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# BMJ Open

## Assessing health impacts of home food gardens with Wind River Indian Reservation families: protocol for a randomised controlled trial

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17 Assessing health impacts of home food gardens with Wind River Indian Reservation families: protocol  
18 for a randomised controlled trial  
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## ABSTRACT

**Introduction:** This community-based participatory research (CBPR), called *Growing Resilience*, will be the first randomised controlled trial we have identified designed to evaluate impacts of home gardening on family health. It is based on observational studies suggesting home food gardening has myriad health benefits, Wind River Indian Reservation (WRIR) families' interest in home gardening, and the need to end Native American health disparities with empowering, appropriate, and effective health interventions.

**Methods and analysis:** A total of 100 Native American families in WRIR who have not gardened recently but want to start a garden will be randomly allocated (1:1) to intervention (receiving two years of support designing, installing, and maintaining a home food garden of at least 80 square feet) or to delayed-intervention control (receiving same gardening support after two years of data collection). Willing family members aged 5 and up will participate in data collection sessions each February and August for 2 years, with blood, biometric, and survey measures at each. The primary outcome is adult body mass index (BMI). Secondary outcomes include child BMI, physical and mental health, hand strength, diabetes control, and food security. Primary analysis will be intent to treat (ITT), using univariate and bivariate descriptive statistics followed by a mixed model to estimate the ITT effect of the intervention using ANCOVA estimation. We will also examine treatment affects using a gardening fidelity measure, combined adult and child BMI outcomes using an LMS z-score reference data set, and possible mechanisms of health impacts.

**Ethics and dissemination:** This protocol was approved by the University of Wyoming Institutional Review Board and the project's Community Advisory Board. De-identified data will be shared with each tribe, and results will be published in peer-reviewed journals, summarized for distribution in WRIR, and shared at a national event to be hosted in WRIR in 2020.

**Key Words:** protocol, RCT, CBPR, home gardens, Native American, Wind River Reservation, LMS z-score, BMI

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study leverages WRIR assets of land, family, culture, and community health organizations to learn how to reduce health disparities by supporting Native American families and communities in improving their health.
- While home food gardening shows promise as a family-based health promotion intervention, this will be the first randomised controlled trial of the health impacts of home food gardens.
- By generating an LMS z-score reference data set from recent NHANES data for people aged 5 to 74, this study aims to provide the first internally consistent single health outcome measure for interventions that may impact BMI of all family members.
- Participants are drawn from a population interested in starting home food gardens. Not all families, in any community, will wish to garden.
- This study cannot be blinded due to the nature of gardening and to conducting a study in a tightly knit community as part of a participatory action research partnership.

## INTRODUCTION

As in all sovereign nations in the US, the Northern Arapaho and Eastern Shoshone tribes that share the Wind River Indian Reservation (WRIR) in Fremont County, Wyoming are survivors of the historical trauma of colonialism. The average age of death for Native Americans in Fremont County is just over 53 years old, with immediate causes including murder, suicide, traffic accidents, chronic liver disease, cancer, diabetes, and cardiovascular disease [1, 2]. Type II diabetes rates in WRIR are at least 11%, double the state-wide rate [3, 4]. Approximately 60% of middle-school-aged children are overweight or obese, also more than double the rates for children overall in Wyoming,[5] and over 70% of adults in WRIR are obese, nearly triple the state-wide rate [4]. Effective and appropriate health promotion interventions for tribal families, in WRIR specifically and among sovereign nations in the US generally, are desperately needed.

Home food gardening shows promise as a family-based health promotion intervention. A growing body of observational research suggests that home and community gardens improve health in many ways, including increasing food security,[6, 7] fruit and vegetable intake,[8-11] and physical activity [8, 12, 13] while reducing stress [14, 15]. However, to date, no randomised controlled trials have been done to more conclusively identify health impacts of home gardening.

Specifically within WRIR, many families showed interest in receiving technical and financial help in establishing or expanding home gardens during a five-year participatory action and research partnership called Food Dignity. In response, partners at University of Wyoming (UW) and WRIR tribal health and community-based organizations partnered in 2013 to co-design and implement a feasibility pilot study about health impacts of home gardens on the reservation. The Growing Resilience project, for which the protocol is described here, grew out of that pilot study. This appears to be the first randomised controlled trial (RCT) of the health impacts of home food gardens, in any community setting. This study will also contribute to a limited literature about effective and appropriate health promotion strategies for use in and by Native American communities.

## METHODS

### Study Design Overview

About 100 Native American families in WRIR who are interested in starting a new home food garden will be recruited over three years. Participants will be randomly assigned by household to one of two arms: home gardening support for two years or control with delayed intervention after two years. This RCT was designed using the CONSORT checklist and is registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (number NCT02672748).

Participants will take part in four health data collection sessions, two per year. These sessions will be in February, prior to gardening activities each year, and again in August at the height of gardening season. Adult data collection includes biometric information (BMI, waist circumference, blood pressure, and hand strength); blood serum analysis (including a standard blood chemistry panel, HbA1c, vitamin D, and serum beta carotene); and survey-based measures including food security and physical and mental wellness. Child measures (ages 5-17) collected include BMI, waist circumference, and HbA1c via finger-prick blood testing.

Adult BMI is the primary health outcome. Primary analysis is a mixed model that will be used to test for the effect of the garden intervention on adult BMI, controlling for baseline weight, gender, age, and tribe and accounting for household clustering.

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3 Secondary analyses will study the effects on a range of other biometric, blood and survey health outcome  
4 variables and on intra-household effects. Beyond BMI, health outcomes of particular interest are impacts  
5 on mental and physical health, hand strength, food security among food insecure households, and diabetes  
6 control among those who are either diabetic or pre-diabetic.  
7

8 To investigate the intra-household effects we will compare relative changes of individual-level BMI Z-  
9 scores for all children and adults in a survey household. These Z-scores will be constructed using  
10 NHANES survey data for people aged 5 to 74 as the reference population and following the statistical  
11 methodology developed in Naschold (2018) [16].  
12

13 We will also examine possible mechanisms that cause changes in health outcomes (e.g., serum status of  
14 Vitamin D and/or beta-carotene). We also briefly describe protocol development for analyzing outcomes  
15 with adjustment for any reported changes in medication or supplement dosage.  
16

17 In addition, qualitative methods for shedding light on project process, outcomes and mechanisms will also  
18 be used, including photo narratives, focus groups, participation and observation, and interviews. These  
19 methods will be described elsewhere.  
20

## 21 **Project Partners**

22 Growing Resilience is a community-based participatory research project. It was co-designed by WRIR-  
23 based and UW partners, largely during the 2013 feasibility pilot, and is overseen by a Community  
24 Advisory Board. Reservation-based partner organizations include native-run non-profit organization Blue  
25 Mountain Associates (BMA), community health representatives (CHRs) from Eastern Shoshone Tribal  
26 Health and the Wind River Development Fund (whose CHR focuses primarily on Northern Arapaho  
27 family recruitment). Non-reservation-based partners include staff at UW's division of Kinesiology and  
28 Health, staff at the UW-based Wyoming Survey & Analysis Center (WYSAC), UW technicians who  
29 assist at the health data collection sessions, and phlebotomists from the non-profit health organization  
30 Wyoming Health Fairs.  
31

32 BMA leads design and implementation of the gardening intervention, including development of a garden  
33 guide, overseeing an annual gardening workshop, assisting with garden installation, and providing  
34 ongoing support and mentorship for all project gardeners. CHRs lead family recruitment and retention  
35 efforts. UW leads collection of health metrics and data analysis efforts. The Community Advisory Board  
36 participates in policy decision-making in regard to ongoing project design and public representation;  
37 advocates for community interests in regard to research data collection, ownership and dissemination;  
38 serves as an additional contact point for all research participants seeking information or assistance with  
39 their involvement in the project; and considers how to maintain the capacity, infrastructure, and  
40 momentum of the gardening program beyond the life of the funded project.  
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## 44 **Participants**

45 To be eligible to participate, a family must meet the following requirements: 1) live within the boundaries  
46 of the Wind River Reservation (including Riverton, WY); 2) have at least one member enrolled in a  
47 federally-recognized tribe; 3) have at least two adults (or one adult for single-adult families) willing  
48 participate in two years of gardening and four health data collection sessions over two years; and 4) have  
49 interest in starting and sustaining a home food garden, but don't currently have a garden over 30 square  
50 feet. Though the gardening intervention will be at the household level, data collection and analysis will be  
51 at the individual level. Adults living in the household and children aged 5 or older can enroll in the study  
52 to participate in the data collection.  
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3 Even though adult BMI is the primary outcome of this study, being overweight or obese is not part of the  
4 eligibility criteria. About 70% of adults in Wind River are obese [4] and perhaps another 20% are  
5 overweight, and at least two adults per participating household are expected to enroll in the study. Thus,  
6 the study team and the advisory board for the pilot study decided that the ethical and practical issues that  
7 screening for eligibility by BMI would raise were not worth surmounting.  
8

9 Children are included in the study because family health and participation was a priority set by the  
10 advisory group during the pilot phase, which had included only adult family members in data gathering.  
11 Children who are under 5 years old when the family enrolls in the project may “age in” to data collection  
12 procedures as long as they can participate in at least two data collection sessions. Similarly, youth who  
13 turn 18 during their family’s enrollment in the study may elect to participate in adult data measures (i.e.  
14 blood draw, blood pressure, hand strength, and survey). If a participant becomes pregnant or incarcerated  
15 while taking part in the study, he or she will not undergo data collection for the duration of pregnancy or  
16 incarceration.  
17

18  
19 The goal is to enroll 100 families in three waves over the first three years of Growing Resilience, with 20  
20 in the first year and then 40 in each of the next two years. Eastern Shoshone Tribal Health and the Wind  
21 River Development Fund each aim to recruit 50 households. They will primarily draw from the hundreds  
22 of families they already serve, though public events and media advertising will also be used.  
23

### 24 **Patient and Public Involvement**

25 As discussed in the introduction, Growing Resilience was designed to meet the expressed needs of  
26 families in WRIR for more home gardens. Project partners from UW, tribal health programs, and BMA  
27 focused on home gardens based on families’ experience that food sovereignty depends on having food  
28 (including food gardens) close to their homes, given the large geographic size of WRIR and many  
29 families’ lack of access to reliable transportation.  
30

31  
32 Partners then collected feedback on the 2013 pilot from project participants. Changes resulting from this  
33 feedback included adding children aged 5-17 to the study (based on participants’ priorities for family-  
34 based interventions); setting incentive amounts for participating in health data collection sessions (based  
35 on participants’ assessment of the burden of participation); modifying survey questions and adding  
36 multiple modes of survey administration (based on participants’ experience and preferences taking the  
37 pilot survey); and setting the intervention duration to two years (based on project partners’ observation  
38 that most participants needed more than one year of gardening support to develop successful gardens.)  
39 One of the participants from the 2013 pilot project is now on the project’s Community Advisory Board  
40 but otherwise participants are not directly involved in ongoing study recruitment and conduct. However,  
41 many new participants join because they have heard of the project from current participants and wish to  
42 take part.  
43

44 Participants receive ongoing reports of their personal health information (including biometrics and blood  
45 chemistry panel) after each data collection session they attend. Additionally, results will be summarized  
46 for distribution in WRIR and shared at a national event to be hosted in WRIR in 2020.  
47

### 48 **Calculation of Sample Size**

49  
50 Sample size calculations were performed with adult BMI as the primary outcome. The feasibility pilot  
51 study data, combined with demographic data about WRIR, implies that the average participating family  
52 would have 2 adult and 2 child participants in the study. Thus, 100 families would include 200 adult  
53 participants.  
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The 80% power calculations below include a family-cluster design effect of 1.1 among adults in one household [17], an attrition rate of 16%, and a difference in adult BMI change between control and intervention groups of 0.5 over the two years of intervention (0.75 vs. 0.25; with a two-tailed test,  $\alpha=0.05$ ;  $\sigma=1.1$ ) [18]. Assumptions are based on the literatures cited and on our pilot data.

Design effect of household adult clusters =  $1.1 = 1 + (m-1)*ICC = 1 + (2 \text{ adults} - 1)*0.1$

Sample size needed (each group) =  $76 = 2[(1.96+.842)^2*\sigma^2]/(u1-u2)^2 = 2[(1.96+.842)^2*(1.1)^2]/(0.75-0.25)^2$

Planned sample size (each group) =  $100 = 50 \text{ families} * 2 \text{ adult participants per family on average}$

Planned sample size (each group) including design effect of household clusters:  $91 = 100/1.1$

Adult attrition rate this allows:  $16\% = 1 - (76/91)$ .

In sum, before attrition and adjustment for family cluster effects, this study requires 152 adults (76 per group) to power the study at 80%. “Discounting” the planned sample of 100 adults per group for family cluster effects means reaching the recruitment goal statistically provides “91” adults per group. Thus, this sample size adequately powers the study, allowing for 16% attrition, while attending to constraints of budget and institutional capacity. Additional families will be recruited in the fourth year if attrition or a smaller effect size necessitate that.

### Randomisation and Group Assignment

A total of 100 families will be recruited and enrolled in the study in three waves. The first wave, recruited in the first year, will include 20 families. Wave 2 in year 2 of the project and wave 3 in year 3 of the project will include 40 families each. About half of the families in each wave will be recruited by CHRs from Eastern Shoshone Tribal Health (with a focus on Eastern Shoshone families) and the other half by Wind River Development Fund (with a focus on Northern Arapaho families).

Staff at UW’s WYSAC will oversee the randomisation process. Each wave will be randomised to control or intervention groups in a 1:1 ratio using fixed-block randomisation, with half of Northern Arapaho-recruited families and half of Eastern Shoshone-recruited families assigned to get gardens and half assigned as controls/delayed intervention. The rationale for fixed-block (rather than simple) randomisation is practical and cultural. Practically, establishing the intervention gardens is so time and planning intensive that BMA needs managed and predictable numbers of families with whom they will work. Culturally and politically speaking, each tribe prefers to receive approximately equal services each year. In addition, families are informed of their assignment before the first baseline data collection, as this was an ethical priority for tribal partners. The flow chart in Figure 1 summarizes the randomisation, intervention, and data gathering design.

[FIGURE 1]

### Garden Intervention

Families randomly assigned to intervention receive a full gardening support package for two years from BMA. After the baseline data gathering session each February, the half-time, year-round garden manager will meet with each family to plan their garden. The first-year support package includes the following: 1)



consultation (on location; whether in-ground, raised bed, container; and what they would like to grow), 2) garden bed installation, 3) purchase of materials (e.g. tools, starts, and seeds), 4) ongoing mentorship including garden visits, and 5) gardening workshops. The planned average budget for this package is \$700 per family, excluding the manager's time and the labor costs of seasonal hires. Gardeners will maintain gardens through the season (e.g. watering, weeding, and harvesting). Each garden will be different, based on the participants' interests and needs, but will be a minimum of 80 square feet per family. Who participates in gardening is at the household's discretion.

During the second year of garden support, BMA will provide additional soil, soil amendments, seeds, seedlings, and tools as needed, and ongoing mentorship and support for renewing the food garden. The planned average budget, per family, for the second year of support is \$200.

Primary outcomes will be analyzed as intent to treat, regardless of implementation fidelity. However, we will also consider fidelity in secondary analyses, running a mixed model of significant outcomes against a measure of garden success. This measure is in development based on a combination of two indicators. One is the percent of planted garden square footage in August out of the square footage planned and prepared in May (with prepared plot size provided by the BMA gardening manager and planted size estimated from photos taken by BMA staff and the participants themselves). The other is an assessment by the gardening manager of the extent to which each family planted and maintained their garden, using a 5-point scale. Implementation fidelity will also be compared with the records of intervention support to inform intervention design.

After the two seasons of gardening support and four data collection sessions are over, then families assigned to the control condition will receive the same first-year gardening support services from BMA as the intervention families do. In their second year they will receive \$200 in credit at the gardening store of their choice to purchase what they need for renewing their gardens.

### Quantitative Data Collection

Twice per year for two years, trained technicians will collect health indicator data from adult and child participants. The primary outcome after two years of gardening support is adult BMI. Secondary adult outcomes include physical and mental health (on the SF-12v2 survey), food security, hand strength, and HbA1c. For children 5 and older, we are collecting BMI data and, via finger-prick tests, HbA1c. Table 1 summarizes the quantitative data collected at each of the four sessions.

Table 1: Health indicator data collected for adults and children, in Feb and Aug each year for two years.

