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A workforce enhancement model for Australian remote community Primary Health Care services: implementation of a stepped-wedge cluster randomised trial (SW-CRT)

Amanda Jane Leach^{1*}, Amelia McCullough¹, Emily Websdale¹, Tarrant Tolotta¹, Jiunn-Yih Su¹, Victor M Oguoma^{1,2}, Peter Stanley Morris^{1,3}, Sean Taylor^{1,3}, Sandra Nelson³, Kelvin Kong⁴, John Paterson⁵, Jody Dixon⁶, Alan Cass¹

¹ Menzies School of Health Research, Charles Darwin University. Darwin. POBox 41096 Casuarina, Northern Territory, Australia

² Thompson Institute, University of the Sunshine Coast, Birtinya, Queensland, Australia

³ Department of Health, Northern Territory Government. Manunda Place, 38 Cavenagh Street, Darwin, NT, 0800 Australia. PO Box 40596, Casuarina NT 0811

⁴ John Hunter Children's Hospital, Hunter ENT Konara Suite 1, Level 3, 15 Lambton Road, Broadmeadow New South Wales 2292, Australia

⁵ Aboriginal Medical Services Alliance of the Northern Territory. Moonta House, 43 Mitchell Street, Darwin, NT, 0800, Australia

⁶ Department of Education, Northern Territory Government. Level 11, Mitchell Centre, 55-59 Mitchell Street, Darwin. GPO Box 4821, Darwin, NT 0801, Australia

*Corresponding author: amanda.leach@menzies.edu.au

Abstract

Background: First Nations people in Australia continue to experience a high level of socio-economic disadvantage, driven by the ongoing injustices of colonisation. In remote communities in the Northern Territory (NT) First Nations children experience early onset and persistence of middle ear infections (otitis media), preventable conductive hearing loss and developmental delay, which contribute to a trajectory of further disadvantage, particularly in education and employment. Health services are not resourced to deliver adequate care for these children. This trial of First Nations workforce enhancement is the first to address these issues.

Methods: This open cohort stepped-wedge cluster randomised trial of on-country training and new job creation was implemented in 2 pilot and 18 randomised remote communities. Governance of all aspects was co-designed, and First Nations led. Qualified trainers delivered three Certificate II units in Aboriginal Primary Health Care (2 weeks), and competency training in ear and hearing health, otoscopy, tympanometry, and hearScreen® (4 weeks). Community residents were eligible for training if they met criteria for NT Government employment. Here we report baseline characteristics and intervention implementation outcomes.

Results: On-country training commenced in April 2020 and completed in November 2023. A new job description was approved for Ear Health Facilitators. Two randomised communities declined participation. The COVID-19 pandemic caused direct and long-term disruptions. From 167

expressions of interest, 53 of 89 (60%) enrolled participants completed all training. Lack of services interrupted attendance, whereas Liaison Assistants, meals, and payment were enablers. English language and numeracy were barriers. Trainee self-evaluations showed substantial increases in confidence, knowledge, and skills. Trainers assessed performance against 38 competencies, identifying strengths and areas for training modification. Trainees requested more flexibility and catch-up opportunities, more time for two-way learning, and to practice ear assessments. Thirteen communities employed 15 Ear Health Facilitators.

Conclusions: This trial of a remote health workforce enhancement model demonstrated feasibility and preference for on-country work-readiness and technical training with harmonised job creation. This has the potential to improve effectiveness and sustainability of priority health services – in this case, ear and hearing health care. Infrastructure to support development of this workforce was a major barrier. Evaluation of workplace integration, sustainability, and impact on ear and hearing services will be reported separately.

Trial registration: This trial was registered on clinicaltrials.gov on 16 April 2019, ID NCT03916029.

Keywords: primary health care, rural, remote, Australia, otitis media, child, workforce, training, job creation, stepped-wedge cluster randomised trial.

1. Background

Our research has shown that for decades, young First Nations children living in remote Northern Territory (NT) communities have the world's highest reported rates of chronic suppurative otitis media (CSOM)(1), persistent otitis media with effusion (OME)(2, 3), and disabling hearing loss.(4) Whilst rates of CSOM have halved (~12% in 2020s),(1, 3) prevalence remains well above the World Health Organization's criteria of 4% which indicates a massive public health problem needing urgent attention.(5) Importantly, less than 10% children under the age of 3 years have bilateral healthy ears and up to 41% have moderate (disabling) hearing loss.(4, 6, 7)

First Nations children with otitis media or hearing loss are further disadvantaged compared to their peers with normal hearing. Hearing loss is negatively associated with early childhood development,(8) school readiness,(9) attendance,(10) and performance,(11, 12) child behavioural problems in school,(13) child maltreatment,(14) youth detention,(15) and incarceration.(16)

