Clinical effectiveness of DREAMS START (Dementia Related Manual for Sleep; Strategies for Relatives) versus usual care for people with dementia and their carers: a single-masked, phase 3, parallel-arm, superiority randomised controlled trial

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Summary

Background Sleep disturbances are common and distressing for people with dementia and their families. Non-pharmacological interventions should be first-line management, avoiding harmful pharmacological side-effects, but there is none with known effectiveness. We aimed to establish whether DREAMS START, a multicomponent intervention, reduced sleep disturbance in people with dementia living at home compared with usual care.

Methods We conducted a phase 3, two-arm, multicentre, parallel-arm, superiority randomised controlled trial with masked outcome assessment, recruiting dyads of people with dementia and sleep disturbance and family carers from community settings. Randomisation to the DREAMS START intervention (plus usual treatment) or usual treatment was conducted at dyadic level, blocked, and stratified by site, with a web-based system assigning allocation. DREAMS START is a six-session, manualised intervention delivered face to face or remotely by non-clinically trained graduates over an approximately 3-month period. The primary outcome was sleep disturbance measured by the Sleep Disorders Inventory (SDI) at 8 months. Analyses were on the intention-to-treat population. This trial is registered with ISRCTN 13072268.

Findings Between Feb 24, 2021, and March 5, 2023, 377 dyads were randomly assigned (1:1), 189 to usual treatment and 188 to intervention. The mean age of participants with dementia was 79·4 years (SD 9·0), and 206 (55%) were women. The mean SDI score at 8 months was lower in the intervention group compared with the usual treatment group (15·16 [SD 12·77], n=159, *vs* 20·34 [16·67], n=163]; adjusted difference in means –4·70 [95% CI –7·65 to –1·74], p=0·002). 17 (9%) people with dementia in the intervention group and 17 (9%) in the control group died during the trial; the deaths were unrelated to the intervention.

Interpretation To our knowledge, DREAMS START is the first multicomponent intervention to improve the sleep of people living at home with dementia more than usual clinical care. It had sustained effectiveness beyond intervention delivery. The intervention's delivery by non-clinically trained graduates increases the potential for implementation within health services, adding to usual clinical care.

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Introduction

In 2019, 57 million people worldwide had dementia, and this number is projected to increase to 153 million by 2050, with an estimated cost of care in 2019 in excess of US$1 trillion.[1,2] Sleep disturbance is common in people with dementia and can affect all aspects of mental and physical functioning. Our recent meta-analysis of sleep disturbance in people living at home with dementia found pooled prevalence of 26%.[3] In addition to the possible negative effect of sleep disruption on dementia trajectory, family members find it difficult to cope with disturbed sleep.[4,5] Sleep disturbances predict family carer depressive symptoms, burden, and care home admission, all of which contribute to the individual, societal, and economic impact of dementia.[6,7]

Neurodegeneration of brain structures involved in sleep and circadian rhythm regulation, including the suprachiasmatic nucleus, are likely to mediate changes in sleep timing, sleep continuity, and sleep architecture in dementia.[8] Dementia can result in impaired sleep initiation, reduced night-time sleep, difficulty staying asleep, increased night-time wandering, and excessive daytime sleepiness.[9] More than 90% of people with dementia have at least one additional long-term health condition and might experience pain, discomfort, or mood disturbances,[10] which further affect sleep. Treating sleep problems could improve the daytime functioning and quality of life of people with dementia and, given the hypothesised bidirectional relationship between sleep disruption and amyloid

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Research in context

Evidence before this study

We searched MEDLINE, Embase, PsycINFO, and the Cochrane Dementia and Cognitive Improvement Group's specialised Register from database inception to April 23, 2023, using search terms: (sleep* OR somnolence OR insomnia OR hypersomnia) AND (dement* OR Alzheimer*) AND (intervention OR therapy OR treatment OR effectiveness), without restriction on language for studies of non-pharmacological interventions for sleep disturbance in people with dementia. We included randomised and non-randomised trials measuring sleep disturbance with actigraphy, polysomnography, or validated questionnaires as an outcome for people diagnosed with dementia living at home, and excluded studies reporting on primary sleep disorder (eg, obstructive sleep apnoea or rapid-eye-movement sleep behaviour disorder) rather than sleep disturbances. We identified 14 relevant trials. Five studies measured sleep by standardised questionnaires, three by actigraphy, and six by both. Only one study was rated as having consistently low risk of bias. Most studies were preliminary studies with small sample sizes and high heterogeneity. Results from included studies of light therapy or activity-based interventions alone were inconclusive. Two pilot studies in community-dwelling people with dementia, and our DREAMS START (Dementia RElAted Manual for Sleep; STrAtegies for RelaTives) feasibility randomised controlled trial, found potential benefits of combining light with other components, including sleep education and hygiene, exercise, daytime activity, and cognitive behavioural therapy. The pilot studies had high dropout rates (40–50%) but our feasibility randomised controlled trial did not (8%).

Added value of this study

DREAMS START, a multicomponent intervention, showed a sustained reduction in sleep disturbance for people with all severities of dementia living at home, beyond the duration of the intervention and more than usual clinical care. It also showed high levels of intervention attendance in contrast to previous multicomponent pilot studies, and is the first to test and show effective delivery by non-clinically trained graduates both face to face and remotely.

Implications of all the available evidence

To date, there has been no conclusive evidence supporting the use of pharmacological or non-pharmacological interventions for sleep disturbance in dementia, despite the prevalence and impact on those affected by dementia. To our knowledge, DREAMS START is the first definitive randomised controlled trial of a multicomponent intervention for sleep disturbance in people living at home with dementia. Previously, no such treatments have been known to be effective.

deposition and tau pathology,[8] could potentially slow disease progression.

