CLINICAL RESEARCH

Advanced Bionics Remote Programming

The AB Remote Programming solution comprises the clinician-facing Target CI fitting software and a recipient-facing AB Remote Support smartphone app. With Marvel CI's universal Bluetooth® connectivity that provides wireless two-way streaming from any Bluetooth audio device, the AB Remote Support app turns the recipient's Apple iOS or Android OS smartphone into a wireless programming interface for Remote Programming. For the first time, hearing care professionals (HCPs) can connect with cochlear implant (CI) recipients from the comfort and convenience of their homes (or anywhere with cellular or Internet connection) to provide complete programming services without shipping additional hardware (Cochlear Limited, 2022).

HOW DOES IT WORK?

Following an initial in-person clinic appointment, Target CI v1.5 (or later) enables real-time video and audio communication between HCPs and Marvel CI recipients using the AB Remote Support app. This allows recipients to attend subsequent programming sessions from a remote location instead of in-person at the clinic. Programming adjustments initiated by an HCP in Target CI are transmitted over the internet to a cloud service that forwards the programming command to the AB Remote Support app through a Wi-Fi or cellular connection (Figure 1). The programming command is then transmitted from the AB Remote Support app to the Marvel CI sound processor and Link M hearing aid (if applicable) through a standard Bluetooth low-energy 2.4 GHz wireless connection. This allows the HCP to make programming adjustments, counsel on device use, and discuss plans for (re)habilitation remotely, reducing the need for travel and missed time at work or school for recipients and, in some cases, their partners, relatives, or other caretakers.

WHY REMOTE PROGRAMMING MATTERS FOR IMPROVING ACCESS TO CI SERVICES

Complexities in treatment delivery have been acknowledged as part of the reason for the underutilization of cochlear implants (Nassiri et al., 2021, 2022). Globally, around 3.4 billion people, or 43% of the world's population, reside in rural areas (Ritchie & Roser, 2018). In developed nations such as the United States, about 60 million people (one in five Americans) live in rural areas (Ratcliffe et al., 2016). Older residents are more likely to live in rural areas where healthcare is often less accessible (Symens Smith & Trevelyan, 2019). In parts of the United States, access to CIs can also be challenging for veterans with more than 80% residing more than 180 miles from the nearest Veterans Health Administration facility providing CI services (Shayman et al., 2019).

