



Synopsis

The clinical and cost-effectiveness of improving sleep via carer delivered strategies in people with dementia: the DREAMS START parallel multi-centre RCT

Penny Rapaport^{1,2*}, Sarah Amador¹, Mariam Adeleke³, Julie Barber³, Sube Banerjee⁴, Ankita Bhojwani¹, Georgina Charlesworth^{5,6}, Chris Clarke⁷, Colin Espie⁸, Lina Gonzalez⁹, Rossana Horsley¹⁰, Rachael Hunter⁹, Simon Kyle⁸, Monica Manela¹, Naaheed Mukadam¹, Malvika Muralidhar¹, Malgorzata Raczek¹¹, Zuzana Walker^{1,12}, Lucy Webster¹, Hang Yuan¹³ and Gill Livingston^{1,2}

¹Division of Psychiatry, University College London, London, UK

²North London Mental Health Partnership NHS Foundation Trust, London, UK

³Department of Statistical Science, University College London, London, UK

⁴Faculty of Medicine and Health Sciences, University of Nottingham, Nottingham, UK

⁵Division of Psychology and Language Sciences, University College London, London, UK

⁶North East London NHS Foundation Trust, Rainham, UK

⁷Tees Esk and Wear Valleys NHS Foundation Trust, Darlington, UK

⁸Sir Jules Thorn Sleep and Circadian Neuroscience Institute, Nuffield Department of Clinical Neurosciences, University of Oxford, Oxford, UK

⁹Department of Primary Care and Population Health, University College London, London, UK

¹⁰Alzheimer's Society, London, UK

¹¹Centre for Dementia Studies, Brighton and Sussex Medical School, Brighton, UK

¹²Essex Partnership University NHS Foundation Trust, Essex, UK

¹³Nuffield department of Population Health, University of Oxford, Oxford, UK

*Corresponding author p.rapaport@ucl.ac.uk

Published February 2026

DOI: 10.3310/GJPR2620

Volume 30 • Issue 17

Abstract

Background: Sleep disturbances are common and distressing for people with dementia and their family carers and can lead to carers having interrupted sleep, low mood and care breakdown. Medication can have harmful side effects and is generally ineffective. Non-pharmacological interventions should be first-line treatments, yet until now there have not been effective treatments.

Objectives: To establish whether Dementia RElAted Manual for Sleep; STRAtegies for RelaTives (DREAMS START), a multicomponent intervention, reduced sleep disturbance in people with dementia living at home at 8 months compared with National Health Service treatment (treatment as usual).

Design and methods: We conducted a two-arm, multicentre, parallel-arm, superiority randomised controlled trial with masked outcome assessment. Participants were randomised (1 : 1 ratio) to DREAMS START intervention plus treatment as usual or treatment as usual alone. Analyses were intention to treat. We conducted a mixed-method process evaluation with additional substudies: one exploring how United Kingdom-based South Asians experience sleep disturbance and dementia, and one exploring the interaction of sleep, dementia and long-term conditions.

Settings and participants: We recruited dyads of people with dementia and sleep disturbance living at home and family carers from 12 National Health Service trusts and the Join Dementia Research service in England.

Interventions: DREAMS START is a six-session, multicomponent, manualised intervention delivered to family carers of people with dementia who implement strategies to improve their relatives' sleep. It is delivered face to face or remotely by non-clinically trained graduates weekly or fortnightly and incorporates information about sleep and dementia, promotes de-arousal at night, adaptive stimulus control (e.g. bedtime routine maintenance), daytime behavioural activation, increasing access to light, improving carer sleep and making a tailored action plan.

Main outcome measures: The primary outcome was sleep disturbance measured using the Sleep Disorders Inventory at 8 months.

Results: Between February 2021 and March 2023, 377 dyads were randomly assigned, 189 to treatment as usual and 188 to DREAMS START plus treatment as usual. Mean age of participants with dementia was 79.4 years (standard deviation 9.0), and 206 (55%) were women. Mean Sleep Disorders Inventory score at 8 months was lower in the intervention versus treatment-as-usual arm [15.16 (standard deviation 12.77), $n = 159$, vs. 20.34 (16.67), $n = 163$]; adjusted difference in means [-4.70 (95% confidence interval -7.65 to -1.74); $p = 0.002$]. Seventeen (9%) people with dementia in the intervention and 17 (9%) in the control arm died during the trial; deaths were unrelated to the intervention. The mean incremental difference in health and care costs incorporating wider costs was £116 less per dyad (95% confidence interval -£5769 to £5536) for DREAMS START compared to treatment as usual. There was a 78% probability that DREAMS START is cost-effective compared to treatment as usual at a £20,000 decision threshold with no significant difference in quality of life.

Conclusion: DREAMS START plus treatment as usual is clinically effective in reducing sleep disturbance in people living at home with dementia at 8 months, demonstrating sustained effectiveness beyond intervention delivery. DREAMS START is likely to be cost-effective, and delivery by non-clinically trained graduates increases potential for National Health Service implementation at scale.

Limitations: We relied upon family carers' proxy and self-reported outcomes, with intervention participants potentially more invested and optimistic, increasing risk of bias. Additionally, based on our feasibility randomised controlled trial, we did not include actigraphy or another direct measure of sleep and activity.

Future work: Studies should explore the longer-term effect of DREAMS START (we are following up participants at 2 years), and there should be an implementation study considering delivery and scaling up DREAMS START in real-world healthcare settings.

Funding: This synopsis presents independent research funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as award number NIHR128761.

A plain language summary of this synopsis is available on the NIHR Journals Library website <https://doi.org/10.3310/GJPR2620>.

Introduction

Some material in this synopsis is reproduced with permission from Rapaport *et al.*¹ This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: <https://creativecommons.org/licenses/by/4.0/>. The text below includes minor additions and formatting changes to the original text.

This report summarises our work testing the Dementia REIAted Manual for Sleep; STrAtegies for RelaTives (DREAMS START), multicomponent intervention for sleep disturbance in dementia in a randomised controlled trial (RCT) to determine its clinical and cost-effectiveness. This work builds on our earlier NIHR HTA-funded intervention development and randomised feasibility trial (NIHR/HTA

14/220/06) that found the intervention and planned trial procedures to be feasible and acceptable.

Rationale for research and background

In 2019, 57 million people worldwide had dementia; this is projected to increase to 153 million by 2050, with an estimated cost of care of a trillion US dollars.² Sleep disturbance is common in people with dementia (PwD) and can impact on all aspects of mental and physical functioning. Our recent meta-analysis of sleep disturbance in people living at home with all-cause dementia found pooled prevalence of 26% at any one time.³ In addition to the possible negative impact 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, contributing 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 PwD often have impaired sleep initiation, reduced night-time sleep, difficulty staying asleep, increased night-time wandering and excessive daytime sleepiness.⁹ Over 90% of PwD have at least one additional long-term condition (LTC) and may experience pain, discomfort or mood disturbances¹⁰ which further impact sleep. Treating sleep problems may improve daytime functioning of PwD, and their quality of life, and given the hypothesised bi-directional relationship between sleep disruption and amyloid deposition and treatment as usual (TAU) pathology,⁸ it could potentially slow disease progression.

To our knowledge, there are no definitive RCTs demonstrating efficacy of pharmacological, non-pharmacological or light-based treatment for sleep disturbance in people living at home with 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 While melatonin, although safe, is not effective in improving sleep in dementia,¹¹ in a recent trial, suvorexant was well tolerated and effectively increased total sleep time in people with mild to moderate probable Alzheimer's disease and insomnia.¹³ 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 PwD, their families, and the health and social care systems supporting them.

Aims and objectives

Overall aim

To determine whether a manualised, multicomponent, non-pharmacological treatment package delivered by supervised non-clinically qualified psychology graduates will deliver significant benefits for people living with dementia (PLWD) and their family carers. Additionally, to assess the process and fidelity of delivery of the intervention and explore the experiences of family carers receiving the intervention.

Primary randomised controlled trial objective

To determine whether the DREAMS START intervention improves sleep disturbance in PLWD at home at 8 months compared to usual NHS treatment.

Secondary randomised controlled trial objectives

To determine:

1. Whether the DREAMS START intervention improves sleep disturbance in PLWD at home at 4 months.
2. Whether it reduces daytime sleepiness.
3. Whether it increases PwD and family carers' quality of life.
4. Whether it improves family carers' sleep and decreases their affective symptoms and burden.
5. The role of psychotropic medication and melatonin in any change.
6. Whether it is cost-effective.

Process evaluation objectives

To determine:

7. What are the mechanisms of change?
8. If effective, how can we optimise the intervention for implementation at scale in the NHS?

Additional substudy objectives

9. To understand how PwD from UK South Asian groups experience sleep disturbances and the impact this has on family carer and other family members to inform future cultural adaptation.
10. To translate DREAMS START into Hindi, a common South Asian language.
11. To assess suitability of DREAMS START for PwD and LTCs and understand how LTCs impact upon engagement with the intervention.
12. To investigate whether PwD, LTC and sleep disturbance tolerate wearing a wireless electroencephalogram (EEG) device and to compare EEG measure of sleep compared to questionnaires and actigraphy data.

Methods

Protocols

The project was pre-registered on the International Standard Randomised Controlled Trial Number (ISRCTN) registry. The research pathway for the RCT and additional substudies is shown in [Figure 1](#). Full methodological details for all work are given in our protocol, which can be accessed here, and the main RCT protocol was published alongside a Standard Protocol Items: Recommendations for Interventional Trials checklist and is available here.¹⁴

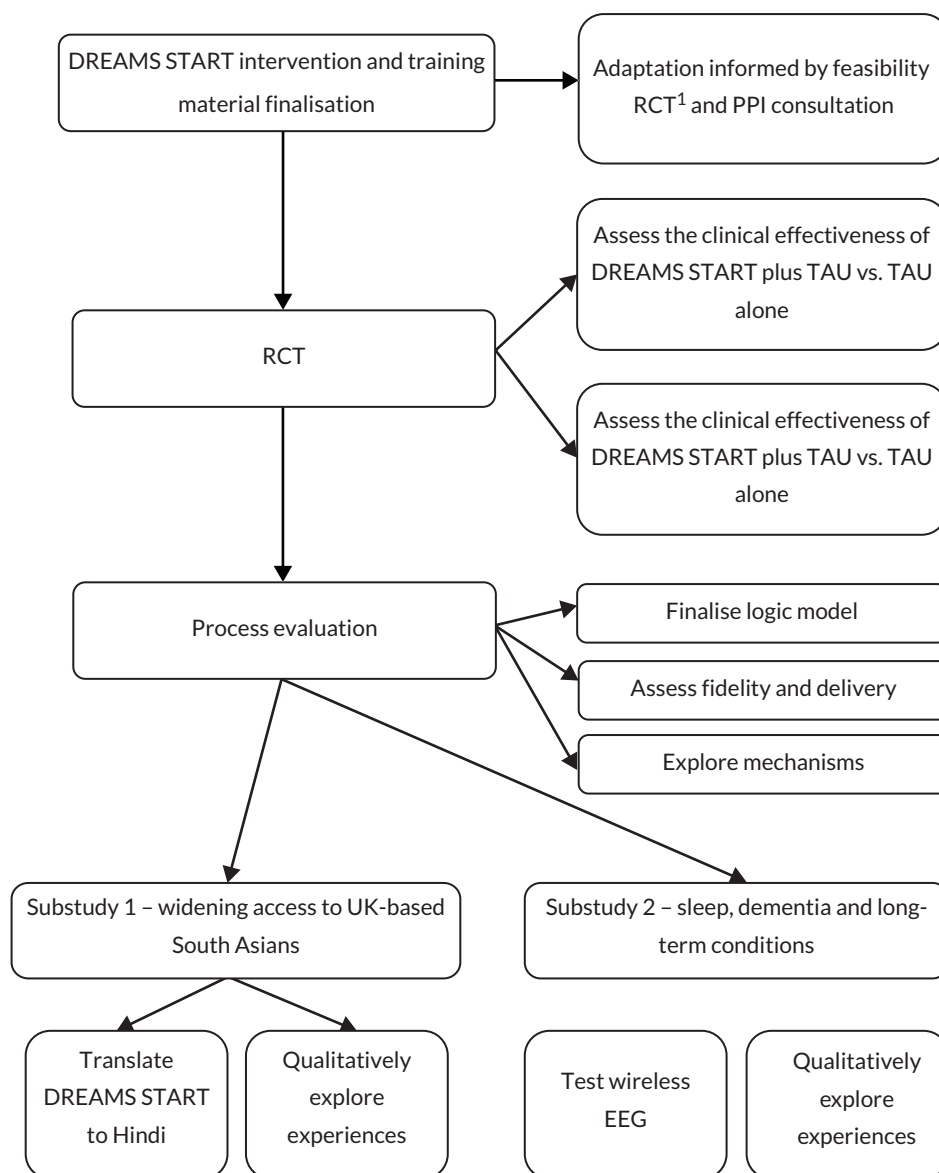


FIGURE 1 Research pathways for study components. PPI, patient and public involvement.

