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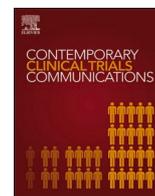
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## Southwest Harvest for Health: Adapting a mentored vegetable gardening intervention for cancer survivors in the southwest

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### ABSTRACT

Few diet and physical activity evidence-based interventions have been routinely used in community settings to achieve population health outcomes. Adapting interventions to fit the implementation context is important to achieve the desired results. Harvest for Health is a home-based vegetable gardening intervention that pairs cancer survivors with certified Master Gardeners from the Cooperative Extension Service with the ultimate goal of increasing vegetable consumption and physical activity, and improving physical functioning and health-related quality-of-life. Harvest for Health has potential for widespread dissemination since Master Gardener Programs exist throughout the United States. However, state- and population-specific adaptations may be needed to improve intervention adoption by other Master Gardener Programs. Our primary objective was to adapt this evidence-informed intervention that was initially incepted in Alabama, for the drastically different climate and growing conditions of New Mexico using a recommended adaptation framework. Our secondary objective was to develop a study protocol to support a pilot test of the adapted intervention, Southwest Harvest for Health. The adaptation phase is a critical first step towards widespread dissemination, implementation, and scale-out of an evidence-based intervention. This paper describes the adaptation process and outcomes, and the resulting protocol for the ongoing pilot study that is currently following 30 cancer survivors and their paired Extension Master Gardener mentors.

### 1. Background

By 2022, there will be 18 million cancer survivors living in the U.S [1]. Cancer survivors are at increased risk for treatment-related comorbidity, including cardiovascular disease, diabetes, osteoporosis, and reduced quality of life (QOL) [2–11]. 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 can lead patients to reconsider their lifestyle behaviors, a large proportion of cancer survivors do not meet the recommendations for a healthy lifestyle that includes ample amounts of high-nutrient foods, such as vegetables, and regular physical activity [12–15]. Many diet and physical activity interventions have been shown to be efficacious in cancer survivors [16–18]. However, few interventions have been

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successfully translated into practice, i.e., routinely used in community settings to achieve population health outcomes [18–20].

Emerging data suggests that vegetable gardening may provide an integrated approach to promote a healthful diet, physical activity, stress relief, and psychosocial well-being [21–28]. Furthermore, gardening has great potential for long-term engagement given that it provides access to seasonal fresh produce and exposure to a variety of gardening activities and tasks, which may prevent satiation common with other diet and exercise programs [29]. Additionally, gardening provides continual behavioral cues since plants require regular care (watering, pest control) and attention (harvesting) [22]. Harvest for Health is a home-based, mentored vegetable gardening intervention for cancer survivors [21–23,30]. Preliminary results suggest that this intervention increases vegetable consumption and physical activity, and improves physical functioning and health-related quality of life (hrQOL) [21–23]. To date, it has been tested among cancer survivors living in Alabama.

Harvest for Health was designed with dissemination in mind. The gardening experts providing one-on-one mentorship to cancer survivors are part of an extant infrastructure — the Cooperative Extension Master Gardener Program [31,32]. The Cooperative Extension Service, is the education and outreach arm of land-grant universities nationwide [32]. The Master Gardener Program is one of many educational outreach programs offered by the Extension, and exists in all states and territories of the United States, as well as some Canadian provinces and South Korea [31,33]. Master Gardener volunteers are trained by land-grant university staff to provide research-based gardening education to the local community. These programs typically have widespread coverage throughout the state, thus serving both urban and rural communities. Depending upon the state, Master Gardeners typically complete 50–100 h of training, plus additional community service to become certified; moreover, 20–50 h of volunteer community service may be required each year to maintain active status. While community service is not required by all Master Gardener Programs, the original and defining purpose of the program is to provide volunteers to assist the Extension. The type of community service projects performed by Master Gardeners is dependent on the needs and interests of their communities. While there is potential for widespread dissemination of Harvest for Health through the Extension Master Gardener Program, evidence is needed for scaling out to an Extension in another state [34].

