Deaf Weight Wise 2.0 (NCT03060525)
Cover page, Protocol and Statistical Analysis Plan Supplement
Rochester Prevention Research Center: National Center for Deaf Health Research
University of Rochester, Rochester NY

Protocol Note:
The initial trial protocol was approved 6/16/2016. The protocol version we include here was amended and approved 10/17/2017, which changed the age range of the study, from ages 21 to 40, as originally approved, to ages 21 to 70. The purpose of this change in enrollment criteria/age range was to increase study enrollment due to slower than expected enrollment of participants ages 21 to 40 during the first 6 months of active recruitment (the first participant enrolled in January 2017). Three goals of this research were 1) to evaluate DWW with a new age group, 2) evaluate DWW with a new modality (videophone), and 3) evaluate a revised/updated DWW curriculum. Our enrollment as of summer 2017 was insufficient to test these components. We know from our previous experience with Deaf Weight Wise 1.0 (previous clinical trial with ages 40 to 70), that the intervention was popular and effective with participants ages 40 to 70. The change in age in October 2017 allowed us to test the effectiveness of the newly adapted Deaf Weight Wise 2.0 intervention and curriculum with a broader range of participants. All clinical trial and intervention components remained the same and were safe for participants ages 40 to 70 (as previously confirmed in Deaf Weight Wise 1.0).

Statistical Analysis Plan (SAP)
The original Statistical Analysis Plan can be found on pages 17-18 of the attached protocol.

Statistical Analysis Plan (SAP) changes and additional information:

1) In our original SAP, we identified the analysis of the International Physical Activity Questionnaire (short form) as an item for secondary analysis. We have since made this IPAQ (short form) one of the primary outcome measures, to be consistent with our primary outcomes in the original clinical trial of Deaf Weight Wise 1.0 (Barnett et al, *Obesity* April 2023), where change in physical activity was one of the primary outcome measures. The IPAQ short form allowed us to calculate amount of physical activity by weighting each type of activity (walking, moderate, and vigorous activity) by its energy requirements defined in METs (METs are multiples of resting metabolic rate) to yield a score in MET-minutes which is then used to compute a MET score by the number of minutes performed of each type of activity, per week.[1] The IPAQ Research Committee proposes that these data are reported as comparisons of median values and interquartile ranges for different populations.[2]
    1. Craig CL,Marshall A , Sjostrom M et al. International Physical Activity Questionnaire: 12 country reliability and validity. *Med Sci Sports Exerc* 2003 Aug; 35(8):1381-95.
    2. The IPAQ Research Committee. Guidelines for Data Processing and Analysis of the IPAQ-Short Form; April 2004.

2) 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),[3-5] 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,[6,7] while controlling for participant age and intervention attendance (attended 0 to 16

intervention sessions). 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.

3. van Buuren S, Boshuizen HC, Knook DL. Multiple imputation of missing blood pressure covariates in survival analysis. Stat Med 1999;18:681-94.
4. Permutt T. Sensitivity analysis for missing data in regulatory submissions. Stat Med 2016;35:2876-9.
5. Rubin DB. Multiple imputation for nonresponse in surveys. Hoboken, NJ: Wiley; 1987.
6. Coffman CJ, Edelman D, Woolson RF. To condition or not condition? Analysing 'change' in longitudinal randomised controlled trials. BMJ Open 2016;6:e013096.
7. Murray DM. Design and Analysis of Group-Randomized Trials. New York, NY: Oxford University Press Inc; 1998.

Deaf Weight Wise 2.0 Study Protocol: RSRB # 57628
Rochester Prevention Research Center: National Center for Deaf Health Research
Amended 10/17/2017

This amendment proposes to change the age range of the study, from ages 21 to 40, as originally approved, to ages **21 to 70**. The purpose of this change in enrollment criteria/age range is to increase study enrollment due to slower than expected enrollment of participants ages 21 to 40 during the first 6 months of active recruitment. Three goals of this research were 1) to evaluate DWW with a new age group, 2) evaluate DWW with a new modality (videophone), and 3) evaluate a revised/updated DWW curriculum. Our current enrollment is insufficient to test these components. We know from our previous experience with Deaf Weight Wise 1.0 (previous clinical trial RSRB#34096 with ages 40 to 70), that the intervention was popular and effective with participants ages 40 to 70. The current proposed change will allow us to test the effectiveness of the newly adapted Deaf Weight Wise 2.0 intervention and curriculum with a broader range of participants. All clinical trial and intervention components will remain the same for this current study, and are safe for participants ages 40 to 70 (as previously confirmed in Deaf Weight Wise 1.0). The only change is the upper age limit.

I. PURPOSE OF THE STUDY AND BACKGROUND

1. Purpose of the study.

The purpose of the Deaf Weight Wise 2.0 (DWW 2.0) study is to test an evidence-based, comprehensive program to modify obesity-related health behaviors with Deaf people ages 21 to 70 who use American Sign Language (ASL) as their primary language.

The study aims are:
1. Adapt an evidence-based healthy weight program, recently delivered and evaluated as an ASL-based in-person group intervention with Deaf adults ages 40-70, for use with Deaf adults ages 21-70 as an in-person group intervention and an individual counseling videophone (VP) intervention.
2. Conduct the DWW 2.0 randomized clinical trial, with 132 overweight/obese (BMI 25-45) Deaf participants aged 21-70 in Rochester, and randomize to one of four arms: immediate intervention vs. intervention delayed one year, and in-person group vs. individual counseling VP intervention.
3. Implement the intervention across the four study arms: immediate vs. delayed intervention and group vs. individual VP intervention.
4. Collect and analyze data on health characteristics and behaviors of subjects at 5 data points over 2 years: baseline (data point 1), 6 months (data collection point 2), 12 months (data collection point 3), 18 months (data collection point 4), and 24 months (final data collection point 5).

The study has the following hypotheses:
1. Participants in the immediate DWW 2.0 intervention will increase their physical activity and reduce their caloric intake and body weight compared with those in usual care (no intervention yet).
2. DWW 2.0 delivered as VP individual counseling will be non-inferior to DWW 2.0 delivered as an in-person group intervention in terms of changes in body weight, physical activity and caloric intake.

   [Rationale for non-inferiority: The advantage of the VP intervention is scalability and reach, creating opportunities for health promotion with Deaf individuals without access to an in-person group intervention. The purpose of the comparison is to assess whether an individual intervention via VP is worse, or at least as effective, as the in-person group intervention.]

2. Background.

The National Center for Deaf Health Research (NCDHR) was established in 2004 through a Prevention Research Center grant from the Centers for Disease Control and Prevention (CDC). The mission of NCDHR is health promotion and disease prevention with Deaf sign language users and people with hearing loss through community-based participatory research. NCDHR follows the tenets of CBPR[1], in which community members are involved in every stage of the research process. Various NCDHR community committees collaborate with researchers on designing, implementing, and evaluating research projects. Many aspects of this study, including selection of the intervention topic (obesity and healthy lifestyle), design of study procedures, and development of the informed consent process, are based on direct feedback from Deaf community members. The National Technical Institute for the Deaf (NTID) at Rochester Institute of Technology is a subcontractor and long-time partner in research. Collectively, the team has extensive experience working with deaf populations in medical, academic, and community settings, as well as in translating and interpreting, research, and survey methodology.

Little is known about health or health promoting interventions in Deaf communities nationally or worldwide. Deaf individuals comprise an understudied and medically underserved population. Access to health services, research, and health information is confounded by communication and literacy barriers. One of the challenges of health research with deaf people is creating survey instruments and interventions that are culturally and linguistically appropriate.

Consistent with the lack of health surveillance data in deaf populations, very little clinical research has been performed with deaf persons. Jones, et al. have investigated the feasibility of interpreter-translated health surveys in ASL, demonstrating high levels of consistency [2]. Jones, et al. then surveyed 111 deaf adults about their risk for cardiovascular disease, demonstrating a high prevalence of overweight (43%), low physical activity levels (54% <3 times/week), and high fat diets (49%)[3,4]. Margellos-Anast, et al. conducted ASL interviews with 203 deaf adults from Chicago without a comparison group, and found low levels of knowledge about symptoms of heart disease and stroke [5]. The only intervention identifiable in the literature is a study of 32 deaf participants who received 12 hours of didactic instruction about cardiovascular risk factors, compared to 52 deaf persons from another city who had no education intervention [6].

ASL is a distinct language that is different from English. The average English reading comprehension among deaf high school seniors is at the 4th grade level [7], and we have found that deaf and hard-of-hearing college students have reading levels ranging from 4th-12th grade levels. Therefore, the fund of information on health is ill-defined in the Deaf community, with less accessibility to newspapers, magazines, television, etc. [8-10]. As a consequence, deaf people have a limited fund of knowledge about many health related topics [11,12]. U.S. deaf adults' knowledge of English Language medical terminology is similar to that of non-English speaking immigrants to the U.S. [13]. Moreover, adults who use ASL report being dissatisfied with doctor-patient communication [14,15] and prefer qualified interpreters or sign-fluent and/or deaf clinicians [16,17]. Few health education resources are otherwise available for primary ASL users, to substitute for the extremely limited numbers of ASL-fluent clinicians.

The NCDHR is unique in its capacity to collect reliable and accurate health information for Deaf persons using ASL video technology. The research team has extensive cultural and linguistic competence working with deaf populations and translating surveys from English to ASL or English-based sign language. During its first funding cycle (2004-2009), NCDHR developed linguistically and culturally appropriate survey methods that provide an assessment of the health status of deaf populations (the Deaf Health Survey, see RSRB # 20189).[18]

The original Deaf Weight-Wise Study (see RSRB # 34096) was the core research project for the second Prevention Research Center funding cycle (2009-2014), and was the first adequately powered trial of an evidence-based healthy weight/lifestyle intervention to be carried out in Deaf people.[19] It is based on the University of North Carolina's Weight Wise program and was selected based on 1) its proven effectiveness with a minority population, 2) having a scope and approach consistent with Deaf Community preferences, and 3) solely focused on weight and its related behaviors and showed significant and important changes in outcomes.[20] It represented a pioneering effort to collect new health information and develop intervention tools in a very understudied and underserved minority group.

Deaf Weight Wise 2.0 is the core research project for NCDHR's third funding cycle (2014-2019), and will build on this research team's experience with the original Deaf Weight Wise trial for ages 40-70. DWW 2.0 will be an adaptation of the original Deaf Weight Wise curriculum to suit ages 21-70, and will also evaluate the additional component of the one-to-one individual counseling intervention in addition to the group intervention format.