The RCT statistical analysis plan (see [Report Supplementary Material 1](#)) and the RCT health economics analysis plan (see [Report Supplementary Material 2](#)) can be accessed here.

Results summary

In addition to the published trial protocol,¹⁴ five results papers have been submitted for publication to date, four of which are now published¹ ([Table 1](#)). Key findings from these papers are summarised below.

Randomised controlled trial: clinical effectiveness (primary and secondary randomised controlled trial objectives 1–5, paper 1)

We conducted a two-arm, multicentre, parallel-arm, superiority trial with masked outcome assessment, recruiting dyads of PwD and sleep disturbance and family

carers from 12 English NHS sites. Randomisation (in a 1 : 1 ratio) to DREAMS START intervention (plus TAU) or TAU alone was conducted at dyadic level, blocked and stratified by site, with a web-based system assigning allocation. The primary outcome was sleep disturbance measured by the Sleep Disorders Inventory (SDI) at 8 months. Analyses were intention to treat and conducted in accordance with Consolidated Standards of Reporting Trials guidelines reported in full in our main published paper.¹ Trial registration ISRCTN13072268.

Intervention finalisation

DREAMS START is a coproduced, six-session manual-based multicomponent intervention for carers of PwD to build personalised strategies and make changes to their relatives' sleep. It was previously tested in our

TABLE 1 Status of results papers from the project

#	Component	Title	Status
1	RCT clinical effectiveness	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	Published in <i>The Lancet Healthy Longevity</i> . ¹ https://doi.org/10.1016/j.lanhl.2024.08.004
2	Cost-effectiveness analysis	Cost-utility analysis of the DREAMS START intervention for people living with dementia and their carers: a within-trial economic evaluation	Published in <i>The Lancet Healthy Longevity</i> . ¹⁵ https://doi.org/10.1016/j.lanhl.2025.100708
3	Process evaluation	Process evaluation in a randomised controlled trial of DREAMS-START (dementia related manual for sleep; strategies for relatives) for sleep disturbance in people with dementia and their carers	Published in <i>Age and Ageing</i> . ¹⁶ https://doi.org/10.1093/ageing/afaf053
4	Widening access substudy	Sleep Disturbances and Dementia in the UK South Asian Community: A Qualitative Study to Inform Future Adaptation of the DREAMS-START Intervention	Published in <i>Geriatrics</i> . ¹⁷ https://doi.org/10.3390/geriatrics10050121
5	LTCs substudy	Long-term health conditions and their impact on people with sleep disturbances and dementia	Published in <i>BMC Geriatrics</i> . ¹⁸ https://doi.org/10.1186/s12877-025-06045-x
6 ^a	Pre-implementation study paper	DREAMS START: a pre-implementation qualitative study with NHS staff	This manuscript was submitted as a MSc dissertation and is being prepared for submission to <i>BJPsych Open</i>

a This was not part of planned publication strategy but has been completed additionally to support preparation of legacy implementation grant applications.

earlier feasibility trial, and we made minimal changes to the intervention prior to recruitment for the RCT.^{19,20} Our published protocol describes how the intervention adheres to the Template for Intervention Description and Replication checklist.¹⁴ The intervention includes psychoeducation, day-and-night routine, light, increased daytime activity and light exercise and carer support.⁷ The intervention integrates actigraphy data from devices worn by participants with dementia at baseline to personalise strategies. Carers retain personalised manuals and equipment and make an individual plan to continue using after intervention completion. We held two workshops with co-applicants and patient and public involvement (PPI) representatives in July and September 2020 and, following this, sought additional written feedback from co-applicants and PPI, with the final manual ready by February 2021. Changes from the feasibility RCT were minimal and included simplifying the manual content, making recording forms and sleep diaries more user-friendly, adding more vignettes and quotations describing lived experiences and adding additional prompts for facilitators around personalisation, action planning and behaviour change. We also refined our training programme for facilitators: a 2-day interactive training focused on dementia and sleep-wake regulation, empathic listening skills, facilitating behaviour change, interpreting actigraphy, using supervision effectively and working collaboratively with family carers and PwD. As part of

the training to increasingly standardise the intervention delivery, all facilitators were observed role-playing the manualised intervention in full and 'signed off' as ready to deliver by one of the team clinicians (Penny Rapaport, Gill Livingston, Chris Clarke) as ready prior to being allocated a dyad for delivery of the intervention (*Figure 2* for a graphical illustration of the intervention components).

Recruitment

Between 24 February 2021 and 5 March 2023, we assessed 1632 dyads for eligibility, 1253 (76.8%) of whom were excluded. Of those excluded, 719 (57.4%) did not meet eligibility criteria, 505 (40.3%) declined to participate, 6 (0.5%) consented but were too unwell to continue or dropped out and 23 (1.8%) did not progress as recruitment target was reached. Of the 377 dyads randomised, 189 were allocated to TAU and 188 to the intervention; 176/189 (93.1%) of those allocated to TAU and 170/188 (90.4%) of those allocated to intervention were included in the primary analysis.

Primary outcome

DREAMS START plus TAU was superior to TAU alone on the SDI at 8 months post randomisation. Average SDI scores at 8 months were 15.16 [standard deviation (SD) 12.77, $n = 159$] in the intervention arm and 20.34 (SD 16.67, $n = 163$) for TAU; -4.70 points (95% CI -7.65 to -1.74 , $p = 0.002$, $n = 346$) in the primary

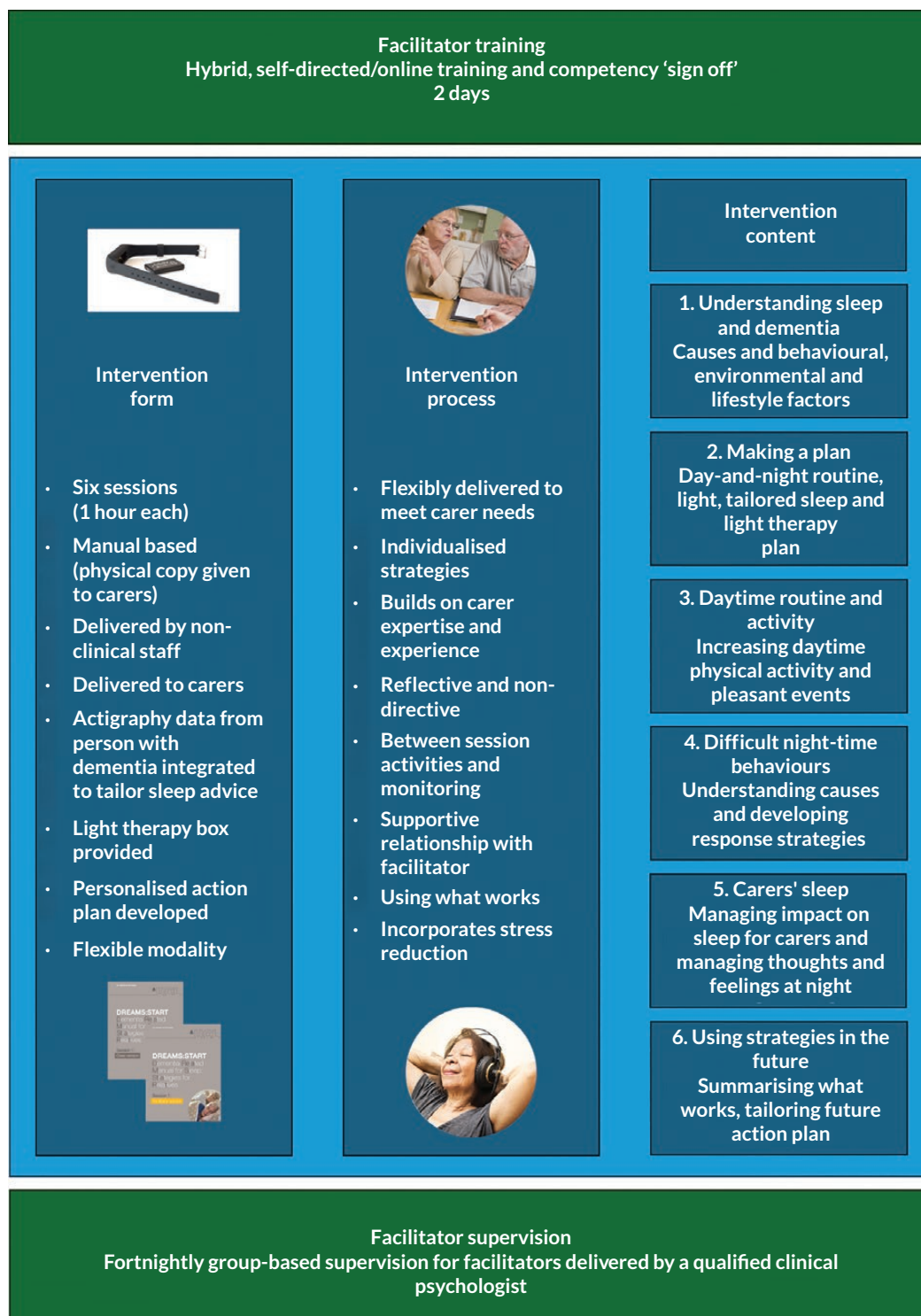


FIGURE 2 DREAMS START intervention components.

analysis adjusted model. At 4 months (immediately post intervention), the difference in SDI scores was similar in magnitude to 8 months [-4.42 (-7.32 to -1.53), $p = 0.003$, $n = 346$]. A decrease of ≥ 4 points is the suggested minimum clinically important difference (MCID).²¹ The effect exceeded the MCID on the SDI, suggesting it is clinically important and meaningful, and

this effect was immediate and sustained beyond the end of the intervention. All sensitivity and supplementary analyses showed similar effect sizes, suggesting our findings were robust. To our knowledge, this is the first definitive RCT of a multicomponent treatment for sleep disturbance in dementia at home to demonstrate sustained clinical effectiveness.

Secondary outcomes

For PwD, neuropsychiatric symptom scores for PwD at 8 months were significantly lower in the intervention arm versus TAU [difference in means -4.54 (95% CI -8.71 to -0.37)]. For family carers, at 8 months, carer sleep [difference in means 1.84 (95% CI 0.32 to 3.35)] and carer anxiety [difference in means -0.86 (95% CI -1.71 to -0.01)] were significantly lower in the intervention arm versus TAU. No other secondary outcomes differed significantly between arms, but summary scores across measures indicated that results consistently favoured the intervention. There was no difference between the groups in terms of harms and side effects at follow-up.

Intervention delivery

DREAMS START was delivered with high fidelity to the intervention and good attendance rates. We trained 76 facilitators to deliver the intervention, of whom 49 went on to deliver the intervention to a mean of 3.6 (SD 3.12, range 1–15) participants each. About 149/180 (82.8%) of surviving intervention participants adhered to the intervention, receiving $\geq 4/6$ intervention sessions; 142 received all 6 sessions; and 8 participants died before completing 4 sessions. We aimed to record one DREAMS START session per participant to rate intervention fidelity. One intervention session was recorded and available for 143/188 (76.0%) participants. The mean fidelity score was 95.4% (SD 0.08). We also measured four therapeutic process measures; for each, the median score was 5/5 [interquartile range (IQR) 5–5]. Due to the COVID-19 pandemic, we delivered the intervention flexibly based on restrictions and carer preference. DREAMS START was delivered in person to 77 (43.8%) participants, to 31 (17.6%) by video call, to 28 (15.9%) by telephone, to 33 (18.8%) by a mix of remote and in-person sessions, and to 7 (4%) by a mix of video or telephone delivery.

Randomised controlled trial: cost-effectiveness (secondary randomised controlled trial objective 6, paper 2)

In our health economic analysis, we evaluated the cost-effectiveness of DREAMS START plus TAU compared to TAU.¹⁵ The primary aim was to report the mean incremental cost per quality-adjusted life-year gained of DREAMS START delivered to family carers of PLWD at home from a health and Personal Social Services perspective over 8 months compared to TAU using participant-level RCT data. For PwD, we collected EuroQol-5 Dimensions, five-level version (EQ-5D-5L) proxy,²² Dementia Quality of Life proxy²³ and a modified version of the Client Service Receipt Inventory.²⁴ For the family carer, we collected EQ-5D-5L,²² a modified resource use measure, and the Brief Work

Productivity and Activity Impairment²⁴ questionnaire to measure impact on absenteeism (time taken off work) and presenteeism (productivity while at work) for the family carer. All measures were collected at baseline, 4 months and 8 months.

