Baylor Institute for Rehabilitation
Institutional Review Board

Protocol Template (for Investigator Initiated Studies)

Title: Group Lifestyle Balance Adapted for Impaired Mobility (GLB-AIM): Translating the GLB to Promote Healthy Weight in People with Mobility Disability (Impairment)

1. Introduction and Purpose:

This study will test **the effectiveness of the Group Lifestyle Balance**™ (GLB) program **adapted specifically for people with impaired mobility** using standard behavioral approaches for weight loss. The *overarching aim* of this study is to promote health and reduce chronic disease risk among people with mobility impairment by building an evidence base for weight loss. Our *central hypothesis* is that participants randomized to the intervention arm of the adapted GLB will show significant improvements on primary outcomes of weight and PA compared to a 6-month wait-list control group at 3 and 6 months, and will show improvements on several secondary health outcomes.

We propose the following *specific aims* and hypotheses:

Aim 1: To create an appropriate and usable adaptation of the GLB program for people with mobility impairment.

Hypothesis 1.1: *Advisory board participants will identify key adaptations to make the GLB materials appropriate and usable for individuals with impaired mobility.*

Aim 2: To establish whether the adapted GLB program for people with mobility impairment is a feasible intervention.

Hypothesis 2.1: *Intervention participants will rate the program satisfactorily and attend at least 2/3rd of the weekly group-based meetings and monthly individualized phone calls. Lifestyle coaches will also rate the adapted program satisfactorily.*

Aim 3: To determine if the GLB intervention adapted for those with mobility impairment is effective as determined by significant improvement in the primary and secondary outcomes in the intervention group compared to the wait-list control group at 3 and 6 months from baseline.

Hypothesis 3.1: *The intervention group will demonstrate significantly greater improvements in our primary outcomes (weight and PA) than the wait list control group at 3 and at 6 months and will show significant improvements in secondary outcomes at 6 months.*

Hypothesis 3.2: *Both groups combined will demonstrate significantly greater improvements in the primary outcomes (weight and PA) after 3, 6 and 12 months of intervention and secondary outcomes after 6 and 12 months of intervention.*

Our *rationale* for this research is that study results, if found to be successful, will provide an evidence-based framework to undertake a large-scale randomized control trial (RCT) to improve long-term health outcomes for individuals with a mobility disability.

The *primary study endpoints* are the feasibility and effectiveness of the adapted intervention as measured by outcomes listed in Aims 1-3. The *primary safety endpoints* include no increased risk of secondary health conditions that are related to participants' primary disability.

The risks posed to study subjects (discomfort associated with blood draws, injury while engaging in physical activity, psychological stress associated with behavior change) are minimal, while the intervention poses multiple substantial benefits to the study participants in terms of health, chronic disease risk, skill-building, and quality of life. The research poses potentially great benefits to society, as individuals with impaired mobility experience a higher prevalence of obesity(1) and greater burden of obesity-related chronic conditions,(1, 2) including a four times higher rate of diabetes.

2. Background: Despite striking weight-related heath disparities, people with mobility impairments remain underserved by public health efforts to address weight loss(3) and effective lifestyle

interventions are lacking.(3-7) People with mobility impairments are also less physically active(8) than those without disability and report being less likely to receive exercise counseling.(9) Additionally, the adverse effects of obesity for those with mobility impairments may be greater than in the general population as excess weight and additional health problems may further restrict people's functioning and independence.(3) The tenets of weight loss to eat less and exercise more are equally relevant for people with mobility impairments; however, approaches to deliver the message and facilitate adherence must be tailored to address the unique physical, environmental, and attitudinal barriers associated with mobility impairment.

Community-based interventions that can be delivered in group settings to people with mobility impairment may be particularly advantageous(10) given persistent transportation barriers.(11) Evidence that lifestyle intervention can lower risk for type 2 diabetes through weight loss and increasing physical activity (PA) has been demonstrated by the mainstream Diabetes Prevention Program (DPP). (12-15) The Group Lifestyle Balance (GLB) program,(16, 17) a direct adaptation of the DPP lifestyle intervention for group delivery in the community, has been shown to be effective in lowering weight and increasing PA in multiple community settings.(18-21)

To our knowledge, only three published studies have addressed weight loss interventions in individuals with physical disability(22-24). All of these support the use of lifestyle intervention as an effective means for encouraging weight loss. In 2014 the PI and program coordinator implemented a pilot study of the proposed research among a sample of 10 individuals with mobility impairments. Feasibility results showed that 70% participated in the program and these individuals attended an average of 79.3% of sessions and self-monitored more than half of the weeks. Usability results revealed high participant approval, with mean overall scores of 6.3±0.3 and 6.2±0.6 out of 7 on helpfulness and satisfaction scales, respectively. Program completers experienced a significant mean weight loss of 8.86±8.37 kg, or 7.4% of their start weight, and significantly reduced their BMI. These results compare favorably with those of the mainstream GLB and support further investigation.

The lifestyle changes the GLB recommends follow current national recommendations for physical activity by the American College of Sports Medicine/American Heart Association (ACSM/AHA)(25) and dietary recommendations follow the US Department of Agriculture 2010 dietary guidelines.(26) Physical activity recommendations suggest everyone, including those with disabilities who are capable, should engage in at least 150 moderate to vigorous physical activity each week. USDA dietary recommendations target healthy diet by reducing caloric consumption, increasing fruits/vegetables, and reducing consumption of saturated fatty acids, sodium, and cholesterol.

