HHS Public Access

Author manuscript

Obesity (Silver Spring). Author manuscript; available in PMC 2024 April 01.

Published in final edited form as:

Obesity (Silver Spring). 2023 April ; 31(4): 965–976. doi:10.1002/oby.23702.

Deaf Weight Wise: A novel randomized clinical trial with Deaf sign language users

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Abstract

Objective: To address the absence of evidence-based weight control programs developed for use with Deaf people.

Methods: Community-based participatory research informed the design of the Deaf Weight Wise (DWW) trial and intervention. DWW focuses primarily on healthy lifestyle and weight through change in diet and exercise. We enrolled 104 Deaf adults aged 40-70 years with a BMI of 25-45 from community settings in Rochester, NY, and randomized participants to immediate intervention (n=48) or one-year delayed intervention (n=56). The delayed intervention serves as a no-intervention comparison until the trial mid-point. We collected data five times (every 6 months) from baseline to 24-months. All DWW intervention leaders and participants are Deaf people who use American Sign Language (ASL).

Results: At 6-months, the difference in mean weight change for the immediate intervention arm versus the delayed intervention arm (no intervention yet) was −3.4kg (multiplicity-adjusted p=0.0424; 95% CI: −6.1 to −0.8 kg). Most (61.6%) in the immediate arm lost ≥5% of baseline weight versus 18.1% in the no-intervention-yet arm (p<0.001). Participant engagement indicators include mean attendance of 11/16 sessions (69%), and 92% completed 24-month data collection.

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TRIAL REGISTRATION: ClinicalTrials.gov NCT01452269

DISCLOSURE: All authors have completed the ICMJE Form for Disclosure of Potential Conflicts of Interest. We declare that there are no conflicts of interest. Aside from the above listed grant funding for this research from USA Department of Health & Human Services (CDC, NIH, and/or AHRQ), the authors have no financial relationships with any organization that might have an interest in the submitted work; there are no other relationships or activities that could appear to have influenced the submitted work.

Conclusion: Deaf Weight Wise, a community-engaged, culturally-appropriate and language-accessible behavioral weight loss intervention was successful with Deaf ASL-users.

Keywords

Behavioral strategies; Minorities; Overweight; Obesity; Weight control

INTRODUCTION

Deaf people who use sign language comprise medically underserved language minority populations that have much in common with other language minority populations.[1–3] Deaf sign language users are often excluded from health research and public health surveillance, so we know relatively little about their health and health risks.[4] Health outcomes in Deaf communities are likely worse than those in the general population because of inequitable access to healthcare, health information, education, and economic resources.[4]

A community-engaged process with Deaf populations in Rochester NY identified obesity as a priority for intervention.[3,5] No evidence-based weight control programs existed that were developed for use with Deaf people. Limitations to participation by Deaf people in mainstream programs include discordant language (American Sign Language [ASL] is not English), other communication barriers, cultural incongruence with the program and participants, and isolation from being the only Deaf ASL-user in the program; that isolation limits access to the benefits of the peer-support component of group interventions. The Deaf Weight Wise (DWW) study arose to address this gap in evidence-based programs. The overall hypothesis is that an evidence-based multicomponent program to modify obesity-related health behaviors will be effective with Deaf people after adapting the program to be culturally appropriate and language accessible.

METHODS

Study design

We used community-based participatory research as our research paradigm.[3] The DWW study maintained a community committee comprised of Deaf community members who partnered with the research team on all aspects of the study design and implementation. Study team members who interacted with research participants were Deaf and/or ASL-fluent. The overall design of this clinical trial has two arms, with randomization to immediate intervention versus intervention delayed one-year. We randomized 45% to immediate intervention and 55% to delayed intervention to prepare for potential attrition of those randomized to delayed intervention, either from their own withdrawal from the study or the need to exclude delayed intervention participants from data analyses because of cross-participation, such as being exposed to DWW materials from a participant in the immediate intervention arm (Figure 1).

The University of Rochester Research Subjects Review Board (RSRB) reviewed and approved the study protocol. The DWW study team worked closely with RSRB to implement an informed consent process that presented information in ASL. ASL, like many

of the world's languages, has no written form.[6] We adapted the video novella approach[3,7] to present consent information in ASL, and DWW study staff who are ASL-fluent confirmed comprehension and consent prior to enrollment.[3]

Community-based participatory research

The Rochester Deaf Health Task Force, comprised of Deaf community members, clinicians, researchers, and other stakeholders, identified the need for health research with Deaf populations to determine community strengths and health disparities.[3] The Deaf Health Community Committee (DHCC) and researchers partnered to develop and field a survey in ASL in Rochester. The community-researcher partnership conducted community forums to present analyses of survey data, discuss interpretation of findings, and select health priorities for intervention research.[3,5] The community-researcher partnership identified overweight/obesity and the attainment of healthy weight as a top priority,[3,5] and worked together to select an evidence-based weight program and adapt it for use with Deaf ASL-users. DHCC made key recommendations for the Deaf Weight Wise (DWW) study design, such as the delayed intervention arm (to ensure that all research participants received the intervention), as well as feedback about the informed consent process (a video novella format in ASL).[3] DHCC helped identify potential DWW trial participants. All study-related communication with trial participants was in ASL, either direct communication with research staff and DWW intervention counselors, or via interpreter services for communication with research nurses who are not ASL-fluent. Qualitative interviews in ASL with DWW research participants provided information on the experiences with the DWW intervention and randomized trial. The community-researcher partnership shared information with Deaf communities about DWW trial preliminary findings via community forums.

