Southwest Harvest for Health Vegetable Gardening Intervention

NCT04251299

Dr. Cindy K. Blair

University of New Mexico

The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

Key Information for *Southwest Harvest for Health*

You are being invited to take part in a research study that will test the benefits of a home-based, vegetable gardening program for cancer survivors.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

By doing this study, we hope to learn how a vegetable gardening program affects diet, physical activity, and health-related quality of life. Your participation in this research will last about 10 months. The study will provide participants with gardening tools and supplies. A Master Gardener from the New Mexico State University Cooperative Extension System will be your mentor and provide guidance throughout the study.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There may be possible benefits to your health and quality of life through gardening, and by eating healthier and becoming more active. You may take pride in contributing to research designed to promote better health and well-being in cancer survivors throughout New Mexico. Refer to the Detailed Consent for additional benefits.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may experience some inconvenience with participation in this or any research study. For a complete description of the risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Dr. Cindy Blair of the University of New Mexico Health Sciences Center, Department of Internal Medicine. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, you may call Dr. Blair at 505-925-7907 or email to CiBlair@salud.unm.edu.

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

DETAILED CONSENT

Version 2/12/2020

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You would not qualify for this study if you currently have a vegetable garden or had a vegetable garden within the past year. You would also not qualify for this study for the following reasons: a) never diagnosed with cancer; b) diagnosed with metastatic cancer; c) unable to participate in light physical activities, such as leisurely walking and gardening; or d) already meeting recommended guidelines of eating five or more fruit and vegetable servings per day and exercising 30 minutes or more each day.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at your home. The three home visits to collect data will take approximately 45 minutes to 1 hour each. In-person visits and phone calls with your Master Gardener mentor will vary based on possible issues with your garden and the level of advice or guidance needed. However, we estimate 10 minutes for each phone call/email correspondence and 30-45 minutes for each in-person visit. The post-study telephone survey will take no longer than 30 minutes to complete. Most of your time commitment to the study will be in planting and caring for your vegetable garden. We estimate approximately 30 minutes at least 3 days per week to properly care for and enjoy your garden. The estimated time for participation in this study is approximately 70 hours over the course of 10-months.

WHAT WILL YOU BE ASKED TO DO?

If you agree to be in this study, you will be asked to read and sign this Consent Form. After you sign the Consent Form, we would ask you to do the following:

1. Home visits: Three times over the study period (at the beginning, and 6 and 9 months later) two members of the UNM study team will come to your home to assess your height, weight, and waist size. We will also ask you to perform tests of physical function, such as the number of times you can stand up and sit down in 30 seconds, how many times you can step up and down in two minutes, and your hand grip strength. These home visits will take 45-60 minutes each.
    a. Health questionnaires: Prior to these home visits, you will be asked to complete questionnaires about your diet, physical activity, sleep quality, health, and quality of life.
2. Activity monitor: We will ask you to wear an electronic activity monitor for 7 days at the beginning, and 6 and 9 months later. The small, thin device (like a patch) will be worn on your leg (day and overnight). This is not a tracking device and we

will not be able to tell what kind of specific activity is happening. Instead, this monitor records general movement and will enable us to get a better idea of your daily activity level. Instructions will be provided for applying and removing the monitor.

3. Gardening Intervention: You will be paired with a certified Master Gardener from the New Mexico Cooperative Extension who will mentor you in planting and tending to three seasonal vegetable gardens throughout the year (spring, summer and fall).
    a. You will be invited to attend a meet-and-greet event where you will meet your Master Gardener and members of the study team in person. This meeting will give you the opportunity to set up the best days/times to meet with your Master Gardener mentor, and to start planning your first garden.
    b. Supplies needed to begin your home vegetable garden will be delivered to you. These include but are not limited to: soil, plants, seeds, and fertilizer to support either 4 container-style garden boxes (which can be used to garden on balconies, patios or decks) or 1 raised bed garden. These supplies will be provided free of charge.
    c. Your Master Gardener mentor will help guide you in setting-up the garden, maintaining it, and replanting it season-to-season.
    d. In providing this support, your Master Gardener will make monthly visits to your home to check on the status of your garden, offer advice, or help troubleshoot any issues with your garden. Between visits, you will communicate either by telephone or email, based on your preference.
    e. Each month, a photograph with you and your Master Gardener mentor next to your garden will be taken and sent to the Southwest Harvest for Health study team so that we may monitor your progress throughout the intervention.
4. Follow-up Interviews/ Questionnaires: Upon completion of the study, we will ask your opinions of the Southwest Harvest for Health program and what aspects were helpful to you, and which were not. Only you, your master gardener, and the study team will see the photograph that is taken.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Participation in this study may involve some risks and discomforts:

a. As you will be performing gardening activities outdoors, you may be exposed to sunlight, which may cause a sunburn if your skin is not protected. You may also be exposed to bacteria while working in the soil. Additionally, you may receive mild cuts or scrapes as you work in the garden. Because of these risks, we suggest wearing protective clothing and gloves while outdoors gardening.

b. There is a slight risk of skin irritation on your leg due to the adhesive used to attach the activity monitor. Instructions will be provided on how to remove the monitor, if irritation occurs, and an alternative attachment method will be provided to reposition the monitor.

c. You will be asked to complete physical performance tests to measure balance, muscular strength and endurance. It is possible that you may become fatigued or unable to complete one or more of the tests. While these are well-validated tests of physical function, there is still a minimal risk of tripping or falling during some of the tests we will ask you to do. Every precaution will be taken by study investigators to prevent you from falling and becoming injured. For example, we will check the test area and remove any tripping hazards. We will spot you during your balance assessment.

d. You may feel some discomfort when disclosing personal information. When answering the survey, you can skip any question that you do not want to answer.

e. While it is our intention to protect your privacy and the information collected about you, there is a small chance of a breach in confidentiality. However, we are taking necessary precautions (e.g. all information kept in a locked cabinet or on a password protected server) to ensure your information is kept private.

Other risks to participate in this study are no greater than the risks of day-to-day living. However, if you do experience any discomfort or negative feelings associated with participation, Dr. Cindy Blair, the lead investigator of the study will be glad to discuss them with you. Dr. Blair can be reached at (505) 925-7907 or CiBlair@salud.unm.edu.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from participating in this study. However, some people have experienced improvement in physical functioning and quality of life when improving their diet and increasing their physical activity through gardening. If you take part in this study, information learned may help us to better understand ways to promote health and well-being in cancer survivors throughout New Mexico.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in the study. To compensate you for your time and participation in the study, you will receive a $20 merchandise card after completing each home visit, for a total of $60. Additionally, you will be receiving gardening supplies valued at roughly $350, which are yours to keep after the study ends.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private. We will make every effort to prevent anyone who is not on the research team from knowing that you gave information, or what the information is. Your name and other identifying information will be maintained in locked files, available only to authorized members of the research team, for the duration of the study. For any information entered onto a computer, the only identifier will be a unique study identification (ID) number. Any personal identifying information and any record linking that information to study ID numbers will be destroyed 4 years beyond the end of the study. This will allow the study team the necessary time to complete the analyses of all the collected data.

You should know there are some circumstances in which we may have to show your information to other people who provide regulatory and ethical oversight of human research. Examples include the UNM Human Research Review Committee (HRRC) and the UNM Comprehensive Cancer Center Data Safety & Monitoring Committee. Also, the law may require us to share your information with the following agencies and for the following reasons:

- The law requires us to share your information with authorities if you report information about a child being abused
- If you pose a danger to yourself or someone else.
- A court or agencies, if you have a reportable disease or condition.
- Authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else.

REDCap is a secure, web-based program to capture and store data at the University of New Mexico. Please be aware, while we make every effort to safeguard your data once received on servers via REDCap, given the nature of online surveys, as with anything involving the internet, we can never guarantee the confidentiality of the data while still in route to the server.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if the investigators determine that:

- You no longer qualify to take part
- You are not able to follow the directions
- Participation in the study is more risk than benefit to you

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEACH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may not take part in this study if you are currently involved in another research study focused on improving diet or increasing physical activity. It is important to let the investigator know if you are in another research study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Cindy Blair at 505-925-7907 immediately.

It is important for you to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of New Mexico will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm should be sought from your insurer, managed care plan, or other benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will receive a $20 merchandise card after completing each home visit, for a total of $60 for taking part in this study. Additionally, you will receive gardening supplies valued at roughly $350, which are yours to keep after the study ends.

If you earn $600 or more by participating in research, it is potentially reportable for tax purposes.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests and other data collected for research purposes are not meant to provide clinical or other information to the study participant. Therefore, individual results will not be returned. However, if at the end of the study, you would like to know the results of your physical function tests or other measurements, please contact Dr. Blair (505-925-7907) or her Project Manager (505-272-2274).

The University of New Mexico Comprehensive Cancer Center is providing financial support for this study.

A description of this clinical trial will be available on ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website any time.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of 25-30 people to do so.

FUTURE USE OF YOUR PROTECTED HEALTH INFORMATION.

Your information or samples collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name or date of birth.

HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATIN (PHI).

As part of this study, we will be collecting health information about you and sharing it with others. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)

By signing this Consent Document, as described in this consent form, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information includes demographic information (your name, where you live, phone number, e-mail address, etc.), information about your cancer diagnosis (type of cancer, year of diagnosis, type of treatment(s)), clinical data collected during the study (height, weight, waist circumference), information from questionnaires (medical history, lifestyle behaviors, etc.), and information from physical function tests and the physical activity monitor.

In addition to researchers and staff at UNMHS and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include health oversight activities and public health measures, safety, and monitors.

Right to Withdraw Your Authorization

Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. This is because the information used and created during the study may be analyzed for many years and it is not possible to know when this will be complete. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your

authorization at any time provided you notify the UNM investigators in writing. To do this, please send letter notifying them of your withdrawal to:

Dr. Cindy Blair
MSC07-4025
One University of New Mexico
Albuquerque New Mexico 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before the date that your withdrawal is received.

