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Walk, Talk and Listen: A pilot randomized controlled trial targeting functional fitness and loneliness in older adults with hearing loss.

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Abstract

Background: Age-related hearing loss (HL) is a prevalent disability associated with loneliness, isolation, falls, hospitalization and premature mortality. Audiological rehabilitation (AR) addresses communication issues but not the physical decline associated with falls, hospitalization and premature mortality among older adults with HL. **Objectives**: Determine the feasibility, acceptability and participant outcomes of an intervention that provides AR and aims to reduce the risk for falls among older adults with HL. **Trial design:** A 10-week, single-blind, pilot randomized control trial (RCT) that took place in a community-based recreation facility. **Participants:** Eligibility criteria included ambulatory adults aged 65 years or older with self-reported HL. **Interventions**: Seventy-one participants were screened. Thirty-five were randomized to intervention (strength and resistance exercise, health education, group auditory rehabilitation (GAR: hearing education, communication strategies, psychosocial support) or control (n=31) (GAR only). **Outcomes**: Ninety-five percent of eligible participants were randomized. GAR and exercise adherence rates were 80% and 85% respectively, and 88% of participants completed the study. Intervention group functional fitness improved significantly (gait speed: Effect Size: 0.57, 30-second Sit to Stand Test: Effect size: 0.53). Significant improvements in HRQL (Effect Size: 0.76), and loneliness (Effect size: 1.16) were related to GAR attendance and poorer baseline HRQL. Forty-two percent of participants increased their social contacts outside the study. **Discussion**: Walk, Talk and Listen was feasible and acceptable. Exercise improved key fitness measures but provided no additional benefit to GAR alone. This is the first study to provide preliminary evidence about the benefits of exercise on fitness and the benefits of a communication program on loneliness among older adults with HL. **Implications**: This pilot trial provided key information on the sample size required for a larger, longer-term RCT to determine the enduring effects of this intervention that addresses the negative psychosocial and musculo-skeletal downstream effects of HL among older adults.

Strengths and Limitations of the study:

- First study to examine the effects of exercise intervention and auditory rehabilitation on functional fitness and loneliness among older adults with hearing loss.
- Fifty seven percent of participants are male: unusual for a community exercise program
- This is a single blind pilot randomized controlled trial
- There is not a control group with no intervention

BACKGROUND:
Hearing loss (HL) is a prevalent and under recognized disability that is associated with significant psychosocial and physical challenges. Large surveys [1, 2] indicate that between 65-77% of North American adults aged 60 to 79 have audiometrically measured HL. The World Health Organization International Classification of Functioning, Disability and Health (ICF) [3] is a conceptual framework used to understand the all-encompassing influence of HL as a disability and to evaluate the impact of interventions. The disability of HL may influence or be influenced by interactions between all domains of the ICF including personal or contextual factors (socioeconomics, education), environmental factors (listening environment, social stigma), activity limitations (difficulty hearing TV or speech), participation restrictions (visiting friends/relatives less than desired), declines in body functions (auditory, cognitive and musculo-skeletal) and limitations in activities of daily living (self-care, mobility) [4]. Epidemiologic studies have established independent associations between untreated HL and loneliness, social isolation [5 6], depression, cognitive decline, increased physical dependence (admission to nursing homes, requiring assistance at home), declines in functional fitness, increased falls, hospitalizations and premature mortality [7].

Provision of hearing aids (HA) and communication programs (one-on-one or group auditory rehabilitation (GAR)) are currently the approach to treating HL. Education about hearing and hearing devices/technologies, psychosocial support and enhancing communication skills are the primary components of communication programs [8]. Effective auditory rehabilitation may improve activity and participation limitations [9], however has not yet been shown to address musculo-skeletal or functional fitness.

Much attention has been paid to documenting the functional physical declines associated with untreated HL. Encouragingly, a longitudinal observational study suggests that "muscle strengthening exercise" may increase longevity among adults with moderate to severe HL [10]. However, there are no published controlled exercise interventions addressing the declines in functional fitness in older adults with HL. There is a need for more research exploring the effectiveness of strategies that not only address activity and participation limitations related to impaired auditory function but that also improve functional fitness.

Walk, Talk and Listen (WTL) is a community-based pilot randomized controlled trial of a communication program (GAR), and physical activity versus GAR alone [11]. The intervention was designed in participatory collaboration with a group of older adults with HL [12].

Objectives:
1) Explore the acceptability and feasibility of the WTL intervention for older adults with HL; 2) provide preliminary information about the sample size required to answer the research question: In older adults with HL, what effect does a group exercise and socialization/health education intervention added to GAR have on: functional fitness, activity limitations and participation restrictions and perceptions of loneliness and social isolation among older adults with HL?

DESIGN AND METHODS:
Patient and public involvement: Twenty-eight older adults with hearing loss participated in the design of the intervention for this clinical trial [12]. WTL participants helped, by word of mouth,

to recruit several other participants. WTL participants provided ongoing and end of study feedback and helped to disseminate the trials results. One participant and the principle investigator continue to deliver GAR sessions twice a year in the local community.

Detailed WTL methodology is reported elsewhere [11]. In partnership with the YMCA Okanagan, WTL was a 10-week prospective single-blind randomized controlled pilot trial of interactive GAR (control) versus GAR plus socialization, health education (SHE) and exercise in older adults with self-reported [13] HL (clinicaltrials.gov NCT02662192. Registered Jan 14, 2016). Participants were recruited over the two-month period preceding the trial (September 2017 through March 2017) through local newspaper ads, strategically placed posters and word of mouth. Eligibility and baseline assessments were completed by students and research team members after informed consent and prior to randomization and allocation by our statistician. Control group GAR sessions occurred once a week. Intervention group GAR sessions were followed by 60 minutes of exercise (strength, resistance and coordination training: 45 minutes) and walking (outside or on indoor track: 15 minutes). On their second weekly visit, intervention participants attended a one-hour interactive SHE session followed by 60 minutes of exercise and walking. A certified YMCA trainer facilitated the exercise sessions. Participants were encouraged to walk between sessions and were provided a pedometer and tracking sheets to motivate them. At study end, control group participants were offered the exercise program and provided a pedometer. Trained students helped the principle investigator facilitate the GAR and SHE sessions. Interactive GAR sessions were guided by a modification of the GROUP program [14] and provided hearing education, goal setting and psychosocial and behavior change exercises including mindfulness, acceptance of HL, assertiveness training, communication strategies, problem-solving, anticipatory and repair strategies. Participants were encouraged to review class handouts with their communication partners (spouse, significant other or friend). One three-hour communication partner session was held near the end of the study.

Feasibility and acceptability:
Measures assessing feasibility included recruitment strategies and rates, acceptability/willingness to be randomized, adverse events, GAR attendance rates, overall retention rates, and acceptability of the GAR and exercise components assessed by questionnaire at the end of the study. A priori, it was decided that a definitive RCT would be feasible if at least 120 individuals contacted the pilot trial center, ≥ 90% of eligible participants were randomized and 70 % of those completed the study. The WTL intervention was acceptable if at least 85% of participants found the GAR, exercise and SHE sessions highly acceptable or acceptable.

The international outcomes inventory-alternative interventions (IOI-AI) [15] and the modified Client Oriented Scale of Improvement (COSI) questionnaires [16] at study end evaluated the GAR intervention. An end of study evaluation questionnaire assessed the acceptability of the exercise and GAR sessions, acceptance and attitude about their HL, HL-related problem solving, stress management, and self confidence in social situations.

Participant-specific outcomes:
Demographic data was collected at baseline, the remaining measures were collected at baseline and end of study.

Functional fitness outcomes included 30-Second Chair Stand Test (STS) [17], gait speed (GS): 6-Minute Walk Test (6MWT) [18], Timed Up and Go Test (TUG) [18] and the one-foot balance test [19], grip strength [20], Chair Sit and Reach test [21] and the Back Scratch [22].

Psychosocial measures included hearing and health–related quality of life (Hearing Handicap Inventory for the Elderly [HHIE-25]) [13]) and The Rand SF-36 [23] respectively, loneliness [24], social support (the Medical Outcomes Trial-Social Support Survey [25]), and depression (Geriatric Depression Scale [26]).

Sample size:
At least 23 people per group were needed to show a clinically meaningful increase in STS of 2 or more [27]: the main fitness outcome. This sample size was inflated by 20% to account for drop outs. This sample size ensured the generation of a reliable SE, SD and 95% CI on the sample size required for a large RCT with this measure as the primary outcome [28].

Statistical methods
For feasibility and acceptability measures, analyses were descriptive and expressed as frequency and percentage for data relating to recruitment, adherence, overall retention rates, plus all other categorical data. Continuous data were expressed as mean plus standard deviation or median and interquartile range (for non-normal data). For secondary outcomes, baseline data was compared between groups using the independent samples t-test or Mann Whitney U test where appropriate. Intention-to-treat (ITT) analyses were conducted to examine change over time in functional fitness and psychosocial measures. Effect sizes (ES) [29] and 95% confidence intervals for within group changes and between group differences are reported. Confounding and effect modification were examined using linear regression modeling with the change score as the dependent variable. GAR attendance was determined a priori as a potential confounding factor and HHIE was included post-hoc to account for the unanticipated baseline differences. All results are presented as ITT using the baseline observation carried forward to produce the most conservative results. A sensitivity analyses was conducted using available data (no imputation) and these results are presented in supplementary tables. All analyses were conducted in Stata S/E Version 15 ((Stata® (StataCorp. Stata Statistical Software: Release 15, College Station, TX, USA: StataCorp LLC) and $p<0.05$ was considered statistically significant.

RESULTS:
The Walk, Talk and Listen CONSORT diagram is shown in Figure 1. One hundred and thirty-seven individuals contacted the study center, 119 completed an initial phone screen, and 71 completed full eligibility screening. Ninety-six percent of eligible participants (n=69) were randomized (n=66) and 88% of participants (n=58) completed the study. GAR and exercise attendance rates were 80% and 85% respectively. There was one adverse event (fall with hip fracture) within the trial during an exercise session and two outside the study in control group participants (one fall with hip fracture, one foot infection). Primary reasons for ineligibility included, too young (33%) and no self-reported HL (67%). Newspaper ads were the most successful recruitment strategy (74%) followed by word of mouth (18%), and community posters or social media (8%) (data not tabled). The main reasons for withdrawal during enrollment (n=42) were time commitment (50%) and inconvenient location (24%).

Baseline measures (Table 1): Among the 66 participants in the study, the mean age was 74.5 years, 57% were male, 94% Caucasian, 67% married/common-law, 64% had completed some college/university or above 54% reported an annual household income above $(CDN) 50,000.00, and 88% were retired. Ten participants used mobility or balance aids, just over half used HA and 11 reported one or more falls in the previous 3 months. Groups did not differ on any functional fitness or psychosocial measure with the exception of the total HHIE score (Control median=56; Intervention Median=38; p=0.045).

Table 1. Baseline demographics, functional fitness, and psychosocial measures, by group (control N = 31; intervention N = 35) and for the overall sample (N=66).

Demographics	**Control n (%)**	**Intervention n (%)**	**Overall n (%)**
Age (years), Mean (SD)	74.8 (6.1)	74.3 (6.3)	74.5 (6.2)
Male gender	17 (54.8)	21 (60.0)	38 (57.6)
Caucasian Ethnicity	30 (96.8)	32 (91.4)	62 (93.9)
Married/Common law	22 (71.0)	22 (62.9)	44 (66.7)
College/University/Graduate Studies	19 (61.3)	23 (65.7)	42 (63.6)
Annual Income >$50,000	18 (60.0)	17 (48.6)	35 (53.9)
Retired	29 (93.6)	29 (82.9)	58 (87.9)
Living Alone	10 (32.3)	9 (25.7)	19 (28.8)
Uses Mobility or Balance Aids	6 (19.4)	4 (11.4)	10 (15.2)
Wears Hearing Aids	18 (58.1)	17 (48.6)	35 (53.0)
Any Falls in the Past Three months	7 (22.6)	4 (11.4)	11 (16.7)
Functional Fitness Measures	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
Gait speed (m/s)	1.25 (0.20)	1.28 (0.25)	1.26 (0.23)
Sit-To-Stand (30s)	12.7 (3.2)	12.9 (2.7)	12.8 (2.9)
Grip Strength (kg)	68.0 (19.4)	71.5 (21.6)	69.8 (20.5)
8ft Get up and Go (s)	6.4 (1.9)	6.1 (1.5)	6.3 (1.7)
Sit and Reach (cm)	-4.6 (20.8)	-1.9 (20.9)	-3.2 (20.8)
Back Scratch (cm)	-38.8 (21.0)	-39.7 (25.5)	-39.2 (23.3)
Balance (s)	49.3 (33.3)	45.9 (34.2)	47.5 (33.5)
Psychosocial Measures	**Median (IQR)**	**Median (IQR)**	**Median (IQR)**
HHIE Total	56 (28, 68)	38 (24, 56)	46 (26, 64)
Emotional Subscale	30 (14, 40)	18 (14, 30)	20 (14, 32)
Social Subscale	26 (16, 32)	18 (12, 30)	24 (14, 30)
Geriatric Depression Scale	2 (1, 6)	2 (1, 3)	2 (1, 4)
De Jong Loneliness Total	7 (3, 10)	6 (2, 9)	7 (3, 9)
Emotional Loneliness	3 (1, 5)	3 (0, 5)	3 (0, 5)
Social Loneliness	3 (2, 5)	4 (1, 5)	3 (2, 5)
MOS Social Support Total	76 (50, 86)	76 (49, 93)	76 (50, 93)
Emotional Support	69 (38, 84)	75 (50, 91)	73 (38, 88)
Tangible Support	88 (50, 100)	75 (44, 94)	78 (50, 100)
Affectionate Support	92 (50, 100)	83 (50, 100)	83 (50, 100)
Positive Social Interaction	75 (50, 100)	75 (50, 100)	75 (50, 100)
Additional Item	63 (50, 75)	75 (50, 100)	75 (50, 100)

SF-36 Health Survey			
Physical functioning	80 (55, 95)	85 (65, 90)	83 (65, 90)
Role limitations physical	75 (50, 100)	75 (50, 100)	75 (50, 100)
Role limitations emotional	100 (33, 100)	100 (67, 100)	100 (33, 100)
Energy/fatigue	60 (50, 80)	60 (45, 75)	60 (45, 75)
Emotional well-being	80 (64, 88)	80 (72, 92)	80 (68, 88)
Social functioning	75 (63, 100)	88 (63, 100)	75 (63, 100)
Pain	68 (45, 90)	68 (55, 80)	68 (55, 80)
General Health	75 (60, 85)	70 (65, 85)	75 (65, 85)

Change in functional fitness and psychosocial measures (Table 2 and Supplement 1): After adjusting for baseline HHIE imbalance, gait speed improved more in the intervention group compared to the control group by an average of 0.05 m/s (95% CI=0.0,0.09; p=0.046; ES=0.57). Compared to the control group, STS in the intervention group improved significantly more than the control group by an average of 1.0 STS (95% CI=0.1, 2.0; p=0.037; ES=0.53). Back scratch improved by an average of 4cm more in the intervention group compared to the control group (95% CI=0.2, 7.7; p=0.039; ES=0.54). The de Jong emotional loneliness subscale showed greater improvement in the control group: average difference in change of 0.6 (95% CI=0.1, 1.2; p=0.043; ES=-0.54). There were no significant differences for total or social de Jong loneliness subscales, GDS, or MOS social support or SF-36 measures (all p>0.05).

Table 2. Mean change and difference between control and intervention groups for functional fitness, psychosocial, and quality of life outcome measures, adjusted for baseline HHIE score.

Functional Fitness	**Control Group N=31 Mean Δ (95%CI)**	**Intervention Group N=35 Mean Δ (95% CI)**	**Difference between groups Mean Δ (95% CI)**	**Effect Size**
Gait Speed (m/s)	0.07 (0.04, 0.11)	0.12 (0.09, 0.15)	0.05 (0.0, 0.09) *	0.57
Sit-To-Stand (30 s)	0.6 (-0.1, 1.3)	1.6 (1.0, 2.3)	1.0 (0.1, 2.0) *	0.53
8ft Get up and Go (s)	-0.5 (-0.9, -0.2)	-0.8 (-1.1, -0.5)	-0.3 (-0.8, 0.2)	0.32
Grip Strength (kg)	1.3 (-0.8, 3.5)	2.8 (0.8, 4.8)	1.5 (-1.5, 4.5)	0.26
Sit and Reach (cm)	0.8 (-3.6, 5.2)	3.6 (-0.5, 7.8)	2.8 (-3.3, 9.0)	0.23
Back Scratch (cm)	0.0 (-2.7, 2.7)	4.0 (1.4, 6.5)	4.0 (0.2, 7.7) *	0.54
Balance (s)	6.0 (0.1, 11.9)	6.8 (1.2, 12.3)	0.8 (-7.4, 9.1)	0.05
Psychosocial & Quality of Life				
GDS Total	-0.9 (-1.8, 0.1)	-0.9 (-1.8, 0.2)	0 (-1.3, 1.3)	0
DeJong Total	-1.5 (-2.1, -0.9)	-0.9 (-1.4, -0.3)	0.6 (-0.2, 1.5)	-0.35
Emotional Subscale	-0.9 (-1.3, -0.5)	-0.3 (-0.7, 0.1)	0.6 (0.1, 1.2) *	-0.54
Social Subscale	-0.6 (-1.2, -0.1)	-0.5 (-1.0, -0.1)	0.1 (-0.6, 0.8)	-0.07
MOS Total	5.0 (0.8, 9.1)	0.8 (-3.0, 4.6)	-4.2 (-9.9, 1.6)	-0.38

Emotional Support	6.8 (1.4, 12.1)	1.1 (-4.0, 6.1)	-5.7 (-13.2, 1.8)	-0.39
Tangible Support	2.3 (-2.9, 7.5)	1.5 (-3.4, 6.4)	-0.8 (-8.1, 6.4)	-0.06
Affectionate Support	4.2 (-0.6, 9.0)	-0.4 (-4.9, 4.2)	-4.6 (-11.2, 2.2)	-0.35
Social Interaction	2.5 (-2.0, 7.0)	0.4 (-3.8, 4.7)	-2.1 (-8.3, 4.2)	-0.17
Additional Item	8.5 (1.0, 16.0)	0.6 (-6.4, 7.5)	-7.9 (-18.4, 2.5)	-0.39
SF-36 Health Survey				
Physical functioning	4.0 (-3.2, 11.2)	0.9 (-5.8, 7.7)	-3.1 (-13.1, 7.0)	-0.16
RLP	-2.4 (-14.9, 10.2)	1.4 (-10.4, 13.2)	3.8 (-13.8, 21.3)	0.11
RLE	0.1 (-10.4, 10.5)	-3.8 (-13.7, 6.0)	-3.9 (-18.5, 10.7)	-0.15
Energy/fatigue	0.5 (-4.2, 5.2)	3.0 (-1.4, 7.4)	2.5 (-4.1, 9.1)	0.19
Emotional well-being	0.7 (-3.2, 4.7)	-2.0 (-5.7, 1.7)	-2.7 (-8.3, 2.7)	-0.25
Social functioning	0.0 (-6.5, 6.6)	0.0 (-6.2, 6.1)	0.0 (-9.2, 9.1)	0
Pain	0.6 (-5.7, 6.9)	5.6 (-0.3, 11.5)	5.0 (-3.7, 13.8)	0.29
General Health	-0.3 (-4.8, 4.2)	1.4 (-2.9, 5.7)	1.7 (-4.6, 8.0)	0.14

Notes: RLP = Role limitations physical; RLE = Role limitations emotional
*$p < 0.05$

Improvements in HHIE and de Jong loneliness were influenced by GAR attendance (Table 3). Total, emotional and social HHIE subscales showed significant improvement for those who attended ≥ 80% of GAR sessions: total: 95% CI=-19.7, -2.6; p=0.012; ES=0.76, emotional: 95% CI=-11.0, -1.1; p=0.018; ES=0.71, social: 95% CI=-9.5, -0.8; p=0.022; ES=0.69, regardless of group assignment. Similarly, those with ≥80% GAR attendance had a greater decrease in de Jong total (95% CI=-2.7, -0.9; p=<0.001; ES=1.16) and emotional loneliness (95% CI=-1.7, -0.4; p=0.002; ES=0.96).

Table 3. Impact of group and GAR attendance on mean change and difference in change for the HHIE and deJong loneliness scales.

	HEARING HANDICAP FOR THE ELDERLY			**DEJONG LONELINESS AND ISOLATION**		
GROUP	**Total Score Mean Δ 95% CI**	**Emotion Subscale Mean Δ 95% CI**	**Social Subscale Mean Δ 95% CI**	**Total Score Mean Δ 95% CI**	**Emotion Subscale Mean Δ 95% CI**	**Social Subscale Mean Δ 95% CI**
Control Group	-9.1	-5.8	-3.3	-1.5	-0.9	-0.6
	-14.4, -3.7	-8.9, -2.7	-6.0, -0.6	-2.1, -0.9	-1.3, -0.5	-1.1, -0.1
Intervention Group	-5.1	-3.4	-1.6	-0.9	-0.3	-0.5
	-10.1, -0.1	-6.3, -0.5	-4.2, 0.9	-1.4, -0.3	-0.7, 0.1	-1.0, -0.1
Group Difference	4.0	2.4	1.7	0.6	0.6	0.1
	-3.4, 11.4	-1.9, 6.7	-2.1, 5.5	-0.1, 1.4	0.0, 1.1	-0.6, 0.8
p	0.285	0.276	0.375	0.107	0.047	0.771
Effect Size	-0.27	-0.28	-0.23	-0.39	-0.57	-0.07
GAR ATTENDANCE						
<80% attendance	1.3	-0.1	1.4	0.2	0.2	0.0

	-6.0, 8.6	-4.3, 4.1	-2.3, 5.1	-0.6, 1.0	-0.4, 0.8	-0.7, 0.7
≥80% attendance	-9.8	-6.1	-3.7	-1.6	-0.8	-0.8
	-14.0, -5.6	-8.5, -3.7	-5.9, -1.6	-2.1, -1.2	-1.1, -0.5	-1.2, -0.4
Group Difference	-11.1	-6.0	-5.1	-1.8	-1.0	-0.8
	-19.7, -2.6	-11.0, -1.1	-9.5, -0.8	-2.7, -0.9	-1.7, -0.4	-1.6, 0.1
p	0.012	0.018	0.022	<0.001	0.002	0.061
Effect Size	0.76	0.71	0.69	1.16	0.96	0.58

GAR evaluation: At study end, participant responses to the seven IOI-IA questions (Table 4) revealed that 67% of participants were using GAR communication strategies on a daily basis for at least one hour. The majority reported moderate or greater benefit from using GAR strategies, satisfaction with the GAR program, and improvement in participation restriction and activity limitations. COSI results were favorable overall (Supplement 2). Participants reported slightly better or greater progress in their goals of improving "conversations with one or two or a group of people in a quiet environment" (67%) or "noisy" environment (53%), half (51%) felt less embarrassed or stupid and 42% increased the amount of their social contact (such as attending more social events, social situations or going out in public).

Table 4. Percent distribution of participant responses for each item on the IOI-IA at follow-up (N=57).

Item					
Use	None	<1 hr/day	1-4 hr/day	4-8 hr/day	>8 hr/day
%	3.5	29.8	49.1	12.3	5.3
Benefit	Not at all	Slightly	Moderately	Quite a lot	Very much
%	0	35.1	29.8	31.6	3.5
RAL	Very much	Quite a lot	Moderate	Slight	None
%	3.5	3.5	49.1	38.6	5.3
Sat	Not at all	Slightly	Moderately	Quite a lot	Very much
%	0	8.8	19.3	28.1	43.8
RPR	Very much	Quite a lot	Moderate	Slight	None
%	0	17.6	31.6	36.8	14.0
Ioth	Very much	Quite a lot	Moderate	Slight	None
%	0	3.5	17.2	48.3	31.0
QOL	Worse	No change	Slightly	Quite a lot	Very much
%	0	10.3	44.8	38.0	6.9

Notes: RAL = residual activity limitations; Sat = satisfaction; RPR = residual participating restrictions; Ioth = impact on others; QOL = quality of life

[a]Statistically significant difference between control and intervention groups (Control: Not at all = 0%, Slightly = 26.9%, Moderately = 19.2%, Quite a lot = 46.2%, Very much = 7.7%; Intervention: Not at all = 0%, Slightly = 41.9%, Moderately = 38.7%, Quite a lot = 19.4%, Very much = 0%; $p = 0.040$)

Program evaluation (Supplement 3) questions were filled out by 24 control group and 33 intervention group participants. The data revealed that a large proportion of both control and intervention participants agreed or strongly agreed that GAR helped them: better recognize and accept their HL (93%); be more confidant to speak out about their HL in social situations (98%); and to have a better attitude toward HL (95%). The majority (89%) felt that GAR helped them improve their problem-solving abilities. Intervention group participants reported that they were satisfied with the exercise (100%) and reported it was fun (100%). The majority (75%) indicated they increased their physical activity level outside the program, and 88% were confident they would continue with regular exercise after the program ended. When asked what could improve the program, participants favored a larger GAR session room, more emphasis on hearing assistive technologies (telephones, for example) with presentations by commercial companies producing these items, better acoustics in the gym (e.g. no fan noise in the background) with an improved sound system and instructors that could speak more slowly and clearly (data not tabled).

