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A trial comparing the effectiveness of an online sleep behavioural intervention versus standard care in children with rolandic epilepsy

Submission date
06/09/2021

Recruitment status
No longer recruiting

Registration date
09/09/2021

Overall study status
Completed

Last Edited
12/09/2024

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Epilepsy is a common condition among children in the UK. Families have identified sleep problems in their children with epilepsy and also amongst parents as a major issue that doesn't get enough attention. Sleep problems can be present while they are being followed up by their paediatrician for seizures and even persist after the seizures have gone away. Sometimes their learning, behaviour, self-esteem and mood are affected too.
Sleep problems can be managed through practice. There are guidelines to help children in general with their sleep, but there is nothing available that specifically helps children with epilepsy and their parents address sleep problems and improve their sleep quality.
The CASTLE Sleep-E study aims to find out whether giving families access to an online sleep intervention (known as the CASTLE Online Sleep Intervention or "COSI" for short) will help improve their quality of sleep. We will compare the child and parent's sleep quality at the start and after three months. In order to make a fair and balanced comparison, half the families will receive COSI and the other half will receive standard care from their paediatrician. With these equally divided groups we'll be able to evaluate if COSI works or not.

Who can participate?
Children aged 4 to 13 years who have Rolandic epilepsy and sleep problems.

What does the study involve?
Families who are happy to participate in CASTLE Sleep-E will be followed up for 6 months after randomisation. Participants and their primary carers are asked to complete a number of questionnaires and assessments during their time on the trial. Site research teams will also collect data using electronic Case Report Forms (eCRFs) at clinic appointments planned at baseline, randomisation and 3 and 6 months post-randomisation. Data collection for CASTLE Sleep-E has been designed to be completed remotely, removing the need for participants to attend hospital visits in person.
Prior to entering the study, families will be invited to discuss the study with a member of their local research team and if happy to proceed, will be asked to provide consent and assent (if appropriate) using an e-consent system. Access to this e-consent system will be emailed to the

primary carer. The possibility of taking part in qualitative interviews will also be discussed at this visit, however if a family does not wish to consent to this activity, it will not impact their participation in the main trial.
Once valid consent is obtained, participants and one of their primary carers will be asked to wear an actigraph (sleep monitor) for 2 weeks. During this actigraphy period, families will also be asked to complete some electronic questionnaires and the participant will be asked to complete an iPad game, called SleepSuite. The actigraph and study iPad will be delivered directly to the participant's address at a time which is convenient for them.
Once the 2-week actigraphy period is over and the minimum dataset obtained, participants will be randomised to receive either the online behavioural sleep intervention or standard care. If a participant is randomised to the sleep intervention, log in details and instructions will be emailed directly to the primary carer. Those participants randomised to standard care will be followed up as per their clinician's normal practice.
After randomisation, participants will be followed up at 3 months and 6 months timepoints, regardless of allocation. At 3 months, participants and their primary carer will again be asked to wear an actigraph, complete electronic questionnaires and the SleepSuite assessment. At 6 months, only questionnaires are required to be completed by families.
If consent for the qualitative interviews was obtained during the initial consent discussion, families will be contacted by researchers at 3 and 6 months after randomisation. Interview topic guides will be sent to families to give them time to prepare. Interviews are semi-structured and can be tailored to each family, depending on themes to be discussed.
At the end of the trial, participants will be given the option to receive PDF copies of the COSI content, irrespective of their trial allocation. Further information about the trial can be found in the Parent/Guardian Patient Information Sheet.

What are the possible benefits and risks of participating?
Participants recruited into the trial will receive standard NHS care during the conduct of the trial. The main potential benefit from COSI is in terms of improved sleep compared to standard treatment for both patient and carer. Participants may also feel the benefit from a regular and rigorous follow-up schedule. The risks of participating in the trial are no greater than those encountered in standard care.

Where is the study run from?
King's College, London (UK).