The NT remote community Primary Health Care workforce is also in crisis, with high staff turnover,(17, 18) high costs of short-stay fly-in/fly-out staff,(19) with detrimental impacts on health.(20) A strengthened Primary Health Care workforce will reduce the waitlist and cost of specialist services.(21, 22) Increased support for First Nations employment pathways, and greater engagement, training, and retention of a First Nations workforce have been identified as priorities by consumers and policy.(23-25)

Advances in technology such as video-otoscopy,(26) the hearScreen® mobile phone device,(27) and compact hand-held tympanometers suggest that objective measures may be made by trained non-professionals outside the clinic environment, such as at pre-schools and homes, with asynchronous assessments by health professionals.(27) Further research in understanding and responding to costly short-term professional health services is underway.(28) However, our innovative model of upskilling resident First Nations people as Ear Health Facilitators (EHFs) has

potential to contribute to sustainable, safe, culturally appropriate services that support health professionals and meet the needs of children at high risk of chronic ear and hearing problems.

Our stepped-wedge cluster randomised trial (SW-CRT)(29) is the first study to design and evaluate workforce innovation as recommended by many reviews and committee reports including the World Health Organization's World Report on Hearing,(30) the Australian Government Roadmap for Hearing Health initiatives,(31) the Siggins Millar report on Indigenous Ear and Hearing Health initiatives,(32) Closing the Gap in ear disease in Aboriginal and Torres Strait Islander children,(33) and the National Aboriginal and Torres Strait Islander Health Workforce Strategic Framework and Implementation Plan 2021-2031.(25)

The aim of the Hearing for Learning Initiative was to improve the ear and hearing health of First Nations children living in the Northern Territory. Our primary hypothesis is that the HfLI workforce enhancement model will increase ear and hearing health surveillance among children less than 17 years of age. Our additional hypotheses were firstly that this model would improve the cascade of ear and hearing care.(34) Secondly, that community-based training, job creation, and employment of First Nations community residents as Ear Health Facilitators would have substantial benefits for social, economic, and health outcomes compared to no training or job creation.

Our objective was to conduct a stepped-wedge cluster randomised trial to evaluate the implementation and impact of an innovative model of workforce enhancement (training and job creation) on ear and hearing services and outcomes.

2. Methods:

2.1. Design

The HfLI Governance structure consisted of an Advisory Board, a Research Executive Committee, a Training Working Group, an Integration Working Group, and a Community Reference Group in each participating community. Each group was chaired by a First Nations leader who determined terms of reference. A quorum of 2-3 First Nations people was required at meetings (Fig. 1).

Figure 1. Governance structure

During stakeholder consultations it was recommended that all participating communities should receive the study intervention, i.e., no permanent control communities. A SW-CRT was therefore agreed. Clusters (discrete remote communities with one identified Aboriginal Medical Service managed by NT Health or ACCHOs) were the unit of randomisation. The design incorporated five sequences of control and intervention periods with 2, 4, 4, 4, and 4 communities (18 clusters) randomised to each sequence. The open cohort includes the same and different child participants assessed in different periods.(29) The trial involved a Lead-in phase which commenced on the unblinding date, a Training phase which commenced within 3 months of unblinding, and Integration and Employment phase which commenced on the date of trainee Graduation and concluded on 30 June 2023, later extended to 30 June 2024 (Fig. 2, Table 1).

Figure 2. Phases of the Hearing for Learning Initiative

The Lead-in phase involved three on-site 3-day visits by a research nurse for community consultation, recruitment of a Liaison Assistant, selection of Community Reference Group members, promotion of the training opportunity, seeking expressions of interest from potential trainees, and completing employment paperwork for individuals selected by the Community Reference Group to complete training. The Training phase involved on-country face-to-face training for up to five community residents for 120 hours over 6-weeks within a 3-month period. The Employment and Integration phase commenced on the Graduation date and involved three 2–3-day visits by a research nurse and 6-monthly competency and needs-based refresher training.

The study protocol was published in 2021.(29) Further minor co-designed amendments to the protocol were made, which were approved by the Ethics committee. Our reporting adheres to the CONSORT guidelines(35). This paper reports the implementation and evaluation of the Lead-in and Training phase (Intervention arm-only).