To our knowledge, there are no definitive randomised controlled trials showing efficacy of pharmacological, non-pharmacological, or light-based treatment for sleep disturbance in dementia at all severities.[7,11] Pharmacological interventions such as antipsychotics and hypnotics can have adverse effects[11] including increased mortality in older adults,[12] whereas melatonin, although safe, is not effective in improving sleep in dementia.[11] In a 2020 trial,[13] suvorexant was well tolerated and effectively increased total sleep time in people with mild to moderate probable Alzheimer's disease and insomnia. A recent Cochrane review of non-pharmacological interventions in dementia concluded that multicomponent, complex interventions have the strongest potential to improve sleep disturbance.[7] We need effective interventions for sleep disturbance in people with dementia, their families, and the health and social care systems supporting them.

This research builds on our successful feasibility randomised controlled trial of DREAMS START (Dementia RElAted Manual for Sleep; STrAtegies for RelaTives), a tailored intervention to address the varied and often multiple underlying reasons for sleep disturbance in people with dementia.[14,15] This study aims to determine whether this intervention delivers benefits for people with dementia of all types and severity and their family carers.

For the **study protocol** see https://bmjopen.bmj.com/content/14/2/e075273

Methods

Study design

This two-armed, multicentre, parallel-arm, superiority, pragmatic, randomised controlled trial with masked outcome assessment was conducted across 12 English National Health Service (NHS) sites. The trial is registered with ISRCTN 13072268, and was approved by the London—Camden & Kings Cross Ethics Committee (20/LO/0894) on Aug 21, 2020. The published protocol is available online.[16]

Participants

Participant dyads of people with dementia and family carers were recruited from community NHS memory services and older adult mental health services in England (Greater London, Essex, Sussex, and Tees, Esk, and Wear Valleys) and from Join Dementia Research, a free, secure online and telephone service for potential dementia research participants run by the National Institute for Health and Care Research. We included people who had a documented diagnosis of any dementia type and severity; scored 4 or higher (clinically significant sleep disturbance) on any item they or their family judged problematic on the Sleep Disorders Inventory (SDI), a valid and reliable tool for people with dementia;[17] and lived in their own home with somebody present at night. People with dementia were excluded if they had a known primary sleep disorder preceding dementia, were currently drinking heavily

(Alcohol Use Disorders Identification Test—Consumption score ≥8), were unavailable for more than 3 weeks during the trial, or were enrolled in another non-pharmacological dementia randomised controlled trial. We included family carers with capacity to give informed consent who supported their relative at least weekly, practically or emotionally. Sex was self-reported as male or female.

Randomisation and masking

Randomisation was conducted at participant (dyad) level, blocked, and stratified by site. Dyads were randomly allocated (1:1) to intervention or treatment as usual (TAU). Allocation was through a web-based system, Sealed Envelope, provided by PRIMENT Clinical Trials Unit. The trial manager performed randomisation after consent and baseline data collection or, if unavailable, randomisation was conducted by a research team member not involved in recruitment or follow-up. Researchers collecting outcome data were masked to allocation. We were unable to mask participants and intervention facilitators to allocation, as is common in psychological intervention trials. We minimised the risk of assessors being unmasked by ensuring the person facilitating the intervention was different from the researcher conducting follow-up assessments, and by reminding participants not to mention the intervention to the assessor and to hide materials or equipment. Across sites, if an assessor was unmasked, this was reported to the trial manager and recorded, and an alternative researcher conducted future assessments. We have successfully adopted this approach in previous trials of non-pharmacological and pharmacological interventions.[15,18,19]

Procedures

Participants (people with dementia and family carers) assessed as having capacity to consent to the study gave written or audio-recorded informed consent on the basis of preferences and COVID-19 restrictions. When participants with dementia did not have capacity to consent, family members acted as consultees. Data were collected from family carers at baseline, 4 months, and 8 months. All outcome measures related to participants with dementia were proxy reported by family carers, to minimise burden upon the people with dementia and to ensure comparable data, as cognitive impairment can preclude many people with dementia from completing self-report measures. If family carers agreed, we audio-recorded one intervention session to assess intervention fidelity.

DREAMS START is a co-produced, six-session, manual-based, multicomponent intervention for carers of people with dementia to build personalised strategies and make changes to their care recipient's sleep.[14,15] We incorporated psychoeducation, routine, light, increased activity, exercise, and carer's support.[7] This included information about sleep and dementia, support for carers to use practical zeitgebers (circadian rhythm cues, eg, regular timing of bed, rising, and meals), use morning wake-up light (natural and phototherapy), establish adaptive stimulus control (eg, pre-bed settling routine, management of wakeful episodes), promote de-arousal at night (eg, relaxation, bedroom comfort, no caffeine or alcohol pre-bed), use daytime behavioural activation to maintain alertness and reduce naps, and look after their own (sleep) health. The intervention integrated actigraphic data from devices worn by participants with dementia at baseline to personalise strategies. Carers retained personalised manuals and equipment and made an individual plan to continue using after intervention completion (appendix p 2). Intervention sessions were delivered to carers weekly or fortnightly in person, online via video call, or by telephone depending on preference and COVID-19 restrictions. People with dementia could join their carer in sessions if they wished.

