

# CASTLE FAQs

## Eligibility:

- 1. If patients/families decline to take part in the treatment arm of the study, are they recruited in the sleep part?**  
No
- 2. Implications for the study if parents using epilepsy monitors.**  
Epilepsy monitors have no implications for the study.
- 3. If child has been prescribed melatonin for the study, are they eligible for the study? What about ADHD medications?**  
If stable on melatonin before starting the trial then it's fine but not when the participant has already joined the study. Same for ADHD medications.
- 4. Does prescription of buccal midazolam affect inclusion of the study?**  
Prescription of buccal midazolam does not affect inclusion to the study.
- 5. What if parent doesn't have good English/internet access.... ?**  
This is an unavoidable limitation at this stage. If this is the case, the family are not eligible for this study.
- 6. Are patients still eligible if they have been treated with rescue medication when they went to A&E?**  
Yes they are.

## Informed consent:

- 1. Can research nurse take informed consent and randomise?**  
Yes as long as allowed by the site.
- 2. Some studies have produced a pre-consent discussion and the day on the consent discussion leaflet. Would this be possible for the CASTLE study? Due to amount of information to give to family**  
Not something that we plan on producing right now.
- 3. What time allowed between giving PIS and decision made?**  
Any time the patients feel they need, can be even done at the same but I patient/parent are happy to. Best practice tends to be 24h.

## Randomisation and Treatment Questions:

- 1. What happens to a child who is randomised to no-medication if the parents want medication?**  
If that happens, it would be considered a failure of the informed consent process, which always has to address patient preference. It is important that equipoise is accurately conveyed to parents at clinic visits to ensure good recruiting rates. If you would like help in addressing patient preference, please review the site training materials or get in touch with the Trial Coordinator.

2. **What happens if the patient needs to be moved from treatment to no treatment (or vice versa) due to clinical care? Do they remain in the study?**  
Yes, they still remain in the trial (in the same arm they were initially allocated to) and will be followed up until the end.
3. **Who provides the ongoing prescriptions of the AEDs that child has been randomised in?**  
The GP usually does just as in normal clinical care.
4. **How much information needs to be shared with GP in a form of a usual clinic letter?**  
An initial GP letter is sent to the GP to inform them their patient has been enrolled into a clinical trial (they can get a copy of the consent form if they want to). Additionally, a follow-up GP letter is sent later if the participant misses any clinical appointments to try and obtain any data that have been missed.
5. **Clinics are noisy places and in most sites is not possible to book an extra room to see participants. Could headphones be an option to deliver CANTAB and questionnaires?**  
It was decided that headphones could not be used as it could produce a high degree of inconsistency between visits if in one of them headphones are not worn. It was agreed that although clinics can be noisy, it was most important to prioritise uniformity of environment conditions for each timepoint.
6. **Can nurse prescribers provide the prescription for CASTLE?**  
No, only medically qualified doctors present in the delegation log can prescribe for this trial.
7. **Can a nurse be the co-Investigator (co-I) for the study?**  
Nurses can undertake most study activities but only medically qualified doctors can be Co-Is
8. **Can questionnaires be sent to parents at home?**  
No, questionnaires have to be completed at site visits. This is because questionnaires taken home are rarely returned and this creates a missing data problem. Better to have the participant fill out the form there and then.
9. **Can the 6 month visit be done over the phone since no questionnaires or iPad games are provided at this visit?**  
No, the trial was envisaged to mimic routine practice and it's expected that all visits will happen at clinic. If a telephone follow-up does take place at 6 months this should be counted as an unscheduled visit.
10. **Are telephone call considered unscheduled visits?**  
Yes and the appropriate data collection form should be completed.

### Expenses:

1. **It can be argued that the first visit is above standard care as it will not be possible to complete during a routine clinic appointment.**  
The first visit does not necessarily have to be above standard care if the site can organise it well. For the pilot, travel/parking expenses will not be reimbursed as the first visit because it is

considered standard care. If this creates many issues and sites find themselves creating extra visits, the subject can be revisited and expenses reimbursed after the pilot period.

