Title: Cooking for Health

Trial registration: This study was registered on ClinicalTrials.gov on October 9, 2018 with Identifier NCT03699709.

Version: 06/07/22

Purpose/Rationale:
The purpose of the Cooking for Health Study is to develop a distance-learning-based culturally-adapted healthy food budgeting, purchasing, and cooking intervention, adapted from Cooking Matters®, for American Indian (AI) adults with type 2 diabetes who reside in an AI community in South Dakota, and to test the efficacy of the intervention on: (1) change (from baseline) in self-reported intake of sugar-sweetened beverages (SSBs); and (2) change (from baseline) in the frequency of healthy and unhealthy food purchases.

Methods/Design:
Study design
The Cooking for Health Study is a randomized controlled trial (RCT), which will enroll 165 AIs who reside in a reservation community in South Dakota. Participants will be randomized to a 12-month intervention or control arm using a 1:1 randomization scheme. Participants in the intervention arm will complete a 12-month curriculum, which includes 12 distance-learning lessons (i.e., both paper material and videos) related to healthy food budgeting, purchasing, and cooking skills. Participants in the control arm will receive access to the intervention materials at the end of the study. All study participants will attend three in-person study visits for data collection at baseline (month 0), month 6 and month 12.

Study population
AI men and women 18+ years old with a physician-diagnosis of type 2 diabetes[17] who reside on the reservation or in a border town and self-report doing most of their household's food shopping and meal preparation will be eligible to participate in the study. Only one person per household will be eligible to participate to avoid non-independence of food choices and potential cross-arm contamination. Individuals who are pregnant, have a history of bariatric surgery, are on dialysis (or with underlying chronic kidney disease), or are cognitively impaired will be excluded from participation as these conditions may influence diet or ability to engage with the intervention. Additionally, individuals without a reliable place to cook or store food (e.g., homeless) will be ineligible to participate.

Curriculum Development
The Cooking for Health Study used Cooking Matters® as a foundation for intervention development. Investigators planned to: (1) modify and supplement the curriculum to use a distance-learning platform (versus standard in-person delivery) to maximize reach in a resource-limited setting; (2) implement a more comprehensive and longer-term curriculum (12 months rather than six weeks used by Cooking Matters®); and (3) focus on adults with type 2 diabetes (versus families with school-aged children, the current population on which Cooking Matters® focuses). However, focus groups with community members highlighted the need for more substantial adaptations to the curriculum. Further adjustments included: (1) a greater focus on food budgeting and meal planning for multi-generational families with limited budgets, including how to most effectively use government assistance, such as the Food Distribution Program on Indian Reservations (FDPIR), commonly known as commodity foods, or SNAP; (2) incorporation of healthy, traditional and locally available foods into the curriculum and recipes; (3) more detailed instruction on unit pricing, particularly for individuals with low literacy and numeracy skills; (4) focusing the curriculum on the ADA consensus recommendations for effective diabetes nutrition for management of type 2 diabetes, including limiting unhealthy

food and SSBs [12]; (5) food safety, including proper storage of fresh and frozen fruits, vegetables, and meats; and (6) the incorporation of culturally meaningful language, art, and photos throughout the curriculum. All modifications were made following the stages of cultural adaptation, as described by Barrera and Castro[18].

Informed consent

All research activities were approved by the University of Washington Institutional Review Board (IRB), the Indian Health Services Great Plains Area IRB, and the tribal health board. Study staff will obtain written informed consent from all study participants before data collection at their first study visit. Study staff will describe all study procedures and the risks and benefits of participation. Study staff will inform potential participants that participation in the study is voluntary, and participants may withdraw at any time. After study staff have addressed any questions or concerns, they will ask the participant to sign the consent form.

In-person study visits

All study participants will complete in-person study visits at baseline, month 6, and month 12 at the study field site on the reservation. Each in-person study visit includes a personal interview, a physical exam, fasting blood draw, and completion of several questionnaires to ascertain usual (i.e., past six months) diet and other diet-related behaviors (e.g. frequency of healthy and unhealthy food purchases, cooking confidence, food resource management, and household food shopping habits). During months 6 and 12, a random subsample of participants in the intervention arm (n=30) will partake in semi-structured interviews.

Randomization

Investigators will generate a 1:1 randomization sequence using a permuted block design with concealed blocks of variable size. Investigators will provide study staff with sequentially numbered sealed opaque envelopes that contain treatment assignment. After each participant's baseline data is collected, study staff will open the next-in-order sealed envelope to determine the participant's arm assignment (i.e., intervention or control).

Intervention materials

After randomization, participants assigned to the intervention arm will receive all intervention materials, including a binder with all paper materials (i.e., lesson handouts, recipes), a username and password to access videos on Canvas®, and a reusable shopping bag with several tools intended to enhance engagement with the study materials (i.e., calculator, measuring cup set for dry and liquid ingredients, measuring spoon set, stirring/cooking spoons, rubber scraper, turner, whisk, cutting board, knife set, and CalorieKing© Book). Participants randomized to the control arm will receive these materials at the end of the study.

Outcomes

The effect of the intervention on change (from baseline) in self-reported intake of SSBs and frequency of healthy and unhealthy food purchases are the primary outcomes of interest.

Statistical Analyses Plan

Intent-to-treat analyses will estimate the effect of the intervention on all outcomes of interest, compared to control, longitudinally across groups using general linear models.

Data management

REDCap®, a secure web application for building and managing online surveys and databases, will be used for data capture of all questionnaires using password-protected computers[32]. All data will be transferred, encrypted, and backed-up daily, except the food frequency questionnaire—which will be sent to the Fred Hutchinson Cancer Research Center (Seattle, WA) for analysis.

Data safety monitoring

Investigators will provide study oversight, ensure that the trial is conducted according to the study protocol, and will be responsible for the data and safety monitoring by ensuring the safety of all participants. As the risks of participating in the study are minimal, we do not anticipate numerous adverse events (AEs). All AEs will be reported according to the UW Institutional Review Board (IRB) and the Great Plains Area Indian Health Services IRB.

Discussion:

There is a critical need to develop novel, targeted, and sustainable interventions to promote healthy diet in rural AI communities. In partnership with the community, the work described herein will develop and test the effect of a culturally-adapted intervention to improve diet among AIs with type 2 diabetes. If successful, the intervention can be tailored to other rural and underserved communities. The results of this study will also inform further efforts to design and implement diet interventions in AI communities or other resource-limited settings.