

Ready, set, blow: A mixed method enquiry into the use of nasal balloon auto-inflation treatment for otitis media with effusion

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Background and objective

Otitis media with effusion (OME) is a common condition in Aboriginal and Torres Strait Islander children. Nasal balloon auto-inflation is a potential low-cost alternative to surgery to manage OME; however, the experiences of healthcare practitioners and parents in using this treatment strategy are not well understood. This study aimed to understand the experiences of using nasal balloon auto-inflation as a treatment for childhood OME.

Methods

Caregivers of 69 Aboriginal and Torres Strait Islander children using auto-inflation in the AutoInFLation for Aboriginal and Torres Strait Islander Children with Bilateral OME (INFLATE) randomised clinical trial answered the questionnaires. Interviews were undertaken with caregivers and Aboriginal community research officers.

Results

The novelty of the experience excited children initially, but caregivers needed to ensure the treatment remained enjoyable and incorporated into the daily routine. The device was easy to use for most, with twice daily inflations the most manageable. The family dynamic (number of children, split-care arrangements) affected success.

Discussion

Gamification of treatment, as well as regular check-ins by healthcare practitioners, can increase adherence and achievability of the treatment plan for Aboriginal and Torres Strait Islander children.



CAREGIVERS will seek the advice of healthcare professionals when their child's behaviour or disposition changes. Caregivers (the adult caring for the child, inclusive of parents, grandparents, relative or not biologically related carers) might discover that their child is not ignoring them, but rather cannot hear them due to the presence of otitis media with effusion (OME).¹ Also known as 'glue ear', OME is a build-up of fluid within the middle ear. When persistent, OME can have significant impacts on hearing, speech development, behaviour and schooling.² Persisting OME (typically more than three months) is predominantly treated with surgery to insert tympanostomy tubes (also known as grommets or ventilation tubes) in the tympanic membrane to help ventilate the ear and drain the fluid.² Surgery, however, has risks and consequences including persistent tympanic membrane perforation, distress to the child, cost and/or potentially significant wait times within a public healthcare system.³

Opportunistic pre-surgery management with a nasal balloon auto-inflation device aims to improve drainage of ear fluid through the Eustachian tube by children blowing their nose enough to inflate an attached balloon.² This technique can reduce the need for surgery by aerating the middle ear through this self-Valsalva manoeuvre.⁴ The nasal balloon auto-inflation device is available on the market in Australia and has been recommended in general practice guidelines,⁵ but investigations are still ongoing into the efficacy of auto-inflation devices in improving hearing. An unanswered question in many studies is adherence to this treatment and the practicality of families implementing this treatment within the home.

This research was conducted as part of a larger randomised clinical trial (RCT) and focuses on real-life experience of using auto-inflation by Australian Aboriginal and Torres Strait Islander children who experience among the highest rates of severe ear disease in the world.² This study aims to better understand the experiences of families and healthcare providers in using nasal balloon auto-inflation as treatment for childhood OME, including what they can do to increase treatment success.

Methods

The study context

Our study was embedded within the AutoINFLation for Aboriginal and Torres Strait Islander Children with Bilateral OME (INFLATE) trial (NHMRCGNT: 1120317), which ran between 2016 and 2023. The trial randomised Aboriginal and Torres Strait Islander children between ages 3 and 16 years to usual care (monitoring) or to use nasal balloon auto-inflation.⁶ The trial partnered with several Australian Aboriginal and Torres Strait Islander Medical Services (AMS) in Townsville, Gold Coast, Sydney and Canberra and a government-run Indigenous health service in Brisbane, Australia. An AMS is typically a community-controlled primary health service for the local Aboriginal and Torres Strait Islander community. Members of the local communities were employed as research officers (ROs) to facilitate the trial within services. Senior Aboriginal researchers provided cultural oversight throughout the trial and ROs were engaged in investigator meetings to continually provide cultural guidance on behalf of every participating community. Approval was received from the AMS CEOs, research committees and/or Boards prior to commencement and feedback was provided throughout the trial. The following ethics committees, which had mandatory identified Aboriginal and/or Torres Strait Islander representation, provided additional approval: Aboriginal Health and Medical Research Council Ethics Committee (1286/17), Western Sydney University (1286/17), Department of Health and Menzies School of Health (2017-2895), Metro South Human Research Ethics Committee (HREC/17/QPAH/461) and The University of Queensland (2017000984/1286/17).

