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The Group Lifestyle Balance Adapted for individuals with Impaired Mobility (GLB-AIM): Outcomes for six-month randomized controlled trial and combined groups at 12 months

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Abstract

Introduction: This study examined feasibility and effectiveness of an intensive lifestyle intervention adapted for people with impaired mobility.

Design: Randomized, wait-list controlled trial. Experimental group immediately received the 12-month weight loss program; wait-list control group received it after a 6-month delay. Between-group comparisons were conducted for 6-month RCT study design. Repeated measures were conducted for both groups combined after receiving the 12-month intervention. Data were collected August 2015—February 2017 and analyzed 2017.

Setting/Participants: Community-based sample, hospital-based delivery. Participants with impaired mobility (N=66) were middle-aged (49.80±11.37 years), mostly White (66.7%), female (66.7%), and most commonly had spinal cord injury (47.0%).

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Intervention: The 12-month GLB-AIM delivers 23 group-based sessions that promote weight loss through reducing caloric intake and increasing physical activity.

Main Outcome Measures: Effectiveness measured as change in weight and time spent in moderate physical activity (MPA) were primary outcomes. Feasibility was assessed in 12-month combined-group analyses, measured as retention, attendance, and dietary self-monitoring.

Results: Six-month RCT results show immediate and delayed groups differed significantly ($p < 0.05$) in weight (−1.66 ± 4.42 kg loss vs. 0.05 ± 4.15 kg gain) and MPA (52.93 ± 90.74 min./wk. increase vs. −14.22 ± 96.02 min./wk. decrease), accounting for baseline weight, time with disability, and age of onset. Twelve-month results with groups combined demonstrate 74.2% retention and 77.7% core session attendance. Self-monitoring was higher in the delayed group (77.3%), who used a smartphone app, than immediate group (47.3%) who mostly used paper trackers. Participants achieved significant 12-month weight loss of 3.31 ± 10.13 kg ($d = 0.33$) in mixed modeling analyses with groups combined, yet did not significantly increase MPA.

Conclusion: GLB-AIM is a feasible, effective approach to teach healthy lifestyle skills to individuals with mobility impairment, yielding modest weight loss and enhanced self-efficacy.

Trial Registration: This study is registered at www.clinicaltrials.gov NCT03307187.

Americans with disabilities who represent about one-quarter of our population[1,2] experience significantly higher obesity rates (41.6%) than those without disabilities (29.2%)[3–5] and have been largely invisible in obesity surveillance and intervention efforts. Yet weight-related disparities for Americans with disabilities are striking. They are 4 times more likely have diabetes, 2 times more likely to have hypertension, and 1.5 times more likely to have high cholesterol.[3] This symptom cluster of more body fat, hypertension, elevated blood sugar and triglycerides, and dyslipidemia[3] known as metabolic syndrome[6] increases risk for both type 2 diabetes and cardiovascular disease (CVD).

Lifestyle changes that yield 10% weight loss[7–9,10] are recommended as frontline therapy for individuals with ≥1 chronic condition who are overweight/obese. National guidelines advise healthcare providers to refer their overweight/obese patients with risk factors to a multicomponent intensive behavioral intervention program that provides healthy diet and physical activity (PA) counseling.[8] Federal law mandates that patients with a physician referral are eligible to receive health insurance coverage (private and federal) for intensive lifestyle counseling.[11,12] Notably, the Centers for Medicare and Medicaid Services reimburses providers who deliver a Centers for Disease Control and Prevention (CDC) recognized diabetes prevention program that meets the specifications of an intensive lifestyle intervention (ILI).[13] ILI programs must include 6 components: (1) be delivered by a trained interventionist, (2) target dietary change, (3) prescribe ≥150 weekly minutes of moderate-intensity PA (MPA), (4) teach behavioral skills (e.g., goal setting), (5) convene ≥16 meetings over six-months, and (6) meet monthly for 12 months.[14]

Mobility impairment is the most common disability reported by Americans.[1,2] Notably, people with mobility impairment have higher prevalence of obesity (55%), chronic conditions (51.4%), and lower prevalence of meeting PA guidelines (20.6%) than those with other impairment types, including cognitive, vision, or hearing impairment.[5] The negative

health impacts of obesity may be greater for those with mobility impairment as the increased health burden of obesity and related chronic conditions contributes to greater functional impairment.[15]

Despite these disparities, evidence is limited to guide health care providers' recommendations for weight loss approaches to their mobility impaired patients. Several studies report yielding modest, but significant weight loss among people with mobility impairment that averaged 5.29 kg (weighted mean, range 2.1 kg–10.2 kg) across 12 weeks to 12 months.[16–22] Behavioral theory informed the intervention approach in two studies[18,21] but only one included most of the ILI components.[23] In their 12-month program, Reichard and colleagues[23] provided participants 6 months of portion controlled meals to support calorie reduction plus incorporated several ILI components: self-monitoring, exercise, and monthly in-person sessions. These weight loss programs provided nutrition and exercise education either by phone[16,18,19,22] in person,[17,20,22,23] or virtually[21] and several offered group exercise sessions.[16,17,20]

To address the evidence gap, this study examined the feasibility and effectiveness of delivering an adapted 12-month, multi-component ILI designed for those with mobility impairment. The paper reports results of a 6-month randomized wait-list controlled trial and combined analyses of 12-month outcomes for both groups.

Methods

Participants and Design

Study staff enrolled people whose mobility impairment etiology included cerebral palsy, spina bifida, multiple sclerosis, spinal cord injury (SCI), and amputation, and intentionally limited enrolling those with age-related mobility issues. Eligible participants were 18–75 years old; with permanent mobility impairment for at least one year (based on responses to 7 items assessing mobility limitation from the National Health and Nutrition Examination Survey);[24] BMI ≥25 indicating overweight[25] or the equivalent value for SCI (>22)[26] or amputation (adjusted for missing limbs);[27,28] self-reported sufficient upper-arm mobility to perform arm-based physical activity; phone access; physician approval; and attendance at an informational session. Ineligibility criteria included cognitive impairment that affects autonomy (determined by an adapted everyday autonomy scale);[29] pregnancy; medical contraindications for MPA (e.g., uncontrolled hypertension, coronary heart disease); and not fluent in English.

