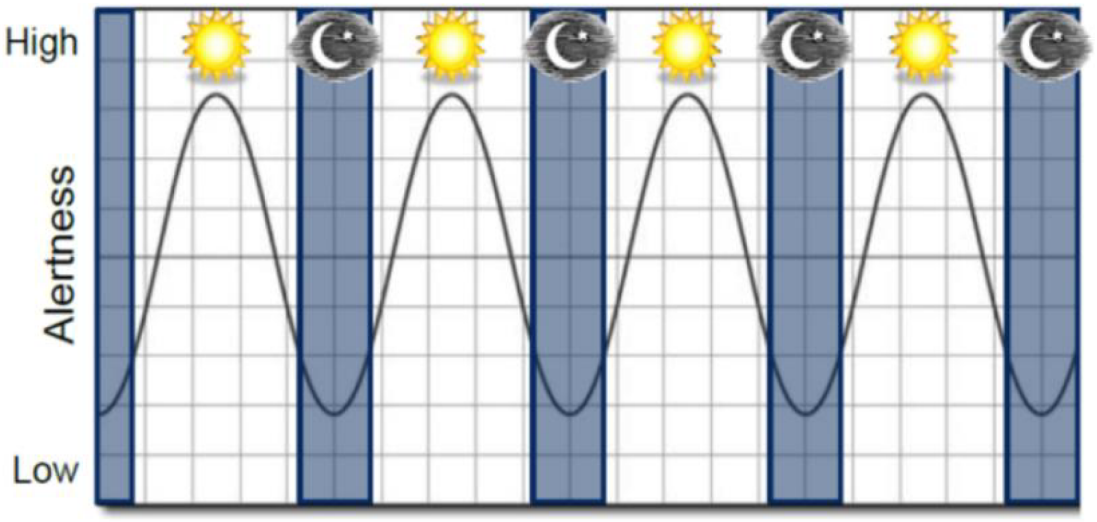
- Circadian rhythm is our body clock which helps us to make sense of our environment, for example when it will be light or dark. This shows our brains and bodies *when* and *how much to sleep*.

- The brain controls the body clock.

- When we sleep well at night, our body clock creates a balance and we feel refreshed and alert in the day.

- There are times when our body clock gets 'out of sync', for example, when jet-lagged.

- A good sleeper with a regular pattern will get up early in the morning feeling wide awake. This peaks around midday. After a 'post lunch dip' our wakefulness continues to fall until bedtime and sleep.



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- Dementia can affect the part of the brain that controls our ‘body clock’.
- This can make people more alert or active at night and less alert or active during the day.
- Reduced physical activity, irregular meal times, and reduced exposure to natural sunlight can disrupt the “body clock” so that they wake more at night.
- Light, exercise and food all play a role in helping the brain and body to understand what time of day it is, allowing the brain to work out when it should be awake or asleep.

Key Point:

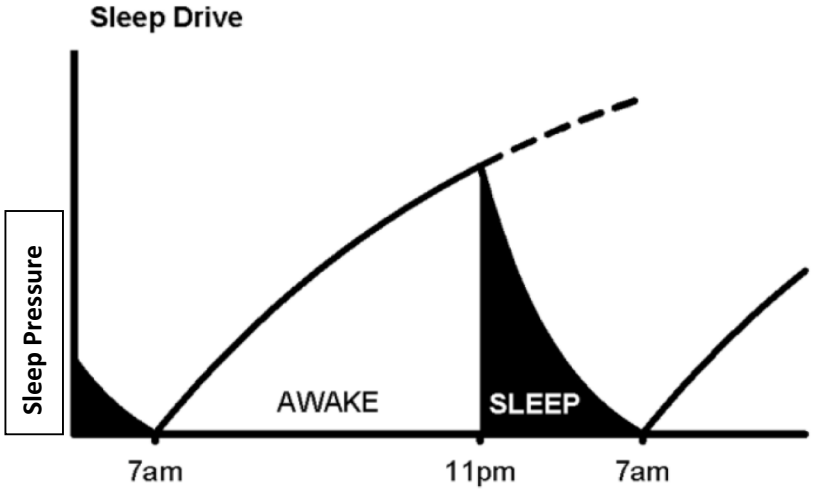
People with dementia often have a disrupted body clock which makes it harder to know when it is day or night



Session 1 Version 1

Sleep pressure

- 'Sleep pressure' is the brain's need for sleep. It increases the longer you are awake.
- When we wake up in the morning after a good night's sleep, we will have a very low sleep pressure. Sleep pressure will increase during the day until bedtime.
- By going to bed and having a good night's sleep, then sleep pressure will be reset for the start of the next day.
- So, at bed time, the 'sleep pressure' is at its highest, creating the perfect opportunity for sleep.



Why is sleep important?

- When we do not get enough sleep, our concentration, mood and memory is affected.
- We also know that people who have poor sleep over long periods of time are more likely to get health problems like cardiovascular disease and diabetes.
- Going to bed and getting up at the same times each day, makes us more likely to experience good quality sleep and therefore be awake, active and healthy during the day.

Talking point:

Did your relative have problems sleeping before the diagnosis, if so, what helped then?

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What causes sleep problems in dementia?

Talking point:

People often have thoughts about what could be causing sleep problems in their relatives, is this something that you have thought about? What ideas have you had?

There are many reasons why sleep patterns are disturbed in dementia. Some changes occur as we become older and may affect you and your relative:

- ☐ Having more physical health problems, including pain
- ☐ Spending less time in deep restorative sleep and more time in lighter sleep
- ☐ Needing to go to the toilet more in the night
- ☐ Side effects of medication
- ☐ Not being active / napping during the day
- ☐ Not being in daylight
- ☐ Being confused about night and day
- ☐ Being frightened at night
- ☐ Going to bed very early and then waking up early



Session 1 Version 1

Making changes to improve sleep

- In our next session we will develop a plan to help you manage your relative's sleep difficulties based on the Actigraph information (wrist watch they wore), sleep diaries and our discussions today.

- In the meantime we will look at changes to your relative's lifestyle that can improve sleep.

Lifestyle factors that can impact on sleep:



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Caffeine

- Caffeine perks you up and it can be good to have in the morning to help wake up!
- Most people know caffeine is in coffee and tea, but it's also in chocolate, some soft drinks (i.e. coke), and also in some medicines. Check labels if you are not sure.
- If someone naps during the day or goes to bed early in the evening, having caffeine up until 6pm may help them to stay awake during early evening.
- However caffeine's effects can last for many hours so it is a good idea not to give your relative any caffeine for 4 to 6 hours before bedtime, or even the middle of night. Try decaffeinated drinks.



Alcohol

- Alcohol can disrupt sleep and may make your relative more confused or likely to fall.
- Alcohol may help people fall into a deep sleep at the beginning of the night, but it will then lead to disturbed sleep later in the night.
- Limit it to one small glass of wine or half a pint of beer. Do not drink a lot of alcohol in the evening.



Nicotine

- Nicotine in cigarettes has effects like caffeine on sleep, making it harder to fall asleep and to stay asleep.
- If you or your relative smoke, try to cut down in the evening before you go to bed, and try not to smoke at all during the night.

Diet



- Hunger can wake people, so a light snack a little before bedtime can help sleep, but going to bed too full can disturb sleep.
- It may be true that milk and other dairy products help to promote sleep and, usually, makes people less hungry.
- Try to avoid giving your relative snacks during the middle of the night as the body may come to expect food at this time and it will get in the way of having a good day and night pattern.



Exercise

- People who are physically active have a better quality of sleep, so a good way to promote sleep is to get active, by exercising three times a week for 20-30 minutes!
- The type of exercise you and your relative do really depends on what you enjoy and your ability. We will be talking more about activities in future sessions.



Pain

- Although pain is not a lifestyle factor it can interfere with sleep, and your relative may not be able to tell you if they are in pain.
- Do you feel your relative is in pain? If so, what do you do to manage the pain? And does it help?

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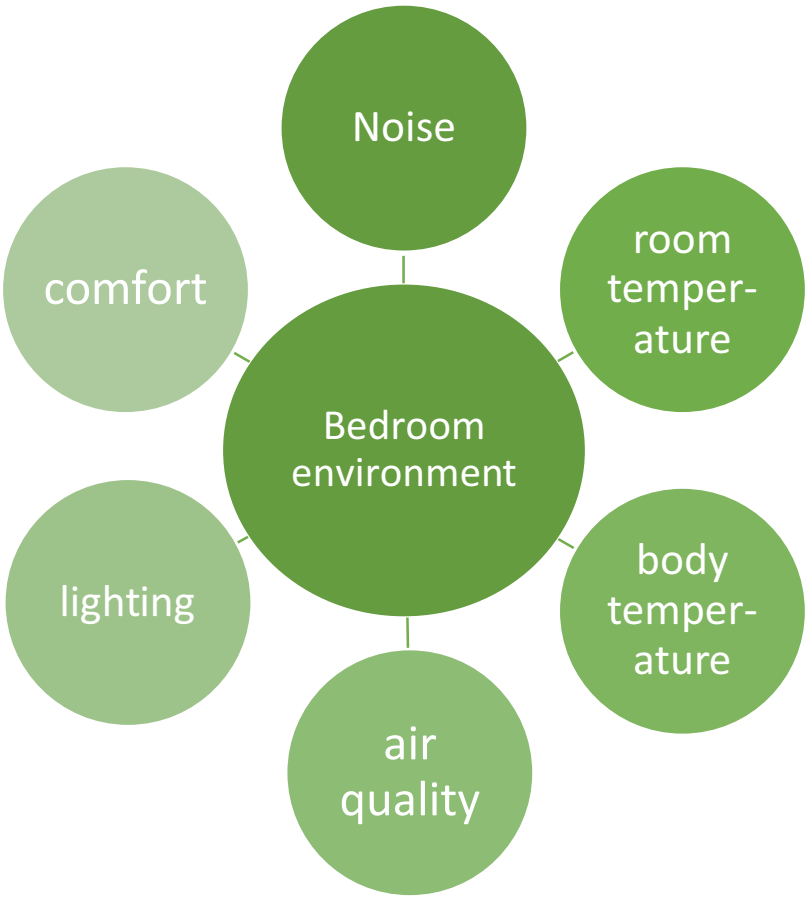
The bedroom environment

Being in relaxed surroundings is important for everyone, however people with dementia are particularly sensitive and discomfort makes it harder to sleep.



Session 1 Version 1



Noise

- Unexpected, sudden, loud noises will stop most people sleeping. It may also be difficult to fall back asleep having woken up. However, people can get used to noise after a while.

- Nonetheless sleep may be lighter if there is noise, so try and make sure the bedroom is as quiet as possible.



Room Temperature

- The recommended room temperature for most people is around **18° C**.

- Being too hot or too cold affects sleep. A hot room (more than 24° C) leads to restless and broken sleep. A cold room (less than 12° C) makes it difficult to get to sleep and can cause unpleasant and emotional dreams.

- It is a good idea to have a thermometer in the bedroom to help you get the blend of fresh air and temperature about right during different seasons.



Body Temperature

- Some people like a hot bath to relax before bed. However, poor sleepers often feel hot. We can best prepare for bed by having a bath about two hours before bedtime.

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Air quality

- A stuffy room may cause an uncomfortable sleep. Fresh air promotes sleep. It may help to open a window for a bit before going to bed.



Lighting

- Too much light keeps people awake. Strong street lighting and thin curtains should be avoided! The simplest solution is to cover windows with thick curtains or blinds. Curtains in dark colours especially help to block out light.

- If you are worried about your relative getting confused or distressed when they wake up in the dark, you could try a plug-in night light that gives a little light, but is not too bright.



Comfort

- Feeling worried, frightened or upset can keep all of us awake, including when we wake in the middle of the night. This is no different for people with dementia, who may become especially agitated around bedtime.

- As well as having a relaxing bedroom, have a bedtime routine, including soothing activities, like a hand massage or listening to music, may help relax your relative before bed. If it's in the middle of the night, you can reassure them it is safe.

My mother likes to have a hot water bottle or something … I think she finds comfort in that to help her sleep



You know, we sleep in single beds but for her to fall asleep I go to hold her hand and wait until she is fast asleep.



Let's fill in the changes you mentioned (on the table on page 28)…



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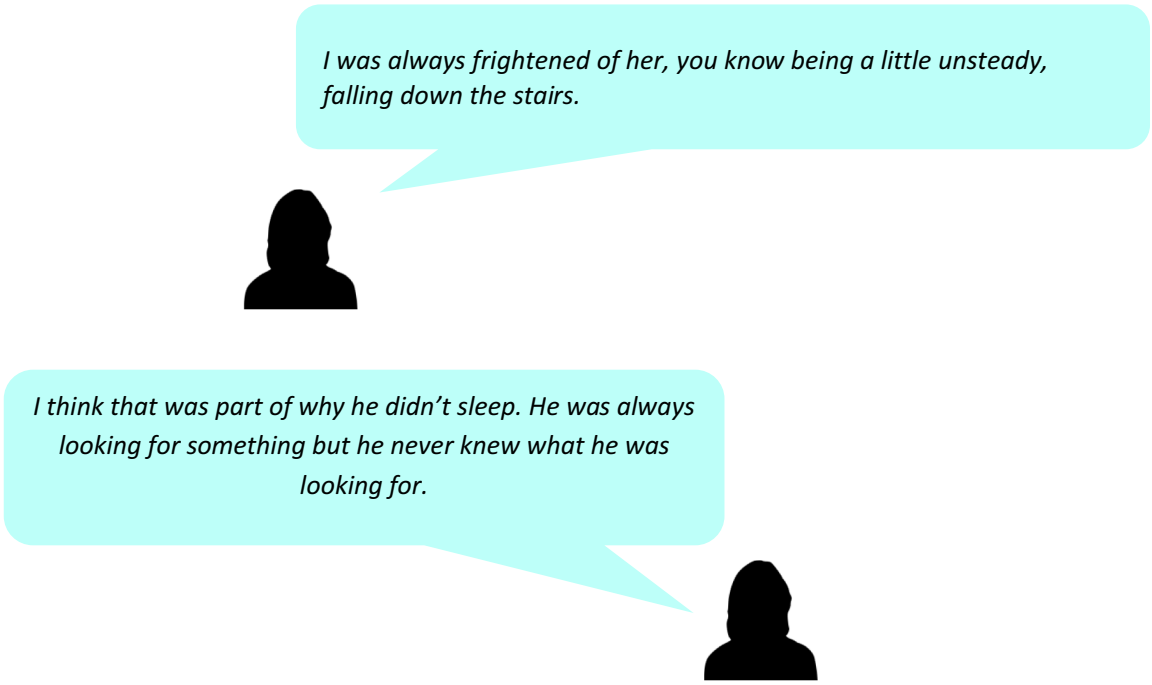
The impact of sleep problems on you and your relative



Which sleep problems are the most distressing for your relative?

Out of these, which one causes you the most stress?

How do your relative's sleep problems affect you and your own sleep?

Key Point:

If you are worried about your relative hurting themselves or falling at night, social services or your GP can advise you on 'telecare' and how to reduce any risks.

Session 1 Version 1

Managing the stress of sleep problems

- Caring for people with dementia can be physically and emotionally draining, especially if you are not sleeping well.

- Over time, stress can impact on your health and well-being and affect your sleep. While the challenges cannot be avoided, you can take steps to reduce the effect on you.

Common stress reactions include feeling:



Key Point:

We will provide you with some new skills and techniques which do not take up too much time and which are easy to do at home, even when your relative is around.

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DREAMS: START

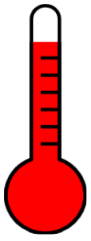
Managing Stress 1:

The Signal Breath



- The Signal Breath is a simple stress reduction technique that may help when you are coping with stressful situations.
- You can use it *anywhere*, at *any time*, and it is *quick*.
- Your relative may enjoy trying these exercises as well. Being more relaxed may help improve their sleep.

Stress Rating Before Exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- First, please rate your level of stress or tension right now, before we practice the signal breath.

Q! On a scale of 1 to 5, how would you rate your tension? _____

Session 1 Version 1

Summary

Today, we have talked about:

- Sleep and dementia
- What is sleep?
- What causes sleep problems in dementia?
- Making changes to improve sleep
- The impact of sleep problems on you and your relative
- Managing the stress that sleep problems can bring
- Managing stress: The signal breath

Key Point:
Although sleep difficulties in dementia are different for everyone and may be very complicated, there are small changes that you can try which may make a difference.

Session 1

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FOR NEXT WEEK: *Putting it into practice*



- **The signal breath:**

Try to practice this every day and to use it in stressful situations. See if it helps.



- **Lifestyle and bedroom changes:**

Please try out at least three of the changes you suggested on p.28 over the next week. There is a planning record on p.27 which you can note how it is going.



- **Sleep diary:**

Please complete the sleep diary on p.26 about your relative's sleep each day over the coming week and bring it with you next time.

DREAMS: START *Putting it into Practice*

- Is there anything that might get in the way?
- Is there anything that might make it easier?
- **You can listen to these managing stress exercises any time on your CDs or by visiting: https://soundcloud.com/dreams-start**

Session 1

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DOI: 10.3310/hta22710

Weekly Sleep Diary

Date	Noon	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am
Tuesday May 14th	O		N							/			X X		X				/				N	O

Key:

/ = When your relative went to bed and when they got up in the morning

X = Every time your relative gets up in the night

N = When your relative takes a nap during the day

O = When your relative has been out of the house

E = When your relative has done any physical exercise

Session 1

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Planning record

- Here is a way of monitoring how the changes have gone for you and your relative.

Date(s)	What did you try?	How did it go for your relative?	How did it go for you?

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DOI: 10.3310/hta22710

Changes to improve sleep

Lifestyle or bedroom changes to improve your relatives sleep	
1.	4.
2.	5.
3.	6.

Session 1

DREAMS: START

Dementia Related Manual for Sleep: Strategies for Relatives

Facilitator Version



Facilitator Key
Numbers in blue boxes let you know how long each section should take.
Information in yellow boxes give instructions on how to facilitate tasks, as well as prompts for feedback and discussion.
Quotations in orange boxes are phrases you should say directly.

Session 1 Version 1

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6th Floor Maple House
149 Tottenham Court Road
London W1T 7NF
United Kingdom

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General Tips for facilitating the intervention

Before you start:

- BE PREPARED: Be prepared for each session, bring all materials and equipment and when appropriate integrate individual data in advance of the session.

- STICK TO TIME, try and follow time guidelines for each section. Give yourself a few minutes to get organized and engage the carer before you start.

You will need:

- Manuals
- Pens
- Watch
- Relaxation CDs
- Light box
- Exercise leaflets and CD

General tips:

- If you feel that the examples are not relevant to the carer, try to think with the carer and between sessions of more relevant examples. **If a section really does not apply to them, for example their relative does not nap during the day or is already very active, then miss these bits out.**

- Carers will understand and use ideas from the manual at a difference pace and will vary in their literacy levels. It is important to adapt the pace to match the person you are delivering to. Repeat ideas if that is necessary.

- Encourage carers to write down key ideas and plans.

- Be observant; notice which sections work well and how the carer responds. Keep notes on what worked well and any challenges you faced.

- Undoubtedly problems will arise in sessions that haven't been anticipated. These should be recorded after the session to discuss during supervision.

- Balance making carers feel listened to and understood, with keeping focused on the manual. During talking points – facilitate discussion whilst being aware of sticking to time.

Key themes:

- Carers have a great deal of experience, it is important to value their experience and build upon their existing strategies and knowledge throughout the sessions.

- The importance of trying out tasks between sessions is highlighted in the first session. Try to reinforce the benefits of doing tasks throughout and offer encouragement when between session tasks have been completed.

Session 1 Version 1

5 mins

Introduction

Introduce yourself and ask: "What would you like me to call you" Remember what term they prefer and use it throughout the sessions.

- This is your manual to use.

"You can draw diagrams or write in it and you can look back over the manual in between sessions and after the sessions are finished".

- These sessions are about you, your rela
both.
- They are based on **what has been shown to work**, and **what we know about people with dementia and with sleep problems**.
- Over the next few weeks we will work together to:
    - Understand your relative's sleep pattern
    - Try out new strategies to help
    - Use information about sleep problems in dementia
    - Develop a regular sleep pattern for your relative and help you sleep too
- You may feel **'I have tried it all before'** and you are probably already using some of the strategies. We hope to build on what you do now and introduce new ideas, doing more of what works and less of what does not.

Key Point:

Although not all difficulties will change, putting what you learn in DREAMS: START into practice should make things better.

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What to expect

- Our discussions will be based on **you and your relative's experiences**.
- We will make a plan together to improve sleep **based on** the particular challenges you and your relative face, as with sleep, it is not 'one size fits all'.
- You will **put strategies into practice** during, and between sessions.

There will be six sessions each lasting **one hour and each will include:**

- A new topic to discuss.
- Making a plan for you to try out between sessions.
- A new way of reducing stress for you and your relative.
- Ways to monitor progress between sessions.

"Each of the 6 sessions are outlined below for you to refer back to."

DREAMS: START

Session 1: Understanding sleep and dementia
Session 2: Making a plan
Session 3: Daytime activity and routine
Session 4: Difficult night-time behaviours
Session 5: Taking care of your own sleep
Session 6: What works? Using strategies in the future

Session 1 Version 1

DREAMS: START

Session 1:

Understanding sleep and dementia



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Plan for today

"This is the contents page for you to refer back to"

Refer to the contents but do not read the full list

Sleep and dementia	p. 7
What is sleep?	p. 8
What causes sleep problems in dementia?	p. 12
Making changes to improve sleep	p. 13
The impact of sleep problems on you and your relative	p. 20
Managing the stress that sleep problems can bring	p. 21
Managing stress: The signal breath	p. 22
Summary	p. 24
Putting it into practice	p. 25

Session 1 Version 1

5 mins

Sleep and dementia

Talking point:

Tell me about your relative's sleep problems?

- Sleep disturbance is very common in dementia. 50-90% of people with dementia have disturbed sleep at some point.
- Sleep difficulties can often start several years before being diagnosed with dementia and worsen as dementia becomes more severe.
- Some of the difficulties that you may see happening include:

"Tick the ones which you feel apply for your relative." Discuss any difficulties that have not been ticked/mentioned…

☐ Waking up several times during the night, often confused

☐ Waking up too early

☐ Being very sleepy or falling asleep during the day

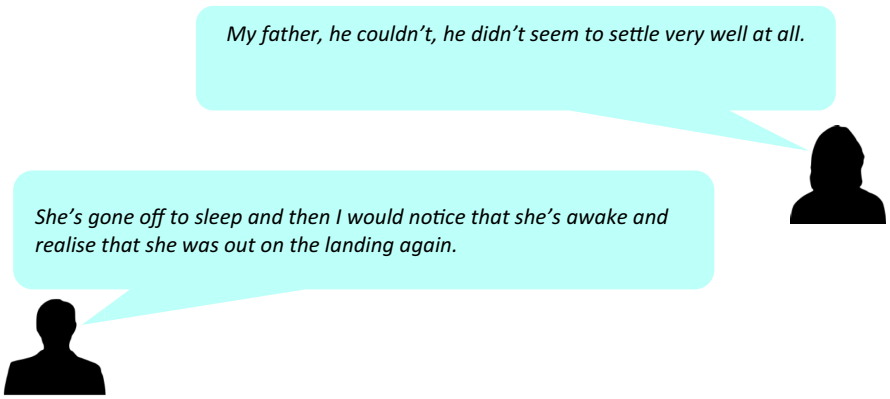
☐ Having a disturbed sleep pattern e.g. asleep during the day and awake at night

☐ Agitation or restlessness in the evening or at night

☐ Difficulty falling asleep

☐ Pacing or wandering

☐ Other_____



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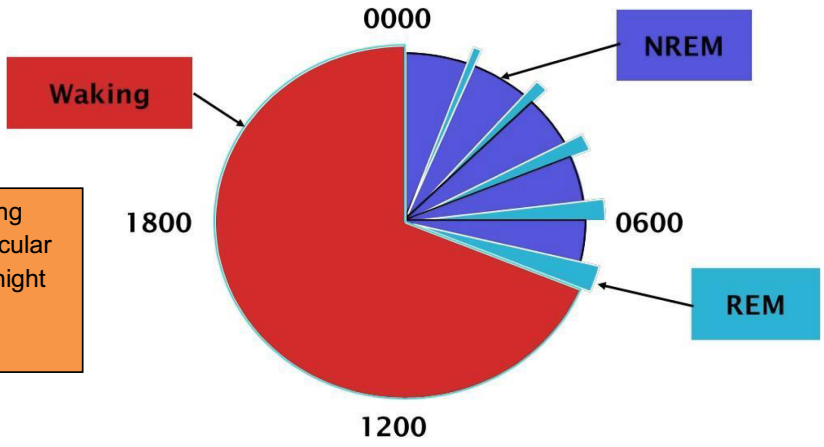
10mins

What is sleep?

Talking point:

What do you notice happening to you and your relative when you don't get a good night's sleep?

- Sleep is an important time for us to refresh our brain and body.
- The sleeping brain is not simply in "off-mode", but instead goes through various stages of sleep. Throughout the night we move between two types of sleep:
    - Non-REM (NREM) sleep happens more at the beginning of the night consisting of phases of light and deep sleep. When in the deepest sleep, we are harder to wake up.
    - REM (rapid-eye movement) sleep happens later in the night; here we experience brief bursts of eye movements and dream.
- The brain's 'sleep cycles' each last about 90 minutes, and move from NREM to REM sleep. Good sleepers typically have 4-5 sleep cycles each night.



"Do you think being woken up at particular times during the night are worse than others?"

A typical sleep-wake cycle for someone going to bed at midnight and getting up at 7am

How does sleep work?

- Sleep is automatic and controlled by two processes which work together so that we sleep well at night. These are:

    1. The Circadian Rhythm or 'the body clock'
    2. 'Sleep pressure'

Circadian rhythm

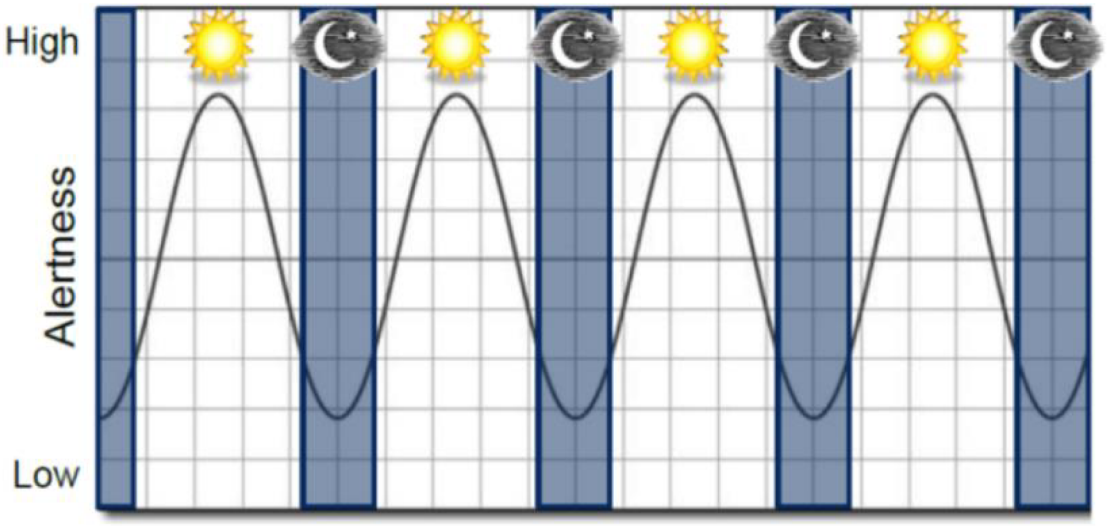
- Circadian rhythm is our body clock which helps us to make sense of our environment, for example when it will be light or dark. This shows our brains and bodies *when* and *how much to sleep*.

