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Multi-site feasibility and fidelity of remote yoga intervention to improve management of type-2 diabetes: Design and methods of the HA1C (Healthy Active and In Control) study

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ABSTRACT

Introduction: Diabetes is a leading cause of death in the United States placing tremendous burden on individuals and the health care system. Yoga could be an attractive option for adults with diabetes with potential benefits for glycemic control and stress reduction.

Methods: Healthy Active and In Control is a study examining multi-site fidelity and feasibility of remote yoga compared to standard exercise intervention for diabetes management. Adults (N = ~30 per site) with type II diabetes (T2DM), are recruited from three sites and randomized to receive either a 12-week program of yoga or standard exercise. The yoga intervention is delivered remotely via zoom twice weekly. Participants in the standard exercise group engage in self-paced aerobic exercise with weekly staff check-in. Assessments are conducted at enrollment, end of treatment (week 12), and at 3- and 6-months post-intervention. The primary aim is to assess whether intervention components can be delivered with fidelity across the three sites. Feasibility and acceptability of the yoga and exercise interventions are compared. Data on biological (HbA1c), behavioral (e.g., physical activity, diabetes self-care behaviors), and psychological factors (e.g., mindfulness, diabetes distress) related to diabetes management are also explored along with factors associated with yoga and exercise adherence.

Conclusion: This study uses rigorous methodology to establish the feasibility and acceptability of remote-delivered yoga for individuals with T2DM from diverse populations and to assess whether the remote intervention can be delivered with fidelity across sites in preparation for a future multisite efficacy trial.

1. Introduction

Diabetes is a leading cause of mortality in the United States affecting over 38 million Americans [1]. About 90–95 % of these cases are type 2 diabetes (T2DM). It is projected that by 2050, diabetes will affect about 1 in 4 Americans [2]. Uncontrolled diabetes causes damage to multiple organs, is a major contributor to heart disease and stroke, posing a tremendous burden on individuals [3–5] and accounting for $1 of every $4 in national health care costs [6]. Moreover, T2DM disproportionately affects racial and ethnic minorities contributing to substantial health disparities [4,7]. In light of this huge health and economic impact, interventions are urgently needed to help people effectively manage their diabetes.

Medication alone is often insufficient for diabetes management: a healthy diet and regular exercise are vital for health benefits [8–10]. The American Diabetes Association (ADA) recommends at least 150 min per

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week of moderate-intensity physical activity for adults with T2DM [11]. However, adults with T2DM are twice as likely as those without it to be under-active [12]. National data indicate that only about a third of adults with T2DM are adequately physically active [13].

Stress is a key factor that plays a role in influencing diabetes outcomes [14]. Stress can affect the neuroendocrine system leading to excess cortisol secretion directly increasing blood glucose levels [15,16]. Emotional stress can also indirectly impact diabetes outcomes by influencing behaviors such as physical activity, diet, medication adherence, and smoking [17,18]. A diabetes diagnosis can cause ongoing stress related to managing this chronic condition [19]. Diabetes-related distress is present in about 35–45 % of people with diabetes [20,21] and negatively affects their health outcomes and quality of life [22,23]. Psychological interventions that address stress and diabetes distress have shown clinically meaningful benefits [24,25], and separately, clinical trials have shown that yoga practice can also help with stress reduction [26,27]. However, the role of yoga for individuals with diabetes is not thoroughly investigated.

Yoga, an alternative form of exercise, has been associated with significant improvements in physical functioning, blood pressure, body weight and stress reduction, thus it may be particularly relevant for diabetes management [28–30]. Yoga practice includes postures, breathwork and meditation, which aim to induce relaxation responses and increase attention to body sensations and present moment experiences (mindfulness) [31,32]. Such mindfulness training can increase one's ability to recognize and skillfully respond to emotional stress, leading to more effective coping responses [33,34]. Evidence indicates that yoga may reduce activation of the sympathoadrenal system, enhancing parasympathetic activity, and may also decrease the stress hormone cortisol [35,36]. Moreover, through improvements in stress and mindfulness, yoga could facilitate participation in self-care behaviors (dietary choices, physical activity) which further assists with diabetes management.

