Uniform distributional benefit of community-delivered social prescribing on hearing-related intrinsic capacity in older adults: a quantile regression reanalysis of the HEARS trial.

Abstract:

Background: The HEARS randomized trial demonstrated that a low-cost hearing care intervention delivered by community health workers improved hearing-related communication function in older adults. However, mean-based analyses do not characterize how treatment effects vary across the outcome distribution. We examined the distributional pattern of the intervention effect using an aggregate-data-informed simulation approach.

Methods: Synthetic baseline and 3-month Hearing Handicap Inventory for the Elderly-Screening Version (HHIE-S) scores were generated for 68 observations per group using published means and standard deviations. Scores were sampled from group-specific truncated bivariate normal distributions bounded between 0 and 40, assuming a baseline-to-follow-up correlation of 0.50. Baseline-adjusted conditional quantile regression coefficients were estimated from τ=0.05 to τ=0.95. Clinical response was assessed using improvements of at least 8, 10, and 12 points. Stability was evaluated across 200 independently generated synthetic datasets.

Results: In the primary synthetic dataset, the baseline-adjusted mean difference in 3-month HHIE-S score was −12.7 points (95% confidence interval [CI], −15.1 to −10.3). Conditional quantile regression coefficients were −11.04 (95% CI, −14.45 to −7.64) at τ=0.25, −13.48 (95% CI, −17.16 to −9.80) at τ=0.50, and −13.49 (95% CI, −17.15 to −9.84) at τ=0.75. The quantile-effect curve remained relatively flat across the evaluated distribution. A 10-point improvement was achieved by 54.4% of intervention observations and 8.8% of control observations (adjusted odds ratio, 26.70; 95% CI, 7.85–90.8; P<0.001). Treatment coefficients remained consistently negative across repeated simulations, with between-simulation standard deviations of no more than 1.74 points.

Conclusions: Under the specified distributional and correlation assumptions, the mean benefit reported in the HEARS trial was compatible with relatively consistent treatment contrasts across the conditional distribution of 3-month HHIE-S scores. Analysis of the original individual participant data is required to determine whether the intervention provides uniform benefits across participants and population subgroups.

Keywords: hearing loss; community health workers; quantile regression; synthetic data

Introduction

Population aging has made maintaining intrinsic capacity (IC)a core goal of healthy aging, whichi represents the composite of an individual's physical and mental capacities.[1] Within IC, sensory capacity, particularly hearing, is vital for social participation and autonomy. Age-related hearing loss is highly prevalent and closely linked to social isolation, depression, cognitive decline, and frailty.[2] However, conventional specialist-centered, high-cost hearing care models create severe barriers for socioeconomically disadvantaged populations, exacerbating health inequalities.[3,4]To address these barriers, community-based care and social prescribing strategies have emerged as scalable solutions. The landmark Hearing Health Equity Through Accessible Research and Solutions (HEARS) randomized trial demonstrated that training community health workers (CHWs) to deliver low-cost, over-the-counter amplification technologies significantly improved communication function, reducing the Hearing Handicap Inventory for the Elderly-Screening Version (HHIE-S) score by an average of 13 points.[5]

Nevertheless, evaluating interventions solely through average treatment effects (ATEs) can obscure meaningful heterogeneity in treatment response or hide outcome polarization. From a health equity perspective, it remains unknown whether community-delivered care uniformly benefits individuals across the entire spectrum of communication impairment, especially those with the most severe baseline limitations. This study aimed to determine whether a CHW-delivered social prescribing intervention promotes equitable improvements in sensory intrinsic capacity across all levels of baseline severity by examining intervention effects across the full outcome distribution.

Methods

Study design and data source

This study was a secondary quantitative reanalysis of the HEARS trial. The original trial evaluated the effectiveness of a CHW-delivered hearing care intervention incorporating low-cost over-the-counter amplification technology among older adults with hearing loss. The primary endpoint was self-perceived communication function measured using the Hearing Handicap Inventory for the HHIE-S, which ranges from 0 to 40, with higher scores indicating greater impairment.