See Online for appendix

DREAMS START was delivered by trained, non-clinically qualified psychology graduates to maximise potential for delivery at scale in clinical settings, an approach we have previously successfully adopted. Facilitators participated in a 2-day online training programme delivered by our team. Training was interactive and experiential and focused on dementia and sleep–wake regulation, empathic listening skills, behaviour change, interpreting actigraphy, using supervision, and working collaboratively with family carers and people with dementia. Each facilitator was observed role-playing the intervention by a team clinician (PR, GL, or CC) and signed off as ready to deliver the intervention. Facilitators attended fortnightly group supervision with a clinical psychologist (PR or CC) with additional individual advice available. We used this model in our feasibility randomised controlled trial, where the intervention was delivered with high fidelity.[15]

As this is a pragmatic trial to inform clinical practice in real-world settings, we chose a usual-care comparator rather than an active control condition.[20] All participants received TAU, which varies geographically and according to need and service configuration but might include medication for sleep. The care incorporated National Institute for Health and Care Excellence guidelines for dementia, consisting of assessment, diagnosis, symptomatic interventions, risk assessment and management, advice, and information.[21]

Outcomes

Our primary outcome was sleep disturbance in people with dementia at 8 months on the SDI, a proxy measure completed by the family carer and validated against clinical variables, measuring frequency (scale 0: not present in the last 2 weeks, to 4: once or more per day [every night]) and severity (scale 1: mild, to 3: marked). Each item was calculated by multiplying frequency by severity (possible score 0–12). This measure has been used in pilot and care home randomised controlled trials of multicomponent interventions.[15,22,23] A decrease of 4 points or more is the suggested minimum clinically important difference.[24] The SDI is derived from the sleep domain of the Neuropsychiatric Inventory (NPI).[25] Questions encompass: difficulty falling asleep; getting up during the night; wandering, pacing, or getting involved in inappropriate activities at night; awakening the carer during

the night; awakening at night, dressing, and planning to go out, thinking that it is morning and time to start the day; awakening too early in the morning (earlier than is their habit); and sleeping excessively during the day. The SDI was collected at baseline, 4 months, and 8 months. In our feasibility randomised controlled trial, carers and our patient and public involvement group judged important outcomes to be that their relative was less restless and distressed during the night, did not do anything dangerous, was more awake during the day, and disturbed them less. These dimensions are all measured by the SDI suggesting good ecological validity, reflecting what matters to those affected by dementia.

Prespecified secondary outcomes were measured at baseline, 4 months, and 8 months (health economic outcomes and analyses will be reported separately). For the person with dementia, prespecified secondary outcomes (all proxy rated) were: NPI, a measure of neuropsychiatric symptoms, with 12 symptoms scored for the previous 4 weeks (score range 0–144, with higher scores indicating worse symptoms);[25] Epworth Sleepiness Scale, an eight-item measure assessing daytime sleepiness (score range 0–24, with a score of greater than 10 indicating excessive sleepiness);[26] safety and tolerability assessment to record falls, dizziness, headaches, gastrointestinal symptoms (appetite or bowel symptoms), and other possible side-effects, whether mild, moderate, or severe; Dementia Quality of Life Questionnaire, a 31-item measure assessing quality of life (score range 31–124, with higher scores indicating better quality of life);[27] and psychotropic medication. For the family carer, prespecified secondary outcomes were: Sleep Condition Indicator, an eight-item scale to assess carer sleep disturbance (score range 0–32, with higher scores indicating better sleep and below 16 consistent with clinical insomnia);[28] Hospital Anxiety and Depression Scale, a 14-item scale measuring anxiety and depression (anxiety and depression score ranges both 0–21, with higher scores indicating worse depression or anxiety);[29] Zarit Burden Interview, a 22-item scale for carer burden (score range 0–88, with higher scores indicating more burden);[30] and 12-item Health Status Questionnaire, a measure of health-related quality of life (score range 0–100, with higher scores indicating better health status).[31]

We collected demographic and illness characteristics at baseline. These were the age, sex, ethnicity, and education of both the person with dementia and their carer; the relationship of the carer to the recipient; and dementia subtype and severity measured using the Clinical Dementia Rating scale.[32] We recorded deaths and care home transition at each timepoint.

We recorded the number of sessions attended for each intervention participant and delivery modality (in person, remote, or mixed remote and in person). We asked people with dementia to wear an AX3 wrist-worn actigraph accelerometer (Axivity, Newcastle, UK), which measures movement, for one week at each timepoint. The UK Biobank Accelerometer Analysis tool was used to generate the data. These data were used to inform understanding of the movement of the person with dementia for the intervention and our process evaluation.

For the **UK Biobank Accelerometer Analysis tool** see https://www.cardioscience.ox.ac.uk/tools-and-facilities/biobank-accelerometer-analysis-tool

To analyse delivery fidelity, we applied content checklists for a randomly selected audio-recorded intervention session for each participant. A mean fidelity score was produced by dividing the number of items delivered by the number of items that should be delivered. Additional process measures (range 1: not at all, to 5: very much) included managing each carer's concerns, keeping the carer engaged, keeping the carer focused on the manual, and keeping to time. We predefined fidelity as high (>80 to 100%), moderate (>50 to 80%), and low (≤50%).

Statistical analysis

A detailed statistical analysis plan is preregistered (appendix pp 3–17). Our a priori sample size calculation required 370 participant dyads (185 per group) to detect a difference in average SDI of 5·5 between the intervention and TAU groups with 90% power and 5% significance. This calculation used the SD of baseline SDI scores (15·74) and the correlation between baseline and follow-up measurements (0·57) observed in our feasibility trial.[15] We allowed for up to 15% dropout rate and included an inflation for potential non-normality of SDI (suggested in the feasibility work).[33] To account for possible facilitator clustering in the intervention group, we assumed an intracluster correlation coefficient as observed in earlier studies[18] (0·03) and approximately 15 participants per facilitator. We aimed to estimate the effect of the intervention compared with TAU regardless of post-randomisation events including non-compliance or intervention discontinuation, hospitalisation, moving to a care home, and assuming the person living with dementia is alive at 8 months (appendix p 10).