The total mean cost per dyad of the DREAMS START intervention (including sessions, equipment and facilitator training and supervision) was £574.38. The mean incremental difference in health and care costs was £59 less per dyad (95% CI $-\text{£}5168$ to $\text{£}5050$) for DREAMS START compared to TAU, and incorporating wider costs was £116 (95% CI $-\text{£}5769$ to $\text{£}5536$). There was a 78% probability that DREAMS START is cost-effective compared to TAU at a £20,000 decision threshold. There was no significant difference in quality of life.

Randomised controlled trial: process evaluation (objectives 7 and 8, paper 3)

We conducted a process evaluation using a mixed-methods design to enhance our understanding of the DREAMS START RCT results.¹⁶ To examine how the intervention was delivered in practice, we measured intervention adherence, fidelity and additional therapeutic process measures. To explore mechanisms of behaviour change underpinning DREAMS START, we qualitatively interviewed 43/188 active arm participants, and 9/49 intervention facilitators conducting a reflective thematic analysis²⁵ guided by a prespecified theory of change logic model,¹⁴ and measured movement using an actigraph worn by the person with dementia at baseline, 4-month and 8-month follow-up. We purposively interviewed a maximum variation sample of carers allocated to DREAMS START [different sites; sex, age, ethnicity, relationship with PwD; intervention completers and non-completers, and caregiving contexts (live in/live out)]. Similarly, we interviewed a range of staff delivering DREAMS START (different sites, number of times delivering, job role).

The intervention was well received by participants, who, despite competing demands, usually attended sessions (82.8% attended $\geq 4/6$ sessions). Mean fidelity score (95.4%; SD 0.08) and median score for all four process measures assessed (5/5; IQR 5–5) was high, meaning the intervention was facilitated consistently and with high fidelity. We identified three overarching themes aligned with our model: (1) knowledge and facilitation enable behaviour change, (2) increasing sleep pressure and developing skills to manage sleep disturbances and (3) establishing a routine and sense of control. Our findings suggest that (1) the sustained intervention effect observed in the RCT after 8 months is potentially tied to trained, supervised facilitators supporting behaviour

change to become embedded through personalisation, setting and reviewing goals, and future action planning and (2) the significant reduction in carer anxiety levels and improvement in their sleep observed in the RCT may be tied to carers' increased self-efficacy and belief in their ability to adaptively respond to their relative's sleep disturbance. We were unable to collect sufficient data for pre-specified actigraphy data analysis exploring underlying mechanism of action. About 135 (72%) intervention arm participants had actigraphy data available at baseline, 65 (35%) at 4 months and 38 (20%) at 8 months. About 132 (70%) TAU participants had actigraphy data at baseline, 67 (35%) at 4 months and 46 (24%) at 8 months (reasons for missing actigraphy data are given in [Table 2](#)).

Overall, this work has elucidated the behaviour change mechanisms underlying DREAMS START and will inform future work and implementation.

Substudy 1: widening access (objectives 9 and 10, paper 4)

In substudy 1, we qualitatively interviewed family carers who had participated in the DREAMS START ($n = 7$) trial or other dementia studies ($n = 4$), conducting reflective thematic analysis.²⁵ In the interviews, we explored how sleep disturbances and DEAMS START are experienced by UK-based South Asian families affected by dementia. In parallel, we translated the DREAMS START intervention into Hindi and consulted with Hindi speakers with

experience in dementia care, revising iteratively. We identified two overarching themes.

Theme 1: the impact of dementia-related sleep disturbance in South Asian families

This explored the impact of dementia-related sleep disturbances upon South Asian families. For those interviewed, living in multigenerational households meant more people are affected but more help and support may also be available. Cultural and familial expectations around the authority of older people and not taking PwD out and caring responsibility impacted sleep management at night and activity during the day.

Theme 2: considerations for cultural adaptation of DREAMS START

We identified considerations for the cultural adaptation of DREAMS START: speaking English as a second language may limit engagement with the current intervention, linguistic changes and adaptation to peripheral intervention content to increase engagement and relevance were identified. This included culturally competent facilitation of DREAMS START when delivered to UK South Asians.

Overall, this work has resulted in Hindi translation of DREAMS START and recommendations for cultural adaptation of the peripheral intervention content and facilitator training to increase relevance of and engagement

TABLE 2 Reasons for missing actigraphy data at baseline, 4-month and 8-month time points

Reason	Time point		
	Baseline	4 months	8 months
PwD found wearing the watch uncomfortable or distressing	63 (16.7%)	124 (32.9%)	146 (38.7%)
FC declined due to practicalities (e.g. postage, sleep diary)	2 (0.5%)	36 (9.5%)	22 (5.8%)
PwD too unwell or in hospital	3 (0.8%)	18 (4.8%)	18 (4.8%)
PwD in a care home	0	10 (2.7%)	18 (4.8%)
Participants away and unable to receipt	0	14 (3.7%)	11 (2.9%)
Risk of PwD swallowing the watch	0	1 (0.3%)	1 (0.3%)
Technical/procedural issues (e.g. recording error/watch lost in transit)	41 (10.9%)	11 (2.9%)	10 (2.7%)
Death (prior to actigraphy data collection)	1 (0.3%)	0	0
Withdrawals from study	0	13 (3.5%)	21 (5.6%)
Deaths	0	18 (4.8%)	16 (4.2%)
Total people with actigraphy data	267 (70.8%)	132 (35%)	84 (22.3%)
Total	377	377	377

FC, family carer.

with DREAMS START, with potential to increase access within the UK South Asian community. As Hindi is not as widely spoken in UK South Asian communities (relative to Urdu, Punjabi and Bengali), our work to date is potentially limited, and we aim to extend this in our planned future work.

Substudy 2: sleep, dementia and long-term conditions (objectives 11 and 12, paper 5)

In this substudy,¹⁸ we qualitatively interviewed 17 family carers from the DREAMS START intervention arm who were caring for a relative with other LTCs alongside dementia and sleep disturbance and conducted reflective thematic analysis.²⁵ We identified two overarching themes:

Theme 1: complex interaction of long-term conditions, sleep and dementia

Participants highlighted how LTCs, including pain, interacted with dementia symptoms to worsen sleep and physical health in their relatives describing a 'perfect storm' which compounded the health burden experienced by PwD and carers. Carers highlighted dilemmas in use of sleep and pain medication and would often minimise physical symptoms and causes and sometimes avoided using analgesia thinking sleep disturbance was all due to the impact of dementia itself.

Theme 2: long-term conditions get in the way of implementing DREAMS START

Physical health symptoms of PwD sometimes impeded carers trying out DREAMS START strategies. This was both as a direct impact of issues, such as pain and poor mobility, and as it made behaviour change challenging, especially in the context of carers being exhausted themselves or managing their own health conditions.

This qualitative substudy deepens our understanding of the interacting effects of dementia and LTCs on sleep disturbance, and when considered alongside, our DREAMS START RCT findings have potential to enhance applicability of the intervention for those with multiple LTCs alongside.

For the wireless EEG study, we approached 53 RCT participant dyads, following their 8-month follow-up, inviting them to wear a wireless EEG Dreem (Beacon Biosignals, Inc; Boston, MA) headband for 2–4 nights. Of those approached, 19 declined because the family carer was worried that it would be uncomfortable and disturb their relative's sleep, 18 declined because they were not interested and felt too busy, and 18 declined as their relative had not liked the actigraph watch and they reasoned that the headband would be similarly

received. Nine dyads were uncontactable, and four had moved into a care home (some carers gave more than one reason). One dyad consented to take part in the EEG study, and the PwD wore the headband for 2 nights. The Dreem headband calculates data quality across three EEG channels – left (L), centre (C) and right (R). This metric is defined as the percentage proportion of good-quality EEG over the recording for a given channel.

- Data quality for night 1 was 22% (L), 74% (C) and 46% (R).
- Data quality for night 2 was 57% (L), 47% (C) and 53% (R).

During both nights, the PLWD took the headband off multiple times due to discomfort. This was evidenced by reports from the family carer and the poor channel quality. In summary, we concluded from this work that the wireless headband was not feasible or acceptable for use by PwD and sleep problems at home in the context of their participation in the wider study. We were unable to compare the EEG data with questionnaires and actigraphy as planned. Further detail on steps we took to increase uptake are detailed in [Challenges faced and limitations](#).

Discussion/interpretation

Principal findings and achievements per project outcome

The main findings and achievements in this project are listed below:

1. We demonstrated that DREAMS START plus TAU is safe and clinically effective at reducing sleep disturbance in PwD living at home at after 4 months, and this is sustained at 8 months post randomisation. We also demonstrated beneficial effects for family carers (improved sleep and reduced anxiety) at 8 months (paper 1).
2. We showed that there is a moderate probability that DREAMS START is cost-effective relative to NHS TAU (paper 2).
3. We demonstrated that DREAMS START can be delivered flexibly with high fidelity across modalities (in person, by video call or telephone) and qualitatively elucidated the mechanisms of behaviour change informed by our logic model to inform future implementation (paper 3).
4. We translated the DREAMS START intervention to Hindi ready for testing. We have added to the literature on cultural considerations and have delineated future cultural adaptation of the intervention

alongside considerations for clinicians and service providers on supporting South Asian families affected by dementia and sleep disturbance (paper 4). We will apply for funding test this translated and culturally adopted version.

5. We added to what is qualitatively understood about the intersection of sleep, dementia and LTCs and made recommendations for clinicians and services (paper 5).
6. We demonstrated that a wireless EEG device is not acceptable for those living at home with dementia and sleep disturbance in the context of our trial, adding to what is already known about limitations of actigraphy-based technology, highlighting a gap in acceptable ways to directly measure sleep in those living at home with dementia (papers 3 and 5).

Contribution to existing knowledge

Prior to this project, definitive evidence for any treatment for sleep disturbance in dementia was lacking.^{7,11} DREAMS START, a multicomponent intervention, demonstrated 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. We also demonstrated high levels of intervention attendance in contrast to previous multicomponent pilot studies^{7,26,27} and is the first to test and demonstrate effective delivery by non-clinically trained graduates both face to face and remotely. Additionally, we have built on what is known and understood about the challenges of using direct measures of sleep in real-world, home-based contexts for PwD and sleep disturbance. Our qualitative work has highlighted the intersectional complexities of sleep disturbance, LTCs, dementia and ethnicity.

Strengths and weaknesses in relation to other studies

As noted above, this was, to our knowledge, the first definitive RCT of a multicomponent treatment for sleep disturbance in people living at home with dementia to demonstrate sustained clinical effectiveness. The trial was successfully delivered with a high follow-up rate, with 92% of participants included in the primary analysis, and good intervention attendance, with 83% of surviving intervention arm participants receiving $\geq 4/6$ intervention sessions. This is in the context of the global COVID-19 pandemic during which we conducted the trial, recruiting to time and target with minimal delays, despite the devastating impact of the pandemic on those affected by dementia.²⁸ We think that because of restrictions, people were less able to increase exposure to natural light and activity than we had envisaged, but nevertheless the trial

demonstrated efficacy. Additionally, the trial has good external validity with no clear differences in those who did and did not consent, and recruiting from NHS trusts serving geographically, ethnically and socioeconomically diverse populations. We actively sought to recruit from populations typically under-represented in clinical trials,²⁹ and overall, 25% of our participants were from minoritised communities and with 20% without post-school education.

Despite these strengths, our trial had methodological weaknesses. There was a risk of response bias, as we relied upon family carers' proxy and self-reported outcomes, with intervention arm participants potentially more invested and optimistic.³⁰ We were unable to mask participants or facilitators to group allocation, and unmasked carers reported proxy outcomes increasing risk of bias. This is not uncommon in trials of psychological and behavioural interventions,³⁰ and we took steps to mitigate against researchers becoming unblinded to allocation status, following procedures we have successfully adopted in earlier trials.^{19,31,32} A further weakness was the of lack of actigraphy or other direct sleep and activity data as a RCT outcome measure. This methodological decision was informed by our feasibility RCT when using actigraphy as a primary outcome was unfeasible as it had inadequate validity for PwD and was unacceptable to some.¹⁹ Other dementia studies have reported actigraphy limitations and challenges, particularly during the pandemic when carers had less direct support to use devices.³³ Importantly, multiple studies in dementia have found large discrepancies between questionnaire and actigraphy sleep measures,^{34,35} and arguably questionnaires better reflect the clinical impact of sleep disturbance on those with dementia, something which our PPI representatives felt strongly about during our feasibility RCT. However, reliance on carer-reported outcomes for sleep disturbance without objective sleep measures does introduce potential reporting bias, particularly given the unblinded nature of the intervention. Additionally, we did not include an active control group, so it cannot be certain that the effect of the intervention is not a reflection of the contact with a supportive facilitator. However, 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.³⁶

Take-home messages

DREAMS START is clinically effective in improving sleep disturbance in PwD (at 4 months), and this is sustained at 8 months. It also led to a significant improvement in family carer sleep and reduction in their anxiety at 8 months.

