

Longitudinal remote sleep and cognitive research in older adults with mild cognitive impairment and dementia: a prospective feasibility cohort study

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Abstract

Background: Sleep holds promise as a modifiable risk factor for neurodegenerative diseases and dementia. Clinical trials to modify sleep in people at-risk or at early stages of dementia are needed. Monitoring naturalistic sleep from home would support pragmatic and decentralised large-scale clinical trials. However, whether longitudinal sleep research can be successfully delivered remotely in this population had not yet been established.

Objective: We investigated the feasibility of remote longitudinal research using wearable devices and smartphone applications to record sleep and cognition in older adults with mild cognitive impairment (MCI) or dementia.

Methods: Older adults with MCI or dementia due to Alzheimer's disease (AD) or Lewy body disease (LBD) and cognitively healthy participants completed at-home sleep and circadian monitoring (digital sleep diaries, actigraphy, wearable sleep electroencephalography (EEG), saliva samples) and digital cognitive assessments for 8 weeks. Feasibility outcomes included recruitment, retention, and data completeness.

Results: 41 participants consented (10 AD, 11 LBD, and 20 controls) and 40 completed the 8-week study. Data completeness for sleep EEG was 91% and ranged from 79% to 97% for all remote tasks. 12/40 (30%) participants reported receiving external support with completing study tasks.

Conclusions: Longitudinal multimodal sleep and cognitive profiling using novel technology is feasible in older adults with MCI and dementia and healthy older adults.

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Original Manuscript

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VGG: Conceptualisation, Methodology, Software, Project administration, Resources, Investigation, Data curation, Formal analysis, Visualisation, Writing – Original draft preparation, Writing – Review & editing. **JB:** Conceptualisation, Methodology, Software, Formal analysis, Investigation, Writing – Review & editing, Funding acquisition. **HDM:** Conceptualisation, Methodology, Investigation, Writing – Review & editing, Funding acquisition. **HL:** Investigation, Project administration, Formal analysis. **AK:** Conceptualisation, Methodology, Formal analysis. **NT:** Methodology, Funding acquisition, Writing – Review & editing. **RG:** Conceptualisation, Funding acquisition. **BB:** Methodology. **EC:** Conceptualisation, Methodology, Resources, Writing – Review & editing, Supervision, Funding acquisition.

Abstract

BACKGROUND: Sleep holds promise as a modifiable risk factor for neurodegenerative diseases and dementia. Clinical trials to modify sleep in people at-risk or at early stages of dementia are needed. Monitoring naturalistic sleep from home could support pragmatic and decentralised large-scale clinical trials. However, whether longitudinal sleep research can be successfully delivered remotely in this population had not yet been established.

OBJECTIVE: We investigated the feasibility of remote longitudinal research using wearable devices and smartphone applications to record sleep and cognition in older adults with mild cognitive impairment (MCI) or dementia.

METHODS: Older adults with MCI or dementia due to Alzheimer's disease (AD) or Lewy body disease (LBD) and cognitively healthy participants completed at-home sleep and circadian monitoring (digital sleep diaries, actigraphy, wearable sleep electroencephalography (EEG), saliva samples) and digital cognitive assessments for 8 weeks. Feasibility outcomes included recruitment, retention, and data completeness.

RESULTS: 41 participants consented (10 AD, 11 LBD, and 20 controls). Participants were predominantly male and White British with a mean age of 71 years. Retention was very high, with 40 participants completing 8 weeks of remote monitoring. Data completeness for sleep EEG was 91% and ranged from 79% to 97% for all remote tasks and was overall high across all participant subgroups. 12/40 (30%) participants reported receiving external support with completing study tasks.

CONCLUSIONS: High rates of retention, data completeness, and data quality suggest that longitudinal multimodal sleep and cognitive profiling using novel and remote monitoring technology is feasible in older adults with MCI and dementia and healthy older adults, even without study partner support. Remote monitoring should be considered for mechanistic and interventional trials. Careful consideration should be given on how to ensure remote monitoring technologies reduce burden and enhance inclusivity, particularly in communities traditionally under-served by research and those with lower digital literacy.

Keywords

feasibility; sleep; remote study design; mild cognitive impairment; dementia; electroencephalography; EEG; actigraphy; saliva; digital biomarkers

Introduction

Sleep disturbances such as insomnia, fragmented sleep, daytime sleepiness, and sleep-disordered breathing are common features of Alzheimer's disease (AD) and Lewy body disease (LBD) and often appear early in the disease course and before clinical diagnosis [1, 2]. Short and fragmented sleep are associated with processes linked to neurodegeneration including reduced glymphatic clearance of waste [3], increased amyloid beta (A β) and tau burden [4], increased neuroinflammation [5], and impaired cardiovascular health [6]. Several small studies of sleep apnoea treatment have demonstrated improvement in cognitive outcomes and blood biomarkers of amyloid and tau, suggesting that sleep interventions could improve prognosis in mild cognitive impairment (MCI) and dementia [7-9]. Poor quality or insufficient sleep in midlife increases risk of all-cause dementia and MCI [10, 11], indicating that improving sleep may also protect against dementia. Large-scale clinical studies are needed to enhance our mechanistic understanding of sleep, confirm the most promising therapeutic targets, and monitor the effectiveness and safety profile of sleep interventions [12, 13].

However, selecting sleep assessment tools is challenging, particularly in populations with cognitive

impairment. Self-report is convenient, inexpensive, and scalable, and has often been used to examine sleep in people with dementia and MCI [14], however it is potentially prone to recall bias due to memory deficits or anosognosia. Self-report also correlates poorly with objective sleep measures, particularly in participants with MCI or dementia [15, 16] and those with subjectively poor sleep [17], and cannot inform on key components of sleep such as sleep staging or micro-architecture. Polysomnography (PSG) is typically considered the gold standard for sleep measurement, as it provides rich objective sleep data. However, PSG typically requires expert set-up, analysis, and a controlled clinic environment, meaning it is expensive, not easily scalable, and therefore typically used for one or a few nights [18, 19]. PSG set-up, especially in an artificial environment, may also not reflect natural sleep [19] as it disrupts usual routines. Longitudinal data collection in sleep research would be beneficial for monitoring clinical trials and disease progression, and could account for variation in sleep from external factors such as acute illness or stress as well as naturalistic intra-individual sleep variation [19].

Wearable devices, smartphone applications and telemedicine, with the exception of actigraphy devices, have rarely been utilised in MCI or dementia research [20], but offer an opportunity to collect objective and subjective data longitudinally in a natural setting [21], often at relatively low-cost. Detailed and accurate sleep analysis can now be achieved through wireless technology, including electroencephalography (EEG) headbands and overnight pulse oximetry [21, 22]. While actigraphy has been used in dementia research, EEG headbands and pulse oximetry are less well tested, especially in the earlier stages of impairment [23-25]. There is also increasing interest in remote cognitive testing and digital biomarkers for diagnosis and monitoring progression [26]. Despite this, the adoption of digital health technologies into neurology clinical trials, particularly in older people, has been slow [27].

Remote sleep and cognitive data collection has potential to de-centralise clinical trials, making research more convenient for participants and reducing the costs, participant burden, and carbon footprint associated with study visits, whilst enabling real-time longitudinal data collection of treatment effects. Improved digital access and literacy among older adults [28] and the use of technology among patients living with MCI/dementia to support independent living and for recreation indicates increasing acceptance of technology [29]. However, not all older adults are comfortable using technology, and changes to cognition, sensory processing, and communication might negatively impact the usability and acceptability of novel devices for research purposes in people with cognitive impairment [29, 30]. The few studies which have tested wearable devices and digital health technologies for sleep and dementia research in the home have predominantly collected feasibility data for a single device across only a few nights [31] and required support from a study partner or care home staff [32-34]. Before trials invest in digital health technologies and remote study designs, it is important to know whether participants can and are willing to engage and provide data in such studies over a longer period and how much support might be required. This study aimed to establish feasibility of predominantly technology-based sleep and cognitive assessments longitudinally from home in older adults with and without MCI/dementia.

Methods

The Remote Evaluation of Sleep To enhance understanding of Early Dementia (RESTED) study was a prospective longitudinal observational cohort study involving remote sleep and cognitive monitoring of participants with MCI or dementia and age-matched cognitively healthy controls. The full study protocol has been previously published online [35]. The study has been reported in line with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (Supplementary Materials 1) and was approved by the Health Research Authority (Yorkshire and the Humber—Bradford Leeds Research Ethics Committee, reference 21/YH/0177). This study was conducted in accordance with the principles of the Declaration of Helsinki [36]. All

participants provided written informed consent prior to engaging in any study activities.

Study population

The RESTED study recruited community-dwelling adults aged 50 years or older with internet access at home. Participants were recruited to one of three participant subgroups according to clinical diagnosis meeting standardised diagnostic criteria [37-40]. Participants with MCI or mild dementia due to probable AD were recruited to the AD group, participants with MCI or mild dementia due to probable LBD or Parkinson's disease (PD) were recruited to the LBD group, and sex- and age-matched individuals with no known neurodegenerative conditions or cognitive impairment were recruited as controls. Exclusion criteria included advanced dementia, acute or terminal illness, and significant unrelated comorbidities which might interfere with sleep, except for individuals undergoing treatment for OSA.