When is the study starting and how long is it expected to run for?
May 2018 to September 2024

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Lucy Stibbs-Eaton, castlesleepe@liverpool.ac.uk

Study website
http://www.castlesleepetrial.org.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
289580

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50413, Grant Codes: RP-PG-0615-20007, IRAS 289580

Study information

Scientific Title
Randomised controlled trial comparing online behavioural sleep intervention with standard care in children with rolandic epilepsy

Acronym
CASTLE Sleep-E

Study objectives
To determine if an Online Sleep Behavioural Intervention is superior to standard care with respect to 3-month sleep problem frequency measured by Children's Sleep Habits Questionnaire (CSHQ).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/10/2021, East Midlands - Nottingham 1 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; no telephone number provided; Nottingham1.rec@hra.nhs.uk), ref: 21/EM/0205

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Sleep quality in children with rolandic epilepsy

Interventions
CASTLE Sleep-E is a randomised controlled trial comparing an online sleep behaviour intervention against standard care in children with epilepsy.

There is a target recruitment of 110 participants in total. Participants will be children with RE in the UK. All patients aged between 5 and <13 years with diagnosis of RE will be screened at the trial centres to identify potentially eligible participants for the trial. Potentially eligible patients and those providing consent (person with parental responsibility) will be invited to participate in the trial and provided with a patient information sheet and consent form in either an electronic format. There is an option for a paper version of this document to be provided for review, however ultimately all consent/assent for the study will be obtain electronically.
The patient and the person providing consent will be allowed sufficient time to discuss the trial and decide whether to consent/assent to trial entry.

The trial will be open to recruitment for 12 months. Participants will be followed up at 3 and 6 months after randomisation.

At visit 1 (T-4 weeks), a review of medical history and EEG results will be completed. An assessment of the patient against the eligibility criteria will be performed and full eligibility will be confirmed. If the patient is eligible for the study, consent and assent (if the child is 7 years or older and capable) will be sought.
Patient demographics will be collected and a COVID screener questionnaire will also be completed at this visit. Additionally, families be asked to consider taking part in the interview component of the trial, however this is optional and declining to this activity will not impact their recruitment to the main study.
Consent and assent will be completed electronically at this visit. The appropriate information sheet and consent/assent forms being available through a secure e-consent system. The primary carer and participant's contact details will be collected at this visit as part of the consent form. Once signed, a copy of the consent/assent form will be provided electronically or participant will

be provided with a printed copy.
Participants will not receive their treatment allocation at Visit 1. Instead, they will be randomised to their treatment arm following the collection of baseline actigraphy and questionnaire data.

All participants and one of their primary carers will be asked to wear an actigraph (a watch that records your sleep) for 2 weeks at 2 different times during the study: after visit 1 and after visit 3 (3 months).
Once valid consent is obtained for the study, the sleep team for CASTLE Sleep-E at Oxford Brookes University will be notified via email. The team will use the contact details collected during the consent discussion to contact the primary carer to arrange delivery of the actigraphs and study iPad, the latter will be used to complete an online SleepSuite assessment throughout the study. The study iPad may also be used to complete study questionnaires. Participants and their primary carers will be provided with instructions for the actigraphs/iPad and how to return these devices.

During the actigraphy period, participants and primary carers are asked to complete a number of questionnaires electronically. Participants are also asked to complete an online SleepSuite assessment during this time. An email containing a web link to the questionnaires will be sent to participants after the dispatch of their actigraphs. Participants will also be prompted to complete the online SleepSuite assessment on the study iPad.

Once the actigraph period has ended and the minimum dataset have been completed, the participant can be randomised to the study. Randomisation will be completed as part of a telephone/video call or face-to-face visit (Visit 2 - T0).
During Visit 2, there will be a review of contact details and confirmation of continued eligibility. Baseline medical and school absence information will be collected from the participant and primary carer. Randomisation will then take place.

If the child is allocated to receive sleep intervention, the details to access the sleep training plan will be sent via email to the primary carer. To access the intervention, they will have to click on the link sent via email through their laptop, tablet or smartphone.