3. Concise Summary of Project:

The study will take place over 3 years and consists of two phases. Phase 1 will involve using community-based participatory research (CBPR) to adapt the evidence-based GLB program to assure the needs of people with mobility impairment are appropriately addressed. Phase 2 will consist of a RCT to assess feasibility and effectiveness of the adapted GLB program on primary (i.e., weight and PA) and secondary health outcomes (i.e., waist circumference, upper arm circumference, BP, A1c, serum lipids, self-efficacy, function, and QOL). In Phase 2, 64 individuals (32 per group) with physical disabilities will be recruited via organizations that provide services to those with disabilities and randomized to an intervention group or a 6-month wait-list control group. To ensure the participation of 64 individuals, up to 75 eligible individuals will be consented. We expect to obtain sufficient participants to enroll everyone with the same start date, but if necessary, the study may be conducted among 3 cohorts with staggered start dates.

Phase 1. Adapting the GLB and assessing usability. We will use CBPR to *adapt the GLB* in iterative fashion guided by input from a 12-member **Advisory Board** comprised of community stakeholders. Members represent people with mobility impairment from the independent living community and scientists, plus health professionals. Board members will receive a small honorarium for their time.

The board will guide the team's efforts in adapting the GLB materials and content in year 1 and provide ongoing input and direction over years 2 and 3 as the team delivers the intervention and assesses its effects.

Phase 2. Assess feasibility and effectiveness of the adapted GLB for people with mobility impairment. A two-group (experimental and wait-list control), RCT will assess feasibility of delivering the intervention and its effectiveness on primary and secondary outcomes. Those assigned to the **control group** will wait 6 months before receiving the intervention. During the 6 month waiting period, the control group will be mailed monthly newsletters that address topics of making healthy lifestyle choices (achieve good sleep; reduce stress; spend time with friends; follow recommended schedule of vaccines & cancer screening; reduce risk of common conditions such as pain, depression; know your rights).

GLB intervention.

Origin and format. The GLB program selected for this proposed study was translated directly from the successful multi-center DPP. Study co-investigator, Dr. M. Kaye Kramer directs the Diabetes Prevention Support Center (DPSC) at the University of Pittsburgh, where the DPP lifestyle intervention was initially developed. Dr. Kramer and colleagues adapted and updated the original 16 session one-on-one DPP to a group-based format consisting of 12-weekly core sessions followed by 4 biweekly core and 6 monthly support sessions, for a total of 22 sessions delivered over one year. Other modifications included emphasizing self-monitoring of calories and fat intake from the beginning of the intervention and an enhanced focus on pedometer use. The GLB program has been successfully delivered in numerous settings (e.g., health care, (16, 17, 27-29) YMCA,(30) churches,(31) community centers(32, 33)), with various populations at risk for diabetes, and has been offered in person and via DVD.(27, 28)

Components. The intervention encourages participants to adopt a moderate calorie, moderate fat diet (1200-2000 calories, depending on start weight, with ≤ 25% of calories from fat) and to increase exercise progressively to meet ACSM/AHA recommendations of 150 minutes per week. The program facilitates the accomplishment of these goals by teaching skills including self-monitoring, problem solving, assertiveness, cues, and stress management. Participants are encouraged to set a weight loss goal of 7%. Coaches facilitate skillbuilding and provide positive reinforcement, while group members offer peer support.

Modifications. The proposed study will follow the 12-month GLB schedule for delivering the adapted GLB. The anticipated plan for implementation is to initiate the program with an in-person instructional kickoff meeting and the deliver the content primarily through telephone conference calls, with once a month in-person meetings offered. The content includes **6 primary components**. Participants will be:

1) Given the modified GLB curriculum materials, adapted in response to Advisory Board input to make them appropriate for the mobility impaired audience;

2) Invited to participate in teleconference-based group meetings, delivered in accordance with the GLB schedule and led by a trained lifestyle coach; meetings will be offered via a videoconferencing technology, such as Adobe Connect, which allows people to connect by landline, cell phone, tablet, or computer and connect either via audio alone or audio and video.

3) Invited to an optional in person meeting each month, during which participants can be weighed;

4) Offered monthly individualized phone support from a lifestyle coach;

5) Invited to include caretakers or key family support in meetings, if desired

6) Offered exercise aids that are appropriate for individuals with impaired mobility, including disability appropriate exercise DVDs, Garmin vivofit arm-based exercise trackers with heart rate monitors, pedal exercisers, and therabands (versus the GLB's offering of nonmodified exercise DVDs, pedometers, and other incentives). Participants will also be given Calorie

King™ calorie counting books, measuring cups, and a scale, in accordance with the mainstream GLB.

Conditions that may result in the subject exiting the study before the expected completion date include subject withdrawal of consent or decision not to continue their participation. Because of the remote nature of the intervention, participants may choose to continue the study despite adverse health events including hospitalization. However, participants will be explicitly advised to follow their doctors orders in all matters, including those most relevant to the study—physical activity and diet.

Outcome measures.

Feasibility measures will assess participants' adherence with key intervention components: **1)** group meeting attendance, **2)** individualized phone call attendance, and **3)** for the first 12 weeks only, self-monitoring of food intake and PA.

Effectiveness measures. **Primary outcomes** to assess the GLB effects will be collected at baseline and again at 3, 6, and 12 months. These will include participant's weight, PA, self-efficacy, function, and QOL. **Secondary outcomes** will be measured at baseline, 6, and 12 months and will include waist circumference, BP, A1c, serum lipids.

Safety measures will include assessment of participants' 1) albumin levels, to assure adequate protein intake, 2) upper arm circumference, to assure preservation of lean muscle mass, and 3) weekly reporting of health events and pressure sores in particular.

