Official Title: Deaf Weight Wise: Community-engaged Implementation Research to Promote Healthy Lifestyle Change With Deaf American Sign Language Users

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Deaf Weight Wise: Implementation Research
Study Protocol: RSRB # 5784
Rochester Prevention Research Center: National Center for Deaf Health Research

I. PURPOSE OF THE STUDY AND BACKGROUND

Purpose of the study

The purpose of the Deaf Weight Wise Implementation Study is to study with diverse partners the approaches and strategies that lead to successful implementation of Deaf Weight Wise (DWW), RPRC's evidence-based healthy lifestyle intervention for use with Deaf adult American Sign Language (ASL) users.

The study aims are:

Aim 1: Adapt and implement DWW with partner organizations at different sites in upstate NY.

Aim 2: Assess the factors influencing adoption, adaptation and maintenance of the DWW intervention components using mixed methods.

Aim 3: Perform economic modeling to assess the cost-benefit of DWW, and associations with contextual factors and implementation strategies.

Aim 4: Assess with DWW participants the health-related outcomes and intervention experiences, and the associations of those outcomes with fidelity to DWW intervention components and implementation strategies.

Implementation (site-level) hypothesis: Diverse community organizations will successfully implement DWW with their constituents.

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.

The fund of information on health is ill-defined in Deaf communities, with less access to information in newspapers, magazines, television, etc.[2-4] As a consequence, deaf people have a limited fund of knowledge about many health related topics.[5,6] 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 and disseminate reliable and accurate health information for use with Deaf persons using ASL video. 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).[7]

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.[8] It is based on the University of North Carolina's Weight Wise program and was selected based on 1) its proven effectiveness with an underserved 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.[9] 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 (see RSRB #57628) was the core research project for NCDHR's third funding cycle (2014-2019), and was built on this research team's experience with the original Deaf Weight Wise trial for ages 40-70. DWW 2.0 was an adaptation of the original Deaf Weight Wise curriculum to suit ages 21-70, and evaluated the additional component of the one-to-one individual counseling intervention delivered remotely over videophone (like Skype/Zoom) in addition to the group intervention format.

This new Deaf Weight Wise implementation research proposed here will allow us to work with community partner organizations, to train them to implement DWW at their own sites/agencies. This will fulfill the goal of disseminating DWW broadly to Deaf communities. We will conduct research to study the process of implementation of DWW at each site. This advances DWW along the translational spectrum to ensure that DWW is not only a research project, but becomes a sustainable, community-based program.

II. CHARACTERISTICS OF THE RESEARCH POPULATION

1 **Number of subjects**. 108.
2 **Gender of Subjects.** Subjects of all genders will be included.
3 **Age of Subjects**. Subjects will be age 18 or older.
4 **Racial and Ethnic Origin**. Subjects of any race/ethnicity will be included. Although the demographic characteristics of the Western New York Deaf communities 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 people ages 18+ who use sign language and live in one of the following three regions: Buffalo, Rochester, or Syracuse and/or part of the typical clientele/populations that the partner agency/site serve; have a body mass index (BMI) of 18.5 or higher (normal BMI category or higher). Eligible subjects who wish to participate in the intervention component of the program (16-weeks plus 6-month maintenance phases) must also have permission from a healthcare provider to participate in the intervention 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), 4) are pregnant (self-reported), and 5) has a BMI over 45. 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 group sessions, and to participate in data collection requirements.

6 **Exclusion Criteria**. Those who are unable or unwilling to provide informed consent, and inability to see and interact with computer-based questionnaires and educational interventions will be excluded. Subjects with any of the following conditions who wish to participate in the intervention component of the program but do not have permission from a clinician may be instructed to abstain from specific intervention components (see Medical Clearance section below); including those who reported 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, 4) are pregnant, or 5) has a BMI over 45.

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 use with 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. This research includes the guidance of Deaf community advisory boards, 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

Overall study design

The overall design of the DWW Implementation Study will have up to nine sites hosting DWW in three cities. NCDHR is working with each site to establish a timeline for beginning the program; as each new site is added, we will upload their Letter of Cooperation as a Modification to our application (we will upload each Letter of Cooperation as an amendment, once they are received). It is important to note that these sites are NOT engaged in the research, as per the federal definition.

The total length of the full study at each site is about 18 months for individual participants (baseline and two follow-up data collection points). Interventions will consist of 16-week group counseling Zoom sessions led virtually by trained, ASL-fluent Deaf counselors. Following the

16-week intervention, subjects will enter a 6-month “maintenance phase” with less intense interventions. This study is by definition a single-arm interventional clinical trial; we will register this study on clinicaltrials.gov as required, and will submit a modification to enter the NCT number prior to conducting the study.