II. CHARACTERISTICS OF THE RESEARCH POPULATION

1 **Number of subjects**. 132.
2 **Gender of Subjects.** Subjects of both genders will be included.
3 **Age of Subjects**. Subjects will range from ages 21-70.
4 **Racial and Ethnic Origin**. Subjects of any race/ethnicity will be included. Although the demographic characteristics of the Rochester Deaf community are unknown, we expect that approximately 80% of subjects will be White and 10% of subjects will be African American, and 10% will represent other diverse racial groups. For ethnicity, we estimate 5% will be Hispanic.
5 **Inclusion Criteria**. The inclusion criteria for study subjects will include deaf men and women ages 21-70 years who use sign language and live in the Rochester Metropolitan Statistical Area (MSA), have a body mass index (BMI) of 25-45. Eligible subjects must also have permission to participate from a primary healthcare provider if: 1) self-reported diagnosis of a recent cardiovascular disease event (heart attack or stroke in past 6 months), 2) self-reported heart condition, chest pain, dizziness, or other reason not to participate in physical activity, 3) had weight loss surgery in the previous 2 years (self-reported), and 4) are pregnant (self-reported). Subjects must also be willing to follow a healthy dietary pattern and to abstain from using weight loss medications during the study, and be willing and able to attend either group or videophone sessions, and to participate in data collection requirements.
6 **Exclusion Criteria**. Exclusion criteria include: subjects without medical clearance who had 1) a cardiovascular disease event in the past six months, 2) or heart condition, chest pain, dizziness, or other reason not to participate in physical activity, 3) or weight loss surgery in the past two years, or 4) are pregnant. Participants with these conditions (as determined by the PAR-Q Physical Activity Readiness-Questionnaire and other questions administered during the initial study screening visit) must obtain medical clearance from their primary healthcare clinician (or maternity care clinician for pregnancy) to be eligible. Those who are unable or unwilling to provide written, informed consent, and inability to see and interact with computer-based questionnaires and educational interventions will be excluded.
7 **Vulnerable Subjects**. There are no special classes of individuals who may be considered vulnerable subjects that are targeted for enrollment in this study. Specific modifications have been made to make this study culturally and linguistically appropriate for Deaf participants. The researchers who have direct contact with study subjects, including the researchers who obtain informed consent and deliver the health intervention modules, will be fluent in ASL. The DWW 2.0 intervention is specifically being adapted to target varying levels of sign language fluency and English language skill level. Our informed consent materials will be available in sign language and English formats. Some subjects may have limited literacy in written English. Low literacy is one

reason that prior health research has been limited in the Deaf community. This study is designed specifically for deaf ASL-users, a population that is generally not included in research. This research includes the guidance of Deaf community advisory boards, the majority of whose members are deaf adult ASL-users. No children will be included in the research. Prisoners or institutionalized individuals will not participate in this research.

III. METHODS AND PROCEDURES

Methods and Procedures.

Overall study design (see Figure 1)
The overall design of this clinical trial of DWW 2.0 has four arms, with randomization to immediate intervention (phase 1) versus delayed intervention (phase 2), and group vs. videophone intervention. Multiple discussions with Deaf Community members made it clear that a "usual care" option or treatment vs. placebo would be poorly received, so a delay of approximately one year will allow the intervention vs. no intervention outcomes to be compared at interim data collection points (points 2 and 3), after which the remaining half of subjects will receive the interventions. This delay of one year allows us to account for any potential seasonal differences in body weight, diet, and hormonal changes that occur throughout the year that would affect our study outcomes. The total length of the full study is about 24 months (baseline and four follow-up data collection points).

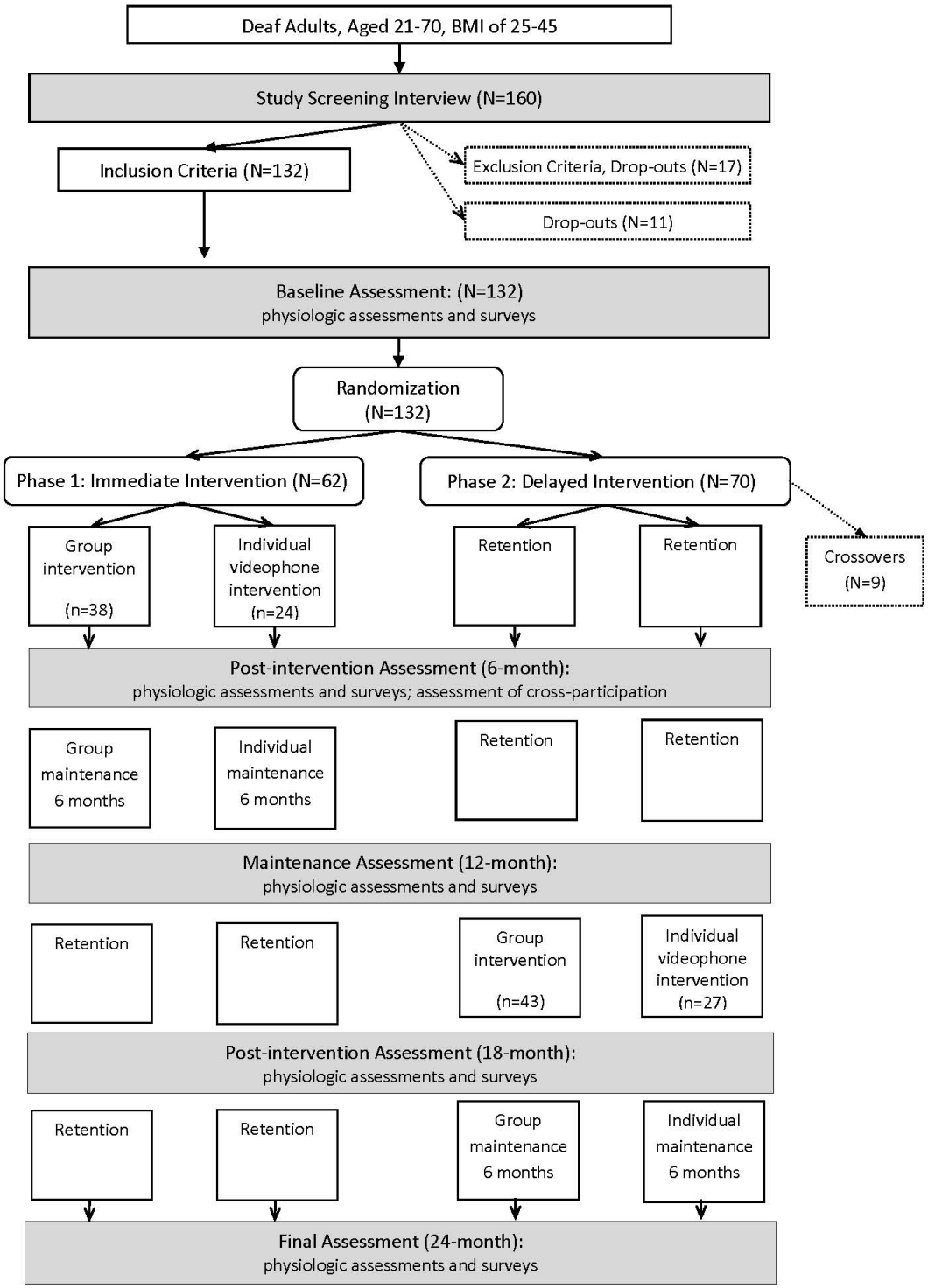
Interventions will consist of 16-week group counseling sessions or 16-week individual videophone counseling sessions led by trained, ASL-fluent Deaf counselors. Following the 16-week intervention, subjects will enter a 6-month "maintenance phase" with less intense interventions.

DWW 2.0 will focus primarily on healthy lifestyle and the prevention of weight gain through change in diet and physical activity. The dietary changes include: 1) caloric restriction; 2) increases in daily consumption of fruits and vegetables; 3) reduction in saturated and trans fat intake; and 4) increase in low-fat dairy intake consistent with the DASH eating pattern.[20] The goals of physical activity were increases to > 150 minutes per week of physical activity. The intervention emphasizes daily self-monitoring of type and quantity of foods, number of servings of fruits and vegetables, calories, and minutes of physical activity.

One issue that this research team has discussed is that in a close-knit community such as the Rochester Deaf community, there is the possibility of "contamination" of subjects from the delayed intervention arm by influences from the immediate intervention group. Therefore, we will strongly recommend that subjects randomly allocated to the delayed arm not adopt any of the programs or tools of the immediate intervention groups. This recommendation will be communicated in-person to subjects and via ASL-video at the beginning of the study. Moreover, additional persons will be randomized into the delayed intervention group (see Figure 1). At the end of the delay period, we will ask subjects in the delayed intervention arm if they received or reviewed information from the immediate intervention in any way. Based on our experience with the original Deaf Weight Wise trial, we did not find any "cross-participation" between immediate and delayed arms. We did account for up to 9 "crossovers" in this study design, who would then be excluded from some of the analysis but will still be allowed to participate in all aspects of the program.

We will also collect data on direct and indirect costs of the interventions. This will provide guidance to future interventions as to the effectiveness and cost/benefit ratios of group counseling, as well as feasibility of individual videophone interventions with Deaf participants.

Figure 1. Deaf Weight Wise 2.0 Study Design (with updated age range).



Note about English language study materials prepared/submitted for this RSRB review
Based on the original Deaf Weight Wise RSRB application (#34096), previous meetings with OHSP and RSRB leadership over several years, and other deaf health research conducted by NCDHR at University of Rochester, we are submitting the English versions of all study materials with this application because it has been previously determined that sign language versions of the materials do not need to be reviewed upon application submission. This research team is highly invested in producing the highest quality intervention for deaf ASL-users. We will only use the best possible ASL and English-based sign language translations of the consent, curricula, and data collection measures in order to best serve our target community and to be able to demonstrate accurate, high-quality intervention results. All study components will be available in sign language. Please note that while the primary language of the majority of our study participants will be ASL, we expect that most will also be English-proficient.

Study Screening Visit
Subjects will complete the brief study screening interview with a member of the research team (see Study Screening Interview Form attached with this application) to determine preliminary eligibility. As part of this interview, a trained member of the research team will: 1) ask the subject their age, 2) measure the subject's height and weight to calculate BMI, and 3) ask the Study Screening Interview, which includes the Physical Activity Readiness-Questionnaire, to determine whether the subject will need permission from their healthcare provider to participate in the 16-week intervention component of the study. Eligible subjects will be re-contacted to schedule their study enrollment visit. We will retain Study Screening Visit data from ineligible subjects; these data will be analyzed anonymously in order to obtain descriptive and comparative findings of deaf community members who did not qualify for the study. Ineligible subjects will be asked to join the NCDHR contact list to be notified of future studies (see RSRB approved protocol #33598 Deaf Health Research Contact List). Joining the Contact List is an entirely separate activity from their involvement in the DWW Study Screening Visit; the Contact List has its own stand-alone protocol/consent process. Other studies conducted by NCDHR have included information about joining the Contact List at the end of study participation (Deaf Health Survey #20189 and Deaf Healthcare Survey #35088 and Deaf Weight Wise #34096). Information that ineligible DWW 2.0 subjects may provide as part of the Contact List is completely separate from DWW 2.0 and will never be linked to DWW 2.0 study data.
Addition 3/30/17: Some potential participants have reported challenges to attending this initial study screening visit, including transportation barriers and lack of childcare. We would like to be able to offer a home visit for potential participants, to conduct this study screening portion of the visit only. This would only be offered to a small number of participants who would benefit from this option. Study screening would involve the same methods as if the appointment were on site, including taking height, weight, and the screening interview questions to determine eligibility. The screening visit takes about 15-20 minutes to complete. If the participant qualifies, we would schedule a separate appointment at Saunders Building for the full enrollment and informed consent process to occur.
When conducting home visits, 2 members of the research team would always travel together; we would never send a staff person alone to someone's home. The home visit team would check in with the Study Coordinator when they arrive at the home, and immediately upon completion of the visit. There is no subject payment at the screening visit so staff will not have any monetary value on hand. There are no mandated reporters on the data collection/staff team.