4. Study Procedures:

Phase 1. Board members will address the content, layout, format, language, behavior change strategies, and delivery approaches for adapting the GLB program for a mobility impaired sample. To facilitate building rapport, the first board meeting will be convened in person (Dallas, TX). The full-day meeting will allow members to critically review and discuss the existing program and materials and offer recommendations for specific adaptations. GLB materials will be mailed in advance to assure everyone has sufficient time to review information before the meeting. Changes recommended during initial meetings will be fully reviewed and discussed during subsequent teleconferences. The board will convene multiple times per year during the 3 year study, with meetings scheduled 3 times in year 1, 2 times in year 2, and 4 times in year 3 as the team analyzes results and plans next steps.

Phase 2.

The PI and the program coordinator will perform testing and deliver the intervention with the assistance of a trained research assistant. The PI has conducted exercise interventions for people with disabilities for 15 years and is knowledgeable about different types of disabilities (e.g., spinal cord injury, MS, cerebral palsy) and exercises that are appropriate to do within the context of the specific impairments and limitations. The program coordinator is a graduate student at the UT School of Public Health who has completed the University of Pittsburgh Diabetes Prevention Support Center training to deliver the GLB. She assisted with delivery and testing of a pilot modification of the GLB for impaired mobility in 2014. The research assistant will be hired from one of the graduate programs at UT Southwestern, either Health Promotion/Behavioral Sciences in Public Health, Psychology, Physical Therapy, or Vocational Rehabilitation. The PI will supervise all study staff.

It is anticipated that intervention group participants will be involved for 12 months and wait-list control group participants for 18 months.

Visits. Participants in the experimental group will be tested at baseline, 3 months, 6 months, and 12 months. Participants in the 6 month wait-list control group will be tested at baseline, 3 months, and 6 months, (for comparison to control group) and again at 9 months, 12 months, and 18 months (to assess intervention). Testing will be conducted in a private room at Dr. Froehlich-Grobe's research office at Baylor Institute for Rehabilitation Labwork will be processed at a UTSouthwestern lab, with

costs paid for by the study. All other testing will be performed by the PI, the trained program coordinator, or the trained research assistant. We estimate that the first visit will last approximately 1,5 hours, and each subsequent visit will last approximately 1 hour.

All visits (Baseline, 3 months, 6 months, 12 months):

1) Study staff will measure participants' weight using an accessible Seca scale (#676).(34) Weight for wheelchair users will be conducted first by measuring the total weight of the person in their wheelchair, the person will then transfer out of the chair to a mat table and those unable to transfer will be raised from their chair using a Hoyer lift, then the wheelchair will be weighed separately without the person in the chair. Patients who do not require a Hoyer lift but who do require assistance in transferring from their chair will to a mat table be assisted by study staff, who have been trained by physical therapists in performing transfer assists. The weight of the wheelchair will be subtracted from the total weight. Finally, staff will ask participants to report the use of any medications to control blood pressure or cholesterol, or any medications that may influence weight (such as certain medications to treat depression/anxiety, diabetes, or pain).

2) Participants will be asked to complete a pencil/paper questionnaire to measure self-reported physical activity (using the IPAQ short form), self-rated health abilities (SRAHP), quality of life (SF36E(35)), and to report on any change in medications that may influence weight, cholesterol, or blood pressure.

Baseline only:

1) Height will be measured with participants in a supine position when possible. Participants who have higher level injuries and/or difficulties in lying down will be asked to self-report their height.
2) Participants will be asked to complete a pencil/paper survey to gather demographic information; weight loss history; and history of common health complications.

Baseline, 6 months, and 12 months:

1) Study staff will measure participants' blood pressure using an automatic cuff (Omron 7 Series wrist blood pressure monitor); upper arm circumference, and waist circumference measured at the umbilicus, with participants in a supine position when possible. Participants who have higher level injuries and/or difficulties in lying down will be measured in a seated position, or if they choose, transferred to the mat using a Hoyer lift.(34) Patients who do not require a Hoyer lift but who do require assistance in transferring from their chair will to a mat table can choose to be assisted by study staff, who have been trained by physical therapists in performing transfer assists.

2) A phlebotomist will draw participants' blood via venipuncture, and a UTSW lab will measure serum lipids to assess cardiovascular disease risk, A1c to assess participants' average blood sugar level over the past 2-3 months, and albumin to assess blood protein levels and nutritional status. The total volume of blood drawn will be 10mL, collected in 2 vials of 4-5 mL each.

Baseline and final visit (12 months for experimental group, 18 months for control):

1) In addition to the above, participants will be asked to answer paper/pencil survey questions to assess the following: functional abilities in activities of daily living and instrumental activities of daily living (using the LIFE-H short form questionnaire);

functional abilities around diet, eating, and fitness (using portions of the LIFE-H long form); and types of physical activities (using the 1-year MAQ).

2) Structured interviews with participants, conducted either in person or by phone, will gather qualitative information on topics such as motivation for joining the program; past weight loss experiences; who selects, purchases, and prepares food in the home; changes in these roles over time; the process of lifestyle change and its effects on sense of self and relationships; and barriers and facilitators to change. Similar questions may be asked and responses gathered during one or more of the monthly individualized phone support calls throughout the course of the program. Interviews may be recorded to ensure participant responses are accurately captured.

Final visit only:

1) Participants will be asked to complete a paper/pencil exit survey(36) to obtain participants' satisfaction, perceived benefits and barriers of the intervention, and recommendations to improve it. The survey will be mailed in advance and returned at this visit or by mail, if participants for some reason are unable to return.

Travel monies for transportation costs for assessments will be made available for participants without access to transportation.