DISCUSSION:

In this pilot trial, the feasibility, acceptability and preliminary evidence for the efficacy of a group auditory rehabilitation, health education and exercise intervention for older adults with HL was evaluated. Recruitment and retention rates suggested the study was well received. Walk, Talk and Listen was found to be feasible and highly acceptable. Strengthening, resistance and coordination exercises coupled with GAR and health education improved lower extremity strength, gait speed and upper body flexibility. While exercise improved these key functional fitness measures, it provided no additional benefit beyond GAR alone. Significant improvements in hearing-related quality of life (HHIE), total and emotional loneliness were found for those attending ≥ 80% of the GAR sessions and in those with the poorest baseline self-reported hearing handicap (HHIE). Delivery of GAR by a non-audiologist health provider appeared to be of similar benefit to participants as seen in the literature. To our knowledge, this is the first study to provide an approach to the treatment of HL in older adults that addresses the ICF domains of hearing loss-related activity limitations, participation restrictions in addition to physical function (impaired musculoskeletal function), and that showed an improvement in total and emotional loneliness.

Feasibility and acceptability.

Implementation of the Walk, Talk and Listen proved to be feasible and acceptable to participants. Recruitment strategies, randomization, study implementation and study completion rates (88%) reached the a priori required feasibility goals and more than 95% of participants found the program acceptable/highly acceptable.

Together, the GAR evaluation tools (IOI-IA, COSI and qualitative feedback) suggested that the GAR program was highly appreciated, benefited and improved self-efficacy of participants. When compared with other studies where communication strategies and psychosocial counselling were key features of GAR, improvement in HHIE (ES=0.69-0.76) was similar to that in one study (ES 0.67-0.78) [30] and slightly greater than that in another (ES =0.25) [16]. Furthermore, outcomes in all domains of the IOI-IA and relevant COSI outcomes compared favorably with these same established communication programs [15, 16, 30]. Inclusion of communication strategies and facilitating behavior change was associated with enhanced self-

efficacy a consistent finding in the literature [31, 32]. As participants gain confidence in managing their HL and achieving their communication and social goals, their hearing-related quality of life improves [30, 33]. These findings are encouraging and add to the emerging evidence suggesting that with adequate training and resources, a non-audiologist may help to build capacity for increased access to effective community-based GAR programming [34-36].

Functional physical fitness changes.

Preliminary evidence for efficacy of the exercise intervention on physical function was determined using effect sizes in order to help decide upon future sample size considerations. Effect sizes were calculated on a small sample, therefore need to be interpreted with that in mind [37]. They suggest that the physical activity and GAR interventions were of some benefit and deserve further investigation in a larger sample.

The WTL exercise intervention was associated with significant improvements in two major functional fitness measures (gait speed; ES 0.57 and 30 sec STS; ES0.53) associated with improved ability for maintenance of ongoing physical independence [22]. Adherence to the exercise intervention was excellent and end of study evaluations indicated that participants were satisfied with the exercise sessions. Lower body muscle strengthening and improved gait speed are expected to provide long-term benefit as shown in a prospective analysis of longitudinal data from NHANES (2003-2006) where adults with at least moderate HL who undertook two+ sessions/week of muscle strengthening exercises were at a 71% reduced risk of 7-year all-cause mortality [10]. However, static (one foot stand) or dynamic (Timed Up and Go) balance was not improved. Furthermore, there was one fall during a fast-paced "tag"-like exercise where a participant tripped on another participant's foot. While published rates of falls during fall prevention programs range from 5-25% (depending on baseline risk for falls) [38], these findings have important implications for the design of future exercise interventions. Rather than rapid agility/coordination exercises, exercises should include more balance training such as the in-home or facility-based Otago Falls prevention exercise program or Tai Chi [39] which have been shown to reduce falls in the general population of older adults. Incorporation of these focused exercises may be more effective in improving balance in those with HL. The improvement in gait speed and lower extremity muscle strength seen in this pilot trial are encouraging and suggest that such an intervention, if carried on longer term, and which includes more aggressive balance training might be of survival benefit in older adults with HL.

Hearing and health-related quality of life, loneliness and social network.

Improvements in loneliness, participation restrictions and activity limitations were related to higher (worse) baseline HHIE and higher GAR attendance. Hearing-related quality of life has been found to be an effect modifier in other studies. Using a similar assessment of hearing-related quality of life (Hearing Attitudes to Rehabilitation Questionnaire) [16] found that higher baseline scores in this measure were also associated with greater benefit from a GAR program for participation restrictions and activity limitations. The addition of exercise to GAR was of no added benefit for any of the psychosocial outcomes. This was an unexpected finding given the proven benefits of exercise in many of these realms [40]. It is unknown as to whether poorer hearing-related quality of life supersedes the psychosocial benefits of exercise. Further research is need in order understand this interaction

That GAR attendance had a strong influence on psychosocial outcomes is consistent with the findings of others who have found that GAR attendance is imperative for optimizing the outcomes of AR [41]. Our adherence rates of 87% were comparable or better than other group-based communication programs where rates ranged from 56-68% [9] to 96% [30].

The association between untreated HL and loneliness is well known [24]. Treatment with cochlear implantation [42] and provision of HAs [43]) has been shown to reduce loneliness in older adults with audiometrically measured mild to severe HL. To the authors knowledge, only one study has looked at the effect of AR on loneliness. In this study [44], participants were provided with an assistive hearing device (not a HA) and with their CP undertook a one-time 1.6-2-hour AR session delivered by a trained clinician. Participants were given AR manuals and workbooks to complete at home. Despite a significant decrease in HHIE at 3 months, loneliness (as measured by the UCLA loneliness scale) increased. In the current study, greater improvements in emotional loneliness were seen among those with higher baseline HHIE scores. However, even greater benefit in both total and emotional loneliness was realized by those with higher GAR attendance compared with poor attenders, who saw no benefit.
Furthermore, while social isolation was not formally assessed, the COSI results indicate that 42 percent of participants increased the amount of their social contact (such as attending more social events, social situations or going out in public) which might be expected to decrease social isolation if maintained over time.
While group or home AR improves hearing-related quality of life, it appears that group contact may more conducive than home-based AR to addressing HL-related loneliness and should likely remain a component of GAR.

Health-related quality of life:
Health-related quality of life, as assessed using the RAND SF36, did not show change by group assignment, GAR attendance or baseline HHIE score. This finding is in agreement with others who also used generic health-related quality of life tools (World Health Organization Disability Assessment Schedule II (WHODASII) [33] [30]: Short-Form 36 (SF-36) [16]) as a communication program outcome measure. This was not unexpected given that the content of this questionnaire has little to do with communication and supports our finding that added exercise and health education did affect generic quality of life measures.

Strengths and Limitations:
This study had several strengths: 57% of our participants were male. While not uncommon for GAR interventions, it is uncommon to see > 30% of males participating in community-based exercise programs [45 46]. This may simply reflect the higher prevalence of HL in men, or some other factor: qualitative work is underway to examine this.

In this pilot feasibility trial, a control group receiving no intervention was not included. This would have made for a more accurate determination the effects of GAR. However, one potential interpretation is that GAR can be effective when given alone or part of a more holistic health behaviour intervention. Secondly, participants were self-selected which may have introduced a bias favoring positive outcomes [47]. However, recruitment occurred in the 'real world" community setting and is representative of the population of hearing impaired older adults that have reached the stage of hearing help seeking. Thirdly, the baseline difference between groups

in the baseline HHIE scores is likely due to the small sample size. Although comparisons were reported in terms of relative improvements and not strict comparisons, this should be noted as a potential bias. This study provided only immediate post-program results and may have been underpowered to detect changes in the other fitness measures. There is a need for more longitudinal follow-up in a larger sample to determine if the positive changes can be sustained.

Finally, this is the first study to obtain preliminary information on the effectiveness of an exercise intervention to improve functional fitness, total and emotional loneliness and social support in older adults with self-reported HL. GAR lead by non-audiologist shows potential as a way to improve the accessibility of GAR programs.

Age-related HL is a prevalent, under recognized and significant disability that when untreated is associated with profound negative downstream effects. This study contributes to emerging evidence of the benefit of providing accessible community-based communication programs delivered outside the traditional audiology clinical setting. Addition of an exercise component shows at least short-term functional fitness benefits. Further research is needed to determine the long-term benefits of combining communication and exercise programs on the bio-psychosocial domains among older adults with hearing loss

Implications:
A larger, long-term study is needed to determine the enduring effects of this novel, community-based, holistic intervention in addressing both the negative psychosocial and functional physical effects of HL among older adults. Use of the home or facility-based Otago falls prevention exercise program (muscle strengthening and a more focused approach to balance training) may be necessary to improve balance in older adults with hearing loss. Face-to-face GAR sessions may be necessary in order to provide additional benefits on loneliness and social support. Provision of GAR by students and non-audiologists may improve accessibility of audiological rehabilitation programs.

References

1. Lin FR, Niparko JK, Ferrucci L. Hearing loss prevalence in the United States. *Arch. Intern. Med.* 2011;171(20):1851-2.
2. Statistics Canada. Canadian Health Measures Survey. Hearing Loss of Canadians, 2012 to 2015. In: Statistics Canada ed. Ottawa, 2016.
3. WHO. ICF. International Classification of Functioning, Disability and Health. Geneva, Switzerland., 2001.
4. Hickson L, Scarinci N. Older adults with acquired hearing impairment: Applying the ICF in rehabilitation *Semin. Speech Lang.* 2007;28:283-90.
5. Mick P, Kawachi I, Lin FR. The Association between Hearing Loss and Social Isolation in Older Adults. *Otolaryngol. Head Neck Surg.* 2014;150(3):378-84.
6. Strawbridge WJ, Wallhagen MI, Shema SJ, Kaplan GA. Negative Consequences of Hearing Impairment in Old Age: A Longitudinal Analysis. *The Gerontologist* 2000;40:320-26.
7. Davis A, McMahon CM, Pichora-Fuller KM, et al. Aging and Hearing Health: The Life-course Approach. *Gerontologist* 2016;56 Suppl 2:S256-67.

8. Millett P, Jutras B, Noel G, Pichora-Fuller K, Watson C, Nelson A. Canadian Guideline on Auditory Processing Disorder in Children and Adults: Assessment and intervention: Canadian Interorganizational Steering Group for Audiology and Speech-Language Pathology, 2012.
9. Laplante-Levesque A, Hickson L, Worrall L. Rehabilitation of older adults with hearing impairment: a critical review. *J. Aging Health* 2010;22(2):143-53.
10. Loprinzi PD. Muscle strengthening activities and mortality with considerations by hearing sensitivity. *Int. J. Audiol.* 2016;55(5):320-2.
11. Lambert J, Ghadry-Tavi R, Knuff K, et al. Targeting functional fitness, hearing and health-related quality of life in older adults with hearing loss: Walk, Talk 'n' Listen, study protocol for a pilot randomized controlled trial. *Trials* 2017;18(1):47.
12. Jutras M, Lambert J, Hwang J, et al. Targeting the psychosocial and functional fitness challenges of older adults with hearing loss: a participatory approach to adaptation of the Walk and Talk for your Life program *Int. J. Audiol.* 2018.
13. Chang H-P, Ho C-Y, Chou P. The Factors Associated with a Self-Perceived Hearing Handicap in Elderly People with Hearing Impairment Results from a Community-Based Study. *Ear Hear.* 2009;30:576-83.
14. Montano JJ, Preminger JE, Hickson L, Gregory M. A new web-based tool for group audiologic rehabilitation. *Am J Audiol* 2013;22(2):332-4.
15. Hickson L, Worrall L, Scarinci N. Measuring outcomes of a communication program for older people with hearing impairment using the International Outcome Inventory. *Int. J. Audiol.* 2006;45(4):238-46.
16. Hickson L, Worrall L, Scarinci N. A randomized controlled trial evaluating the active communication education program for older people with hearing impairment. *Ear Hear.* 2007;28(2):212-30.
17. Tiedemann A, Shimada H, Sherrington C, Murray S, Lord S. The comparative ability of eight functional mobility tests for predicting falls in community-dwelling older people. *Age Ageing* 2008;37(4):430-5.
18. Steffen TM, Hacker TA, Mollinger L. Age- and gender-related test performance in community-dwelling elderly people: Six-Minute Walk Test, Berg Balance Scale, Timed Up & Go Test, and gait speeds. *Phys. Ther.* 2002;82(2):128-37.
19. Springer BA, Marin R, Cyhan T, Roberts H, Gill NW. Normative values for the unipedal stance test with eyes open and closed. *J. Geriatr. Phys. Ther.* 2007;30(1):8-15.
20. Leong DP, Teo KK, Rangarajan S, et al. Prognostic value of grip strength: findings from the Prospective Urban Rural Epidemiology (PURE) study. *Lancet* 2015;386:266-73.
21. Jones CJ, Rikli RE, Max J, Noffal G. The reliability and validity of a chair sit-and-reach test as a measure of hamstring flexibility in older adults. *Res. Q. Exerc. Sport* 1998 69:338-43.
22. Rikli RE, Jones CJ. Development and validation of criterion-referenced clinically relevant fitness standards for maintaining physical independence in later years. *Gerontologist* 2013;53(2):255-67.
23. Ware JE, Jr., Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF- 36): I. Conceptual Framework and Item Selection *Med. Care* 1992;30:473-83.
24. de Jong-Gierveld J, ; Kamphuis, F. The Development of a Rasch-Type Loneliness Scale. *Appl. Psychol. Meas.* 1985;9:289-99.
25. Sherbourne CD, Stewart AL. The MOS social support survey. *Soc. Sci. Med.* 1991;32(6):705-14.

26. Vinkers DJ, Gussekloo J, Stek ML, Westendorp RG, Van Der Mast RC. The 15-item Geriatric Depression Scale (GDS-15) detects changes in depressive symptoms after a major negative life event. The Leiden 85-plus Study. *Int. J. Geriatr. Psychiatry* 2004;19(1):80-4.
27. Jones CJ, Rikli RE, Beam WC. A 30-s chair-stand test as a measure of lower body strength in community-residing older adults. *Res. Q. Exerc. Sport* 1999;70(2):113-9.
28. Whitehead AL, Julious SA, Cooper CL, Campbell MJ. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Stat. Methods Med. Res.* 2016;25(3):1057-73.
29. Cohen J. *Statistical power analysis for the behavioral sciences.* 2nd ed ed. Hillsdale, NJ, USA: Lawrence Earlbaum Associates, 1988.
30. Preminger JE, Yoo JK. Do group audiologic rehabilitation activities influence psychosocial outcomes? *Am J Audiol* 2010;19(2):109-25.
31. Smith SL, West RL. The application of self-efficacy principles to audiologic rehabilitation: a tutorial. *Am J Audiol* 2006;15(1):46-56.
32. Marrone N, Ingram M, Somoza M, et al. Interventional Audiology to Address Hearing Health Care Disparities: Oyendo Bien Pilot Study. *Semin Hear* 2017;38(2):198-211.
33. Preminger JE, Ziegler CH. Can auditory and visual speech perception be trained within a group setting? *Am J Audiol* 2008;17(1):80-97.
34. Sanchez D, Adamovich S, Ingram M, et al. The Potential in Preparing Community Health Workers to Address Hearing Loss. *J. Am. Acad. Audiol.* 2017;28(6):562-74.
35. Nieman CL, Lin FR. Increasing access to hearing rehabilitation for older adults. *Curr. Opin. Otolaryngol. Head Neck Surg.* 2017;25(5):342-46.
36. Preminger JE. Issues associated with the measurement of psychosocial benefits of group audiologic rehabilitation programs. *Trends in amplification* 2007;11(2):113-23.
37. Durlak JA. How to select, calculate, and interpret effect sizes. *J. Pediatr. Psychol.* 2009;34(9):917-28.
38. Sherrington C, Michaleff ZA, Fairhall N, et al. Exercise to prevent falls in older adults: an updated systematic review and meta-analysis. *Br. J. Sports Med.* 2017;51(24):1750-58.
39. Gillespie LD, Robertson MC, Gillespie WJ, et al. Interventions for preventing falls in older people living in the community. *Cochrane Database Syst Rev* 2012(9):CD007146.
40. Gaz DV, Smith AM. Psychosocial benefits and implications of exercise. *PM R* 2012;4(11):812-7.
41. Chisolm TH, Saunders GH, Frederick MT, McArdle RA, Smith SL, Wilson RH. Learning to listen again: the role of compliance in auditory training for adults with hearing loss. *Am J Audiol* 2013;22(2):339-42.
42. Poissant SF, Beaudoin F, Huang J, Brodsky J, Lee DJ. Impact of cochlear implantation on speech understanding, depression, and loneliness in the elderly. *J. Otolaryngol. Head Neck Surg.* 2008;37(4):488-94.
43. Weinstein BE, Sirow LW, Moser S. Relating Hearing Aid Use to Social and Emotional Loneliness in Older Adults. *Am J Audiol* 2016;25(1):54-61.
44. Nieman CL, Marrone N, Mamo SK, et al. The Baltimore HEARS Pilot Study: An Affordable, Accessible, Community-Delivered Hearing Care Intervention. *Gerontologist* 2016.
45. Clare L, Nelis SM, Jones IR, et al. The Agewell trial: a pilot randomised controlled trial of a behaviour change intervention to promote healthy ageing and reduce risk of dementia in later life. *BMC Psychiatry* 2015;15:25.

46. Gandy R, Bell A, McClelland B, Roe B. Evaluating the delivery, impact, costs and benefits of an active lives programme for older people living in the community. *Prim. Health Care Res. Dev.* 2016:1-13.
47. Knudsen LV, Oberg M, Nielsen C, Naylor G, Kramer SE. Factors influencing help seeking, hearing aid uptake, hearing aid use and satisfaction with hearing aids: a review of the literature. *Trends in amplification* 2010;14(3):127-54.

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Ethical approval: The study was approved by the University of British Columbia Okanagan Research Services Behavioural Research Ethics Board. UBC BREB number: H15-02319. Written consent was obtained for all participants.

Competing interests: The authors have no conflicts of interest to report.

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Data Sharing:
UBC library Data Management Repository — UBC Library has implemented a robust data management software – Abacus Dataverse – collaborating with Harvard and supporting other BC schools (UNBC, UVic and SFU). The system is designed to manage and preserve data and it is opened to UBC researchers, labs and institutes. UBC will then assign DOI's to the UBC Library digital datasets, via our Open Collections portal. DOIs increase the further citability and discoverability of UBC research data.

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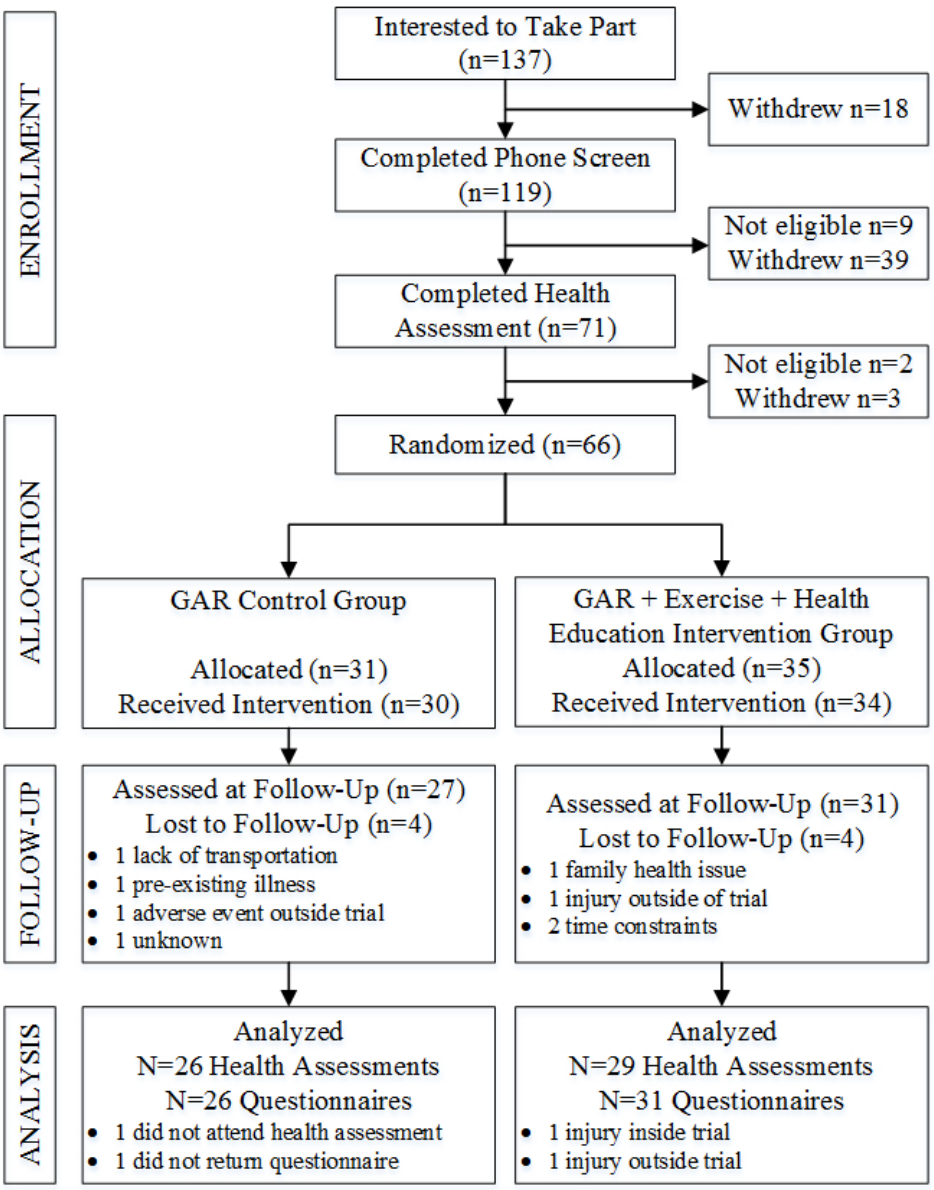

Figure 1: Walk, Talk and Listen CONSORT diagram

138x176mm (120 x 120 DPI)

Supplement 1. Table 1: Complete case (per protocol) analysis for data in Table 2 and Table 3.

FUNCTIONAL FITNESS MEASURES	Control Group Mean Δ (95%CI)	Intervention Group Mean Δ (95%CI)	Difference between groups	p	Effect Size
Gait Speed (m/s), N=55	0.09 (0.06, 0.12)	0.14 (0.11, 0.18)	0.05 (0.01, 0.1)	0.030	0.60
Sit-To-Stand (30 s), N=53	0.8 (-0.1, 1.6)	2.1 (1.3, 2.9)	1.3 (0.2, 2.5)	0.024	0.66
8ft Get up and Go (s), N=55	-0.6 (-1.0, -0.2)	-0.9 (-1.3, -0.6)	-0.3 (-0.9, 0.2)	0.262	0.30
Grip Strength (kg), N=53	1.7 (-1.0, 4.5)	3.3 (0.9, 5.8)	1.6 (-2.2, 5.4)	0.397	0.25
Sit and Reach (cm), N=54	1.1 (-4.4, 6.6)	4.3 (-0.8, 9.4)	3.2 (-4.4, 10.9)	0.401	0.32
Back Scratch (cm), N=53	0.0 (-3.4, 3.3)	5.0 (1.8, 8.1)	5.0 (0.3, 9.7)	0.038	0.61
Balance (s), N=54	7.6 (0.4, 14.9)	8.0 (1.3, 14.7)	0.4 (-9.7, 10.5)	0.942	0.02
PSYCHOSOCIAL OUTCOME MEASURES					
Geriatric Depression Scale	-1.0 (-2.1, 0.1)	-1.0 (-2.1, 0)	0 (-1.6, 1.6)	0.984	0
deJong Loneliness Total	-1.8 (-2.5, -1.1)	-1.0 (-1.6, -0.3)	0.8 (-0.2, 1.8)	0.117	-0.45
Emotional Subscale	-1.1 (-1.6, -0.6)	-0.4 (-0.8, 0.1)	0.7 (0.1, 1.4)	0.040	-0.59
Social Subscale	-0.8 (-1.4, -0.1)	-0.6 (-1.2, -0.1)	0.2 (-0.7, 1.0)	0.742	-0.13
MOS Social Support Total	5.9 (0.9, 10.8)	1.0 (-3.4, 5.4)	-4.9 (-11.7, 2.0)	0.161	-0.41
Emotional Support	8.2 (1.6, 14.8)	1.4 (-4.5, 7.3)	-6.8 (-16.0, 2.3)	0.141	-0.43
Tangible Support	2.9 (-3.5, 9.4)	1.7 (-4.1, 7.4)	-1.2 (-10.2, 7.6)	0.771	-0.08
Affectionate Support	5.2 (-0.8, 11.1)	-0.4 (-5.7, 4.9)	-5.6 (-13.8, 2.6)	0.178	-0.39
Positive Social Interaction	2.7 (-2.8, 8.3)	0.7 (-4.2, 5.7)	-2.0 (-9.7, 5.7)	0.607	-0.15
Additional Item	10.3 (1.2, 19.3)	0.6 (-7.5, 4.9)	-9.7 (-22.2, 2.8)	0.126	-0.45

Table 2. Mean change and difference between control and intervention groups for functional fitness and psychosocial outcome measures, adjusted for baseline HHIE score.