Eligible children with OME who were randomised to the auto-inflation group were given a nasal balloon auto-inflation device and shown how to use it by ROs in person and/or by using a culturally appropriate video.⁶ Participants were asked to inflate the balloon with each nostril, three times a day for one month. Adherence diary and stickers were provided to track progress as well as a fabric pouch (handmade by a Community Elder) to hold the device and balloons (Figure 1). Participants were followed-up with weekly phone calls and in-person visits at one, three and six months. If OME had not

improved at the one-month visit, participants were asked to continue auto-inflation until the three-month visit before ceasing use.

Researcher positioning

The cultural integrity of the research was closely monitored by the lead Aboriginal (LC) researcher who worked as an RO at one of the AMS trial sites. By embodying insider and outsider status to the participants and the research,¹ the lead author has a cultural relationship to the work, outcomes and an obligation to ensure the project has met the principles of Indigenous health research.^{7,8} The research engaged Aboriginal and Torres Strait Islander children, adult caregivers and researchers as active and central participants in the conception, decision making, leadership, the data, data analysis and communication of the research.⁶ By focusing on lived experience and the needs of community members in the treatment of OME, the research learnings are intended to aide in the sovereignty of Aboriginal and Torres Strait Islander people in their ear and hearing health journey. In keeping with cultural ways of conducting research,⁸ both quantitative and qualitative data were necessary to appropriately communicate the story of community in engaging with OME treatment and understand the best strategies for success. The non-Indigenous

researchers served as outsider contributors and moderators.

Quantitative data

Participants were selected from families attending AMSs during the trial period who consented to be screened for ear disease, met eligibility criteria and agreed to participate in the trial.⁶ Questionnaires (Table 1) and adherence diaries (Figure 2) were obtained from 75 children (aged 3–15 years, 53% female) randomised to the auto-inflation arm of the INFLATE trial.^{1,6} Caregivers were asked by ROs at one-month and three-month follow-up visits to provide estimates of frequency of use, experiences with the device, perceptions of the training and adherence to diary usage.

Qualitative data

Caregivers and ROs were asked to consent to participate in interviews as part of a process evaluation of the trial, which included questions about auto-inflation.⁹ Five team members conducted semi-structured interviews and predominately used a yarning style.^{10,11} Six caregivers who had at least one child attempting auto-inflation consented to be interviewed (and recorded) about their experience between December 2019 and December 2020 (mean duration [M]=23 minutes, range [R]=19–29 minutes).



Figure 1. Hand-made pouch to contain adherence diary, stickers and auto-inflation device.

Table 1. Questionnaire items related to the auto-inflation treatment group**Auto-inflation treatment adherence**

These questions are intended for children in the auto-inflation group only. If a child is in the standard care group, tick 'Not applicable'

| | | | | | |
|--|---|---|---|--|---|
| How often did your child use the device in the past 4 weeks? | <input type="checkbox"/> Not at all | <input type="checkbox"/> Some of the time | <input type="checkbox"/> Most of the time | <input type="checkbox"/> All of the time | <input type="checkbox"/> Not applicable |
| Did your child permanently stop using the device in the past 4 weeks, before today? | <input type="checkbox"/> Yes, <1 week ago | <input type="checkbox"/> Yes, 1–2 weeks ago | <input type="checkbox"/> Yes, 3–4 weeks ago | <input type="checkbox"/> No | <input type="checkbox"/> Not applicable |
| How many days did your child use the device, if used, in the past week? | <input type="checkbox"/> 1–2 days | <input type="checkbox"/> 3–4 days | <input type="checkbox"/> 5–7 days | <input type="checkbox"/> Not applicable | |
| How many times per day (approximately) did your child use the device, if used, in the past week? | <input type="checkbox"/> 1 time/day | <input type="checkbox"/> 2 times/day | <input type="checkbox"/> 3 times/day | <input type="checkbox"/> Not applicable | |