Intervention delivery

Staff training. Lifestyle coaches will complete training at the 2-day GLB workshop conducted by Dr. Kramer and the faculty of the DPSC at the University of Pittsburgh. The DPSC will listen in on the first 3 group-based teleconference calls to monitor fidelity and also offer ongoing support and guidance to lifestyle coaches through regularly scheduled calls for problem solving and e-mail communication as needed.

Venue. To facilitate group cohesion and regular weighing, participants and their helpers or caretakers, if desired, will be invited to attend the first session and one session per month in person. In-person sessions will take place at one of the primary recruitment sites, Baylor Institute for Rehabilitation, REACH, or NeuroFitness Foundation) or at their affiliated community centers. Pilot participants and other potential mentors from the community may be invited to join these sessions to speak, answer questions, and provide peer support. These in-person sessions may be video recorded so that a DVD may be given to participants who are unable to travel to the meeting. In-person sessions may include adaptive cooking demonstrations by a licensed dietician and guided exercise by an exercise specialist with experience training mobility impaired individuals. A separate support-group style in-person meeting may be offered for the caretakers to share information and problem solve collectively. The majority of sessions will be delivered by conference call. Thus, for these sessions, participants will be given a toll free number to dial to join the conference call. Optionally, participants may join the meeting through a flexible video conferencing technology such as Adobe Connect. As with the in-person sessions, conference calls/videoconferences will be video/audio recorded. Recording is a default function of the Adobe Connect technology and will allow study staff to share a private/secure link with participants who miss a session. (Staff is able to restrict viewing permissions to specific users.) Recordings will be destroyed upon the conclusion of the study.

Self-monitoring and compliance data collection. Participants will be mailed or emailed the session materials before each session. In line with the GLB curriculum, participants will be asked to track their daily calorie and fat intake and PA and to submit their logs to study staff once per week for the first 12 weeks, and as desired thereafter. To increase feasibility of this component, particularly for individuals with impaired finger function, participants will be given the option to complete either paper or electronic logs or use calorie counting apps, such as LoseIt, MyFitness Pal, or Fooducate. Guided by the advisory board input, the study staff will identify and encourage use of the most appropriate and reliable app. When possible, to increase feasibility and usability of self-monitoring and to facilitate

feedback, study staff will use the "coordinator" role within the app to enable participants to submit their logs virtually. Study staff will periodically review logs and deliver written comments to the participant via mail or email.

As pedometers may not be appropriate exercise aids for individuals with impaired mobility, participants will instead be given Garmin vivofit bands with a heart rate monitor. The vivofit is a commercially available arm-based activity trackers that has a visual display. Participants will be informed that the reliability of these bands has not been tested, but that their purpose is to provide participants with feedback to them gradually increase their physical activity according to the program recommendations. Participants will be asked to regularly sync their arm-bands to their phone or computer so that they and the lifestyle coaches can review their activity and heart rate reports. To facilitate this information sharing, participants will be given a randomly generated unique password that both they and study staff will use to access the data. Passwords will be deidentified and stored in a separate password-protected file.

Communication. To facilitate appointment scheduling and timely, ongoing communication between study staff and participants, study staff will communicate with participants via their preferred methods of communication (established during screening), whether phone, email, or text message. Participants will be asked not to transmit sensitive health information via text message, but will be given a secure email message (using Baylor's secure email encryption) that they can reply to when communicating sensitive health information digitally. Participants will be informed that they may be responsible for charges incurred by text messages. To further facilitate group cohesion and peer support, participants will be given the option to join a closed Facebook page where they may ask each other questions, share challenges and successes, provide encouragement, and share resources. (See section 12 remarks on confidentiality regarding this and other technologies used in delivery.)

5. Sub-Study Procedures:

To test the accuracy of the Garmin wrist bands in converting arm-based movement to “step counts”, we would like to compare the Garmin activity tracker counts with an ActiGraph monitor, which has become the gold standard device used in physical activity research. ActiGraph accelerometers, while exceptionally accurate for detecting both walking based activity when worn on the hip and arm-based activity when worn on the wrist, are simply encased in plastic and do not provide any visual information about the movement they are tracking. We would like to provide a subsample of 10-12 participants enrolled in the weight loss program the ActiGraph to be able to do this comparison. Selecting participants for this portion to wear the ActiGraph would be based on their manner of mobility. Thus, we would give them to 3-4 manual wheelchair users, 3-4 power wheelchair users, and 3-4 ambulatory individuals.

Participants will be verbally asked by telephone if they would be willing to wear the additional device, with an understanding that doing so is voluntary and will not affect their participation in the primary study. Those who agree will be mailed an ActiGraph monitor with written instructions that explain how it should be worn on the wrist. They will be asked to wear the ActiGraphs for 5 consecutive days, beginning on a mutually agreed-upon day, while also wearing the Garmin wrist bands. They will also be asked to record the type and duration of physical activity performed each day for those 5 days on a written log. Participants will be asked to return both devices via prepaid mail, or in person should the timing coincide with a scheduled data collection visit. The data obtained would allow us to assess the vivofit’s accuracy in capturing arm-based movement for these individuals.

6. Criteria for Inclusion of Subjects:

Eligibility criteria include being over 18 years old, having a permanent mobility impairment for at least 1 year, being overweight as evidenced by BMI $\geq$ 25 or the equivalent value recommended for spinal cord injury and amputee populations(37, 38), having sufficient upper arm mobility to engage in exercise, having access to a telephone, and obtaining physician signed clearance to participate in the weight management intervention.