Participants were recruited from the city of Bristol, United Kingdom and the surrounding areas via cognitive and movement disorders clinics and research volunteer databases, including Join Dementia Research. Our original target sample size of 75 participants [41]. Due to the coronavirus pandemic, the study was delayed and the budget was partially re-allocated to studies which required no patient contact [13, 42, 43]. Therefore, we revised the target sample size to 40 participants and recruited from a single site (North Bristol NHS Trust).

We did not recruit nor require participants to have a study partner. Participants were welcome to invite someone to support them and study support was recorded.

Study procedures

Screening and baseline

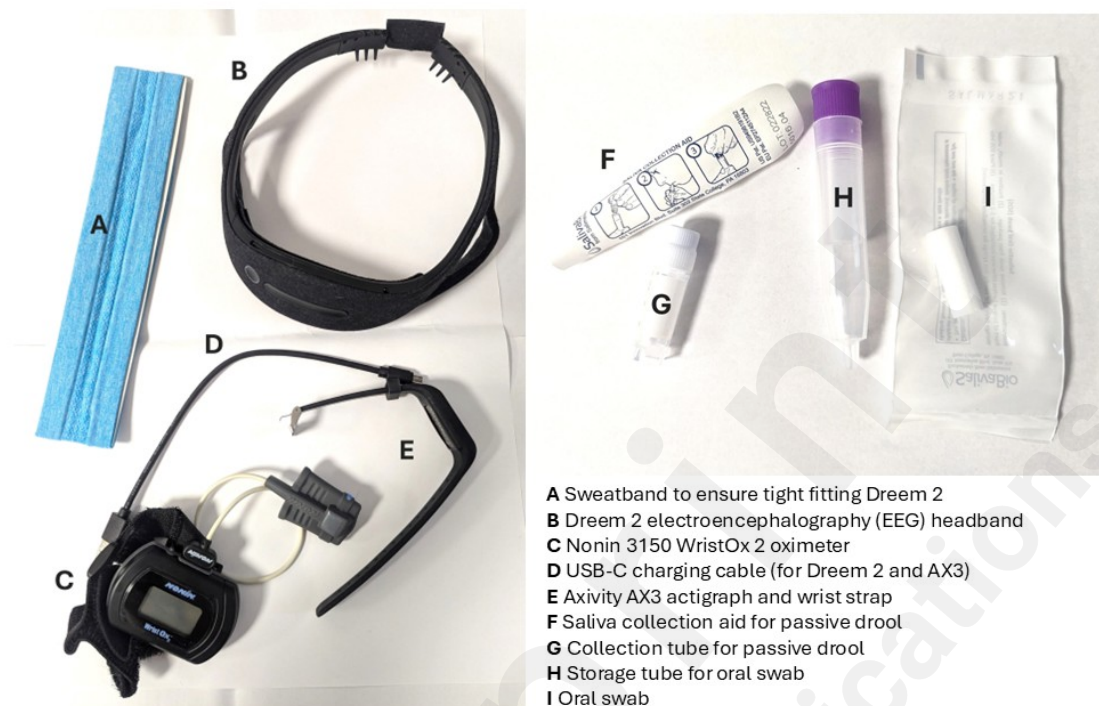
Participants were pre-screened for eligibility over the telephone and invited to complete consent and screening in-person. Participants who scored less than 11/30 on the Montreal Cognitive Assessment (MoCA) at screening were considered too clinically impaired to participate and were withdrawn. Eligible participants completed baseline questionnaires with a researcher to assess sleep quality (Pittsburgh Sleep Quality Index, PSQI [44]), daytime sleepiness (Epworth Sleepiness Scale, ESS [45]), OSA risk (STOP-Bang [46]), symptoms of depression (Geriatric Depression Scale – 15 item, GDS [47]), anxiety (Generalised Anxiety Disorder - 7 item, GAD-7 [48]), and apathy (Apathy Evaluation Scale – Self, AES-S [49]). Demographic information and medical histories were also recorded.

Participants were provided with a study kit (**Figure 1**) consisting of an Axivity AX3 actigraphy watch, Dreem 2 wireless sleep EEG headband [23], a USB charger, a home saliva collection kit for passive drool (for a dim-light melatonin onset assay) and oral swabs (for a cortisol awakening response assay) and an overnight pulse oximeter. Participants who requested a study device were provided with a tablet. Details on devices and the study kit are provided in **Supplementary Materials 2**. All participants were provided with a printed participant guide with instructions for each remote study task and research team contact details.

Figure 1. The study kit provided to RESTED participants. Participants were additionally required to use a smartphone or tablet to complete digital assessments.

At baseline, participants were provided with support to download and use the MyDignio application,

a



telemedicine cloud-based software which was used to deliver digital sleep diaries, questionnaires, and reminders to complete study tasks. Participants were also familiarised with the study schedule and tasks and offered support and training ad-hoc throughout the study.

Main study period

Participants completed 56 days of continuous sleep and regular cognitive monitoring in their own home using an Axivity AX3 actigraphy watch and daily sleep diaries [50] delivered via the MyDignio application. Participants were scheduled to complete a set of three online cognitive tests (choice reaction time, forward digit span, self-ordered search) twice weekly on a bespoke study version of the online assessment platform Cognitron (<http://www.cognitron.co.uk/>).

Intensive week

For 7 days during the 8-week period, participants also completed an “intensive week”, consisting of daily cognitive tasks on Cognitron and nighttime sleep recordings using the Dreem 2, a wireless sleep EEG headband. The Dreem sleep staging algorithm has comparable accuracy to manual sleep expert scoring of PSG [23], including in cognitively healthy older adults as well as patients with AD [51] and PD [52]. Sleep recordings were initiated by the participant at their natural bedtime each night and terminated after natural awakening each morning. Data was uploaded via Bluetooth and Wi-Fi to a server accessible to the research team. Additional study tasks during the intensive week included four verbal memory assessments involving immediate and delayed free recall and a target-distractor recognition task with a researcher via videoconferencing software and serial saliva samples across one evening to assess dim-light melatonin onset and one morning to assess cortisol awakening response.

Participants were also invited to undergo two nights of pulse oximetry for sleep apnoea screening

and a blood test for plasma biomarker analysis of A β 42:40, phosphorylated tau (p-tau) 181 and 217, neurofilament light chain (NFL), and glial fibrillary acidic protein (GFAP). A protocol amendment approved partway through the study introduced bespoke questionnaires probing study expectations, reasons for participation, experience with technology, and how acceptable they found the intensive week study tasks. Participants were also invited to attend a remote end-of-study interview to share their experiences and asked to return for a 6-month follow-up to complete a MoCA and any outstanding study tasks (e.g., missed blood test). Participant feedback from qualitative interviews and questionnaires as well as sleep characteristics for the cohort will be analysed and presented separately.

Feasibility and acceptability outcomes

Recruitment and retention

Consent, recruitment, and retention rates were recorded and are summarised in a flowchart, alongside reasons for non-participation at each stage of the recruitment process.

Data quality and completeness

For each remote study task, data completeness was assessed by the average number and percentage of completed tasks or nights' use per participant per participant group (data completeness rate). The number and percentage of individuals who completed the maximum number of data points for a given study task (e.g., completed all requested 7 nights of EEG) is also provided. For EEG, signal quality is reported based on Dreem's automated algorithm. Optimal signal quality is considered $\geq 85\%$ and good quality is considered $\geq 70\%$.

Associations between participant characteristics and adherence

To explore potential associations between key clinical and demographic variables and adherence, we examined the correlation between two continuous measures of adherence (number of sleep diaries completed and mean record quality of Dreem EEG data) and four continuous variables which might impact digital literacy and/or engagement (age at consent, apathy, subjective sleep quality as assessed by the PSQI total score, and baseline cognitive impairment as assessed by MoCA total score).

Study support and resource use

The number of participants who attended study visits with someone to support, reported having a partner or relative who could support study tasks, and reported receiving support on at least one study task was recorded and is summarised descriptively.

Data analysis

Unless otherwise stated, descriptive statistics are provided as mean (standard deviation, SD) for continuous variables, and frequency and percentage for categorical variables, and provided for the full cohort as well as by participant subgroup (AD vs LBD vs controls). Data analysis was performed using R (version 4.3.1) and R Studio software (version 2023.6.0.421). Actigraphy data was processed using the open source AX3/AX3 OGUI application and analysed in R using the *GGIR* package[53]. Where available, sleep timing was adjusted using participants' sleep diaries, otherwise *GGIR* uses the Heuristic algorithm looking at Distribution of Change in Z-Angle (HDCZA)[54] to estimate sleep timing. All files were also visually inspected to check for accuracy of sleep timing. Quality of the Dreem 2 recordings was assessed by inspecting Dreem's automated record quality index in the sleep report for each night, which indicates the percentage of the recording that is of scorable quality for sleep analysis. Associations between participant characteristics and adherence

were calculated using Spearman's rank correlation with alpha set to $p < 0.05$. Reasons for non-participation and missing data are provided where known and mapped to the Capability Opportunity Motivation model of behaviour change (COM-B model)[55]. Where additional data was collected on any outcome (e.g., participants completed an additional night of EEG than instructed), additional datapoints are removed prior to analysis to avoid biasing feasibility metrics.