There is a high probability that adding the DREAMS START intervention to TAU is cost-effective compared to TAU alone over 8 months. Even with the addition of the cost of the DREAMS START intervention costs, participants with dementia and their carers incurred £116 less in health, social services and wider costs over 8 months than participants in the control arm.

DREAMS START can be flexibly delivered in varied modes of delivery by non-clinically trained facilitators, to a high standard of fidelity and is being made ready for implementation in real-world NHS settings, with guidance available on how best to achieve this.

DREAMS START can be tailored to meet the needs of those living with multiple LTCs and UK-based South Asian communities without significant changes to the core components of the intervention.

Reflections and what could have been done differently

As in all dementia trials, there is tension between gathering meaningful and informative data and not overburdening participants. In our trial, to reduce unnecessary burden on PwD and to increase consistency, we collected all data by proxy report from family carers. Additionally, we did not collect information on medical comorbidities, such as other sleep disorders, beyond our initial screening, or measure symptoms, such as pain. This information would have enabled us to explore further the interactions of LTCs, sleep and dementia in our data set across the trial. We may have also been able to collect this information by accessing people's medical records directly. We also did not collect qualitative data from participants with dementia about the impact of the intervention, especially where they had chosen to participate in DREAMS START sessions; this would have given voice to an additional perspective and understanding of the impact of the intervention upon PwD themselves.

Challenges faced and limitations

The COVID-19 pandemic undoubtedly shaped the trial and was the backdrop to many of the challenges and limitations we faced. We delayed our project start from April 2020 to September 2020, which enabled us to develop robust plans and protocols that would allow us to deliver the trial flexibly in the context of the pandemic. This preparation which included enabling fully remote data collection and intervention delivery was essential; however, the pandemic still had a profound impact on the trial delivery, the staff working on the trial and the participants and their ability to change behaviour, which potentially worsened sleep.

The biggest challenge we had was the collection of the actigraphy data, and in our LTCs substudy, we struggled to get people to wear the wireless EEG. We planned to include actigraphy to measure movement as a potential intervention mechanism. At baseline, 4-month and 8-month follow-up, only 71%, 35% and 22% of participants, respectively, had 7 days of actigraphy and associated sleep diary data available, so we could not conduct planned mediation analysis. We took various steps to increase uptake and wear of the actigraphs; this included trying to have clear instructions enclosed with devices and a follow-up call to go through these with the carer and, where possible, having research staff deliver and explain in person, and we tried to simplify all related procedures. The reasons for not wearing the actigraphs are presented in [Table 2](#). The most common reason given was discomfort or distress at wearing the watch. This was higher at follow-up when people had generally previously tried the watch and may have found it unacceptable. For many, the practicalities of organising receipt and collection of the watch through couriers, keeping a diary over 7 days and monitoring wear by the PwD was prohibitive, and perhaps a reflection of how burdensome it was for already-exhausted family carers. Additionally, there were many who did not wear the watch because they were too unwell, and those lost to follow-up because of death or transition to care home also have no watch data available. The pandemic had a profound impact upon the health and well-being of those living with dementia,²⁸ and we had much higher levels of death and illness across the trial than in our feasibility RCT¹⁹ (although there was shorter follow-up), which will also have impacted on our actigraphy data collection. We found even greater resistance to wearing the wireless EEG (detailed above), which is perhaps unsurprising, since it is a bigger and more uncomfortable piece of equipment than the actigraphy watches, and there was no longer the potential of benefit, as it was outside the trial. Our experiences, although compounded by the pandemic, reinforces the need for non-invasive, easy-to-use and ideally entirely passive technology which can accurately measure movement and sleep for PwD and other LTCs living at home in the community.^{37,38}

Another key challenge was finding and retaining staff to deliver the intervention. Ideally, we planned to recruit non-clinically trained staff (e.g. assistant psychologists or dementia support workers) from within memory services. This was challenging, because there was a lack of staff available to train, and limited resources meant services were reluctant to release staff for training to deliver

the intervention. We overcame this by recruiting trust research assistants where clinical staff were unavailable. Additionally, staff illness (sometimes due to COVID-19) and very high turnover meant that of the 76 staff that we trained and 'signed off' ready to deliver DREAMS START, only 49 went on to deliver the intervention, making delivery very resource-intensive. Therefore, it was a challenge to maintain consistency with enough staff available to deliver. Throughout the trial, we endeavoured to ensure that we trained the facilitators to a high standard to ensure that the intervention was delivered as intended. We had a standardised training manual, in-depth live training, and we (either Penny Rapaport or Gill Livingston as clinician cochief investigators) also met with each potential facilitator to role-play each session with them to 'sign off' that they were ready to deliver the intervention. Clinical supervision was also mandatory for all of those delivering the intervention and was delivered by Penny Rapaport and Chris Clarke (both clinical psychologists) fortnightly in small groups and with additional individual supervision available on an ad hoc basis. We would also listen to recordings of sessions where we believed there were challenges and would discuss potential or actual intervention withdrawals with facilitators in supervision. Additionally, our central University College London (UCL) researchers were available to facilitate the intervention if a site had no one available. Despite these challenges, the intervention was delivered to a high standard, with high levels of attendance and high fidelity as well as no therapist clustering effect found in our analysis. Undoubtedly, staff turnover will be one of the key challenges to future delivery, and we have a 2-day online training package available which can be locally adapted and, in future, can be applied via a 'train the trainers' approach so that knowledge and expertise become embedded in services.

Engagement with partners and stakeholders

We partnered with the Alzheimer's Society, who chaired our annual DREAMS START community of interest (CoI) (a network of academic researchers, policy-makers, stakeholders, including the NHS England Dementia Clinical Network and PPI), where we focused on refining our plans for dissemination, implementation and public engagement (see [Impact and learning](#)). We have also worked with the North Thames Applied Research Collaboration (ARC) who are funding our 2-year follow-up data collection and have funded an animation of our DREAMS START findings targeting strategic managers and commissioners. For our widening access work, we engaged with the Subco Trust, an organisation for South Asian carers in East London. We have worked developed links with the Lewy Body Society and Dementia UK, with planned future collaborations and

grant applications, and we have submitted an expression of interest to the North Thames ARC for a future grant (detailed below).

Capacity strengthening activities

The DREAMS START work has supported capacity building of future dementia academics and clinicians. During this work, we have supported (through supervision and interview and application preparation) six research staff to obtain a place on a clinical or counselling psychology doctorate programme, one onto a MSc and one onto a PhD programme. We have had three sleep-related MSc students who have completed dissertations related to sleep and dementia (Tala Koren, Danyang Liao and Vrushti Mehta); one has been published,³ and two are being prepared for publication. Our trial manager Sarah Amador has led on the process evaluation and implementation work and has completed the Economic and Social Research Council ARC Accelerator programme, developing skills in building a social venture which will be applied to our future DREAMS START work. Penny Rapaport, who was a new chief investigator supported by an experienced chief investigator (Gill Livingston), has successfully delivered DREAMS START, her first large grant, and during the study has successfully gained a NIHR Advanced Fellowship and been promoted to professor. During the trial, four other co-applicants have been promoted to professor (Julie Barber, Georgina Charlesworth, Rossana Horsley, Simon Kyle), also contributing to broader sleep and dementia research capacity.

Patient and public involvement

Aim

We aimed to embed meaningful PPI throughout each element of this study to ensure that the voices and lived experience of those affected by dementia were integral. We have also tried to ensure that as a research team, we were held to account by our PPI collaborators. We achieved this through various means.

What did we do?

We judge the quality and success of our feasibility RCT and the acceptability of our coproduced intervention to be a direct result of the meaningful and ongoing contribution of those with lived experience of dementia.²⁰ Rossana Horsley, who has lived experience as a carer and is a member of the Alzheimer's Society Volunteer Network, led PPI on our feasibility RCT and continued in this role in this study, and we have partnered with the Alzheimer's Society throughout. At the start of this study, we convened a virtual PPI group where PLWD or caring for a relative with

dementia joined us and agreed individually how they would like to contribute, to best align with their skills, abilities, interests and available time. This was a dynamic group, with new members joining throughout. For our additional work packages, we were aware that our group was lacking in ethnic diversity and worked with community organisations, linking with other projects to recruit PPI members from UK-based Asian communities to work with us. From this wider group, we allocated two PPI members (Rossana Horsley and Jane Ward) to attend Trial Management Group meetings and one member (Sube Banerjee) to attend our Trial Steering Committee (TSC), and all our PPI group were invited to contribute to our Col group.

In refining our RCT study protocol and the DREAMS START intervention, PPI involvement helped us to clarify our research questions, our outcome measures and our inclusion criteria. Specifically, our PPI representatives directly influenced our decision to use the SDI as our primary outcome measure. They judged that important outcomes were that the PwD was less restless during the night, did not try to do anything dangerous, was more awake during the day and disturbed them less (all measured in the SDI). In these circumstances, they felt that actigraphy measurements of sleep did not give additional outcome information and were not accurate. Within our intervention refinement, our PPI members worked hard to adapt the sleep diaries and record forms to ensure that they were readable and user-friendly, especially for tired and busy family carers; we also incorporated direct quotations from our family carer PPI members into the DREAMS START manuals. PPI and community engagement were integral to the work, translating and culturally adapting DREAMS START. We consulted with our PPI and community partners on the nuances of the translation, sense checking around colloquialisms and providing feedback on the translated versions.

Our PPI members have been central to our dissemination and knowledge exchange activities, especially our dissemination to participants and related public communities (see [Report Supplementary Material 3](#) for lay summary). Our PPI members worked with us to develop our dissemination and impact strategy, and Rossana Horsley coauthored our published protocol and main paper. Jane Ward contributed to a video and content now online at (<https://livingwithdementiatoolkit.org.uk/>) talking about their experiences of caring for a relative with dementia and sleep disturbance and how they have contributed to DREAMS START. Jane Ward also copresented with Penny Rapaport a webinar to the Alzheimer's Society research network on sleep and dementia and then to an article on supporting a relative with sleep disturbance.

(www.alzheimers.org.uk/get-support/publications-and-factsheets/dementia-together/aug-sept-2021/research-support-carers-dementia-disturbed-sleep). Rossana Horsley spoke at our DREAMS START knowledge exchange event about her contribution to the project and her motivations for working with us on DREAMS START. Additionally, our team has run workshops and discussions about sleep and dementia to community and patient groups at the Lewy Body Society, Subco Trust and South Asian day centres in West London. We have written a blog on sleep and dementia for the North Thames ARC as part of Dementia Awareness Week.

Reflections and critical perspective

An ongoing challenge in dementia research is that involvement is often dominated by carers of PwD rather than PwD themselves. This was the case in our DREAMS START work, although we were testing an intervention delivered to family carers and were interested in their experiences. Jane Ward supported us to reach out to dementia advocacy organisations Dementia Engagement and Empowerment Project and Together in Dementia Everyday to ensure that we included those living with dementia in our wider PPI group. As researchers and clinicians, we also tried to redress this imbalance in perspectives in our conversations with family carers; we asked questions to foreground the perspective of those that they had been caring for, what was important to them and how DREAMS START may have fitted their lives. Most of our PPI came via the Alzheimer's Society research network, and ultimately, we were working with a relatively small group of committed individuals whose lives had been affected by dementia. Patient representatives in research are less commonly from Black and minority ethnic backgrounds and are less likely to come from socioeconomically disadvantaged groups, limiting the opportunity to develop a greater understanding of ways to widen access and develop interventions that are fitting and meet the needs of marginalised groups.³⁹ We worked hard to diversify our PPI representation, although arguably we only did this once we were focusing on widening access in our substudy, and this is something that we should have worked harder to do throughout.

Equality, diversity and inclusion

There are widening inequalities in dementia risk, outcome and treatment access,⁴⁰ and by developing and testing interventions such as DREAMS START with diverse participants, we can begin to redress these disparities. The 2024 Alzheimer's Society-funded Office of Health Economics report found 110 inequalities relating to

dementia, primarily around ethnicity, socioeconomic position and rurality.⁴¹ Disparities exist in dementia diagnosis rates and outcomes across the disease course. UK-based South Asian people (the largest non-White group) are diagnosed with dementia and die younger than White people.⁴² Little is known about experiences of sleep disturbance and its wider impact in South Asian families, although the experiences of sleep disturbances have been explored in Black, Hispanic and non-Hispanic White populations but not in the UK,^{43,44} and there are also inequalities in terms of experiences of LTC in minoritised communities in the UK.⁴⁵

In our DREAMS START RCT, we targeted and recruited ethnically and socioeconomically diverse populations typically under-represented in clinical trials, with 25.2% of participants with dementia from minoritised communities (12.5% Asian, 8.5% Black, 0.8% Mixed and 3.4% other ethnicities) and 23.3% with no formal qualifications. In the 2021 (England and Wales) census, 81.7% of the population was White; people from Asian ethnic groups made up the second largest percentage of the population (9.3%), followed by Black (4.0%), Mixed (2.9%) and other (2.1%) ethnic groups; and 18.2% reported no formal qualifications.^{46,47} In comparison to these census results, participants with dementia from minoritised ethnic communities were over-represented in our sample, as were those without formal education, which may be seen as a proxy for socioeconomic status. This may also indicate that our findings are relatively generalisable to those living with dementia in the UK. We worked hard from the outset to recruit NHS sites which served diverse geographical, socioeconomic and ethnic communities, including rural and semirural and coastal communities, where there are higher levels of deprivation. We used the NIHR INCLUDE guidance⁴⁸ for inclusion of underserved groups in clinical research and would discuss at our weekly meetings with research delivery staff how to increase access to those from underserved groups and maximise engagement, for example, by sharing successful flexible outreach and approach strategies and discussing best practice in working with interpreters to collect outcomes. Similarly, we incorporated into our facilitator training how to manage difference and power imbalance in delivering DREAMS START and used supervision to explore ways to deliver the intervention when working with an interpreter or with those with lower literacy levels. We made sure during our intervention finalisation that the names, photographs and examples included in the DREAMS START manuals included broad representation.

