Family-Based, Culturally-Centered Diabetes Intervention With Ojibwe Communities

NCT04734015

DECEMBER 4, 2024

STUDY PROTOCOL

Version 11/January 2025

OBJECTIVE

The purpose of this study is to implement Community-Based Participatory Research (CBPR) with 5 American Indian (AI; Ojibwe) reservation communities in the Midwest U.S. Following the principles of CBPR, all study protocols will be reviewed, collaboratively developed, and/or amended by community/tribal research teams; any proposed changes to protocol will be submitted to Johns Hopkins University Institutional Review Board (JHU IRB) for review and approval prior to any human subjects contact. The JHU IRB will serve as the primary institutional oversight for the project.

The research team includes University study staff, Family Health Coaches (FHCs) in tribal communities to deliver the intervention in participants' homes, and Independent Evaluators (IEs) in tribal communities to conduct evaluation assessments.

We will enhance, adapt, implement and evaluate (via wait-list Randomized Control Trial/RCT) *Together on Diabetes* (TOD), a family-based, culturally grounded intervention designed with AI communities to intervene on Type 2 Diabetes (T2D) among adult caregivers and prevent T2D among youth.

AIMS of the STUDY

The aims of the study are as follows:

Aim 1: To determine the effectiveness of TOD for improving diabetes-related health outcomes for diagnosed AI adults and their youth, compared to controls, at 3, 6, 12, 18 and 24-months follow-up.

> *Hypothesis 1a. Adults:* TOD-enrolled adults will have significantly improved HbA1c (primary outcome) and additional physiological (e.g., lipids, BMI), mental (e.g., depressive symptoms, empowerment) and behavioral (e.g., medication, physical activity, diet adherence) diabetes risk indicators, and increased coping resources and responses (e.g., family support, stress management).
>
> *Hypothesis 1b. Youth:* TOD-enrolled youth will experience lower zBMI scores, reduced depressive symptoms, increased physical activity, better nutrition (e.g., reduced sugar-sweetened beverage intake), and increased coping resources and responses (e.g., family support, stress management).

Aim 2: To identify how coping mechanisms influence intervention effects on targeted physical, mental and behavioral health outcomes among participating adults and youth.

> *Hypothesis 2.* Increases in coping resources (e.g., family support, communal mastery, cultural involvement) and responses (e.g., stress management, coping skills) will mediate the impact of TOD on adults' and youth's physical, mental and behavioral health outcomes.

Secondary Aim 1: To qualitatively determine multidirectional and multilevel processes of change resulting from the TOD intervention. Using a simple, powerful, participatory qualitative evaluation approach, *Ripple Effects Mapping* (REM), we will assess multidirectional impacts of TOD on adults, youth, families, and participating communities with a subsample of intervention participants and community stakeholders.

STUDY DESIGN - OVERVIEW

This research will continue our CBPR with five American Indian (AI) Ojibwe reservation communities in the Midwest U.S.

We will use a RCT methodology to evaluate the effectiveness of the TOD intervention on diabetes related knowledge, biomedical outcomes, psychosocial health, behaviors, sociocultural outcomes and family outcomes among Ojibwe adults with Type 2 Diabetes and their Ojibwe youth.

The study will consist of three phases.
Phase 1 includes adapting and piloting of the curriculum with n = 20 families.
Phase 2 includes the evaluation of the Together on Diabetes program through a waitlist RCT.
Phase 3 includes a ripple effects mapping exercise to further evaluate the global impact of the Together on Diabetes program.

We will evaluate TOD, a 14-lesson prevention/management program delivered in the home to family dyads consisting of an adult with Type 2 Diabetes and the participating youth aged 10-16 years of age (to which the enrolled adult is a caregiver). Intervention lessons (lessons 1- 14), ranging from 45-90 minutes each, are delivered by a trained Family Health Coach (FHC) over the first 6 months. Over the second 6-month period, FHCs will meet with family dyads on a monthly basis for follow-up/maintenance visits, ranging from 30-60 minutes. (See Table 1). The total program duration is 17-27 hours.

Table 1. Lesson Timing and Length

Lesson numbers	**Frequency of Delivery**	**Length**
Lessons 1-4	Weekly	45-90 min
Lessons 5-14	Biweekly (every other week)	45-90 min
Follow-up/Maintenance Lessons 15-20	Monthly	30-60 min

Ojibwe adults with Type 2 diabetes and their youth/eligible youth family member (dyads) will be randomized to receive the TOD program or to the waitlist control. Participants randomized to the waitlist control will receive standard care. Upon completion of the 24-month assessment, participants randomized to the waitlist group will receive the TOD program as a service.