- 2. Payment for recruitment/research nurses, what if we recruit, see twice then they drop out. It's a lot of work. Do we still get some reimbursement?**

Per patient payment will be split into 2 payments, a small one after recruitment & randomisation (30%) and the rest at the end of the trial (70%).

- 3. If the child is not on any treatment as decided by the clinical team but allocated to the drug arm, is this not an extra research cost rather than standard care so should be funded by the study?**

The answer is no because treatments are NHS stock and the trial does not allocate a higher percentage of patients to a treatment compared to the real world.

### COSI:

- 1. Can clinicians have access to COSI, so they know what parents are looking at if they have any queries?**

The consensus is that clinicians won't have access to COSI as this could affect the 'standard care' that patients receive. There is some information about COSI at [castle-study.org.uk](http://castle-study.org.uk) and also at [castle-trial.org.uk](http://castle-trial.org.uk) including an overview and screenshots to give a general idea. But clinicians can rest assured that parents will have support from Georgia (Oxford Brookes University) if they have queries (about content or functionality - or anything else). It is also important that parents address questions to Georgia and not the clinicians because this way we can monitor if COSI is working fine or what exactly works best. This 'point of contact' will be made clear in the email which gives them their logon ID.

- 2. For using COSI, how do you deal with families where there are 2 parents living separately and the child spends time in each house?**

This is of course the 'real world' and we want this to be as pragmatic as possible. Often one parent/caregiver reports concerns about sleep more than the other or is more interested in a sleep intervention trial. In these circumstances we usually work through this caregiver. Sometimes it is the parent where the child spends most nights, but this will not necessarily always be the case. The parents or caregivers have to come to an agreement about who will fulfil this role because they will have to collect the data and perhaps also wear an actigraph three times during the study for a week at a time.

- 3. Will we look at COSI evaluation as the trial proceeds and make adaptations as necessary or wait until the end of the trial to collate evaluations?**

Glitches or things that don't function properly will be reported to CTIRC Information Systems Department after the pilot period to be solved.

- 4. If multiple children from one family participate how will this be managed in terms of randomisation/exposure to COSI?**

Randomising siblings in the same "bucket" (family stratification) is not something that has been incorporated in the randomisation system for now as it is quite time consuming to do for such a small population (1%). After the pilot, it can be reassessed to whether it should be incorporated.

## CANTAB:

1. **Can research nurses have access to a test version of CANTAB so that they can practice to familiarise themselves with the tests (both before and during the trial - latter needed as it could be months between test sessions, depending on number of patients they recruit)?**  
Yes, there is a test version of CANTAB that nurses will have to practice to get familiar with the tests. Practicing with the test version will be imperative for those who will be delivering CANTAB.
2. **What if parents ask for CANTAB scores?**  
Scores will not be available to child/parent/RN etc. Research nurses will present CANTAB to kids as a game and not a test. There are no scores available.
3. **Is there a need to maintain consistency in the time of day that participants complete assessments such as CANTAB?**  
Ideally there should be consistency in the time of day participants complete CANTAB because we need to prioritise uniformity of environment conditions for successive timepoints.
4. **If there is only research nurse at a setting, how will maintain consistency of testing time frames in case she is ill/on AL? Will epilepsy nurses/others also be trained to collect relevant data such as CANTAB?**  
Ideally sites will be asked to get 2 people trained in CANTAB (where possible) to minimise these kinds of situations.
5. **Is there going to be anything to give to the child after completing the assessments (sticker/certificate/badge)?**  
Yes, we are developing a CANTAB certificate.
6. **Can CANTAB/other testing be done only in clinic or also at home?**  
Only at clinic.
7. **CANTAB RVP- Timing is too long? PAL- Too difficult? SWM – Difficult for young children**  
Our team has tested CANTAB in children and they actually do fine/better than adults and probably enjoy it more since they like to play games.