Patient and public involvement

Patient and public involvement (PPI) was sought from individuals with lived experience of MCI and dementia before and throughout the study. PPI contributors reviewed and improved study documents and advised on the acceptability of adding blood biomarker testing. The PPI group strongly endorsed our additional recruitment materials (including an advertisement poster and a Plain English participant information sheet) that we introduced partway through the study, after we received feedback from a prospective participant that standard participant information sheets are too long and use inaccessible language for people with cognitive impairment. We also introduced a reduced study protocol which involved use of a paper (rather than digital) sleep diary, actigraphy, and EEG, to encourage recruitment of participants who may be more comfortable with less frequent use of technology, however nobody chose the reduced protocol; they either declined altogether or participated in the full study.

Results

Participant characteristics and enrolment

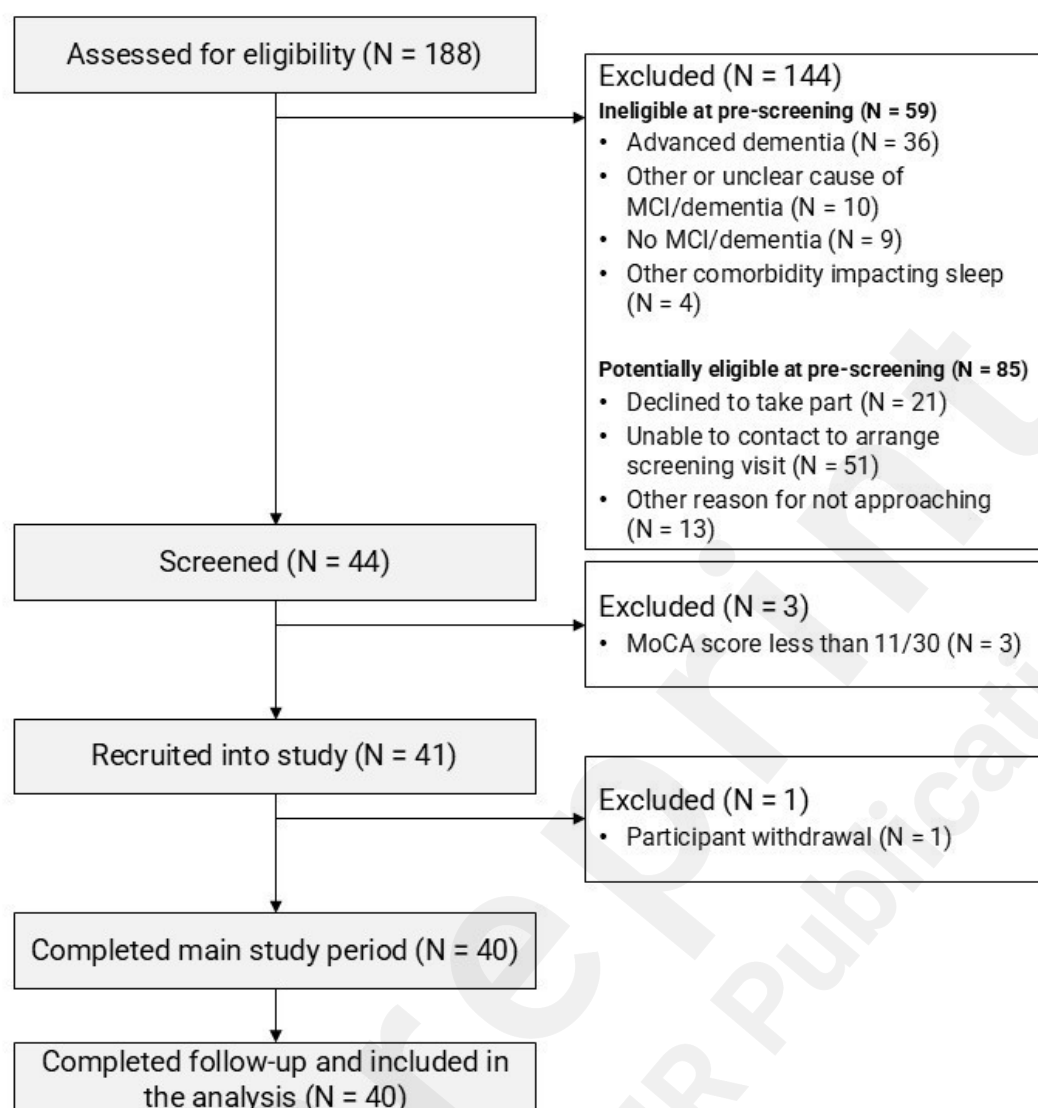


Figure 2. Participant flow through the RESTED study. Of 129 potentially eligible participants, 44 (34%) consented to participate and 41 (32%) were recruited. Retention was very high (98%).

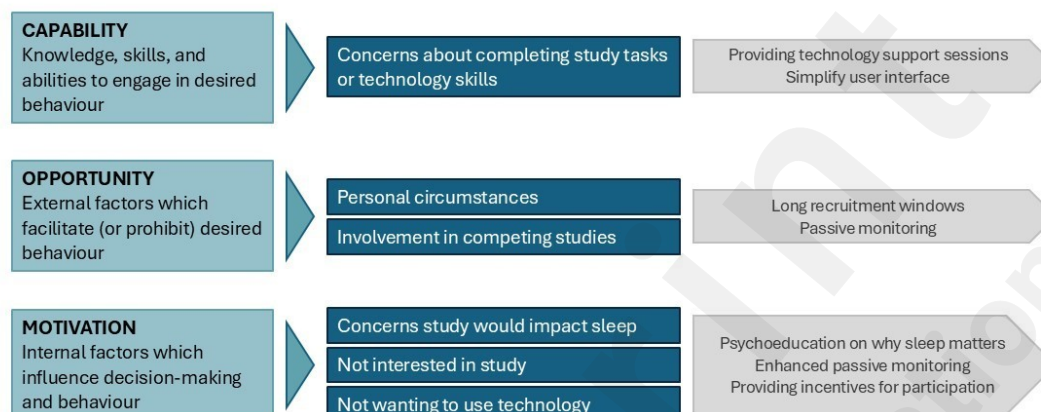
Recruitment

Participant flow through the study is shown in **Figure 2**. Recruitment was open for 17 months from February 2022 to July 2023 with an average recruitment rate of 3 participants per month. Of 129 individuals identified as potentially eligible during pre-screening, 44 individuals consented to take part, giving a consent rate of 34%. Participants described different motivations for taking part, including wanting to support dementia research, perceiving the study as helpful for themselves and/or others, and because the study sounded interesting or novel. Reasons for declining to take part in the study are described in **Figure 3** and mapped to the Capability Opportunity Motivation-Behaviour (COM-B) model of behaviour change [55].

Figure 3. Reasons for declining to participate in the study could be categorised according to the Capability Opportunity Motivation-Behaviour (COM-B) model of behaviour change (blue). Opportunities to increase capability, opportunity, and motivation to take part in the research are outlined (grey).

Retention

Of 44



individuals who completed screening, three scored less than 11 on the MoCA and were withdrawn. 41 participants were eligible and completed all baseline assessments and training in the at-home study tasks. One participant withdrew prior to starting the at-home study tasks due to personal circumstances and perceived study burden. All remaining 40 participants completed the main 8-week study period and 6-month follow-up and were included in the analysis, giving a retention rate of 98%.

Participant characteristics

Participant demographics and baseline variables are presented in **Table 1**. The sample was predominantly male with a mean age at consent of 70.9 years (SD = 5.9, range = 57 to 81). Most participants were retired (82.5%) and all identified as White British. 25/40 participants completed a questionnaire on experiences of digital technology and expectations of the study, which was introduced via an amendment

Table 1. Participant characteristics for the study cohort.