We used a wait-list control design to recruit and retain individuals living with mobility impairment, which allowed all participants to take part in the program. To minimize unequal distribution of potential confounds and contamination between groups, we placed participants into one of four strata based on wheelchair use and a close friend enrolling (wheelchair use [yes/no] × friend enroll [yes/no]=4 strata). After baseline testing, the PI randomly assigned participants within each strata into two groups using a random number generator. Groups received the 12-month intervention immediately (immediate) or after a 6-month delay (delayed). The design allowed for between-group comparisons at the 6-month assessment periods and for longitudinal comparisons across the four assessment periods

(baseline, 3, 6, and 12 months) with groups combined. This paper presents results from both comparisons, similar to previous ILI research.[30]

A-priori power analysis suggested n=64 would provide adequate power (≥.80) to detect medium differences (Cohen's f=0.29) in primary outcomes with 33% attrition. We screened 107 people (Figure 1 Consort Diagram); 15 were ineligible and 26 did not matriculate into the study, yielding a sample of 66 participants.

Recruitment

Study fliers were given to locations across north Texas that serve people with mobility impairment, including disability service organizations; a private, non-profit accessible gym; durable medical equipment providers; and outpatient physical medicine and rehabilitation clinics. Ads were also placed with two direct mail coupon services that target lower income zip code areas. The study was approved by IRBs (UTHealth #HSC-SPH-15–0011 and Baylor Research Institute #15–049) and registered with Clinical Trials.Gov (ID#NCT03307187). Study staff obtained informed consent in person before enrollment.

Program Description

The GLB-AIM was formally adapted from the Diabetes Prevention Program Group Lifestyle Balance program (DPP GLB)[31–33] with guidance from a national advisory board, detailed elsewhere.[34] The DPP GLB targets reducing diabetes risk, which people with mobility impairment experience higher prevalence than the general population.[3] We opted to adapt this evidence-based program for people with mobility impairment because the DPP GLB (1) is a 12-month ILI that targets changes in dietary intake and increased PA, (2) has yielded strong data across diverse samples,[30,3536,37] different settings,[38,39] and different platforms,[40] (3) offers the program materials online for free, and (4) delivers in-person training sessions.

Both the DPP GLB and GLB-AIM programs use group-based sessions with a trained lifestyle coach and written materials to promote 5%−7% weight loss by reducing calorie intake and increasing MPA to 150 minutes per week.[25,41] The theoretical basis for the behavioral principles used and the specific topics covered in each GLB-AIM session are detailed elsewhere.[34] Both programs provide individual daily calorie and fat gram goals based on baseline weight, designed to promote weekly weight loss of 1–2 pounds. Both programs encourage reduced dietary fat intake; increased fruit and vegetable intake; and portion control. The DPP GLB emphasizes walking for MPA, while the GLB-AIM encourages walking or wheeling plus various adaptive exercises. To reduce injury risk, the GLB-AIM emphasizes progressive PA increases designed to achieve 150 MPA minutes by week 12. The University of Pittsburgh's Diabetes Prevention Support Center (DPSC) faculty, who were part of the original DPP and adapted the intervention to the DPP GLB, approved all adaptations.

GLB-AIM lifestyle coaches included the PI and two public health graduate students; all attended a 2-day DPSC delivered training. GLB-AIM sessions were held weekly for 13 weeks ("Core Program"), bi-weekly for the next 2 sessions ("Transition Phase"), and monthly thereafter ("Support Phase"). Whereas all DPP GLB sessions are held in person, to reduce transportation barriers GLB-AIM core sessions were delivered in-person once a

month (90 minutes, with conference line available) and as teleconference calls on intervening sessions (60 minutes). Participants were encouraged to self-monitor daily calorie and fat intake and PA, using either paper logs and a provided CalorieKing® book[b] or a free smart phone app (i.e., MyFitnessPal). Participants received a food scale plus measuring cups and spoons and were loaned Vívofit® (Garmin Ltd., Lenexa, KS)[a] arm-based activity trackers that record and display daily activity levels on the watch, plus heart-rate monitors. Watches were used to prompt movement and promote a gradual increase of daily PA. Coaches advised participants that while watches captured arm-based movements, they measured steps and so absolute daily step-counts may not be accurate for wheelchair users. Thus, movement count goals were not recommended. Coaches provided written feedback on participants' weekly food logs, returned by mail using preaddressed, prepaid envelopes or electronically.

At monthly in-person sessions participants received feedback on their weight loss efforts during weigh-ins; this is less frequent than in the DPP GLB, where every session is in-person and participants are always weighed by a coach. GLB-AIM participants were encouraged to self-weigh over intervening weeks if possible and were offered use of our accessible scale between scheduled sessions.

Wait-list Control (Delayed Group)

During the 6-month waiting period, staff contacted this group about four times, via phone and mail. Contacts included scheduling testing appointments, sending general health information (e.g., managing stress, improving sleep), and holiday cards.

Outcome Measures

Study staff (i.e., lifestyle coaches) collected all data and were not blinded to group assignment. Program **feasibility** was assessed based on (a) *retention*, defined as attending at least 4 sessions, having not formally withdrawn, and returning for 12-month testing; (b) *attendance* at weekly sessions or completing a "make up" option (watching a DPP GLB DVD, listening to the audio recording, or reviewing session materials) and (c) *adherence* with weekly self-monitoring for the 13 core sessions (returning logs that were >50% complete). **Satisfaction** derived from participant ratings about the helpfulness of and satisfaction with the overall program and program components on a survey given after the 12-month program.

Effectiveness outcomes included 1) weight loss and 2) increased PA at 3, 6 and 12 months as compared to baseline. Secondary outcomes were physiologic measures (BMI, waist circumference, blood pressure, cholesterol, and A1c) and self-efficacy for healthy behaviors.