- The brain controls the body clock.

- When we sleep well at night, our body clock creates a balance and we feel refreshed and alert in the day.

- There are times when our body clock gets 'out of sync', for example, when jet-lagged.

- A good sleeper with a regular pattern will get up early in the morning feeling wide awake. This peaks around midday. After a 'post lunch dip' our wakefulness continues to fall until bedtime and sleep.



Check that they have understood circadian rhythms, if not, clarify.

Session 1 Version

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- Dementia can affect the part of the brain that controls our ‘body clock’.
- This can make people more alert or active at night and less alert or active during the day.
- Reduced physical activity, irregular meal times, and reduced exposure to natural sunlight can disrupt the “body clock” so that they wake more at night.
- Light, exercise and food all play a role in helping the brain and body to understand what time of day it is, allowing the brain to work out when it should be awake or asleep.

Key Point:

People with dementia often have a disrupted body clock which makes it harder to know when it is day or night

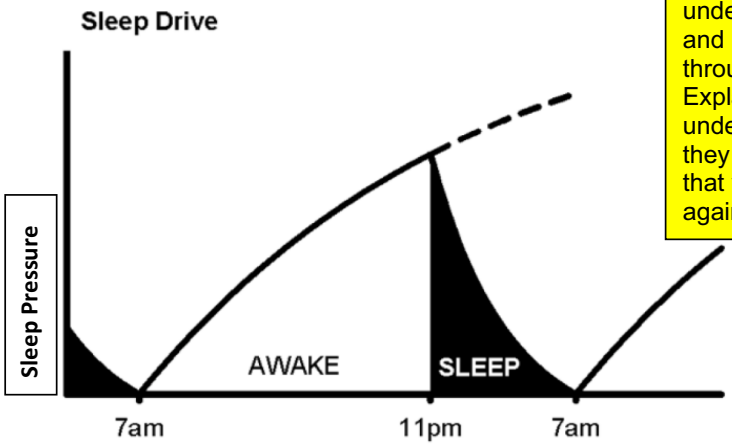


Session 1 Version 1

Sleep pressure

- 'Sleep pressure' is the brain's need for sleep. It increases the longer you are awake.
- When we wake up in the morning after a good night's sleep, we will have a very low sleep pressure. Sleep pressure will increase during the day until bedtime.
- By going to bed and having a good night's sleep, then sleep pressure will be reset for the start of the next day.
- So, at bed time, the 'sleep pressure' is at its highest, creating the perfect opportunity for sleep.

Check that they have understood 'sleep pressure' and if not, explain it / talk through the diagram again. Explain that if they do not understand any of the ideas they should let you know so that you can talk through it again.



Why is sleep important?

- When we do not get enough sleep, our concentration, mood and memory is affected.
- We also know that people who have poor sleep over long periods of time are more likely to get health problems like cardiovascular disease and diabetes.
- Going to bed and getting up at the same times each day, makes us more likely to experience good quality sleep and therefore be awake, active and healthy during the day.

Talking point:

Did your relative have problems sleeping before the diagnosis, if so, what helped then?

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5 mins

What causes sleep problems in dementia?

Talking point:

People often have thoughts about what could be causing sleep problems in their relatives, is this something that you have thought about? What ideas have you had?

There are many reasons why sleep patterns are disturbed in dementia. Some changes occur as we become older and may affect you and your relative:

"Let's go through this list, tick the ones that you think may apply to your relative"

- ☐ Having more physical health problems, including pain
- ☐ Spending less time in deep restorative sleep and more time in lighter sleep
- ☐ Needing to go to the toilet more in the night
- ☐ Side effects of medication
- ☐ Not being active / napping during the day
- ☐ Not being in daylight
- ☐ Being confused about night and day
- ☐ Being frightened at night
- ☐ Going to bed very early and then waking up early

If it seems that there may be untreated medical problems or medication side effects recommend that they discuss with a pharmacist or a GP



Session 1 Version 1

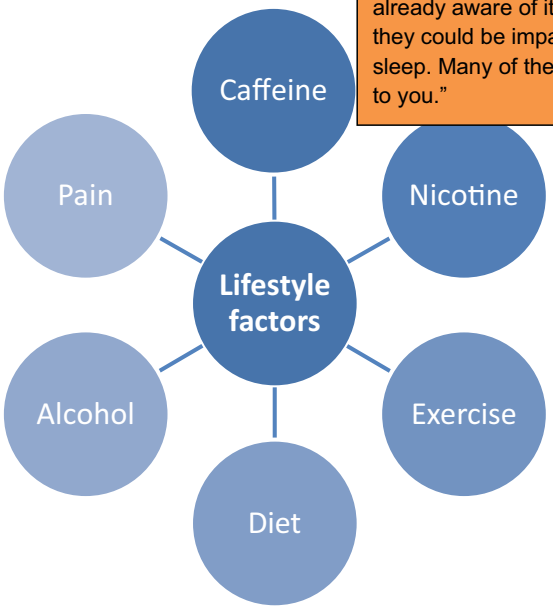
10mins Making changes to improve sleep

- In our next session we will develop a plan to help you manage your relative's sleep difficulties based on the Actigraph information (wrist watch they wore), sleep diaries and our discussions today.

- In the meantime we will look at changes to your relative's lifestyle that can improve sleep.

Lifestyle factors that can impact on sleep:

"Some of these ideas will be familiar to you and may seem obvious, whilst others may be new. Even with the factors you were already aware of it is worth considering if they could be impacting upon your relative's sleep. Many of these factors will also apply to you."



As you go through the factors ask "What do you think could help?" to any factor that the carer feels is contributing to sleep difficulties.

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"Tell me if each of these applies to your relative"

Caffeine

- Caffeine perks you up and it can be good to have in the morning to help wake up!
- Most people know caffeine is in coffee and tea, but it's also in chocolate, some soft drinks (i.e. coke), and also in some medicines. Check labels if you are not sure.
- If someone naps during the day or goes to bed early in the evening, having caffeine up until 6pm may help them to stay awake during early evening.
- However caffeine's effects can last for many hours so it is a good idea not to give your relative any caffeine for 4 to 6 hours before bedtime, or even the middle of night. Try decaffeinated drinks.



Ask if they or their relative drink alcohol

Alcohol

- Alcohol can disrupt sleep and may make your relative more confused or likely to fall.
- Alcohol may help people fall into a deep sleep at the beginning of the night, but it will then lead to disturbed sleep later in the night.
- Limit it to one small glass of wine or half a pint of beer. Do not drink a lot of alcohol in the evening.



Ask if they or their relative smoke

Nicotine

- Nicotine in cigarettes has effects like caffeine on sleep, making it harder to fall asleep and to stay asleep.
- If you or your relative smoke, try to cut down in the evening before you go to bed, and try not to smoke at all during the night.



Diet

- Hunger can wake people, so a light snack a little before bedtime can help sleep, but going to bed too full can disturb sleep.

- It may be true that milk and other dairy products help to promote sleep and, usually, makes people less hungry.

- Try to avoid giving your relative snacks during the middle of the night as the body may come to expect food at this time and it will get in the way of having a good day and night pattern.



Exercise

- People who are physically active have a better quality of sleep, so a good way to promote sleep is to get active, by exercising three times a week for 20-30 minutes!

- The type of exercise you and your relative do really depends on what you enjoy and your ability. We will be talking more about activities in future sessions.

We know that for some people moving at all can be difficult. In session three we will introduce a seated exercise plan for those with limited mobility. You can listen to this on: https://soundcloud.com/dreams-start and in session 3 we will talk more about putting it into practice.



Pain

- Although pain is not a lifestyle factor it can interfere with sleep, and your relative may not be able to tell you if they are in pain.

- Do you feel your relative is in pain? If so, what do you do to manage the pain? And does it help?

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The bedroom environment

Being in relaxed surroundings is important for everyone, however people with dementia are particularly sensitive and discomfort makes it harder to sleep.



Session 1 Version 1

Ask "What do you think could help?" to any factor that the carer feels is contributing to sleep difficulties.

"Tell me if each of these applies to you".



Noise

- Unexpected, sudden, loud noises will stop most people sleeping. It may also be difficult to fall back asleep having woken up. However, people can get used to noise after a while.

- Nonetheless sleep may be lighter if there is noise, so try and make sure the bedroom is as quiet as possible.



Room Temperature

- The recommended room temperature for most people is around **18° C**.

- Being too hot or too cold affects sleep. A hot room (more than 24° C) leads to restless and broken sleep. A cold room (less than 12° C) makes it difficult to get to sleep and can cause unpleasant and emotional dreams.

- It is a good idea to have a thermometer in the bedroom to help you get the blend of fresh air and temperature about right during different seasons.

"Does your relative shower or bath?"



Body Temperature

- Some people like a hot bath to relax before bed. However, poor sleepers often feel hot. We can best prepare for bed by having a bath about two hours before bedtime.

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Air quality

- A stuffy room may cause an uncomfortable sleep. Fresh air promotes sleep. It may help to open a window for a bit before going to bed.



Lighting

- Too much light keeps people awake. Strong street lighting and thin curtains should be avoided! The simplest solution is to cover windows with thick curtains or blinds. Curtains in dark colours especially help to block out light.

- If you are worried about your relative getting confused or distressed when they wake up in the dark, you could try a plug-in night light that gives a little light, but is not too bright.



Comfort

- Feeling worried, frightened or upset can keep all of us awake, including when we wake in the middle of the night. This is no different for people with dementia, who may become especially agitated around bedtime.

- As well as having a relaxing bedroom, have a bedtime routine, including soothing activities, like a hand massage or listening to music, may help relax your relative before bed. If it's in the middle of the night, you can reassure them it is safe.

"Different people like different strategies. One carer said…"

My mother likes to have a hot water bottle or something … I think she finds comfort in that to help her sleep



You know, we sleep in single beds but for her to fall asleep I go to hold her hand and wait until she is fast asleep.



Let's fill in the changes you mentioned (on the table on page 28)…



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5 mins The impact of sleep problems on you and your relative



Which sleep problems are the most distressing for your relative?

Out of these, which one causes you the most stress?

How do your relative's sleep problems affect you and your own sleep?

"Do you know about telecare?"

If no, then outline key point.

Key Point:

If you are worried about your relative hurting themselves or falling at night, social services or your GP can advise you on 'telecare' and how to reduce any risks.

Session 1 Version 1

10mins Managing the stress of sleep problems

- Caring for people with dementia can be physically and emotionally draining, especially if you are not sleeping well.

- Over time, stress can impact on your health and well-being and affect your sleep. While the challenges cannot be avoided, you can take steps to reduce the effect on you.

Common stress reactions include feeling:



"You've talked about some of these emotions."

"Are there any other emotions that you experience?"

Key Point:

We will provide you with some new skills and techniques which do not take up too much time and which are easy to do at home, even when your relative is around.

Session 1 Version 1

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"During the sessions we are going to help you to learn both how to recognise stress and gain control over it, we are not here to say, "When you are stressed, just relax", but to give you tools to reduce the effect on you. Some of the techniques will work for you and others won't, the key is to find the ones that fit for you. We are now going to try one of these techniques called the 'Signal breath…

DREAMS: START

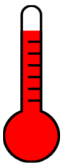
Managing Stress 1:

The Signal Breath



- The Signal Breath is a simple stress reduction technique that may help when you are coping with stressful situations.
- You can use it *anywhere*, at *any time*, and it is *quick*.
- Your relative may enjoy trying these exercises as well. Being more relaxed may help improve their sleep.

Stress Rating Before Exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- First, please rate your level of stress or tension right now, before we practice the signal breath.

Q! **On a scale of 1 to 5, how would you rate your tension?** _____

Session 1 Version 1

Summary

Today, we have talked about:

- Sleep and dementia
- What is sleep?
- What causes sleep problems in dementia?
- Making changes to improve sleep
- The impact of sleep problems on you and your relative
- Managing the stress that sleep problems can bring
- Managing stress: The signal breath

Key Point:
Although sleep difficulties in dementia are different for everyone and may be very complicated, there are small changes that you can try which may make a difference.

Session 1

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10mins

FOR NEXT WEEK: *Putting it into practice*



- **The signal breath:**

Try to practice this every day and to use it in stressful situations. See if it helps.

"If you would prefer to listen to the relaxation exercises on your smart phone or tablet you can access the MP3 files at: https://soundcloud.com/dreams-start
There is also a seated exercise plan that we will come to in session 3"



- **Lifestyle and bedroom changes:**

Please try out at least three of the changes you suggested on p.28 over the next week. There is a planning record on p.27 which you can note how it is going.



- **Sleep diary:**

Please complete the sleep diary on p.26 about your relative's sleep each day over the coming week and bring it with you next time.

DREAMS: START *Putting it into Practice*

- Is there anything that might get in the way?
- Is there anything that might make it easier?
- **You can listen to these managing stress exercises any time on your CDs or by visiting: https://soundcloud.com/dreams-start**

Session 1

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DOI: 10.3310/hta22710

"Let's put tonight's date in the first box to get started…"

Weekly Sleep Diary

Date	Noon	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am
Tuesday May 14th	O		N							/			X X		X				/				N	O

Key:

/ = When your relative went to bed and when they got up in the morning

X = Every time your relative gets up in the night

N = When your relative takes a nap during the day

O = When your relative has been out of the house

E = When your relative has done any physical exercise

Session 1

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Planning record

- Here is a way of monitoring how the changes have gone for you and your relative.

Date(s)	What did you try?	How did it go for your relative?	How did it go for you?

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DOI: 10.3310/hta22710

Changes to improve sleep

Lifestyle or bedroom changes to improve your relatives sleep	
1.	4.
2.	5.
3.	6.

Session 1

DREAMS: START

Dementia Related Manual for Sleep:

Strategies for Relatives

Session 2: Making a plan



Session 2 Version 1

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Session 2 Version 1

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Plan for today's session

Recap on understanding sleep and dementia	p. 3
Light and sleep	p. 4
Light, dementia and the body clock	p. 6
Your relative's sleep pattern	p. 13
Making a new sleep routine: Your relative's plan	p. 18
Managing stress 2: Focused Breathing	p. 19
Summary	p. 22
Putting it into practice	p. 23

Recap of session one: Understanding sleep and dementia

We talked about:

- Sleep and dementia
- What is sleep?
- What causes sleep problems in dementia?
- Making changes to improve sleep
- The impact of sleep problems on you and your relative
- Managing the stress that sleep problems can bring
- Managing stress 1: The signal breath

Q! **Did you make lifestyle or bedroom changes to improve your relative's sleep?**

Yes	No
• What changes did you try out? • How did it go? • What went well?	• What do you think got in the way? • What would make it easier in the future?

Yes	No
• How did it go? • What went well? • Did you notice any patterns?	• What do you think got in the way? • What would make it easier in the future?

Q! **Did you have a chance to complete the sleep diary?**

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Light and sleep

- We talked about ‘sleep pressure’ and the ‘body clock’, the two ways our brain gives us a good sleep pattern.

- We discussed how the body clock helps us sleep when it’s dark (at night) and be awake when it’s light (during the day).

- The body clock works out the time most importantly by sunlight because it is the brightest; but also by temperature and when mealtimes or activities happen.

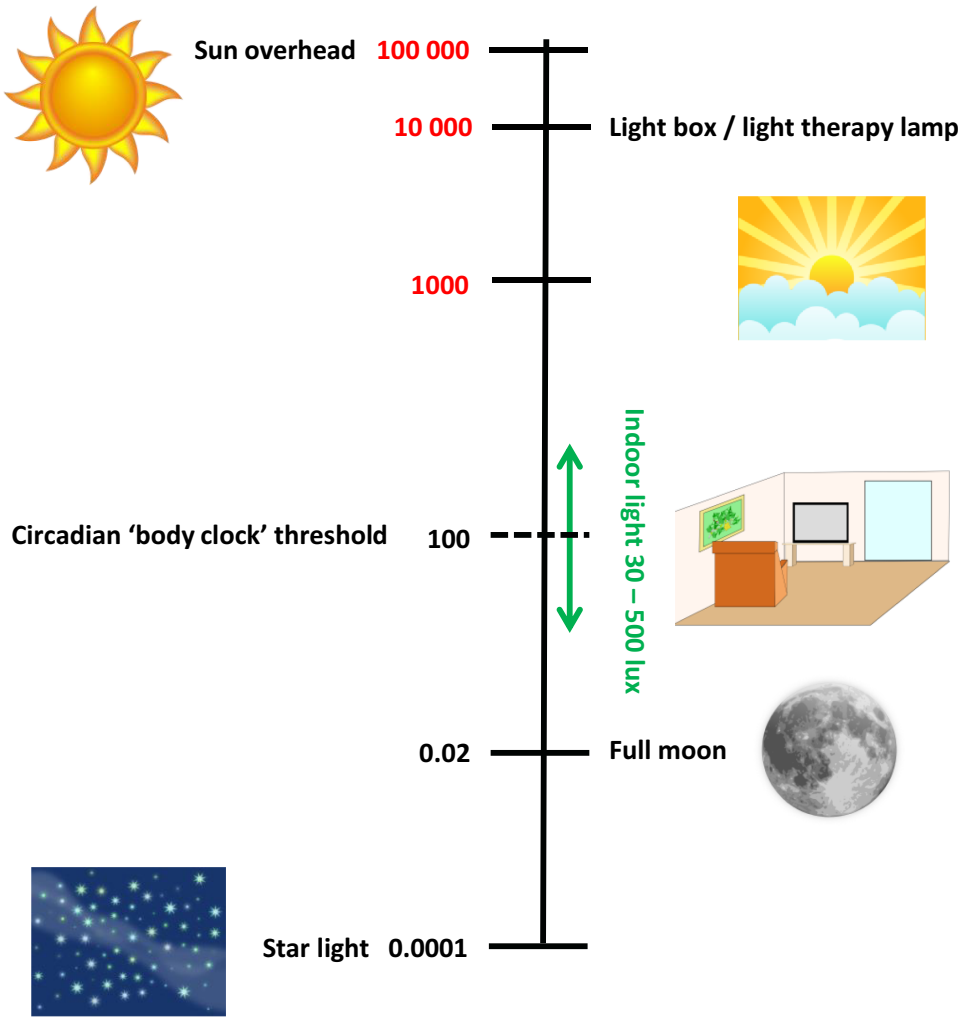
- Sunlight during the day tells the brain and body that it should be awake; helping us to concentrate and be active.

- Regular light and being awake during the day helps us to sleep undisturbed through the night. This **creates a strong and stable sleep pattern.**

- Look at the picture on the opposite page.



Session 2 Version 1



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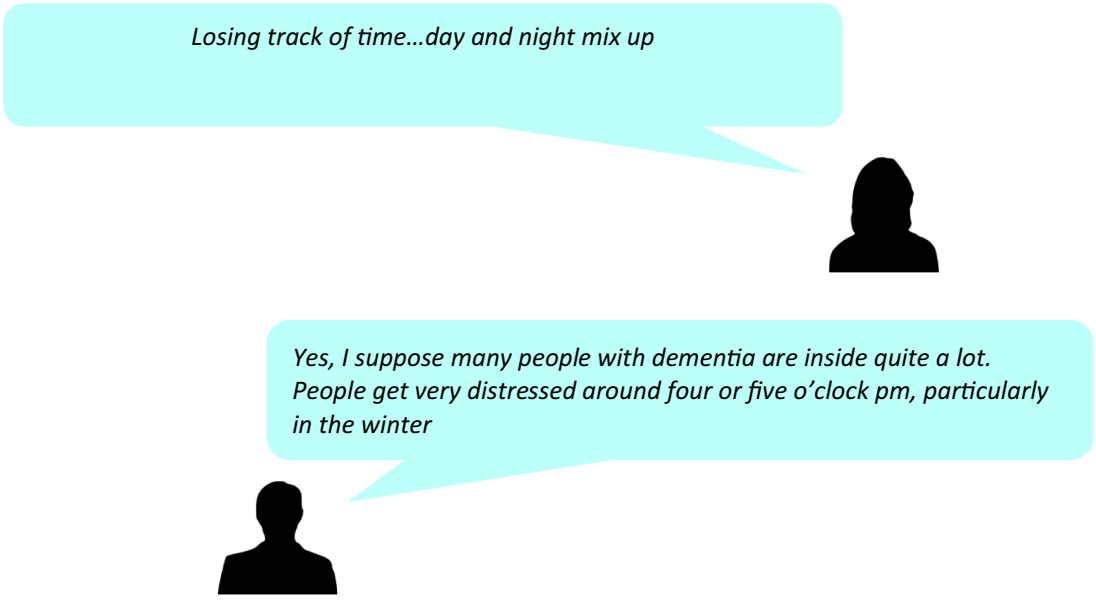
Light, dementia and the body clock

- You may have noticed that your relative mixes up night and day and is sleepy or wide awake at the wrong times.
- One reason for this is that dementia can damage the part of the brain controlling the 'body clock', giving people wrong signals about night and day.
- So people with dementia can be sleepier in the day or awake at night.
- As we get older our ability to see light through our eyes also gets worse, so less light gets to the body clock in the brain. This is worse in those with dementia.

Key Point:
Ensuring people with dementia receive enough light during the day is extremely important for their sleep at night



Session 2 Version 1

- Getting outdoors during the day (e.g. for a walk in a garden), even if the sun is not shining brightly, will help strengthen your relative's body clock.

- We know that getting outside with people with dementia is not always possible, perhaps your relative does not want to go out or they are not able to walk or manage stairs. However even very short periods of time outside can make a big difference.

- Before we make a plan for your relative, let's talk about how much light your relative is getting.

Q! **How much time do you think your relative is in natural light on a typical day?**

- Let's look at the information from the watch your relative wore for two weeks before we met. We will discuss how much your relative's is in light now, and their movement data a little later on in the session.



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Your relative's light exposure

Insert the Actigraph data here in advance of session 2

Average lux:

Session 2 Version 1

Making a light therapy plan

- Let's make a plan to help your relative have more daytime light.

1. Increasing access to natural light:

- Let's write three activities to increase your relative's exposure to natural light. (Use the questions on the right to help you make a plan).

1. _____

2. _____

3. _____

- How often could you do this?
- What would make it easier?
- How long would it take?
- Could they do it alone or with you or someone else?
- Is there anything that could make it safer?

Try and get your relative out into natural light at least 3 times over the next week, if you do more, that's great.

2.



Session 2 Version 1

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2. Using artificial light in the form of a light box or 'phototherapy':

- A light box may improve sleep in people with dementia.

- By providing strong light during the day, like natural light, our body-clock will get better at knowing when to be awake and when to be asleep.



- Use the light box for **30 minutes at the same time each morning**.

- Place the light box at arms-length with the screen towards your relative's face, so that the light reaches their eyes.

- Your relative does not need to stare at the box but can use it whilst doing other things like reading, having breakfast or watching TV.

- Dark glasses, tinted lenses and closing the eyes will reduce how well this works.

Q! **What difficulties do you see in using the light box?**

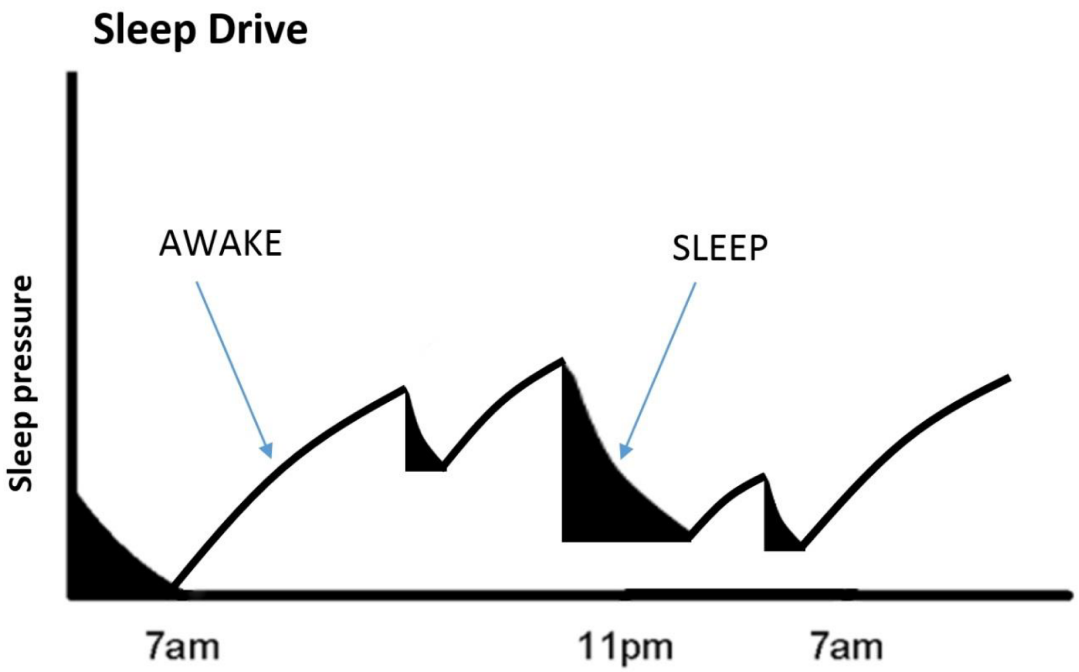
What would help to overcome these difficulties?

Session 2 Version 1

Your relative's sleep pattern

- We have talked about how the body-clock controls sleep and wake periods. We also need to think about 'sleep pressure' in relation to your relative's Actigraph.

- If a person naps during the day there is less "sleep pressure", so they will find it harder to fall asleep and are more likely to wake in the night



- If we go to bed too early, before sleep pressure is high and before the body-clock is ready to send sleep signals, then we may toss and turn, and become frustrated - it may lead to more broken sleep.

- Daytime napping, being inactive and going to bed early are all common in people with dementia and make it harder for them to sleep well.

- Let's now look at the information we obtained from the watch your relative wore that measured movement. This shows us how long your relative took to fall asleep and how many times they woke up in the night.

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Actigraph data:

Insert data chart here and below in advance of session 2

Session 2 Version 1

Summary:

- Your relative spends around X hours in bed and sleeps for about X hours each night.
- This ratio of sleep time to time in bed is called **sleep efficiency**.
- **Your relative's sleep efficiency is X%.**
- Effective methods to improve sleep efficiency involve:
  1) Eliminating / reducing daytime naps
  2) Delaying the start of sleep by going to bed later.

Session 2 Version 1

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Making a new routine - your relative's plan

Now let's use all that we have talked about today to make a plan on page 25.



Next week we will be talking more about increasing pleasant daytime events and activities for you and your relative.

Session 2 Version 1

DREAMS: START

Managing Stress 2:

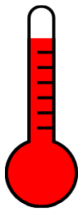
Focused breathing

Focused Breathing is a useful stress reduction technique:



- It can relax you, reducing the tension and stress that can come from caring.
- It can help you to briefly focus on yourself, and have a break from caring.
- It can also help you get to sleep after a stressful day.
- Focused breathing may also be a way for your relative to get nice and relaxed before bed time.

Stress Rating Before Exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- First, please rate your level of stress or tension right now before we practice the Focused Breathing.

Q! **On a scale of 1 to 5, how would you rate your tension? _____**

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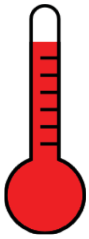
Tension Rating After Exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- How would you rate your tension level now after practicing the Focused Breathing exercise?

Q! **Now, please rate your tension or stress level from 1 to 5 _____**

Session 2 Version 1

Summary

Today, we have talked about:

- Recap on understanding sleep and dementia
- Light and sleep
- Light, dementia and the body clock
- Your relative's sleep pattern
- Making a new sleep routine: Your relative's plan
- Managing stress 2: Focused Breathing

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FOR NEXT WEEK: Putting it into practice

Key Point:

It is important for you try out the plan we have made building it into your routine. Using the plan regularly will help us see whether it works and help us to make further changes if it is not helping.



