INTERNATIONAL JOURNAL OF AUDIOLOGY
https://doi.org/10.1080/14992027.2020.1805804

ORIGINAL ARTICLE

OPEN ACCESS Check for updates

Teleaudiology hearing aid fitting follow-up consultations for adults: single blinded crossover randomised control trial and cohort studies

Karina F. M. Tao[a,b,c,d,e], Tais de C. Moreira[f], Dona M. P. Jayakody[a,b], De Wet Swanepoel[a,b,g], Christopher G. Brennan-Jones[c,e,h], Lize Coetzee[a,b] and Robert H. Eikelboom[a,b,g]

[a]Ear Sciences Centre, Medical School, The University of Western Australia, Perth, Australia; [b]Ear Science Institute Australia, Perth, Australia; [c]Ear Health Team, Telethon Kids Institute, The University of Western Australia, Perth, Australia; [d]CAPES Foundation, Ministry of Education of Brazil, Brasilia, Brazil; [e]Faculty of Health and Medical Sciences, The University of Western Australia, Perth, Australia; [f]Department of Social Responsibility, Hospital Moinhos de Vento, Porto Alegre, Brazil; [g]Department of Speech-Language Pathology and Audiology, University of Pretoria, Pretoria, South Africa; [h]Department of Audiology, Perth Children's Hospital, Perth, Australia

ABSTRACT

Objective: To evaluate and compare the effectiveness and quality of standard face-to-face and teleaudiology hearing aid fitting follow-up consultations and blended services for adult hearing aid users.

Design and Study sample: Fifty-six participants were randomly allocated to two equal groups, with equal numbers of new and experienced users. One standard and one teleaudiology follow-up consultation were delivered by an audiologist, the latter assisted by a facilitator. The order was reversed for the second group. Outcome measurement tools were applied to assess aspects of participants' communication, fitting (physical, sensorial), quality of life, and service. Cross-sectional and longitudinal outcomes were analysed.

Results: Most participants presented with moderate, sloping, and symmetrical sensorineural hearing loss. The duration of teleaudiology (42.96 ± 2.73 min) was equivalent to face-to-face consultations (41.25 ± 2.61 min). All modes of service delivery significantly improved outcomes for communication, fitting, and quality of life ($p > 0.05$). Satisfaction for both consultation modes was high, although significantly greater with standard consultations. The mode and order of delivery of the consultations did not influence the outcomes.

Conclusion: Teleaudiology hearing aid follow-up consultations can deliver significant improvements, and do not differ from standard consultations. Blended services also deliver significant improvements. Satisfaction can be negatively impacted by technical or human-related issues.

ARTICLE HISTORY
Received 11 April 2020
Revised 26 June 2020
Accepted 2 August 2020

KEYWORDS
Telehealth; audiology; hearing aids; rehabilitation; intervention; health service delivery

Introduction

In order to address the global burden of hearing loss, there is an increasing focus on teleaudiology rehabilitation services (Bush et al. 2016; Swanepoel and Hall 2010; Tao et al. 2018). Models for delivering some audiology rehabilitation services with minimal involvement of a clinician (e.g. over the counter/online sales of hearing aids, self-fitting hearing aids) have been proposed as an alternative for individuals with hearing loss with difficult access to hearing aid (HA) services. However, these investigations have not demonstrated effectiveness and showed the need for clinician involvement in the delivery of interventions (Convery et al., 2017; Humes et al., 2017; Keidser and Convery, 2016; Rogers et al., 2017).

Over the past 10–15 years, there has been a growing amount of published literature on HA teleaudiology services delivered by clinicians that investigate the feasibility and effectiveness of such services (Bush et al. 2016; Swanepoel and Hall 2010; Tao et al. 2018). More recently, a review of outcomes from HA rehabilitation services for adults delivered by teleaudiology demonstrated insufficient and low-quality evidence to support its implementation into routine clinical practice (Tao et al. 2018). Hence, there is a need for further investigation in this field; comparative studies which evaluate the outcomes of new services versus the gold standard face-to-face ones are essential (Kothari et al. 2009). Such studies would provide evidence for the translation of the new services into routine clinical practice (Atkins et al., 2005).

Hearing aid rehabilitation services are generally delivered in fitting and follow-up consultations (Dillon 2012), of which follow-up consultations are the most frequently delivered service. In contrast to HA fitting consultations that focus on fitting of the HA to physical and audiological parameters, follow-up consultations can be challenging due to the complexity of adjusting HAs to the patients' ongoing individual needs and expectations (Dillon 2012). Whilst HA follow-up consultations can potentially be delivered exclusively remotely, a blended service combining face-to-face and remote consultations may also be envisaged, as it is likely that HA clinics offering this mode of service to their clients will have the flexibility to adapt to patient's need. The

CONTACT Karina F. M. Tao karina.tao@telethonkids.org.au Ear Health Team, Telethon Kids Institute, 15 Hospital Ave., Perth 6009, Australia

Supplemental data for this article can be accessed here.

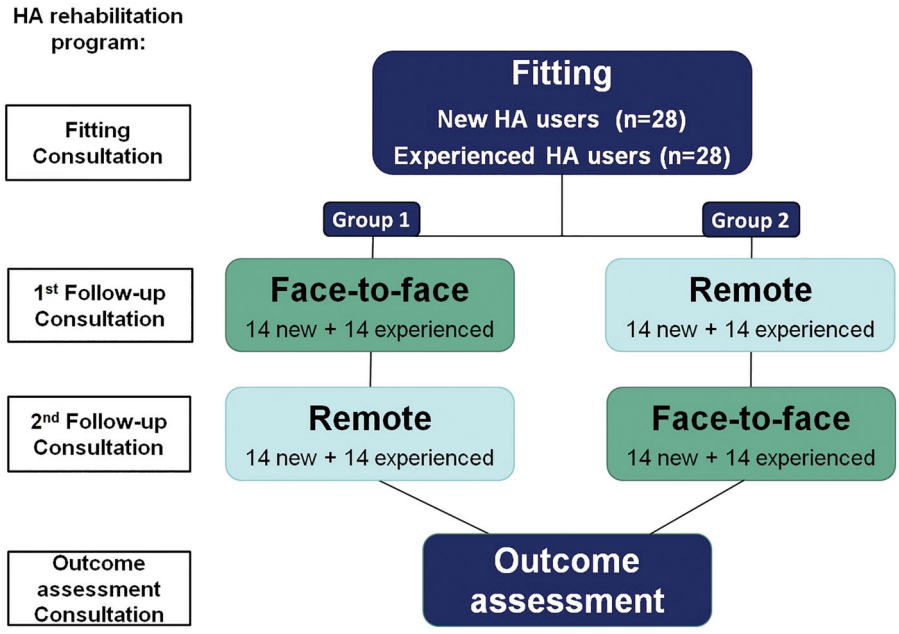

Figure 1. Study design used by the series of studies, and showing each step of the design, and the number of participants involved.

investigation of blended follow-up services described in this study was designed to determine whether the mode and order of delivery of consultations affect outcomes. As investigations on the comparison between face-to-face and remote services are also important, crossover design was employed to allow all these investigations as well as a robust interwoven analysis of the effect of the interventions, mode, and order of delivery of consultations.

This article describes two interwoven studies that investigated real-world[1] patient-centred follow-up HA consultations by teleaudiology that were implemented into routine clinical practice, comparing face-to-face consultations to teleaudiology consultations, and also blended services to two cohorts by applying patient- and service-centred tools.

Study 1: A crossover RCT study in which teleaudiology consultations were compared to gold standard face-to-face consultations.

Study 2: A longitudinal progressive cohort study using the two groups as cohorts and investigating a blended service for each cohort (i.e. teleaudiology consultation followed by a face-to-face consultation or vice-versa).

The research questions of these interwoven studies were as follow:

i. Are the participants' communication, fitting, and service satisfaction outcomes from teleaudiology HA fitting follow-up consultations (remote) different to those from standard consultations (face-to-face)?
ii. Are the participants' communication, fitting, quality of life, and service satisfaction outcomes from blended services of each cohort different from each other?
iii. Are these outcomes related to the mode and order of service-delivery of the teleaudiology and standard consultations?

The hypotheses of this series of studies were that there would be no difference between outcomes from face-to-face and remote consultations for cross-sectional comparisons, but not for longitudinal comparisons of outcomes resulting from before HA fitting and after two follow-up consultations (entire rehabilitation programme), and from before and after the two follow-up consultations (follow-up rehabilitation programme). In addition, there would be no effect of the mode or order of delivery of the consultations on the outcomes.

Due to the intrinsic and interwoven methodology between the RCT and cohort studies conducted, it was decided to use the word "study" to refer to these series of studies as one study throughout this manuscript.

Methods

The study was approved by the Human Research Ethics Committee of The University of Western Australia (UWA) and registered in the Australian New Zealand Clinical Trials Registry (ANZCTR) platform (reference: ACTRN12619000286145). The study was incorporated into the routine clinical practice of three audiology clinics (Lions Hearing Clinics) in Perth, Western Australia.