DWW 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.[9] The goals of physical activity are 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.

Our primary outcomes for this research are related to implementation, rather than effectiveness. A quasi-experimental pre-/post- design is appropriate. The outcomes of the DWW randomized trials previously conducted demonstrate effectiveness.

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. Cost data--such as counselor hours needed and intervention materials and supplies--will be collected and reviewed by the study coordinator and CTSI finance team that administers NCDHR funding; these financial data are maintained on the NCDHR-CTSI shared private network folder. No participant-level cost-related data will be collected and no identifiers are needed for cost-related data. These costs are helpful in determining sustainability plans for community-based interventions.

Note about English language study materials prepared/submitted for this RSRB review

Based on the previous NCDHR research, previous meetings with OHSP and RSRB leadership over several years, 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 use with deaf ASL-users. We will only use the best possible ASL 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 Interview

Subjects will first complete the brief study screening interview one-on-one with a member of the research team via Zoom or videophone (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, gender, 2) ask for the subject’s self-reported height and weight to calculate BMI, 3) general location where they live such as county or which part of state, 4) ask their internet access and device status and to ensure they are able to participate in Zoom group meetings or offer videophone one-on-one back up option, and 5) ask

the Study Screening Interview, which includes the Physical Activity Readiness-Questionnaire,[10] to determine whether the subject will need permission from their healthcare provider to participate in the 16-week intervention component of the study. If qualified, then we will ask if they want to enroll today or schedule an appointment on different date.

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 for how to sign up on the NCDHR website. Other studies conducted by NCDHR have included information about joining the Contact List at the end of study participation. Information that ineligible DWW subjects may provide as part of the Contact List is completely separate from DWW and will never be linked to DWW study data.

Medical Clearance Process

As part of the baseline study screening interview, subjects will be asked a brief series of questions that will determine their eligibility to participate in the study (see: Physical Activity Readiness Questionnaire). To determine any potential health related concerns, there are questions that ask the following:

- 2 questions 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;
- 2 questions about recent overnight hospitalization and emergency room visits;
- 1 question to determine whether the subject has had weight loss surgery in the previous two years;
- 1 question to determine if the subject is pregnant.
- Calculate BMI using self-reported height and weight.

If a subject answers positively to any of these items, or has a BMI of 45.0 or higher, they will be required to obtain permission from their Primary Care Provider (or maternity care clinician as appropriate) to participate in the DWW Intervention as it is designed (see Physician Permission Letters / Tracking Form uploaded in the online application). First, subjects who fall under this criteria will be asked to sign a HIPAA Authorization form - SH 48 MR (Authorization for Release of Medical / Behavioral Health information; this fillable PDF form is found here: https://www.urmc.rochester.edu/health-information-management/roi-forms.aspx . Once the subject completes this form, this will allow our study team to prepare the medical clearance letter that the subject will then give to their healthcare provider (the letter will state that the subject reports having a heart attack or stroke or weight loss surgery or pregnancy or BMI over 45.0). There are two levels of permission: one to obtain clearance to participate in the whole DWW intervention, 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 participate in the relevant 16-week intervention component(s). These procedures were successfully implemented in the first two

clinical trials of Deaf Weight Wise; in fact, only a very small proportion of participants in the first two clinical trials needed permission from their provider based on their screening answers, and were able to successfully get that permission.

At the time of enrollment/baseline appointment, we will still enroll the subject even if medical clearance is required for the DWW intervention component. If the subject does not obtain medical clearance before their 16-week zoom-based intervention begins, the research team will consult with the PI (Dr. Barnett is also a physician) to determine whether participation should be halted entirely or whether the subject should be encouraged to not engage in the exercise or diet modification components. There are no other language-accessible health intervention programs for Deaf sign language users available. If we decline enrollment entirely based on needing provider permission for only those with a health issue, this team feels it is a missed opportunity for these Deaf participant(s), given the minimal risk nature of the study and the benefit to promoting healthy lifestyle. However, if we allow enrollment at the point of screening, and then await provider permission before the intervention starts, we help to ensure that these Deaf participants will not have missed an opportunity to participate. Based on the timing of each site's enrollment, there may not otherwise be an opportunity for these particular Deaf participant(s) in the future if we decline enrollment at that point of screening.

