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

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Scientific summary

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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).

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.

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

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.

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