Research design

A single-blinded crossover randomised controlled trial (RCT) in which one group (G1) received face-to-face consultation followed by teleaudiology consultation, and another group (G2) received these consultations in the reverse order (Figure 1), in both cases after an initial HA fitting consultation was conducted. A final face-to-face consultation (outcome assessment) was also conducted to examine the effect of the services that were provided in the earlier consultations. The follow-up consultations delivered only differed from each other in the mode of delivery. This crossover design allowed for cross-sectional comparisons between groups, and two prospective mini-cohorts for longitudinal comparisons within and between groups as the blended services. This design also allowed the hypotheses to be tested, by comparing the effect of the intervention on both groups as a result of both consultations.

Participants were recruited from those who were booked in for a HA fitting. As hearing aid experience may influence response to treatment, equal numbers of new and experienced

HA users were recruited and randomly allocated to the two groups. Inclusion criteria: (i) new HA users, defined as those who were to be fitted with HAs for the first time, (ii) experienced HA users, defined as those with at least 1 year of HA use and to be fitted with a new but different model of HAs compared to those previously wore, (iii) were over 18 years of age, (iii) could speak fluent English, and (iv) were in good general health. All types, severities and configurations of hearing loss were accepted. About 75% of those who were invited, accepted the invitation to participate, and there were no withdrawals from the study.

Controls

To control for confounders: (i) all consultations were delivered by one experienced audiologist using the same clinical practice protocols. However, the HAs were fitted by one of ten audiologists with varied levels of experience, this replicated as closely as possible the real-world clinical practice in many clinical settings (Bennett, Meyer, and Eikelboom 2016); (ii) Volunteers with a similar level of experience and skills in the hearing field were recruited as facilitators to assist at the remote site (see below for more details). They were all first-year Masters of Audiology students, with basic audiology knowledge but no practical experience with HAs, and limited HA knowledge; (iii) Participants did not receive extra consultations or any other clinical assistance between consultations, either at the clinic, in-person, or by phone or email; (iv) Despite re-bookings resulting from unexpected issues (e.g. sickness), the interval between consultations was, in most cases, between 7 and 14 days.

Blinding

In this study, blinding was to minimise or avoid bias that could affect the reliability of responses to the investigations related to the treatment that was the same in nature (clinical protocols with a patient-centered approach) by both teleaudiology and traditional face-to-face services. The investigations of treatment delivered in both services are regarding the effect of the treatment related to the mode and order of their delivery. Blinding of these treatment investigations were not possible to the audiologist who delivered the interventions to all the participants in both group 1 and 2 (Akobeng 2005). The mode of delivery of consultations (remote or face-to-face) is obvious to participants, facilitators and the audiologist and therefore they could not be blinded to this aspect. However, the investigation of the order effect on the treatment outcomes was not known to the participants and facilitators, who were thus blinded to this allocation aspect. Therefore, this is a single-blinded study, which blinding refers to group assignment. Regarding the administration of the outcome measurement tools, the study audiologist applied two of the six measurements: the improvement of communication and fitting issues, as to not affect the conduct of the studies and to be closely aligned with and reflect real-world clinical practice protocols. The other tools were self-reports and hence, were completed by the participants without the facilitator's or audiologist's assistance who were blinded to these outcome assessments.

Training

The facilitator role was to set up the equipment at the remote site, and be the "hands" and occasionally the "ears" and "mouth" for the audiologist (facilitators role is explained in more detail under "clinical procedures" below). Each facilitator assisted the audiologist in a similar number of consultations. All the facilitators received two full days of face-to-face training on the technical and clinical tasks that they would be required to undertake and participated in a pilot test prior to commencing the studies. Facilitators were trained in using a laptop and software to establish a remote connection; manipulation of HAs; earpieces and accessories; grinding and drilling ear molds; ear and ear canal inspection for the orientation of properly inserting and positioning HAs in and on the ear. Facilitators were also trained to assist the audiologist in inspecting the HA and ear canal for wax blockage, comfort issues, and the sizing of HA domes using an otoscope. The facilitator was equipped with HA accessories (e.g. otoscope, domes, cerustops, magnets, rotary tool for drilling and grinding, cleaning kit, receivers, slim tubes), and paper copies of the self-report surveys for completion by participants immediately after the remote consultations.

Equipment

Two laptop computers with a Microsoft Windows 10 operating system 4G mobile internet connectivity were used for remote consultations. Both laptops had the same configurations and replicated the standard audiology computer system including software packages: (a) Noah (HIMSA, Copenhagen, Denmark) with Phonak and Unitron fitting software (Sonova Group, Stäfa, Switzerland) to programme HAs, and (b) TeamViewer Business (Göppingen, Germany) to enable the remote laptop to be controlled by the audiologist's laptop and video-conferencing between the two sites.

A portable Bluetooth speaker on the remote site was used to provide sound to the participant and the facilitator, and the laptop's microphone was used to capture the voices of the participants and facilitators. The audiologist used a headset with a microphone.

The facilitator completed all the technical setup at the remote site. During remote consultations, if on occasions the internet connection or transmission of data was poor such that it compromised communication between sites, a mobile telephone using the speaker-phone facility was used to maintain voice communication.

HAs were either Unitron (North and Tempus platforms) or Phonak (Venture and Belong platforms) models. All devices were wirelessly programmed using the iCube II (Phonak, Stäfa, Switzerland) or Noahlink (HIMSA, Copenhagen, Denmark) programming interface.

Outcome measurement

The methodology of this research was based on the understanding that in conventional practice, patients come to the clinic to have their hearing-related problems solved or improved. Thus, clinical interventions were personalised for each participant in order to address their individual needs, just as they would in real-world patient-centred practice. In keeping with this, patient- and service-centred tools were used for assessing outcomes.

The following tools, including two with minor alterations and two developed for this study (see Supplementary material (S.1 to S.4)), were used:

i. The International Outcome Inventory for Hearing aids (IOI-HA; Cox and Alexander 2002), a seven-item self-report questionnaire evaluating aspects of quality of life

Table 1. Timing (before, during or after) of use of assessment tools in the four types of consultations over time.

	First fitting	First follow-up		Second follow-up		Outcome assessment consultation
	Before	During	End	During	End	During
COSI	x[a]	x[b]		x[b]		x[b]
IOI-HA	x					x
HAUQ						x
HAII		x[a]		x[a,b]		x[a,b]
HASS-P			x		x	
HASS-A			x		x	

COSI: Client Oriented Scale of Improvement; HAII: Hearing Aid Issues Instrument; IOI-HA: International Outcome Inventory for Hearing Aids; HAUQ: Hearing Aid User's Questionnaire; HASS-P: Hearing Aid Service Satisfaction for Patients/Participants; HASS-A: Hearing Aid Service Satisfaction for Audiologists; During: During consultation but prior to the intervention; End: At the end of consultation.
[a]Identification of issues; [b]Measurement of the degree of change of issues as perceived by the participant.

resulting from HA interventions at the end of the rehabilitation programme. A subset of the survey was completed by the participants themselves at the clinic's reception prior to the HA fitting consultation and the full version in the outcome assessment consultation. The wording of four questions was altered slightly to make them suitable for pre-fitting administration and hence, allowing for before-after HA rehabilitation programme comparisons.

ii. Hearing Aid Users' Questionnaire (HAUQ; Dillon, Birtles, and Lovegrove 1999; Forster and Tomlin 1988), a self-report questionnaire which assesses a participant's remaining problems related to communication in pre-established situations and fitting, their satisfaction with and opinion about the service received, and self-perceived need of continuity of care after a rehabilitation programme. This was completed by the participants themselves in the outcome assessment consultation. Items #6 and #7 were slightly altered to assess the overall aspects of the service and generalise it to any hearing aid clinic.

iii. Client Oriented Scale of Improvement (COSI; Dillon, James, and Ginis 1997; Dillon et al. 1991), which is used to identify up to five specific listening situations the patient wants to improve with HAs, and the degree of change in patient's hearing ability with HAs in these specific situations relative to before the rehabilitation commences. These were recorded by the participant's original audiologist; the audiologist conducting the follow-up consultations assessed the extent of change for each situation and recorded any new issues.

iv. Hearing Aid Issues Instrument (HAII) was designed for this study. Using a similar approach to the COSI, this tool identifies and measures changes in fitting issues. This tool was administered by the audiologist conducting the follow-up consultations. Face and concept validity was established by consulting a group of audiologists and pilot testing it on 10 patients fitted with new HAs. The pilot test did not indicate that any changes were required. Validation was completed with the evaluation of the responsiveness of this tool (ability to show change over time, Guyatt, Feeny, and Patrick 1993). Responsiveness was measured through the effect size and statistical power of its application in this study – evaluative property).

v. HA Services Satisfaction of Patients/Participants [HASS-P] and of Audiologists [HASS-A]: These self-report tools were designed for this study to evaluate both teleaudiology and standard consultations, covering overall satisfaction with the consultation and with each main clinical procedure, and whether there were any technical- or human-related problems that affected satisfaction. These tools were completed immediately after a consultation. The audiologist had a list of options from which to choose to report the problem(s) that they may have experienced. These options were not provided to participants, as the intention was to avoid inducing responses, but rather to prompt participants to report remarkable items. These tools were validated in a similar manner to the HAII; further validation of these tools by assessing responsiveness or even test-retest reliability could not be conducted because patient hearing status is likely to change after intervention with HA use and these tools do not measure the change in satisfaction with consultation/procedure over time.