We will assess TOD's impact on key outcomes at 3-months (mini-assessment) 6-months, 12-months, 18-months (mini-assessment) and 24 months following randomization. A proportion of participants and community stakeholders will also be asked to participate in the phase 3 REM exercise; REM involves a

community meeting (2 distinct REM sessions per community) lasting up to 2 hours and including up to 20 participants per site (a mix of phase 2 RCT participants and stakeholders/community members). Participants will only participate in one REM exercise.

STUDY DESIGN - DETAILED DESCRIPTION

A more detailed description of the 3 distinct phases of our research design follows.

Phase 1. Adapting and piloting the TOD curriculum and assessments involves formative work to adapt the TOD curriculum for relatability for Ojibwe families and to target adult patients while maintaining youth-appropriate lessons to increase adult motivation, promote family-based changes, and prevent T2D in the next generation.

- Stage 1: Community Research Councils (CRCs) will evaluate lessons and assessment materials for cultural fit, relevance and acceptability. Utilizing their feedback, the lesson and assessment materials will be updated and finalized for the pilot (i.e., formative, non-research related activities).
- Stage 2: Upon finalization of the materials, we will engage a convenience sample of CRC members and youth that they care for (n=20) for a rapid pilot of curriculum. Study staff will obtain feedback with each participant dyad for each lesson reviewed. Each family will pilot up to 3-4 lessons at each visit so that we may expedite and triangulate feedback from multiple families.

UPDATE: Phase 1 is complete as of January 2021.

Phase 2. Waitlist Randomized Controlled Trial involves implementation of the TOD program and evaluation via wait-list RCT This includes the following stages:

- Stage 1: Enrollment. This includes recruitment of family dyads (adult and youth) and initial screening for eligibility, consent of the adult participant followed by parental permission/assent for the youth participant. After completing informed consent/assent participants will complete a baseline assessment. After completion of the baseline assessment, they will be randomized to the TOD intervention program (Group A) or the waitlist control (Group B). Study enrollment will be ongoing until the sample size of n=75 dyads is reached.
- Stage 2: Intervention or Waitlist. Families randomized to Group A (TOD program) will immediately begin to receive 20 lessons over 12 months. Families randomized to Group B (waitlist) will continue to receive standard of care and will begin to receive the program lessons after 2 years. To keep all participants engaged and in contact with the study team, small retention items containing the project logo, name, reminder of next visit timeframe, and contact information (examples: postcard, bookmark, post-its, stickers) will be mailed to participants at various timepoints throughout the first two years.
- Stage 3: Follow-up data collection. Adult participants and their enrolled youth from the intervention and control groups will complete an assessment at 3 (mini), 6, 12, 18 (mini) and 24 months after baseline assessment. If participant dyads move outside of the study area after

their baseline assessment, remaining follow up assessments (survey measures only) will be completed by phone.

- Stage 4: Waitlist control receives TOD intervention. The Waitlist control group will receive the TOD intervention following completion of their 24-month assessment. This will be completed as a service, and no data will be collected from participants after the 24-month assessment listed in Stage 3.

Phase 3. Ripple Effects Mapping (REM): We will conduct REM a qualitative participatory evaluation of the TOD program. This includes the following stages:

Round 1

- Stage 1: Enrollment. This includes recruitment of 1) participants who completed the TOD program in phase 2 (both those randomized to the TOD group and waitlist group) and 2) stakeholders from the local community. Participants from phase 2 and stakeholders recruited for REM will complete informed consent/assent for their participation in this part of the study.
- Stage 2: REM meetings. We will conduct 10 REM meetings (2 per site; once following Group A completion of TOD; once after Group B completion of TOD). Participants will only participate in one REM meeting.

Round 2

- Stage 1: Enrollment. This includes recruitment of 1) Family Health Coaches who delivered TOD program lessons to phase 2 participants, 2) Independent Evaluators who completed data collection assessments with phase 2 participants, 3) Community Research Council members who guided the planning and implementation of the TOD study, and 4) JHU study team members including investigators, coordinators, and data managers. Participants will complete informed consent/assent for their participation in this part of the study.
- Stage 2: REM meeting. We will conduct 1 REM meeting for the study team at the end of the project.

The communities with whom we co-lead this research have decided to call the REM sessions Mino Dibaajimowinan (Good Stories) sessions. This name is therefore used in all community- and participant-facing materials.

METHODS

RECRUITMENT

Phase 1. Piloting the TOD curriculum and assessments.

CRC members have participated in various past research programs conducted by the PI, Dr. Walls and her team in the program communities. They will provide written and verbal feedback on the curriculum which will inform initial adaptations. CRC members who are caregivers to youth aged 10 – 18 years will also be asked to participate in rapid mini pilots of the curriculum in-person, via Skype, telephone calls (or similar video/call software) with JHU study staff.

