

# Pitfalls and Promise of Clinical Trials in the Community: Community engagement and participatory research with underserved populations

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# **Pitfalls and Promise of Clinical Trials in the Community:**

Community engagement and participatory  
research with underserved populations

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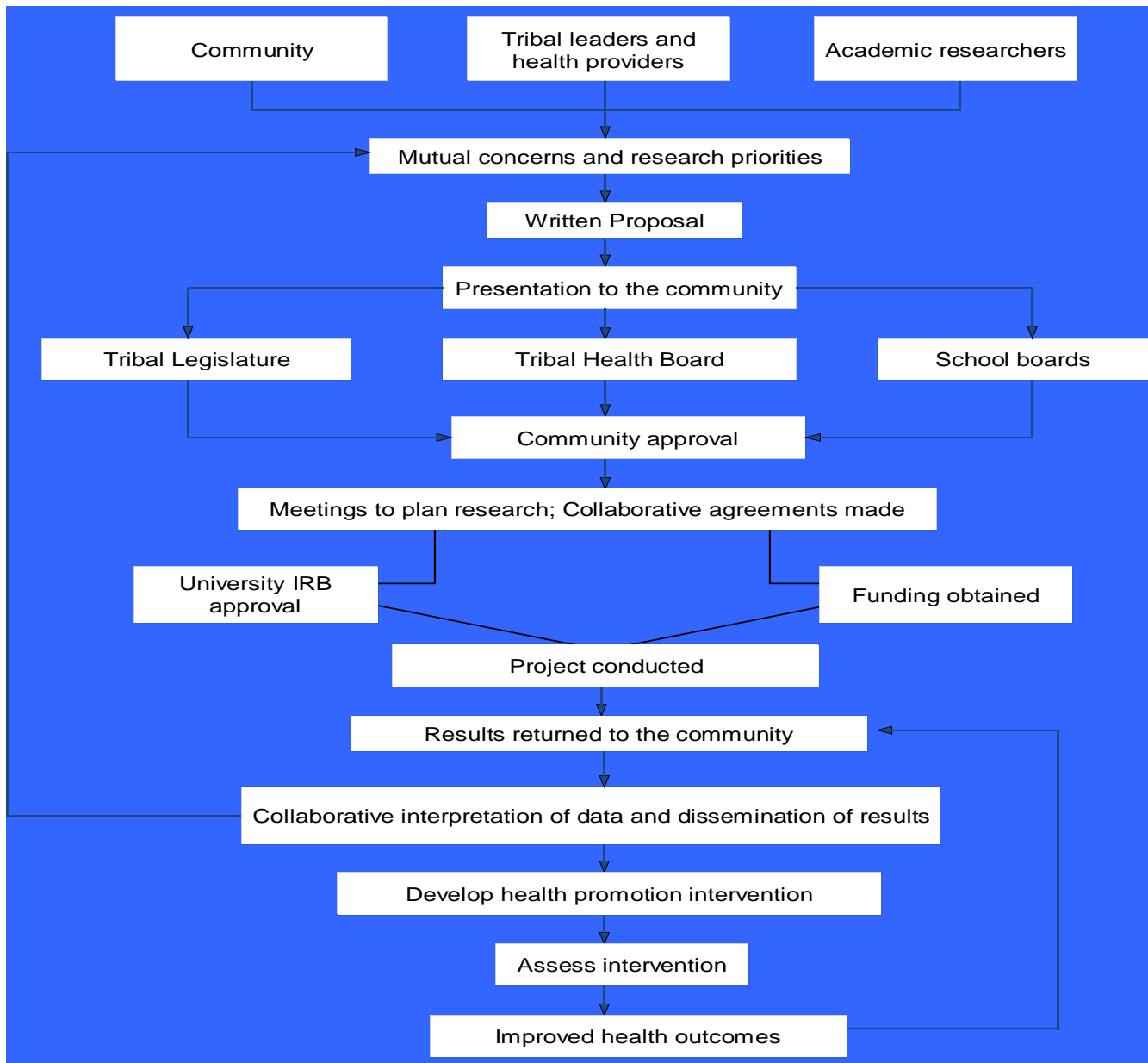
# Objectives

- Community based participatory research (CBPR)
- 3 research examples
  - Guardians of The Living Water
  - Ft. Peck Sexual Health Project
  - Healthy Children, Strong Families
- CBPR and COVID