Study enrollment virtual visit and baseline data collection

If the subject is eligible as per the study screening interview, they will continue with the initial study enrollment visit via Zoom or videophone (1:1 with a research coordinator) to complete the following baseline activities:

1) Potential subjects will view the informed consent video in ASL which includes an overview of the DWW study. They will also have a one-on-one discussion with a member of the research team through Zoom or videophone to obtain informed consent if they are interested in participating. (see Consent Process section of Protocol)
2) Following the consent process, subjects will assigned a study ID number and will be asked to complete the one-on-one qualitative baseline health interview in ASL (included with this application).
3) The research coordinator will inform the subject that they then need to complete a baseline health survey on a REDCap website, which they will be instructed to do on their own time (see English version of surveys included with this application). They will be given their study ID number to enter into the REDCap survey to ensure their survey is completed. There are no other identifiers in the REDCap survey.
4) The research coordinator will work with the subject to fill out the Participant Contact Form also available in REDCap to be able to contact the participant for intervention scheduling and future follow up appointments (see PDF version of this form included with this application).

Modification July 13, 2023: As of this date, we have one implementation partner, the YMCA, who has not yet implemented an intervention group. The DWW intervention counselor for this group is now trained and ready to lead a group of participants starting in mid-August 2023. We will now recruit and enroll up to 10 participants for this virtual intervention group. Due to funding for this study ending in September 2024, we propose here to change the final data collection appointment for these final 10 participants only, so their final appointment will be 12 months

from enrollment instead of 18 months from enrollment. We will make this change to the Study Information Sheet (please see Consent section of protocol). All other study activities will be the same as what is already approved.

Post-intervention virtual data collection

Subjects will have 6-month and 18-month follow-up appointments via Zoom or videophone, to assess change since baseline as well as post-intervention outcomes. The one-on-one qualitative health interview with a researcher and the REDCap health survey will be repeated at the 6-month and 18-month time points (see English version of surveys included with this application). These visits do NOT require in-person contact; they are all virtual.

Modification July 13, 2023: For the 10 participants in the YMCA-based virtual intervention group: Due to funding for this study ending in September 2024, we propose here to change the final data collection appointment for these final 10 participants only, so their final appointment will be 12 months from enrollment instead of 18 months from enrollment. Study coordinators will use the same 18-month data collection measures forms at the 12-month appointment with these 10 participants.

Health Survey in REDCap (see Table 1 below): Some data collection will be carried out in sign language along with English text version on a REDCap survey. We have developed a special external module in REDCap in collaboration with the REDCap creators at Vanderbilt University, which allows all of our survey questions to have ASL video in addition to English text, as well as unique features such as color changes and text size changes for use with Deaf-Blind respondents. 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 REDCap survey 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 video, 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 depending on what device they use. 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.

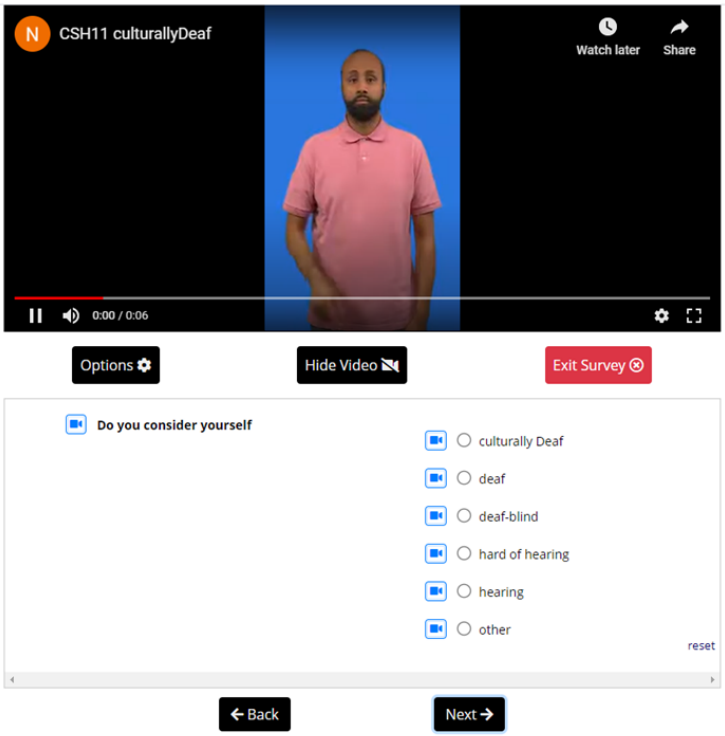

Table 1. Data collection measures with DWW subjects				
Measure/Description	**Baseline**	**6 mo**	**18 mo**	**Mode of Administration**
Demographics Deaf demographics Health history Healthcare access Weight loss history	X	X	X	Computer-based survey in ASL
Block fruit, vegetable, fiber screener[12]	X	X	X	Interview in ASL
International Physical Activity Question (IPAQ)[13]	X	X	X	Interview in ASL
Physical Activity Readiness (PARQ)[10]	X	X	X	Interview in ASL
Emotional eating	X	X	X	Interview in ASL
Food & Fitness diaries	X			Collected from subjects during 16-week intervention
Intervention Attendance	X			Recorded by DWW counselor
Weekly body weight	X			Recorded by DWW counselor
Physiologic measure Weight (lbs) Height (inches)	X	X	X	Interview in ASL
DWW program satisfaction		X	X	Interview in ASL
Recruitment evaluation	X			Interview in ASL