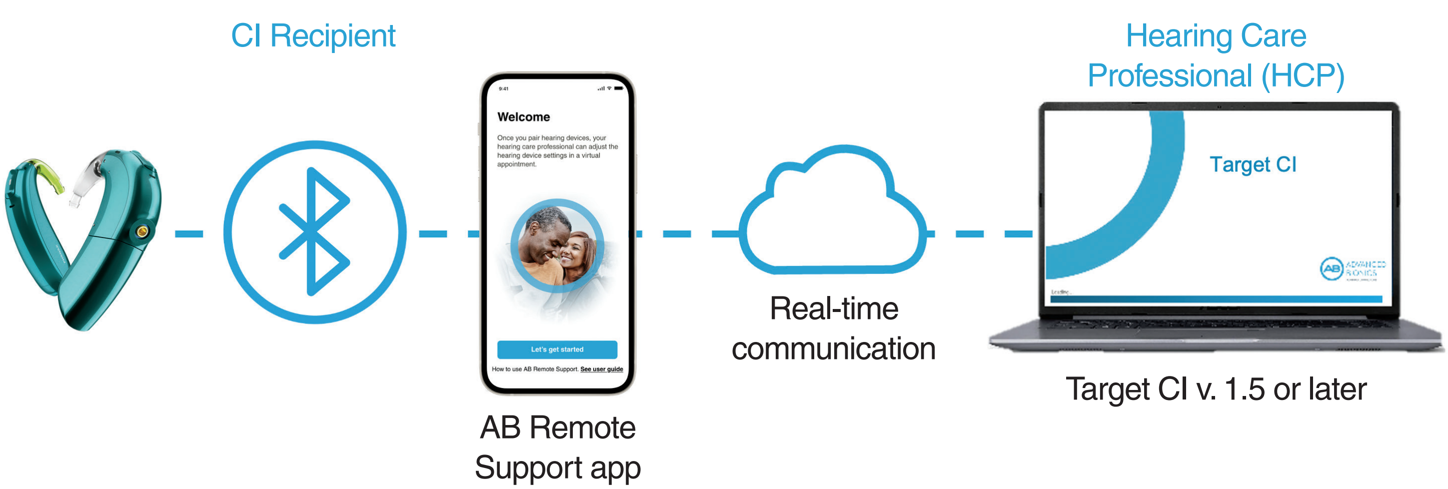

Figure 1: Participating in a Remote Programming session for unilateral, bilateral, and bimodal CI recipients is designed for simplicity. The recipient begins by connecting to the Remote Programming session via the AB Remote Support app. The HCP then connects via Target CI, allowing the systems to communicate in real-time for updates to programming.

For developing nations, insufficient access to audiological services is even more pronounced. In the World Health Organization African Region, 78% of countries have fewer than one audiologist per one million people. Similarly, in South-East Asian nations, the density is less than five audiologists per million people, with 44% of these countries having fewer than one audiologist per million people (World Report on Hearing, 2021). Extending audiology services via AB's Remote Programming solution to underserved rural and remote areas will be one step toward improving accessibility to and affordability of audiology services.

For individuals who successfully navigate the cochlear implantation process despite the geographical and economic constraints, keeping up with the numerous post-activation programming and (re) habilitation appointments can be a significant hurdle, especially during the first year. Working parents might need to find time to bring their child to a CI center or hearing care professional for programming. Teenagers might need to organize their fitting appointments around active academic and social lives, while busy professionals might be unable to leave the office for appointments. These are just some examples of obstacles in the care delivery process.

Accessibility, convenience, efficiency, and reduced costs have been drivers in telehealth uptake (Ratanjee-Vanmali et al., 2020; Swanepoel & Hall, 2020). The pandemic accelerated the adoption of telehealth as the primary means of seeing noncritical patients, with healthcare providers quickly adapting to digital care (Jacqueline & Maria, 2022). The AB Remote Programming solution is the first to enable access to all the programming parameters without the need for shipping programming hardware.

CLINICAL STUDY

Advanced Bionics (Valencia, CA, USA) conducted a multi-center pivotal clinical trial to evaluate the safety and efficacy of cochlear implant remote fitting with Marvel CI. The study employed a prospective, within-participants, repeated-measures design to determine whether hearing performance is similar in programs created via a Remote Programming session and an in-person programming visit. Participants evaluated each program chronically for two to three weeks, allowing for exposure to a variety of everyday situations. The study used a non-inferiority design to determine whether speech recognition in quiet with a program created in a Remote Programming session was no worse than speech recognition in quiet with a program created in an in-person setting. The primary efficacy endpoint was the comparison of AzBio sentence recognition in quiet after chronic use of a program fitted in-person to chronic use of a program fitted with Remote Programming. The data to follow support this primary endpoint and show that Remote Programming presents an opportunity for time and cost savings.

PARTICIPATING U.S. SITES

Austin ENT (Austin, TX, USA)

University of Colorado (Boulder, CO, USA)

Saint Luke's Hospital Midwest Ear Institute (Kansas City, MO, USA)

Vanderbilt University Medical Center (Nashville, TN, USA)

Washington University in St Louis (St. Louis, MO, USA)

MATERIALS AND METHODS

Participants: Seventeen CI recipients participated in the study, of which three were under the age of 18 years at the time of study enrollment. Participants were enrolled in either electric-only (EO) or aidable residual hearing (ARH) cohorts based on the level of unaided audiometric thresholds in their implanted ear. Additional participant demographics are shown in Table 1.

