Cover page for:

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

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Study protocol and statistical analysis plan.

In this single-blind, randomized controlled pilot trial, 60 ambulatory adults aged 65 years or older, with self-reported HL will be randomized into either the WListen intervention group (exercise, SHE sessions and GAR) or the control group (GAR alone). Control-group participants will be asked not to change their current physical activity levels and will be offered the 10-week exercise component after the trial is complete. The trial will take place in the "real life" context of a local sports and recreation facility (YMCA Okanagan) and will be free of charge to all participants. Interactive GAR and SHE sessions will be small, closed groups of no more than 12 participants and facilitated for the most part by CAJ and KK. An audiologist (KVB) will deliver a GAR session on the anatomy and process of HL and hearing assistive technologies. This trial will examine recruitment efficacy, reasons for participant interest in joining the trial, attrition rates and reasons, acceptability of GAR, SHE and physical activity interventions along with changes in the functional fitness and psychosocial measures relative to the control group. The findings will inform the design of a larger, multisite RCT.

Trial population and randomization

Ambulatory, community-dwelling adults aged 65 years or older will be invited to participate either directly by their audiologist, or through posters and information sheets placed in 10 Kelowna audiologists' offices, otolaryngologists' offices, local seniors' venues, the YMCA, local non-profit seniors' agency newsletters and local newspaper ads. Potential participants who call the trial telephone number will be given information by the trial coordinator (TC: CR) about the trial and, if still interested, will undergo a preliminary telephone eligibility assessment.

Preliminary telephone eligibility assessment

Table 1 provides the detailed inclusion and exclusion criteria. The trial coordinator, the principle investigator (PI: CAJ), will verbally review the Consent Form with potential participants and answer any questions that arise.. After verbal consent is obtained, participants will be again asked, "Do you have difficulty hearing when conversing with another person in a noisy environment?" [30]. Those answering "yes" will be guided through the validated Physical Activity Readiness Questionnaire (PARQ+) [31] to confirm that they meet the inclusion criteria and are healthy enough to participate in the intervention without exacerbating any existing symptomatology [32]. Those who pass the initial PARQ+ screen and/or those who provide a physician-signed CSEP letter of "exercise readiness" and:

- Self-report less than 150 min per week of physical activity [33]
- Have not participated in any organized exercise program for at least 6 months
- Are available and willing to attend at least 80% of the 10-week sessions in addition to completing baseline and final assessments, will be invited for final eligibility assessment

Final eligibility assessment

Final eligibility assessment (functional fitness testing) and baseline questionnaire completion will take place at the trial site (a local YMCA site) and be performed by members of the trained research team after signed informed consent has been obtained.

Randomization

Participants will be randomized (Stata® (StataCorp. 2013. Stata Statistical Software: Release 13, College Station, TX, USA: StataCorp LP) by an independent statistician (JS) into two groups, using permuted blocks of random sizes, stratifying on gender and age (below 73 years/73+ years) to ensure even distribution of these variables. The block sizes will not be disclosed to ensure concealment [34, 35]. When either of a couple is randomized to a different group (one to the control group and one to the intervention group), a fair coin toss will be used to decide which group they will both be assigned to (heads = control; tails = intervention). The randomization sequence will be concealed from the researchers who will confirm consent and eligibility with participants before allocation is revealed. Participants will be enrolled and assigned to the time and day(s) of the week by the project coordinator in consideration of their personal schedules. It is not feasible to mask participants or researchers after group allocation as the intervention includes an exercise program and the control does not.

Research team development

The research team will include the PI, the PC, two to four students per semester and their faculty supervisors (CAJ, HM, DK, GJ, JL, M-AM) from medicine, psychology, nursing, human kinetics and social work, respectively. This research team will be responsible for pre-and post-intervention assessments and training students and staff to conduct sessions in either the intervention or the control group.