Participants completed surveys during lab visits for physiologic data collection. **Weight** was measured using a wheelchair accessible Seca scale (#676).[c] Weight measured twice and averaged, unless the measures differed by more than 1 kg, then a third was taken and all

[b] CalorieKing® book
[a] Garmin vívofit® (Garmin Ltd., Lenexa, KS)
[c] Seca scale (#676)

averaged. Device weight(s) (e.g., prosthetic, wheelchair) was subtracted from the total weight to determine body weight. **Physical activity** was measured using the 7-item International Physical Activity Questionnaire short form (IPAQ). The IPAQ assessed time spent in four activity types: 1) walking/wheeling, 2) MPA, 3) VPA, and 4) sitting. Frequency (measured in days/week) and duration (minutes/day) were reported separately for each activity type.[42]

Secondary outcomes included: **BMI**, with height measured while participants laid on the mat table, using a tool constructed for this study (two 48-inch T-squares, affixed with wooden braces screwed together to allow the rulers to slide open and closed, with small metal plates positioned at the feet and head); **waist circumference** at the umbilicus while participants were supine; **resting blood pressure** twice, with an Omron automatic blood pressure monitor (7 series, model BP652)[d] and the average reported; and total **serum cholesterol** and **A1c** via non-fasting venipuncture blood draw. **Self-efficacy** for healthy behaviors was measured using the 27-item Self-Rated Abilities for Health Practices (SRAHP), which yields a total and 4 subscales scores (Nutrition, Exercise, Health Promotion, and Physical Well Being).[43] The SRAHP has demonstrated high internal consistency (Cronbach's α=.77–.91) with a sample with disabilities; and good content, discriminant, and convergent validity.[43]

Intervention Fidelity

We implemented 3 steps to assure fidelity. First, the adapted curriculum was approved by the DPSC faculty for fidelity to the original program. Second, interventionists attended a two-day, in-person GLB training conducted by the DPSC, a CDC-approved training organization, Third, the interventionists met before every session to review the program materials, which included the DPP GLB Leaders Guide that outlines preparations for each meeting and what to cover. Fidelity of delivering curriculum content was not measured, but interventionists followed the participants' session handouts for every session. Intervention fidelity was tracked in a database of participants' weekly logs to assure participants received weekly feedback for dietary self-monitoring.

Statistical Analysis

Randomized Controlled Trial (0–6 months).—Descriptive statistics were calculated for changes at 3 and 6 months within each group and for differences between the immediate and delayed groups at each time point. Mixed modeling was conducted for each outcome to estimate overall group difference (group effect), change from baseline to 3 and 6 months (time effect), and group difference in this change (group-by-time interaction), accounting for baseline weight, time with disability, and age of disability onset. Further, participant subgroups (sex; impairment severity: mild, moderate, or severe; wheelchair use: no, manual, or power wheelchair) were tested for heterogeneity (i.e., moderation) of intervention effectiveness by estimating group-by-time-by-subgroup interactions. Intent-to-treat analyses utilized all available data, and full information maximum likelihood (FIML) in mixed

[d]Omron automatic blood pressure monitor (7 series, model BP652)

modeling to produce asymptotically optimal estimates of model parameters and smallest possible standard errors.[44]

Combined Groups (0–12 months).—Descriptive statistics were calculated for changes at 3, 6, and 12 months. Mixed modeling examined change from baseline to 12 months (time effect), accounting for baseline weight, time with disability, age of disability onset, and program cohort (immediate or delayed). Mixed models further estimated interactions between time and participant subgroups of sex, impairment severity, or wheelchair use to evaluate potential moderation of the intervention effectiveness. All analyses were conducted using SAS 9.4.[e]

Results

Participants (N=66) were 49.80±11.37 years old, experienced disability onset at 37.57±13.58 years old and lived 12.23±10.33 years with disability (Table 1). Participants were mostly White (66.7%) and female (66.7%); 45.5% were married; and 33.3% were employed. The most common mobility impairment etiologies included SCI (47%), multiple sclerosis (19.7%), arthritis (9.1%), and amputation (7.6%); and 59.1% used a wheelchair.

Randomized controlled trial

Immediate group participants lived fewer years with disability (9.29±7.34 vs. 15.34±12.11 years, p<0.05) and were more likely to have diabetes (26.5% vs. 6.1%, p<0.05) than those randomized to the delayed group. No other baseline physiological measures differed significantly between groups. While not significant, the immediate group was about 7 years older at disability onset (p=0.06) and they were nearly 10 kg heavier (p=0.13) than the delayed group.

Physiologic outcomes.—Table 2 presents physiological outcomes. At 6 months the immediate group lost 1.66±4.42 kg; which corresponded to a 1.5±3.9% loss of their baseline weight and a 0.6±1.5% decrease in BMI. In contrast, the delayed group showed essentially no change (0.05±4.15 kg gain). These findings were supported by the mixed modeling results after accounting for baseline weight, time with disability, and age of disability onset. The group-by-time interaction was significant (p<0.05) indicating that the 6-month weight change (kg) differed significantly between the groups. More than half of immediate participants (55.6%) lost weight over 6 months, with an average loss of 4.61 kg or 4.2% of their baseline weight. Clinically significant weight loss (i.e., ≥5%) was achieved at 6 months by 18.5% of immediate participants, whose loss averaged 7.4%. No significant changes occurred in other physiological measures nor did weight change differ between subgroups based on sex, impairment severity, or wheelchair use, nor for changes in other physiological measures (all p for group-by-time-by-subgroup interaction >0.05). These results should be interpreted with caution as subgroup comparisons may be underpowered.

[e]SAS 9.4. SAS Institute. (2002–2010). *SAS/STAT 9.4 user's guide*. Cary, NC: SAS.

Self-reported outcomes.—Both groups reported improved overall self-efficacy plus self-efficacy for nutrition, exercise, and health promotion over 6-months. Immediate group participants increased their MPA minutes (52.93±90.74 min./wk.), while the delayed group showed reduced PA (−14.22±96.02 min./wk.). Findings were supported by the significant group-by-time interaction in mixed modeling ($p<0.05$). There were no significant changes in other self-reported measures.