Table 1. Schedule of recruitment, implementation, and evaluation

Activity	Control period pre-unblinding	Lead-in phase	Training phase	Graduation	Integration and employment phase
Community (cluster) recruitment, letters of support, RGO and Ethics approvals	✓				
Participation Agreements executed		✓			
Community and population baseline characteristics		✓			
Applicant eligibility (Eols and LLN)		✓			
Trainee baseline characteristics			✓		
Training implementation			✓	✓	
Trainee self-evaluation			✓	✓	
Trainer evaluation			✓	✓	
Graduation				✓	
Community Reference Group recommendation		✓		✓	
EHF selection and employment contracts				✓	
EHF integration support					✓
EHF refresher training – 6 monthly to 30 June 2024					✓
Stakeholder evaluations					✓
Electronic health record data extraction	✓	✓	✓	✓	✓

2.2. Participants

The implementation and evaluation of the Training phase involved several participant groups: communities (clusters), trainees, and Ear Health Facilitators (EHFs).

Briefly, communities were eligible for the study if they met Modified Monash Model criteria for rural or remote Aboriginal communities located in the NT(36, 37), the population included ~100 children less than 17 years of age, there were facilities to support delivery of the 6-week training course, and the governing body provided letters of support to the Ethics committee.

Trainees were eligible for training if they were community residents and identified as Aboriginal and/or Torres Strait Islander, could commit to the training program, were at least 18 years of age, were recommended by the Community Reference Group, and met criteria for Health sector employment, including Level 2 or equivalent in English Language, Literacy, and Numeracy (LLN).

Trainees were eligible to apply for employment as Ear Health Facilitators in their health service if they successfully completed the training course, wanted the job, had a Working with Children card, a good level of plain English, and were recommended by the Community Reference Group.

Baseline community and population characteristics were obtained from the Australian Bureau of Statistics 2021 census.(38) Individual trainee level factors were obtained during Lead-in phase from written expressions of interest (supplementary material S1), enrolment forms and standardised assessments of Language, Literacy, and Numeracy (LLN)(39) (Data aggregated at community or regional level are presented).

2.3. Interventions

The control condition was no ear health training or employment.(29) The Training intervention was co-designed by the First Nations-led Training Working Group and reviewed throughout the trial by the Integration Working Group (Fig. 1).(29) Trainees were employed by the project on casual basis. The course consisted of 2-weeks for accredited units of the Certificate II in Aboriginal Primary Health Care, HLT20113; Participate in Workplace Health and Safety HLTWHS001; Work with Aboriginal clients HLTAHW001; and Write simple workplace information FSKWTG006. The 4-week non-accredited ear and hearing training package consisted of units of competency in ear and hearing health including health promotion, otoscopy, tympanometry, and hearScreen®. Where possible volunteers consented to a trainer-assisted ear check by the trainees. The HfLI training package (copyright) is available at <https://www.menzies.edu.au/>. Training was delivered on-country by Clinical Training Research Officers (CTRO), other than in four communities where the accredited training was delivered by the Registered Training Organisation, Ninti One. CTROs had health

qualifications or experience, a current Certificate IV in Training and Assessment (TAE40116), and a full day of cultural awareness training. All trainees had their achievements acknowledged at a Graduation Ceremony held in their community. The CTRO evaluations of trainee performance and the Community Reference Group recommendations, in addition to written job applications by the nominated trainee, were provided to the health service manager to inform selection of the Ear Health Facilitator(s).

2.4. Outcomes

Secondary outcomes reported in this paper are descriptive statistics related to participant and researcher evaluations of the intervention implementation using structured questionnaires, Likert scales, and thematic analysis of free text. Trainee pre- and post-training self-evaluations used an adaptation of a 5 Likert scale which replaced terms with plain English responses such as no, little bit, medium, a lot, very much. The CTRO recorded performance of trainees against 39 measures in 9 areas of competency, using the standard 5 Likert scale (Strongly Disagree to Strongly Agree). The measures, designed by the Training Working Group were: Preparation for ear checks (3 measures); establish a relationship with client (4); conduct otoscopy (6); conduct tympanometry (3); conduct hearing test (5); review and act on results (3); clean and store equipment (3); participation and attitude to training (6); and ability to perform health promotion (6). Barriers and enablers are thematically summarised.

Minor changes to secondary outcome measures were made in response to co-design approach of our Governance structure.

2.5. Sample size

The sample size calculation is detailed in the published study protocol(29). No interim analysis was planned. The Advisory Board voted against stopping the trial following the start of the COVID-19 pandemic.

2.6. Randomisation

Twenty communities (clusters) were enrolled; one community with a health service managed by the NT Government Department of Health (NT Health) and one with an Aboriginal Community Controlled Health Organisation (ACCHO) service volunteered to be pilot communities. In early 2020, 18 communities (clusters) were allocated by the trial biostatistician according to a computer-generated randomisation list, to one of five unblinding dates commencing on 1 April 2020 (2, 4, 4, 4, 4 clusters per step). Stratification was by community size (large if population of age-eligible children was > 300, otherwise small), and region, broadly defined as Top End or Central Australian.