Participant eligibility

DWW participants are Deaf ASL-users ages 40-70 years, with a BMI of 25-45, who live in the Rochester (NY) Metropolitan Statistical Area. We required clinician clearance for those with a cardiovascular disease event or symptoms in the prior six months, safety issues related to engaging in physical activity,[8] or weight loss surgery in the past two years. DWW participants agreed to participate in the DWW program and data collection, and to abstain from weight loss medications during the study. Exclusion criteria include pregnancy, breastfeeding, or planning a pregnancy. During eligibility screening, no potential participants reported current or planned pregnancy or breastfeeding.

Cross-participation

Rochester's Deaf community is close-knit; there was a risk that delayed intervention controls would be influenced by interactions with participants in the immediate intervention arm. We anticipated that a small number of DWW participants would have a spouse, partner, or roommate also enrolled in DWW. During baseline enrollment, a member of the research team asked each participant about cohabitation and relationships with anyone enrolled in DWW. We also cross-checked participants' addresses to determine if any lived in the same household. To avoid cross-participation, we assigned to the same intervention arm participants who lived together and reported that their DWW-relevant behaviors were similar (e.g., food shopping, meal preparation, eating habits). The first person in the relationship to

enroll was randomly assigned to one of the two study arms; we then assigned the second person in the relationship to that same arm. We assessed cross-participation with in-person interviews during the 6-month and 12-month data collection visits; no cross-participation was reported.

Randomization

After informed consent, baseline assessment, and medical clearance, we randomly allocated participants to one of two arms. We used block randomization to ensure balanced distribution between study arms. Dr. Yang, a biostatistician and author of this study, generated the random list and assigned the study arms without knowledge of the participant's identity.

Intervention

Deaf Weight Wise focuses primarily on healthy lifestyle and the prevention of weight gain through change in diet and physical activity. To create DWW, Deaf and hearing researchers and community members selected the Weight Wise Program (WWP), an evidence-based behavioral weight loss intervention developed for use with rural North Carolina women,[9] and adapted the program content, counselor training curriculum, and research measures to be language accessible and culturally appropriate for use in Rochester NY with Deaf adult ASL-users. We worked with the University of North Carolina (UNC) WWP team throughout the adaptation process and the DWW clinical trial.

The UNC WWP was adapted from the Diabetes Prevention Program (DPP)[10] and the Dietary Approaches to Stop Hypertension (DASH)[11] intervention tested in the PREMIER trial,[12] and follows the theoretical framework and core behavioral components of those interventions.[9] The UNC WWP targeted lifestyle changes to yield weight loss of 0.45-0.9 kg/week over 16-weeks. The intervention emphasizes daily self-monitoring of type and quantity of foods, calories, and >150 minutes/week of physical activity.

The DWW intervention consists of 16-weekly two-hour group intervention sessions led by trained counselors who are Deaf ASL-users. The 16-week curriculum incorporates experiential learning ("taste-its," "do-its") in addition to group support/interaction and motivational interviewing techniques implemented by the counselor. Similar to WWP, DWW used incentives ("Wise Bucks") to promote daily self-monitoring using their food/fitness diary, but not weight loss. Participants redeemed Wise Bucks for items useful to support program goals regarding physical activity and healthy eating (examples include yoga mats, blenders, lunch boxes to encourage healthy meal preparation at home). Following the 16-week intervention, participants entered a 6-month "maintenance phase" with less intense intervention. The DWW 6-month maintenance phase consisted of two two-hour meetings of the original intervention group, one each in maintenance months 3 and 6. This meeting included a weigh-in, review of self-monitored diet and physical activity, and problem-solving, goal-setting, and action-planning to achieve long-term success. Group attendees were encouraged to continue to interact with their group's members during the maintenance phase. Counselors contacted participants individually via email every two weeks and once monthly via videophone during the 6-month maintenance phase to

reinforce DWW lessons and support each participant to make and maintain lifestyle changes, including self-monitoring, in order to achieve individual goals.

For the DWW randomized trial, we formed 13 intervention groups (six in the immediate arm and seven in the delayed arm). The initial size of each group averaged 7-8 participants (range 5-12).

Retention

We designed retention materials for use with participants not currently in the intervention or maintenance phases of DWW (Figure 1). Retention materials provided culturally and linguistically appropriate health information not related to weight, nutrition or exercise (e.g., skin cancer, flu).

Measures

Data collection occurred five times over 24 months (baseline, 6-months, 12-months, 18-months and 24-months), and included biometric measures, 1:1 in-person interviews in ASL, and custom video surveys in ASL.[13] Biometric outcomes include changes in weight, waist circumference, and Body Mass Index (BMI), measured by an experienced research nurse. BMI is calculated from measured height and weight during each data collection visit. Communication during DWW lab appointments with a research nurse (not ASL-fluent) was facilitated by sign language interpreter services. Diet and physical activity were self-reported during 1:1 interviews in ASL with DWW study personnel. Similar to the UNC WWP trial,[9] we used the Dietary Risk Assessment (DRA)[14] and the Physical Activity Assessment (PAA)[15] to record self-reported diet and physical activity. Examples of items on the DRA include number of servings of fruits and vegetables, servings of different dairy foods, and frequency of restaurant meals. PAA items capture intensity, type, and minutes of physical activity. We used computer-based surveys in ASL to collect demographics and self-reported information about health, such as depression symptoms using the PHQ-9.[16] Participants were paid for data collection visits ($20 each for initial and 6-month visit, $30 each for the 12- and 18-month visits, and $50 for the final visit at 24-months).

The URMC Clinical Research Center provided an experienced research nurse to measure weight, height, and waist circumference during each of the five DWW data collection visits. The research nurses were not connected with the Rochester Deaf community, were unaware of each participant's assigned intervention arm, and did not have access to each participant's biometric measures from prior data collection visits at the time of the current data collection appointment. The research nurses had no other connection with the DWW study.

Primary and exploratory outcomes

Our pre-specified primary outcomes are changes in mean weight, diet (DRA) and physical activity (PAA) from baseline to 6-months, comparing the immediate intervention arm with the no intervention yet comparison arm. Exploratory analyses examined other time points during the 24-month trial, and other biometric measures, such as BMI and waist circumference.