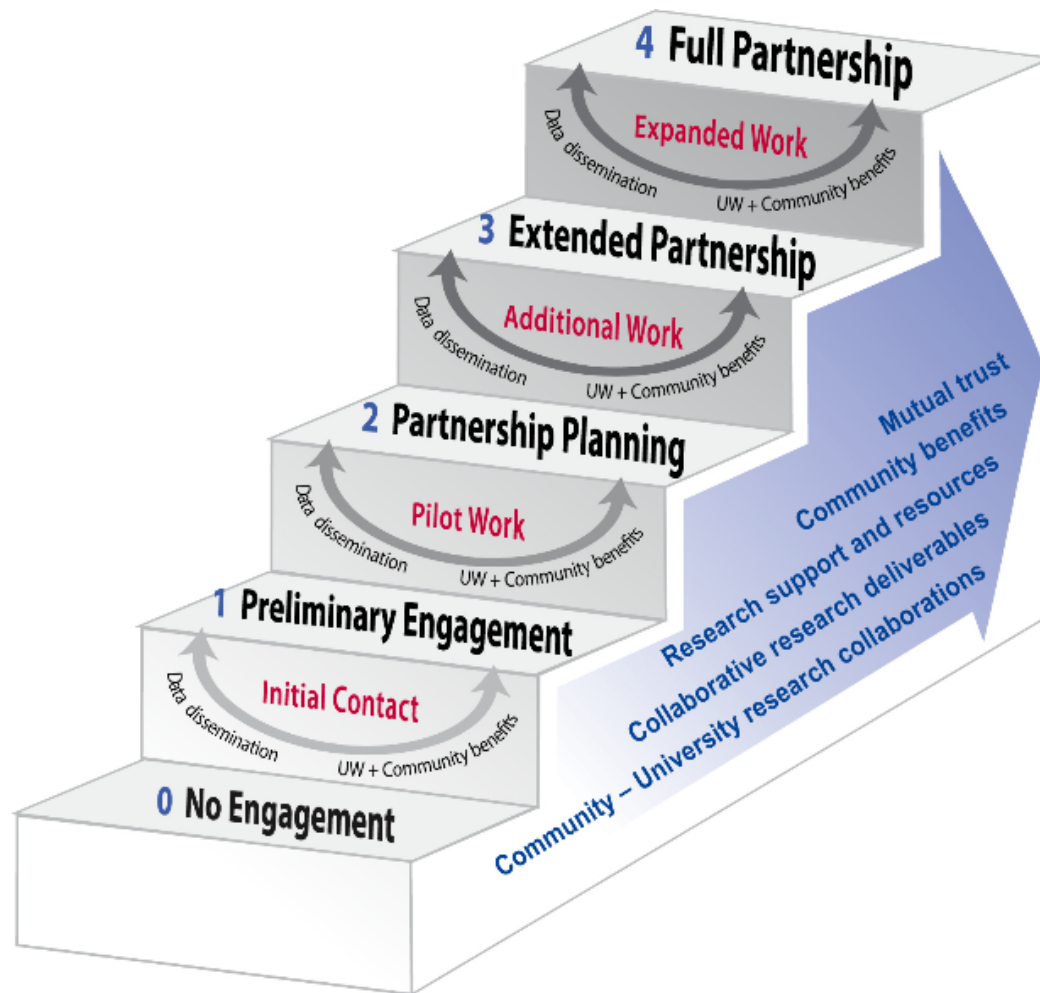
# Community Based Participatory Research

- Is a mutually respectful partnership between the researchers and the community being studied
  - Includes participation in formation of research question, research design, data collection, data analysis, and dissemination of results
- Value placed on the knowledge generated from the experience, lives and self-concept of the people involved in the research
- Intended outcome is individual and community empowerment to define issues and take action
- A process that educates both the researchers and the research participants

*Tsark, 2001.*



# Steps Model for Community Engagement and Evaluation



Adams, Academic Medicine, '17



# Guardians of the Living Water

Children as agents of change,  
increasing  
environmental health literacy.

Project Partners:

- Crow Environmental Health Steering Committee (CEHSC)
- Little Big Horn College (LBHC)
- Crow Agency Public School (CAPS)
- Montana State University (MSU)

Vanessa Simons, PhD  
Montana State University



# Specific Aims & Project Timeline

AIM 1: Extend CBPR partnership (LBHC, CAPS, MSU, CEHSC)  
Use CBPR process at all stages of research

Outcomes

AIM 2: Develop  
intervention

AIM 2: Refine intervention

Hypotheses:  
Children as agents of  
change increase  
Environmental Health  
Literacy  
↑ Functional Literacy  
↑ Interactive Literacy  
↑ Critical Literacy