2.7. Allocation concealment and unblinding

The allocation sequence was stored on a password protected secure server concealed from investigators, researchers and communities. At each 6-monthly unblinding date the Menzies Senior Data Manager provided the names of the communities allocated by the statistician to that date, to the co-Chair and Clinical Trial Team Manager.

2.8. Consent

Participants provided written informed consent to complete semi-structured questionnaires and evaluations of the study.

2.9. Similarity of treatments

The template for intervention description and replication (TIDieTR) was used to describe in detail the differences between intervention and control periods.(40) Primary Health Care and specialist services in ear and hearing service continued in all clusters throughout control and intervention periods.

2.10. Statistical methods

Data on community and trainee baseline characteristics, and evaluations of Training intervention are reported as counts, proportions, means and standard deviations or medians and interquartile ranges.

3. Results:

3.1. Participant flow – communities

During 2018-2019, NT Health (managing 76 community health centres), Aboriginal Medical Services Alliance of the NT and six ACCHOs (managing 44 community health centres), were consulted via requested research application processes (Fig. 3). Of these, 100 declined participation or were ineligible (population too small); two ACCHOs managing 11 community health centres advised that

they were unable to participate or had a moratorium on research. By January 2020, 20 eligible communities had provided letters of support to the Ethics committee. One NT Health and one ACCHO volunteered to be pilot communities. Eighteen communities were randomised.

Figure 3. Participant flow – Communities (clusters). NT: Northern Territory. AMSANT: Aboriginal Medical Services Alliance NT. ACCHO: Aboriginal Community Controlled Health Organisation. ATP: According to protocol. ITT: Intention to treat

Two of the 18 randomised communities declined the training and employment opportunity after randomisation; one of these also declined execution of the Data Sharing Agreement. Two pilot and 16 randomised communities fully participated in the Lead-in and Training phases.

3.2. Participant flow – Trainees

Overall, 159 community residents discussed participation with the research team. A further eight were included for professional development-only and were excluded from analyses (Fig. 4). Of 122 (77%) residents who provided consent to participate as a trainee, 33 (27%) declined further participation. Thus 89 of 159 (56%) community residents consented, completed Expression of Interest (EoI) or enrolment forms, and commenced training. Of these 89 trainees, 53 (60%) completed all accredited and non-accredited units and were eligible to apply for the Ear Health Facilitator role. In each pilot and randomised community the study funded the employment of one half-time position which could be shared between two EHF. Of the 53 Graduates eligible for the Ear Health Facilitator role, 15 were employed as EHF in 13 communities. Seven communities did not employ an Ear Health Facilitator.

Figure 4. Participant flow – Trainees and Ear Health Facilitators. EHF Ear Health Facilitator LLN Language Literacy Numeracy

3.3. Recruitment dates

The original SW-CRT design included seven 6-month periods, ending 30 June 2023.(29) However due to the COVID-19 pandemic and other delays the study extended to nine 6-month periods, ending 30 June 2024. Unblinding clusters for each step occurred on-time.

Table 2 shows for each community the Intervention dates for Intention to Treat (ITT) and According to Protocol (ATP) analyses. The design matrix schema (Fig. 5) gives a visual summary of these phases.

Table 2. Intervention dates: Unblinding, Training, Graduation, and Employment start dates for ITT and ATP analyses

Cluster (Community) Number	Unblinding	Training Intervention start date	Training Intervention end date (Graduation) and ITT Employment start date	Training Intervention duration*** (Start to Graduation) days	Step duration (days taken for all clusters to complete Training)	ATP Employment Intervention Start date First day worked	Employment Start date delays (Graduation to First day worked) days
01	Pilot	03-02-20	14-08-20	193	220	14-04-21	243
02	Pilot	18-02-20	10-09-20	205		22-02-21	165
03	01-04-20	13-10-20	26-11-20	44	44	04-10-21	312
04	01-04-20	20-10-20	18-11-20	29		21-04-21	183
05	01-10-20	06-04-21	27-05-21	51	248	03-08-21	68
06	01-10-20	31-08-21	10-12-21	101			
07	01-10-20	10-05-21	18-06-21	39			
08	01-10-20	24-04-21	11-06-21	48			
09	01-04-21	03-09-22	01-12-22	89	409		
10	01-04-21	18-10-21	29-04-22	193		06-03-23	311
11	01-04-21	30-05-22	01-09-22	94		07-12-22	97
12	01-04-21	19-09-22	24-11-22	66		27-02-23	95
13	01-10-21	02-05-23	22-06-23	51	129	21-08-23	60

14	01-10-21	13-02-23	06-04-23	52		21-08-23	137
15**	01-10-21						
16	01-10-21	13-02-23	06-04-23	52	135	02-05-23	26
17	01-04-22	10-10-23	30-11-23	51			
18	01-04-22	18-07-23	07-09-23	51		14-11-23	68
19*	01-04-22		(07-09-23)*				
20	01-04-22	10-10-23	30-11-23	51		11-06-24	194

ITT (Intention to Treat) start date is Graduation date or *anticipated Graduation date ().