Statistical analysis

For the primary outcome of weight change from baseline to 6-months, the study was designed to have 80% power to detect at least 4.4kg to 1.5kg weight change difference between the immediate intervention arm (treatment) and the delayed intervention arm (no intervention yet control) with a total sample size of 20 to 142, assuming weight changes for the delayed intervention are similar to the control group in the WWP randomized trial.[9] Analyses also explored changes from baseline to other data collection points. We used multiple imputation with fully conditional specification method for missing data treatment under the assumption of missing at random (MAR). Baseline values and characteristics were used in missing data calculation. The robustness of conclusions under MAR was explored by sensitivity analysis with pattern mixture models under the assumption of missing not at random (MNAR),[17–19] where a rescaling parameter indicates that a participant who drops out from the study was assumed to have on average 1%-5% more weight compared to a participant with similar characteristics who remained in the study. We used mixed-effect models with unstructured covariance to examine time, treatment, and their interaction effects, and to take into account the within-subject and within-group correlation,[20,21] while controlling for some baseline characteristics. The mixed-effect models were simultaneously used to test for differences within each arm, from baseline to each time point, and difference between the immediate- and delayed- intervention arms from baseline to each time point. For primary outcomes, ANCOVA with a random effect modeling within-group correlation was also applied to changes from baseline to 6-months, to control for possible effect of baseline values on outcome changes, in addition to adjustment to other baseline characteristics. We used Bonferroni correction,[22] a conservative method for multiple adjustment. Analyses used SAS 9.4 statistical software.[23]

RESULTS

We enrolled 104 participants over seven months and randomized 48 to receive the intervention immediately and 56 to receive the intervention after a one-year delay. Only diastolic blood pressure and high-density lipoprotein (HDL) cholesterol had statistically significant differences between arms at baseline (Table 1). There were no study-related adverse events.

Primary outcomes – intervention vs no intervention

At the six-month data collection time point, we compared the mean post-intervention outcome changes of the immediate intervention arm participants to the six-month outcomes of those in the delayed intervention arm (no intervention yet). DWW was better than no intervention for change in weight. Immediate intervention participants had a mean weight change of −5.7kg, whereas delayed intervention control participants had a mean weight change of −2.3 kg, for a statistically significant difference of −3.4kg (p=0.0106 and adjusted p=0.0424). For the primary outcomes of diet and physical activity, we did not find a difference between study arms for change in mean DRA or PAA scores from baseline to 6-months (Table 2). The sensitivity analyses (Tables S1 & S2), and the ANCOVA with random effects model (Table S3), all yielded similar results.

Exploratory analyses (not adjusted for multiple comparisons)

Intervention vs no intervention yet controls: DWW was better than no intervention for change in BMI (Table 3). In addition, at the six-month data collection time point, most participants in the immediate intervention arm (61.6%) lost ≥5% of their baseline weight versus 18.1% of participants in the delayed intervention arm (no intervention yet) ($p<.001$), a statistically significant and clinically meaningful difference.

Pre-intervention to post-intervention biometrics: We conducted analyses that examined within-arm pre- and post-intervention measures and found similar improvements in mean weight, BMI and waist circumference in each arm (Table 3).

Weight loss maintenance: Many participants in the immediate- and delayed-intervention arms achieved persistent post-intervention weights that were ≥5% less than their baseline weight. After finishing the 16-week DWW intervention, 61.6% of immediate participants and 60.8% of delayed participants had weights that were at least 5% less than baseline weight. Six months after the 16-week DWW intervention, 48.3% of immediate participants and 49.1% of delayed participants had weights that were at least 5% less than baseline. The longer post-intervention follow-up with immediate arm participants found that 49.6% and 44.7% had weights that were at least 5% less than their baseline at 12-months and 18-months after the 16-week DWW intervention, respectively. Figure 2 shows mean weight, waist circumference and BMI at each time point separately for each intervention arm, under MAR assumption.

Participation and Retention

The mean number of DWW sessions attended for all participants (n=104) was 11/16 sessions (69%). Of the 85 participants who attended at least one DWW session, 88.2% attended 10 or more sessions; by study arm, this includes 83.7% (36/43) of the immediate participants and 92.9% (39/42) of delayed participants. In addition, 92% of eligible participants completed data collection at the final (24-month) time-point.

DISCUSSION

Deaf Weight Wise, an intervention developed with Deaf people and led by Deaf people to address a health priority identified by Deaf community members was successful at addressing overweight and obesity. DWW resulted in clinically meaningful weight loss that persisted post-intervention. Our findings are consistent with or better than outcomes reported in a systemic review of behavioral weight loss interventions used with other populations.[24]

The Deaf Weight Wise intervention and DWW randomized trial are novel for a number of reasons, such as our use of community-based participatory research methods, our approach to informed consent using a video-novella format in ASL to provide information in the primary language of the research participants, and our inclusion of deaf sign language users as research participants, DWW intervention leaders, and community stakeholders who informed decisions about the design of the DWW intervention and DWW research. We believe that our community-based participatory approach contributed to DWW's success,

with a strong sense of community ownership of the intervention and research. Another contributor to success is that this is the first time that these participants had access to a culturally appropriate and language accessible behavioral intervention to address obesity risks. Rochester Deaf communities identified obesity as a priority,[5,25] and were enthusiastic participants in the DWW program and research that we collaboratively developed to address that priority.