The primary outcome (SDI at 8 months) was compared between groups using a difference in mean SDI score with 95% CI. This estimate was obtained from a three-level linear mixed-effects regression model with random effects to allow for repeated outcome measurements at 4 and 8 months, and for clustering by facilitator in the intervention group. The model included as fixed effects a treatment group indicator, baseline SDI score, study site, a time indicator, and an interaction between treatment group and time. Analyses of secondary clinical outcomes took a similar approach. For binary outcomes, mixed-effects binomial and logistic models were used to estimate risk differences and odds ratios. Analyses used all available outcome data at 4 months or 8 months with an assumption that missing values, for any reason (including moves to a care home or death), were missing at random.

In sensitivity analyses, the primary outcome model was refitted adjusting for baseline variables associated with missingness identified using logistic regression models comparing participants with and without missing outcomes. We also imputed missing values using multiple imputation; the model included baseline SDI score, site, variables associated with missingness, and other sociodemographic characteristics. Additional analyses used a pattern mixture

approach to considered missing not at random scenarios, as those who move to a care home are likely to have worse sleep (appendix p 20). We refitted the primary analysis model excluding cases where the outcome data (4 months and 8 months) were collected outside the prespecified window of assessment (within 4 weeks either side).

A complier average causal effect analysis, using a two-stage least-squares instrumental variables regression, was used to estimate the treatment effect among participants adhering to the intervention, which was predefined as participation in at least four sessions.[15] We also refitted the primary analysis model using imputed 8-month outcome data but excluding those who had died.

We explored whether the treatment effect differed according to baseline Clinical Dementia Rating and carer physical health (Health Status Questionnaire physical health score), which could interfere with implementation. These analyses added interaction terms between treatment group and the baseline factor to the primary outcome analysis model. Finally, we estimated treatment effects according to whether delivery was remote, in person, or mixed, using a regression model as in the primary analysis but with two treatment indicators representing modes of delivery and adjusting for age of carer, ethnicity, relationship to care recipient, type of dementia, and carer physical health.

We planned to use actigraphy data in mediation analyses to assess whether clinical change was related to increased movement, but these analyses were not performed due to extensive missing follow-up data (appendix pp 26–27).

Role of the funding source

The funder had no role in study design, data collection, analysis, interpretation, or writing of the report.

Results

Between Feb 24, 2021, and March 5, 2023 (when the recruitment target was reached), we assessed 1632 dyads for eligibility, 1253 (76·8%) of whom were excluded (figure 1). Of those excluded, 719 (57·4%) did not meet eligibility criteria. There were no clear imbalances in sex or relationship with people with dementia between eligible people in the trial and those not in the trial (appendix p 18). Of the 377 dyads randomly allocated, 189 (50%) were allocated to the TAU group and 188 (50%) to the intervention group. 176 (93%) of those allocated to TAU and 170 (90%) of those allocated to intervention were included in the primary analysis. 12 sites recruited a mean of 31·4 dyads (SD 21·8, range 3–64). The mean age of participants with dementia was 79·4 years (SD 9·0); 206 (55%) were women and 171 (45%) men; and 282 (75%) identified as White, 47 (12%) as Asian, and 32 (8%) as Black. Most people with dementia had Alzheimer's disease (206 [55%]), vascular dementia (64 [17%]), or mixed dementia (41 [11%]). 292 (77%) participants with dementia had no undergraduate or postgraduate qualification (table 1). Characteristics of both participants with dementia and their carers (table 2) were similar across groups.

Each of the 49 facilitators delivered the intervention to a mean of 3·6 participants (SD 3·12, range 1–15). 149 (83%) of the 180 surviving intervention participants adhered to the intervention, receiving at least four out of six intervention sessions; 142 (79%) received all six sessions; and eight (4%) participants died before completing four sessions (appendix pp 18–19). The median session duration was 60 min (IQR 55–75). 77 (44%) of 176 participants who received any intervention sessions received intervention in person, 31 (18%) by video call, 28 (16%) by telephone, 33 (19%) by a mix of remote and in-person sessions, and seven (4%) by a mix of video or telephone delivery. One intervention session was recorded and available for 143 (76%) of the 188 participants in the intervention group. The mean fidelity score was 95·4% (SD 0·08). For all four process measures assessed, the median score was 5 out of 5 (IQR 5–5).

Average SDI scores at 8 months were 15·16 (SD 12·77, n=159) in the intervention group and 20·34 (16·67, n=163) for TAU (table 3, figure 2); the mean difference was –4·70 points (95% CI –7·65 to –1·74, p=0·0018, n=346) in the primary analysis adjusted model. Complier average causal effect analysis found adherent participants had a mean difference at 8 months of –5·84 (–9·25 to –2·43). Sensitivity analyses adjusting for variables associated with missingness (age, education, and accommodation of the person with dementia; dementia diagnosis and age at diagnosis; and relationship with carer) and imputing missing values under missing at random and missing not at random assumptions gave similar findings to the primary model (appendix pp 18–21). Excluding cases where the outcome data lay outside the prespecified window of assessment, and an analysis of imputed data excluding those with missing values due to death, gave similar findings to the primary model (appendix pp 22–23). At 4 months, the difference in SDI scores was similar in magnitude to that at 8 months (–4·42 [–7·32 to –1·53], p=0·0027, n=346; table 3, figure 2).

For secondary outcomes, neuropsychiatric symptom (NPI) scores for people with dementia at 8 months were statistically significantly lower in the intervention group versus the TAU group (difference in means –4·54 [95% CI –8·71 to –0·37]; table 3, appendix pp 23–25). At 8 months, carer sleep (difference in means 1·84 [0·32 to 3·35]) and carer anxiety (–0·86 [–1·71 to –0·01]) were statistically significantly lower in the intervention group versus the TAU group (table 4). There were no other statistically significant differences between groups on other secondary outcomes.