NO IMPUTATION	DEJONG LONELINESS AND ISOLATION			HEARING HANDICAP FOR THE ELDERLY		
GROUP	Total Score	Emotional Subscale	Social Subscale	Total Score	Emotional Subscale	Social Subscale
Control Group Mean Δ	-1.7	-1.0	-0.7	-10.0	-6.6	-3.6
(95% CI)	(-2.4, -1.1)	(-1.5, -0.5)	(-1.3, -0.1)	(-16.4, -3.7)	(-10.3, -2.9)	(-6.8, -0.3)
Intervention Group Mean Δ (95% CI)	-1.0 (-1.6, -0.4)	-0.4 (-0.8, 0)	-0.6 (-1.2, -0.1)	-6.3 (-12.1, -0.6)	-4.2 (-7.5, -0.8)	-2.2 (-5.1, 0.8)
Mean Difference Between Groups	0.7	0.6	0.1	3.7	2.4	1.4
(95% CI)	(-0.2, 1.6)	(-0.1, 1.2)	(-0.7, 0.9)	(-5.1, 12.6)	(-2.7, 7.6)	(-3.1, 5.9)
p-value	0.143	0.074	0.811	0.402	0.351	0.541
Effect Size	-0.42	-0.54	-0.07	-0.24	-0.26	-0.18
GAR ATTENDANCE						
<80% attendance Mean Δ	0.4	0.5	0	3.4	0	3.3
(95% CI)	(-0.9, 1.6)	(-0.4, 1.3)	(-1.1, 1.1)	(-8.2, 15.0)	(-6.7, 6.8)	(-2.6, 9.2)
≥80% attendance Mean Δ	-1.6	-0.8	-0.8	-9.9	-6.1	-3.8
(95% CI)	(-2.1, -1.2)	(-1.2, -0.5)	(-1.2, -0.4)	(-14.4, -5.4)	(-8.7, -3.5)	(-6.1, -1.5)
Mean Difference Between Groups	-2.0	-1.3	-0.8	-13.3	-6.1	-7.1
(95% CI)	(-3.4, -0.7)	(-2.2, -0.3)	(-2.0, 0.4)	(-25.9, -0.7)	(-13.5, 1.2)	(-13.5, -0.7)
p-value	0.004	0.010	0.205	0.039	0.098	0.030
Effect Size	1.2	1.17	0.54	0.85	0.67	0.90

Supplement 2. Distribution of COSI responses at follow-up, by group (Control N=26; Intervention N=31) and overall (N=57).

Situation	Amount of change experienced				
	Worse n (%)	No difference n (%)	Slightly better n (%)	Better n (%)	Much better n (%)
1. Conversations with 1 or 2 people in a quiet environment.					
Control	0 (0)	10 (38.5)	6 (23.1)	6 (23.1)	4 (15.4)
Intervention	0 (0)	9 (29.0)	7 (22.6)	13 (41.9)	2 (6.5)
Overall	0 (0)	19 (33.3)	13 (22.8)	19 (33.3)	6 (10.5)
2. Conversations with 1 or 2 people in a noisy environment.					
Control	1 (3.9)	12 (46.2)	7 (26.9)	6 (23.1)	0 (0)
Intervention	1 (3.2)	13 (41.9)	8 (25.8)	9 (29.0)	0 (0)
Overall	2 (3.5)	25 (43.9)	15 (26.3)	15 (26.3)	0 (0)
3. Conversations with a group in a quiet environment.					
Control	0 (0)	8 (30.8)	7 (26.9)	8 (30.8)	3 (11.5)
Intervention	0 (0)	8 (25.8)	11 (35.5)	10 (32.3)	2 (6.5)
Overall	0 (0)	16 (28.1)	18 (31.6)	18 (31.6)	5 (8.7)
4. Conversations with a group in a noisy environment.					
Control	1 (3.9)	10 (38.5)	10 (38.5)	4 (15.4)	1 (3.9)
Intervention	1 (3.2)	15 (48.4)	11 (35.5)	3 (9.7)	1 (3.2)
Overall	2 (3.5)	25 (43.9)	21 (36.8)	7 (12.3)	2 (3.5)
5. Hearing the television or radio at normal volume.					
Control	0 (0)	16 (61.5)	7 (26.9)	3 (11.5)	0 (0)
Intervention	0 (0)	17 (54.8)	6 (19.4)	7 (22.6)	1 (3.2)
Overall	0 (0)	33 (57.9)	13 (22.8)	10 (17.5)	1 (1.8)
6. Speaking with a familiar person on the phone.					
Control	0 (0)	17 (65.4)	3 (11.5)	5 (19.2)	1 (3.9)
Intervention	0 (0)	22 (71.0)	2 (6.5)	6 (19.4)	1 (3.2)
Overall	0 (0)	39 (68.4)	5 (8.8)	11 (19.3)	(3.5)
7. Speaking with an unfamiliar person on the phone.					
Control	1 (3.9)	17 (65.4)	5 (19.2)	3 (11.5)	0 (0)
Intervention	1 (3.2)	19 (61.3)	7 (22.6)	3 (9.7)	1 (3.2)
Overall	2 (3.5)	36 (63.2)	12 (21.0)	6 (10.5)	1 (1.8)
8. Hearing the phone ring from another room.					
Control	0 (0)	22 (84.6)	2 (7.7)	2 (7.7)	0 (0)
Intervention	1 (3.2)	22 (71.0)	6 (19.4)	1 (3.2)	1 (3.2)
Overall	1 (1.8)	44 (77.2)	8 (14.0)	3 (5.2)	1 (1.8)

9. Hearing the front door bell or someone knocking on the door.					
Control	0 (0)	19 (73.1)	5 (19.2)	2 (7.7)	0 (0)
Intervention	1 (3.2)	21 (67.7)	5 (16.1)	2 (6.5)	2 (6.5)
Overall	1 (1.8)	40 (70.2)	10 (17.5)	4 (7.0)	2 (3.5)
10. Hearing traffic (while walking outside or driving)					
Control	1 (3.9)	19 (73.1)	4 (15.4)	2 (7.7)	0 (0)
Intervention	1 (3.2)	23 (74.2)	3 (9.7)	3 (9.7)	1 (3.2)
Overall	2 (3.5)	42 (73.7)	7 (12.3)	5 (8.7)	1 (1.8)
11. Your amount of social contact (such as attending more social events or social situations or going out in public)					
Control					
Intervention	0 (0)	14 (53.9)	6 (23.1)	5 (19.2)	1 (3.9)
Overall	1 (3.2)	18 (58.1)	5 (16.1)	7 (22.6)	0 (0)
	1 (1.8)	32 (56.1)	11 (19.3)	12 (21.0)	1 (1.8)
12. Feeling embarrassed or stupid.					
Control	0 (0)	11 (42.3)	4 (15.4)	9 (35.6)	2 (7.7)
Intervention	0 (0)	17 (54.8)	9 (29.0)	2 (6.5)	3 (9.7)
Overall	0 (0)	28 (49.1)	13 (22.8)	11 (19.3)	5 (8.7)
13. Feeling left out.					
Control	0 (0)	11 (42.3)	7 (26.9)	8 (30.8)	0 (0)
Intervention	0 (0)	18 (58.1)	8 (25.8)	3 (9.7)	2 (6.5)
Overall	0 (0)	29 (50.9)	15 (26.3)	11 (19.3)	2 (3.5)
14. Feeling upset or angry.					
Control	0 (0)	14 (53.9)	5 (19.2)	7 (26.9)	0 (0)
Intervention	0 (0)	17 (54.8)	10 (32.3)	2 (6.5)	2(6.5)
Overall	0 (0)	31 (54.4)	15 (26.3)	9 (15.8)	2 (3.5)
15. Attending church or group meetings					
Control					
Intervention	0 (0)	18 (69.2)	4 (15.4)	4 (15.4)	0 (0)
Overall	0 (0)	24 (77.4)	3 (9.7)	2 (6.5)	2 (6.5)
	0 (0)	42 (73.7)	7 (12.3)	6 (10.5)	2 (3.5)

Supplement 3. Program Evaluation Questions and Distribution of Responses (Intervention N=33; Control N=24).

Exercise sessions (Intervention Participants)	**Strongly Agree n (%)**	**Agree n (%)**	**Disagree n (%)**	**Strongly Disagree n (%)**	**Don't know n (%)**
Overall, I was satisfied with the exercise program.	18 (55)	15 (44)	0 (0)	0 (0)	0 (0)
The exercise program was fun.	15 (45)	18 (55)	0 (0)	0 (0)	0 (0)
I did not enjoy the exercise sessions.	0 (0)	2 (6)	10 (30)	20 (61)	1 (3)
The exercises were too easy.	0 (0)	2 (6)	10 (30)	20 (61)	1 (3)
The exercise room was suitable for the program.	9 (27)	21 (64)	3 (9)	0 (0)	0 (0)
The fitness instructor clearly demonstrated the exercises.	17 (52)	16 (48)	0 (0)	0 (0)	0 (0)
The fitness instructor suggested modifications for the exercises to accommodate different fitness levels.	10 (30)	22 (67)	1 (3)	0 (0)	0 (0)
The fitness instructor was encouraging.	19 (58\)	14 (42)	0 (0)	0 (0)	0 (0)
The fitness instructor was approachable.	19 (59)	13 (41)	0 (0)	0 (0)	0 (0)
The fitness instructor spoke clearly.	9 (27)	20 (61)	4 (12)	0 (0)	0 (0)
There were a good variety of exercises.	14 (42)	18 (55)	1 (3)	0 (0)	0 (0)
I have increased my physical activity level outside of the program.	9 (27)	16 (48)	5 (15)	0 (0)	3 (9)
By participating, I feel I improved my strength and stamina.	9 (27)	20 (61)	2 (6)	0 (0)	2 (6)
By participating, I feel I improved my balance.	7 (21)	15 (45)	6 (18)	0 (0)	5 (15)
By participating, I feel I improved my flexibility.	6 (18)	23 (70)	2 (6)	0 (0)	2 (6)
As a result of the program, I walk more often.	8 (24)	17 (52)	7 (21)	0 (0)	1 (3)

Health Education Sessions (Intervention Participants)	**Strongly Agree n (%)**	**Agree n (%)**	**Disagree n (%)**	**Strongly Disagree n (%)**	**Don't know n (%)**
The presentation topics were interesting.	13 (39)	20 (61)	0 (0)	0 (0)	0 (0)
There were a good variety of presentation topics.	12 (36)	21 (64)	0 (0)	0 (0)	0 (0)
The information presented encouraged group discussions.	17 (52)	16 (48)	0 (0)	0 (0)	0 (0)
I did not enjoy the group discussions.	0 (0)	1 (3)	15 (45)	17 (52)	0 (0)
I often participated in the group discussions.	5 (15)	27 (82)	1 (3)	0 (0)	0 (0)
I learned about a healthy lifestyle for the health education sessions.	10 (30)	20 (61)	3 (9)	0 (0)	0 (0)
I enjoyed the student presentations.	14 (42)	18 (55)	1 (3)	0 (0)	0 (0)
I would have liked more student presentations.	4 (12)	17 (52)	8 (24)	1 (3)	3 (9)
I enjoyed the guest speaker presentations.	14 (45)	13 (42)	1 (3)	1 (3)	2 (6)
I would have liked more guest speaker	7 (23)	14 (45)	4 (13)	1 (3)	5 (16)

presentations.					
The information presented was difficult to understand.	0 (0)	0 (0)	20 (67)	10 (33)	0 (0)
I could see the speakers clearly.	13 (42)	17 (55)	1 (3)	0 (0)	0 (0)
I could hear the speakers clearly.	14 (45)	15 (48)	1 (3)	1 (3)	0 (0)

Walk Talk and Listen Program Overall (Intervention Participants)	**Strongly Agree n (%)**	**Agree n (%)**	**Disagree n (%)**	**Strongly Disagree n (%)**	**Don't know n (%)**
The program helped me to feel more comfortable in social situations.	2 (12)	13 (76)	1 (6)	0 (0)	1 (6)
The program helped to improve my emotional and mental wellbeing.	3 (18)	10 (59)	1 (6)	0 (0)	3 (18)
Overall, my lifestyle is healthier since I joined the program.	3 (18)	10 (59)	1 (6)	0 (0)	3 (18)
I am confident that I will continue with regular exercise after the program ends.	5 (29)	10 (59)	2 (12)	0 (0)	0 (0)

Group Auditory Rehab (GAR) sessions (Intervention and Control Participants)	**Strongly Agree n (%)**	**Agree n (%)**	**Disagree n (%)**	**Strongly Disagree n (%)**	**Don't know n (%)**
The meeting room was suitable for the program.	10 (37)	17 (63)		0 (0)	0 (0)
The GAR sessions helped me to recognize and better accept my hearing loss.	22 (39)	31 (55)	2 (3)	0 (0)	2 (3)
The GAR sessions helped me to become more self-confident in speaking out about my hearing loss in social situations.	24 (42)	32 (56)	0 (0.0)	0 (0)	1 (2)
The GAR sessions helped to improve my stress management skills.	6 (11)	36 (63)	7 (12)	0 (0)	8 (14)
The GAR sessions helped me to change my attitude about hearing loss for the better.	19 (33)	35 (61)	2 (4)	0 (0)	1 (2)
The GAR sessions helped me gain more problem solving skills.	9 (16)	41 (73)	1 (2)	0 (0)	5 (9)

Notes: There were no differences between control and intervention groups for GAR session evaluation questions (all $p > 0.05$)

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	x
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	x
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	x
	2b	Specific objectives or research questions for pilot trial	x
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	x
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	x
	4b	Settings and locations where the data were collected	x
	4c	How participants were identified and consented	x
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	x
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	x
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	x
Sample size	7a	Rationale for numbers in the pilot trial	x
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Detailed in a reference article

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	x
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Single blind
	11b	If relevant, description of the similarity of interventions	x
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	x
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	x
	13b	For each group, losses and exclusions after randomisation, together with reasons	x
Recruitment	14a	Dates defining the periods of recruitment and follow-up	x
	14b	Why the pilot trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	x
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	x
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	x
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	x
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	x
	19a	If relevant, other important unintended consequences	x
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	x
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	x
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	x
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	x
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	x
Protocol	24	Where the pilot trial protocol can be accessed, if available	x
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	x
	26	Ethical approval or approval by research review committee, confirmed with reference number	x

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Walk, Talk and Listen: A pilot randomized controlled trial targeting functional fitness and loneliness in older adults with hearing loss.

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Walk, Talk and Listen: A pilot randomized controlled trial targeting functional fitness and loneliness in older adults with hearing loss.

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Abstract

Background: Age-related hearing loss (HL) is a prevalent disability associated with loneliness, isolation, declines in cognitive and physical function and premature mortality. Group audiological rehabilitation (GAR) and hearing technologies address communication and cognitive decline., however, the relationship between loneliness, physical function and GAR among older adults with HL has not been studied.
Objectives: Explore the impact of a group exercise and socialization/health education intervention and GAR on physical function and loneliness among older adults with HL.
Trial design: A YMCA-based 10-week, single-blind, pilot randomized control trial
Participants: Ambulatory adults aged 65 years or older with self-reported HL.
Interventions: Seventy-one participants were screened. Thirty-five were randomized to intervention (strength and resistance exercise, socialization/health education) and GAR (hearing education, communication strategies, psychosocial support) or control (n=31): GAR only.
Outcomes: Ninety-five percent of eligible participants were randomized. GAR and exercise adherence rates were 80% and 85% respectively. 88% of participants completed the study. Intervention group functional fitness improved significantly (gait speed: Effect Size: 0.57, 30-second Sit to Stand Test: Effect size: 0.53). Significant improvements in emotional and social loneliness (Effect size: 1.16) and hearing-related quality of life (HRQL: Effect Size: 0.76) were related to GAR attendance and poorer baseline HRQL. Forty-two percent of participants increased social contacts outside the study.
Discussion: Walk, Talk and Listen was feasible and acceptable. Exercise and socialization/health education improved loneliness and key fitness measures but provided no additional benefit to GAR only for loneliness. This is the first preliminary evidence about the benefits of exercise on fitness and a communication program on loneliness among older adults with HL.
Implications: This pilot trial provides key information on the sample size required for a larger, longer-term RCT to determine the enduring effects of this intervention that addresses the negative psychosocial and musculo-skeletal downstream effects of HL among older adults.

Strengths and Limitations of the study:

- First study to examine the effects of exercise intervention and auditory rehabilitation on functional fitness and loneliness among older adults with HL.
- Fifty seven percent of participants are male: unusual for a community exercise program
- This is an exploratory single blind pilot randomized controlled trial
- There is not a control group with no intervention

BACKGROUND:

Hearing loss (HL) is a prevalent and under recognized disability that is associated with significant psychosocial and physical challenges. Large surveys [1 2] indicate that between 65-77% of North American adults aged 60 to 79 have audiometrically measured HL.

Untreated HL is associated with increased rates of loneliness, social isolation [3 4], depression, accelerated cognitive decline, declines in physical function, gait speed, balance, frailty, increased falls, hospitalizations and premature mortality [5].

These downstream effects of HL are interrelated. Numerous theories exist regarding the mechanism of these associations. One suggests that increased cognitive energy is used to comprehend sound/language, leaving less cognitive reserve for complicated tasks such as memory, social interaction and walking [5]. Work is ongoing in this area [6 7]. Another theory posits that HL–related social isolation and loneliness are linked to the cognitive decline, depression, impaired physical function, falls and mortality among older adults [4 8 9].

Social isolation is an objective measure of lack of contact/interactions with others, [10]while loneliness is a subjective feeling of the lack of meaningful social connections [11]. Linked to HL-related decreases in social participation, loneliness has also been independently associated with depression, cognitive decline, reduced physical functioning, and mortality. (Reviewed in:[12 13]).

Hearing technologies (hearing aids, assistive technologies and cochlear implants) and communication programs (one-on-one or group auditory rehabilitation (GAR)) are the current approaches to treating HL. GAR programs include education about hearing, hearing devices/technologies, enhancing communication skills and psychosocial support [14]. Hearing technologies improve auditory function, cognitive decline, depression and loneliness[15 16] [17]. GAR improves objective measures of social participation (social isolation)[18] and hearing-related quality of life, however, to our knowledge, no studies explore how GAR programs impact loneliness or physical function among older adults with HL.

Group programs for lonely/socially isolated older adults involving interactive shared activities (e.g. social/cultural, educational or physical activities), as opposed to independent activities (e.g. reading or watching TV), improve quality of life, loneliness, [19-22] and in those that included exercise interventions, physical function and premature mortality [23]. [22].

Since HL, loneliness and physical inactivity are inter-related and associated with multiple co-morbidities, it is of interest to explore interventions that improve loneliness and physical function among older adults with HL. In this pilot randomized controlled trial, Walk, Talk and Listen (WTL), we begin to explore the impact of GAR on loneliness and physical function, and importantly, whether addition of an interactive/social group educational and physical strengthening intervention is of any additional benefit in older adults with HL.

Objective:
1) Examine the feasibility and impact of a group exercise and socialization/health education intervention added to GAR on physical function, hearing-related quality of life and loneliness among older adults with HL.

DESIGN AND METHODS:
Patient and public involvement: Twenty-eight older adults with HL participated in the design of the intervention for this clinical trial [24]. WTL participants helped, by word of mouth, to recruit several other participants. WTL participants provided ongoing and end of study feedback and helped to disseminate the trials results. One participant and the principle investigator continue to deliver GAR sessions twice a year in the local community.

Detailed Walk, Talk and Listen (WTL) methodology is reported elsewhere [25]. Briefly, in partnership with the YMCA Okanagan, WTL was a 10-week prospective single-blind randomized controlled pilot trial of interactive GAR (control) versus GAR plus interactive socialization/health education (SHE) and strengthening exercises in community-dwelling, ambulatory older adults (age 55 or above) with self-reported [26] HL. (clinicaltrials.gov NCT02662192. Registered Jan 14, 2016). Participants were recruited over the two-month period preceding the trial (September 2017 through March 2017) through local newspaper ads, strategically placed posters and word of mouth. Potential participants contacting the trial center underwent preliminary telephone eligibility assessment after the study was briefly described and verbal consent obtained. At the YMCA, eligible [25] participants signed informed consent and underwent baseline (week 0) and follow-up (week 11) assessments completed by trained students and research team members. All procedures included groups of 10-20 participants and took place in a small, acoustically favorable meeting room and/or a small gym at the same YMCA site over a period of 10 weeks. One hour control group GAR-only sessions occurred once a week. Intervention group one-hour GAR sessions were followed by 60 minutes of exercise (strength, resistance and coordination training: 45 minutes) and walking (outside or on indoor track: 15 minutes). On their second weekly visit, intervention participants attended a one-hour interactive SHE session [25] followed by 60 minutes of exercise and walking. A certified YMCA trainer facilitated the exercise sessions. Participants were encouraged to walk between sessions and were provided a pedometer and tracking sheets to motivate them. At study end, control participants were offered the exercise program and provided a pedometer. Trained students helped the principle investigator facilitate the GAR and SHE sessions. Interactive GAR sessions were guided by a modification of the GROUP program [27] and provided hearing education, goal setting and psychosocial and behavior change exercises including mindfulness, acceptance of HL, assertiveness training, communication strategies, problem-solving, anticipatory and repair strategies. Participants were encouraged to review class handouts with their communication partners (spouse, significant other or friend). One three-hour large-group communication partner session was held near the end of the study.

Feasibility and acceptability:
Measures assessing feasibility included recruitment strategies and rates, acceptability/willingness to be randomized, adverse events, GAR attendance rates, overall retention rates, and acceptability of the GAR and exercise components assessed by follow-up (end of study) questionnaire. A priori, it was decided that a definitive RCT would be feasible if at least 120

individuals contacted the pilot trial center, ≥ 90% of eligible participants were randomized and 70 % of those completed the study. The WTL intervention was acceptable if at least 85% of participants found the GAR, exercise and SHE sessions highly acceptable or acceptable.

Participant-specific outcomes:
Demographic data was collected at baseline (week 0), the remaining measures were collected at baseline and follow-up (week 11).

Standard functional fitness outcomes included 30-Second Chair Stand Test (STS) [28], gait speed (GS): 6-Minute Walk Test (6MWT) [29], Timed Up and Go Test (TUG) [29] and the one-foot balance test [30], grip strength [31], Chair Sit and Reach test [32] and the Back Scratch [33].

Psychosocial measures included hearing and health–related quality of life (Hearing Handicap Inventory for the Elderly [HHIE-25]) [26]) and The Rand SF-36 [34] respectively, de Jong loneliness [35], social support (the Medical Outcomes Trial-Social Support Survey [36]), and depression (Geriatric Depression Scale [37]).

Group Auditory Rehabilitation evaluation:
The international outcomes inventory-alternative interventions (IOI-AI) [38] and the modified Client Oriented Scale of Improvement (COSI) questionnaires [39] were completed by all participants at follow-up. A follow-up evaluation questionnaire assessed the acceptability of the exercise and GAR sessions, acceptance and attitude about their HL, HL-related problem solving, stress management, and self confidence in social situations.

Sample size:
At least 23 people per group were needed to show a clinically meaningful increase in Sit To Stands of 2 or more [40]: the primary fitness outcome. This was inflated by 20% to account for drop outs and ensured generation of a reliable standard error (SE), standard deviation (SD) and 95% confidence intervals (CI) on the sample size required for a large RCT with this measure as the primary outcome [41].