	AD group N=10	LBD group N=10	Control group N=20
Diagnosis at consent ¹			
Mild cognitive impairment	4 (40%)	6 (60%)	0
Dementia	6 (60%)	4 (40%)	0
Blood biomarkers of neurodegeneration/AD pathology ¹ , pg/mL	0.064 (0.006)	0.062 (0.006)	0.072 (0.007)

Aβ40:42	26.2 (7.1)	24.9 (12.7)	24.9 (12.7)
p-tau181	0.7 (0.4)	0.8 (0.4)	0.6 (0.4)
p-tau217	102.2 (28.1)	140.9 (56.4)	103.5 (48.1)
GFAP	23.9 (18.0)	18.7 (6.5)	13.4 (5.1)
NFL			
Age at consent, years	69.2 (7.9)	73.9 (2.8)	70.3 (5.7)
Female sex ¹	2 (20%)	2 (20%)	5 (25%)
Employment status ¹			
Full-time employment	2 (20%)	0	2 (10%)
Part-time employment	0	0	3 (15%)
Retired	8 (80%)	10 (100%)	15 (75%)
Education ¹			
Secondary (≤ 12 years)	4 (40%)	5 (50%)	4 (20%)
Further or higher (> 12 years)	6 (60%)	5 (50%)	16 (80%)
Co-morbid diagnoses ¹			
Obstructive sleep apnoea*	0	1 (10%)	2 (10%)
Musculoskeletal/pain	3 (30%)	3 (30%)	8 (40%)
Urinary/prostate	3 (30%)	2 (20%)	3 (15%)
Depression/anxiety	1 (10%)	0	1 (5%)
Medications ¹			
Cognitive enhancer	6 (60%)	6 (60%)	0
Dopaminergic	0	8 (80%)	0
Melatonin	0	3 (30%)	0
Hypnotic/sedative	0	2 (20%)	1 (5%)
Antidepressant	4 (40%)	4 (40%)	4 (20%)
Baseline cognition ² : MoCA	23.0 (4.9)	22.0 (4.3)	27.1 (1.4)
Subjective sleep quality ² : PSQI	4.3 (2.0)	7.8 (3.0)	6.0 (3.9)
Self-reported anxiety ² : GAD-7	5.6 (5.2)	3.5 (2.1)	3.6 (4.3)
Self-reported depression ² : GDS-15	4.5 (3.3)	4.1 (2.3)	2.2 (2.2)
Self-reported apathy ² : AES-S**	62.2 (6.0)	53.8 (9.9)	62.8 (8.6)

¹ Frequency (%); ² Mean (SD); *Participants with obstructive sleep apnoea were included only if they were on treatment with continuous positive airway pressure; ** One participant had a missing value for one item, so this score was imputed using simple imputation. *Abbreviations:* MoCA: Montreal Cognitive Assessment; PSQI: Pittsburgh Sleep Quality Index; GAD-7: Generalised Anxiety Disorder – 7; GDS-15: Geriatric Depression Scale – 15-item scale; AES-S: Apathy Evaluation Scale – Self; SD: standard deviation.

partway through the recruitment period. Of these, most participants reported frequent use of

smartphones or other smart technology (18/25, 72%), however only 3/25 (12%) participants had previously used a wearable to monitor their sleep.

Data quality and completeness (adherence)

Adherence to the sleep and cognitive tasks is shown in **Table 2**. Adherence was very high across all study groups and tasks. Reasons for missing data are summarised in **Figure 4** with additional detail provided in **Supplementary Materials 3**.

Table 2. Summary of feasibility outcomes relating to data quality and adherence for wearable devices and remote/online cognitive assessments.

Study task (Device/Software) Description	Adherence/data quality metric	AD (N=10)	LBD (N=10)	Controls (N=20)	Total (N=40)
Wearable devices					
Sleep EEG (Dreem 2) <i>Participants were asked to complete 7 nights of consecutive overnight EEG recordings to record nighttime sleep.</i>	Number of nights	5.9 (2.0)	6.5 (0.7)	6.6 (0.9)	6.4 (1.2)
	Full dataset provided (7 nights)	7/10 (70%)	6/10 (60%)	16/20 (80%)	29/40 (73%)
	Average record quality*	83.5 (12.1)	84.1 (15.0)	85.0 (18.4)	84.4 (15.8)
Actigraphy (Axivity AX3) <i>Participants were asked to complete 24-hour wrist actigraphy continuously for 8 weeks (56 nights).</i>	Number of nights	50.3 (13.1)	52.2 (6.8)	54.4 (3.2)	52.8 (7.6)
	Full dataset provided (56 nights)	5/10 (50%)	5/10 (50%)	14/20 (70%)	24/40 (60%)
Pulse oximetry (Nonin WristOx2 3150) <i>Participants were asked to complete 2 nights of overnight pulse oximetry.</i>	Completed 1+ recording	9/10 (90%)	6/9 (75%)	18/18 (100%)	33/37 (89%)
	Full dataset provided (2 nights)	6/10 (60%)	5/9 (63%)	15/18 (83%)	26/37 (70%)
Remote online assessments					
Digital sleep diary (MyDignio) <i>Participants were prompted to complete daily sleep diaries for 56 consecutive nights</i>	Number of diaries completed	48.2 (13.4)	51.1 (9.8)	53.8 (3.1)	51.7 (8.6)
	Full dataset provided (56 nights)	1/10 (10%)	4/10 (40%)	8/20 (40%)	12/40 (30%)
	Digit spans completed	17.6 (4.3)	17.6 (4.7)	16.8 (4.7)	17.2 (4.5)
Online cognitive tests (Cognitron) <i>Participants were prompted to complete a digit span, choice reaction time (CRT), and self-ordered search (SOS) tasks on 21 days across the 8 weeks.</i>	CRT completed	16.9 (4.2)	13.9 (7.5)	16.7 (4.8)	16.1 (5.4)
	SOS completed	17.5 (4.3)	17.5 (4.6)	16.6 (4.7)	17.0 (4.5)
	Completed 1+ online cognitive task	10/10 (100%)	8/10 (80%)	20/20 (100%)	38/40 (95%)
	Full dataset provided	2/10	2/10	2/20	6/40

			(all three cognitive tasks completed on 21 days)	(20%)	(20%)	(10%)	(15%)
Verbal memory tasks (Videoconferencing)		Number of memory tasks completed		3.2 (1.7)	3.4 (1.3)	3.9 (0.4)	3.6 (1.1)
<i>Participants were asked to complete two evening 'learn' tasks and two morning recall/recognition tasks scheduled with researchers.</i>			Full dataset provided (4 tasks completed)	8/10 (80%)	8/10 (80%)	19/20 (95%)	35/40 (88%)

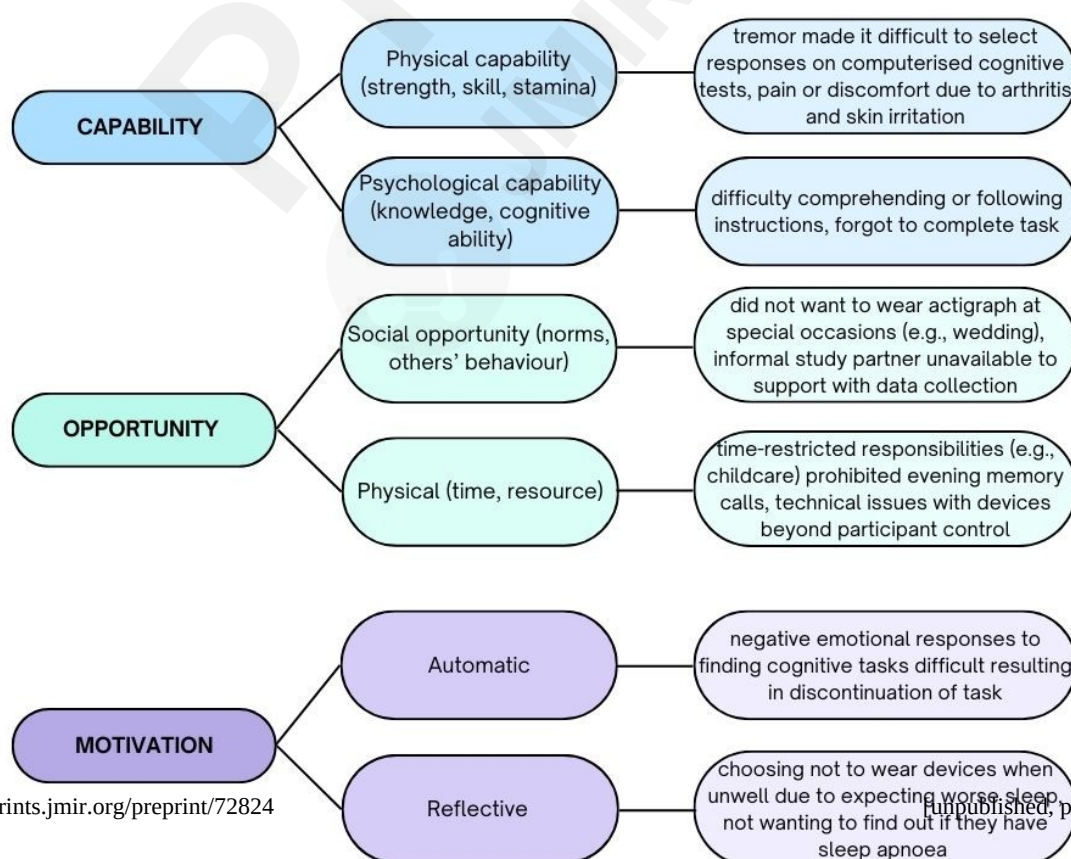
Data are provided as mean (SD) or N (%) unless otherwise stated. * Mean first calculated for each participant across all available recordings. *Abbreviations:* EEG = electroencephalography; AD = Alzheimer's disease; LBD = Lewy body dementia; CRT = Choice Reaction Time; SOS = Self-ordered search.

Sleep EEG

In total, 257 recordings were made using the Dreem 2. One participant accidentally completed an eighth recording which was removed from subsequent analyses to reduce bias.