ATP (According to Protocol) start date is First day worked.

* 15: Participation Agreement not executed. No intervention.

**19: Participation Agreement executed, however declined intervention.

*** Training duration was planned to be up to 6 weeks (42 days) in each community and completed for each Step within 3-6 months (91 to 182 days)

Figure 5. Design matrix schema with critical dates. Cluster (Community number): **bold is NT Health**; non-bold is ACCHO (Aboriginal Community Controlled Organisation). * 15: Participation Agreement not executed. No intervention. No data. **19: Participation Agreement executed. Declined intervention. Data included for control and ITT periods as per allocation. Anticipated Graduation (9/23) used for switch date in ITT analysis. Unblinding date (dd/mm/yy), Training month(s) (~mm/yy), Graduation date (mm/yy) First day worked (mm/yy). ITT final date 30/06/24

3.4. Baseline characteristics

Stratification allocated 16 (80%) communities as Top End and four (20%) as Central Australian; seven (35%) communities were allocated as large, 13 (65%) as small. The total population of children under the age of 14 years was 5187, approximating to 6250 children less than age 17 years. Eighteen (90%) communities were Modified Monash model MM category 7, two (10%) were MM category 6. The Indigenous Relative Socioeconomic Outcomes (IRSEO) index(41) varied from -1.38171 to -6.21808 (least to most disadvantaged); the lowest 20% of all IRSEO scores. Ten health services were managed by NT Health, and 10 by ACCHOs. At baseline, we documented health care staff availability for support of the project; all primary health care services had a clinic manager, five had a child health nurse, four had an Aboriginal Health Practitioner, one a General Practitioner, one had a part-time audiologist; and ten had identified a preceptor for the Ear Health Facilitator. Availability of a culturally- and gender-safe adult education space was important to our study. We also required access by foot or public transport, facilities that met work, health, and safety standards, and included kitchen and bathroom facilities. No community had a dedicated or equipped adult education or learning centre which could accommodate the HfLI program and 6-week schedule. No community had a public transport system that met the needs of trainees. Across the participating communities, data from the 2021 census confirm very low levels of secondary school completion or tertiary education attainment and poor engagement in the labour force. Employment in the health sector requires a basic level of English. The census question regarding use of English-only in the home was below 5% in 13 remote communities compared to the NT First Nations average of 33% and the Australian First Nations average of 84%. Family commitments are a common barrier to workforce participation. The census asks whether respondents provided unpaid childcare in the 2 weeks prior to census date; across the study communities, between 24 to 74% had recently cared for children, the Australian First Nations average being 31%. Fourteen communities had Child Care services and seven had Aged Care services listed on NT Government websites. Nine communities had Families as First Teachers (FaFT) services, but these are not a childcare service for working parents. The median family weekly income was below \$500 for 5 study communities, the average number of persons per household ranged from 3.1 to 6.6. Transport and car ownership are critical to workforce participation in Australia; there were ≤ 0.5 registered vehicles per household in 12 (60%) communities (Table S3 – Supplementary). Data were obtained from Expression of Interest (Eoi) or enrolment forms (supplementary material S1) which were sought in all but one pilot community. Thirteen of 89 trainees (15%) were male. Mean age was 34 years and ranged from 16 to 65 years. Trainees held a diversity of current or previous roles in the community; most (47/89, 53%) did not specify their prior work experience; respondents were either unemployed (11, 26%), health staff (10, 24%), school staff (9, 21%), or various services (12, 29%). Half the respondents were motivated to enrol in the training for

'personal development' one third were motivated 'to have a job, gain skills or for study' (Table S4 Supplementary). Of the 49 trainees asked about work skills (supplementary material S1), more than 75% had used a computer, a printer, had experience looking after children, or worked as a part of a team. Half had written a resume, two thirds had been interviewed for a job, and around half had written a letter or given a speech in front of a crowd (data not shown).