A few studies of yoga among adults with T2DM have shown small to moderate improvements in glycemic control, body mass index and cortisol levels [37,38]. Although promising, past research in this area had some methodological limitations such as lack of controls [39], absence of random assignment [40], and/or no long-term follow-up [40]. Also, the majority of this research was conducted in other countries [37] precluding any conclusions about the feasibility of yoga among adults with T2DM in the United States. To our knowledge, there have been no large randomized controlled trials examining yoga among people with diabetes in the United States. Our pilot study indicated high feasibility and acceptability of yoga as a complementary therapy for adults with T2DM [41], and found preliminary evidence of improvements in glycemic control and diabetes-related emotional distress [41]. However, that pilot study was conducted at a single site with a majority white, urban population. It is unknown whether yoga is acceptable across diverse populations, and it is not known which factors may promote long-term adherence to yoga practice. As an intermediate step between a relatively small, single site pilot study and a large multi-site efficacy trial, this multi-site study will assess whether intervention can be delivered with fidelity across multiple sites, and to determine feasibility and acceptability of a 12-week Yoga intervention for adults with T2DM compared to a standard exercise (SE) intervention.

2. Methods

2.1. Study design

The '*Healthy Active and In Control*' study is conducted to examine the multisite feasibility and fidelity of delivering a yoga intervention for the management of T2DM. This is a randomized controlled study with parallel group design comparing a 12-week program of yoga to standard exercise for adults with T2DM (18–74 years old). Study procedures are implemented at three sites: Rhode Island (main coordinating center), Massachusetts and Alabama. The sites are selected based on high prevalence of diabetes (Providence, RI 10.4 %, Lowell, MA 10.3 %, Birmingham, Alabama 13.5 %) [42] and their demographic and cultural differences (Birmingham, AL with 69 % Black or African Americans; Lowell, MA with 23 % Asians and 18 % Hispanic; Providence, RI, with 43 % Hispanic) to ensure recruitment of a diverse population [43]. Assessments are conducted at program entry (baseline), week 12 (end of treatment [EOT]) and 3- and 6-month post-intervention. Qualitative data are collected in focus group discussions with participants from each group at each site at EOT. (Clinical trial # NCT04982640).

2.2. Study aims

1) To assess whether the yoga intervention can be delivered with fidelity across three sites. Scores corresponding to >80 % will be considered high treatment fidelity; 2) To determine feasibility and acceptability of yoga practice across diverse populations. It is hypothesized that higher satisfaction ratings will be observed among Yoga vs. SE participants; 3) To assess the preliminary efficacy of the intervention on diabetes outcomes, behavioral and psychosocial factors related to diabetes management. It is anticipated that those randomized to yoga will show clinically meaningful improvements in HbA1c and fasting glucose; and 4) To identify factors associated with adherence to yoga practice. Personal (age, gender, race, ethnicity), environmental and other factors (e.g., outcome expectations, barriers to home practice) that predict maintenance of yoga will be identified.

2.3. Study procedures

2.3.1. Eligibility criteria

Adults (18–74 years of age) with self-reported diagnosis of T2DM for at least 6 months and on stable diabetes medication regimen for at least 3 months (i.e., no medication or dose changes) are eligible for the study. To ensure participant safety, individuals with serious complications from diabetes, co-morbid conditions or other conditions limiting exercise are excluded. Individuals with Body Mass Index (BMI) >45, current or planned pregnancy and those who have engaged in any mindfulness-based (i.e. yoga, tai Chi) practice in the past month are also excluded (Detailed criteria listed in Supplement).

2.3.2. Recruitment

2.3.2.1. Screening and consent. Recruitment of participants is conducted through advertising by Trialfacts, a HIPAA compliant recruitment service. Advertisements are posted on social media platforms (e.g., Facebook), online platforms (e.g., Google), worksite postings and flyers in local community settings. Potential participants are directed to an online screener through a link on advertisements. The revised Physical Activity Readiness Questionnaire (PAR-Q+) [44] is used to screen for safety for physical activity. Individuals who are provisionally eligible based on their screener are redirected to a Research Electronic Data Capture (REDCap) [45] secure web application that explains the study in detail and presents the IRB-approved informed consent form for electronic signature. Individuals provide their contact information for research staff to reach them for next steps.

2.3.2.2. Orientation. Provisionally eligible individuals attend an in-person orientation visit at their local site. Study staff review the consent form and procedures with participants, addressing their questions, measure participant's height and weight to confirm BMI eligibility and record waist/hip circumference. Participants receive accelerometers and saliva kits with detailed instructions with a demonstration on wearing the monitor and collecting saliva samples. Participants then complete the online baseline survey at home and visit their local laboratory for blood draws for analysis of HbA1c, and fasting glucose.