Phase 2. Waitlist Randomized Controlled Trial.

For the RCT, we will post recruitment flyers, brochures and put one-page handouts in community gathering spots (i.e., supermarket, community centers, clinics, fitness centers, etc.). We will also utilize PSAs on local radio stations, print ads in local newspapers, visual monitor ads at clinics, online ads, a study web page, Facebook page and YouTube page. The study web page will provide contact information and a link for submitting an initial interest form. All recruitment materials will include local and JHU contact numbers and a link to the study web page. We will also conduct in-services with providers to provide study information and inclusion/exclusion criteria. We will then supply providers at local clinics with study packets containing the study brochure, provider verification form and HIPAA release of information form and ask them to discuss the study with adult patients with T2D and refer interested patients to study staff. Clinic partners have also agreed to mail letters to patients on their diabetes patient rosters. Letter mailings will include a study brochure and information about the TOD program, as well as a link to the study webpage and contact information for the study team. A template for this clinic letter is attached.

Interested persons will be contacted by study staff. When study staff speak with the potential adult/youth participant, they will explain the study utilizing a recruitment script. The recruitment script asks specifically about each set of inclusion criteria. If the adult participant does not yet have a completed provider verification form confirming type 2 diabetes diagnosis, the study team member will work with the potential participant to obtain confirmation of type 2 diabetes diagnosis from local clinics using the clinic specific HIPAA Authorization. The study team will also accept patient portal printouts from potential participants as verification of type 2 diabetes diagnosis as long as they are clearly printed from MyHealth/online patient portals. If the potential participant indicates they do not meet the inclusion criteria, they will be thanked for their time and told they are not eligible for the study.

After confirming all eligibility criteria have been met, the study staff member will schedule a time to meet with the potential participant in a private location to initiate the consent process.

During recruitment, a contact information form will be completed by study staff to gather and confirm current contact information for the adult and the youth participant.

All recruitment activities will be completed by individuals employed/trained by Johns Hopkins University employees. All study staff will be required to complete training led by the University research team members and to sign confidentiality agreements for the project. Training occurs over multiple days and includes didactic lectures, discussions, and role play exercises. Training materials will include human subject safety and protections, ethics, confidentiality and privacy information, recruitment, the consenting process, computer-assisted interviewing, interviewing techniques, and data collection procedures. Booster trainings with study staff will be held annually. The Investigator team will have weekly web-based meetings or conference calls with program staff to monitor study progress and assure that the study is being implemented according to protocol. Additional one-on-one communications between University research team and community study staff will occur as needed.

NOTE: The adult participant is considered the "target" study participant; youth enrollment/participation is dependent upon the adult participant.

Phase 3: Ripple Effects Mapping.

All recruitment activities will be completed by individuals employed/trained by Johns Hopkins study team members.

Round 1

For Round 1, we will recruit 1) phase 2 participants who are finished with data collection assessments and have successfully completed at least 4 core lessons of the TOD intervention and 2) community members who are knowledgeable about TOD's impacts (guests invited by phase 2 participants and stakeholders invited by Community Research Councils) to participate in a REM exercise. Both intervention and waitlist participants who meet the inclusion criteria will be invited to the REM sessions. Community Research Councils will determine the most appropriate date, time, and location for each REM session to ensure that they are accessible and allow for privacy.

Our purposive sampling plan will involve first identifying which phase 2 participant dyads completed at least 4 core lessons and are done with data collection assessments and sharing this information with community teams (CRC members, IEs, and FHCs). Local teams will hold meetings to plan their REM session, review the list of eligible TOD phase 2 families, and make a recruitment plan delineating who will contact each eligible participant. These individuals will be mailed information about the REM activity via a one-page invitation. The invitation will include contact information for local and JHU study staff. After invitations are sent, staff will also reach out to eligible phase 2 participants and stakeholders to invite them to the REM session via phone calls, text messages, emails, and/or Facebook messages. Staff will explain the Phase 3 study utilizing a recruitment script.

Phase 2 dyads will be encouraged to bring one guest who accompanied them at TOD lessons and/or supported their healthy lifestyle changes with them to the REM session; this person may be a relative, friend, coworker, healthcare provider, etc. Dyads are responsible for inviting their guest, if desired. Community Research Councils may also invite local stakeholders with knowledge of TOD's impacts in the community to attend the REM session – for example, nurses from the local clinic who regularly interact with phase 2 participants. Study staff will recruit stakeholders using a recruitment script.

Study staff will share the date and location of the REM session with eligible phase 2 participants and stakeholders (phase 2 stakeholders will be responsible for sharing information with their invited guests); they will securely collect names and contact information for those who plan to attend using a REDCap survey in order to send reminder messages shortly before the REM session.