Generation of synthetic participant-level data

Because the original individual participant data were unavailable, synthetic baseline and 3-month HHIE-S values were generated separately for each treatment group using the published sample sizes, means, and standard deviations. Values were sampled from a bivariate normal distribution truncated to the theoretical HHIE-S range of 0–40. As the correlation between baseline and follow-up scores was not reported, a within-participant correlation of 0.50 was assumed. A fixed random seed was used to ensure reproducibility.The generated observations represent synthetic

participant-level data consistent with the selected published summary statistics and should not be interpreted as the original trial records.

Quantile and supplementary analyses

Conditional quantile regression was used to examine the association between treatment assignment and 3-month HHIE-S scores across the outcome distribution. Models included treatment assignment and baseline HHIE-S score as covariates. Treatment coefficients were estimated from τ=0.05 to τ=0.95 at increments of 0.05, with detailed results reported at τ=0.25, 0.50, and 0.75. Negative coefficients indicated more favorable outcomes in the intervention group.

Clinical response was evaluated using improvements of at least 8, 10, and 12 HHIE-S points from baseline, with a 10-point improvement used as the primary threshold. Logistic regression adjusted for baseline HHIE-S score was used to estimate the association between treatment assignment and response. Descriptive analyses were also conducted according to baseline HHIE-S severity.

Statistical analysis

The baseline-adjusted mean treatment effect was estimated using linear regression. Standard errors for the selected quantile regression models were obtained using 1,000 bootstrap replications; 500 replications were used for each estimate in the full quantile-effect curve. Wald-type 95% confidence intervals were calculated using the bootstrap standard errors.

The stability of the quantile estimates was examined across 200 independently generated synthetic datasets under the same parametric assumptions. Treatment coefficients at τ=0.25, 0.50, and 0.75 were summarized using their means, standard deviations, and empirical 95% intervals.All tests were two-sided, and $P<0.05$ was considered statistically significant. Analyses were performed using R version 4.5.2.

Results

Basic characteristics

The primary synthetic dataset included 136 observations, with 68 assigned to each treatment group. Mean baseline HHIE-S scores were 21.1±8.6 in the intervention group and 21.0±8.1 in the control group. The corresponding mean 3-month scores were 10.5±7.2 and 23.1±8.4, respectively.After adjustment for baseline HHIE-S score, the intervention was associated with a 12.7-point lower mean 3-month score than the control condition (95% CI, −15.1 to −10.3). This estimate was similar to the mean treatment effect reported in the original HEARS trial, indicating that the primary simulation reproduced the overall between-group treatment contrast.

Clinically meaningful improvement

In the primary synthetic dataset, 37 of 68 observations (54.4%) in the intervention group achieved an improvement of at least 10 HHIE-S points, compared with 6 of 68 observations (8.8%) in the control group. After adjustment for baseline HHIE-S score, intervention assignment was associated with higher odds of achieving a 10-point

improvement (adjusted odds ratio, 26.70; 95% CI, 7.85–90.8; P<0.001).Consistent patterns were observed using alternative response thresholds. The proportions achieving improvements of at least 8 points were 60.3% and 11.8% in the intervention and control groups, respectively; the corresponding proportions for improvements of at least 12 points were 39.7% and 1.5% (Table 2).

Outcomes according to baseline HHIE-S severity

Descriptive analyses suggested that the magnitude of improvement increased with baseline HHIE-S severity (Table 3 and Figure 2). Among synthetic observations with significant baseline impairment (HHIE-S ≥26), the mean improvement was 16.51±9.69 points in the intervention group and 3.86±7.12 points in the control group. The corresponding proportions achieving an improvement of at least 10 points were 77.3% and 33.3%, respectively.Among observations with mild-to-moderate baseline impairment, the mean changes were an improvement of 7.93±6.94 points in the intervention group and a deterioration of 4.24±7.13 points in the control group. The corresponding 10-point response rates were 44.4% and 0%, respectively. These subgroup findings were descriptive and reflect the synthetic data generated under the specified distributional and correlation assumptions.

Stability across repeated simulations

Across 200 independently generated synthetic datasets, the conditional quantile regression coefficients remained consistently negative at τ=0.25, 0.50, and 0.75 (Figure 1). The between-simulation standard deviations of the treatment coefficients were no greater than 1.74 points, indicating limited Monte Carlo variability under the specified parametric assumptions. The distributions of the estimates were broadly similar across the three quantiles, supporting the reproducibility of the observed conditional quantile pattern within the simulation framework.

