Multicentre randomised controlled trial of digital parent guided sleep intervention (Sleep Buddy) versus usual care in children aged 6-12 years with ADHD and chronic insomnia.

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FUNDER

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Protocol Information

This protocol describes the DISCA trial and provides information about procedures for entering participants. The protocol should not be used as a guide for the treatment of other non-trial participants; every care was taken in its drafting, but corrections or amendments may

be necessary. These will be circulated to investigators in the trial, but sites entering participants for the first time are advised to contact Southampton Clinical Trials Unit to confirm they have the most recent version.

Compliance

This trial will be conducted in compliance with the approved protocol and will adhere to the principles of GCP guidelines, the current Data Protection Regulations, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as appropriate.

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list of abbreviations

AE	Adverse Event
ADHD	Attention Deficit Hyperactivity Disorder
SASS-Y	Split week self-assessment of sleep
CI	Chief Investigator
CPT	Continuous Performance Task
CRF	Case Report Form
CSRI	Client Service Receipt inventory
CTCAE	Common Terminology Criteria for Adverse Events
DMEC	Data Monitoring and Ethics Committee
DMP	Data Management Plan
GCP	Good Clinical Practice
IDMC	Independent Data Monitoring Committee
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
NCI	National Cancer Institute
OSQ	Omnibus Sleep Questionnaire
PI	Principal Investigator
PIS	Participant Information Sheet
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SCTU	Southampton Clinical Trials Unit
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
UC	Usual Care
WEMWBS	Warwick-Edinburgh Mental Wellbeing scale WEMWBS

Keywords

[Attention deficit hyperactivity disorder, chronic insomnia, children, digital intervention, randomised controlled trial]

trial synopsis

Short title	Digital Sleep Support for Children with Attention-Deficit/Hyperactivity Disorder (The DISCA study)
Full title:	Multicentre randomised controlled trial of digital parent-guided sleep intervention (Sleep Buddy) versus usual care in children aged 6-12 years with ADHD and chronic insomnia

Phase:	Phase III with internal pilot.
Population:	Children aged 6-12 years (inclusive) with an ADHD diagnosis (including Attention Deficit Disorder) experiencing chronic insomnia.
Primary Objective:	To determine whether the addition, to Usual Care (UC), of a digital parent-guided sleep intervention reduces mean sleep onset latency at 3 months post-randomisation, in children with ADHD and chronic insomnia.
Secondary Objective:	1. To assess the effect of the intervention on secondary outcomes including ADHD symptom severity, behavioural and emotional functioning, wider subjective sleep variables, cognitive variables, quality of life, and parental well-being. 2. A within-trial cost-effectiveness analysis and decision model to estimate long-term costs and quality-adjusted life years for the digital intervention versus UC. 3. A nested process evaluation to assess mechanisms of change and to inform implementation planning
Rationale:	The overall aims of the DISCA programme are to address the lack of practical help for sleep problems in children with ADHD and chronic insomnia. Low-cost, rapid assessment tools are needed to help clinicians identify sleep problems and then signpost parents to an accessible novel digital sleep intervention to effectively manage their child's chronic insomnia. Sleep problems in children have a profound impact on child wellbeing - worsening behaviour, affecting learning, and increasing risk of obesity. The impact is not confined to the child. Exhausted parents are more likely be depressed, misuse substances, suffer poor physical health, experience road traffic accidents and unemployment. The societal cost of poor sleep in children is estimated in the UK at 1.8% of GDP (or £35 billion in 2020).[139-140] Empowering professionals to identify sleep problems in children with ADHD and offering a low cost, widely available effective solution could have far reaching benefits beyond those of the affected child. The trial will assess a novel digital sleep intervention (Sleep Buddy) that aims to: 1. Deliver health, behavioural and cognitive benefits to children with ADHD through improved sleep; 2. Improve quality of life and wellbeing for parents of children with ADHD through indirect benefit of improved parental sleep and improved child daytime behaviour and functioning; 3. Generate NHS cost savings: effective treatment of chronic insomnia in children with ADHD could reduce escalating melatonin prescription costs for children which, in NHS England alone, rose from £28 to £39

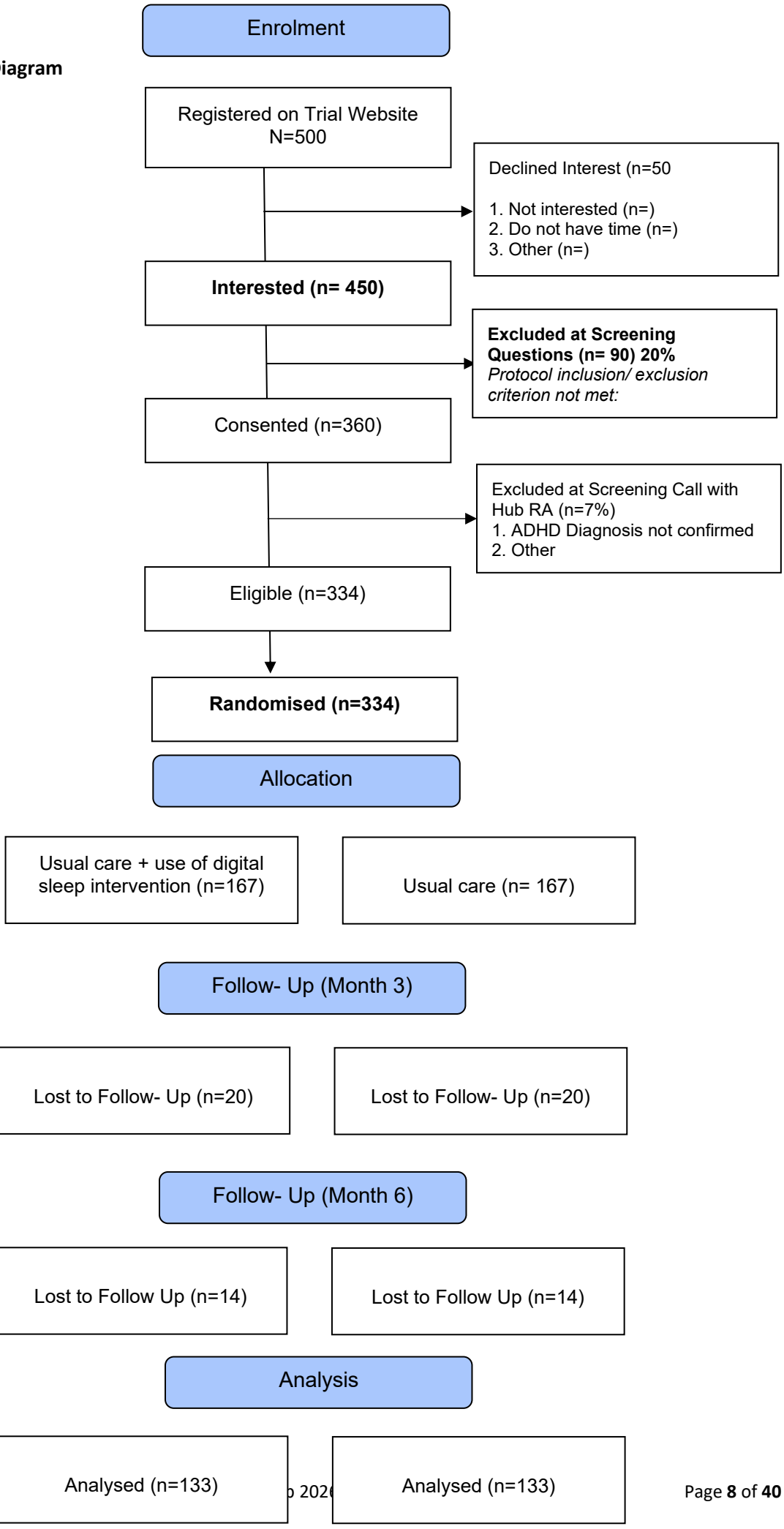
	million between 2015 and 2020. Furthermore, with improved sleep, reductions in children's daytime ADHD symptoms could reduce the need for stimulant treatment.
Trial Design:	A multicentre Randomised Controlled Trial (RCT) with two parallel arms, incorporating an internal pilot.
Sample size:	334 (167 per arm).
Treatment/Intervention:	Digital parent-guided sleep intervention compared to Usual Care.