	<b>Biometric</b>	<b>Blood-Based</b>	<b>Survey-Based</b>
<b>Adults</b>	<ul style="list-style-type: none"> <li>• BMI (height &amp; weight)</li> <li>• Waist circumference</li> <li>• Blood pressure</li> <li>• Hand strength</li> </ul>	<ul style="list-style-type: none"> <li>• Full 32-level chemistry profile</li> <li>• Hemoglobin A1C (diabetes)</li> <li>• Vitamin D (sun exposure)</li> <li>• Serum beta carotene (vegetable consumption)</li> </ul>	<ul style="list-style-type: none"> <li>• Food security</li> <li>• Physical &amp; mental wellness (SF-12v2)</li> <li>• Health management</li> <li>• Physical activity</li> <li>• Vegetable intake management</li> <li>• Medications and supplements</li> </ul>

<b>Children</b>	<ul style="list-style-type: none"> <li>• BMI (height &amp; weight)</li> <li>• Waist circumference</li> </ul>	<ul style="list-style-type: none"> <li>• Hemoglobin A1C via finger prick</li> </ul>	N/A
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### Primary Outcome Measurement

Height will be measured using a Seca 213 Mobile Stadiometer. Participants will remove shoes and socks and stand with feet together, heels and back to the stadiometer. Technicians will ensure participant's head is in the Frankfort Plane, ask the participant to take and hold a deep breath, and then lower the sliding headboard until it is contact with the head, compressing hair if needed. Participant will then be asked to bend knees and step away from stadiometer. The technician will record height to the nearest half inch, written on a scrap piece of paper. The technician will measure height a minimum of three times, continuing to take measurements until they have a minimum of two height measures that match to the half inch.

Weight will be measured for most participants using a Tanita SC-331S Body Composition Analyzer. After verifying that the participant has no internal electronic devices (such as a pacemaker or diabetes pump), the technician will enter the participant's measured height (to the half inch), age, self-identified gender, clothing weight (standardized at 3 lbs. for adults and 2 lbs. for children), and body type (standardized as "normal" for all participants) into the Tanita. The participant will then step onto the unit, which measures weight to the 0.2 pound and also calculates BMI. Weight of participants who cannot use the Tanita will be weighed using a MyWeigh XL-High Capacity Scale.

### Other Outcome Measurement

Waist circumference of adults and children will be measured using a Gulick II Tape Measure. The technician will request that the participant hold the zero of the tape measure on her navel and then ask the participant to turn in a circle. The technician will adjust the tape measure so that it lies parallel to the floor while remaining across the navel. The technician will then pull tension on the tape measure to 4 oz. as displayed on the tape's tension indicator and then record waist circumference to the nearest half inch.

Adult blood pressure will be taken using an Omron 10 Plus Series Upper Arm Blood Pressure Monitor with ComFit Cuff. The technician will wrap the cuff around a participant's bicep, as the participant to rest her arm on a table, then will initiate the automatic monitor process. If the cuff is too small to fit around a participant's arm comfortably, technicians will read blood pressure by wrapping the cuff around the participant's forearm instead of bicep.

Hand strength provides a surprisingly strong nutrition indicator and disability and mortality predictor [19-21]. Hand strength of adult participants will be measured with a Jamar Hydraulic Hand Dynamometer. The technician will instruct the participant to hold the dynamometer facing away from themselves, elbow tight to waist and at a 90-degree angle from the upper arm. The participant will then squeeze the dynamometer and the technician will record hand strength to the nearest pound. The process will then be repeated for the other hand.

Adult participants will also complete a survey comprised of a maximum of 46 questions, depending on skip patterns. Survey questions include physical and mental wellness (SF-12v2® Health Surveys), [22] food security (USDA U.S. Household Food Security Survey Module Six-Item Short Form [23]), confidence managing health, demographics, and issues related to the Growing Resilience garden intervention. Medication and supplement data is also being collected by interviews and, when consent is given, medication lists from the participants' health care providers. Though the survey will not be administered to children, child gender and birthdate data will be collected as part of intake procedures for use in BMI-for-age z-score calculations.

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3 For the blood-based measures, trained phlebotomists from WHF will draw venous blood from adults for  
4 analysis by LabCorps. For adults 18 years and older, the chemistry panel including measures of HbA1c,  
5 beta-carotene (as a proxy for vegetable consumption), vitamin D (as a proxy for sunlight exposure),  
6 cholesterol, and triglycerides. HgA1c in youth aged 17 years and younger will be measured using A1C  
7 Now diagnostic kits that use a finger prick to obtain a small blood sample.  
8

### 9 **Data collection and management procedures**

10  
11 The health data collection sessions will take place twice each year (February and August) in a public  
12 building that is relatively centrally located in WRIR. The community health representatives will schedule  
13 appointments with each participating family and, if needed, assist with transportation. Families will move  
14 through six stations: check in, phlebotomy, biometrics, survey, medications and supplements interview,  
15 and check out.  
16

17 At their first check in, after completing informed consents and assents, each family member will be  
18 assigned a unique identification number and will choose a code name. Both, along with date of birth and  
19 self-identified gender, will be written on the back of a paper “health passport” that participants take from  
20 station to station within each data gathering session. Real names will be linked with these numbers in a  
21 password-protected Excel sheet with a paper back-up copy stored in a locked cabinet on the UW campus.  
22 The identification numbers will contain seven digits that signify the participant’s tribal health association  
23 (Eastern Shoshone or Northern Arapaho), recruitment wave (1-3), intervention status (garden or control),  
24 household, and if she or he is head of that household. These identification numbers will help ensure  
25 participants are given the correct survey versions (e.g., control participants do not answer questions about  
26 gardening and only heads of households receive the food security questions). The code names, which are  
27 words chosen by the participant at enrollment, will enable both participants and staff to easily keep track  
28 of health passports and confirm identity at each data collection station. Participants also will be given the  
29 option to fill out paperwork to have a copy of blood lab results from the day sent to a specified health care  
30 provider. UW staff will keep health passports between data collection sessions. At each of the subsequent  
31 three sessions, family members will be returned their health passport to use during the session.  
32  
33

34 Wyoming Health Fairs will staff the phlebotomy station and conduct blood draws for adults and HbA1c  
35 finger sticks for children. Participants will be invited to help themselves to the provided breakfast any  
36 time after completing the phlebotomy station.  
37

38 The biometrics station, staffed by a combination of UW and Wyoming Health Fairs technicians, will  
39 include collection of height, weight, body composition (for people without pacemakers), blood pressure,  
40 waist circumference, and hand strength. Generally, one technician will conduct the measurements while  
41 the other records measurements in the participants’ passport and in an online survey form (Qualtrics).  
42

43 The survey station will be staffed by two UW technicians who will facilitate survey administration to  
44 adult participants. Participants may choose to complete the survey electronically (using Qualtrics), on  
45 paper, or in interview-style with a technician reading the questions and entering participant answers  
46 online.  
47

48 At the medications and supplements interview station, adult participants will share current medications  
49 and supplements with a UW technician. When available, the technician will use a participant’s physician-  
50 provided medication list to guide the interview. The technician will enter all medications and supplements  
51 into a Microsoft Access database designed by WYSAC for this study.  
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54 Finally, at the check-out station, a UW technician will review participants’ passports to ensure completion  
55 of each station and will cross-check written information in passports to that in emailed Qualtrics reports  
56 and (if available) on the printout from the Tanita body composition monitor. She will log any  
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3 inconsistencies in the designated error database for later correction and facilitate re-measurements if  
4 necessary. The technician will then conduct a short exit interview with participants to ask how the project  
5 is going and to ask for any feedback participants might have at that time. Finally, participants will receive  
6 cash stipends (\$40 per adult, \$15 per child, and a \$20 gas stipend per household). UW will keep one copy  
7 of each participant's Tanita printout and will keep passports until after a participant's final data collection  
8 session, at which point each participant may keep his or her passport. Participants keep one copy of their  
9 Tanita body composition print-out and adults will receive a copy of their blood test results in the mail.  
10

11 To improve the chance that participants will arrive having fasted for 12 hours (unless they are diabetic or  
12 have another reason to avoid fasting), sessions will take place from 7am to no later than 1pm. CHR's will  
13 use a scheduling software with automatic email and text reminders to set up times and dates for  
14 participants to attend sessions. CHR's and UW staff will also follow up with any participants who are late  
15 for or miss a scheduled session. Any participant who does not attend a main data collection session will  
16 have the option to attend a "sweep" session for just biometric and survey data collection (no blood draw),  
17 scheduled around the participant's calendar in the weeks following the full data gathering sessions.  
18  
19

20 In the fifth and final year of the project, in 2020, all participating families will be invited to return for a  
21 final data collection session. The design of this session will be constrained by funding, but otherwise  
22 shaped by the Community Advisory Board, feedback from the families, and the partner organizations.  
23 The principal investigator also plans to seek supplemental funding to support annual data gathering with  
24 families after they have matriculated from the main two-year RCT design.  
25

## 26 **Outcomes and Analysis Methods**

### 27 **Primary outcome (BMI) analysis**

28 The primary analysis will use an intent to treat (ITT) analysis to examine the effect of gardening on  
29 changes in BMI. Adult BMI data will be analyzed separately from child BMI Z-score data. Z-scores will  
30 be constructed from CDC growth charts. To begin we will present univariate and bivariate descriptive  
31 statistics.  
32  
33

34 Then, we will use a mixed model to estimate the ITT effect of the intervention. Estimation will be via  
35 ANCOVA as this method has been shown to have more statistical power than traditional difference  
36 regressions [24]. For exposition and comparison we will also present less efficient difference regressions  
37 that are traditionally reported. ANCOVA's gain in efficiency rises the smaller the degree of  
38 autocorrelation in the dependent variable over time. We will test for autocorrelation in all dependent  
39 variables as ANCOVA's advantage is likely larger for some of the other health outcomes discussed under  
40 'Secondary Outcome Analysis' below that may be (even) less correlated over time than BMI.  
41  
42

43 Change in adult BMI (and child BMI Z-scores) is the dependent variable in primary outcome model. The  
44 fixed effects of interest in the model will be the indicator variable for 'garden' (treatment). As families  
45 will be recruited in three annual waves we will include an indicator variable for wave to control for  
46 recruitment year. Further, our estimations will control for baseline weight, gender, age, and tribe. Due to  
47 the longitudinal nature of our data we can also include individual- and household-level effects to control  
48 for unobserved, non-independence of observations. We include these as random effects, if possible, or as  
49 fixed effects if required by Hausman model specification tests.  
50

51 While the primary BMI analysis will examine adult and child outcomes separately, we will also use a  
52 novel technique that allows us to assess BMI outcomes for the entire sample (child and adult combined).  
53 Applying Naschold's (2018) [16] LMST-based method we will first construct BMI Z-scores for all  
54 participants aged 5-74 using NHANES data as the reference population. These Z-scores provide an  
55 internally consistent outcome measure for interventions expected to impact BMI of all family members.  
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3 Biologically and statistically this is as reasonable as the common practice of comparing z-scores among  
4 children of varying ages. Using BMI Z-scores for all participants has two distinct advantages. First,  
5 combining children and adults in the same analysis increase the number of observations and, thus,  
6 statistical precision. And second, it will allow us to look at the intra-household effects of the intervention,  
7 for instance, we can test whether gardens benefitted children more or less than adults in the same  
8 household.  
9

## 10 Secondary outcome analyses

11 Because this is the first RCT on health impact of home gardens, our secondary outcome analysis will  
12 replicate the ANCOVA analysis outlined above using the whole range of other biometric, blood serum  
13 and survey health outcomes (see table 1) as dependent variables. However, mental and physical health,  
14 hand strength, food security among food insecure households, and diabetes control among those whose  
15 HbA1C and/or survey responses identify them as either diabetic or pre-diabetic are the priority secondary  
16 outcome analyses.  
17

18  
19 We will also use the gardening fidelity measures described above to analyze treatment effects on these  
20 primary and secondary outcomes, in addition to the primary ITT analysis.  
21

## 22 Accounting for changes in medications and supplements

23 During focus groups in the pilot phase of this project several participants reported that they reduced the  
24 dosage or discontinued medications for several chronic conditions including diabetes, blood pressure,  
25 depression and anxiety, and/or pain. Since changes in medication could either mask or amplify perceived  
26 health impacts of the gardening intervention, the protocol for this study includes gathering information  
27 about medication and supplement use and changes from participants. A pharmacist on the study team will  
28 then explore methods of accounting for any impacts of such changes on assessed health outcomes,  
29 especially for physical and mental health (on the SF-12v2 survey), blood pressure, and HbA1C, as part of  
30 secondary analyses.  
31

32  
33 A review of the literature for a standardized way to accomplish this revealed no previous studies. When a  
34 participant reports medication or supplement changes that plausibly would impact a health outcome  
35 measured in this study, then a pharmacist on the research team will advise on development and use of two  
36 approaches for a secondary analysis of those health outcomes that accounts for those changes. One  
37 approach will be to quantify estimated impact of the medication change on a target outcome, if data is  
38 available to make such estimates. For example, if a participant is taking 1,000 mg of metformin twice  
39 daily for treatment of diabetes at the start of the study and stops the medication during the intervention,  
40 this could be translated to a 1 percentage point reduction in HbA1c [25]. Where such data is not available,  
41 such as for pain or anti-depressant medications, the approach will be to develop an internally consistent  
42 scale for estimating impact of medication changes on outcome variables, and to report such outcomes  
43 qualitatively.  
44

## 45 Missing data treatment

46 The CHRs at Wind River Development Fund and Eastern Shoshone Tribal Health, as well as BMA  
47 garden staff, will follow up closely with the participants and make great efforts to obtain complete data  
48 for all the participants. Any participant with two or more data points (out of the four) will be included in  
49 analysis. Missing data patterns will be examined to identify and apply the appropriate method to deal with  
50 it (e.g. multiple imputation, Full Information Maximum Likelihood, propensity scoring).  
51

## 52 Insight into mechanisms

53  
54 The mechanisms of any health changes attributable to the intervention are likely multifaceted. Each of the  
55 biometric and survey measures discussed above can potentially impact changes in BMI. For example,  
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3 sunshine exposure alone might improve mental wellness and blood glucose regulation [26]. The wide  
4 range of biometric, physical and mental health indicators collected will be used as explanatory variables  
5 in a panel data regression model. We will also test for potential complementarities between these  
6 indicators by including respective interaction terms. In addition to controlling for these observable  
7 characteristics, we will exploit the panel data structure to also control for sources of unobserved  
8 heterogeneity through the use of wave, household and individual dummy variables. This multivariate  
9 panel regression model will allow assessment of the effect each observable factor has on changes in  
10 participants' BMI. Moreover, it helps to determine the *relative importance* of each of these factors, for  
11 example, whether a reduction in BMI is more strongly driven by increased vegetable consumption versus  
12 improved mental health. The point estimates from our regression will also be used to predict what  
13 changes in BMI are possible based on achievable ranges of changes in our biometric and survey  
14 measures. Qualitative data analysis will also inform quantitative estimation strategies for mechanism  
15 exploration. Overall, mechanism analyses will provide insight but not conclusions about how gardening  
16 may work to improve health, if indeed improvements are identified.  
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18

### 19 Expected outcomes

20 Better outcomes in nutritional, physical and emotional health are expected among family members in  
21 gardening households than in control households, measured per the above. Differences in adult BMI is the  
22 primary outcome. The pilot data and previous observational research indicate other significant outcomes  
23 may include improvements in emotional health, blood glucose levels and control, and hand strength.  
24  
25

### 26 Potential problems and alternative strategies

27 The incentives for participation are high enough that the team expects enough enrollment and retention to  
28 support this study. Yet, attrition and missed data gathering appointments are the most likely challenges,  
29 especially given the transportation issues many families face. However, the tribal health CHRs build and  
30 maintain strong relationships with the families they serve, and they will support families in making and  
31 keeping their data gathering appointments, including picking them up and bringing them if transportation  
32 is a problem. If families miss a main data collection time point, follow-up "sweep" sessions for just  
33 biometrics and survey data collection (no blood draw) will be scheduled around those families' schedules.  
34  
35

36 If provisional data analysis indicates the study is impacting BMI but is not powered sufficiently to detect  
37 differences (e.g., if attrition exceeds the maximum 16% assumed in the power calculations above or if the  
38 impact on BMI is smaller than estimated from pilot data), then the team will recruit additional families to  
39 the study in a fourth wave.  
40

## 41 DISCUSSION

42 This Growing Resilience research project leverages WRIR assets of land, family, culture and community  
43 health organizations to develop and evaluate home food gardens as a family-based health promotion  
44 intervention to reduce disparities suffered by Native Americans in nearly every measure of health. As a  
45 tribal health partner said during the pilot phase of this project, "We need to put health back into the hands  
46 of the people."  
47

48 The central scientific hypothesis in this study is that, after two years of home gardening, the BMI and  
49 other objectively verifiable health indicators in members of intervention families will show positive and  
50 significant differences from those of control families. The long-term goal is to build tribal capacity to  
51 improve Native American health by identifying and evaluating suitable, scalable and sustainable health  
52 promotion interventions aimed at ending health disparities. If results from this study are positive, then  
53 supporting home gardens with tribal families will become a culturally relevant and empowering health  
54 promotion strategy for tackling health disparities.  
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3 Regardless of the RCT results, an immediate goal is to support WRIR organizations in establishing and  
4 sustaining home food gardening as an option for any family on the reservation who would like to start  
5 growing some of their own food. Benefits of such gardening likely extend beyond narrow measures of  
6 health such as those quantitatively assessed in this study (citation of paper by first author redacted for  
7 review).