Eighteen percent of participants in the delayed intervention arm achieved clinically meaningful weight loss (≥5% of their baseline weight) during the year prior to beginning their DWW intervention. The reporting of DWW baseline biometric results is one potential explanation. Each DWW participant was informed of their biometric results directly in ASL by an ASL-fluent research coordinator via a videophone call. Direct information in ASL about one's own health is a rare experience for many Deaf ASL-users. Knowing and understanding their own biometric results may have motivated some research participants to change health related behaviors. After the videophone call, DWW mailed a personalized letter to each participant summarizing the biometric measures and encouraging the participant to share the information with their own doctor. These letters may have motivated some of the participants' physicians to intervene in ways that contributed to weight changes prior to beginning the DWW intervention. The use of a delayed intervention arm helped to isolate the effect of the DWW behavioral intervention from the effect of informing participants of their biometric results.

Another benefit associated with the use of a delayed intervention arm is that it allowed everyone to receive the DWW intervention, and the research could compare those who received the DWW intervention with those who had not yet. No participants were assigned to receive no intervention at all. This was vitally important, especially given that there are no other options for programs with Deaf people to prevent or address overweight and obesity. This study design decision helped build relationships and trust, and contributed to the success of the research.

Our primary outcomes for changes in diet and exercise were not significant. We selected the DRA and PAA, written English measures used in the WWP trial. For DWW, we administered the DRA and PAA via standardized interviews in ASL, the primary language of DWW participants, because English is a second language for many Deaf ASL-users. DWW study coordinators reported that the DRA and PAA did not work well with DWW participants, whereas DWW counselors reported that DWW participants indicated changes to their diet and activity during DWW intervention sessions. The changes in weight associated with DWW are likely related to changes in diet and/or exercise not captured with the DRA and PAA.

Rochester NY is unique in terms of Deaf populations.[3] Rochester has one of the largest per capita Deaf populations anywhere, and many Deaf people in Rochester have high educational attainment.[5,25,26] Rochester has a history of collaborative health research with Deaf communities.[3,27,28] The population size and strong community-researcher-clinical relationships make Rochester an ideal place to develop health interventions with Deaf

communities, to evaluate interventions with randomized trials, and then work with partners in new locations to disseminate, implement, adapt, and study those interventions.

Deaf people outside of Rochester would likely benefit from DWW.[29–32] Some Deaf communities do not have the resources to support a trained local DWW intervention leader or sufficient numbers to form a local DWW intervention group. Centralized services are a cost-effective way to deliver remote behavioral interventions with other language minority populations (via telephone).[33,34] Additional research with DWW should develop, pilot and study novel delivery modalities, such as video-remote intervention delivery, as well as novel approaches to remotely train, supervise and support DWW intervention leaders.

Limitations

Rochester NY Deaf communities are unique,[3] and findings from research in Rochester may not be generalizable to Deaf communities elsewhere. Our study did not collect data from participants' clinicians or medical records, so we do not know about initiation or changes to medications that might be associated with some of the biometric outcomes. Data collection for weight change occurred at 6-months, whereas the DWW intervention was 16-weeks, so our weight measure may underestimate the weight loss immediately post-intervention.

CONCLUSION

Deaf Weight Wise is the first randomized trial of a behavioral weight loss intervention with Deaf sign language users. This culturally appropriate and language accessible intervention was successful in terms of participation and outcomes with this underserved and rarely studied population. The DWW study serves as a model of using community engaged approaches to successfully develop, implement, and assess programs to address population health with Deaf communities.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

ACKNOWLEDGEMENTS

We thank Alice Ammerman DrPH, Christopher Lehfeldt DDS, Ann Miller MS RN, Brian Piotrowski MD, Song Hoa Choi MA, and members of the Deaf Health Community Committee. The work presented here represents the collective effort of a large team of community members, researchers, staff, and students.

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FUNDING:

This research was supported by U48-DP000031, U48-DP001910, U48-DP005026, and U48-DP006394 from the Centers for Disease Control and Prevention (CDC) Prevention Research Centers (PRC) Program, K08-HS15700 from the Agency of Healthcare Research and Quality, and T32-HL007937 from the National Institutes of Health. The funding sources had no role in the study design, conduct, analyses, interpretation of findings, or publication decisions. The contents of this article are solely the responsibility of the authors and do not necessarily represent the official views of the funders.

Data sharing statement:

Will individual de-identified participant data be available? Yes, de-identified participant data and a data dictionary will be available.

When will data be available? With publication and ending 5 years following article publication.

What other documents will be available? Informed consent form in written English and informed consent video in American Sign Language (ASL); study protocol; statistical analysis plan.

With whom will data be shared? Those with an approved Data Use Agreement.

What types of analyses? Research with an approved Data Use Agreement.

By what mechanism will data be made available? Email requests to ncdhr@urmc.rochester.edu

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STUDY IMPORTANCE

What is already known?

- Healthcare, including weight control programs, experience barriers to engaging with deaf people, for example, providing interpreter services necessary for effective communication. These barriers persist despite laws requiring their elimination.
- Inequities in access to information and programs to prevent and address obesity, coupled with inequities in social determinants of health (e.g., education and employment), are likely associated with health disparities experienced by Deaf communities.

What does this study add?

- Deaf Weight Wise, an intervention developed with deaf sign language users and led by deaf sign language users to address a health priority identified by Deaf community members was successful at addressing overweight and obesity.
- This study demonstrates the feasibility of a “deaf-to-deaf” approach to promote health, which means that health programs with deaf populations can move forward without being hindered by communication barriers that persist in some public health and healthcare systems.

How might these results change the direction of research or the focus of clinical practice?

- The “deaf-to-deaf” approach creates education and employment opportunities – such as becoming a credentialed DWW counselor – that help address social determinants of health and create opportunities to disseminate and implement DWW to reach other Deaf communities, and opportunities to study DWW’s dissemination and implementation.
- DWW models a community-partnered and language-concordant approach to promote healthy weight that could be adapted for use with other language minority communities.