URL for Database:	https://www.trial-deck.com/projects
URL for randomisation:	https://www.trial-deck.com/projects

Primary Trial Endpoints:	Sleep onset latency, based on parent-completed sleep diaries, measured at 3-months post randomisation.
Secondary Trial Endpoints:	Nocturnal sleep time Wake after sleep onset Sleep efficiency ADHD symptom severity Irritability Warwick-Edinburgh Mental Wellbeing scale Omnibus Sleep Questionnaire EQ-5D-5L Child Health Utility 9D index (CHU-9D) 2 -back working memory task Go/no-go task Mackworth Clock task CPT task **<u>Embedded Process Evaluation:</u>** Parent engagement with Sleep Buddy advice Parent enablement and acceptability of Sleep Buddy
Total Number of Sites:	Recruitment will take place via 7 main routes: 1. Advertising in NHS ADHD clinics across 4 research hubs sampling the diversity of UK ADHD as well as in primary care setting 2. Conducting mailshots to carers of potentially eligible children who are on NHS Hubs sleep clinic waiting lists 3. Advertisement and mailshots to carers of potentially eligible children at primary care settings 4. Hampshire foster care services 5. Social media channels of National ADHD charities (e.g. ADDISS) and National Foster Care Charities (Foster Talk). 6. Social Media (Facebook, Instagram, LinkedIn and X) 7. Advertisements and mailshots to carers of potentially eligible children within school settings

trial schema

Figure 1 – CONSORT Diagram



SCHEDULE OF OBSERVATIONS AND PROCEDURES

Visit:	Screening/ baseline	Screening call	**Randomisation (T0)**	Month 1	Month 2	**Month 3 (T1) +4 weeks**	Month 4	Month 5	**Month 6 (T2) +4 weeks**
Time (days):			**Ideally within 4 weeks from Informed Consent[7]**						
Potentially eligible parents of ADHD children (signposted to the trial website by clinicians at the participating Hubs/posters in clinics/ GP surgeries/ Foster care services and ADHD Charities) and invited to participate (via link to GI Platform)	**X**								
Informed consent (e-consent)	**X**								
Screening questions[1]	**X**								
Confirmation of child ADHD diagnosis (to be completed with Hub Research Assistant)[2]		**X**							
Eligibility evaluation to be signed by hub RA		**X**							
ADHD Medication (stimulant/non-stimulant) and Sleep Medication check (child) (completed by Hub RA)[2]		**X**				**X**			**X**
Concomitant medications/ therapies (child) (completed by Hub RA)[2]		**X**				**X**			**X**
Deprivation index (Based on IMD from postcode) (completed by Hub RA)[2]		**X**							
Essential demographic/medical history of the child to include age, month/ year of birth, sex, gender, ethnicity, and comorbidities[1].	**X**								
Essential demographic/medical history of primary caregiver to include age, gender, ethnicity, education, relationship to child,	**X**								

Visit:	Screening/ baseline	Screening call	**Randomisation (T0)**	Month 1	Month 2	**Month 3 (T1) +4 weeks**	Month 4	Month 5	**Month 6 (T2) +4 weeks**
Time (days):			**Ideally within 4 weeks from Informed Consent[7]**						
parental status, English literacy, and comorbidities[1].									
Duration of Call with Hub RA (completed by Hub RA)[2]		**X**				**X**			**X**
Split week self-assessment of sleep (SASS-Y) 14 items[1]	**X**					**X**			**X**
Sleep diary (one week) 3 questions each morning[1]	**X**					**X**			**X**
Omnibus sleep questionnaire (OSQ) 30 items[1]	**X**								**X**
SNAP-IV-parent – ADHD symptoms 18 items[1]	**X**					**X**			**X**
CHU 9D child quality of life – 9 items parent version)[1]	**X**					**X**			**X**
EQ-5D-5L – parent quality of life (5 questions)[1]	**X**					**X**			**X**
Warwick-Edinburgh Mental Wellbeing scale (WEMWBS) 14 items [1]	**X**					**X**			**X**
Affective reactivity index (ARI-P) 7 items [1]	**X**					**X**			**X**
Subjective sleep rating (mild/mod/severe)[1]	**X**					**X**			**X**
Client Service Receipt inventory (CSRI) (completed by Hub Research Assistant at scheduled calls) [2]		**X**				**X** (brief version)			**X**
Patient Enablement Instrument (PEI)[1]	**X**					**X**			**X**
Theoretical framework of acceptability (TFA) questionnaire[1,4]						**X**			
Adverse Events [1]						**X**			**X**

Visit:	Screening/ baseline	Screening call	**Randomisation (T0)**	Month 1	Month 2	**Month 3 (T1) +4 weeks**	Month 4	Month 5	**Month 6 (T2) +4 weeks**
Time (days):			**Ideally within 4 weeks from Informed Consent[7]**						
A 2 back working memory task (support from KCL researcher/ Hub RA)[3, 6]	**X**					**X**			**X**
Go/no go task (support from KCL researcher/ Hub RA)[3, 6]	**X**					**X**			**X**
Mackworth Clock task (support from KCL researcher/ Hub RA) [3, 6]	**X**					**X**			**X**
Continuous Performance Task (CPT) (support from KCL researcher/ Hub RA) [3, 6]	**X**					**X**			**X**
Randomisation			**X**						
Use of DISCA digital sleep intervention[4]			**X**	**X**	**X**	**X**	**X**	**X**	**X**
Qualitative Interviews (25-30 parents and carers) [5]						**X**			

NB: The Participant/legal representative is free to withdraw consent at any time without providing a reason. When withdrawn, the participant will continue to receive standard clinical care. Follow up data will continue to be collected (unless the participant/legal representative has specifically stated that they do not want this to happen).

[1]*Completed by parent, on the study website.*
[2]*Completed by the parent during a scheduled video call with the Hub RA, inputted into the study website by the Hub RA.*
[3]*Completed by the child online, during a scheduled video call with a Researcher from Kings College London. The Researcher will support the child with the completion of the tasks. The tasks will be completed early evening or on weekend days. The participant must continue to use the same device for the task completion, at baseline and month 3 and month 6 follow-up. The tasks can be completed on a tablet (with keyboard), laptop or desktop computer.*
[4]*Participants in the intervention arm only. The intervention is designed to be used flexibly by parents from randomisation to the month 6 follow-up.*
[5]*Participants randomised to the Intervention Arm to be interviewed while using the intervention or at the point of withdrawal (for participants that cease trial participation before month 6).*
[6] *Cognitive tasks Call to be completed between 2pm-6pm (Mon-Sat). Saturdays should only be booked where there are no weekday options. Where possible, tasks should be completed at a similar time during the month 3 and month 6 follow-ups. Where possible, the cognitive tasks will be consistent with respect to whether they are completed on a school versus non-school day.*
[7]*Randomisation within 4 weeks of informed consent is an ideal timeframe. Participants may still be randomised beyond 4 weeks since informed consent.*
Questionnaires will primarily be completed online in the GI Platform Trial Deck. Reminder emails and texts will be sent automatically (via the GI platform, using Twilio SMS and email communication platform) and manually (using text anywhere SMS communication platform) to inform the participant that the Baseline, month 3 and month 6 questionnaires are ready to complete on the Sleep Buddy website. If the questionnaires are not completed within 2 weeks of the questionnaire being available to complete on the Sleep Buddy website, a researcher from the Hub or the Trial Management Team SCTU will call the participant to collect the primary outcome measures and further measures from the questionnaire battery at the respective follow-up point if participant willing to do so.

1 INTRODUCTION

1.1 BACKGROUND

Attention-Deficit/Hyperactivity Disorder (ADHD), defined by developmentally inappropriate, persistent, and impairing levels of inattention and/or hyperactivity-impulsivity,[1(1)] is the most common neurodevelopmental disorder in school-aged children. The population prevalence of ADHD has been stable over the past two decades, affecting around 3-6% of children worldwide.[2(2)] According to the Mental Health of Children and Young people in England survey, 2017, 1.6% of children (5-19 years) have a diagnosis of Hyperkinetic disorder.[(3)] This is a conservative estimate of ADHD prevalence as Hyperkinetic disorder (ICD-10 definition) represents only about 50% of children with ADHD as per DSM-5 criteria.[(1)] In the UK, this translates to a prevalence of 3-4%, or at least one child in each school class. Untreated ADHD imposes a considerable societal burden in terms of psychological dysfunction, family stress, and financial costs. The estimated mean annual NHS cost for a child with ADHD is four times that of a child without ADHD (£1,327 vs. £328).[(4)]

ADHD is frequently comorbid with other (neuro)psychiatric disorders, such as anxiety or mood disorders,[(2)] and/or somatic conditions (e.g., obesity[(5)] or asthma[(6)]), which increase its personal and societal burden. Amongst comorbidities, sleep problems are reported in up to 73% of children.[(7)] Meta-analytic evidence shows that parents of children with ADHD, compared to parents of children without ADHD, reported significantly more severe bedtime resistance, problems falling asleep, night awakenings, difficulties with morning awakenings, sleep disordered breathing, and daytime sleepiness in their children. Objective sleep measures also indicate children with ADHD take significantly longer to fall asleep and were more likely to have sleep disordered breathing, worse sleep quality, shorter total sleep time, and more day sleepiness.[(8)]

Sleep problems are a uniquely relevant co-morbidity in ADHD as they can:

1. worsen ADHD core symptoms (i.e., inattention, hyperactivity and impulsivity).[(9)] Indeed, experimental evidence indicates a causal role of sleep restriction (limiting total sleep time) in increasing the severity of inattention and oppositional behaviours in children with ADHD;[(10)]
2. independently impact on cognitive and academic functioning, emotional regulation, mood, and risk taking.[(9)] Meta-analytic evidence indicates that short sleep duration in children is significantly and negatively associated with cognitive performance, executive functioning and school performance.[(11),(12)] Shorter sleep duration is associated with both internalizing (e.g., low mood) and externalizing (e.g., conduct disorder) behavioural problems[(12)], as well as irritability[13)] and difficulty focusing on tasks due to mind-wandering;[(14)]
3. worsen associated somatic conditions such as overweight/obesity;[(15)]
4. cause significantly poorer quality of life (QoL) in children with transient or persistent sleep problems versus those with no sleep problems.[(17)]
5. negatively impact on family members, with sleep deprivation in primary carers (from here the term 'parents' will denote primary carers) limiting their capacity to cope with daytime behavioural challenges.[(16)]

An international consensus of experts in the field of ADHD and sleep highlighted that sleep problems in ADHD may be caused by a variety of sleep disorders, including behaviourally based chronic insomnia, circadian rhythm disorder, sleep-disordered breathing, and restless legs syndrome/periodic limb movement disorder. Behaviourally based chronic insomnia (i.e., difficulties falling asleep and/or staying asleep and/or early morning waking on >3 nights a week for > 3 months) is the most frequently reported sleep disorder in children with ADHD.[(18)] Based on evidence of the effectiveness and tolerability of behavioural interventions for sleep onset delay in children and adolescents,[(19),(20)] expert consensus recommended behavioural sleep interventions for chronic insomnia in ADHD. Pharmacologic treatment, in particular melatonin, for which most evidence is available, was recommended as second line. Other sleep disorders (e.g., circadian rhythm disorder, restless legs syndrome or sleep disordered breathing) require specific treatments.[(7)]

However, the current management of sleep problems in children with ADHD in the UK does not reflect these recommendations. We surveyed parents of UK children with ADHD in 2020 [(22)]. Of 168 respondents, 142 (85%)

reported sleep problems in their children, with no difference in prevalence between age groups (6% were under 5-years; 57% aged 5-10 years, and 37% aged 11-16 years). Only 2/3 of those reporting sleep problems were offered help by their ADHD clinic. For almost 80%, this involved a melatonin prescription, without behavioural sleep intervention. Furthermore, the sleep problem only improved in 54% of those offered help. Overall, resolution of sleep problems was only achieved in just under a third of children. This provides contemporary UK evidence, directly from parents, that provision of practical help for sleep problems in children with ADHD is inadequate.

1.2 RATIONALE AND RISK BENEFITS FOR CURRENT TRIAL

DISCA aims to address the lack of practical help for sleep problems in children with ADHD with an accessible novel digital sleep intervention to effectively manage their child's chronic insomnia.

Sleep problems in children have a profound impact on child wellbeing – worsening behaviour [32], affecting learning [24] [25] and increasing risk of obesity [26]. The impact is not confined to the child. Exhausted parents are more likely be depressed, misuse substances, suffer poor physical health, road traffic accidents and unemployment. The societal cost of poor sleep in children is estimated in the UK at 1.8% of GDP (or £35 billion in 2020). Empowering professionals to identify sleep problems in children with ADHD and offering a low cost, widely available effective solution could have far-reaching benefits beyond those of the affected child.

The trial aims to:

1. Deliver behavioural, cognitive and quality of life benefits to children with ADHD through improved sleep;

2. Improve wellbeing and quality of life for parents of children with ADHD through indirect benefit of improved parental sleep and improved child daytime behaviour and functioning;

3. Generate NHS cost savings: effective treatment of chronic insomnia in children with ADHD could reduce escalating melatonin prescription costs for children which, in England alone, rose from £28 to £39 million between 2015 and 2020. Furthermore, with improved sleep, reductions in children's daytime ADHD symptoms could reduce the need for stimulant treatment.

2 TRIAL OBJECTIVES AND ENDPOINTS

2.1 PRIMARY TRIAL OBJECTIVE AND ENDPOINT

To evaluate the cost-effectiveness of the digital parent-guided sleep intervention compared to Usual Care. The primary endpoint is sleep onset latency, based on parent-completed sleep diaries measured 3 -months post randomisation.

TABLE OF ENDPOINT/OUTCOMES

	Objective	Outcome Measures	Summary method(s)
Primary	- Sleep onset latency	Sleep onset latency measured by parent-completed 10-day sleep diaries (in minutes)	• Mean and SD • Median and range • Primary: mean difference between groups (from linear regression) • Secondary: odds ratio for group based on binary split at 30 minutes

Secondary	- Effect of the intervention on sleep variables	• Mean total nocturnal sleep time • Wake after sleep onset • Sleep efficiency Measured by parent-completed SASS-Y	• Mean and SD • Median and range
		Categorical classification of sleep problem	• Frequencies and percentages per category
		Omnibus Sleep Questionnaire (OSQ)	• Mean and SD • Median and range
	- ADHD symptom severity	Severity of ADHD core symptoms measured by SNAP-IV-parent report (total scores)	• Mean and SD • Median and range
	- Behavioural and emotional functioning	Affective Reactivity Index (ARI)	• Mean and SD • Median and range
		Warwick-Edinburgh Mental Wellbeing scale (WEMWBS)	• Mean and SD • Median and range
	- Quality of life	EQ-5D-5L (parent)	• Mean and SD • Median and range
		Child Health Utility 9D index (CHU-9D) (for children aged 7-12y) proxy	• Mean and SD • Median and range
	- Neurocognitive variables	Working memory, measured by 2 - back working memory task	• Mean accuracy (SD)
		Selective attention and motor response inhibition, measured by Go/no-go task	• Mean probability of inhibition (%) • Mean reaction time • Intrasubject variability of reaction time
		Sustained attention/vigilance on the detection of rare signals, measured by	• Mean Omission and commission errors (%)

		Mackworth Clock task	
		A CPT task	• Mean Omission and commission errors
Process Evaluation	- Parent enablement - Intervention acceptability - Engagement with the intervention	- Patient Enablement Instrument (PEI) - Theoretical framework of acceptability (TFA) questionnaire - Intervention usage	• Frequency and percentage • Mean and SD • Median and range

3 OVERALL TRIAL DESIGN

A multicentre, phase III, randomised trial with internal pilot comparing parent-led digital sleep intervention to usual care. Participants will be randomised to A) usual care plus access to the digital parent-guided sleep intervention (Sleep Buddy) for a 6-month period or B) usual care for a 6-month period.

We hypothesise that participants in the digital sleep intervention group have shorter sleep onset latency at 3-month and 6-month follow-ups than those in the usual care group.

Prospective participants will be invited to take part using targeted mailshots at each of the 4 NHS participating Hubs. The study will be advertised in NHS ADHD and sleep clinics at each of the 4 research Hubs, and across national ADHD and foster care charities. Charities will use their existing ways of working and utilise their established links to disseminate information about the trial to potentially eligible families. The study will also be advertised within Hampshire Foster care services.

Approximately 334 (167 in each arm) participants will be recruited.

We will use four main routes to recruit children and their parents to the study:

- NHS ADHD and sleep clinics across 4 research hubs sampling the diversity of UK ADHD.
- Hampshire foster care services will invite foster carers of looked after children with ADHD and sleep problems (470 foster carers and 733 looked after children).
- National ADHD charities (e.g. ADDISS who have an estimated 750 families on their databases with children in the target age range with ADHD).
- Other relevant national charities, such as Foster Talk.

Other methods of recruitment will be used, such as:

- Prospective participants to be identified from sources such as Consent 4 Contact (C4C) and Clinical Record Interactive Search (CRIS).
- Advertisement (including targeted mailshots) within ADHD / parent support groups and discussion forums (including internet-based groups), GP practices, pharmacies, schools, private clinics, and University research circulars (King's College London, Nottingham Trent University, University of Newcastle upon Tyne, University of Southampton).
- Social media advertisements (Facebook, Instagram, Bluesky, LinkedIn and X) and national advertisements of the trial via radio and television. Optimum exposure times will inform the time of social media post (for example, between Friday Lunchtime and Monday Lunchtime).
- Database search and mailout outs via primary care settings.
- Advertisement and targeted mailshot at other NHS Trusts.

- Be part of research: Advertisements and Invitations to members on the NIHR Be Part of Research Volunteer Service (BPORVS) register.
- We will seek guidance from the study PPI networks, for recommendations of other suitable charities and avenues of recruitment.

The trial will include a 9-month internal pilot with clear stop-go criteria based on recruitment rates and data completeness:

Table 1: Stop/ Go Criteria for Internal Pilot

Measure	Green	Amber	Red
Accrual at 9 months from start of randomisation	>=111 participants (100% of modelled accrual in accrual scenario)	>=80 participants	< 80 participants
Follow-up of primary outcome, assessed monthly once 50 participants have reached primary outcome point	>= 80% of expected based on actual accrual	>= 70% of expected based on actual accrual	< 70% of expected
Secondary outcome completion rate	>=70%	<70%	--

Actions:

- Red: Identify and address issues, to be discussed by the PMG and TSC, to determine if the trial can be rescued. If a rescue plan cannot be identified and delivered this may result in a recommendation to close.
- Amber: Identify and address issues, to be discussed by the PMG and TSC, to find a mitigation.
- Green: Continue.