The researchers agree to only share your health information with the people listed in this document. Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form it will not affect your:

- Current or future healthcare at the University of New Mexico;
- Current or future payments to the University of New Mexico;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to Dr. Cindy Blair at MSC07-4025; One University of New Mexico; Albuquerque New Mexico 87131 to inform her of your decision.
- Researchers may use and release your health information already collected for this research study.

You understand that you will not be allowed to review the information collected for his research study until after the study is completed. When the study is over, you will have the right to access the information.

The use and sharing of your information have no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of New Mexico Health Sciences Privacy Officer between the business hours of 8am and 5pm Mountain Pacific Time, Monday-Friday at (505) 272-1493.

INFORMED CONSENT SIGNATURE PAGE

You are participating or are authorized to act on behalf of the participant. This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

_____ _____

Signature of research subject, *or if applicable, *research subject's legal representative*

Date

_____

Printed name of research subject, *or if applicable, research subject's legal representative*

*If applicable, please explain Representative's relationship to subject and include a description of representative's authority to act on behalf of subject: Click or tap here to enter text.

I have witnessed the informed consent process. This informed consent form was verbally reviewed with the subject in addition to the HRRC approved short consent form and will act as the written summary of the discussion.

_____ _____

Witness (translator) printed name **Witness (translator) signature and date**

_____ _____

Printed name of [authorized] person obtaining informed consent/HIPAA Authorization

Date

_____

Signature of [authorized] person obtaining informed consent/HIPAA Authorization

PROTOCOL TITLE:

Southwest Harvest for Health: A Mentored Vegetable Gardening Intervention for Cancer Survivors in New Mexico (original grant title)
Aka: Southwest Harvest for Health Pilot (name of study to be included on all study materials for study participants)

PRINCIPAL INVESTIGATOR:

Name	Cindy K. Blair, PhD
Department	Internal Medicine
Telephone Number	505-925-7907
Email Address	CiBlair@salud.unm.edu

ADMINISTRATIVE CONTACT:

Name	Cindy K. Blair, PhD
Department	Internal Medicine
Telephone Number	505-925-7907
Email Address	CiBlair@salud.unm.edu

VERSION NUMBER:

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DATE:

November 1, 2020

REGULATORY FRAMEWORK:

Please indicate all that apply:

☐	DOD (Department of Defense)
☐	DOE (Department of Energy)
☐	DOJ (Department of Justice)
☐	ED (Department of Education)
☐	EPA (Environmental Protection Agency)
☐	FDA (Food and Drug Administration)
☒	HHS (Department of Health and Human Services)
☐	VA
☐	Other:

FUNDING:

This study is funded by a grant from the UNM Comprehensive Cancer Center: Research Support Pilot Project #1441.

CLINICAL TRIALS

Is this a clinical trial per the NIH definition of a Clinical Trial? ☒ Yes ☐ No

NIH Definition of a Clinical Trial:

A research study in which one or more human subjects are prospectively assigned to one or more interventions. An "intervention" is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Use the following four questions to determine the difference between a clinical study and a clinical trial:

1) Does the study involve human participants? ☒ Yes ☐ No
2) Are the participants prospectively assigned to an intervention? ☒ Yes ☐ No
3) Is the study designed to evaluate the effect of the intervention on the participants? ☒ Yes ☐ No
4) Is the effect being evaluated a health-related biomedical or behavioral outcome? ☒ Yes ☐ No

Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if…

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention

If yes to all 4 questions, please confirm that the research team is familiar with and agrees to comply with the investigator requirement to register the study on the ClinicalTrials.gov database. Additionally, the approved consent document(s) must be uploaded to the ClinicalTrials.gov database ☒ Yes ☐ No

For any assistance with registration of your trial or the requirements, please contact HSC-CTSCResearchConcierge@salud.unm.edu

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ABSTRACT

Few lifestyle behavior change interventions have been successfully translated into practice. Addressing this research-to-practice gap is a significant research and public health priority. "Harvest for Health" is a home-based vegetable gardening intervention that pairs cancer survivors with certified Master Gardeners from the Cooperative Extension System. The parent study was started at the University of Alabama at Birmingham and is currently being conducted throughout the entire state of Alabama. Preliminary findings suggest that this intervention increases vegetable consumption and physical activity, and improves physical functioning and health-related quality of life. We propose a feasibility study to adapt this promising program to the multi-cultural population of cancer survivors and for the local context (physical, social, and cultural environment) of New Mexico. We will then implement the adapted program, "Southwest Harvest for Health" and evaluate feasibility, acceptability, and fidelity. The adaptation phase is a critical first step towards widespread dissemination, implementation, and scale-up of an evidence-based intervention. Results from this feasibility study will be used to inform a larger, definitive R01 study with statistical power to assess the efficacy of the program in the culturally, geographically, and socioeconomically diverse population of cancer survivors throughout New Mexico.

Objectives

Specific Aims

"Harvest for Health" is a home-based vegetable gardening intervention that pairs cancer survivors with certified master gardeners (MGs) from the Cooperative Extension System, the education and outreach arm of land-grant universities nationwide.[1-5] Preliminary results suggest that this intervention increases vegetable consumption and physical activity, and improves physical functioning and health-related quality of life (hrQoL).[1-3] The "Harvest for Health" program has tremendous potential for sustainability, and widespread dissemination and implementation since MG programs exist in all 50 United States.[6,7] To date, it has been tested in primarily non-Hispanic white cancer survivors living in Alabama. We propose a pilot study to adapt this promising program to the multi-cultural population of cancer survivors and for the local context (physical, social, and cultural environment) of New Mexico. We will then implement the adapted program, "Southwest Harvest for Health", and evaluate the feasibility and acceptability through a pilot study taking place in Bernalillo and Southern Sandoval Counties in New Mexico. Our transdisciplinary research team is well-poised to pursue the following specific aims:

Aim 1: Adapt the "Harvest for Health" intervention to the drastically different climate and growing conditions, and the multi-cultural population of New Mexico using a recommended adaptation framework.[8,9]

Aim 2: Assess the feasibility and acceptability of the "Southwest Harvest for Health" program through recruitment and retention rates, adherence/fidelity to the intervention, and acceptability of the program for both cancer survivors (participants) and Cooperative Extension Master Gardeners (volunteer mentors). We hypothesize that we will be able to

recruit 25-30 cancer survivor / MG dyads (based on similar geographic location) within 6 months, retain >80% of the sample, and achieve 80% adherence/fidelity to the protocol and intervention. We also hypothesize that we will receive positive feedback on the mentored vegetable gardening program from both participants and MGs.

Aim 3: Obtain estimates on pre-post changes in secondary endpoints including vegetable servings per day, physical activity, sleep quality, physical functioning and performance, and hrQoL.

Aim 4: Conduct a process evaluation using qualitative and quantitative measures to inform a larger definitive trial

The proposed study is an excellent opportunity to help grow the "Harvest for Health" program and reach a greater number of cancer survivors. The adaptation phase is a critical first step towards widespread dissemination, implementation, and scale-up of an evidence-based intervention. Results from this pilot study will be used to inform a larger, definitive R01 study with statistical power to assess the efficacy of the program in the culturally, geographically, and socioeconomically diverse population of cancer survivors throughout New Mexico (e.g., PAR-18-869, PA-18-385).

1. Background and Significance

By 2022, there will be 18 million cancer survivors living in the U.S.[10] Cancer survivors are at increased risk for treatment-related comorbidity, including cardiovascular disease, diabetes, osteoporosis, impaired physical functioning, and reduced hrQOL.[11-20] A healthful diet and regular physical activity may help prevent, delay or mitigate poor health outcomes associated with cancer and its treatment. While a cancer diagnosis is considered a "teachable moment" for improving lifestyle behaviors,[21] a large proportion of cancer survivors do not adhere to guidelines for a healthy lifestyle.[22-24] While many lifestyle interventions conducted among cancer survivors have demonstrated efficacy in improving diet, physical activity, or quality of life, the long-term durability of these interventions remains unanswered, and the potential for widespread dissemination for many of these center- and clinic-based programs is limited.

Emerging data suggests that vegetable gardening may provide an integrated approach to promote a healthful diet, physical activity and functioning, stress relief, and psychosocial well-being.[1-3,25-29] Furthermore, gardening has great potential for sustainability given its holistic nature and wide range of benefits. The variety of gardening activities and tasks may prevent boredom, which is common with other exercise programs and can jeopardize adherence long term.[30] Additionally, gardening may provide a sense of accomplishment and an increased satisfaction and quality of life that comes from nurturing and observing new life and growth. More importantly, gardening provides natural motivation since plants require regular care (watering, pest control) and attention (harvesting) and serve as continual and dynamic behavioral cues.

The "Harvest for Health" program utilizes the infrastructure of the Cooperative Extension MG Program.[5,7] The MG Program, one of many educational outreach programs offered in each US state by the National Institute of Food and Agriculture through the Cooperative Extension System, recruits and trains volunteers to help disseminate research-based information on landscaping and gardening to the general public. Certified MGs complete >60 hours of training and community service, with many states requiring additional volunteer service (e.g., >40 hours) annually to maintain active status. Based on studies conducted in Alabama,[1-3] "Harvest for Health" has been a popular and rewarding volunteer experience for MGs.[1-3] The MG program exists in all 50 US states and thus provides the capacity for sustainability and wide-spread dissemination. With minor adaptions (e.g. cold framing) for colder climates with only two growing seasons, this intervention could be implemented in 72% of US states. Furthermore, these programs typically have wide-spread coverage throughout the state, thus allowing both urban and rural individuals the opportunity to participate.