Scaling out refers to adapting and delivering evidence-based interventions to either new populations, new delivery systems, or both [34]. Evidence beyond the original trial(s) is needed to determine whether the core elements of the intervention can be delivered with fidelity and whether the new context is supportive of delivery of the intervention [34]. Since the Master Gardener Programs vary among states, and even by counties within a state, further study is necessary to understand how to effectively scale out the Harvest for Health intervention from one state to another [35–37]. Differences between programs might include availability of staffing or financial resources, leadership structure, or organizational culture, including priorities and goals [37–39]. Thus, state- and population-specific adaptations may be needed to improve intervention adoption by other Master Gardener Programs throughout the Extension [35,36]. Adapting these interventions to fit the implementation context is important to achieve the desired impact [40–42].

Building on the promising results of Harvest for Health, the first objective of the current study was to adapt the intervention for the local context of New Mexico, i.e., the physical, social, and cultural environment, and for delivery by the New Mexico Extension Master Gardener Program. Answering the call for a proactive, systematic approach to adaptation [40,42,43], we used the Framework for Reporting Adaptations and Modifications to Evidence-based interventions (FRAME) by Stirman and colleagues to guide the adaptation process, including detailed documentation of adaptations. Our second objective was to develop a study protocol to support a pilot test of the adapted intervention, Southwest Harvest for Health. The current paper describes the

adaptation process and outcomes, and the resulting study protocol for the ongoing pilot study that is currently following 30 cancer survivors and their paired Extension Master Gardener mentors.

## 2. Methods

### 2.1. Frameworks guiding the adaptation process

#### 2.1.1. Adaptation process

The primary objective of this study was to systematically identify, document, and test the adaptations needed for the Harvest for Health intervention to be successfully implemented in New Mexico, while maintaining fidelity to the original intervention. Fidelity refers to the degree to which an intervention is implemented as intended [44], often focusing on the core components of the intervention believed to be essential for producing the desired outcomes [42,45]. Adaptation refers to the degree to which an intervention is modified to improve the fit to the local population or context [44]. Balancing fidelity and adaptation requires the identification and preservation of the core components of the original intervention [44,46]. For Harvest for Health, the primary core component is the one-on-one mentoring of the cancer survivor by a certified Master Gardener. Another core component includes the provision of gardening tools, supplies, and an assortment of plants and seeds for the cancer survivor to establish a home vegetable garden.

We began by following the intervention adaptation steps identified by Escoffery et al. who summarized common steps from existing frameworks for adapting evidence-based interventions [47]. The eleven key adaptation steps include: 1) assess the community, which refers both to the target population and the capacity of the community organization to implement the intervention; 2) understand the intervention, including the behavioral theory behind the intervention and the core elements of the intervention; 3) select the intervention; 4) consult with experts, including developers of the original intervention; 5) consult with stakeholders from the beginning and throughout; identify program champions; 6) decide what needs adaptation, such as program structure, content, delivery methods, while retaining fidelity to the core elements; 7) adapt the original program (or intervention); 8) select and train staff to ensure quality implementation; 9) test the adapted materials via readability tests or pilot study; 10) develop implementation plan and test the adapted intervention; and 11) evaluate the process and outcomes of the adapted intervention, and document the adaptation process [47]. Specific details about how this process was applied to this study are included in Table 1.

#### 2.1.2. Documentation of adaptations

As stated, the adaptation process, including detailed documentation of adaptations, was guided by FRAME [41] which includes the following elements for documenting adaptations: 1) point during the implementation process the modification occurred (e.g., pre-implementation, implementation, scale-up/scale-out); 2) whether the modification was planned (proactive) or unplanned (reactive); 3) who participated in the decision to modify (e.g., researcher, community members, intervention team); 4) what was modified (e.g., content, context, training and evaluation); 5) for whom the modification was made (e.g., individual, organization, network system); 6) nature of content modification (e.g., adding or removing intervention elements; shortening or lengthening intervention); 7) whether modification was fidelity consistent or inconsistent regarding preservation of core elements of the intervention; 8) reasons for the modification, including the goal (e.g., reduce costs, increase reach/engagement) and contextual factors that influenced the decision (e.g., available resources, cultural norms) [40,41,48]. The FRAME Coding Manual and checklist were used to document each adaptation [41,49].