The tools above were administered at baseline (i.e. before HA fitting), during or at the end of a consultation (Table 1). At the end of the study and after addressing new or persistent issues identified in this final (outcome assessment) consultation, participants were given options for further follow-up consultations with their original audiologist.

Clinical procedures and application of outcome measures

All consultations were carried out according to clinical best practices. For each consultation the audiologist:

i. Investigated patient experiences with HAs over the period since the last consultation, and their current individual needs by (a) enquiring whether there was any improvement in communication difficulties reported prior to the HA fitting, and (b) enquiring and assessing whether there were any fitting issues to identify the fitting needs necessary to be addressed. Clinical procedures include the inspection of the ear and HAs positioning and adequate fit to the ear; checking whether the HAs were functioning properly (e.g. ear wax in the HA tube); and whether the patient was using their HAs properly (e.g. ability to manipulate and manage the HA's manual functions, experiences and expectations with the performance of the device related to the quality and loudness of the sounds, physical and sensorial comfort, and ease of management);

ii. Identified any issues that the patient was experiencing, or that were noticeable in the consultation. Any new or persistent issues were then addressed through adjusting the HAs (e.g. fine-tuning frequency-specific gain and adjusting signal-processing features, and improving physical fit), counselling regarding expectations and limitations (taking into consideration the emotional aspects and providing with communication strategies, as required), and instructing on how to use and manage the HAs (including demonstrations and testing, for example, phone use and troubleshooting);

Table 2. Comparisons of new and experienced HA users, and both sub-groups of new HA users and experienced HA users.

(A)										(B)			
	New & Experienced HA users			New HA users			Experienced HA users			New vs	New vs	New G1 vs	New G2 vs
Variables	G1	G2	Total	G1	G2	Total	G1	G2	Total	Exp. G1	Exp. G2	Exp. G2	Exp. G1
Gender													
Female	10 (35.7)	11 (39.3)	21 (37.5)	6 (42.9)	3 (21.4)	9 (32.1)	4 (28.6)	8 (57.1)	12 (42.9)				
Male	18 (64.3)	17 (60.7)	35 (62.5)	8 (57.1)	11 (78.6)	19 (67.9)	10 (71.4)	6 (42.9)	16 (57.1)				
Age (years)**	75.2 (±10), 50-90	74.2 (±9.2), 51-93	74.7 (±9.5), 50-93	72.7 (±10.4), 50-85	72.8 (±9.8), 51-86	75.7 (±9.9), 50-86	77.8 (±9.2), 61-90	75.64 (±8.7), 64-93	76.71 (± 8.9), 61-93				
Age group													
18–50 years	1 (3.6)	0	1 (1.8)	1 (7)	0	1 (3.6)	0	0	0				
51–65 years	4 (14.3)	4 (14.3)	8 (14.3)	2 (14.4)	3 (21.4)	5 (17.8)	2 (14.4)	1 (7)	3 (10.7)				
66–80 years	13 (46.4)	17 (60.7)	30 (53.6)	7 (50)	7 (50)	14 (50)	6 (42.8)	10 (71.5)	16 (57.2)				
81–95 years	10 (35.7)	7 (25)	17 (30.4)	4 (28.6)	4(28.6)	8 (28.6)	6 (42.8)	3 (21.5)	9 (32.1)				
4FPTA (dB HL)**													
	R - 45.75 (±7.17), 15–85	R - 48 (±16.79), 14–90	R - 46.87 (±16.87), 14–90	R - 39.73 (±16.80), 15–85	R - 39.01 (±11.11), 14–57	R - 39.37 (±13.98), 14–85	R - 51.78 (±15.87), 30–79	R - 56.96 (±16.99), 27–90	R - 54.37 (±16.35), 27–90		R - $t(26) = -3.30$, $p = 0.03$	R - $t(26) = -2.69$, $p = 0.012$	R - $t(26) = -2.46$, $p = 0.021$
	L - 48.34 (±18.45), 10–86	L – 45.14 (±12.83), 20–117	L - 48.03 (±18.35), 10–117	L - 40.71 (±15.90), 10–74	L - 38.66 (±7.02), 20–49	L - 39.68 (±12.11), 10–74	L - 55.98 (±18.14), 27–86	L - 56.78 (±22.16), 27–117	L - 56.38 (±19.87), 27–90	L - $t(26) = -2.36$, $p = 0.026$		L - $t(26) = -2.20$, $p = 0.037$	L - $t(26) = -3.33$, $p = 0.003$
HL degree													
Normal	R - 0	R - 1 (3.6)	R - 0	R - 0	R - 1 (3.6)	R - 1 (3.6)	R - 0	R - 0	R - 0			R - $\chi^2(4) = 10.933$, $p = 0.027$	L - $\chi^2(3) = 10.111$, $p = 0.018$
	L - 1 (3.6)	L - 0	L - 1 (1.8)	L - 1 (7.1)	L - 0	L - 0	L - 0	L - 0	L - 0				
Mild	R - 8 (28.6)	R - 8 (28.6)	R - 17 (30.4)	R - 6 (42.9)	R - 6 (42.9)	R - 12 (42.9)	R - 2 (14.3)	R - 2 (14.3)	R - 4 (14.3)				
	L - 7 (25)	L - 10 (35.7)	L - 17 (30.4)	L - 5 (35.7)	L - 7 (50)	L - 12 (42.9)	L - 2 (14.3)	L - 3 (21.4)	L - 5 (17.9)				
Moderate	R - 14 (50)	R - 9 (32.2)	R - 23 (41.1)	R - 7 (50)	R - 6 (42.9)	R - 13 (46.4)	R - 7 (50)	R - 3 (21.4)	R - 10 (35.7)				
	L - 11 (39.3)	L - 13 (46.4)	L - 24 (42.9)	L - 6 (42.9)	L - 7 (50)	L - 13 (46.4)	L - 5 (35.7)	L - 6 (42.9)	L - 11 (39.3)				
Mod-severe	R - 3 (10.7)	R - 7 (25)	R - 10 (17.9)	R - 0	R - 1 (7.1)	R - 1 (3.6)	R - 3 (21.4)	R - 6 (42.9)	R - 9 (32.1)				
	L - 5 (17.9)	L - 3 (10.7)	L - 8 (14.3)	L - 1 (7.1)	L - 0	L - 1 (3.6)	L - 4 (28.6)	L - 3 (21.4)	L - 7 (25)				
Severe	R - 3 (10.7)	R - 2 (7)	R - 5 (9)	R - 1 (7.1)	R - 0	R - 1 (3.6)	R - 2 (14.3)	R - 2 (14.3)	R - 4 (14.3)				
	L - 4 (14.3)	L - 1 (3.6)	L - 5 (9)	L - 1 (7.1)	L - 4 (14.3)	L - 1 (3.6)	L - 3 (21.4)	L - 1 (7.1)	L - 4 (14.3)				
Severe Profound	R - 0	R - 1 (3.6)	R - 1 (1.8)	R - 0	R - 0	R - 0	R - 0	R - 1 (7.1)	R - 1 (3.6)				
	L - 0	L - 1 (3.6)	L - 1 (1.8)	L - 0	L - 0	L - 0	L - 0	L - 1 (7.1)	L - 1 (3.6)				
HL configuration ***													
Sloping	R - 24 (85.7)	R - 18 (66.7)	R - 42 (75)	R - 12 (85.7)	R - 9 (69.2)	R - 21 (77.7)	R - 12 (85.7)	R - 9 (64.3)	R - 21 (75)				
	L - 22 (81.5)	L - 19 (67.9)	L - 41 (74.5)	L - 12 (92.3)	L - 11 (78.6)	L - 23 (85.2)	L - 10 (71.4)	L - 8 (57.2)	L - 18 (64.3)				
Linear	R - 4 (14.3)	R - 9 (33.3)	R - 13 (23.6)	R - 2 (14.3)	R - 4 (30.8)	R - 6 (22.2)	R - 2 (14.3)	R - 5 (35.7)	R - 7 (25)				
	L - 5 (18.5)	L - 9 (32.1)	L - 14 (25)	L - 1 (7.7)	L - 3 (21.4)	L - 4 (14.8)	L - 4 (28.6)	L - 6 (42.8)	L - 10 (35.7)				
HL symmetry													
Symmetric	18 (64.3)	16 (57.1)	34 (60.7)	9 (64.3)	9 (64.3)	18 (64.3)	9 (64.3)	7 (50)	16 (57.1)				
Asymmetric	10 (35.7)	12 (42.9)	22 (39.3)	5 (35.7)	5 (35.7)	10 (35.7)	5 (35.7)	7 (50)	12 (42.9)				
HL type**													
Sensorineural	R - 26 (93)	R - 23 (82.1)	R - 49 (87.5)	R - 14 (100)	R - 13 (93)	R - 27 (96.4)	R - 12 (87.5)	R - 10 (71.4)	R - 22 (78.6)			R - $\chi^2(1) = 4.667$, $p = 0.031$	
	L - 25 (92.6)	L - 25 (89.3)	L - 50 (91)	L - 12 (92.3)	L - 13 (93)	L - 25 (92.6)	L - 13 (93)	L - 12 (87.5)	L - 25 (89.3)				
Mixed	R - 2 (7)	R - 5 (17.9)	R - 7 (12.5)	R - 0	R - 1 (7)	R - 1 (3.6)	R - 2 (14.3)	R - 4 (28.6)	R - 6 (21.4)				
	L - 2 (7.4)	L - 3 (10.7)	L - 5 (9)	L - 1 (7.7)	L - 1 (7)	L - 2 (7.4)	L - 1 (7)	L - 2 (14.3)	L - 3 (10.7)				
HA fitting													
Monaural	1 (3.6)	1 (3.6)	2 (3.6)	1 (7)	1 (7)	2 (7)	0	0	0				
Binaural	27 (96.4)	27 (96.4)	54 (96.4)	13 (93)	13 (93)	26 (93)	14 (100)	14 (100)	28 (100)				
Total	$n = 28$	$n = 28$	$n = 56$	$n = 14$	$n = 14$	$n = 28$	$n = 14$	$n = 14$	$n = 28$				

Legend: (A) Participants' demographics per group (G1 and G2) and in total for three individual studies. (B) Comparisons on the distribution of participants demographics in G1 and G2 between new and experienced users (results of statistic tests showing only significant values ($p < 0.05$) of comparisons between and within groups) R: right ear; L: left ear; *p value <0.05; Exp.: experienced.