2. Study Design

As this is a small feasibility study, a single-arm study design will be employed, where all participants receive the 10-month mentored vegetable gardening intervention at their homes. Therefore, given a single arm pre-post intervention design, blinding of study participants and study staff is not applicable. The focus of this pilot study is to systematically identify, document, test, and evaluate the adaptations needed for the "Harvest for Health" program to be successfully implemented in New Mexico. Using the NCI Research-tested Intervention Programs (RTIPs) adaptation guidelines, we will identify changes needed for our population and local context, while maintaining fidelity to the original intervention (see Table 1).[8,9]

Table 1. Key Steps for the Adaptation of "Harvest for Health" to "Southwest Harvest for Health"		**Status**
Adaptation	**Description**	
1. Assess Community	• F&V intake, physical activity, & hrQOL are low in many NM cancer survivors • Bernalillo County MG Program has the capacity to provide & support MG volunteers for the study (>300 active MGs; based on discussions/meetings)	
2. Understand the Intervention	• Harvest for Health intervention materials have been shared • Theory behind program is understood & core elements have been identified	
3. Consult w/ Experts	• Consult with Dr. Demark-Wahnefried (developer of original program) and local MG Program experts (currently underway) • Incorporate expert advice into new program	
4. Decide what needs adaptation	• Determine how original & new target population/context differ • Identify potential ways to implement new program • Retain fidelity to core elements of original program • Document the process from the beginning (for later evaluation)	

5. Adapt original program	• Work with consultant to ensure adapted procedures/materials maintain accuracy of originals • Make cultural adaptations continuously	
6. Train staff	• Recruit and train MGs and staff to ensure quality implementation	
7. Implement	• Implement program (25-30 cancer survivor / MG dyads, 3 gardening seasons)	
8. Evaluate	• Evaluate the process & outcomes of adapted program (e.g., fidelity, barriers & facilitators to implementation) using the RE-AIM evaluation framework [31] • Modify adapted program based on feedback (for evaluation of effectiveness in a larger trial, i.e., R01 trial, before moving to D&I on a larger scale)	

3. Inclusion and Exclusion Criteria

Screening

Passive recruitment methods will be used for this small, feasibility study. Recruitment flyers will be distributed in community locations such as libraries, grocery stores, community centers, senior centers, and cancer survivor support groups in Bernalillo and South Sandoval counties. Additionally, oncologists or physicians may refer their patients (cancer survivors) to the study by giving them a study flyer. Faculty and staff from the Division of Epidemiology, Biostatistics, and Preventive Medicine and the UNM Comprehensive Cancer Center will be emailed a copy of the study flyer, provided approval from leadership (i.e., Division Chief, Associate Directors or Program Leaders). The email will briefly explain the study, and indicate a $5 gift card for one of UNM HSC campus coffee shops will be provided for anyone referring an individual to the study, regardless of final eligibility (referred individual must contact study staff).

Cancer survivors interested in participating will contact a member of the Southwest Harvest for Health (SWH4H) study team. The screening will take place by telephone. The study coordinator/recruiter will provide additional information about the study, answer questions and assess eligibility using the study recruitment script.

Inclusion Criteria

Twenty-five adult (50 years and older) male and female cancer survivors residing within Bernalillo and southern Sandoval County will be recruited for this study. Additional eligibility criteria include:

- Diagnosed with an invasive, non-metastatic cancer; metastatic cancer patients are eligible with MD written or verbal approval
- Completed primary treatment (surgery, radiation, chemotherapy); note that endocrine therapy is allowed.
- Able to read, speak, and understand English. (The future larger trial will include Spanish-Speaking participants)

- Not told by a physician to limit physical activity and no pre-existing medical condition(s) that would preclude gardening, e.g., severe orthopedic conditions, hip or knee replacement surgery within 6 months), end-stage renal disease, paralysis, dementia, blindness, unstable angina, untreated stage 3 hypertension, or recent history of myocardial infarction, congestive heart failure, or pulmonary conditions that required oxygen or hospitalization within 6 months.
- Community dwelling and not residing in a skilled nursing or assisted living facility (must be able to tend to their garden and cook their own meals).
- Residing within 30 miles of one of the Master Gardener volunteer mentors
- Currently not adhering to the recommended number of fruit and vegetable servings per day (consuming fewer than 5 servings of vegetables and fruits/day and not meeting the recommended guidelines for moderate-to-vigorous physical activity (< 150 minutes/week)
- Reside in a location that can accommodate a 4' x 8' raised garden bed or 4 (29" x 14") garden containers, or adequate (at least 4 hours) of sunlight per day and have access to running water
- No existing or recent (within the past year) experience with vegetable gardening
- Able to participate in the 10-month intervention (all three seasonal gardens; roughly from mid-February through early November 2020)

Exclusion Criteria

Individuals will be excluded from participation if they:

- Are not able to consent
- Are not competent due to mental health or other very serious comorbid conditions (e.g., stroke, degenerative neurological conditions)
- Have any medical condition that substantially limits daily light-intensity physical activity (i.e. activities of daily living: bending, stooping, walking, etc.)

Also excluded from participation in the proposed study:

- Due to the focus on older cancer survivors, individuals who are not yet adults (infants, children, teenagers) or who are considered adolescent and young adults (ages 15-39) will be excluded from this study. In the future, this study may be adapted to suit adolescent and younger cancer survivors.
- Given the focus on older (50+ years) cancer survivors, women who are pregnant or who are planning to become pregnant, will be excluded from this study.
- Prisoners may not participate in this study as this is a home-based gardening intervention and we are seeking participants who are able to pursue lifestyle changes independently and not as the result of institutional control

Note: Verification of adequate space, sunlight, and running water to support a vegetable garden will occur at the baseline home visit. If these criteria are not met, then the individual

is not eligible to participate and will receive a $20 merchandise card for their time. Note that this assessment will take place before any further collection of data.

4. Number of Subjects

The proposed study will enroll 25 to 30 cancer survivors. This study has proved to be very popular, and with multiple recruiters, we reached our original accrual goal of 25, and now have a waitlist. We would like to allow an additional 5 participants (30 maximum).

5. Study Timelines

The proposed grant period is two years with the actual intervention being 10 months (plus or minus 14 days due to scheduling difficulties). Recruitment will occur over a four month period, beginning November 2019. Enrollment of 25-30 participants will be completed by late February/early March 2020. All participants are expected to begin the intervention at the same time (plus or minus 10 days to account for weather and/or scheduling conflicts between the Master Gardener and the participant). The proposed intervention is expected to begin in early March 2020 and end in mid-November 2020, coincident with three gardening seasons (spring, summer, and fall). Data analyses will be completed before March 2021.

Study Timeline: August 2019 – July 2021																		
	2019		2020												2021			
Month	A - O	N - D	J	F	M	A	M	J	J	A	S	O	N	D	J - F	M - A	M - J	J
Development																		
Recruitment																		
Intervention delivery																		
Data cleaning/prep																		
Analyses																		
Publications							1									2		
Grant Submissions												3						4

[1] Study protocol paper
[2] Study outcomes paper
[3] Initial R01 submission
[4] Revised R01 submission

6. Study Endpoints

Primary and secondary study endpoints

The primary aim is to adapt the Harvest for Health intervention to the multi-cultural population of cancer survivors and for the local context (physical, social, and cultural environment) of New Mexico. The endpoint is systematic documentation of the adaptation process using a recommended framework.

Other endpoints are to assess the feasibility and acceptability of the "Southwest Harvest for Health" mentored gardening program through recruitment and retention rates, adherence/fidelity to the intervention, and acceptability of the program for both cancer survivors (participants) and Cooperative Extension Master Gardeners.

Secondary endpoints include estimates on pre-post changes in vegetable servings per day, physical activity, sleep quality, physical functioning and performance, and hrQOL. Pre-post change data will inform the sample size for the future, larger study.

Primary and secondary safety endpoints

Gardening could result in cuts or scrapes which could expose the participant to bacteria in the soil or exacerbate lymphedema. Cancer survivors for whom gardening activities could pose excess risk will be excluded from the study.

Additionally, gardening involves a variety of movements, i.e., bending, kneeling, stooping, getting up and down, and other light-to-moderate intensity physical activity, which could result in soreness, stiffness, and other potential issues (e.g., sunburn) if substantially different than the participants' normal daily activities. To mitigate these issues, participants will receive a notebook containing information on gardening safety, e.g., protecting knees and back, sun protection, etc.

All adverse events associated with the performance tests will be tracked. The performance tests incorporate movements typically undertaken during normal daily activities (standing from a chair, walking a short distance, sitting on a chair, lifting a light object, etc.), and thus represent tests that are more likely to be safely performed. One or more members of the study team will be present in the participant's home during the performance tests. Safety checks will be made prior to the performance tests.

Exploratory endpoints

There are no exploratory endpoints.

7. Research Setting

This is a home-based intervention. The garden will be located at the participant's home. Members of the UNM study team will visit the participant at their home on three separate occasions (baseline, mid-point, follow-up) during the study to assess health behaviors and outcomes. Study staff will also verify inclusion criteria specific to gardening, i.e., absence of an existing vegetable garden, adequate apace, sun and running water to accommodate a successful home vegetable garden.

Recruitment flyers will be distributed in community locations such as libraries, grocery stores, community centers, senior centers, and cancer survivor support groups.

Study staff will be housed in the Cancer Research Facility, where recruitment and screening will take place.

COVID-19 Modifications

Due to COVID-19, the mid-point and final assessment of health behaviors and outcomes will be conducted remotely (i.e., via mailed and telephone-administered surveys) rather than home visits.