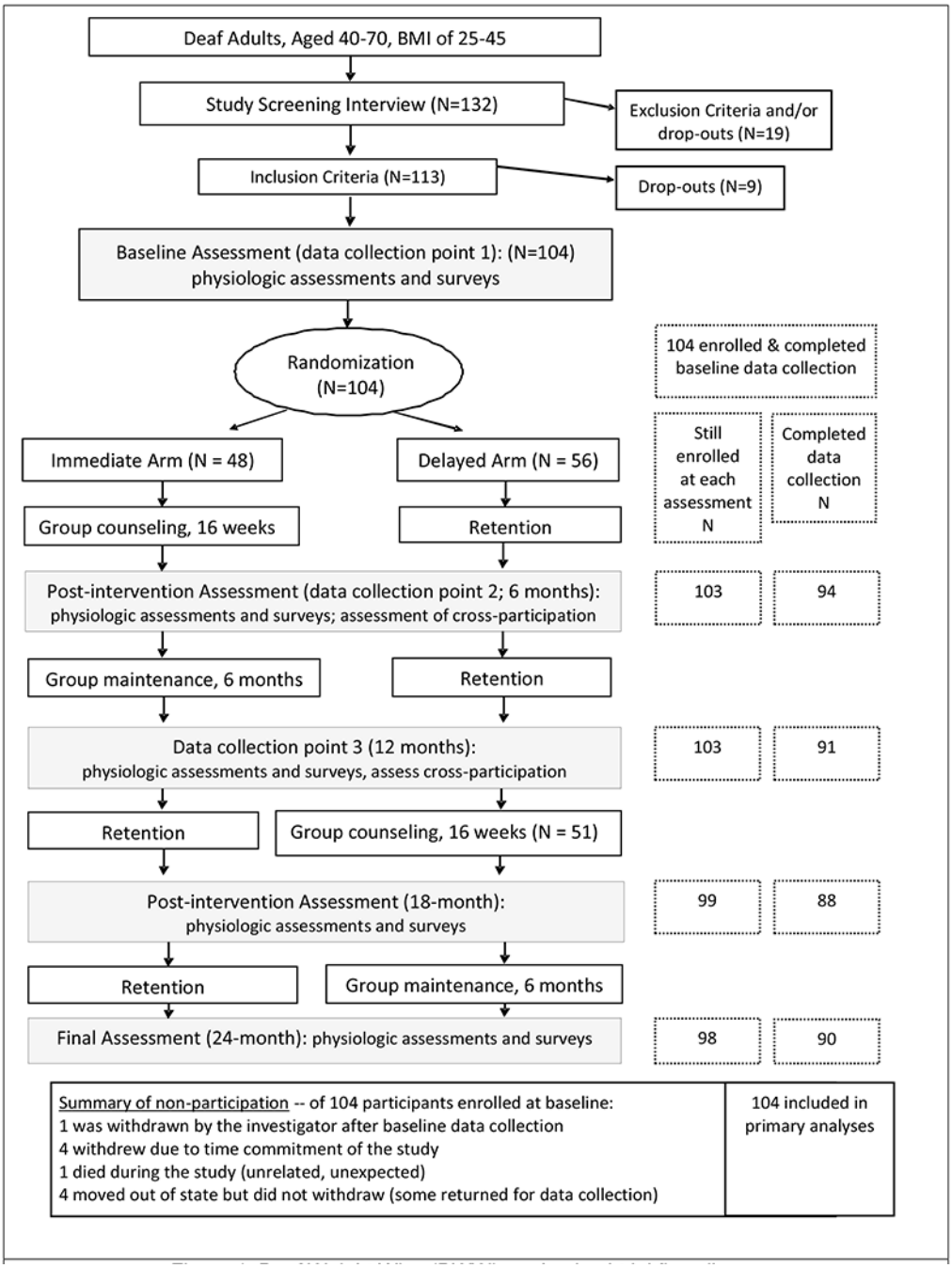
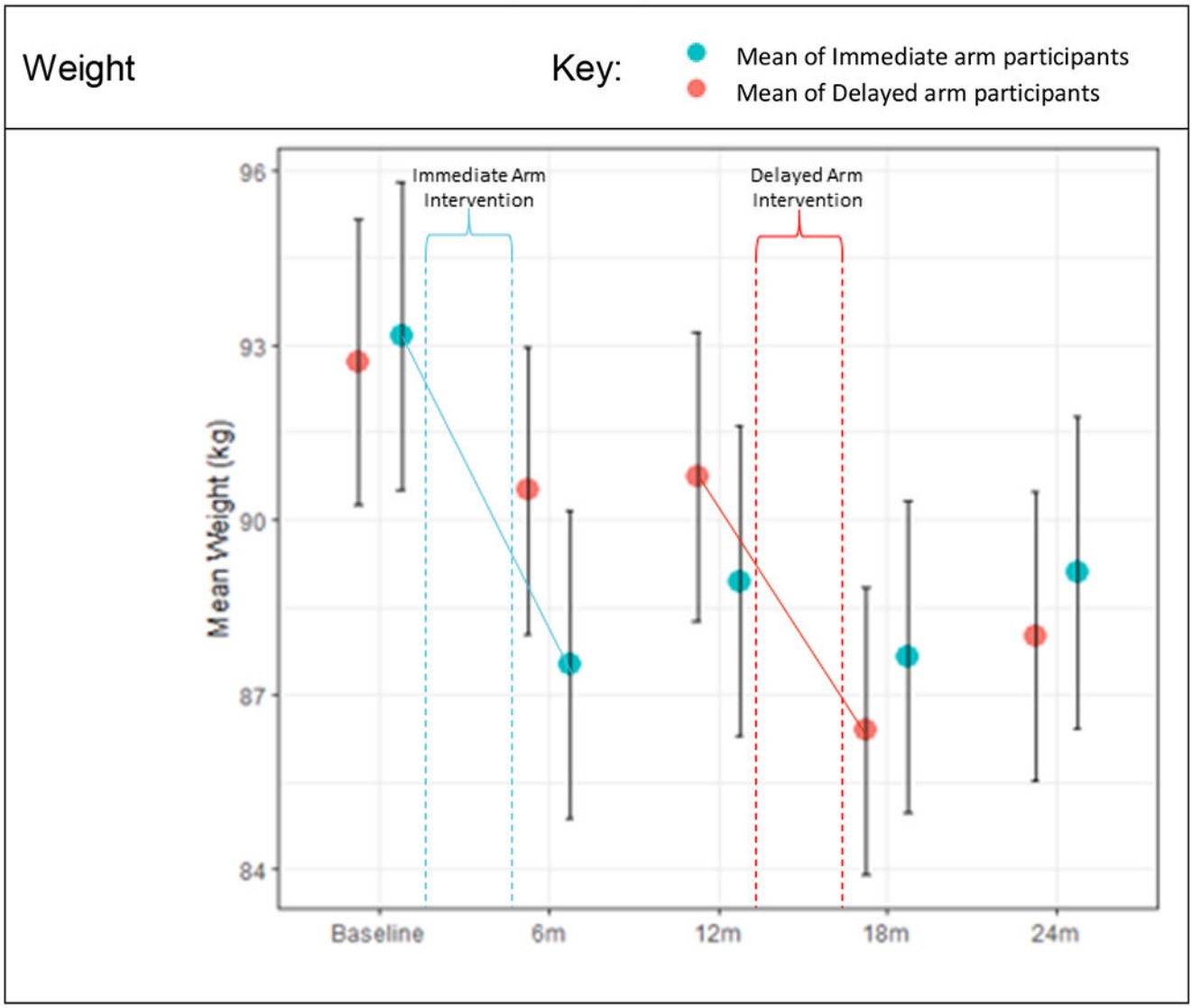