8  
9 As the first RCT about health impacts of home gardening, which observational studies suggest improves  
10 health, results of this study may also be relevant for families in other settings and of other cultures. In  
11 addition, development of an LMS z-score BMI curve might enable future studies to measure BMI  
12 outcomes in adults and children who are 5 or older as one population.  
13

## 14 Ethics

15  
16 This study was co-designed with tribal health organizations, gardeners, UW-based researchers, and a  
17 tribal community based organization. This study was approved by the University of Wyoming  
18 Institutional Review Board (Protocol #20150626CP00852), the Northern Arapaho Business Council, and  
19 the Eastern Shoshone Business Council. A Community Advisory Board is overseeing and advising the  
20 study implementation and dissemination. About half of the direct-cost budget for the project is allocated  
21 to WRIR-based partners and people and half to UW for data collection and analysis costs. Growing  
22 Resilience also responds to extensive interest in home gardening among WRIR families that emerged  
23 during an earlier UW-WRIR action-research collaboration.  
24

25 However, the families who wait two years for their gardens – the controls – are bearing the costs of the  
26 rigor of a RCT design. Are the costs of this knowledge gain fair or right to ask anyone, especially in a  
27 Native American community, to bear?  
28

29 Additional ethical questions are raised by widening the lens to examine the enormous political,  
30 institutional and financial power differences between a university, such as UW, and tribal organizations.  
31 For example, NIH has awarded UW \$570,856 in indirect costs for this project; the other partner  
32 organizations, together, will receive a total of \$106,700 in funding for overhead. UW incurs substantial  
33 compliance and contract management costs that subawardees do not, but perhaps not costs that are more  
34 than five times those of community organizations.  
35  
36

## 37 Dissemination

38 Dissemination will include conference presentations, journal publications, “grey literature” reports for  
39 practitioner and local use, Facebook and a project website, news media coverage, and a national  
40 conference to be held in Wind River Indian Reservation in 2020 to share our results with and learn from  
41 other Sovereign Nation efforts to promote health with food-related interventions. We will also produce  
42 gardening intervention guide tailored for reservation-based gardening programs, drawing on BMA’s  
43 experience and on existing resources, such as existing family garden guides [27].  
44  
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## 46 Conclusion

47 This paper summarizes the rationale and design for a randomised controlled trial that will support  
48 development of a tribal-led home garden support program, provide home food gardens to 100 Eastern  
49 Shoshone and Northern Arapaho families, and assess the health outcomes from this gardening  
50 intervention. This is the first RCT to evaluate the health impacts of home food gardening, to the  
51 knowledge of the authors. The goal is to identify and support desirable, empowering and effective family-  
52 based health promotion strategies that will help families in Wind River Indian Reservation, and possibly  
53 in other communities, take control of and improve their health.  
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## AUTHOR CONTRIBUTIONS

CP conceived the study and developed and designed it with AW, Blue Mountain Associates, Eastern Shoshone Tribal Health, and Northern Arapaho Tribal Health. AW led design of data gathering procedures with assistance from Wyoming Health Fairs and CP. FN and SH designed data analysis methods and LF is designing approaches to secondary analyses that account for reported medication and supplement changes. CP and AW wrote the bulk of this protocol paper, with the other co-authors drafting the sections relevant to their design contributions. All authors, plus the Community Advisory Board, reviewed and approved this manuscript for submission.

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## COMPETING INTERESTS STATEMENT

The authors of this paper do not have any competing interests.

## LIST OF FIGURES AND FIGURE LEGENDS

Figure 1: Flow chart of Growing Resilience study design.

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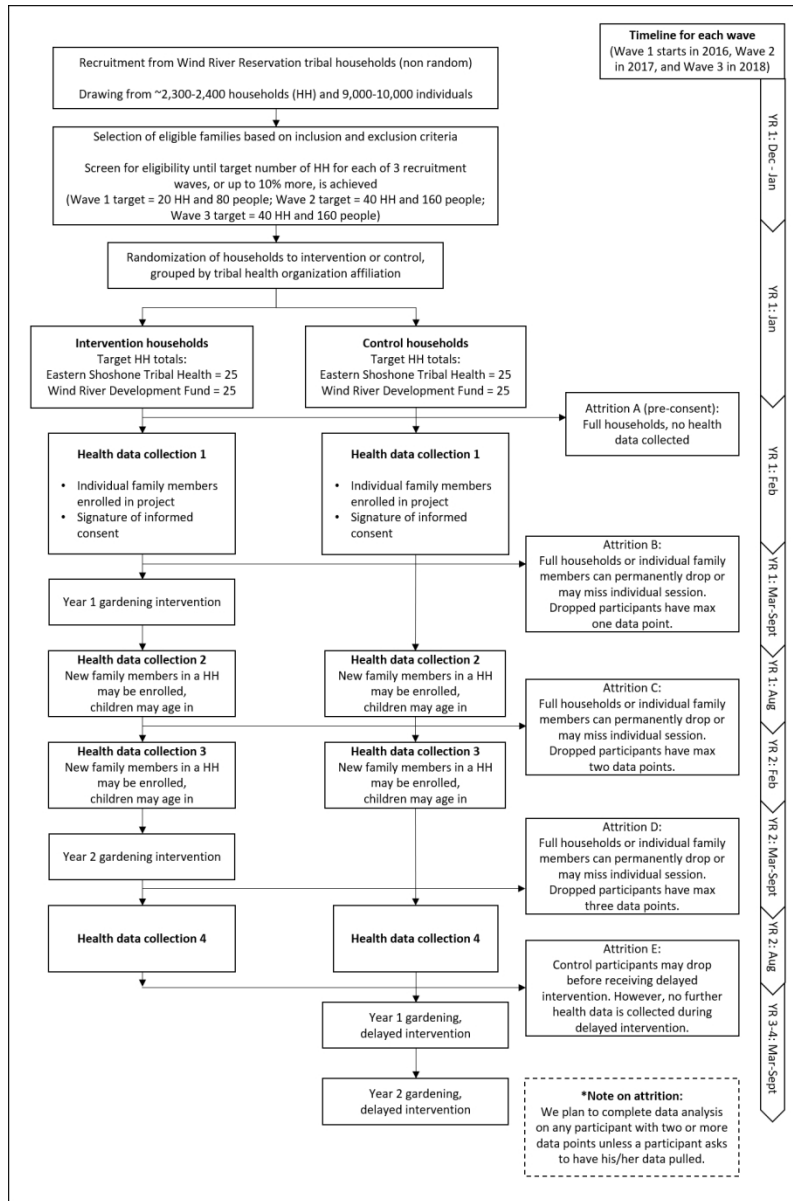


Figure 1: Flow chart of Growing Resilience study design.

118x177mm (300 x 300 DPI)

# BMJ Open

## Assessing health impacts of home food gardens with Wind River Indian Reservation families: protocol for a randomised controlled trial

Journal:	<i>BMJ Open</i>
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<b>Primary Subject Heading</b>:	Research methods
Secondary Subject Heading:	Evidence based practice, Public health
Keywords:	Protocol, RCT, CBPR, Home Gardens, Native American, Wind River Indian Reservation

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17 Assessing health impacts of home food gardens with Wind River Indian Reservation families: protocol  
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## ABSTRACT

**Introduction:** This community-based participatory research (CBPR), *Growing Resilience*, will be the first full-scale randomised controlled trial we identified designed to evaluate impacts of home gardening on family health. It is based on observational studies suggesting home food gardening has myriad health benefits, Wind River Indian Reservation (WRIR) families' interest in home gardening, and the need to end Native American health disparities with empowering, appropriate, and effective health interventions.

**Methods and analysis:** A total of 100 Native American families in WRIR who have not gardened recently but want to garden will be randomly allocated (1:1) to intervention (receiving two years of support designing, installing, and maintaining a home food garden of at least 80 square feet) or to delayed-intervention control (receiving same gardening support after two years of data collection). Willing family members aged 5 and up will participate in data collection each February and August for 2 years, with blood, biometric, and survey measures at each. The primary outcome is adult body mass index (BMI). Secondary outcomes include child BMI, and adult hand strength and self-reported physical and mental health, diabetes control, and food security. Primary analysis will be intention to treat (ITT), using univariate and bivariate descriptive statistics followed by a mixed model to estimate the ITT effect of the intervention using ANCOVA estimation. We will also examine treatment affects using a gardening fidelity measure, combined adult and child BMI outcomes using an LMS z-score reference data set, and possible mechanisms of health impacts.

**Ethics and dissemination:** This protocol was approved by the University of Wyoming Institutional Review Board and the project's Community Advisory Board. De-identified data will be shared with each tribe, and results will be published in peer-reviewed journals, summarized for distribution in WRIR, and shared at a national event to be hosted in WRIR in 2020.

**Key Words:** protocol, RCT, CBPR, home gardens, Native American, Wind River Reservation, LMS z-score, BMI

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study leverages WRIR assets of land, family, culture, and community health organizations to learn how to reduce Native American health disparities with a family-based gardening intervention.
- While home food gardening shows promise as a family-based health promotion intervention, this will be the first full-scale randomised controlled trial of the health impacts of home food gardens.
- This study aims to provide the first internally consistent health outcome measure for interventions that may impact BMI of both child and adult family members by generating and using an LMS z-score reference data set from recent NHANES data.
- In any community, not all families will wish to garden, which limits the reach of the proposed intervention.
- Due to the nature of gardening and of working with a tightly knit community, this study cannot be blinded and some intervention benefits may "contaminate" control families.

## INTRODUCTION

As in all sovereign nations in the US, the Northern Arapaho and Eastern Shoshone tribes that share the Wind River Indian Reservation (WRIR) in Fremont County, Wyoming are survivors of the historical trauma of colonialism. The average age of death for Native Americans in Fremont County is just over 53 years old, with immediate causes including murder, suicide, traffic accidents, chronic liver disease, cancer, diabetes, and cardiovascular disease.[1, 2] Type II diabetes rates in WRIR are at least 11%, double the state-wide rate.[3, 4] Approximately 60% of middle-school-aged children are overweight or obese, also more than double the rates for children overall in Wyoming,[5] and over 70% of adults in WRIR are obese, nearly triple the state-wide rate.[4] Effective and appropriate health promotion interventions for tribal families, in WRIR specifically and among sovereign nations in the US generally, are desperately needed.

Home food gardening shows promise as a family-based health promotion intervention. A growing body of observational research suggests that home and community gardens improve health in many ways, including increasing food security,[6, 7] fruit and vegetable intake,[8-12] and physical activity [8, 13, 14] while reducing stress.[15, 16] Since these outcomes would plausibly help reduce or prevent obesity, and because observation research has found positive associations between gardening and healthier BMI,[12, 17] gardening shows promise as an obesity intervention. However, to date, no full-scale randomised controlled trials have been done to more conclusively identify health impacts of home gardening.

Specifically within WRIR, many families showed interest in receiving technical and financial help in establishing or expanding home gardens during a five-year participatory action and research partnership called Food Dignity. In response, partners at University of Wyoming (UW) and WRIR tribal health and community-based organizations partnered in 2013 to co-design and implement a feasibility pilot study about health impacts of home gardens on the reservation.[18] The Growing Resilience project, for which the protocol is described here, grew out of that pilot study. This appears to be the first randomised controlled trial (RCT) of the health impacts of home food gardens. Results from a pilot RCT with older cancer survivors was recently published, which found a trajectory toward positive outcomes.[19] Also, an RCT of health impacts of community gardens is currently underway.[20] In addition to being the first scaled RCT of home gardens, this research will contribute to a limited literature about effective and appropriate health promotion strategies for use in and by Native American communities.

## METHODS

### Study Design Overview

Starting in 2016, about 100 Native American families in WRIR who are interested in starting a new home food garden will be recruited over three years. Participants will be randomly assigned by household to one of two arms: home gardening support for two years or control with delayed intervention after two years. This RCT was designed using the CONSORT checklist, adheres to the SPIRIT checklist, and is registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (number NCT02672748, registered 3 February 2016). The first wave of participants will enroll in the study on 15 February 2016.

Participants will take part in four health data collection sessions, two per year. These sessions will be in February, prior to gardening activities each year, and again in August at the height of gardening season. Adult data collection will include biometric information (BMI, waist circumference, blood pressure, and hand strength); blood serum analysis (including a standard blood chemistry panel, HbA1c, vitamin D, and serum beta carotene); and survey-based measures including food security (USDA 6-question food security survey) and physical and mental wellness (SF-12v2 survey). Child (ages 5-17) measures collected will include BMI, waist circumference, and HbA1c via finger-prick blood testing. Participants will be encouraged to fast for 12 hours prior to data collection, and we will record fast status prior to each

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3 data collection session. However, a failure to fast will not disqualify participants from a data collection  
4 session.  
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6 Adult BMI will be the primary health outcome. Primary analysis will be a mixed model that will be used  
7 to test for the effect of the garden intervention on adult BMI, controlling for baseline weight, gender, age,  
8 and tribe and accounting for household clustering.  
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10 Secondary analyses will study the effects on a range of other biometric, blood and survey health outcome  
11 variables and on intra-household effects. Beyond BMI, health outcomes of particular interest are impacts  
12 on mental and physical health, hand strength, food security among food insecure households, and diabetes  
13 control among those who are either diabetic or pre-diabetic.  
14

15 To investigate the intra-household effects, we will compare relative changes of individual-level BMI Z-  
16 scores for all children and adults in a survey household. These Z-scores will be constructed using  
17 NHANES survey data for people aged 5 to 74 as the reference population and following the statistical  
18 methodology developed in Naschold (2018) [21] .  
19

20 We will also examine possible mechanisms that cause changes in health outcomes (e.g., serum status of  
21 Vitamin D and/or beta-carotene). In this manuscript, we also briefly describe protocol development for  
22 analyzing outcomes with adjustment for any reported changes in medication or supplement dosage.  
23  
24

25 In addition, we will use qualitative methods for providing insights into project process, outcomes and  
26 mechanisms, including photo narratives, focus groups, participation and observation, and interviews with  
27 gardening families. Though this will not impact our primary quantitative analyses described here, these  
28 results may help with interpretation or understanding of potential mechanisms and variations between  
29 gardening families within results. They will also inform both the gardening support strategies and the  
30 overall partnership process. These methods will be described elsewhere.  
31

### 32 **Project Partners**

33 Growing Resilience is a community-based participatory research project. It was co-designed by WRIR-  
34 based and UW partners, largely during the 2013 feasibility pilot, and is overseen by a Community  
35 Advisory Board. Reservation-based partner organizations include native-run non-profit organization Blue  
36 Mountain Associates (BMA), community health representatives (CHRs) from Eastern Shoshone Tribal  
37 Health and the Wind River Development Fund (whose CHR focuses primarily on Northern Arapaho  
38 family recruitment). Non-reservation-based partners include staff at UW's division of Kinesiology and  
39 Health, staff at the UW-based Wyoming Survey & Analysis Center (WYSAC), UW technicians who  
40 assist at the health data collection sessions, and phlebotomists from the non-profit health organization  
41 Wyoming Health Fairs.  
42  
43

44 BMA, and particularly their garden manager, will lead design and implementation of the gardening  
45 intervention, including development of a garden guide, overseeing an annual gardening workshop,  
46 assisting with garden installation, and providing ongoing support and mentorship for all garden-  
47 intervention participants. CHRs will lead family recruitment and retention efforts. UW will lead  
48 collection of health metrics and data analysis efforts. The Community Advisory Board (CAB) will  
49 participate in policy decision-making in regard to ongoing project design and public representation;  
50 advocate for community interests in regard to research data collection, ownership and dissemination;  
51 serve as an additional contact point for all research participants seeking information or assistance with  
52 their involvement in the project; and consider how to maintain the capacity, infrastructure, and  
53 momentum of the gardening program beyond the life of the funded project. Seven members of the WRIR  
54 community make up the CAB.  
55  
56  
57



## Participants

To be eligible to participate, a family must meet the following requirements: 1) live within the boundaries of the Wind River Reservation (including Riverton, WY); 2) have at least one member enrolled in a federally-recognized tribe; 3) have at least two adults (or one adult for single-adult families) willing to participate in two years of gardening and four health data collection sessions over two years; and 4) have interest in starting and sustaining a home food garden, but don't currently have a garden over 30 square feet. Though the gardening intervention will be at the household level, data collection and analysis will be at the individual level. Adults living in the household and children aged 5 or older can enroll in the study to participate in the data collection.

Even though adult BMI will be the primary outcome of this study, being overweight or obese will not be part of the eligibility criteria. About 70% of adults in Wind River are obese,[4] perhaps another 20% are overweight, and at least two adults per participating household are expected to enroll in the study. Thus, the study team and the advisory board for the pilot study decided that the ethical and practical issues that screening for eligibility by BMI would raise were not worth surmounting.