Discussion

In this analysis, the intervention was associated with lower 3-month HHIE-S scores across the evaluated conditional outcome distribution. The estimated treatment coefficients were similar at the 25th, 50th, and 75th percentiles, and the overall quantile-effect curve was relatively flat. Simulated responder and baseline-severity analyses also consistently favored the intervention. These findings suggest that, under the specified distributional and correlation assumptions, the large mean effect reported in the original HEARS trial is compatible with a broadly distributed shift in hearing-related communication outcomes rather than an effect confined to a single part of the outcome distribution.

The original HEARS trial[5] demonstrated that a low-cost hearing intervention delivered by CHW substantially improved self-perceived communication function. Conventional mean-based analyses provide an estimate of the overall treatment effect but do not describe how the effect may vary across the outcome distribution.[6,7] In the present

analysis, baseline-adjusted conditional quantile coefficients remained between approximately −11 and −15 points from the lower to the upper quantiles. This pattern indicates that the simulated between-group difference was not materially attenuated at either end of the conditional outcome distribution. However, because the analysis was based on synthetic rather than original participant-level data, these estimates should not be interpreted as evidence that every participant benefited equally or that individual treatment responses were homogeneous.

The responder analyses provided a clinically interpretable representation of the simulated treatment contrast. More than half of the synthetic observations in the intervention group achieved an improvement of at least 10 HHIE-S points, compared with fewer than 10% in the control group. Similar patterns were observed using 8- and 12-point thresholds. Nevertheless, these responder rates depended on the assumed joint distribution of baseline and follow-up scores, particularly the assumed within-participant correlation. They should therefore be viewed as model-derived estimates rather than as recovered response rates from the original trial. The particularly large odds ratio at the 12-point threshold was also imprecise because very few control observations met this criterion.

The descriptive baseline-severity analysis suggested greater absolute improvement among simulated observations with higher baseline HHIE-S scores. This pattern is clinically plausible because participants with greater initial impairment have more opportunity to improve, but it may also reflect regression to the mean, scale boundaries, and the assumed correlation between baseline and follow-up measurements. Consequently, these findings do not establish that the intervention preferentially benefits individuals with more severe impairment. Confirmation would require original participant-level data and a formally specified treatment-by-baseline-severity interaction analysis.

These results may nevertheless have implications for the evaluation of accessible, community-based hearing care. The HEARS intervention was designed to reduce barriers associated with cost, specialist availability, transportation, and conventional hearing-care pathways.[5] Such features are relevant to broader social prescribing and healthy-aging strategies that seek to connect older adults with accessible community resources.[8,9] The present findings show that the published aggregate results are compatible with a distribution-wide benefit under the primary simulation assumptions. They do not, however, directly demonstrate that the intervention reduced health inequalities or functioned as an inherently equitable intervention. Assessment of equity would require individual-level information on socioeconomic position, health literacy, social support, race and ethnicity, access to care, and other potential sources of treatment-effect heterogeneity.[10,11]

This study also illustrates both the potential and limitations of using aggregate trial results for exploratory distributional analyses. Quantile regression can complement

mean-based analyses by characterizing treatment contrasts at different points of a conditional outcome distribution.[12] When original participant-level data are unavailable, simulation based on published summary statistics may be useful for evaluating whether a proposed distributional pattern is compatible with the available evidence and for generating hypotheses for subsequent investigation. Repeated simulations in the present study showed limited Monte Carlo variability under the specified model. This finding demonstrates computational stability conditional on the assumed parameters, rather than robustness to uncertainty in the original data-generating process.

Several limitations should be emphasized. First, the synthetic observations were generated from published sample sizes, means, and standard deviations and were not reconstructed records of the original HEARS participants. The true marginal and joint distributions of baseline and follow-up HHIE-S scores were unknown. Second, a truncated bivariate normal distribution and a within-participant correlation of 0.50 were assumed. The flat conditional quantile pattern may partly reflect these assumptions, particularly the similar published follow-up standard deviations in the two treatment groups. Third, the HHIE-S is a bounded and discrete scale, whereas the simulation generated continuous values within the 0–40 range. Fourth, responder rates, individual changes, and baseline-severity subgroups depend on the simulated pairing of baseline and follow-up values and cannot be considered observed findings from the original trial. Fifth, the analysis did not incorporate uncertainty in the published means and standard deviations or assess alternative distributional forms and correlation structures. Finally, conditional quantile regression coefficients describe differences in conditional outcome distributions and do not identify individual-level treatment effects.