All participants successfully recorded at least one night of sleep, with an average of 6.4 (1.2) nights across the cohort or 91.4% data completeness rate (**Table 2**). 29/40 (73%) provided data for all 7 nights. Average record quality was also high at 84.4% (15.8), indicating nearly optimal record quality on average across the cohort. One participant wore the Dreem 2 but did not successfully initiate the recording during the intensive week but completed 7 successful nights of recording on a second attempt later in the study. Record quality for individual EEG channels is provided in **Supplementary Material 4**.

Figure 4. Reasons for missing data are mapped the Capability Opportunity Motivation-Behaviour (COM-B) model of behaviour change.



Actigraphy

2,332 nights of data across the full cohort was collected. 189 of these nights contained no data, either at the beginning or the end of the actigraphy file and were removed from sleep analyses. Following visual inspection, a further 9 nights were removed due to sustained non-wear. Therefore, 2,134 nights were of sufficient quality for sleep analysis.

Across the cohort, participants provided an average of 52.8 (7.6) out of 56 analysable nights, giving a data completeness rate of 94.3%. 24/40 (60%) provided 56 analysable nights. All participants recorded at least 14 days' of actigraphy. Unexpected battery failure outside of participants' control (due to long-term storage without use during the coronavirus pandemic) affected two participants' recordings and was identified during data check at the midpoint study visit. No participants refused to wear or prolonged discontinued use of the actigraphy device, though several reported forgetting or choosing not to wear it on certain days or taking brief breaks due to minor skin irritation.

37 diary entries were manually entered based on visual analysis of the actigraphy data due to missing sleep diaries and poor HDCZA algorithm detection of the sleep period. Finally, the sleep analysis software was instructed to solely rely on sleep diary information for 166 nights due to clear misclassification of sleep period.

Overnight pulse oximetry

As three participants were already on treatment for established OSA, 37 participants were offered overnight pulse oximetry. Two participants (5.4%) declined, and one participant was unable to tolerate wearing the device. The remaining 33 (89.1%) participants completed at least one successful overnight recording, with 26 (70.3%) recorded successful oximetry traces on both nights. Data completeness rate was 79.7% for those eligible and asked to complete overnight pulse oximetry. Referrals to a sleep clinic for either sleep apnoea or incidental findings (such as abnormal pulse rise index) were indicated for 21/37 participants (56.8%). Four participants (10.8%) declined referral due to not wanting a formal diagnosis, not wanting to be put on sleep apnoea treatment, and inconvenience of travelling to the clinic. 17 (45.9%) participants agreed to a referral.

Digital sleep diaries

Although few participants completed all 56 sleep diaries (12/40, 30%), overall adherence was high. Participants completed an average of 51.7 (8.6) sleep diaries and only two participants completed fewer than 75% of their sleep diaries. Data completeness rate was 92.3%.

One participant completed sleep diaries on paper whilst her partner who facilitated entries into MyDignio was away. Three participants had technical issues with data entry into the MyDignio app lasting several days due to a software update and provided some of their sleep diaries via email which were then entered by the study team.

At the time of study set-up, Dignio did not offer data format validation and free-text response boxes were used for several questions. Participants often did not input data in the format requested and inconsistency in reporting prohibited reliable automated re-coding, however most were manually interpretable by the research team. Where a range of values were provided, a mean was calculated and the value was rounded to the nearest whole minute (e.g., 5 to 10 minutes was re-coded to 8 minutes). One diary entry was manually corrected by the research team to align with other diary entries and the actigraphy file. It was not possible to re-code some responses due to ambiguity (e.g., responses of "not long", "several minutes", or "unsure"), leaving 43 completed sleep diaries incomplete on at least one sleep variable. Questions most likely to have a missing value were questions on sleep onset latency and length of nocturnal awakenings.

Video-based verbal memory tasks

37/40 (92.5%) participants completed at least one completed verbal memory task with a researcher.

Data was missing for one participant as the task was considered inappropriate due to their specific language difficulties, one participant due to technical issues with video calling, and one due to distress during the first learning trial. Most participants (35/40, 88%) completed all four verbal memory tasks, with two participants completing only two of the tasks due to work or childcare commitments. Overall, data completeness rate was 90%. Three participants reported finding the task difficult, two reported feeling distracted during the encoding tasks, two reported finding the encoding task distracting rather than helpful, and two reported finding that usual memory techniques such as the story technique or rehearsing words in an auditory loop were difficult to do in this task. One participant commented that they already write a brief diary of things that happened that day.

Online cognitive tests

Few participants completed all 21 cognitive tasks: 6 (15%) participants completed all three cognitive tasks on all 21 occasions. 7 (17.5%) provided complete data for CRT tasks, 8/40 (20%) for the SOS, and 9 (22.5%) for the digit span task. However, on average data completeness was good with 79.8% of allocated online cognitive tasks completed. One participant with PD attempted the tasks but stopped due to frustration at not being able to do the tasks, as they required speed and accuracy. Several participants reported misunderstanding the CRT task and clicking outside of the response window.

Saliva samples

Outcomes for saliva and blood samples are summarised in **Table 3**.

Dim-light melatonin assay: Passive drool samples

Most saliva samples (272/280, 97%) were collected as requested. Data completeness rate for analysable samples was 97.1% across the cohort. One participant provided no saliva samples, and 1 participant provided 9/10 samples. Participant-reported sample times were available for 236/272 (86.7%) samples. 120/236 (51%) samples were reported to have been completed within 15 minutes of the scheduled time, as calculated by average bedtimes reported in the sleep diary. On average, participants completed their samples around 7 minutes early (*Table 3*). Previous studies have identified highly variable salivary melatonin secretion, with peaks from 2 pg/mL to 84 pg/mL [56]. Across the cohort, values ranged from beneath detectable levels (<1.37 pg/mL) to 92.4 pg/mL.

Table 3. Outcomes relating to data quality and adherence for biomarker analysis: blood biomarkers, salivary dim-light melatonin and salivary cortisol awakening response.

Study task (Sample type) <i>Description</i>	Adherence/data quality metric	AD (N=10)	LBD (N=10)	Controls (N=20)	Total (N=40)
	Number of participants who provided blood for biomarker testing	9/10 (90%)	10/10 (100%)	18/20 (90%)	37/40 (92.5%)
Neurodegenerative and AD biomarker samples (Blood)	Number of samples analysed for all biomarkers	8/10 (80%)	8/10 (80%)	14/20 (70%)	30/40 (75%)
<i>Participants were asked to have blood drawn for biomarker testing.</i>	Number of samples analysed for 1+ biomarker	9/10 (90%)	10/10 (100%)	18/20 (90%)	37/40 (92.5%)
Melatonin samples (Passive drool)	Analysable samples provided per	6.3 (2.2)	6.9 (0.3)	7.0 (0.0)	6.8 (1.1)

Participants were asked to complete 7 hourly samples across one evening, starting from 5 hours before bed, and record the sample time	participant ¹ Participants who completed all 7 samples ²	9/10 (90%)	9/10 (90%)	20/20 (100%)	38/40 (95%)
	Average discrepancy between scheduled time and reported time of completion (mins)*	5.6 (53.4)	-13.9 (32.6)	-9.2 (37.1)	-7.0 (41.0)
Cortisol samples (Oral swab)	Analysable samples provided per participant ¹	2.7 (0.9)	3.0 (0.0)	3.0 (0.0)	2.9 (0.5)
Participants were asked to complete 3 samples across one morning: at wake, wake + 30 minutes, and wake + 60 minutes, and record the sample time	Participants who completed all 3 samples ²	9/10 (90%)	10/10 (100%)	20/20 (100%)	39/40 (98%)
	Average discrepancy between scheduled time and time completed (mins)*	22.5 (27.8)	24.3 (17.0)	24.6 (23.8)	24.0 (23.2)

*Positive numbers here refer to a sample being taken later than scheduled, and negative numbers refer to a sample being taken earlier than scheduled. ¹Mean (standard deviation); ²Frequency (%). Abbreviations: AD = probable Alzheimer's disease dementia or mild cognitive impairment; LBD = mild cognitive impairment or dementia due to probable Lewy body disease or Parkinson's disease.

Cortisol awakening response: oral saliva swabs

Participants were instructed to provide saliva samples at wake, after 30 minutes, and after 60 minutes on one morning during the intensive week. Data completeness rate for analysable samples was 96.7% across the cohort. We compared reported saliva sample timings to their scheduled timings, based on final awakening time estimated by EEG. Participant-reported sample times and EEG awakening time was available for 85/117 (72.6%) cortisol samples. Two participants' EEG recordings (6 samples) suggested wake times later than the first sample recording time and were removed from analysis due to suspected error in recorded saliva timing or date. Participants recorded their first cortisol saliva swab an average of 23 minutes after awakening and overall cortisol samples were generally 24 minutes later than scheduled across the three timepoints (*Table 3*). Previous studies have identified variable salivary cortisol awakening values from 3 µg/L to 19 µg/L in healthy adults[57]. Across the cohort, values ranged from 0.9 µg/L to 13.4 µg/L.