Children will be included in the study because family health and participation was a priority set by the advisory group during the pilot phase, which had included only adult family members in data gathering. Children who are under 5 years old when the family enrolls in the project may "age in" to data collection procedures as long as they can participate in at least two data collection sessions. Similarly, youth who turn 18 during their family's enrollment in the study may elect to participate in adult data measures (i.e. blood draw, blood pressure, hand strength, and survey). If a participant becomes pregnant or incarcerated while taking part in the study, he or she will not undergo data collection for the duration of pregnancy or incarceration.

The goal is to enroll 100 families in three waves over the first three years of Growing Resilience, with 20 in the first year and then 40 in each of the next two years. Eastern Shoshone Tribal Health and the Wind River Development Fund each will aim to recruit 50 households. They will primarily draw from the hundreds of families they already serve, though joint public events and media advertising will also be used.

## Participant and Public Involvement

As discussed in the introduction, Growing Resilience was designed to meet the expressed needs of families in WRIR for more home gardens. Project partners from UW, tribal health programs, and BMA focused on home gardens based on families' experience that food sovereignty depends on having food (including food gardens) close to their homes, given the large geographic size of WRIR and many families' lack of access to reliable transportation.

Partners then collected feedback on the 2013 pilot from project participants. Changes resulting from this feedback will include adding children aged 5-17 to the study (based on participants' priorities for family-based interventions); providing financial compensation for participating in each health data collection session (based on participants' assessment of the burden of participation); modifying survey questions and adding multiple modes of survey administration (based on participants' experience and preferences taking the pilot survey); removing the use of activity trackers (these were not well used nor received by participants); and setting the intervention duration to two years (based on project partners' observation that most participants needed more than one year of gardening support to develop successful gardens.) We also will move data collection sessions to a central location on the reservation, providing transport as needed, instead of visiting participant homes (due to logistics of adding blood draws, which were not part of the pilot, and to both partner and participant preferences). One of the participants from the 2013 pilot project is now on the project's Community Advisory Board, but otherwise participants are not directly

involved in ongoing study recruitment and conduct. However, new participants may join because they have heard of the project from current participants and wish to take part.

Participants will receive ongoing reports of their personal health information (including biometrics and blood chemistry panel) after each data collection session they attend. Additionally, results will be summarized for distribution in WRIR and shared at a national event to be hosted in WRIR in 2020.

### Calculation of Sample Size

Sample size calculations were performed with adult BMI as the primary outcome. The feasibility pilot study data, combined with demographic data about WRIR, implies that the average participating family would have 2 adult and 2 child participants in the study. Thus, 100 families would include 200 adult participants.

The 80% power calculations below include a family-cluster design effect of 1.1 among adults in one household,[22] an attrition rate of 16%, and a difference in adult BMI change between control and intervention groups of 0.5 over the two years of intervention (0.75 vs. 0.25; with a two-tailed test,  $\alpha=0.05$ ;  $\sigma=1.1$ ).[23] Assumptions are based on the literatures cited and on our pilot data.

Design effect of household adult clusters =  $1.1 = 1 + (m-1)*ICC = 1 + (2 \text{ adults} - 1)*0.1$

Sample size needed (each group) =  $76 = 2[(1.96+.842)^2*\sigma^2]/(u1-u2)^2 = 2[(1.96+.842)^2*(1.1)^2]/(0.75-0.25)^2$

Planned sample size (each group) =  $100 = 50 \text{ families} * 2 \text{ adult participants per family on average}$

Planned sample size (each group) including design effect of household clusters:  $91 = 100/1.1$

Adult attrition rate this allows:  $16\% = 1 - (76/91)$ .

In sum, before attrition and adjustment for family cluster effects, this study requires 152 adults (76 per group) to power the study at 80%. “Discounting” the planned sample of 100 adults per group for family cluster effects means reaching the recruitment goal statistically provides “91” adults per group. Thus, this sample size adequately powers the study, allowing for 16% attrition, while attending to constraints of budget and institutional capacity. Additional families will be recruited in the fourth year if attrition or a smaller effect size necessitate that. Attrition rates are based on the relatively low mobility of families in this community, the strong existing relationships between the CHRs and many of the families in the community, and previous research collaborations among this research team with participants from this community.

### Randomisation and Group Assignment

A total of 100 families will be recruited and enrolled in the study in three waves. The first wave, recruited in the first year, will include 20 families. Wave 2 in year 2 of the project and wave 3 in year 3 of the project will include 40 families each. About half of the families in each wave will be recruited by CHRs from Eastern Shoshone Tribal Health (with a focus on Eastern Shoshone families) and the other half by Wind River Development Fund (with a focus on Northern Arapaho families).

Staff at UW’s WYSAC will oversee the randomisation process. Each wave will be randomised to control or intervention groups in a 1:1 ratio using stratified block randomisation. First, we will stratify by tribe to

1  
2  
3 ensure each tribe has an equal number of participants. Second, we will use fixed-block randomisation  
4 within each tribe strata so that 50% of Northern Arapaho-recruited families and 50% of Eastern  
5 Shoshone-recruited families get gardens and half are assigned as controls/delayed intervention.  
6 Randomisation occurs by inputting both tribal groups into an IBM SPSS datasheet and selecting the 1<sup>st</sup> 10  
7 of each tribal group by using a continuous uniform distribution method to randomly select exactly 10  
8 cases from the first n cases. The random cases selected are then input into a separate IBM SPSS datasheet  
9 where approximately 50% of the cases are randomly selected using IBM SPSS simple random sample  
10 without replacement. The randomly selected cases become the treatment groups and the cases not selected  
11 become the control/delayed intervention groups.  
12

13  
14 The rationale for stratified block (rather than simple) randomisation is practical and cultural. Practically,  
15 establishing the intervention gardens is so time and planning intensive that BMA needs managed and  
16 predictable numbers of families with whom they will work. Culturally and politically speaking, each tribe  
17 prefers to receive approximately equal services each year. The actual randomisation process will be  
18 blinded, i.e., participants will be unable to manipulate the randomisation process itself. The flow chart in  
19 Figure 1 summarises the randomisation, intervention, and data gathering design.  
20

21 Strategies for engaging families who are randomised to control will include issuing a project newsletter to  
22 all participants and the CHRs staying in touch with those families until they have completed the four data  
23 collection sessions and can begin planning their gardens with BMA.  
24

25 [FIGURE 1]  
26

### 27 **Garden Intervention**

28 Families randomly assigned to intervention will receive a full gardening support package for two years  
29 from BMA. After the baseline data gathering session each February, the half-time, year-round garden  
30 manager will meet with each family to plan their garden. BMA's garden manager is Northern Arapaho, a  
31 long-time gardener, and also was previously a Diabetes Navigator for Northern Arapaho Tribal Health,  
32 giving her particular insight and expertise in both gardening and health promotion. The first-year support  
33 package will include the following: 1) consultation (on location; whether in-ground, raised bed, container;  
34 and what they would like to grow), 2) garden bed installation, 3) purchase of materials (e.g. tools, starts,  
35 and seeds), 4) ongoing mentorship including garden visits, and 5) gardening workshops. The planned  
36 average budget for this package will be \$700 per family, excluding the manager's time and the labor costs  
37 of seasonal hires. Garden-intervention participants will be in charge of maintaining their gardens through  
38 the season (e.g. watering, weeding, and harvesting). Because there will be no parameters regarding what a  
39 family chooses to grow, each garden will be different, based on the participants' interests and needs, but  
40 will be a minimum of 80 square feet per family. Which family members participate in gardening will be  
41 at the household's discretion.  
42  
43

44 During the second year of garden support, BMA will provide additional soil, soil amendments, seeds,  
45 seedlings, and tools as needed, and ongoing mentorship and support for renewing the food garden. The  
46 planned average budget, per family, for the second year of support will be \$200.  
47  
48

49 Primary outcomes will be analysed as intention to treat, regardless of implementation fidelity. However,  
50 we will also consider fidelity in secondary analyses, running a mixed model of significant outcomes  
51 against a measure of garden success. This measure is in development based on a combination of two  
52 indicators. One is the percent of planted garden square footage in August out of the square footage  
53 planned and prepared in May (with prepared plot size provided by the BMA gardening manager and  
54 planted size estimated from photos taken by BMA staff and the participants themselves). The other is an  
55 assessment by the gardening manager of the extent to which each family planted and maintained their  
56 garden, using a 5-point scale. Implementation fidelity will also be compared with the records of  
57  
58

intervention support to inform intervention design. Finally, the survey measures will ask each adult in an intervention family how many hours they spent gardening, and we will conduct a secondary analysis of individual health outcomes for adults vs. self-reported hours spent in the garden.

After the two seasons of gardening support and four data collection sessions are over, families assigned to the control condition will receive the same first-year gardening support services from BMA as the intervention families do. In their second year they will receive \$200 in credit at the gardening store of their choice to purchase what they need for renewing their gardens.

### Quantitative Data Collection

Twice per year for two years, trained technicians will collect health indicator data from adult and child participants. The primary outcome after two years of gardening support is adult BMI. Secondary adult outcomes include physical and mental health (on the SF-12v2 survey), food security (USDA six-item), hand strength, waist circumference, blood pressure, and fasting (when possible) blood-based measures including HbA1c. For children 5 and older, we are collecting BMI data, waist circumference, and, via finger-prick tests, HbA1c. Table 1 summarizes the quantitative data collected at each of the four sessions.

Table 1: Health indicator data collected for adults and children, in Feb and Aug each year for two years.

	Biometric	Blood-Based	Survey-Based
<b>Adults</b>	<ul style="list-style-type: none"> <li>• BMI (height &amp; weight)</li> <li>• Waist circumference</li> <li>• Blood pressure</li> <li>• Hand strength</li> </ul>	<ul style="list-style-type: none"> <li>• Full 32-level chemistry profile</li> <li>• Hemoglobin A1C (diabetes)</li> <li>• Vitamin D (sun exposure)</li> <li>• Serum beta carotene (vegetable consumption)[24]</li> </ul>	<ul style="list-style-type: none"> <li>• Food security</li> <li>• Physical &amp; mental wellness (SF-12v2)</li> <li>• Health management</li> <li>• Physical activity</li> <li>• Confidence about and frequency of vegetable intake</li> <li>• Medications and supplements</li> </ul>
<b>Children</b>	<ul style="list-style-type: none"> <li>• BMI (height &amp; weight)</li> <li>• Waist circumference</li> </ul>	<ul style="list-style-type: none"> <li>• Hemoglobin A1C via finger prick</li> </ul>	N/A

### Primary Outcome Measurement

Height will be measured using a Seca 213 Mobile Stadiometer. Participants will remove shoes and socks and stand with feet together, heels and back to the stadiometer. Technicians will ensure participant's head is in the Frankfort Plane, ask the participant to take and hold a deep breath, and then lower the sliding headboard until it is contact with the head, compressing hair if needed. Participant will then be asked to bend knees and step away from stadiometer. The technician will record height to the nearest half inch, written on a scrap piece of paper. The technician will measure height a minimum of three times, continuing to take measurements until they have a minimum of two height measures that match to the half inch.

Weight will be measured for most participants using a Tanita SC-331S Body Composition Analyzer. After verifying that the participant has no internal electronic devices (such as a pacemaker or diabetes

1  
2  
3 pump), the technician will enter the participant's measured height (to the half inch), age, self-identified  
4 gender, clothing weight (standardized at 3 lbs. for adults and 2 lbs. for children), and body type  
5 (standardized as "normal" for all participants) into the Tanita. The participant will then step onto the unit,  
6 which measures weight to the 0.2 pound and also calculates BMI. Weight of participants who cannot use  
7 the Tanita will be weighed using a MyWeigh XL-High Capacity Scale.  
8

### 9 Other Outcome Measurement

10  
11 Waist circumference of adults and children will be measured using a Gulick II Tape Measure. The  
12 technician will request that the participant hold the zero of the tape measure on her navel and then ask the  
13 participant to turn in a circle. The technician will adjust the tape measure so that it lies parallel to the floor  
14 while remaining across the navel. The technician will then pull tension on the tape measure to 4 oz. as  
15 displayed on the tape's tension indicator and then record waist circumference to the nearest half inch.  
16

17  
18 Adult blood pressure will be taken using an Omron 10 Plus Series Upper Arm Blood Pressure Monitor  
19 with ComFit Cuff. The technician will wrap the cuff around a participant's bicep, as the participant to rest  
20 her arm on a table, then will initiate the automatic monitor process. If the cuff is too small to fit around a  
21 participant's arm comfortably, technicians will read blood pressure by wrapping the cuff around the  
22 participant's forearm instead of bicep.

23  
24 Changes in hand strength provide a surprisingly strong nutrition indicator and disability and mortality  
25 predictor.[25-27] Hand strength of adult participants will be measured with a Jamar Hydraulic Hand  
26 Dynamometer. The technician will instruct the participant to hold the dynamometer facing away from  
27 themselves, elbow tight to waist and at a 90-degree angle from the upper arm. The participant will then  
28 squeeze the dynamometer and the technician will record hand strength to the nearest pound. The process  
29 will then be repeated for the other hand.  
30

31  
32 Adult participants will also complete a survey comprised of a maximum of 46 questions, depending on  
33 skip patterns. Survey questions will include physical and mental wellness (SF-12v2® Health  
34 Surveys),[28] food security (USDA U.S. Household Food Security Survey Module Six-Item Short  
35 Form.)[29] confidence managing health, demographics, and issues related to the Growing Resilience  
36 garden intervention. Questions also will ask participants to estimate their physical activity, vegetable  
37 consumption, and (for the intervention group) how many hours they spent gardening each week.  
38 Medication and supplement data will be collected via interviews and, when consent is given, medication  
39 lists from the participants' health care providers. Though the survey will not be administered to children,  
40 child gender and birthdate data will be collected as part of intake procedures for use in BMI-for-age z-  
41 score calculations.

42  
43 For the blood-based measures, trained phlebotomists from WHF will draw venous blood from adults for  
44 analysis by LabCorps. For adults 18 years and older, the chemistry panel including measures of HbA1c,  
45 beta-carotene (as a proxy for vegetable consumption),[24] vitamin D (as a proxy for sunlight exposure),  
46 cholesterol, and triglycerides. HgA1c in youth aged 17 years and younger will be measured using A1C  
47 Now diagnostic kits that use a finger prick to obtain a small blood sample. Participants will be encouraged  
48 to fast for 12 hours prior to data collection, and we will record fast status prior to each data collection  
49 session. However, a failure to fast will not disqualify participants from a data collection session.  
50

### 51 Data Collection and Management Procedures

52  
53 The health data collection sessions will take place twice each year (February and August) in a public  
54 building that is relatively centrally located in WRIR. The community health representatives will schedule  
55 appointments with each participating family and, if needed, assist with transportation. Families will move  
56  
57

1  
2  
3 through six stations: check in, phlebotomy, biometrics, survey, medications and supplements interview,  
4 and check out.  
5

6 At their first check in, participants will review and sign consent (adults) and assent (children) forms along  
7 with protected health information sharing forms (to allow WHF and UW to share participant health  
8 information for reporting purposes). UW staff will oversee this process and will be on hand to assist (e.g.  
9 reading aloud forms, as needed) and answer questions. After completing informed consents and assents,  
10 each family member will be assigned a unique identification number and will choose a code name. Both,  
11 along with date of birth and self-identified gender, will be written on the back of a hard-copy data  
12 collection booklet called “Your Health Data Passport” (henceforth referred to only as a participant’s  
13 “health passport”) that participants take from station to station within each data gathering session. Real  
14 names will be linked with these numbers in a password-protected Excel sheet with a paper back-up copy  
15 stored in a locked cabinet on the UW campus. Template consent and data collection forms are available  
16 by request to the corresponding author.  
17

18  
19 The identification numbers will contain seven digits that signify the participant’s tribal health association  
20 (Eastern Shoshone or Northern Arapaho), recruitment wave (1-3), intervention status (garden or control),  
21 household, and if she or he is head of that household. These identification numbers will help ensure  
22 participants are given the correct survey versions (e.g., control participants will not answer questions  
23 about gardening and only heads of households will receive the food security questions). The code names,  
24 which are words chosen by the participant at enrollment, will enable both participants and staff to easily  
25 keep track of health passports and confirm identity at each data collection station. Participants also will be  
26 given the option to fill out paperwork to have a copy of blood lab results from the day sent to a specified  
27 health care provider. UW staff will keep health passports between data collection sessions. At each of the  
28 subsequent three sessions, family members will be returned their health passport to use during the session.  
29

30 Wyoming Health Fairs will staff the phlebotomy station and conduct blood draws for adults and HbA1c  
31 finger sticks for children. Participants will be invited to help themselves to the provided breakfast any  
32 time after completing the phlebotomy station.  
33