At baseline, 52 (28%) participants with dementia in the intervention group were prescribed hypnotic or anxiolytic medications, including melatonin versus TAU frequency of 48 (25%). At 4 months this was 50 (30%) of the intervention group versus TAU frequency of 50 (29%), and at 8 months it was 49 (31%) of the intervention group versus TAU frequency of 51 (31%; appendix p 26). There was no difference in the rate of hypnotics (including melatonin) or at least one

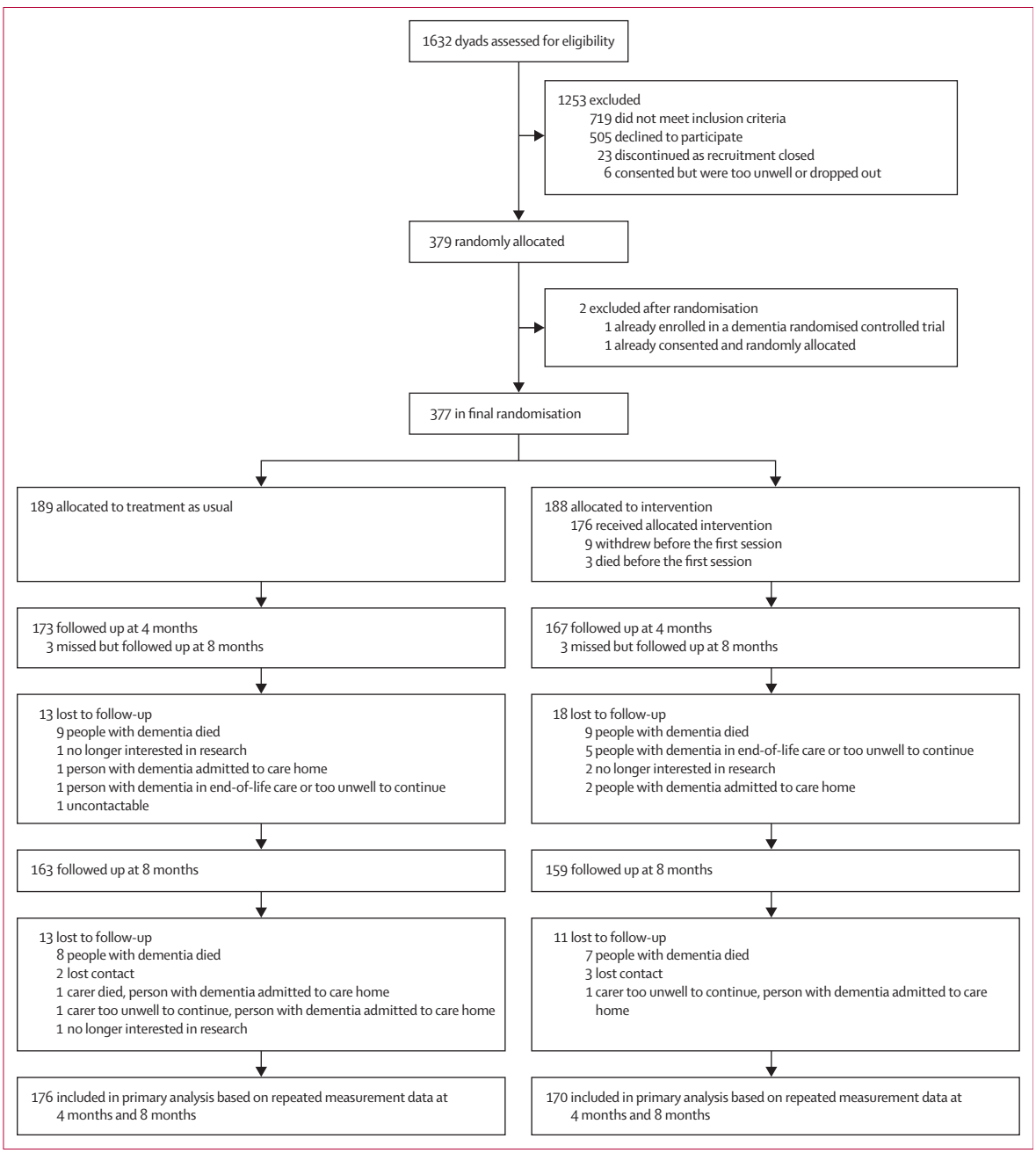

Figure 1: **Trial profile**

psychotropic medication prescription at 8 months in the intervention versus TAU group (appendix p 26).

During the study, 17 people with dementia in each group died, and nine in the intervention group and 12 in the TAU group were moved to a care home. At 4 months, 70 (43%) participants in the intervention group and 61 (37%) in the TAU group had experienced falls, and at 8 months these numbers were 53 (35%) in the intervention group and 58 (37%) in the TAU group. There is no clear difference between groups in comorbid illnesses and side-effects, and no harms in either group were related to the intervention (appendix p 27).

In the intervention group, 135 (72%) participants with dementia had actigraphy data available at baseline, 65 (35%) at 4 months, and 38 (20%) at 8 months. In the TAU group, 132 (70%) participants with dementia had actigraphy data at baseline, 67 (35%) at 4 months, and 46 (24%) at 8 months (appendix pp 26–27).