Comment:

These questions are intended for children in the auto-inflation group only. If a child is in the standard care group, tick 'Not applicable'

| | | | | | | | |
|--|---|--------------------------------|------------------------------------|-----------------------------------|--|---|---------------------------------------|
| I believe my child received sufficient training to use the device | <input type="checkbox"/> Strongly agree | <input type="checkbox"/> Agree | <input type="checkbox"/> Undecided | <input type="checkbox"/> Disagree | <input type="checkbox"/> Strongly disagree | <input type="checkbox"/> Not applicable | <input type="checkbox"/> Missing data |
| The device was easy for my child to use | <input type="checkbox"/> Strongly agree | <input type="checkbox"/> Agree | <input type="checkbox"/> Undecided | <input type="checkbox"/> Disagree | <input type="checkbox"/> Strongly disagree | <input type="checkbox"/> Not applicable | <input type="checkbox"/> Missing data |
| I found using the device 3 times a day was achievable for my child | <input type="checkbox"/> Strongly agree | <input type="checkbox"/> Agree | <input type="checkbox"/> Undecided | <input type="checkbox"/> Disagree | <input type="checkbox"/> Strongly disagree | <input type="checkbox"/> Not applicable | <input type="checkbox"/> Missing data |
| Using the device was pain free for my child | <input type="checkbox"/> Strongly agree | <input type="checkbox"/> Agree | <input type="checkbox"/> Undecided | <input type="checkbox"/> Disagree | <input type="checkbox"/> Strongly disagree | <input type="checkbox"/> Not applicable | <input type="checkbox"/> Missing data |

Parent/carer experience on use of the device (if applicable):

| | | | | | | | |
|---|---|--------------------------------|------------------------------------|-----------------------------------|--|---|---------------------------------------|
| I thought the daily adherence (sticker) diary was easy to use | <input type="checkbox"/> Strongly agree | <input type="checkbox"/> Agree | <input type="checkbox"/> Undecided | <input type="checkbox"/> Disagree | <input type="checkbox"/> Strongly disagree | <input type="checkbox"/> Not applicable | <input type="checkbox"/> Missing data |
| I thought the daily adherence (sticker) diary was a useful way to record whether my child used the device | <input type="checkbox"/> Strongly agree | <input type="checkbox"/> Agree | <input type="checkbox"/> Undecided | <input type="checkbox"/> Disagree | <input type="checkbox"/> Strongly disagree | <input type="checkbox"/> Not applicable | <input type="checkbox"/> Missing data |

Parent/carer experience on use of the daily adherence (sticker) diary (if applicable):

Eleven RO interviews from four different ROs (2016–20), which were recorded with consent and contained reflections on auto-inflation, were included in our analysis (M=47 minutes, R=18–143 minutes). Interviews were transcribed verbatim and de-identified for analysis. Interviews and qualitative data from the questionnaires were analysed with a constructivist grounded theory¹² approach of initial coding and co-coding with memo writing by two separate authors (LC and SS) and then themes refined through discussion (LC, SS and PA).

Final themes were checked with Aboriginal and/or Torres Strait Islander representatives from all the participating AMSs.

Results

Findings integrating the qualitative and quantitative data are presented as three themes: (1) perceptions of the treatment; (2) engagement with the treatment; and (3) 'the inside story'. Participant identifiers are used to show if they are a primary caregiver (PC) or research officer (RO).