34 The biometrics station, staffed by a combination of UW and Wyoming Health Fairs technicians, will  
35 include collection of height, weight, body composition (for people without pacemakers), blood pressure,  
36 waist circumference, and hand strength. Generally, one technician will conduct the measurements while  
37 the other records measurements in the participants’ passport and in an online survey form (Qualtrics).  
38

39 The survey station will be staffed by two UW technicians who will facilitate survey administration to  
40 adult participants. Participants may choose to complete the survey electronically (using Qualtrics), on  
41 paper, or as an oral interview with a technician reading the questions and entering participant answers  
42 online.  
43

44  
45 At the medications and supplements interview station, adult participants will share current medications  
46 and supplements with a UW technician. When available, the technician will use a participant’s physician-  
47 provided medication list to guide the interview. The technician will enter all medications and supplements  
48 into a Microsoft Access database designed by WYSAC for this study.  
49

50 Finally, at the check-out station, a UW technician will review participants’ passports to ensure completion  
51 of each station and will cross-check written information in passports to that in emailed Qualtrics reports  
52 and (if available) on the printout from the Tanita body composition monitor. She will log any  
53 inconsistencies in the designated error database for later correction and facilitate re-measurements if  
54 necessary. The technician will then conduct a short exit interview with participants to ask how the project  
55 is going and to ask for any feedback participants might have at that time. Finally, participants will receive  
56  
57

1  
2  
3 cash stipends (\$40 per adult, \$15 per child, and a \$20 gas stipend per household). UW will keep one copy  
4 of each participant's Tanita printout and will keep health passports until after a participant's final data  
5 collection session, at which point each participant may keep his or her health passport. Participants keep  
6 one copy of their Tanita body composition print-out and adults will receive a copy of their blood test  
7 results in the mail.  
8

9 To improve the chance that participants will arrive having fasted for 12 hours (unless they are diabetic or  
10 have another reason to avoid fasting), sessions will take place from 7am to no later than 1pm. CHR's will  
11 use a scheduling software with automatic email and text reminders to set up times and dates for  
12 participants to attend sessions. CHR's and UW staff will also follow up with any participants who are late  
13 for or miss a scheduled session. These contact procedures will be adapted as needed to meet participant  
14 preferences and most effectively reach them. Any participant who does not attend a main data collection  
15 session will have the option to attend a "sweep" session for just biometric and survey data collection (no  
16 blood draw), scheduled around the participant's calendar in the weeks following the full data gathering  
17 sessions.  
18

19  
20 In the fifth and final year of the project, in 2020, all participating families will be invited to return for a  
21 final data collection session. The design of this session will be constrained by funding, but otherwise  
22 shaped by the Community Advisory Board, feedback from the families, and the partner organizations.  
23 The principal investigator also plans to seek supplemental funding to support annual data gathering with  
24 families after they have matriculated from the main two-year RCT design.  
25

26 In addition to the above-described check-out station data cross checks between participant health  
27 passports, emailed Qualtrics reports, and printed Tanita receipts, we will be using several automated data  
28 checking approaches to ensure data integrity and avoid duplicate case entry. We will in particular check  
29 for and reviewing any inconsistencies in BMI-related variables. Also, UW has a Data and Safety  
30 Monitoring Board (DSMB) to which we report. All members of the data gathering team, including WHF,  
31 are responsible for reporting adverse events. CHR's and WHF will follow up if needed with individual  
32 participants. In addition, the PI will assign severity values to such events and report them annually to the  
33 DSMB and IRB.  
34

## 35 **Outcomes and Analysis Methods**

### 36 **Primary outcome (BMI) analysis**

37 The primary analysis will use an intention to treat (ITT) analysis to examine the effect of gardening on  
38 changes in BMI. Adult BMI data will be analyzed separately from child BMI Z-score data. Z-scores will  
39 be constructed from CDC growth charts. To begin we will present univariate and bivariate descriptive  
40 statistics.  
41  
42

43 Then, we will use a mixed model to estimate the ITT effect of the intervention. Estimation will be via  
44 ANCOVA as this method has been shown to have more statistical power than traditional difference  
45 regressions.[30] For exposition and comparison we will also present less efficient difference regressions  
46 that are traditionally reported. ANCOVA's gain in efficiency is larger the smaller the degree of  
47 autocorrelation in the dependent variable. We will test for autocorrelation in all dependent variables as  
48 ANCOVA's advantage is likely larger for some of the other health outcomes discussed under 'Secondary  
49 Outcome Analysis' below that may be (even) less correlated over time than BMI.  
50  
51

52 Change in adult BMI (and child BMI Z-scores) will be the dependent variable in primary outcome model.  
53 The fixed effects of interest in the model will be the indicator variable for 'garden' (treatment). As  
54 families will be recruited in three annual waves we will include an indicator variable for wave to control  
55 for recruitment year. Further, our estimations will control for baseline BMI, gender, age, and tribe. Due to  
56  
57

1  
2  
3 the longitudinal nature of our data we can also include individual- and household-level effects to control  
4 for unobserved, non-independence of observations. We include these as random effects, if possible, or as  
5 fixed effects if required by Hausman model specification tests.  
6

7 While the primary BMI analysis will examine adult and child outcomes separately, we will also use a  
8 novel technique that allows us to assess BMI outcomes for the entire sample (child and adult combined).  
9 Applying Naschold's (2018) [21] LMST-based method we will first construct BMI Z-scores for all  
10 participants aged 5-74 using NHANES data as the reference population. These Z-scores will provide an  
11 internally consistent outcome measure for interventions expected to impact BMI of all family members.  
12 Biologically and statistically this is as reasonable as the common practice of comparing z-scores among  
13 children of varying ages. Using BMI Z-scores for all participants has two distinct advantages. First,  
14 combining children and adults in the same analysis will increase the number of observations and, thus,  
15 statistical precision. And second, it will allow us to look at the intra-household effects of the intervention,  
16 for instance, we can test whether gardens benefitted children more or less than adults in the same  
17 household.  
18

### 19 20 Secondary outcome analyses

21 Because this is the first full-scale RCT on health impact of home gardens, our secondary outcome  
22 analysis will replicate the ANCOVA analysis outlined above using the whole range of other biometric,  
23 blood serum and survey health outcomes (see table 1) as dependent variables. However, mental and  
24 physical health, hand strength, food security among food insecure households, and diabetes control  
25 among those whose HbA1C and/or survey responses identify them as either diabetic or pre-diabetic will  
26 be the priority secondary outcome analyses.  
27

28 We will also use the gardening fidelity measures described above to analyze treatment effects on these  
29 primary and secondary outcomes, in addition to the primary ITT analysis.  
30

### 31 32 Accounting for changes in medications and supplements

33 During focus groups in the pilot phase of this project, several participants reported that they reduced the  
34 dosage or discontinued medications for several chronic conditions including diabetes, blood pressure,  
35 depression and anxiety, and/or pain. Since changes in medication could either mask or amplify perceived  
36 health impacts of the gardening intervention, the protocol for this study includes gathering information  
37 about medication and supplement use and changes from participants. A pharmacist on the study team will  
38 then explore methods of accounting for any impacts of such changes on assessed health outcomes,  
39 especially for physical and mental health (on the SF-12v2 survey), blood pressure, and HbA1C, as part of  
40 secondary analyses.  
41

42 A review of the literature for a standardized way to accomplish this revealed no previous studies. When a  
43 participant reports medication or supplement changes that plausibly would impact a health outcome  
44 measured in this study, then a pharmacist on the research team will advise on development and use of two  
45 approaches for a secondary analysis of those health outcomes that accounts for those changes. One  
46 approach will be to quantify estimated impact of the medication change on a target outcome, if data are  
47 available to make such estimates. For example, if a participant is taking 1,000 mg of metformin twice  
48 daily for treatment of diabetes at the start of the study and stops the medication during the intervention,  
49 this could be translated to a 1 percentage point reduction in HbA1c.[31] Where such data are not  
50 available, such as for pain or anti-depressant medications, the approach will be to develop an internally  
51 consistent scale for estimating impact of medication changes on outcome variables, and to report such  
52 outcomes qualitatively.  
53  
54  
55  
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57



### Missing data treatment

The CHRs at Wind River Development Fund and Eastern Shoshone Tribal Health, as well as BMA garden staff, will follow up closely with the participants and make great efforts to obtain complete data for all the participants. Any participant with two or more data points (out of the four) will be included in analysis. Missing data patterns will be examined to identify and apply the appropriate method to deal with it (e.g. multiple imputation, Full Information Maximum Likelihood, propensity scoring).

### Insight into mechanisms

The mechanisms of any health changes attributable to the intervention are likely multifaceted. Each of the biometric and survey measures discussed above can potentially impact changes in BMI. For example, sunshine exposure alone might improve mental wellness and blood glucose regulation.[32] The wide range of biometric, physical and mental health indicators collected will be used as explanatory variables in a panel data regression model. We will also test for potential complementarities between these indicators by including respective interaction terms. In addition to controlling for these observable characteristics, we will exploit the panel data structure to also control for sources of unobserved heterogeneity through the use of wave, household and individual dummy variables. This multivariate panel regression model will allow assessment of the effect each observable factor has on changes in participants' BMI. Moreover, it helps to determine the *relative importance* of each of these factors, for example, whether a reduction in BMI is more strongly driven by increased vegetable consumption versus improved mental health. The point estimates from our regression will also be used to predict what changes in BMI are possible based on achievable ranges of changes in our biometric and survey measures. Qualitative data analysis will also inform quantitative estimation strategies for mechanism exploration. Overall, mechanism analyses will provide insight but not conclusions about how gardening may work to improve health, if indeed improvements are identified.

### Expected outcomes

Better outcomes in nutritional, physical and emotional health are expected among family members in gardening households than in control households, measured per the above. Differences in adult BMI is the primary outcome. The pilot data and previous observational research indicate other significant outcomes may include improvements in emotional health, blood glucose levels and control, and hand strength.

### Potential problems and alternative strategies

The incentives for participation are high enough that the team expects enough enrollment and retention to support this study. Yet, attrition and missed data gathering appointments are the most likely challenges, especially given the transportation issues many families face. However, the tribal health CHRs build and maintain strong relationships with the families they serve, and they will support families in making and keeping their data gathering appointments, including picking them up and bringing them if transportation is a problem. If families miss a main data collection time point, follow-up "sweep" sessions for just biometrics and survey data collection (no blood draw) will be scheduled around those families' schedules.

Contamination, i.e., the spread of some benefits of gardening from intervention to control families, is possible. For example, intervention families may share their harvest or even just their excitement, and control families may help intervention families with their gardens. In addition, though control families will agree to wait to garden until data collection is complete, and will not receive gardening support until then, they are free to start a garden if they wish. These issues would reduce the ability of this study to detect any positive health impacts of gardening; yet, they also would suggest that such positive impacts are socially contagious. The qualitative research accompanying these RCT methods will help provide insight into these issues, but will not change our primary ITT analysis.

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3 If provisional data analysis indicates the study is impacting BMI but is not powered sufficiently to detect  
4 differences (e.g., if attrition exceeds the maximum 16% assumed in the power calculations above or if the  
5 impact on BMI is smaller than estimated from pilot data), then the team will rerun power calculations  
6 based on observed attrition rates and BMI changes to inform how many additional families to recruit in a  
7 supplemental fourth wave.  
8

## 9 **DISCUSSION**

10  
11 This Growing Resilience research project leverages WRIR assets of land, family, culture and community  
12 health organizations to develop and evaluate home food gardens as a family-based health promotion  
13 intervention to reduce disparities suffered by Native Americans in nearly every measure of health. As a  
14 tribal health partner said during the pilot phase of this project, “We need to put health back into the hands  
15 of the people.”  
16

17 The central scientific hypothesis in this study is that, after two years of home gardening, the BMI and  
18 other objectively verifiable health indicators in members of intervention families will show positive and  
19 significant differences from those of control families. The long-term goal is to build tribal capacity to  
20 improve Native American health by identifying and evaluating suitable, scalable and sustainable health  
21 promotion interventions aimed at ending health disparities. If results from this study are positive, then  
22 supporting home gardens with tribal families will become a culturally relevant and empowering health  
23 promotion strategy for tackling health disparities.  
24

25  
26 Regardless of the RCT results, an immediate goal is to support WRIR organizations in establishing and  
27 sustaining home food gardening as an option for any family on the reservation who would like to start  
28 growing some of their own food. Benefits of such gardening likely extend beyond narrow measures of  
29 health such as those quantitatively assessed in this study (citation of paper by first author redacted for  
30 review).  
31

32 As the first full-scale RCT about health impacts of home gardening, which observational studies suggest  
33 improves health, results of this study may also be relevant for families in other settings and of other  
34 cultures. In addition, development of an LMS z-score BMI curve might enable future studies to measure  
35 BMI outcomes in adults and children who are 5 or older as one population.  
36

## 37 **Ethics**

38  
39 This study was co-designed with tribal health organizations, gardeners from the WRIR community,  
40 garden-intervention participants from the project’s pilot study, UW-based researchers, and a tribal  
41 community based organization. This study was approved by the University of Wyoming Institutional  
42 Review Board (Protocol #20150626CP00852), the Northern Arapaho Business Council, and the Eastern  
43 Shoshone Business Council. A Community Advisory Board is overseeing and advising the study  
44 implementation and dissemination. Additionally, all de-identified data will be shared with each tribe, and  
45 any major protocol modifications will be discussed with the CAB and shared with both tribes and the UW  
46 IRB. About half of the direct-cost budget for the project is allocated to WRIR-based partners and people  
47 and half to UW for data collection and analysis costs. Growing Resilience also responds to extensive  
48 interest in home gardening among WRIR families that emerged during an earlier UW-WRIR action-  
49 research collaboration.  
50

51 However, the families who wait two years for their gardens – the controls – are bearing the costs of the  
52 rigor of a RCT design. Are the costs of this knowledge gain fair or right to ask anyone, especially in a  
53 Native American community, to bear?  
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3 Additional ethical questions are raised by widening the lens to examine the enormous political,  
4 institutional and financial power differences between a university, such as UW, and tribal organizations.  
5 For example, NIH has awarded UW \$570,856 in indirect costs for this project; the other partner  
6 organizations, together, will receive a total of \$106,700 in funding for overhead. UW incurs substantial  
7 compliance and contract management costs that subawardees do not, but perhaps not costs that are more  
8 than five times those of community organizations.  
9

## 10 **Dissemination**

11  
12 Dissemination will include conference presentations, journal publications, “grey literature” reports for  
13 practitioner and local use, Facebook and a project website, news media coverage, and a national  
14 conference to be held in Wind River Indian Reservation in 2020 to share our results with and learn from  
15 other Sovereign Nation efforts to promote health with food-related interventions. We will also produce  
16 gardening intervention guide tailored for reservation-based gardening programs, drawing on BMA’s  
17 experience and on existing resources, such as existing family garden guides.[33]  
18

## 19 **Conclusion**

20  
21 This paper summarizes the rationale and design for a randomised controlled trial that will support  
22 development of a tribal-led home garden support program, provide home food gardens to 100 Eastern  
23 Shoshone and Northern Arapaho families, and assess the health outcomes from this gardening  
24 intervention. This is the first RCT to evaluate the health impacts of home food gardening, to the  
25 knowledge of the authors. The goal is to identify and support desirable, empowering and effective family-  
26 based health promotion strategies that will help families in Wind River Indian Reservation, and possibly  
27 in other communities, take control of and improve their health.  
28

## 29 **AUTHOR CONTRIBUTIONS**

30  
31 CP conceived the study and developed and designed it with AW, Blue Mountain Associates, Eastern  
32 Shoshone Tribal Health, and Northern Arapaho Tribal Health. AW led design of data gathering  
33 procedures with assistance from Wyoming Health Fairs and CP. FN and SH designed data analysis  
34 methods and LF is designing approaches to secondary analyses that account for reported medication and  
35 supplement changes. CP and AW wrote the bulk of this protocol paper, with the other co-authors drafting  
36 the sections relevant to their design contributions. All authors, plus the Community Advisory Board,  
37 reviewed and approved this manuscript for submission.  
38

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40  
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43

## 44 **COMPETING INTERESTS STATEMENT**

45  
46 The authors of this paper do not have any competing interests.  
47

## 48 **LIST OF FIGURES AND FIGURE LEGENDS**

49  
50 Figure 1: Flow chart of Growing Resilience study design.  
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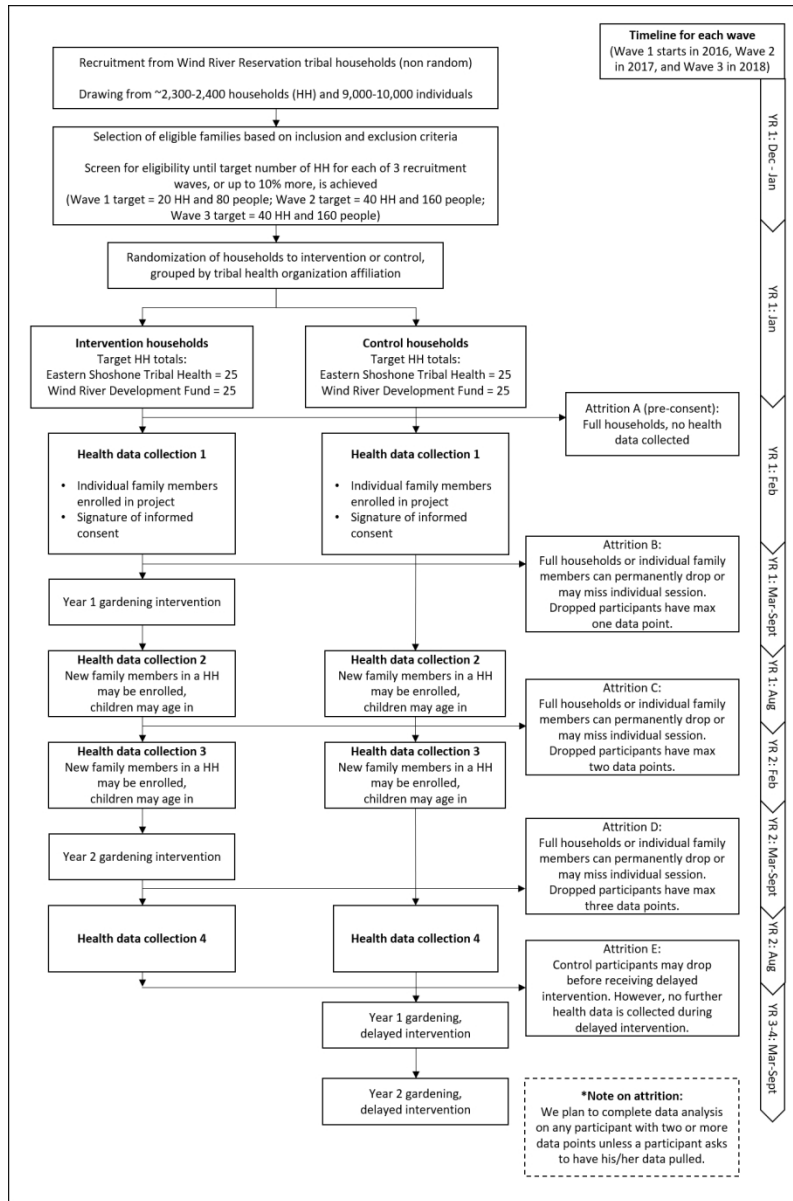


Figure 1: Flow chart of Growing Resilience study design.