AIM 2: Pilot test  
intervention

AIM 3: Implement intervention & conduct  
process evaluation

AIM 3: Analyze outcomes

Year 1

Year 2

Year 3

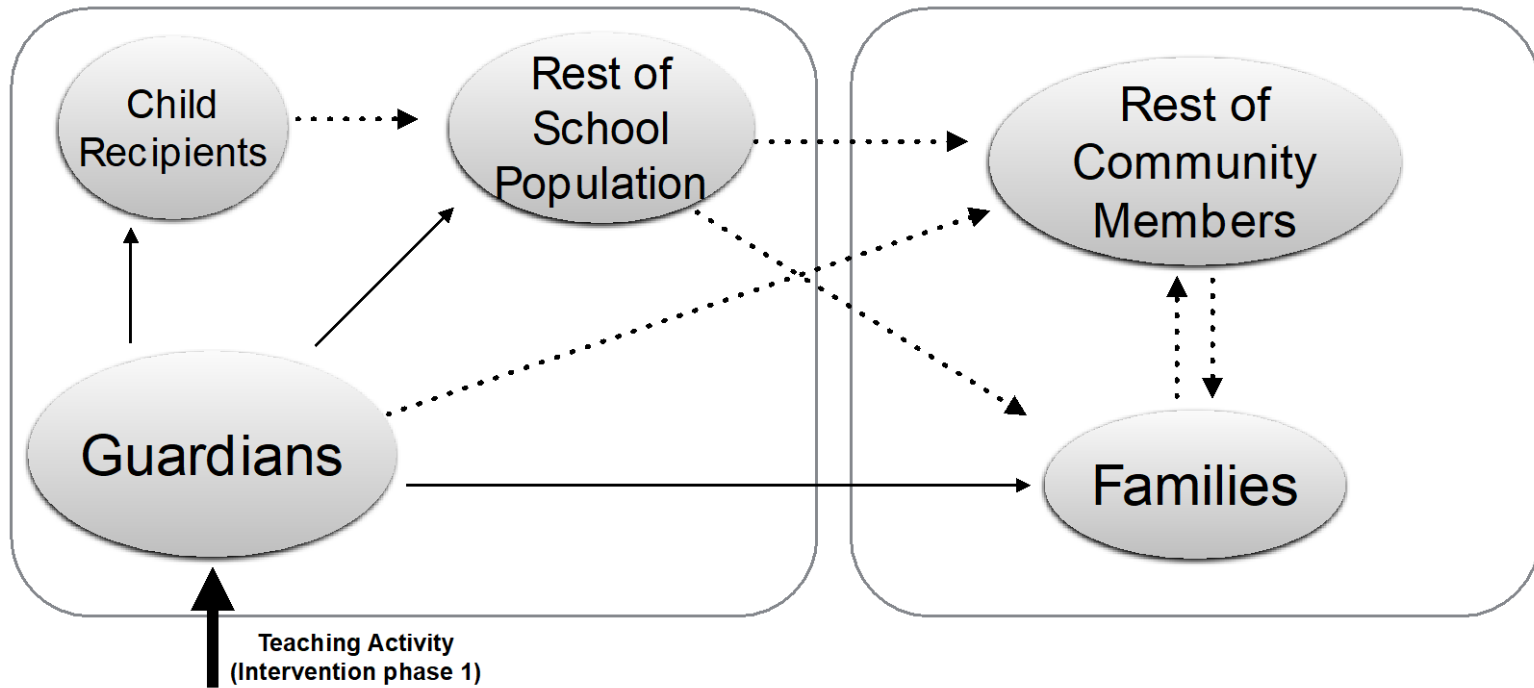
Year 4

Year 5



# SCHOOL

# COMMUNITY



**KEY:**

- Direct Influence of Guardians
- .....→ Indirect Influence of Guardians or Child Recipients
- Phase 1 of the Intervention conducted by teachers

Adapted from:  
Onyango-Ouma W, Aagaard-Hansen J, Jensen BB. The potential of schoolchildren as health change agents in rural western Kenya. *Social science & medicine*. 2005;61(8): 1711-22. do: 10. 1016/j.socscimed.2005.03.041. PubMed PMID: 15967559.



Photovoice presentations



Advocacy skills

Water testing

# Components of Curriculum

- Science based activities from Project Wet
  - Ask the bugs, Aqua Bodies, Life Box
- Field Trips
  - Water treatment plant, Stream assessment, Spring sample collection
- Art based activities
  - Drama Activities, Posters
- Storytelling



# Results so far:

- Our team has developed
  - Working definition of environmental health literacy
  - Model for a youth change agent program at Crow
  - Summer camp training manual for project staff
  - Curriculum for afterschool program
  - Evaluation plan
  
- Our team has implemented the Summer Camp and Fall afterschool program for past 3 years
  - Data collection and analysis
  - NSF grant submission, fall 2019