Note. Values are n (%), except for values with "**" symbol, where the values are mean (standard deviation), range; ***ear with normal hearing was excluded.

Pearson Chi-square test of homegeinety and independent samples t-tests were used. Significance values >0.05 were obtained for all the variables in (A), thereby they are not shown.

iii. Addressed any further questions or doubts the participant and/or his/her significant other had;
iv. Informally verified whether participants could detect and/or discriminate speech sounds essential for speech recognition (e.g. phonemes using Ling test/s, ʃ, ɔ, i, a, m/, and other extra phonemes compromised with mid to high-frequency hearing loss/p, k, t, f, Ø/, usually presented without visual cues by facing the participant) (Agung, Purdy, and Kitamura 2005);
v. Informed the patient about the next steps and what he/she and the audiologist would expect over the period until the next scheduled consultation;
vi. Made sure that any instructions to the patient were clear, and that they were happy with given explanations, solutions, and apparent result; and
vii. Finalised the consultation.

Face-to-face follow-up consultations were delivered in an audiology clinic. Remote follow-up consultations were delivered in synchronous mode with the assistance of a facilitator who travelled to the place of the participants choosing, ideally their home but it could be at their workplace or another clinical location if this was more convenient for them.

Facilitators assisted the clinician with performing procedures required for the participant by acting as the clinician's "hands" (e.g. demonstrating how to better insert and remove the HAs), "eyes" (e.g. checking for wax blockage), or "mouth" (e.g. repeating the audiologist's message to the participant when audio and/or video was not optimal, and applying informal speech testing) when requested by the clinician. They also assisted with some other tasks as required by the clinician (e.g. tested the clarity of the TV or speaking from another room in the house, checked for referred ambient noises in the house or surroundings).

Data analysis

The assessment of benefit from the interventions related to the follow-up consultations and entire rehabilitation programme determined the *effectiveness* of the services (COSI, HAII, items #1–4 and 8 of the HAUQ, and #1–3, 5–7 of the IOI-HA). The assessment of satisfaction with clinical interventions and device determined the *quality* of the service (HASS-P/A, items #5–7, 9–11 of the HAUQ, and #4 of the IOI-HA, and the extra question regarding participants' opinion on the equivalency of face-to-face to remote consultations). Barriers to satisfaction with service-delivery were also investigated using the HASS-P/A and items from the HAUQ, as part of the investigation of the quality of the service.

The start and end times of the consultations with the clinician were recorded, to enable a comparison of the time taken for face-to-face and remote consultations. Not included in the timing was the time for the technical set up by the facilitator, and travel time to the participant's home.

HA daily use was subjectively recorded on questions from HAUQ and IOI-HA (the average amount of hours that participants wore their HAs per day). Objective data recorded in the HA (data logging) was used as a secondary outcome, to determine whether participants were able to adequately self-report their HA daily average use.

The null hypothesis (H_0) of this study was that there is no difference between outcomes from face-to-face and remote consultations. This hypothesis was expected to be true for cross-sectional comparisons and to be false for longitudinal comparisons (i.e. no significant difference between the groups at any stage through the study, but significant difference across the course of the study for both groups).

A sample size calculation indicated that a sample of 14 participants in each group was needed for comparisons between related observations, and 25 participants in each group for comparisons between independent observations (two-tailed $\alpha = 0.05$), with an 80% chance to detect a difference of at least 0.55 between average scores within participants from baseline to the end of the assessment period, and between participants in the control and experimental groups, and also assuming a standard deviation (*SD*) of 0.64 (as reported for the COSI by Dillon, James, and Ginis 1997).

Likert scales were used to record the responses in the IOI-HA, COSI, HAII, HASS P/A, and some items of HAUQ. These were treated as ordinal and/or scale variables when scores were averaged within or across participants.

The Shapiro–Wilk statistical test was used for testing the normality of data distribution. As this showed that the majority of data were not normally distributed (also after attempts to transform the data), nonparametric statistical tests were used where appropriate for the data analysis. All the required test assumptions were met for these to be used. Means and medians were calculated and used for parametric (*t*-tests) and non-parametric tests (described below) respectively, and were reported accordingly.

The Kruskal–Wallis H test, was used to determine whether there were any statistical differences between responses of independent observations (different participants in each group) of two or more groups. The Wilcoxon signed-rank test was used to determine whether there were any statistical differences between responses of two related groups (same participants in both groups) whereas the Friedman test was used for three or more related groups. These tests were used to examine the difference in the distribution of scores, medians and/or mean-ranks of two groups, which measures the effect of a condition on the location of the distribution regarding the outcome of interest. A post-hoc test with Bonferroni correction to the alpha values was run to determine where the significant differences were; this performs multiple pairwise comparisons when testing more than two groups (e.g. subgroups, new and experienced users) and controlling for Type I errors (Pallant 2007, 228). Pearson chi-square test of homogeneity was used to determine whether there were any statistical differences between population characteristics (qualitative variables) between two independent groups. Effect size estimates (r) were calculated and assessed against Cohen's criteria (Small <0.3; Medium 0.3 to 0.5; Large effect >0.5, Cohen 1988).

Statistical analyses were carried out using IBM SPSS Statistics for Windows version 22 (2013) and G*Power version 3.1.9.2 (2013).

Sufficient detail has been provided here and elsewhere to enable replication (Tao 2020), and to trigger future research.

Results

The remote consultations were all delivered to participants' homes, except in one instance where it was to a participant's office, and twice the participant went to an audiology clinic but where the audiologist had no face-to-face contact with them.

There were no significant differences between groups related to age, gender, hearing threshold average, hearing loss type, degree, configuration, symmetry, and HA fitting laterality (Table 2). Separating groups into new and experienced users also

showed no significant differences except that the four-frequency pure-tone average of thresholds (mean threshold of 0.5, 1, 2 and 4 kHz) and degree of hearing loss were greater for the experienced HA users in the left ear of those in G1 and the right ear of those in G2 (Table 2). The mean age of the participants was 74.7 years ($SD = 9.5$, range: 50–93 years), and 62.5% were males. The majority presented with a moderate (right ear 41.1% and left 42.9%), sloping (right ear 75% and left ear 74.5%) and symmetrical (60.7%) sensorineural (right ear 87.5% and left ear 91%) hearing loss, almost all fitted bilaterally with HAs (96.4%), almost all with behind-the-ear HAs (Table 2). Two-thirds of the participants were fitted under the Australian Government's Office of Hearing Services' scheme and obtained their HAs free of charge. None of the participants returned their HAs and all publicly funded (i.e. OHS) participants signed-off on keeping their HAs at the end of the studies.

There was no statistically significant difference between new and experienced HA users for the primary outcomes of interest (participants' communication, fitting issues, and satisfaction with services). Therefore, results are reported for new and experienced users combined.

The mean interval between consultations was 12.24 days ($SD = 4.63$). There was no statistically significant difference for consultation intervals between G1 and G2 but there was within G1 only ($p = 0.013$) for the interval between the fitting and first follow-up ($p = 0.027$, after Bonferroni correction) (Supplementary material S.5). However, correlation coefficients obtained between the intervals and the outcome variables in this study showed no associations with coefficients statistically lower than the critical value ($r_s = 0.268$) for a two-tailed test (Spearman's rank-order correlation test, $n = 56$, $v = 54$ for $\alpha = 0.05$). The length of the intervals did not, therefore, affect the results.

The median time taken for remote and face-to-face consultations was approximately 43 and 41 min, respectively, which was not significantly different between groups but was significantly different within the groups, that is, related to the mode of the consultation ($p = 0.103$ and 0.404 for G1 and G2 respectively). This was because the remote consultations took slightly longer (G1: Mdn = 42, IQR = 40–45; G2: Mdn = *43*, IQR = 42–45) compared to face-to-face consultations (G1: Mdn = 42, IQR = 40–43; G2: Mdn = 40.5, IQR = 40–42) in both groups.

Effectiveness

There was a mean of 2.37 COSI goals ($SD = 0.90$, range: 1–5) across participants prior to HA fitting with the distribution not significantly different between G1 and G2 ($p = 0.651$).