Statistical methods
Categorical data was expressed as frequency and percentage (e.g. recruitment, adherence, overall retention rates. Continuous data were expressed as mean plus standard deviation or median and interquartile range (for non-normal data). Baseline data was compared between groups using the independent samples t-test or Mann Whitney U test where appropriate. Intention-to-treat (ITT) analyses were conducted to examine change over time in functional fitness and psychosocial measures. Effect sizes (ES) [42] and 95% confidence intervals for within group changes and between group differences are reported. Confounding and effect modification were examined using linear regression modeling with the change score as the dependent variable. GAR attendance was determined a priori as a potential confounding factor and HHIE was included post-hoc to account for the unanticipated baseline differences. All results are presented as ITT using the baseline observation carried forward to produce the most conservative results. Analyses were conducted in Stata S/E Version 15 (Stata® (StataCorp. Stata Statistical Software: Release 15, College Station, TX, USA: StataCorp LLC)) and $p<0.05$ was considered statistically significant.

RESULTS:

Feasibility: The Walk, Talk and Listen CONSORT diagram is shown in Figure 1. One hundred and thirty-seven individuals contacted the study center, 119 completed the initial phone screen, and 71 completed full eligibility screening. Ninety-six percent of eligible participants (n=69) were randomized (n=66) and 88% of participants (n=58) completed the study. GAR and exercise attendance rates were 80% and 85% respectively. There was one adverse event (fall with hip fracture) within the trial during an exercise session and two outside the study in control group participants (one fall with hip fracture, one foot infection). Primary reasons for ineligibility included, too young (33%) and no self-reported HL (67%). Newspaper ads were the most successful recruitment strategy (74%) followed by word of mouth (18%), and community posters or social media (8%) (data not tabled). The main reasons for withdrawal during enrollment (n=42) were time commitment (50%) and inconvenient location (24%).

Baseline measures (Table 1): Among the 66 participants in the study, the mean age was 74.5 years, 57% were male, 94% Caucasian, 67% married/common-law, 64% had completed some college/university or above 54% reported an annual household income above $(CDN) 50,000.00, and 88% were retired. Ten participants used mobility or balance aids, just over half used hearing aids and 11 reported one or more falls in the previous 3 months. Groups did not differ on any functional fitness or psychosocial measure with the exception of the total HHIE score (Control median=56; Intervention Median=38; p=0.045).

Table 1. Baseline demographics, functional fitness, and psychosocial measures, by group (control N = 31; intervention N = 35) and for the overall sample (N=66).

Demographics	**Control n (%)**	**Intervention n (%)**	**Overall n (%)**
Age (years), Mean (SD)	74.8 (6.1)	74.3 (6.3)	74.5 (6.2)
Male gender	17 (54.8)	21 (60.0)	38 (57.6)
Caucasian Ethnicity	30 (96.8)	32 (91.4)	62 (93.9)
Married/Common law	22 (71.0)	22 (62.9)	44 (66.7)
College/University/Graduate Studies	19 (61.3)	23 (65.7)	42 (63.6)
Annual Income >$50,000	18 (60.0)	17 (48.6)	35 (53.9)
Retired	29 (93.6)	29 (82.9)	58 (87.9)
Living Alone	10 (32.3)	9 (25.7)	19 (28.8)
Uses Mobility or Balance Aids	6 (19.4)	4 (11.4)	10 (15.2)
Wears Hearing Aids	18 (58.1)	17 (48.6)	35 (53.0)
Any Falls in the Past Three months	7 (22.6)	4 (11.4)	11 (16.7)
Functional Fitness Measures	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
Gait speed (m/s)	1.25 (0.20)	1.28 (0.25)	1.26 (0.23)
Sit-To-Stand (30s)	12.7 (3.2)	12.9 (2.7)	12.8 (2.9)
Grip Strength (kg)	68.0 (19.4)	71.5 (21.6)	69.8 (20.5)
8ft Get up and Go (s)	6.4 (1.9)	6.1 (1.5)	6.3 (1.7)
Sit and Reach (cm)	-4.6 (20.8)	-1.9 (20.9)	-3.2 (20.8)
Back Scratch (cm)	-38.8 (21.0)	-39.7 (25.5)	-39.2 (23.3)

Balance (s)	49.3 (33.3)	45.9 (34.2)	47.5 (33.5)
Psychosocial Measures	**Median (IQR)**	**Median (IQR)**	**Median (IQR)**
HHIE Total	56 (28, 68)	38 (24, 56)	46 (26, 64)
Emotional Subscale	30 (14, 40)	18 (14, 30)	20 (14, 32)
Social Subscale	26 (16, 32)	18 (12, 30)	24 (14, 30)
de Jong Loneliness Total	7 (3, 10)	6 (2, 9)	7 (3, 9)
Emotional Loneliness	3 (1, 5)	3 (0, 5)	3 (0, 5)
Social Loneliness	3 (2, 5)	4 (1, 5)	3 (2, 5)

IQR: Interquartile Range, SD: Standard Deviation

Change in functional fitness and psychosocial measures (Table 2): After adjusting for baseline HHIE imbalance, gait speed improved more in the intervention group compared to the control group by an average of 0.05 m/s (95% CI=0.0,0.09; p=0.046; ES=0.57). Compared to the control group, STS in the intervention group improved significantly more than the control group by an average of 1.0 STS (95% CI=0.1, 2.0; p=0.037; ES=0.53). Back scratch improved by an average of 4cm more in the intervention group compared to the control group (95% CI=0.2, 7.7; p=0.039; ES=0.54). The de Jong emotional loneliness subscale showed greater improvement in the control group: average difference in change of 0.6 (95% CI=0.1, 1.2; p=0.043; ES=-0.54). There were no significant differences for GDS, MOS social support or SF-36 measures (all p>0.05) (Supplement 1).

Table 2. Mean change and difference between control and intervention groups for functional fitness and loneliness, adjusted for baseline HHIE score.

Functional Fitness	**Control Group Mean Δ (95%CI)**	**Intervention Group Mean Δ (95% CI)**	**Difference between groups Mean Δ (95% CI)**	**Effect Size**
Gait Speed (m/s)	0.07 (0.04, 0.11)	0.12 (0.09, 0.15)	0.05 (0.0, 0.09) *	0.57
Sit-To-Stand (30 s)	0.6 (-0.1, 1.3)	1.6 (1.0, 2.3)	1.0 (0.1, 2.0) *	0.53
8ft Get up and Go (s)	-0.5 (-0.9, -0.2)	-0.8 (-1.1, -0.5)	-0.3 (-0.8, 0.2)	0.32
Grip Strength (kg)	1.3 (-0.8, 3.5)	2.8 (0.8, 4.8)	1.5 (-1.5, 4.5)	0.26
Sit and Reach (cm)	0.8 (-3.6, 5.2)	3.6 (-0.5, 7.8)	2.8 (-3.3, 9.0)	0.23
Back Scratch (cm)	0.0 (-2.7, 2.7)	4.0 (1.4, 6.5)	4.0 (0.2, 7.7) *	0.54
Balance (s)	6.0 (0.1, 11.9)	6.8 (1.2, 12.3)	0.8 (-7.4, 9.1)	0.05
de Jong Loneliness Total	-1.5 (-2.1, -0.9)	-0.9 (-1.4, -0.3)	0.6 (-0.2, 1.5)	-0.35
Emotional Subscale	-0.9 (-1.3, -0.5)	-0.3 (-0.7, 0.1)	0.6 (0.1, 1.2) *	-0.54
Social Subscale	-0.6 (-1.2, -0.1)	-0.5 (-1.0, -0.1)	0.1 (-0.6, 0.8)	-0.07

Notes: *$p < 0.05$, Mean Δ**: mean change, 95% CI: 95% confidence interval, s: seconds**

Improvements in HHIE and de Jong loneliness were influenced by GAR attendance (Table 3). Total, emotional and social HHIE subscales showed significant improvement for those who attended ≥ 80% of GAR sessions: total: 95% CI=-19.7, -2.6; p=0.012; ES=0.76, emotional: 95% CI=-11.0, -1.1; p=0.018; ES=0.71, social: 95% CI=-9.5, -0.8; p=0.022; ES=0.69, regardless of

group assignment. Similarly, those with ≥80% GAR attendance had a greater decrease in de Jong total (95% CI=-2.7, -0.9; p=<0.001; ES=1.16) and emotional loneliness (95% CI=-1.7, -0.4; p=0.002; ES=0.96).

Table 3. Impact of group and GAR attendance on mean change and difference in change for the HHIE and de Jong loneliness scales (N=57).

	Hearing handicap for the elderly			**de Jong loneliness and isolation**		
Gar attendance	Total Score **Mean Δ 95% CI**	Emotion Subscale **Mean Δ 95% CI**	Social Subscale **Mean Δ 95% CI**	Total Score **Mean Δ 95% CI**	Emotion Subscale **Mean Δ 95% CI**	Social Subscale **Mean Δ 95% CI**
<80% attendance	1.3 -6.0, 8.6	-0.1 -4.3, 4.1	1.4 -2.3, 5.1	0.2 -0.6, 1.0	0.2 -0.4, 0.8	0.0 -0.7, 0.7
≥80% attendance	-9.8 -14.0, -5.6	-6.1 -8.5, -3.7	-3.7 -5.9, -1.6	-1.6 -2.1, -1.2	-0.8 -1.1, -0.5	-0.8 -1.2, -0.4
Group Difference	-11.1 -19.7, -2.6	-6.0 -11.0, -1.1	-5.1 -9.5, -0.8	-1.8 -2.7, -0.9	-1.0 -1.7, -0.4	-0.8 -1.6, 0.1
p	0.012	0.018	0.022	<0.001	0.002	0.061
Effect Size	0.76	0.71	0.69	1.16	0.96	0.58

GAR evaluation: At study end, participant responses to the seven IOI-IA questions (Table 4) revealed that 67% of participants were using GAR communication strategies on a daily basis for at least one hour. The majority reported moderate or greater benefit from using GAR strategies, satisfaction with the GAR program, and improvement in participation restrictions (visiting friends/relatives less than desired), and activity limitations (difficulty hearing TV or speech). COSI results were favorable overall (Supplement 2). Participants reported slightly better or greater progress in their goals of improving "conversations with one or two or a group of people in a quiet environment" (67%) or "noisy" environment (53%), half (51%) felt less embarrassed or stupid and 42% increased the amount of their social contact (such as attending more social events, social situations or going out in public).

Table 4. Percent distribution of participant responses for each item on the IOI-IA at follow-up (N=57).

Item	Percent (%) Reported				
	None	<1 hr/day	1-4 hr/day	4-8 hr/day	>8 hr/day
Use %	3.5	29.8	49.1	12.3	5.3
	Not at all	Slightly	Moderately	Quite a lot	Very much
Benefit %	0	35.1	29.8	31.6	3.5
Sat %	0	8.8	19.3	28.1	43.8
	Very much	Quite a lot	Moderate	Slight	None
RAL %	3.5	3.5	49.1	38.6	5.3
RPR %	0	17.6	31.6	36.8	14.0
Ioth %	0	3.5	17.2	48.3	31.0
	Worse	No change	Slightly	Quite a lot	Very much
QOL %	0	10.3	44.8	38.0	6.9

Notes: RAL = residual activity limitations; Sat = satisfaction; RPR = residual participating restrictions; Ioth = impact on others; QOL = quality of life

[a]Statistically significant difference between control and intervention groups (Control: Not at all = 0%, Slightly = 26.9%, Moderately = 19.2%, Quite a lot = 46.2%, Very much = 7.7%; Intervention: Not at all = 0%, Slightly = 41.9%, Moderately = 38.7%, Quite a lot = 19.4%, Very much = 0%; $p = 0.040$)

Program evaluation (Supplement 3) questionnaires were filled out by 24 control group and 33 intervention group participants. The data revealed that a large proportion of both groups agreed or strongly agreed that GAR helped them: better recognize and accept their HL (93%); be more confidant to speak out about their HL in social situations (98%); and to have a better attitude toward HL (95%). The majority (89%) felt that GAR helped them improve their problem-solving abilities. Intervention group participants reported that they were satisfied with the exercise (100%) and reported it was fun (100%). The majority (75%) indicated they increased their physical activity level outside the program, and 88% were confident they would continue with regular exercise after the program ended. When asked what could improve the program, participants favored a larger GAR session room, more emphasis on hearing assistive technologies (telephones, for example) with presentations by commercial companies producing these items, better acoustics in the gym (e.g. no fan noise in the background) with an improved sound system and instructors that could speak more slowly and clearly (data not tabled).

DISCUSSION:

In this pilot trial, the feasibility, acceptability and preliminary evidence for the efficacy of a group auditory rehabilitation, socialization/health education and exercise intervention for older adults with HL was evaluated. Recruitment and retention rates suggested the study was well received. Walk, Talk and Listen was found to be feasible and highly acceptable. Strengthening, resistance and coordination exercises coupled with GAR and socialization/health education improved lower extremity strength, gait speed and upper body flexibility. While exercise

improved these key functional fitness measures, it provided no additional benefit beyond GAR alone for measures of hearing-related quality of life (HHIE) and loneliness. Significant improvements in hearing-related quality of life (HHIE), total and emotional loneliness were found for those attending ≥ 80% of the GAR sessions and in those with the poorest baseline self-reported hearing handicap (HHIE). Delivery of GAR by a non-audiologist health provider appeared to be of similar benefit to participants as seen in the literature. To our knowledge, this is the first study to provide an approach to the treatment of HL in older adults that addresses HL-related activity limitations, participation restrictions in addition to physical function (impaired musculoskeletal function), and that showed an improvement in total and emotional loneliness.

Feasibility and acceptability.
Implementation of the Walk, Talk and Listen proved to be feasible and acceptable to participants. Recruitment strategies, randomization, study implementation and study completion rates (88%) reached the a priori required feasibility goals and more than 95% of participants found the program acceptable/highly acceptable.

Functional physical fitness changes.
Preliminary evidence for efficacy of the exercise intervention on physical function was determined using effect sizes in order to help decide upon future sample size considerations. Effect sizes were calculated on a small sample, therefore need to be interpreted with that in mind [43]. They suggest that the physical activity and GAR interventions were of some benefit and deserve further investigation in a larger sample.

The WTL exercise intervention was associated with significant improvements in two major functional fitness measures (gait speed; ES 0.57 and 30 sec STS; ES0.53) which have been associated with reduced risk for falls and improved maintenance of physical independence [33]. Adherence to the exercise intervention was excellent and end of study evaluations indicated that participants were satisfied with the exercise sessions. Lower body muscle strengthening and improved gait speed are expected to provide long-term benefit as shown in a prospective analysis of longitudinal data from NHANES (2003-2006) where adults with at least moderate HL who undertook two+ sessions/week of muscle strengthening exercises were at a 71% reduced risk of 7-year all-cause mortality [44]. However, static (one foot stand) or dynamic (Timed Up and Go) balance was not improved. Furthermore, there was one fall during a fast-paced “tag”-like exercise where a participant tripped on another participant’s foot. While published rates of falls during fall prevention programs range from 5-25% (depending on baseline risk for falls) [45], these findings have important implications for the design of future exercise interventions. Rather than rapid agility/coordination exercises, exercises should include more balance training such as the in-home or facility-based Otago Falls prevention exercise program or Tai Chi [46] which have been shown to reduce falls in the general population of older adults. Incorporation of these focused exercises may be more effective in improving balance in those with HL. The improvement in gait speed and lower extremity muscle strength seen in this pilot trial are encouraging and suggest that such an intervention, if carried on longer term, and which includes more aggressive balance training might be of survival benefit in older adults with HL.

Hearing and health-related quality of life, loneliness and social network.

Improvements in loneliness, participation restrictions and activity limitations were related to higher (worse) baseline HHIE (hearing-related quality of life) and higher GAR attendance. Hearing-related quality of life has been found to be an effect modifier in other studies. Using a similar assessment of hearing-related quality of life (Hearing Attitudes to Rehabilitation Questionnaire) [39] found that higher baseline scores in this measure were also associated with greater benefit from a GAR program for participation restrictions and activity limitations. The addition of exercise to GAR was of no added benefit for any of the psychosocial outcomes. This was an unexpected finding given the proven benefits of exercise in many of these realms [47]. It is unknown as to whether poorer hearing-related quality of life supersedes the psychosocial benefits of exercise. Further research is need in order understand this interaction

That GAR attendance had a strong influence on psychosocial outcomes is consistent with the findings of others who have found that GAR attendance is imperative for optimizing the outcomes of GAR [48]. Our adherence rates of 87% were comparable to other group-based communication programs where rates ranged from 56-68% [18] to 96% [49].

The association between untreated HL and loneliness is well known [35]. Treatment with cochlear implantation [17] and provision of hearing aids [16] has been shown to reduce loneliness in older adults with audiometrically measured mild to severe HL. To the authors knowledge, only one study has looked at the effect of AR on loneliness. In this study [50], participants were provided with an assistive hearing device (not a HA) and with their CP undertook a one-time 1.6-2-hour AR session delivered by a trained clinician. Participants were given auditory rehabilitation manuals and workbooks to complete at home. Despite a significant decrease in HHIE at 3 months, loneliness (as measured by the UCLA loneliness scale) increased. In the current study, greater improvements in emotional loneliness were seen among those with higher baseline HHIE scores. However, even greater benefit in both total and emotional loneliness was realized by those with higher GAR attendance compared with poor attenders, who saw no benefit.

Furthermore, while social isolation was not formally assessed, the COSI results indicate that 42 percent of participants increased the amount of their social contact (such as attending more social events, social situations or going out in public) which might be expected to decrease social isolation if maintained over time.

While group or home auditory rehabilitation improves hearing-related quality of life, it appears that group contact may more conducive than home-based auditory rehabilitation to addressing loneliness.

Health-related quality of life:

Health-related quality of life, as assessed using the RAND SF36, did not show change by group assignment, GAR attendance or baseline HHIE score. This finding is in agreement with others who also used generic health-related quality of life tools (World Health Organization Disability Assessment Schedule II (WHODASII) [51] [49]: Short-Form 36 (SF-36) [39]) as a communication program outcome measure. This was not unexpected given that the content of this questionnaire has little to do with communication and supports our finding that added exercise and health education did affect generic quality of life measures.

GAR evaluation.
Together, the GAR evaluation tools (IOI-IA, COSI and qualitative feedback) suggested that the GAR program was highly appreciated, benefited and improved self-efficacy of participants. When compared with other studies where communication strategies and psychosocial counselling were key features of GAR, improvement in HHIE (ES=0.69-0.76) was similar to that in one study (ES 0.67-0.78) [49] and slightly greater than that in another (ES =0.25) [39]. Furthermore, outcomes in all domains of the IOI-IA and relevant COSI outcomes compared favorably with these same established communication programs [38 39 49]. Inclusion of communication strategies and facilitating behavior change was associated with enhanced self-efficacy a consistent finding in the literature [52 53]. As participants gain confidence in managing their HL and achieving their communication and social goals, their hearing-related quality of life improves [49 51]. These findings are encouraging and add to the emerging evidence suggesting that with adequate training and resources, a non-audiologist may help to build capacity for increased access to effective community-based GAR programming [54-56].

Strengths and Limitations:
This study had several strengths: 57% of our participants were male. While not uncommon for GAR interventions, it is uncommon to see > 30% of males participating in community-based exercise programs [57 58]. This may simply reflect the higher prevalence of HL in men, or some other factor: qualitative work is underway to examine this.

In this pilot trial, a control group receiving no intervention was not included. This would have made for a more accurate determination the effects of GAR. However, one potential interpretation is that GAR can be effective when given alone or part of a more holistic health behaviour intervention. Secondly, participants were self-selected which may have introduced a bias favoring positive outcomes [59]. However, recruitment occurred in the 'real world" community setting and is representative of the population of hearing impaired older adults that have reached the stage of hearing help seeking. Thirdly, the baseline difference between groups in the baseline HHIE scores is likely due to the small sample size. Although comparisons were reported in terms of relative improvements and not strict comparisons, this should be noted as a potential bias. This study provided only immediate post-program results and may have been underpowered to detect changes in the other fitness measures. There is a need for more longitudinal follow-up in a larger sample to determine if the positive changes can be sustained.

Finally, this is the first study to obtain preliminary information on the effectiveness of an exercise intervention to improve functional fitness, and GAR to improve total and emotional loneliness and social support in older adults with self-reported HL. GAR lead by non-audiologist shows potential as a way to improve the accessibility of GAR programs.

Age-related HL is a prevalent, under recognized and significant disability that when untreated is associated with profound negative downstream effects. This study contributes to emerging evidence of the benefit of providing accessible community-based communication programs delivered outside the traditional audiology clinical setting. Addition of an exercise component shows at least short-term functional fitness benefits. Further research is needed to determine the long-term benefits of combining communication and exercise programs on the bio-psychosocial domains among older adults with HL.

Implications:
A larger, long-term study is needed to determine the enduring effects of this novel, community-based, holistic intervention in addressing both the negative psychosocial and functional physical effects of HL among older adults. Use of the home or facility-based Otago falls prevention exercise program (muscle strengthening and a more focused approach to balance training) may be necessary to improve balance in older adults with HL. Face-to-face GAR sessions may be necessary in order to provide additional benefits on loneliness and social support. Provision of GAR by students and non-audiologists may improve accessibility of audiological rehabilitation programs.

Figure 1: Participant time line: Consolidated Standards of Reporting Trials (CONSORT)-style flow chart

References

1. Lin FR, Niparko JK, Ferrucci L. Hearing loss prevalence in the United States. *Arch. Intern. Med.* 2011;171(20):1851-2.
2. Canada S. Hearing Loss of Canadians, 2012 to 2015. In: Canada S, ed. Ottawa, 2016.
3. Mick P, Kawachi I, Lin FR. The Association between Hearing Loss and Social Isolation in Older Adults. *Otolaryngol. Head Neck Surg.* 2014;150(3):378-84.
4. Strawbridge WJ, Wallhagen MI, Shema SJ, Kaplan GA. Negative Consequences of Hearing Impairment in Old Age: A Longitudinal Analysis. *The Gerontologist* 2000;40:320-26.
5. Davis A, McMahon CM, Pichora-Fuller KM, et al. Aging and Hearing Health: The Life-course Approach. *Gerontologist* 2016;56 Suppl 2:S256-67.
6. Agmon M, Lavie L, Doumas M. The Association between Hearing Loss, Postural Control, and Mobility in Older Adults: A Systematic Review. *J. Am. Acad. Audiol.* 2017;28(6):575-88.
7. Bruce H, Lai L, Bherer L, Lussier M, St-Onge N, Li KZH. The effect of simultaneously and sequentially delivered cognitive and aerobic training on mobility among older adults with hearing loss. *Gait Posture* 2019;67:262-68.
8. Seeman TE. Health promoting effects of friends and family on health outcomes in older adults. *Am. J. Health Promot.* 2000;14:362-70.
9. Berkman LF, Glass T, Brissette I, Seeman TE. From social integration to health: Durkheim in the new millennium. *Soc. Sci. Med.* 2000;51:843-57.
10. Leigh-Hunt N, Bagguley D, Bash K, et al. An overview of systematic reviews on the public health consequences of social isolation and loneliness. *Public Health* 2017;152:157-71.
11. Savikko N, Routasalo P, Tilvis RS, Strandberg TE, Pitkala KH. Predictors and subjective causes of loneliness in an aged population. *Arch. Gerontol. Geriatr.* 2005;41(3):223-33.
12. Rico-Uribe LA, Caballero FF, Martin-Maria N, Cabello M, Ayuso-Mateos JL, Miret M. Association of loneliness with all-cause mortality: A meta-analysis. *PLoS One* 2018;13(1):e0190033.
13. Contrera KJ, Betz J, Genther DJ, Lin FR. Association of Hearing Impairment and Mortality in the National Health and Nutrition Examination Survey. *JAMA Otolaryngol Head Neck Surg* 2015;141(10):944-6.
14. Millett P, Jutras B, Noel G, Pichora-Fuller K, Watson C, Nelson A. Canadian Guideline on Auditory Processing Disorder in Children and Adults: Assessment and intervention:

Canadian Interorganizational Steering Group for Audiology and Speech-Language Pathology, 2012.
15. Contrera KJ, Sung YK, Betz J, Li L, Lin FR. Change in loneliness after intervention with cochlear implants or hearing aids. *Laryngoscope* 2017.
16. Weinstein BE, Sirow LW, Moser S. Relating Hearing Aid Use to Social and Emotional Loneliness in Older Adults. *Am J Audiol* 2016;25(1):54-61.
17. Poissant SF, Beaudoin F, Huang J, Brodsky J, Lee DJ. Impact of cochlear implantation on speech understanding, depression, and loneliness in the elderly. *J. Otolaryngol. Head Neck Surg.* 2008;37(4):488-94.
18. Laplante-Levesque A, Hickson L, Worrall L. Rehabilitation of older adults with hearing impairment: a critical review. *J. Aging Health* 2010;22(2):143-53.
19. Hwang J, Wang L, Siever J, Medico TD, Jones CA. Loneliness and social isolation among older adults in a community exercise program: a qualitative study. *Aging & mental health* 2018:1-7.
20. Cohen-Mansfield J, Perach R. Interventions for Alleviating Loneliness Among Older Persons: A Critical Review. *Am. J. Health Promot.* 2015.
21. Gardiner C, Geldenhuys G, Gott M. Interventions to reduce social isolation and loneliness among older people: an integrative review. *Health & social care in the community* 2018;26(2):147-57.
22. Pitkala KH, Routasalo P, Kautiainen H, Tilvis RS. Effects of psychosocial group rehabilitation on health, use of health care services, and mortality of older persons suffering from loneliness: a randomized, controlled trial. *J. Gerontol. A Biol. Sci. Med. Sci.* 2009;64(7):792-800.
23. McPhee JS, French DP, Jackson D, Nazroo J, Pendleton N, Degens H. Physical activity in older age: perspectives for healthy ageing and frailty. *Biogerontology* 2016;17(3):567-80.
24. Jutras M, Lambert J, Hwang J, et al. Targeting the psychosocial and functional fitness challenges of older adults with hearing loss: a participatory approach to adaptation of the Walk and Talk for your Life program *Int. J. Audiol.* 2018.
25. Lambert J, Ghadry-Tavi R, Knuff K, et al. Targeting functional fitness, hearing and health-related quality of life in older adults with hearing loss: Walk, Talk 'n' Listen, study protocol for a pilot randomized controlled trial. *Trials* 2017;18(1):47.
26. Chang H-P, Ho C-Y, Chou P. The Factors Associated with a Self-Perceived Hearing Handicap in Elderly People with Hearing Impairment Results from a Community-Based Study. *Ear Hear.* 2009;30:576-83.
27. Montano JJ, Preminger JE, Hickson L, Gregory M. A new web-based tool for group audiologic rehabilitation. *Am J Audiol* 2013;22(2):332-4.
28. Tiedemann A, Shimada H, Sherrington C, Murray S, Lord S. The comparative ability of eight functional mobility tests for predicting falls in community-dwelling older people. *Age Ageing* 2008;37(4):430-5.
29. Steffen TM, Hacker TA, Mollinger L. Age- and gender-related test performance in community-dwelling elderly people: Six-Minute Walk Test, Berg Balance Scale, Timed Up & Go Test, and gait speeds. *Phys. Ther.* 2002;82(2):128-37.
30. Springer BA, Marin R, Cyhan T, Roberts H, Gill NW. Normative values for the unipedal stance test with eyes open and closed. *J. Geriatr. Phys. Ther.* 2007;30(1):8-15.
31. Leong DP, Teo KK, Rangarajan S, et al. Prognostic value of grip strength: findings from the Prospective Urban Rural Epidemiology (PURE) study. *Lancet* 2015;386:266-73.