Focused breathing:

- Try to practice this every night before bed and with your relative if that is possible. See if it helps.



Putting the plan into action:

- Try and use the plan we made on page 25. Please continue to keep a sleep diary for your relative and try and fill in the record form on p.25.

DREAMS: START

Putting it into Practice

- When will you have an opportunity to do this?
- What might get in the way?
- What might make it easier?

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DOI: 10.3310/hta22710

Weekly Sleep Diary

Date	Noon	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am
Tuesday May 14th	**O**		**N**							**/**			**X X**		**X**				**/**				**N**	**O**

Key:

/ = When your relative went to bed and when they got up in the morning

X = Every time your relative gets up in the night

N = When your relative takes a nap during the day

O = When your relative has been out of the house

E = When your relative has done any physical exercise

L = When you relative has used the light box

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Planning record

- Here is a way of monitoring how the changes have gone for you and your relative.

	Action plan	How did it go for your relative?	How did it go for you?
Light box			
Increasing natural light			
Reducing daytime naps			
Time to bed and rise			
Lifestyle changes			

Facilitator Version

DREAMS: START

Dementia Related Manual for Sleep: Strategies for Relatives

Session 2: Making a plan



For each session:

- Encourage the carer to write down what works or key strategies or plans to refer back to.
- If content is clearly irrelevant or does not fit, for example someone is very active all day will not need a plan around daytime naps, miss these parts out.
- When setting exercises at the end, check that they remember what is in the plan if not explicitly covered in the content.

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United Kingdom

Session 2 Version 1

Plan for today's session

"This is the contents page for you to refer back to"

Refer to the contents but do not read the full list

Recap on understanding sleep and dementia	p. 3
Light and sleep	p. 4
Light, dementia and the body clock	p. 6
Your relative's sleep pattern	p. 13
Making a new sleep routine: Your relative's plan	p. 18
Managing stress 2: Focused Breathing	p. 19
Summary	p. 22
Putting it into practice	p. 23

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5mins

Recap of session one: Understanding sleep and dementia

We talked about:

"What stuck in your mind from last week? What were the changes that you wanted to make?"

- Sleep and dementia
- What is sleep?
- What causes sleep problems in dementia?
- Making changes to improve sleep
- The impact of sleep problems on you and your relative
- Managing the stress that sleep problems can bring
- Managing stress 1: The signal breath

"Let's talk about how this went – write down what you found so that you can look over it in the future"

Q! **Did you make lifestyle or bedroom changes to improve your relative's sleep?**

Yes	No
• What changes did you try out? • How did it go? • What went well?	• What do you think got in the way? • What would make it easier in the future?

Q! **Did you have a chance to complete the sleep diary?**

Yes	No
• How did it go? • What went well? • Did you notice any patterns?	• What do you think got in the way? • What would make it easier in the future?

"Keep using any strategies that you found helpful for you or your relative and continue to use the sleep diary over the coming week."

20mins Light and sleep

- We talked about 'sleep pressure' and the 'body clock', the two ways our brain gives us a good sleep pattern. Check that they recall the discussion on sleep pressure and circadian rhythms – remind them of the key points
- We discussed how the body clock helps us sleep when it's dark (at night) and be awake when it's light (during the day).
- The body clock works out the time most importantly by sunlight because it is the brightest; but also by temperature and when mealtimes or activities happen.
- Sunlight during the day tells the brain and body that it should be awake; helping us to concentrate and be active.
- Regular light and being awake during the day helps us to sleep undisturbed through the night. This **creates a strong and stable sleep pattern.**
- Look at the picture on the opposite page.



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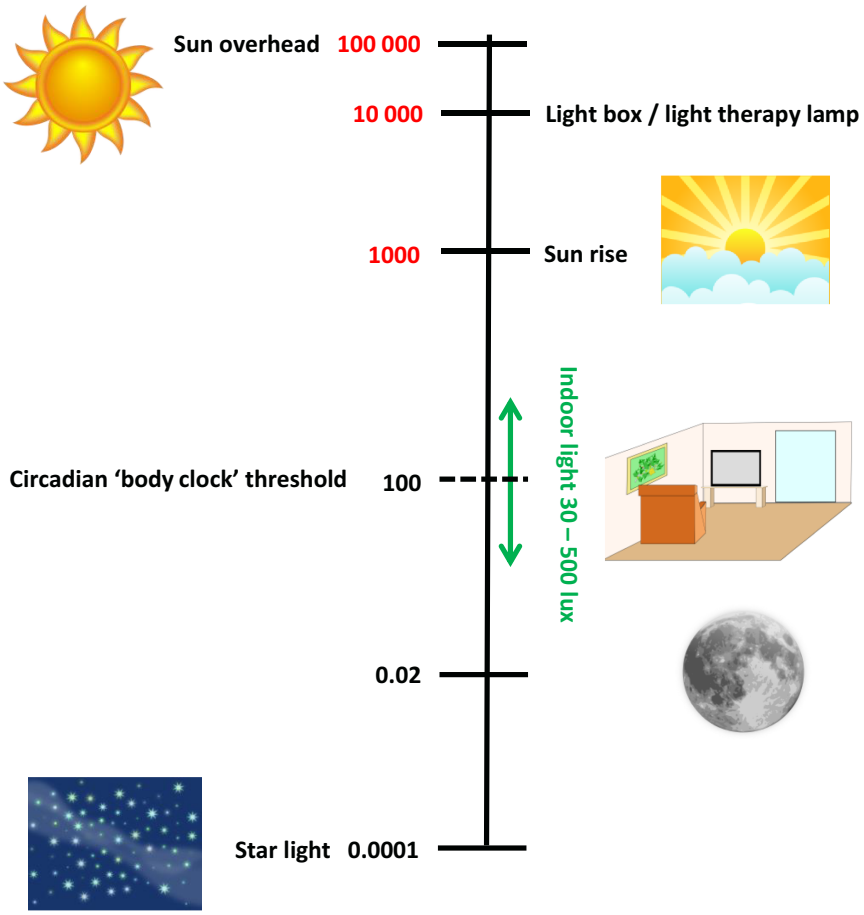
"This diagram shows how much light we get from different sources, showing how much more light we get from being out in natural light than artificial light. Talk through the diagram and check they have understood. Is this surprising for you?"



Session 2 Version 1

Light, dementia and the body clock

- You may have noticed that your relative mixes up night and day and is sleepy or wide awake at the wrong times.
- One reason for this is that dementia can damage the part of the brain controlling the 'body clock', giving people wrong signals about night and day.
- So people with dementia can be sleepier in the day or awake at night.
- As we get older our ability to see light through our eyes also gets worse, so less light gets to the body clock in the brain. This is worse in those with dementia.

Key Point:
Ensuring people with dementia receive enough light during the day is extremely important for their sleep at night

Losing track of time…day and night mix up



Yes, I suppose many people with dementia are inside quite a lot. People get very distressed around four or five o'clock pm, particularly in the winter



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- Getting outdoors during the day (e.g. for a walk in a garden), even if the sun is not shining brightly, will help strengthen your relative's body clock.

- We know that getting outside with people with dementia is not always possible, perhaps your relative does not want to go out or they are not able to walk or manage stairs. However even very short periods of time outside can make a big difference.

- Before we make a plan for your relative, let's talk about how much light your relative is getting.

Q! **How much time do you think your relative is in natural light on a typical day?**

Prompts if needed
Do they get out and about?
How often and where?

Do they sleep with a light on?
Do they ever get mixed up between day and night?

- Let's look at the information from the watch your relative wore for two weeks before we met. We will discuss how much your relative's is in light now, and their movement data a little later on in the session.



Session 2 Version 1

Your relative's light exposure

Insert the Actigraph data here in advance of session 2

Average lux:

Make sure that you have done this in advance of the session and that you are prepared to talk through the data and summarise the findings.

Talk through the data explaining what it means and what the data shows. Summarise the key patterns / findings

Check that they have understood what you are showing them.

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Making a light therapy plan

- Let's make a plan to help your relative have more daytime light.

1. Increasing access to natural light:

- Let's write three activities to increase your relative's exposure to natural light. (Use the questions on the right to help you make a pla

Use the questions to guide your discussion and encourage them to write down specifics of what they are going to try out

1. _____

- How often could you do this?
- What would make it easier?

2. _____

- How long would it take?
- Could they do it alone or with you or someone else?

3. _____

- Is there anything that could make it safer?

Try and get your relative out into natural light at least 3 times over the next week, if you do more, that's great.

2.



If they are stuck you can prompts them.

e.g.
- Sitting out in the garden/ balcony
- Going on local errands either alone or together
- Visiting the park
- Sitting by open windows
- Walking instead of driving
- Any other activities

If they say they do not think they can do anything, do not push them, talk with them about what the barriers are and what might have to happen for things to be different.

Session 2 Version 1

"It might not always be possible for your relative to get out into natural light but there are other ways to increase their access to light whilst indoors. We are going to talk about one of these now…"

2. Using artificial light in the form of a light box or 'phototherapy':

- A light box may improve sleep in people with dementia.

- By providing strong light during the day, like natural light, our body-clock will get better at knowing when to be awake and when to be asleep.

Show the person how to use the light box and check that they understand the mechanism and can work it independently.

Try to keep the light box on in the session so people can get used to it.

Remind them that they do not have to be staring at it but having it nearby and getting on with other activities is fine as



Think in advance based upon Actigraph data what time it may be best in the morning for them to use the box but be tentative and flexible with any suggestions, based upon what they feel would work best.

- Use the light box for **30 minutes at the same time each morning**.

- Place the light box at arms-length with the screen towards your relative's face, so that the light reaches their eyes.

- Your relative does not need to stare at the box but can use it whilst doing other things like reading, having breakfast or watching TV.

- Dark glasses, tinted lenses and closing the eyes will reduce how well this works.

Q! **What difficulties do you see in using the light box?**

What would help to overcome these difficulties?

Session 2 Version 1

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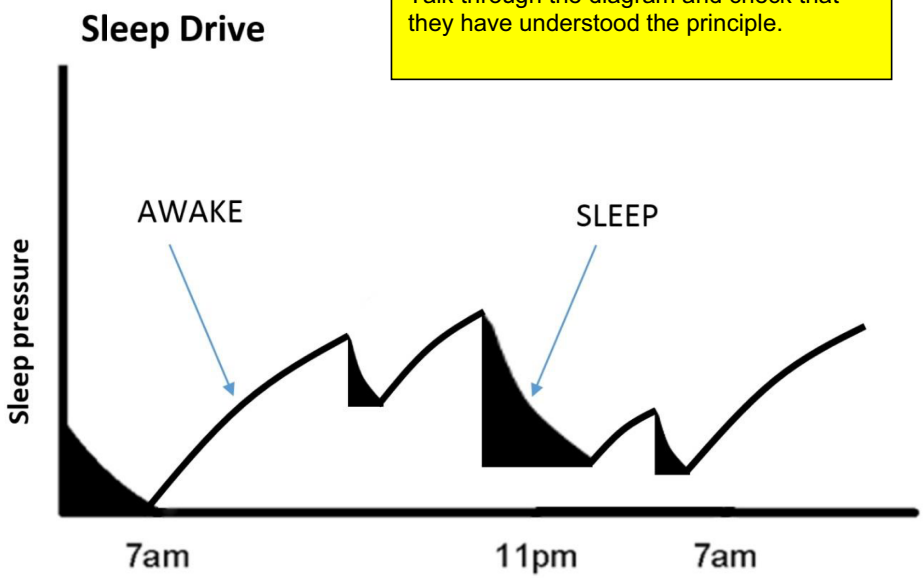
10 mins Your relative's sleep pattern

- We have talked about how the body-clock controls sleep and wake periods. We also need to think about 'sleep pressure' in relation to your relative's Actigraph.

- If a person naps during the day there is less "sleep pressure", so they will find it harder to fall asleep and are more likely to wake in the night

Talk through the diagram and check that they have understood the principle.



- If we go to bed too early, before sleep pressure is high and before the body-clock is ready to send sleep signals, then we may toss and turn, and become frustrated - it may lead to more broken sleep.

- Daytime napping, being inactive and going to bed early are all common in people with dementia and make it harder for them to sleep well.

- Let's now look at the information we obtained from the watch your relative wore that measured movement. This shows us how long your relative took to fall asleep and how many times they woke up in the night.

Actigraph data:

Insert data chart here and below in advance of session 2

Make sure that you have done this in advance of the session and that you are prepared to talk through the data and summarise the findings.

Check that they have understood what you are showing them. Try to link it to what they have just told you about their relative's sleep pattern.

Ask them if what you can see in the data fits with their experiences' of their relatives sleep pattern

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Summary:

Fill in in advance of the session

- Your relative spends around X hours in bed and sleeps for about X hours each night.
- This ratio of sleep time to time in bed is called **sleep efficiency**.
- **Your relative's sleep efficiency is X%.**
- Effective methods to improve sleep efficiency involve:
    1) Eliminating / reducing daytime naps
    2) Delaying the start of sleep by going to bed later.

Consider this in advance of the session, it may not be relevant for everyone.

Q! **If your relative tends to nap often, what would help you to reduce this?**

If your relative goes to bed very early, do you think you could keep them awake later?

What effect would these changes have on you?

Could you try to shift bedtime to _____ and encourage your relative to get up at _____

10mins

Making a new routine - your relative's plan

Now let's use all that we have talked about today to make a plan on page 25.



Next week we will be talking more about increasing pleasant daytime events and activities for you and your relative.

"Each week we are going to try a new stress reduction technique. Last week we learnt the 'signal breath'. This week we will practise a focused breathing exercise."

First, let's think about the signal breath. Did you get a chance to try it out this week?

If you did, how did you find it? When did you use it? What effect did it have on how you felt?

If you did not get a chance to try it, what got in the way?

Please try and carry on practising the signal breath.

Now we are going to learn a new stress reduction technique, 'focused breathing'."

Session 2 Version 1

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10 mins

DREAMS: START

Managing Stress 2:

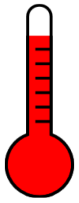
Focused breathing

Focused Breathing is a useful stress reduction technique:



- It can relax you, reducing the tension and stress that can come from caring.
- It can help you to briefly focus on yourself, and have a break from caring.
- It can also help you get to sleep after a stressful day.
- Focused breathing may also be a way for your relative to get nice and relaxed before bed time.

Stress Rating Before Exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

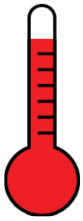
- First, please rate your level of stress or tension right now before we practice the Focused Breathing.

Q! **On a scale of 1 to 5, how would you rate your tension? _____**

"Now I am going to talk you through the focused breathing exercise…"

Session 2 Version 1

Tension Rating After Exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- How would you rate your tension level now after practicing the Focused Breathing exercise?

Q! **Now, please rate your tension or stress level from 1 to 5 _____**

Discuss:
- Did your level of tension change?
- What was this experience like for you?
- Can you think of specific times when this might have helped?

Session 2 Version 1

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Summary

Today, we have talked about:

- Recap on understanding sleep and dementia
- Light and sleep
- Light, dementia and the body clock
- Your relative's sleep pattern
- Making a new sleep routine: Your relative's plan
- Managing stress 2: Focused Breathing

Session 2 Version 1

5mins

FOR NEXT WEEK: Putting it into practice

Key Point:

It is important for you try out the plan we have made building it into your routine. Using the plan regularly will help us see whether it works and help us to make further changes if it is not helping.



Focused breathing:

- Try to practice this every night before bed and with your relative if that is possible. See if it helps.



Putting the plan into action:

- Try and use the plan we made on page 25. Please continue to keep a sleep diary for your relative and try and fill in the record form on p.25.

Go through the forms and check that they have a clear plan written down and have understood the task

DREAMS: START

Putting it into Practice

- When will you have an opportunity to do this?
- What might get in the way?
- What might make it easier?

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Weekly Sleep Diary

"We have added the letter L to the key for when your relative has used the light box. Otherwise, the sleep diary is the same as last week"

Date	Noon	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am
Tuesday May 14th	**O**		**N**							**/**			**X X**		**X**				**/**				**N**	**O**

Key:

/ = When your relative went to bed and when they got up in the morning

X = Every time your relative gets up in the night

N = When your relative takes a nap during the day

O = When your relative has been out of the house

E = When your relative has done any physical exercise

L = When you relative has used the light box

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Planning record

"We can write in the action plan together now…If you would like to make it simpler for how each action plan went then you can use a tick or a cross."

- Here is a way of monitoring how the changes have gone for you and your relative.

	Action plan	How did it go for your relative?	How did it go for you?
Light box			
Increasing natural light			
Reducing daytime naps			
Time to bed and rise			
Lifestyle changes			

Remember to encourage them to develop SMART goals based on discussion for each point and write down specifics. **Get them to write the specific plan down on the record form.**

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DREAMS: START

Dementia Related Manual for Sleep:

Strategies for Relatives

Session 3: Daytime activity and routine



Session 3 Version 1

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Plan for today's session: Daytime activity and routine

Recap on making a plan	p. 3
The importance of daytime activity and routine	p. 5
Planning daytime activity	p. 6
Sleep, exercise and physical activity	p. 9
Establishing a good day and night routine	p. 11
Managing stress 3: Guided Imagery	p. 14
Summary	p. 17
Putting it into practice	p. 18
Seated exercises visual guide	p. 21

Recap of session 2: Making a plan

We talked about:

- Light and sleep
- Light, dementia and the body clock
- Your relative's sleep pattern
- Making a new sleep routine: Your relative's plan
- Focused Breathing
- Summary
- Putting it into practice

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Q! **Did you have a chance to try out the plan we made together last week and record it on the record form? Let's have a look at the record form and sleep diary you completed last week.**

Area for change	How did it go?	
	What made it harder?	What made it easier?
Light box		
Increasing natural light		
Reducing daytime naps		
Time to bed and rise		
Lifestyle changes		

Please continue to use the plan and complete the sleep diary. Remember, completing the record form helps us to see what is working and what is not.

Session 3 Version 1

The importance of daytime activity and routine

- This session is about things people enjoy: pleasant daytime events and physical activity.
- Poor sleep at night is often related to having too few stimulating and pleasant activities in our lives. This is no different for people with dementia.
- People with dementia find it harder to organise their own activities. Even with lots of people around they can still feel lonely or bored.
- Caring for a relative with dementia can also mean that you find it hard to make time for your own enjoyment and activity, which may make you feel worse and sleep less well.
- You may think "It seems like there's nothing I can do to make things better." However, you can feel better by making sure your day has a few events that bring you pleasure.

List two activities that your relative enjoys	**List two activities that you enjoy**
1. 2.	1. 2.

Key Point:
Anything a person likes to do is a pleasant event. People's interests can change when they have dementia and they may enjoy activities that they did not before, or no longer enjoy what they used to.

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Planning daytime activity

- Pleasant activities don't have to be long. They don't need a lot of planning or to be big activities. Small things can make a big difference and might make somebody's day.

- Here are some examples of pleasurable and stimulating activities, not all of these activities will suit your relative. Take a few moments to look over this list and tick the activities you think they would enjoy either together or separately.

Events	**Tick** ✓	**Events**	**Tick** ✓
Listen to music		Go to a place of worship	
Go to the shops		Watch sports	
Go for a walk		Talk about happy memories	
Read/listen to books, newspapers, magazines or prayer books		Holding things like a stress ball or bubble wrap	
Sit with them for a tea and chat		Have a leisurely bath	
Relaxation and sensory exercises		Chat to friends or family on the phone	
Write letters or cards etc		Spend time on an ipad using apps or skype	
Drawing, painting, crafts		Play cards, games or puzzles	
Exercise e.g. yoga, chair based exercise, stretching		Talk about family or current events	
Watch a film		Special occasion meals or parties	
Go into the garden or balcony		Dance	
Have a picnic or a BBQ		Live musicians / concerts / singing	
DIY / Sewing		Bingo	
Gardening		Cook or bake	
Listen to the radio		Helping with domestic tasks e.g. setting the table	
Watch a favourite TV programme		Have a glass of wine or beer (if appropriate)	
Watch wildlife or be around animals or pets		Hold soft toys or dolls	
Look at photos		Have hair done / manicure / pedicure	
Memory books / boxes		Hand or foot massage	
Other activities:			

Let's think of four pleasant activities for you and your relative. If possible choose at least two that would need your relative to be physically active:

1

2

3

4.

Key Point:

It is important to plan activities or events that are manageable and achievable.





When planning activities, ask yourself: Is it possible to still do those activities? If not, can they be changed in any way?

For example, if you used to take long walks together, can you now take short walks? As long as you find things your relative enjoys and is able to do, you will be helping them to be stimulated and feel better.

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Some activities require more planning than others. Because we want you to be successful in planning pleasant events for your relative, we have put together a list of questions to help you plan:

Choose one of the pleasant activities that you would like to try with your relative:

- What materials or preparation are needed?
- When will it take place?
- How often can it be done?
- How much time will it take?

Before the next session with your relative we would like you to try out a new pleasant activity.

Remember:

- Don't force them to participate: Encourage or reward him/her often.
- Try to think of things that are similar to some hobbies, interests, or games they used to enjoy.
- Have a few activities available, so if they become bored you can switch easily.
- Plan to do activities in short bursts
- Try to involve other friends or family if at all possible.
- Activities that involve movement can be good, since people with dementia are often restless and have relatively short attention spans.
- There is no harm if your relative enjoys crafts, games, or music that are simpler than before.





Session 3 Version 1

Sleep, exercise and physical activity

- We know that as people get older there are many reasons why it may be harder to exercise, but even lighter forms of exercise like walking, can improve sleep in older people and those with dementia.
- Physical activity is good for our mental and physical health, it helps keep our bodies and mind in good shape.
- People who are physically active are more likely to have regular, good quality sleep at night and be more alert during the day.
- Physical activity may improve sleep by making people feel better and telling our body clock that it is time to be awake.
- For those with mobility problems it is recommended that they have at least three periods of physical activity a week to improve balance and prevent falls.



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Q! **Let's look again at the sleep diary from last week:**

- **How much physical activity does your relative get?**
- **What type of physical activity do they enjoy?**
- **What type of physical activity are they able to do?**

Key Point:
If possible, we would like your relative to walk for up to 30 minutes at least three times a week, you may wish to build up to this gradually.

- Let's talk together about whether this would be possible for your relative and what you may be able to try instead.
- What concerns do you have, if any, about your relative being more physically active?
- If your relative finds it difficult to walk, what else could they try instead? (Let's look at this leaflet from the Alzheimer's Society which has some good ideas.)

Walking / exercise goal:

Write down a realistic and achievable walking goal for your relative over the next week

Walking for _____ minutes at least _____ times / week

Or _____ for _____ minutes at least _____ times/week

Session 3 Version 1

Establishing a good day and night routine

- So far we have talked about a number of small changes that could help improve your relative's sleep. These include:
    - Lifestyle changes
    - The bedroom environment
    - Natural and artificial light
    - Reducing daytime naps
    - Going to bed at a regular time
    - Being physically and mentally active during the day
- All of these things remind the body clock that it should be awake during the day and asleep at night and help the brain feel pressure to fall asleep.
- As we discussed, it can help to **build a strong link between bed and sleep**.
- Things you can do to help your relative to make a strong connection between sleep and bed include:

Bedtime wind-down

Your relative's pre-bed routine should start about 60 - 90 minutes before bed when you can start helping them to relaxing and prepare for sleep. This could include things like stopping activity, brushing teeth or putting pyjamas on.

The routine may be more involved: for example encouraging your relative to sit down an hour or so before bedtime with a decaffeinated drink, read or watch TV or listen to relaxing music.

Bedtime activities

It is important not to use your bed for anything except sleep. This means that watching TV, reading, eating, and using a phone or iPad are out!

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Avoiding napping

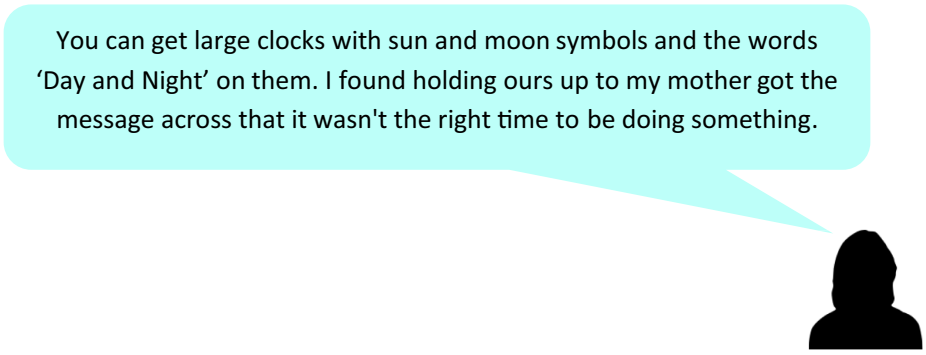
As we discussed last week, napping during the day can weaken the pressure to sleep at night. Being more active during the day, especially out in natural light, will reduce the amount of time your relative is unstimulated and perhaps dozing, during the day.

Feeling sleepy

It is important to only go to bed when feeling sleepy. Try to encourage your relative not to go to bed too early, we know that evenings may be an important time for you to get things done around the house, but going to bed too early can weaken the link between bed and sleep.

Regular mealtimes & a day time routine

As you will know, for people with dementia, who may have a disrupted body clock making it harder to know when it is day or night, any clues to remind people that it is day time or night time will be helpful. This may be having meals or doing certain activities at a set time or it may be making sure they get out into daylight every day.



Key Point:

Many of these points will apply for you too! Don't forget to think about what might help you to improve your own sleep.

Q! How can you strengthen your relative's bed-sleep connection?

Strengthening the link between bed and sleep	Suggestions	What could you try for your relative?	What could you try for yourself?
Bedtime wind down	• Having warm (caffeine free) drink) • Getting into bed clothes • Listening to relaxing music		
Bedtime activities	• Turning off the TV or radio in the bedroom. • Leaving phones or ipad away from the bed		
Daytime napping	• Involving your relative in chores at home • Doing gentle physical activity • Making sure the room is well lit • Keeping active after lunch		
Feeling sleepy	• Having a chat or playing a game in the early evening • Delaying bedtime until your relative is tired		
Daytime routine	• Having meals at a regular time • Having activities planned during the day		

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DREAMS: START

Managing Stress 3:

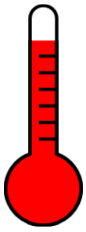
Guided Imagery - Meadow and Stream



Guided Imagery is a stress reduction technique that allows you to have "time out" from daily worries.

- It should be done in a quiet setting where you will not be disturbed.
- Some people find use this type of exercise before they go to bed in the evening. It is best to get used to it at other times of day first.
- The more you practice, the more useful it will be.

Stress Rating Before Exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- First, please rate your level of stress or tension right now, before we practice the Guided Imagery exercise.

Q! **On a scale of 1 to 5, how would you rate your tension? _____**

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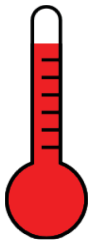
Tension Rating After Exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- How would you rate your tension level now, after practicing the Guided Imagery exercise?

Q! Now, please rate your tension or stress level from 1 to 5 _____

Session 3 Version 1

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Summary

Today, we have talked about:

- Recap on making a plan
- The importance of daytime activity and routine
- Sleep, exercise and physical activity
- Planning daytime activity
- Establishing a good day and night routine
- Managing stress 3: Guided imagery

FOR NEXT WEEK: Putting it into practice

Key Point:
Doing more during the day, being stimulated, active and exposed to natural light will help your relative sleep better at night-time.