For these COSI goals over the course of the study (i) there were no significant differences in the scores between the groups at each of the three consultations ($p > 0.05$, (B) in Supplementary material S.6, and S.7), (ii) there was a significant improvement in scores over the course of follow-up consultations in both groups between outcomes resulting from the fitting and second follow-up consultations in both G1 (before: Mdn = 4.12, IQR = 3.00–4.91; after: Mdn = 5.00, IQR = 4.50–5.00; $p < 0.001$) and G2 (before: Mdn = 4.33, IQR = 3.74–5.00; after: Mdn = 5.00, IQR = 4.56–5.00; $p = 0.001$) ((D) in Supplementary material S.6, and S.7), and (iii) there were no significant differences between the groups in the changes of scores ($p > 0.05$), that is, score change between the first follow-up consultation compared to the fitting consultation (G1: $M_{diff} = 0.41$, $SD = 1.11$, G2: $M_{diff} = 0.46$, $SD = 0.80$; Kruskal–Wallis H test, $p = 0.437$), and the second consultation compared to both the fitting consultation (G1: $M_{diff} = 0.86$, $SD = 0.90$, G2: $M_{diff} = 0.66$, $SD = 0.87$; Kruskal–Wallis H test, $p = 0.311$) and the first follow-up consultation (G1: M_{diff}=0.45, $SD = 0.73$; G2: M_{diff}=0.20, $SD = 0.35$; Kruskal–Wallis H test, $p = 0.160$). There was a large effect size with high statistical power ($r = 0.85$, $1 - \beta = 1$) for the change in scores (before-after the follow-up programme) for the participants as a group, and also for G1 ($r = 0.84$, $1 - \beta = 0.998$) and G2 ($r = 0.53$, $1 - \beta = 0.85$).

Almost all the participants (96.42%) presented satisfactory outcomes in their communication goals at the end of the study (final score from 4 to 5); 67.85% had a "much better" improvement (final score was 5), and 28.57% had an overall "better" improvement (final score was 4 or between 4 and 5), and 3.52% reported no change or a decline (scores 3 or lower) as a result of the rehabilitation. Further analysis showed that as for COSI, there were no significant differences between groups ($p = 0.902$) in communication issues for the results of HAUQ item #3 assessed at the end of the study.

A mean of 2.64 fitting issues ($SD = 0.96$, range: 1 to 4) across participants were identified by the HAII. The majority of participants (98.2%) had fitting issues related to sound parameters ($M = 2.21$, $SD = 2.21$), 26.8% of which were related to physical comfort ($M = 0.26$, $SD = 0.44$) and 17.9% related to device management ($M = 0.19$, $SD = 0.44$). At the first follow-up consultation, there was a mean of 1.93 issues ($SD = 0.78$, range: 1 to 4), and at the second follow-up consultation, there was a mean of 0.71 new issues ($SD = 0.80$, range: 0 to 3). There was no significant difference in the overall number of fitting issues between G1 and G2 ($p = 0.325$), and between first ($p = 0.324$) or second ($p = 0.802$) follow-up consultations. None of the participants presented new fitting issues at the outcome assessment consultation.

Analyses of the fitting issues showed:(i) There was no significant difference in outcome scores between G1 and G2 for initial and total issues[2] resulting from the interventions delivered in the follow-up consultations, or for new issues resulted from the second follow-up consultations; (ii) There was a significant improvement in outcome scores of issues resulting from each follow-up consultation within both groups; (iii) There was no difference in changes of scores over the course of follow-up consultations between groups (mean difference of 0.62 ($SD = 0.75$) in scores (Mdn_{diff}=0.5, IQR = 0.0-1.0) for all the participants as a group; G1: M_{diff}=0.55, $SD = 0.80$, G2: M_{diff}=0.69, $SD = 0.70$) (Supplementary material S.8 and S.9). There was a large effect size ($r = 0.78$, $1 - \beta = 0.999$) between before and after the follow-up programme for the participants as a group, as well as for G1 ($r = 0.71$, $1 - \beta = 0.823$) and G2 ($r = 0.84$, $1 - \beta = 0.998$).

At the end of the study, 62.5% of participants improved their score, 28.6% had no change, and 8.9% had a reduced score. The majority (62.5%) of participants did not have any remaining fitting issues (HAUQ item #4), and the remaining 37.5% of participants presented with two fitting issues. Of these 21 participants, 14 reported issues related to sound parameters, for eight they were related to device management and for five they were related to physical comfort. However, only four participants believed they would need another consultation to address these issues (derived from the HAUQ item #8). The remaining 17 participants believed that they would require only acclimatisation or practice managing their HA/earpiece, as these processes were the source of their remaining issues. Consequently, none of these participants returned to the clinic for another consultation within 6 months of this last consultation.

Four items of the IOI-HA were used for before-after comparisons, to evaluate (i) self-perceived residual activity limitations (RAL), (ii) participation restrictions (RPR), (iii) impact on others (ImpOth), and (iv) self-perceived level of hearing difficulty (self-perceived HL). There was a significant improvement of responses with the rehabilitation for all within-group comparisons (all participants as a group, and within both groups G1 and G2) for each of these three first items, with high effect size and 99.9% statistical power (RAL $r = 0.88$, RPR $r = 0.79$, and ImpOth $r = 0.80$, $p < 0.001$). Similar improvement was shown for all corresponding analyses (within and between groups) of self-perceived hearing difficulty; the changes in responses were also not significantly different between G1 and G2 for each of the other three items (Mann–Whitney U test, $p > 0.05$ for all the comparisons) (Supplementary material S.10).

Regarding the other IOI-HA items related to effectiveness (HA use, HA benefit, HA changing the enjoyment of life) which were applied only after treatment, there were no significant differences between the groups for HA use, and HA changing the enjoyment of life ($p > 0.05$); however, participants in G2 (89.2%) reported significantly greater self-perceived HA benefit than those in G1 (75%) (Kruskal–Wallis H test, $z = 7.984$, $p = 0.05$). HA use (daily hours of use) was also recorded by HAUQ item #2. The majority of the participants (80.4%) reported that they used their HA(s) more than 8 h per day, whereas 17.9% used them between 4 and 8 h per day, 1.8% used them between 1 and 4 h, and all of those fitted bilaterally (96.4%) reported that wore both HAs at the same time. These reports of HA usage were consistent with the HA data-logging data during their rehabilitation.

Quality of the service and barriers to satisfaction

The HASS-P scores were used to assess participants' satisfaction with single consultations and changes in satisfaction with a consecutive consultation, alongside IOI-HA item #4 scores that were used to assess HA satisfaction after the treatment. Scores at or approaching 5 for all aspects were desired as indicating complete satisfaction with the services provided. There were no significant differences in HA satisfaction between groups after treatment (Kruskal–Wallis H test, $z = 1.028$, $p = 0.311$) assessed by the IOI-HA item. There were also no differences in satisfaction with each procedure of the consultation assessed by HASS-P (instructions, audiologist and facilitator communication, adjustments and counselling) and with overall consultation between first and second consultations for the participants in each group, and for all the participants as a group ($p > 0.05$). However, there were significant differences in satisfaction between groups with the first follow-up consultation only ($p < 0.05$), as follows. Regarding the first follow-up consultation, 100% of G1 participants and 85.7% of G2 participants were completely satisfied with the overall consultation. Three of the four who were not completely satisfied in G2, improved their satisfaction from neutral or somewhat satisfied to completely satisfied after receiving the second consultation as face-to-face. Furthermore, two participants in G1 reduced their overall satisfaction to somewhat satisfied after receiving the second consultation as remote. These participants' changes in scores after a consecutive follow-up overall consultation did not significantly impact results within groups (Wilcoxon test, G1: $z = -1.414$, $p = 0.157$; G2: $z = 1.633$, $p = 0.102$) (Supplementary material S.11).

The distribution of these changes which occurred in opposite directions was statistically different between G1 and G2 for the overall consultation ($p = 0.026$, Supplementary Table 4.6), but with a very weak and no significant association between the groups (r_s=0.09, $p = 0.627$, Spearman's rho correlation). This showed that the increased satisfaction scores with face-to-face consultations and reduced scores with remote consultations are not a trend. In addition, there was no significant difference in satisfaction between second follow-up consultations (face-to-face and remote) between G1 and G2 (Mann-Whitney U test, $U = 406$, $z = 0.588$, $p = 0.556$).

There were similar findings for communication with the audiologist. There was a significant difference between groups with the change in scores in opposite directions resulting from the follow-up consultations ($p = 0.045$, supplemental material S.11) (three participants in G2 improved scores whilst one participant in G1 reduced score with the second consultation for this consultation procedure). However, it was with a very weak and no significant association between the groups (r_s=0.22, $p = 0.248$, Spearman's rho correlation, and these changes did not impact results within groups; there were no significant differences within groups and between groups for the first and second consultations ($p > 0.05$, Supplementary material S.11).

The HASS-P scores for human or technical aspects showed that the less than completely satisfied responses for remote consultations were related to the following factors: (i) technical issues related to the delay between the audio and video, audio distortion or disruption, and participants' personal needs of relying on visual cues ($n = 5$), and (ii) technical issues related to the facilitator's difficulty of connecting to the remote computer, the occasional loss of visual contact with the audiologist on screen, and for not feeling comfortable with the facilitator ($n = 1$).