Study enrollment visit and baseline data collection
At the initial study enrollment visit, potential subjects will view the informed consent video which includes an overview of the DWW 2.0 study and dialogic scenarios between deaf people and researchers. They will also have a one-on-one discussion with a member of the research team, behind a privacy curtain, to obtain informed consent if they are interested in participating. Following the consent process, subjects will be asked to complete the baseline questionnaires

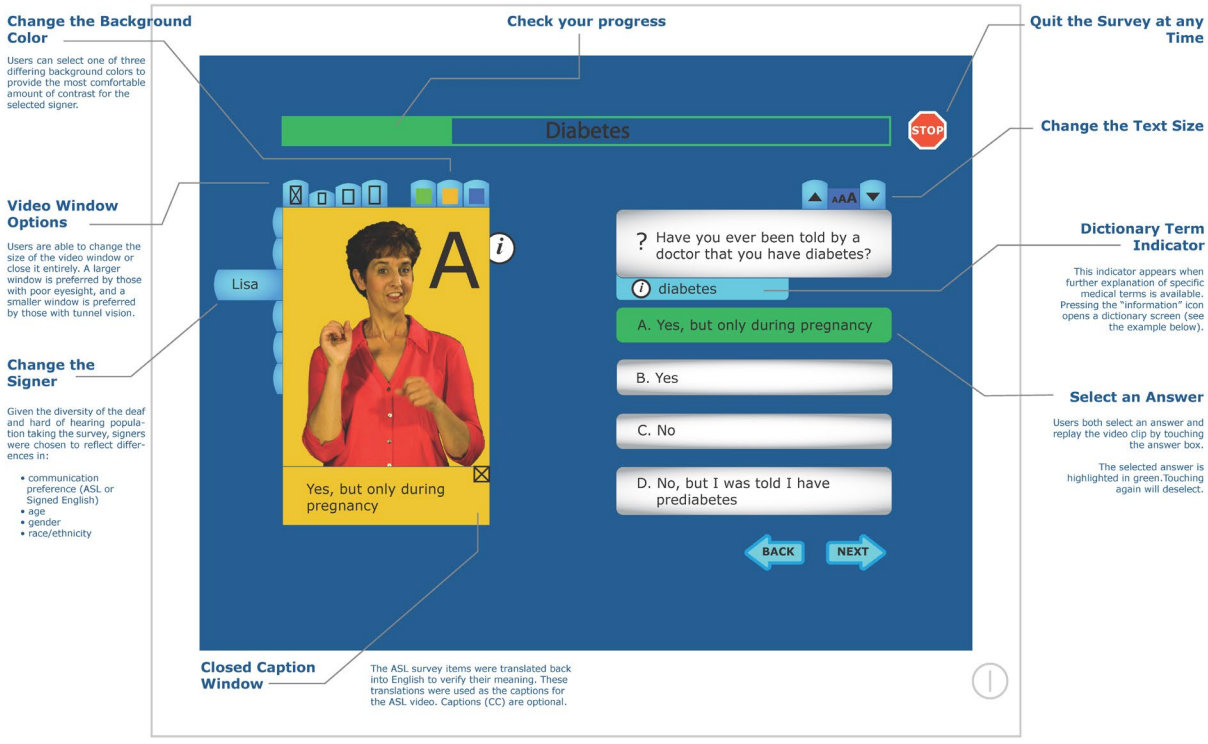
behind privacy curtains (on the computer kiosk and in-person interviews) and will be asked to report to the Clinical Research Center for physiologic data collection on subsequent days. We anticipate holding several study enrollment sessions over several months in order to accommodate 132 subjects.

Description of Data Collection/Study Outcome Measures

After providing informed consent, DWW 2.0 subjects in all arms of the study will have descriptive and outcome measures assessed at 5 points: (Baseline, 6-month, 12-month, 18-month, and 24-month final) (Figure 1). Each session will require about 90 minutes and will be supervised by trained deaf and hearing ASL-fluent research staff.

Questionnaires (see Table 1/pg. 8): Data collection for most questionnaire data will be carried out in sign language on a computer kiosk with direct response on the computer screen, behind privacy curtains. NCDHR sign language surveys have been successfully used in computer-based kiosk other UR protocols. At the beginning of the survey, the subject chooses a "sign model" to guide them through the survey, based on their preferred language and/or communication style (ASL or English-based sign language). The kiosk also has the ability to show instructions on how to use the survey. Once the survey begins, each survey item and response is shown in sign language, followed by the English text of the question and response choices. The respondent enters or clicks on their response (and has the option to skip the item if they do not want to respond) using the mouse or touch screen technology. Respondents can choose a different sign model at any point in the survey, and English captions can be turned on or off at any time.

Figure 2. Screenshot of the NCDHR ASL Data Collection/Survey Software Platform.



In-person ASL interview questionnaires (see Table 1/pg. 8): Some items will also be administered by trained, sign-fluent research staff. An English version of all DWW 2.0 questionnaires are

included in section 1.3.1 of the application. Interviews are conducted 1-on-1 behind privacy curtains or in private offices.

The primary outcome variables for this study will be weight change and BMI change between baseline and point 2 (post intervention group 1).

Table 1. Deaf Weight Wise 2.0 Computer and Interview Measures

Name of Measure	Description	Base line	6 mo	12 mo	18 mo	24 mo	Mode of Administration
Demographics	From NCDHR Deaf Health Survey	X	X (some)	X (some)	X (some)	X (some)	Computer kiosk; interview
Deaf Demographics	From NCDHR Deaf Health Survey	X					Computer kiosk
Health History; Healthcare Access	From NCDHR Deaf Health Survey	X	X (some)	X (some)	X (some)	X (some)	Computer kiosk; interview
Weight Loss History	Weight loss, eating habits, food availability	X	X (some)	X (some)	X (some)	X (some)	Computer kiosk; interview
Interpersonal Needs (INQ)	Social networks/ connectedness	X	X	X	X		Computer kiosk
PHQ-9	Depressive Symptoms	X	X	X	X	X	Computer kiosk
Mental health and suicide history	From NCDHR Deaf Health Survey	X	X		X		Computer kiosk
Sleep quality	From BRFSS	X	X	X	X	X	Computer kiosk
Block fruit, vegetable, fiber screener	Food intake	X	X	X	X	X	in-person interview
International Physical Activity Questionnaire	Exercise habits	X	X	X	X	X	in-person interview
Physical Activity Readiness	For medical clearance process	X		X delayed only			In-person interview
FEICS	Family Functioning			X			Computer kiosk
Emotional Eating	Emotional eating	X	X	X	X	X	In person interview
Adverse Childhood Experiences	Childhood trauma and adult health outcomes		X				Computer kiosk
Parent-child/family communication	Family dynamic and communication during childhood		X				Computer kiosk
Marlowe-Crowne Short Form 10(2)	Social desirability measure					X	Computer kiosk
Cross-participation assessment	Assess in delayed group		X	X			in-person interview
DWW program satisfaction	Evaluate participant satisfaction		X	X	X	X	in-person interview
Recruitment evaluation	Evaluate recruitment methods	X				X	in-person interview

Description of Translation Working Groups: ASL and English-based sign language questionnaires were adapted from English questions by the ASL and English-based sign language Translation Working Groups (TWGs), made up of NCDHR Research Committee and Deaf Community members who have extensive collective experience developing and translating health and educational materials and working with deaf populations.[21]

ASL-TWG: This group is made up of bilingual (ASL and English) individuals who have extensive experience in English-ASL translation and in Deaf and hearing cross-cultural relations.[19] TWG members include deaf members who are native users of ASL and hearing members who are native users of English. The TWG has members with expertise in research methodology, health terminology, healthcare practice, Deaf culture, the healthcare knowledge and experiences of deaf people, medical interpreting, and sign language preferences and fluency variations within the deaf population, including the 21-70 age group.

English-based sign language TWG: This TWG is composed of deaf and hearing individuals who use the ASL TWG's translated materials and the original English source material to develop an English-based sign language (EBS) script. EBS follows English grammar and syntax rules and is different from ASL.[21]

Backtranslation: Once the translation process is complete, NCDHR will give all sign language translation video clips to at least two independent back-translators (one for ASL and one for EBS). The back-translators review the ASL video and produce a written English translation of the survey item. An NCDHR researcher then compares/reconciles the English back-translation to the original source English question, to check for consistency/meaning equivalence.[21]

Physiologic and Laboratory Measures: These will be carried out at baseline, point 2 (6mo), point 3 (12mo), point 4 (18mo), and final (24mo) data collection points (Figure 1). Study subjects will be seen in the Clinical Research Center (CRC) at the University of Rochester Medical Center. In order to accommodate subjects' work schedules, we will offer flexible appointment times for collection of physiologic measures at the CRC, including possible Saturday morning appointment times for those who cannot report in a fasting state on a weekday morning.

CRC staff or trained research staff will perform the physiologic measures specified below. Only CRC staff or clinicians trained in blood-drawing procedures will collect blood specimens. All trained research staff and clinicians will be sign language fluent or will work with interpreter services during the collection of blood and other biometrics. Results will be recorded on the physiologic data collection forms (attached at the end of each Baseline, point 2, point 3, point 4, and final data collection/questionnaire forms in section 1.3.1; we also prepared a "What to Expect at the CRC" form for subjects that we will distribute at the study enrollment visit). We expect that collection of all physiologic measures will require about 30 minutes per subject. Visits to the CRC for physiologic data collection will take place at baseline, point 2, point 3, point 4, and final assessment (point 5).

Weight will be measured on a balance beam scale. Duplicate weights will be collected at each visit. Subjects will be asked to remove their footwear. Members of the NCDHR research team will also measure participants' weight at each data collection visit if the visit falls on a different day than their CRC appointment.

Height will be measured on a stadiometer attached to the scale.

Body Mass Index will be calculated based on height and weight measurements.