In conclusion, this analysis suggests that the mean benefit reported in the HEARS trial is compatible with relatively consistent treatment contrasts across the conditional distribution of 3-month HHIE-S scores under the specified assumptions. Access to the original individual participant data, together with sensitivity analyses across alternative distributional and correlation assumptions, would be required to determine whether the observed mean effect reflects genuinely uniform benefits across participants and population subgroups.

Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Human Ethics and Consent to Participate declarations

Not applicable

Author Contributions

Zhen Du: Writing – Original draft, Conceptualization, Methodology, Software, Formal analysis, Data Curation, Visualization; Guangqing Fu: Writing – Review & Editing, Conceptualization, Methodology, Data curation, Supervision, Project administration; Mei Huang: Writing – Review & Editing, Methodology, Project administration, Supervision.

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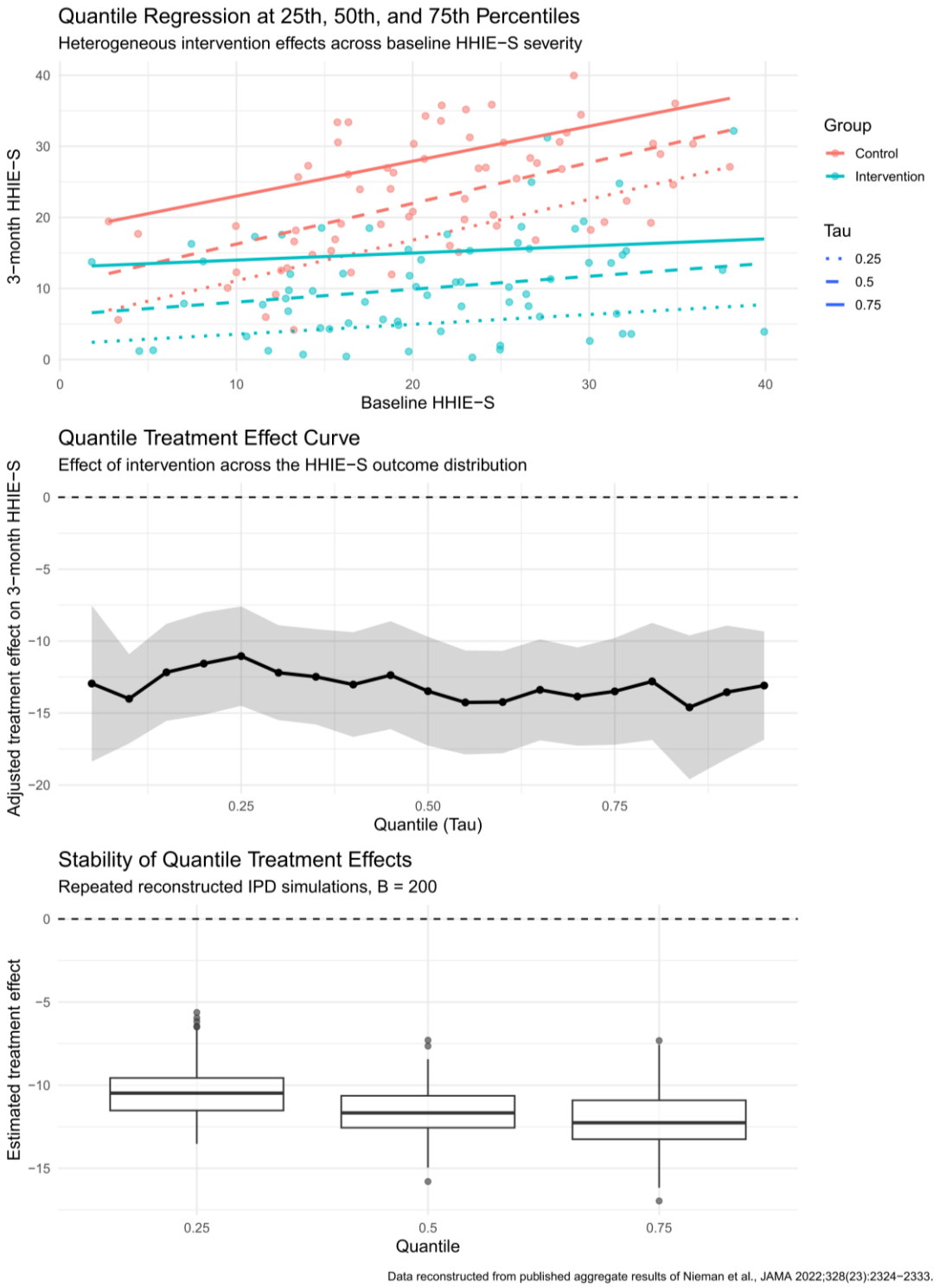