	EO COHORT	ARH COHORT
TOTAL PARTICIPANTS	12	5
Age (years)		
Mean (SD)	45.2 (22.9)	67.0 (7.2)
Median	49.5	68
Range	15*; 77	60; 78
Gender		
Male	5 (41.7%)	1 (20%)
Female	7 (58.3%)	4 (80%)
Implanted Devices		
HiRes Ultra 3D	6 (25.0%)	1 (4.2%)
HiRes Ultra	1 (4.2%)	0 (0.0%)
HiRes 90K Advantage	3 (12.5%)	4 (16.7 %)
HiRes 90K	9 (37.5%)	0 (0.0%)

Table 1: Participant demographics for electric only (EO) and aidable residual hearing (ARH) cohorts.
Note: Implanted device percentages are based on the total number of implanted devices in the study (n = 24).
*Three participants were under the age of 18.

Study hardware and software: Participants were fitted with an investigational Marvel CI sound processor in the audiologist's office using Target CI v1.5. ARH participants were fitted with an acoustic earhook, and EO participants were fitted with an M T-Mic™ microphone. The AB Remote Support app was installed on study-dedicated smartphones.

Test measures: All participants underwent standard audiometric testing to determine cohort eligibility and completed the Mobile Device Proficiency Questionnaire (MDPQ-16; Roque & Boot, 2018). The MDPQ-16 assesses the ability to perform various tasks with a mobile device. The responses are as follows: 1 (never tried), 2 (not at all), 3 (not very easily), 4 (somewhat easily), 5 (very easily). The median MDPQ-16 score was 4.70, with a range of 3.1 to 5.0. One participant was excluded from participation at visit one after scoring an average score of less than 3, which fell below the qualification threshold of ≥ 3. The study was conducted over three visits, as illustrated in Figure 2. During visit 1, fittings were performed in the investigator's office using Target CI. At visit 2, the participants were placed in a remote location in the clinic with the study smartphone, and fittings were completed through the smartphone app. After each chronic period, speech recognition was tested in quiet in an audiometric sound booth (65 dBA from speaker in front) using two lists of AzBio sentences (Spahr et al., 2012). Testing was performed unilaterally for unilaterally implanted participants and bilaterally for bilaterally implanted participants. Contralateral ear devices were removed for unilaterally implanted participants, and, if necessary, foam plugs were used to isolate the test ear.

The abbreviated Speech, Spatial, and Qualities of Hearing Scale (SSQ-12; Noble et al., 2013) was used to evaluate the chronic experience with each fitting in the participants' everyday hearing environments. Custom questionnaires were completed to assess the opinions of the participants and audiologists toward remote fitting. Supporting data including in-person fitting and remote fitting durations, psychophysical data (adjustments to the acoustic component for participants in the (ARH) cohort and M-level changes), and electrophysiological data (threshold neural response imaging (tNRI) measurements and impedance measurements) were also collected.

Statistical analyses: Non-inferiority analyses were based on paired t-tests for the mean differences in speech scores with the remotely fit program and the in-person program. Performance falling outside the 95% confidence interval (CI), established by Spahr et al. (2012) for AzBio sentences, were considered for clinically significant differences. Thus, mean paired differences of less than 10% for AzBio in quiet would support the observation that remotely fit programs are non-inferior to in-person fit programs.