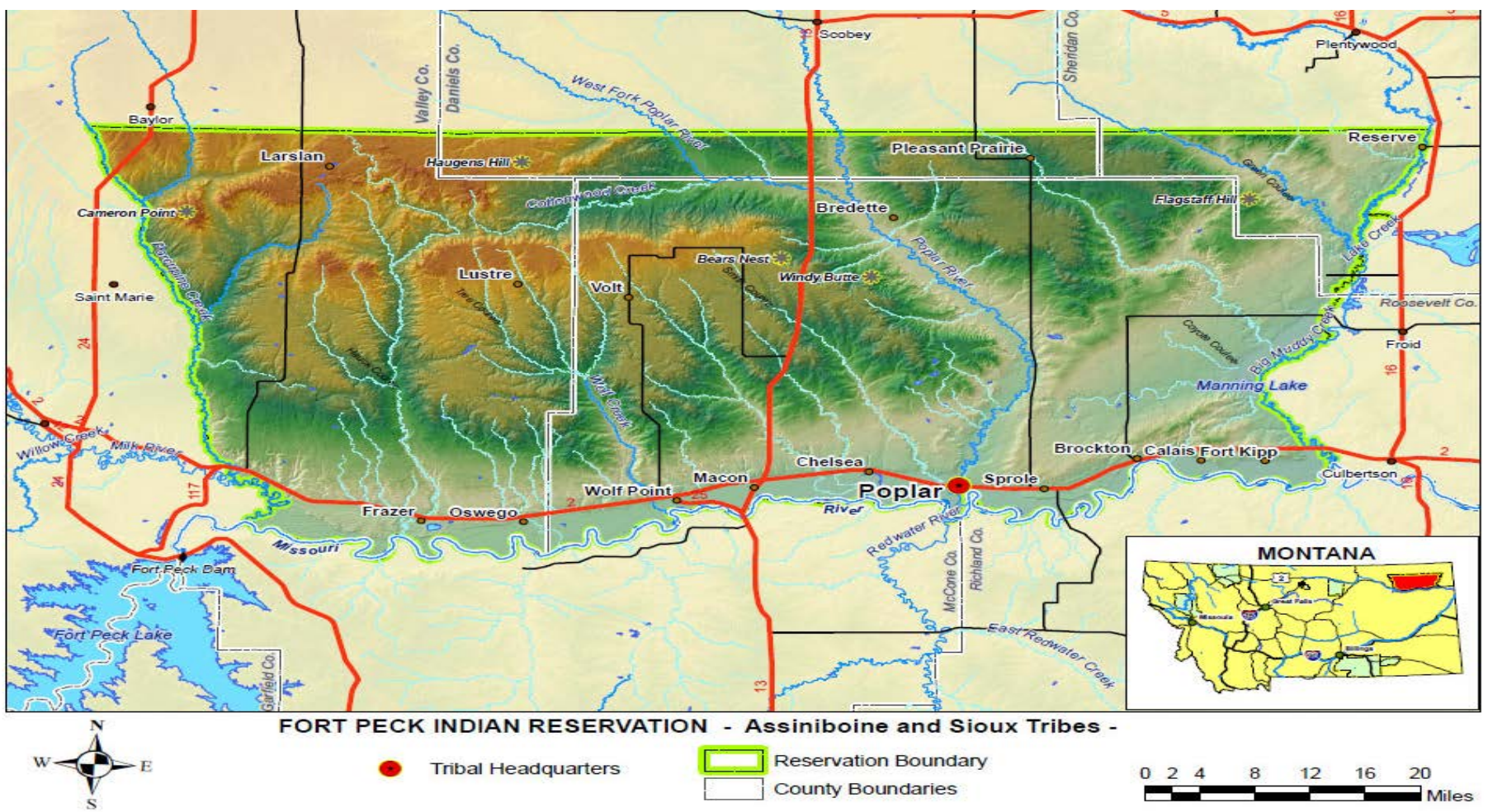


# EDAHIYEDO (They are There Now): The Fort Peck Sexual and Reproductive Health Project



Elizabeth Rink, PhD, MSW  
Montana State University





Indian Health Services  
 Fort Peck Tribal Health Department  
 Fort Peck Tribal Executive Board  
 Fort Peck Language and Culture Department  
 Roosevelt County Health Department  
 Fort Peck Tribal College

4 on reservation and 1 off reservation school  
 5 member community advisory board  
 4 Tribal Elders as needed consultants

# EDAHIYEDO OVERVIEW

- Target population is 15 to 18 year old Fort Peck Tribal members.
  - Sample Size = 315
- A community based participatory research (CBPR) multi level sexual and reproductive health (SRH) intervention constructed on ecological systems theory, utilizing a stepped wedge design (SWD).
  - A cluster randomized trial cross over design.
  - The 5 schools on the Fort Peck Indian Reservation will be the clusters that are randomized into the intervention.
  - NIMHD R01 started Fall, 2019

# COMPONENTS OF EDAHIYEDO

1. An school-based SRH curriculum specifically for AI youth called Native Stand design to address **individual level** factors that lead to sexual risk behaviors.
2. A **family level** curriculum called Native Voices tailored to increase communication between adult family members and youth about SRH topics.
3. A cultural mentoring component at the **community level** that pairs AI youth with older adults and elders to discuss traditional AI beliefs and practices about SRH.
4. A mobilizing strategy to activate a network of education, health care, and social service agencies at the **systems level** in Fort Peck to coordinate SRH services for 15- to 18-year old AI youth.



# OUTCOME VARIABLES

- Primary sexual risk behavior outcome: Condom use.
- Secondary outcome variables: Other sexual risk behaviors.
  - Onset of sexual intercourse, number of sex partners, other birth control use, and substance use.
- Measure coordination among education, health care, and social service organizations on the Fort Peck Indian Reservation to increase access to SRH services for AI youth.