As noted above, in our two substudies, we wanted to explore in depth the experience of two underserved

dementia communities, those experiencing multiple LTCs and those from South Asian backgrounds. This work is detailed above; however, in addition to the broader strategies we adopted, for these studies we worked to engage community groups and added two sites which had large South Asian populations. Although our wider research delivery teams and clinical facilitators were diverse in terms of age, gender and ethnicity, our core research team was predominantly White, and for our substudy, we recruited two bilingual research assistants from South Asian background (Malvika Muralidhar and Ankita Bhojwani) to recruit and collect data and translate the intervention and a South Asian dementia academic (Naaheed Mukadam) to act as a consultant on our widening access work. Although we believe that our findings are potentially generalisable to those from diverse backgrounds, a caveat to this is that we excluded from the trial those living alone with dementia. This decision was based upon difficulties for those living alone or without a carer participating in both the intervention and trial procedures in our feasibility RCT. We acknowledge this is an underserved group who may face inequalities in access to dementia health and social care,⁴¹ and future research would benefit from adapting multicomponent interventions such as DREAMS START to meet the needs of this group.

Impact and learning

What difference have we already made?

We hope that the primary difference we have already made is for those who participated in the trial. Our results demonstrate that we have improved the sleep of those living with dementia and their relatives and seen reduction in service use for those who received DREAMS START. Our qualitative feedback has been predominantly positive, suggesting that our work was well received and felt to have made a difference. As noted above, we trained 76 non-clinical staff to deliver the intervention building their understanding of sleep and dementia as well as their broader knowledge of psychological interventions and clinical skills. They have fed back via facilitator interviews (incorporated in paper 3) the direct impact upon them and their development as well as them being ready in services to share learning and potentially implement DREAMS START in the future.

Throughout the course of this project, we have sought to raise awareness and understanding of the impact of sleep disturbance in dementia in various ways. Our team acted as consultants to the Alzheimer's Society and to the Lewy Body Society on their factsheets on sleep disturbance and dementia for those affected, and we (research and PPI

co-applicants) have contributed to public engagement work via webinars delivered via these organisations. We contributed to a 'living well with dementia' online toolkit, including on online conversation between Penny Rapaport (chief investigator) and Jane Ward (PPI) about the project described in our PPI section above.

We have also added to academic knowledge in the field with our team supervising MSc students to publish on the MCID for the SDI²¹ and the prevalence of sleep disturbances in people living at home with dementia.³ By recruiting a diverse sample to our RCT, we have also contributed to what is known about successful inclusive recruitment strategies, which we have already shared with a UCL-led project inclusive of research practices in dementia research. Our additional work packages focused on widening access to under-represented groups, and those living with multiple LTCs have already resulted in tailored recommendations for widening access and a translated version of the intervention.

What longer-term impact might there be?

DREAMS START is the first non-pharmacological intervention to reduce sleep difficulties in people living at home with dementia, where currently no definitive research evidence exists, and as such, we anticipate it will be widely adopted within the NHS as the only evidence-based intervention package incorporating all aspects of the National Institute for Health and Care Excellence (NICE) recommendations.⁴⁹ Although we did not see a difference in prescribing of non-evidence-based psychotropic medications with harmful side effects or a delay to care home transition, with longer follow-up and scaled up implementation we may see this. The programme has significant potential for societal and economic impact.

Lessons for future work

Having adapted to the unprecedented context of COVID-19, we have learnt from both our successes and our challenges in delivering the trial flexibly and often remotely. We had not anticipated DREAMS START being delivered by telephone or video call; however, having done so, we have contributed to understanding of flexible and varied models of implementation with the potential to reach underserved communities, such as those living in remote rural areas, or those unable to leave their homes due to mobility issues or caring responsibilities. Although not powered to do so, we found no difference in treatment effect based on delivery mode, highlighting the strength of this flexible approach. Within our future planned implementation work detailed below, we hope to incorporate and test technology, including digital health applications, in order to ensure that the intervention is both

scalable and accessible for those who may find it difficult to receive in-person intervention, for example, those in more remote, underserved geographical areas or those with additional long-term mobility issues. We have also learnt from our challenges. We struggled to adequately collect technological (actigraphy and EEG) data, and in future, we would account for this in our planning, allocating additional resources and specialist expertise to maximise the potential to collect these data as intended. Even with additional resources and expertise, it did seem that the devices we used were not acceptable to those living with dementia, sleep disturbances and often additional LTCs, which reiterates the need for more less-burdensome and intrusive ways to measure sleep and activity.

Related work

Having demonstrated the immediate and sustained effect of DREAMS START, it is important to understand how this effect changes over time. We successfully applied to the North Thames ARC for funding to undertake a 2-year follow-up study of our key clinical and cost outcomes. This long-term follow-up study, DREAM LONGER, is ongoing, and we will report our findings in late 2025. We have also been funded by the North Thames ARC to commission a short animation describing the need for DREAMS START, what we did and our key findings. This was designed to appeal to commissioners and managers and to introduce DREAMS START to the public. We have an English and a Hindi version of the animation ready for dissemination (www.ucl.ac.uk/psychiatry/research/mental-health-older-people/dreams-start). We have also recently completed a small pre-implementation study. A MSc student (Vrushti Mehta) conducted qualitative interviews with managers and clinicians not involved in the trial to explore barriers and facilitators to future implementation of DREAMS START. We will use this to inform future implementation work and will submit for publication in early 2025.

Future collaborations and potential funding

Building upon our existing collaborations with the North Thames ARC, we have submitted an expression of interest for submission as part of their ARC 2 funding application. This expression of interest was not taken forward as part of ARC 2 submission as it was not aligned with the wider funding call; therefore, we are preparing an application for submission to the NIHR Health and Social Care Delivery Research stream in September 2025: the aim of this work would be to conduct an implementation study with evaluation, and specific planned objectives are to:

1. Co-design an implementation package, including consultation with stakeholders, to ensure

- technological components (i.e. wearable accelerometer data and phototherapy lights), and staffing can work within NHS systems.
2. Determine uptake, use and necessary resources for DREAMS START in participating NHS and third-sector services and identify factors which inhibit or facilitate DREAMS START implementation.
 3. Adaptation and evaluation of DREAMS START for minoritised groups, including older Black and UK-based South Asian communities.

If this application is unsuccessful, we will apply to submit a similar study to the Alzheimer's Society.

We are collaborating with Dr Emma Wolverson (Research Lead, Dementia UK), Rachel Thompson (Consultant Admiral Nurse, Lewy Body Society) and Professor Suzanne Reeves (UCL Division of Psychiatry and UCLH mental health BRC Neurodegeneration Theme) to explore how DREAMS START could be adapted for those living with Dementia with Lewy Bodies and Parkinson's Disease Dementia. We will begin with a MSc project qualitatively exploring how DREAMS START could be optimised for these groups, and we will use this preliminary work to inform a legacy grant application to the Lewy Body Society for a targeted implementation study.

Gill Livingston is leading a strategic partnership between UCL and Osaka University on Ageing and Dementia, and Penny Rapaport is part of the working group on sleep detection and treatment in dementia and neurodegenerative illnesses. In November, we will contribute to a joint conference which will involve developing applications for small Proof of Concept grants, strengthening the UCL/Osaka collaboration and potentially leading to bigger future grant applications in sleep, dementia care and technology.

Aspirations for dissemination and implementation

We have outlined our plans for implementation studies above under future collaborations and potential funding, and we held a public dissemination event at UCL, chaired by Malayka Rahman-Amin (Alzheimer's Society) and attended by over 80 stakeholders, where we presented our initial findings and plans for dissemination and future implementation. We have developed DREAMS START as a mixture of product and procedure: a structured, manualised, transferable package incorporating practice guidelines and a lay summary and video animation for commissioners and

training materials. We have also made recommendations on using the intervention with those with multiple LTCs and will make the Hindi version and guidelines available via our website. These products will be made publicly available to reduce barriers to implementation. We have extensive experience within the team of implementing evidence-based interventions and recently have employed consultants to explore the potential and provide materials and costing of developing a social enterprise to support the delivery of our evidence-based Strategies for Relatives (START) (not DREAMS START) intervention for family carers. Having done this work, we aim to adapt our processes in the future to speed up our pathway to impact for DREAMS START. We collaborate with Professor Aimee Spector (UCL Psychology), who has developed an online training academy www.ucl-dementiatrainingacademy.org/, which signposts practitioners and other stakeholders to evidence-based interventions in dementia care, and we will add DREAMS START to their platform. In our DREAMS START CoI, we have and will work with NHS England, the Memory Services National Accreditation Programme (MSNAP), the Royal College of Psychiatrists and the British Psychological Society Faculty for the Psychology of Older People to ensure that we are widening awareness of what is already known and what DREAMS START adds via presentations, in anticipation of future implementation. Our pre-implementation work informed by the Consolidated Framework for Implementation Research (manuscript being prepared) has involved interviews with stakeholders not involved in the trial, as well as data from DREAMS START facilitator interviews on potential implementation challenges. This work highlighted the importance of perceived need for DREAMS START and lack of available alternatives in services, the need for robust evidence and clear referral processes/pathways in services, managerial/strategic support to start delivering DREAMS START, robust processes for training and supervision and team champions leading on embedding and sustaining the intervention. We intend to extend this work to develop an implementation logic model and toolkit to support services to deliver the intervention. We believe that the intervention is likely to best fit within post-diagnostic support pathways in memory services; however, we will be testing this and other potential pathways in our future work.

Implications for decision-makers

Recent Cochrane reviews of pharmacological and non-pharmacological interventions for sleep disturbance in dementia have highlighted a paucity of

available evidence.^{7,11} Other than highlighting the lack of effectiveness of melatonin, authors found a lack of evidence for any drug treatment to guide decision-making and uncertainty around the balance of benefits and risks of medication. For non-pharmacological intervention, authors concluded that no intervention could be identified as suitable for widespread implementation, despite promise from pilot multicomponent interventions. Current NICE guidelines for dementia do not make specific recommendations, yet state: 'For PLWD who have sleep problems, consider a personalised multicomponent sleep management approach that includes sleep hygiene education, exposure to daylight, exercise and personalised activities'.⁴⁹ Consequently, as the first adequately powered RCT of a multicomponent intervention addressing sleep disturbance in dementia, this project represents a step forward in available clinical and cost-effectiveness evidence to inform decision-making. We aim to lobby NICE and work with key stakeholders, including NHS leaders and commissioners, the Alzheimer's Society, the Lewy Body Society and Dementia UK, to support the integration of the evidence from the DREAMS START RCT into national guidelines. The published results will be reviewed and integrated into the next standing Lancet Commission on Dementia, widening potential impact in international settings. Having already submitted an expression of interest for NIHR ARC funding, completed an animated summary for commissioners and undertaken a pre-implementation study being prepared for publication, we believe we are well placed to provide specific guidance to policy-makers and Integrated Care Boards, including guidance on widening access to UK-based South Asian communities and those living with dementia and additional LTCs. Our teams will build on our experiences of leading on the implementation of the highlight impactful START intervention both nationally and internationally, using our established networks and pathways, to impact to expedite this process for delivery of DREAMS START in NHS memory services, third-sector providers and eventually internationally. Now that we have published our health economic analysis, detail costings are available on the intervention training, supervision and delivery. The total cost per dyad of the DREAMS START intervention, including DREAMS START intervention sessions, equipment (light box, watch) and facilitator training and supervision, was £574. There is potential for this cost to be reduced if the intervention is scaled up, as costs of supervision and training facilitators would be lower and equipment could be reused. We plan to produce evidence summaries to support policy decision-making.

Research recommendations

In addition to our future plans for implementation-based research, this project has highlighted areas of uncertainty and gaps in what is known with respect to non-pharmacological interventions for sleep and sleep and dementia more broadly.