Figure 1:
Deaf Weight Wise (DWW) randomized trial flow diagram.



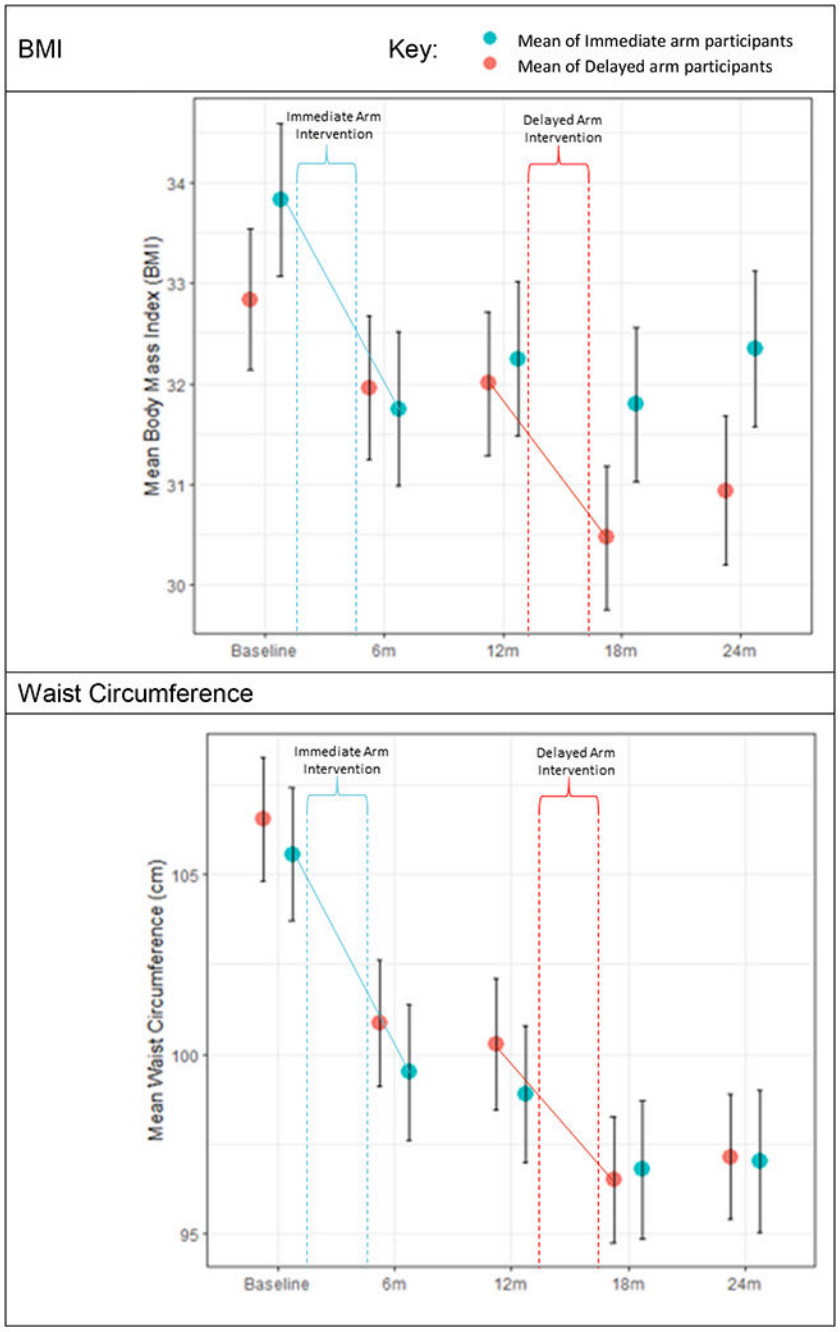


Figure 2:

Mean Weight, BMI, and Waist Circumference of the Immediate- and Delayed-Intervention arms at all data collection points

Notes:

1. Bars represent 95% CI at each time point.

2. Results for mean weight, mean BMI, and mean waist circumference are based on mixed-effect model fitting of imputed data, controlling for diastolic blood pressure and HDL

cholesterol, as these two variables showed statistically significant differences between arms at baseline after randomization.