Waist circumference will be measured parallel to the ground at the level of the iliac crest. This measure is taken at the level of the midpoint between the inferior margin of the last rib and the crest of the ilium in the mid-axillary plane. The landmarks should be located by palpation, marked, and the midpoint should be found using a tape measure. The measurement is taken at the end of a normal expiration with the arms relaxed at the sides. This measurement should be taken without

clothing, that is, directly over the skin. If this is not possible, the measurement may be taken over light clothing.

Sitting height allows us to calculate leg length and trunk length, which is a proxy for early childhood growth restriction that triggers metabolic consequences on fat storage and weight.[22-24] Sitting height gives a measure of the length of the trunk. It is a measurement of the distance from the highest point on the head to the base sitting surface. A stadiometer is required. The subject sits on a measuring box or level chair or platform of known height, with both feet on the floor, the lower back and shoulders against the wall, looking straight ahead, with hands resting on their thighs. Distance can be measured from the floor, and the height of the box is measured and subtracted from the total distance. Sitting height will be obtained by NCDHR research staff during the 6-month CRC visit. We will calculate leg length (standing height minus sitting height) and trunk length (sitting height minus height of sitting surface) to obtain different measures of possible growth delay.

Blood pressure will be collected in an automated digital blood pressure monitor which does not require auscultation. Three blood pressure measures will be taken 4 minutes apart, with averages of the last two measures used as the outcome measure. The right arm will selected for measurement and should be free of any clothing.

Blood sampling:
Subjects will be asked to fast overnight (8-10 hours prior to their scheduled visit) and report to the Clinical Research Center for a phlebotomy sample. (Note: Any subjects who work nights or would require a late afternoon appointment may fast 8-10 hours during the daytime.) Diabetic patients on medications or insulin will be required to bring their medication with them and to take them after their blood measurement and not before.

All personnel involved in collecting blood samples will employ universal precautions to prevent the spread of infection. Sterile gloves will be worn by all such personnel and subjects will be asked if they have an allergy to latex. We will use sterile blood drawing equipment with a sterile needle. Personnel will prepare all equipment prior to venipuncture. The puncture site will be cleaned with an alcohol swab and allowed to dry prior to puncture. One serum separator tube of approximately 7ml of blood will be collected for blood glucose and fasting lipid profile, and a purple-top tube of 4 ml of blood will be collected for hemoglobin A1C. The needle is then withdrawn and the subject will be given a cotton ball to press on the puncture. Following collection of the sample, a sterile gauze pad will be applied to the wound location and held in place, followed by the application of a sterile bandage. Personnel will immediately dispose of sharps in an approved biohazard container.

A **fasting lipid profile** (total and HDL cholesterol levels, triglyceride level, LDL cholesterol level calculated from the Friedewald equation [25]) will be collected. The lipid profile will be analyzed with measurement of total cholesterol and triglyceride and measurement of HDL cholesterol after precipitation of B-containing lipoproteins. **Blood glucose** levels will also be obtained. Laboratory values will be checked for fasting status, and non-fasting triglyceride, LDL cholesterol, and blood glucose values will not be used. A purple-top tube of 4 ml of blood will also be collected to analyze **hemoglobin a1C** as a measure of blood glucose control over approximately 3 months.

Blood samples will be sent to URMC LABS (Clinical Trial Central Lab Services) where they will be analyzed and disposed of in accordance with the Lab's standard procedures; laboratory results will be sent to the Study Coordinator for data entry. (Blood samples do *not* need to be spun at the CRC prior to transport.)

Sharing Results of Physiologic and Laboratory Measures:

Subjects will be provided with their results of all five physiologic assessments at each data collection point, including body weight, waist circumference, blood pressure, blood lipids, glucose, and hemoglobin a1C. A trained DWW 2.0 counselor from the research team will discuss the results of these assessments after each data collection visit, via a videophone call conducted in ASL (see Sample Lab Results Call Log included with this application). If any values fall within the high tier, subjects will be encouraged to seek urgent help, including relevant health information and counseling from qualified, sign-fluent study personnel, or as outlined under "Referral Values" below, receiving an immediate referral to an accessible healthcare provider or the emergency department (with interpreter services). Subjects will also be given a copy of their results that they can then send to their physician if desired. While the study team does not give personal recommendations or medical advice about individuals' results, we do encourage participants to share the results with their physician and ask their physician any questions they may have.

URMC laboratory results from blood draws will be shown in eRecord, and we will also enable the results to be viewed in MyChart. These test results could potentially inform the participant and their physician of a new or ongoing condition (e.g., diabetes risk, high cholesterol risk) that could be intervened upon if needed, that could benefit and/or improve their health outcomes. The study team already shares the bloodwork results with the participant, in their own language, once results are obtained and reviewed by the study physician/PI. By including the results in eRecord and MyChart, we further promote potential information sharing about the participant's health. The Informed Consent process includes information about eRecord and MyChart.

Referral Values

We have developed two tiers of abnormal values for physiologic values that would prompt non-urgent or urgent referral to a healthcare provider. These are derived from questions in the medical history (administered via the survey kiosk), blood pressure, or blood lipids/glucose. The lower tier would have abnormal values which will be discussed with the subject; the subject will be encouraged to contact their primary care provider (PCP) to discuss their results. A higher tier of values would prompt immediate referral to a healthcare provider, including, in very unusual circumstances, delivering the subject to an emergency department.

	Lower tier values; encourage subject to contact their own healthcare provider	**Higher tier values: immediate referral to healthcare provider**
Systolic BP	≥140 mm Hg	≥ 160
Diastolic BP	≥90 mm Hg	≥ 120
Fasting Total Cholesterol	> 200 mg/dl	-
Fasting LDL	> 160mg/dl	-
Fasting Triglyceride	> 200mg/dl borderline high	> 1,000 mg/dl
Fasting HDL	<35 mg/dl	-
Fasting Glucose	>=126 mg/dl; ≤50 mg/dl	≥ 160
Hemoglobin A1c	> 7.0	> 10.0
Body Mass Index	>45 not eligible at baseline	-

Medical Clearance Process

As part of the baseline study screening interview, subjects will be asked a brief series of questions that will determine their medical eligibility to participate in the study (The Physical Activity Readiness Questionnaire). Two questions ask about heart attack or stroke in the past 6 months; 5 questions ask about chest pain, heart condition, dizziness, shortness of breath, and other limitations during physical activity; and 2 questions ask about overnight hospitalization and emergency room visits. We also added an item to determine whether the subject has had weight loss surgery in the previous two years, and if the subject is pregnant. If a subject answers positively to any of these items, he or she will be required to obtain permission from their Primary Care Provider (or maternity care clinician as appropriate) to participate in the study (see Physician Permission Letters / Tracking Form uploaded in section 1.3.1 of the online application). Subjects who report having a stroke or myocardial infarction in the past 6 months or weight loss surgery in the past 2 years will sign a HIPPA Authorization form - SH 48 MR (Authorization for Release of Medical / Behavioral Health information) - to allow our study team to prepare the medical clearance letter that the subject will give to their doctor (which states that they report having a heart attack or stroke or weight loss surgery). There are two levels of permission: one to obtain clearance to participate in the whole study, and the other to participate only in the educational and dietary components (but be excluded from the physical activity components). Subjects will be required to obtain permission from their provider on their own (using the Physician Permission Form) and to return the completed form to the research team in order to be eligible for enrollment, participation, and randomization to a study arm. This process will be repeated at data collection point 3 for subjects in the delayed intervention group (phase 2), so that they will also be cleared for participation immediately prior to the start of their 16-week intervention.

Ineligibility after baseline data collection

Upon review of baseline data, medical clearance results, and other data pertaining to exclusion criteria, the research team will identify any subjects who are not eligible to continue in the study. We anticipate approximately 28 subjects will be excluded or will drop out prior to randomization to intervention (Figure 1). Excluded subjects will be referred to their own PCP or another accessible healthcare provider such as the URMC Deaf Wellness Center Mindful Eating Group for healthy lifestyle education or medical treatment as needed.

Randomization

After informed consent, baseline assessment, and medical clearance, subjects will be randomly allocated to one of four arms (immediate vs. delayed, and group vs. videophone). Randomization will be carried out by the NCDHR Biostatistician, Dr. Hongmei Yang, who will have generated a random list of subject ID numbers and will assign the person to one of the four arms, without knowledge of the person's identity. The randomization schedule using the above method will be generated using SAS 9.4. Block randomization will be used to ensure appropriate allocation to each of the four arms based on the study flowchart (Figure 1). Slightly more subjects will be assigned to the delayed intervention arms (n=70) compared to the immediate intervention arms (n=62); this design accounts for drop-out rates and/or crossovers (contamination) of participants who may have learned of curriculum components through interaction with immediate intervention participants. A total of 81 subjects will be assigned to the group intervention, and 51 will be assigned to the one-to-one videophone intervention; this is based partially on resources allocated to the Gallaudet University-based intervention counselors. Our total sample size of 132 accounts for possible pregnancy among women participants during the 2-year study. In the event that some participants become pregnant and their main outcome data (weight, BMI, other characteristics) therefore becomes skewed, we will not include their individual data in the main analyses of the study sample but will still be able to maintain statistical power to show possible difference between groups. We used national pregnancy rates for this age group to calculate the expected rate of pregnancy among the sample over time.

We anticipate that a small number of subjects may have a spouse, partner, or roommate who is also enrolled in DWW 2.0. At the baseline enrollment visit, a member of the research team will ask each subject if they live with or are in a relationship with anyone who is enrolled in DWW 2.0; we will also cross-check subject addresses to determine if any subjects live in the same household. If any subjects live together and report that their behaviors are similar to the other person's (e.g., food preparation and shopping, eating habits), they will be randomized to the same block to avoid cross-participation. We followed this same procedure in the original DWW trial (#34096, now completed), and it was carried out successfully.

Intervention Description

Group Intervention (expected N = 81) (38 in immediate intervention + 43 in delayed intervention): The group intervention will consist of groups of approximately 6-8 subjects who meet together for 16 weeks, for two hours each week. A trained, deaf, ASL-fluent DWW 2.0 counselor will lead the sessions. We estimate that 4 to 5 groups will be established during each of the intervention arms (immediate and delayed); group sessions will be offered at a variety of times and days of the week. We have done this in order to accommodate participants' schedules (e.g., some work during the day and can only attend an evening group session, while others may work a night shift and can only attend a morning group session). As we match participants' and counselors' schedules, our intervention group sizes may range slightly in size. Subjects will be encouraged to continue with the same group throughout the 16 week program, to take best advantages of social interactions and group dynamics.