The HAUQ (items #5 to #7) investigated the participants' satisfaction with the HA, the patient service received at the clinic, and the personal treatment provided to the patient by all involved. The results showed that most participants reported being very satisfied with the service (91.1%), the way they were treated (94.6%), and with the HAs (75%) after treatment. There was no significant difference between groups. Furthermore, answers to items #9 to #11 (open-ended questions regarding their satisfaction, related to what they liked most, least or would change regarding the HA or service) showed that the majority of participants (94.6%) reported having liked most aspects of the service, reporting aspects such as reduced disability, personalised assistance, hearing treatment received, the approach of personal treatment, and home care. In addition, they reported that they would not change anything related to the service received. The other participants (5.3%, $n = 2$) provided suggestions that were largely unrelated to the study, for example, reducing the cost of HAs and requiring improvements in HA technology. Regarding the responses as to what they liked least, 85.7% of participants responded with "not applicable" as they had no comment to provide about this aspect; this made this question unusable for analysis. 14.2% of participants responded to what they liked least: 3.6% reported not liking the travel to a clinic and the remote consultation as a mode of service, 7.14% reported not liking items unrelated to the scope of the study (i.e. the HA expenses, insertion in the ear and that it captures background noises); the remaining 85.7% of participants offered no comment on this item.

The majority of participants (80.3%) reported that both consultations were of similar quality, most of which (52.5%) reported no preference for either face-to-face or remote consultations. The others (27.8%) indicated a preference for face-to-face consultations but would request remote consultations in

situations where they could not reach a clinic. On the other hand, approximately one-fifth of participants (19.7%) reported that they did not feel that a remote consultation attended to their needs as well as a face-to-face consultation, but some of them reported that only one consultation was probably not enough for them to provide a fair response. Interestingly, none reported a preference for remote consultations over face-to-face consultations.

Audiologist's satisfaction, recorded by the HASS-A, showed significantly higher satisfaction with face-to-face consultations (G1 92.9%, and G2 92.9%), than with remote consultations (G1 50%, and G2 71.4%) (between-group comparisons for first consultation $U = 279$, $z = -2.782$, $p = 0.005$, second consultation $U = 533.5$, $z = 3.244$, $p = 0.001$, and for the changes between both consultations $U = 610$, $z = 4.125$, $p < 0.001$). The audiologist's satisfaction was noted to be affected by the technical and human-related issues during the remote consultations. The audiologist also reported that because of these issues, she would prefer delivering face-to-face consultations over remote consultations, but if these problems are solved or significantly improved, the preference would not be one over the other.

Discussion

The major findings of this study were:

i. Outcomes from face-to-face and remote consultations are similar for the participants' communication, fitting, and service satisfaction and improvement of quality of life. There was also a significant longitudinal improvement in all these measures with blended services (face-to-face and remote consultations). There was no effect of the order or mode (remote or face-to-face) of the consultations on these outcomes.
ii. Four out of five participants were completely and similarly satisfied with both face-to-face and remote consultations, even though satisfaction with remote consultations was somewhat affected by technical issues relating to the quality of the audio and video communication. These technical issues affected the audiologist's satisfaction with the delivery of the consultation.
iii. Although there was a statistically significant difference in the duration of face-to-face and remote consultations, the median difference of 2 min for approximately 40-min consultations is not of clinical significance.

Considering the limited number of intervention studies that included aspects of HA follow-up consultations (e.g. HA programming, counselling, and instructions) (reviewed in Tao et al. 2018; Angley, Schnittker, and Tharpe 2017), comparison of these results is difficult. The closest studies of teleaudiology services have been those examining real ear measurements (Campos and Ferrari 2012; Pross, Bourne, and Cheung 2016), counselling programme (Cherry and Rubinstein 1994, 1995; Laplante-Levesque, Pichora-Fuller, and Gagne 2006; Lundberg, Andersson, and Lunner 2011; Thoren et al. 2011; Thoren et al. 2014), and of specific procedures performed by teleaudiology but in isolation from the other procedures (Tao et al. 2018; Ferrari 2006; Ferrari and Bernardez-Braga 2009; Reginato and Ferrari 2014; Campos and Ferrari 2012; Pearce, Ching, and Dillon 2009; Penteado et al. 2012, 2014; Venail et al. 2019). None of these were implementation studies or compared the outcomes of remote to face-to-face follow-up services, nor was there assistance of a trained facilitator.

Despite the lack of similar studies to this one, systematic reviews have investigated the effects of other rehabilitation-related consultations delivered remotely compared to those delivered face-to-face. Speyer et al. (2018) conducted a meta-analysis to investigate the effect of rehabilitation face-to-face consultations compared to remote consultations which were delivered by allied health professionals and nurses in rural and remote areas. It included 43 studies (6 were RCT) with a majority of strong methodological quality and representing the fields of nursing and psychology. They analysed the effect per type of intervention approach and concluded that both telehealth and face-to-face were similarly effective, especially for interventions using a combination of physical and cognitive approach (respectively, interventions targeting physical symptoms, and behavioural and speech and language problems) in the consultations. A Cochrane systematic review performed by Flodgren et al. (2015) investigated a wide range of health services related to any clinical condition delivered by telemedicine using a direct patient-provider interaction. 93 trials evaluated the effectiveness of interactive telemedicine for monitoring, providing treatment or rehabilitation, training, education, and advice for self-management, diagnosis, and plan of action or screening of a health condition. They concluded that the effectiveness of telemedicine depends on numerous factors such as those related to the population studied, the severity of the condition, the purpose of delivery of care, and need of accessing health services. Rogante et al. (2015) assessed the quality of ten systematic reviews on telerehabilitation and identified that five high quality reviews provided mounting evidence of the effectiveness of telemedicine or telerehabilitation services. However, these generalised results described above may not be applicable for all health conditions, types of intervention, or lengths of treatment (Rogante et al. 2015). The effect of the interventions in this present study was evaluated over a short-term through a series of follow-up consultations for new and experienced HA users.

The treatment effect observed in this study may not be maintained over a longer-term due to factors associated with hearing loss and deterioration, acclimatisation to amplification, and unaddressed future fitting and hearing issues (Bennett et al. 2018). Therefore, a routine follow-up programme should be provided to patients after their initial rehabilitation programme ends in order to monitor and maintain the benefits (Barker et al. 2016; Brennan-Jones, Bennett, and Barker 2017). Future research investigating the outcomes of a routine follow-up programme delivered by teleaudiology would be of interest.

Satisfaction is a quality indicator of the service provided. The services delivered in this series of studies were of high quality, demonstrated by the high satisfaction rates for both teleaudiology and standard consultations. Four out of five participants were satisfied with the teleaudiology service provided despite some experiencing and reporting technical issues during the delivery of their remote consultations. To our knowledge, no previous teleaudiology studies have reported factors related to satisfaction. However, the main factors contributing to satisfaction with telehealth, in general, have been related to improved outcomes, preferred modality, ease of use, low cost, improved communication and decreased travel time (Kruse et al. 2017). Although the benefit of accessing hearing health services through telehealth by those with more difficulty to move to the clinic is another factor usually commented in the general literature, it has not yet been investigated through closed questions in audiology research. In addition, these factors above were not directly investigated in this study and may have contributed to the fact of two out of

ten participants be not completely satisfied with teleaudiology consultations. Investigation of these factors is desired in future research for a better understanding of the determinants of service quality.

Furthermore, satisfaction with and acceptability of telerehabilitation consultations have also been generally high and similar to standard face-to-face consultations in other healthcare fields (Rogante et al. 2015; Flodgren et al. 2015). Convenience, efficiency, easy communication, privacy, and comfort are some factors that appear to be associated with acceptance of real-time video telehealth services in medical primary care (Powell et al. 2017). However, acceptability may be an independent factor to preference, something that is important when considering a teleaudiology service. All the same, the use of telehealth/telemedicine may not be the preferred choice of all patients and health care providers (Flodgren et al. 2015; Ravi et al. 2018). The results of this current study showed that eight out of ten participants felt that both modes of consultations similarly attended to their needs but none of them reported to have preferred teleaudiology over the face-to-face consultation. This indicates that even though telehealth provided similar benefits in outcomes and presented equally high satisfaction to face-to-face services, telehealth technology could not replicate the standard consultation experience for participants. It is possible that participants' preferences play a role in how they perceived their experiences because their preferences were based on a comparison that they made when exposed to both modes of consultations for the same type of consultation (follow-up HA fitting). However, the interventions delivered in both consultations were subject to the circumstances of the patient in the consultation which vary from one consultation to another and will provide different experiences. Thus, factors related to participant preferences and experience with one or both modes of consultations (blended or purely remote/face-to-face) should be included in the investigation of satisfaction in future research.

One of the challenges of validating teleaudiology services, also for this study, is that there is not an established set of outcome measures for validation of teleaudiology, or even a standard in clinical practice (Barker et al. 2016; Brennan-Jones, Bennett, and Barker 2017). In the absence of published tools for assessing teleaudiology, and even to a degree audiology services, this project used validated tools (COSI, IOI-HA, HAUQ) and new tools (HAII, HASS-P, HASS-A). All tools proved to be suited to the task in terms of useability and sensitivity, in that they could be utilised within the consultation, for example, to identify issues that needed to be resolved and were able to measure the effect of the intervention.