1. *How can we measure sleep directly in people living at home with dementia, and what are the quantitative mechanisms underpinning DREAMS START?*

In addition to practical challenges related to the acceptability of wearing an actigraph or a wireless EEG for those experiencing sleep disturbance and dementia that we experienced in our study, there remains uncertainty about the validity of data for this population when it is collected. Studies in dementia have found large discrepancies between questionnaire-based and actigraphy measures of sleep,^{34,35} and arguably questionnaires better reflect the clinical impact of sleep disturbance on those affected by dementia. However, having accurate, valid and reliable measurement of direct sleep and movement remains a priority, and future testing of entirely passive and non-intrusive technology is needed.^{37,38} Linked to the need to develop and test technologies for measuring sleep in PwD, the specific mechanisms underpinning the intervention remain unclear. We were unable to collect sufficient data for pre-specified actigraphy data analysis exploring underlying mechanism of action, so we could not report on several intervention targets, for example, circadian rest-activity rhythms (or direct measures of circadian phase) and changes in pattern of light exposure, sleep-wake timing and consolidation and reduction in napping. Being able to quantitatively explore these mechanisms would enable us to better understand which aspects of the intervention (e.g. light or increasing activity) work for whom and in what ways – which has the potential to lead to further personalisation and targeting of the intervention. It would also be useful to further examine how the intervention may work differentially for those with different dementia subtypes, such as Lewy body dementia, with a view to further targeted tailoring and adaptation.

2. *What is the long-term effectiveness of DREAMS START?*

We have demonstrated via our primary analysis a sustained effect of DREAMS START; however, we do not know whether this effectiveness is sustained over time.

We could hypothesise that over time, we may see further differentiation in service use and potential delays to care home admission. We are in the process of being able to explore this, as we have gained funding from the NIHR ARC to collect follow-up clinical and cost-effectiveness data at 2 years.

3. *How can multicomponent interventions for sleep, such as DREAMS START, be adapted to benefit those living alone with dementia?*

Following our feasibility RCT when we found that delivery of DREAMS START to those living alone with dementia was challenging, we added to our inclusion criteria that PwD needed to have someone (a relative or a paid carer) present at night, and clarified that the intervention would be delivered to a carer who would support behaviour changes. Little is known or understood about how sleep disturbances are experienced by people living alone with dementia, and in the first instance, it is important to explore this further. Additional research adapting and testing interventions like DREAMS START for with people living alone with dementia is also recommended.

4. *Is an adapted version of DREAMS START clinical and cost-effective for addressing sleep disturbance in people living in care homes with dementia?*

As noted above, sleep disturbance is often a precipitant of care home admission, and the prevalence of sleep disturbance is higher in people in care homes [38% of people with all-cause dementia in care homes experience symptoms of sleep disturbance (95% CI 33% to 44%)]³⁴ compared to those living at home [26% of people with all-cause dementia living at homes experience symptoms of sleep disturbance (95% CI 23% to 30%)]³. This suggests that sleep may worsen following care home admission, and undoubtedly, the complex care home environment may be less controllable and more dependent on variable care quality. As such, interventions designed for delivery at home in a more controlled and contained setting cannot simply be transferred to a care home context. There remains limited evidence for multicomponent, non-pharmacological interventions for sleep in care homes, with one recent cluster RCT showing short-term improvements in SDI scores for those in the intervention group versus usual care at 16 weeks albeit with methodological limitations.³³ Future research would benefit from adaptation of DREAMS START for complex care home environments and delivery by paid care home staff, followed by testing of clinical and cost-effectiveness in a cluster RCT.

Conclusions

DREAMS START plus TAU is clinically and likely to be cost-effective in reducing sleep disturbance in people living at home with dementia after 8 months, demonstrating an effect sustained beyond immediate intervention delivery. The intervention can be delivered flexibly across a range of modalities and safely, as evidenced by high attendance and intervention fidelity rates, no evidence that intervention effects vary based on delivery modality and no evidence of harm related to the intervention. Our process evaluation findings highlight that the intervention was generally positively received as well as informing our understanding or how the intervention may be working in line with our theoretically informed logic model. We have added value to our main study via substudies, elucidating the experiences of people with additional LTCs, sleep disturbance and dementia and those caring for a relative with sleep disturbance from UK-based South Asian communities. DREAMS START is potentially scalable, and further implementation-focused research will assist the translation of our findings from a controlled research settings to complex real-world delivery. Further research is needed to fully understand how DREAMS START can be further personalised and targeted, especially in the context of resource-limited settings, and development of acceptable ways to directly measure sleep in PwD with disturbed sleep is required.

Additional information

CRedit contribution statement

Penny Rapaport (<https://orcid.org/0000-0003-0479-6950>): Conceptualisation, Formal analysis, Funding acquisition, Investigation, Methodology, Resources, Supervision, Visualisation, Writing – original draft, Writing – reviewing and editing.

Sarah Amador (<https://orcid.org/0000-0003-4196-6410>): Conceptualisation, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Resources, Supervision, Visualisation, Writing – original draft, Writing – reviewing and editing.

Mariam Adeleke (<https://orcid.org/0000-0002-7272-2462>): Data curation, Formal analysis, Investigation, Methodology, Writing – reviewing and editing.

Julie Barber (<https://orcid.org/0000-0001-5762-762X>): Conceptualisation, Formal analysis, Funding acquisition,

Investigation, Methodology, Software, Writing – reviewing and editing.

Sube Banerjee (<https://orcid.org/0000-0002-8083-7649>): Conceptualisation, Funding acquisition, Methodology, Writing – reviewing and editing.

Ankita Bhojwani (<https://orcid.org/0009-0003-6545-1654>): Investigation, Project administration, Writing – reviewing and editing.

Georgina Charlesworth (<https://orcid.org/0000-0002-5278-1756>): Conceptualisation, Funding acquisition, Methodology, Writing – reviewing and editing.

Chris Clarke (<https://orcid.org/0000-0001-8957-0795>): Conceptualisation, Funding acquisition, Methodology, Supervision, Writing – reviewing and editing.

Colin Espie (<https://orcid.org/0000-0002-1294-8734>): Conceptualisation, Funding acquisition, Methodology, Writing – reviewing and editing.

Lina Gonzalez (<https://orcid.org/0009-0008-7050-8906>): Data curation, Formal analysis, Investigation, Methodology, Writing – reviewing and editing.

Rossana Horsley (<https://orcid.org/0000-0003-4966-5997>): Conceptualisation, Funding acquisition, Investigation, Methodology, Writing – reviewing and editing.

Rachael Hunter (<https://orcid.org/0000-0002-7447-8934>): Conceptualisation, Formal analysis, Funding acquisition, Investigation, Methodology, Software, Writing – reviewing and editing.

Simon Kyle (<https://orcid.org/0000-0002-9581-5311>): Conceptualisation, Funding acquisition, Methodology, Writing – reviewing and editing.

Monica Manela (<https://orcid.org/0000-0003-4522-7105>): Data curation, Investigation, Project administration, Writing – reviewing and editing.

Naaheed Mukadam (<https://orcid.org/0000-0001-8635-9521>): Investigation, Writing – reviewing and editing.

Malvika Muralidhar (<https://orcid.org/0009-0007-4925-8909>): Investigation, Project administration, Writing – reviewing and editing.

Malgorzata Raczec (<https://orcid.org/0000-0001-9507-3293>): Methodology, Writing – reviewing and editing.

Zuzana Walker (<https://orcid.org/0000-0001-7346-8200>): Conceptualisation, Funding acquisition, Methodology, Writing – reviewing and editing.

Lucy Webster (<https://orcid.org/0000-0001-9152-4990>): Conceptualisation, Funding acquisition, Investigation, Methodology, Writing – reviewing and editing.

Hang Yuan (<https://orcid.org/0000-0001-5944-1925>): Data curation, Formal analysis, Investigation, Methodology, Writing – reviewing and editing.

Gill Livingston (<https://orcid.org/0000-0001-6741-5516>): Conceptualisation, Funding acquisition, Investigation, Methodology, Supervision, Visualisation, Writing – original draft, Writing – reviewing and editing.

Acknowledgements

Note: Named individuals are listed in alphabetical order.

Participants

We would like to express our sincere thanks and gratitude to the PwD and their family carers who participated in the studies presented here.

Patient and public involvement

We would also like to extend our sincere thanks and gratitude to our PPI members, including Rossana Horsley and Jane Ward who sat on the Trial Management Group, Sue Boex who sat on the TSC, and Frank Arrojo, Sanjiv Gupta, John Hammond, Shirley Nurock and Karin Webb who contributed to our wider PPI group and Col. We would also like to thank all members of our DREAMS START Col group: Naheed Anwar (Subco Trust), Colin Capper (Alzheimer's Society), Laura Cook (Dementia Clinical Network, NHS England and NHS Improvement), Lydia Drummond (London Borough of Newham), Jennifer Farren (London Dementia Clinical Network – NHS England), Sheila Fletcher (NHS Vale of York CCG), Sanjiv Gupta (PPI member), Rossana Horsley (PPI member), Gerry Okello (London Borough of Newham), Malayka Rahman-Amin (Alzheimer's Society), Taskin Saleem (Subco Trust), Tim Shakespeare (Zinc), Helen Souris (NHS England), Rachel Thompson (Dementia UK), Gavin Terry (Alzheimer's Society), Karin Webb (PPI member).

Oversight groups

We thank members of the TSC Claire Surr (Chair), Sue Boex, Vivienne Gould, Hilary Watt, and Raphael Wittenberg, and Data Monitoring and Ethics Committee (DMEC) George Bouliotis (Chair), Christoph Mueller and Geraint Price.

Therapists and supervisors

We thank facilitators who delivered the intervention in the RCT: Reanne Anad, Elise Armsby, Ariska Barbosa, Simran Bhatia,

Kantimar Noi Buthong Jessica Cardona, Denisa Clisu, Caroline Connell, Rebecca Cox, Mia Dale, Lucy Davies, Hope Donnelly, Didiana Dos Santos, Ron Druyeh, Guy Emery, Janice Ethapemi, Lily Felton, Olivia Gorzynska, Helena Grant, Rebecca Griffiths, Jasmine Harju-Seppanen, Kaira Hayhurst, Lara Horrax, Fawziyah Ikhlaiq, Nadia Iqbal, Oktavian Janicki, Sarah Jewers, Anita Jibero, Diyana Kirilova, Ho-Yun Lee, Nabeela Malik, Sophie Marron, Hayley Metcalfe, Maija Morton, Freda Nsumba, Lauren Otchelio, Emily-Beth Patton, Beth Philipps, Liam Pikett, Mia Purcell, Jessica Rapley, Emily Rosewood, Elle Ross, Amanda Sarpong, Paria Partovi Tabar, Emma Thornton, Shashya Wijesinghe, Abbie Woolridge, Karthik Yogarjah. We also thank supervisors who supervised the delivery of the intervention: Chris Clarke and Penny Rapaport.

Recruitment sites/trial research team

We thank primary investigators (PI) and staff across sites who were involved in recruitment and research delivery: Barnet, Enfield and Haringey Mental Health NHS Trust – Ruth Lukeman (PI) Thomas Freeth, Hayley Metcalfe, Lauren Otchelio, Jessica Rapley. Camden and Islington NHS Foundation Trust – Gill Livingston (PI) Ariska Barbosa, Didiana Dos Santos, Lindsay McGregor-Johnson. Central and North-West London NHS Foundation Trust – Sarah Johnson/Abhishek Shastri (PIs) Jessica Cardona, Denisa Clisu, Olivia Gorzynska, Rebecca Griffiths, Lauren Stevens, Doriana Taccardi. East London NHS Foundation Trust – Michelle Hamill (PI) Zainab Dedat, Zivile Jakaite, Simi Kaur, Ben Olby-Clements. Essex Partnership University NHS Foundation Trust – Zuzana Walker (PI) Helen Blake, Ron Druyeh, Lara Horrax, Ho-Yun Lee, Beth Philips, Veera Ramphal, Natalie Rodney, Pauline Young. NOCLOR – Joshua Graham, Ellie Broadhead, Karthik Yogarjah. North-East London NHS Foundation Trust – Georgina Charlesworth (PI) Jane Burgess, Thomas Gant, Fiona Horton, Harmony Jiang, Ritchard Ledgerd, Hara Margariti, Theodora Mircea, Erica Sugita. Oxleas NHS Foundation Trust – Adam Kadri (PI) Anthony Davis, Josy Pereira. Sussex Partnership NHS Foundation Trust – Gosia Raczek (PI) Elise Armsby, Guy Emery, Natalie Portwine, Abbie Wooldridge. Tees, Esk and Wear Valleys NHS Foundation Trust – Chris Clarke (PI) Heather Baker, Sarah Bentley, Charlotte Mackney-Hudson, Clive Nicholson. University College London Hospitals NHS Foundation Trust – Nick Fox (PI) Suzie Barker, Jess Jiang, Subarna Roy, Yukari Sakagami. West London NHS Foundation Trust – Oliver Hill (PI) Reanne Anad, Lizzie Cox, Helena Grant, Sophie Marron, Emily Rosewood, Shashya Wijesinghe. South-West London and St George's Mental Health NHS Trust – Robert Lawrence (PI) Jennifer Bonner, Jhian Cadimas, Rebecca Cox, Tasnim Fakira, Anita Jibero, Tania West. We thank the trial research team Caroline Connell, Monica Manela, Sarah Morris, Liam Pikett, Emma Thornton. We thank Adam Waters for his collection of qualitative data. We thank Tala Koren, Danyang Liao and Vrushti Mehta for their MSc project work which has informed our DREAMS START work.