# Community Responsive Trial Design

**Figure 4. Trial design and timeline for implementing N/E relative to grant and sites/schools.**

YEAR 1 (2018)				YEAR 2 (2019)				YEAR 3 (2020)				YEAR 4 (2021)				YEAR 5 (2022)											
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4								
Refine and tailor components of N/E	Site 1	<i>bsln</i>		<i>3mf</i>	<i>N/E</i>		<i>9mf</i>	<i>12mf</i>				Analysis / Sustainability Planning	Publication and Dissemination														
	Site 2	<i>bsln</i>		<i>3mf</i>	<i>N/E</i>		<i>9mf</i>	<i>12mf</i>																			
	Site 3	<i>bsln</i>		<i>3mf</i>	<i>N/E</i>		<i>9mf</i>	<i>12mf</i>																			
	Site 4	<i>bsln</i>		<i>3mf</i>	<i>N/E</i>		<i>9mf</i>	<i>12mf</i>																			
	Site 5	<i>bsln</i>		<i>3mf</i>	<i>N/E</i>		<i>9mf</i>	<i>12mf</i>																			
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;"></td> <td style="width: 80%;">Cluster unexposed to N/E</td> </tr> <tr> <td style="background-color: #d9e1f2;"></td> <td>Intervention cluster</td> </tr> <tr> <td style="background-color: #fff2cc;"></td> <td>Post-intervention cluster</td> </tr> <tr> <td colspan="2"> <i>bsln</i> = baseline data collection;  <i>mf</i> = 3, 9, or 12 months         </td> </tr> </table>																					Cluster unexposed to N/E		Intervention cluster		Post-intervention cluster	<i>bsln</i> = baseline data collection; <i>mf</i> = 3, 9, or 12 months	
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# Healthy Children, Strong Families (**HCSF2**)



- Community-engaged approach to improve young child health through home/family-based healthy lifestyles toolkit
- Based on Native approach of elders teaching life skills, instilling values of healthy eating and physical activity to the next generation

# Partners



Menominee Nation  
Wisconsin



Seneca Nation  
New York



First Nations Healthsource  
New Mexico



White Earth Nation  
Minnesota



Blackfeet Nation  
Montana



University of  
Wisconsin

*Funded by NIH R01-HL114912*



## HEALTHY CHILDREN, STRONG FAMILIES Six Targets to Reach a Healthy Life Balance



As part of the Healthy Children Strong Families program, you and your children will learn about six targets to help bring your lives into a healthy balance. These six lifestyle targets are based on traditional values of healthy eating, lots of activity, stress management and good sleep habits with the goal of preventing future disease. A key part of making changes is tracking your progress – both through goal setting and in pictures! Throughout the year, grab your camera and snap photos of your family being active and enjoying time together! These photos will come in handy at the end of the program....wait and see!

1) Be more active



3) Eat more fruits and vegetables



2) Reduce screen time



4) Drink less soda and sugary beverages, eat less candy and other "junk" foods



5) Manage Stress



6) Improve Sleep

# Breathe. Just Breathe.

Ever had one of those crazy stressful days when you feel like your shoulders are up near your ears and you almost need someone to push them back down to where they belong???

In addition to increased muscle tension, we also don't breathe deeply when we're feeling stressed out. Deep breathing can help release some of the tension and give us a mini-break so we can get on with our day.

Try this breathing technique the next time you're at the end of your rope. Yes, you may feel silly doing this, so try it when you're alone. (Although laughter is another good tension buster!)

- 1) With your right thumb, close your right nostril and inhale slowly through your left nostril.
- 2) Now close your left nostril with your pinky and ring fingers, release your thumb, and exhale slowly through your right nostril.
- 3) Keep your right nostril open, inhale, then close it, open the left nostril, and exhale slowly through the left.

That's one round. Start with three rounds, and work your way up to five. Then practice whenever you're feeling stressed out!

right!!

## PRIORITIZE HEALTHY EATING

Don't deprive yourself! Instead choose foods that you actually enjoy that are also lower in fat, sugar, and calories. Feel free to fill your plate at holiday feasts, but select fresh fruits, salad greens, and filling veggies instead of sugary desserts, fried foods, mountains of breads, or starchy entrees. You can still eat the "other" foods you enjoy, but take a smaller portion.

Here are some more ideas for keeping trim during the holidays.

- When eating turkey, choose white meat over dark. A 3-ounce serving of turkey breast (skinless) has 119 calories and 1 gram of fat (compared to dark meat with 145 calories/6 grams).
- If you're cooking, provide at least one healthier option per category. For dessert, offer a fresh fruit option. For side dishes, offer a vegetable option instead of potatoes or rice.
- If you are going to a party, bring a healthy dish that you can enjoy. Have a light snack beforehand so you're not starving and easily tempted when you get to the party or buffet.
- When dining out, decline the bread and butter plate or limit yourself to just one piece.