**Table 1**  
Key steps for the adaptation of harvest for health to southwest harvest for health.

Adaptation Step <sup>a</sup>	Description
1. Assess community	<ul style="list-style-type: none"> <li>•Based on our review of the literature, low levels of vegetable intake, physical activity, and quality of life were noted among many NM cancer survivors</li> <li>•We assessed the capacity of the number and size of Master Gardener Programs across the state through ten key informant interviews. There are over 300 active Master Gardeners in the Albuquerque Area Extension Master Gardener (AAEMG) Program; moreover, additional Master Gardener Programs exist throughout the state for potential future scale-up (expansion within the NM Extension)</li> <li>•We met with an Extension agent and Master Gardeners to assess facilitators and barriers to gardening in NM, and the type of volunteer opportunities (community service) for Master Gardeners within the AAEMG and whether a mentored gardening intervention for cancer survivors might be a suitable option.</li> </ul>
2. Understand the intervention	<ul style="list-style-type: none"> <li>•The study PI worked on the initial pilot study for the Harvest for Health intervention in 2011. The UNM study team has strengthened their understanding of subsequent iterations of the study through discussions with the developers, who have shared all study materials with the UNM study team</li> <li>•Through discussions with the developers and review of the publications, we obtained an understanding of the theory behind the intervention and the core elements</li> <li>•The intervention uses the Social Cognitive Theory and Social Ecological Model as theoretical frameworks to promote behavior change.</li> </ul>
3. Select intervention	<ul style="list-style-type: none"> <li>•Given its integrated nature to improve multiple health behaviors (diet, physical activity) and health outcomes (physical function, quality life), and an active Master Gardener Program in NM, we decided to move forward and adapt the Harvest for Health intervention to the southwest</li> </ul>
4. Consult w/experts	<ul style="list-style-type: none"> <li>•We have been consulting with the developers of the original intervention regarding the study logistics, study materials, and the most common issues that arise during implementation</li> <li>•We are incorporating expert advice into the adapted intervention</li> </ul>
5. Consult with stakeholders	<ul style="list-style-type: none"> <li>•Through several initial meetings, we sought input from members of the local Extension office and AAEMG members</li> <li>•We also had several discussions with the new manager of the statewide Master Gardener program about the fit of Harvest for Health in the NM Extension</li> <li>•We identified partners from the Extension and Master Gardener Program who can champion intervention adoption in this new setting and ensure fidelity. These champions represent the Master Gardener Leadership Team on the study.</li> <li>•Members of the UNM study team visited five local gardening projects to talk with Master Gardeners, present an overview of the study and obtain feedback, and assess initial interest in choosing the study as their volunteer opportunity during 2020</li> </ul>
6. Decide what needs adaptation	<ul style="list-style-type: none"> <li>•Through discussions and meetings with multiple stakeholders, we determined how the original and new target population and context differed (primarily related to growing conditions: heat, lack of precipitation, soil quality, wind, pests/wildlife, etc.)</li> <li>•We then identified which parts of the intervention required adaptation, while retaining fidelity to core elements</li> </ul>
7. Adapt original program	<ul style="list-style-type: none"> <li>•We are working with our consultants (original developers) to ensure that the adapted procedures and materials maintain the accuracy of the originals</li> <li>•We are using the FRAME adaptation framework to guide the systematic identification and documentation of adaptations (See Table 3 for a description of adaptations)</li> </ul>
8. Train staff	<ul style="list-style-type: none"> <li>•The Master Gardener Leadership team is primarily responsible for recruiting Master Gardeners into the study, and providing support during the study.</li> <li>•A training meeting was held with the Master Gardeners</li> </ul>

**Table 1 (continued)**

9. Test the adapted materials	<ul style="list-style-type: none"> <li>•We are currently pilot testing the adapted intervention, Southwest Harvest for Health, among 30 cancer survivor/Master Gardener dyads</li> </ul>
10. Implement	<ul style="list-style-type: none"> <li>•Upon completion of the pilot study, we will evaluate the process and outcomes of the adapted intervention as implemented (e.g., acceptability, appropriateness, fidelity, as well as barriers &amp; facilitators to implementation)</li> </ul>
11. Evaluate	<ul style="list-style-type: none"> <li>•If needed, we will modify the adapted intervention based on feedback from the Master Gardener mentors, cancer survivors, and the Master Gardener Leadership Team, (for evaluation of effectiveness in a future, larger trial)</li> </ul>

<sup>a</sup> Intervention adaptation steps from scoping study of adaptation frameworks by Escoffery et al.