Sponsor team/Clinical Trials Unit, and University College London staff

We thank the Sponsor team at NOCLOR (Priscilla Essuman, Dhanasekar Govindasamy, Lynis Lewis, Nicholas Portman, Emmanuel Rollings-Kamara, Angela Williams), PRIMENT Clinical Trials Unit (CTU) research staff (Lana Amyri, Anne Marie Downey, Tola Erinle, Sharon Forsyth, Zohrah Khan, Kate Sparksman), UCL research staff (Laiba Ahmad, Ruo Chen Gan, Jasmine Harju-Seppanen, Paria Partovi Tabar, Marija Taneska, Zuyu Wang), and UCL professional services (Mohammed Alom, Belen Altozano Gosalvez, Shanaz Begum, Christopher Cross, Seema Duggal, Daisy Gnandi, Selin Gurdere, Charlotte McElvaney, Anouchka Sterling). We thank John Adams for specialist IT support throughout the trial.

Collaborators

We thank Aiden Doherty for advising on collection and analysis of the actigraphy data, Huw Jones for designing the DREAMS START manual and Malayka Rahman-Amin for chairing the DREAMS START community of practice on behalf of the Alzheimer's Society.

Data-sharing statement

The qualitative and quantitative data sets generated during and/or analysed during the current study are available upon request from PRIMENT CTU Data Management Group on priment@ucl.ac.uk in collaboration with members of 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 data sets, stored on the publicly available UCL Research Data Repository <https://rdr.ucl.ac.uk/> will be shared.

Ethics statement

The RCT, including the process evaluation, was approved by London – Camden and Kings Cross Ethics Committee (20/LO/0894) on 21 August 2020. A substantial amendment to conduct the LTCs substudy was approved on 6 June 2022, and a substantial amendment to conduct the widening access substudy was approved on 7 July 2022.

Information governance statement

University College London and North London Mental Health Partnership NHS Trust (Formerly Camden and Islington NHS Foundation Trust) are committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation. North London Mental Health Partnership NHS Trust (Formerly Camden and Islington NHS Foundation Trust) is the Data Controller and we process personal data in accordance with their instructions. You can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for University College London's Data Protection Officer here: www.ucl.ac.uk/data-protection/data-protection-0. You can also contact the sponsor, Camden and Islington NHS Foundation

Trust Data Protection Officer by e-mail at information.request@candi.nhs.uk or call 020 3317 7094 and ask to speak to the Data Protection Officer.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at <https://doi.org/10.3310/GJPR2620>.

Primary conflicts of interest: Penny Rapaport declares grants from NIHR Academy, NIHR PGfAR with no conflicts of interest with current work.

Sube Banerjee declares grants from NIHR, CIHR, ESRC, HEE, ESRC, Alzheimer's Society, and the Alzheimer's Association with no conflicts of interest with current work. Colin Espie declares grants from NIHR-HTA, NIHR-EME, NIHR-BRC, Wellcome Trust with no conflicts of interest with current work. Outside the submitted work Sube Banerjee declares personal fees and non-financial support from Lilly, personal fees from Boehringer-Ingelheim, personal fees from Axovant, personal fees from Lundbeck, personal fees from Nutricia and honoraria from the Hamad Medical Service for lectures and talks. Sube Banerjee is a trustee of the Alzheimer's Society and NED at the Somerset NHS Foundation Trust.

Outside the submitted work Colin Espie declares stock/stock options from Big Health Limited developers of Sleepio. Colin Espie is deputy editor of the Journal of Sleep Research and on the editorial board of Sleep Medicine reviews.

Simon Kyle reports current grant support from the Wellcome Trust (refs: 227684/Z/22/Z and 227093/Z/23/Z), the NIHR (refs: EME131789 and NIHR203667), and the Oxford Health NIHR Biomedical Research Centre (ref: NIHR203316). Outside the submitted work, Simon Kyle declares non-financial support from Big Health Ltd in the form of no cost access to the digital sleep improvement programme, Sleepio, for use in clinical research.

Malgorzata Raczec declares a grant from NIHR ARC KSS and ARUK with no conflicts of interest with current work. Outside the submitted work, Malgorzata Raczec declares Honorarium for presentation on Lewy body dementias for GE.

Hang Yuan received studentship from Novo Nordisk with no conflicts of interest with the current work.

Gill Livingston, Penny Rapaport and Julie Barber are supported by University College London Hospitals' National Institute for Health Research NIHR BRC, and Gill Livingston is also supported by North Thames NIHR ARC and as an NIHR Senior Investigator and has grants from NIHR PGfAR, Alzheimer's Association,

Norwegian Research Council and Wellcome with no conflicts of interest with current work.

All other authors declare no competing interests.

Department of Health and Social Care disclaimer

This publication presents independent research commissioned by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, MRC, NIHR Coordinating Centre, the Health Technology Assessment programme or the Department of Health and Social Care.

This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Trial registration

This study is registered as ISRCTN13072268.

Funding

This synopsis presents independent research funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as award number NIHR128761.

Award publications

This synopsis provided an overview of the research award *A parallel multi-centre randomised controlled trial to determine the clinical and cost-effectiveness of DREAMS START (Dementia RElAted Manual for Sleep; STRAtegies for RelAtives)*.

Other articles published as part of this thread are:

Rapaport P, Amador S, Adeleke MO, Barber JA, Banerjee S, Charlesworth G, *et al*. 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. *Lancet Healthy Longev* 2024;5:100635. <https://doi.org/10.1016/j.lanhl.2024.08.004>

Gonzalez L, Rapaport P, Livingston G, Amador S, Adeleke MO, Barber JA, *et al*. Cost-utility analysis of the DREAMS START intervention for people living with dementia and their carers: a within-trial economic evaluation. *Lancet Healthy Longev* 2025;6:100708. <https://doi.org/10.1016/j.lanhl.2025.100708>

Amador S, Rapaport P, Adeleke MO, Barber JA, Yuan H, Banerjee S, *et al*. Process evaluation in a randomised controlled

trial of DREAMS-START (dementia related manual for sleep; strategies for relatives) for people with dementia and their carers. *Age Ageing* 2025;**54**:afaf053. <https://doi.org/10.1093/ageing/afaf053>

Rapaport P, Bhojwani A, Webster L, Amador S, Muralhidar M, Livingston G. Long-term health conditions and their impact on people with sleep disturbances and dementia. *BMC Geriatr* 2025;**25**:376. <https://doi.org/10.1186/s12877-025-06045-x>

Rapaport P, Muralhidar M, Amador S, Mukadam N, Bhojwani A, Beeson C, Livingston G. Sleep Disturbances and Dementia in the UK South Asian Community: A Qualitative Study to Inform Future Adaptation of the DREAMS-START Intervention. *Geriatrics* 2025;**10**:121. <https://doi.org/10.3390/geriatrics10050121>

For more information about this research please view the award page (www.fundingawards.nihr.ac.uk/award/NIHR128761).

Additional outputs

Rapaport P, Amador S, Adeleke MO, Barber JA, Banerjee S, Charlesworth, G, *et al.* Clinical and cost-effectiveness of DREAMS START (Dementia RElAted Manual for Sleep; STRAtegies for RelaTives) for people living with dementia and their carers: a study protocol for a parallel multicentre randomised controlled trial. *BMJ Open* 2024;**14**:e075273. <https://doi.org/10.1136/bmjopen-2023-075273>

Conference presentations

Rapaport P, Amador S, Barber JA, Adeleke MO, Webster L, Banerjee S, *et al.* Clinical-effectiveness of DREAMS START an intervention for people with dementia and sleep disturbance and their caregivers: a single masked, phase 3, parallel arms superiority randomised controlled trial. Paper presented at the Alzheimer's Association International Conference (AAIC), Philadelphia, USA, July 2024.

Rapaport P. The DREAMS START RCT. Tackling sleep disturbance in people living with dementia. Paper presented at the North London Mental Health Partnership NHS Foundation Trust Research Conference, London, July 2024.

Rapaport P, Amador S, Barber JA, Adeleke MO, Webster L, Banerjee S, *et al.* Clinical-effectiveness of DREAMS START an intervention for people with dementia and sleep disturbance and their caregivers: A single masked, phase 3, parallel arms superiority randomised controlled trial. Paper presented at the Alzheimer Europe Conference, Geneva, Switzerland, October 2024.

Livingston G. Effectiveness of DREAMS START RCT: an intervention for people with dementia and sleep

disturbance and their carers. Paper presented at Royal College of Psychiatrists MSNAP 15th Annual Forum, Online, October 2024.

About this synopsis

The contractual start date for this research was in September 2020. This synopsis began editorial review in November 2024 and was accepted for publication in July 2025. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The Health Technology Assessment editors and publisher have tried to ensure the accuracy of the authors' article and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this synopsis.

Copyright

Copyright © 2026 Rapaport *et al.* This work was produced by Rapaport *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This is an Open Access publication distributed under the terms of the Creative Commons Attribution CC BY 4.0 licence, which permits unrestricted use, distribution, reproduction and adaptation in any medium and for any purpose provided that it is properly attributed. See: <https://creativecommons.org/licenses/by/4.0/>. For attribution the title, original author(s), the publication source – NIHR Journals Library, and the DOI of the publication must be cited.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Newgen Digitalworks Pvt Ltd, Chennai, India (www.newgen.co).

Disclaimer

Every effort has been made to obtain the necessary permissions for reproduction, to credit original sources appropriately and to respect copyright requirements. However, despite our diligence, we acknowledge the possibility of unintentional omissions or errors and we welcome notifications of any concerns regarding copyright or permissions.

List of supplementary material

Report Supplementary Material 1

Statistical analysis plan

Report Supplementary Material 2

Health economics analysis plan

Report Supplementary Material 3

Lay summary

Supplementary material can be found on the NIHR Journals Library report page (<https://doi.org/10.3310/GJPR2620>).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

The supplementary materials (which include but are not limited to related publications, patient information leaflets and questionnaires) are provided to support and contextualise the publication. Every effort has been made to obtain the necessary permissions for reproduction, to credit original sources appropriately, and to respect copyright requirements. However, despite our diligence, we acknowledge the possibility of unintentional omissions or errors and we welcome notifications of any concerns regarding copyright or permissions.