2.3.2.3. Randomization. After baseline assessments are completed, staff calls the participant to deliver their randomization assignment. Participants are randomized in a 1:1 ratio to receive either Yoga or SE, stratified by HbA1c levels at baseline ($\leq$9 % vs. >9 %) and sex (male/female). The randomization scheme generated by the study Biostatistician is based on a stratified, permuted block-randomization procedure (with small, random-sized blocks). The randomization assignment is built into the REDCap system and is accessed by staff during this phone call with participants. This method ensures allocation concealment, maximizes ease of delivery of randomization and consistency between sites. Participants receive information about the logistics of their intervention and schedule a second visit to return the accelerometer and saliva tubes, and collect supplies based on their assigned condition.

2.3.3. Sample size and power calculations

A sample size of 30 per site was targeted to estimate: (1) recruitment rate of 25 % to within a 95 % confidence interval of +/− 15 % (2) attendance rates of 70 % to within a 95 % confidence interval of +/− 16 % (3) self-reported adherence to home yoga of 50 % to within a 95 % confidence interval of +/− 17 % (3) retention rates at completion of the study and acceptability of 80 % to within a 95 % confidence interval of +/− 14 %. Thirty participants per site will also provide sufficient power (80 %) to estimate site-differences in feasibility measures with medium-sized effects, f = 0.25 [46].

2.4. Intervention

2.4.1. Yoga

Participants in the yoga arm attend 60-min remote group classes twice weekly for 12 weeks via Zoom. Iyengar yoga was chosen for its use of props (e.g., blocks, blankets, etc.) to achieve and maintain postures, making it suitable for adults who may be physically deconditioned and have no prior yoga experience. Iyengar yoga emphasizes postural alignment and involves precise use of instructions so that delivery can be consistent across all sites. Experienced Iyengar instructors selected poses and sequences for each class and a detailed manual was developed for site instructors with photos and steps for each pose (Table 1). Each site has a primary instructor and back-up instructors if needed. Instructors for RI and MA site are certified in Iyengar style. Since there is no Iyengar certified teacher in Birmingham, AL, instructor with 200-h teacher training certificate was selected. All site instructors have at least 10 years' experience teaching yoga to individuals with chronic conditions. During class the instructor demonstrates the poses and provide verbal instructions, allowing for modifications based on participants' needs to ensure safety during practice.

Each participant is provided with yoga props (mat, blanket, two blocks, and strap). Before the first class, participants are provided with detailed instructions on using Zoom and setting up their space for yoga practice. All sessions are attended by one staff member to address any technical issue that may arise and to ensure participant safety. Participants receive biweekly handouts via email for 12-weeks and are encouraged to practice independently twice weekly for 30 min and to

Table 1
Yoga poses included in the 12-week intervention.

English name of poses with the Sanskrit name in brackets
Mountain Pose (*Tadasana*) with Upward Hand Pose (*Urdhva Hastasana*) to Bound Knuckle Pose (*Baddhanguliyasana*)
Mountain Pose (Tadasana) with Upward Hand Pose (*Urdhva Hastasana*) to Cow Face Pose (*Gomukhasana*)
Extended Triangle Pose (*Utthita Trikonasana*)
Revolved Triangle Pose (*Parivrtta Trikonasana*)
Extended Side Angle Pose (*Utthita Parsvakonasana*)
Intense Side Stretch Pose (*Parsvottanasana*)
Intense Leg Stretch Pose (*Prasarita Padottanasana*)
Half Intense Forward Stretch (*Ardha Uttanasana*)
Downward Facing Dog Pose (*Adho Mukha Svanasana*)
Extended Standing Twist Pose (*Utthita Marichyasana*)
Chair Pose (*Utkatasana*)
Warrior 1 Pose (*Virabhadrasana 1*)
Torso Twist Pose on Chair (*Bharadvajasana*)
Torso and Leg Stretch Pose (*Marchiyasana*)
Downward Facing Hero Pose *(Adho Mukha Virasana)*
Supported Bridge Pose (*Setu Bandhasana*)
Four Footed Pose (*Chatush Padasana*)
Locust Pose (*Salabhasana*)
Boat Pose (*Paripurna Navasana*)
Supine Big Toe Pose (*Supta Padangustasana 1*)
Supine Big Toe Pose Lateral (*Supta Pandangustasana 2*)
Reclining Bound Angle Pose (*Supta Baddha Konasana*)
Legs-up-the-wall Pose (*Viparita Karani*)
Corpse Pose (*Savasana*)

Note: Each session covered 9 to 12 poses with new pose being introduced in order of difficulty. Each pose was repeated about 2 times during the session with emphasis on holding the poses rather than practicing a flow-based style. Breathwork was linked with physical movements and instructions included body and emotional awareness. Each session ended with relaxation poses.