Figure 1. Conditional quantile regression and stability analyses based on synthetic HEARS trial data.(A) Quantile regression lines at τ=0.25, 0.50, and 0.75 for the association between baseline and 3-month HHIE-S scores, presented separately by treatment group. Points represent synthetic observations. (B) Baseline-adjusted intervention coefficients estimated from τ=0.05 to τ=0.95. The solid line represents the conditional quantile regression coefficient, the shaded area its 95% confidence interval, and the dashed horizontal line the null value. (C) Distributions of treatment coefficients at τ=0.25, 0.50, and 0.75 across 200 independently generated synthetic

datasets under the same parametric assumptions. Boxplots show medians, interquartile ranges, and distributions of the estimates. Negative coefficients favor the intervention. HHIE-S, Hearing Handicap Inventory for the Elderly-Screening Version.

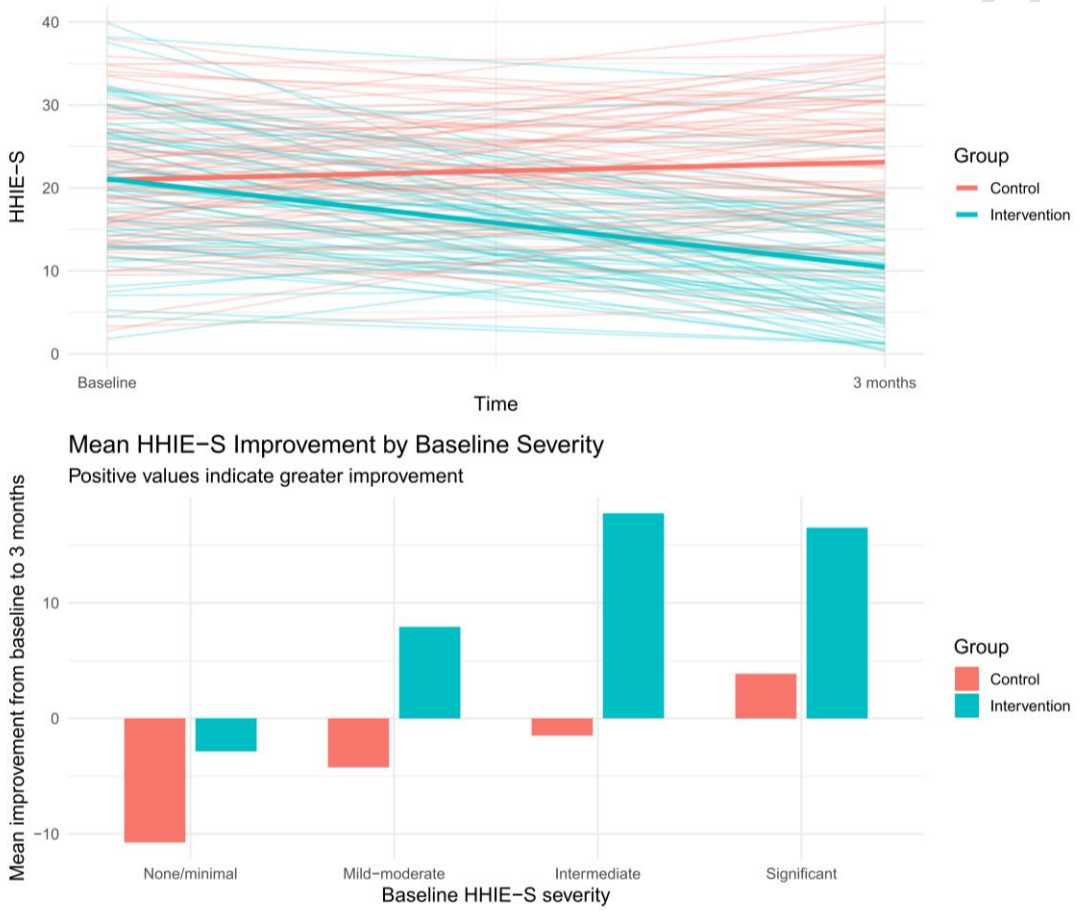

Figure 2. Simulated HHIE-S trajectories and changes according to baseline severity.(A) Simulated HHIE-S trajectories from baseline to 3 months by treatment group. Faint lines represent individual synthetic observations, and bold lines represent group-specific means. (B) Mean improvement in HHIE-S score, calculated as the baseline score minus the 3-month score, according to baseline severity and treatment group. Positive values indicate improvement in hearing-related communication function. HHIE-S, Hearing Handicap Inventory for the Elderly-Screening Version.

Table 1. Adjusted quantile regression estimates for self-perceived communication function (HHIE-S score) at 3 months.

Quantile (τ)	Coefficient Term	Estimate	SE	t-value	95% CI	p-value
0.25	Intercept	10.8	2.8	3.85	5.31 to 16.29	< 0.001
	Group (Intervention)	**-11.04**	**1.74**	**-6.36**	**-14.45 to -7.64**	**< 0.001**