4 SELECTION AND ENROLMENT OF PARTICIPANTS

CONSENT

Consent to enter the trial will be completed on the study website by the child's parent (or carer/local authority with parental responsibility) after they have accessed the Participant Information Sheet (PIS) and have had the opportunity to ask questions. Information will also be provided for children and parents will be asked to confirm their assent. Participant consent will be obtained electronically using the GI Platform for both the RCT and qualitative interviews (which are optional). Notification of consent will be confirmed by an automated email sent from the GI platform to the Trial Management Team at SCTU.

Research Assistants supporting the cognitive tasks will be asked to obtain verbal assent from the child before cognitive testing.

The right of the parent or child to refuse to participate without giving reasons will be respected. All participants are free to withdraw at any time from the trial without giving reasons and without their level of care or legal rights being affected. Participants will be provided with a contact point where they may obtain further information about the trial.

Upon completion of the informed consent form, a copy will be made available to the participant, and a copy of the consent form will be filed at SCTU to allow for central monitoring and audit/inspection purposes as required.

Primary caregivers can share the Information Sheet for Health Care Professionals, with any relevant healthcare professional involved in their child's care.

Consent for Qualitative Interviews

All participants will be asked for consent to be contacted about the qualitative interviews, this is optional and is not required to take part in the main trial. Participants will also give consent for their contact details to be shared with the qualitative researcher. The contact details will be accessed securely by the researcher who will contact these participants directly by telephone/MS Teams call.

4.1.1 INCLUSION CRITERIA

1. Child aged 6-12 years inclusive
2. Diagnosis of ADHD (including ADD)
3. Child meets the criteria for chronic insomnia based on primary carer report (sleep onset latency > 30 minutes for >3 nights/week for >3 months)
4. Sufficient understanding of English by primary carer to allow access to the digital sleep intervention (our digital interventions are aimed at a reading age of 11 years so will be accessible to adults with English as a second language)
5. UK Resident at the time of registration and intend to live in the UK for the 6-month trial duration.

EXCLUSION CRITERIA

1. Child has sleep-related rhythmic movement disorder
2. Child has severe learning disabilities
3. Child with physical ill health or disability likely to require admission to hospital during the 6-month trial period.
4. Child with long term health problems that affect their sleep. (e.g. severe eczema or epilepsy)
5. Primary carer has participated in the DISCA study 'think aloud' interviews during Sleep Buddy development
6. Primary carer (or child) is currently participating in another research study relating to the child, where the study is detrimental to the objectives and outcomes of this study. Concurrent recruitment to observational studies is acceptable.

5 TRIAL PROCEDURES

5.1 RECRUITMENT

Research assistants based in the 4 NHS research hubs will liaise with clinicians to signpost parents of ADHD children in the target age range to participate in the RCT. Multi-method approaches will be used including, where feasible, targeted mailshot of families (e-mail where available), information distributed with clinic appointments/ letters, posters in clinics, website advertising and GP newsletters.

ADHD charity partners and national foster care charities will post information about the study on their websites and in newsletters, signposting to the DISCA platform. The study will be advertised on social media platforms such as Facebook, Instagram and/or X.

Hampshire County Council will invite foster carers caring for children with ADHD and sleep problems to participate with information distributed through local foster carer support groups or 'hives'.

If initial recruitment does not meet target, we will investigate targeted recruitment through Primary Care Research Delivery Networks. Additional NHS may be approached too. Ethical approval from the applicable regulatory authorities will be sought when necessary.

5.2 SCREENING PROCEDURES

In all cases, interested parents will be directed to a study website where they can learn about the study from participant information materials developed with PPI panel support and subsequently register their interest. Parents will provide their email address on the trial website, for registration purposes. There will be a contact email address for families to ask any questions that they may have regarding the trial.

Parents willing to participate, will complete initial screening questions on the study website that will check their suitability to take part (inclusion/ exclusion criteria online, see section 4.1.1). Parents will indicate their consent (and child's assent) via the online platform.

If the child meets initial online eligibility criteria, and the family are happy and able to provide written confirmation of ADHD diagnosis they will then be asked to select a final screening call appointment with one of the hub researchers via an online calendar.

The hub researcher will review the screening questions prior to the call. During the call, the hub researcher will request documentary evidence of the child's ADHD diagnosis and current sleep and ADHD medication (if relevant). If this is provided, they will confirm eligibility on the platform and complete the Client Service Receipt inventory with the primary caregiver. They will remind the participant to complete their sleep diary and their Baseline questionnaires online. If the participant is willing to complete their Baseline questionnaires during the call, the Hub RA will collect these. Participants who have not completed their baseline after 2 weeks of these being available online, will be contacted by the Trial Management team at SCTU, and they will be collected over the telephone. The person collecting the measures over the telephone at SCTU will follow a hierarchy of measures, as detailed in the Screening, Month 3, and Month 6 Follow Up guidance document.

During the Screening call, the Hub RA will book a time for the participant to complete their cognitive task call with the cognitive researcher. A meeting link will be sent to the participant. The cognitive tasks must be completed within 4 weeks of the participant signing their informed consent form (or within 5 weeks if it is not possible to book a Baseline task call within this time). Where the participant does not complete their cognitive tasks within the 4-week window, this would not prevent them from progressing to randomisation, though incompletion should be monitored by SCTU, Hub RA, and the cognitive researcher, to ensure that the participant does not complete the cognitive tasks at month 3 and month 6 follow-up.

Randomisation will ideally occur within 4 weeks of the participant signing their informed consent form**. All participants must complete 5 Days of the 10-Day Sleep Diary as a minimum to progress through to randomisation.** Ideally, they will also complete the SASS-Y, though failure to do this would not stop them from progressing to randomisation.

All participants will be encouraged to complete the secondary outcomes as per their Baseline Questionnaires, though incompletion of secondary outcomes would not stop them from progressing to Randomisation. Baseline questionnaires, the 10-day sleep diary, and the cognitive measures will be completed by the primary caregiver and child via the online platform.

5.2.1 Screen Failures

The online platform will clearly state the process of failing screening. Those who do not reach the threshold for chronic insomnia and/or those who are unable to provide written confirmation of an ADHD diagnosis will

be ineligible and classed as a screen failure. These families will be thanked for their interest and, data will be retained on the online system.

5.2.2 Payment

Participants participating in the qualitative interviews will receive a £20 Love2Shop or Amazon gift voucher. Children will be incentivised to complete the online cognitive tasks by inclusion in a prize draw, all children who complete these tasks will have the chance to win a £25 Love2shop or Amazon gift voucher. There will be 20 prizes of this amount.

5.3 REGISTRATION AND RANDOMISATION PROCEDURES

Following informed consent, completion of screening, baseline measurements, and confirmation of eligibility by the Hub RA, participants will be randomised as part of the online platform 1:1 via the GI platform managed by Southampton CTU to the digital parent-guided sleep intervention (Sleep Buddy) or usual care. Stratification variables will include NHS region, age, sex, and ADHD medication status (stimulant/non-stimulant treatment). It will not be possible to blind participants to their allocation.

Randomisation will ideally take place within 4 weeks of the participant signing their informed consent form. **All participants must complete 5 Days of the 10-Day Sleep Diary as a minimum to progress through to randomisation.** Ideally, they will also complete the SASS-Y, though failure to do this would not stop them from progressing to randomisation.

5.4 BLINDING AND PROCEDURES FOR PLANNED & EMERGENCY UNBLINDING

It will not be possible to blind participants to their allocation, but they will be reminded to not disclose their status if contacted by the SCTU trial management team for questionnaire or diary data.

5.5 TRIAL PROCEDURES

Participants randomised to the intervention arm will access Sleep Buddy for the 6 month duration of the trial. At the end of the study, participants randomised to the usual care arm will receive access to the Sleep Buddy website.

For both Arms, Usual Care will be captured through the adapted Client Service Receipt Inventory at baseline (T0); 3 months (brief version) (T1) and 6 months (T2).

Digital Intervention + Usual care

Participants allocated to this arm will continue to receive usual care for their ADHD and chronic insomnia from Primary Care and Child and Adolescent Mental Health Services. In addition, they will receive access to Sleep Buddy. Sleep Buddy is an interactive multi-session digital behavioural intervention that provides participants with accessible information, tools and support to effectively manage their child's chronic insomnia. The intervention was developed using a content management system created by the web developer Global Initiative.