Facilitators played an important role in this project, to set up the equipment, conduct minor repairs, and be the "ears" and "hands" of the audiologist as required. Training of facilitators for tele-audiology services is essential (Govender and Mars 2017; Coco et al., 2020) and hence they received 2 days of training. An assessment of their activities was not included in the study, although anecdotally we can report that facilitators need to be carefully selected and trained. This topic deserves further examination, especially as facilitators are an important element in determining the economic viability of teleaudiology services.

Strengths and limitations

The strength of this study is that it is well powered, that the crossover design eliminated many confounders and enabled the mode and order of the delivery of the services (face-to-face and remote) to be examined.

This study represents a step towards gathering the evidence necessary to support the translation of teleaudiology into practice, being the first to contribute a randomised trial of teleaudiology HA rehabilitation services to be carried out in a real-world clinical setting and to include remote follow-up HA fitting consultations delivered at the patients' preferred location (e.g. home, office). Although this contributes to the highest quality of evidence available to date to answer these research questions, the evidence to support the implementation of teleaudiology into practice is still "moderate." This is because more than one study using a similar methodology with consistent findings is required to strongly support the implementation of teleaudiology into practice (Tao et al. 2018); a similar study with concurring evidence is therefore still required.

Possible bias was potentially introduced in this by having one audiologist to conduct the consultations and collect some of the research data. However, it should be noted that neither the assessor of some of the outcomes (the clinician) nor the participant could have been blinded to the mode of delivery of the service, due to the obvious nature of these deliveries (face-to-face or remote). Furthermore, this research reflected real-world clinical practice, where the outcomes (also those measured in this study) are mostly reported by the participant/patient. The tools used in this study were deliberately chosen to be patient- and service-centred and generate real-world responses to questions. The audiologist, besides conducting the consultation according to the clinical-best-practice protocols, recorded the responses as in real-world clinical practice.

Conclusions

This study is a contribution to the implementation of teleaudiology HA fitting follow-up consultations and found that it would be acceptable for most adults:

i. Teleaudiology follow-up consultations in this study were of similar effectiveness, quality, length of time, and can deliver similar results as face-to-face consultations when implemented into routine practice settings for new or experienced HA users.
ii. A blended follow-up service, which involves both standard face-to-face and teleaudiology HA follow-up consultations using synchronous mode with assistance by a facilitator at a patient's preferred location, can provide an effective, high-quality service irrespective of the mode or order of delivery of the consultation.

Additional studies with similar methodologies are needed to add to the evidence generated by this clinical trial of telehealth follow-up for hearing aid services. Translational and implementation studies would be of particular benefit.

Notes

1. The terminology 'real-world clinical practice' used in this manuscript refers to the clinical practice protocols delivered in the consultations independent on the mode of their delivery (e.g. use of a facilitator or not, or whether it was face-to-face or remote). This terminology also refers to almost every other aspect of the consultation, from booking and managing appointments, software and equipment used, to conduct of the session.
2. Initial fitting issues were identified in the first follow-up consultations. The new fitting issues were identified in the second follow-up consultations. The total fitting issues were those initial issues that were reassessed and new issues identified in the second follow-up

consultations. All the comparisons between consultations for these type of issues were made against the initial issues identified in the first consultation (statistical results are shown in Supplementary material S.8).

Acknowledgements

This paper is part of a PhD thesis of the first author (Tao 2020), available through the library of The University of Western Australia. We would like to thank all the participants and families involved in the study, the volunteers who assisted as facilitators (Kayla Harvey, Erin Kosovic, Shelley Li, and Stella Kristanto) and the Lions Hearing Clinic's staff at their Joondalup, Mount Lawley and Winthrop clinics. Christopher Brennan-Jones is supported by an NHMRC Research Fellowship #1142897.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Funding

This work was supported by CAPES foundation, Process number BEX 13410/13-0, Science without borders program, Brazil (for Karina FM Tao), Ear Science Institute Australia, Perth, Australia, and Telethon Kids Institute (Ear Health), Perth, Australia.

ORCID

Karina F. M. Tao http://orcid.org/0000-0001-7666-4899
Tais de C. Moreira http://orcid.org/0000-0003-0968-9599
Dona M. P. Jayakody http://orcid.org/0000-0001-5814-4355
De Wet Swanepoel http://orcid.org/0000-0001-8313-1636
Christopher G. Brennan-Jones http://orcid.org/0000-0001-7216-8097
Robert H. Eikelboom http://orcid.org/0000-0003-2911-5381

References

Agung, K. B., S. C. Purdy, and C. Kitamura. 2005. "The Ling Sound Test Revisited." *Australian and New Zealand Journal of Audiology* 27 (1): 33–41. doi:10.1375/audi.2005.27.1.33

Akobeng, A. K. 2005. "Understanding Randomised Controlled Trials." *Archives of Disease in Childhood* 90 (8): 840–844. doi:10.1136/adc.2004.058222.

Angley, G. P., J. A. Schnittker, and A. M. Tharpe. 2017. "Remote Hearing Aid Support: The Next Frontier." *Journal of the American Academy of Audiology* 28 (10): 893–900. doi:10.3766/jaaa.16093.

Atkins, D., K. Fink, and J. Slutsky. 2005. "Better Information for Better Health Care: The Evidence-Based Practice Center Program and the Agency for Healthcare Research and Quality." *Annals of Internal Medicine* 142 (12 Pt 2): 1035–1041. doi:10.7326/0003-4819-142-12_part_2-200506211-00002.

Barker, F., E. Mackenzie, L. Elliott, S. Jones, and S. de Lusignan. 2016. "Interventions to Improve Hearing Aid Use in Adult Auditory Rehabilitation." *Cochrane Database of Systematic Reviews* 8: 2016. doi:10.1002/14651858.cd010342.pub3

Bennett, R. J., A. Laplante-Lévesque, C. J. Meyer, and R. H. Eikelboom. 2018. "How Do Hearing Aid Owners Respond to Hearing Aid Problems?" *Ear and Hearing* 39 (1): 172–187. doi:https://doi.org/10.1097/AUD.0000000000000595. doi:10.1097/AUD.0000000000000477.

Bennett, J. R., C. Meyer, and R. H. Eikelboom. 2016. "Does Clinician Continuity Influence Hearing Aid Outcomes?" *International Journal of Audiology* 55 (10): 556–563. doi:10.1080/14992027.2016.1185169.

Brennan-Jones, C. G., R. J. Bennett, and F. Barker. 2017. "Cochrane Corner: Interventions to Improve Hearing Aid Use in Adult Auditory Rehabilitation." *International Journal of Audiology* 56 (9): 618–621. doi:10.1080/14992027.2017.1338763.

Bush, M. L., R. Thompson, C. Irungu, and J. Ayugi. 2016. "The Role of Telemedicine in Auditory Rehabilitation: A Systematic Review." *Otology & Neurotology* 37 (10): 1466–1474. doi:10.1097/MAO.0000000000001236.

Campos, P. D., and D. V. Ferrari. 2012. "Teleaudiology: Evaluation of Teleconsultation Efficacy for Hearing Aid Fitting." *Jornal da Sociedade Brasileira de Fonoaudiologia* 24 (4): 301–308. doi:10.1590/s2179-64912012000400003.

Cherry, R., and A. Rubinstein. 1994. "The Effect of Telephone Intervention on Success with Amplification." *Ear and Hearing* 15 (3): 256–261. doi:10.1097/00003446-199406000-00006.

Cherry, R., and A. Rubinstein. 1995. "The Long-Term Effect of Early Telephone Intervention on Hearing Aid Success." *Scandinavian Audiology* 24 (4): 243–246. doi:10.3109/01050399509047543.

Coco, L., A. Davidson, and N. Marrone. 2020. "The Role of Patient-Site Facilitators in Teleaudiology: A Scoping Review." *American Journal of Audiology* : 1–15. doi:10.1044/2020_AJA-19-00070. 32692575

Cohen, J. 1988. *Statistical Power Analysis for the Behavioral Sciences*. 2nd ed. New York, NY: Lawrence Erlbaum Associates Publishers.

Convery, E., G. Keidser, M. Seeto, and M. Mclelland. 2017. "Evaluation of the Self-Fitting Process with a Commercially Available Hearing Aid." *Journal of the American Academy of Audiology* 28 (2): 109–118. doi:10.3766/jaaa.15076. 28240978

Cox, R. M., and G. C. Alexander. 2002. "The International Outcome Inventory for Hearing Aids (IOI-HA): Psychometric Properties of the English Version." *International Journal of Audiology* 41 (1): 30–35. doi:10.3109/14992020209101309.

Dillon, H. 2012. *Hearing Aids*. 2nd ed. New York, NY: Thieme Medical Publishers.

Dillon, H., A. James, and J. Ginis. 1997. "Client Oriented Scale of Improvement (COSI) and Its Relationship to Several Other Measures of Benefit and Satisfaction Provided by Hearing Aids." *Journal of the American Academy of Audiology* 8 (1): 27–43.