7. Criteria for Exclusion of Subjects:
Reasons for *ineligibility* include 1) disabilities for which cognitive impairment substantially impairs autonomy (e.g. mental retardation), as determined by a 5-item everyday autonomy scale(39), 2) medical issues for which exercise is contraindicated such as uncontrolled hypertension or coronary heart disease, 3) age 75 or older, 4) pregnancy, and 5) not fluent in English language. The upper age cut off is intended to ensure that the sample consists of a population whose permanent mobility impairment is unrelated to aging. Pregnancy is excluded because it is directly related to weight gain. Due to the group-based nature of the intervention and the English-language existing curriculum materials, participants must be fluent in English. The limited funds of this pilot study will not enable the study staff to hire translators.

8. Sources of Research Material:
No existing records or sources will be consulted to obtain participant information. Trained study staff will obtain data directly from the participants and specifically for the purposes of this research. Blood draws will occur at Baylor Institute for Rehabilitation and will be analyzed at UT Southwestern labs; blood samples for the desired markers and report the results to the study staff.

9. Recruitment Methods and Consenting Process:

Potential subjects will not be patients of the investigators. We will recruit in the Dallas/Fort Worth metro area through the following organizations that have regular contact with those who experience mobility impairments: **1)** Physical Medicine and Rehabilitation Departments and related clinics at Baylor Institute for Rehabilitation; **2)** disability service organizations, such as REACH Independent Living Center, Amputee Coalition of America, Arthritis Foundation, MS Society, and the NeuroFitness Foundation (an accessible gym); and **3)** durable medical equipment providers, such as Advanced Mobility Systems of Texas and Lift-Aids. We anticipate recruitment will take 2-6 months to achieve the desired sample size of 64. We will also place advertisements through local radio and print media, such as Val Pak and Ad Pages, as well as radio stations, venues which have demonstrated effectiveness(40) in reaching consumers with mobility impairment. Furthermore, we will post an announcement on digital classified ad sites, such as Craigslist.

Flyers and signs will be posted in Baylor Institute for Rehabilitation outpatient clinics in the metroplex. In addition, members of the study team will attend team meetings for all appropriate diagnosis to meet with clinicians and physicians and inform them about the purpose of the study. Members of the research team, clinicians and physicians will then discuss the study with appropriate patients and distribute materials. Flyers will also be distributed to the above-mentioned organizations in the community to be posted or handed out, and announcements will be placed in these organizations' newsletters. These organizations may also post the flyer on their Facebook pages and/or Websites.

In addition, organizations may mass email or mail the flyer to consumers who have agreed to be included in mailing lists notifying them of programs that may be of interest to people with disabilities, including health and wellness programs. These may include recreational and programming arms affiliated with physical medicine and rehabilitation clinics at Baylor. Individual email addresses will not be visible to recipients.

Eligible individuals will contact the study staff by phone or email to learn more about the study and undergo telephone screening. A snowball technique will be used to further recruitment, and interested participants will be invited to ask mobility-impaired individuals they know to contact the study staff about participation. Eligible consumers will also be invited to attend an **information session** held at one of the recruitment sites to gain a deeper understanding of the study and ask questions of the study staff as well as participants of the 2014 pilot study. Small items such as pens, magnets, or notepads may be given at the information session to help remind participants about the study and thus facilitate enrollment.

Upon eligibility determination, participants will be mailed a consent form and scheduled for their baseline assessment. Informed consent will be obtained by study staff at the initial baseline assessment visit, to assure that consent is not influenced by relationships with recruiting physicians. Participants will be informed about the study and consent will be obtained in a private room to protect against others influencing participants' decision to participate or not participate.

10. Potential Risks:

Individuals with impaired mobility are at elevated risk for myriad conditions, such as chronic pain, spasticity, fractures, fatigue, depression, bowel and bladder problems (including urinary tract infections and kidney stones), and pressure sores. We expect any of these conditions to occur during the course of the study but do not anticipate that they will be related to the study. There is no published evidence to suggest that intentional weight loss poses an increased risk for these health problems above their existing risk. Nevertheless, given the dearth of weight loss research in this population, multiple safety measures (as described in 11 below) will be implemented. As research suggests that *unintentional* weight loss can increase the risk of pressure sores in the elderly, and as pressure sores are a common but potentially serious complication among people of all ages with mobility impairments, particular attention will be paid to the prevention and reporting of pressure sores.

Risks to being active include minor musculoskeletal pain and injuries (e.g., soreness, bruising) and cardiovascular events, generally seen in people with underlying disease. Minor discomforts and injuries such as soreness are likely for those who have not previously been exercising. Injury is less likely for those who have been exercising and progress at the recommended level. Risks and discomforts associated with increased fiber and fluid intake may include increased gas, bloating, and potential changes to the timing of bowel and bladder programs that participants should consider. Participants may experience psychological stress associated with health behavior change.

11. Subject Safety and Data Monitoring:
The procedures in place to assure appropriate precautions for safety include the following.

Eligibility and intervention.

1) Participants are only eligible to participate in the intervention once their primary care physician provides signed approval that they have no contraindications to initiating a program of moderate intensity exercise and dietary change to promote weight loss.
2) In terms of the dietary change, the intervention is NOT a very low calorie diet, but targets reducing daily caloric consumption to 1200-1500 calories per day, in line with moderate weight loss of 1 pound per week. The importance of taking in sufficient calories, protein, and fluids to preserve lean muscle mass, prevent pressure sores and speed their healing, and assure adequate nutrition will be emphasized.
3) Participants will be instructed in additional precautions regarding pressure ulcers (e.g. keeping skin clean and dry after exercise, performing daily skin checks).
4) To reduce likelihood of injury, participants will receive a recommendation to progressively increase their physical activity over time by adding days and minutes each week (e.g., increase duration and frequency in successive steps alternating duration and days each week; increase duration by 5-10 minutes per bout, add an additional day the next week, proceeding in this fashion as long as injury free until reaching 150 minutes per week).
5) Participants will be instructed in precautions to take when exercising (e.g. warming up and cooling down, staying hydrated, proper techniques for certain exercises) and cooking and handling foods (e.g. proper technique for adapted cooking methods, care in handling hot and cold foods).
6) To reduce discomforts and bowel program complications associated with increased fiber intake, participants will likewise be encouraged to add fiber to their diet progressively.