8. Resources Available

Study Personnel

Cindy K. Blair, PhD, Principal Investigator: Dr. Blair is an Assistant Professor in the Division of Epidemiology, Biostatistics, and Preventive Medicine and a member of the Cancer Control Research Program within the UNM Comprehensive Cancer Center. Dr. Blair has a PhD in Epidemiology and has experience in study design, intervention delivery, project management (data collection and management, supervision of staff, coordination of activities), data analyses, and manuscript preparation. Dr. Blair completed a two-year NCI R25 postdoctoral fellowship in Cancer Prevention and Control at the University of Alabama at Birmingham (UAB). At UAB, she was the project manager for the original "Harvest for Health" mini-pilot study. She then assisted Dr. Demark-Wahnefried (mentor) in the submission of NCI and foundation grants to support larger pilot studies. Thus, Dr. Blair is very familiar with the study design and methods of the "Harvest for Health" mentored vegetable gardening intervention and thus is well-suited to be the PI of the proposed feasibility study.

Sally M. Davis, PhD, Co-Investigator. Dr. Davis is the Director of the UNM Cancer Prevention Center and Chief of the Division of Prevention and Population Sciences in the School of Medicine. She has extensive experience in prevention and population research with rural and racial-ethnic minorities in the Southwest. Her recent research involves the dissemination and implementation (D&I) of evidence-based programs. Her current study, VIVA Connects, is a D&I study to help rural communities to put physical activity recommendations into practice. This experience will be invaluable as we adapt the "Harvest for Health" study for the multi-cultural population and context of New Mexico. Similarly, Dr. Davis' experience will be key for planning the R01 study after the feasibility study is completed.

Andrew Sussman, PhD, MCRP, Co-Investigator. Dr. Sussman, is an Associate Professor in the Department of Family and Community Medicine and Director of the UNMCCC Behavioral Measurement and Population Sciences (BMPS) Shared Resource. Dr. Sussman has designed and led numerous qualitative and mixed method research studies and has experience in participatory and community engaged approaches to

research. Most of his research has been conducted in NM populations with health disparities, predominantly Hispanic communities. His experience and input will be invaluable during the systematic adaptation process of the "Harvest for Health" program to New Mexico. He will also provide input on the mixed methods evaluation of the study.

Linda Cook, PhD, Co-Investigator. Dr. Cook is a Co-Program Leader of the Cancer Control & Population Science Research Program at the UNM Comprehensive Cancer Center. She is also a Professor in the Division of Epidemiology, Biostatistics, and Preventive Medicine. Dr. Cook is a cancer epidemiologist with expertise in biologic specimen collection (blood, saliva, etc.) and cancer disparities research. While the proposed feasibility study did not request funds for analyses of biologic specimens (given small sample size), the future larger R01 study will collect more biologic specimens and analyze the results. Dr. Cook will be essential during the planning phases of the R01 study.

Zoneddy Dayao, MD, Co-Investigator. Dr. Dayao is an Assistant Professor of Hematology/Oncology at the UNM Comprehensive Cancer Center. As a breast oncologist and clinical trialist, Dr. Dayao has excellent experience in oncology and recruiting patients for clinical trials. She is also a member of the NCI Steering Committee for symptom control and quality of life in cancer survivors, which is highly relevant to the current proposal. As a Co-Investigator, Dr. Dayao will help ensure the safety of the cancer survivor participants in the gardening intervention through specification of appropriate inclusion/exclusion criteria and necessary safety precautions during the intervention.

Dolores Guest, PhD, RD, Co-Investigator. Dr. Guest is the Associate Director for the Behavioral Measurement and Population Science Shared Resource and a research Assistant Professor in the Division of Epidemiology, Biostatistics, and Preventive Medicine. As a registered dietician, she has expertise in the measurement of diet and in dietary behavioral change interventions. Dr. Guest will help determine the best way to assess change in diet over the course of the intervention, in a way that doesn't burden study participants (e.g., not using a full food frequency questionnaire). This study coincides with Dr. Guest's research interests involving improvement of diet and quality of life in cancer survivors.

Shane Pankratz, PhD, Biostatistician/Co-Investigator. Dr. Pankratz is the Director of the UNM CCC Biostatistics Shared Resource and a Professor in the Department of Internal Medicine. He has extensive experience in statistical design, management, and analyses of clinical trials. He will meet with Dr. Blair to discuss the data analyses. His expertise will be invaluable for planning the larger, definitive R01 study with statistical power to assess the efficacy of the "Southwest Harvest for Health" program.

Elizabeth Harding, PhD, Project Manager/Co-Investigator. Dr. Harding has been working with Dr. Blair on her research studies for three years, and thus has excellent experience in project management and outcomes assessment for lifestyle behavioral interventions. She will assist Dr. Blair to prepare the regulatory documents, assist with eligibility screening and recruitment, coordinate and conduct the home visits (baseline, mid- and post-intervention follow-up), and other project management duties. She will also

assist with providing descriptive statistics, and manuscript and grant preparation and submission.

Joseph Rodman, MA, Project Assistant. Mr. Rodman is the Scientific Research Manager of the Behavioral Measurement and Population Science Shared Resource. Mr. Rodman will assist Dr. Harding with the home visits and other project tasks.

Ellen Burgess, MPH, Project Assistant. Ms. Burgess is a Research Projects Specialist working in the Behavioral Measurement & Population Sciences Shared Resource. She has excellent experience in recruiting study participants and collecting data. She will assist the team with home visits and other project tasks.

Towela King, Project Assistant. Ms. King is currently a medical school student who is interested in assisting with various tasks on the study, including home visits.

Prajakta Adsul, MBBS, MPH, PhD, Co-Investigator. Dr. Adsul is a new faculty member in the Department of Internal Medicine and a member of the Cancer Control & Population Sciences research program at the UNM Comprehensive Cancer Center. Dr. Adsul has expertise in Implementation Science. Her expertise will be extremely valuable for planning for the R01 application.

Clinical and Translational Science Center (CTSC) Community and Engagement Research Core (CERC)(Heidi Rishel Brakey and Magdalena McWethy). The CERC group includes Community Research Specialists and Qualitative Analysts. Members of the CERC have expertise in conducting research with the various communities in New Mexico. Ms. Rishel Brakey and Ms. McWethy will conduct the one-on-one qualitative interviews and the qualitative analyses. Additionally they will assist Dr. Blair and her Co-Investigators on manuscript preparation.

Community Partners

This study will be conducted through a community-based partnership between the University of New Mexico and New Mexico State University's Cooperative Extension (NMSUCE). Neither the NMSUCE nor MG volunteers are responsible for enrolling, monitoring, or collecting data from study participants (cancer survivors). Instead, NMSUCE's role is to provide support to the Master Gardeners (MGs) and Volunteer Coordinator assigned to this project. In both the Bernalillo County and Sandoval County MG programs, volunteer gardening opportunities must be approved. Once approved, a Volunteer MG Coordinator is assigned to oversee and provide support for MGs who select the project for their volunteer experience. Thus, the identification of study participants, and subsequent accrual, consent, enrollment and in person visits to assess clinical outcomes will be conducted by SWH4H UNM study staff.

Note: MGs who volunteer to mentor a Cancer Survivor to create and maintain a vegetable garden at the Survivor's home do not meet the definition of investigators.

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html

"The HHS regulations at 45 CFR part 46 use the term "investigator" to refer to an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. For the purposes of the HHS regulations, OHRP interprets an "investigator" to be any individual who is involved in conducting human subjects' research studies. Such involvement would include:
•obtaining information about living individuals by intervening or interacting with them for research purposes;
•obtaining identifiable private information about living individuals for research purposes;
•obtaining the voluntary informed consent of individuals to be subjects in research; and
•studying, interpreting, or analyzing identifiable private information or data for research purposes."

Based on this definition of investigators, the MG volunteers are not research investigators. MGs will be performing their regular activities, which include disseminating their horticultural knowledge to the general public via volunteer opportunities. Southwest Harvest for Health will be offered as a volunteer opportunity for certified MGs from Bernalillo and Sandoval counties for 2020.

Time Devoted to Conduct the Research

This is a two-year study. Within the first six months, we will finalize study materials and identify potentially eligible cancer survivors. Data cleaning and preparation for analyses will be ongoing. Analyses will be conducted and manuscripts prepared during the last two months of the study.

Study Timeline: August 2019 – July 2021

	2019		2020												2021			
Month	A-O	N-D	J	F	M	A	M	J	J	A	S	O	N	D	J-F	M-A	M-J	J
Development																		
Recruitment																		
Intervention delivery																		
Data cleaning/prep																		
Analyses																		
Publications							[1]									[2]		
Grant Submissions												[3]						[4]

[1] Study protocol
[2] Study outcomes
[3] Initial R01 submission
[4] Revised R01 submission

8.1. *Describe other resources available to conduct the research:*

This is a small feasibility study (25-30 Cancer Survivors) with broad eligibility criteria (e.g., 50 years and older, any local or regionally staged cancer type, etc.); therefore, we do not anticipate having difficulty recruiting for this study. Additionally, the study design seeks to reduce participant burden by providing a home-based intervention, i.e., a vegetable garden at their home and home visits to assess study outcomes. Also, the study is designed for sustainability as the participants will keep the study provided gardening supplies.

Facilities where Research will be conducted

This is a home-based study. The intervention and assessment of health, health behaviors and physical function will take place by trained investigators in the participant's home. Recruitment and screening will take place in a private office in the UNM's Cancer Research Facility. Data management and data analyses will also take place in the UNM's Cancer Research Facility.

COVID-19 Modification
Due to COVID-19, the mid-point and final assessment of health behaviors and outcomes will be conducted remotely (i.e., via mail and telephone-administered surveys) rather than home visits.

Availability of Medical or Psychological Resources

This is a minimal risk study; thus these resources will not be made available. The participant will continue to have access to their general practitioner and oncologists as per usual care.

Study Protocol, Research Procedures, and Duties and Functions

The finalized protocol and research procedures will be distributed to all persons assisting with the research. In addition, meetings will be held with team members to review the specific duties and functions of each member.

9. Prior Approvals

Departmental scientific review and approval was obtained on 10/15/2019 and assigned as protocol INST UNM 1905.

