

Perth Children's Hospital (PCH) Healthy Ears: A telehealth-facilitated randomised-controlled trial utilising a health promotion intervention to resolve otitis media with effusion for children on specialist Ear, Nose and Throat (ENT) waiting lists.

ACTRN12622000546752

Status	RECRUITING
Sponsor	Telethon Kids Institute
Enrollment	250 participants

Plain Language Summary

Middle ear infections and fluid behind the eardrum (otitis media with effusion, or OME) are extremely common in young children. Persistent OME can muffle sounds and interfere with a child's ability to hear clearly during the critical years when they are learning to speak and understand language. The usual surgical treatment is to insert small ventilation tubes (grommets) to drain the fluid, but many children may not actually need surgery if their OME resolves on its own.

This study tests whether a simple, family-led health promotion programme delivered via telehealth can help children's ear fluid resolve without surgery. Families at Perth Children's Hospital on the waitlist for ENT assessment are given guidance on things like reducing secondhand smoke exposure, managing allergies, and encouraging nasal breathing. Their ear status is re-checked after the programme to see how many children improved without needing grommets.

Your child may be eligible if they are between 3 and 7 years old, have been referred to Perth Children's Hospital for hearing or ear concerns, and have had persistent OME confirmed by a tympanometry test for at least 3 months. Children with conditions like Down syndrome, cleft palate, or other complex medical needs are not eligible.

Key Eligibility Criteria

Inclusion (7)

- Children aged between three years old and seven years old.
 - Children identified during the triage of initial referral to PCH for hearing or ear-related presenting complaints.
 - Children who have the capacity to comply with study procedures, including follow up, regardless of residential geographical location.
 - Children who have been assessed and subsequently confirmed persistent otitis media with effusion (greater than or equal to 3 months) within a twelve month period as well as the following clinical criteria:
 - a) Type B tympanometry,
- ... and 2 more (see full listing online)

Exclusion (6)

- Children who are known to be scheduled to undergo surgical intervention within four weeks.
- Children who have been diagnosed with any of the following complex medical conditions which increases the risk of complications; cleft lip and palate, Down syndrome, major chromosomal anomalies, craniofacial anomalies, chronic suppurative otitis media, or congenital ear anomalies.
- Children who are actively participating in another ear intervention study.
- Children are unable to comply with relevant study procedures due to any physical, medical, developmental, behavioural or cognitive condition.
- Guardian(s) decline to cease the use of ear clearing devices for the four-to-six-week duration of the intervention and control, ie. ear syringe, ear candle, ear relief device (EarPopper®), over-the-counter ear drops, nasal balloon etc.

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12622000546752>

Locations (1 total)

Perth Children's Hospital - Nedlands, WA, Australia