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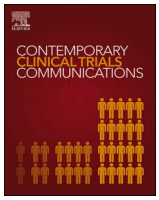

A randomized controlled trial protocol for people with traumatic brain injury enrolled in a telehealth delivered diabetes prevention program (tGLB-TBI)

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ABSTRACT

Obesity rates after traumatic brain injury (TBI) are high and are associated with greater risk of morbidity (diabetes, hypertension) and mortality when compared to the general population. Evidence-based interventions for this population are needed and our work modifying and examining the efficacy of the Diabetes Prevention Program Group Lifestyle Balance (GLB-TBI) are promising. Our recent randomized controlled trial included 57 adults with TBI who completed the GLB-TBI in-person and lost 17.8 ± 16.4lbs (7.9% body weight) compared to the attention control (0%). To broaden the accessibility of the intervention we will complete an RCT to assess the efficacy of telehealth delivery (tGLB-TBI) by enrolling 88 participants over a 3 year period. Results will provide a scalable telehealth weight-loss program that clinicians and community workers across the country can use to help people with TBI lose weight and improve health. The long-term goal is to reduce health inequities and broaden program dissemination to people with TBI that lack access due to environmental barriers, including living rurally or lacking transportation.

1. Introduction

Obesity after traumatic brain injury (TBI) is a public health issue that exacerbates the prevalence and impact of morbidity and mortality [1]. Incidence of overweight and obesity have been shown to increase from 55% 1-year post TBI to 65% at 20-years and weight problems were significantly associated with hypertension, heart failure, diabetes, and poorer self-reported health [1]. Research into rehospitalization of individuals with TBI between 2006 and 2014 found that 3158 of 4779 patients (66%) required further inpatient care during that time-period, and hypertension (46%) and diabetes (30%) were frequent reasons for rehospitalization [2]. There is a lack of evidence-based interventions to address the issue of obesity and diabetes prevention after TBI [3], yet our program of research has involved systematically addressing the problem. First, we successfully modified the evidence-based Diabetes Prevention Program Group Lifestyle Balance (DPP-GLB) intervention with a group of stakeholders to meet the unique needs of people with TBI (GLB-TBI) [4]. We recently completed a randomized controlled trial (RCT) examining the efficacy of in-person participation in the GLB-TBI on weight-loss compared to an attention control group. Individuals in the GLB-TBI group (n = 27) lost −17.8 ± 16.4lbs (−7.9%) over the 12-month program and the attention control group (n = 28) lost 0 ± 55.4lbs (0%) [5]. The GLB-TBI group also had significant improvements ($p < 0.05$) in diastolic blood pressure (−16 mmHg), waist circumference (−3.4in), triglycerides (−53.1mg/DL), HDL cholesterol (+3.9mg/DL), metabolic syndrome risk (84% reduction), diabetes risk (37% reduction), 6-min walk test (+50 m), self-efficacy and self-report habits for diet and exercise when compared to the attention control. To broaden accessibility of the GLB-TBI program this protocol paper describes a RCT for telehealth delivery of the intervention (tGLB-TBI). This protocol paper used the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist to report relevant clinical trial details

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as recommended by the Enhancing the Quality and Transparency of Health Research Network.

1.1. Objectives and aims

Aim 1: To examine the efficacy of the tGLB-TBI intervention compared to an attention control at 3, 6, and 12-months from baseline using a randomized controlled trial (RCT). Hypothesis: *The tGLB-TBI will result in significant improvements in primary (weight) and secondary outcomes when compared to the attention control group.*

Aim 1.2: To examine participant engagement with the telehealth delivered GLB-TBI (tGLB-TBI). Hypotheses: *Intervention participants will attend at least 85% of the telehealth sessions, submit 75% of food logs, and submit 70% of self-weights.*

Aim 1.3: Evaluate the fidelity of tGLB-TBI Coach Interventionists delivering the program. Hypothesis: *Coach Interventionists will achieve >90% fidelity when delivering tGLB-TBI sessions.*

Aim 1.4: To assess participant-perceived usability and satisfaction of the tGLB-TBI through the Telehealth Use Questionnaire [6] and Exit Survey at 12-months. Hypotheses: *Participants will endorse scores of ≥ 5 out of 7 on all subscales of the Telehealth Use Questionnaire* [6] *(usefulness, ease of use, effectiveness, reliability, satisfaction) and endorse high satisfaction for the tGLB-TBI.*

2. Methods

2.1. Study design

This study is a single phase, assessor-blinded, parallel-group randomized controlled trial (see Fig. 1). This study has been approved by the local Institutional Review Board (IRB) and has been registered on clinicaltrials.gov (NCT05699772).