Associations between participant characteristics and adherence

There was some evidence of a weak correlation between MoCA score at baseline and EEG record quality, where those with greater cognitive impairment had lower average EEG record quality ($r = 0.31$, $p = 0.05$). Spearman's rank correlations revealed no evidence of correlations between EEG record quality and age ($r = -0.10$, $p = 0.54$), apathy ($r = 0.16$, $p = 0.31$), or PSQI score ($r = 0.19$, $p = 0.24$). There was also no evidence of correlation between the number of sleep diaries completed and age ($r = -0.15$, $p = 0.35$), MoCA score ($r = 0.11$, $p = 0.48$), apathy ($r = 0.07$, $p = 0.69$), or PSQI score ($r = 0.12$, $p = 0.47$).

Resource use

Support from partners and relatives

36% (4/11) of individuals with AD, 85% (11/13) of individuals with PD or LBD, and 10% (2/20) controls attended their consent visit with a partner or relative. 32/40 (80%) participants reported that there would be someone external to the research team (e.g., partner or relative) who could support them with study tasks if needed at baseline. 12/40 (30%) participants reported receiving support with completing study tasks (3 AD, 8 LBD, 1 control). Support from outside of the study team was predominantly from partners and included reminders to complete tasks, device set-up, and troubleshooting technical problems. Three participants who required technical support from a partner or relative or used their devices to complete study tasks reported missing study tasks due to their partner or relative being unavailable during the study period. The participant who withdrew following baseline reported having someone who could support them at home.

Support and contact with the research team

Participants received in-person and remote training and support from a researcher to complete study tasks at baseline (including downloading and setting up applications and turning on recording devices) and offered a refresher training session prior to the intensive week. Participants were also provided with a written instruction manual, scheduled in-app and email reminders, and ad-hoc support as requested by participants or where the team noticed three or more consecutive days of missing sleep diary data. All participants had at least one in-person visit from a researcher (e.g., to download midpoint actigraphy data or retrieve study equipment) during the study period. Participants were advised to contact the research team if they had questions during the study by their preferred method (from email, phone, video call, or instant messaging on the MyDignio app). Support from the research team during the study was most often provided by e-mail and involved responding to participant queries on initial set up (e.g., downloading the MyDignio app), reminders (e.g., tasks to complete or passwords), and technical issues (e.g., links not arriving for Cognitron). Some participants also requested telephone-based, video-based, or home-based support (e.g., to refresh training on the intensive week study tasks). Most participants did not receive regular reminders from the study team to complete tasks.

Device use

One participant was provided with a study tablet upon request, as they wanted to keep study activities and apps separate to their personal devices. All other participants used their own smart devices for study activities (i.e., smartphones, tablets, and personal computers). Most participants utilised more than one device to complete online study tasks due to personal preference or convenience. No devices provided by the study team were lost or damaged during the study, though some participants cut the actigraphy watch strap for comfort.

Discussion

Here, we show that it is feasible to remotely measure sleep and cognition longitudinally in community-dwelling older adults with MCI and dementia due to AD and LBD and healthy older adults. Eligible participants were interested in, enrolled, and remained in the study, despite being asked to complete a high volume of remote and novel study tasks across an eight-week period whilst continuing their usual routines. Only one participant withdrew from the study, and this was before remote data collection started. Most participants were receptive to multimodal home-based research using technology and alternatives to in-lab sleep assessment. Across the cohort, data completeness rate was high and ranged from 79.8% to 97.1%. Our findings support the use of remote, technology-supported research methods to study naturalistic sleep in future trials and indicate some areas where

further improvements and refinements would be helpful. With just under half of our sample having possible undiagnosed sleep apnoea, our results also highlight the importance of sleep apnoea screening in older adults, as a risk factor and potentially reversible contributor to cognitive impairment and poor sleep quality [58].

Many older adults with MCI and dementia routinely leverage technology for cognitive stimulation, performing activities of daily living (such as shopping and banking), entertainment, and socialising and utilise assistive technology solutions such as reminders and navigation to support independence [59]. However, cognitive impairment might impact ability to understand or remember to complete remote or technology-based study tasks, resulting in missing data, and may trigger anxiety if patients feel unable to perform tasks correctly [60]. Although a few previous studies had examined use of sleep wearables in adults with AD, this was typically done over a brief period, examined feasibility of using only one digital health technology, or required input from a carer or study partner [31-34, 61]. Our study demonstrates that older adults with MCI and dementia can successfully complete novel multimodal sleep and cognitive assessments including longitudinal concurrent use of wrist actigraphy, online cognitive tests, digital sleep diaries, and wireless EEG headbands. However, more effort will be required to recruit samples which are representative of the older adult population and those with MCI/dementia, as our study predominantly recruited White males who were familiar with smart technology, albeit not the devices used in RESTED.

Data completeness rates, reflecting both ability to complete study tasks and produce data of analysable quality, were high across all study tasks and participants. Remote data collection comes with a risk of missing data or non-adherence, however we were able to mitigate this risk by using devices which upload data to servers at regular intervals (e.g., Dreem, Dignio) and, less conveniently, by downloading data manually from devices to check compliance and data quality and offer support where needed (e.g., actigraphy). Passive monitoring devices and devices which upload to servers automatically can simultaneously reduce burden on participants and researchers whilst minimising data loss by allowing researchers to monitor and respond quickly to any user or technical issues.

Reasons for missing data were usually known and typically related to infrequent but intentional decisions to remove a device (e.g., due to a social event or illness) or, in most cases, technical issues with devices or software beyond the participants' control, which would not introduce bias. We observed a weak correlation between EEG record quality and baseline cognitive impairment which could be explained by cognitive impairment impacting ability to correctly wear the EEG headband for maximal impedance or reflect that patients were moving more during the night. Even subtle movements can shift the headband and reduce signal quality, and getting optimal signal quality across entire or several recordings is a recognised challenge for dry EEG [51]. More comprehensive cognitive assessment than the MoCA, particularly deeper assessment of executive dysfunction and long-term memory, might find a stronger relationship between cognitive impairment and adherence, though recent studies using remote monitoring technologies found that although patients with more advanced neurodegenerative disease or cognitive impairment reported more problems and were less compliant, the study remained feasible [62, 63]. Larger studies may also want to consider regression analyses to identify key predictors of adherence to identify where support might be most indicated by the research team or caregiver support. Importantly, however, overall record quality remained high across the cohort. Having mild cognitive impairment or mild dementia did not preclude study participation, adherence to remote supervised and unsupervised study tasks, or obtaining good quality data.

Use of remote sleep and cognitive monitoring can help to partly or fully de-centralise research, as participants can utilise their own devices or be provided with technology via post where needed [64], which is more scalable for clinical trials [65]. Frequent or lengthy clinic visits, particularly those which require overnight stays for sleep analysis, can be burdensome for participants and may reduce inclusivity by requiring participants to live near a study site or travel long distances. More frequent but briefer remote assessments may also help to mitigate against the risk of large amounts of missing

data resulting from a missed clinic appointment, can act as ‘digital biomarkers’ that may be able to detect changes more sensitively than an annual follow-up [66] and are more convenient for participants [67]. Though not the focus of our work, research could also explore the use of digital tools to assess fluctuations in cognition over the day in LBD (where fluctuation in cognition is a key diagnostic criteria) and AD (where a sundowning effect of heightened distress is often observed during the evening hours), both of which are difficult to assess in clinical settings [68, 69].

Whilst high adherence has been previously demonstrated in feasibility studies of remote monitoring technologies in participants with cognitive impairment or neurodegenerative conditions, most studies have required intensive study partner support throughout the study period as an eligibility criterion [62, 70]. It has been argued that study partners are essential for participant safety and wellbeing in dementia research, even at the preclinical stage where cognitively normal individuals are enrolled [71]. For some participants, partners or relatives provided essential support for study participation. However, many participants provided good quality data with minimal to no input from others. Crucially, several participants would not have been able to participate if there was a study partner requirement. Strict eligibility criteria for trials are a recognised barrier to research participation [72]. Requiring a study partner for all studies may be unnecessarily increasing burden for relatives already providing care or support, reducing the participant pool and may disproportionately affect different groups in society who are under-served by research [73, 74]. Our findings encourage researchers to consider inclusive and flexible research designs, including options to formally recruit and collect data from study partners without excluding participants who do not have someone available to support them in research studies.

There are an increasing number of options when considering how to measure sleep and cognition from home including both research-grade and consumer sleep trackers [75] [76]. We opted to utilise existing technologies which were non-invasive, affordable, required minimal training or supervision, were commercially available research-grade or consumer-grade devices which met necessary data privacy regulations, and provided data in a format which could be analysed using open-source software. Existing technologies can be implemented immediately, reducing time and cost to set up research studies, have a more mature user interface and are less error-prone than a newly developed solution, and crucially may be easier to compare amongst studies for meta-analysis. Several study tasks required ongoing technical support or services from the manufacturers and/or developers. As a customer rather than a collaborator, we could not always identify or respond to technical problems and with some providers we were not informed in advance of several significant changes which impacted the study or its participants resulting in data loss. Collaborating with industry, ideally at an early stage of the research process, might ensure longevity and continued support throughout the life course of the study and increased flexibility to adapt technology to better fit research (e.g., data validation for digital patient-reported outcomes).

