

A multilevel obesity prevention trial for American Indian communities

Submission date 09/05/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/05/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 12/09/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims:

Obesity is a serious problem in the United States, especially in minority populations such as American Indian (AI) adults. There are many risk factors for overweight and obesity in AI adults, such as excess energy intake, high fat intake, and low physical activity (PA). For example, AI diets have been described as being high in fat, low in fruit and vegetable intake, and high in high-fat or empty calorie foods like fry bread, home-fried potatoes, bacon, sausage, and soft drinks. As far as PA, about half of AI adults do not meet federal PA guidelines. Reports show low PA and high inactivity in Chippewa and Menominee, Anishinaabe First Nations, AI adults in Kansas, and participating tribes in the Strong Heart Family Study. Obesity interventions with a focus on improving dietary intake and PA have taken place in AI communities, but with varied success. The Obesity Prevention and Evaluation of InterVention Effectiveness in NaTive North Americans (OPREVENT) intervention was designed to address the problem of obesity at multiple levels within a community, thereby increasing the likelihood of program participation and exposure. This study aimed to recruit several AI communities, and 424 community members, to participate. The goal is to improve the food and PA environments within the communities such that they are supportive of obesity prevention behaviors, including eating a healthy diet and being physically active. The study's findings will help to serve as a model for similar programs to be implemented in other AI communities.

Who can participate?

Adults between the ages of 18-65 years who are either the main food shopper or main food preparer in their households, a tribal member, and not pregnant

What does the study involve?

Participants complete several questionnaires at the start of the study (summer 2011) and at follow-up (fall 2013 and spring 2014). The questionnaires ask for information about diet, physical activity, food shopping habits, health attitudes, and environment. Three communities are randomly allocated to receive the intervention immediately, and two are randomly allocated to receive the intervention delayed or after completion in the immediate communities. The delayed start allows all communities to receive the intervention. The intervention consists of several activities within food stores, worksites, schools, and other community locations such as health centers. Activities include taste tests, cooking demos, community walking events, and

educational sessions. All activities are voluntary. Educational materials are also displayed and made available throughout the community.

What are the possible benefits and risks of participating?

Participants may benefit from improved health as measured by improved diet, being more physically active, or adopting healthier food and PA related behaviors. There should also be benefits to the community and future health status of community members because the results of the study are likely to influence future health programs. The main risk of participation is that there may be health, diet, and PA questions that are uncomfortable to answer.

Where is the study run from?

The study is run from the Johns Hopkins Bloomberg School of Public Health in Baltimore, Maryland. However, the intervention takes place within the specific communities and is implemented by local field staff. Exact locations cannot be disclosed at this time in order to respect the privacy of the participating tribal communities, however, general locations include the upper Great Lakes and Southwest regions.

When is the study starting and how long is it expected to run for?

April 2010 to March 2015

Who is funding the study?

US Department of Agriculture National Institute of Food and Agriculture

Who is the main contact?

Dr Joel Gittelsohn

Contact information

Type(s)

Public

Contact name

Dr Joel Gittelsohn

Contact details

615 N. Wolfe St.
Baltimore
United States of America
21205

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MDR-2009-05068

Study information

Scientific Title

Obesity prevention and research evaluation of intervention effectiveness in Native North Americans

Acronym

OPREVENT

Study objectives

H1: Compared with control communities, program participants in intervention communities will have significantly increased intakes of fruits and vegetables and fiber and reduced total energy and fat intakes, and subsequently reduced percent of energy from fat.

H2: Compared with control communities, program participants in intervention communities will have significantly reduced percent of time spent in sedentary activity and significantly increased total activity counts post-intervention.

H3: Compared with control communities, program participants in intervention communities will have significantly lower BMI, waist circumference and percent body fat post-intervention.

H4: Exposure to the intervention will be associated with improvements in knowledge, self-efficacy, risk perception, outcome expectations, behavioral intentions, and family social support which in turn will be associated with changes in PA and dietary behaviors.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Johns Hopkins University Bloomberg School of Public Health Institutional Review Board (JHSPH IRB), 06/05/2010, #2866
2. Indian Health Service, 10/01/2011, #N10-N-11
3. Navajo Nation Human Research Review Board, 21/12/2010, #NNR-10.287

Study design

Community randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Obesity

Interventions

The 14-month, six phase multi-level, multi-component obesity intervention administered by local trained field staff within food stores, schools, and worksites in five AI communities (three randomly allocated to receive the intervention immediately, two randomly allocated to receive the intervention delayed or after completion in the immediate communities). Intervention content aimed to change the food-purchasing environment, improve nutritional intake, and increase PA among community members. Intervention materials and activities included posters, brochures, flyers, newsletters, radio announcements, a school curriculum, giveaways, cooking demos, and taste tests. Outcomes were measured at follow-up in the fall of 2013 and spring of 2014, which was 14-18 months after baseline data collection in summer 2011.