32. Jones CJ, Rikli RE, Max J, Noffal G. The reliability and validity of a chair sit-and-reach test as a measure of hamstring flexibility in older adults. *Res. Q. Exerc. Sport* 1998 69:338-43.
33. Rikli RE, Jones CJ. Development and validation of criterion-referenced clinically relevant fitness standards for maintaining physical independence in later years. *Gerontologist* 2013;53(2):255-67.
34. Ware JE, Jr., Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF- 36): I. Conceptual Framework and Item Selection *Med. Care* 1992;30:473-83.
35. de Jong-Gierveld J, ; Kamphuis, F. The Development of a Rasch-Type Loneliness Scale. *Appl. Psychol. Meas.* 1985;9:289-99.
36. Sherbourne CD, Stewart AL. The MOS social support survey. *Soc. Sci. Med.* 1991;32(6):705-14.
37. Vinkers DJ, Gussekloo J, Stek ML, Westendorp RG, Van Der Mast RC. The 15-item Geriatric Depression Scale (GDS-15) detects changes in depressive symptoms after a major negative life event. The Leiden 85-plus Study. *Int. J. Geriatr. Psychiatry* 2004;19(1):80-4.
38. Hickson L, Worrall L, Scarinci N. Measuring outcomes of a communication program for older people with hearing impairment using the International Outcome Inventory. *Int. J. Audiol.* 2006;45(4):238-46.
39. Hickson L, Worrall L, Scarinci N. A randomized controlled trial evaluating the active communication education program for older people with hearing impairment. *Ear Hear.* 2007;28(2):212-30.
40. Jones CJ, Rikli RE, Beam WC. A 30-s chair-stand test as a measure of lower body strength in community-residing older adults. *Res. Q. Exerc. Sport* 1999;70(2):113-9.
41. Whitehead AL, Julious SA, Cooper CL, Campbell MJ. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Stat. Methods Med. Res.* 2016;25(3):1057-73.
42. Cohen J. *Statistical power analysis for the behavioral sciences.* 2nd ed ed. Hillsdale, NJ, USA: Lawrence Earlbaum Associates, 1988.
43. Durlak JA. How to select, calculate, and interpret effect sizes. *J. Pediatr. Psychol.* 2009;34(9):917-28.
44. Loprinzi PD. Muscle strengthening activities and mortality with considerations by hearing sensitivity. *Int. J. Audiol.* 2016;55(5):320-2.
45. Sherrington C, Michaleff ZA, Fairhall N, et al. Exercise to prevent falls in older adults: an updated systematic review and meta-analysis. *Br. J. Sports Med.* 2017;51(24):1750-58.
46. Gillespie LD, Robertson MC, Gillespie WJ, et al. Interventions for preventing falls in older people living in the community. *Cochrane Database Syst Rev* 2012(9):CD007146.
47. Gaz DV, Smith AM. Psychosocial benefits and implications of exercise. *PM R* 2012;4(11):812-7.
48. Chisolm TH, Saunders GH, Frederick MT, McArdle RA, Smith SL, Wilson RH. Learning to listen again: the role of compliance in auditory training for adults with hearing loss. *Am J Audiol* 2013;22(2):339-42.
49. Preminger JE, Yoo JK. Do group audiologic rehabilitation activities influence psychosocial outcomes? *Am J Audiol* 2010;19(2):109-25.

50. Nieman CL, Marrone N, Mamo SK, et al. The Baltimore HEARS Pilot Study: An Affordable, Accessible, Community-Delivered Hearing Care Intervention. *Gerontologist* 2016.
51. Preminger JE, Ziegler CH. Can auditory and visual speech perception be trained within a group setting? *Am J Audiol* 2008;17(1):80-97.
52. Smith SL, West RL. The application of self-efficacy principles to audiologic rehabilitation: a tutorial. *Am J Audiol* 2006;15(1):46-56.
53. Marrone N, Ingram M, Somoza M, et al. Interventional Audiology to Address Hearing Health Care Disparities: Oyendo Bien Pilot Study. *Semin Hear* 2017;38(2):198-211.
54. Sanchez D, Adamovich S, Ingram M, et al. The Potential in Preparing Community Health Workers to Address Hearing Loss. *J. Am. Acad. Audiol.* 2017;28(6):562-74.
55. Nieman CL, Lin FR. Increasing access to hearing rehabilitation for older adults. *Curr. Opin. Otolaryngol. Head Neck Surg.* 2017;25(5):342-46.
56. Preminger JE. Issues associated with the measurement of psychosocial benefits of group audiologic rehabilitation programs. *Trends in amplification* 2007;11(2):113-23.
57. Clare L, Nelis SM, Jones IR, et al. The Agewell trial: a pilot randomised controlled trial of a behaviour change intervention to promote healthy ageing and reduce risk of dementia in later life. *BMC Psychiatry* 2015;15:25.
58. Gandy R, Bell A, McClelland B, Roe B. Evaluating the delivery, impact, costs and benefits of an active lives programme for older people living in the community. *Prim. Health Care Res. Dev.* 2016:1-13.
59. Knudsen LV, Oberg M, Nielsen C, Naylor G, Kramer SE. Factors influencing help seeking, hearing aid uptake, hearing aid use and satisfaction with hearing aids: a review of the literature. *Trends in amplification* 2010;14(3):127-54.

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Ethical approval: The study was approved by the University of British Columbia Okanagan Research Services Behavioural Research Ethics Board. UBC BREB number: H15-02319. Written consent was obtained for all participants.

Competing interests: The authors have no conflicts of interest to report.

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Data Sharing:
UBC library Data Management Repository — UBC Library has implemented a robust data management software – Abacus Dataverse – collaborating with Harvard and supporting other BC schools (UNBC, UVic and SFU). The system is designed to manage and preserve data and it is opened to UBC researchers, labs and institutes. UBC will then assign DOI's to the UBC Library

digital datasets, via our Open Collections portal. DOIs increase the further citability and discoverability of UBC research data.

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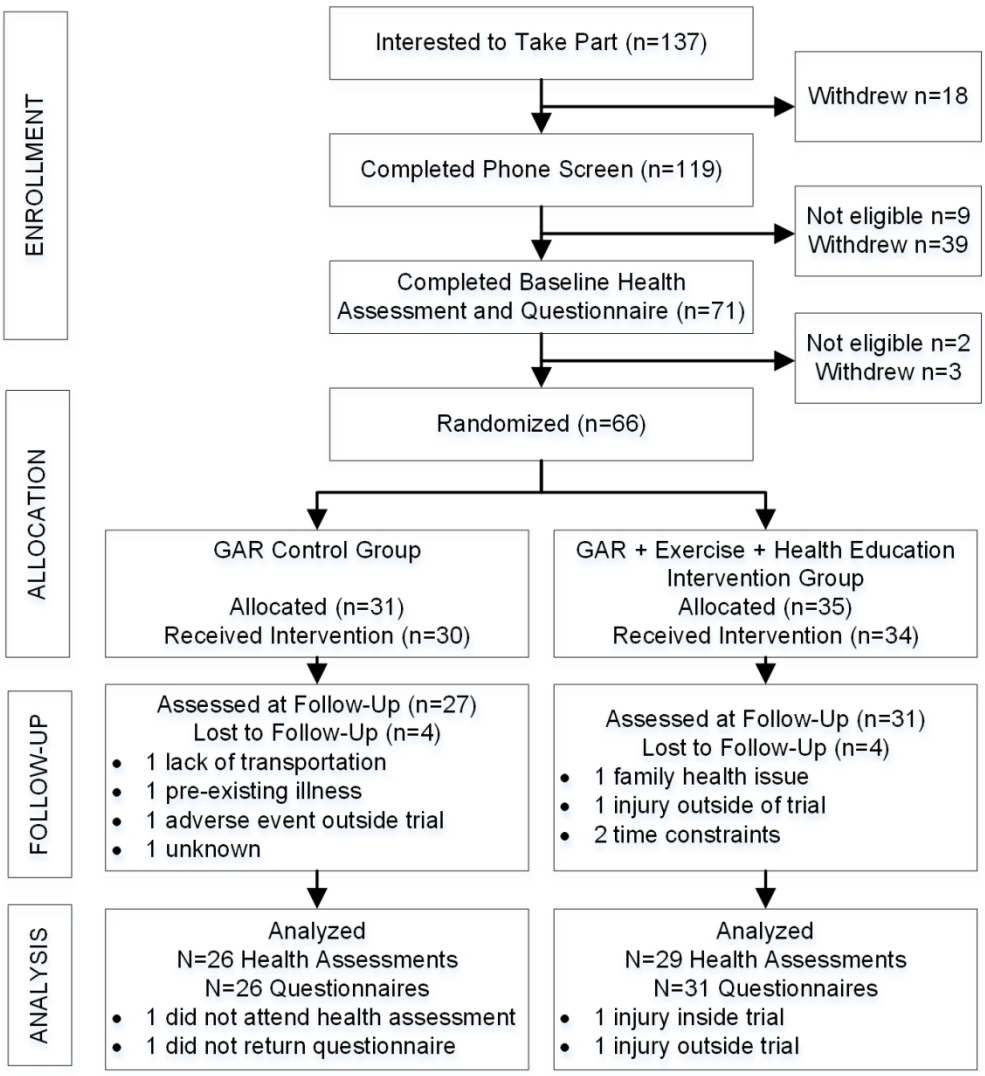

Figure 1: Participant time line: Consolidated Standards of Reporting Trials (CONSORT)-style flow chart

117x127mm (300 x 300 DPI)

Supplement 1. Geriatric Depression Scale, MOS Social Support Scale, and SF-36 Health Survey results by group

	Baseline Values		Change over Time (adjusted for baseline HHIE score)			
Measure	**Control Median (IQR)**	**Intervention Median (IQR)**	**Control Mean Δ (95%CI)**	**Intervention Mean Δ (95% CI)**	**Difference between Groups Mean Δ (95% CI)**	**Effect Size**
Geriatric Depression Scale	2 (1, 6)	2 (1, 3)	-0.9 (-1.8, 0.1)	-0.9 (-1.8, 0.2)	0 (-1.3, 1.3)	0
MOS Social Support Scale						
MOS Total Score	76 (50, 86)	76 (49, 93)	5.0 (0.8, 9.1)	0.8 (-3.0, 4.6)	-4.2 (-9.9, 1.6)	-0.38
Emotional Support	69 (38, 84)	75 (50, 91)	6.8 (1.4, 12.1)	1.1 (-4.0, 6.1)	-5.7 (-13.2, 1.8)	-0.39
Tangible Support	88 (50, 100)	75 (44, 94)	2.3 (-2.9, 7.5)	1.5 (-3.4, 6.4)	-0.8 (-8.1, 6.4)	-0.06
Affectionate Support	92 (50, 100)	83 (50, 100)	4.2 (-0.6, 9.0)	-0.4 (-4.9, 4.2)	-4.6 (-11.2, 2.2)	-0.35
Positive Social Interaction	75 (50, 100)	75 (50, 100)	2.5 (-2.0, 7.0)	0.4 (-3.8, 4.7)	-2.1 (-8.3, 4.2)	-0.17
Additional Item	63 (50, 75)	75 (50, 100)	8.5 (1.0, 16.0)	0.6 (-6.4, 7.5)	-7.9 (-18.4, 2.5)	-0.39
SF-36 Health Survey						
Physical functioning	80 (55, 95)	85 (65, 90)	4.0 (-3.2, 11.2)	0.9 (-5.8, 7.7)	-3.1 (-13.1, 7.0)	-0.16
Physical role limitations	75 (50, 100)	75 (50, 100)	-2.4 (-14.9, 10.2)	1.4 (-10.4, 13.2)	3.8 (-13.8, 21.3)	0.11
Emotional role limitations	100 (33, 100)	100 (67, 100)	0.1 (-10.4, 10.5)	-3.8 (-13.7, 6.0)	-3.9 (-18.5, 10.7)	-0.15
Energy/fatigue	60 (50, 80)	60 (45, 75)	0.5 (-4.2, 5.2)	3.0 (-1.4, 7.4)	2.5 (-4.1, 9.1)	0.19
Emotional well-being	80 (64, 88)	80 (72, 92)	0.7 (-3.2, 4.7)	-2.0 (-5.7, 1.7)	-2.7 (-8.3, 2.7)	-0.25
Social functioning	75 (63, 100)	88 (63, 100)	0.0 (-6.5, 6.6)	0.0 (-6.2, 6.1)	0.0 (-9.2, 9.1)	0
Pain	68 (45, 90)	68 (55, 80)	0.6 (-5.7, 6.9)	5.6 (-0.3, 11.5)	5.0 (-3.7, 13.8)	0.29
General Health	75 (60, 85)	70 (65, 85)	-0.3 (-4.8, 4.2)	1.4 (-2.9, 5.7)	1.7 (-4.6, 8.0)	0.14

Notes: IQR: interquartile range, Mean Δ**:** mean change, 95% CI: 95% confidence interval, *$p < 0.05$

Supplement 2. Distribution of COSI responses at follow-up, by group (Control N=26; Intervention N=31) and overall (N=57).

Situation	Amount of change experienced				
	Worse n (%)	No difference n (%)	Slightly better n (%)	Better n (%)	Much better n (%)
1. Conversations with 1 or 2 people in a quiet environment.					
Control	0 (0)	10 (38.5)	6 (23.1)	6 (23.1)	4 (15.4)
Intervention	0 (0)	9 (29.0)	7 (22.6)	13 (41.9)	2 (6.5)
Overall	0 (0)	19 (33.3)	13 (22.8)	19 (33.3)	6 (10.5)
2. Conversations with 1 or 2 people in a noisy environment.					
Control	1 (3.9)	12 (46.2)	7 (26.9)	6 (23.1)	0 (0)
Intervention	1 (3.2)	13 (41.9)	8 (25.8)	9 (29.0)	0 (0)
Overall	2 (3.5)	25 (43.9)	15 (26.3)	15 (26.3)	0 (0)
3. Conversations with a group in a quiet environment.					
Control	0 (0)	8 (30.8)	7 (26.9)	8 (30.8)	3 (11.5)
Intervention	0 (0)	8 (25.8)	11 (35.5)	10 (32.3)	2 (6.5)
Overall	0 (0)	16 (28.1)	18 (31.6)	18 (31.6)	5 (8.7)
4. Conversations with a group in a noisy environment.					
Control	1 (3.9)	10 (38.5)	10 (38.5)	4 (15.4)	1 (3.9)
Intervention	1 (3.2)	15 (48.4)	11 (35.5)	3 (9.7)	1 (3.2)
Overall	2 (3.5)	25 (43.9)	21 (36.8)	7 (12.3)	2 (3.5)
5. Hearing the television or radio at normal volume.					
Control	0 (0)	16 (61.5)	7 (26.9)	3 (11.5)	0 (0)
Intervention	0 (0)	17 (54.8)	6 (19.4)	7 (22.6)	1 (3.2)
Overall	0 (0)	33 (57.9)	13 (22.8)	10 (17.5)	1 (1.8)
6. Speaking with a familiar person on the phone.					
Control	0 (0)	17 (65.4)	3 (11.5)	5 (19.2)	1 (3.9)
Intervention	0 (0)	22 (71.0)	2 (6.5)	6 (19.4)	1 (3.2)
Overall	0 (0)	39 (68.4)	5 (8.8)	11 (19.3)	(3.5)
7. Speaking with an unfamiliar person on the phone.					
Control	1 (3.9)	17 (65.4)	5 (19.2)	3 (11.5)	0 (0)
Intervention	1 (3.2)	19 (61.3)	7 (22.6)	3 (9.7)	1 (3.2)
Overall	2 (3.5)	36 (63.2)	12 (21.0)	6 (10.5)	1 (1.8)
8. Hearing the phone ring from another room.					
Control	0 (0)	22 (84.6)	2 (7.7)	2 (7.7)	0 (0)
Intervention	1 (3.2)	22 (71.0)	6 (19.4)	1 (3.2)	1 (3.2)
Overall	1 (1.8)	44 (77.2)	8 (14.0)	3 (5.2)	1 (1.8)

9. Hearing the front door bell or someone knocking on the door.					
Control	0 (0)	19 (73.1)	5 (19.2)	2 (7.7)	0 (0)
Intervention	1 (3.2)	21 (67.7)	5 (16.1)	2 (6.5)	2 (6.5)
Overall	1 (1.8)	40 (70.2)	10 (17.5)	4 (7.0)	2 (3.5)
10. Hearing traffic (while walking outside or driving)					
Control	1 (3.9)	19 (73.1)	4 (15.4)	2 (7.7)	0 (0)
Intervention	1 (3.2)	23 (74.2)	3 (9.7)	3 (9.7)	1 (3.2)
Overall	2 (3.5)	42 (73.7)	7 (12.3)	5 (8.7)	1 (1.8)
11. Your amount of social contact (such as attending more social events or social situations or going out in public)					
Control					
Intervention	0 (0)	14 (53.9)	6 (23.1)	5 (19.2)	1 (3.9)
Overall	1 (3.2)	18 (58.1)	5 (16.1)	7 (22.6)	0 (0)
	1 (1.8)	32 (56.1)	11 (19.3)	12 (21.0)	1 (1.8)
12. Feeling embarrassed or stupid.					
Control	0 (0)	11 (42.3)	4 (15.4)	9 (35.6)	2 (7.7)
Intervention	0 (0)	17 (54.8)	9 (29.0)	2 (6.5)	3 (9.7)
Overall	0 (0)	28 (49.1)	13 (22.8)	11 (19.3)	5 (8.7)
13. Feeling left out.					
Control	0 (0)	11 (42.3)	7 (26.9)	8 (30.8)	0 (0)
Intervention	0 (0)	18 (58.1)	8 (25.8)	3 (9.7)	2 (6.5)
Overall	0 (0)	29 (50.9)	15 (26.3)	11 (19.3)	2 (3.5)
14. Feeling upset or angry.					
Control	0 (0)	14 (53.9)	5 (19.2)	7 (26.9)	0 (0)
Intervention	0 (0)	17 (54.8)	10 (32.3)	2 (6.5)	2(6.5)
Overall	0 (0)	31 (54.4)	15 (26.3)	9 (15.8)	2 (3.5)
15. Attending church or group meetings					
Control					
Intervention	0 (0)	18 (69.2)	4 (15.4)	4 (15.4)	0 (0)
Overall	0 (0)	24 (77.4)	3 (9.7)	2 (6.5)	2 (6.5)
	0 (0)	42 (73.7)	7 (12.3)	6 (10.5)	2 (3.5)

Supplement 3. Program Evaluation Questions and Distribution of Responses (Intervention N=33; Control N=24).