Resolve to maintain and don't gain and you'll have NO regrets come January 1<sup>st</sup>!



**What is TV Turnoff Week?** This is a week for families to reconnect with each other by turning off, or dramatically reducing entertainment screen time (TV, video games, internet games etc.).

**Why should I try this with my family?** Consider some facts:

- The average American youth spends more than 7 1/2 hours a day using electronic media (TV, computers, video games, cell phones etc.). That's almost 53 hours a week – more time than most adults spend at work!
- Kids with a TV in their bedroom watch an additional 4.8 hours of TV every week!
- Time in front of a screen is related to weight gain, poor sleep and other health issues, and that's even true if the TV is "just on" but you're not actively watching!



The goal of TV Turnoff Week is not to banish screens from your home forever, but to take a break and see how it feels to be together without any distractions. You can use this week to discover active leisure pastimes the whole family enjoys! You might also take this week to decide what your family's screen time rules will be once TV Turnoff week is over!

How can you manage your family's screen time?

No muffin tins? No problem! Simply use paper muffin cups instead of the tin. Bonus - using paper muffin cups alone, or inside the tins will speed clean-up even more.

Need some suggestions for what to serve? Try these:



baby carrots  
sandwich cut-outs  
applesauce

low fat ranch dip  
broccoli trees  
peas



string cheese  
apple slices  
green beans

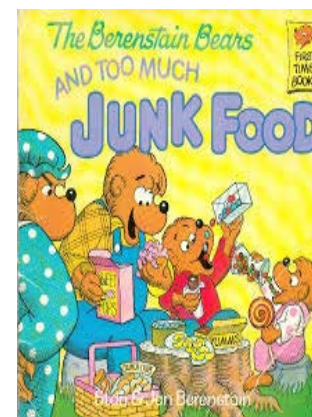
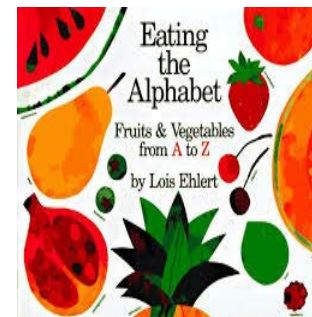
whole grain crackers or pretzels  
noodles with tomato sauce  
graham cracker squares

Have older kids who need larger servings? Use a twelve-cup muffin tin. Even teens will get a kick out of dinner this way!

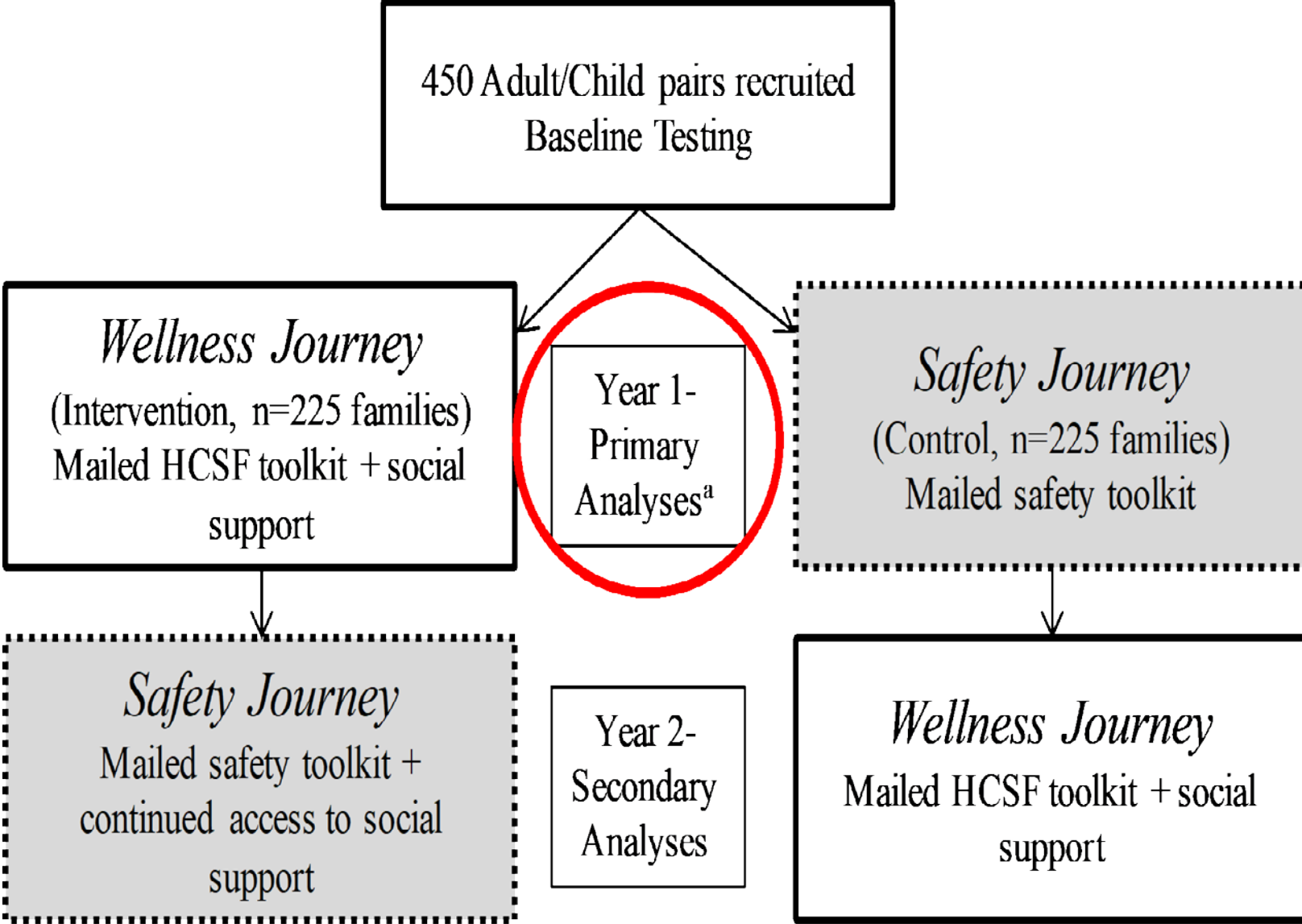
Another sure fire way to get more veggies into kids? Serve them veggies first! A recent study has shown that if you serve kids a vegetable BEFORE they have their regular meal (think carrots, celery or other favorite bite size veggies) they will eat those vegetables AND they will eat more of the vegetables that you serve with their meal.