Round 1 Alternate Plan

In communities that do not have enough eligible phase 2 participants to conduct a REM session, an eligible adult-youth dyad will be invited to complete a qualitative interview. A member of the local community team will invite the dyad using a recruitment script (attached to this amendment). If the

participants are interested in completing the interview, the team member will schedule a date, time, and private location to meet. The adult may participate in the interview alone if the youth is unable or uninterested in participating.

Round 2

For Round 2, all TOD study team members (JHU team, CRC members, IEs, and FHCs) will be invited to attend a joint meeting to conduct the final REM session evaluating the impacts of working on TOD together. We will send team-wide emails to inform everyone of the meeting date, location, and agenda. Team members will not be required to participate in the REM session if they do not want to.

CONSENT

Trained study staff will obtain informed written consent from all adult participants and parental permission/assent for youth participants. As previously noted, all study staff will complete extensive training led by the University investigative team members and will have signed confidentiality agreements on file at JHU administrative offices. Training occurs over multiple days and includes didactic lectures, discussions, and role play exercises prior to consenting individuals into the study. Training materials will include human subject safety and protections, ethics, confidentiality and privacy information, recruitment, the consenting process, computer-assisted interviewing, interviewing techniques, and data collection procedures. Booster trainings with study staff will be held annually. The Investigator team will have weekly web-based meetings or conference calls with program staff to monitor study progress and assure that the study is being implemented according to protocol. Additional one-on-one communications between University research team and community study staff will occur as needed.

Adult consent, parent permission, and youth assent will be obtained before any research-related activities and occurs as a process involving use of fliers, brochures, and scripts as described above. Typically, the consent process and consent form/parental permission/assent itself will be signed at the home of the potential participants immediately prior to trial enrollment (for the RCT). REM consent forms will be signed just prior to the REM activities at the meeting location.

Oral consent, parent permission and youth assent will be obtained prior to completing piloting of the curriculum in phase 1. Phase 2 RCT consent forms will be signed by all participants at baseline. Phase 3 REM consent/assent forms will be signed by all participants at the start of each session or interview.

STUDY IMPLEMENTATION

Phase 1: Adaptation and Pilot of TOD.

Adapting Measures and Curriculum with the CRCs: CRCs will review all curriculum lessons during CRC meetings. They will also review and contribute to design of all assessments. These changes will be discussed by the study team and edits to the curriculum and assessment measures will be made as indicated by the CRCs and agreed upon by the study team. Any major changes to the curriculum content will be submitted as an amendment to the JHU IRB. All edits to the assessments will be submitted for approval to the IRB prior to implementation of phase 2.

The curriculum was pilot tested with 256 Navajo and Apache youth through JHU IRB protocol #4505. Adaptations to the program for the current study have been made including: 1) addition of 2 stress identification and reduction lessons; 2) reframing the focus from youth to adults; and 3) updating the program to be more in line with the Ojibwe culture (as opposed to Navajo and Apache).

Pilot TOD curriculum:

During a pilot visit, each family dyad will review/provide feedback on up to four of the TOD lessons. They will meet or discuss with a study staff member over skype or phone to go over the lessons. During the administration of the lessons, the study staff will ask questions to assess participant understanding, cultural and contextual fit, etc.

Phase 2: Randomized Waitlist Control Trial.

Group A (Together Overcoming Diabetes Intervention):

The TOD program consists of 14 intervention lessons and 6 follow-up/maintenance lessons delivered to an adult with Type 2 diabetes and their enrolled youth. All lessons are delivered in a mutually convenient location (home, local study office, clinic, etc.) by trained American Indian Family Health Coaches (FHCs). FHCs will also work to connect participants with community activities and assist in connecting participants with their healthcare provider as requested by the participant.

The curricular schedule is designed to provide key knowledge about and build skills that are critical to diabetes management and prevention. Each FHC visit is structured to include: a) a defined warm-up period, b) review of last lesson, c) check on progress towards health goals, d) cover teaching points for the lesson, d) activities related to the teaching points, f) participant review and summary of key lesson points, g) question and answer period, h) set next health goals, and i) set up next visit.

FHCs will conduct a Social Support Visit with a participant if they arrive to a scheduled visit and it is apparent that the participant is not ready to discuss curriculum content due to difficult circumstances in their life. FHCs will be trained to provide support and refer the participant to appropriate resources in the community.

The intervention consists of a 14-lesson curriculum that will be delivered in the first 6 months of the program, followed by monthly follow-up maintenance lessons that will be delivered for the second 6 months of the program.

During the second lesson visit, the participant will complete a Diabetes Management Plan based on their knowledge from visits with their provider. If there are questions in the Diabetes Management Plan that the participant does not know how to answer, the FHC will encourage them to bring the plan with them to their next clinic visit to fill in.