Guided imagery:

- Try to practice this every day and to use it in stressful situations. See if it helps. If possible, try it with your relative as part of a bed time wind-down.



Daytime activity:

- Try out a daytime activity with your relative every day over the next week, even if it is the same one every day or if it is just for fifteen minutes. Record how it went on the record form on the next page.

- If appropriate, try out the walking / exercise plan we made on page 10.

Continue to follow the plan we made last week using light and establishing a regular routine.

DREAMS: START *Putting it into Practice*

- When will you have an opportunity to do this?
- What might get in the way?
- What might make it easier?

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Pleasant events record:

Day	What did you try?	How did it go?

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DOI: 10.3310/hta22710

Weekly Sleep Diary

Date	Noon	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am
Tuesday May 14th	O		N							/			X X		X				/				N	O

Key:

/ = When your relative went to bed and when they got up in the morning

X = Every time your relative gets up in the night

N = When your relative takes a nap during the day

O = When your relative has been out of the house

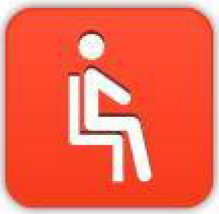
E = When your relative has done any physical exercise

L = When you relative has used the light box

Session 3 Version 1

NHS choices

Exercises for older people



Sitting

Getting started

If you've not done much physical activity for a while, you may want to get the all-clear from a GP before starting.

For the exercises that require a chair, chose one that is stable, solid and without wheels. You should be able to sit with feet flat on the floor and knees bent at right angles. Avoid chairs with arms as this will restrict your movement.

Wear loose, comfortable clothing and keep some water handy.

Try to attempt these exercises at least twice a week, this will help to improve muscle strength, balance and co-ordination.

Build up slowly and aim to increase the repetitions of each exercise over time.

As your fitness improves, why not look for a group session near you? Age UK have lots of ideas. **www.ageuk.org.uk**

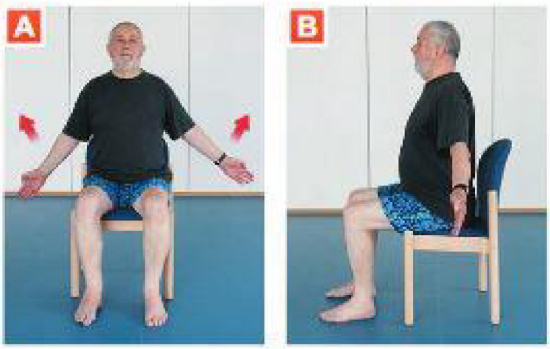
There are three other sets of exercises in this series: Flexibility, Strength and Balance.
Go to **www.nhs.uk/exercises-for-older-people** to download.

www.nhs.uk

Session 3 Version 1

Sitting

CHEST STRETCH



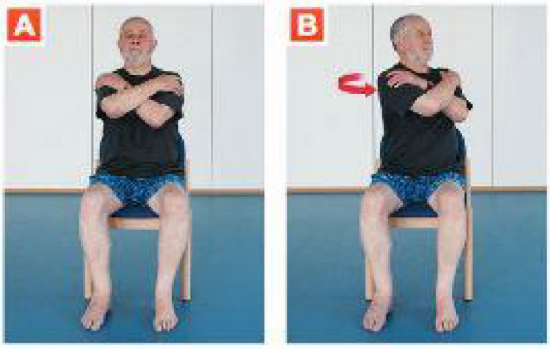
This stretch is good for posture.

A. Sit upright and away from the back of the chair. Pull your shoulders back and down. Extend arms out to the side.

B. Gently push your chest forwards and up until you feel a stretch across your chest.

Hold for five to 10 seconds and repeat five times.

UPPER BODY TWIST



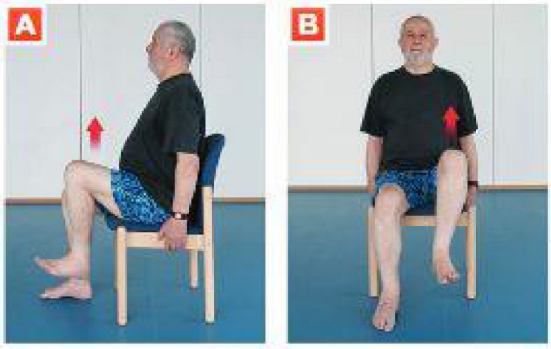
This will develop and maintain flexibility in the upper back.

A. Sit upright with feet flat on the floor, cross your arms and reach for your shoulders.

B. Without moving your hips, turn your upper body to the left as far as is comfortable.

Hold for five seconds. Repeat going right. Do five of each.

HIP MARCHING



This will strengthen hips and thighs and improve flexibility.

A. Sit upright and away from the back of the chair. Hold on to the sides of the chair.

B. Lift your left leg, with your knee bent, as far as is comfortable. Place foot down with control.

Repeat with the opposite leg. Do five lifts with each leg.

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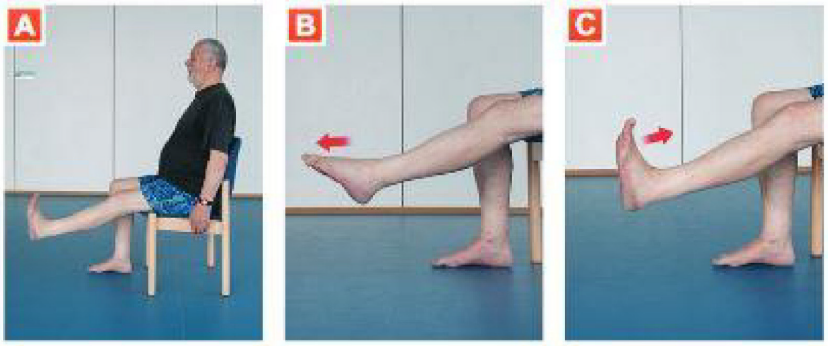
Sitting

ANKLE STRETCH



This will improve ankle flexibility and reduce blood clot risk.

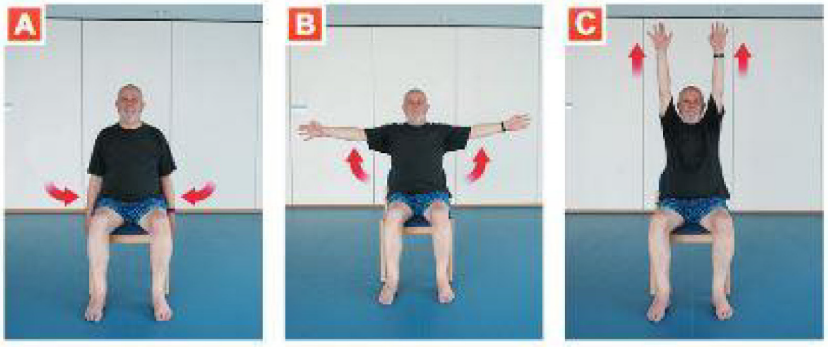
A. Sit upright, hold on to the side of the chair and straighten your left leg with your foot off the floor.

B. With leg straight and raised, point your toes away from you.

C. Point toes back towards you.

Try two sets of five stretches with each foot.

ARM RAISES



This builds shoulder strength.

A. Sit upright, arms by your sides.

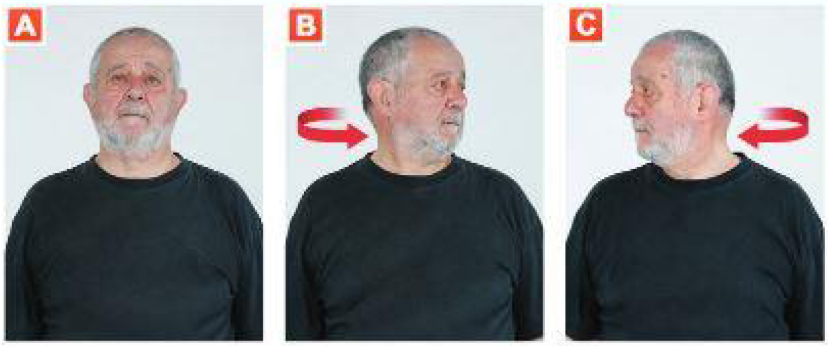
B. With palms forwards, raise both arms out and to the side and up as far as is comfortable. Then return.

C. Keep your shoulders down and arms straight throughout.

Breathe out as you raise your arms and breathe in as you lower them. Repeat five times.

Sitting

NECK ROTATION



This stretch is good for improving neck mobility and flexibility.

A. Sit upright with shoulders down. Look straight ahead.

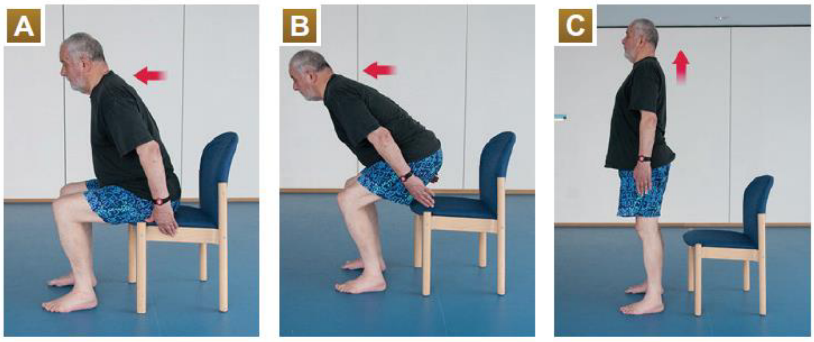
B. Slowly turn your head towards your left shoulder as far as is comfortable. Hold for five seconds and return to starting position.

C. Repeat going right.

Do three rotations on each side.

Strength

SIT TO STAND



This is good for leg strength.

A. Sit on the edge of the chair, feet hip-width apart. Lean slightly forwards.

B. Stand up slowly, using your legs, not arms. Keep looking forwards, not down.

C. Stand upright before slowly sitting down, bottom-first.

Aim for five repetitions - the slower the better.

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Facilitator Version

DREAMS: START

Dementia Related Manual for Sleep: Strategies for Relatives

Session 3: Daytime activity and routine



For each session:

- Encourage the carer to write down what works or key strategies or plans to refer back to.
- If content is clearly irrelevant or does not fit, for example someone is very active all day will not need a plan around daytime naps, miss these parts out.
- When setting exercises at the end, check that they remember what is in the plan if not explicitly covered in the content.

Session 3 Version 1

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Plan for today's session: Daytime activity and routine

"This is the contents page for you to refer back to"

Refer to the contents but do not read the full list

Recap on making a plan	p. 3
The importance of daytime activity and routine	p. 5
Planning daytime activity	p. 6
Sleep, exercise and physical activity	p. 9
Establishing a good day and night routine	p. 11
Managing stress 3: Guided Imagery	p. 14
Summary	p. 17
Putting it into practice	p. 18
Seated exercises visual guide	p. 21

Session 3 Version 1

10mins

Recap of session 2: Making a plan

We talked about:

- Light and sleep
- Light, dementia and the body clock
- Your relative's sleep pattern
- Making a new sleep routine: Your relative's plan
- Focused Breathing
- Summary
- Putting it into practice

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Q! **Did you have a chance to try out the plan we made together last week and record it on the record form? Let's have a look at the record form and sleep diary you completed last week.** "Write down what you found, especially what worked well so that you can use this in future"

Area for change	How did it go?	
	What made it harder?	What made it easier?
Light box		
Increasing natural light		
Reducing daytime naps		
Time to bed and rise		
Lifestyle changes		

Please continue to use the plan and complete the sleep diary. Remember, completing the record form helps us to see what is working and what is not.

Session 3 Version 1

10mins

The importance of daytime activity and routine

- This session is about things people enjoy: pleasant daytime events and physical activity.
- Poor sleep at night is often related to having too few stimulating and pleasant activities in our lives. This is no different for people with dementia.
- People with dementia find it harder to organise their own activities. Even with lots of people around they can still feel lonely or bored.
- Caring for a relative with dementia can also mean that you find it hard to make time for your own enjoyment and activity, which may make you feel worse and sleep less well.
- You may think "It seems like there's nothing I can do to make things better." However, you can feel better by making sure your day has a few events that bring you pleasure.

Key point: You don't need to plan big activities to make a difference to people's lives – it is about building on what is already happening

List two activities that your relative enjoys	**List two activities that you enjoy**
1. 2.	1. 2.

Key Point:
Anything a person likes to do is a pleasant event. People's interests can change when they have dementia and they may enjoy activities that they did not before, or no longer enjoy what they used to.

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10mins Planning daytime activity

- Pleasant activities don't have to be long. They don't need a lot of planning or to be big activities. Small things can make a big difference and might make somebody's day.

- Here are some examples of pleasurable and stimulating activities, not all of these activities will suit your relative. Take a few moments to look over this list and tick the activities you think they would enjoy either together or separately.

Events	Tick	Events	Tick
Listen to music		Go to a place of worship	
Go to the shops		Watch sports	
Go for a walk		Talk about happy memories	
Read/listen to books, newspapers, magazines or prayer books		Holding things like a stress ball or bubble wrap	
Sit with them for a tea and chat		Have a leisurely bath	
Relaxation and sensory exercises		Chat to friends or family on the phone	
Write letters or cards etc		Spend time on an ipad using apps or skype	
Drawing, painting, crafts		Play cards, games or puzzles	
Exercise e.g. yoga, chair based exercise, stretching		Talk about family or current events	
Watch a film		Special occasion meals or parties	
Go into the garden or balcony		Dance	
Have a picnic or a BBQ		Live musicians / concerts / singing	
DIY / Sewing		Bingo	
Gardening		Cook or bake	
Listen to the radio		Helping with domestic tasks e.g. setting the table	
Watch a favourite TV programme		Have a glass of wine or beer (if appropriate)	
Watch wildlife or be around animals or pets		Hold soft toys or dolls	
Look at photos		Have hair done / manicure / pedicure	
Memory books / boxes		Hand or foot massage	
Other activities:			

"Include things that you are already doing, some are activities can easily be done and others require a bit more planning?" (Give a couple of minutes)

"Are there any other activities or events that you would add to the list?"

Session 3 Version 1

Let's think of four pleasant activities for you and your relative. If possible choose at least two that would need your relative to be physically active:

1

2

3

4.

Encourage people to choose activities that are realistic and can easily be built into existing routines without too much adjustment.

Explain that you will be talking about the importance of physical activity for sleep next, unless it is not appropriate e.g. the person is unable to be physically active.

Key Point:

It is important to plan activities or events that are manageable and achievable.





When planning activities, ask yourself: Is it possible to still do those activities? If not, can they be changed in any way?

For example, if you used to take long walks together, can you now take short walks? As long as you find things your relative enjoys and is able to do, you will be helping them to be stimulated and feel better.

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Some activities require more planning than others. Because we want you to be successful in planning pleasant events for your relative, we have put together a list of questions to help you plan:

Choose one of the pleasant activities that you would like to try with your relative:

- What materials or preparation are needed?
- When will it take place?
- How often can it be done?
- How much time will it take?

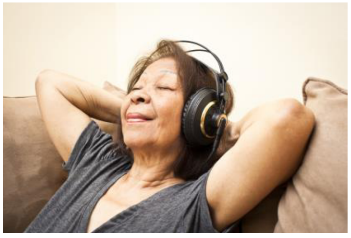
Give them the leaflet that could help with any travel or financial barriers to planning activities.

Before the next session with your relative we would like you to try out a new pleasant activity.

Remember:

- Don't force them to participate: Encourage or reward him/her often.
- Try to think of things that are similar to some hobbies, interests, or games they used to enjoy.
- Have a few activities available, so if they become bored you can switch easily.
- Plan to do activities in short bursts
- Try to involve other friends or family if at all possible.
- Activities that involve movement can be good, since people with dementia are often restless and have relatively short attention spans.
- There is no harm if your relative enjoys crafts, games, or music that are simpler than before.





Session 3 Version 1

Sleep, exercise and physical activity

- We know that as people get older there are many reasons why it may be harder to exercise, but even lighter forms of exercise like walking, can improve sleep in older people and those with dementia.
- Physical activity is good for our mental and physical health, it helps keep our bodies and mind in good shape.
- People who are physically active are more likely to have regular, good quality sleep at night and be more alert during the day.
- Physical activity may improve sleep by making people feel better and telling our body clock that it is time to be awake.
- For those with mobility problems it is recommended that they have at least three periods of physical activity a week to improve balance and prevent falls.



"Now we are going to talk about how much physical activity your relative is currently doing, we know that everyone has different levels of mobility and that for some people moving even small amounts can be very hard. We also know that it is not always easy to get a person with dementia to do something that they do not want to. We will talk about what is realistic and achievable for you and your relative."

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Q! **Let's look again at the sleep diary from last week:**

- **How much physical activity does your relative get?**
- **What type of physical activity do they enjoy?**
- **What type of physical activity are they able to do?**

Key Point:

If possible, we would like your relative to walk for up to 30 minutes at least three times a week, you may wish to build up to this gradually.

This is for people without any mobility problems – make clear we do not expect those with more limited mobility or those at risk of falls to do this.

- Let's talk together about whether this would be possible for your relative and what you may be able to try instead.
- What concerns do you have, if any, about your relative being more physically active?
- If your relative finds it difficult to walk, what else could they try instead? (Let's look at this leaflet from the Alzheimer's Society which has some good ideas.)

Talk through seated exercise plan where appropriate and give them the recording and leaflet, answer any questions. Explain that it will be easier for their relative to follow if they do it at the same time with the audio playing so that their relative has visual cues.

Walking / exercise goal:

Write down a realistic and achievable walking goal for your relative over the next week

Walking for _____ minutes at least _____ times / week

Or _____ for _____ minutes at least _____ times/week

Session 3 Version 1

10mins

Establishing a good day and night routine

- So far we have talked about a number of small changes that could help improve your relative's sleep. These include:
    - Lifestyle changes
    - The bedroom environment
    - Natural and artificial light
    - Reducing daytime naps
    - Going to bed at a regular time
    - Being physically and mentally active during the day
- All of these things remind the body clock that it should be awake during the day and asleep at night and help the brain feel pressure to fall asleep.
- As we discussed, it can help to **build a strong link between bed and sleep**.
- Things you can do to help your relative to make a strong connection between sleep and bed include:

"You may already be doing some of these things but there may also be some new ideas that you could try"

Bedtime wind-down

Your relative's pre-bed routine should start about 60 - 90 minutes before bed when you can start helping them to relaxing and prepare for sleep. This could include things like stopping activity, brushing teeth or putting pyjamas on.

The routine may be more involved: for example encouraging your relative to sit down an hour or so before bedtime with a decaffeinated drink, read or watch TV or listen to relaxing music.

Bedtime activities

It is important not to use your bed for anything except sleep. This means that watching TV, reading, eating, and using a phone or iPad are out!

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Avoiding napping

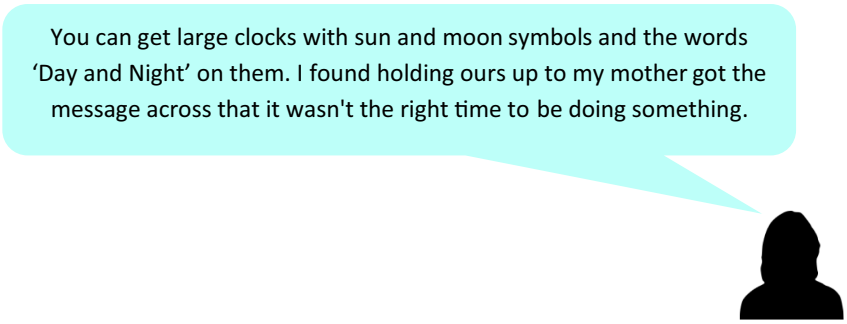
As we discussed last week, napping during the day can weaken the pressure to sleep at night. Being more active during the day, especially out in natural light, will reduce the amount of time your relative is unstimulated and perhaps dozing, during the day.

Feeling sleepy

It is important to only go to bed when feeling sleepy. Try to encourage your relative not to go to bed too early, we know that evenings may be an important time for you to get things done around the house, but going to bed too early can weaken the link between bed and sleep.

Regular mealtimes & a day time routine

As you will know, for people with dementia, who may have a disrupted body clock making it harder to know when it is day or night, any clues to remind people that it is day time or night time will be helpful. This may be having meals or doing certain activities at a set time or it may be making sure they get out into daylight every day.



Key Point:

Many of these points will apply for you too! Don't forget to think about what might help you to improve your own sleep.

Session 3 Version 1

Q! How can you strengthen your relative's bed-sleep connection?

Strengthening the link between bed and sleep	Suggestions	What could you try for your relative?	What could you try for yourself?
Bedtime wind down	• Having warm (caffeine free) drink) • Getting into bed clothes • Listening to relaxing music		
Bedtime activities	• Turning off the TV or radio in the bedroom. • Leaving phones or ipad away from the bed		
Daytime napping	• Involving your relative in chores at home • Doing gentle physical activity • Making sure the room is well lit • Keeping active after lunch		
Feeling sleepy	• Having a chat or playing a game in the early evening • Delaying bedtime until your relative is tired		
Daytime routine	• Having meals at a regular time • Having activities planned during the day		

Not all of these will be relevant – skip the ones that do not apply.

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10mins

DREAMS: START

Managing Stress 3:

Guided Imagery - Meadow and Stream

"Now we are going to try a new stress reduction technique, last week we learnt the 'focused breathing'. This week we will practise a guided imagery exercise.

First, let's think about the focused breathing. Did you get a chance to try it out this week?

If you gave it a go, how did you find it? When did you use it? What effect did it have on how you felt?

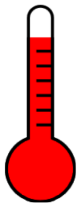
If you did not get a chance to try it, what got in the way?

Please try and carry on practicing the focused breathing exercise."

Guided Imagery is a stress reduction technique that allows you to have "time out" from daily worries.

- It should be done in a quiet setting where you will not be disturbed.
- Some people find use this type of exercise before they go to bed in the evening. It is best to get used to it at other times of day first.
- The more you practice, the more useful it will be.

Stress Rating Before Exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- First, please rate your level of stress or tension right now, before we practice the Guided Imagery exercise.

Q! **On a scale of 1 to 5, how would you rate your tension? _____**

"Now I am going to talk you through the guided imagery exercise…"

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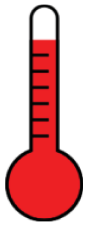
Tension Rating After Exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- How would you rate your tension level now, after practicing the Guided Imagery exercise?

Q! Now, please rate your tension or stress level from 1 to 5 _____

Discuss:
- Did your level of tension change?
- What was this experience like for you?
- Can you think of specific times when this might have helped?

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Summary

Today, we have talked about:

- Recap on making a plan
- The importance of daytime activity and routine
- Sleep, exercise and physical activity
- Planning daytime activity
- Establishing a good day and night routine
- Managing stress 3: Guided imagery

10mins

FOR NEXT WEEK: Putting it into practice

Key Point:

Doing more during the day, being stimulated, active and exposed to natural light will help your relative sleep better at night-time.



Guided imagery:

- Try to practice this every day and to use it in stressful situations. See if it helps. If possible, try it with your relative as part of a bed time wind-down.



Daytime activity:

- Try out a daytime activity with your relative every day over the next week, even if it is the same one every day or if it is just for fifteen minutes. Record how it went on the record form on the next page.
- If appropriate, try out the walking / exercise plan we made on page 10.

Continue to follow the plan we made last week using light and establishing a regular routine.

DREAMS: START *Putting it into Practice*

- When will you have an opportunity to do this?
- What might get in the way?
- What might make it easier?

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Pleasant events record:

Day	What did you try?	How did it go?

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DOI: 10.3310/hta22710

Weekly Sleep Diary

Date	Noon	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am
Tuesday May 14th	O		N							/			X X		X				/				N	O

Key:

/ = When your relative went to bed and when they got up in the morning

X = Every time your relative gets up in the night

N = When your relative takes a nap during the day

O = When your relative has been out of the house

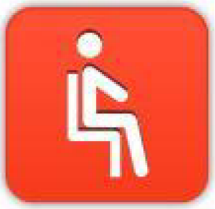
E = When your relative has done any physical exercise

L = When you relative has used the light box

Session 3 Version 1

NHS choices

Exercises for older people



Sitting

Getting started

If you've not done much physical activity for a while, you may want to get the all-clear from a GP before starting.

For the exercises that require a chair, chose one that is stable, solid and without wheels. You should be able to sit with feet flat on the floor and knees bent at right angles. Avoid chairs with arms as this will restrict your movement.

Wear loose, comfortable clothing and keep some water handy.

Try to attempt these exercises at least twice a week, this will help to improve muscle strength, balance and co-ordination.

Build up slowly and aim to increase the repetitions of each exercise over time.

As your fitness improves, why not look for a group session near you? Age UK have lots of ideas. **www.ageuk.org.uk**

There are three other sets of exercises in this series: Flexibility, Strength and Balance.
Go to **www.nhs.uk/exercises-for-older-people** to download.

www.nhs.uk

Session 3 Version 1

Sitting

CHEST STRETCH





This stretch is good for posture.

A. Sit upright and away from the back of the chair. Pull your shoulders back and down. Extend arms out to the side.

B. Gently push your chest forwards and up until you feel a stretch across your chest.

Hold for five to 10 seconds and repeat five times.

UPPER BODY TWIST





This will develop and maintain flexibility in the upper back.

A. Sit upright with feet flat on the floor, cross your arms and reach for your shoulders.

B. Without moving your hips, turn your upper body to the left as far as is comfortable.

Hold for five seconds. Repeat going right. Do five of each.

HIP MARCHING





This will strengthen hips and thighs and improve flexibility.

A. Sit upright and away from the back of the chair. Hold on to the sides of the chair.

B. Lift your left leg, with your knee bent, as far as is comfortable. Place foot down with control.

Repeat with the opposite leg. Do five lifts with each leg.

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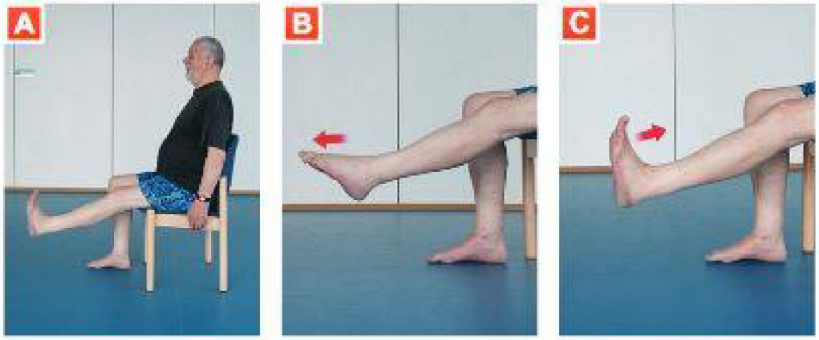
Sitting

ANKLE STRETCH



This will improve ankle flexibility and reduce blood clot risk.

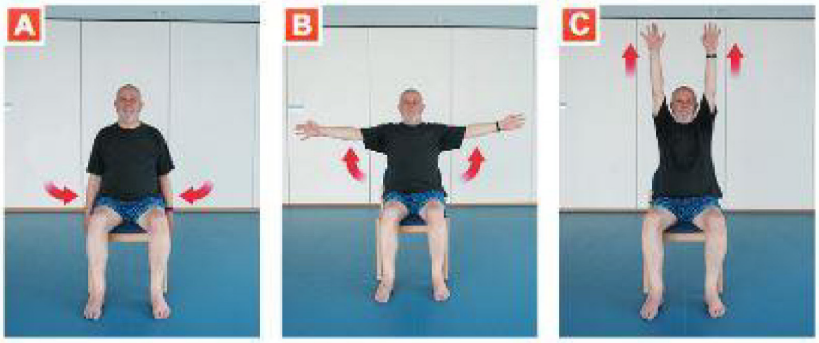
A. Sit upright, hold on to the side of the chair and straighten your left leg with your foot off the floor.