2.2. Study setting

All tGLB-TBI and attention control classes will be hosted using Microsoft Teams, a web-based video conferencing platform approved by hospital Corporate Compliance and Legal, which is compatible with Windows, MacOS and Linux, as well as iOS and Android phones and tablets. Teams is certified by the Health Information Trust (HITRUST) Alliance, and compliant with the Health Insurance Portability and Accountability Act (HIPAA), Health Information Technology for Economic and Clinical Health (HITECH) Act, and American Disabilities Act (ADA) Revised Section 508 Standards, and has multiple accessibility features including customized font size, keyboard shortcuts, screen reader capabilities, and real-time captioning (Communication Access Realtime Translation [CART] standards). Microsoft Teams meetings also have a call-in option for audio only. We will ask participants about accessibility needs prior to study start to ensure program delivery and assessments are accessible and support the diverse needs of participants.

2.3. Participants/recruitment

Participants will be enrolled into 3 cohorts (n = 29–30 each) across a 3-year period. This approach was recommended by our stakeholders to reduce the size of classes (8–12 people/class) [,7] and was used in our previous GLB trials (NCT03594734, NCT03873467) [7]. Participants will be recruited from national organizations serving people with TBI including the Model System Knowledge Translation Center, Brain Injury Association of America, National Association of State Head Injury Administrators, and National Rehabilitation Information Center through their websites, social media platforms, newsletters, and state affiliate groups. Using a cross-organization and cross-platform approach will enable us to reach a more diverse group of individuals who might have been excluded from other interventions due to accessibility barriers.

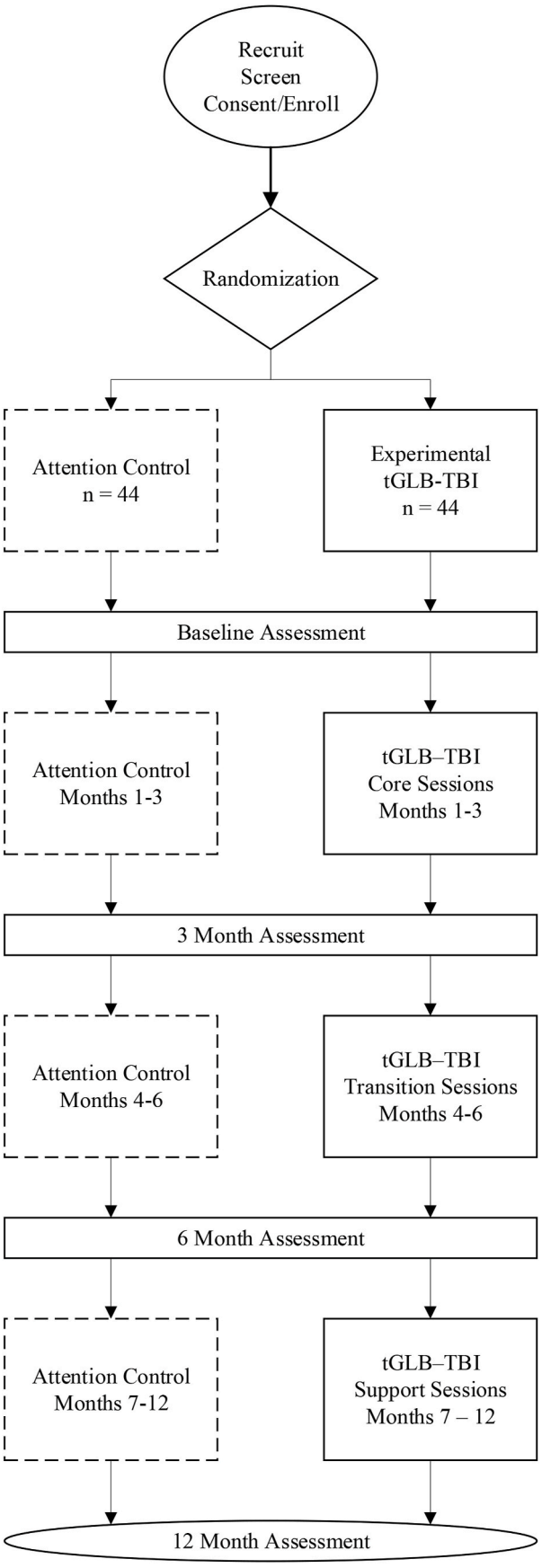

Fig. 1. Enrollment and assessment.