The English version of selected sessions of the DWW 2.0 Group Curriculum is included in this application; select counselor lesson plans/guides and counselor powerpoint presentations are also included. Subjects will be asked to complete a daily food and physical activity diary during the course of the 16-week intervention (via the MyFitnessPal online app or MyFitnessPal website, or via the DWW 2.0 Subject Food Diary uploaded in section 1.3.1 of the application). Subjects will complete a food diary using MyFitnessPal, or a "calorie counter" book called "The Calorie King." Each intervention session will include a weigh-in, group sharing and problem solving, discussion of a weight management topic, which may include watching a powerpoint presentation and/or ASL video; and a discussion on goal setting and action planning for the next week. A key principle of the DWW 2.0 Curriculum is motivational interviewing, in which the counselor acts as a facilitator to: 1) help participants identify/recognize their own unhealthy behaviors, 2) help individuals build skills that will promote behavior change, and 3) help group members to support each other to make behavior changes. The Curriculum includes group exercise activities ("Do It!"), experiential learning activities ("Try It!" such as learning how to read a nutrition label or modify a recipe to make it healthier), and group activities related to food preparation or sampling healthy foods ("Taste It!"). During each week's session, the group counselor weighs each participant and collects the summary/cover page of each participant's Food Diary (which summarizes daily caloric intake, daily exercise, and daily fruit and vegetable consumption for the previous week). A member of the research team records each participant's weight, attendance record (present or absent for that week), and Food Diary information. At weeks 6, 11, and 16, each subject receives a Personal Feedback Report [see template included with the curriculum] which reviews their physical activity and food consumption diaries and their weight changes. By the end of the 16-week curriculum, each individual will have approximately 32 hours of group contact time.

Over the course of the 16 week intervention, subjects will be able to earn points for attendance, completeness of their food and physical activity diary, for including calorie counts on at least 6 days per week, and for meeting physical activity requirements for the week. Subjects will be able to redeem these points (called "Wisebucks") at three different sessions (sessions 6, 11, and 16) for a variety of items including water bottles, adjustable measuring spoons, and other prizes.

The group maintenance phase starts immediately after the 16-week intervention, and consists of two meetings of the original group; one at month 3 of the 6-month maintenance period and one at month 6 of the 6-month maintenance period (see select Maintenance Curriculum materials uploaded in section 1.3.1 of the online application). This will again consist of a weigh-in, review of self-monitored diet and physical activity, problem solving and goal setting/action planning for their long-term program. Group attendees will be encouraged to interact with their group members during the intervention and maintenance phases. Each person will receive videophone calls/reinforcements at the end of months 1, 2, 4, and 5 of the 6-month maintenance period. Counselors will also email participants bi-weekly to check in with participants and provide additional support.

Group meetings will be held at the Saunders Research Building, and other locations if needed (see letters of cooperation included with this application).

Individual Videophone (VP) Intervention (expected N = 51): (24 in immediate intervention + 27 in delayed intervention)
The participant and their intervention counselor will have one-on-one sessions that take place via videophone, for one hour each week. Each session will be led by a trained deaf, ASL-fluent DWW 2.0 counselor and will be held at a scheduled appointment time that is agreed upon by the subject and the counselor.

Update 10/17/17: DWW 2.0 videophone counselors were based at Gallaudet University in Washington, DC, to test/demonstrate the feasibility of remote videophone counseling – this occurred only for Waves 1 and 2 of Year 1 of the study. Gallaudet University has partnered with NCDHR since 2004 (see letter of cooperation included in this application). Due to a change in counselor staffing at Gallaudet University, we will now have all videophone counselors based in-house at NCDHR/University of Rochester. Upon approval of this amendment, participants in Waves 3 and 4 of Year 1 as well as all videophone participants in Year 2 of the study will receive their videophone intervention from a Rochester-based counselor. NCDHR is responsible for all research activities (counselor hiring and training, recruitment, data collection, intervention fidelity assessment). NCDHR research staff will provide videophone counselors with the contact information (name, email address, videophone number) for their assigned VP intervention participant prior to intervention Week 1, so that they can schedule their weekly sessions. NCDHR will also provide the counselor with the participant's recommended daily caloric intake based on their body weight. During the 16 weeks of intervention and throughout the 6-month maintenance phase, videophone counselors will collect each participant's self-reported body weight and discuss food diary information. Participants will send their completed weekly food diaries directly to the NCDHR research staff using the Deaf Weight Wise secure email address. The required language regarding this exchange of PHI has been added to the HIPAA Authorization section of the updated Study Information Sheet included in this amendment.

The videophone intervention uses the same curriculum content as the group intervention, although videophone counselors will be trained on how to make special modifications that are applicable to this individualized, one-on-one format. Subjects will be asked to complete a daily food and physical activity diary during the course of the 16-week intervention (via the MyFitnessPal online app or website, or via the DWW 2.0 Subject Food Diary uploaded in section 1.3.1 of the application). Subjects will complete a food diary using MyFitnessPal, or a "calorie counter" book called "The Calorie King." Each intervention session will include a self-report of the subject's weight, review of self-monitored diet and physical activity behaviors and data, problem solving, and discussion of a weight management topic, and a segment on goal setting and action plan for the next week. At

weeks 6, 11, 16, each subject receives a Personal Feedback Report [see template included with the curriculum] which reviews their physical activity and food consumption diaries and their weight changes. Each individual will have had approximately 16 hours of counselor contact time.

Over the course of the 16 week intervention, subjects will be able to earn points for attendance, completeness of their food and physical activity diary, for including calorie counts on at least 6 days per week, and for meeting physical activity requirements for the week. Subjects will be able to redeem these points (called "Wisebucks") for a variety of items including water bottles, adjustable measuring spoons, and other prizes.

The individual maintenance program consists of brief monthly videophone calls with their videophone counselor, and two longer videophone sessions (one at month 3 of the 6-month maintenance period and one at month 6 of the maintenance period). This will again consist of a self-report of the subject's weight, review of self-monitored diet and physical activity, problem solving, and goal setting/action planning for their long-term program. Counselors will also email participants bi-weekly to check in with participants and provide additional support. Each person will receive email or videophone contacts with that counselor each month during the 6-month maintenance period.

We estimate that the vast majority of the Rochester Deaf community in this age group has a videophone; actual data on the prevalence of videophones is the Rochester Deaf community does not exist. Subjects will be asked if they have access to a VP, whether it is in their own home, at a friend/family home, or at another location that they could access during the study. Alternatively, NCDHR has 3 VP stations available that subjects will be able to use at any time during the course of the VP pilot study. If subjects choose to conduct their VP counseling sessions at NCDHR, privacy curtains will be set up around each station to ensure that all sessions are completely confidential for both the counselor and the subject, and that no visual distractions are present.

Training of DWW 2.0 Counselors
DWW 2.0 counselors who will deliver the intervention sessions will be deaf, sign-fluent, and will have a background in clinical, educational, or health-related fields. Counselors will be members of the NCDHR research team, including staff and research fellows, and will have experience facilitating similar groups or individual interactions focused on educational or behavioral content. Group and Videophone Counselors will attend 3 training sessions to prepare them for facilitating groups or videophone sessions (see DWW 2.0 Counselor Training Curriculum attached in section 1.3.1 of the online application). Two experienced DWW Counselors from NCDHR will travel to Gallaudet University to train the Videophone Counselors. During the training process, all counselors will be acquainted with the study design, specific aims, data collection, recruitment strategies, and enrollment criteria. They will be provided with a manual that includes the enrollment packet, intervention curriculum and other resources. Training will cover weight management techniques including nutrition and physical activity, the facilitation of group/individual meetings, and the use of counseling strategies such as motivational interviewing. Lastly, counselors will discuss subject responsibilities and will review the incentives that can be earned for fulfilling specific weekly requirements. Counselors (in Rochester and Washington DC) will meet bi-weekly via videoconference during the 16-week intervention to maintain intervention fidelity, and to share experiences and suggest techniques as issues arise. They will regularly report back to the research team during Research Committee meetings.

Retention Materials for Subjects Not in Intervention or Maintenance Phases:
Half of the subjects will have their intervention delayed about 1 year, during which there should be no receipt of DWW 2.0 intervention materials (Figure 1). Multiple retention strategies will be implemented to reduce any potential loss to follow ups as well as preventing drop outs during this waiting period. To maintain ongoing interest in the study, we will provide the following retention

tools. Each one of these tools will be available to subjects who are not currently receiving the 16-week intervention.

1. Vlogs (video version of blogs) will be used to disseminate health information, and will be sent to the subject's email address. The vlog will also be posted on the NCDHR website. The vlogs will cover multiple health topics (but not any weight loss or obesity-related topics to avoid contaminating the study's findings). Examples of health topics will include common infections (Flu), skin care/cancer prevention, and safety pointers. The English version of an example vlog titled "Deaf Health News: Skin Cancer- What to Look For?" is uploaded with this application in section 1.3.1 as part of the Retention Materials.
2. Newsletters will also be emailed to subjects. This will incorporate similar messages as those in the vlogs but will be provided in a print form for those who prefer this medium. An example of the newsletter titled "What's Up?" that covers common colds is uploaded.
3. Email health pointers will be sent monthly. They will provide information on health information sources or recent health findings that may be of interest to the subjects. Two examples are: "Did you know that tanning beds can increase your skin cancer risk even more than outdoor sun exposure?" and "Sun rays are strongest between the hours of 10 am and 3 pm."

At the end of the waiting period, delayed arm subjects will be asked to initiate the intervention. At the point 2 and point 3 data collection visits, they will complete a "cross-participation" questionnaire about participation in any of the DWW 2.0 programs of the immediate intervention arm. If they answer positively, their level of involvement will be recorded. If more than superficial, the subject will be welcome to continue in the intervention but his/her results will be excluded from the analysis. We expect 9 or fewer persons will cross-over in this fashion (we did not experience any cross-participation in the original DWW, as determined by subject self-report in ASL interviews).

The immediate intervention arm will be followed for 1 year following their maintenance phase (Figure 1), to assess retention of diet, physical activity, and weight loss in the absence of active or maintenance interventions. Immediate arm participants will also receive the retention tools described above to maintain their interest in returning for the remaining data collection visits.

Data Analysis and Monitoring

Data Analysis: At the completion of each of the five data collection periods, cleaned data will be summarized for frequencies of discrete variables and descriptive statistics of continuous variables, using SAS and other statistical packages. Continuous variables which show significant skewness and kurtosis will undergo log or square root transformation to approach a normal distribution. Tables will be constructed for baseline characteristics of the total study population and each of the arms of the interventions.

The success of randomization to the arms of the study will be tested by Chi square for discrete variables and t tests (or nonparametric Wilcoxon signed-ranks test if the data are not normal) for continuous variables for significance of differences between immediate and delayed intervention groups. Significant differences will require adjustment for the unbalanced variable in further analyses.

The occurrence of participation by delayed intervention subjects in the immediate interventions will be assessed by questionnaire at the end of the delayed period; if the subject reports interaction with the immediate intervention, their data will not be included in the analyses. Up to 9 persons could be removed from the analysis before there is any compromise of power.

The primary study hypotheses will be tested by comparing change in weight and change in BMI between baseline and data point 2 in the immediate versus the delayed arm subjects, using t-tests (or nonparametric Wilcoxon signed-ranks test if the data are not normal). Finally, if either or both are significant, an analysis of variance for the arms of the study will be carried out using orthogonal comparisons to determine sources of variance between the arms of the study.