Table 2
Weekly handouts for exercise intervention.

Week	Topic
1	Welcome HA1C Study & Benefits of Walking for Exercise Exercise Safely with Diabetes
2	Exercise Intensity and Monitoring Heart Rate Exercise and Sleep
3	Physical Activity and Mood Goal Setting
4	How to get support and Improve Motivation Flexibility and Avoiding Falls
5	Appropriate Clothing for Physical Activity Reducing Sedentary Habits
6	Stretching and Flexibility Hydration and Sports Drinks
7	Strength Training 1.0 Strength Training 2.0
8	Exercise and Body Weight Handling Setbacks
9	Active Video Games for Physical Activity Dealing with Bad Weather
10	Boredom and Staying Motivated How Much Walking is Too Much?
11	*Re*-Framing Exercise for Sustainability Changing Your Mental Focus
12	Physical Activity Resource Guide (Local Resources) Program Farewell

log their practice weekly using an online survey. A video is also provided to facilitate continued home yoga practice after the 12-week supervised sessions.

2.4.2. Exercise comparison group

Individuals in the SE arm participate in a 12-week self-paced unsupervised aerobic exercise program. Participants can choose their preferred activity (e.g., walking, home or gym workout) but are instructed to maintain a perceived exertion level of "fairly light" to "somewhat hard" to match the intensity of the yoga practice. Participants are instructed that they should be able to speak in full sentences while exercising, rather than being breathless. They receive a wearable fitness tracker at enrollment and biweekly handouts via email to encourage engagement (Table 2). Study staff conduct weekly phone check-ins to monitor progress and use a checklist to ensure consistency in the content of these contacts across sites. Participants log their activities in a weekly online survey.

2.4.3. Diet counseling

All participants in both groups receive a 30-min one-on-one counseling session via zoom with a registered dietitian (RD) at the start of their program. The purpose of this session is to provide basic essential information related to diet for diabetes management (e.g., types of carbohydrate and its metabolism, eating practices for blood sugar stability) based on ADA recommendations. The RD also discusses participant's dietary goals and addresses any questions they may have regarding their dietary practices. The RD is blinded to the participant's randomization assignment. Participants receive printed materials on diabetes care topics such as foot care, hypoglycemia, and diet and are advised to continue with their medical treatment as prescribed by their physicians.

2.5. Data collection and blinding

Assessments are conducted at eligibility screening, enrollment (baseline), weekly during 12-week intervention, at EOT and 3- and 6-months post-intervention. Qualitative data are collected through focus groups for each group at EOT. Participants complete surveys online through REDCap and collect saliva and accelerometer data at home. Body composition and laboratory assessments are collected at local sites by personnel blinded to randomization assignment. For follow-up visits, participants can either receive the assessment material (i.e., accelerometer, saliva kit) by mail or pick them up at study center. Participants can schedule a morning measurement visit to arrive fasting for same day blood draws, reducing the number of trips to the study center. Except for focus groups and intervention attendance records, all data collected by staff are blinded. Participants receive $50 e-gift card for completing assessment at each time point. Study measures and schedules are detailed in Table 3.

Table 3
Measures and schedule of assessment.

Measure	
Demographics, Diabetes History (screening and baseline)	Data on demographic and diabetes history is collected through online surveys.
Feasibility and Acceptability Measures	
Recruitment, attendance and retention rates (throughout the study)	Feasibility is assessed by overall recruitment, program attendance and retention rates.
Program satisfaction (EOT)	Acceptability is determined by the Participant Satisfaction Scale which is completed by participants in both groups at EOT.
Focus Groups data (EOT)	Focus group discussions conducted at EOT will provide in-depth feedback on program acceptability and satisfaction.
Diabetes Related Measures	
HbA1c, Fasting glucose (baseline, EOT, 3- & 6-month follow-up)	Participants visit the local laboratory for HbA1c and Fasting glucose test.
Diabetes medication (baseline, EOT, 3- & 6-month follow-up)	Diabetes medication type and dosage is reported by participants at baseline and each follow-up visit. Participants will be categorized as either "increased", "decreased", or "no change" in dose and "change" or "no-change" in type of diabetes medications based on baseline and follow-up data.
Height & weight, waist & hip circumference (baseline, EOT, 3- & 6-month follow-up)	Trained research staff measure body weight to the nearest 0.1 kg and height to the nearest millimeter to calculate BMI (weight [kilograms]/ height [meters^2]). Waist circumference is measured at the point immediately above the iliac crest on the mid-axillary line in standing position at the end of normal expiration [58]. Hip circumference is measured at the largest circumference around the buttocks.