B. With leg straight and raised, point your toes away from you.

C. Point toes back towards you.

Try two sets of five stretches with each foot.

ARM RAISES



This builds shoulder strength.

A. Sit upright, arms by your sides.

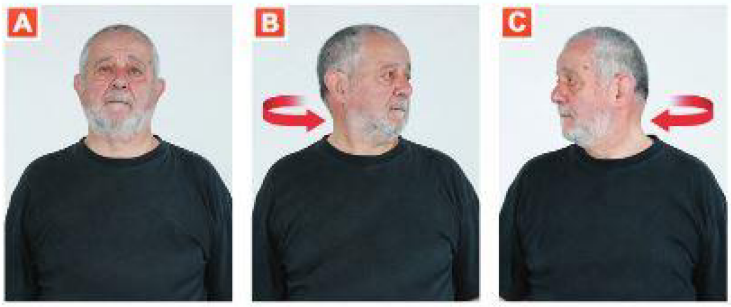
B. With palms forwards, raise both arms out and to the side and up as far as is comfortable. Then return.

C. Keep your shoulders down and arms straight throughout.

Breathe out as you raise your arms and breathe in as you lower them. Repeat five times.

Sitting

NECK ROTATION



This stretch is good for improving neck mobility and flexibility.

A. Sit upright with shoulders down. Look straight ahead.

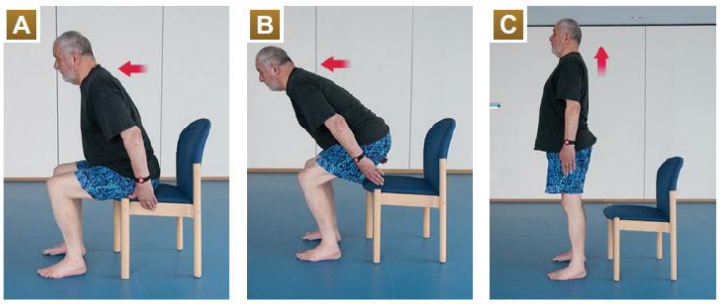
B. Slowly turn your head towards your left shoulder as far as is comfortable. Hold for five seconds and return to starting position.

C. Repeat going right.

Do three rotations on each side.

Strength

SIT TO STAND



This is good for leg strength.

A. Sit on the edge of the chair, feet hip-width apart. Lean slightly forwards.

B. Stand up slowly, using your legs, not arms. Keep looking forwards, not down.

C. Stand upright before slowly sitting down, bottom-first.

Aim for five repetitions - the slower the better.

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DREAMS: START

Dementia Related Manual for Sleep:

Strategies for Relatives

Session 4:

Difficult night-time behaviours



Session 4 Version 1

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Session 4 Version 1

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Plan for today's session

Recap on daytime activity and routine	p. 3
Troubleshooting: putting plans into action	p. 4
Managing night-time behaviour problems	p. 8
Describing and investigating behaviours	p. 9
Managing stress 4: Stretching	p.16
Summary	p. 18
Putting it into practice	p. 19

Session 4 Version 1

Recap of session 3: Daytime activities and routine

We talked about:

- The importance of daytime activity and routine
- Sleep, exercise and physical activity
- Planning daytime activity
- Establishing a good day and night routine
- Managing stress 3: Guided imagery
- Summary
- Putting it into practice



Q! **Did you have a chance to try out new daytime activities and exercise with your relative and record this on the form?**

If Yes…	
How did this go?	
What did you notice happening?	
What made it easier?	
If No…	
What got in the way?	
What would make it easier in the future?	

Key Point:
Please continue to put the agreed plan into action and complete the sleep diary / record forms. Remember, completing the record forms helps to see what is working and what is not.

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Troubleshooting: putting plans into action

So far, during the sessions we have made a plan to help improve your relative's sleep. Depending on their situation this may have involved:

- Increasing daytime stimulation, pleasant activity and exercise
- Being in daylight at set times and using the light box
- Establishing daytime and bedtime routines
- Making lifestyle and bedroom changes
- Using relaxation exercises (you and your relative)

It can take a while for these changes to take effect so please keep going with them. Now let's look at the plans we made in session 2 & 3 and discuss how this has been working so far for you and your relative.



Session 4 Version 1

Your relative's plan

Area for change	Action
Light box	
Increasing natural light	
Reducing daytime naps	
Time to bed and rise	
Lifestyle changes	
Increasing daytime activity / physical exercise	

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Talking point:

- Which parts have you managed to do?

- What effects have you noticed on your relative?

- What effects have you noticed on yourself?

- Is there anything else you have noticed happening?



Session 4 Version 1

- Which are the parts that you are finding harder to put into practice?

- Can you think of some reasons why you and/or your relative are finding these parts more difficult to do?



Let's think together about possible solutions to these difficulties and how we could adapt the plan to make it easier for you to use:

1.

2.

3.

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Managing night-time behaviour problems

During our first session, we identified these difficult behaviours:

- X
- Y
- Z
-

Would you keep the same list or add any other behaviours? Let's rank these in order of how difficult they are to manage:

1.

2.

3.

Key Point:
There is always a cause for night-time behaviours, but the person with dementia is not doing it on purpose and can't control these.

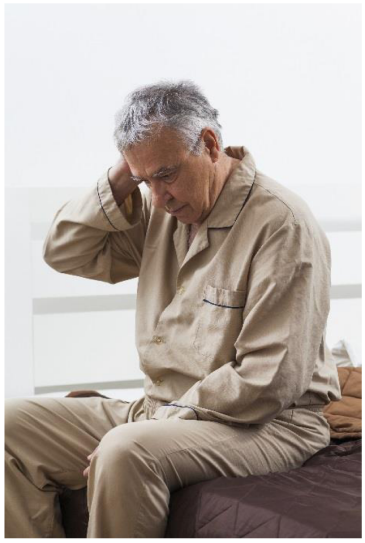
- Often there will be several factors causing night-time behaviours. Our challenge is to work out **what is causing each behaviour** and **what we can do about it.**

Describing and investigating behaviours

Describing in detail difficult night-time behaviours can help to make sense of what is happening and work out how to make it happen less.

Choose one of the sleep problems you identified on the previous page. Start by describing what happens. Imagine it as a film and try to be as detailed as possible. Use the questions below to help:

- **What exactly happens?**
- **How often and at what time does it happen?**
- **Where exactly does it happen?**
- **Does your relative talk to you at the time, what do they say?**
- **How do you think they are feeling at the time?**
- **What might they be thinking?**
- **How do you react when it happens?**



Now let's think about what may be causing this behaviour.

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- Here are some of the main causes of sleep difficulties, which we will next discuss in turn:





1. Environment / routine
2. Fears or emotions
3. How we respond
4. Pain and discomfort
5. The effects of dementia





Session 4 Version 1

1. Is there something about the environment/routine?

- **There may be things about a person's surroundings or routine that may increase sleep difficulties. These may include:**

  - Too much noise or light in the bedroom
  - Uncomfortable surroundings e.g. too warm or cold
  - Sleeping during the day or lack of activity
  - Change in routine e.g. irregular meal or bed times
  - Fear the dark / disorientation
  - Being inside all the time and not getting enough fresh air and light



Talking point:

Think of the difficulty you described a few minutes ago. Do you think it could be caused or made worse by surroundings or routine?

Have any of the changes you have already been trying made a difference to this problem?

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2. Are they feeling distressed or frightened?

Key Point:

Having dementia can be frightening and distressing for people, who cannot always explain or understand their own feelings. Like for all of us, this can feel worse at night.

Some of what you may see happening includes:

- Nightmares
- Waking up distressed or confused
- Being frightened to go to bed or be alone
- Fear of the dark
- Screaming or crying out in the night



Even though you could see her worrying, she was silent, but when we weren't there then she was continually on the phone no matter what time of day or night it was



It can be hard to work out what a person with dementia is feeling and they may not always be able to tell you, especially at night.

Talking point:

What would be signs to you that your relative was feeling upset or frightened in the night? What do you notice happening?

What do you find helps to comfort or calm down your relative?

3. Are night-time difficulties affected by how we respond?

- We know that being woken up or disturbed in the night can be extremely stressful and it is not always easy to think clearly in the middle of the night, especially when you are exhausted.

- There may be practical ways of responding during the night or things you can do in advance to make it easier for you and your relative to get back to sleep.

Key Point:
Changing how we react to difficult night-time behaviours can help to manage the problem.



Talking point Let's look at the example below:

Ted is caring for his wife Lena who has dementia. Lena wakes up three or four times in the night and wanders around the house. She goes downstairs and tries to make toast. Ted has been woken by the smoke alarm a few times.

Ted has started to lock their bedroom door so that Lena cannot go downstairs. When Lena tries to open the door she gets upset, crying and wakes up Ted, saying she needs to get the breakfast ready for the children in time for school.

What could Ted try in this situation?

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4. Are difficulties caused by pain or discomfort?

There may be physical problems that are waking or keeping your relative up at night, but they may not always know or be able to tell you what is wrong. These could include:

- Pain
- Incontinence
- Needing to go the toilet often

Talking point:

Let's think of three things that you can do to find out if a person is unwell or in pain?

1.

2.

3.

Some common medical problems that can cause sleep difficulties include:

Problem	What you may notice
Pain	• Holding or rubbing part of body • Fast breathing • Groaning or moaning • Tension • Making a face or grimacing • Pushing away when touched
Constipation	• Pain and difficulty opening bowels • Hard faeces • Pain on touching stomach
UTI (Urinary tract infections)	• Urinating more frequently • Cloudy or different smelling urine • Pain in back when touched • Being more confused • Burning pain on passing urine

5. Are difficulties caused by the dementia?

Dementia may directly cause sleep difficulties through its effects on the brain and therefore our body-clock. Below is a reminder of some of the sleep difficulties that may occur in dementia.

- Not feeling tired at night
- Waking during the night
- Being more mixed up and restless at night
- Excessive sleepiness during the day
- Restlessness during sleep (e.g. acting out dreams)
- Breathing pauses during sleep (sleep apnoea)
- Restless/fidgety legs before or during sleep

Talking point:

Think back to the examples you described earlier in the session.
How might your relative's sleep difficulties been caused by their dementia?



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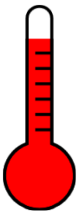
DREAMS: START

Managing Stress 4: *Stretching*



- Simply stretching tired muscles can go a long way toward reducing tension and stress.
- Stretching exercises can be used almost anywhere, at any time, for as long as you want, so they can be an especially convenient relaxation technique.
- It is important to do stretching exercises that feel good to you. As we practice this today, please tell us if you experience any discomfort.

Tension rating before exercise



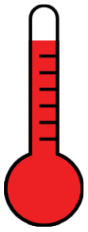
5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- First, please rate your level of stress or tension right now, before we practise the stretching exercise.

Q! **On a scale of 1 to 5, how would you rate your tension? ____**

Session 4 Version 1

Tension rating after exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- How would you rate your tension level now after practising the stretching exercise?

Q! **Now, please rate your tension or stress level from 1 to 5 _____**

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Summary

Today, we have talked about:

- Recap on daytime activity and routine
- Troubleshooting: putting plans into action
- Managing night-time behaviour problems
- Describing and investigating behaviours
- Managing stress 4: Stretching






Session 4 Version 1

FOR NEXT WEEK: Putting it into practice



Stretching:

- Try to practice this every day and to use it in stressful situations. See if it helps.



Managing night-time behaviour problems:

- Try to complete the behaviour record on p.20 for three separate episodes of difficult night-time behaviours this week. Try to focus on **describing** and **investigating** what happened.



Putting the plan into action:

- Continue to use the sleep plan we made for your relative, thinking about any changes we talked about earlier to make the plan more manageable.
- Keep a sleep diary for you and your relative this week so we can compare them next time.

DREAMS: START

Putting it into practice

- When will you have an opportunity to do this?
- What might make it easier?
- What might get in the way?

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Behaviour Record

Describe	Investigate…	What did you find out?
	☐ Environment/routine?	
	☐ Fears or emotions?	
	☐ How we respond?	
	☐ Uncomfortable /Unwell?	
	☐ Dementia?	
	☐ Environment/routine?	
	☐ Fears or emotions?	
	☐ How we respond?	
	☐ Uncomfortable /Unwell?	
	☐ Dementia?	
	☐ Environment/routine?	
	☐ Fears or emotions?	
	☐ How we respond?	
	☐ Uncomfortable /Unwell?	
	☐ Dementia?	

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DOI: 10.3310/hta22710

Weekly Sleep Diary (Carer)

Date	Noon	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am
Tuesday May 14th	O		N							/			X X		X				/				N	O

Key:

/ = When you went to bed and got up in the morning

X = Every time you get up in the night

N = When you take a nap during the day

O = When you have been out of the house

E = When you have done any physical exercise

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Weekly Sleep Diary (Relative)

Date	Noon	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am
Tuesday May 14th	O		N							/			X X		X				/				N	O

Key:

/ = When your relative went to bed and when they got up in the morning

X = Every time your relative gets up in the night

N = When your relative takes a nap during the day

O = When your relative has been out of the house

E = When your relative has done any physical exercise

L = When you relative has used the light box

Facilitator Version

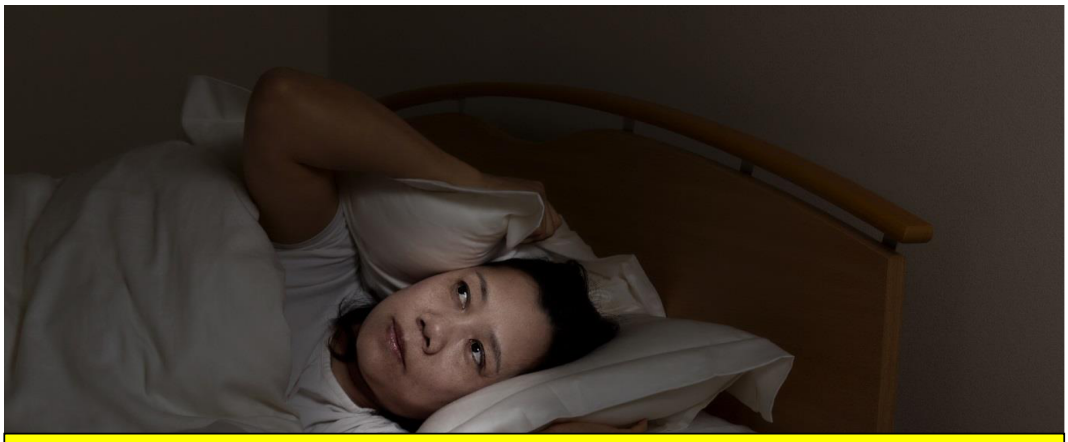
DREAMS: START

Dementia Related Manual for Sleep:

Strategies for Relatives

Session 4:

Difficult night-time behaviours



For each session:

- Encourage the carer to write down what works or key strategies or plans to refer back to.
- If content is clearly irrelevant or does not fit, for example someone is very active all day will not need a plan around daytime naps, miss these parts out.
- When setting exercises at the end, check that they remember what is in the plan if not explicitly covered in the content.

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Session 4 Version 1

Plan for today's session

"This is the contents page for you to refer back to"

Refer to the contents but do not read the full list

Recap on daytime activity and routine	p. 3
Troubleshooting: putting plans into action	p. 4
Managing night-time behaviour problems	p. 8
Describing and investigating behaviours	p. 9
Managing stress 4: Stretching	p.16
Summary	p. 18
Putting it into practice	p. 19

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15mins

Recap of session 3: Daytime activities and routine

We talked about:

- The importance of daytime activity and routine
- Sleep, exercise and physical activity
- Planning daytime activity
- Establishing a good day and night routine
- Managing stress 3: Guided imagery
- Summary
- Putting it into practice



Q! **Did you have a chance to try out new daytime activities and exercise with your relative and record this on the form?**

"Write down what you found, especially what worked well so that you can use this in future"
Remember to ask about pleasant activities and exercise ask what they did

If Yes…	
How did this go?	
What did you notice happening?	
What made it easier?	
If No…	
What got in the way?	
What would make it easier in the future?	

Key Point:
Please continue to put the agreed plan into action and complete the sleep diary / record forms. Remember, completing the record forms helps to see what is working and what is not.

Now let's talk more generally about how the changes are going…

Troubleshooting: putting plans into action

So far, during the sessions we have made a plan to help improve your relative's sleep. Depending on their situation this may have involved:

- Increasing daytime stimulation, pleasant activity and exercise
- Being in daylight at set times and using the light box
- Establishing daytime and bedtime routines
- Making lifestyle and bedroom changes
- Using relaxation exercises (you and your relative)

It can take a while for these changes to take effect so please keep going with them. Now let's look at the plans we made in session 2 & 3 and discuss how this has been working so far for you and your relative.



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Your relative's plan

Type up the plan made in session 2 and add in the exercise activity plan from session 3 and insert here. You should also bring **an extra typed up copy** to give to carers so they can keep referring to the table as they work through the talking points over the page (allowing them to take notes if they wish to.)

Area for change	Action
Light box	
Increasing natural light	
Reducing daytime naps	
Time to bed and rise	
Lifestyle changes	
Increasing daytime activity / physical exercise	

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Talking point:

Remember to try and make this an open discussion, not jumping in with solutions too quickly encouraging people to come up with their own strategies. Refer to sleep diary if completed.

- Which parts have you managed to do?

- What effects have you noticed on your relative?

- What effects have you noticed on yourself?

- Is there anything else you have noticed happening?



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- Which are the parts that you are finding harder to put into practice?

- Can you think of some reasons why you and/or your relative are finding these parts more difficult to do?



Encourage them to make a specific change to the plan and write down clearly here.

Let's think together about possible solutions to these difficulties and how we could adapt the plan to make it easier for you to use:

1.

2.

3.

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5mins Managing night-time behaviour problems

During our first session, we identified these difficult behaviours:

- X
- Y
- Z
-

Insert the behaviours identified in session 1 here in advance of the session

Would you keep the same list or add any other behaviours? Let's rank these in order of how difficult they are to manage:

1.

2.

3.

Key Point:
There is always a cause for night-time behaviours, but the person with dementia is not doing it on purpose and can't control these.

- Often there will be several factors causing night-time behaviours. Our challenge is to work out **what is causing each behaviour** and **what we can do about it.**

20mins Describing and investigating behaviours

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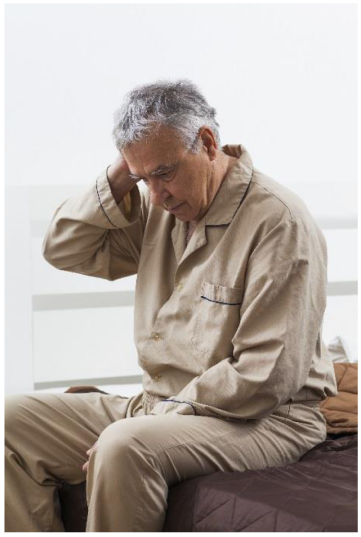
Describing in detail difficult night-time behaviours can help to make sense of what is happening and work out how to make it happen less.

Choose one of the sleep problems you identified on the previous page. Start by describing what happens. Imagine it as a film and try to be as detailed as possible. Use the questions below to help:

"These questions are a guide, there are no right or wrong answers, it is more to help us work out together what might be happening"

- **What exactly happens?**
- **How often and at what time does it happen?**
- **Where exactly does it happen?**
- **Does your relative talk to you at the time, what do they say?**
- **How do you think they are feeling at the time?**
- **What might they be thinking?**
- **How do you react when it happens?**



Now let's think about what may be causing this behaviour.

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- Here are some of the main causes of sleep difficulties, which we will next discuss in turn:

"We will go through these one by one but often they occur together. Understanding and investigating what may be causing sleep difficulties can help us to work out the best ways to manage it"





1. Environment / routine
2. Fears or emotions
3. How we respond
4. Pain and discomfort
5. The effects of dementia





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1. Is there something about the environment/routine?

- **There may be things about a person's surroundings or routine that may increase sleep difficulties. These may include:**

  - Too much noise or light in the bedroom
  - Uncomfortable surroundings e.g. too warm or cold
  - Sleeping during the day or lack of activity
  - Change in routine e.g. irregular meal or bed times
  - Fear the dark / disorientation
  - Being inside all the time and not getting enough fresh air and light



Talking point:

Think of the difficulty you described a few minutes ago. Do you think it could be caused or made worse by surroundings or routine?

Have any of the changes you have already been trying made a difference to this problem?

Encourage people to write down ideas they had not thought of before

Session 4 Version 1

2. Are they feeling distressed or frightened?

Key Point:

Having dementia can be frightening and distressing for people, who cannot always explain or understand their own feelings. Like for all of us, this can feel worse at night.

Some of what you may see happening includes:

- Nightmares
- Waking up distressed or confused
- Being frightened to go to bed or be alone
- Fear of the dark
- Screaming or crying out in the night



Even though you could see her worrying, she was silent, but when we weren't there then she was continually on the phone no matter what time of day or night it was



It can be hard to work out what a person with dementia is feeling and they may not always be able to tell you, especially at night.

Talking point:

What would be signs to you that your relative was feeling upset or frightened in the night? What do you notice happening?

Prompts:
Crying, calling out, wandering around, looking for people that are not there, wanting people with them

What do you find helps to comfort or calm down your relative?

Prompts:
Staying with them, having a warm, drink, reassurance, touch, night light.

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3. Are night-time difficulties affected by how we respond?

- We know that being woken up or disturbed in the night can be extremely stressful and it is not always easy to think clearly in the middle of the night, especially when you are exhausted.

- There may be practical ways of responding during the night or things you can do in advance to make it easier for you and your relative to get back to sleep.

Key Point:
Changing how we react to difficult night-time behaviours can help to manage the problem.



Talking point: Let's look at the example below:

Ted is caring for his wife Lena who has dementia. Lena wakes up three or four times in the night and wanders around the house. She goes downstairs and tries to make toast. Ted has been woken by the smoke alarm a few times.

Ted has started to lock their bedroom door so that Lena cannot go downstairs. When Lena tries to open the door she gets upset, crying and wakes up Ted, saying she needs to get the breakfast ready for the children in time for school.

What could Ted try in this situation?

Prompts:
- Making sure she is safe, e.g. telecare sensors / moving the toaster at night
- Settling her to get to sleep using touch / relaxation / talking / singing
- Reassurance and talking with her about the children
- Using cues to remind her it is night time.

4. Are difficulties caused by pain or discomfort?

There may be physical problems that are waking or keeping your relative up at night, but they may not always know or be able to tell you what is wrong. These could include:

- Pain
- Incontinence
- Needing to go the toilet often

Talking point:

Let's think of three things that you can do to find out if a person is unwell or in pain?

1.
2.
3.

Prompts:
- Ask them if they are in pain (even if they cannot say , they may show you)
- Touch them gently in places that they may be in pain – see their response
- Be observant – watch, notice if they are groaning, crying, tensing, especially when touched
- Give them pain medication e.g. paracetamol and see if this reduces agitation

Some common medical problems that can cause sleep difficulties include:

Problem	What you may notice
Pain	• Holding or rubbing part of body • Fast breathing • Groaning or moaning • Tension • Making a face or grimacing • Pushing away when touched
Constipation	• Pain and difficulty opening bowels • Hard faeces • Pain on touching stomach
UTI (Urinary tract infections)	• Urinating more frequently • Cloudy or different smelling urine • Pain in back when touched • Being more confused • Burning pain on passing urine

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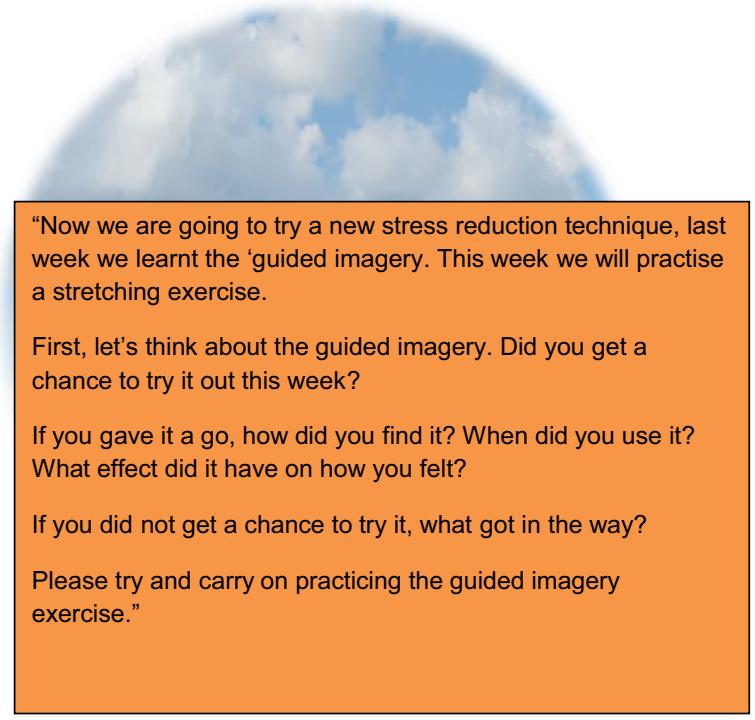
5. Are difficulties caused by the dementia?

Dementia may directly cause sleep difficulties through its effects on the brain and therefore our body-clock. Below is a reminder of some of the sleep difficulties that may occur in dementia.

- Not feeling tired at night
- Waking during the night
- Being more mixed up and restless at night
- Excessive sleepiness during the day
- Restlessness during sleep (e.g. acting out dreams)
- Breathing pauses during sleep (sleep apnoea)
- Restless/fidgety legs before or during sleep

Talking point:

Think back to the examples you described earlier in the session.
How might your relative's sleep difficulties been caused by their dementia?



Session 4 Version 1

10mins

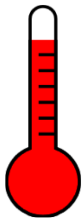
DREAMS: START

Managing Stress 4: *Stretching*



- Simply stretching tired muscles can go a long way toward reducing tension and stress.
- Stretching exercises can be used almost anywhere, at any time, for as long as you want, so they can be an especially convenient relaxation technique.
- It is important to do stretching exercises that feel good to you. As we practice this today, please tell us if you experience any discomfort.

Tension rating before exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- First, please rate your level of stress or tension right now, before we practise the stretching exercise.

Q! **On a scale of 1 to 5, how would you rate your tension? ____**

"Now I am going to talk you through the stretching exercise…"

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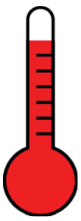
Tension rating after exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- How would you rate your tension level now after practising the stretching exercise?

Q! **Now, please rate your tension or stress level from 1 to 5 _____**

Discuss:
- Did your level of tension change?
- What was this experience like for you?
- Can you think of specific times when this might have helped?

Session 4 Version 1

Summary

Today, we have talked about:

- Recap on daytime activity and routine
- Troubleshooting: putting plans into action
- Managing night-time behaviour problems
- Describing and investigating behaviours
- Managing stress 4: Stretching



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10mins

FOR NEXT WEEK: Putting it into practice



Stretching:

- Try to practice this every day and to use it in stressful situations. See if it helps.

If your relative is physically very frail or has found it difficult to do the seated exercise introduced last week, you could try this simpler stretching exercise with them.



Managing night-time behaviour problems:

- Try to complete the behaviour record on p.20 for three separate episodes of difficult night-time behaviours this week. Try to focus on **describing** and **investigating** what happened.

"Look back over the session to help you with this…"
Talk through the behaviour record form and check that they have understood the task.



Putting the plan into action:

- Continue to use the sleep plan we made for your relative, thinking about any changes we talked about earlier to make the plan more manageable.

- Keep a sleep diary for you and your relative this week so we can compare them next time.