10. Multi-Site Research

NA - this is a single-site study.

11.Study Procedures

The proposed study includes three visits to the participant's home, a mentored-gardening intervention and follow-up telephone interview.

1. Home visits: Home visits to assess study outcomes will occur three times over the study period: baseline (within one month of beginning the intervention), mid-intervention (around 6 months) and post-intervention (at 10 months). Two members of the SWH4H study team will visit the participant at their residence to assess the participant's health status such as their height, weight, and waist size and physical function through a series of physical performance tests (i.e. walking speed, ability to rise from a chair). These home visits will take 45-60 minutes each. In addition to home visits, participants will be mailed questionnaires approximately 10 days prior to their baseline and follow-up home visits. These questionnaires will be collected by study investigators upon arrival. Questionnaires will assess the following:

    a. Participant characteristics: Data will be collected on age, race/ethnicity, education, income range, marital status, occupation, and smoking status. Cancer related data will be obtained via self-report from participants (treatment (yes/no): surgery, radiotherapy, chemotherapy, hormone therapy; diagnosis year; cancer type).
    b. Lifestyle behaviors: Participants will also be asked to complete questionnaires about their vegetable and fruit intake (servings per day), physical activity, sedentary behavior, physical function, sleep-behaviors, health, and quality of life.

Anthropometrics

Height, weight, and waist circumference will be measured during home assessments using a calibrated scale (to nearest 0.1 kg), a portable stadiometer (nearest 0.5 cm), and non-stretch, tension-controlled tape measure (nearest 0.5 cm), respectively.

Physical Function/Performance

Senior Fitness Test Battery:
Measures physical function in four domains: (1) lower & upper body strength (30-sec chair stand, arm curl); (2) endurance (2-min step test); (3) flexibility (chair sit-and-reach, back scratch); and (4) agility/dynamic balance (8-ft Get-up and go).

Grip Strength:
Measures participant's functional limitation and disability using a hand-held dynamometer.

Usual (comfortable) and rapid gait speed:
Predictive of functional health and mortality

Fruit and Vegetable Dietary Intake

Eating at America's Table Screener (EATS): a 10-item questionnaire developed by the NCI will be used to assess fruit and vegetable dietary intake.

Health Related Quality of Life (HRQOL)

PROMIS-57:
The PROMIS-57 is a 57-item survey covering seven domains (physical function, anxiety, depression, fatigue, pain, sleep disturbance, and social functioning)

Sleep Impairment
The PROMIS sleep related impairment short-form 8a questionnaire will also be used to assess the effect of sleep disturbance, if noted.

Comorbidity:
The Older Americans Resources & Services (OARS) Comorbidity Index will be used to assess the number of chronic medical conditions/ symptoms and their functional impact (severity).

Reassurance of Worth:
One of 6 subscales of the Revised Social Provision Scale, this measure will be used to assess the psychosocial benefits of gardening. Several gardening studies have reported enhanced self-esteem, increased independence, and increased zest for life.

Physical Activity and Sedentary Behavior

Godin Leisure Time Physical Activity Questionnaire:
Short questionnaire used to assess an adult's self-reported leisure-time physical activity. It includes type, frequency, and duration of activities at three intensity levels (light, moderate, and vigorous).

PACE Adult Sedentary Behavior Questionnaire
Short questionnaire used to estimate an adult's self-reported sedentary activities during a typical weekday and during a typical weekend. Response items range from none to 6 or more hours per day for a variety of common activities (e.g., watching tv, using a computer, etc.).

Accelerometry:
Participants will be asked to wear the activPAL3, an electronic activity monitor, for the objective assessment of sedentary activity and physical activity. The small, thin device (like a patch) will be worn on their mid-thigh (day and overnight) for 7 days

at the beginning, at 6 months, and at the end of the study. This is not a tracking device. The activity monitor will record general movement (sitting, standing, and stepping) and will enable us to get a better idea of the participant's daily activity and inactivity levels (versus self-report alone). We will also provide participants instructions for applying and removing the monitor. The activPAL3 monitor will be collected during the home visits for additional outcome assessment. Note: The activPAL3 is attached to the thigh using Tegaderm Dressing (a transparent dressing/tape; see Tegaderm Dressing.PDF uploaded under Local Site Documents – Other Attachments).

Mediators

Community-Level: Participant-MG dyads will independently assess the participant's local environment for support of vegetable gardening considering the following factors: 1) availability of garden stores; 2) presence of pests (i.e., insects, deer); 3) neighborhood covenants that impose landscaping restrictions; and 4) sense of belonging with other gardeners in local community.

Interpersonal: We will use the Social Support & Eating Habits (10 items) & Exercise Surveys.

Individual: This assessment will measure the participant's self-efficacy (survivors' beliefs in their ability to maintain a successful vegetable garden).

<u>COVID-19 Modifications</u>

The following modifications will be made to the mid-point and final (post-intervention) assessment of study outcomes due to COVID-19.

The visit by study investigators to the participant's home will be replaced with remote methods (mail and telephone) in order to avoid any in-person contact between members of the study team and participants in an indoor setting.

Due to this change (from home visit to mail/telephone), the following aspects of data collection will also require change:

- Collect self-reported weight
- Skip all objective measures of physical functioning (i.e., physical performance). Note that while some research studies are moving to a remote assessment of physical performance, this study does not have the resources to be able to collect this type of data remotely at this time.
- Administer the Fruit & Vegetable Dietary Intake (Using same EATS survey) over the phone rather than in-person. The food models will be replaced with "show cards" that include the frequency of intake and some example portion sizes to help the participant more accurately report the amount consumed. The show cards will be included in a sealed envelope to be opened during the phone call. Otherwise,

seeing the dietary questions could influence the participants eating behaviors during the week prior to the phone assessment.

- Self-reported physical activity (using same Godin Leisure Time Physical Activity Questionnaire) will be administered over the phone to improve the accuracy of reporting.

2. Gardening Intervention: Cancer survivors (participants) will be paired with a certified Master Gardener from the Albuquerque Area Cooperative Extension or Sandoval County Extension who will mentor the participants in planting and tending to three seasonal vegetable gardens throughout the year (spring, summer and fall)

    a. Participants will be invited to attend a meet-and-greet event where they will meet their Master Gardener mentor and members of the study team in person. This meeting will provide the study participants the opportunity to pick up their gardening supplies and communicate the best days/times to meet with their Master Gardener mentors.
    b. Supplies needed to begin the participants' home vegetable gardens will be picked-up by participants at the meet-and-greet event and/or delivered to their homes. These include but are not limited to: soil, plants, seeds, and fertilizer to support either 4 container-style garden boxes (which can be used to garden on balconies, patios or decks) or 1 raised bed garden (equivalent square footage). These supplies will be provided free of charge.
    c. The Master Gardener mentors will help guide the study participants in setting-up the garden, maintaining it, and replanting it season-to-season.
    d. In providing this support, the Master Gardener mentors will make monthly visits to participants' home and will also speak with them over the phone or communicate with them via email on a monthly basis to check-in on how they are doing with their gardens (e.g. troubleshoot issues or offer advice)
    e. Master Gardener mentors or study participants will take photographs of the gardens to share with the SWH4H study team to assess fidelity to the intervention. At least one photo during the home visit must include both the Master Gardener mentor and the study participant, with the garden in the background. This is used to assess fidelity to the intervention (i.e., monthly home visits).

    Note: Process data (photographs, documentation of telephone calls and home visits, etc.) will be collected and used to evaluate adherence and fidelity of the intervention

COVID-19 Modifications

This study launched in March of 2020, just before the many restrictions went into place (UNM limited operations, NM stay-at-home order, etc.). Therefore, all participants and

Master Gardener mentors were notified that there would be no home visits (i.e., no in-person contact) until further notice.

COVID-19 Modifications (continued)

A key aspect of this study, as originally designed, was to have each Master Gardener visit their participant's (outdoor) vegetable garden once per month. This visit would allow the Master Gardener to see firsthand, the condition of the garden, offer advice, and help trouble shoot problems. Once the temperatures reached and remained in the 90s, many participants starting having a lot of problems with their garden, and remote mentoring has not worked very well for many participant/Master Gardener teams. We propose to allow once monthly visits to start and go through the end of the study (November, 2020), to increase the participant's confidence (self-efficacy) in gardening, so they can continue on their own next year. We propose to take the following precautions to keep people safe:

- Each member of the team (study participant and their assigned Master Gardener) must mutually agree to the first, and each subsequent, monthly (outdoor) visit, i.e., the monthly visit is optional.
- The vegetable gardening containers are located outside, typically, but not necessarily in the back yard. The Master Gardener will only enter this area of the yard, and will not enter the house.
- The Master Gardener and participant will limit the visit to 45 minutes maximum, maintain social distancing, and wear face masks and (gardening) gloves.
- Master Gardeners already own gloves, and study participants were provided with gardening gloves at the beginning of the study.
- The study will provide both participants and Master Gardeners with high-quality cloth masks to use (and keep), if they don't already own a high-quality mask. Each mask is constructed with 3 layers of fabric, adjustable (ear) straps and a metal nose clip for a tight fit.

NOTE (11/1/2020): The New Mexico State University Extension never approved home visits, so home visits never started.