Visits 3 and 4 (at 3 and 6 months respectively) may be carried out face-to-face or by telephone /video call. The research team will ask questions about the participant's health and well-being. Around these timepoints, an email will be sent to primary carers and participants asking them to complete study questionnaires. The SleepSuite assessment will be completed on the study iPad at Visit 3 only.
Additionally, the sleep team at Oxford Brookes will be in contact to arrange delivery of the actigraphs which participants are asked to wear for 2 weeks at 3 months post randomisation (Visit 3).
If the family consented to taking part in the interview component of the trial during Visit 1, they may be contacted by the qualitative team at Edge Hill University in the weeks following Visits 3 and 4. These interviews will be audio-recorded (with permission) and transcribed. Interviews with minors will be supported with the use of activity booklets.
Families will be given the option to receive study postcards at three different timepoints during and shortly after the study. They will be sent to families between months 1-2 and 4-5 of trial participation and 4-8 week after the final study visit. The postcards will be sent via post (in a sealed envelope) and will be addressed to the child (courtesy of their primary carer). They will contain child-orientated activities (e.g. a wordsearch, scavenger hunt and maze). The final postcard will be accompanied by a study certificate.
An internal pilot will be carried out during the first 6 months of recruitment to review the

recruitment and consent rate.
Formal interim analysis will not be performed, however the IDSMC will be asked to review and consider the information collected during the internal pilot and make recommendations to the TSC as to whether further recruitment and follow up should continue.

Intervention Type
Behavioural

Primary outcome measure
1. Total child sleep problem score as measured by the Child Sleep Habit Questionnaire at baseline and 3 months.
2. Cost utility of COSI reported as incremental cost per QALY gained will be measured using the EQ-5D-Y, CHUD-9D, Resource Use Questionnaire, study visits CRFs, concomitant medications, serious adverse events and utility questionnaires at baseline, 3, and 6 months. PLICS and HES data will be used at the end of trial.

Secondary outcome measures
1. Total child sleep problem score as measured by the Child Sleep Habit Questionnaire at baseline and 6 months.
2. Time to first seizure measured using study CRF data at 3 and 6 months.
3. Time to 6-month seizure remission measured using study CRF data at 3 and 6 months.
4. Parental sleep-related knowledge is measured by the score of the Knowledge about Sleep in Childhood (KASC) scale at baseline and 3 months.
5. Parental Anxiety is measured by the score of the Hospital Anxiety and Depression Scale (HADS) at baseline, 3 and 6 months.
6. Parental sleep problems are recorded by the Insomnia Severity Scale (ISI) at baseline, 3 and 6 months.
7. Children's sleep-related reaction time and executive function is measured by the score of the SleepSuite assessment (iPad game) at baseline and 3 months.
8. Health-related quality of life is measured by the CHEQOL score change in Children / WHO-5 score change in primary carers at baseline and 6 months.
9. Children's behaviour is measured by the total score of the Strength and Difficulties Questionnaires at baseline, 3 and 6 months.
10. Parenting self-efficacy is measured using score changes in the Parenting Self Agency Measure (PSAM) at baseline, 3 and 6 months.
11. Changing sleep parameters measured by the collection of actigraphy data for 2 weeks at baseline and 3 months.
12. Sickness-related school absences are recorded using study CRFs at randomisation, 3 and 6 months.
13. Child health utilities and QALYs are measured using the score changes/differences in CHU-9D and EQ-5D-Y utilities/QALYs at baseline, 3 and 6 months.
14. Parent health utilities and QALYs are measured using the score changes in EQ-5D-5L and differences in EQ-5D-DL/ISI QALYs.
15. NHS/Personal Social Service costs measured using the Resource Use Questionnaire, CRF data and PLICS/HES data at baseline, 3 and 6 months.
16. Indirect and direct non-medical costs measured by CRF data and Resource Use Questionnaire data at baseline, 3 and 6 months.
17. The cost-utility under alternative scenarios measured using the Resource Use Questionnaires and Study CRFs at baseline, 3 and 6 months and PLICS/HES at the end of the trial.

Qualitative outcomes
1. The qualitative experiences of primary carers and children will be collected during interviews conducted at 3 months and 6 months.