Make sure they understand that they should keep a diary for themselves as well.

DREAMS: START

Putting it into practice

- When will you have an opportunity to do this?
- What might make it easier?
- What might get in the way?

Behaviour Record

Describe	Investigate…	What did you find out?
	☐ Environment/routine?	
	☐ Fears or emotions?	
	☐ How we respond?	
	☐ Uncomfortable /Unwell?	
	☐ Dementia?	
	☐ Environment/routine?	
	☐ Fears or emotions?	
	☐ How we respond?	
	☐ Uncomfortable /Unwell?	
	☐ Dementia?	
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	☐ How we respond?	
	☐ Uncomfortable /Unwell?	
	☐ Dementia?	

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Weekly Sleep Diary (Carer)

Date	Noon	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am
Tuesday May 14th	O		N							/			X X		X				/				N	O

Key:

/ = When you went to bed and got up in the morning

X = Every time you get up in the night

N = When you take a nap during the day

O = When you have been out of the house

E = When you have done any physical exercise

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DOI: 10.3310/hta22710

Weekly Sleep Diary (Relative)

Date	Noon	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am
Tuesday May 14th	O		N							/			X X		X				/				N	O

Key:

/ = When your relative went to bed and when they got up in the morning

X = Every time your relative gets up in the night

N = When your relative takes a nap during the day

O = When your relative has been out of the house

E = When your relative has done any physical exercise

L = When you relative has used the light box

Session 4 Version 1

DREAMS: START

Dementia **Re**l**a**ted **M**anual for **S**leep:

Str**a**tegies for **R**ela**t**ives

Session 5:

Taking care of your own sleep



Session 5 Version 1

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Plan for today's session

Recap on night-time behaviour problems	p. 3
Creating strategies for managing behaviours	p. 4
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Recap of session 4: Difficult night-time behaviours

We talked about:

- Troubleshooting putting plans into action
- Managing night-time behaviour problems
- Describing and investigating behaviours
- Managing stress: Stretching
- Summary
- Putting it into practice



- *Q!* Did you get a chance to use the behaviour record to describe and investigate three separate episodes of difficult night-time behaviours this week?

If Yes…	
How did this go?	
What did you notice happening?	
What made it easier?	

If No…	
What got in the way?	
What would make it easier in the future?	

Please continue to use the plan we have made for improving sleep

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Creating strategies for managing behaviours

Choose one of the behaviours you recorded during the week or we discussed last week. Let's remind ourselves what you identified as the possible causes of the behaviour:





1. Environment / routine
2. Fears or emotions
3. How we respond
4. Pain and discomfort
5. The effects of dementia





We will now think of *strategies* that you can use to *prevent* the behaviour from occurring or to help you respond differently. Be creative, and write down at least **two** in the behaviour record on page 21.

- Regardless of which behaviour and strategies you choose, try to be consistent and use the strategy **every time** even if it doesn't work every time.

- **Problem-solving is a process of trial and error. There is no right or wrong answers.** It's possible that the strategy that you came up with may work at some times and not others. Be flexible, patient and creative!

Session 5 Version 1

Managing your own sleep

- We know from existing research and talking to people caring for a relative with dementia, that sleep difficulties are also common among people caring for a relative. Your relative's sleep difficulties are likely to affect your own sleep.



- This may be because you are being woken up at night or early in the morning, or it may be that you are feeling stressed and worried and that this is affecting your sleep.

Q! How do you feel that your sleep is affected by your relative's sleep difficulties and dementia?

- Many carers report that they go to bed late or get up early so that they can have a little more time to themselves or get things done. This may then lead to a change in your own sleep pattern and routine.

- Although caring for a relative is time consuming, it is important that you make time for things you enjoy. This is because if you spend all your time caring, you may begin to feel burned out and frustrated, and also find it harder to sleep.

- In addition to the relaxation exercises we have each week, there are other simple things you could try to improve your sleep. Even if your sleep is not a problem you may find some of the following advice useful.

When the carer hasn't had any sleep they are short tempered in the morning and it is very difficult to cope, you know how you should be coping but it's not so easy to do it when you've not had any sleep



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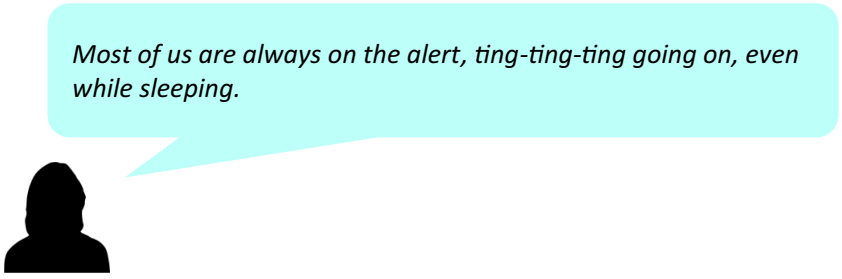
Managing thoughts and feelings



There are a number of other techniques that you can use to manage the thoughts and feelings that keep you awake at night:

1. **Putting the day to rest**

You may find this technique useful for thoughts that have to do with your caring role. The aim is to put the day to bed so that you can get to sleep.

To put the day to rest you need to follow these simple steps:

- Set aside 20 minutes in the early evening (say around 7 pm)
- Sit down with a pen and paper
- Think of what has happened during the day, how it has gone and how you feel about it - put it to rest!
- Write down anything you still need to do on a 'to do' list with steps that you can take to complete any 'loose ends'
- Try to use your 20 minutes to leave you feeling more in control
- When it comes to bedtime remind yourself that you have already dealt with things
- If new thoughts come up in bed note them down on a piece of paper at your bedside to be dealt with the next day.



Session 5 Version 1

2. Thought-blocking

Another way to manage repetitive thoughts in your mind is called thought blocking. This works best with trivial, unimportant thoughts rather than with more worrying problems.

Sometimes these thoughts come to people when they wake up in the middle of the night. It is best to start the thought blocking immediately upon wakening before you get too wide awake!

To use thought blocking follow three simple steps:

- Repeat the word "the" every 2 seconds in your head with your eyes closed
- Don't say it out loud, but it sometimes helps to 'mouth' it
- Keep up the repetitions for about 5 minutes (if you can!)

3. The 15 minute rule

Of course, there will be nights when you put your head down and sleep will not come quickly. When this happens, try not to just lie in bed worrying about your sleep.

Here are the steps you can take to follow the 15 minute rule:

- If sleep does not come within 15 minutes, you should get out of bed and go into another room.
- If it feels hard to get out of bed to make it easier you could:
    - leave the heating on
    - leave a lamp on in the living room
    - prepare a flask of a warm drink before bed
    - listen to music, read or do relaxation when you are up

Go back to bed when you feel sleepy again.
If you still cannot sleep get up again.

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4. Giving up trying

Sometimes people are unable to sleep because they are simply trying too hard! Trying to fall asleep actually keeps you wakeful and may lead to irritability when you don't succeed.

Unlike many other things in life, sleep is not something that you can make happen by sheer force of will. In fact, the harder you try, the less likely it is to happen.

[redacted]



Talking point: Which of these techniques do you think may help you?

Challenging unhelpful thoughts and feelings

- Looking after someone with dementia, especially if you are being kept awake at night, can leave you overwhelmed and stressed. When we feel like this, it can be helpful to pay attention to our thoughts.

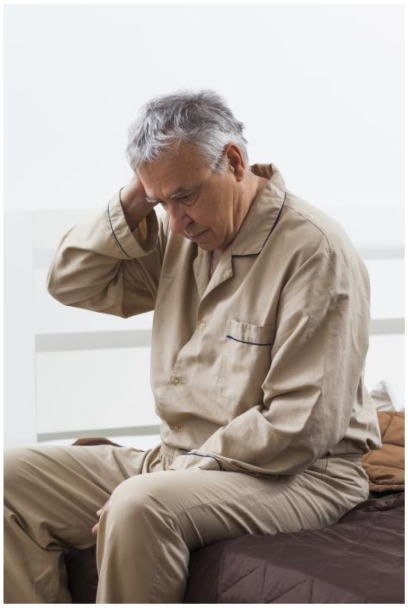
- In general, our feelings are linked to our thoughts. **The way you think about something directly affects the way you feel about it.** So thoughts can make you feel worse.

- You may use your time in bed as a time to think things through, but if you have trouble sleeping or are woken in the night, thoughts and worries could keep you awake. Thinking at night because of your busy life may not be a good solution.

- Some say that they feel exhausted, but still they can't stop that racing mind!

- First of all, let's consider the kinds of things that we think about when we are in bed and unable to get to sleep. There are several 'types' of thoughts that are common:

  - Rehearsing and planning
  - Problem-solving
  - Thinking about your relative's and your own health
  - Thinking about your relative's and your own sleep
  - Thinking about thinking
  - Worrying about the future



- There are three steps to changing your unhelpful thoughts:

  1. S*top and identify* your current thoughts.
  2. C*hallenge and replace* your unhelpful thoughts with more helpful ones.
  3. *Pay attention to how you feel* in that moment

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1. We will start by focusing on step one, which is to ***stop and identify*** the thoughts that are contributing to your unpleasant feelings.

What are the thoughts that go around your head or keep you awake at night?

_____

_____

_____

_____

2. The next step is to ***challenge and replace your unhelpful thoughts*** with more helpful ones. This can be difficult at times, but with practice you should find it helps. There are common patterns of thinking called “automatic thought patterns”. Here are some techniques for changing unhelpful thoughts.

    1. Look at it from someone else’s point of view.
    2. Ask other people what they think or get more information (during the day!).
    3. Change how you talk to yourself.
    4. Try not to jump to conclusions.
    5. Decide to think about something pleasant at night

Let’s consider the following example whilst going through these thought challenging techniques:

Alice is 64 years old and cares for her 90 year old mother. She believes that she is not a good daughter. She feels guilty as she wants to visit her friends. Alice thinks, "I should always stay with my mother because something bad will happen to her when I leave. Other people can't take care of her the way I do. If something happens I will never forgive myself for not being a good daughter."

1. **Look at it from a different point of view:** Talk to yourself as if someone who cares about you is talking to you.

In our example, as Alice blames herself for wanting to spend time away from home, she could ask herself: "How would my close friend Marie view this - and what would she have to say about my situation?" Alice could also imagine what her friend (who cares about her) would think about her leaving her mother for short periods.

Talking point:

- What do you think Alice's friend Marie would say?

- If your friend was here what would they say to you?

- What if your friend was in your situation, what would you say to them?

2. **Take action/ Ask others:**

Some carers find it helpful to get additional information to challenge their unhelpful thoughts.

Alice could challenge her thoughts about "not being a good daughter" by talking to other carers about how they handle similar situations. Alice could also plan to leave her mother with someone she trusts for a short period, to test out her concerns that her mother will have a crisis when she is gone.

Talking point:



- Is there anyone you can talk to about your caring role?

- What do you believe you need to do, to be a dependable carer?

- Do you have any concerns? What could you do to test out your concerns?

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3. Change how you talk to yourself:

We often create negative labels for others or ourselves without realising what we are doing, for example thinking “If I can’t be there all the time, I am not good enough, I am not giving what my relative deserves”.

We also may believe that we must behave, think, or feel a certain way. This might often include us saying things to ourselves like “I must/ I should do ... ”. Allowing yourself to think “It’s OK not to be perfect” and “It’s also important I look after myself” can help you see the situation from a different point of view.

If Alice tried to think about what her label of "Not being a good daughter” really meant, she would see that she was expecting the impossible and this expectation would set herself up to fail.

She could also change, "I should always stay with mother" to, "My mother likes me being there, but she could enjoy being with others too, and it would be good for both of us if I get a break and feel a bit better".

Talking point:



- Do you ever have these kinds of thoughts?
- How else could you think about your situation? Is there any other way you could think about your situation?

4. Try not to think of things as all or nothing:

Remind yourself to think of different options. Don't assume that if you can't do something perfectly; it is not worth doing at all.

Could Alice consider other alternatives to never going out? Must she think of herself as either a good daughter **OR** *not* a good daughter?

It is important Alice recognises all the good things she is doing and how much she is coping with.



Talking point:

- Do you ever have these kinds of thoughts?

- Tell me some of the positives about caring for your relative

Key Point:

Remember that the thoughts that interfere at bedtime will be easier to dismiss if they have already been dealt with… at a time when you were more awake!

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Making time for yourself

- As we discussed for your relative, daytime napping and lack of daytime activity can make it harder to sleep at night, the same will be true for you.

- Building pleasurable activity and time for yourself into the day will also have a positive effect upon your mood.

Yes I think it's essential for every carer to have something that they can do that's totally different from the caring role, you know, to survive



Key Point:
Anything you like to do is a pleasant event, e.g. having lunch with a friend or calling a relative for a chat

- Adding pleasant events to your daily life can be difficult. You may think "I don't have the time to do pleasant activities!" or feel guilty about making time for yourself or having time apart from the person you care for.

- These can be barriers but it is important to overcome them. **Being a good carer means taking care of yourself too!**



Rule A: ***Start small and be simple.*** The most important thing to remember is to choose events that you can do everyday or a few times a week. You may enjoy travelling, but realistically you cannot take a trip every day.

A smaller and more realistic activity would be going to the shops, cycling or walking.

Rule B: ***Focus on events you want to do more often.***

Let's think of four pleasant activities for you

1

2

3

4

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DREAMS: START

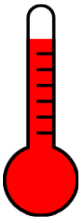
Managing Stress 5:

Guided Imagery – Ocean Escape



Today we are going to do another Guided Imagery exercise. This exercise will involve imagining your experience at the ocean, far away from the cares of everyday life.

Stress rating before exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- First, please rate your level of stress or tension right now, before we practise the guided imagery.

Q! **On a scale of 1 to 5, how would you rate your tension? _____**

Session 5 Version 1

Stress Reduction Technique
Guided Imagery – Ocean Escape

We are about to begin the guided relaxation imagery exercise. Soon, I will be describing a relaxing scene for you. But first of all, make sure you get yourself into a comfortable position in your chair, with your arms by your side.

Close your eyes, and take in a deep signal breath, holding it for a few moments... and then let go, relaxing as you do so.

Now as I continue talking to you, you can allow a calm relaxed feeling to settle over your body and mind…Let go of any unnecessary tension in your shoulders, arms, and hands.... As your shoulders and arms hang loosely by your side, let all of the tension drain out through the tips of your fingers.

Let the relaxation flow from your shoulders into the back of your neck ... as the tension dissolves and melts away... relaxing your neck and scalp... and also your face, including your mouth, tongue, and jaw.

Let the relaxation flow down the rest of your body... your chest... abdomen... and back.

Feel all the muscles of your body becoming loose and relaxed. Letting the relaxing feelings flow into your legs, ankles, and feet. Just allow your entire body to become loose, heavy, and relaxed. And now... picture yourself somewhere by the ocean.

Just project yourself to any relaxing place along the ocean... perhaps a place you have been to or a place you would like to go... It may be a sandy beach or a rocky beach... you may be on a pier or even on a cliff, overlooking the ocean... any place you choose is fine..

Look around... what do you see? Can you see it clearly in your mind? ... Do you notice the vastness of the ocean... stretching out as far as you can see? Perhaps you see a dolphin or whale swimming by...Now inhale deeply, smelling the fresh sea air.... Feel the warmth of the sun,... the cool breeze. How peaceful and relaxing it is...

And now listen more closely to the sounds... especially the sound of the waves. Pay close attention to the sound of the waves and notice how soothing and relaxing the sound is...as you hear the waves roll in... and out again... In... and out...the constant rhythm of the waves... the ebb... and flow... And each time the waves flow in... and out, you find yourself becoming more deeply relaxed... deeper... and deeper... as your muscles go loose... and limp... and the tranquility of this place surrounds you. *[Long pause]*

And now spend a few minutes doing whatever you would like. You may just want to lie on the sand and soak up the sun...

you may want to walk along the beach... or swim in the cool water... perhaps you

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would like to do some fishing... go sailing...Whatever you would like to do at the ocean is okay... but no matter what you do, just continue being aware of this relaxation...

[*Allow participants a few moments to enjoy this imagery*]. And now, I will bring you back slowly from this relaxation by counting backwards from 3 to 1. When I get to 1, you'll be alert, refreshed, and comfortable.

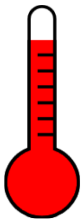
Okay,

"3" much more alert;

"2" feeling refreshed and comfortable, and

"1" as you open your eyes and return your awareness to the room you are in.

Stress rating after exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- How would you rate your tension level now, after practicing the guided imagery exercise?

Q! **Now, please rate your tension or stress level from 1 to 5 _____**

Session 5 Version 1

Summary

Today, we have talked about:

- Recap on night-time behaviour problems
- Creating strategies for managing behaviours
- Managing your own sleep
- Challenging unhelpful thoughts and feelings
- Managing stress 5: Guided imagery – Ocean escape







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FOR NEXT WEEK: Putting it into practice



Guided imagery: Ocean escape:

- Try to practice this every day and to use it in stressful situations. See if it helps.



Trying out strategies for managing difficult behaviours / challenging unhelpful thoughts about sleep:

- Try out the strategies developed on the behaviour record with your relative each night, and record what happened.
- Make time to do something pleasant for yourself at least three times this week.
- Try to complete the thought record on p.24 at least three times this week.



Putting the plan into action:

- Continue to use the sleep plan we made for your relative and record how it goes.

DREAMS: START

Putting it into Practice

- When will you have an opportunity to do this?
- What might make it easier?
- What might get in the way?

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DOI: 10.3310/hta22710

Behaviour record

Try out these strategies over the next week and note on the behaviour record what happens.

Describe	Investigate	Create Strategies	Evaluate Did it work?
	☐ Environment/routine?		
	☐ Fears or emotions?		
	☐ How we respond?		
	☐ Uncomfortable /Unwell?		
	☐ Dementia?		
	☐ Environment/routine?		
	☐ Fears or emotions?		
	☐ How we respond?		
	☐ Uncomfortable /Unwell?		
	☐ Dementia?		

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Thought record

Thoughts I have in bed	How they make me feel	An alternative response would be

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DOI: 10.3310/hta22710

Weekly Sleep Diary

Date	Noon	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am
Tuesday May 14th	O		N							/			X X		X				/				N	O

Key:

/ = When your relative went to bed and when they got up in the morning

X = Every time your relative gets up in the night

N = When your relative takes a nap during the day

O = When your relative has been out of the house

E = When your relative has done any physical exercise

L = When you relative has used the light box

Session 5 Version 1

DREAMS: START

Dementia Related Manual for Sleep:

Strategies for Relatives

Facilitator Version

Session 5:

Taking care of your own sleep



For each session:

- Encourage the carer to write down what works or key strategies or plans to refer back to.
- If content is clearly irrelevant or does not fit, for example someone is very active all day will not need a plan around daytime naps, miss these parts out.
- When setting exercises at the end, check that they remember what is in the plan if not explicitly covered in the content.

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Plan for today's session

"This is the contents page for you to refer back to"

Refer to the contents but do not read the full list

Recap on night-time behaviour problems	p. 3
Creating strategies for managing behaviours	p. 4
Managing your own sleep	p. 5
Challenging unhelpful thoughts and feelings	p. 9
Managing stress 5: Guided imagery – ocean escape	p. 16
Summary	p. 19
Putting it into practice	p. 20

10mins Recap of session 4: Difficult night-time behaviours

We talked about:

- Troubleshooting putting plans into action
- Managing night-time behaviour problems
- Describing and investigating behaviours
- Managing stress: Stretching
- Summary
- Putting it into practice



- *Q!* Did you get a chance to use the behaviour record to describe and investigate three separate episodes of difficult night-time behaviours this week?

If Yes…	
How did this go?	
What did you notice happening?	
What made it easier?	

If No…	
What got in the way?	
What would make it easier in the future?	

Please continue to use the plan we have made for improving sleep

"How has this been going, did you make changes based on the troubleshooting last week, is there anything you would like to discuss now?"

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10mins Creating strategies for managing behaviours

Choose one of the behaviours you recorded during the week or we discussed last week. Let's remind ourselves what you identified as the possible causes of the behaviour:

Choose together one of the episodes they described and talk about what they feel is causing the difficulties, explain that you are now going to go on and look at potential solutions





1. Environment / routine
2. Fears or emotions
3. How we respond
4. Pain and discomfort
5. The effects of dementia





Ask them to write in their strategies in the behaviour record on page 21.

We will now think of *strategies* that you can use to *prevent* the behaviour from occurring or to help you respond differently. Be creative, and write down at least **two** in the behaviour record on page 21.

- Regardless of which behaviour and strategies you choose, try to be <u>consistent</u> and use the strategy **every time** even if it doesn't work every time.

- **Problem-solving is a process of trial and error. There is no right or wrong answers.** It's possible that the strategy that you came up with may work at some times and not others. Be flexible, patient and creative!

5mins

Managing your own sleep

"Now let's spend some time thinking about your own sleep…

- We know from existing research and talking to people caring for a relative with dementia, that sleep difficulties are also common among people caring for a relative. Your relative's sleep difficulties are likely to affect your own sleep.



- This may be because you are being woken up at night or early in the morning, or it may be that you are feeling stressed and worried and that this is affecting your sleep.

Q! How do you feel that your sleep is affected by your relative's sleep difficulties and dementia?

Ask about what they noticed completing a sleep diary for themselves and their relatives this week.

- Many carers report that they go to bed late or get up early so that they can have a little more time to themselves or get things done. This may then lead to a change in your own sleep pattern and routine.

- Although caring for a relative is time consuming, it is important that you make time for things you enjoy. This is because if you spend all your time caring, you may begin to feel burned out and frustrated, and also find it harder to sleep.

- In addition to the relaxation exercises we have each week, there are other simple things you could try to improve your sleep. Even if your sleep is not a problem you may find some of the following advice useful.

When the carer hasn't had any sleep they are short tempered in the morning and it is very difficult to cope, you know how you should be coping but it's not so easy to do it when you've not had any sleep



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Managing thoughts and feelings

Most of us are always on the alert, ting-ting-ting going on, even while sleeping.



There are a number of other techniques that you can use to manage the thoughts and feelings that keep you awake at night:

"Not all of these ideas will fit for you, but there may be some techniques here that you might want to give a go"

1. Putting the day to rest

You may find this technique useful for thoughts that have to do with your caring role. The aim is to put the day to bed so that you can get to sleep.

To put the day to rest you need to follow these simple steps:

- Set aside 20 minutes in the early evening (say around 7 pm)
- Sit down with a pen and paper
- Think of what has happened during the day, how it has gone and how you feel about it - put it to rest!
- Write down anything you still need to do on a 'to do' list with steps that you can take to complete any 'loose ends'
- Try to use your 20 minutes to leave you feeling more in control
- When it comes to bedtime remind yourself that you have already dealt with things
- If new thoughts come up in bed note them down on a piece of paper at your bedside to be dealt with the next day.



Session 5 Version 1

2. Thought-blocking

Another way to manage repetitive thoughts in your mind is called thought blocking. This works best with trivial, unimportant thoughts rather than with more worrying problems.

"We are going to talk next about how to manage the more complex and worrying thoughts that you may be having."

Sometimes these thoughts come to people when they wake up in the middle of the night. It is best to start the thought blocking immediately upon wakening before you get too wide awake!

To use thought blocking follow three simple steps:

- Repeat the word "the" every 2 seconds in your head with your eyes closed
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- Keep up the repetitions for about 5 minutes (if you can!)

3. The 15 minute rule

Of course, there will be nights when you put your head down and sleep will not come quickly. When this happens, try not to just lie in bed worrying about your sleep.

Here are the steps you can take to follow the 15 minute rule:

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    - prepare a flask of a warm drink before bed
    - listen to music, read or do relaxation when you are up

Go back to bed when you feel sleepy again.
If you still cannot sleep get up again.

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4. Giving up trying

Sometimes people are unable to sleep because they are simply trying too hard! Trying to fall asleep actually keeps you wakeful and may lead to irritability when you don't succeed.

Unlike many other things in life, sleep is not something that you can make happen by sheer force of will. In fact, the harder you try, the less likely it is to happen.

[redacted]



Talking point: Which of these techniques do you think may help you?

10mins Challenging unhelpful thoughts and feelings

- Looking after someone with dementia, especially if you are being kept awake at night, can leave you overwhelmed and stressed. When we feel like this, it can be helpful to pay attention to our thoughts.

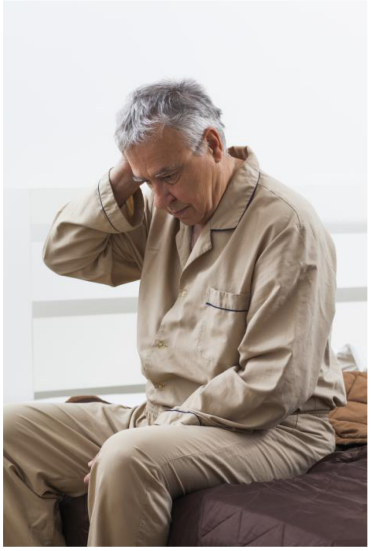
- In general, our feelings are linked to our thoughts. **The way you think about something directly affects the way you feel about it.** So thoughts can make you feel worse.

- You may use your time in bed as a time to think things through, but if you have trouble sleeping or are woken in the night, thoughts and worries could keep you awake. Thinking at night because of your busy life may not be a good solution.

- Some say that they feel exhausted, but still they can't stop that racing mind!

- First of all, let's consider the kinds of things that we think about when we are in bed and unable to get to sleep. There are several 'types' of thoughts that are common:

  - Rehearsing and planning
  - Problem-solving
  - Thinking about your relative's and your own health
  - Thinking about your relative's and your own sleep
  - Thinking about thinking
  - Worrying about the future



- There are three steps to changing your unhelpful thoughts:

  1. S*top and identify* your current thoughts.
  2. C*hallenge and replace* your unhelpful thoughts with more helpful ones.
  3. *Pay attention to how you feel* in that moment

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1. We will start by focusing on step one, which is to ***stop and identify*** the thoughts that are contributing to your unpleasant feelings.

What are the thoughts that go around your head or keep you awake at night?

_____

_____

_____

_____

2. The next step is to ***challenge and replace your unhelpful thoughts*** with more helpful ones. This can be difficult at times, but with practice you should find it helps. There are common patterns of thinking called “automatic thought patterns”. Here are some techniques for changing unhelpful thoughts.

    1. Look at it from someone else’s point of view.
    2. Ask other people what they think or get more information (during the day!).
    3. Change how you talk to yourself.
    4. Try not to jump to conclusions.
    5. Decide to think about something pleasant at night

Let’s consider the following example whilst going through these thought challenging techniques:

Alice is 64 years old and cares for her 90 year old mother. She believes that she is not a good daughter. She feels guilty as she wants to visit her friends. Alice thinks, "I should always stay with my mother because something bad will happen to her when I leave. Other people can't take care of her the way I do. If something happens I will never forgive myself for not being a good daughter."

1. **Look at it from a different point of view:** Talk to yourself as if someone who cares about you is talking to you.

In our example, as Alice blames herself for wanting to spend time away from home, she could ask herself: "How would my close friend Marie view this - and what would she have to say about my situation?" Alice could also imagine what her friend (who cares about her) would think about her leaving her mother for short periods.

Talking point:

- What do you think Alice's friend Marie would say?

- If your friend was here what would they say to you?

- What if your friend was in your situation, what would you say to them?

2. **Take action/ Ask others:**

Some carers find it helpful to get additional information to challenge their unhelpful thoughts.

Alice could challenge her thoughts about "not being a good daughter" by talking to other carers about how they handle similar situations. Alice could also plan to leave her mother with someone she trusts for a short period, to test out her concerns that her mother will have a crisis when she is gone.

Talking point:



- Is there anyone you can talk to about your caring role?