Description of Translation Process: ASL questionnaires were adapted from English questions and were translated by NCDHR Research Committee and Deaf Community members who have extensive collective experience developing and translating health and educational materials and working with deaf populations.[8,11] Translators have 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.

Once the translation process is complete, NCDHR gives all sign language translation video clips to independent back-translators. 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.[11] If the back-translation is deemed to not match the source English, the item is returned to the translation team for a new translation.

Research Coordinator Training and Team Debriefings during Data Collection Phases

All research coordinators and intervention counselors who are interacting with participants on Zoom or videophone will complete training on protecting privacy and confidentiality in a work-from-home environment. These staff will be required to commit to using a private space for video calls with no other members of their household visible. Intervention group members will make a commitment to each other to protect everyone's privacy and be mindful of best practices on video calls.

Team members/research coordinators directly involved in data collection will also hold a team debriefing during each week of data collection 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.

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 PI as well as the RSRB. Potential adverse events that could occur as a result of study participation include: (1) re-evaluation of the subject's medical clearance to participate in the intervention component of the study; (2) serious adverse psychological reactions such as feeling upset, embarrassed, or uncomfortable as a result of participation in the intervention group 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.

Ineligibility after baseline data collection

Upon review of baseline data, the research team will identify any subjects who are not eligible to continue in the study. Excluded subjects will be referred to their own healthcare provider or another accessible healthcare provider such as the URMC Deaf Wellness Center Mindful Eating Group for healthy lifestyle education or medical treatment as needed. Also, we will give all participants a resource list with local and regional referrals regardless of their qualification status.

Intervention Description

NCDHR researchers have been establishing relationships with community partners in three regions: Rochester, Buffalo, and Syracuse. Partners in these regions are from the following sites:

DWW implementation partners	
Partner categories	**Partners**
Deaf community -- social organizations	Rochester Recreation Club of the Deaf
	Buffalo Club of the Deaf (BUF)
Deaf community – service organizations	Deaf Access Services (BUF)
	Aurora of Central NY (SYR)
	Whole Me (SYR)
Income-restricted apartment complex	Rochester View Apartments
Community organizations -- mainstream	YMCA of Greater Rochester
Workplace wellness programs	Better Me, Rochester Institute of Technology
Clinical-community linkages	Deaf Wellness Center, URMC

NCDHR is working with each site to establish a timeline for beginning the program; as each new site is added, we will upload their Letter of Cooperation as a Modification to our application (see one Letter of Cooperation included with our application to date).

NCDHR research coordinators who have also been DWW counselors will train a new DWW counselor(s) at each of these partner sites, so that they can implement DWW within their own agencies/communities. The DWW intervention has been studied as an in-person group intervention, and also as a 1-on-1 individual video remote intervention. Due to the COVID-19 pandemic and the need to have remote participation with no in-person contact, we have adapted the DWW intervention to be held in a group format over Zoom, with a DWW counselor and several subjects meeting virtually. Partner sites will begin the DWW intervention sequentially in a staggered timeline, depending on when the site is prepared to start the intervention and once a counselor has been identified and trained. Not all DWW groups will run at the same time; we expect small groups of subjects to be enrolled at the different sites over a period of 12-18 months.

Update as of 5/2/2022: We have established a work flow for intervention counselors, with University of Rochester Purchasing. Deaf Weight Wise intervention counselors will become approved independent contractors with University of Rochester. The counselors are NOT working for the implementation partner sites, and therefore the implementation partner sites are not engaged in the research. All intervention counselors will be approved contractors. All counselors will complete the required CITI training and will be added to this study application as external team members. See page 12 of the protocol for a description of other Training the counselors will receive from this study team. Counselors will have weekly and if needed, daily oversight from NCDHR Lead Counselors as well as the Deputy Director/Study Coordinator of this study team, to assist with any issues that arise. Counselors will not be supervised by anyone at the external partner implementation sites (the sites are only assisting with recruitment as per their letters of cooperation).