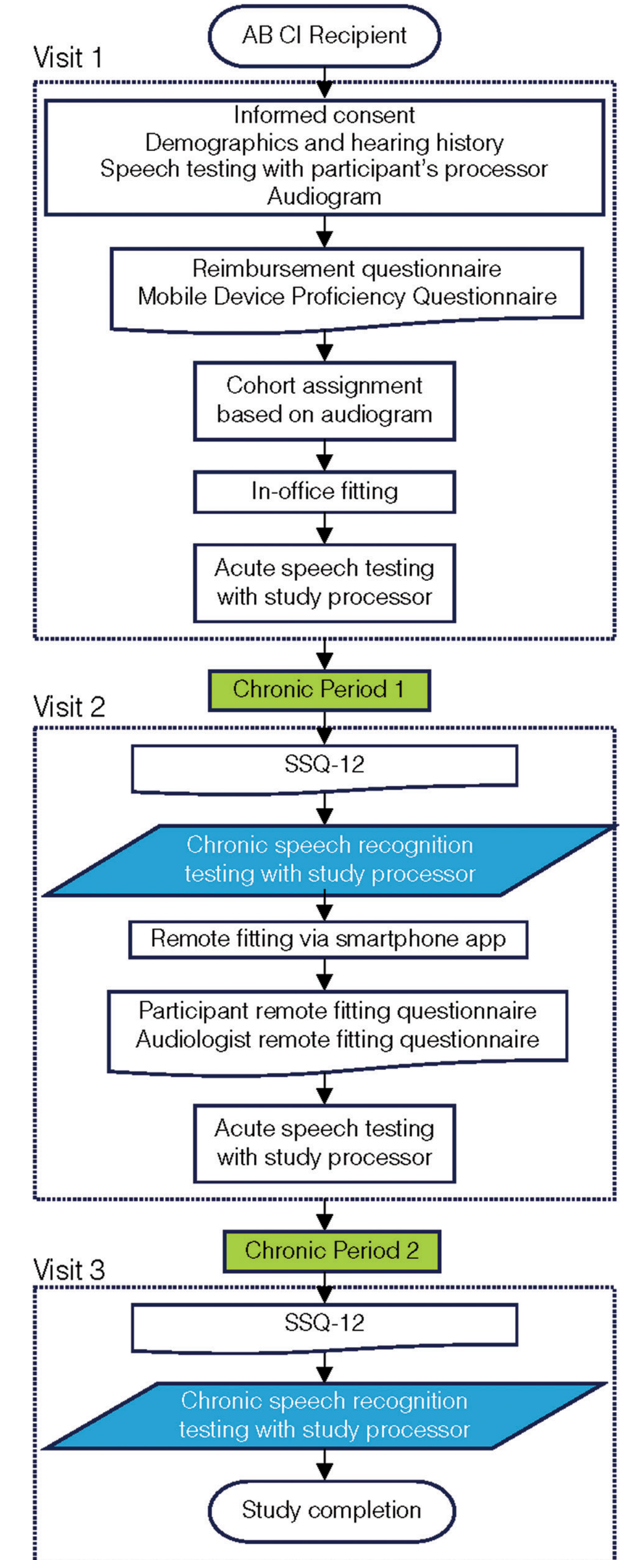

Figure 2: Study flow chart. Blue shapes indicate data for primary endpoint. Participants were experienced listeners of Marvel CI. Programming at both visits was completed with the participant's everyday listening program.

RESULTS

REMOTE PROGRAMMING IS NON-INFERIOR TO IN-PERSON FITTINGS

Figure 3a shows the mean AzBio sentence recognition scores in quiet after chronic use of the remotely fitted program and the in-person fitted program for the EO cohort (n = 12). The mean AzBio speech recognition score for the program created in-person was 89.28% (*SE* = 3.48), while the mean AzBio speech recognition for the program created via AB's Remote Programming solution was 91.94% (*SE* = 2.76). This paired difference is 2.66 (*SE* = 0.99), with a two-sided 95% CI [0.48, 4.84]. The observed p value was < 0.001, rejecting the null hypothesis of inferiority, confirming that sentence recognition with AB's Remote Programming solution is not significantly inferior to that with in-person fitting.

A non-inferiority evaluation was also completed with the EO and ARH cohorts pooled together (n = 17; Figure 3b). The mean speech recognition score for the program created in-person was 89.04% (*SE* = 2.66), while the mean speech recognition score for the program created via AB's Remote Programming solution was 90.99% (*SE* = 2.09). This paired difference equals 1.95 (*SE* = 1.31), with a two-sided 95% CI [-0.81, 4.72]. The observed p value was < 0.001, thereby rejecting the null hypothesis of inferiority, again supporting that sentence recognition with AB's remote fitting solution is non-inferior to in-person fittings.