118x177mm (300 x 300 DPI)



# BMJ Open

## Assessing health impacts of home food gardens with Wind River Indian Reservation families: protocol for a randomised controlled trial

Journal:	<i>BMJ Open</i>
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<b>Primary Subject Heading</b>:	Research methods
Secondary Subject Heading:	Evidence based practice, Public health
Keywords:	Protocol, RCT, CBPR, Home Gardens, Native American, Wind River Indian Reservation

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17 Assessing health impacts of home food gardens with Wind River Indian Reservation families: protocol  
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## ABSTRACT

**Introduction:** This community-based participatory research (CBPR), *Growing Resilience*, will be the first full-scale randomised controlled trial we identified designed to evaluate impacts of home gardening on family health. It is based on observational studies suggesting home food gardening has myriad health benefits, Wind River Indian Reservation (WRIR) families' interest in home gardening, and the need to end Native American health disparities with empowering, appropriate, and effective health interventions.

**Methods and analysis:** A total of 100 Native American families in WRIR who have not gardened recently but want to garden will be randomly allocated (1:1) to intervention (receiving two years of support designing, installing, and maintaining a home food garden of at least 80 square feet) or to delayed-intervention control (receiving same gardening support after two years of data collection). Willing family members aged 5 and up will participate in data collection each February and August for 2 years, with blood, biometric, and survey measures at each. The primary outcome is adult body mass index (BMI). Secondary outcomes include child BMI, and adult hand strength and self-reported physical and mental health, diabetes control, and food security. Primary analysis will be intention to treat (ITT), using univariate and bivariate descriptive statistics followed by a mixed model to estimate the ITT effect of the intervention using ANCOVA estimation. We will also examine treatment affects using a gardening fidelity measure, combined adult and child BMI outcomes using an LMS z-score reference data set, and possible mechanisms of health impacts.

**Ethics and dissemination:** This protocol was approved by the University of Wyoming Institutional Review Board and the project's Community Advisory Board. De-identified data will be shared with each tribe, and results will be published in peer-reviewed journals, summarized for distribution in WRIR, and shared at a national event to be hosted in WRIR in 2020.

**Key Words:** protocol, RCT, CBPR, home gardens, Native American, Wind River Reservation, LMS z-score, BMI

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study leverages WRIR assets of land, family, culture, and community health organizations to learn how to reduce Native American health disparities with a family-based gardening intervention.
- While home food gardening shows promise as a family-based health promotion intervention, this will be the first full-scale randomised controlled trial of the health impacts of home food gardens.
- This study aims to provide the first internally consistent health outcome measure for interventions that may impact BMI of both child and adult family members by generating and using an LMS z-score reference data set from recent NHANES data.
- In any community, not all families will wish to garden, which limits the reach of the proposed intervention.
- Due to the nature of gardening and of working with a tightly knit community, this study cannot be blinded and some intervention benefits may "contaminate" control families.

## INTRODUCTION

As in all sovereign nations in the US, the Northern Arapaho and Eastern Shoshone tribes that share the Wind River Indian Reservation (WRIR) in Fremont County, Wyoming are survivors of the historical trauma of colonialism. The average age of death for Native Americans in Fremont County is just over 53 years old, with immediate causes including murder, suicide, traffic accidents, chronic liver disease, cancer, diabetes, and cardiovascular disease.[1, 2] Type II diabetes rates in WRIR are at least 11%, double the state-wide rate.[3, 4] Approximately 60% of middle-school-aged children are overweight or obese, also more than double the rates for children overall in Wyoming,[5] and over 70% of adults in WRIR are obese, nearly triple the state-wide rate.[4] Effective and appropriate health promotion interventions for tribal families, in WRIR specifically and among sovereign nations in the US generally, are desperately needed.

Home food gardening shows promise as a family-based health promotion intervention. A growing body of observational research suggests that home and community gardens improve health in many ways, including increasing food security,[6, 7] fruit and vegetable intake,[8-12] and physical activity [8, 13, 14] while reducing stress.[15, 16] Since these outcomes would plausibly help reduce or prevent obesity, and because observation research has found positive associations between gardening and healthier BMI,[12, 17] gardening shows promise as an obesity intervention. However, to date, no full-scale randomised controlled trials have been done to more conclusively identify health impacts of home gardening.

Specifically within WRIR, many families showed interest in receiving technical and financial help in establishing or expanding home gardens during a five-year participatory action and research partnership called Food Dignity. In response, partners at University of Wyoming (UW) and WRIR tribal health and community-based organizations partnered in 2013 to co-design and implement a feasibility pilot study about health impacts of home gardens on the reservation.[18] The Growing Resilience project, for which the protocol is described here, grew out of that pilot study. This appears to be the first full-scale randomised controlled trial (RCT) of the health impacts of home food gardens. Results from a pilot RCT with older cancer survivors was recently published, which found a trajectory toward positive outcomes. Also, an RCT of health impacts of community gardens is currently underway.[19] In addition to being the first scaled RCT of home gardens, this research will contribute to a limited literature about effective and appropriate health promotion strategies for use in and by Native American communities.

## METHODS

### Study Design Overview

About 100 Native American families in WRIR who are interested in starting a new home food garden have been or will be recruited over three years, starting in 2016. Participants will be randomly assigned by household to one of two arms: home gardening support for two years or control with delayed intervention after two years. This RCT was designed using the CONSORT checklist, adheres to the SPIRIT checklist, and is registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (number NCT02672748, registered 3 February 2016). The first wave of participants will enroll in the study on 15 February 2016.

Participants will take part in four health data collection sessions, two per year. These sessions will be in February, prior to gardening activities each year, and again in August at the height of gardening season. Adult data collection will include biometric information [body mass index (BMI), waist circumference, blood pressure, and hand strength]; blood serum analysis (including a standard blood chemistry panel, HbA1c, vitamin D, and serum beta carotene); and survey-based measures including food security (USDA 6-question food security survey) and physical and mental wellness (SF-12v2 survey). Child (ages 5-17) measures collected will include BMI, waist circumference, and HbA1c via finger-prick blood testing. Participants will be encouraged to fast for 12 hours prior to data collection, and we will record fast status

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3 prior to each data collection session. However, a failure to fast will not disqualify participants from a data  
4 collection session.  
5

6 Adult BMI will be the primary health outcome. Primary analysis will be a mixed model that will be used  
7 to test for the effect of the garden intervention on adult BMI, controlling for baseline weight, gender, age,  
8 and tribe and accounting for household clustering.  
9

10 Secondary analyses will study the effects on a range of other biometric, blood and survey health outcome  
11 variables and on intra-household effects. Beyond BMI, health outcomes of particular interest are impacts  
12 on mental and physical health, hand strength, food security among food insecure households, and diabetes  
13 control among those who are either diabetic or pre-diabetic.  
14

15 To investigate the intra-household effects, we will compare relative changes of individual-level BMI Z-  
16 scores for all children and adults in a survey household. These Z-scores will be constructed using  
17 NHANES survey data for people aged 5 to 74 as the reference population and following the statistical  
18 methodology developed in Naschold (2018) [20] .  
19

20 We will also examine possible mechanisms that cause changes in health outcomes (e.g., serum status of  
21 Vitamin D and/or beta-carotene). In this manuscript, we also briefly describe protocol development for  
22 analyzing outcomes with adjustment for any reported changes in medication or supplement dosage.  
23  
24

25 In addition, we will extensively use qualitative methods for providing insights into project process,  
26 outcomes and mechanisms, including photo narratives, focus groups, participation and observation, and  
27 interviews with gardening families. Though this will not impact our primary quantitative analyses  
28 described here, these results may help with understanding of potential mechanisms and with interpreting  
29 any variations in results among gardening families. They will also inform both the gardening support  
30 strategies and the overall partnership process. These methods will be described elsewhere.  
31

### 32 **Project Partners**

33 Growing Resilience is a community-based participatory research project. It was co-designed by WRIR-  
34 based and UW partners, largely during the 2013 feasibility pilot, and is overseen by a Community  
35 Advisory Board. Reservation-based partner organizations include native-run non-profit organization Blue  
36 Mountain Associates (BMA), community health representatives (CHRs) from Eastern Shoshone Tribal  
37 Health and the Wind River Development Fund (whose CHR focuses primarily on Northern Arapaho  
38 family recruitment). Non-reservation-based partners include staff at UW's division of Kinesiology and  
39 Health, staff at the UW-based Wyoming Survey & Analysis Center (WYSAC), UW technicians who  
40 assist at the health data collection sessions, and phlebotomists from the non-profit health organization  
41 Wyoming Health Fairs.  
42  
43

44 BMA, and particularly their garden manager, will lead design and implementation of the gardening  
45 intervention, including development of a garden guide, overseeing an annual gardening workshop,  
46 assisting with garden installation, and providing ongoing support and mentorship for all garden-  
47 intervention participants. CHRs will lead family recruitment and retention efforts. UW will lead  
48 collection of health metrics and data analysis efforts. The Community Advisory Board (CAB) will  
49 participate in policy decision-making in regard to ongoing project design and public representation;  
50 advocate for community interests in regard to research data collection, ownership and dissemination;  
51 serve as an additional contact point for all research participants seeking information or assistance with  
52 their involvement in the project; and consider how to maintain the capacity, infrastructure, and  
53 momentum of the gardening program beyond the life of the funded project. Seven members of the WRIR  
54 community make up the CAB.  
55  
56  
57

## Participants

To be eligible to participate, a family must meet the following requirements: 1) live within the boundaries of the Wind River Reservation (including Riverton, WY); 2) have at least one member enrolled in a federally-recognized tribe; 3) have at least two adults (or one adult for single-adult families) willing to participate in two years of gardening and four health data collection sessions over two years; and 4) have interest in starting and sustaining a home food garden, but don't currently have a garden over 30 square feet. Though the gardening intervention will be at the household level, data collection and analysis will be at the individual level. Adults living in the household and children aged 5 or older can enroll in the study to participate in the data collection.

Even though adult BMI will be the primary outcome of this study, being overweight or obese will not be part of the eligibility criteria. About 70% of adults in Wind River are obese,[4] perhaps another 20% are overweight, and at least two adults per participating household are expected to enroll in the study. Thus, the study team and the advisory board for the pilot study decided that the ethical and practical issues that screening for eligibility by BMI would raise were not worth surmounting.

Children will be included in the study because family health and participation was a priority set by the advisory group during the pilot phase, which had included only adult family members in data gathering. Children who are under 5 years old when the family enrolls in the project may "age in" to data collection procedures as long as they can participate in at least two data collection sessions. Similarly, youth who turn 18 during their family's enrollment in the study may elect to participate in adult data measures (i.e. blood draw, blood pressure, hand strength, and survey). If a participant becomes pregnant or incarcerated while taking part in the study, he or she will not undergo data collection for the duration of pregnancy or incarceration.

The goal is to enroll 100 families in three waves over the first three years of Growing Resilience, with 20 in the first year and then 40 in each of the next two years. Eastern Shoshone Tribal Health and the Wind River Development Fund each will aim to recruit 50 households. They will primarily draw from the hundreds of families they already serve, though joint public events and media advertising will also be used.

## Participant and Public Involvement

As discussed in the introduction, Growing Resilience was designed to meet the expressed needs of families in WRIR for more home gardens. Project partners from UW, tribal health programs, and BMA focused on home gardens based on families' experience that food sovereignty depends on having food (including food gardens) close to their homes, given the large geographic size of WRIR and many families' lack of access to reliable transportation.

Partners then collected feedback on the 2013 pilot from project participants. Changes resulting from this feedback included adding children aged 5-17 to the study (based on participants' priorities for family-based interventions); providing financial compensation for participating in each health data collection session (based on participants' assessment of the burden of participation); modifying survey questions and dramatically shortening the survey (attention and participation began dropping after 20 minutes, including because children were often present); adding multiple modes of survey administration (based on participants' experience and preferences taking the pilot survey); removing the use of activity trackers (these were not well used nor received by participants); and setting the intervention duration to two years (based on project partners' observation that most participants needed more than one year of gardening support to develop successful gardens.) We also will move data collection sessions to a central location on the reservation, providing transport as needed, instead of visiting participant homes (due to logistics of adding blood draws, which were not part of the pilot, and to both partner and participant preferences).

One of the participants from the 2013 pilot project is now on the project's Community Advisory Board, but otherwise participants are not directly involved in ongoing study recruitment and conduct. However, new participants may join because they have heard of the project from current participants and wish to take part.

Participants will receive ongoing reports of their personal health information (including biometrics and blood chemistry panel) after each data collection session they attend. Additionally, results will be summarized for distribution in WRIR and shared at a national event to be hosted in WRIR in 2020.

### Calculation of Sample Size

Sample size calculations were performed with adult BMI as the primary outcome. The feasibility pilot study data, combined with demographic data about WRIR, implies that the average participating family would have 2 adult and 2 child participants in the study. Thus, 100 families would include 200 adult participants.

The 80% power calculations below include a family-cluster design effect of 1.1 among adults in one household,[21] an attrition rate of 16%, and a difference in adult BMI change between control and intervention groups of 0.5 over the two years of intervention (0.75 vs. 0.25; with a two-tailed test,  $\alpha=0.05$ ;  $\sigma=1.1$ ).[22] Assumptions are based on the literatures cited and on our pilot data.

Design effect of household adult clusters =  $1.1 = 1 + (m-1)*ICC = 1 + (2 \text{ adults} - 1)*0.1$

Sample size needed (each group) =  $76 = 2[(1.96+.842)2*\sigma^2]/(u1-u2)^2 = 2[(1.96+.842)2*(1.1)^2]/(0.75-0.25)^2$

Planned sample size (each group) =  $100 = 50 \text{ families} * 2 \text{ adult participants per family on average}$

Planned sample size (each group) including design effect of household clusters:  $91 = 100/1.1$

Adult attrition rate this allows:  $16\% = 1 - (76/91)$ .

In sum, before attrition and adjustment for family cluster effects, this study requires 152 adults (76 per group) to power the study at 80%. "Discounting" the planned sample of 100 adults per group for family cluster effects means reaching the recruitment goal statistically provides "91" adults per group. Thus, this sample size adequately powers the study, allowing for 16% attrition, while attending to constraints of budget and institutional capacity. Additional families will be recruited in the fourth year if attrition or a smaller effect size necessitate that. Attrition rates are based on the relatively low mobility of families in this community, the strong existing relationships between the CHRs and many of the families in the community, and previous research collaborations among this research team with participants from this community.