Combined Groups

Feasibility and Satisfaction—Participant **retention** over the 12-month period was 74.2%, with withdrawal reasons reported in Figure 1. More withdrew from the delayed group, but there were no significant differences for any variables between those who remained vs. withdrew (all $p>0.05$). Withdrawals tended to be younger (48.5±10.8 vs. 50.3±11.6 years old), lived longer with disability (13.5±10.4 vs. 11.8±10.4 years), and more likely to use a wheelchair (82.4% vs. 59.2%, $p=0.08$).

Attendance (Figure 2) averaged 77.7% during the core sessions but dropped to 55.7% during the support sessions. Those who attended at least 4 sessions ($n=62$) made 15.4±6.4 of the 23 sessions. Self-monitoring differed by group, the immediate group's average self-monitoring rate was 47.3%, while self-monitoring by the delayed group was 77.3%. Due to the immediate group's low self-monitoring and because self-monitoring is a core component, GLB-AIM coaches strongly urged and facilitated the delayed group's electronic self-monitoring with MyFitnessPal. Although app use was higher among the delayed group than the immediate group, regardless of tracking method, participants self-monitored an average of about 8.5 weeks (data not shown). The mixed modeling results showed that participants with higher attendance ($p<0.01$) and self-monitoring ($p<0.05$) lost significantly more weight at 12 months when baseline weight, time with disability, age of disability onset, and program cohort were controlled. Attendance and self-monitoring were comparable between participant subgroups of sex or wheelchair use (all $p>0.05$). Participants' reporting severe impairment showed significantly higher attendance ($p<0.05$) and self-monitoring ($p<0.01$) than those reporting mild impairment.

Participants' **satisfaction** ratings ($n=51$, 77%) of the GLB-AIM program and components (1–5 scale, with 5 the best rating) indicated that participants rated the overall GLB-AIM 4.4 for helpfulness and 4.5 for satisfaction. GLB-AIM staff received the highest program component rating with scores of 4.8 for helpfulness and 4.9 for satisfaction. Nearly everyone (47/48) said they would recommend the GLB-AIM program.

Effectiveness

Physiologic outcomes.: Table 3 presents physiological outcomes for each assessment period over the 12-months. Participants achieved a weight loss of 3.31±10.13 kg at 12 months, or 2.8±8.4% loss of their baseline weight and a 1.0±3.4% BMI decrease. Program efficacy on weight was confirmed by the mixed modeling results—time effect was significant ($p<0.001$) after controlling for baseline weight, time with disability, age of disability onset, and program cohort. An underpowered follow-up analysis showed that weight change did not differ between participant subgroups of sex, impairment severity, or wheelchair use; nor

were there significant changes in other physiological measures (all p for group-by-time-subgroup interaction >0.05). However, a trend of less weight loss occurred among women (1.36 kg) than men (5.58 kg, data not shown). One-third (32.7%) of participants achieved ≥5% weight loss at 12 months and lost an average 11.5% of their baseline weight. Participants who lost 5% or more weight had significantly higher self-monitoring over the core sessions (p<0.01) and higher attendance at the support sessions (p<0.05) compared to those who lost <5%.

Self-reported outcomes.: At 12 months (Table 3), participants reported significantly improved self-efficacy for nutrition, health promotion, exercise, and physical well-being when their baseline weight, time with disability, age of disability onset, and program cohort were accounted for in mixed modeling (all p for time effect <.05).

Adverse Events.: Participants reported health issues on their self-monitoring logs and contacted study staff about serious health events, which were reported to the IRB. Participants reported 324 total health events, an average of 4.9/person, although none resulted from study participation. Notably, 60.2% were secondary conditions, meaning they occurred because of the primary mobility impairment (e.g., urinary tract infections, pressure sores, overuse-related chronic joint pain). Further, 25.8% of participants had 34 hospitalizations (e.g., shoulder surgery, baclofen pump replacement, serious medication side effects, c-diff, sepsis).

Discussion

These findings suggest the GLB-AIM is a feasible and effective ILI for promoting weight loss among individuals with impaired mobility. Six-month RCT results showed significant between group differences for weight loss and MPA minutes. Combined group analyses demonstrated good retention (74.2%); solid attendance over “core” sessions (77.7%); significant, yet modest weight loss of 3.31±10.13 kg; and significantly decreased BMI. Participants also reported significantly increased self-efficacy, including for nutrition, but no significant MPA increases.

Weight loss is challenging, but may be more difficult for people with mobility impairments who have lower resting metabolic rates (RMR),[45,46] fewer PA options,[47–49] and face functional and environmental limitations that impact their dietary and PA options.[50] The sample’s ability to achieve weight loss is positive, particularly because American adults gain about .5 kg per year[51] and continue gaining weight over 20[52] to 25[53] years. Managing weight may be important for people with impaired mobility, as suggested for other groups such as African American women.[54–56] While 5%−7% weight loss is recommended, a 3% sustained loss has been associated with improved metabolic outcomes,[7] although not observed among our sample.

Numerous GLB-AIM participants shared noteworthy benefits. Several wheelchair users reported functional benefits (e.g., easier wheelchair transfers) and some ambulatory participants reported improved walking. One wheelchair user with severely limited walking

ability, walked into the final session on crutches. Some who experienced little/no weight loss reported feeling better, which they attributed to lifestyle changes.