Intervention

The trial will occur at different times on the same days for the intervention and the control groups. The intervention groups (GAR-SHE-exercise) will visit the YMCA twice a week (2 days apart) for 10 weeks. On the first visit each week they will attend a 1-h interactive GAR session (details of the session will be the same as for the control groups) and 90 min of exercise and walking. On their second visit each week they will attend a 1-h interactive SHE session followed by 90 min of exercise and walking. The exercise intervention will be offered to the control group after the RCT is completed (weeks 13–24). Control groups (GAR only) will attend a 1-h interactive GAR session at the YMCA once a week for 10 weeks. Trained students will help the PI to facilitate the GAR and SHE sessions. GAR sessions will be held in the same small, carpeted room and exercise sessions will occur in a small gym facilitated by a fitness instructor using a microphone and FM amplification system.

GAR sessions

GAR sessions (control and intervention groups) will be guided by a modification of the GROUP program [36] (http://idainstitute.com/toolbox/group/). The GROUP program is an IDA Institute-sponsored, web-based, interactive video-enabled program that provides a step-by-step guide for implementing and facilitating GAR programs. The guide provides instructions and informational content/handouts of best practices informed by leading GAR experts along with ethnographic videos allowing facilitators to see GAR in action. In addition, an audiologist (CVB) will facilitate the GAR session on HAs and hearing assistive technology for all groups. GAR sessions will include ice-breaking activities, ground rules for participants, goal setting, multiple communication strategies, coping with HL, handling difficult listening situations, types and uses of hearing assistive technologies, local resources and "advocating for yourself and others with HL." Psychosocial, mindfulness and stress-reduction strategies will also be included. Participants will engage in practical exercises to do as a group and at home. They will be encouraged to review their GAR handouts with their communication partners (CPs: spouse, significant other or friend). In addition to the weekly sessions, a single 3-h session will be scheduled to include participants' CPs. In this session, participants and their communication partners will discuss their own communication challenges and together decide upon and practice relevant communication strategies.

Socialization/health education (SHE) sessions

The interactive SHE sessions (intervention group only) will begin with a physical activity goal-setting session while the subject matter of the remaining nine SHE sessions topic areas will be decided upon by trial participant consensus. As for the WTL program [28], these sessions will, for the most part, be developed and facilitated by the students although some invited speakers will facilitate sessions in their area of expertise.

Exercise and walking sessions

A certified YMCA trainer will facilitate the 1-h exercise and 30-min walking-track sessions. These sessions will follow the standardized YMCA Fit for Life 50+ Program (https://www.h2okelowna.ca/Programs/Health-Fitness/Land-Fitness/Fit-for-Life-50?location=13ee95d3-cc67-48ca-9adb-c05d2d27fdc4) designed to build up strength, movement, coordination and balance. It incorporates TRX™, free weights and the walking track. Participants who miss an exercise session are asked to "make each one up" by either attending another Fit for Life 50+ Program session or doing a set of home-based Otago Falls Prevention Program exercises [37]. Participants are also encouraged to walk between trial sessions and will be provided a pedometer and tracking sheets to motivate and encourage them.

The interactive GAR and SHE sessions will begin with structured goal-setting interviews based on the model of social cognitive theory of behavior change [38], motivational interviewing [39] and collaborative goal setting [40]. Two to three specific, measurable, achievable, realistic goals for both auditory and physical activity outcomes will be identified and prioritized by participants. Goal setting and attainment will be revisited at each session using the social cognitive approach to motivate, empower and encourage adherence.

Measures

The primary measures: feasibility outcomes and acceptability of the pilot RCT:

1. Recruitment strategies (how did participants hear of the trial, willingness of hearing clinics to recruit participants, number of potential participants contacting the research team and by consulting the pilot trial participants, optimal ways to reach out to isolated individuals with HL)
2. Recruitment rates: numbers of potential participants that contact the trial center; of those, how many participated in telephone interview, how many gave verbal consent, and completed functional physical fitness testing and baseline questionnaires
3. Eligibility: how many potential participants were eligible, how many injuries, adverse events or dropouts)
4. Randomization: acceptability/willingness to be randomized, how baseline measures compared between groups
5. Session adherence and overall retention rates (intervention versus control groups' daily sign in sheets), final questionnaire completion rates and discontinuation rates (and reasons if given)
6. Overall acceptability of the program (control versus intervention) and GAR, SHE and exercise components (participant evaluation questionnaire: Likert-style and open-ended questions)
    - What aspects need to change? What should those changes be and how?
    - Acceptability of student participation in the HE and GAR sessions; capacity for student trainees – benefit to research and community? Role or impact of older adult/student relationship might be something to measure in relation to loneliness…
    - Acceptability and capacity of the YMCA to host the definitive RCT
    - Cost recovery processes for the YMCA: need to fund YMCA space, staff and time for budgeting purposes

The secondary measures: participant-specific outcomes (defined below) in order to generate estimates of data variation (standard deviations (SDs), standard error of the means (SE)), 95% confidence intervals (CIs) around the differences between control and intervention groups, and to determine the sample size estimate for the primary outcome of the definitive RCT:

1. Questionnaire measures:

    data collected at initial assessment include: age, sex, living situation (alone or with someone), marital status, ethnicity, highest level of education, annual household income before taxes, employment status, use of mobility or balance aids, falls over the previous 3 months, and HA use

2. Functional fitness measures:

measures taken at initial assessment and at the end of the 10-week intervention will include a battery of tests found to be reasonable estimates of the level of fitness associated with remaining physically mobile and independent in later life [41]. All assessments will be conducted over the 1-week period immediately before and at the end of the trial at the same locale using the same protocol and instruments. With the exception of the 6-min Walk Test (6MWT), all tests will be repeated twice for each limb (as appropriate) and the better of the two measures will be recorded (for each limb as appropriate).

- Muscular endurance of the lower limbs will be assessed using the 30-s Chair Stand Test (30SCST) [42]
- Aerobic fitness using gait speed in a 6MWT [43]
- Agility and balance using the Timed Up and Go Test (TUGT) [43]
- Grip strength (isometric muscular strength of the hand and forearm) [44] using a Smedley handgrip dynamometer (Fabrication Enterprises, Elmsford, NY, USA)
- The One-foot Balance Test [45] to examine balance and leg strength/endurance
- Flexibility (lower limbs and lumbar spine) using the Chair Sit and Reach Test [46]; the Back Scratch Test to assess the general shoulder range of motion [41]

3. Measures of hearing and health-related quality of life: (ICF outcomes: activities limitations, participation restrictions) at initial and end of intervention will include:
    - The Hearing Handicap Inventory for the Elderly (HHIE-25) [47], a validated 25-item questionnaire assessing the social, emotional and psychological challenges associated with HL and correlates well with audiometrically measured moderate to severe HL
    - The RAND SF-36 [48] (ICF outcomes: physical function, activities limitations, participation restrictions, a 36-item health-related quality of life measure with eight subscales including physical functioning, role functioning, bodily pain, general health, vitality, mental health, emotional role limitation and social functioning and social support
4. Measures of loneliness and social connectedness at initial and end of intervention:
    - De Jong-Gierveld Loneliness Scale [49])
    - Social participation using eight items developed for the Canadian Community Health Survey 4.2 [50], to determine the frequency of participation in family, friendship, and activities with other people outside of the household
    - Availability of social support using the Medical Outcomes Trial-Social Support Survey [51], a validated scale of overall social support and four domains of social support (emotional/informational, tangible, affectionate and positive interactions)
    - The Geriatric Depression Scale, a15-item questionnaire used as a screening tool in the older population [52]

5. Blood pressure and heart rate (initially and at end of intervention) according to Canadian Hypertension Education Program guidelines [53] using the validated BPM-100 (BpTRU Medical Devices, Coquitlam, BC, Canada), an automated oscillometric noninvasive blood pressure monitor

   Measures taken at the end of the trial.