### Randomisation and Group Assignment

A total of 100 families will be recruited and enrolled in the study in three waves. The first wave, recruited in the first year, will include 20 families. Wave 2 in year 2 of the project and wave 3 in year 3 of the project will include 40 families each. About half of the families in each wave will be recruited by CHRs from Eastern Shoshone Tribal Health (with a focus on Eastern Shoshone families) and the other half by Wind River Development Fund (with a focus on Northern Arapaho families).

1  
2  
3 Staff at UW's WYSAC will oversee the randomisation process. Each wave will be randomised to control  
4 or intervention groups in a 1:1 ratio using stratified block randomisation. First, we will stratify by tribe to  
5 ensure each tribe has an equal number of participants. Second, we will use fixed-block randomisation  
6 within each tribe strata so that 50% of Northern Arapaho-recruited families and 50% of Eastern  
7 Shoshone-recruited families get gardens and half are assigned as controls/delayed intervention.  
8 Randomisation occurs by inputting both tribal groups into an IBM SPSS datasheet and selecting the 1<sup>st</sup> 10  
9 of each tribal group by using a continuous uniform distribution method to randomly select exactly 10  
10 cases from the first n cases. The random cases selected are then input into a separate IBM SPSS datasheet  
11 where approximately 50% of the cases are randomly selected using IBM SPSS simple random sample  
12 without replacement. The randomly selected cases become the treatment groups and the cases not selected  
13 become the control/delayed intervention groups.  
14

15  
16 The rationale for stratified block (rather than simple) randomisation is practical and cultural. Practically,  
17 establishing the intervention gardens is so time and planning intensive that BMA needs managed and  
18 predictable numbers of families with whom they will work. Culturally and politically speaking, each tribe  
19 prefers to receive approximately equal services each year. The actual randomisation process will be  
20 blinded, i.e., participants will be unable to manipulate the randomisation process itself. The flow chart in  
21 Figure 1 summarises the randomisation, intervention, and data gathering design.  
22

23 Strategies for engaging families who are randomised to control will include issuing a project newsletter to  
24 all participants and the CHR's staying in touch with those families until they have completed the four data  
25 collection sessions and can begin planning their gardens with BMA.  
26

27 [FIGURE 1]  
28

### 29 **Garden Intervention**

30  
31 Families randomly assigned to intervention will receive a full gardening support package for two years  
32 from BMA. After the baseline data gathering session each February, the half-time, year-round garden  
33 manager will meet with each family to plan their garden. BMA's garden manager is Northern Arapaho, a  
34 long-time gardener, and also was previously a Diabetes Navigator for Northern Arapaho Tribal Health,  
35 giving her particular insight and expertise in both gardening and health promotion. The first-year support  
36 package will include the following: 1) consultation (on location; whether in-ground, raised bed, container;  
37 and what they would like to grow), 2) garden bed installation, 3) purchase of materials (e.g. tools, starts,  
38 and seeds), 4) ongoing mentorship including garden visits, and 5) gardening workshops. The planned  
39 average budget for this package will be \$700 per family, excluding the manager's time and the labor costs  
40 of seasonal hires. Garden-intervention participants will be in charge of maintaining their gardens through  
41 the season (e.g. watering, weeding, and harvesting). Because there will be no parameters regarding what a  
42 family chooses to grow, each garden will be different, based on the participants' interests and needs, but  
43 will be a minimum of 80 square feet per family. Which family members participate in gardening will be  
44 at the household's discretion.  
45

46 During the second year of garden support, BMA will provide additional soil, soil amendments, seeds,  
47 seedlings, and tools as needed, and ongoing mentorship and support for renewing the food garden. The  
48 planned average budget, per family, for the second year of support will be \$200.  
49

50  
51 Primary outcomes will be analysed as intention to treat, regardless of implementation fidelity. However,  
52 we will also consider fidelity in secondary analyses, running a mixed model of significant outcomes  
53 against a measure of garden success. This measure is in development based on a combination of two  
54 indicators. One is the percent of planted garden square footage in August out of the square footage  
55 planned and prepared in May (with prepared plot size provided by the BMA gardening manager and  
56 planted size estimated from photos taken by BMA staff and the participants themselves). The other is an  
57



assessment by the gardening manager of the extent to which each family planted and maintained their garden, using a 5-point scale. Implementation fidelity will also be compared with the records of intervention support to inform intervention design. Finally, the survey measures will ask each adult in an intervention family how many hours they spent gardening, and we will conduct a secondary analysis of individual health outcomes for adults vs. self-reported hours spent in the garden.

After the two seasons of gardening support and four data collection sessions are over, families assigned to the control condition will receive the same first-year gardening support services from BMA as the intervention families do. In their second year they will receive \$200 in credit at the gardening store of their choice to purchase what they need for renewing their gardens.

### Quantitative Data Collection

Twice per year for two years, trained technicians will collect health indicator data from adult and child participants. The primary outcome after two years of gardening support is adult BMI. Secondary adult outcomes include physical and mental health (on the SF-12v2 survey), food security (USDA six-item), hand strength, waist circumference, blood pressure, and fasting (when possible) blood-based measures including HbA1c. For children 5 and older, we are collecting BMI data, waist circumference, and, via finger-prick tests, HbA1c. Table 1 summarizes the quantitative data collected at each of the four sessions.

Table 1: Health indicator data collected for adults and children, in Feb and Aug each year for two years.

	<b>Biometric</b>	<b>Blood-Based</b>	<b>Survey-Based</b>
<b>Adults</b>	<ul style="list-style-type: none"> <li>• BMI (height &amp; weight)</li> <li>• Waist circumference</li> <li>• Blood pressure</li> <li>• Hand strength</li> </ul>	<ul style="list-style-type: none"> <li>• Full 32-level chemistry profile</li> <li>• Hemoglobin A1C (diabetes)</li> <li>• Vitamin D (sun exposure)</li> <li>• Serum beta carotene (vegetable consumption)[23]</li> </ul>	<ul style="list-style-type: none"> <li>• Food security</li> <li>• Physical &amp; mental wellness (SF-12v2)</li> <li>• Health management</li> <li>• Physical activity</li> <li>• Confidence about[24] and frequency of[25] vegetable intake</li> <li>• Medications and supplements</li> </ul>
<b>Children</b>	<ul style="list-style-type: none"> <li>• BMI (height &amp; weight)</li> <li>• Waist circumference</li> </ul>	<ul style="list-style-type: none"> <li>• Hemoglobin A1C via finger prick</li> </ul>	N/A

### Primary Outcome Measurement

Height will be measured using a Seca 213 Mobile Stadiometer. Participants will remove shoes and socks and stand with feet together, heels and back to the stadiometer. Technicians will ensure participant's head is in the Frankfort Plane, ask the participant to take and hold a deep breath, and then lower the sliding headboard until it is contact with the head, compressing hair if needed. Participant will then be asked to bend knees and step away from stadiometer. The technician will record height to the nearest half inch, written on a scrap piece of paper. The technician will measure height a minimum of three times, continuing to take measurements until they have a minimum of two height measures that match to the half inch.

1  
2  
3 Weight will be measured for most participants using a Tanita SC-331S Body Composition Analyzer.  
4 After verifying that the participant has no internal electronic devices (such as a pacemaker or diabetes  
5 pump), the technician will enter the participant's measured height (to the half inch), age, self-identified  
6 gender, clothing weight (standardized at 3 lbs. for adults and 2 lbs. for children), and body type  
7 (standardized as "normal" for all participants) into the Tanita. The participant will then step onto the unit,  
8 which measures weight to the 0.2 pound and also calculates BMI. Weight of participants who cannot use  
9 the Tanita will be weighed using a MyWeigh XL-High Capacity Scale.

### 11 Other Outcome Measurement

12  
13 Waist circumference of adults and children will be measured using a Gulick II Tape Measure. The  
14 technician will request that the participant hold the zero of the tape measure on her navel and then ask the  
15 participant to turn in a circle. The technician will adjust the tape measure so that it lies parallel to the floor  
16 while remaining across the navel. The technician will then pull tension on the tape measure to 4 oz. as  
17 displayed on the tape's tension indicator and then record waist circumference to the nearest half inch.  
18 Like other common methods for measuring waist circumference, this approach yields internally consistent  
19 and replicable results, while also being comparatively simple to use.[26]

20  
21 Adult blood pressure will be taken using an Omron 10 Plus Series Upper Arm Blood Pressure Monitor  
22 with ComFit Cuff. The technician will wrap the cuff around a participant's bicep, as the participant to rest  
23 her arm on a table, then will initiate the automatic monitor process. If the cuff is too small to fit around a  
24 participant's arm comfortably, technicians will read blood pressure by wrapping the cuff around the  
25 participant's forearm instead of bicep.

26  
27 Changes in hand strength provide a surprisingly strong nutrition indicator and disability and mortality  
28 predictor.[27-29] Hand strength of adult participants will be measured with a Baseline 12-0240 Standard  
29 Hand Dynamometer. The technician will instruct the participant to hold the dynamometer facing away  
30 from themselves, elbow tight to waist and at a 90-degree angle from the upper arm. The participant will  
31 then squeeze the dynamometer and the technician will record hand strength to the nearest pound. The  
32 process will then be repeated for the other hand.

33  
34  
35 Adult participants will also complete a survey comprised of a maximum of 46 questions, depending on  
36 skip patterns. Survey questions will include physical and mental wellness (SF-12v2® Health  
37 Surveys),[30] food security (USDA U.S. Household Food Security Survey Module Six-Item Short  
38 Form,)[31] confidence managing health, demographics, and issues related to the Growing Resilience  
39 garden intervention. Questions also will ask participants to estimate their physical activity, vegetable  
40 consumption, and (for the intervention group) how many hours they spent gardening each week. The need  
41 to limit overall survey length to a 20-30 minute time burden on participants heavily constrained the  
42 number of questions that could be posed and answered with attention, or at all, by participants. Thus, for  
43 example, the survey includes the 7 vegetable consumption questions from the National Cancer Institute's  
44 Quick Food Scan[25], which shows reliability but little precision in measuring intake.[32] Physical  
45 activity estimates are requested in just one question ["Think about your level of physical activity in the  
46 past four weeks. How often have you done moderate or high levels of physical activity (for example,  
47 pushing a vacuum cleaner, gardening, playing horse shoes, walking, running, or playing basketball)?"],  
48 with examples derived from the pilot experience and the 11 response options modelled on the vegetable  
49 consumption questions. Medication and supplement data will be collected via interviews and, when  
50 consent is given, medication lists from the participants' health care providers. Though the survey will not  
51 be administered to children, child gender and birthdate data will be collected as part of intake procedures  
52 for use in BMI-for-age z-score calculations.

53  
54  
55 For the blood-based measures, trained phlebotomists from WHF will draw venous blood from adults for  
56 analysis by LabCorps. For adults 18 years and older, the chemistry panel including measures of HbA1c,

1  
2  
3 beta-carotene (as a proxy for vegetable consumption),[23] vitamin D (as a proxy for sunlight exposure),  
4 cholesterol, and triglycerides. HgA1c in youth aged 17 years and younger will be measured using A1C  
5 Now diagnostic kits that use a finger prick to obtain a small blood sample. Participants will be encouraged  
6 to fast for 12 hours prior to data collection, and we will record fast status prior to each data collection  
7 session. However, a failure to fast will not disqualify participants from a data collection session.  
8

### 9 **Data Collection and Management Procedures**

10  
11 The health data collection sessions will take place twice each year (February and August) in a public  
12 building that is relatively centrally located in WRIR. The community health representatives will schedule  
13 appointments with each participating family and, if needed, assist with transportation. Families will move  
14 through six stations: check in, phlebotomy, biometrics, survey, medications and supplements interview,  
15 and check out.  
16

17 At their first check in, participants will review and sign consent (adults) and assent (children) forms along  
18 with protected health information sharing forms (to allow WHF and UW to share participant health  
19 information for reporting purposes). UW staff will oversee this process and will be on hand to assist (e.g.  
20 reading aloud forms, as needed) and answer questions. After completing informed consents and assents,  
21 each family member will be assigned a unique identification number and will choose a code name. Both,  
22 along with date of birth and self-identified gender, will be written on the back of a hard-copy data  
23 collection booklet called “Your Health Data Passport” (henceforth referred to only as a participant’s  
24 “health passport”) that participants take from station to station within each data gathering session. Real  
25 names will be linked with these numbers in a password-protected Excel sheet with a paper back-up copy  
26 stored in a locked cabinet on the UW campus. Template consent and data collection forms are available  
27 by request to the corresponding author.  
28

29  
30 The identification numbers will contain seven digits that signify the participant’s tribal health association  
31 (Eastern Shoshone or Northern Arapaho), recruitment wave (1-3), intervention status (garden or control),  
32 household, and if she or he is head of that household. These identification numbers will help ensure  
33 participants are given the correct survey versions (e.g., control participants will not answer questions  
34 about gardening and only heads of households will receive the food security questions). The code names,  
35 which are words chosen by the participant at enrollment, will enable both participants and staff to easily  
36 keep track of health passports and confirm identity at each data collection station. Participants also will be  
37 given the option to fill out paperwork to have a copy of blood lab results from the day sent to a specified  
38 health care provider. UW staff will keep health passports between data collection sessions. At each of the  
39 subsequent three sessions, family members will be returned their health passport to use during the session.  
40

41 Wyoming Health Fairs will staff the phlebotomy station and conduct blood draws for adults and HbA1c  
42 finger sticks for children. Participants will be invited to help themselves to the provided breakfast any  
43 time after completing the phlebotomy station.  
44

45 The biometrics station, staffed by a combination of UW and Wyoming Health Fairs technicians, will  
46 include collection of height, weight, body composition (for people without pacemakers), blood pressure,  
47 waist circumference, and hand strength. Generally, one technician will conduct the measurements while  
48 the other records measurements in the participants’ passport and in an online survey form (Qualtrics).  
49

50  
51 The survey station will be staffed by two UW technicians who will facilitate survey administration to  
52 adult participants. Participants may choose to complete the survey electronically (using Qualtrics), on  
53 paper, or as an oral interview with a technician reading the questions and entering participant answers  
54 online.  
55  
56  
57

1  
2  
3 At the medications and supplements interview station, adult participants will share current medications  
4 and supplements with a UW technician. When available, the technician will use a participant's physician-  
5 provided medication list to guide the interview. The technician will enter all medications and supplements  
6 into a Microsoft Access database designed by WYSAC for this study.  
7

8 Finally, at the check-out station, a UW technician will review participants' passports to ensure completion  
9 of each station and will cross-check written information in passports to that in emailed Qualtrics reports  
10 and (if available) on the printout from the Tanita body composition monitor. She will log any  
11 inconsistencies in the designated error database for later correction and facilitate re-measurements if  
12 necessary. The technician will then conduct a short exit interview with participants to ask how the project  
13 is going and to ask for any feedback participants might have at that time. Finally, participants will receive  
14 cash stipends (\$40 per adult, \$15 per child, and a \$20 gas stipend per household). UW will keep one copy  
15 of each participant's Tanita printout and will keep health passports until after a participant's final data  
16 collection session, at which point each participant may keep his or her health passport. Participants keep  
17 one copy of their Tanita body composition print-out and adults will receive a copy of their blood test  
18 results in the mail.  
19  
20

21 To improve the chance that participants will arrive having fasted for 12 hours (unless they are diabetic or  
22 have another reason to avoid fasting), sessions will take place from 7am to no later than 1pm. CHR's will  
23 use a scheduling software with automatic email and text reminders to set up times and dates for  
24 participants to attend sessions. CHR's and UW staff will also follow up with any participants who are late  
25 for or miss a scheduled session. These contact procedures will be adapted as needed to meet participant  
26 preferences and most effectively reach them. Any participant who does not attend a main data collection  
27 session will have the option to attend a "sweep" session for just biometric and survey data collection (no  
28 blood draw), scheduled around the participant's calendar in the weeks following the full data gathering  
29 sessions.  
30

31 In the fifth and final year of the project, in 2020, all participating families will be invited to return for a  
32 final data collection session. The design of this session will be constrained by funding, but otherwise  
33 shaped by the Community Advisory Board, feedback from the families, and the partner organizations.  
34 The principal investigator also plans to seek supplemental funding to support annual data gathering with  
35 families after they have matriculated from the main two-year RCT design.  
36  
37

38 In addition to the above-described check-out station data cross checks between participant health  
39 passports, emailed Qualtrics reports, and printed Tanita receipts, we will be using several automated data  
40 checking approaches to ensure data integrity and avoid duplicate case entry. We will in particular check  
41 for and reviewing any inconsistencies in BMI-related variables. Also, UW has a Data and Safety  
42 Monitoring Board (DSMB) to which we report. All members of the data gathering team, including WHF,  
43 are responsible for reporting adverse events. CHR's and WHF will follow up if needed with individual  
44 participants. In addition, the PI will assign severity values to such events and report them annually to the  
45 DSMB and IRB.  
46