The FHC will review the Diabetes Management Plan with the adult participant to ensure understanding and work with them to develop personal goals. Depending on clinic preference, we may work with clinic providers to establish procedures for sharing information from FHC visits regarding progress towards

health behavior goals, as well as the adult participant's physiological data from assessment visits (weight, height, waist circumference, blood pressure, HbA1c level). Each clinic site will determine how and if they will incorporate that information into the participant's medical record so that the provider has access to that information.

Lesson	Content
1	Diabetes 101 and Goal Setting. Overview of what diabetes is, what the risk factors are and how to manage diabetes. Also review on goal settings.
2	Additional review of diabetes information
3	Historical Trauma and diabetes
4	Stress and diabetes
5	Basic nutritional knowledge including information about food labels and the difference between micro and macro nutrients
6	Basic exercise knowledge including information about the impact of exercise on the body and how to be safe during exercise
7	Learning how to problem solve
8	Mindful Eating
9	Self-Esteem and Positivity
10	Nutrition lesson focused on how to choose healthy foods and behaviors that can set you up to eat healthy
11	Information about physical activity including ideas for exercises that can fit into your daily life
12	Communication
13	Nutrition lesson including meal planning and a review of food groups
14	Lesson focused on working together as a family to live a healthy life including identifying support networks in and outside of your home.
15	Follow-up/Maintenance Lessons 1-6. Working with the health coach to address challenges to living a healthy lifestyle. All lessons will be tailored to each participant and focus on the topic area (nutrition, diabetes management, physical activity, life skills) selected by the participant.
16	
17	
18	
19	
20	

Group B (Wait List Control):

Participants randomized to the waitlist control group will receive usual care as well as receive occasional small token retention items by mail (postcard, bookmark, post-its, stickers) in the first 24 months following randomization. After they complete the 24-month assessment, the wait-list group will begin to receive the TOD intervention.

Data Collection (Evaluation):

The assessment battery consists of a combination of health check and survey measures designed to assess the primary aims of the pilot study. Measures were also included to allow for exploration of secondary outcomes and mediators and moderators of intervention response. Study measures were carefully selected as the best and/or most widely used instruments available for their purpose, with careful consideration dedicated to the cultural appropriateness of such measures. The limited

psychometric data available on American Indians for some of the instruments reflects the current state of the field.

All participants will complete assessments at baseline (prior to randomization and participation in the first program lesson) and at 3 (mini-assessment), 6, 12, 18 (mini-assessment), and 24 months following baseline assessment. A trained Independent Evaluator (IE), (a staff member who does not deliver the intervention), will administer all assessments in a private location of the participant's choosing. IEs will be blinded to the participant study condition and will be specially trained and certified to work with human subjects. They will conduct computer-assisted personal interviews (CAPI) with participants on password protected devices. Whenever possible, two IEs will visit families to complete youth and adult evaluations in a single visit.

Biomedical Assessment Measures:

The following measures will be collected by the IEs at assessments and involve either physical measurements and/or blood collection.

a. *Fasting HbA1c (Adults only):* Glycosylated hemoglobin is formed in a non-enzymatic pathway by the normal exposure of hemoglobin to high plasma levels of glucose. The glucose in the blood binds irreversibly to hemoglobin to form a glycated hemoglobin complex, Hemoglobin A1C. The normal life span of a red blood cell is approximately 120 days; therefore, the hemoglobin A1c level will change as new red blood cells are made. Hence, the hemoglobin A1Cvalue gives an estimation of what a person's average blood glucose has been for the past 2 to 3 months. The correlation of A1c levels and blood glucose levels, make glycated hemoglobin a useful method to monitor long-term glucose levels (Nathan). Previous studies including The Diabetes Control and Complications Trial (DCCT) have shown that glycemic control is associated with fewer diabetes-related complications. A1c can be measured by a variety of techniques including point of care assays.

   Afinion HbA1c test cartridge and Afinion Analyzer measure the total glycated hemoglobin and the total hemoglobin concentration. The ratio between them is proportional to the % HbA1c of the sample. The analyzer calculates the ratio, and the test result is displayed as % HbA1c. The Afinion HbA1c reportable range is 4.0-15.0% HbA1c.

   The HbA1c results are displayed in 0.1% intervals. The hemoglobin measuring range is 6.0-20.0 g/dL. If the patient's HbA1c or hemoglobin value is outside range, no test result will be reported, and the corresponding information code will be displayed.

   All IEs and senior study staff are trained by the manufacturing company (Abbott) to collect and discard finger stick blood samples utilizing the Afinion. Results will be reported to participants after the IE has confirmed and recorded them. All IEs will be trained to report and explain the test results to the participant. The test results will not be used to diagnose diabetes, nor will

they be used to inform medical management. The results will be used to track changes over time in blood sugar levels.