- What do you believe you need to do, to be a dependable carer?

- Do you have any concerns? What could you do to test out your concerns?

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3. Change how you talk to yourself:

We often create negative labels for others or ourselves without realising what we are doing, for example thinking “If I can’t be there all the time, I am not good enough, I am not giving what my relative deserves”.

We also may believe that we must behave, think, or feel a certain way. This might often include us saying things to ourselves like “I must/ I should do ... ”. Allowing yourself to think “It’s OK not to be perfect” and “It’s also important I look after myself” can help you see the situation from a different point of view.

If Alice tried to think about what her label of "Not being a good daughter” really meant, she would see that she was expecting the impossible and this expectation would set herself up to fail.

She could also change, "I should always stay with mother" to, "My mother likes me being there, but she could enjoy being with others too, and it would be good for both of us if I get a break and feel a bit better".

Talking point:



- Do you ever have these kinds of thoughts?
- How else could you think about your situation? Is there any other way you could think about your situation?

4. Try not to think of things as all or nothing:

Remind yourself to think of different options. Don't assume that if you can't do something perfectly; it is not worth doing at all.

Could Alice consider other alternatives to never going out? Must she think of herself as either a good daughter **OR** *not* a good daughter?

It is important Alice recognises all the good things she is doing and how much she is coping with.



Talking point:

- Do you ever have these kinds of thoughts?

- Tell me some of the positives about caring for your relative

Key Point:

Remember that the thoughts that interfere at bedtime will be easier to dismiss if they have already been dealt with… at a time when you were more awake!

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5mins

Making time for yourself

- As we discussed for your relative, daytime napping and lack of daytime activity can make it harder to sleep at night, the same will be true for you.
- Building pleasurable activity and time for yourself into the day will also have a positive effect upon your mood.

Yes I think it's essential for every carer to have something that they can do that's totally different from the caring role, you know, to survive



Key Point:

<u>Anything you like to do</u> is a pleasant event, e.g. having lunch with a friend or calling a relative for a chat

- Adding pleasant events to your daily life can be difficult. You may think "I don't have the time to do pleasant activities!" or feel guilty about making time for yourself or having time apart from the person you care for.
- These can be barriers but it is important to overcome them. **Being a good carer means taking care of yourself too!**



Rule A: ***Start small and be simple.*** The most important thing to remember is to choose events that you can do everyday or a few times a week. You may enjoy travelling, but realistically you cannot take a trip every day.

A smaller and more realistic activity would be going to the shops, cycling or walking.

Rule B: ***Focus on events you want to do more often.***

Let's think of four pleasant activities for you

1

2

3

4

"Now we are going to try a new stress reduction technique, last week we learnt the stretching. This week we will practise another guided imagery exercise.

First, let's think about the stretching. Did you get a chance to try it out this week?

If you gave it a go, how did you find it? When did you use it? What effect did it have on how you felt?

If you did not get a chance to try it, what got in the way?

Please try and carry on practicing the stretching exercise."

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10mins

DREAMS: START

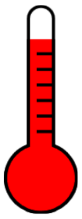
Managing Stress 5:

Guided Imagery – Ocean Escape



Today we are going to do another Guided Imagery exercise. This exercise will involve imagining your experience at the ocean, far away from the cares of everyday life.

Stress rating before exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- First, please rate your level of stress or tension right now, before we practise the guided imagery.

Q! **On a scale of 1 to 5, how would you rate your tension? _____**

"Now I am going to talk you through the guided imagery exercise…"

Session 5 Version 1

Stress Reduction Technique
Guided Imagery – Ocean Escape

We are about to begin the guided relaxation imagery exercise. Soon, I will be describing a relaxing scene for you. But first of all, make sure you get yourself into a comfortable position in your chair, with your arms by your side.

Close your eyes, and take in a deep signal breath, holding it for a few moments... and then let go, relaxing as you do so.

Now as I continue talking to you, you can allow a calm relaxed feeling to settle over your body and mind…Let go of any unnecessary tension in your shoulders, arms, and hands.... As your shoulders and arms hang loosely by your side, let all of the tension drain out through the tips of your fingers.

Let the relaxation flow from your shoulders into the back of your neck ... as the tension dissolves and melts away... relaxing your neck and scalp... and also your face, including your mouth, tongue, and jaw.

Let the relaxation flow down the rest of your body... your chest... abdomen... and back.

Feel all the muscles of your body becoming loose and relaxed. Letting the relaxing feelings flow into your legs, ankles, and feet. Just allow your entire body to become loose, heavy, and relaxed. And now... picture yourself somewhere by the ocean.

Just project yourself to any relaxing place along the ocean... perhaps a place you have been to or a place you would like to go... It may be a sandy beach or a rocky beach... you may be on a pier or even on a cliff, overlooking the ocean... any place you choose is fine..

Look around... what do you see? Can you see it clearly in your mind? ... Do you notice the vastness of the ocean... stretching out as far as you can see? Perhaps you see a dolphin or whale swimming by...Now inhale deeply, smelling the fresh sea air.... Feel the warmth of the sun,... the cool breeze. How peaceful and relaxing it is...

And now listen more closely to the sounds... especially the sound of the waves. Pay close attention to the sound of the waves and notice how soothing and relaxing the sound is...as you hear the waves roll in... and out again... In... and out...the constant rhythm of the waves... the ebb... and flow... And each time the waves flow in... and out, you find yourself becoming more deeply relaxed... deeper... and deeper... as your muscles go loose... and limp... and the tranquility of this place surrounds you. *[Long pause]*

And now spend a few minutes doing whatever you would like. You may just want to lie on the sand and soak up the sun...

you may want to walk along the beach... or swim in the cool water... perhaps you

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would like to do some fishing... go sailing...Whatever you would like to do at the ocean is okay... but no matter what you do, just continue being aware of this relaxation...

[*Allow participants a few moments to enjoy this imagery*]. And now, I will bring you back slowly from this relaxation by counting backwards from 3 to 1. When I get to 1, you'll be alert, refreshed, and comfortable.

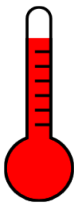
Okay,

"3" much more alert;

"2" feeling refreshed and comfortable, and

"1" as you open your eyes and return your awareness to the room you are in.

Stress rating after exercise



5 = Terribly tense
4 = Really tense
3 = Moderately tense
2 = Slightly tense
1 = Not at all tense

- How would you rate your tension level now, after practicing the guided imagery exercise?

Q! **Now, please rate your tension or stress level from 1 to 5 _____**

Discuss:
- Did your level of tension change?
- What was this experience like for you?
- Can you think of specific times when this might have helped?

Session 5 Version 1

Summary

Today, we have talked about:

- Recap on night-time behaviour problems
- Creating strategies for managing behaviours
- Managing your own sleep
- Challenging unhelpful thoughts and feelings
- Managing stress 5: Guided imagery – Ocean escape







Session 5 Version 1

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10mins

FOR NEXT WEEK: Putting it into practice



Guided imagery: Ocean escape:

- Try to practice this every day and to use it in stressful situations. See if it helps.



Trying out strategies for managing difficult behaviours / challenging unhelpful thoughts about sleep:

- Try out the strategies developed on the behaviour record with your relative each night, and record what happened.
- Make time to do something pleasant for yourself at least three times this week.
- Try to complete the thought record on p.24 at least three times this week.



Putting the plan into action:

- Continue to use the sleep plan we made for your relative and record how it goes.

DREAMS: START

Putting it into Practice

- When will you have an opportunity to do this?
- What might make it easier?
- What might get in the way?

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Give people time to consider what might work. Ask open questions and think about the possible causes. If people are struggling make tentative suggestions but check that these fit for them. The strategies may be things that they are already doing that they can do more of.

Behaviour record

Try out these strategies over the next week and note on the behaviour record what happens.

Describe	Investigate	Create Strategies	Evaluate Did it work?
	☐ Environment/routine?		
	☐ Fears or emotions?		
	☐ How we respond?		
	☐ Uncomfortable /Unwell?		
	☐ Dementia?		
	☐ Environment/routine?		
	☐ Fears or emotions?		
	☐ How we respond?		
	☐ Uncomfortable /Unwell?		
	☐ Dementia?		

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Thought record

Thoughts I have in bed	How they make me feel	An alternative response would be

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Weekly Sleep Diary

Date	Noon	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am
Tuesday May 14th	O		N							/			X X		X				/				N	O

Key:

/ = When your relative went to bed and when they got up in the morning

X = Every time your relative gets up in the night

N = When your relative takes a nap during the day

O = When your relative has been out of the house

E = When your relative has done any physical exercise

L = When you relative has used the light box

Ses

DREAMS: START

Dementia **Re**l**a**ted **M**anual for **S**leep:

Str**a**tegies for **R**el**a**t**t**ives

Session 6:

What works? Using strategies in the future



Session 6 Version 1

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Plan for today's session

Putting it all together	p. 4
What works? Light, sleep and dementia	p. 5
What works? The importance of daytime activity	p. 6
What works? Making a new sleep routine	p. 7
What works? Making changes to improve sleep	p. 8
What works? Managing night-time behaviours	p. 9
What works? Challenging unhelpful thoughts and feelings	p. 10
What works? Relaxation	p. 11
Keeping it going – developing an action plan	p. 12
Action plan for you and your relative	p. 13
Summary	p. 14

Session 6 Version 1

Putting it all together



- Today is about bringing together **what works for you,** both **old and new strategies**. We will use this to put together a **personal** sleep action plan so that you can keep using DREAMS: START in the future.



Session 6 Version 1

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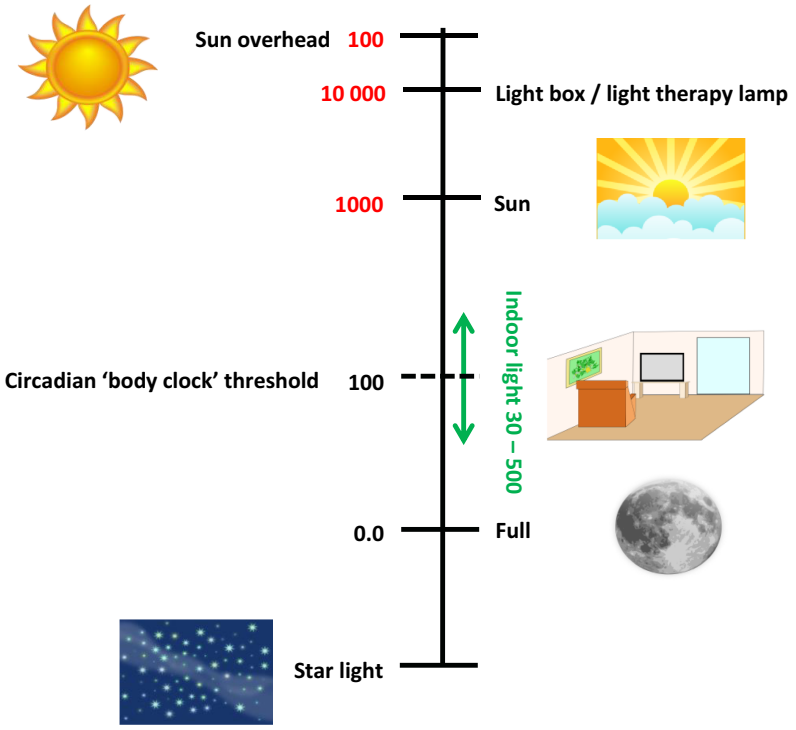
What works? Light, sleep and dementia

In session two we talked about how important light is for good sleep, especially for people with dementia. We made a plan for increasing your relative's time in natural light and for using the light box.



Talking point:

- Shall we talk through how you have increased your relative's access to light?

Summary – light and sleep: What worked best?

What works? The importance of daytime activity

In session three we talked about how pleasant activities and physical exercise can help people to stay alert during the day and get better sleep at night.

We made a plan for increasing exercise and pleasant events for your relative.





Talking point:

- Let's talk through how you have increased your relative's pleasant activities and physical exercise? What has gone well?

Summary – daytime activity: What worked best?

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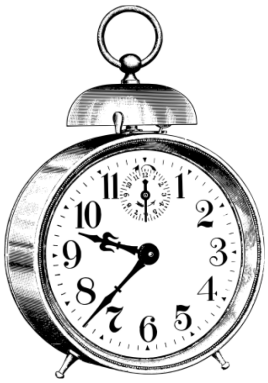
What works? Making a new sleep routine

In sessions two and three we discussed how daytime napping, spending too much or too little time in bed (e.g through going to bed too early or late), and having a variable sleep pattern from night-to-night, can make it harder for people with dementia to sleep well.

We looked at ways to strengthen the link between bed and sleep.Some of the ways we discussed included:



- Winding down at bedtime
- Using the bedroom only for sleeping
- Reducing daytime napping
- Increasing daytime activity
- Only going to bed when tired
- Using the 15 minute rule
- Having a daytime routine
- Going to bed and getting up at a set time

Talking point:

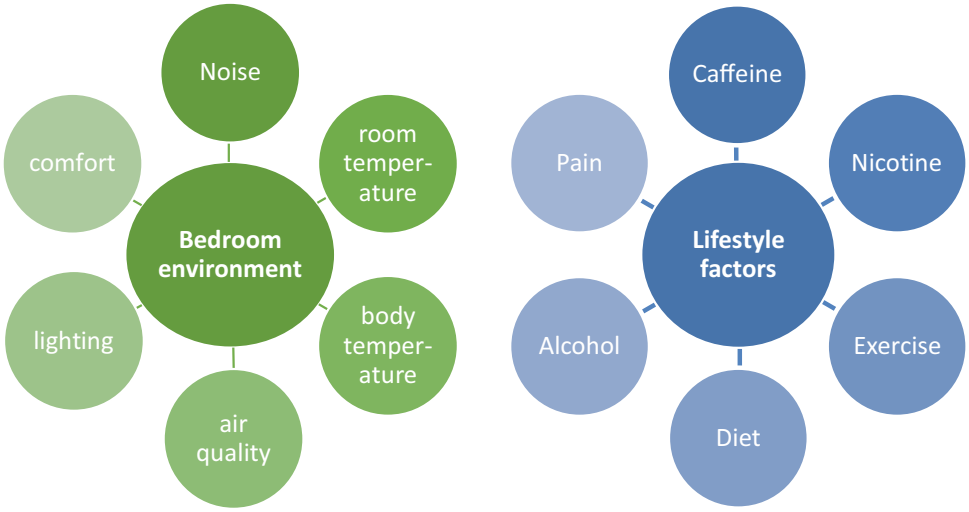
- Let's discuss any changes to your relatives sleep routine. What worked well?

Summary – sleep routine: What worked best?

Session 6 Version 1

What works? Making changes to improve sleep

In our first session we identified small changes that can be made to improve sleep.



Talking point:

- Let's discuss any changes you have made for you or your relative? Which did you find helpful?

Summary – bedroom and lifestyle: What worked best?

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What works? Managing night-time behaviour

In sessions four and five we discussed how describing and investigating behaviours can help us to develop specific strategies to try and overcome problems.

Remember, there is always a cause for night-time behaviours, but the person with dementia is not doing it on purpose and can't control these.





1. Environment / routine
2. Fears or emotions
3. How we respond
4. Pain and discomfort
5. The effects of dementia





Talking point:

- Have you been able to use this approach to managing night-time behaviour problems? If so, did you find helpful?

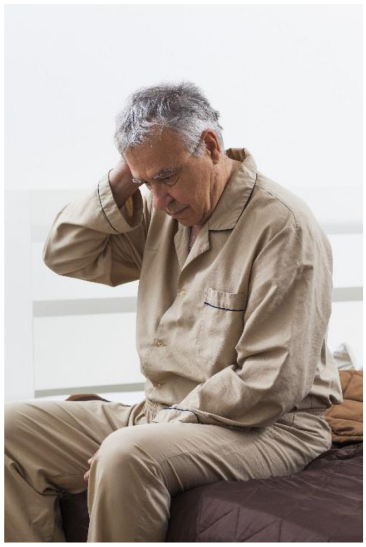
Summary – night-time behaviours: What worked best?

What works? Challenging unhelpful thoughts and looking after yourself

In session five we talked about how to manage your own sleep and make time to look after yourself.

We discussed how to challenge the thoughts that can keep you awake at night by:

1. *Stopping to identify* your current thoughts.
2. *Challenging and replacing* unhelpful thoughts with more helpful ones.
3. *Paying attention to how you feel* in that moment.



We also discussed how making time to look after yourself.

Talking point:

- Shall we talk about how you found challenging unhelpful thoughts and making time to look after yourself?

Summary – thoughts and feelings: What worked best?

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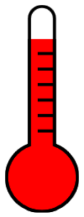
What works? Relaxation

Each week we have practiced a different relaxation technique for you and/or your relative to use. These included:

1. Signal breath
2. Focused breathing
3. Guided imagery: Meadow and stream
4. Stretching
5. Guided imagery: Ocean escape



Talking point:

- Let's talk about how you found the relaxation exercises. Which did you find most helpful?

Summary – relaxation techniques: What worked best?

Session 6 Version 1

Keeping it going: Developing an action plan

- We know from experience that making changes and keeping them going is difficult and that some changes will work and others will not. Try not to be too discouraged.

- Some of the reasons it can be difficult include:
  - The advice and strategies are not relevant to you
  - It is tricky to get the hang of some of the strategies
  - It is hard to break established patterns

- Here are some suggestions to help you keep going!
  - Make use of the manual to remind yourself what you learnt in sessions
  - Keep using the sleep diary and record forms to notice patterns, especially to see what is working
  - Remember small changes can make a big difference over time, so keep trying things out and practicing



Key Point:

Please continue to put into practice what you have learnt during DREAMS: START. Focus on doing what works and be flexible. If it stops working, try something else.

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Action plan for you and your relative

Let's go through your old plan and update it based on what worked best and what you want to keep doing more of. Remember to think about yourself and your relative.

Area for change	Action
Increasing natural light / Light box	
Increasing daytime activity / physical exercise	
Making a new routine / strengthening the link between bed and sleep	
Bedroom and lifestyle changes to improve sleep	
Managing night-time behaviours	
Looking after yourself / challenging unhelpful thoughts	
Relaxation	

Session 6 Version 1

Summary

We hope you have found these sessions helpful and will continue to use what you have learnt for you and your relative.

You have told us what you have found helpful and what strategies you will keep using.

You can keep and refer back to the manual to remind yourself of the techniques discussed throughout the sessions.

We have included copies of all the record forms and sleep diary at the end of this session.

Different researchers will be coming back to see how doing this has affected you and your relative. Do not tell them whether you received these sessions or not so we can fairly judge how much it helps! (This will mean putting the light box, thermometer, CD and the manual out of sight when they visit.)

Thank you for taking part.



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Copies of record forms / sleep diary

Planning record

Date(s)	What did you try?	How did it go for your relative?	How did it go for you?

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Planning record

	Action plan	How did it go for your relative?	How did it go for you?
Light box			
Increasing natural light			
Reducing daytime naps			
Time to bed and rise			
Lifestyle changes			

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Pleasant events record:

Day	What did you try?	How did it go?

Behaviour Record

Describe	Investigate…	What did you find out?
	☐ Environment/routine?	
	☐ Fears or emotions?	
	☐ How we respond?	
	☐ Uncomfortable /Unwell?	
	☐ Dementia?	
	☐ Environment/routine?	
	☐ Fears or emotions?	
	☐ How we respond?	
	☐ Uncomfortable /Unwell?	
	☐ Dementia?	
	☐ Environment/routine?	
	☐ Fears or emotions?	
	☐ How we respond?	
	☐ Uncomfortable /Unwell?	
	☐ Dementia?	

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Behaviour record

Describe	Investigate	Create Strategies	Evaluate Did it work?
	☐ Environment/routine?		
	☐ Fears or emotions?		
	☐ How we respond?		
	☐ Uncomfortable /Unwell?		
	☐ Dementia?		
	☐ Environment/routine?		
	☐ Fears or emotions?		
	☐ How we respond?		
	☐ Uncomfortable /Unwell?		
	☐ Dementia?		

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Thought record

Thoughts I have in bed	How they make me feel	An alternative response would be

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Weekly Sleep Diary

Date	Noon	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am
Tuesday May 14th	O		N							/			X X		X				/				N	O

Key:

/ = When your relative went to bed and when they got up in the morning

X = Every time your relative gets up in the night

N = When your relative takes a nap during the day

O = When your relative has been out of the house

E = When your relative has done any physical exercise

L = When you relative has used the light box

DREAMS: START

Dementia Related Manual for Sleep:

Strategies for Relatives

Facilitator Version

Session 6:

What works? Using strategies in the future



Session 6 Version 1

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- ***Look at your notes from all prior sessions before the final session so that you are able to suggest and review ideas around each of the sessions e.g. “Do you think that using this strategy helped with xxx” or being able to remind people of the list of lifestyle changes or daytime activities”***.
- The purpose of the session is to get people to continue to use helpful strategies in the future.
- Try to encourage people to **focus on what worked** and if something was not useful, move on to the next section. Ask lots of questions to generate ideas**.**
- **Be flexible in this session, if people have not found a particular area useful do not push them, move on to the next thing.**
- Encourage people to write down what works and remind people to continue to use the record forms

Put/ print the action plan on page 13 separate. For each topic, discuss and then (if relevant) get the carer to decide on a goal and write it into the action plan as you go along.

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Plan for today's session

"This is the contents page for you to refer back to"

Refer to the contents but do not read the full list

Putting it all together	p. 4
What works? Light, sleep and dementia	p. 5
What works? The importance of daytime activity	p. 6
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What works? Making changes to improve sleep	p. 8
What works? Managing night-time behaviours	p. 9
What works? Challenging unhelpful thoughts and feelings	p. 10
What works? Relaxation	p. 11
Keeping it going – developing an action plan	p. 12
Action plan for you and your relative	p. 13
Summary	p. 14

10mins Putting it all together



- Today is about bringing together **what works for you,** both **old and new strategies**. We will use this to put together a **personal** sleep action plan so that you can keep using DREAMS: START in the future.



"We are now going to talk through the different parts of the DREAMS: START sessions to see what worked well and what you would like to do more of in the future."

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What works? Light, sleep and dementia

In session two we talked about how important light is for good sleep, especially for people with dementia. We made a plan for increasing your relative's time in natural light and for using the light box.



Sun overhead 100

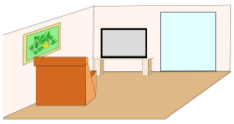
10 000 Light box / light therapy lamp



1000 Sun

Indoor light 30 – 500

Circadian 'body clock' threshold 100





0.0 Full



Star light

Talking point:

- Shall we talk through how you have increased your relative's access to light?

"Let's make a note of what worked best while we talk."

Summary – light and sleep: What worked best?

Prompts:

Remind people of key ideas including:

- Getting enough light during the day is extremely important for sleep at night
- Natural light is best – even if only for a small amount of time.

Ask them what worked best and what effects they have noticed on their relative during the day and at night.

Ask what made it easier for them to increase natural light.

What works? The importance of daytime activity

In session three we talked about how pleasant activities and physical exercise can help people to stay alert during the day and get better sleep at night.

We made a plan for increasing exercise and pleasant events for your relative.





Talking point:

- Let's talk through how you have increased your relative's pleasant activities and physical exercise? What has gone well?

Summary – daytime activity: What worked best?

Prompts:

Remind people of key ideas including:

- Stimulation during the day helps the body-clock know when it is time to be awake or asleep and can help improve mood.
- Even small activities can make a big difference

Ask what worked best? What have they noticed happening? What did their relatives enjoy most? Have there been things that they have done together? How do they encourage their relatives? What made it easier?

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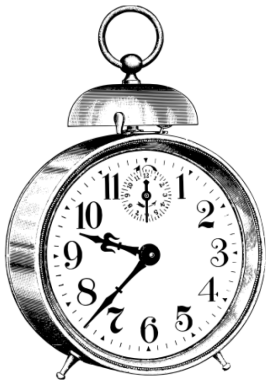
What works? Making a new sleep routine

In sessions two and three we discussed how daytime napping, spending too much or too little time in bed (e.g through going to bed too early or late), and having a variable sleep pattern from night-to-night, can make it harder for people with dementia to sleep well.

We looked at ways to strengthen the link between bed and sleep.Some of the ways we discussed included:



- Winding down at bedtime
- Using the bedroom only for sleeping
- Reducing daytime napping
- Increasing daytime activity
- Only going to bed when tired
- Using the 15 minute rule
- Having a daytime routine
- Going to bed and getting up at a set time

Talking point:

- Let's discuss any changes to your relatives sleep routine. What worked well?

Summary – sleep routine: What worked best?

Prompts:

Remind people of key ideas including:

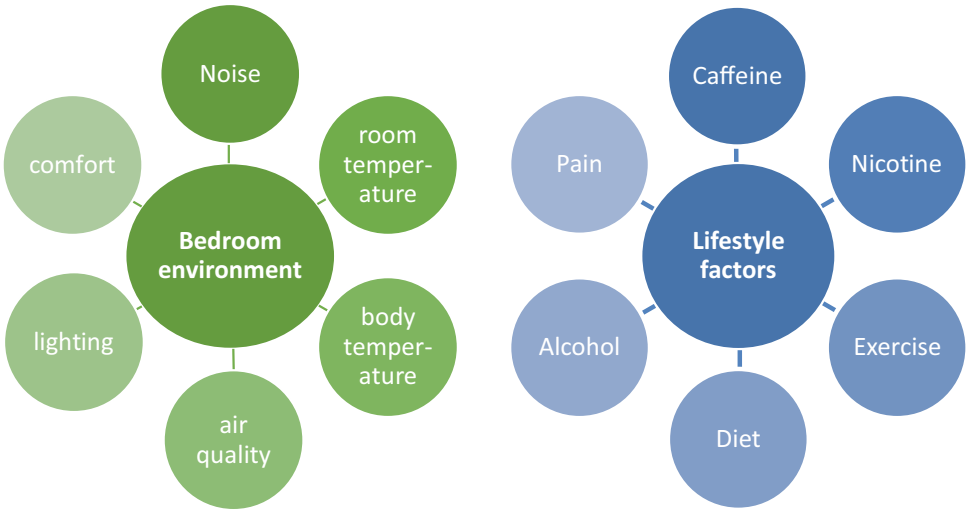
Reducing daytime naps / doing more during the day / having meals at set times can help, it will vary from person to person.

Ask them what worked best and what effects they have noticed on their relative during the day and at night and what made it easier?

Ask them if they have made any changes to their own sleep routine / habits

What works? Making changes to improve sleep

In our first session we identified small changes that can be made to improve sleep.



Talking point:

- Let's discuss any changes you have made for you or your relative? Which did you find helpful?

Summary – bedroom and lifestyle: What worked best?

Prompts:

Remind people of key ideas including:

- What works will vary from person to person and small changes can make a big difference.

  Ask them what worked best and what effects they have noticed on their relative? Have they noticed any effects on themselves? What made it easier for them to make the changes?

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What works? Managing night-time behaviour

In sessions four and five we discussed how describing and investigating behaviours can help us to develop specific strategies to try and overcome problems.

Remember, there is always a cause for night-time behaviours, but the person with dementia is not doing it on purpose and can't control these.





1. Environment / routine
2. Fears or emotions
3. How we respond
4. Pain and discomfort
5. The effects of dementia





Talking point:

- Have you been able to use this approach to managing night-time behaviour problems? If so, did you find helpful?

Summary – night-time behaviours: What worked best?

Prompts:

Recap on the approach:

- Describe – in as much detail as possible, be specific
- Investigate
- Create strategies
- Evaluate – It is really important to try see what does and does not work to keep things going.