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Table 3 (*continued*)

Diabetes Related Measures	
Behavioral and Psychological Factors related to Diabetes	
Physical activity – Actigraph & IPAQ (baseline, EOT, 3- & 6-month follow-up)	Physical activity is assessed using ActiGraph accelerometers worn for four consecutive days including one weekend day. Self-reported physical activity is collected using the International Physical Activity Questionnaire (IPAQ) [59]. Participants also respond to weekly online surveys to indicate home practice.
Barriers to Home Exercise Scale (baseline, EOT, 3- & 6-month follow-up), Outcome Expectations of Yoga & Exercise Scales (baseline)	Factors that may influence long-term yoga or exercise practice are being assessed using Barriers to Home Exercise Scale [60], Outcome Expectations of Yoga [61] and Outcome Expectations for Exercise Scales [62].
Diet – Rate Your Plate (baseline, EOT, 3- & 6-month follow-up)	Dietary habits are assessed using the Rate Your Plate questionnaire [63].
Sleep – PSQI (baseline, EOT, 3- & 6-month follow-up)	Sleep duration and quality is assessed using Pittsburgh Sleep Quality Index [64].
Diabetes Self-Care Activities (baseline, EOT, 3- & 6-month follow-up)	Behaviors related to diabetes self-management such as frequency of blood glucose testing, footcare, etc. are reported using the Summary of Diabetes Self-care Activities measure [65].
Mindfulness – FFMQ & Mindful Eating (baseline, EOT, 3- & 6-month follow-up)	Mindfulness is assessed using the Five Facet Mindfulness Questionnaire (FFMQ) [66], and mindful eating is assessed using the Mindful Eating questionnaire [67].
Quality of Life - Diabetes-39 (baseline, EOT, 3- & 6-month follow-up)	Quality of life is assessed using the Diabetes-39 instrument [68].
Problem Areas in Diabetes Scale (baseline, EOT, 3- & 6-month follow-up)	Diabetes-related emotional distress is assessed using the Problem Areas in Diabetes (PAID) scale [69].
Salivary Cortisol (baseline, EOT)	Morning and evening salivary cortisol is tested as a biomarker of stress. Participants are asked to collect saliva samples three times daily for two consecutive days based on MacArthur recommendations [70] (1) immediately at wake time, (2) 30 min after being awake, (3) bedtime, allowing assessment of cortisol output over the day. Saliva samples are collected at baseline and EOT. Participants receive detailed written and oral instructions and reminder on the day before sampling. Participant samples are stored at −80 degrees at the local study sites until being shipped for analysis.
Group Cohesion (EOT – Yoga group only)	Effect of social support from group members in the yoga arm is assessed using Group Cohesion scale.

EOT: End of treatment.

2.5.1. Process and fidelity measures

The REDCap database is used to track screened, consented, and randomized individuals and all contacts with participants. Checklists are completed by staff, documenting completion of procedures including RD visit, weekly reminders, check-ins, handouts emailed, attendance at sessions and follow-ups with notes for non-compliance or non-adherence to procedures.

Multi-site fidelity is assessed using strategies recommended by the Treatment Fidelity Workgroup of the NIH Behavior Change Consortium (Table 4) [47,48]. Fidelity objectives are met if there are not significant

Table 4
Intervention fidelity procedures and assessments.

1. STUDY DESIGN: *Factors to be considered in designing the trial and in reporting to evaluate and replicate the trial.*
Describe the intervention:

- A detailed manual was developed for the supervised yoga, and exercise interventions.
- The Yoga manual includes details on practice (poses & sequences) covered at each session. The manual includes pictures and text to be used by instructors.
- The Standard Exercise manual covers types of physical activity, resources and information about weekly check-in.
- The RD counseling manual follows a standard protocol developed in collaboration with study investigators and the RD. A checklist was developed for use by the RDs.
- A manual with Standard Operating Procedures (SOPs) was developed for each aspect of the study (e.g., screening, orientation, randomization, data collection & management).

Specify dose in each component:

- Supervised Yoga: Twenty-four 60-min sessions (2 x week for 12 weeks).
- Exercise: Twenty-four emailed program sheets (2 x week for 12 weeks), plus once weekly staff check-in.
- RD counseling: Single 30 min counseling session at program start.

Plan for implementation setbacks:

- Backup instructors identified with similar training to ensure instructor availability.