Exercise sessions (Intervention Participants)	**Strongly Agree n (%)**	**Agree n (%)**	**Disagree n (%)**	**Strongly Disagree n (%)**	**Don't know n (%)**
Overall, I was satisfied with the exercise program.	18 (55)	15 (44)	0 (0)	0 (0)	0 (0)
The exercise program was fun.	15 (45)	18 (55)	0 (0)	0 (0)	0 (0)
I did not enjoy the exercise sessions.	0 (0)	2 (6)	10 (30)	20 (61)	1 (3)
The exercises were too easy.	0 (0)	2 (6)	10 (30)	20 (61)	1 (3)
The exercise room was suitable for the program.	9 (27)	21 (64)	3 (9)	0 (0)	0 (0)
The fitness instructor clearly demonstrated the exercises.	17 (52)	16 (48)	0 (0)	0 (0)	0 (0)
The fitness instructor suggested modifications for the exercises to accommodate different fitness levels.	10 (30)	22 (67)	1 (3)	0 (0)	0 (0)
The fitness instructor was encouraging.	19 (58\)	14 (42)	0 (0)	0 (0)	0 (0)
The fitness instructor was approachable.	19 (59)	13 (41)	0 (0)	0 (0)	0 (0)
The fitness instructor spoke clearly.	9 (27)	20 (61)	4 (12)	0 (0)	0 (0)
There were a good variety of exercises.	14 (42)	18 (55)	1 (3)	0 (0)	0 (0)
I have increased my physical activity level outside of the program.	9 (27)	16 (48)	5 (15)	0 (0)	3 (9)
By participating, I feel I improved my strength and stamina.	9 (27)	20 (61)	2 (6)	0 (0)	2 (6)
By participating, I feel I improved my balance.	7 (21)	15 (45)	6 (18)	0 (0)	5 (15)
By participating, I feel I improved my flexibility.	6 (18)	23 (70)	2 (6)	0 (0)	2 (6)
As a result of the program, I walk more often.	8 (24)	17 (52)	7 (21)	0 (0)	1 (3)

Health Education Sessions (Intervention Participants)	**Strongly Agree n (%)**	**Agree n (%)**	**Disagree n (%)**	**Strongly Disagree n (%)**	**Don't know n (%)**
The presentation topics were interesting.	13 (39)	20 (61)	0 (0)	0 (0)	0 (0)
There were a good variety of presentation topics.	12 (36)	21 (64)	0 (0)	0 (0)	0 (0)
The information presented encouraged group discussions.	17 (52)	16 (48)	0 (0)	0 (0)	0 (0)
I did not enjoy the group discussions.	0 (0)	1 (3)	15 (45)	17 (52)	0 (0)
I often participated in the group discussions.	5 (15)	27 (82)	1 (3)	0 (0)	0 (0)
I learned about a healthy lifestyle for the health education sessions.	10 (30)	20 (61)	3 (9)	0 (0)	0 (0)
I enjoyed the student presentations.	14 (42)	18 (55)	1 (3)	0 (0)	0 (0)
I would have liked more student presentations.	4 (12)	17 (52)	8 (24)	1 (3)	3 (9)
I enjoyed the guest speaker presentations.	14 (45)	13 (42)	1 (3)	1 (3)	2 (6)
I would have liked more guest speaker	7 (23)	14 (45)	4 (13)	1 (3)	5 (16)

presentations.					
The information presented was difficult to understand.	0 (0)	0 (0)	20 (67)	10 (33)	0 (0)
I could see the speakers clearly.	13 (42)	17 (55)	1 (3)	0 (0)	0 (0)
I could hear the speakers clearly.	14 (45)	15 (48)	1 (3)	1 (3)	0 (0)

Walk Talk and Listen Program Overall (Intervention Participants)	**Strongly Agree n (%)**	**Agree n (%)**	**Disagree n (%)**	**Strongly Disagree n (%)**	**Don't know n (%)**
The program helped me to feel more comfortable in social situations.	2 (12)	13 (76)	1 (6)	0 (0)	1 (6)
The program helped to improve my emotional and mental wellbeing.	3 (18)	10 (59)	1 (6)	0 (0)	3 (18)
Overall, my lifestyle is healthier since I joined the program.	3 (18)	10 (59)	1 (6)	0 (0)	3 (18)
I am confident that I will continue with regular exercise after the program ends.	5 (29)	10 (59)	2 (12)	0 (0)	0 (0)

Group Auditory Rehab (GAR) sessions (Intervention and Control Participants)	**Strongly Agree n (%)**	**Agree n (%)**	**Disagree n (%)**	**Strongly Disagree n (%)**	**Don't know n (%)**
The meeting room was suitable for the program.	10 (37)	17 (63)		0 (0)	0 (0)
The GAR sessions helped me to recognize and better accept my hearing loss.	22 (39)	31 (55)	2 (3)	0 (0)	2 (3)
The GAR sessions helped me to become more self-confident in speaking out about my hearing loss in social situations.	24 (42)	32 (56)	0 (0.0)	0 (0)	1 (2)
The GAR sessions helped to improve my stress management skills.	6 (11)	36 (63)	7 (12)	0 (0)	8 (14)
The GAR sessions helped me to change my attitude about hearing loss for the better.	19 (33)	35 (61)	2 (4)	0 (0)	1 (2)
The GAR sessions helped me gain more problem solving skills.	9 (16)	41 (73)	1 (2)	0 (0)	5 (9)

Notes: There were no differences between control and intervention groups for GAR session evaluation questions (all $p > 0.05$)

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	Page 1:Title, page 2: abstract, page 3 and throughout the manuscript
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	Page 2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	Pages 2-3
	2b	Specific objectives or research questions for pilot trial	Page 3
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	Page 4
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	Page 4 and protocol paper
	4b	Settings and locations where the data were collected	Page 4
	4c	How participants were identified and consented	Page 4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 4
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Page 5
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	Page 5

Sample size	7a	Rationale for numbers in the pilot trial	Pages 4 and 5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	In the protocol paper
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	In the protocol paper
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Detailed in the protocol paper
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Detailed in the protocol paper
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Detailed in the protocol paper
	11b	If relevant, description of the similarity of interventions	Page 4
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	Pages 4 and 5
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Figure 1 and page 6
	13b	For each group, losses and exclusions after randomisation, together with reasons	Page 6 and figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 5
	14b	Why the pilot trial ended or was stopped	Page 4
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Page 6
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Figure 1
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Pages 6-9
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	Page 10

Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Figure 1 and pages 6 and 10
	19a	If relevant, other important unintended consequences	
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	Page 12
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	Pages 10-12
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	Pages 10-13
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	Pages 10-13
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	Page 4
Protocol	24	Where the pilot trial protocol can be accessed, if available	Pages 4 and page 15
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 13
	26	Ethical approval or approval by research review committee, confirmed with reference number	Page 13

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Walk, Talk and Listen: A pilot randomized controlled trial targeting functional fitness and loneliness in older adults with hearing loss.

Why:	Page 3: Since HL, loneliness and physical inactivity are inter-related and associated with multiple co-morbidities, it is of interest to explore interventions that improve loneliness and physical function among older adults with HL. In this pilot randomized controlled trial, Walk, Talk and Listen (WTL), we begin to explore the impact of GAR on loneliness and physical function, and importantly, whether addition of an interactive/social group educational and physical strengthening intervention is of any additional benefit in older adults with HL.
What (material):	Page 4: Detailed Walk, Talk and Listen (WTL) methodology is reported elsewhere [Lambert J, Ghadry-Tavi R, Knuff K, et al. Targeting functional fitness, hearing and health-related quality of life in older adults with hearing loss: Walk, Talk 'n' Listen, study protocol for a pilot randomized controlled trial. *Trials*2017;18(1)]. One hour control group GAR-only sessions occurred once a week. Intervention group one-hour GAR sessions were followed by 60 minutes of exercise (strength, resistance and coordination training: 45 minutes) and walking (outside or on indoor track: 15 minutes). On their second weekly visit, intervention participants attended a one-hour interactive SHE session [Lambert J et al: above}]followed by 60 minutes of exercise and walking.
What (procedures):	Page 4: Interactive GAR sessions were guided by a modification of the GROUP program [27]and provided hearing education, goal setting and psychosocial and behavior change exercises including mindfulness, acceptance of HL, assertiveness training, communication strategies, problem-solving, anticipatory and

	repair strategies.[Montano JJ, Preminger JE, Hickson L, Gregory M. A new web-based tool for group audiologic rehabilitation. *Am J Audiol*2013;22(2):332-4].
Who provided:	Page 4: A certified YMCA trainer facilitated the exercise sessions.Trained students helped the principle investigator facilitate the GAR and SHE sessions.
How (mode of delivery; individual or group):	Page 4: .All procedures included groups of 10-20 participants and took place in a small, acoustically favorable meeting room and/or a small gym at the same YMCA site. One hour control group GAR-only sessions occurred once a week. Intervention group one-hour GAR sessions were followed by 60 minutes of exercise (strength, resistance and coordination training: 45 minutes) and walking (outside or on indoor track: 15 minutes). On their second weekly visit, intervention participants attended a one-hour interactive SHE session [25]followed by 60 minutes of exercise and walking.
Where:	Page 4: All procedures took place in a small acoustically favorable meeting room and/or a small gym at the same YMCA site
When and how much:	Page 4: All procedures included groups of 10-20 participants and took place in a small, acoustically favorable meeting room and/or a small gym at the same YMCA site over a period of 10 weeks. One hour control group GAR-only sessions occurred once a week. Intervention group one-hour GAR sessions were followed by 60 minutes of exercise (strength, resistance and coordination training: 45 minutes) and walking (outside or on indoor track: 15 minutes). On their second weekly visit, intervention participants attended a one-hour interactive SHE session [25]followed by 60 minutes of exercise and walking
Tailoring:	Page 4: (intervention) Participants were encouraged to walk between sessions and were provided a pedometer and tracking sheets to motivate them.
How well (planned):	Page 6: **Feasibility:** The Walk, Talk and Listen CONSORT diagram is shown in Figure 1. One hundred and thirty-seven individuals contacted the study center, 119 completed the initial phone screen, and 71 completed full eligibility screening. Ninety-six percent of eligible participants (n=69) were randomized (n=66) and 88% of participants (n=58) completed the study. GAR and exercise attendance rates were 80% and 85% respectively
How well (actual):	Page 6: GAR and exercise attendance rates were 80% and 85% respectively

BMJ Open

Walk, Talk and Listen: A pilot randomized controlled trial targeting functional fitness and loneliness in older adults with hearing loss.

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Walk, Talk and Listen: A pilot randomized controlled trial targeting functional fitness and loneliness in older adults with hearing loss.

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List of abbreviations:

HL : Hearing loss
GAR: Group auditory rehabilitation

WTL: Walk, Talk and Listen
SHE: socialization/health education
RCT: Randomized controlled trial
HHIE-25: hearing Handicap for the Elderly: a 25-item questionnaire measure of hearing-related quality of life
SF-36: Short Form Health Survey SF-36 is a set of generic quality-of-life measures.
IOI-AI: international outcomes-alternative interventions
COSI: Client Oriented Scale of Improvement
ES: effect size

Abstract

Background: Age-related hearing loss (HL) is a prevalent disability associated with loneliness, isolation, declines in cognitive and physical function and premature mortality. Group audiological rehabilitation (GAR) and hearing technologies address communication and cognitive decline., However, the relationship between loneliness, physical function and GAR among older adults with HL has not been studied.
Objectives: Explore the impact of a group exercise and socialization/health education intervention and GAR on physical function and loneliness among older adults with HL.
Trial design: A YMCA-based 10-week, single-blind, pilot randomized control trial
Participants: Ambulatory adults aged 65 years or older with self-reported HL.
Interventions: Seventy-one participants were screened. Thirty-five were randomized to intervention (strength and resistance exercise, socialization/health education) and GAR (hearing education, communication strategies, psychosocial support) or control (n=31): GAR only.
Outcomes: Ninety-five percent of eligible participants were randomized. GAR and exercise adherence rates were 80% and 85% respectively. 88% of participants completed the study. Intervention group functional fitness improved significantly (gait speed: Effect Size: 0.57, 30-second Sit to Stand Test: Effect size: 0.53). Significant improvements in emotional and social loneliness (Effect size: 1.16) and hearing-related quality of life (Effect Size: 0.76) were related to GAR attendance and poorer baseline hearing-related quality of life. Forty-two percent of participants increased social contacts outside the study.
Discussion: Walk, Talk and Listen was feasible and acceptable. Exercise and socialization/health education improved loneliness and key fitness measures but provided no additional benefit to GAR only for loneliness. This is the first preliminary evidence about the benefits of exercise on fitness and GAR on loneliness among older adults with HL.
Implications: This pilot trial provides key information on the sample size required for a larger, longer-term RCT to determine the enduring effects of this holistic intervention addressing the negative psychosocial and musculo-skeletal downstream effects of HL among older adults.

Strengths and Limitations of the study:

- First study to examine the effects of exercise intervention and auditory rehabilitation on functional fitness and loneliness among older adults with HL.
- Fifty seven percent of participants are male: unusual for a community exercise program
- This is an exploratory single blind pilot randomized controlled trial
- There is not a control group with no intervention

BACKGROUND:

Hearing loss (HL) is a prevalent and under recognized disability that is associated with significant psychosocial and physical challenges. Large surveys [1 2] indicate that between 65-77% of North American adults aged 60 to 79 have audiometrically measured HL.

Untreated HL is associated with increased rates of loneliness, social isolation [3 4], depression, accelerated cognitive decline, declines in physical function, gait speed, balance, frailty, increased falls, hospitalizations and premature mortality [5].

These downstream effects of HL are interrelated. Numerous theories exist regarding the mechanism of these associations. One theory suggests that increased cognitive energy is used to comprehend sound/language, leaving less cognitive reserve for complicated tasks such as memory, social interaction and walking [5]. Work is ongoing in this area [6 7]. Another theory posits that HL–related social isolation and loneliness are linked to the cognitive decline, depression, impaired physical function, falls and mortality among older adults [4 8 9].

Social isolation is an objective measure of lack of contact/interactions with others, [10]while loneliness is a subjective feeling of the lack of meaningful social connections [11]. Linked to HL-related decreases in social participation, loneliness has also been independently associated with depression, cognitive decline, reduced physical functioning, and mortality. (Reviewed in:[12 13]).

Hearing technologies (hearing aids, assistive technologies and cochlear implants) and communication programs (one-on-one or group auditory rehabilitation (GAR) are the current approaches to treating HL. GAR programs include education about hearing, hearing devices/technologies, enhancing communication skills and psychosocial support [14]. Hearing technologies improve auditory function, cognitive decline, depression and loneliness[15 16] [17]. GAR improves objective measures of social participation (social isolation)[18] and hearing-related quality of life, however, to our knowledge, no studies explore how GAR programs impact loneliness or physical function among older adults with HL.

Group programs for lonely/socially isolated older adults involving interactive shared activities (e.g. social/cultural, educational or physical activities), as opposed to independent activities (e.g. reading or watching TV), improve quality of life, loneliness, [19-22] and in those that included exercise interventions, physical function and premature mortality [23]. [22].

Since HL, loneliness and physical inactivity are inter-related and associated with multiple co-morbidities, it is of interest to explore interventions that improve loneliness and physical function among older adults with HL. In this pilot randomized controlled trial, Walk, Talk and Listen (WTL), we begin to explore the impact of GAR on loneliness and physical function, and importantly, whether addition of an interactive/social group educational and physical strengthening intervention is of any additional benefit to older adults with HL.

Objective:
1) Examine the feasibility and impact of a group exercise and socialization/health education intervention added to GAR on physical function, hearing-related quality of life and loneliness among older adults with HL.

DESIGN AND METHODS:
Patient and public involvement: Twenty-eight older adults with HL participated in the design of the intervention for this clinical trial [24]. WTL participants helped, by word of mouth, to recruit several other participants. WTL participants provided ongoing and end of study feedback and helped to disseminate the trials results. One participant and the principle investigator continue to deliver GAR sessions twice a year in the local community.

Trial Protocol: Detailed Walk, Talk and Listen (WTL) methodology is reported elsewhere [25]. Briefly, in partnership with the YMCA Okanagan, WTL was a 10-week prospective single-blind randomized controlled pilot trial of interactive GAR (control) versus GAR plus interactive socialization/health education (SHE) and strengthening exercises in community-dwelling, ambulatory older adults (age 65 or above) with self-reported [26] HL. (clinicaltrials.gov NCT02662192. Registered Jan 14, 2016). Participants were recruited over the two time periods preceding the trial (January-February 2016 and July-August 2016) through local newspaper ads, strategically placed posters and word of mouth. Potential participants contacting the trial center underwent preliminary telephone eligibility assessment after the study was briefly described and verbal consent obtained. At the YMCA, eligible [25] participants signed informed consent and underwent baseline (week 0) and follow-up (week 11) assessments completed by trained students and research team members. All procedures included groups of 10-20 participants and took place in a small, acoustically favorable meeting room and/or a small gym at the same YMCA site over a period of 10 weeks. One hour control group GAR-only sessions occurred once a week. Intervention group one-hour GAR sessions were followed by 60 minutes of exercise (strength, resistance and coordination training: 45 minutes) and walking (outside or on indoor track: 15 minutes). On their second weekly visit, intervention participants attended a one-hour interactive SHE session [25] followed by 60 minutes of exercise and walking. A certified YMCA trainer facilitated the exercise sessions. Participants were encouraged to walk between sessions and were provided a pedometer and tracking sheets to motivate them. At study end, control participants were offered the exercise program and provided a pedometer. Trained students helped the principle investigator facilitate the GAR and SHE sessions. Interactive GAR sessions were guided by a modification of the GROUP program [27] and provided hearing education, goal setting and psychosocial and behavior change exercises including mindfulness, acceptance of HL, assertiveness training, communication strategies, problem-solving, anticipatory and repair strategies. Participants were encouraged to review class handouts with their communication partners (spouse, significant other or friend). One three-hour large-group communication partner session was held near the end of the study. The trial was conducted over two separate 10-week time periods (with different participants) to accommodate YMCA scheduling and allow for smaller participant groups.

Feasibility and acceptability:
Feasibility, including recruitment strategies and rates, acceptability/willingness to be randomized, adverse events, GAR attendance rates, overall retention rates, and acceptability of

the GAR and exercise components was assessed by follow-up (end of study). A priori, it was decided that a definitive RCT would be feasible if at least 120 individuals contacted the pilot trial center, ≥ 90% of eligible participants were randomized and 70 % of those completed the study. The WTL intervention was acceptable if at least 85% of participants found the GAR, exercise and SHE sessions highly acceptable or acceptable.

Participant-specific outcomes:
Demographic data was collected at baseline (week 0), and the remaining measures at baseline and follow-up (week 11).

Standard functional fitness outcomes included 30-Second Chair Sit to Stand Test [28], gait speed: 6-Minute Walk Test [29], Timed Up and Go Test [29], one-foot balance test [30], grip strength [31], Chair Sit and Reach test [32] and the Back Scratch [33].

Psychosocial measures included self-reported hearing–related quality of life or hearing handicap (Hearing Handicap Inventory for the Elderly [HHIE-25]) [26]) and The Rand SF-36 [34] (Short Form [general] quality of life measure) respectively, de Jong loneliness [35], social support (the Medical Outcomes Trial-Social Support Survey [36]), and depression (Geriatric Depression Scale [37]).

Group Auditory Rehabilitation evaluation:
The international outcomes inventory-alternative interventions (IOI-AI) [38] and the modified Client Oriented Scale of Improvement (COSI) questionnaires [39] were completed by all participants at follow-up. A follow-up evaluation questionnaire assessed the acceptability of the exercise and GAR sessions, acceptance and attitude about their HL, HL-related problem solving, stress management, and self confidence in social situations.

Sample size:
At least 23 people per group were needed to show a clinically meaningful increase in Sit To Stands of 2 or more [40]: the primary fitness outcome. This was inflated by 20% to account for drop outs and ensured generation of a reliable standard error (SE), standard deviation (SD) and 95% confidence intervals (CI) on the sample size required for a large RCT with this measure as the primary outcome [41].

Statistical methods
Categorical data was expressed as frequency and percentage (e.g. recruitment, adherence, overall retention rates. Continuous data were expressed as mean plus standard deviation or median and interquartile range (for non-normal data). Baseline data was compared between groups using a Fisher's exact test or independent samples t-test (Mann Whitney U test where appropriate). Intention-to-treat analyses were conducted to examine change over time in functional fitness and psychosocial measures. Effect sizes (ES) [42] and 95% confidence intervals for within group changes and between group differences are reported. Confounding and effect modification were examined using linear regression modeling with the change score as the dependent variable. GAR attendance was determined a priori as a potential confounding factor and HHIE-25 was included post-hoc to account for the unanticipated baseline differences. All results are presented as intention to treat using the baseline observation carried forward to produce the most

conservative results. Analyses were conducted in Stata S/E Version 15 (Stata® (StataCorp. Stata Statistical Software: Release 15, College Station, TX, USA: StataCorp LLC)) and $p<0.05$ was considered statistically significant.

RESULTS:

Feasibility: The Walk, Talk and Listen CONSORT diagram is shown in Figure 1. One hundred and thirty-seven individuals contacted the study center, 119 completed the initial phone screen, and 71 completed full eligibility screening. Ninety-six percent of eligible participants (n=69) were randomized (n=66) and 88% of participants (n=58) completed the study. GAR and exercise attendance rates were 80% and 85% respectively. There was one adverse event (fall with hip fracture) within the trial during an exercise session and two outside the study in control group participants (one fall with hip fracture, one foot infection). Primary reasons for ineligibility included, too young (33%) and no self-reported HL (67%). Newspaper ads were the most successful recruitment strategy (74%) followed by word of mouth (18%), and community posters or social media (8%) (data not tabled). The main reasons for withdrawal during enrollment (n=42) were time commitment (50%) and inconvenient location (24%).

Baseline measures (Table 1): Among the 66 participants in the study, the mean age was 74.5 years, 57% were male, 94% Caucasian, 67% married/common-law, 64% had completed some college/university or above 54% reported an annual household income above $(Canadian) 50,000.00, and 88% were retired. Ten participants used mobility or balance aids, just over half used hearing aids and 11 reported one or more falls in the previous 3 months. Groups did not differ on any functional fitness or psychosocial measure with the exception of the total HHIE-25 score (Control median=56; Intervention median=38; p=0.045).

Table 1. Baseline demographics, functional fitness, and psychosocial measures, by group (control N = 31; intervention N = 35) and for the overall sample (N=66).

Demographics	**Control n (%)**	**Intervention n (%)**	**Overall n (%)**
Age (years), Mean (SD)	74.8 (6.1)	74.3 (6.3)	74.5 (6.2)
Male gender	17 (54.8)	21 (60.0)	38 (57.6)
Caucasian Ethnicity	30 (96.8)	32 (91.4)	62 (93.9)
Married/Common law	22 (71.0)	22 (62.9)	44 (66.7)
College/University/Graduate Studies	19 (61.3)	23 (65.7)	42 (63.6)
Annual Income >$50,000	18 (60.0)	17 (48.6)	35 (53.9)
Retired	29 (93.6)	29 (82.9)	58 (87.9)
Living Alone	10 (32.3)	9 (25.7)	19 (28.8)
Uses Mobility or Balance Aids	6 (19.4)	4 (11.4)	10 (15.2)
Wears Hearing Aids	18 (58.1)	17 (48.6)	35 (53.0)
Any Falls in the Past Three months	7 (22.6)	4 (11.4)	11 (16.7)
Functional Fitness Measures	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
Gait speed (m/s)	1.25 (0.20)	1.28 (0.25)	1.26 (0.23)
Sit-To-Stand (30s)	12.7 (3.2)	12.9 (2.7)	12.8 (2.9)
Grip Strength (kg)	68.0 (19.4)	71.5 (21.6)	69.8 (20.5)

8ft Get up and Go (s)	6.4 (1.9)	6.1 (1.5)	6.3 (1.7)
Sit and Reach (cm)	-4.6 (20.8)	-1.9 (20.9)	-3.2 (20.8)
Back Scratch (cm)	-38.8 (21.0)	-39.7 (25.5)	-39.2 (23.3)
Balance (s)	49.3 (33.3)	45.9 (34.2)	47.5 (33.5)
Psychosocial Measures	**Median (IQR)**	**Median (IQR)**	**Median (IQR)**
HHIE-25 Total	56 (28, 68)	38 (24, 56)	46 (26, 64)
Emotional Subscale	30 (14, 40)	18 (14, 30)	20 (14, 32)
Social Subscale	26 (16, 32)	18 (12, 30)	24 (14, 30)
de Jong Loneliness Total	7 (3, 10)	6 (2, 9)	7 (3, 9)
Emotional Loneliness	3 (1, 5)	3 (0, 5)	3 (0, 5)
Social Loneliness	3 (2, 5)	4 (1, 5)	3 (2, 5)

IQR: Interquartile Range, SD: Standard Deviation, s: seconds, m/s: meters per second, cm (centimeters)

Change in functional fitness and psychosocial measures (Table 2): After adjusting for baseline HHIE-25 imbalance, gait speed improved more in the intervention group compared to the control group by an average of 0.05 m/s (95% CI=0.0,0.09; p=0.046; ES=0.57). Compared to the control group, intervention group Sit to Stand measures improved significantly more by an average of 1.0 sit to stand (95% CI=0.1, 2.0; p=0.037; ES=0.53). Back scratch improved by an average of 4 centimeters more in the intervention group compared to the control group (95% CI=0.2, 7.7; p=0.039; ES=0.54). The de Jong emotional loneliness subscale showed greater improvement in the control group: average difference in change of 0.6 (95% CI=0.1, 1.2; p=0.043; ES=-0.54). There were no significant differences for depression, social support or SF-36 measures (all p>0.05) (Supplement 1).

Table 2. Mean change and difference between control and intervention groups for functional fitness and loneliness, adjusted for baseline HHIE-25 score.

Functional Fitness	**Control Group Mean Δ (95%CI)**	**Intervention Group Mean Δ (95% CI)**	**Difference between groups Mean Δ (95% CI)**	**Effect Size**
Gait Speed (m/s)	0.07 (0.04, 0.11)	0.12 (0.09, 0.15)	0.05 (0.0, 0.09) *	0.57
Sit-To-Stand (30 s)	0.6 (-0.1, 1.3)	1.6 (1.0, 2.3)	1.0 (0.1, 2.0) *	0.53
8ft Get up and Go (s)	-0.5 (-0.9, -0.2)	-0.8 (-1.1, -0.5)	-0.3 (-0.8, 0.2)	0.32
Grip Strength (kg)	1.3 (-0.8, 3.5)	2.8 (0.8, 4.8)	1.5 (-1.5, 4.5)	0.26
Sit and Reach (cm)	0.8 (-3.6, 5.2)	3.6 (-0.5, 7.8)	2.8 (-3.3, 9.0)	0.23
Back Scratch (cm)	0.0 (-2.7, 2.7)	4.0 (1.4, 6.5)	4.0 (0.2, 7.7) *	0.54
Balance (s)	6.0 (0.1, 11.9)	6.8 (1.2, 12.3)	0.8 (-7.4, 9.1)	0.05
de Jong Loneliness Total	-1.5 (-2.1, -0.9)	-0.9 (-1.4, -0.3)	0.6 (-0.2, 1.5)	-0.35
Emotional Subscale	-0.9 (-1.3, -0.5)	-0.3 (-0.7, 0.1)	0.6 (0.1, 1.2) *	-0.54
Social Subscale	-0.6 (-1.2, -0.1)	-0.5 (-1.0, -0.1)	0.1 (-0.6, 0.8)	-0.07

Notes: *$p < 0.05$, Mean Δ**:** mean change, 95% CI: 95% confidence interval**,** s: seconds, m/s: meters per second, cm (centimeters)

Improvements in HHIE-25 and de Jong loneliness were influenced by GAR attendance (Table 3). Total, emotional and social HHIE-25 subscales showed significant improvement for those who attended ≥ 80% of GAR sessions: total: 95% CI=-19.7, -2.6; p=0.012; ES=0.76, emotional: 95% CI=-11.0, -1.1; p=0.018; ES=0.71, social: 95% CI=-9.5, -0.8; p=0.022; ES=0.69, regardless of group assignment. Similarly, those with ≥80% GAR attendance had a greater decrease in de Jong total (95% CI=-2.7, -0.9; p=<0.001; ES=1.16) and emotional loneliness (95% CI=-1.7, -0.4; p=0.002; ES=0.96).