## 2.2. Study protocol for the adapted intervention — Southwest Harvest for Health

Per step 9 in the adaptation process described above, we adapted materials and the intervention to be pilot tested in a new population, utilizing a new delivery system (New Mexico Extension). This section describes the resulting protocol for the ongoing pilot study. The study protocol was approved by the Human Research Review Committee at the University of New Mexico Health Sciences Center. The trial was registered at [ClinicalTrials.gov](https://clinicaltrials.gov) on January 31, 2020 (Identifier NCT04251299).

### 2.2.1. Study design and setting

The pilot study was designed as a single-arm trial. The study is currently being conducted in New Mexico, a large and sparsely populated state, ranking 5th in size and 6th among the lowest population density states [50]. For logistical efficiency (home visits to collect data), the study was restricted to two adjacent counties in New Mexico – one of which is home to the state’s comprehensive cancer center. This is a home-based intervention, whereby participants establish and maintain a vegetable garden at their home.

### 2.2.2. Community partners

Similar to the original Harvest for Health study [21–23,30], the current pilot study is a community-based, partnership between the University of New Mexico (UNM) and the Albuquerque Area Extension Master Gardener Program from New Mexico State University’s Cooperative Extension Service [51–53]. To adapt and pilot the intervention in NM, we specifically partnered with two Master Gardener Programs: Bernalillo County (the largest county in the state with the largest Master Gardener Program, as well as the location of the University of New Mexico research team) and nearby Sandoval County (a rural county with a smaller Master Gardener Program). In NM, community volunteer opportunities for Master Gardeners must be approved by each program’s Board of Directors. Once approved, a volunteer Master Gardener Coordinator is assigned to oversee and provide support for Master Gardeners who select the project for their volunteer experience. Master Gardeners select one or more of the approved community volunteer projects each year to maintain active status.

For this pilot study, the county extension agents and project coordinators from the Master Gardener Program were responsible for recruiting, training, and supporting the Master Gardeners who volunteered to be mentors. Interns who were still in training were paired with a veteran Master Gardener; a veteran Master Gardener attends continuing education classes each year in addition to their volunteer

service. After the cancer survivors were recruited, they were paired with a certified Master Gardener based on proximity (typically <10 miles).

### 2.2.3. Recruitment and eligibility

The UNM Study Team was responsible for enrolling, monitoring, and collecting data from study participants (cancer survivors). Recruitment flyers were distributed in community locations such as cancer survivor groups and community centers in the two counties included in the pilot study. Additionally, oncologists, physicians, and nurse navigators referred patients (cancer survivors) to the study by giving them a study flyer. Interested individuals contacted study staff by telephone or email. Screenings occurred over the telephone. The inclusion criteria included: (1) Aged 50 years or older; (2) Diagnosed with an invasive, non-metastatic cancer; metastatic cancer patients were eligible with MD approval; (3) Community dwelling and not residing in a skilled nursing or assisted living facility (must be able to tend their garden and cook their own meals); (4) Consumed fewer than 5 fruit and vegetable servings per day and spent <150 min per week in moderate-to-vigorous physical activity; (5) Resided in a location that could accommodate a 4' x 8' raised garden bed or 4 (29" x 14") garden containers, and have adequate (at least 6 h) of sunlight per day and access to running water; (6) Able to read, speak, and understand English (future larger trial will include Spanish-speaking participants); and (7) Able to participate in the 9-month intervention (all three seasonal gardens; from March through mid-November 2020). Exclusion criteria included: (1) Told by a physician to limit physical activity or having a pre-existing medical condition (s) that substantially limited daily light-intensity physical activity (i.e. activities of daily living: bending, stooping, walking, etc.) that would preclude gardening; and (2) Existing or recent (within the past year) experience with vegetable gardening or living with someone who has had a successful vegetable garden within the past year. After written informed consent was obtained, a home visit was scheduled to collect baseline data.