2.4. Eligibility

All study procedures will be approved by the IRB and approved flyers will be distributed to our national partners encouraging interested individuals to contact the study team. Individuals will be screened telephonically, and eligible participants (see Table 1) will be invited to review and sign an electronic, informed consent form delivered via REDCap (Research Electronic Data Capture [8,9]), a secure web-based application. The informed consent form will be reviewed by a study team member with the participant and all study questions will be answered prior to consent. If the participant enrolls in the study, they will be instructed on how to sign the e-consent form in REDCap and scheduled for a baseline telehealth assessment.

2.5. Intervention

2.5.1. Telehealth group lifestyle balance for people with TBI (tGLB-TBI)

The Diabetes Prevention Program Group Lifestyle Balance (DPP-GLB) is an evidence-based and CDC-recognized self-management intervention designed to reduce weight and risk for Type 2 diabetes [10,11]. The DPP-GLB is theoretically-grounded in the Social Cognitive Theory [12] and the Health Belief Model [13] and promotes participants' engagement in health behavior change. The DPP-GLB is a direct adaptation of the Diabetes Prevention Program (DPP) [14–18], both developed at the University of Pittsburgh Diabetes Prevention and Support Center (DPSC) and has resulted in weight-loss in a variety of settings (e.g., community centers, churches, worksites, healthcare systems) [19–22]. Alternate modes of delivery (e.g., DVD, telehealth, telephone call) have also proven efficacious [23]. The goal of the 12-month, group-based DPP-GLB is for participants to maintain 5–7% weight loss through increased physical activity (i.e., 150 min of moderate intensity activity each week based on American Heart Association and American College of Sports Medicine guidelines) and to improve healthy eating patterns following United States Department of Agriculture and MyPlate guidelines. The DPP-GLB is a 12-month, 22 session program sessions (see Table 2 for curriculum). It begins with 12 weekly sessions called the *Core Program*, followed by a *Transition Phase* consisting of 4 bi-weekly sessions, and a Support *Phase* consisting of 6 monthly sessions. The program materials are publicly available under the Creative Commons licensing agreement.

Table 2
DPP-GLB curriculum and session frequency.

Month	Frequency	DPP-GLB Session Topics
		Core Sessions
1	Weekly	1. Welcome to the GLB Program 2. Be a Calorie Detective 3. Healthy Eating 4. Move Those Muscles
2	Weekly	5. Tip the Calorie Balance 6. Take Charge of What's Around You 7. Problem Solving 8. Step Up Your Physical Activity Plan
3	Weekly	9. Manage Slips/Defeating Thoughts 10. Four Keys to Healthy Eating Out 11. Make Social Cues Work for You 12. Ways to Stay Motivated
		Transition Sessions
4	Bi-Weekly	13. Strengthen Your Activity Plan 14. Take Charge of Your Lifestyle
5	Monthly	15. Mindful Eating, Mindful Movement
6	Monthly	16. Manage Your Stress
		Support Sessions
7	Monthly	17. Sit Less for Your Health
8	Monthly	18. More Volume, Fewer Calories
9	Monthly	19. Stay Active
10	Monthly	20. Balance Your Thoughts
11	Monthly	21. Heart Health
12	Monthly	22. Look Back and Look Forward

Our team modified the DPP-GLB using a community-based participatory research approach in 2015 with a group of stakeholders to meet the unique needs of individuals with TBI (GLB-TBI) [4]. The main modifications included (1) reduced content volume to focus on 2 to 3 main points each session, (2) care partner involvement to provide support (e.g., social support, grocery shopping, meal preparation, transportation) (3) inclusion of peer mentors with TBI to provide support (e.g., social, informational), and lived experiences, (4) TBI-specific exercise recommendations following American College of Sports Medicine guidelines, [29]and (5) inclusion of subject matter experts (e.g., physical

Table 1
Participant inclusion and exclusion criteria.