Table 3. Impact of group and GAR attendance on mean change and difference in change for the HHIE-25 and de Jong loneliness scales (N=57).

	Hearing handicap for the elderly			**de Jong loneliness and isolation**		
Gar attendance	Total Score **Mean Δ 95% CI**	Emotion Subscale **Mean Δ 95% CI**	Social Subscale **Mean Δ 95% CI**	Total Score **Mean Δ 95% CI**	Emotion Subscale **Mean Δ 95% CI**	Social Subscale **Mean Δ 95% CI**
<80% attendance	1.3 -6.0, 8.6	-0.1 -4.3, 4.1	1.4 -2.3, 5.1	0.2 -0.6, 1.0	0.2 -0.4, 0.8	0.0 -0.7, 0.7
≥80% attendance	-9.8 -14.0, -5.6	-6.1 -8.5, -3.7	-3.7 -5.9, -1.6	-1.6 -2.1, -1.2	-0.8 -1.1, -0.5	-0.8 -1.2, -0.4
Group Difference	-11.1 -19.7, -2.6	-6.0 -11.0, -1.1	-5.1 -9.5, -0.8	-1.8 -2.7, -0.9	-1.0 -1.7, -0.4	-0.8 -1.6, 0.1
p	0.012	0.018	0.022	<0.001	0.002	0.061
Effect Size	0.76	0.71	0.69	1.16	0.96	0.58

GAR evaluation: At study end, participant responses to the seven IOI-IA questions (Table 4) revealed that 67% of participants were using GAR communication strategies on a daily basis for at least one hour. The majority reported moderate or greater benefit from using GAR strategies, satisfaction with the GAR program, improvement in participation restrictions (visiting friends/relatives less than desired), and improvement in activity limitations (difficulty hearing TV or speech). COSI results were favorable overall (Supplement 2). Participants reported slightly better or greater progress in their goals of improving "conversations with one or two or a group of people in a quiet environment" (67%) or "noisy" environment (53%), half (51%) felt less embarrassed or stupid and 42% increased the amount of their social contact (such as attending more social events, social situations or going out in public).

Table 4. Percent distribution of participant responses for each item on the IOI-IA at follow-up (N=57).

Item	Percent (%) Reported				
	None	<1 hr/day	1-4 hr/day	4-8 hr/day	>8 hr/day
Use %	3.5	29.8	49.1	12.3	5.3
	Not at all	Slightly	Moderately	Quite a lot	Very much
Benefit %[a]	0	35.1	29.8	31.6	3.5
Sat %	0	8.8	19.3	28.1	43.8
	Very much	Quite a lot	Moderate	Slight	None
RAL %	3.5	3.5	49.1	38.6	5.3
RPR %	0	17.6	31.6	36.8	14.0
Ioth %	0	3.5	17.2	48.3	31.0
	Worse	No change	Slightly	Quite a lot	Very much
QOL %	0	10.3	44.8	38.0	6.9

Notes: RAL = residual activity limitations; Sat = satisfaction; RPR = residual participating restrictions; Ioth = impact on others; QOL = quality of life.
[a]Statistically significant difference between control and intervention groups (Control: Not at all = 0%, Slightly = 26.9%, Moderately = 19.2%, Quite a lot = 46.2%, Very much = 7.7%; Intervention: Not at all = 0%, Slightly = 41.9%, Moderately = 38.7%, Quite a lot = 19.4%, Very much = 0%; $p = 0.040$)

Program evaluation (Supplement 3) questionnaires were filled out by 24 control group and 33 intervention group participants. The data revealed that a large proportion of both groups agreed or strongly agreed that GAR helped them: better recognize and accept their HL (93%); be more confidant to speak out about their HL in social situations (98%); and to have a better attitude toward HL (95%). The majority (89%) felt that GAR helped them improve their problem-solving abilities. Intervention group participants reported that they were satisfied with the exercise (100%) and reported it was fun (100%). The majority (75%) indicated they increased their physical activity level outside the program, and 88% were confident they would continue with regular exercise after the program ended. When asked what could improve the program, participants favored a larger GAR session room, more emphasis on hearing assistive technologies (telephones, for example) with presentations by commercial companies producing these items, better acoustics in the gym (e.g. no fan noise in the background) with an improved sound system and instructors that could speak more slowly and clearly (data not tabled).

DISCUSSION:

In this pilot trial, the feasibility, acceptability and preliminary evidence for the efficacy of a group auditory rehabilitation, socialization/health education and exercise intervention for older adults with HL was evaluated. Recruitment and retention rates suggested the study was well received. Walk, Talk and Listen was found to be feasible and highly acceptable. Strengthening, resistance and coordination exercises coupled with GAR and socialization/health education improved lower extremity strength, gait speed and upper body flexibility. While exercise

improved these key functional fitness measures, it provided no additional benefit beyond GAR alone for measures of hearing-related quality of life (HHIE-25) and loneliness. Significant improvements in hearing-related quality of life, total and emotional loneliness were found for those attending ≥ 80% of the GAR sessions and in those with the poorest baseline self-reported hearing-related quality of life. Delivery of GAR by a non-audiologist health provider appeared to be of similar benefit to participants as seen in the literature. To our knowledge, this is the first study to provide an approach to the treatment of HL in older adults that addresses HL-related activity limitations, participation restrictions in addition to physical function (impaired musculoskeletal function), and that showed an improvement in total and emotional loneliness.

Feasibility and acceptability.
Implementation of the Walk, Talk and Listen proved to be feasible and acceptable to participants. Recruitment strategies, randomization, study implementation and study completion rates (88%) reached the a priori required feasibility goals and more than 95% of participants found the program acceptable/highly acceptable.

Functional physical fitness changes.
Preliminary evidence for efficacy of the exercise intervention on physical function was determined using effect sizes in order to help decide upon future sample size considerations. Effect sizes were calculated on a small sample, therefore need to be interpreted with that in mind [43]. They suggest that the physical activity and GAR interventions were of some benefit and deserve further investigation in a larger sample.

The WTL exercise intervention was associated with significant improvements in two major functional fitness measures (gait speed; ES 0.57 and 30 sec sit to stand; ES0.53) which have been associated with reduced risk for falls and improved maintenance of physical independence [33]. Adherence to the exercise intervention was excellent and end of study evaluations indicated that participants were satisfied with the exercise sessions. Lower body muscle strengthening and improved gait speed are expected to provide long-term benefit as shown in a prospective analysis of longitudinal data from NHANES (2003-2006) where adults with at least moderate HL who undertook two+ sessions/week of muscle strengthening exercises were at a 71% reduced risk of 7-year all-cause mortality [44]. However, static (one foot stand) or dynamic (Timed Up and Go) balance was not improved. Furthermore, there was one fall during a fast-paced “tag”-like exercise where a participant tripped on another participant’s foot. While published rates of falls during fall prevention programs range from 5-25% (depending on baseline risk for falls) [45], these findings have important implications for the design of future exercise interventions. Rather than rapid agility/coordination exercises, exercises should include more balance training such as the in-home or facility-based Otago Falls prevention exercise program or Tai Chi [46] which have been shown to reduce falls in the general population of older adults. Incorporation of these focused exercises may be more effective in improving balance in those with HL. The improvement in gait speed and lower extremity muscle strength seen in this pilot trial are encouraging and suggest that such an intervention, if carried on longer term, and which includes more aggressive balance training might be of survival benefit in older adults with HL.

Hearing and health-related quality of life, loneliness and social network.
Improvements in loneliness, participation restrictions and activity limitations were related to higher (worse) baseline HHIE-25 (hearing-related quality of life) and higher GAR attendance. Hearing-related quality of life has been found to be an effect modifier in other studies. Using a similar assessment of hearing-related quality of life (Hearing Attitudes to Rehabilitation Questionnaire) [39] found that higher baseline scores in this measure were also associated with greater benefit from a GAR program for participation restrictions and activity limitations. The addition of exercise to GAR was of no added benefit for any of the psychosocial outcomes. This was an unexpected finding given the proven benefits of exercise in many of these realms [47]. It is unknown as to whether poorer hearing-related quality of life supersedes the psychosocial benefits of exercise. Further research is need in order understand this interaction

That GAR attendance had a strong influence on psychosocial outcomes is consistent with the findings of others who have found that GAR attendance is imperative for optimizing the outcomes of GAR [48]. Our adherence rates of 87% were comparable to other group-based communication programs where rates ranged from 56-68% [18] to 96% [49].

The association between untreated HL and loneliness is well known [35]. Treatment with cochlear implantation [17] and provision of hearing aids [16] has been shown to reduce loneliness in older adults with audiometrically measured mild to severe HL. To the authors knowledge, only one other study has looked at the effect of audiologic rehabilitation on loneliness. In this study [50], participants were provided with an assistive hearing device (not a HA) and with their communication partners undertook a one-time 1.6-2-hour GAR session delivered by a trained clinician. Participants were given auditory rehabilitation manuals and workbooks to complete at home. Despite a significant decrease in HHIE scores (meaning an improvement in hearing-related quality of life) at 3 months, loneliness (as measured by the University of California Los Angeles (UCLA) loneliness scale) increased. In the current study, hearing-related quality of life (HHIE-25) and loneliness (de Jong loneliness scale), significantly improved in those with higher GAR attendance, compared with poor attenders, who saw no benefit).
Furthermore, while social isolation was not formally assessed, the COSI results indicate that 42 percent of participants increased the amount of their social contact (such as attending more social events, social situations or going out in public) which might be expected to decrease social isolation if maintained over time.
While group or home auditory rehabilitation improves hearing-related quality of life, it appears that group auditory rehabilitation may more conducive than home-based auditory rehabilitation to addressing loneliness.

Health-related quality of life:
Health-related quality of life, as assessed using the SF36, did not show change by group assignment, GAR attendance or baseline HHIE-25 score. This finding is in agreement with others who also used generic health-related quality of life tools (World Health Organization Disability Assessment Schedule II [51] [49]: SF-36 [39]) as a communication program outcome measure. This was not unexpected given that the content of this questionnaire has little to do with communication and supports our finding that added exercise and health education did affect generic quality of life measures.

GAR evaluation.
Together, the GAR evaluation tools (IOI-IA, COSI and qualitative feedback) suggested that the GAR program was highly appreciated, benefited and improved self-efficacy of participants. When compared with other studies where communication strategies and psychosocial counselling were key features of GAR, improvement in HHIE-25 (ES=0.69-0.76) was similar to that in one study (ES 0.67-0.78) [49] and slightly greater than that in another (ES =0.25) [39]. Furthermore, outcomes in all domains of the IOI-IA and relevant COSI outcomes compared favorably with these same established communication programs [38 39 49]. Inclusion of communication strategies and facilitating behavior change was associated with enhanced self-efficacy a consistent finding in the literature [52 53]. As participants gain confidence in managing their HL and achieving their communication and social goals, their hearing-related quality of life improves [49 51]. These findings are encouraging and add to the emerging evidence suggesting that with adequate training and resources, a non-audiologist may help to build capacity for increased access to effective community-based GAR programming [54-56].

Strengths and Limitations:
This study had several strengths: 57% of our participants were male. While not uncommon for GAR interventions, it is uncommon to see > 30% of males participating in community-based exercise programs [57 58]. This may simply reflect the higher prevalence of HL in men, or some other factor: qualitative work is underway to examine this.

In this pilot trial, a control group receiving no intervention was not included. This would have made for a more accurate determination the effects of GAR. However, one potential interpretation is that GAR can be effective when given alone or part of a more holistic health behaviour intervention. Secondly, participants were self-selected which may have introduced a bias favoring positive outcomes [59]. However, recruitment occurred in the 'real world" community setting and is representative of the population of hearing impaired older adults that have reached the stage of hearing help seeking. Thirdly, the baseline difference between groups in the baseline HHIE-25 scores is likely due to the small sample size. Although comparisons were reported in terms of relative improvements and not strict comparisons, this should be noted as a potential bias. This study provided only immediate post-program results and may have been underpowered to detect changes in the other fitness measures. There is a need for more longitudinal follow-up in a larger sample to determine if the positive changes can be sustained.

Finally, this is the first study to obtain preliminary information on the effectiveness of an exercise intervention to improve functional fitness, and GAR to improve total and emotional loneliness and social support in older adults with self-reported HL. GAR lead by non-audiologist shows potential as a way to improve the accessibility of GAR programs.

Age-related HL is a prevalent, under recognized and significant disability that when untreated is associated with profound negative downstream effects. This study contributes to emerging evidence of the benefit of providing accessible community-based communication programs delivered outside the traditional audiology clinical setting. Addition of an exercise component shows at least short-term functional fitness benefits. Further research is needed to determine the

long-term benefits of combining communication and exercise programs on the bio-psychosocial domains among older adults with HL.

Implications:
A larger, long-term study is needed to determine the enduring effects of this novel, community-based, holistic intervention in addressing both the negative psychosocial and functional physical effects of HL among older adults. Use of the home or facility-based Otago falls prevention exercise program (muscle strengthening and a more focused approach to balance training) may be necessary to improve balance in older adults with HL. Face-to-face GAR sessions may be necessary in order to provide additional benefits on loneliness and social support. Provision of GAR by students and non-audiologists may improve accessibility of audiological rehabilitation programs.

Figure 1: Participant time line: Consolidated Standards of Reporting Trials (CONSORT)-style flow chart

References

1. Lin FR, Niparko JK, Ferrucci L. Hearing loss prevalence in the United States. *Arch. Intern. Med.* 2011;171(20):1851-2.
2. Canada S. Hearing Loss of Canadians, 2012 to 2015. In: Canada S, ed. Ottawa, 2016.
3. Mick P, Kawachi I, Lin FR. The Association between Hearing Loss and Social Isolation in Older Adults. *Otolaryngol. Head Neck Surg.* 2014;150(3):378-84.
4. Strawbridge WJ, Wallhagen MI, Shema SJ, Kaplan GA. Negative Consequences of Hearing Impairment in Old Age: A Longitudinal Analysis. *The Gerontologist* 2000;40:320-26.
5. Davis A, McMahon CM, Pichora-Fuller KM, et al. Aging and Hearing Health: The Life-course Approach. *Gerontologist* 2016;56 Suppl 2:S256-67.
6. Agmon M, Lavie L, Doumas M. The Association between Hearing Loss, Postural Control, and Mobility in Older Adults: A Systematic Review. *J. Am. Acad. Audiol.* 2017;28(6):575-88.
7. Bruce H, Lai L, Bherer L, Lussier M, St-Onge N, Li KZH. The effect of simultaneously and sequentially delivered cognitive and aerobic training on mobility among older adults with hearing loss. *Gait Posture* 2019;67:262-68.
8. Seeman TE. Health promoting effects of friends and family on health outcomes in older adults. *Am. J. Health Promot.* 2000;14:362-70.
9. Berkman LF, Glass T, Brissette I, Seeman TE. From social integration to health: Durkheim in the new millennium. *Soc. Sci. Med.* 2000;51:843-57.
10. Leigh-Hunt N, Bagguley D, Bash K, et al. An overview of systematic reviews on the public health consequences of social isolation and loneliness. *Public Health* 2017;152:157-71.
11. Savikko N, Routasalo P, Tilvis RS, Strandberg TE, Pitkala KH. Predictors and subjective causes of loneliness in an aged population. *Arch. Gerontol. Geriatr.* 2005;41(3):223-33.
12. Rico-Uribe LA, Caballero FF, Martin-Maria N, Cabello M, Ayuso-Mateos JL, Miret M. Association of loneliness with all-cause mortality: A meta-analysis. *PLoS One* 2018;13(1):e0190033.
13. Contrera KJ, Betz J, Genther DJ, Lin FR. Association of Hearing Impairment and Mortality in the National Health and Nutrition Examination Survey. *JAMA Otolaryngol Head Neck Surg* 2015;141(10):944-6.

14. Millett P, Jutras B, Noel G, Pichora-Fuller K, Watson C, Nelson A. Canadian Guideline on Auditory Processing Disorder in Children and Adults: Assessment and intervention: Canadian Interorganizational Steering Group for Audiology and Speech-Language Pathology, 2012.
15. Contrera KJ, Sung YK, Betz J, Li L, Lin FR. Change in loneliness after intervention with cochlear implants or hearing aids. *Laryngoscope* 2017.
16. Weinstein BE, Sirow LW, Moser S. Relating Hearing Aid Use to Social and Emotional Loneliness in Older Adults. *Am J Audiol* 2016;25(1):54-61.
17. Poissant SF, Beaudoin F, Huang J, Brodsky J, Lee DJ. Impact of cochlear implantation on speech understanding, depression, and loneliness in the elderly. *J. Otolaryngol. Head Neck Surg.* 2008;37(4):488-94.
18. Laplante-Levesque A, Hickson L, Worrall L. Rehabilitation of older adults with hearing impairment: a critical review. *J. Aging Health* 2010;22(2):143-53.
19. Hwang J, Wang L, Siever J, Medico TD, Jones CA. Loneliness and social isolation among older adults in a community exercise program: a qualitative study. *Aging & mental health* 2018:1-7.
20. Cohen-Mansfield J, Perach R. Interventions for Alleviating Loneliness Among Older Persons: A Critical Review. *Am. J. Health Promot.* 2015.
21. Gardiner C, Geldenhuys G, Gott M. Interventions to reduce social isolation and loneliness among older people: an integrative review. *Health & social care in the community* 2018;26(2):147-57.
22. Pitkala KH, Routasalo P, Kautiainen H, Tilvis RS. Effects of psychosocial group rehabilitation on health, use of health care services, and mortality of older persons suffering from loneliness: a randomized, controlled trial. *J. Gerontol. A Biol. Sci. Med. Sci.* 2009;64(7):792-800.
23. McPhee JS, French DP, Jackson D, Nazroo J, Pendleton N, Degens H. Physical activity in older age: perspectives for healthy ageing and frailty. *Biogerontology* 2016;17(3):567-80.
24. Jutras M, Lambert J, Hwang J, et al. Targeting the psychosocial and functional fitness challenges of older adults with hearing loss: a participatory approach to adaptation of the Walk and Talk for your Life program *Int. J. Audiol.* 2018.
25. Lambert J, Ghadry-Tavi R, Knuff K, et al. Targeting functional fitness, hearing and health-related quality of life in older adults with hearing loss: Walk, Talk 'n' Listen, study protocol for a pilot randomized controlled trial. *Trials* 2017;18(1):47.
26. Chang H-P, Ho C-Y, Chou P. The Factors Associated with a Self-Perceived Hearing Handicap in Elderly People with Hearing Impairment Results from a Community-Based Study. *Ear Hear.* 2009;30:576-83.
27. Montano JJ, Preminger JE, Hickson L, Gregory M. A new web-based tool for group audiologic rehabilitation. *Am J Audiol* 2013;22(2):332-4.
28. Tiedemann A, Shimada H, Sherrington C, Murray S, Lord S. The comparative ability of eight functional mobility tests for predicting falls in community-dwelling older people. *Age Ageing* 2008;37(4):430-5.
29. Steffen TM, Hacker TA, Mollinger L. Age- and gender-related test performance in community-dwelling elderly people: Six-Minute Walk Test, Berg Balance Scale, Timed Up & Go Test, and gait speeds. *Phys. Ther.* 2002;82(2):128-37.
30. Springer BA, Marin R, Cyhan T, Roberts H, Gill NW. Normative values for the unipedal stance test with eyes open and closed. *J. Geriatr. Phys. Ther.* 2007;30(1):8-15.

31. Leong DP, Teo KK, Rangarajan S, et al. Prognostic value of grip strength: findings from the Prospective Urban Rural Epidemiology (PURE) study. *Lancet* 2015;386:266-73.
32. Jones CJ, Rikli RE, Max J, Noffal G. The reliability and validity of a chair sit-and-reach test as a measure of hamstring flexibility in older adults. *Res. Q. Exerc. Sport* 1998 69:338-43.
33. Rikli RE, Jones CJ. Development and validation of criterion-referenced clinically relevant fitness standards for maintaining physical independence in later years. *Gerontologist* 2013;53(2):255-67.
34. Ware JE, Jr., Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF- 36): I. Conceptual Framework and Item Selection *Med. Care* 1992;30:473-83.
35. de Jong-Gierveld J, ; Kamphuis, F. The Development of a Rasch-Type Loneliness Scale. *Appl. Psychol. Meas.* 1985;9:289-99.
36. Sherbourne CD, Stewart AL. The MOS social support survey. *Soc. Sci. Med.* 1991;32(6):705-14.
37. Vinkers DJ, Gussekloo J, Stek ML, Westendorp RG, Van Der Mast RC. The 15-item Geriatric Depression Scale (GDS-15) detects changes in depressive symptoms after a major negative life event. The Leiden 85-plus Study. *Int. J. Geriatr. Psychiatry* 2004;19(1):80-4.
38. Hickson L, Worrall L, Scarinci N. Measuring outcomes of a communication program for older people with hearing impairment using the International Outcome Inventory. *Int. J. Audiol.* 2006;45(4):238-46.
39. Hickson L, Worrall L, Scarinci N. A randomized controlled trial evaluating the active communication education program for older people with hearing impairment. *Ear Hear.* 2007;28(2):212-30.
40. Jones CJ, Rikli RE, Beam WC. A 30-s chair-stand test as a measure of lower body strength in community-residing older adults. *Res. Q. Exerc. Sport* 1999;70(2):113-9.
41. Whitehead AL, Julious SA, Cooper CL, Campbell MJ. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Stat. Methods Med. Res.* 2016;25(3):1057-73.
42. Cohen J. *Statistical power analysis for the behavioral sciences.* 2nd ed ed. Hillsdale, NJ, USA: Lawrence Earlbaum Associates, 1988.
43. Durlak JA. How to select, calculate, and interpret effect sizes. *J. Pediatr. Psychol.* 2009;34(9):917-28.
44. Loprinzi PD. Muscle strengthening activities and mortality with considerations by hearing sensitivity. *Int. J. Audiol.* 2016;55(5):320-2.
45. Sherrington C, Michaleff ZA, Fairhall N, et al. Exercise to prevent falls in older adults: an updated systematic review and meta-analysis. *Br. J. Sports Med.* 2017;51(24):1750-58.
46. Gillespie LD, Robertson MC, Gillespie WJ, et al. Interventions for preventing falls in older people living in the community. *Cochrane Database Syst Rev* 2012(9):CD007146.
47. Gaz DV, Smith AM. Psychosocial benefits and implications of exercise. *PM R* 2012;4(11):812-7.
48. Chisolm TH, Saunders GH, Frederick MT, McArdle RA, Smith SL, Wilson RH. Learning to listen again: the role of compliance in auditory training for adults with hearing loss. *Am J Audiol* 2013;22(2):339-42.
49. Preminger JE, Yoo JK. Do group audiologic rehabilitation activities influence psychosocial outcomes? *Am J Audiol* 2010;19(2):109-25.

50. Nieman CL, Marrone N, Mamo SK, et al. The Baltimore HEARS Pilot Study: An Affordable, Accessible, Community-Delivered Hearing Care Intervention. *Gerontologist* 2016.
51. Preminger JE, Ziegler CH. Can auditory and visual speech perception be trained within a group setting? *Am J Audiol* 2008;17(1):80-97.
52. Smith SL, West RL. The application of self-efficacy principles to audiologic rehabilitation: a tutorial. *Am J Audiol* 2006;15(1):46-56.
53. Marrone N, Ingram M, Somoza M, et al. Interventional Audiology to Address Hearing Health Care Disparities: Oyendo Bien Pilot Study. *Semin Hear* 2017;38(2):198-211.
54. Sanchez D, Adamovich S, Ingram M, et al. The Potential in Preparing Community Health Workers to Address Hearing Loss. *J. Am. Acad. Audiol.* 2017;28(6):562-74.
55. Nieman CL, Lin FR. Increasing access to hearing rehabilitation for older adults. *Curr. Opin. Otolaryngol. Head Neck Surg.* 2017;25(5):342-46.
56. Preminger JE. Issues associated with the measurement of psychosocial benefits of group audiologic rehabilitation programs. *Trends in amplification* 2007;11(2):113-23.
57. Clare L, Nelis SM, Jones IR, et al. The Agewell trial: a pilot randomised controlled trial of a behaviour change intervention to promote healthy ageing and reduce risk of dementia in later life. *BMC Psychiatry* 2015;15:25.
58. Gandy R, Bell A, McClelland B, Roe B. Evaluating the delivery, impact, costs and benefits of an active lives programme for older people living in the community. *Prim. Health Care Res. Dev.* 2016:1-13.
59. Knudsen LV, Oberg M, Nielsen C, Naylor G, Kramer SE. Factors influencing help seeking, hearing aid uptake, hearing aid use and satisfaction with hearing aids: a review of the literature. *Trends in amplification* 2010;14(3):127-54.