A standardised LLN assessment tool was introduced after learning from pilot communities that many trainees would not meet requirement for employment by NT Health due to poor literacy. At least 50 (54%) trainees had an LLN assessment across 5 domains; 43 were assessed using the LLN tool. Level 3 or 4 was achieved by less than 11% (0% for numeracy). Level 2 by around 70% across all domains other than numeracy (26%). Digital literacy was added to the assessment tool in 2023. Digital literacy was Level 1 or lower for 13 of 15 trainees assessed, two achieved level 2. There were no substantial differences between regions in the proportion of trainees who achieved LLN levels below 2, at 2, or above 2.

Fifteen graduates were subsequently employed as Ear Health Facilitators in 13 communities. Baseline data were aggregated by the two major regions of Central, Barkly and Big Rivers, and Top End and East Arnhem. Two (13%) EHF were male. Mean ages were 41 and 32 years in these regions respectively. Ten were previously unemployed, no EHF had been employed in the health sector. Motivation to participate in training was primarily for personal development (10), to obtain a job (8), and to improve community wellbeing (4). LLN assessments for five domains were completed for 10 EHF (i.e., 50 scores); 39 (78%) were Level 2, eight were below Level 2 (half of these in numeracy), and three were above Level 2. Digital literacy was not assessed for any of the 15 employed EHF. Five of 15 EHF had a driver's licence. (Table S5 – Supplementary).

3.5. Trainee performance and competencies

Available data from two pilot and 16 randomised communities (clusters) that participated in Lead-in and Training phases are included. Of the planned maximum of 120 hours training, the mean number of hours delivered per community was 93.5 hours (78%, range 54% to 95%). Self-assessments of confidence, knowledge and skills were completed by 83 trainees pre-training and 59 post-training (supplementary material S2 and S3). The proportion of responses allocated as 'a lot' or 'very much' pre-training was around 42% to 67% for the five questions related to confidence, increasing to 69% to 78% post-training. Knowledge and skills increased from as low as around 10% pre-training to as high as 88% post-training (data not shown).

Figure 6. Proportion of EHF (n=15) and non-EHF (n=48) trainees with high-level competence (proportion achieving Strongly Agree)

Table 3. Proportion of EHF (n=15) and non-EHF (n=48) trainees with high-level competence (proportion achieving Strongly Agree)

Proportion of EHF and non-EHF trainees with high-level competence Domain and measures of competency	% Strongly Agree EHFs N=15	% Strongly Agree Non- EHFs N=48
Prepare for ear/hearing checks. Trainee demonstrates ability to		
1. collect required paperwork and equipment ready for use	87%	43%
2. set up environment ready to conduct ear/hearing checks	60%	44%
3. check and prepare equipment prior to use	87%	45%
Establish a positive relationship with client. Trainee was observed to		
4. accurately taking a client's basic ear health history and explains the ear/hearing checks with the client	53%	43%
5. gain informed consent prior to undertaking ear checks and is able to explain the concept of informed consent	93%	58%
6. give the client the opportunity to ask questions and discuss concerns	67%	37%
7. explain the importance of maintaining confidentiality of client and research information.	80%	46%
Conduct otoscopy. Trainee demonstrates ability to		
8. conduct personal hygiene and infection control measures	100%	72%
9. perform otoscopy in a non-threatening manner	93%	65%
10. apply appropriate technique when performing otoscopy	87%	41%
11. identify abnormalities of the outer ear and ear canal	80%	49%
12. Trainee demonstrates knowledge of contraindications for proceeding with ear check	73%	33%
13. identify abnormalities of the tympanic membrane (ear drum) at a basic level	67%	46%
Conduct tympanometry. Trainee demonstrates ability to		
14. conduct personal hygiene and infection control measures	100%	67%
15. perform tympanometry in a non-threatening manner using an appropriate technique	93%	65%
16. correctly identify tympanometry "Type" and document results	67%	32%
Conduct hearing tests. Trainee demonstrates ability to		
17. select appropriate hearing check and explain procedure to client	79%	52%
18. correctly use of PLUM & HATS and documentation of results for <5-year-old children (n=27)	0%	0%
19. correctly use of HearScreen for 5 – 16-year-old children including correct documentation of results	93%	59%
20. correctly record results on the ear observation form	79%	50%
21. identify a client's potential abnormal hearing function from hearing check results	71%	55%
Review and act upon ear and hearing check results. Trainee demonstrates ability to		
22. communicate results of ear and hearing checks clearly and simply to the client	60%	44%
23. document results	67%	45%
24. appropriately identify when a child needs to be referred to the health clinic and report observations to clinic staff.	80%	42%
Cleans and stores equipment. Trainee demonstrates ability to		
25. clean equipment and attachments in accordance with infection control guidelines	80%	52%
26. appropriately charge, pack and store equipment	80%	44%
27. clean area after use as per infection control guidelines	73%	48%
Participation and attitude to training. Trainee demonstrates ability to		
28. actively participated in all training activities	93%	65%
29. be punctual to training and on return from breaks	80%	31%
30. actively listen to others speaking	93%	65%
31. encourage colleagues to talk and express ideas	93%	52%
32. show empathy and respect to community members, colleagues and training staff	100%	73%
33. cooperate and work well with other health and education service providers	100%	67%
Ability to perform ear and hearing health promotion. Trainee demonstrates ability to		
34. demonstrate basic knowledge of ear anatomy and physiology including structures of the middle ear	93%	60%

