



Where can I get more information?

Further information on the study can also be found on our study website:

www.telethonkids.org.au/projects/the-circa-diem-study

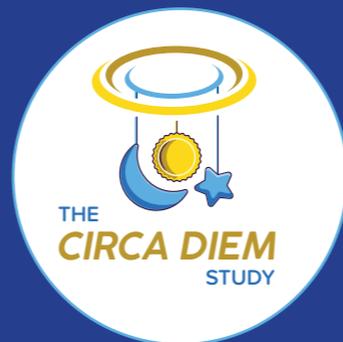
If you have further questions on the study, you can contact the CIRCA DIEM Clinical Research Co-ordinator on circadiem@telethonkids.org.au

Alternatively, you can contact the local CIRCA DIEM Doctor:

Study Doctor:.....

Telephone:

Email:

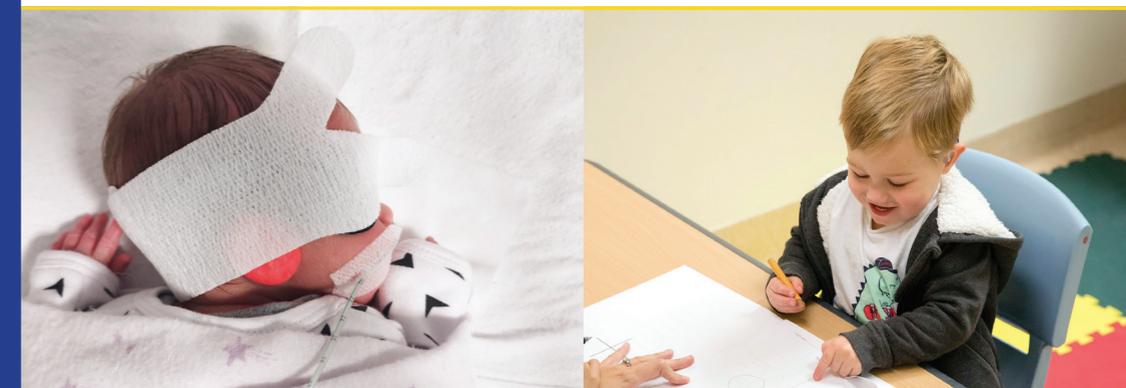
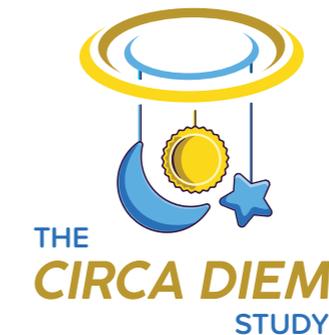


**Cognitive Improvement through early Restoration of CIRCADian rhythms in very preterm Infants via Environmental Modification:
The CIRCA DIEM Study**

FOR FURTHER INFORMATION:

E | circadiem@telethonkids.org.au

W | www.telethonkids.org.au/projects/the-circa-diem-study



Understanding if promoting day and night rhythms in babies during their hospital stay improves child development



Government of Western Australia
Child and Adolescent Health Service

PARENT INFORMATION BROCHURE

Hello!



A team of researchers around Australia are working together to understand whether restoring circadian rhythms with simple interventions in early life can improve brain development in babies born before 32 weeks gestation.

This leaflet is designed to explain simply and clearly the research that we do.

What are circadian rhythms?

The circadian rhythm is the body's internal clock which controls many of our daily biological processes and behaviours. The body's circadian rhythm usually aligns with day and night. An alternating light and dark cycle is a critical part of the signal sent to the brain that stimulates the release of the appropriate hormones necessary for sleepiness and wakefulness. Uninterrupted sleep is important for normal brain development and overall health for babies and children.

What happens to circadian rhythms in preterm babies?

Premature babies may spend many days or even weeks in the Neonatal Intensive Care Unit (NICU). NICUs are often noisy and have constant lighting 24 hours a day. This continuous exposure to noise and light may delay the natural development of circadian rhythms and may slow normal development of important body organs such as the brain.