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Ethical approval: The study was approved by the University of British Columbia Okanagan Research Services Behavioural Research Ethics Board. UBC BREB number: H15-02319. Written consent was obtained for all participants.

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Data Sharing:
UBC library Data Management Repository — UBC Library has implemented a robust data management software – Abacus Dataverse – collaborating with Harvard and supporting other BC schools (UNBC, UVic and SFU). The system is designed to manage and preserve data and it is opened to UBC researchers, labs and institutes. UBC will then assign DOI's to the UBC Library

digital datasets, via our Open Collections portal. DOIs increase the further citability and discoverability of UBC research data.

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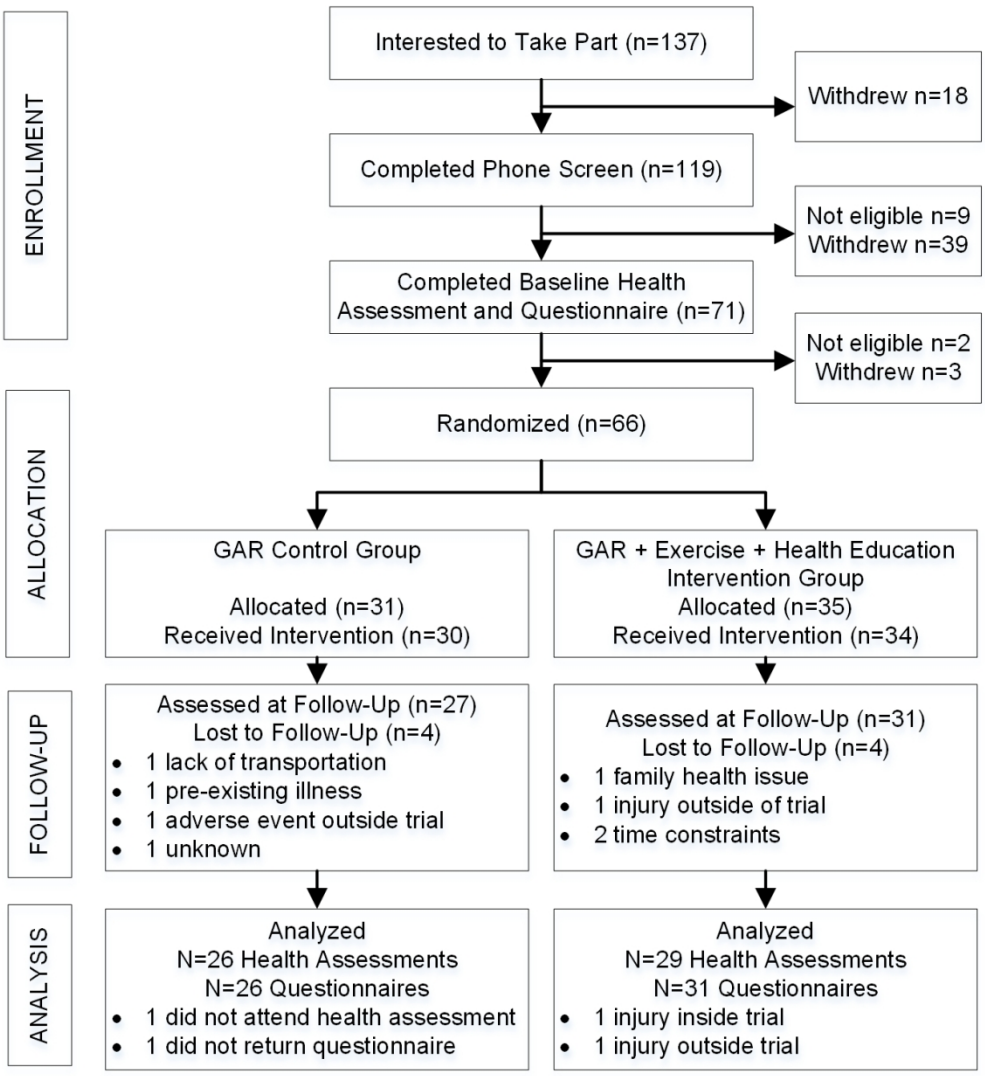

Figure 1: Participant time line: Consolidated Standards of Reporting Trials (CONSORT)-style flow chart

117x127mm (300 x 300 DPI)

Supplement 1. Geriatric Depression Scale, MOS Social Support Scale, and SF-36 Health Survey results by group

	Baseline Values		Change over Time (adjusted for baseline HHIE score)			
Measure	**Control Median (IQR)**	**Intervention Median (IQR)**	**Control Mean Δ (95%CI)**	**Intervention Mean Δ (95% CI)**	**Difference between Groups Mean Δ (95% CI)**	**Effect Size**
Geriatric Depression Scale	2 (1, 6)	2 (1, 3)	-0.9 (-1.8, 0.1)	-0.9 (-1.8, 0.2)	0 (-1.3, 1.3)	0
MOS Social Support Scale						
MOS Total Score	76 (50, 86)	76 (49, 93)	5.0 (0.8, 9.1)	0.8 (-3.0, 4.6)	-4.2 (-9.9, 1.6)	-0.38
Emotional Support	69 (38, 84)	75 (50, 91)	6.8 (1.4, 12.1)	1.1 (-4.0, 6.1)	-5.7 (-13.2, 1.8)	-0.39
Tangible Support	88 (50, 100)	75 (44, 94)	2.3 (-2.9, 7.5)	1.5 (-3.4, 6.4)	-0.8 (-8.1, 6.4)	-0.06
Affectionate Support	92 (50, 100)	83 (50, 100)	4.2 (-0.6, 9.0)	-0.4 (-4.9, 4.2)	-4.6 (-11.2, 2.2)	-0.35
Positive Social Interaction	75 (50, 100)	75 (50, 100)	2.5 (-2.0, 7.0)	0.4 (-3.8, 4.7)	-2.1 (-8.3, 4.2)	-0.17
Additional Item	63 (50, 75)	75 (50, 100)	8.5 (1.0, 16.0)	0.6 (-6.4, 7.5)	-7.9 (-18.4, 2.5)	-0.39
SF-36 Health Survey						
Physical functioning	80 (55, 95)	85 (65, 90)	4.0 (-3.2, 11.2)	0.9 (-5.8, 7.7)	-3.1 (-13.1, 7.0)	-0.16
Physical role limitations	75 (50, 100)	75 (50, 100)	-2.4 (-14.9, 10.2)	1.4 (-10.4, 13.2)	3.8 (-13.8, 21.3)	0.11
Emotional role limitations	100 (33, 100)	100 (67, 100)	0.1 (-10.4, 10.5)	-3.8 (-13.7, 6.0)	-3.9 (-18.5, 10.7)	-0.15
Energy/fatigue	60 (50, 80)	60 (45, 75)	0.5 (-4.2, 5.2)	3.0 (-1.4, 7.4)	2.5 (-4.1, 9.1)	0.19
Emotional well-being	80 (64, 88)	80 (72, 92)	0.7 (-3.2, 4.7)	-2.0 (-5.7, 1.7)	-2.7 (-8.3, 2.7)	-0.25
Social functioning	75 (63, 100)	88 (63, 100)	0.0 (-6.5, 6.6)	0.0 (-6.2, 6.1)	0.0 (-9.2, 9.1)	0
Pain	68 (45, 90)	68 (55, 80)	0.6 (-5.7, 6.9)	5.6 (-0.3, 11.5)	5.0 (-3.7, 13.8)	0.29
General Health	75 (60, 85)	70 (65, 85)	-0.3 (-4.8, 4.2)	1.4 (-2.9, 5.7)	1.7 (-4.6, 8.0)	0.14

Notes: IQR: interquartile range, Mean Δ**:** mean change, 95% CI: 95% confidence interval, *$p < 0.05$

Supplement 2. Distribution of COSI responses at follow-up, by group (Control N=26; Intervention N=31) and overall (N=57).

Situation	Amount of change experienced				
	Worse n (%)	No difference n (%)	Slightly better n (%)	Better n (%)	Much better n (%)
1. Conversations with 1 or 2 people in a quiet environment.					
Control	0 (0)	10 (38.5)	6 (23.1)	6 (23.1)	4 (15.4)
Intervention	0 (0)	9 (29.0)	7 (22.6)	13 (41.9)	2 (6.5)
Overall	0 (0)	19 (33.3)	13 (22.8)	19 (33.3)	6 (10.5)
2. Conversations with 1 or 2 people in a noisy environment.					
Control	1 (3.9)	12 (46.2)	7 (26.9)	6 (23.1)	0 (0)
Intervention	1 (3.2)	13 (41.9)	8 (25.8)	9 (29.0)	0 (0)
Overall	2 (3.5)	25 (43.9)	15 (26.3)	15 (26.3)	0 (0)
3. Conversations with a group in a quiet environment.					
Control	0 (0)	8 (30.8)	7 (26.9)	8 (30.8)	3 (11.5)
Intervention	0 (0)	8 (25.8)	11 (35.5)	10 (32.3)	2 (6.5)
Overall	0 (0)	16 (28.1)	18 (31.6)	18 (31.6)	5 (8.7)
4. Conversations with a group in a noisy environment.					
Control	1 (3.9)	10 (38.5)	10 (38.5)	4 (15.4)	1 (3.9)
Intervention	1 (3.2)	15 (48.4)	11 (35.5)	3 (9.7)	1 (3.2)
Overall	2 (3.5)	25 (43.9)	21 (36.8)	7 (12.3)	2 (3.5)
5. Hearing the television or radio at normal volume.					
Control	0 (0)	16 (61.5)	7 (26.9)	3 (11.5)	0 (0)
Intervention	0 (0)	17 (54.8)	6 (19.4)	7 (22.6)	1 (3.2)
Overall	0 (0)	33 (57.9)	13 (22.8)	10 (17.5)	1 (1.8)
6. Speaking with a familiar person on the phone.					
Control	0 (0)	17 (65.4)	3 (11.5)	5 (19.2)	1 (3.9)
Intervention	0 (0)	22 (71.0)	2 (6.5)	6 (19.4)	1 (3.2)
Overall	0 (0)	39 (68.4)	5 (8.8)	11 (19.3)	(3.5)
7. Speaking with an unfamiliar person on the phone.					
Control	1 (3.9)	17 (65.4)	5 (19.2)	3 (11.5)	0 (0)
Intervention	1 (3.2)	19 (61.3)	7 (22.6)	3 (9.7)	1 (3.2)
Overall	2 (3.5)	36 (63.2)	12 (21.0)	6 (10.5)	1 (1.8)
8. Hearing the phone ring from another room.					
Control	0 (0)	22 (84.6)	2 (7.7)	2 (7.7)	0 (0)
Intervention	1 (3.2)	22 (71.0)	6 (19.4)	1 (3.2)	1 (3.2)
Overall	1 (1.8)	44 (77.2)	8 (14.0)	3 (5.2)	1 (1.8)

9. Hearing the front door bell or someone knocking on the door.					
Control	0 (0)	19 (73.1)	5 (19.2)	2 (7.7)	0 (0)
Intervention	1 (3.2)	21 (67.7)	5 (16.1)	2 (6.5)	2 (6.5)
Overall	1 (1.8)	40 (70.2)	10 (17.5)	4 (7.0)	2 (3.5)
10. Hearing traffic (while walking outside or driving)					
Control	1 (3.9)	19 (73.1)	4 (15.4)	2 (7.7)	0 (0)
Intervention	1 (3.2)	23 (74.2)	3 (9.7)	3 (9.7)	1 (3.2)
Overall	2 (3.5)	42 (73.7)	7 (12.3)	5 (8.7)	1 (1.8)
11. Your amount of social contact (such as attending more social events or social situations or going out in public)					
Control					
Intervention	0 (0)	14 (53.9)	6 (23.1)	5 (19.2)	1 (3.9)
Overall	1 (3.2)	18 (58.1)	5 (16.1)	7 (22.6)	0 (0)
	1 (1.8)	32 (56.1)	11 (19.3)	12 (21.0)	1 (1.8)
12. Feeling embarrassed or stupid.					
Control	0 (0)	11 (42.3)	4 (15.4)	9 (35.6)	2 (7.7)
Intervention	0 (0)	17 (54.8)	9 (29.0)	2 (6.5)	3 (9.7)
Overall	0 (0)	28 (49.1)	13 (22.8)	11 (19.3)	5 (8.7)
13. Feeling left out.					
Control	0 (0)	11 (42.3)	7 (26.9)	8 (30.8)	0 (0)
Intervention	0 (0)	18 (58.1)	8 (25.8)	3 (9.7)	2 (6.5)
Overall	0 (0)	29 (50.9)	15 (26.3)	11 (19.3)	2 (3.5)
14. Feeling upset or angry.					
Control	0 (0)	14 (53.9)	5 (19.2)	7 (26.9)	0 (0)
Intervention	0 (0)	17 (54.8)	10 (32.3)	2 (6.5)	2(6.5)
Overall	0 (0)	31 (54.4)	15 (26.3)	9 (15.8)	2 (3.5)
15. Attending church or group meetings					
Control					
Intervention	0 (0)	18 (69.2)	4 (15.4)	4 (15.4)	0 (0)
Overall	0 (0)	24 (77.4)	3 (9.7)	2 (6.5)	2 (6.5)
	0 (0)	42 (73.7)	7 (12.3)	6 (10.5)	2 (3.5)

Supplement 3. Program Evaluation Questions and Distribution of Responses (Intervention N=33; Control N=24).

Exercise sessions (Intervention Participants)	**Strongly Agree n (%)**	**Agree n (%)**	**Disagree n (%)**	**Strongly Disagree n (%)**	**Don't know n (%)**
Overall, I was satisfied with the exercise program.	18 (55)	15 (44)	0 (0)	0 (0)	0 (0)
The exercise program was fun.	15 (45)	18 (55)	0 (0)	0 (0)	0 (0)
I did not enjoy the exercise sessions.	0 (0)	2 (6)	10 (30)	20 (61)	1 (3)
The exercises were too easy.	0 (0)	2 (6)	10 (30)	20 (61)	1 (3)
The exercise room was suitable for the program.	9 (27)	21 (64)	3 (9)	0 (0)	0 (0)
The fitness instructor clearly demonstrated the exercises.	17 (52)	16 (48)	0 (0)	0 (0)	0 (0)
The fitness instructor suggested modifications for the exercises to accommodate different fitness levels.	10 (30)	22 (67)	1 (3)	0 (0)	0 (0)
The fitness instructor was encouraging.	19 (58\)	14 (42)	0 (0)	0 (0)	0 (0)
The fitness instructor was approachable.	19 (59)	13 (41)	0 (0)	0 (0)	0 (0)
The fitness instructor spoke clearly.	9 (27)	20 (61)	4 (12)	0 (0)	0 (0)
There were a good variety of exercises.	14 (42)	18 (55)	1 (3)	0 (0)	0 (0)
I have increased my physical activity level outside of the program.	9 (27)	16 (48)	5 (15)	0 (0)	3 (9)
By participating, I feel I improved my strength and stamina.	9 (27)	20 (61)	2 (6)	0 (0)	2 (6)
By participating, I feel I improved my balance.	7 (21)	15 (45)	6 (18)	0 (0)	5 (15)
By participating, I feel I improved my flexibility.	6 (18)	23 (70)	2 (6)	0 (0)	2 (6)
As a result of the program, I walk more often.	8 (24)	17 (52)	7 (21)	0 (0)	1 (3)

Health Education Sessions (Intervention Participants)	**Strongly Agree n (%)**	**Agree n (%)**	**Disagree n (%)**	**Strongly Disagree n (%)**	**Don't know n (%)**
The presentation topics were interesting.	13 (39)	20 (61)	0 (0)	0 (0)	0 (0)
There were a good variety of presentation topics.	12 (36)	21 (64)	0 (0)	0 (0)	0 (0)
The information presented encouraged group discussions.	17 (52)	16 (48)	0 (0)	0 (0)	0 (0)
I did not enjoy the group discussions.	0 (0)	1 (3)	15 (45)	17 (52)	0 (0)
I often participated in the group discussions.	5 (15)	27 (82)	1 (3)	0 (0)	0 (0)
I learned about a healthy lifestyle for the health education sessions.	10 (30)	20 (61)	3 (9)	0 (0)	0 (0)
I enjoyed the student presentations.	14 (42)	18 (55)	1 (3)	0 (0)	0 (0)
I would have liked more student presentations.	4 (12)	17 (52)	8 (24)	1 (3)	3 (9)
I enjoyed the guest speaker presentations.	14 (45)	13 (42)	1 (3)	1 (3)	2 (6)
I would have liked more guest speaker	7 (23)	14 (45)	4 (13)	1 (3)	5 (16)

presentations.					
The information presented was difficult to understand.	0 (0)	0 (0)	20 (67)	10 (33)	0 (0)
I could see the speakers clearly.	13 (42)	17 (55)	1 (3)	0 (0)	0 (0)
I could hear the speakers clearly.	14 (45)	15 (48)	1 (3)	1 (3)	0 (0)

Walk Talk and Listen Program Overall (Intervention Participants)	**Strongly Agree n (%)**	**Agree n (%)**	**Disagree n (%)**	**Strongly Disagree n (%)**	**Don't know n (%)**
The program helped me to feel more comfortable in social situations.	2 (12)	13 (76)	1 (6)	0 (0)	1 (6)
The program helped to improve my emotional and mental wellbeing.	3 (18)	10 (59)	1 (6)	0 (0)	3 (18)
Overall, my lifestyle is healthier since I joined the program.	3 (18)	10 (59)	1 (6)	0 (0)	3 (18)
I am confident that I will continue with regular exercise after the program ends.	5 (29)	10 (59)	2 (12)	0 (0)	0 (0)

Group Auditory Rehab (GAR) sessions (Intervention and Control Participants)	**Strongly Agree n (%)**	**Agree n (%)**	**Disagree n (%)**	**Strongly Disagree n (%)**	**Don't know n (%)**
The meeting room was suitable for the program.	10 (37)	17 (63)		0 (0)	0 (0)
The GAR sessions helped me to recognize and better accept my hearing loss.	22 (39)	31 (55)	2 (3)	0 (0)	2 (3)
The GAR sessions helped me to become more self-confident in speaking out about my hearing loss in social situations.	24 (42)	32 (56)	0 (0.0)	0 (0)	1 (2)
The GAR sessions helped to improve my stress management skills.	6 (11)	36 (63)	7 (12)	0 (0)	8 (14)
The GAR sessions helped me to change my attitude about hearing loss for the better.	19 (33)	35 (61)	2 (4)	0 (0)	1 (2)
The GAR sessions helped me gain more problem solving skills.	9 (16)	41 (73)	1 (2)	0 (0)	5 (9)

Notes: There were no differences between control and intervention groups for GAR session evaluation questions (all $p > 0.05$)

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	Page 1:Title, page 2: abstract, page 3 and throughout the manuscript
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	Page 2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	Pages 2-3
	2b	Specific objectives or research questions for pilot trial	Page 3
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	Page 4
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	Page 4 and protocol paper
	4b	Settings and locations where the data were collected	Page 4
	4c	How participants were identified and consented	Page 4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 4
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Page 5
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	Page 5

Sample size	7a	Rationale for numbers in the pilot trial	Pages 4 and 5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	In the protocol paper
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	In the protocol paper
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Detailed in the protocol paper
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Detailed in the protocol paper
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Detailed in the protocol paper
	11b	If relevant, description of the similarity of interventions	Page 4
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	Pages 4 and 5
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Figure 1 and page 6
	13b	For each group, losses and exclusions after randomisation, together with reasons	Page 6 and figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 5
	14b	Why the pilot trial ended or was stopped	Page 4
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Page 6
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Figure 1
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Pages 6-9
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	Page 10

Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Figure 1 and pages 6 and 10
	19a	If relevant, other important unintended consequences	
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	Page 12
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	Pages 10-12
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	Pages 10-13
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	Pages 10-13
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	Page 4
Protocol	24	Where the pilot trial protocol can be accessed, if available	Pages 4 and page 15
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 13
	26	Ethical approval or approval by research review committee, confirmed with reference number	Page 13

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

TIDieR

Walk, Talk and Listen: A pilot randomized controlled trial targeting functional fitness and loneliness in older adults with hearing loss.

Walk, Talk and Listen: A pilot randomized controlled trial targeting functional fitness and loneliness in older adults with hearing loss.

Why: Page 3: Since HL, loneliness and physical inactivity are inter-related and associated with multiple co-morbidities, it is of interest to explore interventions that improve loneliness and physical function among older adults with HL. In this pilot randomized controlled trial, Walk, Talk and Listen (WTL), we begin to explore the impact of GAR on loneliness and physical function, and importantly, whether addition of an interactive/social group educational and physical strengthening intervention is of any additional benefit in older adults with HL.

What (material): Page 4: Detailed Walk, Talk and Listen (WTL) methodology is reported elsewhere [Lambert J, Ghadry-Tavi R, Knuff K, et al. Targeting functional fitness, hearing and health-related quality of life in older adults with hearing loss: Walk, Talk 'n' Listen, study protocol for a pilot randomized controlled trial. *Trials*2017;18(1)]. One hour control group GAR-only sessions occurred once a week. Intervention group one-hour GAR sessions were followed by 60 minutes of exercise (strength, resistance and coordination training: 45 minutes) and walking (outside or on indoor track: 15 minutes). On their second weekly visit, intervention participants attended a one-hour interactive SHE session [Lambert J et al: above}]followed by 60 minutes of exercise and walking.

What (procedures): Page 4: Interactive GAR sessions were guided by a modification of the GROUP program [27]and provided hearing education, goal setting and psychosocial and behavior change exercises including mindfulness, acceptance of HL, assertiveness training, communication strategies, problem-solving, anticipatory and

	repair strategies.[Montano JJ, Preminger JE, Hickson L, Gregory M. A new web-based tool for group audiologic rehabilitation. *Am J Audiol*2013;22(2):332-4].
Who provided:	Page 4: A certified YMCA trainer facilitated the exercise sessions.Trained students helped the principle investigator facilitate the GAR and SHE sessions.
How (mode of delivery; individual or group):	Page 4: .All procedures included groups of 10-20 participants and took place in a small, acoustically favorable meeting room and/or a small gym at the same YMCA site. One hour control group GAR-only sessions occurred once a week. Intervention group one-hour GAR sessions were followed by 60 minutes of exercise (strength, resistance and coordination training: 45 minutes) and walking (outside or on indoor track: 15 minutes). On their second weekly visit, intervention participants attended a one-hour interactive SHE session [25]followed by 60 minutes of exercise and walking.
Where:	Page 4: All procedures took place in a small acoustically favorable meeting room and/or a small gym at the same YMCA site
When and how much:	Page 4: All procedures included groups of 10-20 participants and took place in a small, acoustically favorable meeting room and/or a small gym at the same YMCA site over a period of 10 weeks. One hour control group GAR-only sessions occurred once a week. Intervention group one-hour GAR sessions were followed by 60 minutes of exercise (strength, resistance and coordination training: 45 minutes) and walking (outside or on indoor track: 15 minutes). On their second weekly visit, intervention participants attended a one-hour interactive SHE session [25]followed by 60 minutes of exercise and walking
Tailoring:	Page 4: (intervention) Participants were encouraged to walk between sessions and were provided a pedometer and tracking sheets to motivate them.
How well (planned):	Page 6: **Feasibility:** The Walk, Talk and Listen CONSORT diagram is shown in Figure 1. One hundred and thirty-seven individuals contacted the study center, 119 completed the initial phone screen, and 71 completed full eligibility screening. Ninety-six percent of eligible participants (n=69) were randomized (n=66) and 88% of participants (n=58) completed the study. GAR and exercise attendance rates were 80% and 85% respectively
How well (actual):	Page 6: GAR and exercise attendance rates were 80% and 85% respectively