These findings are consistent with other published studies[17,21–23,57–59] and offer evidence that behaviorally-based ILI weight loss programs for people mobility impairments are feasible and effective. Three-quarters of participants remaining the 12-month program is on par or better than previous studies, where retention ranged from 47.6% to 85.0% across 12 weeks[20] to 12 months.[60] Our sample's average 12-month 3.30 kg weight loss is also similar to other studies.[16–19,21–23]

This study extends previous research by testing the effectiveness of adapting a nationally recognized, highly disseminated, evidence-based ILI program to address issues related to implementing behavioral changes for people with mobility impairment. Partnering with the DPSC ensured integrity of the adapted program and may facilitate dissemination and implementation. The DPP GLB curriculum and Leaders Guide are freely available on the DPSC website through a Creative Commons License agreement (https://www.diabetesprevention.pitt.edu/index.php/group-lifestyle-balance-materials/) and soon the GLB-AIM and Leaders Guide will also be available on the website. Additionally, the CDC Diabetes Prevention Recognition Program has approved both the DPP GLB and GLB-AIM curricula for application for national recognition, which is the first step toward becoming a Medicare Diabetes Prevention Program Supplier (visit https://www.cdc.gov/diabetes/prevention/lifestyle-program/requirements.html). The GLB-AIM could be delivered as a standalone program to predominantly mobility impaired groups or alongside an existing DPP GLB by offering the adapted curriculum and supplementary materials to appropriate attendees.

Several factors may have contributed to the sample's low average weight loss. First, self-monitoring is a key DPP GLB component, yet fewer than half (47%) of the immediate participant group self-monitored. Results that those who lost ≥5% of their baseline weight had significantly higher self-monitoring among indicate that self-monitoring is related to greater weight loss. Second, weekly weigh-ins are a core DPP GLB feature, but to reduce transportation barriers, GLB-AIM used a mixed delivery format that provided participants with only monthly weigh-ins. This diminished external accountability, and because of the lack of accessible scales, wheelchair users had fewer opportunities to receive feedback regarding the impact of lifestyle changes on weight loss. Third, participants reported 324 health issues over the study's 18 months, 60% of which were secondary conditions, and one-quarter of participants were hospitalized. While most issues were not serious, they impacted participants' attendance and adherence with behavior changes.

Study Limitations.

Budget constraints necessitated that the interventionists serve as data collectors, thus were not blinded. Sessions were not formally rated by an outside observer for fidelity of delivery. However, we expect variability to be low, given interventionists' use of the Leaders Guide and participant handouts to guide session delivery and that sessions included two interventionists, enhancing accountability to the curriculum.

In terms of measures, dietary records were not used as an outcome so claims participants made about eating healthier foods could not be verified. The 7-item IPAQ may not have been sufficiently sensitive to capture individual PA change. While arm-based activity trackers provide PA data, we were unable to use the data as a measure of PA given problems retrieving data from watches. Finally, our sample was small; however, using a broad disability definition yielded a heterogeneous sample, enhancing external validity. However, people with SCI were overrepresented and the results cannot be generalized to those with little or no extremity use.

The study used the DPP GLB's calorie and fat gram goals, but for people with impairments that alter RMR, more aggressive goals may be warranted. Given heterogeneity among impairment types/severity among people with mobility impairment and women's lower RMR after menopause, tailoring dietary goals based on RMR may be more effective in promoting weight loss.

Conclusions

GLB-AIM is a promising ILI approach to teach people with mobility impairment healthy lifestyle skills. Results demonstrate the program promoted weight loss and significant increases in health-related self-efficacy. As a CDC-approved curriculum for the national DPP, the potential for wide-spread dissemination is great. Nevertheless, participants' average weight loss of 2.8% and MPA rates were below nationally recommended guidelines. Future studies should examine whether additional or different strategies may increase weight loss and PA.

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Author contributions: Katherine Froehlich-Grobe conceived of and designed the study, oversaw implementation and data acquisition and analysis, interpreted the results, and drafted and critically revised the work. Simon Driver contributed to the study design and measures selection, facilitated the acquisition of data, interpreted the results, and critically revised the work. Andrea C. Betts contributed to the study design and measures selection, implemented the intervention, acquired data, and drafted and critically revised the work. Danielle Carlton implemented the intervention, acquired data, and drafted and critically revised the work. Amber Merfeld Lopez acquired data, and drafted and critically revised the work. Jaehoon Lee contributed to the study design and measures selection, designed and executed the analyses, and drafted and critically revised the work. M. Kaye Kramer contributed to the study design and measures selection, interpreted the results, and critically revised the work. All authors read and approved the final version.

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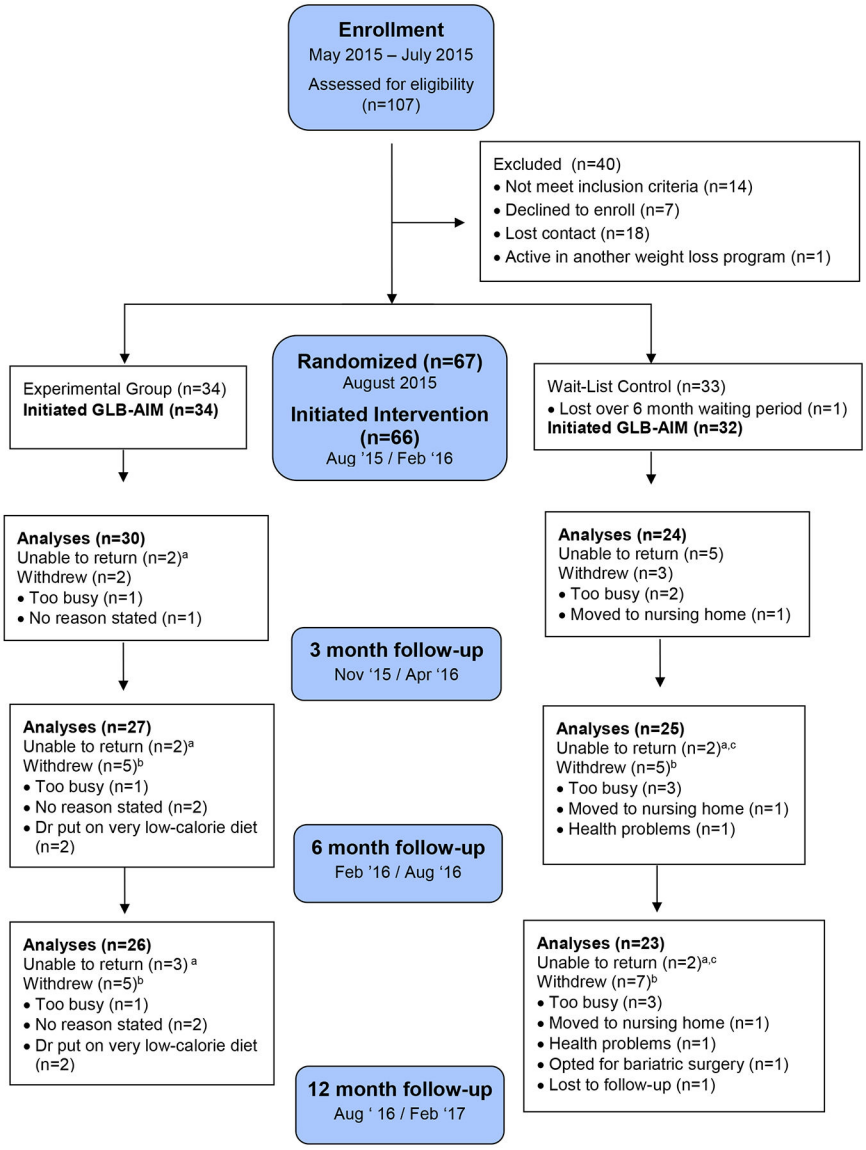