Intervention schedule

Month	Week	Description of activity	Home visit(s)
February	Week 1		Baseline home visits
	Week 2		
	Week 3		
	Week 4	Meet & Greet Event	
March	Week 1	MG & Ppt. plant first garden	
	Week 2		
	Week 3	Phone call/ email check-in	
	Week 4		
April	Week 1	In-person visit; fidelity check	
	Week 2		
	Week 3	Phone call/ email check-in	
	Week 4		
May	Week 1	In-person visit; fidelity check	
	Week 2		
	Week 3	Phone call/ email check-in	
	Week 4		
June	Week 1	In-person visit; fidelity check	
	Week 2		
	Week 3	Phone call/ email check-in	
	Week 4		
July	Week 1	In-person visit; fidelity check	
	Week 2		
	Week 3	Phone call/ email check-in	
	Week 4		
August	Week 1	In-person visit; fidelity check	
	Week 2		
	Week 3	Phone call/ email check-in	Mid-point assessment
	Week 4		
September	Week 1	In-person visit; fidelity check	
	Week 2		
	Week 3	Phone call/ email check-in	
	Week 4		
October	Week 1	In-person visit; fidelity check	
	Week 2		
	Week 3	Phone call/ email check-in	
	Week 4		
November	Week 1	In-person visit; fidelity check	Final Assessment
	Week 2		
	Week 3	Bounty party	CANCELLED DUE TO COVID-19

MG: Master Gardener; Ppt.: Participant;

Fidelity check: refers to submitting photos of garden being submitted to study team;

Meet & Greet: Event where MG and Ppt. will meet for the first time. Participants will also pick up some of their gardening supplies and arrange meeting times/communication with their MG mentor;

Due to the ongoing COVID-19 pandemic, the Bounty Party, which was to be an in-person event has been cancelled.
Bounty party: Event hosted by the Albuquerque Area Master Gardeners and study team to receive in-person feedback about the intervention. Participants will have an opportunity to "show-off" and share their vegetables and herbs from their gardens.

NOTE: We plan to have photographers at both the Meet & Greet event and the Bounty party. Individuals present who are willing to be included in photographs will be asked to sign the Photography Release Form (UNM HSC Public Affairs Consent & Release Form). Individuals who do not want to be photographed will be identified with a sticker, so the photographer can avoid including them in any photographs.

3. Follow-up Interview/ Questionnaires: Upon completion of the intervention, participants will be asked to complete a survey to assess participants' opinions of the program and what components they deemed helpful and which were not. Participants will also be asked whether they intend to continue vegetable gardening and whether they intend to expand their gardening space. Group style, in-person interviews with participants will be conducted at the study's Bounty Party to better inform the statewide, larger mentored gardening study. Participants unable to attend the Bounty Party will have the opportunity to provide feedback on the study via a telephone call and/or a written survey.

Modifications due to COVID-19

Individual Interviews (Study Participants)
Since the Bounty Party has been cancelled due to COVID-19, we will switch to one-on-one interviews with a sample of study participants (8 to 12). The sample will be selected based on level of participation during the study, in order to provide a wide range of responses. The interviews will be conducted by currently approved study members. The interviews will last approximately 30-45 minutes. A semi-structured interview guide with open-ended questions will be used. The interviewer will ask questions about the participants' experience with the study, such as what they found helpful, their biggest challenges, and their experience working with their Master Gardener (see interview guide).

Interviews will take place either by telephone or using Zoom video-conferencing software. If we conduct the interview over Zoom, the interview will be digitally recorded using functions built-into that platform. Only audio recordings will be obtained and uploaded to the UNM HSC approved company for transcription. Please see section 15 for precautions taken to maintain confidentiality.

While interviews are covered in the currently approved consent form, we wish to provide compensation for completion of an interview (a $20 merchandise card). We request a waiver of signed consent for the interview, as no name or personally identifiable information will be included. Please see the Informed Consent Cover Letter, which will be sent to a sample (8-12) of study participants.

4. Follow-up Interview / Questionnaire with Master Gardeners: Upon completion of the intervention, the Master Gardeners will be mailed a survey to assess their opinion of the mentored gardening intervention. The survey will take about 15-20 minutes and includes questions about their role in the study (providing advice and support on vegetable gardening), whether they felt prepared/supported to provide advice and support to their assigned study participant, and their recommendations for improving the study. Participation is completely voluntary; however, we anticipate that most Master Gardeners will be interested in providing feedback as this is generally done at the end of their volunteer projects. (Note: Master Gardeners typically provide 20 hours or more of community service annually. This study served as one of their volunteer opportunities, aka a community service.) Master Gardeners (completing the questionnaire) will be asked if they are also interested in completing an interview to provide more information about their experience and their recommendations for study improvement. Our goal is to interview 10-12 Master Gardeners. The interviews will be conducted by a member of the Clinical and Translational Science Center's (CTSC) Community and Engagement Research Core (CERC). The interviews will last approximately 30-45 minutes. A semi-structured interview guide with open-ended questions will be used. Interviews will take place either by telephone or using Zoom video-conferencing software. If we conduct the interview over Zoom, the interview will be digitally recorded using functions built-into that platform. Only audio recordings will be obtained and uploaded to the UNM HSC approved company for transcription. Please see section 15 for precautions taken to maintain confidentiality.

   We request a waiver of signed consent for both the questionnaire and the interview for the Master Gardeners who volunteered in this study as part of their community service. The personally identifiable information (name, telephone number, email address) from the questionnaire will only be used to determine which Master Gardeners are interested in completing an interview. All identifying information will be removed from the questionnaire prior to storage and analysis. No names or personal identifiers will be included in the audio recording of the interview. Please see the Informed Consent Cover Letter, which will be sent to all Master Gardeners who mentored a study participant. All Master Gardeners will receive a high-quality face mask with their questionnaire. Face masks were purchased for all study participants and Master Gardeners in anticipation of resuming monthly home visits. Since New Mexico State University (operates the Master Gardener Programs) never approved the home visits, we wish to distribute the face masks after study completion as a token of our appreciation. Master Gardeners completing the interview will receive a $20 merchandise card for compensation for their time and participation.

Information from both study participants and Master Gardeners will help inform the next iteration of the Southwest Harvest for Health Study.

12. Data Analysis

12.1. *Describe the data analysis plan, including any statistical procedures.*

The proposed study is a single-arm trial, the objective of which is to obtain preliminary evidence of the feasibility and acceptability of a vegetable gardening intervention among a sample of cancer survivors. Feasibility and acceptability of the proposed mentored vegetable gardening intervention will be assessed thorough the collection of detailed process data which will allow the assessment of accrual, retention, adherence/fidelity, and adverse events. For this feasibility study, we hypothesize that we will be able to recruit 25 to 30 cancer survivors during four months, retain ≥ 80% of our sample, achieve 80% adherence/fidelity with contacts and logs, and experience no serious adverse events attributable to the intervention. No formal statistical analyses are needed for these hypotheses.

We will also evaluate pre-post intervention change for the health outcomes (vegetable & fruit servings per day, physical activity, QOL, etc). These data will be used to inform the power and sample size of a future, larger, randomized controlled trial.

Qualitative Analysis

Digital audio files from the in-depth interviews will be transcribed verbatim. To ensure anonymity, study participants will be asked to not use any names during the interviews. Any personal identifiers from the audio files will be redacted from transcripts. A sample (~20%) will be randomly selected and reviewed by two CERC qualitative analysts to assess quality and determine a coding scheme to code each transcript. The transcripts will be uploaded into NVivo 10 Qualitative Data Management and Analysis software and analyzed to identify key themes and codes. These themes will be summarized, reviewed, and interpreted by the study team, and ultimately will be used to modify and improve the next iteration of the intervention. A summary of the key information will also be used as preliminary data for an R01 grant application. Illustrative quotes for each theme will be identified. Drs. Adsul, Sussman, and Davis (Co-Investigators), along with Dr. Blair will help resolve coding discrepancies, assist with identifying themes, and interpretation of the findings.

12.2. *Provide a power analysis, if applicable*

Not applicable for small feasibility studies.

13. Provisions to Monitor the Data to Ensure the Safety of Subjects

The University of New Mexico Comprehensive Cancer Center (UNMCCC) places a high priority on ensuring the safety of patients participating in clinical trials. All clinical trials require monitoring commensurate with the degree of risk involved in participation of studies. Standard Operating Procedures (SOPs) detail functions and processes found in this plan. SOPs are available at http://cancer.unm-intranet.com/clincial-research-office/standard-operating-procedures/

Data and safety monitoring activities for each study continue until all patients have completed their participation and all patients are beyond the time point at which study-related adverse events would likely be encountered. The UNMCCC has implemented a process for routine real time data monitoring and safety review of Investigator Initiated trials which takes into account the Essential Elements of the National Cancer Institute (NCI) guidelines, the FDA monitoring regulations, Good Clinical Practice Guidelines and other DSM plans and programs approved by the NCI.

Since this is a low risk study, monitoring will be conducted primarily by the principal investigator and the research staff according to the most current version of the UNMCCC data and safety monitoring plan (DSMP). Central elements (i.e. informed consent, subject eligibility, and data quality) will be monitored and reviewed on an annual basis by the PI and research staff. The conduct of the study and any observed adverse events are reported in annual documentation to the IRB of record. This same documentation is also submitted to the Data and Safety Monitoring Committee (DSMC) for review.

In addition to complying with NIH/NCI guidelines, the UNMCCC DSMP complies with, the University of New Mexico Health Sciences Center Human Research Protections Office (HRPO) guidelines for safety and data monitoring. The DSMP is distinct from, and complements, the activities of the Protocol Monitoring & Review Committee (PRMC) and the Clinical Protocol Data Management & Informatics (CPDMI) functions of UNMCCC.

The project director will oversee day-to-day study activities and have daily contact with the PI (Dr. Blair). The project director and other project staff will support regular communication among the research team. There will be 1) regular meetings with project staff and UNMCCC investigators to discuss study progress, adverse events, or other research related issues; 2) monthly contact with study participants and follow up phone calls, text messages, and email, depending on preference for mode(s) of contact.

We do not expect to encounter serious safety issues based on the literature and prior Harvest for Health pilot studies conducted in Alabama. If during the intervention, the staff believe that a participant is expressing significant physical or emotional issues, this will be reported.

14. Withdrawal of Subjects

At any time during the study, participants may ask to withdraw from the study. If the investigator feels that it is no longer safe for the participant to participate in the study, i.e., no longer meets the study eligibility criteria, the participant will be withdrawn from the study without their consent.