	Treatment as usual (n=189)	Intervention (n=188)
Age, years	79·1 (9·3)	79·7 (8·7)
Sex		
Male	85 (45%)	86 (46%)
Female	104 (55%)	102 (54%)
Marital status		
Single	6 (3%)	5 (3%)
Widowed	48 (25%)	48 (26%)
Married or civil partnership	117 (62%)	123 (65%)
Cohabiting	5 (3%)	3 (2%)
Separated	4 (2%)	2 (1%)
Divorced	9 (5%)	7 (4%)
Level of education		
Postgraduate degree	22 (12%)	18 (10%)
Undergraduate degree	20 (11%)	25 (13%)
A level (or equivalent)	19 (10%)	16 (9%)
HNC or HND (or equivalent)	11 (6%)	14 (7%)
NVQ (or equivalent)	9 (5%)	11 (6%)
GCSE (or equivalent)	16 (8%)	22 (12%)
School leaving certificate	33 (17%)	39 (21%)
No formal qualifications	52 (28%)	36 (19%)
Other	7 (4%)	7 (4%)
Ethnicity		
White	142 (75%)	140 (74%)
Mixed	1 (1%)	2 (1%)
Asian	24 (13%)	23 (12%)
Black	14 (7%)	18 (10%)
Arab	4 (2%)	1 (1%)
Other	4 (2%)	4 (2%)
Dementia diagnosis		
Alzheimer's disease	102 (54%)	104 (55%)
Frontotemporal dementia	7 (4%)	7 (4%)
Vascular dementia	34 (18%)	30 (16%)
Lewy body dementia	13 (7%)	16 (9%)
Posterior cortical atrophy dementia	1 (1%)	1 (1%)
Progressive supranuclear palsy	0	1 (1%)
Parkinson's disease	3 (2%)	3 (2%)
Mixed dementia	22 (12%)	19 (10%)
Alcohol related	1 (1%)	0
Semantic dementia	0	1 (1%)
Unable to specify	6 (3%)	6 (3%)
Living situation		
Lives alone or with someone present at night	9 (5%)	8 (4%)
Lives with children	57 (30%)	43 (23%)
Lives with partner or spouse	111 (59%)	120 (64%)
Lives with flatmates or housemates	1 (1%)	1 (1%)
Other	11 (6%)	16 (9%)
Type of accommodation		
Council rented	16 (8%)	19 (10%)
Owner-occupied	149 (79%)	142 (76%)
Housing association rented	11 (6%)	9 (5%)

(Table 1 continues in next column)

	Treatment as usual (n=189)	Intervention (n=188)
(Continued from previous column)		
Private rented	10 (5%)	16 (9%)
Other	3 (2%)	2 (1%)

Data are mean (SD) or n (%). HNC=Higher National Certificate. HND=Higher National Diploma. NVQ=National Vocational Qualification. GCSE=General Certificate of Secondary Education.

Table 1: **Baseline characteristics of people living with dementia by trial group**

	Treatment as usual (n=189)	Intervention (n=188)
Age, years	63·5 (12·9)	64·6 (13·7)
Sex		
Male	52 (28%)	66 (35%)
Female	137 (72%)	122 (65%)
Marital status		
Single	32 (17%)	36 (19%)
Widowed	8 (4%)	3 (2%)
Married or civil partnership	125 (66%)	136 (72%)
Cohabiting	11 (6%)	4 (2%)
Separated	4 (2%)	2 (1%)
Divorced	9 (5%)	7 (4%)
Relationship of carer to care recipient		
Spouse or partner	96 (51%)	105 (56%)
Friend	1 (1%)	1 (1%)
Child	82 (43%)	75 (40%)
Other	10 (5%)	7 (4%)
Currently living with care recipient		
Yes	160 (85%)	163 (87%)
No	29 (15%)	25 (13%)
Level of education		
Postgraduate degree	38 (20%)	37 (20%)
Undergraduate degree	42 (22%)	39 (21%)
A level (or equivalent)	25 (13%)	28 (15%)
HNC or HND (or equivalent)	18 (10%)	12 (6%)
NVQ (or equivalent)	10 (5%)	12 (6%)
GCSE (or equivalent)	33 (17%)	27 (14%)
School leaving certificate	12 (6%)	16 (9%)
No formal qualifications	11 (6%)	10 (5%)
Other	0	7 (4%)
Ethnicity		
White	144 (76%)	139 (74%)
Mixed	1 (1%)	5 (3%)
Asian	25 (13%)	23 (12%)
Black	14 (7%)	16 (9%)
Arab	1 (1%)	1 (1%)
Other	4 (2%)	4 (2%)

Data are mean (SD) or n (%). HNC=Higher National Certificate. HND=Higher National Diploma. NVQ=National Vocational Qualification. GCSE=General Certificate of Secondary Education.

Table 2: **Baseline characteristics of family carers by trial group**

	Treatment as usual		Intervention		Adjusted mean difference	
	n	Mean (SD)	n	Mean (SD)	n	Mean (95% CI)
SDI score						
Baseline	189	33·25 (17·70)	188	31·86 (16·43)	..	..
4 months	173	23·64 (18·66)	167	18·99 (14·98)	346	−4·42 (−7·32 to −1·53)*
8 months	163	20·34 (16·67)	159	15·16 (12·77)	346	−4·70 (−7·65 to −1·74)*
NPI score						
Baseline	189	39·70 (22·34)	188	39·53 (24·29)	..	..
4 months	129	37·47 (23·67)	139	34·37 (21·83)	277	−3·05 (−6·99 to 0·89)
8 months	110	33·72 (23·63)	120	30·53 (21·35)	277	−4·54 (−8·71 to −0·37)
ESS score						
Baseline	181	10·24 (6·60)	185	11·47 (6·36)	..	..
4 months	129	9·24 (6·28)	139	9·09 (5·51)	281	−0·18 (−1·27 to 0·91)
8 months	116	8·87 (5·98)	125	8·93 (5·59)	281	−0·76 (−1·90 to 0·37)
DEMQoL proxy score						
Baseline	187	90·22 (14·70)	187	92·06 (14·59)	..	..
4 months	128	92·88 (14·53)	138	96·54 (13·23)	276	1·40 (−1·02 to 3·82)
8 months	112	96·20 (11·21)	124	96·76 (12·33)	276	−1·40 (−3·93 to 1·14)

Higher scores indicate worse outcomes for SDI, NPI, and ESS. Lower scores indicate worse outcomes for DEMQoL. SDI=Sleep Disorders Inventory. NPI=Neuropsychiatric Inventory. ESS=Epworth Sleepiness Scale. DEMQoL=Dementia Quality of Life. *Intracluster correlation coefficients for the primary model within the intervention group are $1{\cdot}159 \times 10^{-14}$.

