

Testing a new sleep mat, the Sonomat for use to diagnose sleep breathing problems in children with Neurodisability

ACTRN12622001544763

Status	RECRUITING
Sponsor	The University of Queensland
Enrollment	200 participants

Plain Language Summary

Children with neurodisabilities — conditions affecting brain development and function, such as cerebral palsy, Down syndrome, autism spectrum disorder, and ADHD — have a much higher rate of sleep-disordered breathing than other children. Currently, diagnosing these problems requires an overnight sleep study in a hospital, which can be very stressful and difficult for children who may already struggle with new environments and sensory challenges. This study is testing whether a specially designed sleep mat called the Sonomat can accurately detect sleep-disordered breathing in these children at home, making diagnosis much more comfortable and accessible.

Participants will undergo their standard in-hospital sleep study while simultaneously lying on the Sonomat, and will then use the mat at home for three nights. Researchers will compare what the Sonomat records with the results of the hospital sleep study to see whether the device is accurate enough to replace the in-hospital test.

You may be eligible if your child is aged 2 to 18 years, has a neurodisability meeting the study definition, and has already been referred by a sleep physician for a sleep study to assess sleep-disordered breathing. There are no exclusion criteria for this study.

Key Eligibility Criteria

Inclusion (2)

- Children aged 2-18yrs who meet the study definition for ND and who have been deemed to require a PSG clinically by a sleep physician, for assessment of Sleep disordered breathing (SDB).
- Children with Neurodisability (ND): this research will include all children who meet the ICD-11 definition for a neurodisability. Specific conditions include (but are not limited to) Cerebral Palsy, Down syndrome, Prader-Willi syndrome, Angelman's syndrome, Velocardiofacial (22q11deletion) syndrome, Rett syndrome, Fragile X syndrome, William's syndrome, Smith-Magenis Syndrome, Spina Bifida, Autistic Spectrum Disorder and Attention Deficit Hyperactivity Disorder (ADHD). Where there is uncertainty on whether a child meets the criteria, advice will be sought from a neurodevelopmental paediatrician.

Exclusion (1)

- None

Locations (3 total)

Queensland Children's Hospital - South Brisbane, NSW,QLD,VIC, Australia
The Children's Hospital at Westmead - Westmead, NSW,QLD,VIC, Australia
The Royal Childrens Hospital - Parkville, NSW,QLD,VIC, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12622001544763>

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