Table 1:

Baseline characteristics of Deaf Weight Wise (DWW) participants

	Total N=104	Immediate Intervention N=48		Delayed Intervention N=56	
	Mean age	**Mean (s.e.)**	**95% CI**	**Mean (s.e.)**	**95% CI**
Demographics					
Age (years), Mean (s.e.)	53.5 yrs	53.6 (1.1)	(51.5, 55.8)	53.6 (1.1)	(51.1, 55.7)
	% (n)	**% (n)**	**95% CI**	**% (n)**	**95% CI**
Female	68.3 (71)	66.7 (32)	(51.6, 80.0)	69.6 (39)	(55.9, 81.2)
Hispanic	2.9 (3)	4.2 (2)	(0.5, 14.2)	1.8 (1)	(0.04, 9.6)
Race					
White	91.3 (95)	93.8 (45)	(82.8, 98.7)	89.3 (50)	(78.1, 96.0)
Other race	8.7 (9)	6.3 (3)	(1.3, 17.2)	10.7 (6)	(4.0, 21.9)
Education					
High school grad/GED or less	22.1 (23)	20.8 (10)	(10.5, 35.0)	23.2 (13)	(13.0, 36.4)
Some college or higher	77.9 (81)	79.2 (28)	(43.2, 72.4)	76.8 (43)	(63.6, 87.0)
Annual household income < $25,000	39.0 (39)	40.4 (19)	(25.8, 54.7)	35.7 (20)	(23.4, 49.6)
Currently living with spouse or someone like a spouse	65.4 (68)	68.8 (33)	(53.8, 81.3)	62.5 (35)	(48.6, 75.1)
Became deaf ≥ age 3 [a]	91.5 (86)	95.5 (42)	(84.5, 99.4)	88.0 (44)	(75.7, 95.5)
Has health insurance	98.1 (101)	97.9 (47)	(88.9, 99.9)	98.2 (55)	(90.5, 99.9)
Has a personal doctor	97.1 (101)	95.8 (46)	(85.8, 99.5)	98.2 (55)	(90.5, 99.9)
Self-Reported Cardiovascular Risk Factors [b]					
Ever been told you have diabetes	13.5 (14)	12.5 (6)	(4.7, 25.3)	14.3 (8)	(6.4, 26.2)
Currently taking insulin or other diabetes medication	11.5 (12)	8.3 (4)	(2.3, 20.0)	14.3 (8)	(6.4, 26.2)
Ever told you have high blood pressure	37.5 (39)	37.5 (18)	(24.0, 52.7)	37.5 (21)	(24.9, 51.5)
Currently taking blood pressure medication	35.0 (36)	37.5 (18)	(24.0, 52.7)	32.1 (18)	(20.3, 46.0)
Ever told you have high cholesterol	53.8 (56)	54.2 (26)	(39.2, 68.6)	53.6 (30)	(39.7, 67.0)
Currently taking cholesterol medication	42.3 (44)	41.7 (20)	(27.6, 56.8)	48.2(24)	(34.7, 62.0)
Ever told you had a heart attack	1.0 (1)	0.0 (0)	-	1.8 (1)	(0.04, 9.6)
Ever told you had angina or coronary heart disease	2.9 (3)	4.2 (2)	(0.5, 14.2)	1.8 (1)	(0.04, 9.6)
Ever told you had a stroke	0.0 (0)	0.0 (0)	-	0.0 (0)	-
Current smoker [c]	2.1 (2)	2.2 (1)	(0.1, 11.1)	2.0 (1)	(0.1, 10.6)
PHQ-9 score indicative of at least mild depression [d]	39.6 (40)	36.2 (17)	(22.2, 50.5)	41.1 (23)	(28.1, 55.0)
Diet and Physical Activity					
Dietary Risk Assessment score [e]	31.2 (0.9)	31.0 (1.3)	(28.3, 35.6)	31.5 (1.1)	(29.3, 33.8)
Physical Activity Assessment score [f]					
Moderate activities	8.3 (0.4)	9.1 (0.6)	(7.8, 10.3)	7.6 (0.5)	(6.7, 8.5)

	Total N=104	Immediate Intervention N=48		Delayed Intervention N=56	
	Mean age	**Mean (s.e.)**	**95% CI**	**Mean (s.e.)**	**95% CI**
Vigorous activities	3.2 (0.3)	3.6 (0.4)	(2.7, 4.4)	2.9 (0.3)	(2.3, 3.5)
Body Weight, Blood Pressure, Fasting Lipid Profile & HemoglobinA1c					
Weight (kg)	92.9 (1.8)	94.3	(88.8, 99.8)	91.8	(87.0, 96.5)
BMI	33.3 (0.5)	34.0	(32.5, 35.5)	32.7	(31.4, 34.0)
Waist circumference (cm)	106.1 (1.2)	106.5	(103.3, 109.6)	105.8	(102.3, 109.2)
Systolic blood pressure	126.8 (1.6)	129.3	(124.3, 134.4)	124.5	(120.5, 128.6)
Diastolic blood pressure [g]	70.4 (1.1)	72.7	(69.6, 75.8)	68.4	(65.6, 71.2)
Total cholesterol	193.3 (3.4)	194.6	(183.6, 205.7)	192.1	(183.7, 200.5)
HDL cholesterol [g]	51.2 (1.4)	47.6	(44.5, 50.8)	54.3	(50.2, 58.4)
LDL cholesterol	111.2 (3.0)	113.0	(102.6, 123.4)	109.7	(102.6, 116.8)
Hemoglobin A1c	5.9 (0.1)	5.9	(5.7, 6.1)	5.9	(5.6, 6.1)

Notes:

[a] For “age at onset of becoming deaf”, 9 respondents reported “I don’t know,” and were therefore excluded from this analysis.