REMOTE PROGRAMMING IS AN EFFICIENT USE OF TIME

Fitting durations were similar between in-person and Remote Programming fittings. For the purposes of the study, investigators were asked to begin timing the fitting session when they clicked "connect" in the fitting software to connect to the sound processor(s), and the session timing stopped when they clicked "save & close." Differences in overall fitting durations between in-person and Remote Programming fittings ranged from 3 to 11 minutes. For both in-person and Remote Programming fittings, the total fitting durations for bilateral and ARH fittings were longer than the respective unilateral and EO fittings, which is explained by additional time spent fitting the second ear or the acoustic earhook component.

REMOTE PROGRAMMING OFFERS COST AND TIME SAVINGS COMPARED TO A TYPICAL CLINIC VISIT

In-person clinic visits have measurable demands, including time, travel, and possibly financial expenditure. When asked about the "Approximate time spent in total during a typical CI office visit" (e.g., total spent in travel, wait, and appointment times), responses from the 17 participants ranged from less than 1 hour (11.8%), 1 – 2 hours (47.1%), 2 – 4 hours (29.4%), and more than 4 hours (11.8%). This distribution of responses indicated that the total time spent during a typical CI office visit ranged from 1 to more than 4 hours for 88.2% of

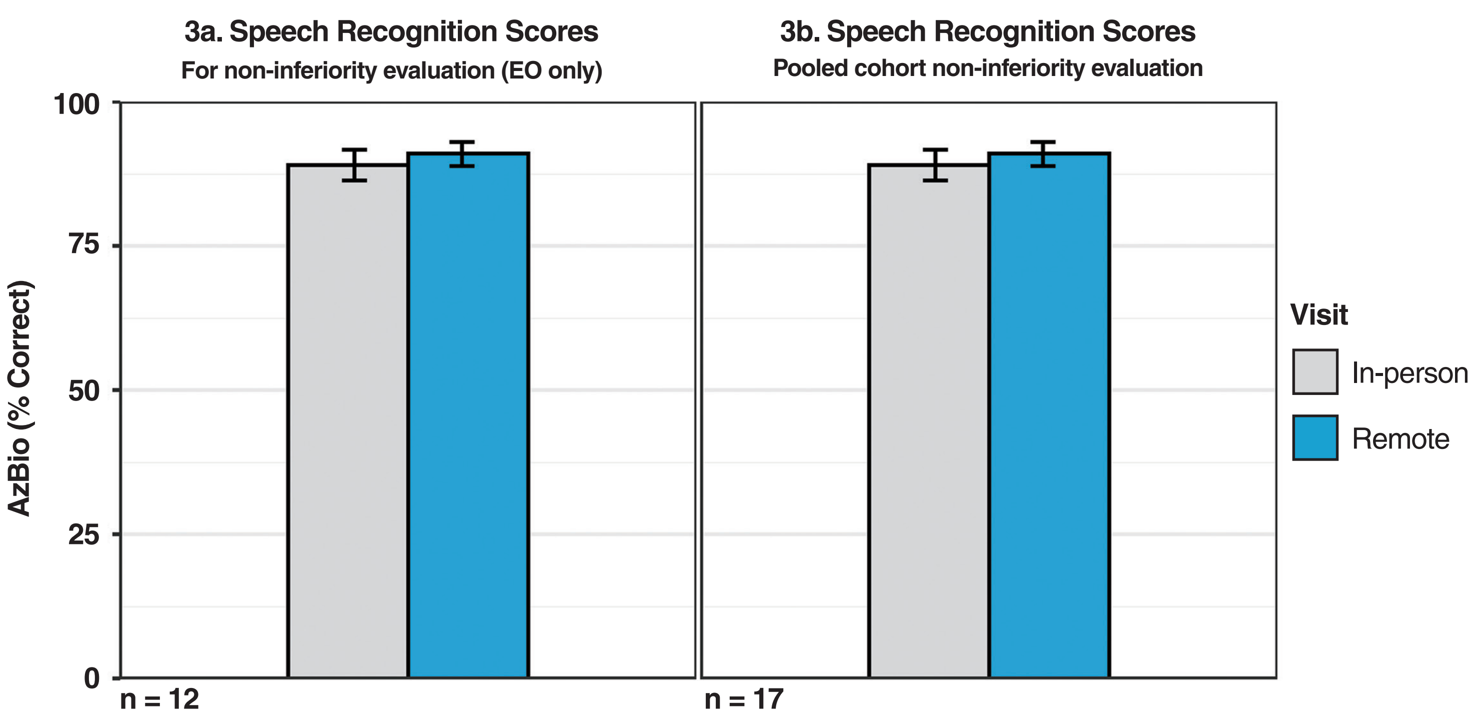

Figure 3: Speech recognition scores are shown in % correct for programs created using in-person (gray) and remote (blue) fitting methods. Error bars show the standard error of the mean. 3a. Electric only (EO) cohort (n = 12; primary efficacy endpoint) 3b. EO and aidable residual hearing (ARH) cohorts pooled together (n = 17)

study participants. When asked if office visits related to CI care were covered by insurance, 41.2% of study participants were not reimbursed for all costs associated with a CI clinic visit.

RECIPIENTS AND AUDIOLOGISTS RATE REMOTE PROGRAMMING POSITIVELY

Opinions towards Remote Programming were positive. Custom questionnaires collected information regarding the investigator's and participant's satisfaction with the Remote Programming experience (Figure 4). The results of the questionnaire, which involved rating the strength of agreement with specific statements, revealed that participant and audiologist ratings did show differences. Specifically, participants exhibited a tendency to express stronger agreement with these statements, suggesting that Remote Programming was similar to their in-person experience. Audiologists reported the remote fitting experience as positive and that they would recommend it as an alternative to some in-clinic visits.