Inclusion Criteria	Rationale for Telehealth Criteria
18–64 years of age	The DPP-GLB and GLB-TBI were developed for this age group. Younger and older individuals are excluded as the national physical activity guidelines are different and the metabolic response to diet and activity is different.
≥6 months post-TBI	This will allow resolution of acute consequences of TBI (e.g., hospitalizations, cognitive recovery process).
Moderate to severe TBI at time of injury	Severity of TBI will be determined by administering the Ohio State University Traumatic Brain Injury Identification Method questionnaire during screening procedures. Severity scores range from 0 (no TBI) to 5 (Severe TBI) [24].
BMI ≥25 kg/m^2	BMI ≥25 kg/m^2 is the definition of overweight or obese by the World Health Organization [25], and places people at greater risk for pre-diabetes or diabetes.
Physical Activity Readiness Questionnaire [26]	Brief 7-item assessment of physical/medical readiness for physical activity that is widely used before engaging in physical activity [26,27]. Individuals who respond "No" to all questions will be eligible [26,27]. If an individual endorses "Yes" for any of the 7-items, we will require the participant to obtain a signed letter from their physician for participation.
Willing to use a tablet/smartphone/computer	Participants must be willing to use a smartphone, tablet, or computer which will be provided to participants who do not have access at no cost.

Exclusion Criteria	**Rationale**
Contraindications to physical activity	Hypertension, angina, severe joint disease, vertigo/dizziness.
Not fluent in the English language	GLB-TBI has been delivered in English only, and its efficacy in other languages is unknown.
Low cognitive function	Is defined as a score <10 on the Cognistat [28]. This is required so participants can understand and comply with the adapted tGLB-TBI program.
Residing in hospital, acute rehab, SNF	The intervention is intended to impact lifestyle behaviors (e.g., diet; increased activity) which are challenging to manage/unlikely to occur in these settings.
Diagnosed with or taking medications for Type 2 diabetes	Type 2 diabetes and Type 2 diabetes medication can result in weight-loss/weight-gain which would confound findings.
Self-Reported Pregnancy	Pregnancy can lead to weight gain and may not allow participants to comply with the calorie and weight-loss goals or complete the 12-month program.
Pre-existing diagnosis of an eating disorder	History of diagnoses for eating disorders (e.g., bulimia, anorexia) require medical and nutrition management, which are beyond the scope of tGLB-TBI.

therapist, dietitian) to provide education, demonstrations, and address questions [4]. All modifications were reviewed by the DPSC at the University of Pittsburgh to ensure that the modifications did not change the theoretical underpinnings or integrity of the DPP-GLB.

The tGLB-TBI will be taught by Coach Interventionists who have completed a standardized 2-day training at the University of Pittsburgh DPSC, one of thirteen organizations in the US recognized by the CDC to provide DPP-GLB lifestyle coach training. Participants will join all sessions using Microsoft Teams and will be asked to self-monitor their daily dietary intake (calories and fat) and physical activity using a tracking log provided by the study team (paper) or an electronic app. Participants will also be asked to monitor their weight on a weekly basis using a cellular-connected scale (©BodyTrace) provided by the study team. Coach Interventionists will review dietary intake, physical activity, and weekly self-weights and provide feedback to the participant the following session. Participants will also be given a wrist-worn activity tracker (GarminVivofit®4) to use a behavioral tool to promote physical activity and track step count. Participants will be mailed all program materials prior to the first session.