Group Intervention *(total expected N = 90 (approximately 10 subjects at each site)*:

The DWW group intervention will consist of groups of approximately 5 subjects who meet together for 16 weeks, for two hours each week. Group meetings will be held virtually on Zoom.

A trained, deaf, ASL-fluent DWW counselor will lead the sessions. We estimate that up to 18 groups will be established during the study period, with each site running two intervention groups (5 subjects in each Zoom group). As we match subjects' 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.

Selected sessions of the DWW Curriculum are 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 Subject Food Diary uploaded in the application). Subjects will complete a food diary using MyFitnessPal, or a "calorie counter" book called "The Calorie King." Each intervention session will include 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 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 encouraging of trying new recipes and healthy foods ("Taste It!").

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.

During the DWW 16-week intervention, each enrolled subject will be provided a scale for them to keep at home. They will use the scale to report their weight during 16-weeks intervention, 6-month maintenance period, and 6-mth and 18-mth follow up appointments.

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 related to the purpose of DWW.

The group maintenance phase starts immediately after the 16-week intervention, and consists of two meetings of the original group via Zoom; one at month 3 of the 6-month maintenance period and one at month 6 of the 6-month maintenance period. This will again consist of 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 or Zoom calls/reinforcements during each month of the 6-month maintenance

period. Counselors will also email participants bi-weekly to check in with participants and provide additional support.

Data management by the DWW counselor: During the DWW 16-week intervention, prior to each week's session, the group counselor will email each participant individually to ask for their weight and collect 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). The counselor will then enter this weekly data into a secure REDCap database that is managed by an NCDHR research coordinator. The research coordinator will monitor and analyze the weekly data from subjects including weight, attendance record (present or absent for that week), and Food Diary information, and will discuss any concerns with the research team and the PI.

Option of 1:1 (one-on-one) Zoom/Videophone intervention - *(total expected N = 18 (approximately 2 subjects at each site)*:

Some circumstances may require that a participant receive the DWW intervention in a one-on-one format over zoom or videophone. Reasons for this may include but are not limited to:

- participant does not have a computer or laptop or device that allows for adequate participation in zoom; participant may be able to use their existing personal videophone only,
- participant is unable to participate effectively in a group setting,
- participant uses a different sign language or other forms of communication which require more intense instruction by the counselor.

If a participant is identified by the research team as needing a one-on-one intervention modality, a trained intervention counselor from this NCDHR research team will deliver the intervention to this participant (meaning, the counselor at the partner site will NOT be required to deliver the intervention one-on-one to these participants). We expect that up to 2 participants at each site may require this one-on-one intervention.

Training of DWW Counselors

DWW counselors who will deliver the intervention sessions will be deaf, sign-fluent, and may have a background in clinical, educational, or health-related fields. Partner sites will work with the NCDHR research team and NCDHR DWW Lead Counselors to identify a counselor(s) to work with the site to deliver the intervention to subjects.

Counselors will attend the online/virtual Counselor training sessions via Zoom to prepare them for facilitating groups or videophone sessions. Experienced DWW Counselors from NCDHR will conduct the training via zoom as each site's counselor is ready to attend training (staggered over the course of the study). 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.

Since counselors will have access to subject identifiers and will be require to enter their weekly individual intervention data into REDCap, all counselors will complete the Social-Behavioral minimal risk training through the CITI program. Each counselor will be added to this study team application as a non-UR investigator with their appropriate CITI completion certificate. The NCDHR lead research coordinator will ensure that all counselors have completed this training prior to obtaining any subject information and identifiers.

NCDHR Lead Counselors will host meetings with site counselors bi-weekly via videoconference during the 16-week intervention to maintain intervention fidelity, and to share experiences and suggest techniques as issues arise. NCDHR Lead Counselors will regularly report back to the research team during NCDHR Research Committee meetings. Counselors will have weekly and if needed, daily oversight from NCDHR Lead Counselors as well as the Deputy Director/Study Coordinator of this study team, to assist with any issues that arise.

Data Analysis and Monitoring

Data Analysis:
Our **primary outcomes for this research are related to implementation of DWW** in our partner sites, rather than individual-level effectiveness of the intervention. Site-level DWW implementation measures have been described in a separate RSRB-approved protocol (#4480 on 2/27/2020) as part of the formative research phase of this study.

Primary Outcome #1: Site-level outcome: Implementation of the Deaf Weight Wise intervention at partner sites

> Description: Number of partner sites implementing the DWW intervention
>
> Time Frame: implementation of the DWW group intervention by the partner site after enrollment of at least 5 participants at that site

Primary Outcome #2: Site-level outcome: Percentage of Deaf Weight Wise intervention groups delivered as intended

> Description: the study team will measure whether the intervention is delivered at each site as intended, as assessed by direct observations of the counselor/group and by bi-weekly counselor meetings
>
> Time Frame: during each site's intervention and maintenance phases

We describe here **the individual-level analyses of subject data**.