All participants, regardless of POC test results, will receive an informational handout for interpreting their results that will include recommended values and current practices for seeking additional medical treatment.

b. *Lipid Panel (Adults only):*
The Alere Cholestech LDX® System is a small, portable analyzer and test cassette system. The Lipid Profile•GLU Cassette is for the quantitative determination of TC (total cholesterol), HDL (high-density lipoprotein cholesterol), TRI (triglycerides) in whole blood. A TC/HDL (total cholesterol/HDL cholesterol) ratio and estimated values for LDL (low-density lipoprotein) and non-HDL cholesterol are calculated by the Alere (now Abbott) Cholestech LDX® Analyzer.

The Cholestech LDX system is able to measure total cholesterol, HDL cholesterol, triglycerides simultaneously from a single blood specimen.

All IEs and senior study staff are trained by the manufacturing company (Abbott) to collect and discard finger stick blood samples utilizing the Cholestech LDX system. Results will be reported to participants after the IE has confirmed and recorded them. All IEs will be trained to report and explain the test results to the participant. The test results will not be used to diagnose, nor will they be used to inform medical management. The results will be used to track changes over time.

c. *BMI (Adult and Youth):* Weight and height are collected in the home by trained IEs. Weight is collected using a digital scale and is recorded to the nearest tenth of a pound. Height is measured to the nearest quarter of an inch. At each timepoint, the height and weight will be taken twice to reduce measurement error. The two measurements will be averaged, and that average will be recorded. BMI z-score is calculated electronically according to Centers for Disease Control gender-specific percentiles for BMI (CDC).

d. *Blood Pressure (Adult & Youth)*: Systolic and Diastolic blood pressure is measured by a digital blood pressure device using the oscillometric method. Blood pressure is collected while the participant is seated and after the IE has confirmed the participant has not done physical activity for at least 5 minutes. To reduce measurement error, Blood Pressure will be taken two consecutive times at each visit the average of the two measurements will be recorded. Independent Evaluators are trained in the proper collection and use of blood pressure monitors. This data is recorded and will be analyzed for a change over time.

e. *Waist Circumference (Adult & Youth):* Waist Circumference is collected by IEs. IEs are trained to measure waist circumference according to the National Health and Nutrition Examination Survey anthropometry procedures (NHANES 2007). Waist circumference is recorded to the

nearest quarter of a centimeter and will be assessed for a change over time. To reduce measurement error, waist circumference is collected twice at each time point and the average between the two will be recorded.

To schedule the 3, 6, 12, 18 and 24-month Assessments, study staff will contact participants first by phone and, if unavailable, through a home visit, to arrange a confidential/private location of their choice for follow-up assessment administration. If participants move outside of the area after completing the baseline assessment, study staff will contact participants over the phone to complete their follow up assessment surveys.

Process Measures:

Process measures include FHC satisfaction and Visit summary forms.

1. *Visit Summary Forms*: Completed by the Family Health Coach at each visit, this form will include information about the visit date, time, participants involved, lesson(s) covered, or other activity completed during the visit, new health goals and reviewing progress on previous health goal/plan and necessary referrals. Visit Summary forms will be completed in REDCap. No time burden for participants.

2. *TOD Satisfaction/Feedback forms:* At two timepoints during their participation: after completion of the intervention lessons 1-14 (approximately 6 months) and again after completion of their last TOD maintenance lesson visit (approximately 12 months), participants will be asked to answer questions and provide feedback regarding their experience in the TOD program. The Satisfaction/Feedback questions will be confidentially completed using REDCap. FHCs and IEs will not have access to participant responses.

Phase 3: Ripple Effects Mapping.

Round 1

Participants who have finished data collection assessments and completed at least 4 core lessons of the intervention will be asked to join a scheduled Round 1 REM discussion. Up to 20 participants will be assigned to each Round 1 REM discussion (1 session in each of the 5 Tribal communities co-leading this research), which will be led by 2-3 trained study staff facilitators. One or two facilitators will guide the participants through the session while another records participants' contributions in the ripple effects mapping software. Sessions will take 3 hours, including a break midway for a meal. Snacks and drinks will also be provided.