Overall study start date
14/05/2018

Completion date
04/09/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 31/01/2023:
Main CASTLE Sleep-E study:
1. Children with clinician-confirmed diagnosis of epilepsy
2. Aged >=4 years and <13 years at the time of randomisation
3. Parent/Carer reported child sleep problem as defined by mild, moderate or severe score on Hiscock Australian global sleep question (Poor sleeper defined by caregiver responding 'Mild', 'Moderate' or 'Severe' to "Over the last 2 weeks, how much of a problem has your child's sleep been?")
4. Documented informed consent received from a person with parental responsibility
5. Family have an email address and mobile phone
6. Parent and child are to have a good enough understanding of the English language to read and answer study questionnaires
In order to participate in the Qualitative Component of the study, the following criteria must be met:
1. Consent of caregiver to participate and for their child to participate (optional item on main trial consent form)
2. Children need to be >=7 years of age

Previous inclusion criteria:
Main CASTLE Sleep-E study:
1. Children diagnosed with RE/CECTS (see International League Against Epilepsy Diagnostic Manual at https://www.epilepsydiagnosis.org/syndrome/ects-overview.html)
2. EEG showing focal sharp waves with normal background (see International League Against Epilepsy Diagnostic Manual at https://www.epilepsydiagnosis.org/syndrome/ects-eeg.html)
3. Aged >=5 years and <13 years at the time of randomisation
4. Parent/Carer reported child sleep problem as defined by mild, moderate or severe score on Hiscock Australian global sleep question (Poor sleeper defined by caregiver responding 'Mild', 'Moderate' or 'Severe' to "Over the last 2 weeks, how much of a problem has your child's sleep been?")
5. Documented informed consent received from a person with parental responsibility
6. Family have an email address and mobile phone
7. Parent and child are to have a good enough understanding of the English language to read and answer study questionnaires

In order to participate in the Qualitative Component of the study, the following criteria must be met:
1. Consent of caregiver to participate and for their child to participate (optional item on main

trial consent form)
2. Children need to be >=7 years of age

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
13 Years

Sex
Both

Target number of participants
Planned Sample Size: 110; UK Sample Size: 110

Total final enrolment
85

Key exclusion criteria
Children with moderate/severe learning disabilities

Date of first enrolment
30/08/2022

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
King's College Hospital
Denmark Hill

London
United Kingdom
SE5 9RS

Study participating centre
St Thomas's Hospital
249 Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Diana Princess of Wales Hospital
Scartho Road
Grimsby
United Kingdom
DN33 2BA

Study participating centre
Norfolk and Norwich Hospital
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
Arrowe Park Hospital
Arrowe Park Road
Wirral
United Kingdom
CH49 5PE

Study participating centre
Craigavon Area Hospital
Lurgan Rd
Craigavon
United Kingdom
BT63 5QQ

Study participating centre
Luton and Dunstable University Hospital
Lewsey Road
Luton
United Kingdom
LU4 0DZ

Study participating centre
University College London Hospital
235 Euston Road
London
United Kingdom
NW1 2BU

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Worthing Hospital
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
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AB15 6RE

Study participating centre
NHS Tayside
Kings Croos
Clepington Road

Dundee
United Kingdom
DD3 8EA

Study participating centre
Airedale General Hospital
Skipton Road
Steeton
Keighley
United Kingdom
BD20 6TD

Study participating centre
Peterborough City Hospital
Edith Cavell Campus
Bretton Gate
Bretton
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
James Paget University Hospital
Lowestoft Road
Gorleston
Great Yarmouth
United Kingdom
NR31 6LA

Study participating centre
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Barnsley Hospital
Gawber Road

Barnsley
United Kingdom
S75 2EP

Study participating centre
Homerton Hospital
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre
Great North Children's Hospital
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Scunthorpe General Hospital
Cliff Gardens
Scunthorpe
United Kingdom
DN15 7BH

Study participating centre
Hinchingbrooke Hospital
Hinchingbrooke Park
Huntingdon
United Kingdom
PE29 6NT

Study participating centre
Oxford Children's Hospital
John Radcliffe Hospital
Oxford
United Kingdom
OX3 0AG

Study participating centre
Princess of Wales Hospital
Coity Road
Bridgend
Bridgend County Borough
United Kingdom
CF31 1RQ

Study participating centre
University Hospital Lewisham
Lewisham High Street
London
United Kingdom
SE13 6LH

Study participating centre
St Richard's Hospital
Spitalfield Lane
Chichester
United Kingdom
PO19 6SE

Sponsor information

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Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol (preprint)	31/05/2022	23/06/2022	No	No
Protocol article	10/03/2023	13/03/2023	Yes	No
HRA research summary		28/06/2023	No	No