We think that's a win, win!

So set out veggies for snacking while you're making dinner and let the kids have at it!

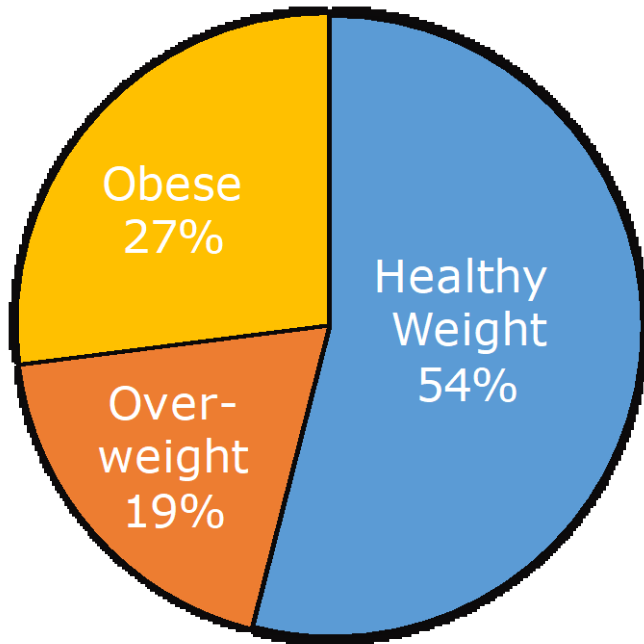


# Community Responsive Trial Design

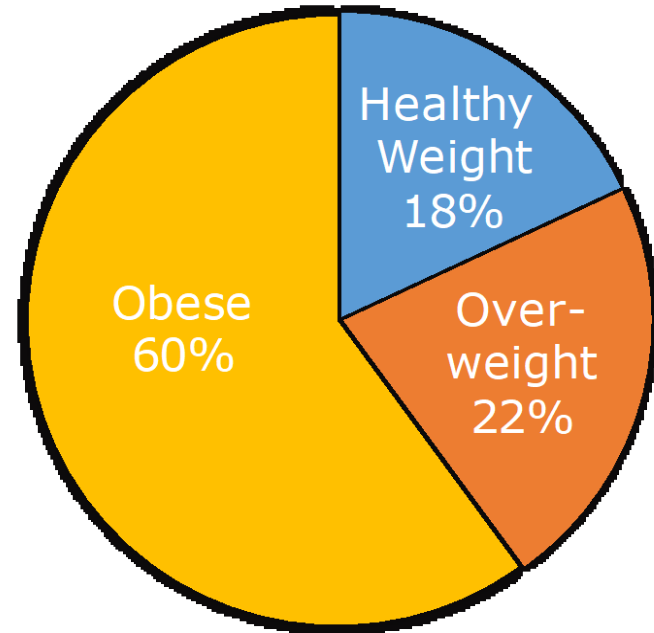


# Baseline

## CHILD WEIGHT STATUS



## ADULT WEIGHT STATUS



450 adult/child pairs = 100 % recruitment  
Year 1 dropout = 16%



# For Wellness Families after Year 1...

- Diet patterns significantly improved (adult and child,  $p < 0.05$ )
- More reported moderate/vigorous physical activity (adult,  $p < 0.05$ )
- Trend for reduced screen time (children,  $p = 0.06$ )
- Readiness to change health behaviors significantly improved (adult,  $p < 0.05$ )
- BMI stabilized or decreased but NS