## 47 **Outcomes and Analysis Methods**

### 48 **Primary outcome (BMI) analysis**

49 The primary analysis will use an intention to treat (ITT) analysis to examine the effect of gardening on  
50 changes in BMI. As the primary outcome, adult BMI data will be analyzed separately from child BMI Z-  
51 score data. Z-scores will be constructed from CDC growth charts. To begin we will present univariate and  
52 bivariate descriptive statistics.  
53  
54  
55  
56  
57

1  
2  
3 Then, we will use a mixed model to estimate the ITT effect of the intervention. Estimation will be via  
4 ANCOVA as this method has been shown to have more statistical power than traditional difference  
5 regressions.[33] For exposition and comparison we will also present less efficient difference regressions  
6 that are traditionally reported. ANCOVA's gain in efficiency is larger the smaller the degree of  
7 autocorrelation in the dependent variable. We will test for autocorrelation in all dependent variables as  
8 ANCOVA's advantage is likely larger for some of the other health outcomes discussed under 'Secondary  
9 Outcome Analysis' below that may be (even) less correlated over time than BMI.  
10

11 Change in adult BMI will be the dependent variable in primary outcome model. The fixed effects of  
12 interest in the model will be the indicator variable for 'garden' (treatment). As families will be recruited  
13 in three annual waves we will include an indicator variable for wave to control for recruitment year.  
14 Further, our estimations will control for baseline BMI, gender, age, and tribe. Due to the longitudinal  
15 nature of our data we can also include individual- and household-level effects to control for unobserved,  
16 non-independence of observations. We include these as random effects, if possible, or as fixed effects if  
17 required by Hausman model specification tests. Analysis will be blind to participant control or  
18 intervention condition.  
19

20  
21 While the primary BMI analysis will examine adult outcomes separately from child outcomes, we will  
22 also use a novel technique that allows us to assess BMI outcomes for the entire sample (child and adult  
23 combined). Applying Naschold's (2018) [20] LMST-based method we will first construct BMI Z-scores  
24 for all participants aged 5-74 using NHANES data as the reference population. These Z-scores will  
25 provide an internally consistent outcome measure for interventions expected to impact BMI of all family  
26 members. Biologically and statistically this is as reasonable as the common practice of comparing z-  
27 scores among children of varying ages. Using BMI Z-scores for all participants has two distinct  
28 advantages. First, combining children and adults in the same analysis will increase the number of  
29 observations and, thus, statistical precision. And second, it will allow us to look at the intra-household  
30 effects of the intervention, for instance, we can test whether gardens benefitted children more or less than  
31 adults in the same household.  
32

### 33 Secondary outcome analyses

34  
35 Because this is the first full-scale RCT on health impact of home gardens, our secondary outcome  
36 analysis will replicate the ANCOVA analysis outlined above using the whole range of other biometric,  
37 blood serum and survey health outcomes (see table 1) as dependent variables. However, mental and  
38 physical health, hand strength, food security among food insecure households, and diabetes control  
39 among those whose HbA1C and/or survey responses identify them as either diabetic or pre-diabetic will  
40 be the priority secondary outcome analyses. We will also examine child BMI outcomes (using BMI-for-  
41 age z-score).  
42

43 We will also use the gardening fidelity measures described above to analyze treatment effects on these  
44 primary and secondary outcomes, in addition to the primary ITT analysis.  
45

### 46 Accounting for changes in medications and supplements

47  
48 During focus groups in the pilot phase of this project, several participants reported that they reduced the  
49 dosage or discontinued medications for several chronic conditions including diabetes, blood pressure,  
50 depression and anxiety, and/or pain. Since changes in medication could either mask or amplify perceived  
51 health impacts of the gardening intervention, the protocol for this study includes gathering information  
52 about medication and supplement use and changes from participants. A pharmacist on the study team will  
53 then explore methods of accounting for any impacts of such changes on assessed health outcomes,  
54 especially for physical and mental health (on the SF-12v2 survey), blood pressure, and HbA1C, as part of  
55 secondary analyses.  
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3 A review of the literature for a standardized way to accomplish this revealed no previous studies. When a  
4 participant reports medication or supplement changes that plausibly would impact a health outcome  
5 measured in this study, then a pharmacist on the research team will advise on development and use of two  
6 approaches for a secondary analysis of those health outcomes that accounts for those changes. One  
7 approach will be to quantify estimated impact of the medication change on a target outcome, if data are  
8 available to make such estimates. For example, if a participant is taking 1,000 mg of metformin twice  
9 daily for treatment of diabetes at the start of the study and stops the medication during the intervention,  
10 this could be translated to a 1 percentage point reduction in HbA1c.[34] Where such data are not  
11 available, such as for pain or anti-depressant medications, the approach will be to develop an internally  
12 consistent scale for estimating impact of medication changes on outcome variables, and to report such  
13 outcomes qualitatively.  
14

### 15 16 Missing data treatment

17 The CHRs at Wind River Development Fund and Eastern Shoshone Tribal Health, as well as BMA  
18 garden staff, will follow up closely with the participants and make great efforts to obtain complete data  
19 for all the participants. Any participant with two or more data points (out of the four) will be included in  
20 analysis. Missing data patterns will be examined to identify and apply the appropriate method to deal with  
21 it (e.g. multiple imputation, Full Information Maximum Likelihood, propensity scoring).  
22

### 23 24 Insight into mechanisms

25 The mechanisms of any health changes attributable to the intervention are likely multifaceted. Each of the  
26 biometric and survey measures discussed above can potentially impact changes in BMI. For example,  
27 sunshine exposure alone might improve mental wellness and blood glucose regulation.[35] The wide  
28 range of biometric, physical and mental health indicators collected will be used as explanatory variables  
29 in a panel data regression model. We will also test for potential complementarities between these  
30 indicators by including respective interaction terms. In addition to controlling for these observable  
31 characteristics, we will exploit the panel data structure to also control for sources of unobserved  
32 heterogeneity through the use of wave, household and individual dummy variables. This multivariate  
33 panel regression model will allow assessment of the effect each observable factor has on changes in  
34 participants' BMI. Moreover, it helps to determine the *relative importance* of each of these factors, for  
35 example, whether a reduction in BMI is more strongly driven by increased vegetable consumption versus  
36 improved mental health. The point estimates from our regression will also be used to predict what  
37 changes in BMI are possible based on achievable ranges of changes in our biometric and survey  
38 measures. Qualitative data analysis will also inform quantitative estimation strategies for mechanism  
39 exploration. Overall, mechanism analyses will provide insight but not conclusions about how gardening  
40 may work to improve health, if indeed improvements are identified.  
41

### 42 43 Expected outcomes

44 Better outcomes in nutritional, physical and emotional health are expected among family members in  
45 gardening households than in control households, measured per the above. Differences in adult BMI is the  
46 primary outcome. The pilot data and previous observational research indicate other significant outcomes  
47 may include improvements in emotional health, blood glucose levels and control, and hand strength.  
48

### 49 50 Potential problems and alternative strategies

51 The incentives for participation are high enough that the team expects enough enrollment and retention to  
52 support this study. Yet, attrition and missed data gathering appointments are the most likely challenges,  
53 especially given the transportation issues many families face. However, the tribal health CHRs build and  
54 maintain strong relationships with the families they serve, and they will support families in making and  
55 keeping their data gathering appointments, including picking them up and bringing them if transportation  
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3 is a problem. If families miss a main data collection time point, follow-up “sweep” sessions for just  
4 biometrics and survey data collection (no blood draw) will be scheduled around those families’ schedules.  
5

6 Contamination, i.e., the spread of some benefits of gardening from intervention to control families, is  
7 possible. For example, intervention families may share their harvest or even just their excitement, and  
8 control families may help intervention families with their gardens. In addition, though control families  
9 will agree to wait to garden until data collection is complete, and will not receive gardening support until  
10 then, they are free to start a garden if they wish. These issues would reduce the ability of this study to  
11 detect any positive health impacts of gardening; yet, they also would suggest that such positive impacts  
12 are socially contagious. A question in the survey administered at each August data gathering will ask  
13 participants if they started or maintained a vegetable garden of any size that summer, which will help  
14 identify families who decide to garden during their period as controls. Additionally, the qualitative  
15 research accompanying these RCT methods will help provide insight into these issues, but will not  
16 change our primary ITT analysis.  
17

18  
19 If provisional data analysis indicates the study is impacting BMI but is not powered sufficiently to detect  
20 differences (e.g., if attrition exceeds the maximum 16% assumed in the power calculations above or if the  
21 impact on BMI is smaller than estimated from pilot data), then the team will rerun power calculations  
22 based on observed attrition rates and BMI changes to inform how many additional families to recruit in a  
23 supplemental fourth wave.  
24

25 The constraints on a feasible and appropriate length of the survey component in this context also limits  
26 the quality and quantity of data collected that might provide additional insight into mechanisms of any  
27 differential outcomes found between the two groups. For example, the beta-carotene blood measure only  
28 provides an indicator of consumption for vegetables rich in that vitamin, and though the brief vegetable  
29 consumption survey module will provide some indicator of vegetable consumption, responses will not  
30 provide precise intake information. However, the range of quantitative indicators combined with deep  
31 qualitative research with gardening and control families should provide a relatively rich data set to  
32 examine for potential mechanisms in any differential outcomes this study may find between the two  
33 groups. Also, this first full-scale RCT study into home garden impacts will provide foundations for future  
34 protocols that can be designed with greater focus into mechanisms and outcomes that this study’s results  
35 indicate are plausible or likely.  
36

## 37 38 **DISCUSSION**

39 This Growing Resilience research project leverages WRIR assets of land, family, culture and community  
40 health organizations to develop and evaluate home food gardens as a family-based health promotion  
41 intervention to reduce disparities suffered by Native Americans in nearly every measure of health. As a  
42 tribal health partner said during the pilot phase of this project, “We need to put health back into the hands  
43 of the people.”  
44

45 The central scientific hypothesis in this study is that, after two years of home gardening, the BMI and  
46 other objectively verifiable health indicators in members of intervention families will show positive and  
47 significant differences from those of control families. The long-term goal is to build tribal capacity to  
48 improve Native American health by identifying and evaluating suitable, scalable and sustainable health  
49 promotion interventions aimed at ending health disparities. If results from this study are positive, then  
50 supporting home gardens with tribal families will become a culturally relevant and empowering health  
51 promotion strategy for tackling health disparities.  
52  
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54 Regardless of the RCT results, an immediate goal is to support WRIR organizations in establishing and  
55 sustaining home food gardening as an option for any family on the reservation who would like to start  
56  
57

growing some of their own food. Benefits of such gardening likely extend beyond narrow measures of health such as those quantitatively assessed in this study (citation of paper by first author redacted for review).

As the first full-scale RCT about health impacts of home gardening, which observational studies suggest improves health, results of this study may also be relevant for families in other settings and of other cultures. In addition, development of an LMS z-score BMI curve might enable future studies to measure BMI outcomes in adults and children who are 5 or older as one population.

## Ethics

This study was co-designed with tribal health organizations, gardeners from the WRIR community, garden-intervention participants from the project's pilot study, UW-based researchers, and a tribal community based organization. This study was approved by the University of Wyoming Institutional Review Board (Protocol #20150626CP00852), the Northern Arapaho Business Council, and the Eastern Shoshone Business Council. A Community Advisory Board is overseeing and advising the study implementation and dissemination. Additionally, all de-identified data will be shared with each tribe, and any major protocol modifications will be discussed with the CAB and shared with both tribes and the UW IRB. About half of the direct-cost budget for the project is allocated to WRIR-based partners and people and half to UW for data collection and analysis costs. Growing Resilience also responds to extensive interest in home gardening among WRIR families that emerged during an earlier UW-WRIR action-research collaboration.

However, the families who wait two years for their gardens – the controls – are bearing the costs of the rigor of a RCT design. Are the costs of this knowledge gain fair or right to ask anyone, especially in a Native American community, to bear?

Additional ethical questions are raised by widening the lens to examine the enormous political, institutional and financial power differences between a university, such as UW, and tribal organizations. For example, NIH has awarded UW \$570,856 in indirect costs for this project; the other partner organizations, together, will receive a total of \$106,700 in funding for overhead. UW incurs substantial compliance and contract management costs that subawardees do not, but perhaps not costs that are more than five times those of community organizations.

## Dissemination

Dissemination will include conference presentations, journal publications, “grey literature” reports for practitioner and local use, Facebook and a project website, news media coverage, and a national conference to be held in Wind River Indian Reservation in 2020 to share our results with and learn from other Sovereign Nation efforts to promote health with food-related interventions. We will also produce gardening intervention guide tailored for reservation-based gardening programs, drawing on BMA's experience and on existing resources, such as existing family garden guides.[36]

## Conclusion

This paper summarizes the rationale and design for a randomised controlled trial that will support development of a tribal-led home garden support program, provide home food gardens to 100 Eastern Shoshone and Northern Arapaho families, and assess the health outcomes from this gardening intervention. This is the first RCT to evaluate the health impacts of home food gardening, to the knowledge of the authors. The goal is to identify and support desirable, empowering and effective family-based health promotion strategies that will help families in Wind River Indian Reservation, and possibly in other communities, take control of and improve their health.



## AUTHOR CONTRIBUTIONS

CP conceived the study and developed and designed it with AW, Blue Mountain Associates, Eastern Shoshone Tribal Health, and Northern Arapaho Tribal Health. AW led design of data gathering procedures with assistance from Wyoming Health Fairs and CP. FN and SH designed data analysis methods and LF is designing approaches to secondary analyses that account for reported medication and supplement changes. CP and AW wrote the bulk of this protocol paper, with the other co-authors drafting the sections relevant to their design contributions. All authors, plus the Community Advisory Board, reviewed and approved this manuscript for submission.

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## COMPETING INTERESTS STATEMENT

The authors of this paper do not have any competing interests.

## LIST OF FIGURES AND FIGURE LEGENDS

Figure 1: Flow chart of Growing Resilience study design.

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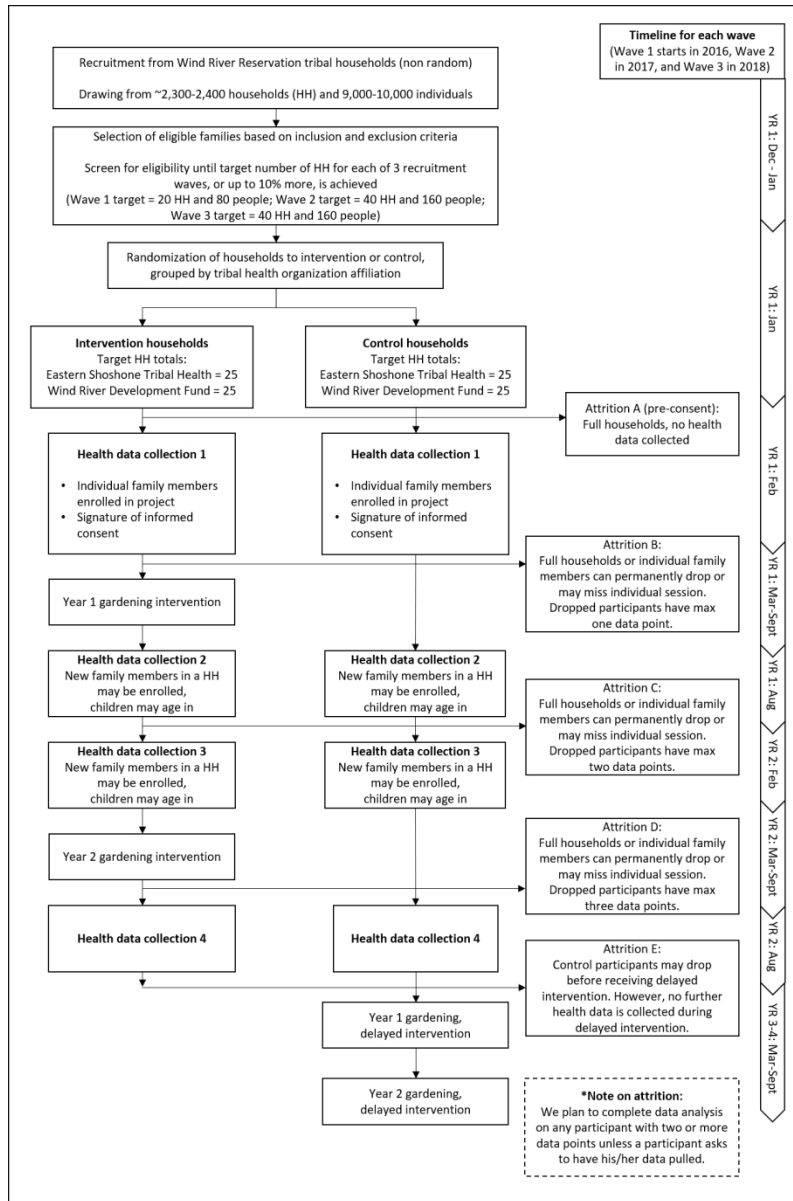


Figure 1: Flow chart of Growing Resilience study design.

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