Secondary analyses will be carried out using paired t-tests to examine significance of differences in weight, Block dietary scores and IPAQ physical activity scores between baseline and the remaining data collection points for each group. Similarly, the costs of interventions at the end of each arm will be compared. Finally, other variables associated with study outcomes of change in body weight, Block score, and IPAQ score will be identified using univariate analysis as described previously. For age, sex, and all baseline variables associated with outcomes at the $P < .10$ level of significance, multivariate linear regression analyses including the intervention arms will be performed to adjust for possible confounders. Interaction terms between age, sex, overweight or obese status, or level of ASL use and the intervention arms will be tested for effect modification in one or more subject subgroups.

In addition to data from the survey questions, the survey software also produces additional user data, including keystroke data indicating that a different sign model was chosen at any point during the survey, that the English captions were turned on or off, that the font size or video background color was changed, that the help function was used during the survey, the time taken to complete the survey, and other user data. We will use this keystroke data to examine user preferences, differences in how groups of respondents use the survey (e.g., older vs. younger respondents), and for quality improvement purposes.

Monitoring: The oversight and monitoring of this study to ensure the safety of subjects and the validity and integrity of the data will occur through the establishment of a Data and Safety Monitoring Plan (DSMP). The DSMP for the Deaf Weight Wise 2.0 intervention will include monitoring by the PI, the RSRB, the NCDHR Data Management and Analysis Team (including daily monitoring by the senior health project coordinator and other members of this research team), and a Data and Safety Monitoring Board (DSMB). This plan includes oversight of the protections for subjects regarding confidentiality safeguards, such as following HIPAA guidelines; minimizing the risk of adverse study reactions; and evaluating the procedure for reporting adverse events.

The DSMB is comprised of Hongmei Yang, PhD (NCDHR's UR faculty statistician), Scott Smith, MD (a deaf ASL-fluent primary care physician and researcher in the Rochester area), and Chris Lehfeldt, DDS (a deaf ASL-fluent community dentist not affiliated with UR). Members of the DSMB will disclose any potential conflicts of interest, either pre-existing or those that develop during their tenure, to the PI. This three-person DSMB will meet quarterly during data collection (or immediately if a serious adverse event is reported). Dr. Yang will analyze data and create reports in preparation for these quarterly meetings. These data will be reviewed by the DSMB, the PI, and the NCDHR Data Management & Analysis Team. This same DSMB successfully carried out their responsibilities for the original DWW clinical trial of ages 40-70 and has agreed to continue to serve as the DSMB for DWW 2.0.

Responsibilities of DSMB Members:

- Maintain confidentiality of the data and the results of the monitoring.
- Review the research protocol and plans for data and safety monitoring.
- Review the quality of outcome data at all sites; subject recruitment, randomization and retention; risk versus benefit ratio for subjects including unanticipated adverse effects; and other factors that may affect the outcome.
- Following DSMB meetings, provide the PIs with written information concerning their findings.

- Submit summary reports of discussions regarding unexpected adverse effects or unanticipated problems involving risks to subjects or others. These reports should include a review of data and outcomes, summary of the review of these events, and any recommendations for modification of the study protocol.
- Oversee that all meeting reports will be forwarded to the RSRB.
- Review proposed modifications to the study prior to their implementation.

Questionnaire and any physiologic data directly entered into the survey computers will be reviewed for invalid answers along with incomplete or missing data. Physiologic measures will be checked for outliers or invalid results before the subject leaves the assessment session. Laboratory values will be checked for fasting status and non-fasting triglyceride, LDL cholesterol, and blood glucose values will not be used. NCDHR's Biostatistician Dr. Hongmei Yang, and the NCDHR Senior Health Project Coordinator, will receive all final datasets electronically in accordance with the procedures outlined in the Data Storage and Confidentiality section, below.

Team members directly involved in data collection will also hold a team debriefing during each day of data collection (for both questionnaire and physiologic data collection sessions) in order to facilitate team communication, monitor protocol adherence, and minimize subject burden. This team will report to the PI on a weekly basis or more frequently as needed. The NCDHR Research Committee (whose members are all listed on this application) meets regularly and will receive reports of study progress and protocol adherence from those who are directly involved in data collection. DWW 2.0 counselors will meet every other week during the course of each 16-week intervention, to monitor protocol/curriculum adherence and share experiences and lessons learned during group or videophone facilitation; they will regularly report back to the research team during Research Committee meetings.

All research team members will be trained to immediately report any adverse events to the PI and determine the appropriate manner in which to proceed. A written report will be submitted describing the adverse event within 72 hours to the DSMB and PI as well as the RSRB. Potential adverse events that could occur as a result of study participation include: (1) hospitalization for acute myocardial infarction, unstable angina, new onset angina (chest pain), or stroke, and other cardio-respiratory symptoms that require medical evaluation and subsequent re-evaluation of the subject's medical clearance to participate in the study (2) serious adverse psychological reactions such as feeling upset, embarrassed, or uncomfortable as a result of participation in the intervention group or VP sessions; (3) breach of subject confidentiality due to failure of data security procedures. The study statistician will also conduct preliminary analyses every 6 months to determine if any adverse (or statistically significant) results are occurring within the study groups and will report such findings to the PI.

Data Storage and Confidentiality.

Data from physiologic measures will be obtained by CRC staff or research staff and will be recorded on the Clinical Research Center Data Collection Forms (enclosed with this application). Laboratory values will be obtained. Data from these forms will be entered into password-protected databases maintained by trained research staff and will be kept indefinitely. Hard copies of all data collection forms will be kept in locked file cabinets in the locked office of the Study Coordinator. These data will be stored for 6 years and then destroyed.

Questionnaire data collected through in-person interviews will be recorded by the interviewer on the designated data collection forms (see copies of these surveys enclosed with this application). Data from these forms will be entered into password-protected databases maintained by trained research staff and will be kept indefinitely. Hard copies of all data collection forms will be kept in

locked file cabinets in the locked office of the Study Coordinator. These data will be stored for 6 years and then destroyed.

Questionnaire/survey data are collected on a laptop computer via the computer-based sign language survey program that is based on a secure URMC web-based server. An NCDHR research team member has to login to the sign survey website using their own unique login and password. One survey will be opened for each subject at the start of their appointment; the subject then enters his or her own unique study ID number into the survey itself as a response to the first question. The survey administrators' login credentials adds an extra layer of security in that it prevents the subjects themselves, or anyone they might tell their study ID to, from getting access to any subject's results stored on the sign survey website UR server. Questionnaire responses will be directly entered by the subject. All laptops will be secured by passwords known only by research team members. Files linking names with unique subject ID numbers will be stored separately in a locked cabinet in the locked office of the Study Coordinator. Questionnaire data are securely stored on the URMC server that is managed by Academic IT. Data will be securely downloaded and stored on the Study Coordinator's and the Biostatistician's password-protected secure UR computer for cleaning and dataset development.

Datasets from the physiologic data and questionnaire data obtained from in-person interviews will be merged with data from laptop-based questionnaires. Final datasets will be stored on the Study Coordinator's and the Biostatistician's password-protected secure UR computers in locked offices. These data will be kept indefinitely.

Subject contact information containing identifiers (see Participant Contact Form included in this application) will be maintained in an entirely separate database and will be used to contact study subjects during the course of the study (e.g., to schedule or remind them of upcoming data collection sessions and to provide them with their lab results). We will aggregate zip code data asked on the Baseline computer-based survey separately, and use it to help establish approximate population estimates and geographic distribution of this segment of the deaf population, since this information is currently unknown. Subjects will complete contact information forms and update them throughout the course of the study; these will be entered into a password-protected database maintained by trained research staff. Paper copies of all contact information forms will be kept in the locked office of the NCDHR Research Group and will be destroyed once they are entered into the database.

Only research team members will have access to data analysis reports and findings. Trained research staff will maintain all deidentified data and reports; hard copies of reports will be maintained in locked file cabinets in locked offices of the Study Coordinator. Findings or reports may be shared with members of the NCDHR Research Committee (who are listed as members of the research team on this application). Study findings may be presented at meetings or in publications but will be reported in summary form only; subjects will never be personally identified.

Strict measures are in place to ensure confidentiality and protect subject identity. Subjects will be assured that their privacy will be protected at all times, that their personal study information will not be shared with anyone, and that they will have the right to discontinue participation at any time. In order to be in compliance with HIPAA regulations, we will obtain HIPAA authorizations from each subject as part of the informed consent process, as described in this protocol.

All study personnel have up-to-date human subject research education certification (Greater than minimal risk behavioral / Human Subject Protection Program (HSPP) or equivalent through the online CITI training). Additionally, all NCDHR researchers have completed the NCDHR Cross-Cultural Research Training Curriculum. This curriculum is a collection of required readings and

recommended materials on sociocultural aspects of deafness and cross-cultural ethics in the conduct of deaf health research.

IV. RISK/BENEFIT ASSESSMENT

1 Risk Category.
Minimal risk study: This study tests the efficacy of an educational intervention. No significant risks are anticipated in relation to the process of learning the information that will be conveyed in our health intervention modules. It is possible that learning about the health risks of high blood pressure, obesity, high cholesterol, or abnormal glucose levels may provoke some mild anxiety in individuals who manifest such health risks, but the health benefit of being aware of increased risk of health problems is judged to outweigh the discomfort of related anxieties. Also, we will offer study subjects referral information to accessible health care providers when health risks such as these are identified. Anxiety may also arise when subjects learn of health history that suggests increased risk for disease. Again, in our judgment, the health benefit of being aware of increased risk of health problems is judged to outweigh the discomfort of related anxieties.

2 **Potential Risks**.
The collection of the venous blood sample carries a risk of infection and discomfort. We foresee no significant risks in the collection of the other biometric data noted above, with the possible exception of mild embarrassment regarding the collection of weight data.

The non-biometric data will be collected during in person interviews or via a kiosk-computer based instrument that uses sign language video and a touch screen interface to collect data confidentially. We anticipate no significant risks in relation to collecting this information from subjects, and all information is collected behind a privacy curtain. Based on our experiences and previous work with the Rochester Deaf community, and because the data will be collected via computer confidentially, we do not expect strong emotional responses to the data collection. Some subjects may have a response to the interpersonal violence questions or the adverse childhood experiences questions.

There is a risk that subjects who participate in health intervention modules delivered in a small group format (i.e., to more than one person) will risk loss of confidentiality of some information, as many individuals in the Rochester deaf community know one another. We do not consider this a serious risk since subjects will know ahead of time that the intervention will be delivered in a small group format and because social contact between deaf individuals is culturally valued, including in educational venues. Further, subjects will not be able to observe or have access to the data being collected from others.

There is also the risk of accidental disclosure of study data. Strict procedures are in place to minimize this risk (see data storage and confidentiality, and protection against risks, below).