Dillon, H., E. Koritschoner, J. Battaglia, R. Lovegrove, J. Ginis, G. Mavrias, L. Carnie, P. Ray, L. Forsythe, E. Towers, et al. 1991. "Rehabilitation Effectiveness II: Assessing the Outcomes for Clients of a National Hearing Rehabilitation Program." *Australian Journal of Audiology* 13 (2): 68–82.

Dillon, H., G. Birtles, and R. Lovegrove. 1999. "Measuring the Outcomes of a National Rehabilitation Program: Normative Data for the Client Oriented Scale and the Hearing Aid User's Questionnaire (HAUQ)." *Journal of the American Academy of Audiology* 10 (2): 67–79.

Ferrari, D. V. 2006. "Remote Programming and Verification as a Mean to Improve Quality of Hearing Aid Fitting." In *Hearing Aid Fitting*, edited by A. N. Rasmussen, T. Paulsen, T. Andersen, C. B. Larsen, Proceedings of the 21st Danavox Symposium Centertryk, 531–544. Danavox Jubillee Foundation.

Ferrari, D. V., and G. R. Bernardez-Braga. 2009. "Remote Probe Microphone Measurement to Verify Hearing Aid Performance." *Journal of Telemedicine and Telecare* 15 (3): 122–124. doi:10.1258/jtt.2009.003005.

Flodgren, G., A. Rachas, A. J. Farmer, M. Inzitari, and S. Shepperd. 2015. "Interactive Telemedicine: Effects on Professional Practice and Health Care Outcomes." *Cochrane Database of Systematic Reviews* 9: CD002098. doi:10.1002/14651858.cd002098.pub2

Forster, S., and A. Tomlin. 1988, May. "Hearing Aid Usage in Queensland." Paper presented at the Audiological Society of Australia Conference, Perth, Australia.

Govender, S., and M. Mars. 2017. "The Use of Telehealth Services to Facilitate Audiological Management for Children: A Scoping Review and Content Analysis." *Journal of Telemedicine and Telecare* 23 (3): 392–401. doi:10.1177/1357633X16645728.

Guyatt, G. H., D. H. Feeny, and D. L. Patrick. 1993. "Measuring Health-Related Quality of Life." *Annals of Internal Medicine* 118 (8): 622–629. doi:10.7326/0003-4819-118-8-199304150-00009.

Humes, L. E., S. E. Rogers, T. M. Quigley, A. K. Main, D. L. Kinney, and C. Herring. 2017. "The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial." *American Journal of Audiology* 26 (1): 53–79. doi:10.1044/2017_AJA-16-0111.

Keidser, G, and E. Convery. 2016. "Self-Fitting Hearing Aids: Status Quo and Future Predictions." *Trends in Hearing* 20: 2331216516643284. doi:10.1177/2331216516643284.

Kothari, A., N. Edwards, N. Hamel, and M. Judd. 2009. "Is Research Working for You? Validating a Tool to Examine the Capacity of Health Organizations to Use Research." *Implementation Science* 4 (1): 46. doi:10.1186/1748-5908-4-46.

Kruse, C. S., N. Krowski, B. Rodriguez, L. Tran, J. Vela, and M. Brooks. 2017. "Telehealth and Patient Satisfaction: A Systematic Review and Narrative Analysis." *BMJ Open* 7 (8): e016242. doi: https://doi.org/10.1136/bmjopen-2017-016242. doi:10.1186/1748-5908-4-46.

Laplante-Levesque, A., K. M. Pichora-Fuller, and J. P. Gagne. 2006. "Providing an Internet-Based Audiological Counselling Programme to New Hearing Aid Users: A Qualitative Study." *International Journal of Audiology* 45 (12): 697–706. doi:10.1080/14992020600944408.

Lundberg, M., G. Andersson, and T. Lunner. 2011. "A Randomized, Controlled Trial of the Short-Term Effects of Complementing an Educational Program for Hearing Aid Users with Telephone Consultations." *Journal of the American Academy of Audiology* 22 (10): 654–662. doi:10.3766/jaaa.22.10.4.

Pallant, J. 2007. *SPSS Survival Manual: A Step by Step Guide to Data Analysis Using SPSS for Windows*. 3rd ed. Maidenhead, UK: Open University Press.

Pearce, W., T. Y. Ching, and H. Dillon. 2009. "A Pilot Investigation into the Provision of Hearing Services Using Tele-Audiology to Remote Areas." *Australian and New Zealand Journal of Audiology* 31 (2): 96–100. doi:10.1375/audi.31.2.96.

Penteado, S. P., R. F. Bento, L. R. Battistella, S. M. Silva, and P. Sooful. 2014. "Use of the Satisfaction with Amplification in Daily Life Questionnaire to Assess Patient Satisfaction following Remote Hearing Aid Adjustments (Telefitting)." *JMIR Medical Informatics* 2 (2): e18. doi:10.2196/medinform.2769.

Penteado, S. P., S. De Lima Ramos, L. R. Battistella, S. A. M. Marone, and R. F. Bento. 2012. "Remote Hearing Aid Fitting: Tele-audiology in the context of Brazilian Public Policy." *International Archives of Otorhinolaryngology* 16 (3): 371–381. doi:10.7162/S1809-97772012000300012.

Powell, R. E., J. M. Henstenburg, G. Cooper, J. E. Hollander, and K. L. Rising. 2017. "Patient Perceptions of Telehealth Primary Care Video Visits." *Annals of Family Medicine* 15 (3): 225–229. Web. doi:10.1370/afm.2095.

Pross, S. E., A. L. Bourne, and S. W. Cheung. 2016. "TeleAudiology in the Veterans Health Administration." *Otology & Neurotology* 37 (7): 847–850. doi:10.1097/MAO.0000000000001058.

Ravi, R., D. R. Gunjawate, K. Yerraguntla, and C. Driscoll. 2018. "Knowledge and Perceptions of Teleaudiology among Audiologists: A Systematic Review." *Journal of Audiology and Otology* 22 (3): 120–127. doi:10.7874/jao.2017.00353

Reginato, T. T. P., and D. V. Ferrari. 2014. "Teleaudiology: Professional-Patient Communication in Hearing Aid Programming and Fitting via Teleconsultation." *Audiology – Communication Research* 19 (3): 299–309. doi:10.1590/S2317-64312014000300015.

Rogante, M., D. Kairy, C. Giacomozzi, and M. Grigioni. 2015. "A Quality Assessment of Systematic Reviews on Telerehabilitation: What Does the Evidence Tell Us?" *Annali dell'Istituto Superiore di Sanità* 51 (1): 11–18. doi:10.4415/ANN_15_01_04.

Rogers, M., B. M. Law, and L. Satterfield. 2017. "Hearing Aid Adoption and Satisfaction Increase with Audiologist Involvement." *The ASHA Leader* 22 (5): 54–57. doi:10.1044/leader.FTR3.22052017.54.

Speyer, R., D. Denman, S. Wilkes-Gillan, Y.-W. Chen, H. Bogaardt, J.-H. Kim, D.-E. Heckathorn, and R. Cordier. 2018. "Effects of Telehealth by Allied Health Professionals and Nurses in Rural and Remote Areas: A Systematic Review and Meta-Analysis." *Journal of Rehabilitation Medicine* 50 (3): 225–235. doi:10.2340/16501977-2297.

Swanepoel, D. W., and Hall J. W., 3rd. 2010. "A Systematic Review of Telehealth Applications in Audiology." *Telemedicine Journal and e-Health* 16 (2): 181–200. doi:10.1089/tmj.2009.0111.

Tao, K. F. M. 2020. "*Teleaudiology hearing aid consultations for adults: towards innovating the service-delivery in clinical practice.*" PhD thesis, The University of Western Australia.

Tao, K. F. M., C. G. Brennan-Jones, D. M. Capobianco-Fava, D. M. P. Jayakody, P. L. Friedland, D. W. Swanepoel, and R. H. Eikelboom. 2018. "Teleaudiology Services for Rehabilitation with Hearing Aids in Adults: A Systematic Review." *Journal of Speech, Language, and Hearing Research* 61 (7): 1831–1849. doi:10.1044/2018_JSLHR-H-16-0397.

Thoren, E. S., M. Oberg, G. Wanstrom, G. Andersson, and T. Lunner. 2014. "A Randomized Controlled Trial Evaluating the Effects of Online Rehabilitative Intervention for Adult Hearing-Aid Users." *International Journal of Audiology* 53 (7): 452–461. doi:10.3109/14992027.2014.892643.

Thoren, E. S., M. Svensson, A. Tornqvist, G. Andersson, P. Carlbring, and T. Lunner. 2011. "Rehabilitative Online Education versus Internet Discussion Group for Hearing Aid Users: A Randomized Controlled Trial." *Journal of the American Academy of Audiology* 22 (5): 274–285. doi:10.3766/jaaa.22.5.4.

Venail, F., M. C. Picot, G. Marin, S. Falinower, J. Samson, G. Cizeron, M. Balcon, D. Blanc, J. Bricaud, J. C. Ceccato, et al. 2019. "Speech Perception, Real-Ear Measurements and Self-Perceived Hearing Impairment after Remote and Face-to-Face Programming of Hearing Aids: A Randomized Single-Blind Agreement Study." *Journal of Telemedicine and Telecare* doi:10.1177/1357633x19883543