35. explain the effect of hearing loss on learning and childhood developmental milestones	60%	36%
36. maintain good ear and hearing health	93%	53%
37. educate clients of varying ages and community members on ear and hearing health at a basic level.	73%	40%
38. appropriately interact with children and their families and is able to alter delivery to suit the age and education of the client.	87%	49%
39. plan and organise health promotion activities with health, education and/or community services at a basic level	77%	40%

Performance of 63 trainees was evaluated by CTROs during the final week of the training (supplementary material S4). Multiple measures within eight domains were assessed using the 5 Likert scale; preparation for ear or hearing checks (3 measures), establishing a positive relationship with a client (4), conducting otoscopy (5), conducting tympanometry (3), conducting a hearing test (5), reviewing and acting on ear and hearing check results (3), cleaning and storage of equipment (3), participation and attitude to training (6), and ability to perform ear and hearing health promotion (6). Very high- or high-level competency (Likert score Agree or Strongly Agree) was achieved for nearly all measures (excluding PLUM(42) and HATS(43) which were not successfully included in training) by almost 80% of 63 trainees. Very-high competency (Strongly Agree) was achieved for 32 of the 39 measures by more than 70% of the trainees who became EHF. Seven measures could be targeted for future training improvement, including identification of abnormalities, documentation, and communication (see measures 2, 4, 6, 13, 16, 22, 23, and 35). For 48 trainees who did not become EHF, fewer than 70% achieved very-high competency for 37 of 39 measures (Fig. 6, Table 3).

Trainee observations of volunteers' ears (OM history, outer ear, ear canal, ear drum visualisation, ear drum perforation, tympanometry, and hearing) were documented on structured forms (supplementary material S5). Overall, 150 forms were available for analysis. Documentation (proportion of data completed yes/no) was highest for outer ear, ear canal and ear drum visualisation (at least 87% forms); around 70% had an observation recorded for ear drum perforation, 76% for tympanometry, and 53% for hearScreen outcome. Clinical findings will be reported in subsequent publications.

3.6. Barriers and enablers

CTROs summarised their experience in delivering training for up to 6 weeks in each community. Barriers included logistical issues associated with complex and remote travel, frequent cancellations and re-bookings. Coordination was difficult due to lack of phone ownership and poor phone coverage. Training spaces were often unavailable and usually not fit for purpose, particularly access to the internet. Childcare was unreliable, weather conditions harsh, public transport limited and inconvenient, and antisocial behaviour in communities common. CTRO fatigue necessitated occasional use of external training providers, although this impacted continuity and rapport with trainees. Key enablers included casual pay for trainees, catering, transport, and community liaison assistants who helped overcome cultural and language barriers. CTROs spent many hours supporting trainees with complex regulatory and job application processes. Trainees valued efforts to integrate cultural aspects into the training. Recommended strategies to improve the training experience were increased community networking to recruit suitable trainees, offering workplace experience or simulations, and providing flexible schedules to accommodate diverse needs. Trainees learned the importance of group training and impact of absenteeism on the group. Although direct harms were not reported, some trainees were hesitant to disclose their employment in the health service to friends and family, due to consequent 'humbug' and potential blame for any poor health outcomes.

4. Discussion

Here we report the implementation of the first two phases of this SW-CRT to ensure that the setting and baseline characteristics of clusters and participants are described, and generalisability of study intervention can be assessed.

The major limitations encountered during the implementation of the Training intervention were the significant delays and therefore departure from the stepped-wedge structure and imbalance of control and intervention periods. This will likely compromise the analysis of primary outcome and potentially affect generalisability of results.(44) Despite the COVID-19 pandemic, the trial was not stopped early. Allocation to unblinding dates for each step remained concealed, although obvious for the final four communities once the previous step was allocated. Limitations related to the statistical analyses and reporting of the primary outcome will be discussed in subsequent publications.