Upon consenting to participating in the proposed study, participants will be made aware that they have a right to withdrawal at any time and that their authorization for the use of their health information for the proposed study shall not expire unless they cancel this authorization. Their health information will be used as long as it is needed for this study. However, the participant may withdraw their authorization at any time provided they notify the UNM investigators in writing.

Upon withdrawal from the study, no additional information will be collected; however, any data obtained before the withdrawal will be included in the study results. If the participant provides a reason for withdrawing from the study, the reason may be kept as part of the study record and reported in aggregate data.

15. Data Management/Confidentiality

Data Collection and Management:
The screening/recruitment and study questionnaire data will be directly entered onto a data collection form in REDCap, a secure UNM Data Security approved system. Access to the study REDCap database will be limited to specific study staff users at the discretion of the study Principal Investigator (PI), Dr. Blair, and in accordance with institutional review board policies. Data generated during the course of the study will be managed in compliance with the general guidelines for the Use of Confidential Data used by our IRB. Unique identification numbers will replace all names whenever a name is not essential for research purposes and will be kept separate from subject identifiers, except in the case of a password protected subject master file created by the PI approved study staff member. Electronic access to all personally identifiable data will be kept to the minimum necessary to accomplish the project and will require approved access to the REDCap database (i.e., projects). All copies of files containing personally identifiable data will be stored in separate, locked cabinets in rooms where unauthorized persons do not have access. All personnel will be trained in appropriate security measures for handling personally identifiable data they will not disclose any such information to any person or agency.

The following steps will be taken to maintain confidentiality:

- Telephone calls will take place in closed door offices or cubicles in the CRF to ensure privacy.
- Study participants will be assigned a unique study ID.
- All data collected will be identified with the unique study ID.
- Identifying information (e.g., name, address, etc.) will be kept separate from the participant's study data.

- Only trained staff will have access to the data.
- Data collected during the study will be stored on a password and firewall protected server and accessed via secured computers in the Cancer Research Facility (CRF). Any paper forms, including informed consent forms will be kept in a locked file cabinet in locked offices of the study staff for up to 4 years after completion of the study.
- Study staff are required to have completed training for the responsible conduct of research.
- Audio files from qualitative interviews will be saved in a secure, locked location/file for up to 4 years upon completion of the study. This time will allow for transcription of files, publication of the study results, and to allow the PI to retrieve any additional information to inform the recruitment strategies of the next intervention trial, if needed.
- No identifying information will be included in the transcripts from audio files. Rather the participant's assigned participant ID number will be recorded.
- Data analysis will occur in closed offices or cubicles in the CRF using de-identified data.
- The data will be published in research and scientific journals without reference to identities of the research participants.
- Research data and samples will not be shared with other collaborators at UNM or any other entity.

Specific to the qualitative data collection, management, and analyses:

- Anonymity will be maintained by asking the interviewees to not use any names during the interviews. Instead, each participant will be assigned a unique identifier to maintain confidentiality. Any names recorded will be redacted from the transcripts.
- Confidentiality of written data (questionnaires) will be maintained by using a study unique identifier as with the audio recordings. Therefore, neither the audio recordings nor any written documents will contain any personal health information.
- Only trained study staff will have access to the data.
- Data collected during the study will be stored on a password and firewall protected server and accessed via secured computers in the Cancer Research Facility.
- Audio files will be saved in a secure, locked file for up to 1 year upon completion of the study. This time will allow for publication of the study results. As a precaution during the study, recordings will be stored with access restricted to study team members.
- Unique, non-identifying codes will be assigned to interview recordings and transcripts by the interviewer. The list of identifying codes and recordings/transcripts will always be stored separately, and only interviewers will have access to code lists.
- If we conduct the interview over Zoom, we will follow Zoom security precautions such as a unique meeting ID and password, the waiting room feature, and locking the room once the participant is present. The interviewer will conduct the interview in a private space. Once the interviewer has answered any questions and obtained verbal consent, the interviewer will inform the participant before recording. Only

audio (no video) recordings will be obtained and uploaded to the UNM HSC approved company for transcription.

COVID-19 Modifications

In accordance with UNM HSC recommendations regarding COVID-19, telephone calls with study participants will take place off-campus. Study team members will place calls from private rooms in their homes, away from other individuals. Since few, if any, study team members own land lines, personal cell phone will be used; however, Google Voice will be used to provide a different phone number and voicemail. This solution will allow study team members to follow-up in a timely manner with their assigned study participant should there be a need for call-backs, rescheduling, etc.

16. Data and Specimen Banking

NA - Data and/or specimens will not be banked locally or archived elsewhere.

17.Risks to Subjects

This study poses minimal risk to participants; however, there are still some potential risks associated with the proposed study:

a. There are minimal risks involved in planting and maintain a small vegetable garden. Depending on the physical condition of the study participant at the beginning of the study, gardening activities involving bending, kneeling, reaching, etc. may result in soreness or stiffness. Instructions will be provided to participants on precautions to take to minimize pain and discomfort.

b. There is a slight risk of skin irritation on the participant's leg due to the adhesive on the leg activity monitor. Instructions will be provided on how to remove the monitor, if irritation occurs, and an alternative attachment method will be provided to reposition the monitor.

c. Participants will be asked to complete physical performance tests to measure balance, muscular strength and endurance. It is possible that a participant may become fatigued or unable to complete one or more of the tests. While these are well-validated tests of physical function, there is still a minimal risk of tripping or falling during some of the physical performance tests. Every precaution will be taken by study investigators to prevent the participant from falling and injury including checking the area

for and removing tripping hazards, and spotting the participant during their balance assessment.

d. Participants may feel some discomfort when disclosing personal information. Participants will be permitted to skip any of the questions that they do not want to answer.

e. There is a small chance of a breach in confidentiality. However, this risk is minimized as all protected health information will be kept in locked cabinet or on a password protected server to ensure participants' information is kept private.

18. Potential Benefits to Subjects

There may be no direct benefit to participants. However, participants may improve the quality of their diet by eating more vegetables from their garden, which could lead to other healthy eating habits. Similarly, gardening may lead to improved balance, flexibility, and strength, and possibly increased physical activity. Additionally, participation in the proposed study may help us understand the effects of a gardening intervention among cancer survivors and inform future interventions for cancer survivors.

19. Recruitment Methods

Recruitment will begin in November of 2019. We aim to recruit 25-30 participants to this study via passive recruitment methods. Recruitment flyers will be distributed in community locations such as libraries, grocery stores, community centers, senior centers, and cancer survivor groups. Additionally, oncologists or physicians may refer their patients (cancer survivors) to the study by giving them a study flyer. Faculty and staff from the Division of Epidemiology, Biostatistics, and Preventive Medicine and the UNM Comprehensive Cancer Center will be emailed a copy of the study flyer, provided approval from leadership (i.e., Division Chief, Associate Directors or Program Leaders). The email will briefly explain the study, and indicate a $5 gift card for one of UNM HSC campus coffee shops will be provided for anyone referring an individual to the study, regardless of final eligibility (referred individual must contact study staff). Upon being contacted, a member of the study team will use a recruitment script to determine level of interest in the study, answer questions and assess eligibility; only trained members of the study team will screen, consent and enroll participants into the study.

20.Provisions to Protect the Privacy Interests of Subjects

The following steps will be taken to secure the data and to maintain participants' privacy:

Maintaining privacy during recruitment

The recruitment screening process will take place over the phone in a private room. Participants not eligible to participate in the study will be asked if they would like to be added to the future contact database (UNM HRPO IRB Protocol Number 18-629) in order to be made aware of future studies. If their answer is "no" all information about the ineligible participant will be destroyed. If "yes", their contact information will be added to the secure future contact database and the paper form of the recruitment screener will be held in a locked cabinet indefinitely.

Maintaining privacy during collection of data for study outcomes

Data collection will occur at the participant's home by trained members of the study team. Note that the Master Gardeners do not collect any data from the study participants.

Maintaining privacy during intervention delivery

The intervention primarily takes place at the participant's home, i.e., establishing and maintaining a vegetable garden. Participation in study events, such as the Meet & Greet, the Bounty Party, and a visit to a gardening center in the participant's community, while strongly encouraged, are not required.

21. Economic Burden to Subjects

Participants will have minimal to no economic burden to participate. Investigators will travel to the participants' homes at the study's expense and appointments for these home-based visits will be made at the participants' convenience. Participants will also receive up to four merchandise cards for a total of $80 ($20 after each of the three assessments and an optional interview). Gardening and other study supplies will be provided at the study's expense. However, participants will travel to their local plant store with their Master Gardener Mentor as part of their experience. These merchandise cards may offset any travel costs accrued.

22. Compensation

Participants will receive a $20 merchandise card to compensate them for their time in completing questionnaires at baseline, mid-study, and follow-up time points (up to $60 in merchandise cards). Participants who complete an interview at the end of the study will receive an additional $20 merchandise card. Additionally, participants will receive the gardening supplies needed to begin and maintain three vegetable gardens over the course of the 10-month study. Participants will be allowed to keep these gardening supplies after the study ends (estimated value of $350) to promote sustainability of the modified health

behaviors and outcomes. Thus the potential compensation in merchandise cards and gardening supplies could be as high as $430.

23.Compensation for Research-Related Injury

NA - this research study does not involve more than minimal risk to subjects

24.Consent Process

Notes: (1) Signed informed consent will be obtained on all study subjects. All team members involved in the consent process will have received proper training in human subjects protection. (2) Study team members responsible for screening and recruiting study participants will not have access to private information to identify potential subjects and/or determine eligibility prior to approaching potential subjects for consent. Oncologists and nurse navigators in cancer centers in Bernalillo and Sandoval counties will not be forwarding any PHI to these study team members; instead, potentially eligible cancer survivors will be provided with a study flyer and asked to call the study team to determine eligibility. Therefore, we are not requesting a waiver of consent for screening purposes.