Table 3: **Main analysis of primary and secondary outcomes for people living with dementia**

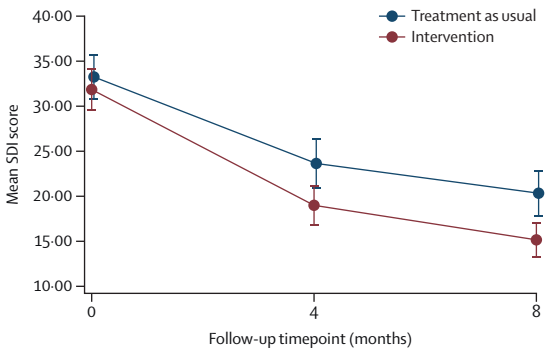

Figure 2: **Unadjusted mean SDI scores at baseline, 4 months, and 8 months by randomised group**

Circles denote mean SDI scores; vertical bars denote 95% CIs. Higher scores indicate greater sleep disturbance. SDI=Sleep Disorders Inventory.

For the primary outcome, there is no evidence that treatment effects at either timepoint differed by Clinical Dementia Rating, Health Status Questionnaire physical health score, or delivery mode (appendix pp 27–28).

Discussion

The DREAMS START manualised multicomponent intervention improved sleep disturbance in people with dementia living at home compared with usual treatment over 8 months. There was also an effect at 4 months of similar magnitude to the 8-month primary endpoint. These results are encouraging and suggest change is becoming embedded. To our knowledge, this is the first definitive randomised controlled trial of a multicomponent treatment for sleep disturbance in dementia at home to show sustained clinical effectiveness. The effect exceeded the minimum clinically important difference on the SDI, suggesting it is clinically important and meaningful. All sensitivity and supplementary analyses showed similar effect sizes, and complier average causal effect analysis revealed a strengthened treatment effect relative to the primary analysis when accounting for treatment engagement. Our findings align with feasibility and pilot interventions of multicomponent interventions for sleep disturbance in people with dementia.[7,22,23]

Sleep disturbance improved in both groups, but there was a statistically significant between-groups difference in favour of DREAMS START. This might reflect our recruitment of people with dementia usually known to clinical services with problematic sleep disturbance and their usual treatment helped them, in addition to possible naturalistic improvement over time. Trial participation is known to be beneficial;[18] however, in our trial there was also a statistically significant difference between trial groups, so DREAMS START adds to the effect of usual care.

Carers randomly assigned to DREAMS START reported statistically significantly improved sleep and reduced anxiety after 8 months relative to TAU carers, suggesting the intervention was also beneficial to family carers. The change from baseline to 8-month follow-up was small but, in the intervention group, moved from clinical to a non-clinical level.[28] Improvements might be because carers were less likely to be woken at night by their relatives, but might also reflect the focus on carers' own sleep difficulties and strategies to minimise the effect of their care recipient's difficulties. Neuropsychiatric symptoms were also statistically significantly reduced in people with dementia in the intervention after 8 months relative to the control group. This is likely to be at least partially due to reduction in the NPI sleep domain.

There were no other statistically significant differences in secondary outcomes between the intervention and control groups, but summary scores across measures indicated that results consistently favoured the intervention. Importantly, there was no difference between groups in terms of harms and side-effects at follow-up. As this was a pragmatic trial, we included people taking psychotropic medication, including hypnotics and melatonin. The rates of psychotropic prescription were similar between groups at each timepoint. Thus, the intervention effect was not driven by participants seeking additional pharmacological intervention, nor did the intervention reduce medication prescription during the trial.

This trial was successfully delivered with a high follow-up rate, with loss to follow-up mainly due to mortality, heightened by the devastating impact of the COVID-19 pandemic on those with dementia.[34] Our intervention was delivered with high fidelity and good attendance; however, participants were less able to go out and participate in activities than we had intended. We were able to train and supervise non-clinically qualified staff to deliver the intervention across sites. We did not include an active control group, so cannot be certain that the effect of the

intervention is not a reflection of the contact with a supportive facilitator. We believe this is unlikely, as the intervention was most effective for sleep-related outcome measures and there is not always an effect of a supportive facilitator in trials in dementia.[35] We started the trial early in the COVID-19 pandemic and had to change our processes, offering remote intervention delivery when needed. We found no clear difference in treatment effect based on delivery mode.

The inclusion of all types of dementia and severity, although biologically heterogeneous, means that the intervention is potentially useful for all dementia types, and the tailored and individualised nature of DREAMS START meant that we were able to account for this heterogeneity. Beyond initial screening, we did not collect information on comorbidities, including the presence of sleep disorders. The trial has good external validity, with no clear differences in those who did and did not consent, recruiting from diverse NHS Trusts. We targeted and recruited ethnically and socioeconomically diverse populations typically underrepresented in clinical trials, with 25% from minoritised communities and more than 20% without post-school education. There are widening inequalities in dementia risk, outcomes, and treatment access,[36] and by developing and testing interventions with a diverse participant population we can begin to redress these disparities. We will report our substudy focused upon widening access to the intervention to minoritised communities, and we have culturally adapted the intervention for South Asian UK carers and translated the manual into Hindi. We excluded people with dementia who were alone at night, a potentially more at-risk and isolated group, so our findings cannot be generalised to this group. This decision was based upon difficulties for those living alone or without a carer in participating in both the intervention and trial procedures in our feasibility randomised controlled trial. We acknowledge this is an underserved group and future research would benefit from adapting multicomponent interventions such as DREAMS START to incorporate this group.