3 **Protection Against Risks**.
The risk of infection from the venous blood draws is a risk in this study. Clinicians trained in blood-drawing procedures will collect blood specimens. These clinicians will be sign language fluent or will work with interpreter services during the collection of blood and other biometrics. All personnel involved in collecting blood samples will employ universal precautions to prevent infection. Gloves will be worn by all such personnel and subjects will be asked if they have an allergy to latex. We will use sterile blood drawing equipment with a sterile needle. Following collection of the sample, a sterile gauze pad will be applied to the wound location and held in place, followed by the application of a sterile bandage.

Some subjects may have a response to the mental health, interpersonal violence, or the adverse childhood experiences questions; deaf-accessible resources for such reactions are provided to subjects in sign language within the survey itself, and a qualified sign-fluent staff member from the Deaf Wellness Center who is also a member of the research team will be “on-call” during all relevant data collection visits (when these specific sensitive survey questions are asked). Subjects who request further information or resources in this regard will be referred to the Deaf Wellness Center in URMC’s Department of Psychiatry.

The risks of mild anxiety associated with learning of disease risks associated with overweight and obesity, high blood pressure, high cholesterol, abnormal blood glucose, or history of disease will be remediated through education and supportive counseling at the time such topics are raised during the study. Subjects who manifest persistent anxiety in this regard will be referred for treatment to the Deaf Wellness Center in URMC’s Department of Psychiatry. The risk of embarrassment associated with the collection of weight data will be avoided by collecting these data in a private location, outside the view of any individuals other than the researcher collecting these data. Subject preferences, if any, regarding researcher gender in the collection of these data will be solicited and respected.

The risk of loss of anonymity of those participating in small group health intervention sessions will be discussed with subjects during the informed consent procedure and only those consenting with full knowledge of this risk will be enrolled in the study. Further protections regarding the risk of accidental disclosure of study data will be addressed as follows. All study data will be stored in secure offices in locked file cabinets. Electronic data will be collected on password protected secure computers and downloaded to password protected secure computers on a daily basis so that old data does not remain on the field computers. Only authorized study personnel will have access to study data. All study personnel will have completed and passed the Human Subject Protection Program (HSPP) or equivalent. Additionally, all researchers will have completed the NCDHR Cross-Cultural Research Competencies Curriculum, as required by NCDHR policy.

Subjects who manifest abnormal blood pressure, cholesterol, glucose, or who endorse any positive response on the past 2 weeks suicidal ideation item on the PHQ-9 depression screener will receive a brief assessment, relevant health information, and counseling referral from qualified, sign-fluent study personnel. Referrals to accessible healthcare providers will be provided to all who need such a referral, whether because they manifest disease risks such as these or for any other reason when necessary.

4 **Potential Benefits to the Subjects**.

The first form of benefits for subjects is that associated with having accurate, up-to-date information about the health risks associated with obesity, high blood pressure, high cholesterol, and abnormal glucose, and the health benefits of having accurate up-to-date information about health promoting behaviors, as well as the benefits of enrollment in a free program designed to lower health risks.

The second form of benefits is that associated with having information regarding one’s own blood pressure, body mass index, cholesterol level, and glucose level. We will share with each subject the results of their physiologic/bio-metric measures. With this knowledge, subjects will be in a much better position to maintain their health, prevent illness, and/or seek necessary treatment as early as possible. For those who manifest health risks associated with high blood pressure, obesity, abnormal glucose and high cholesterol, we expect the knowledge gained through this study to result in increased motivation for reducing arteriosclerotic vascular disease (ASVD) and other health risks through diet, exercise, other lifestyle changes, and medication when necessary and, for some, actual achievement of lowered blood pressure, reduced body mass index, improved glucose and lower cholesterol. We may also uncover previously undiagnosed illness. This earlier diagnosis and our referring the subject to an accessible clinician is a potential benefit to subjects.

These potential benefits are judged to be substantial in relation to the potential risks cited above, including anxiety about health risks, infection from venous blood drawing, embarrassment regarding weight and waist circumference measurement, and potential loss of anonymity or failure of our data security procedures. The risk of infection from the blood drawing is judged to be extremely low, the anxiety and embarrassment risks noted quite minor, the risk of loss of anonymity in study/appointment settings is offset by informing subjects about this prior to obtaining informed consent, and the risk of breach of data security very low. All of these risks we judge to be heavily outweighed by the potential benefit of preventing negative health consequences associated with obesity.

5 **Alternatives to Participation**. Subjects can elect not to participate at any time.
There are currently no sign language accessible alternative obesity interventions. We have not identified alternative data collection procedures that would entail lower risks than the procedures described above. Our current plan for collection of the biometric data reflects minimum risk; there are no alternative data collection procedures that would further reduce the risks described.

V. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT/ASSENT

1 Method Of Subject Identification And Recruitment.

Information about the study will be disseminated through different networks that have already been established by NCDHR (refer to list of organizations in application and provided below). DWW 2.0 will be the first randomized controlled research study of a lifestyle intervention ever done with deaf ASL users ages 21-70. Many deaf ASL users lack experience or understanding on how a research study is designed and conducted. As such, the research team will engage in culturally and linguistically appropriate outreach and recruitment strategies that clarify research concepts (e.g., why a randomized clinical trial design is needed) and how this study may impact the deaf community. To minimize confusion of study subjects, we want to be sure to distinguish DWW 2.0 from local commercial or physician-supervised weight loss programs/clinics; we will consistently advertise our project with the full title, “Deaf Weight Wise 2.0 Research Project” to indicate that this is a research study. Approaches to recruitment are listed below.

Online Recruitment Sources:
Web/Email Recruitment Scripts, and Recruitment Flyers included with this application may be used on these websites. Sign language video-blogs (“vlogs”) containing this information may be posted on these websites as well.

1. The NCDHR website (www.urmc.edu/ncdhr) will be used to disseminate information about the study. The flyers and vlogs will be used on the home page to increase interest as well as to provide easy to read information regarding the reason for the study, eligibility criteria, and how to sign-up for a study screening visit.
2. The NCDHR Facebook fan page (https://www.facebook.com/National-Center-for-Deaf-Health-Research-204749949096/): flyers/vlogs/contact information may be posted; upcoming study informational sessions/enrollment events will be posted.
3. DeafRochy.com (www.deafrochy.com) is a calendar of events for the local Deaf community. Upcoming study informational sessions/enrollment events will be posted on the calendar.
4. NCDHR Twitter: links to flyers/vlogs/contact information may be posted.
5. NCDHR Instagram: the DWW 2.0 logo as well as links to flyers/vlogs/contact information may be posted.

Community-Based, Educational, and Other Organizations:
NCDHR values the role of many different deaf organizations and deaf community leaders and have successfully included these organizations to aid in recruitment for prior studies. Research team members will attend meetings of local organizations and educational institutions with deaf members to make informational presentations about the study during or directly after organizational meetings are held. RSRB-approved materials such as flyers and vlogs may also be posted/shared at these sites. In addition, letters of cooperation indicating the organization's agreement to allow recruitment activities to be conducted at their site will be amended to this application prior to conducting any recruitment activities. Of note, these organizational sites/staff are **not** engaged in the research as per OHRP federal guidance and therefore do not need an Assurance as per http://www.hhs.gov/ohrp/policy/faq/assurance-process/engaged-in-research.html).

Possible future letters of cooperation to be amended to this application prior to conducting any study activities:

Community Based Organizations
1. Center for Disability Rights
2. DePaul

Deaf Membership Organizations
1. Deaf International of Rochester
2. Deaf Women of Rochester
3. Rochester Deaf Mother's Club
4. Rochester Recreation Club for the Deaf
5. Rochester Deaf Rotary
6. Deaf-Blind Support and Social Group
7. Lilac Chapter – Rainbow Alliance of the Deaf
8. Empire State Association of the Deaf
9. RIT/NTID Deaf Professionals Advisory Group

Educational Institutions
1. NTID Alumni Association
2. NTID's Deaf Professional Group (NTID faculty and staff)
3. Rochester School for the Deaf (RSD): Deaf faculty and staff only
4. RSD Alumni Association

Governmental Agencies
1. NYS VESID in Monroe County

Medical Clinics: Medical clinics that are identified as "deaf friendly" are sites where deaf ASL users may go for their medical care. Health care professionals at these clinics are identified as being fluent in ASL or consistently provide interpreter services to ensure accessible medical communication. After letters of cooperation are obtained, we will provide these clinics with recruitment flyers that will be placed in their examination or waiting rooms. Copies of RSRB approved study flyers will be available for interested deaf ASL users to pick up voluntarily. We will not ask health care professionals to directly recruit their patients to become our subjects. Interested subjects are free to discuss with their providers about the program itself to evaluate if it would be safe and possibly beneficial for them. A list of deaf-friendly medical clinics and providers from which letters of cooperation may be obtained are listed below:
1. Folsom Family Medicine
2. Elmwood Dental Care: sign-fluent deaf dentist
3. Park West Women's Health: sign-fluent OB/GYN physician
4. Strong Audiology
5. Rochester Hearing and Speech Center

Networking and Recruitment by Members of the DWW 2.0 Community Committee:
NCDHR has been developing a **Deaf Weight Wise 2.0 Community Committee**, based on our mission and principle of conducting community based participatory research. The DWW 2.0 Community Committee is composed of a diverse group of deaf community members with goals of working with researchers on this and other projects to promote an understanding of Deaf ASL-users and their families' health needs; the majority of the members are Deaf ASL-users. Committee members have extensive connections in the Rochester Deaf community and therefore are able to create excellent networking opportunities with deaf adults and potential study subjects. We anticipate that Committee members will be able to successfully recruit subjects whom we would not otherwise have access to for this research. Community committee members are critical to our recruitment process and can demonstrate a level of familiarity and possible increased trust in NCDHR. Committee members who approach potential subjects will have an understanding of the study components; they will not be directly enrolling subjects or obtaining consent, but will refer potential subjects to contact a member of the research team to learn more or to make an appointment for a study screening visit. Committee members and research team members will use elements of the Study Information Sheet and Recruitment Flyers to convey information when they network with potential subjects. Networking and recruitment by Committee members and research team members will take place at community events, public venues, organizational meetings, and other community-based locations. The Web/Email Recruitment Script included with this application may be emailed by members.

Recruitment from the NCDHR Contact List:
NCDHR maintains a contact list of deaf people who have provided some of their personal contact information (name, mailing address, email address, cell/text number, videophone number, age), in order to be notified of future NCDHR research (see RSRB 33598 Deaf Health Research Recruitment Repository). This information is generally collected via a Business Reply Mail postcard that is distributed at deaf social events, local conferences, and through informal networking by NCDHR staff and its community partners. Web/Email Recruitment Scripts and Recruitment Flyers included with this application will be emailed to contact list members. A link to the Recruitment Video-logs (Vlogs) and the NCDHR website will also be emailed to contact list members (see Vlog scripts enclosed with this application).