### 2.2.4. Harvest for Health gardening intervention

The initial Harvest for Health intervention was developed at the University of Alabama at Birmingham in partnership with the Alabama Cooperative Extension Service. The intervention uses the Social Cognitive Theory (SCT) [54–56] and Social Ecological Model (SEM) [57,58] as theoretical frameworks to promote behavior change [22,30]. The Master Gardeners serve as role models and mentors to promote gardening self-efficacy, provide incremental guidance to participants throughout the intervention, provide reinforcement and encouragement as needed, and strategize to overcome barriers. Moreover, healthy lifestyle behaviors, as well as quality of life, also could be influenced by the relationships between the survivor and their social (e.g. support from Master Gardener mentor) and physical (e.g. outdoor environment including sunshine, fresh air, etc.) environments according to the Social Ecological Model.

Harvest for Health [21–23,30] pairs each cancer survivor with a certified Master Gardener from the Extension. The participant/Master Gardener dyads work together to plan, plant, maintain, and harvest three seasonal gardens at the participants' homes. Participants receive gardening supplies, plants and seeds, and print materials on gardening safety, health, and nutrition. However, most of the gardening knowledge is imparted by working with their assigned Master Gardener mentor. The expectation is that the dyads communicate every two weeks throughout the intervention, alternating between home visits and telephone or email. The components of the adapted intervention — Southwest Harvest for Health — are included in Table 2.

### 2.2.5. Outcomes and measures

**2.2.5.1. Primary outcomes.** The primary outcomes of this ongoing pilot study include the implementation outcomes of acceptability,

**Table 2**  
Adaptations to the Harvest for Health gardening intervention.

Program components	Harvest for Health (Original trial)	Southwest Harvest for Health (Adapted trial)
<i>Duration of study</i>	12-month intervention with 3 seasonal gardens	Shortened to 9-month intervention due to more severe winter weather; still able to include 3 seasonal gardens (just shorter in duration)
<i>Meet &amp; Greet Event</i>	The kick-off event of the intervention where participants meet their Master Gardener mentor, exchange contact information and best days/times/preferences (e.g., email, phone) to communicate.	Same, but we also provided smaller gardening supplies at this event (rather than delivery with larger supplies) to increase engagement.
<i>Participant Study Notebook &amp; Garden Journal:</i>	The notebook includes the following: <ul style="list-style-type: none"> <li>•Basic study information (e.g., schedule and important dates, troubleshooting guide)</li> <li>•Articles on safety while gardening (e.g., protecting your knees and back; protecting your hands and feet)</li> <li>•Helpful resources for starting and maintaining a vegetable garden (e.g., Extension publications, gardening supplies and instructions for setup).</li> <li>•Pages for planning each seasonal garden, including list of vegetables that grow best in each season.</li> <li>•A separate journal was provided for recording observations and notes about their garden.</li> </ul>	The notebook was tailored for the local context: <ul style="list-style-type: none"> <li>•Same</li> <li>•Added additional articles on safety (e.g., sun safety and detecting skin cancer due to climate (state average 280 sunny days) and elevation (state average 5700 feet above sea level)</li> <li>•Replaced all AL Extension articles with NM Extension articles, which are specific to NM growing conditions (e.g., Home Vegetable Gardening in New Mexico, Circular 457)</li> <li>•Dates for each growing season, and the lists of vegetables that grow best (by seed vs. seedling) by season were adapted for the area of NM included in the study.</li> <li>•A monthly garden log was added to the notebook rather than providing a separate journal.</li> </ul>
<i>Gardening Supplies:</i> <sup>a</sup>	Supplies needed to begin a home vegetable garden are provided to the participants (delivered to their homes by Home Depot – common throughout AL). These include: soil/potting mix, plants, seeds, and mulch to support either four container-style garden boxes (20.5 by 24.5 inches; can be used to garden on balconies, patios or decks) or 1 raised bed garden (4 by 8 foot; equivalent square footage). An assortment of gardening tools is also provided (e.g., hand tools, hose, tomato cages, watering can). These supplies are provided free of charge. Participants are allowed to keep their supplies and tools at the end of the study to promote continued gardening.	First, a team of NM Master gardeners reviewed the list of supplies and tools used in AL. Despite alternative options for vendors, the decision was made to purchase through Home Depot for logistical efficiency (adequate supply, delivery, one-stop shopping), especially for scaling-up across the state. Minor modifications were made to the list (replaced more expensive tomato cages with bamboo stakes and twine; added a water meter). Seeds were provided by the local Extension office seed library. We were unable to schedule home deliveries of the larger gardening supplies prior to the statewide stay-at-home order (March 2020). Instead, a single-site distribution center was established, and