2.5.2. Attention control condition: telehealth Brain Health Group (tBHG)

There are potential adverse effects of being randomized to a no-treatment or wait-list control group [30]. Attention control is considered highly valid in behavioral research, as it removes potential threats to internal validity commonly found in waitlist control study designs (e.g., participants on waitlist finding alternative treatments) [30,31]. We developed an attention control condition called the Brain Health Group (BHG) [32], which built upon an existing community-based educational/support group delivered at our hospital. Specifically, we: (1) Worked with the interventionist (speech-language pathologist) delivering the program to integrate theoretical principles from social cognitive theory [30,33] and the health belief model [13] to mirror the self-management structure of the GLB-TBI [21], (2) Integrated Model Systems Knowledge Translation Center's TBI factsheets (https://msktc.org/tbi/factsheets); and (3) Sought feedback on the BHG content and structure from our Advisory Board [32,34]. The BHG met at the same frequency as the GLB-TBI (i.e., 22 group-based sessions, 12 weekly, 4 bi-monthly, and 6 monthly) [32,34]. Examples of topics are (1) depression and anxiety, (2) goal setting, (3) mindfulness, (4) memory and attention, (5) return to work, (6) fatigue, (7) communication and relationships, and (8) purpose after TBI. The focus of the BHG is on brain health education, self-management, and problem-solving and the BHG does not receive any education on weight-loss strategies. This approach ensures that each group receives equal attention, allowing for differences in weight to be attributed to GLB-TBI content rather than social connection. Participants also develop individual short- and long-term goals and review those goals with the interventionist each session and reflect on their progress using a study-issued journal. Results of our RCT showed feasibility and benefit of participation in the BHG as there was high engagement over the 12-months (89% attendance), significant improvement in self-rated abilities for health practices ($p = 0.024$), and high satisfaction with the program (4.85/5) [35]; they also highlighted the intervention-specific differences between groups as the BHG did not experience weight-loss (0 ± 55.4lbs). The tBHG will be delivered using the same telehealth platform (Microsoft Teams) by an interventionist with experience and relevant training on the TBI-specific content.

2.6. Outcome measures

At the baseline assessment we will collect: severity of disability (Modified Rankin Scale) [36]; current age and at injury; sex; self-identified gender, parental history of diabetes; race and ethnicity; education level; pre-morbid history of mental illness; marital/relationship status; diagnosed medical conditions; previous/present smoking and cigarettes/day; alcohol consumption and drinks/week; residence status; annual household income category; insurance type; employment status; physical activity and dietary habits (Behavioral Risk Factor Surveillance Survey items) [37]; and history of weight and weight-loss attempts. Outcome data (Table 3) will be collected at baseline, 3, 6, and 12 months; virtual assessments are estimated to take 30–45 min per person and participants will be reimbursed $25 to complete each assessment (up to $100 total). Participants will be sent a requisition form for weight, height, blood pressure, hip, and waist circumference, and HbA1c, fasting glucose, and lipid panel to be collected at a lab local to the participant. Based on screening recommendations for TBI neuroendocrine dysfunction [38], thyroid-stimulating hormone (TSH) will be collected at the baseline lab visit to evaluate for clinical hypothyroidism, which will be included as a covariate in Aim 1 to account for potential weight gain caused by neuroendocrine dysfunction [39]. Remaining data will be collected telephonically (see Table 3 below).

Participant engagement with the tGLB-TBI intervention will include attendance, submitted food/activity logs, and self-weighing data (submitted automatically from provided smart scale once participant has self-weighed). The interventionist will review all submitted food/activity logs within one week of each session and return to the participant.

2.7. Sample size

We will need to enroll 88 participants (44 per group) to detect a 5% reduction in weight, with a power of 0.8 and assuming a 20% attrition rate. These estimates are based upon our published GLB-TBI RCT weight-loss data [5] summarized below:

Weight at baseline (mean, SD) 221.4 ± 51lbs.

Weight-loss after 12 months of GLB-TBI 17.8 ± 16.4lbs

2.8. Allocation

People meeting eligibility criteria will be screened, consented, and enrolled. After obtaining consent, participants will be randomized to either the experimental (tGLB-TBI) or the attention control group (tBHG) in a 1:1 ratio (blocks of 4–6), using a random number generator and stratified by sex to ensure equal distribution. Due to the type of intervention, it is not practical to blind study participants to group assignment. However, to minimize assessor bias, outcome assessments will be completed by a coordinator who is (1) blinded to group assignment, (2) not included in study team meetings or intervention delivery, (3) has a script to remind participants at the beginning of each assessment to maintain blinding, and (4) has a process for recording unblinding. Participants will be informed that the study is voluntary and that they can discontinue at any time in the trial.