Perceptions of the treatment

The nostril novelty

ROs reported caregivers having mostly positive initial responses to the treatment, describing caregivers as keen to try the novel treatment with the hope of resolving ear disease quicker and avoiding surgery. Children were described by caregivers as enthusiastic and excited to use the device, with some caregivers having to soften the blow and curb their child's enthusiasm to avoid overuse.

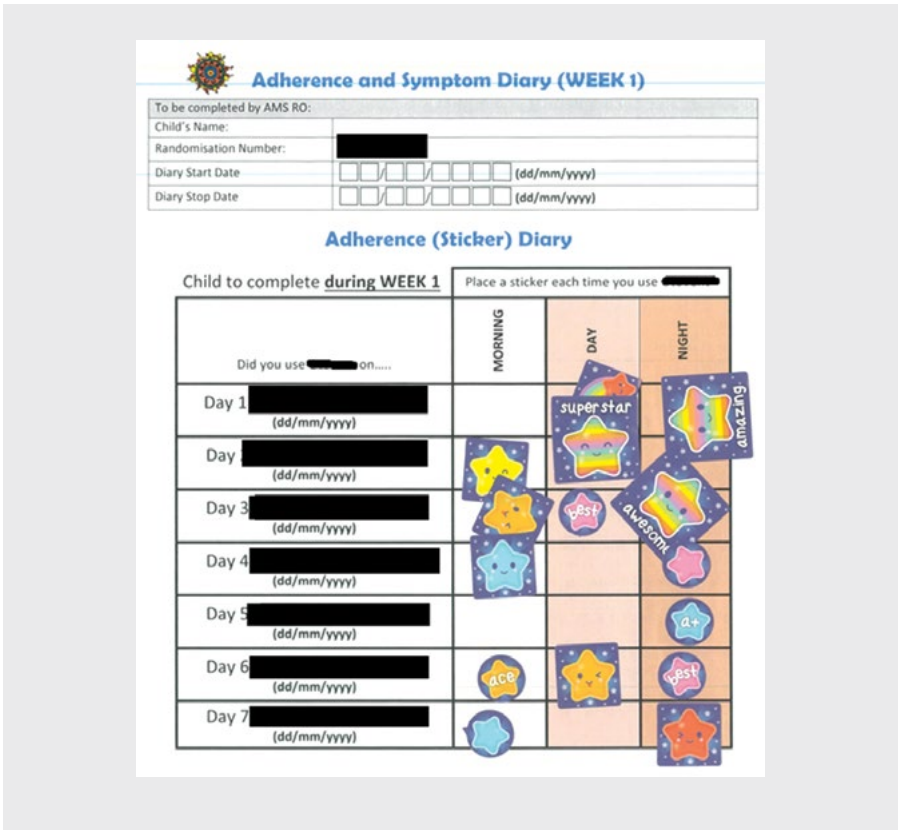


Figure 2. Example of a completed adherence diary from a participant.

(They) just want(ed) to do it all the time, look at me go mum ... I'm like, no, you can't do it 100 times ... you can only do two on each nose ... that was for the first week, (they) was just obsessed with the thing. (PC1)

Inflating enthusiasm

Caregivers were motivated by improvements they noticed within the first seven days in their child's ear health after auto-inflation. Despite the initial excitement, caregivers described loss of interest from the children over time, so they tried making it a game to keep children engaged, as well as involving family in the treatment through show and tell.

And then, I think it was about the third week, (they) was like, oh, do I have to, and I'm like, yes baby, come on you can do it. (PC1)

It was more of a - I'll see if I can blow it, can you blow it. Oh, it's broken, can you do it for

me. You know, those sort of things, make it into a game. (PC4)

... do it in between potty training and stuff, so just associating it with another activity ... Let's have a drink of water and let's blow the balloon up sort of thing, or let's quickly do this and then we'll sit down and play (with toy) It wasn't difficult to fit that in throughout our normal day. (PC5)

Engagement with the treatment

Recording the rate of inflation

Of the 58 participants who attended the one-month visit, five reported not using the device at all, whereas the majority were able to use the device some or most of the time (Table 2). Even in the last week before the one-month follow-up visit, 24% families reported being able to use the device between five and seven days of the week and 33% at least three to four days of the week (Table 2).