Figure 1. Consort diagram

[a] Participants healing pressure sores

[b] Cumulative count

[c] Transportation difficulties

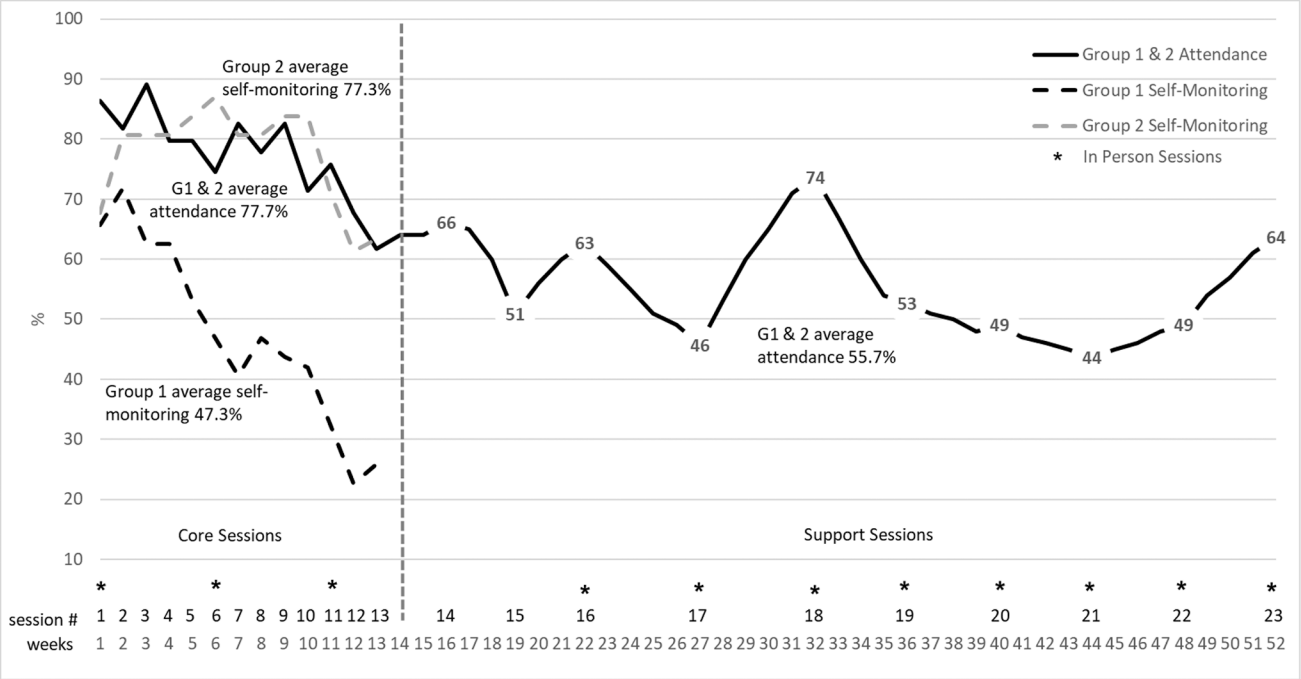

Figure 2. GLB-AIM participants average attendance over 12 months (23 sessions) and self-monitoring over the 13 core sessions

Notes: Self-monitoring was assessed over the 13 weekly core sessions. Attendance across the 12-month program was similar between groups and was thus combined.

Table 1.

Participant demographics

Variable	N	All (*N* = 66) *M*±*SD* / %	Immediate (*n* = 34) *n*	*M*±*SD* / %	Delayed (*n* = 32) *n*	*M*±*SD* / %	*p*
Age (yr) ⊥	66	49.80±11.37	34	49.88±12.03	32	49.74±10.82	0.954
Time with disability (yr) ⊥	66	12.23±10.33	34	9.29±7.34	32	15.34±12.11	**0.018**
Age of disability onset (yr) ⊥	66	37.57±13.58	34	40.58±13.59	32	34.37±13.02	0.062
Sex ≠							0.862
Male	22	33.3%	11	32.4%	11	33.3%	
Female	44	66.7%	23	67.6%	21	63.6%	
Hispanic #							1.000
Yes	4	6.1%	2	5.9%	2	6.1%	
No	51	77.3%	27	79.4%	24	72.7%	
Race #							0.424
White	44	66.7%	20	58.8%	24	72.7%	
Black or African American	15	22.7%	8	23.5%	7	21.2%	
Asian	3	4.5%	2	5.9%	1	3.0%	
American Indian / Alaska Native	2	3.0%	2	5.9%	0	0.0%	
Multiple	2	3.0%	2	5.9%	0	0.0%	
Marital status ≠							0.517
Single	15	22.7%	7	20.6%	8	24.2%	
Married	30	45.5%	14	41.2%	16	48.5%	
Divorced	15	22.7%	8	23.5%	7	21.2%	
Widowed	2	3.0%	1	2.9%	1	3.0%	
Living with significant other	3	4.5%	3	8.8%	0	0.0%	
Primary disability #							0.784
Spinal cord injury	31	47.0%	14	41.2%	17	51.5%	
Multiple sclerosis	13	19.7%	7	20.6%	6	18.2%	
Arthritis[a]	6	9.1%	5	14.7%	1	3.0%	
Neurologic[b]	4	6.1%	2	5.9%	2	6.1%	
Amputation	5	7.6%	3	8.8%	2	6.1%	
Autoimmune[c]	2	3.0%	1	2.9%	1	3.0%	
Other	5	7.6%	2	5.9%	3	9.1%	
Disability severity (SF36) ⊥	66	32.63±10.84	34	30.66±11.14	32	34.73±10.27	0.127
Disability severity							0.881
Moderate	5	7.6%	3	8.8%	2	6.1%	
Mild	27	40.9%	14	41.2%	13	39.4%	
Severe	31	47.0%	15	44.1%	16	48.5%	