Specifically, Sleep Buddy aims to reduce sleep onset latency (time taken to fall asleep) by supporting parents/carers to facilitate: (1) Changes to their physical sleep environment (e.g. remove distractions and minimise device use); (2) Improvements to consistency at bedtime (e.g. same bedtime routine and bedtime/awake time); (3) Increases in healthy lifestyle behaviours (e.g. reduce caffeine intake in the evening, increase physical activity); and (4) Engagement in calming behaviours (e.g. anxiety management strategies). Where relevant, it will also facilitate engagement in delayed bedtime techniques to increase sleep pressure (for limit setting disorder or mild delayed sleep-wake phase syndrome) and increased use of strategies to increase child's sleep independence (e.g. gradual retreat and controlled checking techniques). Content is

delivered across 12 modules, through interactive and audio-visual features (e.g. videos), and covers topics including sleep basics, easing nighttime worries and fears, re-tuning your child's body clock, helping bedtime delay or refusal, ways to motivate your child, and looking after yourself. The intervention provides educational advice on sleep problems in children with ADHD and allows parents/carers to create a Sleep Plan for their child to set behavioural goals and make action plans for achieving these goals. Sleep Buddy was developed following the Person-Based Approach to intervention development (27 to ensure the interventions are meaningful, optimally engaging, and relevant to parents/carers of children with ADHD and chronic insomnia.

Assessments at Baseline (T0) will include:

Call with Hub researcher

- Confirmation of ADHD diagnosis
- Medication check (ADHD and sleep medication) (child) ADHD Medication Status (stimulant/ non-stimulant) NHS Region
- Confirmation of UK Residency (collection of child's GP address)
- Eligibility confirmation
- Concomitant medication/ therapies (child)
- Deprivation index (Based on IMD from postcode)
- Client Service Receipt Inventory (CSRI)
- Primary caregiver postal address (only to be collected for participants who do not have access to a device to complete their study questionnaires or cognitive tasks).
- A reminder to complete their sleep diary and baseline measures (baseline measures can be collected over the telephone if the participant has not yet completed, and they are willing to complete with the Hub RA).
- Hub RA to book a time for the child to complete their cognitive task (the cognitive tasks must be completed within 4 weeks since informed consent).
- Duration of Screening Call with Hub RA

Primary caregiver reported outcomes:

- Age (primary caregiver and child)
- Sex of child (as assigned at birth)
- Gender (primary caregiver, co-parent, and child)
- Ethnic group (primary caregiver and child)
- Highest Educational qualification (primary caregiver)
- Relationship to child (primary caregiver)
- Parental status (single parent/ carer)
- English Literacy (primary caregiver)
- 10-day sleep diary and SASS-Y
- Subjective sleep rating (mild/mod/severe)
- Omnibus Sleep Questionnaire (OSQ)
- SNAP-IV- parent (child ADHD symptoms)
- Affective reactivity index (ARI) parent report
- Warwick-Edinburgh Mental well being scale for parent (WEMWBS)
- EQ-5D-5L quality of life measure parent
- Child Health Utility 9D (CHU-9D) (quality of life scale for children aged 7-12years) Proxy
- Client Service Receipt Inventory (CSRI)
- Patient Enablement Instrument (PEI)
- Primary caregiver Beliefs about intervention- Theoretial Framework of Acceptability questionnaire (TFA)

- Primary caregiver comorbidities: ADHD (including ADD), Autism Spectrum Disorder (ASD), Anxiety Disorders, Alcohol Use Disorder, Bipolar Disorder, Eating Disorders, Obsessive-Compulsive Disorder, Personality Disorders, Post-Traumatic Stress Disorder, Schizophrenia.
- Child comorbidities: Autism Spectrum Disorder (ASD), Anxiety Disorders, Depressive Disorder, Conduct Disorder, Oppositional Defiant Disorder, Tourette's Syndrome, Eating Disorders, Obsessive-Compulsive Disorder, Post-Traumatic Stress Disorder.
- Concomitant therapies/ treatment for sleep problems (child)

Child reported outcomes:

Neurocognitive tasks: (https://www.psytoolkit.org/)

- A 2 back working memory task (5 min) the task measures 1-back and 2-back working memory
- Go/no-go task (the task measures motor response inhibition; 5min)
- Mackworth Clock task (the task measures vigilance; 5 min)
- CPT Task (the task measures sustained attention; 6 min)

The neuropsychological tasks will be completed by the child online with a weblink and data will be stored online on the researchers' accounts on the PsyToolkit website.

5.6 FOLLOW UP

Participants in both Arms will be followed up at 3 (T1) and 6 (T2) months. As detailed below.

Month 3 (T1) assessments:

Call with Hub researcher

- Medication check (ADHD and sleep medication) (child)
- CSRI (brief version) and reminder to complete online measures
- Confirmation of Primary caregiver (or child) concurrent recruitment into other research studies relating to the child
- A reminder to complete cognitive tasks (only if completed at Baseline)
- Duration of Call with Hub RA
- Concomitant medication/ therapies (child)

Primary caregiver reported outcomes:

- 10-day sleep diary and SASS-Y
- Subjective sleep rating (mild/mod/severe)
- SNAP-IV- parent
- Affective reactivity index (ARI) parent report
- Warwick-Edinburgh Mental Wellbeing Scale
- EQ-5D-5L
- CSRI (brief version) Hub RA to collect
- Patient Enablement Instrument (PEI)
- Child Health Utility 9D (for children aged 7-12years) CHU9D – Proxy
- Theoretical framework of acceptability (TFA) questionnaire (intervention arm only)
- Adverse Events

Child reported outcomes:

Neurocognitive tasks: (https://www.psytoolkit.org/)

- A 2 back working memory task (5 min) the task measures 1-back and 2-back working memory
- Go/no-go task (the task measures motor response inhibition; 5min)

- Mackworth Clock task (the task measures vigilance; 5 min)
- CPT Task (the task measures sustained attention; 6 min)
- Child initials and month/ year of birth

Month 6 (T2) assessments:

Call with Hub researcher

- Medication check (ADHD and sleep medication) (child)
- Completion of CSRI (and reminder to complete online measures)
- Confirmation of Primary caregiver (or child) concurrent recruitment into other research studies relating to the child
- Duration of Call with Hub RA
- Concomitant medication/ therapies (child)
- A reminder to complete cognitive tasks (only if completed at Baseline)

Parent reported outcomes:

- 10-day sleep diary and SASS-Y
- Subjective sleep rating (mild/mod/severe)
- OSQ
- SNAP-IV- parent
- ARI - parent report
- EQ-5D-5L
- Warwick-Edinburgh Mental Wellbeing Scale
- CSRI (to be completed with hub researcher)
- Patient Enablement Instrument (PEI)
- Child Health Utility 9D (CHU9D- Proxy)
- Adverse Events

Child reported outcomes:

Neurocognitive tasks: (https://www.psytoolkit.org/)

- A 2 back working memory task (5 min) the task measures 1-back and 2-back working memory
- Go/no-go task (the task measures motor response inhibition; 5min)
- Mackworth Clock task (the task measures vigilance; 5 min)
- CPT Task (the task measures sustained attention; 6 min)

Participants will receive SMS and email reminders to complete the follow-up questionnaires and tasks on the study website. Text messages will be sent using the Text Anywhere SMS system (if sent manually by a study researcher) or using Twilio SMS system (if sent to the participant automatically from the Trial deck); and the text will clearly state who the message is from so participants can identify who is messaging them. A researcher at the Hub or a member of the Trial Management Team at SCTU will arrange to collect follow-up measures over the telephone with participants that have not completed these within 2 weeks of the follow-up being available to complete on the study website.

Participants randomised to the intervention arm will receive SMS and email reminders about top tips relating to the intervention website, once a week, for the first 10 weeks following randomisation. The SMS and email reminders for the intervention will be sent using the Twilio SMS system.

Participants will be instructed to contact the Trial Management Team at SCTU if they would like to opt-out from receiving SMS or email reminders.

5.7 TRIAL INTERVENTION DISCONTINUATION AND PARTICIPANT WITHDRAWAL

In consenting to the study, participants have consented to the Screening Call, Baseline assessments, Trial intervention, follow-up, and data collection. Participants may be discontinued from the Trial procedures at any time.

5.7.1 Discontinuation of Trial Intervention

Reasons for Trial discontinuation

Participants may be discontinued from the Trial in the event of:

- Clinical decision, as judged by the Principal Investigator or Chief Investigator
- Termination of trial by Sponsor
- Participant choice

Full details of the reason for Trial discontinuation should be recorded in the eCRF.

Parents can choose the extent of their engagement (or indeed non-engagement) with the Sleep Buddy intervention. Usage of the digital sleep intervention will be measured as part of the process evaluation. Non-use does not exclude the participant, and analysis will be conducted on an intention to treat basis. Similarly, children may refuse to participate in cognitive assessments, but this will not invalidate their participation in the trial.

5.7.2 Withdrawal

The participant/legal representative is free to withdraw consent from the trial at any time, without providing a reason, and without their medical care or legal rights being adversely affected.

The participant will be reminded of the value of remaining in trial follow-up and allowing these data to be used for trial purposes. Where possible, participants who do not engage with the digital sleep intervention should continue with relevant trial-associated processes as per the Schedule of Observations and Procedures. If participants additionally withdraw consent for this, they will revert to standard clinical care/follow-up as deemed by the responsible clinician.

5.8 DEFINITION OF END OF TRIAL

End of Trial is defined as the date when the last point of data is collected for the last participant from the follow up questionnaires and interviews. End of study is the completion of analysis.