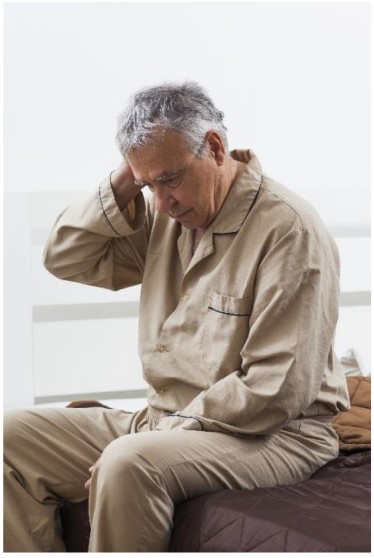
- Ask about specific times / situations – how this approach has helped
- Have people been, using record forms?
- Stress that if strategies do not help, it is good to try something else.

What works? Challenging unhelpful thoughts and looking after yourself

In session five we talked about how to manage your own sleep and make time to look after yourself.

We discussed how to challenge the thoughts that can keep you awake at night by:

1. S*topping to identify* your current thoughts.
2. C*hallenging and replacing* unhelpful thoughts with more helpful ones.
3. *Paying attention to how you feel* in that moment.



We also discussed how making time to look after yourself.

Talking point:

- Shall we talk about how you found challenging unhelpful thoughts and making time to look after yourself?

Summary – thoughts and feelings: What worked best?

Prompts: Recap on the approach

Strategies for managing thoughts that keep you awake also include:

- Putting the day to rest
- Thought blocking
- 15 minute rule
- Giving up trying

Ask if they have been able to make time for themselves, do more pleasant events?

What has worked best and what has made it easier challenge thoughts and do more for self?

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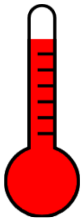
What works? Relaxation

Each week we have practiced a different relaxation technique for you and/or your relative to use. These included:

1. Signal breath
2. Focused breathing
3. Guided imagery: Meadow and stream
4. Stretching
5. Guided imagery: Ocean escape



Talking point:

- Let's talk about how you found the relaxation exercises. Which did you find most helpful?

Summary – relaxation techniques: What worked best?

Prompts:

- What made it easier to find time to practice e.g.
  - Having set times and places to practice
  - Trying it out at home or on journeys
- Have people used relaxation with their relatives?
- Have they noticed an effect on their sleep?

Keeping it going: Developing an action plan

- We know from experience that making changes and keeping them going is difficult and that some changes will work and others will not. Try not to be too discouraged.

- Some of the reasons it can be difficult include:
  - The advice and strategies are not relevant to you
  - It is tricky to get the hang of some of the strategies
  - It is hard to break established patterns

- Here are some suggestions to help you keep going!
  - Make use of the manual to remind yourself what you learnt in sessions
  - Keep using the sleep diary and record forms to notice patterns, especially to see what is working
  - Remember small changes can make a big difference over time, so keep trying things out and practicing



Key Point:

Please continue to put into practice what you have learnt during DREAMS: START. Focus on doing what works and be flexible. If it stops working, try something else.

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Action plan for you and your relative

Let's go through your old plan and update it based on what worked best and what you want to keep doing more of. Remember to think about yourself and your relative.

Area for change	Action
Increasing natural light / Light box	
Increasing daytime activity / physical exercise	
Making a new routine / strengthening the link between bed and sleep	
Bedroom and lifestyle changes to improve sleep	
Managing night-time behaviours	
Looking after yourself / challenging unhelpful thoughts	
Relaxation	

****Have a copy of the plan they made in session 4.** ** Go through each section and update or amend based on what they said worked best.

Remember that some areas won't apply or have worked for them so leave these out.

Make sure that they write a clear plan for the areas they want to keep going, Make sure that they are clear and specific.

Remember to try and make each goal –

S - Specific

M - Measurable

A – Attainable

R – Relevant

T – Time-bound

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Summary

We hope you have found these sessions helpful and will continue to use what you have learnt for you and your relative.

You have told us what you have found helpful and what strategies you will keep using.

You can keep and refer back to the manual to remind yourself of the techniques discussed throughout the sessions.

We have included copies of all the record forms and sleep diary at the end of this session.

Different researchers will be coming back to see how doing this has affected you and your relative. Do not tell them whether you received these sessions or not so we can fairly judge how much it helps! (This will mean putting the light box, thermometer, CD and the manual out of sight when they visit.)

"Not telling the researchers that come back whether you have had the sessions helps us to know whether the training has worked as we do not want them to be affected by what you tell them…"

Remember, the best way to make a difference to your relative's sleep is to keep practicing the strategies you have developed during the sessions."



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Copies of record forms / sleep diary

Planning record

Date(s)	What did you try?	How did it go for your relative?	How did it go for you?

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DOI: 10.3310/hta22710

Planning record

	Action plan	How did it go for your relative?	How did it go for you?
Light box			
Increasing natural light			
Reducing daytime naps			
Time to bed and rise			
Lifestyle changes			

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Pleasant events record:

Day	What did you try?	How did it go?

Behaviour Record

Describe	Investigate…	What did you find out?
	☐ Environment/routine?	
	☐ Fears or emotions?	
	☐ How we respond?	
	☐ Uncomfortable /Unwell?	
	☐ Dementia?	
	☐ Environment/routine?	
	☐ Fears or emotions?	
	☐ How we respond?	
	☐ Uncomfortable /Unwell?	
	☐ Dementia?	
	☐ Environment/routine?	
	☐ Fears or emotions?	
	☐ How we respond?	
	☐ Uncomfortable /Unwell?	
	☐ Dementia?	

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Behaviour record

Describe	Investigate	Create Strategies	Evaluate Did it work?
	☐ Environment/routine?		
	☐ Fears or emotions?		
	☐ How we respond?		
	☐ Uncomfortable /Unwell?		
	☐ Dementia?		
	☐ Environment/routine?		
	☐ Fears or emotions?		
	☐ How we respond?		
	☐ Uncomfortable /Unwell?		
	☐ Dementia?		

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DOI: 10.3310/hta22710

Thought record

Thoughts I have in bed	How they make me feel	An alternative response would be

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Weekly Sleep Diary

Date	Noon	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am
Tuesday May 14th	O		N							/			X X		X				/				N	O

Key:

/ = When your relative went to bed and when they got up in the morning

X = Every time your relative gets up in the night

N = When your relative takes a nap during the day

O = When your relative has been out of the house

E = When your relative has done any physical exercise

L = When you relative has used the light box

Appendix 6 Treatment-as-usual baseline data and information pack

DREAMS: START

Dementia **Re**l**a**ted **M**anual for **S**leep: **St**r**a**tegies for **R**el**a**t**i**ves

Data from the watch

We have now analysed the data from the watch we gave out for two weeks when you joined the study and show the traces from it over the page.

- Light is shown by yellow lines (0-2000 lux). The higher they are the more light there was.
- Movement is shown by black lines (0-5000 activity counts). The higher they are the more movement there was.
- The blue lines mark when the button was pressed (to indicate bed and wake times).

We were therefore able to see how much light per day [the person wearing the watch] was exposed to. This was the right amount / not enough light. (*Only if not enough*: We would recommend they need quite a lot / a little more). The strongest light is natural light outside. The amount of indoor light can be increased by ensuring curtains are open, windows are clean and you sit in a bright room.

We also use movement to work out when someone is asleep. From this we were able to work out what is known as sleep efficiency. This is how much of the time someone is asleep when they are in bed.

The watch indicated that the average time in bed was XX hours XX minutes, the time asleep XX hours XX minutes, and the time awake XX minutes / XX hours XX minutes. [Say something about the sleep pattern.] Sleep efficiency was XX.X%. This is enough. / We would recommend that this is increased. [Add a sentence here about napping too, if relevant]

Improving sleep efficiency/sleep patterns can be done by:

1) Stopping or reducing daytime naps;
2) Delaying the start of sleep by going to bed later;
3) Increasing activity during the day;
4) Increasing light during the day and reducing light during the night.

There are more tips on page 3.

If you have any questions you can contact: X on XXXXXXXXXXX

[Insert watch data – activity & light - on this page (5 examples)]

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Best night

Worst night

Average nights

Good sleep guide

Sleep problems are quite common in people living with dementia.

The causes of sleep problems can be complicated, but by using the tips below you may notice some differences in your relative's sleep or your own sleep.

Small changes can make a difference, but they may need to be used over a number of weeks to see if they help.

In the day

1. Try to help your relative get up at the same time every day for them to get into a sleeping routine.
2. Try to avoid your relative sleeping in the day so they will sleep better at bedtime.
3. Try to help them get outside in the day, particularly in the morning, as outdoor light can help with sleep.
4. If you can, combine going outside with being active as this can also help.

In the evening

1. Encourage your relative to have an evening routine to help them relax. This could include having a warm (caffeine free) milky drink, a warm bath, or listening to soothing music.
2. Discourage your relative from drinking coffee or tea after 6pm.
3. Alcohol at night can upset sleep so discourage your relative from drinking after 7pm.

At bedtime

1. Make sure the bed and bedroom are comfortable - not too cold or too warm. A low cost thermometer, can help you know whether the temperature is right.
2. Make the bedroom quiet (e.g. have the TV on only when not in bed).
3. Make the bedroom as dark as possible. You could use a plug-in night light that gives enough light to see, but is not too bright.

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Appendix 7 End-of-involvement letter template

LONDON'S GLOBAL UNIVERSITY

[Date]

DREAMS START

Dementia Related Manual for Sleep; Strategies for Relatives

Dear [Carer] and [Person with dementia]

I am writing to thank you for having participated in the DREAMS START study. We are very grateful for your time and how you welcomed our team in your home. The study is still ongoing; the last participants will complete follow-up assessments in July 2017.

Please turn over to view results from the acti-watch worn three months after you first joined the study. These results show that [Patient] slept the same/less/more and was awake the same/less/more during the night compared with three months earlier. The sleep pattern changed/did not change from baseline: bedtime is the same/later/earlier as/than before and rise time is the same/later/earlier. Sleep efficiency was XX.X%, compared to the earlier XX.X%. We were also able to see how much light per day [Patient] was exposed to. Compared to three months earlier, [Patient] received the same/less/more light. This is enough. [OR As this is not enough, we would recommend increasing/further increasing light during the day.]

Once all the information we collect from our participants has been analysed and the results written up, we will get in touch to tell you about the findings. In the meantime, updates on the study will be available online: www.twitter.com/dreamsstartucl

Thank you so much once again for working with us and being in the treatment/control group.

Yours sincerely,

P.T.O

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Data from the watch

- Light is shown by yellow lines (0-2000 lux). The higher they are the more light there was.
- Movement is shown by black lines (0-5000 activity counts). The higher they are the more movement there was.
- The grey sections are missing data.
- The blue lines represent times when the event marker on the acti-watch was pressed.

(Insert follow up acti-watch data here)

Appendix 8 Fidelity checklists for intervention sessions

Check List (DREAMS) session 1
Facilitator Name:_____
Assessor Name:_____
Date: _____

Introduction	
All information covered (Inc. key point) or **if not,** an explanation is given for why not covered.	
What to expect	
All information covered	
Outline that carer will put strategies in place during each week	
Sleep and dementia	
All information covered	
Discuss carer quotes	
Facilitate discussion and create list of sleep problems the person living with dementia maybe experiencing	
What is sleep?	
Facilitate discussion of talking point: What do you notice happening to you and your relative when you don't get a good night's sleep?	
All information covered	
Outline diagram	
How does sleep work?	
All information covered (Inc. Key Point)	
Outline diagrams and checked that they have understood. If not, clarify.	
Why is sleep important?	
All information covered	
Facilitate discussion of talking point: Did your relative have problems sleeping before the diagnosis, if so, what helped then?	
What causes sleep problems in dementia?	
All information covered	
Facilitate discussion of *talking point: What do you think may trigger the problems you mentioned on p.11*	

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Making changes to improve sleep	
All information covered	
Discuss lifestyle and bedroom environment factors impact on carer and relative	
Facilitate lifestyle/ bedroom environment changes for the relative	
The impact of sleep problems on you and your relative	
All information covered (Inc. Key point)	
Discuss carer quotes	
Facilitate discussion around sleep problems and which problems are deemed most distressing for both carer and relative	
Managing the stress of sleep problems	
All information covered (Inc. Key point)	
Facilitate discussion around carer stress/ emotions	
The signal breath	
All information covered	
Teach signal breath	
Rate stress before and after	
Putting it into practice	
All information covered	
Summarise the session	
Remind carer to practice stress reduction technique	
Discuss sleep diary with carer	
Discuss Planning record	
Troubleshoot around 'putting it into practice' between session tasks	

Process factors (rate each facilitator separately)	Facilitator 1 not at all – 5 very much
Keeping the session to time	
Keeping the carer focussed on the manual	
Keeping the carer engaged in the session	
Managing concerns of the carer	

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Check List (DREAMS) session 2
Facilitator Name:_____
Assessor Name:_____
Date: _____

Recap on previous session	
Go through Session Plan	
Discuss completion of diary	
Discuss "sleep hygiene" changes	
Light and sleep	
All information covered	
Discuss light diagram	
Light, dementia and the body clock	
All information covered (Inc. key point)	
Discuss carer quotes	
Facilitate discussion around how much time their relative is in natural light on a typical day	
Making a light therapy plan	
Discuss light data from Actigraph	
All information covered	
Facilitate plan around increasing access the natural light	
Introduce light box and provide instructions for use	
Discuss potential difficulties involving use of light box	
Your relative's sleep pattern	
All information covered	
Discuss diagram	
Facilitate discussion around relatives sleep using diary	
Discuss sleep data from Actigraph watch	
Discuss sleep efficiency	
Discuss reducing naps/ changing sleeping pattern (time to bed and time waking up)	

Your relative's plan	
All information covered	
Facilitate carer to plan actions for areas of change	
Managing stress: Focussed breathing	
All information covered	
Talk through experiences of using signal breath	
Teach focussed breathing	
Rate stress before and after	
Putting it into practice	
All information covered	
Summarise the session	
Remind carer to practice stress reduction technique	
Remind carer to try out new actions	
Introduce and encourage use of planning record	
Remind carer to continue using sleep diary	
Troubleshoot around 'putting it into practice' between session tasks	

Process factors (rate each facilitator separately)	Facilitator 1 not at all – 5 very much
Keeping the session to time	
Keeping the carer focussed on the manual	
Keeping the carer engaged in the session	
Managing concerns of the carer	

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Check List (DREAMS) session 3
Facilitator Name:_____
Assessor Name:_____
Date: _____

Recap on previous session	
Go through Session Plan	
Discuss areas for change plan made from previous week and how it went	
The importance of daytime activity and routine	
All information covered (Inc. Key point)	
Discuss pleasant activities that carer enjoys and what relative enjoys	
Planning daytime activity	
All information covered (Inc. key point)	
Discuss list of pleasant activities	
List four pleasant activities for carer and relative	
Sleep, exercise and physical activity	
All information covered (Inc. key point)	
Discussion around exercise using sleep diary	
Discuss walking/ exercise goal if appropriate	
Establishing a good day and night routine	
All information covered (Inc. key point)	
Discussion around relative's bed- sleep connection	
Discuss sleep data from Actigraph watch	
Facilitate the plan for strengthening the link between bed and sleep.	
Managing stress: Guided imagery	
All information covered	
Talk through experiences of using focussed breathing	
Teach guided imagery	
Rate stress before and after	

Process factors (rate each facilitator separately)	Facilitator 1 not at all – 5 very much
Keeping the session to time	
Keeping the carer focussed on the manual	
Keeping the carer engaged in the session	
Managing concerns of the carer	

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Check List (DREAMS) session 4
Facilitator Name:_____
Assessor Name:_____
Date: _____

Recap on previous session	
Go through Session Plan	
Discuss if carer tried new pleasant activities, and what worked/didn't work	
Troubleshooting	
Discuss relative's action plan from sessions 2 and 3	
Facilitate *talking point* regarding how the plan is effecting relative and carer	
Discuss possible solutions to any potential problems	
Managing night-time behaviours	
All information covered (Inc. key point)	
Recap on night-time behaviours from session 1	
Create updated list of night-time behaviours	
Describing and investigating behaviours	
All information covered (Inc. key point)	
Encourage recollection of one sleep problem in detail	
Is there something about the environment/ routine?	
All information covered	
Facilitate conversation regarding environment and if changes already made have had an impact	
Are they feeling distressed or frightened?	
All information covered (Inc. key point)	
Discuss signs relative is upset/frightened and how to comfort them	
Are night-time difficulties affected by how we respond?	
All information covered (Inc. key point)	
Discuss "Ted's situation" and what carer would do in this situation	

Are difficulties caused by pain or discomfort?	
All information covered	
Discuss what carer could do to find out if relative is unwell	
Are difficulties caused by the dementia?	
All information covered	
Discuss how relative's sleep difficulties may have been caused by their dementia	
Managing stress: Stretching	
All information covered	
Talk through experiences of using guided imagery	
Teach stretching exercise	
Rate stress before and after	
Putting it into practice	
All information covered	
Summarise the session	
Remind carer to practice stress reduction technique	
Introduce and encourage use of behaviour record	
Remind carer to continue using sleep diary and to use their own sleep diary this week	
Troubleshoot around 'putting it into practice' between session tasks	

Process factors (rate each facilitator separately)	Facilitator 1 not at all – 5 very much
Keeping the session to time	
Keeping the carer focussed on the manual	
Keeping the carer engaged in the session	
Managing concerns of the carer	

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Check List (DREAMS) session 5
Facilitator Name:_____
Assessor Name:_____
Date: _____

Recap on previous session	
Go through Session Plan	
Discuss if carer used behaviour record	
Creating strategies for managing behaviours	
All information covered (Inc. key point)	
Discuss strategies for managing behaviours and write down list	
Managing your own sleep	
All information covered (Inc. key point)	
Discuss how they their sleep has been affected by their relative's sleep difficulties and dementia.	
Managing thoughts and feelings	
All information covered (Inc. key point)	
Discuss what techniques carer may find helpful	
Challenging unhelpful thoughts and feelings	
All information covered (Inc. key point)	
How to challenge unhelpful thoughts	
Discuss *Alice's situation*	
Talking point: Talking with others about caring role	
Talking point: Discuss carer's thoughts	
Making time for yourself	
All information covered (Inc. Key point)	
Facilitate conversation regarding pleasant activities that carer enjoys	

Managing stress: Ocean escape	
All information covered	
Talk through experiences of using Stretching	
Teach Ocean Escape	
Rate stress before and after	
Putting it into practice	
All information covered	
Summarise the session	
Remind carer to practice stress reduction technique	
Introduce and encourage use of Thought record	
Remind carer to continue behaviour record	
Remind carer to continue using sleep diary	
Troubleshoot around 'putting it into practice' between session tasks	

Process factors (rate each facilitator separately)	Facilitator 1 not at all – 5 very much
Keeping the session to time	
Keeping the carer focussed on the manual	
Keeping the carer engaged in the session	
Managing concerns of the carer	

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Check List (DREAMS) session 6
Facilitator Name:_____
Assessor Name:_____
Date: _____

Putting it all together	
Go through Session Plan	
All information covered	
What works? Light, sleep and dementia	
All information covered	
Discuss session and summarise what worked best	
What works? The importance of daytime activity	
All information covered	
Discuss session and summarise what worked best	
What works? Making a new sleep routine	
All information covered	
Discuss session and summarise what worked best	
What works? Making changes to improve sleep	
All information covered	
Discuss session and summarise what worked best	
What works? Strengthening the link between bed and sleep	
All information covered	
Discuss session and summarise what worked best	
What works? Managing night-time behaviour	
All information covered	
Discuss session and summarise what worked best	
What works? Challenging unhelpful thoughts and feelings	
All information covered	
Discuss session and summarise what worked best	

What works? Relaxation	
All information covered	
Discuss session and summarise what worked best	
Keeping it going: Developing an action plan	
All information covered (Inc. Key point)	
Action plan for you and your relative	
Remind carer of "areas for change" plan and update the actions	
Summary	
Summarise session	
Inform them there are copies of record forms should they wish to continue using them.	
Remind carer about not telling researchers whether they had the intervention during follow-up interview	

Process factors (rate each facilitator separately)	Facilitator 1 not at all – 5 very much
Keeping the session to time	
Keeping the carer focussed on the manual	
Keeping the carer engaged in the session	
Managing concerns of the carer	

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Appendix 9 Schedule for individual qualitative interviews

DREAMS START individual interview post-intervention guide

Before starting the recording

Give the carer a case report form to look at, a copy of the manual and the DREAMS START session card. Let the participant look at these for a few minutes.

Introduction of researchers

Thanks . . . . My name is . . . (As you know) I am a researcher from University College London and will be recording this interview. I am interested in your opinion about and experience of the DREAMS sessions. Everything you say is confidential, but I would like you to introduce yourselves for the recording so that the typist can identify you.

Description of research topic

We are asking you because you have tried out the sessions. We want to know about your experience and what was good and what was less good and how it has made a difference to you and your relative.

As a reminder, here's a card listing the six sessions:

- Session 1: Understanding sleep and dementia.
- Session 2: Making a plan.
- Session 3: Daytime activity and routine.
- Session 4: Difficult night-time behaviours.
- Session 5: Taking care of your own sleep.
- Session 6: What works? Using strategies in the future.

You can use the manual too, if having your copy on hand is helpful.

Q. Can we start by hearing about how you found the intervention in general?

Prompts:

- What did you like best about the sessions?
- Was there anything that you did not like about the sessions?
- Is there anything important that you feel was missing/not covered?
- What were the key points that stood out for you?
- How did you find the length of the sessions? How about the number of the sessions? Were the sessions spaced apart enough?
- What aspects of the sessions/manual have you continued to use? Have you gone back to the manuals since the intervention stopped?
- What difference has the intervention made to you and/or your relative during the day? How about during the night?

Q. What did you think about the content of each sessions?

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Prompts:

How did you find . . .

- Increasing natural light.
- Using the light box (and are you still using the light box now?).
- Increasing daytime activity/physical exercise.
- Making a new routine/strengthening the link between bed and sleep.
- Bedroom and lifestyle changes to improve sleep.
- Managing night-time behaviours.
- Looking after yourself/challenging unhelpful thoughts.
- Relaxation.

Is there anything else you would like to mention regarding content?

Q. How did you find the manual itself?

Prompts:

- How did you find the layout?
- Was it easy to read and follow, for example not too much text on each page/fonts/colours?
- What did you think of the diagrams and pictures – more, less, different?
- Were the sleep diary/record forms easy to use? How could we improve them?

Q. How did you find the plans and trying things out between the sessions?

Prompts:

- What made it easier for you to try things out between the sessions?
- What made it harder for you to do the tasks between the sessions?
- Did it make a difference trying things out together?

Q. How did the intervention fit with the sorts of sleep difficulties that your relative has been experiencing?

Q. How did your relative find wearing the watch?

Q. What did you think about the feedback from the letter comparing the difference in sleep from baseline to 3-month follow-up? What other information would you have liked to know? For example, about naps, if time to bed or rise has changed.

Q. What did you think of the initial and follow-up assessments, particularly the measures (questionnaires) we used?

Q. Before we finish, is there anything else you would like to mention that we have not already covered?

Thank you for taking part in the study and meeting me today.

Appendix 10 Standard operating procedure: processing Actiwatch data

DREAMS START

Standard operating procedure: processing Actiwatch data

Downloading Actiwatch data

a. Clean the watch with an antiseptic wipe (including the insides).
b. Download the data (Read Data) using MotionWare software 1.1.25. Save the data in [Actiwatch participant data folder].
c. Rename the file as, for example, 0101-bl-orig OR -fu-orig for follow-up.
d. IMPORTANT: download the data (Read Data) again, and save the data in [Actiwatch participant data folder].
e. Rename the file as, for example, 0101-bl OR -fu for follow-up. THIS IS THE FILE USED FOR THE REST.
f. Choose Utilities and Shutdown Watch, then disconnect.
g. Choose the file used for the analysis, and in the Actogram window, choose File > Properties, and edit any recording properties [date of birth, UserID (user identification), UserName] before proceeding.

   – The UserID should be like this: 0101.
   – The UserName should contain the UserID and watch serial number: 0101_S004324.

Preparing the data set

a. Select Sleep Analysis.
b. Highlight the whole recording period.
c. Choose Edit to remove missing data from the analysis; anything from 17:01 on day 14 AND all periods when the watch was off the wrist (based on the carer's report and/or judging from the recording).
d. IMPORTANT: make sure that the remaining period is exactly 14 days long; should be from 17:00 of the first day to 17:00 of the last day.
e. IMPORTANT (needed for the manual – see below): find Average Lux by selecting the whole 14-day period. In the Sleep Analysis window, Average Light (in lux) is under the Summary option. Make a note of the lux value, to later record it in the light document (instructions below).
f. IMPORTANT: While the window is still open, click on NPCRA and choose Save Period, to view the edited 14-day actigraphy (otherwise the report will not include NPCRA).

Producing graphs for the manual

a. Each graph will need to be produced separately. To produce:

   – Light graph – click the downwards arrow on the left-hand scale until the black data (activity) disappears. The range for light should always be 0–2000. Then move on to step b.
   – Activity graph – Click the downwards arrow on the right-hand scale until the yellow data (light) disappears. The range for activity will depend on the participant, but 0–5000 appears to work quite well. In some cases, you cannot choose 5000 so either go 4000 or 6000, whichever is better for the participant's activity based on what you know. Move on to step b.

b. Select Tools, then Report.

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c. Under report options, tick only:

   – Include recording properties.
   – Include actogram.
   – Push actogram onto separate page.

d. Keep the default values for all other settings (i.e. do not change anything under Change Actogram Options).
e. Click copy to Word Processor.
f. In Word, create a new document, and paste the clipboard contents.
g. For the:

   – Light graph – use cropping to delete all extra (edited out) periods from the end of the report. Also crop the scale on the left-hand side, leaving only the scale on the right-hand side, as long as this does not cut out the dates.
   – IMPORTANT (needed for the manual – see below): add the Average Lux from above to the light document, just underneath the participant data table.
   – Activity graph – crop the scale on the right-hand side, leaving only the scale on the left-hand side; also delete all extra (edited out) periods from the end of the report.

h. Name the file as, for example, 0101_light-bl OR 0101_activity-bl (-fu for followup) and save in: [intervention delivery actigraph data for session 2 folder].

Obtaining outcome measures

a. Next, using the edited actigraphy, highlight the first sleep period, choosing as the starting and ending points the event button presses (or one of those, preferably the first, if any), then editing and re-editing the period in the Sleep Analysis window as necessary.
b. Once happy with a sleep period, choose Save Sleep Period. Do the same for each night that the watch was worn.
c. N.B. If the carer has been filling in the Actiwatch sleep diary, use Tools > Sleep Summary Table and enter the Lights out (Bed time) and Got up times from the diary to use those as initial start/end points. Then edit the sleep period by editing these times, using the button presses (when available).
d. N.B. If the carer has NOT filled in the Actiwatch sleep diary, highlight the area believed to be the sleep period based on the carer's verbal report and the activity data. If it becomes too difficult to create a sleep window based on activity, then attempt the second strategy: using the light and activity data. When unsure, ask one of the other two researchers to help and reach a consensus on each problematic sleep window.
e. With all Sleep Periods defined, choose Tools and Report. IMPORTANT: make sure both the Sleep Analysis and NPCRA are ticked, then Print Preview. Save the Report in [Actiwatch participant data folder] as, for example, 0101_report-bl (OR -fu).

For those delivering the intervention:

1. Open Session 2 manual and paste the light and activity data into the designated place (light actograms will be placed on p. 8 and activity actograms will be placed on p. 12).
2. Verify that the correct data have been selected for the participant: check the table (i.e. UserID, Sex) and then delete these, leaving only the actograms.
3. Add Average Lux (from the light document) to p. 8 of Session 2.



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