2. TRAINING PROVIDERS: *Procedures to ensure that instructors and study staff have been satisfactorily trained to deliver the intervention to study participants*
Selective in hiring instructors:

- Only certified yoga instructors with experience teaching yoga to people with chronic illness hired to deliver the intervention. RDs who have experience counseling adults with T2DM. Individuals developing the exercise condition have training in physical activity and minimum bachelor's degree in Kinesiology, public health or related field.

Standardize training:

- All yoga instructors and project staff (including volunteers and interns) trained for study specific procedures. The importance of strict adherence to the protocol emphasized repeatedly during training and weekly study meetings. Training sessions include: (1) Study overview, (2) Instructor responsibilities & workflow communication, (3) Quality assurance procedures, and (4) Monitoring & reporting guidelines.

Ensure provider skill acquisition and maintenance over time:

- Yoga instructors maintain all certifications.
- RDs maintain current licensing and Continuing Education Unit credits.
- Weekly meetings with instructors and staff to discuss their experience and facilitate consistency across sites.
- Yoga sessions recorded and reviewed by the site staff & investigators using standardized checklists to provide feedback to instructors.

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Table 4 (*continued*)

3. TREATMENT DELIVERY: *Procedures to monitor and improve delivery of intervention and comparison conditions; ensuring that treatment is delivered as intended.*
Ensure adherence to treatment protocol:

- Instructors complete a checklist after each Yoga session to report adherence or deviation from study protocol. The checklist reviewed at weekly meetings to address any concerns. Data entered into a database to track and analyze deviations across instructors and/or study sites.
- Yoga sessions recorded and 20 % of recordings reviewed to assess if the class sequence was followed as designed. All yoga classes observed in real time by study staff. Standardized checklist used to assess instructor adherence to specified study protocol.
- Checklists, guides and similar tools and procedures used to evaluate the nutrition counseling and Standard Exercise program adherence.

Non-specific treatment effects/ instructor differences:

- Session recordings reviewed to examine instructor characteristics that could lead to treatment effects (e.g., demonstration of poses, corrects improper form) and to provide instructors with feedback.
- Focus group guide includes questions to assess participants' expectations and feedback regarding instructors and interactions with study staff and protocols.

4. RECEIPT OF TREATMENT: *Treatment receipt focuses on the participant and includes procedures to assure that the treatment was both received and understood.*
Ensure participant comprehension and ability to perform the skills:

- Yoga instructors report participant observations after each session (i.e., needs for modifications, effort shown, met minimum standards for the pose, etc.).
- Staff email weekly yoga/exercise survey for participants to report engagement in the intervention.
- Participants self-evaluate their ability to practice yoga or exercise on their own at the end of treatment (week 12) survey and discuss in post-intervention focus group.

Build in strategy to improve performance of skills:

- Participants in the yoga group are given a yoga mat, strap and blocks to encourage home practice, and weekly handouts that include practice guides in form of pictures and written instructions.
- Participants in the Standard Exercise program are given a wearable fitness tracker, relevant printed materials and are encouraged to exercise at home.

Consider multicultural factors in development and delivery of intervention:

- All verbal and written communications are written at the 8th grade reading level to minimize literacy issues.
- To ensure cultural appropriateness, yoga instructors and study staff refrain from using terms or practice related to Hindu religion (i.e., chanting, etc.).

5. ENACTMENT OF TREATMENT SKILLS: *Processes to monitor and improve participant ability to perform treatment-related skills and strategies in relevant real-life settings as intended.*

- Participants report any home practice of yoga / exercise.
- Post-intervention focus groups with study participants to assess the application of yoga and exercise classes/experiences in their daily lives

between-site differences in meeting intervention objectives. For the yoga intervention, a checklist is used to assess how successfully the intervention manual was followed at each site. Scores corresponding to $\geq$80 % will be considered high treatment fidelity. Fidelity to the recruitment and assessment protocols will be measured by monitoring and comparing between-site recruitment rates, percent of missing data at each time point, and the number of protocol deviations.

2.5.2. Qualitative research

Focus group discussions are conducted separately with yoga and exercise groups via zoom at EOT. Trained facilitators use a semi-structured guide to ensure consistent data collection while allowing flexibility to adapt the conversation as relevant content emerges during the discussion. The purpose of the focus groups is to gather feedback on participants' experiences with the remote intervention, perceived facilitators and barriers to participation, and their perceptions about the intervention's impact on diabetes management. All participants are invited for discussion regardless of their adherence to the intervention. Each discussion is planned for approximately 120 min, is audiotaped and transcribed for analysis. Participants receive a $50 e-gift card for attending.