# Challenges

- Geographic distribution of sites
- Family-level challenges
- Cell/internet service interruption



# Successes

Local administration of study

High recruitment and retention

Encouraging behavior change

High participant satisfaction

Family resiliency

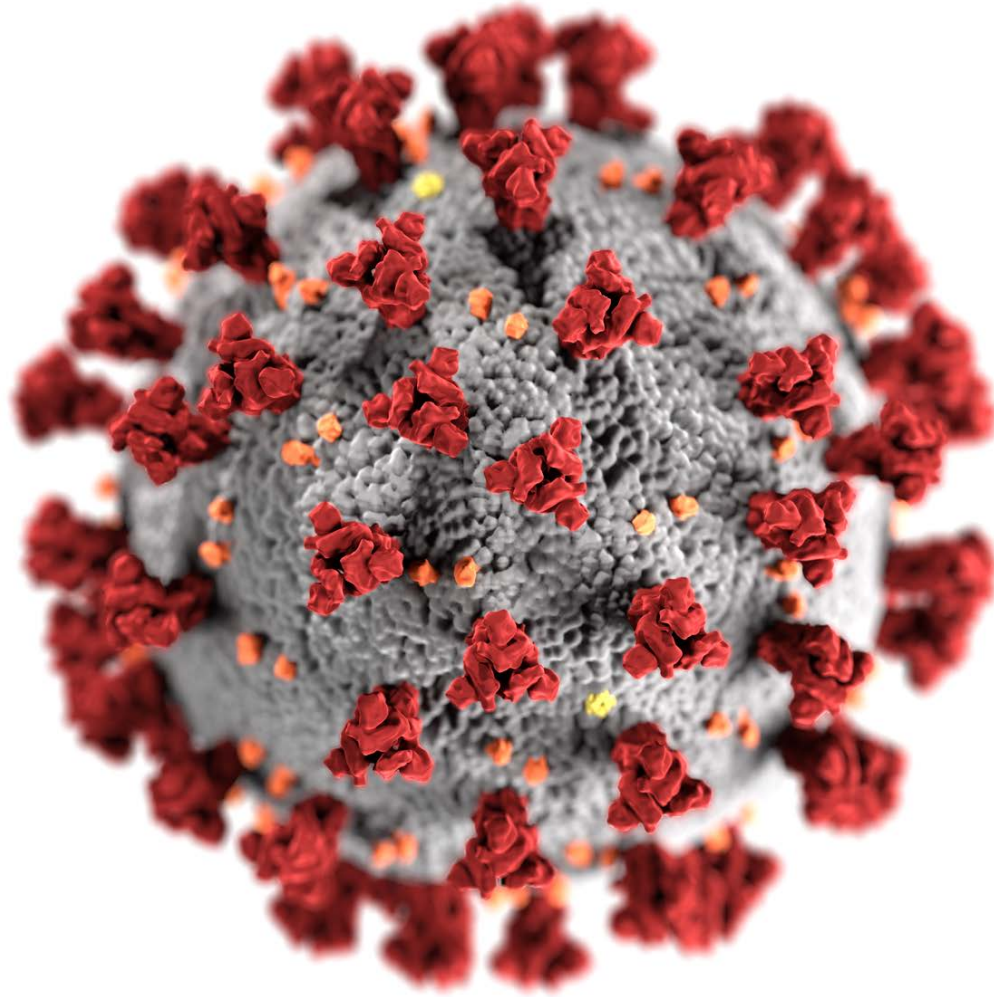
Positive community-level changes



# Conclusions

- Indigenous and Community knowledge and understanding of the root causes of community issues is critical
- Community based data as a catalyst for change
- Use evidence-based approaches AND community input in intervention
- Having a shared vision and multi-sector partnerships moves beyond trauma and into action
- Long-term partnering with communities is essential to promote effective interventions and improve healthy equity

# NOW WHAT?



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# MONTANA COVID STUDY

- We are trying to increase our understanding of the serology of COVID as well as viral sequencing while also increasing public health testing capacity in high-risk rural and tribal communities
- We need \$, supplies, IRB/IBC, epidemiologists, basic scientists, university and local coordinating staff, university support
- We also need clinical partners and public health for coordinating testing efforts with clinical results and public health response in low resource and chaotic environments
  
- “Did I mention that your life is on the line?!”

# CBPR and COVID

- Trying to respond to a pandemic requires: partners that already trust you, solid connections between clinicians, public health and communities, AND responsive and flexible university and governmental systems.
- Partnership development on steroids
- Coordinating center that can pivot
- LOTS of calls/zooms/texts/effort
- Responsive leadership
- Stepping out of our comfort zone
- NOT rearranging our spice cabinets or knitting scarves!



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**Center for American Indian and  
Rural Health Equity (CAIRHE)**  
[www.montana.edu/cairhe](http://www.montana.edu/cairhe)