6. GAR evaluation: at end of intervention. The International Outcomes Inventory-Alternative Interventions (IOI-AI) [54] questionnaire to determine outcomes of GAR programs. A modified Client Oriented Scale of Improvement (COSI) questionnaire [26] to evaluate the extent to which individual goals were reached [55] and overall benefit of the GAR intervention

Serious adverse events

The trial is expected to be low risk for serious adverse events, such as cardiovascular events (myocardial infarction, stroke, etc.), given the validated PARQ+ screen and/or the provision of a physician signed letter of "exercise readiness." While the risk is low, there is a possibility of a fall and or fracture during the supervised exercise sessions. This risk will be minimized with exercise sessions facilitated by Canadian Society for Exercise Physiology (CSEP) certified fitness trainers. If an adverse event does occur, the PI (clinical team member onsite during all session times) and key YMCA staff will be immediately alerted and, research protocols and institute appropriate procedures initiated and changes to the exercise program implemented if deemed necessary.

Sample size

The sample size for this pilot trial [56, 57] is based upon anticipated numbers of potential participants who contact the trial center within an 8-week recruitment period. Based on previous unpublished experience in the WTL program using pre-post data on older adults with HL, we estimate that approximately 15 per week will contact the trial center, 50–60% of those who make initial contact will meet the eligibility criteria and agree to be randomized, and at least 23 people per group at trial end to show a clinically meaningful average increase in the Sit to Stand Test (STS) of 2 [58]. This sample size will also ensure that enough data is available to generate reliable SE, SD and 95% CI on the sample size required for the large RCT with this measure as the primary outcome. A definitive RCT will be deemed feasible when at least 120 individuals contact the pilot trial center, ≥90% fulfill feasibility outcomes 2–4 and at least 70% of randomized participants fulfill outcome number 5. A larger RCT will be deemed acceptable if at least 85% of participants find the GAR, exercise and SHE sessions highly acceptable or acceptable.

Research data and management

Participants will be assigned a participant number upon initial contact with the trial coordinator. Questionnaire and functional fitness testing data will be collected and recorded by the trained research team members on paper-based data collection sheets during the week prior to randomization and during the week after the end of the 10-week trial. Fully anonymized data will

be manually entered into an Excel® spreadsheet, 100% double-checked for errors or omissions by a team member blinded to the participants' group allocation, then cleaned and transferred into Stata® statistical software for analysis.

Knowledge translation

Overall knowledge translation goals will be to increase public and academic awareness of HL as a disability and the need for organized screening initiatives and enhanced programing to support all five ICF domains of disability in older adults with HL. Results will be presented to participants, families and significant others/supports, study partners, at public forums, at local, national and international university academic and health conferences, to health and non-health-related governmental departments and media (radio, local TV). Articles will be published in local newspapers and peer-reviewed academic journals.

Statistical methods

For primary outcome measures, analyses will be descriptive and variables will be expressed as frequency and percentage for all data relating to recruitment, adherence, overall retention rates, plus all other categorical data on program feasibility and acceptability. Any continuous data will be expressed as mean plus SD or median and interquartile range (for non-normal data). Participant demographics at baseline will be described both by group and overall sample. Responses for Likert-type data will be combined into three nominal categories ("strongly agree/agree," "strongly disagree/disagree" and "don't know") and differences between the intervention and control groups analyzed by Fisher's exact test [59]. Responses to open-ended questions will be coded and organized into themes and descriptive statistics (including percentages) will be used to report the results.

For secondary outcomes measures, the main analysis will be intention-to-treat: the group to which a participant is assigned will be the group in which they are analyzed, regardless of participant protocol violations, attendance rate or dropout [60]. Last observation carried forward will be used to impute missing outcome data assuming less than 20% missing data for a given outcome measure. The functional fitness measures will be analyzed using the analysis of covariance method with the baseline measure as the covariate and follow-up measure as the outcome [61]. Data will be transformed for analysis of covariance when initial and end of intervention data is non-normal. Both a complete case and per protocol analysis will also be conducted to study the impact of departures from the assumptions made in the main intention-to-treat analysis. All continuous primary and secondary outcome variables will be assessed for normality visually using histograms and boxplots, with the Shapiro-Wilk test used as a supplement to the graphical assessment.

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