At the completion of each of the three 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 site.

The individual-level analyses will be carried out using paired t-tests to examine significance of differences in weight between baseline and the remaining data collection points. Other variables associated with individual outcomes of body weight will be identified using univariate analysis of correlation analysis or tests for multiple group comparison. Heterogeneity among sites can be explored by marginal analysis and model-based conditional analysis. Multiple regression analyses, including analysis of covariance (ANCOVA), will be based on generalized linear models (GLM), specifically for this project, including multiple linear regression models for continuous outcomes and logistic regression for dichotomous outcomes. Random effects can be incorporated in GLMs to account for correlation among repeated measures. Several least-squares and likelihood based methods, such as the Pearson's chi-squared test, Hosmer-Lemeshow test, and likelihood ratio test can be used to test the lack of fit or violations of assumptions of GLMs. In case of high-dimensional data in different scales, standardization will be applied before model fitting and variable selection. Variable selection approaches using AIC or BIC criteria will be used to select the significant predictors. Penalized-based variable selection procedures such as LASSO or SCAD may be used to overcome the drawbacks of ad-hoc methods of stepwise, best subset selection, etc. Missing (drop-out) data will be handled by appropriate statistical methods, which include maximum likelihood and/or direct maximum likelihood inverse probability weighting, and multiple imputations.

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 will be analyzed. Finally, other variables associated with individual outcomes of change in body weight, Block score, and IPAQ score will be identified using univariate analysis as described previously. For age, gender, and all baseline variables associated with outcomes at the $P < .10$ level of significance, multivariate linear regression analyses will be performed to adjust for possible confounders.

Secondary Outcome #1: Participant-level outcome: Mean change from baseline to 6-months (post-intervention) in number of fruit and vegetable servings per day as measured by the Block fruit, vegetable, fiber screener

> Description: The mean difference from pre to post intervention in self-reported fruit and vegetable servings per day (baseline servings/day - follow-up servings/day) as measured by the Block Fruit-Vegetable-Fiber Screener.
> The Block Fruit-Vegetable-Fiber Screener is a 10-item scale with responses ranging from: (1) Less than 1/week to (5) 2+ a day. Higher scores reflect a better outcome.
> Time Frame: baseline, 6 months (pre and post intervention)

Secondary Outcome #2: Participant-level outcome: Mean change from baseline to 6-months (post-intervention) in physical activity as reported on the International Physical Activity Question (IPAQ)

> Description: The mean difference in self-reported physical activity levels over the past 7 days
> Time Frame: baseline, 6 months (pre and post intervention)

Secondary Outcome #3: Participant-level outcome: Mean change from baseline to 6-months (post-intervention) in self-reported body weight, for participants with BMI above normal range

Description: The mean weight change (in kg) from pre to post-intervention, expressed as a percentage of baseline weight, for any participants with a BMI above 24.9 (above normal range)
Time Frame: baseline, 6 months (pre and post intervention)

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 font size or video background color was changed, , 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.

Data Storage and Confidentiality.

Questionnaire data collected through one-on-one interviews will be recorded by the interviewer on the designated data collection forms. Interview forms will only list the participant's Study ID number and will not contain any identifiers. Data from these forms will be entered into password-protected databases saved on the URMC network and will be maintained by trained research staff and will be kept indefinitely. Hard copies of all data collection forms will be kept in locked file cabinets and ultimately in the locked storage room in the NCDHR suite for up to 6 years.

NCDHR's REDCap web-based custom survey software presents survey items in ASL; subjects enter their response into the computer. The survey software is on a secure URMC REDCap server. All laptops are secured by passwords known only by the research team members. Each research participant will be provided a unique study number and files linking names with study identifiers will be securely stored separately.

Datasets from the data obtained from in-person interviews will be merged with data from REDCap-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.

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. 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).

Only research team members will have access to data analysis reports and findings. Trained research staff will maintain all de-identified data and reports on secured URMC server. 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. All study personnel have up-to-date human subject research education certification through the online CITI training.

IV. RISK/BENEFIT ASSESSMENT

1 Risk Category.

Minimal risk study: This study will yield information on implementation of DWW in different community-based and organizational settings. 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 obesity and related potential complications 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. 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.

Individual-level subject data will be collected during one-on-one Zoom or videophone interviews or via REDCap surveys. We anticipate no significant risks in relation to collecting this information from subjects, and all information is collected virtually. Based on our experiences and previous work with Rochester Deaf communities, and because the data will be collected via computer confidentially, we do not expect strong emotional responses to the data collection.