6 SAFETY

This programme consists of online information to support sleep problems in children with ADHD with low risk of adverse events or safety concerns.

Parents will be provided with means of communication, where they can report any concerns that they have about the trial at any time. A free text option will be included in the month 3 and month 6 follow-up prompting parents to report positive or negative impacts that the study has had on the parent, their child or their families. The SCTU will review the responses submitted by participants monthly. Where a response indicates an adverse event related to the Sleep Buddy Intervention or the trial processes, the SCTU will call the participant to collect any necessary further details, if required.

The SCTU will notify the Clinical Investigator of the potential AE/SAE by sharing the details of the event. The Clinical Investigator will review the potential AE/SAE and (if applicable) will submit the 'Serious Adverse Event Report Form – Non-CTIMP' to ctu@soton.ac.uk within 24 hours of being notified of the event.

Only serious events related to the trial intervention or the trial processes will be reported to REC.

7 STATISTICS AND DATA ANALYSES

7.1 METHOD OF RANDOMISATION

The randomisation will be stratified by NHS region derived from postcode information, age (6-9/10-12 years old), sex, and ADHD medication status (stimulant/nonstimulant treatment). The randomisation will be handled by the GI platform.

7.2 SAMPLE SIZE

Most previous studies have reported sleep onset latency as a binary variable, with a threshold of 30 minutes. However, the dichotomisation of a continuous outcome is less efficient, and may miss meaningful changes that do not fall below the threshold (e.g. a child who improves from a 4-hour period to 1-hour). The largest trial to date in this area found a difference of at least 26% between the arms, equivalent to a relative risk of 1.81 or a standardised effect size of 0.53. We have opted for a more conservative effect size of 0.4.([32]) To achieve 90% power with a standardised effect size of 0.4 would require 133 children per arm. Allowing for 20% loss to follow up would require a trial of 334 children.

7.3 INTERIM ANALYSIS

No interim analysis are planned.

7.4 STATISTICAL ANALYSIS PLAN (SAP)

7.4.1 Primary Endpoint

For the analysis of the full trial, the primary outcome, a linear regression model will be used to analyse difference in sleep onset latency between trial arms at 3 months. The model will adjust for baseline variables (including baseline sleep onset latency, parental socio-economic status, bedroom sharing, mental health comorbidity) and randomisation stratification variables (NHS region, age, sex, and ADHD stimulant medication status). Mean differences with 95% confidence intervals will be reported. The primary analysis will be a modified intention to treat analysis, i.e. participants will be analysed as randomised on a complete cases basis. The frequency and pattern of missing data will be examined, and a multiple imputation model will be used as a sensitivity analysis if appropriate. As a secondary analysis we will also assess sleep onset latency as a binary variable, based on <30 minutes (accepted standard definition of normal sleep onset latency), within a logistic regression model (or other quantile regression model if more appropriate to the data distribution) adjusting for the same covariates as the primary analysis. A comprehensive SAP will be written by the Trial Statistician and reviewed by the Chief Investigator before the database freeze.

7.4.2 Secondary Endpoints

An approach similar to the primary endpoint analysis will be used for continuous secondary endpoints, where a linear regression adjusting for outcome measure at baseline and other covariates will be employed.

7.4.3 Process Evaluation

A mixed-methods process evaluation will explore how participants experience and engage with the Sleep Buddy trial and intervention, and explore the causal mechanisms of the intervention and how these were

influenced by context. Participants from both intervention and control arms of the trial will be included in process analyses to provide comparative insight into the experiences and outcomes of those managing their child's sleep without the Sleep Buddy intervention.

Qualitative process evaluation

Qualitative process interviews will be carried out with 25-30 trial participants to provide in-depth understanding of participant experiences within the trial and provide a better understanding of factors that may influence engagement with the intervention behaviours. We aim to interview approximately 22 people from the intervention group and 8 people from the control group. We will try to achieve a maximum variation sample of included participants with regards to the primary caregiver and child characteristics such as age, gender, ethnicity, level of usage of the online intervention (for intervention group) , socio-economic status (primary caregiver only), and sleep onset latency (child only).

Participants will be identified and invited via their participation in the trial. As part of the trial consent process all participants signing up will be asked if they are willing to be recontacted about later participation in a qualitative interview. Potential participants will then be contacted by phone, text message or email with further information about the interview study and the opportunity to ask questions. They will then be asked to give informed consent online prior to the interview, or if they do not manage to complete online consent but attend for an interview then verbal consent will be recorded at the start of the interview. Participants will be free to withdraw at any time by contacting the research team.

Qualitative interview data will first be analysed using reflexive thematic analysis to construct themes grounded in the data. This will ensure that these represent participant perspectives. We will then examine the ways in which these inductively derived themes may map onto, elaborate or diverge from our theoretical frameworks, so as to relate our context-specific insights to generalisable theoretical constructs where possible and appropriate. The findings will be discussed, and interpretations agreed between the co-investigators (including PPI representatives).

Quantitative process evaluation

Quantitative process data will be collected via self-report questionnaires (patient enablement instrument[31] and Theoretical framework of acceptability (TFA) questionnaire and by measures of intervention usage automatically recorded in the software (with informed participant consent).

Self-reported process measures will be collected as part of the trial data collection which will allow exploration of key constructs: participant enablement and acceptability of Sleep Buddy. The specific measures and their collection time-points are shown in the 'Schedule of Observations and Procedures'.

Objective measures of intervention use will be automatically recorded in Matomo software, with participant consent, will allow evaluations of intervention usage patterns, such as time spent on intervention, number of visits to the intervention website and pages visited.

Descriptive and inferential statistics will be used to describe the quantitative process data and to examine relationships between key variables of interest. We will use baseline data to examine potential predictors and moderator effects of participant characteristics (e.g., age, severity of sleep problem) on outcome.

We will triangulate findings from the quantitative and qualitative process analyses to explore and test the causal mechanisms proposed, to help inform interpretation of trial results, and determine how the interventions could be improved and how implementation into clinical practice could be facilitated.

7.4.4 Health economic evaluation

A within-trial analysis we be conducted to estimate the cost-utility of the digital intervention compared with UC over the 6-month trial period. Quality Adjusted Life Years (QALYs) will be estimated using quality of life data collected at 0, 3 and 6 months: the CHU9D-Proxy and the EQ-5D-5L for parents, scored with UK value sets. QALYs will be estimated from individual-level data using the area under the curve method, and aggregated at the family level, but with values for children and adults also reported separately. Costs will be estimated from NHS and public sector perspectives (including health, social service and education costs), and also from a societal perspective (including costs to families). The cost of developing and delivering the digital intervention will be estimated from trial records. Information about service use and impact on family income and costs will be collected from primary carers at 0, 3 and 6 months using an adapted Client Service Receipt Inventory (CSRI), children's version. Unit costs of services will be taken from national tariffs and Personal Social Services Research Unit (PSSRU) estimates. Results of the within-trial analysis will be reported as between-arm differences in mean QALYs and costs. Analysis will be conducted with a mixed model with appropriate imputation for missing data and adjustment for baseline differences between the arms. An incremental cost-effectiveness ratio (additional cost per QALY gain) will be reported, unless one arm is dominant (less costly and more effective).

If the intervention is effective at improving sleep and/or ADHD symptoms, a decision analytic model will be developed to estimate long-term effects on costs and QALYs. Outcomes from DISCA and comparator trials will be extrapolated using longitudinal evidence from the literature on the relationships between sleep quality/ ADHD symptoms in childhood and adolescence and future educational attainment, employment, earnings, quality of life and use of health and other public services [28][29][30]. The model analyses will be conducted from NHS, public-sector and societal perspectives, over a lifetime horizon and in accordance with the NICE reference case at the time of analysis. Sensitivity and scenario analysis will be used to explore the impact of uncertainty over the long-term extrapolations.

8 REGULATORY COMPLIANCE

8.1 CLINICAL TRIAL AUTHORISATION

This trial is not considered to be a clinical trial of a medicinal product, so clinical trial authorisation from the UK Competent Authority the Medicines and Healthcare products Regulatory Agency (MHRA) is not applicable.

8.2 DEVIATIONS AND SERIOUS BREACHES

Any Trial protocol deviations/violations and breaches of Good Clinical Practice occurring at sites should be reported to the Trial Management Team at SCTU immediately. SCTU Quality & Regulatory Team will review on behalf of Sponsor and advise of and/or undertake any corrective and preventative actions (CAPA) as required.

All serious protocol deviations/violations and serious breaches of Good Clinical Practice and/or the Trial protocol will immediately be reported to the regulatory authorities and other organisations, as required. Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to SCTU. Deviations from the protocol, which are found to frequently recur, are not acceptable and will require immediate action by the Sponsor. Frequent non-compliance could potentially be classified as a serious breach.

Following SCTU standard operating procedures (SOPs), if the deviation is deemed a major CAPA or a potential/serious breach, the sponsor will be notified at researchsafety@uhs.nhs.uk by SCTU.