Intervention Type

Behavioural

Primary outcome measure

1. Dietary quality and nutrient intake (fruit and vegetable servings, total energy, total fat), measured using brief FFQ and 24-hr recall at baseline (summer 2011) and follow-up (fall 2013 and spring 2014)
2. Physical activity (total PA, time spent sedentary), measured using IPAQ at baseline (summer 2011) and follow-up (fall 2013 and spring 2014)

Secondary outcome measures

1. Anthropometric measures (BMI, waist circumference, % body fat) measured at baseline (summer 2011) and follow-up (fall 2013 and spring 2014)
2. Psychosocial variables, measured using Adult Impact Questionnaire developed based on formative work within the five communities, at baseline (summer 2011) and follow-up (fall 2013 and spring 2014)

Overall study start date

01/04/2010

Completion date

31/03/2015

Eligibility

Key inclusion criteria

1. Between the ages of 18 and 65 years old
2. Living within the community for at least 30 days
3. Tribal member
4. Primary food shopper or preparer for the household

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Five clusters (communities); 85 participants per cluster; total n=424

Total final enrolment

299

Key exclusion criteria

1. Currently pregnant

Date of first enrolment

01/07/2011

Date of final enrolment

01/05/2013

Locations**Countries of recruitment**

United States of America

Study participating centre

Johns Hopkins University Bloomberg School of Public Health

Baltimore

United States of America

21205

Sponsor information**Organisation**

Johns Hopkins University Bloomberg School of Public Health

Sponsor details

615 N. Wolfe St.

Baltimore

United States of America

21201

+1 (0)410 955 3193

JHSPH.irboffice@jhu.edu

Sponsor type

University/education

ROR

<https://ror.org/00za53h95>

Funder(s)**Funder type**

Government

Funder Name

US Department of Agriculture National Institute of Food and Agriculture

Results and Publications**Publication and dissemination plan**

Study protocol and statistical analysis plan are not currently available. Study results will be disseminated in quarterly and yearly reports to all communities. Several papers based on formative work have already been published (see citation list below). The trialists intend to publish impact analysis in high-impact peer-reviewed journals within the next 12 months.

1. Gadhoke P, Christiansen K, Swartz J, Erickson K., and Gittelsohn J. 'Cause it's family talking to you': Children acting as change agents for adult food and physical activity in American Indian households in the Upper Midwestern U.S.. *Childhood*. 2015;22(3):346-361.
2. Gadhoke P, Christiansen K, Pardilla M, Frick K, Gittelsohn J. 'We're changing our ways': Women's coping strategies for obesity risk-reducing behaviors in American Indian households. *Ecol Food Nutr*. 2015;54(6):583-602.
3. Trude ACB, Kharmats A, Jock B, Lee K, Liu D, Martins PA, Pardilla M, Swartz J, Gittelsohn J. Patterns of Food Consumption are Associated with Obesity, Self-Reported Diabetes and Cardiovascular Disease in Five American Indian Communities. *Ecol Food Nutr*. 2015;54(5):437-454.
4. Roberts EB, Fleischhacker S, Pardilla M, Truth M, Gadhoke P, Christiansen P, Gittelsohn J. Self-reported physical activity among American Indian adults from two diverse regions. *J Rural Health*. 2015;1-10.
5. Christiansen K. H., Gadhoke, P., Pardilla, M, Gittelsohn, J. Work, Worksites, and Wellbeing among North American Indian Women: A Qualitative Study. 2017. *Ethn Health*. 2017 Apr 10:1-20. doi: 10.1080/13557858.2017.1313964.

Intention to publish date

11/05/2019

Individual participant data (IPD) sharing plan

The dataset is unlikely to be available because the data belongs to the tribal communities in which the intervention took place. American Indians constitute a vulnerable population and research protocol, especially surrounding data sharing, is very strict in order to protect the

privacy of participants and tribes. The data is held at Johns Hopkins University Bloomberg School of Public Health.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2019	12/09/2019	Yes	No