Most commonly, participants used the device twice a day (n=25).

Did not finish the race

Overall, 17 participants assigned to use the device at randomisation were unable to attend or be contacted to re-assess their progress. Of those that attended the one-month study visit, 17 families reported their child stopping use of the device before that visit. Most of those stopped after two weeks, but a large portion (n=7; 41.18%) stopped within one week. All participants agreed that the training provided was sufficient to understand how to use the device. With only two caregivers reporting an experience of ear pain from inflation, we sought other explanations about why families struggled with consistent use.

Measuring practicality

Most of our caregivers agreed the device was easy for their child to use, but achieving multiple inflations in a day was less easy, with 13 (22.41%) caregivers disagreeing or undecided on achievability. Three times a day was deemed achievable by about two-thirds of participating families (n=37, 63.79%). So then, why so many low blows?

The inside story ...

Logistics of life

Interviews revealed that the participants struggling with multiple inflations tended to be school-aged children. Caregivers explained that after school, the busyness of the afternoon and extracurricular activities, homework and dinner preparation often left the device forgotten until bedtime.

... their biggest thing was they said that they couldn't get three times a day in ... trying to get them to do, like, get up in the morning, do your (device) ... do it after school and do it before bed, like, trying to remember that on top of homework and any other activities that they have. I imagine that would be difficult to do ... you have to be really on top of it to get it done every day. (RO19)

Children with multiple caregivers also reported inconsistent use when it was lost or left behind when changing households. Sometimes the disruption was only for a weekend (two days), other times it would be an entire week between use. The disruption

Table 2. Auto-inflation treatment use recorded at the 1-month visit

| | Not at all | Some of the time | Most of the time | All of the time | Not applicable |
|---|------------|------------------|------------------|-----------------|----------------|
| Question 1: How often did your child use the device in the past 4 weeks? | 5 (8.62) | 19 (32.76) | 17 (29.31) | 9 (15.52) | 8 (13.79) |
| | | 1–2 days | 3–4 days | 5–7 days | Not applicable |
| Question 2: How many days did your child use the device, if used, in the past week? | | 9 (15.52) | 19 (32.76) | 14 (24.14) | 16 (27.59) |

Data are presented as n (%).

in routine could also affect the child's interest in the task.

Deflating enthusiasm or conditions

In many cases, the novelty of the device wore off over time. Sometimes it was the child who lost interest and sometimes it was the caregiver. ROs talked about the caregiver's loss of motivation, reporting it was too hard, too much work or just saying they lost it. ROs reported having motivational talks with caregivers throughout the study period to encourage the child and to reiterate the importance of the treatment.

... sometimes it's the child driving the adherence and reminding the parent that they need to do it. Other times it's the parent remembering ... sometimes they're pretty excited about having to blow up a balloon ... they (the child) remind mum that they have to. (RO15)

Our ROs noticed a trend that disinterested caregivers came from larger families, suggesting that those with multiple children appeared to struggle with the treatment requirements more than smaller families. The demands on caregiver time were noted by our ROs and explained as 'forgetfulness' to inflate an inability to achieve three inflations per day.

If they've got too many kids they tend not to use the (device) ... Busy with other kids or, you know ... when you talk to them about it, 'Oh, I forgot to do that', you know, 'I forgot to use this'. They might have gone ... a few days without even remembering to use it. So, I noticed that it's mothers with more than three children. (RO18)

Adherence diaries were sent home as motivation and a data collection tool. Only 11 out of 75 diaries were returned (Figure 2). Few caregivers reported the diary as useful or engaging for their child, with the majority not using it or losing it. ROs expressed little confidence in having them returned after initial attempts to collect them.