OPINIONS TOWARDS REMOTE PROGRAMMING

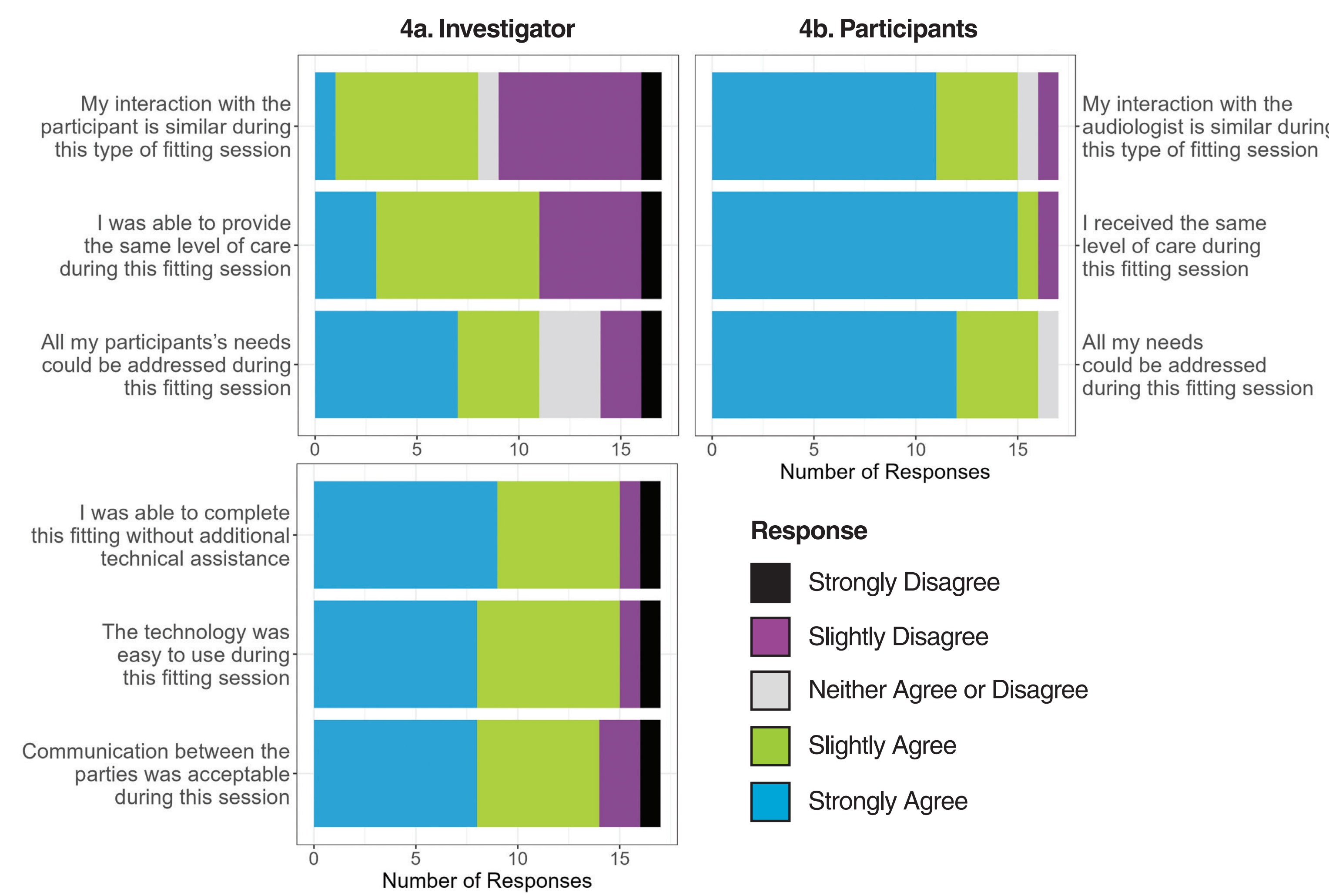

Figure 4: Investigator (4a) and participant (4b) self-reported opinions towards Remote Programming.

PSYCHOPHYSICAL AND ELECTROPHYSIOLOGICAL DATA COLLECTED DURING THE FITTING SESSIONS

Psychophysical and electrophysiological measurements as well as fitting adjustments were logged during the fitting sessions to demonstrate the completion of the programming commands made in Target CI. All measurements and adjustments were completed and accurate. Any instances of incomplete measurements or adjustments were related to clinical factors such as disabled electrodes or stimulus range for tNRI measurements.

SUMMARY

The findings from this clinical study show that Remote Programming is an effective innovation that provides recipients and audiologists with measurable benefits.

Specifically, the results demonstrate that:

- Speech recognition in quiet with remotely created programs is non-inferior to speech recognition in quiet with programs created during an in-person fitting. This finding was observed for unilateral and bilateral, electric-only CI recipients and those with acoustic residual hearing in the implanted ear.
- Overall fitting durations were similar between in-person and remote fittings.
- Remote Programming offers time and cost savings to AB CI recipients compared to routine clinic visits. The total time spent during a typical CI office visit ranged from 1 to more than 4 hours for 88.2% of study participants. Forty percent of participants in this study are not reimbursed for expenses related to a typical clinic visit.
- Research participants and audiologists rate Remote Programming positively. Participant and audiologist ratings did show differences. Specifically, participant ratings were higher on average, suggesting the remote fitting was similar to their in-person experience.

Remote Programming for Marvel CI sound processors and Link hearing aid devices enables professionals to conveniently connect, assist, and support AB recipients' needs by allowing complete CI programming – an industry first for cochlear implants.

See 2023 Target CI and AB Remote Support app Instructions for Use for complete study results. Data protection complies with the Health Insurance Portability and Accountability Act (HIPAA), General Data Protection Regulation (GDPR), and Swiss Federal Data Protection Act (FDRA) policies.

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