(continued on next page)

Table 2 (continued)

Program components	Harvest for Health (Original trial)	Southwest Harvest for Health (Adapted trial)
<i>Master Gardener Mentors:</i> <sup>a</sup>	Each participant is paired with at least one certified Master Gardener from the Cooperative Extension Service to provide personal guidance in setting up the garden, maintaining it, and replanting it season-to-season. In providing this support, the Master Gardener mentors make monthly visits to participants' homes and 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).	participants, while remaining in their vehicle, had their gardening supplies, plants, and seeds loaded into their vehicle by masked and gloved study team members. This resulted in all participants receiving four gardening boxes (smaller, easier to transport than raised bed kits) and a smaller selection of seedlings (limited access/hours of gardening stores). Monthly home visits are being replaced with a telephone call for the foreseeable future due to COVID-19. Participants are encouraged to email or text photos of their garden to their Master Gardener mentor (or videochat) We are allowing Master Gardener interns (still in training) to pair with a certified Master Gardener to co-mentor a participant. This is being evaluated as a way to increase the capacity for potential scale-up of the intervention, i.e., expanded to other Master Gardener Programs within the New Mexico Extension.
<i>Master Gardener Study Notebook</i>	Master Gardeners receive similar notebooks with information on the study (e.g., schedule and important dates, trouble shooting guide), articles on safety while gardening (e.g., protecting your knees and back), and helpful resources for starting and maintaining a vegetable garden. Additionally, the Master Gardeners notebook also includes a section on suggested topics to discuss with their participants during the twice monthly communications (e.g., care of soil, insects/pests, weeds, too much/too little water).	The Master Gardener notebook was aligned to have similar content and page numbers as the participant notebook to encourage and facilitate more discussion (e.g., referring to a particular gardening article, reminding them to record notes in their gardening journal)
<i>Recipes</i>	Recipes featuring vegetables that grow well in the Southeast region of the U.S. (and particularly in Alabama), are provided to participants throughout the study to promote engagement and retention.	New recipes are identified/created to feature vegetables that grow well in the Southwest region of the U.S. (and particularly in New Mexico) and to account for local cultural preferences (e.g., calabacitas vs. okra and collards).
<i>Evaluation of adherence and intervention fidelity</i>	Both study participants and Master Gardeners are asked to document and report to the study team (via email), the frequency of monthly communications and to briefly describe what was discussed/accomplished during the	Since monthly home visits are on hold due to COVID-19, the participants are responsible for taking photographs of their garden and emailing or texting them to the study team. To encourage more timely

Table 2 (continued)

Program components	Harvest for Health (Original trial)	Southwest Harvest for Health (Adapted trial)
<i>Evaluation of acceptability of the intervention</i>	home visit. Each dyad is asked to take photographs of the garden to share with the research team. At least one photo during the home visit should include the Master Gardener mentor, the study participant, and the garden. A semi-structured debriefing telephone call is made to study participants after the intervention to assess satisfaction, gardening fidelity, future gardening plans, and suggestions for the study.	feedback, monthly web-based surveys to both participants and Master Gardeners have replaced the requirement to email the study team each month. A "bounty party" was planned for the end of the study, the Albuquerque Area Extension Master Gardeners and study team were to host an event that would allow participants an opportunity to "show-off" and share their vegetables and herbs from their gardens. Due to the ongoing COVID-19 pandemic, including the recent surge in cases, the "bounty party" was cancelled. Instead, quantitative and qualitative data about the intervention will be collected from both study participants and their volunteer Master Gardeners.

<sup>a</sup> These components are considered the core components of the intervention that are critical for achieving the health outcomes, and thus, should not be modified in order to maintain fidelity to the original intervention.

appropriateness, and feasibility [59]. For Southwest Harvest for Health, acceptability is the perception of the Master Gardeners that the intervention is appealing. Appropriateness is the fit or relevance of the intervention for the Master Gardener Program. Feasibility is the extent to which the mentored gardening intervention can be successfully delivered by the Master Gardeners. These outcomes will be assessed upon completion of the study using quantitative data from surveys, and qualitative data from individual interviews.