Individuals interested in participating in the study will contact a member of the study team and undergo a screening process to determine eligibility. During this screening process, the participant will be given information about their participation in the study (what the study entails, time commitment, etc.) and opportunities to ask questions. Eligible and interested participants will be mailed a copy of the consent form with a self-addressed stamped envelope. Contact information for the researchers, the Human Research Review Committee, and the Human Research Protections Office will be made available to potential participants.

Within a week of mailing the consent form, a study investigator, trained in the consent process, will review the consent form with the individual over the phone. The following questions will be asked to assess the subjects' understanding of the consent process. Do you have any questions about the study? We have covered a lot of information. Could you please describe for me what you think participating in this study requires? Do you have the toll free study telephone number? The subject may decline participation in the study or drop out of the study at any time. This will be stated both verbally (phone call) and in writing (consent form). Once a signed copy of the consent form is received by the study team, the participant will be enrolled in the study and the baseline home visit will be scheduled.

While interviews are covered in the currently approved consent form, we wish to provide compensation for completion of an optional interview (a $20 merchandise card). We request a waiver of signed consent for the interview, as no name or personally identifiable information will be included. Please see the Informed Consent Cover Letter, which will be sent to a sample (8-12) of study participants (aka cancer survivors).

For the duration of the study, the volunteer Master Gardeners mentor a cancer survivor in home vegetable gardening. At the end of the intervention, we wish to administer a questionnaire to the Master Gardeners, to obtain their feedback on the study. A sample of Master Gardeners indicating interest, will be invited to complete a telephone or Zoom interview to provide feedback in greater detail. We request a waiver of signed consent for participation in the voluntary questionnaire and interview. The personally identifiable information (name, telephone number, email address) from the questionnaire will only be used to determine which Master Gardeners are interested in completing an interview. All identifying information will be removed from the questionnaire prior to storage and analysis. No names or personal identifiers will be included in the audio recording of the interview.

25. Documentation of Consent

Participants will have ample opportunity to review the consent form, ask questions, and review the form with a trained study team member. A signed consent form will be mailed to the study team in a self-addressed stamped envelope. The participant will retain a copy of the signed consent form to keep for their records.

While we are requesting a waiver of signed consent for the post-intervention interviews (and questionnaire for Master Gardeners), participants will receive a copy of the consent cover letter for their records.

26.Study Test Results/Incidental Findings

NA - Individual results and incidental findings will not be shared with participants

27.Sharing Study Progress or Results with Subjects

Aggregate data from this study will be published in peer-reviewed journals and presented at local and national conferences.

28.Inclusion of Vulnerable Populations

NA – this study is not enrolling individuals from vulnerable populations.

29.Community-Based Participatory Research

NA - This is not a community-based participatory research project

30. Research Involving American Indian/Native Populations

While the proposed project does not exclude individuals identifying as Native American, American Indian and Native Populations will not be directly targeted for recruitment to the study.

31. Transnational Research

NA - This is not a transnational study.

32. Drugs or Devices

NA - this research does not evaluate the safety or effectiveness of a medical device

The activPAL3 activity monitoring device (worn on the thigh):

a. This is not a device study, i.e., this study does not evaluate the efficacy or safety of a device. There is no information on the FDA website regarding the activPAL3 monitor (NOTE: these monitors are from a company in Scotland, UK). However, these monitors are similar to the ActiGraph monitors except for the attachment method. The activPAL3 monitors are not investigational devices as they are commercially available (http://www.paltechnologies.com/); the shipment of activPAL3 monitors was cleared by the FDA and delivered to the Study PI. These monitors are the gold standard for objectively measuring sedentary behavior and ambulation in research study participants and have been used in many trials in the U.S. The activPAL3 monitors are more expensive than consumer wearable monitors (e.g., FitBit, Jawbone) and require special software to analyze the data, thus these monitors are used in research rather than being purchased by consumers. In this study, the monitors are used to measure outcomes (frequency, duration, and intensity of free-living sedentary behavior and light physical activity), and are not used to diagnosis or treat disease, or to support/sustain life.

b. These monitors do not present a potential for serious risk to the health, safety, or welfare of the subject. There is a potential for a small risk of skin irritation due to the adhesive used to attach the activPAL3 to the thigh. We are minimizing this risk by asking the research participants to check the monitors daily and if skin irritation occurs, to remove the monitor and contact study staff.

To our knowledge, the FDA has not evaluated this device; however, it would likely fall under the same category as a similar research grade activity monitor, ActiGraph (not used in this study). We believe, that like the ActiGraph monitors, the activPAL3 monitors used in this study poses non-significant risk per the FDA definition: i) it is not an implanted device, ii) it is not a life sustaining/ supporting device, iii) it is not “for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health”, and iv) it does not otherwise present “a potential for serious risk to the health safety, or welfare of a subject”.

33.Principal Investigator's Assurance

By submitting this study in the Click IRB system, the principal investigator of this study confirms that:

☒ The information supplied in this form and attachments are complete and correct.

☒ The PI has read the Investigator's Manual and will conduct this research in accordance with these requirements.

☒ Data will be collected, maintained and archived or destroyed per HSC Data Security Best Practices, including:

1. **Best Practice for data collection** is for it to be directly entered onto a data collection form that is in a secured access folder on an HS drive behind a firewall, or in a secure UNM Data Security approved system such as RedCap.
2. **Data collection of de-identified data**, if done in a clinical setting or other setting that does not allow direct entry into a secured system, may be done temporarily using a personal or university owned electronic storage device or hard copy document. **The important security safeguard is that no identifiers be include if the data is entered or stored using an untrusted device or storage.**
3. **Permanent (during data analysis, after study closure**) storage must reside on HSC central IT managed storage. Processing of data (aggregation, etc.) are to be carried out in such a way as to avoid creating/retaining files on untrusted storage devices/computers. Trusted devices are HSC managed and provide one or more of following safeguards: access logs, encryption keys, backups, business continuity and disaster recovery capabilities.
4. **Alternate storage media** must be approve by HSC IT Security as meeting or exceeding HSC central IT provided security safeguards.

Checklist Section

This section contains checklists to provide information on a variety of topics that require special determinations by the IRB. Please complete all checklists relevant to your research.

47. Data Transfer/Sharing (Checklist)

Complete this checklist if the research involves transferring/sharing of data with an external entity (institution, company, etc.).

A. Will data be transferred/shared with an external entity (institution, company, etc.)?

☐ Yes

☒ No. **The remainder of this section does not apply.**

B. Indicate if the data is incoming and/or outgoing:

C. Provide the name of the entity that data will be transferred/shared with:

D. Provide the contact name, email and phone number with whom data is being transferred/shared with:

E. Who is responsible for transmission of the data?

F. Who is responsible for receiving the data?

G. Describe how the data will be transferred/shared. Please note data cannot be transferred/shared without assistance from UNM HSC IT. **Requesting HSC Central IT Transfer is detailed on the Sponsored Projects website:**

H. For data being transferred/shared with outside locations or entities, describe the following:

- Where is data storage and how will it be maintained in a secure manner (i.e. encryption, password protection, use of Qualtrics or REDCap, etc)?
- What is method in which data will be collected and stored (i.e. electronic, hard copy, etc)?
- How long will the data be stored?
- Who will have access to data?

I. Please list all specific data elements, variables, etc. to be sent out and/or received. Indicate if the data contains identifiers and health information. Please note that identifiers that MUST be removed to make health information de-identified are as follows: Names, All geographic subdivision smaller than a State, All elements of year (except year), Telephone, Fax numbers, E-mail addresses, Social Security, Medical record number, Health plan beneficiary, Account numbers, Certificate/license numbers, Vehicle identifiers and serial numbers, Device identifiers and serial numbers, Web URLs, IP address numbers, Biometric identifiers, full face photographic images, and Any other unique identifying number, characteristic or code.)

J. If the research requires the access, use, or disclosure of any of the 18 individually identifiable protected health information (PHI) identifiers that can be used to identify, contact, or locate a person (e.g., name, medical record number, etc.), are the subjects going to consent to or authorize the disclosure of their individually identifiable health information?

   a. ***Or*** is HIPAA authorization altered or waived?

K. What is the classification of the data (de-identified, limited data set, protected health information, other).
L. Does the request to transfer/share data include clinical data that belongs to the UNM Health Systems?
M. Does the data to be transferred/shared include information about patients seen at external health system or at a third party medical provider?
N. Is the external entity a "covered entity"?
O. Is the data that is going to be transferred/shared owned or partially owned by another party or have any type of restrictions including regulatory restrictions (i.e. HIPAA, FERPA, etc.)?
P. Is the data publically available? If yes, please provide details:
Q. Does the data include information about substance abuse treatment, sexually transmitted diseases, genetic testing results, HIV/AIDS testing results, and/or mental health?

48. Specimen Transfer/Sharing (Checklist)
Complete this checklist if the research involves transferring/sharing of specimens with an external entity (institution, company, etc.).

A. Will specimens be transferred/shared with an external entity (institution, company, etc.)?

☐ Yes

☒ No. **The remainder of this section does not apply.**

B. Indicate if the specimens are incoming and/or outgoing:

C. Provide the name of the entity that specimens will be being transferred/shared with:

D. Provide the contact name, email and phone number with whom specimens are being transferred/shared with:

E. Who is responsible for sending out the specimens? Please note specimens cannot be sent out without a fully executed material transfer agreement.

F. Who is responsible for receipt of the specimens? Please note specimens cannot be received without a fully executed material transfer agreement.

G. For specimens being transferred/shared with outside locations or entities, describe the following:

- *Where is specimen storage and how will it be maintained in a secure manner?*
- *What is method in which specimens will be collected and stored?*
- *How long will the specimens be stored?*
- *Who will have access to the specimens?*

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