To maximize recruitment of potential subjects from this contact list, members of the research team may contact deaf adults in the 21-70 age group on the list by videophone. Elements of the approved videophone/email script will be used when contacting potential subjects through videophone.

It is important to emphasize that the NCDHR Contact List information is in no way connected to the Deaf Weight Wise 2.0 Research Study and will never be connected to subject data.

Peer-driven Recruitment Method:
The Deaf community is largely unknown in terms of its size and demographics. This poses unique challenges in assessing adequate sampling strategies. Many recruitment modalities are not available as recruitment options for this community, which is an issue of justice and ensuring the accessibility of research opportunities for all populations. NCDHR learned that some direct recruitment strategies used in other studies were unable to reach certain deaf community members; and that non-white deaf ASL-using individuals were recruited at levels below what is typically represented in demographics of Monroe County. Recruitment struggles listed above are similar to experiences shared by other researchers working with challenging to reach populations such as intravenous drug abusers, HIV-positive populations, and gay or lesbian communities [26-28].

Respondent driven sampling (RDS) is a peer-driven recruitment tool used by other

researchers to avoid selection biases with hard to reach populations. The RDS method has been shown in peer reviewed medical literature to result in greater penetration and recruitment of hard-to-reach community samples[26]. This results in a more representative sample of the targeted group in the community. RDS relies on a system of structured incentives to overcome some of the deficiencies that arise in standard direct community recruitment strategies listed above. An advantage of RDS strategy is the reduction of the expected initial sampling biases that may result from prescreening of interested volunteers from the NCDHR contact list and direct community recruitment by NCDHR research staff.

RDS would assist NCDHR to be able to reach out to hard to reach deaf ASL users and be able to utilize the social connections that these individuals do have to other deaf individuals in the community. Peer-driven recruitment fits with Deaf community values, as the most valued communication in the Deaf community is person to person. We anticipate that peer-driven recruitment will allow us to reach many more potential subjects who are otherwise unreachable and would not be represented in the study sample.

RDS can achieve a community representative sample that is independent of the original subjects who were recruited by staff members of NCDHR. This may help to avoid any sampling biases that could limit the generalizability of study findings. RDS is most effective when a minimum of 9 individuals serve as the initial "recruiters" and each is given 3 to 10 coupons to give to potential participants[26]. Below is a list of the steps that we will take to ensure RDS is carried out effectively. This plan is similar to Heckathorn's strategy[26].

Steps:

1. NCDHR research staff will recruit interested eligible subjects to serve as the initial "seeds." This will be done from the direct recruitment methods outlined above. A minimum of 9 initial "seeds" will be sought.

2. Each seed/peer recruiter will be given 5 coupons. Each coupon will have a unique ID number. The ID number serves two purposes. First, it confidentially links the coupon back to the seed. This will allow us to keep track of the number of subjects referred by each seed and at the end of the enrollment period will help us track payment. Second, the unique ID prevents duplication of the coupon and thus will prevent excessive referrals by one seed. Seeds will be instructed to give coupons to individuals who meet the basic enrollment criteria for the study – 21 to 70 years of age with a BMI between 25 and 45. They will also be told that they will be paid $5 for each coupon that is returned to NCDHR, regardless of whether or not the individual is enrolled in the trial.

3. Individuals who are given coupons and decide that they are interested in DWW 2.0 will sign up for a screening interview. When they come in to sign up for the screening, their coupons will be collected and we will use standard software to track all returned coupons.

4. When the first wave of recruited subjects returns their coupons, the second wave of seeds will be selected from this pool. These seeds will also be given 5 coupons each. This process will continue until NCDHR achieves its enrollment goal.

5. Once study enrollment is complete and the study has begun, seeds will be paid for each coupon that was returned, regardless of whether or not these individuals meet study eligibility criteria. We will not follow up with seeds during the enrollment process. Seeds will not know how many of their coupons were returned until they have been paid. Because of this, there should be no encouragement for seeds to recruit more aggressively, and as such this will help to eliminate the potential for coercion. In addition, payment to seeds will not be linked to any identifying information of peers who are recruited; seeds will be paid a maximum of $25 based on the number of coupons returned and no identifying information of subjects who presented for the screening interview will be disclosed.

This method is consistent with RSRB's peer recruitment policy that "study participation by their peers is not a condition of payment to recruiters." As proposed by RSRB staff in the original Deaf Weight Wise trial, we have designed the study screening interview for DWW 2.0 to be completely separate from determining eligibility criteria and participating in sensitive data collection. Thus, paid peer recruitment can be allowed since this study activity is low risk and is connected to a low incentive amount for seeds ($5 per coupon returned with a maximum payment of $25). This will ensure that peer-driven recruitment activities are not coercive or risky for seeds and peers.

Other Recruitment Strategies:
Our enrollment numbers as of June 2017 are lower than expected; we are experiencing some recruitment challenges and are in need of new recruitment strategies that may be attractive to the study population. We will offer a free Rochester Red Wings baseball game ticket to the next 40 people who complete a study screening visit (beginning immediately after this amendment gets approved; see description of Study Screening Visit on p. 6 of this protocol). The free ticket will be made available to the next 40 individuals who schedule and complete an initial screening appointment, regardless of whether they qualify for the study or not (e.g., those deemed ineligible will still receive the free game ticket). Please see attached new flyer advertising the Red Wings ticket giveaway.

2 **Process of Consent**.
The informed consent process will be conducted only by researchers on this application who are fluent in ASL and able to answer any questions subjects may have about the study and their potential participation. All such individuals also will have currently valid human subject research education certification in the Greater than Minimal Risk – Behavioral / Human Subject Protection Program (HSPP) or the equivalent, administered by the URMC OHSP and online CITI training.

The Informed Consent process proposed here has 3 components. This study team successfully implemented this Informed Consent process in the original Deaf Weight Wise study (RSRB 34096), and received very positive feedback from those original study participants.

1) At the study enrollment visit, an informed consent video presented in American Sign Language will be shown to the subject. The informed consent video will be presented in a series of dialogic scenarios (see English version of Informed Consent video script), which have been shown to be effective with health education materials[29] and are considered to be the optimal learning style for many deaf people due to the dialogic nature of ASL. The consent video scenarios were scripted using information from the English version of the Study Information Sheet. The consent video has been revised to note the change in enrollment criteria, to state that participants ages 21 to 70 are eligible (see text update at 0:28 and 0:56 within this link). Current link to consent video: https://youtu.be/8bhRpoC4KZ8.[Please visit this link to see an example of the completed informed consent video successfully used in the original Deaf Weight Wise study #34096: (ASL with English captions): http://youtu.be/ZVGSOGcQRNU.]
2) Upon completion of the video, the subject will be required to meet one-on-one with a sign-fluent member of the research team (in a privacy-screened area separate from other subjects). Research staff will engage in a one-on-one discussion with each subject privately to answer any questions, confirm that each subject makes a rational and thoughtful decision to participate without any element of coercion or undue influence, and to provide and review as needed the written English version of the Study Information Sheet. Research team members have experience in obtaining informed consent from deaf participants; any new staff will be fully trained prior to enrollment visits.
3) Written evidence of consent (a signature) will be obtained from all study subjects (see Documentation of Consent form). The research staff member will document that they obtained informed consent from the subject and that the subject watched the ASL video.

Potential subjects may review the consent video and documents as many times as they wish. DVD copies of the video and the English consent documents will be available for potential subjects to take home with them both before and after conveying their consent.

3 **Subject Capacity**. All subjects will have the capacity to give informed consent. Subjects who are decisionally impaired or are of questionable capacity will not be enrolled.

4 **Subject/Representative Comprehension**. All components of this intervention will be made available in the respondent's preferred language. Subjects will have an opportunity to ask detailed questions about the study and all questions will be answered. Any subjects who have not demonstrated comprehension will not be eligible to participate. Investigators will ensure that each subject has demonstrated an acceptable level of comprehension before consent is obtained.

5 **Debriefing Procedures**. n/a

6 **Consent Forms**. The written English Study Information Sheets, Documentation of Consent form, and English version of the informed consent video script are enclosed with this application.

7 **Documentation of Consent**.
Valid consent will be obtained and documented by subject signature. The consent process will take place in sign language on video and in one-on-one discussions with the subject and sign-fluent researcher. At the end of the video, the sign model will indicate that the subject should sign the English-language documentation of consent only if the subject has watched and understood the entire content of the video and that he or she has had an opportunity to ask the researcher questions and have those questions answered. The sign model will also indicate that the form should only be signed in the presence of a researcher, as the researcher will confirm informed consent and will sign their name in the "Person Obtaining Consent" field. The documentation of consent form will have a few statements to confirm that the subject watched the corresponding consent video and met with an ASL-fluent researcher and had their questions answered. These English statements will be written at a reading level that is accessible and consistent with the average reading level of the deaf population. The documentation of consent forms containing subject names will be stored in a locked file cabinet in the locked office of the Study Coordinator, separate from any other study documents.

8 **Costs to the Subject**. There are no costs to subjects in this study.

9 **Payment for Participation**.
Subjects will receive incentives for the data collection visits: $20 at the baseline enrollment/data collection visit, $20 at the 6-month data collection visit (point 2), $30 at the 12-month data collection visit (point 3), $30 at the 18-month data collection visit (point 4); at the conclusion of the study, they will receive $50 for the final data collection visit. Subjects will receive payment for each data collection visit at the conclusion of that visit. Subjects have the right to withdraw from the study without penalty but will not receive payment for data collection visits they have not completed.

In addition to monetary incentives for data collection, the DWW 2.0 curriculum offers a toolkit of incentives during the 16-week intervention phase (see DWW 2.0 Rewards System included with the curriculum). Subjects can earn "WiseBucks" based on their attendance, food & fitness diary record keeping, and meeting program goals for weekly physical activity minutes. Wisebucks are assigned to different levels of behavior (such as 1 DWW Buck for 1-2 days of physical activity per week, or up to 4 DWW Bucks for 5-7 days per week of recording their food intake). At sessions 6, 11, and 16, accumulated WiseBucks can be redeemed for small incentives such as water bottles,

measuring spoons, food storage containers, etc. This type of incentive system has been shown to be effective in similar healthy lifestyle/behavior change programs[20]. We will also provide weight scales to all participants in the intervention so they can track their own weekly weight which is a required part of the 16-week program (self-reported weekly weight is a required component of the VP intervention). Participants will keep these scales at the end of the intervention.

In addition to the incentives described above, participants will receive a free parking validation for costs incurred for parking at URMC for any study visits/activities. These parking validations are valued at approximately $4.50 per visit. If participants use the bus to travel to and from study visits and/or intervention group meetings, we will provide them with 2 complementary bus passes (valued at $1 per ride for a total compensation of $2 per visit). Some participants have reported transportation barriers to and from URMC/Saunders Building, so we will offer free transportation by taxi for a small number of participants who request it (the study budget allows for this).

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