2.9. Data management, quality assurance, exclusion of bias

REDCap, a HIPAA-compliant capable secure web application, will be used by trained study staff to enter all outcome data, which is maintained on a secure server. After consent, participants will be given a unique subject ID. All documents thereafter will refer to the participant by subject ID and only authorized study personnel will have access to the decoding matrix. Data management functions will occur on a quarterly basis and will include data quality checks and verification, as well as internal edits and logic checks (e.g., out of range values, internal inconsistencies). Ten percent of charts will be audited for source document and data entry review. Cross tabulation checks using SAS will also be used. Upon completion of the final study visit, a final study audit will be conducted. After all queries have been resolved, all data will be locked before final analysis takes place. Data will be stored and backed-up periodically in the biostatistician's secure filing system on the secure server. Descriptive statistics will be calculated and included into quarterly reports to ensure the quality of data and progress of the study. The

Table 3
Outcome measures for GLB-TBI telehealth project.

Measure/Mode	Properties and Approach
Primary Outcome	
Weight and height (Local Lab)	For Aim 1, weight and height will be obtained at a lab local to the participant based on their preference. For Aim 1.2, weight will be captured via self-weighing using provided BodyTrace Smart Scale, which includes cellular connectivity so weight will be sent directly to the research team. The scales have demonstrated good concordance rates with in-person weighing in previous weight management research [40]. Scales will be setup by our team before being mailed to participants.
Secondary Outcomes	
HbA1c and lipid panel (Local Lab)	Fasting venous sample will be obtained for blood glucose, HDL/LDL cholesterol, and triglyceride level.
Circumference (Local Lab)	Waist circumference measured at the umbilicus and mid-upper arm circumference.
Blood pressure (Local Lab)	Using an automatic cuff (average of three readings, patient seated) diastolic and systolic scores will be recorded
8-year Diabetes Risk (Calculated based on lab data)	The Framingham Heart Study diabetes risk score [41] will be calculated using predictors including age, gender, fasting glucose, BMI, HDL cholesterol and triglyceride levels, blood pressure, and parental history.
Metabolic Syndrome Severity Score [42] (Calculated based on lab data)	Metabolic Syndrome is a cluster of cardiovascular risk factors that include abdominal obesity (large waist circumference, high BMI), high blood pressure, high triglycerides, low HDL cholesterol and high fasting blood sugar. Individuals who have $\geq$3 of these risk factors have metabolic syndrome, placing them at greater risk of developing heart disease and diabetes. As metabolic syndrome is sensitive to lifestyle change, the metabolic syndrome severity score calculator is used to determine risk for future cardiovascular disease compared to the US population [43]. Risk scores below 0 indicate a lower degree of metabolic syndrome risk than the average US adult; scores above 0 are associated with greater risk for disease [43]. A score of 1 indicates risk is higher than 84.1% of US adults and a score of 2 is higher than 97.7% of US adults. Z scores are calculated for BMI and waist circumference [43].
Dietary Assessment (Online – self-report)	The DPP-GLB program itself utilizes food logs as an intervention behavioral tool, however, to further evaluate intervention efficacy we will also assess dietary change at each assessment period. 24-hour dietary recalls will be collected with the latest version of the Automated Self-Administered 24-h (ASA24) Dietary Assessment Tool 1-day prior to the telephonic follow-up. This free online platform (https://epi.grants.cancer.gov/asa24/#what) uses interactive multi-pass methodology [44](gold-standard in dietary assessment) and provides an overall diet quality score [45], the Healthy Eating Index (available online through the NCI website [https://epi.grants.cancer.gov/asa24/resources/hei.html] and aligns with federal recommendations and guidelines) [46].
Neighborhood Environment Walkability Scale (NEWS) (Telephonic)	NEWS assesses participants' perception of neighborhood features related to physical activity and grocery shopping, including residential density, land use mix (including both indices of proximity and accessibility), street connectivity, infrastructure for walking/cycling, neighborhood aesthetics, traffic and crime safety, and neighborhood satisfaction [47]. Scores provide insight into environmental barriers faced, are sensitive to behavior change, and can be used as a covariate for weight-loss.
Self-Rated Abilities for Health Practice (Telephonic)	Includes 28 items to assess health behaviors among people with disabilities and yields a total Health Practices Score plus 4 subscale scores (Exercise, Nutrition, Health Practices, and Psychological Well Being). Items are rated on a 5-point scale from 0 'not at all' to 4 'completely.' Scores range from 0 to 28 with higher scores indicating higher self-efficacy for the health behaviors [48].
Quality of Life After Brain Injury – Overall Scale (Telephonic)	The Quality of Life After Brain Injury – Overall Scale (QOLIBRI-OS) [49] is a six-item self-report questionnaire addressing how satisfied individuals are with aspects of their functioning (physical; cognitive; emotional; participation; social life; future prospects). Answers are on a 5-point Likert scale and the sum of all items are converted to a percentage scale from 0 to 100. The QOLIBRI-OS has excellent reliability and internal consistency [49].
Telehealth Usability Questionnaire (Telephonic)	The Telehealth Usability Questionnaire (TUQ) is a validated assessment that measures 5 usability factors of telehealth (usefulness, ease of use, effectiveness, reliability, and satisfaction). 21 items are scored on level of agreement from 1 to 7, with higher scores indicating greater agreement. All subscales have good to excellent reliability (α = .79-.92) [6].
Exit Survey (Electronic link)	Participants will be asked to complete an exit survey at the 12-month assessment. This survey will ask about participant experience in, and satisfaction with, the GLB-TBI telehealth program and suggestions for improvement. The survey will be emailed to participants via a secure REDCap link.
We will monitor technological challenges faced by participants while using the tGLB-TBI telehealth platform, which will be logged in an Excel spreadsheet and monitored for resolution. Our team successfully used this method for tracking and resolving technology issues in our GLB-TBI RCT [,50].	