Limitations

Women, older adults (80+), and minoritised ethnic groups were under-represented in our study, which is often observed in dementia research [77]. Though some barriers (e.g., mistrust and accessibility of research) and motivators (e.g., altruism) have been identified, further work is needed to identify how to improve research access, inclusion, and participation in dementia research [78]. There may also have been a self-selection bias, whereby individuals who were likely to be more competent and enthusiastic about using technology volunteered to participate in the study. Most of our participants were regular smartphone users, and several prospective participants declined to participate due to concerns regarding their confidence or interest in using the technologies. Though the proportion of older adults in the UK using the internet is increasing, a significant proportion of older adults do not regularly use the internet or lack fundamental skills such as being able to turn on a device and enter login details [28]. Older adults with MCI and dementia who regularly use devices

report that smartphones and tablets can be useful to support activities of daily living, as well as for communication, entertainment, and recreation, but also list concerns including cybersecurity and vulnerability to fraud [79]. Education around sleep and brain health and basic digital skills training on how devices can support individuals living with cognitive impairment may improve perceptions of capability and motivation to participate in similar studies [55, 79]. Exploring the feasibility of more passive monitoring technologies, such as mattress sensors or smartphone-based passive sensing, may help to increase participation and confidence from those with less experience or interest in technology. Though these techniques may invite additional concerns around data privacy, passive monitoring technologies are already being used to support older adults aging in place [80] [81]. Increasing the pool of prospective participants through recruiting via multiple sites and meaningful engagement with community group and considering digital inclusivity is likely to enhance recruitment in future studies. Finally, we did not set *a priori* feasibility cut-offs for study tasks. Despite these limitations, the high completion and retention rate from the RESTED study suggests that remote sleep and cognitive monitoring could offer detailed sleep profiling suitable for tracking change in sleep over disease progression or for monitoring change in sleep clinical trials in older adults with or at risk of dementia.

Conclusion

Practical, detailed, and scalable assessment of sleep is essential for understanding how sleep disturbances affect neurodegeneration over time and to develop and evaluate effective interventions. Our results suggest that it is feasible for older adults with MCI and dementia as well as healthy older adults, to engage in multimodal remote sleep and cognitive research including using wireless EEG, actigraphy, and mobile or web applications. Remote monitoring technologies and research designs offer the opportunity to study naturalistic sleep and its relationship with cognition and dementia over extended periods of time, are scalable, and should be considered when designing future clinical trials in sleep and dementia in these populations

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Conflicts of Interest

The authors declare no conflicts of interest. EC has received funding from Biogen, Eisai, and Lilly for consultancy and providing educational resources.

Abbreviations

AD = Alzheimer's disease, LBD = Lewy body disease, MCI = mild cognitive impairment, NHS =

National Health Service, A β = amyloid-beta, p-tau = phosphorylated tau, NFL = neurofilament light chain, GFAP = glial fibrillary acidic protein.

Data availability

Data is available from the author upon reasonable request.



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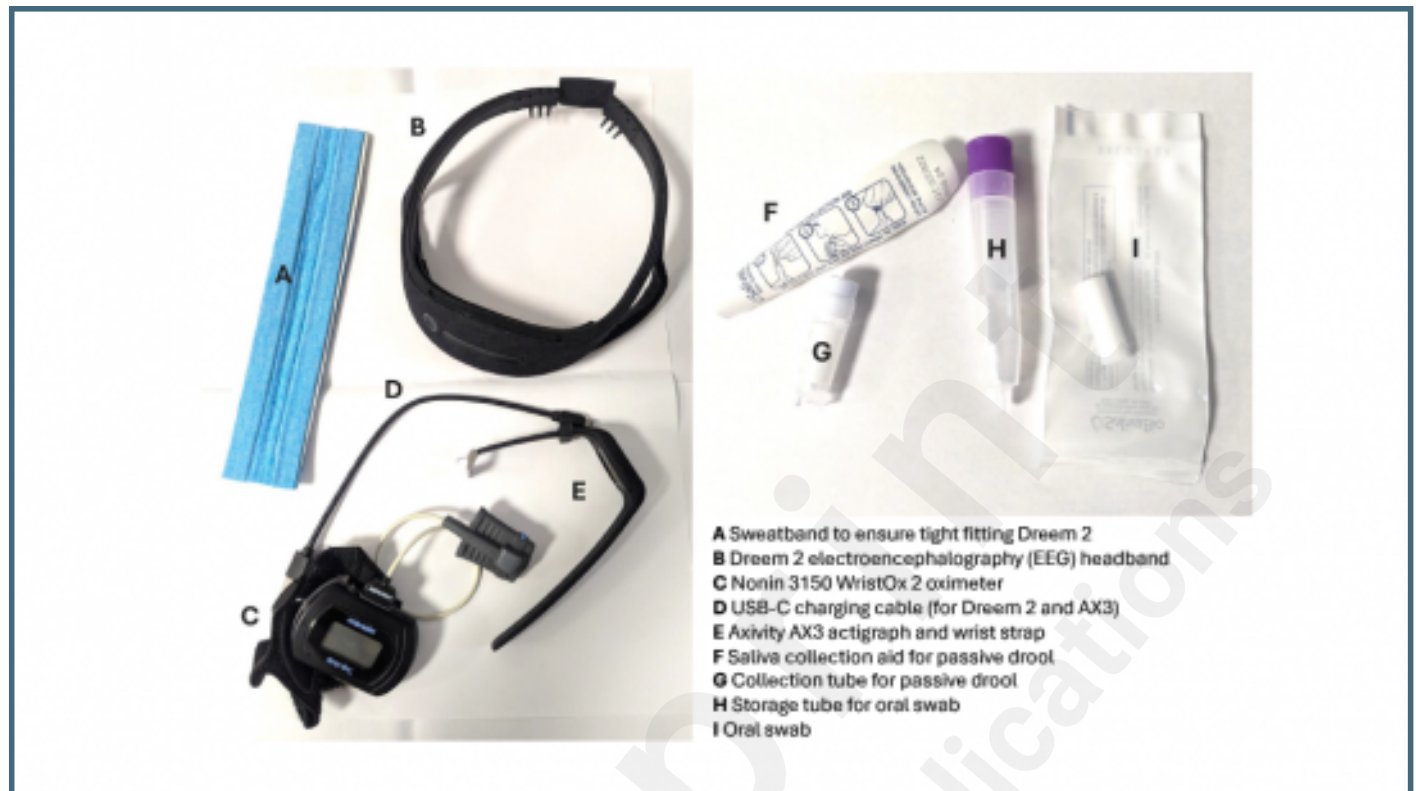
Supplementary Files

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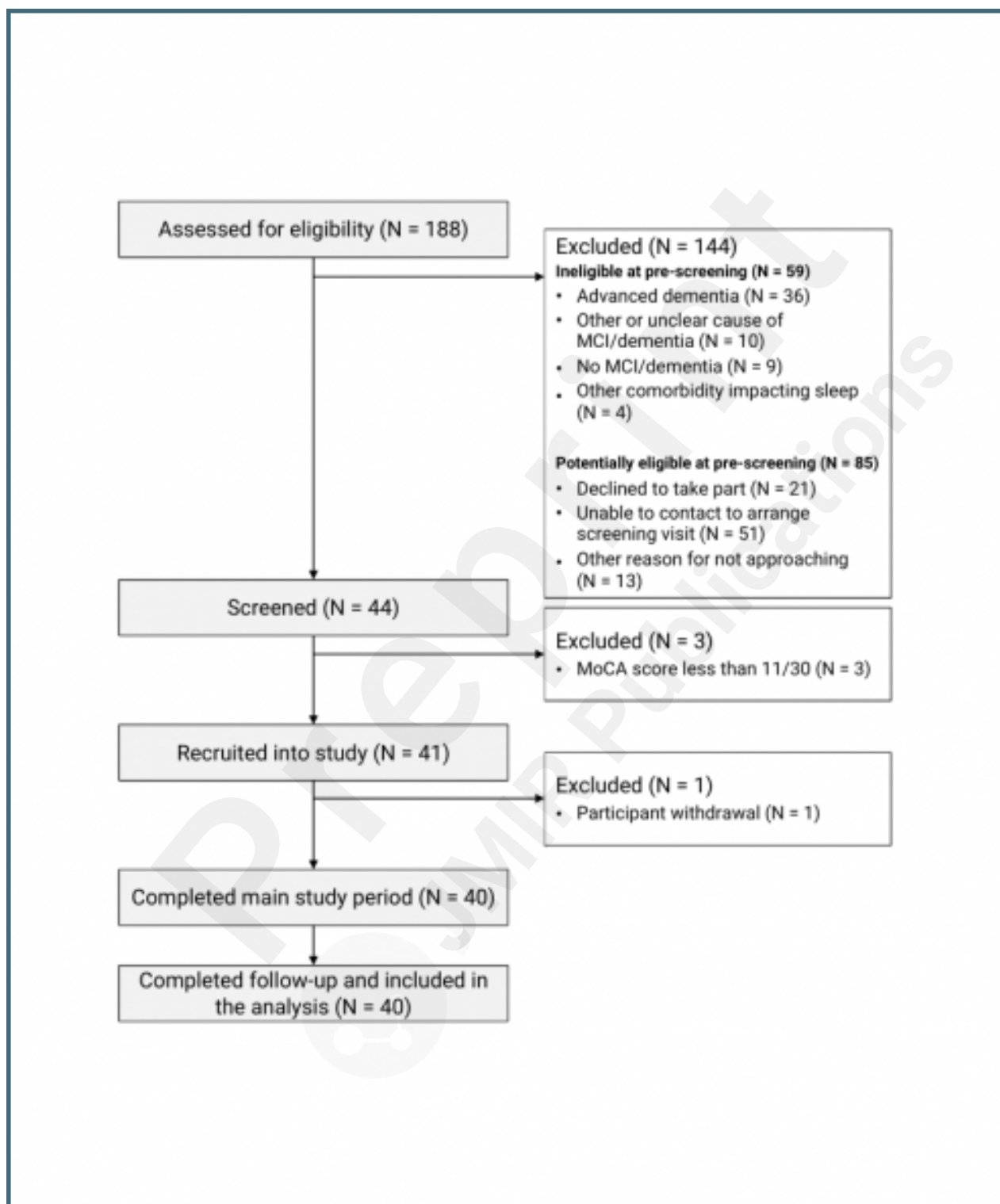
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Figures