The Chief Investigator and all Principal Investigators at participating centres agree to comply with the requirements of the Protocol and Good Clinical Practice. Prospective, planned deviations or waivers to the protocol are not allowed under the UK regulations on Clinical Trials and must not be used e.g. it is not

acceptable to enrol a subject if they do not meet the eligibility criteria or restrictions specified in the trial protocol.

Deviations will be documented in reports to Programme Management Group ahead of meetings of this group. A copy of the PMG report with deviations can be shared with sponsor if requested.

9 ETHICAL CONSIDERATIONS

The trial will be conducted in accordance with the recommendations for physicians involved in research on human participants adopted by the 18th World Medical Assembly, Helsinki 1964 as revised and recognised by governing laws and EU Directives. Each parent participant's consent to participate in the trial should be obtained after a full explanation has been given of treatment options, including the conventional and generally accepted methods of treatment. The right of the participant to refuse to participate in the trial without giving reasons must be respected.

After the participant has entered the study, a clinician may give Usual Care to both arms of the trial if they feel it to be in the best interest of the participant. This will not affect their continued participation and intervention and participants will remain within the trial for the purpose of follow-up and data analysis according to the treatment option to which they have been allocated. Similarly, the participant remains free to withdraw at any time from protocol treatment and trial follow-up without giving reasons and without prejudicing their further treatment or legal rights.

9.1 RESEARCH ETHICS COMMITTEE REVIEW (REC) AND REPORT

The trial protocol has received the favourable opinion of a Research Ethics Committee.

Within one year after the end of trial, the Chief Investigator will submit a final report with the results, including any publication/abstracts, to the REC.

9.2 SPECIFIC ETHICAL CONSIDERATIONS

Sleep Buddy is a parent mediated intervention but the subject is a child. We will seek child assent by way of appropriate information. Consent will be sought from an adult with parental responsibility. In the case of children in foster care we will seek consent from the local authority as well as the foster carer.

9.3 INFORMED CONSENT PROCESS

Informed consent is a process that is initiated prior to an individual agreeing to participate in a trial and continues throughout the individual's participation. In obtaining and documenting informed consent, the investigator should comply with applicable regulatory requirements and should adhere to the principles of GCP.

Discussion of objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted are to be provided to the participant via the participant information sheet on the online platform. This information will emphasise that participation in the trial is voluntary and that the participant may withdraw from the trial at any time, without giving a reason and without their care or legal rights being affected. The participant will be given the opportunity to ask any questions that may arise and be given the opportunity to discuss the trial with family members, friends or an independent healthcare professional outside of the research team and time to consider the information prior to agreeing to participate.

9.4 DATA PROTECTION AND CONFIDENTIALITY

SCTU will preserve the confidentiality of participants taking part in the study in accordance with all applicable data protection legislation.

The Global Initiative teams and SCTU teams must ensure that participants' anonymity will be maintained and that their identities are protected from unauthorised parties. All staff with access to personal data will be compliant with the requirements of the Data Protection Act 2018 (as amended) with regards to the collection, storage, processing, and disclosure of personal information and will uphold the Act's core principles. On e/CRFs, data downloads and trial reports, participants will not be identified by their names, but by a pseudonymised identification code.

Personal identifying information (PII) is collected to register and consent participants, and for trial researchers to communicate with the participants to enable trial conduct procedures to be carried out and for eligibility confirmation and data collection.

All PII collected for the trial will be stored only on Trial Deck (maintained by Global Initiative). This data is categorised as PII within the system, which undergoes additional encryption and cannot be pulled out into data reports with the clinical data.

At the end of the trial, PII will only remain in the database for the time required by the trial. All other data will be archived as per record retention and archiving plan.

10 SPONSOR

SCTU, Chief Investigator and other appropriate organisations have been delegated specific duties by the Sponsor, University Hospital Southampton NHS Foundation Trust and this is documented in the trial task allocation matrix.

The duties assigned to the trial sites (NHS Trusts or others taking part in this study) are detailed in the Non-Commercial Agreement.

10.1 INDEMNITY

For NHS sponsored research HSG (96) 48 reference no.2 applies. If there is negligent harm during the clinical trial when the NHS body owes a duty of care to the person harmed, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the study. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.

10.2 FUNDING

NIHR Programme Grants for Applied Research are funding this study.

10.3 SITE PAYMENTS

The payments assigned to the trial sites (NHS Trusts or others taking part in this study) are detailed in the Non-Commercial Agreement.

This trial is automatically eligible for the NIHR portfolio. This enables Trusts to apply to their comprehensive local research network for service support costs, if required

10.4 PARTICIPANT PAYMENTS

Participants participating in the qualitative interviews will receive a £20 Love2shop or Amazon gift voucher. Children who complete all online tasks will be entered into a prize draw to win a £25 Love2shop or Amazon gift voucher. There will be 20 prizes of this amount.

11 TRIAL OVERSIGHT GROUPS

The day-to-day management of the trial will be co-ordinated through the SCTU and oversight will be maintained by the Programme Management Group, the Trial Steering Committee and the Data Monitoring and Ethics Committee.

11.1 PROGRAMME MANAGEMENT GROUP (PMG)

The TMG is responsible for overseeing progress of the study, including both the clinical and practical aspects. The DISCA Programme Management Group (PMG) will be the TMG. The Chief Investigator will chair the TMG.

The DISCA TMG charter defines the membership, terms of reference, roles, responsibilities, authority, decision-making and relationships of the TMG, including the timing of meetings, frequency and format of meetings and relationships with other trial committees.

11.2 TRIAL STEERING COMMITTEE (TSC)

The TSC act as the oversight body on behalf of the Sponsor and Funder. The DISCA Programme Steering Committee (PSC) will be the TSC. The PSC/TSC will meet at least yearly. The majority of members of the TSC, including the Chair, should be independent of the trial.

The DISCA TSC charter defines the membership, terms of reference, roles, responsibilities, authority, decision-making and relationships of the TSC, including the timing of meetings, frequency and format of meetings and relationships with other trial committees.

There is also a Programme Steering Committee that will have oversight of the entire DISCA Programme.

11.3 INDEPENDENT DATA MONITORING COMMITTEE (IDMC) / DATA MONITORING AND ETHICS COMMITTEE (DMEC)

*(**NB** for the purposes of this protocol, IDMC and DMEC refer to the same committee, and these terms can be used interchangeably).*

The aim of the IDMC is to safeguard the interests of trial participants, monitor the main outcome measures including safety and efficacy, and monitor the overall conduct of the study. These duties will be carried out by the DISCA Programme Steering Committee.

12 DATA MANAGEMENT

Participant data will be collected on Trial Deck, a Global Initiative (GI) platform for data collection. Data will be entered remotely, primarily by the participants themselves. The Hub Research Assistants will enter some eligibility and baseline data on Trial Deck and confirm the participant is eligible. Following non-response from the participant, the site Hub RA (or if not collected during the Hub RA call, a member of the Trial Management Team at the SCTU) will call

the participant to collect questionnaire data (Baseline, Month 3, Month 6) over the telephone. The data collected will be entered onto Trial Deck during the collection over the telephone, alternatively the data will

be entered onto Trial Deck within the timelines specified in the Data Management Plan (DMP). Data will be collected and retained in accordance with the current Data Protection Regulations.

Personnel entering data will be GCP trained, with specific roles assigned to ensure only required data is visible and granted access to enter necessary forms only on Trial Deck.

The participant data is pseudo-anonymised by assigning each participant a participant identifier code which is used to identify the participant during the trial.

Cognitive Task data will be collected using PsyToolkit (https://www.psytoolkit.org/). PsyToolkit is a web-based software to create psychological assessments. Data processed on the PsyToolkit will be pseudonymised by replacing participants' names with a study ID. Psytoolkit servers are located in the EU. The raw data collected from PsyToolkit will be downloaded and stored to a KCL managed SharePoint that only the immediate research team at KCL have access to. The data is hosted and stored in Microsoft's European data centres and protected by multiple layers of security technology and encryption. Data stored on the PsyToolkit servers will be deleted after data collection is completed.

The Participant Information Sheet and Informed Consent Form will outline the participant data to be collected and how it will be managed or might be shared, including handling of all Participant Identifiable Data (PID) and sensitive PID adhering to relevant data protection law.

A DMP will be available providing full details of the data management strategy, data management documentation created for the trial and data management tools used. A Trial Schedule will be created to document all trial-specific data management activities including any central monitoring tasks, and database and data process updates. Timelines for key tasks will be specified in the DMP and tracked in the Trial Schedule.

All entries and alterations made to the GI Platform will be visible via metadata reports and an audit trail which provides the identity of the person who made the change, plus the date and time.

At the end of the trial, once all data has been collected and data processes completed, the Chief Investigator will confirm the integrity of the data by signing a Confirmation of Data Integrity Form. The eCRFs will be archived according to SCTU policy.

Data may be requested from the Data Access Committee at SCTU. Any request will be considered on a regular basis.