2.6. Multi-site study coordination

The Rhode Island site is the coordinating center for the overall study with site investigators responsible for supervising activities of their local site. Consistent study implementation is ensured by using manuals for all Standard Operating Procedures and centralized trainings for research staff, including yoga instructors, and dietitians on protocols relevant to their roles on the study. Regular zoom meetings are attended by investigators and staff to discuss project activities across sites.

2.7. Quality control and assurance

Data collected on case report forms (CRFs) are signed and dated by the staff collecting those data and entering in REDCap. All REDCap entries are 100 % audited. Yoga and RD sessions are recorded and 20 % are audited using quality control checklists, that correspond with content of respective intervention manual. Auditors rate yoga instructors' performance on multiple criteria including demonstration of poses, verbal encouragement, and safety measures using standardized rating sheets. Team meetings are used to review quality control results and provide feedback as needed. Quality assurance checklists are used to ensure adherence to screening, consent, intervention implementation, and assessment procedures.

Each study site is audited by an independent firm on behalf of the funding agency (National Center for Complementary and Integrative Health [NCCIH]) to review CRFs, consent forms, process measures, all data and regulatory documents. These audits conclude with a report by the auditing agency to NCCIH regarding adherence to the NCCIH-approved study protocol.

2.8. Ethical and safety oversight

All study procedures are approved by NCCIH program officers prior to being reviewed by the Institutional Review Board of the coordinating center with agreements between centers. A Data Safety and Monitoring

Board (DSMB) comprised of four members (including PhD-level researchers and MDs) not otherwise affiliated with the study meets at least twice annually to review reports of recruitment, attrition, consent process and adverse events. The DSMB chair submits meeting reports to the NCCIH program officer within seven days of the meeting.

All participants are actively monitored by the staff for adverse events (AEs). An AE is defined as any undesirable medical event during the study regardless of its relation to the study. AEs may include signs, symptoms, abnormal assessments or any combination of these. Abnormal test results due to an existing condition (e.g., high glucose levels) are considered an AE only if they reach critical values. At each contact, participants are asked about any changes in health status. If a participant experiences an injury during the online yoga session, the instructor will advise the participant to refrain from continuing until the injury has been resolved. In case, if injury is serious or requires immediate medical attention, the staff observing the session will promptly call emergency services (e.g., 911) guiding the participant to be in a safe position until help arrives. All participants are reminded at each session to pay attention to their bodies and take breaks as needed and consult with a healthcare professional if they experience persistent pain. All AEs are recorded and categorized by severity (mild, moderate, severe) and relatedness to the study (not related, unlikely, possibly, likely related, definitely related) and reviewed by the site principal investigator in team meetings. Serious AEs that are "related" or "possibly related" to the intervention are reported to the IRB and DSMB immediately. Other AEs are reported to IRB annually and at each DSMB meeting.

2.9. Planned analysis

Between-site differences in recruitment, fidelity to assessment and treatment protocol measures, will be assessed using parametric (ANOVA, chi-squared) and non-parametric (Wilcoxon rank sum) tests as appropriate.

To establish feasibility and acceptability of all intervention components, parametric and non-parametric tests will be used as appropriate. The yoga intervention will be considered feasible if participants attend at least 70 % of planned classes and if retention rates >80 % at the final follow-up. Focus group transcripts will be coded for feasibility and acceptability domains (e.g., experience with yoga/exercise, satisfaction with intervention as an element of diabetes management, and suggestions for revisions, etc.). Data will be analyzed using a framework matrix approach [49,50]. Relevant codes will be reviewed, summarized, and interpreted across yoga and exercise cohorts and sites, and presented, as appropriate, as specific content and/or themes. Particular attention and analysis will focus on the cross-site comparisons to inform multi-site feasibility and acceptability outcomes. Secondarily, intervention acceptability is assessed through the program satisfaction questionnaire. Interventions will be considered acceptable if at least 80 % of participants respond they are at least somewhat satisfied with the intervention.

Within-group changes in HbA1c, salivary cortisol, behavioral and psychological factors related to diabetes management will be explored since these may serve as outcomes or important mediators in a larger, future trial. These analyses will use a series of longitudinal mixed effects models in which outcomes at each follow-up are regressed on time, subject-specific intercept, and covariates. Models will adjust for clustering by cohort within site, as well as instructor/intervention group. Further analyses will examine potential correlation of responses (HbA1c, behavioral and psychological factors) by instructor/intervention group by calculating the Intraclass Correlation Coefficient (ICC). The previous pilot study observed a clinically meaningful improvement in HbA1c among those randomized to yoga [41]. Similar outcomes are anticipated for the present study.