	Baseline HHIE-S	0.29	0.11	2.59	0.07 to 0.51	0.011
0.50	Intercept	15.11	2.94	5.14	9.35 to 20.88	< 0.001
	Group (Intervention)	**-13.48**	**1.88**	**-7.17**	**-17.16 to -9.80**	**< 0.001**
	Baseline HHIE-S	0.4	0.11	3.76	0.19 to 0.61	< 0.001
0.75	Intercept	20.85	3.67	5.68	13.66 to 28.05	< 0.001
	Group (Intervention)	**-13.49**	**1.87**	**-7.24**	**-17.15 to -9.84**	**< 0.001**
	Baseline HHIE-S	0.36	0.15	2.31	0.05 to 0.66	0.023

* Models are adjusted for baseline outcome severity. Bold rows highlight the core quantile treatment effects (QTE).SE, standard errors; CI, confidence intervals.

Table 2. Proportion of clinical responders and logistic regression analysis for achieving meaningful communication improvements.

Improvement threshold	Intervention, n/N (%)	Control, n/N (%)	aOR (95% CI)	P value
>=8 points	41/68 (60.3)	8/68 (11.8)	23.87 (7.66 to 74.39)	<0.001
>=10 points	37/68 (54.4)	6/68 (8.8)	26.69 (7.85 to 90.73)	<0.001
>=12 points	27/68 (39.7)	1/68 (1.5)	79.11 (9.15 to 683.91)	<0.001

aOR, adjusted odds ratio.

Table 3. Subgroup post-intervention status and functional changes according to baseline HHIE-S severity.

Baseline severity category	Group	Subgroup (n)	Mean post-score (M3)	Mean improvement (SD)	≥10-point responder rate
None / Minimal (≤8)	Control	3	14.23	-10.74 (7.51)	0%
	Intervention	5	8.08	-2.86 (7.19)	0%
Mild - Moderate (10 - 24)	Control	41	21.4	-4.24 (7.13)	0%
	Intervention	36	9	7.93 (6.94)	44.40%
Intermediate (25)	Control	6	26.33	-1.50 (6.42)	0%
	Intervention	5	7.61	17.75 (5.80)	80.00%
Significant ≥26	Control	18	27.39	3.86 (7.12)	33.30%
	Intervention	22	14.06	16.51 (9.69)	77.30%

* Positive mean improvement scores indicate an alleviation of self-perceived communication barriers (healthier state). SD, standard deviation.