7) Sessions on stress management, problem solving, and assertiveness, combined with positive reinforcement from the lifestyle coaches and peer support from group members, should reduce psychological stress that behavior change may produce.

Nutrition and adverse event monitoring.

8) Study staff will closely monitor all adverse events, encouraging participants to report any adverse event as soon it occurs and will recommending appropriate treatment when problems arise (e.g., rest, ice, discontinuing the activity or problematic food, or visiting a doctor for pressure sores or more serious injuries).
9) In addition, study staff will use text messages and/or email to send scheduled messages throughout the course of the study, asking participants to report whether any adverse event has occurred. If a participant answers yes, study staff will follow up by phone or encrypted email to ascertain the details of the event. Staff will then follow up with the participant regularly until the issue has been resolved. Participants will be informed that they may be responsible for charges incurred for text messaging.
10) Albumin levels collected at baseline 3 months, 6 months, and 12 months will be assessed for adequate nutrition, and participants at risk for malnutrition will be encouraged to see their doctor and discontinue calorie restriction.
11) Finally, we will give all participants a phone number that provides direct access to the PI 24-hours a day.

12. Procedures to Maintain Confidentiality:

In order to assure participant confidentiality, all participants will be assigned a unique study identification number. Only one master list will be maintained by the PI on a secure network drive in a password protected file. All databases will use the subject ID number rather than names. Signed consent forms will be maintained by the PI behind a locked door in a locked file cabinet separate from the linked file and hard copies of data files. Investigators at the University of Pittsburgh, Baylor Institute for Rehabilitation and Texas Tech University will access the data via a secured shared drive or encrypted flash drive and their respective IRBs' approval to do so will be obtained.

All bloodwork will be conducted by UTSouthwestern labs and collected, analyzed, and disposed of according to the UTSW lab protocols. De-identified blood values for the specified biomarkers only will be communicated to the study staff. The study staff will not store or maintain any specimens.

Participants' use of unsecured technologies, such as the closed Facebook page, will be wholly optional. Joining the closed Facebook group will require approval by the study staff, and participant posts to the closed Facebook page will not be visible to Facebook users who are not members of the group. Likewise, the individual's privacy settings will govern how much of their personal information is visible to group members. However, participants will be advised that information shared on Facebook is not secure. Participants will be encouraged to read and understand Facebook's privacy statements and settings before joining the closed group and posting any content to it. They will also be advised that the Garmin vivofit devices and optional app-based trackers have options to share diet and exercise information with others, and that if they choose to use these features, the information shared will be publicly visible. The Garmin vivofit devices do not have a GPS device, so privacy of participant whereabouts will be preserved.

13. Potential Benefits:

The benefits to participants may include losing weight, being regularly physically active and eating healthier (fewer calories and better foods), reduced stress, more energy, improved stamina, better sleep, and generally feeling better. Participating in this program may have other benefits such as lowered chronic disease risk, greater peer support, and the opportunity for participants to learn more about their health, how to count calories, how to select and prepare healthy foods, the health benefits

of physical activity, how to fit physical activity into daily life, accessible activities that can be performed at home or in the community, and stress management, problem solving, and assertiveness skills.

It is hoped that the information gained from this study will contribute to an evidence base for effective weight loss intervention among this underserved population which experiences substantial health disparities. Furthermore, we expect that the study will result in a modified intervention that is widely translatable in the field, given our collaboration with the Diabetes Prevention Support Center and the widespread implementation of the GLB in communities across the nation.

14. Biostatistics: We will use univariate analysis to summarize the measures of program usability and feasibility and examine their distributional properties (Aims 1 & 2). General/generalized mixed modeling analysis(41, 42) will be conducted for the primary and secondary effectiveness outcomes, to assess initial and sustained impacts of the adapted GLB intervention (Aim 3). More specifically, we will evaluate individual growth models for linear/nonlinear change from baseline to 6 months (level-1, time effects), overall group difference (level-2, group effect), and group difference in change (cross-level, time-by-group interaction effect) (Hypothesis 3.1). Models will be adjusted for demographic variables (e.g. age, gender, ethnicity, disability severity, etc.), particularly if they are imbalanced after randomization, thereby providing more accurate estimates of the intervention impacts. We will also fit separate individual growth models for change from baseline to 12 months within both groups combined (time effects only) (Hypothesis 3.2). Our data will include missing observations due to either attrition or nonresponse. Intent-to-treat analysis will use restricted maximum likelihood estimation, which can produce unbiased estimates under the conditions of incomplete data. Subsequent intent-to-treat analysis will utilize iterative Monte Carlo Markov Chain multiple imputation.(43) This approach includes all selected variables into the imputation process, which allows for greater recovery of the missing data.(44) All analyses will be performed using R(45) and SAS 9.3.(46) Secondary analyses will examine intervention effects for study completers who meet defined program adherence criteria.