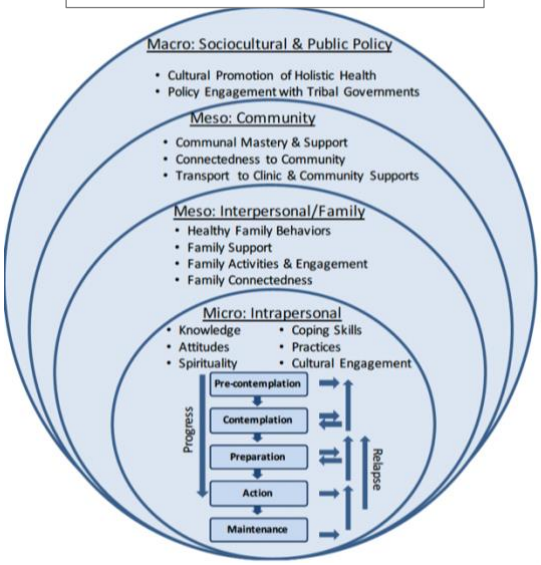
A draft REM session agenda is provided below:

20 minutes	Welcome, Settle In, Opening, Smudge
30 minutes	Consenting, Introductions, Agenda Overview, Demographics Forms
30 minutes	Gathering Stories (Paired Interviews)
30 minutes	Sharing Stories (Mapping)
30 minutes	Break for Meal
30 minutes	Organizing Stories (Theming & Rippling)
10 minutes	Final Reflections and Closing

Before the discussion begins, trained study staff will welcome participants, and a community member will open the session in a good way. The facilitators will then separate adults and youth and go through the relevant consent/assent forms together. After consent/assent forms are fully complete, all attendees will be asked to complete a brief demographics form, then introduce themselves to one another. Once these introductory steps are complete, study staff will summarize the session agenda, turn on the tape recorder, and begin to facilitate the REM exercise.

Facilitators will pair up attendees and provide a list of structured, open-ended Appreciative Inquiry interview questions on their TOD experiences and impacts. There are two separate sets of Appreciative Inquiry questions: Phase 2 participants will be asked questions about how the TOD lessons impacted their lives, while guests and stakeholders will be asked about impacts, they have observed in others. Facilitators will hand out the questions to ensure that the correct set is used. Pairs will interview each other, take notes, then report back to the group. Facilitators will lead collaborative, full group, electronically assisted visual mapping of results with Mind Mapping software as participants identify and describe the "ripples" of TOD effects (e.g., changes in behaviors, social network expansion). One or two facilitators lead the conversation and probe for additional information; another enters data into the mapping software. Participants are urged to note chains of causes and effects ("ripples") as they report TOD impacts**.** As reporting progresses, facilitators encourage classification of ripple "categories" like knowledge, skills, new or changed relationships, new cultural activities, and behavior change**.** Facilitators will also probe for views on multilevel impacts (individual, family, community, etc.) per the TOD Theoretical Model (Figure 1). Final follow-up questions will solicit deeper details and diverse opinions entered into the software for a detailed visual map of TOD impacts. Upon completion of the session, each participant will receive a $50 gift card and 1 entry into a raffle for a TOD logo-emblazoned item (for example, a sweatshirt or canvas tote bag). Each community will have its own raffle.