[b] Self-report of prevalence here may not accurately represent the true prevalence of these conditions in the sample, in-part due to communication barriers between participants and their doctors.

[c] Due to a survey computer program error, we were unable to determine current smoking status for 7 respondents, who were therefore excluded from this analysis.

[d] Score obtained on the Patient Health Questionnaire-9 (PHQ-9) was consistent with mild depression or higher during the past 2 weeks (PHQ-9 score >4).

[e] DRA scores range from 0-96; lower scores are better (improved dietary quality).

[f] PAA moderate activity scores range from 0-27 and vigorous activity scores range from 0-18; higher scores are better (more physical activity).

[g] The only baseline characteristics with statistically significant differences at baseline are diastolic blood pressure (p=.04) and HDL cholesterol (p=.01).

Table 2:

DWW Primary Outcomes: Within-arm comparisons, and Difference between arms

		Immediate Intervention Arm N=48			Delayed Intervention Arm N=56			Difference Between Arms			Key finding
		Pre-intervention to post-intervention			No intervention yet						
		Baseline Mean (SE)	6-month Mean (SE)	Difference (95% CI)	Baseline Mean (SE)	6-month Mean (SE)	Difference (95% CI)	Difference (95% CI)	P value	Bonferroni-adjusted P value	
DWW vs. No intervention	Weight [kg]	93.1 (2.6)	87.4 (2.6)	−5.7 (−7.2, −3.7)	92.8 (2.4)	90.5 (2.5)	−2.3 (−4.1, −0.3)	−3.4 (−6.1, −0.8)	.0106	.0424	**DWW was better than no intervention for change in weight**
	DRA score diet	30.7 (1.2)	23.6 (1.2)	−7.1 (−9.4, −4.8)	31.7 (1.1)	27.9 (1.1)	−3.8 (−5.9, −1.8)	−3.3 (−6.4, −0.1)	.0459	.1836	
	PAA score Moderate physical activity	9.1 (0.6)	10.9 (0.6)	1.8 (0.6, 3.0)	7.6 (0.5)	8.8 (0.5)	1.2 (0.1, 2.3)	0.6 (−1.0, 2.2)	.4707	>.99	
	PAA score Vigorous physical activity	3.6 (0.4)	3.7 (0.4)	0.1 (−0.7, 1.0)	2.9 (0.4)	3.3 (0.4)	0.4 (−0.4, 1.2)	−0.3 (−1.4, 0.9)	.6405	>.99	

Notes: Results are based on mixed-effect models with imputed data and comparing weight/DRA/PAA between Immediate Intervention arm to Delayed Intervention arm, controlling for diastolic blood pressure and HDL cholesterol variables, as these two variables showed statistically significant differences between arms after randomization at baseline.

Abbreviations:

DRA: Dietary Risk Assessment (scores range from 0-96; lower scores are better – indicate improved dietary quality).

DWW: Deaf Weight Wise

PAA: Physical Activity Assessment (higher scores are better – indicate more physical activity)

Table 3:

DWW Exploratory Outcomes: Within-arm comparisons, and Difference between arms

		Immediate Intervention Arm N=48			Delayed Intervention Arm N=56			Difference Between Arms	Key findings
DWW vs. No intervention		**Pre-intervention to post-intervention**			**No intervention yet**				**DWW was better than no intervention for change in BMI**
		Baseline Mean (SE)	6-month Mean (SE)	Difference (95% CI)	Baseline Mean (SE)	6-month Mean (SE)	Difference (95% CI)	Difference (95% CI)	
	BMI	33.8 (0.8)	31.7 (0.8)	−2.1 (−2.9, −1.4)	32.9 (0.7)	32.0 (0.7)	−0.8 (−1.5, −0.1)	−1.3 [a] (−2.3, −0.3)	
	Waist (cm)	105.6 (1.9)	99.2 (1.9)	−6.4 (−8.7, −4.0)	106.5 (1.7)	100.9 (1.8)	−5.6 (−7.9, −3.2)	−0.8 (−4.0, 2.4)	
DWW Intervention (pre/post): Arm 1 and Arm 2		**Pre-intervention to post-intervention (immediate – Arm 1)**			**Pre-intervention to post-intervention (delayed – Arm 2)**			**Difference Between Arms**	
		Baseline Mean (SE)	6-month Mean (SE)	Difference (95% CI)	12-month Mean (SE)	18-month Mean (SE)	Difference (95% CI)	Difference (95% CI)	
	Weight (kg)	93.1 (2.6)	87.4 (2.6)	−5.7 (−7.2, −3.7)	90.6 (2.5)	86.0 (2.6)	−4.4 (−7.0, −1.9)	−1.1 [b] (−4.2, 2.1)	**DWW interventions Arm1 & Arm2 demonstrate similar improvement in biometric outcomes from pre- to post-intervention**
	BMI	33.8 (0.8)	31.7 (0.8)	−2.1 (−2.9, −1.4)	32.0 (0.7)	30.3 (0.8)	−1.7 (−2.8, −0.7)	−0.4 (−1.6, 0.8)	
	Waist (cm)	105.6 (1.9)	99.2 (1.9)	−6.4 (−8.7, −4.0)	100.6 (1.9)	96.1 (2.2)	−4.5 (−7.4, −1.8)	−1.9 (−5.8, 2.0)	

Notes: Results are based on mixed-effect models with imputed data and comparing BMI and waist circumference between Immediate Intervention arm to Delayed Intervention arm, controlling for diastolic blood pressure and HDL cholesterol variables, as these two variables showed statistically significant differences between arms after randomization at baseline. Exploratory outcomes and 95% CIs are not adjusted for multiple comparisons.

[a] p=.0088

[b] rounding affects sum in this row

Abbreviations:

BMI: Body Mass Index

DWW: Deaf Weight Wise