principal investigator will oversee all data entry and proper data monitoring and audit procedures.

All Adverse Events will be identified, graded for severity and assigned causality, reported to the IRB, and compiled for periodic review. After assigning causality, the PI will decide the course of action for the study participant. The PI will evaluate all Adverse Events and determine whether the Adverse Event affects the risk/benefit ratio of the study and whether modifications to the protocol or informed consent form are required. The plan to monitor participant data and safety will specifically include the following: (1) PI will inspect collected data; (2) The IRB offices will be contacted if there is an Adverse Event due to participation; (3) the research protocol will be revised if it is determined that the protocol or intervention presents an unforeseen risk to participants; (4) if an event occurs that requires immediate attention and the PI is unavailable, then members of the research team will follow the emergency procedures put in place by the research team, which may include calling emergency medical services.

2.10. Statistical methods

Aim 1 Analysis: All analysis will be performed using SAS 9.4 with a significance level of 0.05. Evaluation of the primary and secondary outcomes will be performed using general or generalized linear mixed effects models [51,52] for the continuous outcomes including change in

weight from baseline, waist circumference, blood pressure, HbA1c and lipid panel, physical activity and dietary behaviors, quality of life, Metabolic Syndrome Severity, Framingham 8-year diabetes risk score, dietary quality, self-reported abilities for health practices, and neighborhood walkability. A separate model will be run for each outcome. The distribution of each outcome will be assessed to determine if a general linear model will be utilized, or if a generalized linear model with an alternative distribution and link function, such as the gamma distribution with a log link, will be more appropriate. Fixed effects included in each model will be time (3, 6, and 12 months), group (experimental or attention control), time by group interaction, and demographic/baseline variables, particularly if they are imbalanced after randomization, thereby providing more accurate estimates of the intervention impacts. A random effect will be included to account for the correlation among repeated participant measures over time. The appropriate covariance structure for the random effect will be determined by comparing various methods (unstructured, compound symmetry, and first-order autoregressive) to determine which provides the best fit. Model fit will be assessed with Bayesian information criteria, Akaike information criteria, and likelihood ratios.

Initial analysis will include missing observations due to either attrition or non-response. To determine if the results would change with complete data, sensitivity analysis will be performed using iterative Monte Carlo Markov Chain [53] multiple imputation to predict the primary and secondary outcomes that are missing at follow-up time points. All available demographic and lab variables will be used for the imputation process, which allows for greater recovery of the missing data [54]. The multiple imputed datasets will then be analyzed using the same mixed models as for the initial analysis. The final model for the imputed data will be determined by pooling the estimates produced by the analysis of each imputed dataset.

Aim 1.2 Analysis: Session attendance, self-monitoring of dietary and activity behaviors, and self-weights will be summarized and tested against the hypothesized values. One sample proportions tests will be used to determine if the overall attendance rate was $\geq$85%, dietary and activity tracking was $\geq$75%, and $\geq$70% of weekly self-weights were submitted.