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 deaf communities in each of three cities 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. All research staff and counselors will be trained on confidentiality and the importance of privacy in a Zoom/work-from-home environment.

There is also the risk of accidental disclosure of study data. Strict procedures are in place to minimize this risk.

3 Protection Against Risks.

The risks of mild anxiety associated with learning of disease risks associated with overweight and obesity, 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 conversation with 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 URMC servers. Electronic data will be collected on REDCap surveys and downloaded to secure URMC servers that are only accessed by NCDHR research team members. Only authorized study personnel will have access to study data. All study personnel will have completed CITI training.

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, 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 for subjects is that associated with having information regarding one's own body mass index based on weight and height being reported. With this knowledge, subjects will be in a much better position to maintain their health, prevent illness, and/or seek treatment as early as possible. For those who manifest health risks associated with obesity, 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 reduced body mass index.

These potential benefits are judged to be substantial in relation to the potential risks cited above, including anxiety about health risks, embarrassment regarding weight, and potential loss of anonymity or failure of our data security procedures. 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.

V. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT/ASSENT

1 **Method Of Subject Identification And Recruitment**.

DWW will be the first implementation research study of a lifestyle intervention ever done with deaf ASL users ages 18+. 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 and how this study may impact the deaf community. To minimize confusion of study subjects, we want to be sure to distinguish DWW from local commercial or physician-supervised weight loss programs/clinics; we will consistently advertise our project with the full title, "Deaf Weight Wise Research Project" to indicate that this is a research study. Approaches to recruitment are listed below.

Online Recruitment Sources:
RSRB-approved 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 Instagram: the DWW logo as well as links to flyers/vlogs/contact information may be posted.
5. Implementation Site partners' websites or social media accounts

New recruitment method added 11/4/2022: Some in-person recruitment and outreach

Based on the timing of our study (lasting 18 months from baseline enrollment) and our current CDC grant funding cycle, we have set an enrollment deadline of January 18, 2023. For this reason, this DWW research team would like to increase outreach and recruitment efforts by attending some Deaf community events in person. We are learning from our community partners that some members and groups are resuming in person events, keeping in mind safety/health precautions. Examples of these events include gatherings hosted at local deaf clubs or awareness-raising events where the DWW team could make a presentation about what Deaf Weight Wise is. Our Buffalo and Syracuse partners have informed us recently that the concept of research is still new to Deaf communities in their area, and we are definitely noticing this in terms of low enrollment numbers in these regions.

In addition, we would like to add a "sign up" form that is housed within REDCap – which can be found by scanning a QR code that the DWW team would display at an event or put on a flyer (we will get RSRB approval when adding this QR code to future flyers). The QR code would lead to the REDCap sign up form, that would have basic contact information the person could then fill out and submit. This would trigger the DWW team to then be able to follow up with those who signed up, to set up a screening/enrollment appointment. The draft redcap sign up form is included in this modification (it is not live/public yet).

Recruitment through Partner Sites/Organizations and other Deaf Community-Based

Organizations:
Information about the study will be disseminated through different implementation site partners that have already been established as part of this study. 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 host virtual Zoom meetings 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 by Partner Sites. In addition, letters of cooperation indicating the organization's agreement to share recruitment materials within their site will be amended to this application prior to conducting any recruitment activities.

New recruitment strategy added 11/16/22: Flyers posted in some primary care offices:
We have been informed by Deaf community members and partner organizations that there are a few primary care offices with a large number of Deaf patients. In previous NCDHR studies, these offices have been willing to post approved recruitment flyers in their waiting rooms or exam rooms. No clinicians will directly recruit for Deaf Weight Wise. Rather, NCDHR will provide these flyers to these practices, and the practices will then make them available for Deaf patients to take on their own.

Networking and Recruitment by Members of the DWW Community Committee:
NCDHR has a **Deaf Weight Wise Community Committee**, based on our mission and principle of conducting community based participatory research. The DWW Community Committee is composed of a 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. 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 Recruitment Flyers and ASL recruitment vlogs to convey information when they network with potential subjects. We will also share these same recruitment materials with members of NCDHR's Local Partner Advisory Board, a committee made up of representatives from mostly Rochester-based organizations that work with Deaf communities and individuals.

We will work with site partners in Buffalo and Syracuse to form DWW Community Committees to include local Deaf community members in our research.

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 sign-up link on the NCDHR homepage (www.urmc.edu/ncdhr) and also 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 18+ 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 Research Study and will never be connected to subject data.