Sample size and power. Sample size was determined to provide sufficient power for our analyses on the primary outcomes. Previous studies showed that in general DPP translation efforts including the GLB yield large impacts on weight (median d = 0.99 at 3 months, 0.91 at 6 months, 0.74 at 12 months(16, 17, 19-21, 27, 47-49)) and relatively large impacts on PA (d = 0.69 at 3 months(20)). Results also indicated, at most, 16%, 23%, and 33% attrition at 3, 6, and 12 months, respectively. A sample size of 64 will allow greater than 90% power to detect a conservatively assumed group difference of 4% in weight change (95% power) and 80 min./week in PA (92% power). In the event of 33% attrition (the maximum observed in previous GLB studies), we will achieve 83-87% power to detect these differences. Thus, 64 participants (32 per group) will be enrolled.

References

1. Froehlich-Grobe K, Lee J, Washburn RA. Disparities in obesity and related conditions among Americans with disabilities. American Journal of Preventive Medicine 2013;45(1):83-90.
2. Rasch EK, Hochberg MC, Magder L, Magaziner J, Altman BM. Health of community- dwelling adults with mobility limitations in the United States: Prevalent health conditions. Part I. Archives of Physical Medicine and Rehabilitation 2008;89:210 - 218.
3. Froehlich-Grobe K, Lollar D. Obesity and disability: Time to act. American Journal of Preventive Medicine 2011;41(5):541-545.
4. Cervantes CM, Taylor WC. Physical activity interventions in adult populations with disabilities: A review. Quest 2011;63(4):385-410.
5. Nery MB, Driver S, Vanderbom KA. Systematic framework to classify the status of research on spinal cord injury and physical activity. Arch Phys Med Rehabil 2013;94(10):2027-31.
6. Vanderbom KA, Driver S, Nery-Hurwit M. A systematic framework to classify physical activity research for individuals with spina bifida. Disability and Health Journal 2014;7(1):36-41.
7. Dixon-Ibarra A, Driver S, Dugula A. Systematic framework to evaluate the status of physical activity research for persons with multiple sclerosis. Disability and Health Journal 2014.
8. Centers for Disease Control and Prevention. Physical activity among adults with a disability-United States, 2005. Morbidity and Mortality Weekly Report 2007;56(39):1021-1024.
9. Weil E, Wachterman M, McCarthy EP, Davis RB, O'Day B, Iezzoni LI, et al. Obesity among adults with disabling conditions. Journal of the American Medical Association 2002;288(10):1265-1268.
10. Froehlich-Grobe K, Lee J, Aaronson LS, Nary DE, Washburn RA, Little TD. Exercise for Everyone: A randomized controlled trial of Project Workout On Wheels in promoting exercise among wheelchair users. Archives of Physical Medicine and Rehabilitation 2014;95:20-28.
11. National Council on Disability. The current state of transportation for people with disabilities in the United States. In: National Council on Disability; 2005.
12. Kriska A. Can a physically active lifestyle prevent type 2 diabetes? Exercise and Sport Sciences Reviews 2003;31(3):132-7.
13. Wing RR, Hamman RF, Bray GA, Delahanty L, Edelstein SL, Hill JO, et al. Achieving weight and activity goals among diabetes prevention program lifestyle participants. Obesity Research 2004;12(9):1426-34.
14. Hamman RF, Wing RR, Edelstein SL, Lachin JM, Bray GA, Delahanty L, et al. Effect of weight loss with lifestyle intervention on risk of diabetes. Diabetes Care 2006;29(9):2102-7.
15. Kriska AM, Edelstein SL, Hamman RF, Otto A, Bray GA, Mayer-Davis EJ, et al. Physical activity in individuals at risk for diabetes: Diabetes Prevention Program. Med Sci Sports Exerc 2006;38(5):826-32.
16. Kramer MK, Kriska AM, Venditti EM, Miller RG, Brooks MM, Burke LE, et al. Translating the Diabetes Prevention Program: a comprehensive model for prevention training and program delivery. American Journal of Preventive Medicine 2009;37(6):505-11.
17. Kramer MK, McWilliams JR, Chen HY, Siminerio LM. A community-based diabetes prevention program: evaluation of the group lifestyle balance program delivered by diabetes educators. Diabetes Educ 2011;37(5):659-68.
18. Dodani S, Kramer MK, Williams L, Crawford S, Kriska A. Fit body and soul: a church-based behavioral lifestyle program for diabetes prevention in African Americans. Ethnicity and Disease 2009;19(2):135-41.
19. Davis-Smith YM, Boltri JM, Seale JP, Shellenberger S, Blalock T, Tobin B. Implementing a diabetes prevention program in a rural African-American church. J Natl Med Assoc 2007;99(4):440-6.
20. Amundson HA, Butcher MK, Gohdes D, Hall TO, Harwell TS, Helgerson SD, et al. Translating the diabetes prevention program into practice in the general community: findings from the Montana Cardiovascular Disease and Diabetes Prevention Program. Diabetes Educ 2009;35(2):209-10, 213-4, 216-20 passim.