Aim 1.3 Analysis: Attendance for each tGLB-TBI participant will be tracked for all 22 sessions across the 12-month intervention. To determine if there are differences between the tGLB-TBI and attention control groups for attendance, an independent sample *t*-test or Mann-Whitney *U* test, if non-normally distributed, will be run on the average number of intervention sessions attended for each cohort. All tGLB-TBI intervention sessions will be recorded through the telehealth platform. To ensure adequate provider training and consistent delivery of treatment a random 10% of each Coach Interventionist sessions will be reviewed by trained study staff for adherence to DPP-GLB content using a standardized checklist. Checklists will be scored and coaches who do not meet the goal of 90% adherence to components will undergo appropriate retraining. A total fidelity score will be calculated for each coach by averaging their fidelity ratings across checklists to determine if they met an overall 90% fidelity across sessions.

Aim 1.4 Analysis: Participant-perceived usability and satisfaction will be assessed by the Telehealth Use Questionnaire (TUQ) [6] and Exit Survey at 12-months. Usability will be defined as a score of 5 or higher on all 21 items of the TUQ, grouped by subscales outlined in Table 3. We will use means and standard deviations to summarize continuous data and counts and percentages to summarize categorical data. All open-ended, qualitative data from participant Exit Surveys collected directly in REDCap will be evaluated using investigator triangulation to increase validity and rigor [55], which our team successfully used with our previous Exit Survey [56].

3. Discussion

An estimated 2.9 million people in the United States (US) sustain a TBI annually [57], and it is the leading cause of injury-related death and disability, with 610 TBI-related hospitalizations and 174 TBI-related deaths per day nationally [58,59]. More than 5.3 million individuals in the US currently live with TBI-related disability [60], and people with TBI are more likely to develop chronic diseases, such as diabetes, heart disease, obesity, and hypertension, compared to the non-injured population [61,62]. As the population of people with TBI continues to grow and healthcare utilization rates escalate [63–66], a pressing need exists to develop evidence-based approaches to address co-morbid chronic medical conditions, such as diabetes, hypertension, and heart disease to reduce the impact of TBI as a chronic condition [3,67].

Physical activity and healthy eating behaviors promote weight-loss; lower blood pressure; enhance lipid profiles; reduce diabetes risk by improving insulin sensitivity; lower resting heart rate; improve balance, gait, strength, cardiovascular fitness, motor function, self-confidence, and independence; and reduce depression and anxiety [68–71]. Despite the positive impact of physical activity and healthy eating behaviors on weight-loss, most evidence-based interventions have excluded people with TBI. However, the promising results from our work creating the GLB-TBI and demonstrating feasibility and efficacy warrants further testing using a telehealth platform to engage a broader group, who may not typically be able to participate due to accessibility barriers (e.g., lack transportation, live rurally). Completion of our proposed tGLB-TBI work will provide a scalable telehealth weight-loss program that clinicians and community workers across the country can use to help people with TBI lose weight and improve health.

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CRediT statement

Simon Driver: conceptualization, methodology, investigation, writing-original draft, supervision, project administration, funding acquisition. **Evan McShan:** funding acquisition, project administration, supervision, writing-review and editing, conceptualization. **Monica Bennett:** methodology, formal analysis, data curation, writing-review and editing, visualization, funding acquisition. **Stephanie Calhoun:** resources, project administration, writing-review and editing. **Librada Callender:** methodology, project administration, writing-review and editing, funding acquisition. **Chad Swank**: conceptualization, methodology, investigation, writing-review and editing, funding acquisition. **Rosemary Dubiel:** investigation, resources, writing-review and editing, supervision, funding acquisition.

Data availability

De-identified data from this study are not currently available in a public archive. De-identified data from this study will be made available by emailing the corresponding author once the trial is complete.

Analytic code availability

Analytic code used to conduct the analyses presented in this study are not available in a public archive. They may be available by emailing the corresponding author once the trial is complete.

Materials availability

The GLB-TBI curriculum was approved by the Centers for Disease Control and Prevention Diabetes Prevention Recognition Program in June 2021 and can be made available upon request to the corresponding author.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2023.101191.

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