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.

The Informed Consent process proposed here has 3 components and will be conducted virtually via Zoom or videophone. This study team successfully implemented this Informed Consent process in both previous Deaf Weight Wise studies (in person), and received very positive feedback from those original study participants.

1) During the enrollment virtual appointment, an informed consent video will be shown to the subject. The informed consent video will feature Deaf actors using American Sign Language dialogue scenarios (see English version of Informed Consent video script), which have been shown to be effective with health education materials[16] and are considered to be the optimal learning style for many deaf people due to the dialogic nature of ASL. The consent video was scripted using information from the English version of the Study Information Sheet. This has been successfully used in both previous Deaf Weight Wise clinical trials (see example video from Deaf Weight Wise 2.0 study: https://youtu.be/aq2X_NPL4XA).
   The link to the final ASL consent video for this study is: https://www.youtube.com/watch?v=xd4235y-RfU. This video has English captions available (click cc: button to view).
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 (on Zoom or videophone call). 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 (will share a pdf file through e-mail). Research team members have experience in obtaining informed consent from deaf participants; any new staff will be fully trained prior to enrollment visits.
3) Verbal/ASL consent will be obtained from all study subjects live during the Zoom/videophone call. The research staff member will document that they obtained informed consent from the subject and that the subject watched the ASL video (see Documentation of Consent).

Potential subjects may review the consent video and documents as many times as they wish. Subjects will receive the Consent Video link in Youtube and the English.

This consent process proposed here requires an alteration of HIPAA authorization in that we request a waiver of written authorization. This waiver of written authorization is allowable here because this study involves no more than minimal risk to the privacy of individuals and an adequate plan is in place to protect any identifiers/PHI from accidental disclosure, we are destroying identifiers at the earliest opportunity, and identifiers/PHI will not be disclosed to any other entity except as required by law or for authorized oversight of the study. We cannot practicably carry out this virtual research without this waiver of written authorization; the process proposed here is culturally and linguistically appropriate because it is happening live in sign language, the primary language of subjects. Consent/authorization will be documented by trained Deaf research staff who will be able to conduct and assess the subject's consent.

Modification July 13, 2023: As of this date, we have one implementation partner, the YMCA, who has not yet implemented an intervention group. The DWW intervention counselor for this group is now trained and ready to lead a group of participants starting in mid-August 2023. We will now recruit and enroll up to 10 participants for this virtual intervention group. Due to funding for this study ending in September 2024, we propose here to change the final data collection appointment for these final 10 participants only, so their final appointment will be 12 months from enrollment instead of 18 months from enrollment. We have modified the Study Information Sheet to show the change in the final data collection appointment (from 18 months to 12 months). During the informed consent process, these participants will still watch the current approved consent video. Upon completion of the video, the study coordinator will have an in-depth explanation that their final data collection appointment will be at 12 months from now, and will review the DWW-YMCA Study Information Sheet showing the study timeline. All other components of the informed consent process will remain the same.

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**.
We request a waiver of documentation of consent. Valid consent will be obtained and documented by the research staff. 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 give verbal/ASL 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 verbal/ASL consent should only be provided 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, had their questions answered, and provided their consent. 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. We cannot practicably carry out this virtual research without this waiver of written consent; the process proposed here is culturally and linguistically appropriate because it is happening live in sign language, the primary language of subjects.

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: $30 at the baseline enrollment/data collection visit, $40 at the 6-month data collection visit (point 2), at the final 18-month data collection visit, they will receive $50. (For YMCA participants enrolling in July-August 2023, they will receive $50 at their final 12-month data collection appointment as per modification described above.) Subjects will receive payment for each data collection visit in form of gift card being send out in mail to their mailing address. Subjects have the right to withdraw from the study without penalty but will not receive payment for data collection visits they have not completed. This study will use the Participant Payments System established by UR-CTSI's Office of Clinical Research. This system is managed by Forte payments. The Visa Gift Cards provided to subjects through this system are unique to each individual and will be re-loaded each time the subject completes a DWW appointment. The Forte payments system requires collection of the subject's date of birth for purposes of verifying each subject's personal gift card account. The date of birth will only be collected by one study coordinator and will be destroyed immediately after it is entered into the Forte system. It will not be used or connected with any other part of this research program. This process was approved via email by the UR HIPAA Privacy Officer and the RSRB Director on 9/11/2020.

In addition to monetary incentives for data collection, the DWW intervention curriculum offers a toolkit of incentives during the 16-week intervention phase (see Wisebucks 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[9]. 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. Participants will keep these scales at the end of the intervention. The redeemed incentives will be mailed to the participants' mailing address.

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