What will we do in this study?

We will test whether alternating your baby's exposure to light and dark, as well as to noise and quiet, will help your baby to develop a healthy circadian rhythm while they are in hospital. Our main goal is to see if this simple change in the way we care for babies will improve your baby's brain development and general wellbeing.

To test this, babies will be randomly assigned to one of two study groups:

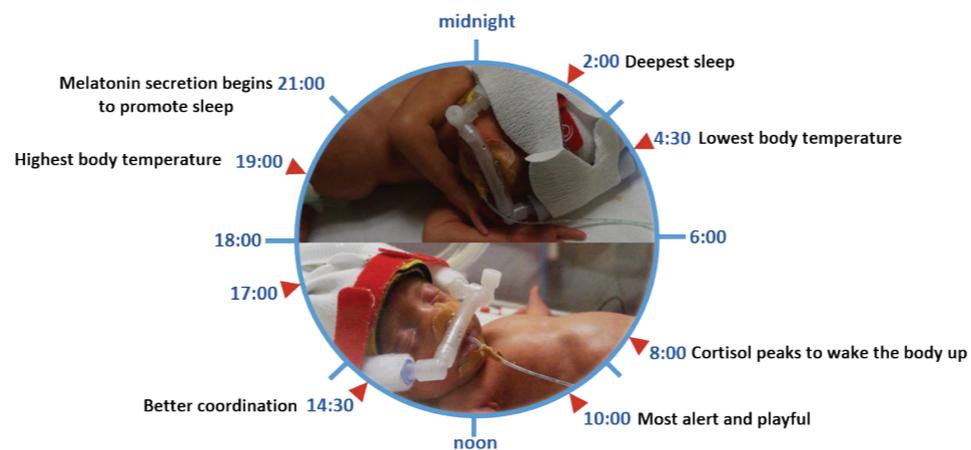
1 Babies assigned to the control group will receive normal care according to unit protocols for light and noise exposure.

2 Babies assigned to the intervention group will receive routine care, but will also be exposed to a simulated day/night time environment.

During the daytime, the cot-cover, eye-masks and ear-plugs will be removed and the light in your baby's cot will be kept at a safe daylight level.

At night, intervention group babies will have a cot-cover and will wear eye-masks, to ensure darkness, and soft silicone ear-plugs to reduce noise exposure.

The below diagram shows how the simulated day/night environment in the intervention group relates to some of the normal biological events usually controlled by circadian rhythms.



Questions you may have

What will we measure and how?

The main study outcome is your baby's understanding and memory at 2 years postnatal age and we will monitor your baby's growth, movements and development intermittently from birth until the 2 year follow-up appointment. Your baby's movements will be recorded on your phone via a special app and when your baby is 3 months and 3½ months old. We will assess your child's development prior to the 2 year follow up appointment by email survey and parent-infant bonding and mother's mental well-being by email survey.

Will the eye-masks and ear-plugs hurt my baby?

Eye-masks and ear-plugs are safe for babies. Eye-masks are regularly used in the NICU. Silicone ear plugs are made of a soft silicone material that will mould to the shape of your baby's ear canal, and will not cause your baby any discomfort.

How long will my baby wear these items?

If your baby is assigned to the intervention group, your baby will only wear the eye-masks and ear-plugs overnight whilst in hospital, until discharged. If your baby is assigned to the control group, your baby will receive routine care, which does not include overnight use of eye-masks or ear-plugs.

Do we, or our baby, need to do anything else?

After your baby goes home, we will follow up on their development, as well as on how you are feeling. Most of these follow-ups are either questionnaires, or a brief video of your baby's movements, which you can do from home.

Does my baby have to take part?

No! Taking part in this study is your decision. You can withdraw from the study at any stage. Your baby will receive the care they need, and would normally receive, whether or not you take part.