List of abbreviations

ARC	Applied Research Collaboration
Col	community of interest
CTU	Clinical Trials Unit
DREAMS START	Dementia RElATED Manual for Sleep; STrAtegies for RelaTives
EEG	electroencephalogram
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
ISRCTN	International Standard Randomised Controlled Trial Number
LTC	long-term condition
MCID	minimum clinically important difference
MSNAP	Memory Services National Accreditation Programme
NICE	National Institute for Health and Care Excellence
PPI	patient and public involvement
PLWD	people living with dementia
PwD	people with dementia

RCT	randomised controlled trial
SDI	Sleep Disorders Inventory
TAU	treatment as usual
TSC	Trial Steering Committee
UCL	University College London

References

- Rapaport P, Amador S, Adeleke MO, Barber JA, Banerjee S, Charlesworth G, *et al*. 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. *Lancet Healthy Longev* 2024;5:100635. <https://doi.org/10.1016/j.lanhl.2024.08.004>
- Nichols E, Steinmetz JD, Vollset SE, Fukutaki K, Chalek J, Abd-Allah F, *et al*. Estimation of the global prevalence of dementia in 2019 and forecasted prevalence in 2050: an analysis for the Global Burden of Disease Study 2019. *Lancet Public Health* 2022;7:E105–25. [https://doi.org/10.1016/S2468-2667\(21\)00249-8](https://doi.org/10.1016/S2468-2667(21)00249-8)
- Koren T, Fisher E, Webster L, Livingston G, Rapaport P. Prevalence of sleep disturbances in people with dementia living in the community: a systematic review and meta-analysis. *Ageing Res Rev* 2023;83:101782. <https://doi.org/10.1016/j.arr.2022.101782>
- Brewster GS, Wang D, McPhillips MV, Epps F, Yang I. Correlates of sleep disturbance experienced by informal caregivers of persons living with dementia: a systematic review. *Clin Gerontol* 2024;47:380–407. <https://doi.org/10.1080/07317115.2022.2139655>
- Webster L, Powell K, Costafreda SG, Livingston G. The impact of sleep disturbances on care home residents with dementia: the SIESTA qualitative study. *Int Psychogeriatr* 2020;32:839–47. <https://doi.org/10.1017/S1041610220000642>
- McCrae CS, Dzierzewski JM, McNamara JP, Vathauer KE, Roth AJ, Rowe MA. Changes in sleep predict changes in affect in older caregivers of individuals with Alzheimer's dementia: a multilevel model approach. *J Gerontol B Psychol Sci Soc Sci* 2014;71:458–62.
- Wilfling D, Calo S, Dichter MN, Meyer G, Möhler R, Köpke S. Non-pharmacological interventions for sleep disturbances in people with dementia. *Cochrane Database Syst Rev* 2023;1:CD011881. <https://doi.org/10.1002/14651858.CD011881.pub2>
- Wang C, Holtzman DM. Bidirectional relationship between sleep and Alzheimer's disease: role of amyloid, tau, and other factors. *Neuropsychopharmacology*

- 2020;**45**:104–20. <https://doi.org/10.1038/s41386-019-0478-5>
9. Cagnin A, Fragiaco F, Camporese G, Turco M, Bussè C, Ermani M, Montagnese S. Sleep-wake profile in dementia with Lewy bodies, Alzheimer's disease, and normal aging. *J Alzheimers Dis* 2017;**55**:1529–36.
 10. Browne J, Edwards DA, Rhodes KM, Brimicombe DJ, Payne RA. Association of comorbidity and health service usage among patients with dementia in the UK: a population-based study. *BMJ Open* 2017;**7**:e012546. <https://doi.org/10.1136/bmjopen-2016-012546>
 11. McCleery J, Sharpley AL. Pharmacotherapies for sleep disturbances in dementia. *Cochrane Database Syst Rev* 2020;**11**:CD009178.
 12. Weich S, Pearce HL, Croft P, Singh S, Crome I, Bashford J, Frisher M. Effect of anxiolytic and hypnotic drug prescriptions on mortality hazards: retrospective cohort study. *BMJ* 2014;**348**:g1996. <https://doi.org/10.1136/bmj.g1996>
 13. Herring WJ, Ceesay P, Snyder E, Bliwise D, Budd K, Hutzelmann J, et al. Polysomnographic assessment of suvorexant in patients with probable Alzheimer's disease dementia and insomnia: a randomized trial. *Alzheimers Dement* 2020;**16**:541–51.
 14. Rapaport P, Amador S, Adeleke M, Banerjee S, Barber J, Charlesworth G, et al. Clinical and cost-effectiveness of DREAMS START (Dementia REIAted Manual for Sleep; STrAtegies for RelaTives) for people living with dementia and their carers: a study protocol for a parallel multicentre randomised controlled trial. *BMJ Open* 2024;**14**:e075273. <https://doi.org/10.1136/bmjopen-2023-075273>
 15. Gonzalez L, Rapaport P, Livingston G, Amador S, Adeleke MO, Barber JA, et al. Cost-utility analysis of the DREAMS START intervention for people living with dementia and their carers: a within-trial economic evaluation. *Lancet Healthy Longev* 2025;**6**:100708. <https://doi.org/10.1016/j.lanhl.2025.100708>
 16. Amador S, Livingston G, Adeleke M, Barber J, Webster L, Yuan H, et al. Process evaluation in a randomised controlled trial of DREAMS-START (dementia related manual for sleep; strategies for relatives) for sleep disturbance in people with dementia and their carers. *Age Ageing* 2025;**54**:afaf053. <https://doi.org/10.1093/ageing/afaf053>
 17. Rapaport P, Muralidhar M, Amador S, Mukadam N, Bhojwani A, Beeson C, et al. Sleep Disturbances and Dementia in the UK South Asian Community: A Qualitative Study to Inform Future Adaptation of the DREAMS-START Intervention. *Geriatrics* 2025;**10**:121. <https://doi.org/10.3390/geriatrics10050121>
 18. Rapaport P, Bhojwani A, Webster L, Amador S, Muralidhar M, Livingston G. Long-term health conditions and their impact on people with sleep disturbances and dementia. *BMC Geriatr* 2025;**25**:376. <https://doi.org/10.1186/s12877-025-06045-x>
 19. Livingston G, Barber JA, Kinnunen KM, Webster L, Kyle SD, Cooper C, et al. DREAMS-START (Dementia REIAted Manual for Sleep; STrAtegies for RelaTives) for people with dementia and sleep disturbances: a single-blind feasibility and acceptability randomized controlled trial. *Int Psychogeriatr* 2019;**31**:251–65. <https://doi.org/10.1017/S1041610218000753>
 20. Rapaport P, Webster L, Horsley R, Kyle SD, Kinnunen KM, Hallam B, et al. An intervention to improve sleep for people living with dementia: reflections on the development and co-production of DREAMS:START (Dementia REIAted Manual for Sleep: STrAtegies for RelaTives). *Dementia* 2018;**17**:976–89. <https://doi.org/10.1177/1471301218789559>
 21. Webster L, Martin A, Livingston G. The minimum clinically important difference on the sleep disorders inventory for people with dementia. *Int J Geriatr Psychiatry* 2020;**35**:1418–23.
 22. Devlin NJ, Shah KK, Feng Y, Mulhern B, van Hout B. Valuing health-related quality of life: an EQ-5D-5L value set for England. *Health Econ* 2018;**27**:7–22.
 23. Mulhern B, Rowen D, Brazier J, Smith S, Romeo R, Tait R, et al. Development of DEMQOL-U and DEMQOL-PROXY-U: generation of preference-based indices from DEMQOL and DEMQOL-PROXY for use in economic evaluation. *Health Technol Assess* 2013;**17**:v–xv, 1.
 24. Beecham J, Knapp M. Costing psychiatric interventions. *Measuring Mental Health Needs* 2001;**2**:200–24.
 25. Braun V, Clarke V. Reflecting on reflexive thematic analysis. *Qual Res Sport Exerc Health* 2019;**11**:589–97. <https://doi.org/10.1080/2159676x.2019.1628806>
 26. Gibson RH, Gander PH, Dowell AC, Jones LM. Non-pharmacological interventions for managing dementia-related sleep problems within community dwelling pairs: a mixed-method approach. *Dementia* 2017;**16**:967–84.
 27. Tewary S, Cook N, Pandya N, McCurry SM. Pilot test of a six-week group delivery caregiver training program to reduce sleep disturbances among older adults with dementia (Innovative practice). *Dementia* 2018;**17**:234–43.
 28. Suárez-González A, Rajagopalan J, Livingston G, Alladi S. The effect of COVID-19 isolation measures on the cognition and mental health of people living with dementia: a rapid systematic review of one year of quantitative evidence. *EClinicalMedicine* 2021;**39**:101047.

29. Nicholls SG, Al-Jaishi AA, Niznick H, Carroll K, Madani MT, Peak KD, *et al.* Health equity considerations in pragmatic trials in Alzheimer's and dementia disease: results from a methodological review. *Alzheimers Dement* 2023;**15**:e12392. <https://doi.org/10.1002/dad2.12392>
30. Juul S, Gluud C, Simonsen S, Frandsen FW, Kirsch I, Jakobsen JC. Blinding in randomised clinical trials of psychological interventions: a retrospective study of published trial reports. *BMJ Evid Based Med* 2021;**26**:109. <https://doi.org/10.1136/bmjebm-2020-111407>
31. Livingston G, Barber J, Marston L, Stringer A, Panca M, Hunter R, *et al.* Clinical and cost-effectiveness of the Managing Agitation and Raising Quality of Life (MARQUE) intervention for agitation in people with dementia in care homes: a single-blind, cluster-randomised controlled trial. *Lancet Psychiatry* 2019;**6**: 293–304.
32. Livingston G, Barber J, Rapaport P, Knapp M, Griffin M, King D, *et al.* Clinical effectiveness of a manual based coping strategy programme (START, STRategies for RelaTives) in promoting the mental health of carers of family members with dementia: pragmatic randomised controlled trial. *BMJ* 2013;**347**:f6276. <https://doi.org/10.1136/bmj.f6276>
33. Dichter MN, Dörner J, Wilfling D, Berg A, Klatt T, Möhler R, *et al.* Intervention for sleep problems in nursing home residents with dementia: a cluster-randomized study. *Int Psychogeriatr* 2024;**36**:965–78. <https://doi.org/10.1017/s1041610223004489>
34. Webster L, Costafreda Gonzalez S, Stringer A, Lineham A, Budgett J, Kyle S, *et al.* Measuring the prevalence of sleep disturbances in people with dementia living in care homes: a systematic review and meta-analysis. *Sleep* 2020;**43**:zsz251. <https://doi.org/10.1093/sleep/zsz251>
35. Blytt KM, Bjorvatn B, Husebo B, Flo E. Clinically significant discrepancies between sleep problems assessed by standard clinical tools and actigraphy. *BMC Geriatr* 2017;**17**:1–8.
36. Howard R, Cort E, Rawlinson C, Wiegand M, Downey A, Lawrence V, *et al.* Adapted problem adaptation therapy for depression in mild to moderate Alzheimer's disease dementia: a randomized controlled trial. *Alzheimers Dement* 2024;**20**:2990–9.
37. Soreq E, Kolanko M, Ravindran KKG, Monica C, Revell V, Daniels S, *et al.*; Group CRT. Contactless longitudinal monitoring in the home characterizes aging and Alzheimer's disease-related night-time behavior and physiology. *Alzheimers Dement* 2025;**21**:e70758. <https://doi.org/10.1002/alz.70758>
38. Yoon H, Choi SH. Technologies for sleep monitoring at home: wearables and nearables. *Biomed Eng Lett* 2023;**13**:313–27. <https://doi.org/10.1007/s13534-023-00305-8>
39. Ocloo J, Matthews R. From tokenism to empowerment: progressing patient and public involvement in healthcare improvement. *BMJ Qual Saf* 2016;**25**:626–32. <https://doi.org/10.1136/bmjqs-2015-004839>
40. Livingston G, Sommerlad A, Orgeta V, Costafreda SG, Huntley J, Ames D, *et al.* Dementia prevention, intervention, and care. *Lancet* 2017;**390**:2673–734.
41. Hodgson S, Hayes H, Cubi-Molla P, Garau M. Evidence Review in England, Wales, and Northern Ireland. Inequalities in Dementia: Unveiling the Evidence and Forging a Path Towards Greater Understanding. OHE Contract Research Report, London: Office of Health Economics. 2024. URL: <https://www.ohe.org/publications/inequalities-in-dementia> (accessed 18 July 2025).
42. Mukadam N, Marston L, Lewis G, Mathur R, Rait G, Livingston G. Incidence, age at diagnosis and survival with dementia across ethnic groups in England: a longitudinal study using electronic health records. *Alzheimers Dement* 2023;**19**:1300–7.
43. Ownby RL, Saeed M, Wohlgemuth W, Capasso R, Acevedo A, Peruyera G, Sevush S. Caregiver reports of sleep problems in non-Hispanic White, Hispanic, and African American patients with Alzheimer dementia. *J Clin Sleep Med* 2010;**6**:281–9.
44. Gallagher VT, Reilly SE, Williams IC, Mattos M, Manning C. Patterns of sleep disturbances across stages of cognitive decline. *Int J Geriatr Psychiatry* 2023;**38**:e5865.
45. Hayanga B, Stafford M, Saunders CL, Becares L. Ethnic inequalities in age-related patterns of multiple long-term conditions in England: analysis of primary care and nationally representative survey data. *Sociol Health Ill* 2024;**46**:582–607. <https://doi.org/10.1111/1467-9566.13724>
46. Office for National Statistics (ONS). *Statistical Bulletin, Ethnic Group, England and Wales: Census 2021*. Released 29 November 2022, ONS website.; 2021. URL: www.ons.gov.uk/peoplepopulationandcommunity/culturalidentity/ethnicity/bulletins/ethnicgroupenglandandwales/census2021#cite-this-statistical-bulletin (accessed 18 July 2025).
47. Office for National Statistics (ONS). *Statistical Bulletin, Education, England and Wales: Census 2021*. Released

10 January 2023, ONS website; 2021. URL: www.ons.gov.uk/peoplepopulationandcommunity/education-andchildcare/bulletins/educationenglandandwales/census2021#:~:text=There%20were%2011.5%20million%20schoolchildren,aged%20five%20years%20and%20over (accessed 18 July 2025).

48. NIHR. *Improving Inclusion of Under-Served Groups in Clinical Research: Guidance from the NIHR-INCLUDE Project*; 2020.
49. NICE. *Dementia: Assessment, Management and Support for People Living with Dementia and Their Carers* [NICE Guideline 97]. London: NICE; 2018.