Variable	N	All (*N* = 66) *M*±*SD* / %	Immediate (*n* = 34) *n*	*M*±*SD* / %	Delayed (*n* = 32) *n*	*M*±*SD* / %	*p*
Wheelchair use ≠							0.438
Manual wheelchair	22	33.3%	9	26.5%	13	39.4%	
Power wheelchair	17	25.8%	9	26.5%	8	24.2%	
No	27	40.9%	16	47.1%	11	33.3%	
Diabetes ≠							**0.024**
Yes	11	16.7%	9	26.5%	2	6.1%	
No	54	81.8%	24	70.6%	30	90.9%	
Insurance #							0.592
Medicare, Medicaid, or dual	21	31.8%	9	26.5%	12	36.4%	
Private	24	36.4%	13	38.2%	11	33.3%	
Dual + private	9	13.6%	6	17.6%	3	9.1%	
No insurance	5	7.6%	3	8.8%	2	6.1%	
Employment status #							0.398
Employed (part/full time)	22	33.3%	9	26.5%	13	39.4%	
Unemployed	27	40.9%	15	44.1%	12	36.4%	
Student / homemaker / retired / other	15	22.7%	9	26.5%	6	18.2%	

† Independent-samples *t*-test,

≠ chi-square test,

Fisher's exact test.

[a] Osteo/rheumatoid/back/knee,

[b] Traumatic brain injury/stroke/cerebral palsy,

[c] Scleroderma/fibromyalgia.

Bold numbers indicate $p < 0.05$.

Table 2.

Physiologic and self-report outcomes over 6 months by group

	Immediate (*n* = 34)									Delayed (*n* = 32)											
	Baseline			6 months			Change from 0 to 6 months			Baseline			6 months			Change from 0 to 6 months			Mixed modeling *p*		
Physiologic Outcomes	***n***	***M***	***SD***	***n***	***M***	***SD***	***n***	***M***	***SD***	***n***	***M***	***SD***	***n***	***M***	***SD***	***n***	***M***	***SD***	**G**	**T**	**G × T**
Weight (kg)	34	104.8	26.84	27	102.5	28.42	27	−1.66	4.42	32	95.95	23.13	32	96	22.94	32	0.05	4.15	0.897	0.063	**0.049**
% weight change ⁄	—	—	—	27	−0.56	3.23	27	−1.45	3.86	—	—	—	29	−0.57	2.73	32	0.17	4.33			
Body measure index	34	35.78	8.62	27	35.75	8.91	27	−0.57	1.46	32	32.87	6.78	32	32.91	6.69	32	0.04	1.43	0.990	0.205	0.138
Waist circumference (in.)	34	45.75	7.43	28	46.25	6.89	28	0.18	3.13	32	44.34	6.26	32	45.11	6.42	32	0.77	2.25	0.252	0.159	0.431
Systolic blood pressure	33	124.00	24.13	27	118.8	22.89	26	−4.47	16.05	32	125.00	18.05	29	123.10	14.08	29	−1.44	15.22	0.927	0.108	0.415
Diastolic blood pressure	33	72.76	14.99	27	72.52	15.83	26	0.37	11.37	32	74.84	12.53	29	74.98	9.98	29	0.7	12.52	0.805	0.882	0.881
Cholesterol	33	171.3	32.88	27	176.6	41.16	26	7.46	25.04	31	190.3	41.23	31	192	45.22	30	2.3	38.14	0.08	0.308	0.596
Hemoglobin A1c	33	5.59	1.03	27	5.78	1.47	26	0.08	0.91	31	5.54	0.95	30	5.54	0.92	29	0.03	0.28	0.361	0.496	0.658
Self-Report Outcomes																					
SRAHP Total	34	71.85	20.26	27	81.56	14.73	27	9.96	19.3	31	78.03	16.92	31	78.06	15.59	30	9.6	18.99	0.562	**0.000**	0.965
SRAHP Nutrition	34	14.76	6.47	27	17.89	4.05	27	3.19	6.35	31	17.29	4.86	31	16.9	5.15	30	2.8	4.98	0.699	**0.000**	0.801
SRAHP Exercise	34	17.38	7.15	27	19.93	4.99	27	3.00	5.02	31	19.16	5.23	31	19.23	6.05	30	2.7	7.17	0.440	**0.001**	0.869
SRAHP PWB	34	18.41	5.95	27	19.78	5.63	27	1.22	7.06	31	18.39	6.17	31	19.42	6.02	30	2.2	8.88	0.749	0.074	0.577
SRAHP HP	34	21.29	5.75	27	23.96	3.67	27	2.56	5.81	31	23.19	4.17	31	22.52	3.36	30	1.9	4.61	0.779	**0.000**	0.585
MPA (min./wk.)	32	45.00	79.07	23	95.54	99.05	23	52.93	90.74	31	94.84	101.2	24	51.17	78.89	23	−14.22	96.02	0.999	0.154	**0.022**
Walk/wheel time (min./wk.)	31	95.89	99.51	24	96.46	92.34	23	0.33	120	27	86.48	93.55	15	76	102	12	−20.83	128.6	0.648	0.955	0.997
Sit time (hr./day)	30	11.70	3.75	21	9.93	5.11	19	−0.92	6.51	27	9.98	4.23	9	9.22	4.68	8	−1.00	4.76	0.714	**0.031**	0.766

⁄ 6 months = change from 3 to 6 months. 3 month data are not presented here but is incorporated into the mixed modeling.