13 DATA SHARING REQUESTS FOR RESULTS THAT ARE AVAILABLE IN THE PUBLIC DOMAIN

In order to meet our ethical obligation to responsibly share data generated by interventional clinical trials, SCTU operate a transparent data sharing request process. As a minimum, anonymous data will be available for request from three months after publication of an article, to researchers who provide a completed Data Sharing Request Form that describes a methodologically sound proposal, for the purpose of the approved proposal and if appropriate a signed Data Sharing Agreement. Data will be shared once all parties have signed relevant data sharing documentation.

Researchers interested in our data are asked to complete the Request for Data Sharing Form (CTU/FORM/5219) [template located on the SCTU website, www.southampton.ac.uk/ctu] to provide a brief research proposal on how they wish to use the data. It will include the objectives, what data are requested, timelines for use, intellectual property and publication rights, data release definition in the contract and participant informed consent etc. If considered necessary, a Data Sharing Agreement from Sponsor may be required.

14 MONITORING

14.1 CENTRAL MONITORING

There are a number of monitoring features in place at SCTU to ensure reliability and validity of the trial data, which will be detailed in the Trial Monitoring Plan.

The DMEC also have responsibility for specific central monitoring activities, as described in protocol section 11.3.
A copy of the consent form will be accessed by the SCTU using the online platform, to allow for central monitoring.

14.2 CLINICAL SITE MONITORING

Given the nature of the trial, site monitoring is not expected. Monitoring will be completed as detailed in the Trial Monitoring Plan.

14.3 SOURCE DATA

Source documents are where data are first recorded, and from which participants' CRF data are obtained. These include electronic data completed by participants and hub researchers online using the GI Platform Trial Deck completed by a researcher at SCTU.

14.4 AUDITS AND INSPECTIONS

The trial may be participant to inspection and audit by University Hospital Southampton NHS Foundation Trust (under their remit as Sponsor), SCTU (as the Sponsor's delegate) and other regulatory bodies to ensure adherence to the principles of GCP, UK Policy Framework for Health and Social Care Research applicable contracts/agreements and national regulations.

15 RECORD RETENTION AND ARCHIVING

Trial documents will be retained in a secure location during and after the trial has finished.

The PI or delegate must maintain adequate and accurate records to enable the conduct of the trial to be fully documented and the trial data to be subsequently verified. After trial closure the PI will maintain all source documents and trial related documents. All source documents will be retained for a period of 10 years following the end of the trial.

Sites are responsible for archiving the ISF and participants' medical records.

The Sponsor is responsible for archiving the TMF and other relevant documentation.

16 PUBLICATION POLICY

Data from all centres will be analysed together and published as soon as possible.

Individual investigators may not publish data concerning their participants that are directly relevant to questions posed by the trial until the Trial Management Group (TMG) has published its report. The TMG will form the basis of the Writing Committee and advise on the nature of publications. All publications shall include a list of investigators, and if there are named authors, these should include the Chief Investigator, Co-Investigators, Trial Manager, and Statistician(s) involved in the trial. Named authors will be agreed by the CI and Director of SCTU. If there are no named authors then a 'writing committee' will be identified.

All publications arising from this work will acknowledge the organisations involved in the research – University of Southampton and University Hospital Southampton NHS Foundation Trust. The policy applies to all staff and students whose research outputs from pre-clinical and clinical research derive from their employment by the University and/or Trust, from research grants awarded to the University and/or Trust or otherwise from the use of University and/or Trust resources and facilities. The policy applies to all authors of publications, and not simply to principal authors or reprint authors. Citing both organisations on all papers covered by this policy acknowledges the success of each organisation resulting from working in partnership.

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18 APPENDICES

(EXAMPLES)

None

19 SUMMARY OF SIGNIFICANT CHANGES TO THE PROTOCOL

e.g. [Populate as per CTU/FORM/5143]

Protocol date and version	Summary of significant changes
V2 17-Mar-2025	**Schedule of Observations and Procedures Table** **Added Text Note:** [6] *Cognitive tasks Call to be completed between 3pm-6pm (Mon-Sat). Saturdays should only be booked where there are no weekday options. During school holidays, the call can take place between 2pm-6pm. The same time slot used at Baseline MUST be kept consistent at Month 3 and Month 6 Follow Ups, give or take an hour.* *Additional wording to table:* ***Hub RA*** *(the ability for Hub RAs to conduct the cognitive task calls too).* *Change of wording to the footnote section. Specially, only one device is needed for the cognitive task call.* **Section 4.1.1 Inclusion Criteria** **Addition of inclusion criterion:** UK Resident at the time of registration and intend to live in the UK for the 6-month trial duration **Section 4.1.1 Exclusion Criteria** **Addition of exclusion criterion:** Primary carer (or child) is currently participating in another research study relating to the child. Concurrent recruitment to observational studies is acceptable. **Section 4 Informed Consent** **Additional wording**: Research Assistants supporting the cognitive tasks will be asked to obtain verbal assent from the child before cognitive testing. **Additional wording**: Primary caregivers can share the Information Sheet for Health Care Professionals, with any relevant healthcare professional involved in their child's care. **Section 5.5 Trial Procedures -** ***Call with Hub researcher*** **Additional procedure:** Confirmation of UK Residency (collection of child's GP address). **Section 5.6 Follow Up** **Additional procedure:** Confirmation of Primary caregiver (or child) concurrent recruitment into other research studies relating to the child. **Terminology: 'Patient' replaced with 'Participant'** Page 13, Section 3, Table 1 & Section 12. **Terminology: 'Patient' replaced with 'Primary Caregiver'** Page 21.

V3 10-Apr-2025	**Section 3** **Use of additional recruitment methods:** Prospective participants to be identified from sources such as Consent 4 Contact (C4C) and Clinical Record Interactive Search (CRIS). Advertisement within ADHD support groups, GP practices, schools, private clinics, and University research circulars (King's College London, Nottingham Trent University, University of Newcastle upon Tyne, University of Southampton). **Removal of wording:** This study will also be advertised via primary care networks, as this is now covered in 'GP practices' as above.
V4 10-Aug-2025	**SCHEDULE OF OBSERVATIONS AND PROCEDURES** **Footnotes updated:** A change to the timing of the window that the cognitive tasks can be completed. Specifically, the change from a window of 3-6pm to a window of 2-6pm. **Additional wording:** Where possible, tasks should be completed at a similar time during the month 3 and month 6 follow-ups. Where possible, the cognitive tasks will be consistent with respect to whether they are completed on a school versus non-school day. **Section 3** **Additional wording:** Charities will use their existing ways of working and utilise their established links to disseminate information about the trial to potentially eligible families. The study will also be advertised within Hampshire Foster care services. Addition of recruitment from parent support groups and clarity that this will involve internet-based groups. Clarity that advertisements may include internet-based groups regarding the ADHD support groups too.
V5 20-Feb-2026	**Cover page** Addition of ISRCTN number **Trial Synopsis Table (page 7)** **Additional Wording:** • Advertisement and mailshots to families of potentially eligible children at primary care settings • Advertisements and mailshots to carers of potentially eligible children within school settings • Addition of LinkedIn as a social media channel • Removal of reference to ADHD Foundation Charity (pages 7 & 17) **SCHEDULE OF OBSERVATIONS AND PROCEDURES** **Additional Wording:** Randomisation: *Ideally* within 4 weeks from Informed Consent **Footnotes updated:** Randomisation within 4 weeks of informed consent is an ideal timeframe. Participants may still be randomised beyond 4 weeks since informed consent.

TABLE OF ENDPOINT/OUTCOMES

Updates to the Summary methods column for Sleep Onset Latency objective:

- Primary: mean difference between groups (from linear regression)
- Secondary: odds ratio for group based on binary split at 30 minutes

Replaced Sleep Quality objective with: Effect of the intervention on sleep variables. Added outcome measure for Sleep Quality:

- Wake after sleep onset
- Sleep efficiency

Sleep problem outcome measure

Replaced Non/Mild/Mod/Severe with Frequencies and percentages per category
Moved the Omnibus Sleep Questionnaire (OSQ) further up the table

Replaced Irritability with Behavioural and emotional functioning

Changes to the wording for the Quality of Life and Neurocognitive variable section to allow for a clearer description of the purpose of each measure.

Section 3

Update to recruitment methods:

Removal of recruitment via ADHD Solutions and ADHD Foundation.

To include targeted mailshots in each of the recruitment settings using advertisements. Addition of the following recruitment method wording:

- Advertisement within pharmacies
- Database search and mailout outs via primary care settings
- Advertisement and targeted mailshot at other NHS Trusts
- Be part of research: Advertisements and Invitations to members on the NIHR Be Part of Research Volunteer Service (BPORVS) register

Section 5.2, Screening Procedures; Section 5.3 Registration and Randomisation Procedures

- Added the ability to complete cognitive tasks within 5 weeks of informed consent.
- Added term 'ideally' to the 4-week window from ICF to randomisation.
- More concise wording for the randomisation process and the minimum measures that need to be completed to progress to randomisation.

Section 5.5 Trial Procedures

Removal of Demographics- types of Demographics (such as Age, sex) are itemised separately.

Section 6, Safety

An update to add clarity to the process of reporting SAE.