Figure 1. TOD Theoretical Model



Alternate Round 1 plan

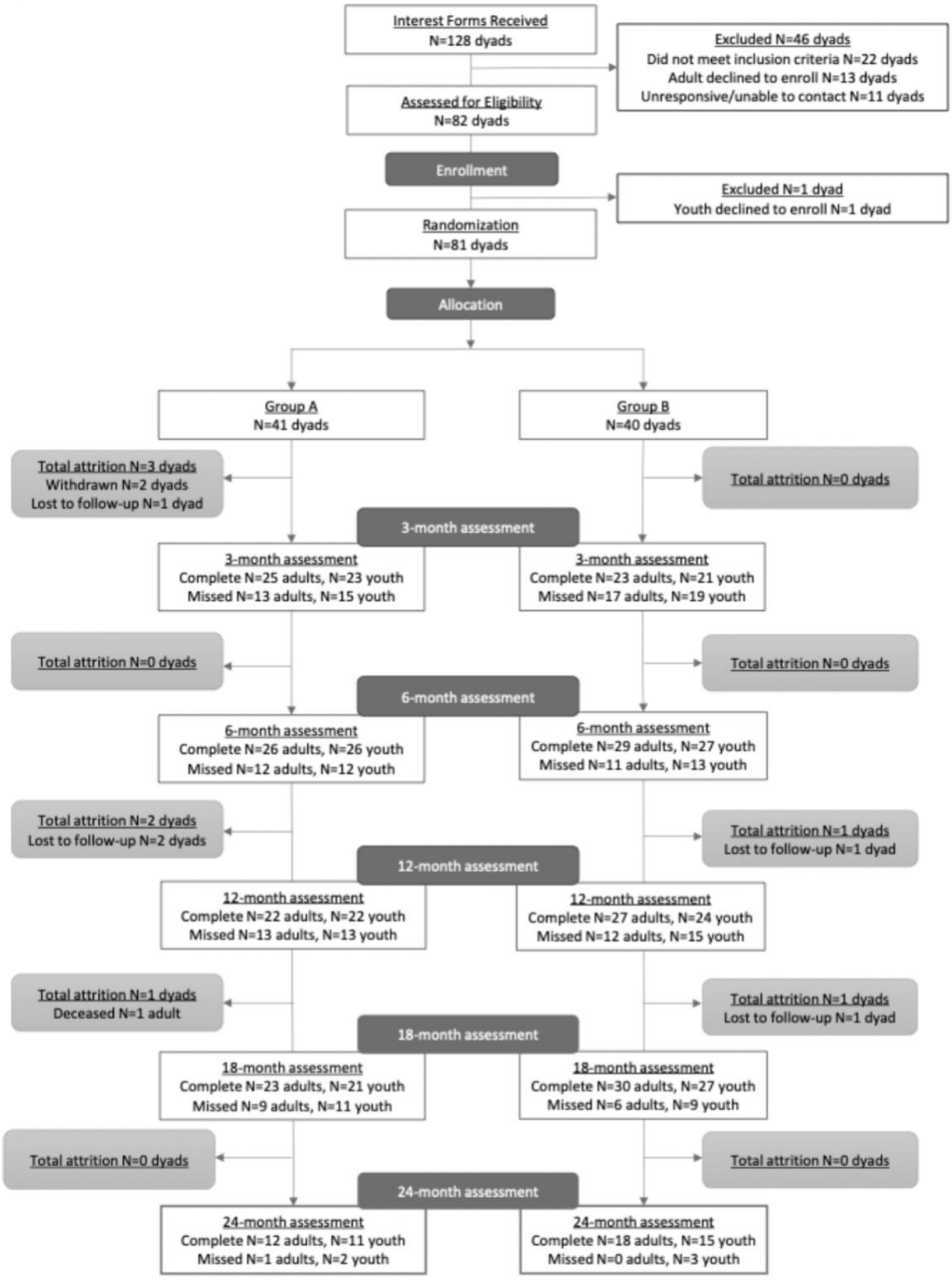
In communities that do not have enough eligible phase 2 participants to conduct a REM session, an eligible adult-youth dyad will be invited to complete a qualitative interview. A trained study team member will conduct the interview, which will take no more than 1 hour. Before the interview begins, the interviewer will walk the adult and youth through their consent/assent forms; the adult may participate in the interview alone if the youth is unable or uninterested in participating. Once consent forms are complete, the interviewer will turn on the audio recorder and ask the Appreciative Inquiry questions designed for phase 2 participants, which inquire about how the TOD lessons have impacted their lives. The interviewer may ask probing questions to better understand "ripples" or chains of causes and effects, and/or multilevel impacts (individual, family, community, etc.) per the TOD Theoretical Model (Figure 1). Upon

completion of the interview, each participant will receive a $50 gift card and 1 TOD logo-emblazoned item.

Round 2

The Round 2 REM session will include up to 50 participants, to be inclusive of the full study team from all communities: JHU team members (e.g., investigators, coordinators, data managers), Community Research Council members, Family Health Coaches, and Independent Evaluators. Two facilitators external to the TOD team will guide this session. Appreciative Inquiry interviews may be done in groups of 3-4, rather than in pairs, depending on the size of the group. Participants in the Round 2 session will be volunteers and will not receive compensation for their REM contributions. Otherwise, procedures for the Round 2 session will be the same as Round 1.

TOD Consort Flow Diagram



AMENDMENT HISTORY

Date	Type	Summary
March 2020	Amendment	Minor changes to Phase 1 (Pilot) protocol and form revisions for both Phase 1 (Pilot) and Phase 2 (RCT)
September 2020	Amendment	Revisions associated with Phase 1 (Pilot)
October 2020	Amendment	Revisions associated with Phase 1 (Pilot)
February 2021	Amendment	Revisions associated with Phase 2 (RCT)
March 2021	Amendment	University required addition of human subject research safety protocols related to COVID-19
May 2021	Amendment	Minor changes to consent and protocol
July 2021	Amendment	Minor changes to safety protocols related to COVID-19
August 2021	Administrative Amendment	Removal/addition of study team members
November 2021	Amendment	Phase 2 (RCT) - Revised self-report survey questions
December 2021	Administrative Amendment	Addition of new study team members
November 2022	Amendment	Phase 2 (RCT) Eligibility
January 2023	Amendment	Phase 2 (RCT) • Reduced sample size • Addition of Miigwech (Thank You) card to participants • New survey measures added at 24-month assessment
March 2024	Administrative Amendment	Removal/addition of study team members
December 2024	Amendment	Phase 3 (Qualitative) Ripple Effects Mapping