An important limitation of our study was the risk of response bias, as we relied upon family carers' proxy and self-reported outcomes, with intervention group participants potentially more invested and optimistic.[37] We were unable to mask participants or facilitators to group allocation and unmasked carers reported proxy outcomes, increasing risk of bias. We took steps to mitigate against researchers becoming unmasked to allocation status. Unmasking was low across the trial; assessors were unmasked at five 4-month follow-up assessments and in these cases a different researcher completed the 8-month assessment. Assessors were unmasked in two 8-month follow-up assessments.

Another limitation was the absence of actigraphic or other direct sleep and activity data as an outcome measure. This methodological decision was informed by our feasibility randomised controlled trial, in which using actigraphy as a primary outcome was unfeasible as it had inadequate validity for people with dementia and was unacceptable to some.[15] Sleep is implied by absence of movement, which might not apply to people with dementia, although is suggested to be an objective sleep measure. We planned to include actigraphy to measure movement as a potential intervention mechanism. Other dementia studies have reported actigraphy limitations and challenges, particularly during the COVID-19 pandemic when carers had less direct support to use devices.[38] Importantly, multiple studies in dementia have found large discrepancies between questionnaire and actigraphic sleep measures,[39,40] and arguably questionnaires better reflect the clinical effect of sleep disturbance on those with dementia. We were, however, able to use baseline data on day and night movement to tailor personalised intervention strategies, for example highlighting the effect of daytime napping or inconsistent bedtimes. Only 70% of participants at baseline, 35% at 4-month follow-up, and 22% at 8-month follow-up had 7 days of actigraphy data and associated sleep diary data available, so we could not conduct planned mediation analysis.

We do not yet know the longer-term effect of the intervention but are following up participants at 2 years. We will publish separate papers evaluating cost-effectiveness and the process evaluation exploring mechanisms of action. This will enable us to develop additional support and guidance on enabling and sustaining strategies for DREAMS START implementation. We are currently conducting a pre-implementation study exploring potential delivery beyond the randomised controlled trial.

	Treatment as usual		Intervention		Adjusted mean difference	
	n	Mean (SD)	n	Mean (SD)	n	Mean (95% CI)
SCI score						
Baseline	189	13·98 (7·95)	188	13·91 (8·31)	..	..
4 months	129	15·70 (8·54)	141	16·11 (8·86)	292	0·24 (–1·26 to 1·73)
8 months	124	15·73 (8·53)	135	17·60 (8·60)	292	1·84 (0·32 to 3·35)
HADS anxiety score						
Baseline	189	8·21 (4·40)	188	8·51 (4·60)	..	..
4 months	127	7·06 (4·48)	137	7·05 (4·48)	274	–0·44 (–1·25 to 0·37)
8 months	111	6·75 (4·26)	120	6·29 (4·28)	274	–0·86 (–1·71 to –0·01)
HADS depression score						
Baseline	189	6·32 (4·31)	188	6·47 (4·38)	..	..
4 months	127	6·08 (3·99)	137	6·18 (4·37)	274	–0·12 (–0·86 to 0·62)
8 months	111	6·17 (4·26)	120	6·08 (4·30)	274	–0·33 (–1·10 to 0·45)
Zarit Burden Interview score						
Baseline	187	36·24 (16·43)	186	35·08 (18·44)	..	..
4 months	124	35·47 (15·04)	138	32·72 (16·34)	274	–1·44 (–3·82 to 0·94)
8 months	109	33·80 (14·76)	120	31·83 (15·85)	274	–0·38 (–2·87 to 2·10)
HSQ mental health score						
Baseline	189	238·66 (68·50)	188	236·99 (71·88)	..	..
4 months	127	253·70 (61·28)	137	247·93 (66·01)	275	–4·19 (–17·06 to 8·69)
8 months	111	245·98 (64·54)	122	248·66 (62·84)	275	4·03 (–9·44 to 17·49)

Lower scores indicate worse outcomes for SCI. Higher scores indicate worse outcomes for HADS depression and anxiety, Zarit, and HSQ. SCI=Sleep Conditions Indicator. HADS=Hospital Anxiety and Depression Scale. HSQ=Health Status Questionnaire.

Table 4: **Main analysis of secondary outcomes for family carers**

DREAMS START is a positive step forward for people with dementia and their families. It is the first manualised, personalised intervention with potential to be delivered at scale. It has definitive evidence of clinical effectiveness sustained beyond the immediate delivery of the intervention and aids sleep in the person with dementia and their family carer.

Contributors

PR was chief investigator and wrote the first draft of this paper with input from GL as senior author and co-chief investigator, SA, MOA, and JAB. MOA conducted the statistical analysis and JAB reviewed this as senior trial statistician. MOA and JAB accessed and verified the data. SA oversaw the data management and managed the trial, supported by MM. PR, GL, JAB, CAE, SDK, and RHo contributed to the DREAMS START intervention development. PR, GL, JAB, CAE, SDK, RHo, SA, MOA, SB, GC, CC, LG, MM, RHu, MR, and ZW contributed to the trial design and protocol development. PR, GL, SDK, LW, and SA trained the intervention facilitators, and PR and CC supervised the intervention delivery. GL, SB, MR, CC, ZW, and GC were site primary investigators and oversaw trial data collection and delivery at sites. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Declaration of interests

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Data sharing

The qualitative and quantitative datasets generated during or analysed during the current study are available upon request from PRIMENT Clinical Trials Unit (CTU) Data Management Group at priment@ucl.ac.uk in collaboration with members of the DREAMS START Trial Team. Any request for data must come through to PRIMENT CTU in the first instance and where the request is reasonable, anonymised datasets, stored on the publicly available UCL Research Data Repository https://rdr.ucl.ac.uk/ will be shared.

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