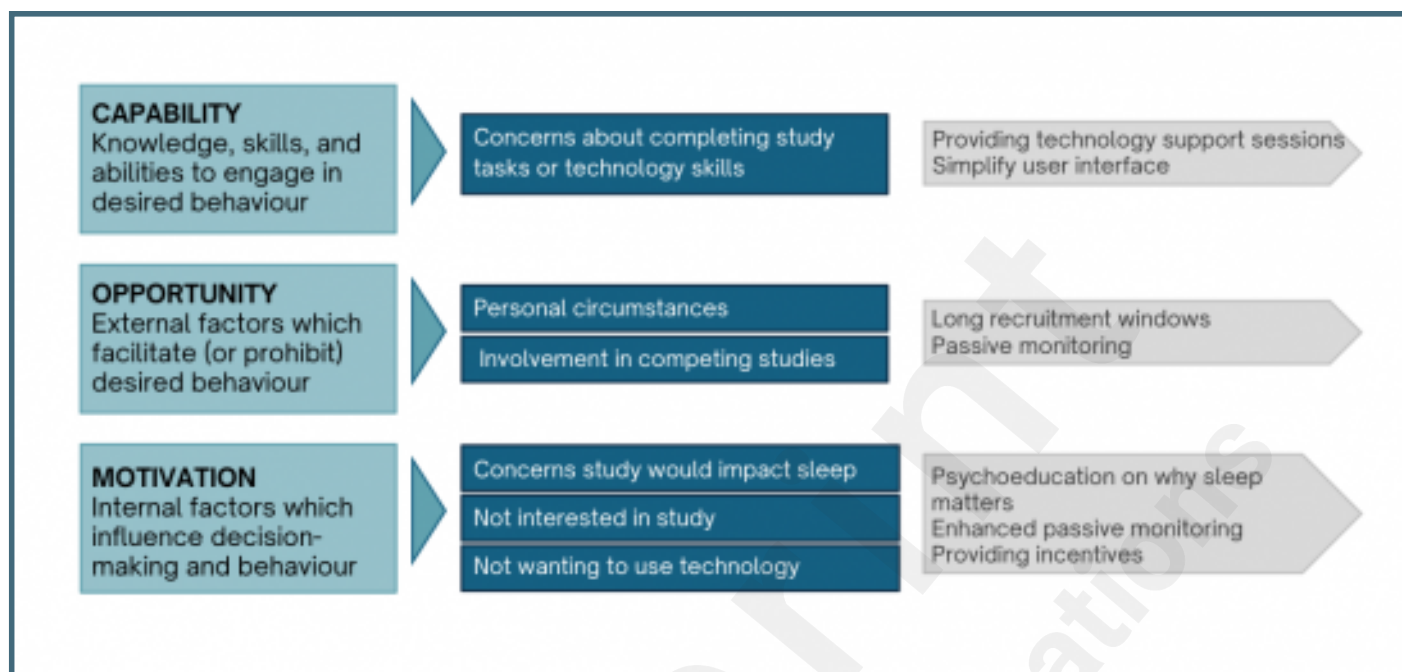
The study kit provided to RESTED participants. Participants were additionally required to use a smartphone or tablet to complete digital assessments.



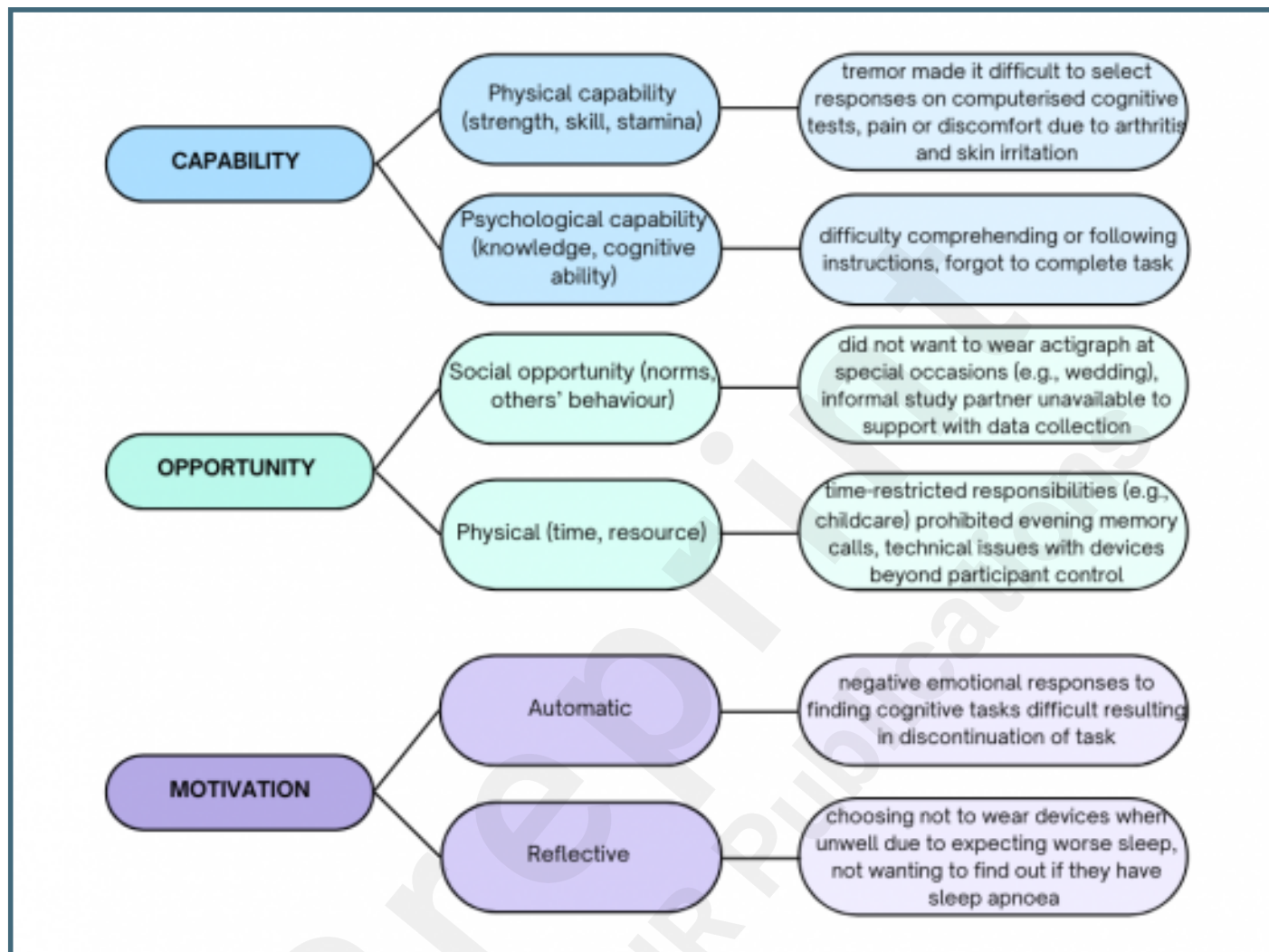
Participant flow through the RESTED study. Of 129 potentially eligible participants, 44 (34%) consented to participate and 41 (32%) were recruited. Retention was very high (98%) following recruitment to the study.



Reasons for declining to participate in the study could be categorised according to the Capability Opportunity Motivation-Behaviour (COM-B) model of behaviour change (blue). Opportunities to increase capability, opportunity, and motivation to take part in the research are outlined (grey).



Reasons for missing data are mapped the Capability Opportunity Motivation-Behaviour (COM-B) model of behaviour change.



Multimedia Appendixes

Supplementary Materials 1: STROBE Statement—checklist of items that should be included in reports of observational studies
Supplementary Materials 2 Further information is provided on the devices used to measure sleep and circadian rhythms.
Supplementary Materials 3 Dreem EEG individual channel metrics
Supplementary Materials 4 Additional information on reasons for missing data and the affected study tasks is provided.

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Lady using her phone at home.