A further limitation potentially affecting confidence in generalisability was the missing data due to late introduction of baseline assessments of language, literacy, and numeracy (57%) and later introduction of digital literacy assessments. From the data that were obtained the overall LLN scores were highly consistent at Level 2 for around 70% trainees in learning, reading, writing, and oral communication, and \leq Level 1 for numeracy for around 70% trainees.

The baseline community and population characteristics of the 20 study communities are not dissimilar to the total NT First Nations population (urban, rural, and remote) for most measures, providing confidence that our findings are generalisable across the NT, and potentially rural and remote communities in other jurisdictions. However, compared to the Australian First Nations population, predominantly urban, most measures for our study show evidence of a substantial gap in social determinants suggesting limited generalisability of this workforce enhancement model for First Nations communities across Australia. However, the successes achieved by our study cannot be ignored. Despite the extreme level of isolation and serious gaps identified, we have demonstrated that workforce gaps can be addressed with targeted alignment of skills development (capability) and elevated motivation with appropriate job creation (opportunity). Regarding low success in implementing PLUM and HATS assessments, we note that validation of the HATS tool was achieved where the tool was conducted by both a health professional and caregiver, possibly also with an interpreter.(43) A recent study found low diagnostic accuracy of PLUM for OM and hearing loss when conducted independently by caregivers (with support).(42) We recommend further co-design and development of tools for regular on-site assessment of early childhood hearing-related developmental delay, such as PLUM and HATS, in high-risk rural and remote settings.

Whilst most concerns about generalizability of research findings more broadly relate to application of findings from RCTs to a more severe condition/setting and therefore a lower effect size, our case is the inverse. Indeed, our study was informed by successful employment of non-professional First Nations community members as research officers in clinical trials at Australian urban Aboriginal Medical Services. Together, these studies strongly suggest that rural and remote communities elsewhere in Australia are likely to be equally or better able to adopt or adapt this model.

A re-structure of the health service workforce should consider how to incorporate health facilitator training and employment in targeted achievable roles that augment best-practice and improve client and health practitioner experience. In this instance highly motivated resident Ear Health Facilitators with local language, cultural knowledge, and plain English became highly skilled in video-otoscopy, tympanometry, and (to a lesser extent) hearScreen. (27) Whilst training has been highly valued and successful, participant evaluations (CTROs, trainees, and EHF) identify areas for improvement. Evaluations of the workforce Integration and Employment phase on service delivery outcomes are underway.

Many of the 89 First Nations trainees in our study had not been employed and believed there were no jobs for them in their community. Limited high school completion and opportunities for tertiary education have left many residents with low English literacy and numeracy which is locking people out of western employment structures, even in their own community. A conference abstract published in 2017 of 670 LLN assessments with Aboriginal adults found levels well below that required for participation in work and education, and questioned who in Government had responsibility for adult LLN in the NT.(45) This study created a new job description within the NT Public Service with a focussed role as EHF and selection criteria that could be achieved by trainees, requiring them to be resident in their community, speak their own language and plain English, and have completed the HfLI training package.

This paper describes the implementation of a co-designed SW-CRT of a health workforce enhancement model for rural and remote communities in the Northern Territory, with potential for implementation across rural remote Australia. The model incorporates and attempts to place western workforce opportunities within reach of First Nations people who believed there were no jobs for them in their own community. Training aligned with appropriate and meaningful jobs must be created that enable local people to do those jobs successfully and with pride.

Protocol

[32].

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Ethical approval

The study protocol was approved by the Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research which is registered and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research* (2023). (Reg no. EC00153). In 1966, the Council issued a Statement on Human Experimentation that expressly drew on the Helsinki Declaration (nhmrc.gov.au). Conditional approval was granted on 3 December 2018 and full approval on 3 April 2019. The Central Australian Human Research Ethics Committee (Ref CA-193308) provided full approval on 5 April 2019.

Consent for publication

Not applicable.

Data availability

The datasets generated and/or analysed during the current study are not publicly available due to potential for re-identification of communities and individuals, but are available from the corresponding author on reasonable request including approval from the above Ethics committees and community.

Competing interests

The authors declare that they have no competing interests.

Author contributions

AJL, KK, AC, PSM, and ST made substantial contributions to study concept, design, gained funding, ethical approval, and established the Governance structure and membership. JP (2018-2022) and JD (2022-2024) chaired Advisory Board, SN chaired the Training Working Group, and ST chaired the Integration Working Group. AJL drafted the first and final versions of the manuscript. AM, EW, and TT delivered the training intervention, assessed competency, collected, cleaned, and summarised data. JY-S coordinated prospective PCIS and Communicare data collection. VO designed the statistical analysis protocol. All authors read and approved the final manuscript.

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