PWB = Physical Well-Being, HP = Health Promotion, MPA = moderate physical activity, G = group effect, T = time effect, G × T = group-by-time interaction.

Bold numbers indicate $p < 0.05$.

Note. Intent-to-treat analyses utilized all available data, and full information maximum likelihood (FIML) in mixed modeling.

The mixed models controlled for baseline weight, time with disability, and age of disability onset. Mixed modeling was not conducted for % weight change because this variable represents changes over time rather than values measured at particular time points.

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Table 3.

Physiologic and self-report outcomes over 12 months for both groups combined

Outcomes	Baseline			3 months			6 months			12 months		
Physiologic	***n***	***M***	***SD***	***n***	***M***	***SD***	***n***	***M***	***SD***	***n***	***M***	***SD***
Weight (kg.)	66	100.51	25.22	54	98.90	25.16	52	98.78	24.80	49	99.50	25.35
BMI	66	34.39	7.82	54	33.99	7.99	52	34.21	7.78	49	34.30	8.46
Waist circ. (in.)	66	45.59	6.66	—	—	—	53	45.53	6.36	48	45.83	7.32
Systolic BP	62	123.57	19.91	—	—	—	47	122.18	20.01	46	125.61	19.15
Diastolic BP	62	73.80	12.84	—	—	—	47	74.84	14.13	46	75.67	13.40
Cholesterol	64	181.31	40.40	—	—	—	51	180.57	38.10	45	182.42	37.54
Hemoglobin A1c	63	5.56	0.97	—	—	—	50	5.69	1.30	45	5.54	0.77
Self-Report												
SRAHP Total	65	74.82	18.31	60	79.95	15.51	53	83.58	14.68	48	82.42	15.29
2003SRAHP Nutrition	65	15.78	5.93	60	17.93	4.59	53	18.87	4.14	48	18.52	3.90
SRAHP Exercise	65	18.26	6.66	60	18.88	5.47	53	19.98	5.15	48	20.04	5.90
SRAHP PWB	65	18.89	5.96	60	19.68	5.56	53	20.66	5.60	48	20.31	5.80
SRAHP HP	65	21.88	4.76	60	23.45	4.02	53	24.08	4.07	48	23.54	3.76
MPA (min./wk.)	58	81.69	198.96	54	94.96	134.58	43	107.97	144.17	40	116.63	154.61
Walk/wheel time (min./wk.)	48	112.14	146.92	44	104.60	146.36	39	119.22	162.62	38	110.61	131.57
Sit time (hr./day)	34	10.01	2.89	45	8.84	3.55	33	8.42	3.55	35	8.44	3.31

	Change from 0 to 3 months				Change from 0 to 6 months				Change from 0 to 12 months				Mixed modeling
Physiologic	***n***	***M***	***SD***	***p***	***n***	***M***	***SD***	***p***	***n***	***M***	***SD***	***p***	***p***
Weight (kg.)	54	−1.89	4.52	**0.003**	52	−2.93	7.12	**0.005**	49	−3.31	10.13	**0.027**	**0.000**
% weight change	54	−1.69	3.94	**0.003**	52	−2.49	6.01	**0.004**	49	−2.76	8.44	**0.026**	—
BMI	54	−0.52	1.59	**0.021**	52	−0.96	2.28	**0.004**	49	−1.03	3.35	**0.036**	**0.003**
Waist circ. (in.)		-	-	-	53	−0.69	2.61	0.060	48	−0.76	2.67	0.054	0.080
Systolic BP		-	-	-	45	−3.24	16.41	0.192	45	−1.33	17.31	0.609	0.885
Diastolic BP		-	-	-	45	0.30	10.81	0.853	45	0.03	10.35	0.983	0.610
Cholesterol		-	-	-	49	−0.45	32.10	0.922	44	2.55	32.09	0.601	0.798
Hemoglobin A1c					48	0.01	0.69	0.933	44	−0.07	0.39	0.247	0.524
Self-report													

SRAHP Total	59	6.03	16.72	**0.008**	53	8.77	18.39	**0.001**	48	8.54	19.27	**0.004**	**0.001**
SRAHP	59	2.32	5.64	**0.003**	53	2.85	5.72	**0.001**	48	2.79	5.30	**0.001**	**0.000**
Nutrition													
SRAHP	59	0.97	6.47	0.256	53	2.02	7.09	**0.043**	48	2.10	7.75	0.066	**0.021**
Exercise													
SRAHP PWB	59	1.24	5.72	0.102	53	1.85	6.46	**0.042**	48	1.79	6.52	0.063	**0.043**
SRAHP HP	59	1.51	4.67	**0.016**	53	2.06	4.94	**0.004**	48	1.85	4.91	**0.012**	**0.004**
MPA (min./week)	53	−37.92	309.60	0.377	43	30.10	213.60	0.361	40	−18.08	265.80	0.670	0.209
Walk/wheel time (min./week)	37	−60.07	261.30	0.171	35	−76.16	343.40	0.198	34	−116.30	306.70	**0.034**	0.870
Sit time (hr./day)	27	−1.31	4.51	0.142	20	−0.38	3.60	0.646	21	−0.91	2.87	0.164	0.165

kg. = kilograms, BMI = body mass index, circ. = circumference, in. = inches, min. – minutes, wk. = week, hr. = hours

Bold numbers indicate $p < 0.05$.

Note. The mixed models controlled for baseline weight, time with disability, age of disability onset, and program cohort (intervention or waitlist control). Mixed modeling was not conducted for % weight change because this variable represents changes over time rather than values measured at particular time points.