Balloons are for big kids

Younger children had difficulty in comprehending how to inflate the balloon with their nose. Despite a caregiver's best efforts and demonstrations, they said their young children were still trying to blow from their mouth. Some children required their caregiver to actively help with holding the device and with blocking the other nostril. Some just needed to be monitored while they were practising to stop them from over-doing it or using it improperly.

(their) heads going red, and I'm thinking why isn't this working. Then I looked at her and it's like pointing right to the side, as if it was going to come out of the side, and I've gone '(child's name)'. So, yeah, you do have to keep an eye on them when they're doing it. (PC1)

Discussion

Our study shows that a community-based approach to treatment with investment from multiple others such as parents, grandparents, siblings and a clinical support person, is likely to be needed to increase the chances of adherence success with auto-inflation. Caregivers reported they needed to take advantage of their child's enthusiasm and keep up their child's motivation over the treatment period, with gamification being a highly useful strategy. Gamification is gaining

increasing interest in the healthcare setting to increase motivation and adherence to tasks and treatment in both children and adults.¹³ Making it a game on a personal scale (between the parent, siblings or other family and the child with OME) or on a systemic level (apps and structured rewards) has been shown to increase engagement with treatments for other conditions such as eczema,¹⁴ diabetes¹⁵ and epilepsy.¹⁶ Our findings support further examination of game elements, digital and/or not digital, in ear health treatment adherence.

The use of sticker diaries as a reward system to track blow by blow is recommended in Australian general practice⁵ and was key to keep auto-inflation fun and engaging in a UK study,¹⁷ but participants in this study did not engage with the diary element. Paper forms of adherence tracking can be less engaging than digital options,^{18,19} so future research could consider the use of a video log, online entry, or phone application/game to motivate the caregiver as well as engage the child. Cultural differences might also play a part, with Aboriginal and Torres Strait Islander families perhaps preferring the social engagement of the RO's calling to check on progress and providing guidance or tips for continuing treatment.⁸

Recommending the treatment is the first step but having primary healthcare practitioners demonstrating their ongoing commitment through regular and timely check-ins might be more motivational for Aboriginal and Torres Strait Islander caregivers. These check-ins develop a trusting relationship between healthcare practitioners and families,²⁰ creating the safety to discuss concerns and share strategies to overcome difficulties within the treatment period. This relational support was identified as particularly important for larger families and single parents

sharing the child's care, because of the different treatment routines needed to accommodate these dynamics. Twice a day inflation could also be considered as a recommendation to caregivers to ensure engagement continues without feeling a burden on the family routine. Future research could review how check-in regularity might need to vary for family or cultural context as well as staff availability within primary healthcare.

Strengths and limitations

This study focussed on the perspective of caregivers and ROs to highlight a firsthand view of implementing nasal balloon auto-inflation treatment in daily life. The study did not include interviews with children directly, but caregivers openly related their children's feelings and engagement with auto-inflation to ROs. Our study provided insight on consistency of use of nasal balloon auto-inflation for the treatment of OME, suggesting the key time to check-in with the family is after 1–2 weeks to encourage compliance. Our data were derived from a limited sample size relying on caregivers engaging with the AMS, and those consenting to an interview were most likely among those who attended follow-up appointments. These participants are the most likely to have had higher commitment to the treatment and therefore adherence. However, by having community ROs as part of the project who are known and trusted within the community, we were able to get information from disengaged participants about why they struggled to meet the treatment and trial requirements.

Conclusion

Engagement in nasal balloon auto-inflation treatment for OME requires buy-in from caregivers and children, as well as ongoing encouragement by surrounding supporters including healthcare practitioners. Optimising results requires motivation strategies like gamification and engaging family members in treatment delivery. When prescribing auto-inflation, healthcare practitioners should be mindful of the family dynamics such as the size of the family and split care arrangements and how these factors can impact on treatment routines. Healthcare practitioners should commit to regular communication with the family to maintain motivation and routines.

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