21. Ackermann RT, Finch EA, Brizendine E, Zhou H, Marrero DG. Translating the Diabetes Prevention Program into the community. The DEPLOY Pilot Study. Am J Prev Med 2008;35(4):357-63.
22. Rimmer JH, Wang E, Pellegrini CA, Lullo C, Gerber BS. Telehealth weight management intevention for adults with physical disabilities: A randomized controlled trial. Archives of Physical Medicine and Rehabilitation 2013;92(9):1-11.
23. Reichard A, Saunders MD, Saunders RR, Donnelly JE, Lauer E, Sullivan DK, et al. A comparison of two weight management programs for adults with mobility impairments. Disabil Health J 2014.
24. Chen Y, Henson S, Jackson AB, Richards JS. Obesity intervention in persons with spinal cord injury. Spinal Cord 2006;44:82-91.
25. Haskell WL, Lee IM, Pate RR, Powell KE, Blair SN, Franklin BA, et al. Physical activity and public health: Updated recommendation for adults from the American College of Sports Medicine and the American Heart Association. Medicine and Science in Sports and Exercise 2007;39(8):1423-1434.
26. U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary guidelines for Americans, 2010. In. 7th Edition ed. Washington, DC: U.S. Government Printing Ofice; 2010.
27. Kramer MK, Kriska AM, Venditti EM, Semler LN, Miller RG, McDonald T, et al. A novel approach to diabetes prevention: evaluation of the Group Lifestyle Balance program delivered via DVD. Diabetes Res Clin Pract 2010;90(3):e60-3.
28. Ma J, Yank V, Ziao L, Lavori PW, Wilson SR, Rosas LG, et al. Translating the diabetes prevention program lifestyle intervention for weight loss into primary care. A randomized trial. Journal of Internal Medicine 2013;173(2):113-121.
29. McTigue KM, Conroy MB, Bigi L, Murphy C, McNeil M. Weight Loss Through Living Well: Translating an Effective Lifestyle Intervention Into Clinical Practice. Diabetes Educator 2009;35(2):199-208.
30. Kramer M, Venditti, EM, Semler, LN, Kriska, AM, Miller, RG, Orchard, TJ. Long-term Strategies for Diabetes Prevention: Evaluation of the Group Lifestyle Balance Post-Core Sessions Focusing on Carbohydrate and Hunger Management. Journal of Diabetes and Metabolism 2012;http://dx.doi.org/10.4172/2155-6156.S2-006.
31. Dodani S, Fields JZ. Implementation of the fit body and soul, a church-based life style program for diabetes prevention in high-risk African Americans: a feasibility study. Diabetes Educ 2010;36(3):465-72.
32. Piatt GA, Seidel MC, Chen H-Y, Powell RO, Zgibor JC. Two-Year Results of Translating the Diabetes Prevention Program Into an Urban, Underserved Community. The Diabetes Educator 2012.
33. Piatt GA, Seidel MC, Powell RO, Zgibor JC. Comparative Effectiveness of Lifestyle Intervention Efforts in the Community: Results of the Rethinking Eating and ACTivity (REACT) study. Diabetes Care. 2013;36(2):202-9. doi: 10.2337/dc12-0824. Epub 2012 Sep 10.
34. Froehlich-Grobe K, Nary DE, VanSciver A, Washburn RA, Aaronson LS. Truth be told: Evidence of wheelchair users accuracy in reporting their height and weight. Archives of Physical Medicine and Rehabilitation 2012;93(11):2055-2061.
35. Froehlich-Grobe K, Andresen EM, Caburnay C, White GW. Measuring health-related quality of life for persons with mobility impairments: an enabled version of the short-form 36 (SF-36E). Quality of Life Research 2008;17(5):751-70.
36. Drum CE, Peterson JJ, Culley C, Krahn G, Heller T, Kimpton T, et al. Guidelines and criteria for the implementation of community-based health promotion programs for individuals with disabilities. American Journal of Health Promotion 2009;24(2):93-101, ii.
37. Yarar-Fisher C, Chen Y, Jackson AB, Hunter GR. Body mass index underestimates adiposity in women with spinal cord injury. Obesity (Silver Spring) 2013;21(6):1223-5.
38. Gater DR. Obesity after spinal cord injury. Physical Medicine and Rehabilitation Clinics of North America 2007;18:333-351.
39. Wehmeyer ML, Bolding N. Self-determination-across living and working environments: A matched samples study of adults wth mental retardation. Mental Retardation 1999;37(5):353-363.

40. Nary DE, Froehlich-Grobe K, Aaronson L. Recruitment issues in a randomized controlled exercise trial targeting wheelchair users. Contemporary Clinical Trials 2011;32(2):188-95.
41. Raudenbush SW, Bryk AS. Hierarchical linear models: Applications and data analysis methods. Thousand Oaks, CA: Sage Publications; 2002.
42. Singer JD, Willett JB. Applied longitudinal data analysis: Modeling change and event occurrence. New York, NY: Oxford University Press; 2003.
43. Enders CK. Applied missing data analysis. New York, NY: Guilford Press; 2010.
44. Schafer JL, Graham JW. Missing data: Out view of the state of the art. Psychological Methods 2002;7:147-177.
45. R Core Team. R: A language and environment for statistical computing. Vienna, Austria: R Foundation for Statistical Computing; 2013.
46. SAS Institute. SAS/STAT 9.3 user's guide. Cary, NC: SAS; 2002-2010.
47. Vadheim LM, McPherson C, Kassner DR, Vanderwood KK, Hall TO, Butcher MK, et al. Adapted diabetes prevention program lifestyle intervention can be effectively delivered through telehealth. Diabetes Educ 2010;36(4):651-6.
48. Katula JA, Vitolins MZ, Rosenberger EL, Blackwell CS, Morgan TM, Lawlor MS, et al. One-year results of a community-based translation of the diabetes prevention program: Healthy-Living partnerships to prevent diabetes (HELP PD) Project. Diabetes Care 2011;34:1451-1457.
49. Vadheim LM, Brewer KA, Kassner DR, Vanderwood KK, Hall TO, Butcher MK, et al. Effectiveness of a lifestyle intervention program among persons at high risk for cardiovascular disease and diabetes in a rural community. J Rural Health 2010;26(3):266-72.