Predictors of adherence to yoga practice (sustainability) will be examined using generalized linear models (with link function determined by the outcome distribution). Univariate models will be run as a preliminary step. A multivariate model will include predictors that are associated with adherence at the $p < .10$ level.

3. Discussion

The American Diabetes Association recommends lifestyle changes focusing on exercise and diet for the management of T2DM [11]. However, most adults with T2DM do not get enough exercise [13,51]. Yoga may be an attractive alternative form of exercise for this population and a facilitator of healthy behaviors and emotional well-being. The *Healthy Active and In Control* study will examine the feasibility and acceptability of yoga in comparison with a standard exercise group using rigorous methodology in three locations. The prevalence of diabetes in these three regions is above the national average of 8.4 % [42]. Recruitment of diverse participants will be useful to assess the generalizability of study findings.

There is ample evidence to suggest that yoga is a safe practice and it offers some health benefits [52,53]. Therefore, comparing yoga to usual care or wait-list control is not sufficient to advance scientific knowledge related to yoga practice [54]. Comparing yoga to a program of standard exercise will help to determine whether the effects of yoga are merely due to the physical activity component, or whether the psychological effects (e.g., mindfulness and stress reduction) associated with yoga may influence outcomes [54]. Yoga may be a more acceptable and feasible option for overweight individuals with diabetes who perceive higher levels of discomfort and low pleasure during traditional aerobic exercise [55]. Even if yoga offers equivalent benefits to exercise, this study design with long-term follow-up will help to determine whether yoga might be a preferred and sustainable activity compared to traditional aerobic exercise and if there are long-term changes in study outcomes.

The protocol of the current study differs somewhat from the previous single site pilot study [41]. Initial eligibility is determined using an online screener unlike the telephone screening used in the pilot. Individuals who pass the online screener are contacted by the study staff to confirm their eligibility. This strategy reduces staff burden, considering that ~73 % of individuals screened on phone for the pilot were found to be ineligible or declined to participate after learning about study commitment.

Yoga and exercise sessions were initially planned to be conducted in person, similar to the pilot study [41]. However, due to the concerns around Covid-19, a remote-delivery protocol was developed to minimize in-person contact. Although the yoga classes are supervised in a group format via live video conferencing, a group format for the SE group was not deemed feasible. Pilot study results indicated that walking was the most preferred activity for the exercise participants. Supervised group walking would not be realistic in the remote format. Moreover, providing the comparison group options to choose the type, location and time of exercise helps to simulate the real-world conditions. However, although the intervention is delivered entirely remotely, about five visits to the study center are still required for biometric assessments. This may deter some individuals from joining the study due to transportation or other commitment issues.

The main purpose of this study is to test the role of yoga for diabetes management. However, based on participant feedback from the pilot, a diet counseling component was added to the current study. Most participants in the pilot felt that they lacked good understanding and confidence about how to make best dietary choices. Most participants in the pilot had either never received diet counseling or had a single experience several years to more than a decade before study participation. This finding is consistent with national surveys showing that only 9 % of those with T2DM receive annual dietary and nutrition counseling per ADA recommendations [56,57]. Given the wide range of experience with nutrition counseling it was deemed necessary to provide a single session with an RD at program entry in the current study to provide all participants an even baseline of nutrition counseling.

The current study has several strengths. Yoga is being tested as a promising complimentary therapy for T2DM, a major public health

concern in the U.S. Rigorous methodology is designed to test the role of yoga for American T2DM patients from diverse populations. This study explores the effect of yoga on a wide range of biological, behavioral and psychological outcomes related to diabetes management using validated measures and quantitative and qualitative methods. Overall, this study will provide the essential data regarding feasibility and multisite fidelity prior to launching a larger multisite efficacy trial.

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CRediT authorship contribution statement

Herpreet Thind: Writing – original draft, Writing – review & editing, Supervision, Project administration, Investigation, Funding acquisition. **Dorothy Pekmezi:** Writing – review & editing, Supervision, Project administration, Funding acquisition. **Shira Dunsiger:** Writing – review & editing, Software, Resources, Data curation, Funding acquisition. **Kate M. Guthrie:** Writing – review & editing, Investigation, Funding acquisition. **Laura Stroud:** Writing – review & editing, Funding acquisition. **Wen-Chih Wu:** Writing – review & editing, Funding acquisition. **Kristen Walaska:** Writing – review & editing, Investigation, Project administration. **Beth C. Bock:** Writing – original draft, Writing – review & editing, Supervision, Project administration, Funding acquisition.

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.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cct.2025.107842.

Data availability

Data will be made available on request.

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