2.2.5.2. *Secondary outcomes.* As with most pilot studies, the Southwest Harvest for Health study was not powered to detect clinically meaningful nor significant changes in measures of diet, physical activity, physical performance, and quality of life. However, the pre-post changes will be used to generate estimates for a future, larger trial. Home visits to assess secondary study outcomes occur three times over the study period: baseline (within one month prior to intervention start), mid-intervention (around 6 months) and post-intervention (at 10 months). At baseline, two members of the study team visited the participant at their residence to assess the participant's health status. Prior to the home visit, participants were mailed questionnaires to be completed, and then collected by study investigators during the home visit. Verification of adequate space, sunlight, and running water to support a vegetable garden occurred at the baseline home visit. Due to COVID-19, follow-up home visits were replaced with telephone, and mail or digital surveys. The following data are collected:

1. *Anthropometrics:* Height (nearest 0.5 cm) and weight (to nearest 0.1 kg) (baseline only, due to COVID-19).
2. *Vegetable Dietary Intake:* Eating at America's Table Screener (EATS): a 10-item questionnaire developed by the NCI is used to assess vegetable dietary intake (since vegetables are a more concentrated source of nutrients than fruit, and more likely to change during a vegetable

gardening intervention) [60]. Questions include frequency (ranging from never to multiple times per day) and amount (ranging from none to more than two cups) for selected foods.

3. **Physical Activity and Sedentary Behavior:** Subjective measures include the Godin Leisure Time Physical Activity Questionnaire to assess self-reported leisure-time physical activity. It includes type, frequency, and duration of activities at three intensity levels (light/mild, moderate, and vigorous) [61–63]. The PACE Adult Sedentary Behavior Questionnaire is used to estimate 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 nine common activities (e.g., watching television, using a computer, reading, etc.) [64]. Objective measures of both physical activity and sedentary behavior are measured using accelerometry. Participants are asked to wear the activPAL3, a small, thin device (like a patch) that is worn on the mid-thigh (day and overnight) for 7 days at the beginning, at 6 months, and at the end of the study [65–68]. Verbal and written Instructions for applying and removing the monitor are provided to the participant.
4. **Physical Performance:** The Senior Fitness Test Battery includes measures of physical function in four domains: (1) lower & upper body strength (30-s chair stand, arm curl); (2) endurance (2-min step test); (3) flexibility (chair sit-and-reach, back scratch); and (4) agility/dynamic balance (8-foot Get-up and go, which was replaced with the 10-foot Timed Up & Go test) [69–73]. Grip Strength measures participant's functional limitation and disability using a hand-held dynamometer [74,75]. (baseline only, due to COVID-19)
5. **Health Related Quality of Life (HRQOL):** The PROMIS-57 is a 57-item survey covering seven domains (physical function, anxiety, depression, fatigue, pain, sleep disturbance, and social functioning) [76, 77].
6. **Sleep quality:** Sleep impairment is assessed in addition to sleep disturbance; each is measured using the PROMIS short-form 8a questionnaires [67,68,76].
7. **Comorbidity:** The Older Americans Resources & Services (OARS) Comorbidity Index is used to assess the number of chronic medical conditions and symptoms and their functional impact [78]. The survey includes 42 conditions and symptoms (not including cancer), and whether each condition/symptom interferes with activities (not at all, a little, a great deal) [78].
8. **Perceived Social Support:** The Social Provision Scale is used to assess the psychosocial benefits of gardening. It includes six subscales including: emotional support or attachment, social integration, opportunity for nurturance, reassurance of worth, reliable alliance, and guidance [79]. Several gardening studies have reported enhanced self-esteem, increased independence, and increased zest for life [80, 81].
9. **Mediators:** Community-Level: Participants will assess their local environment for support of vegetable gardening considering the following factors: 1) availability of garden stores; 2) presence of pests/wildlife (i.e., insects, deer, coyotes); 3) neighborhood covenants that impose landscaping restrictions; and 4) sense of belonging with other gardeners in local community [30]. Interpersonal: We will use the Social Support & Eating Habits & Exercise Surveys adapted for gardening (12 items) [30,82]. Individual: This assessment will measure the cancer survivors' self-efficacy (survivors' beliefs in their ability to maintain a successful vegetable garden; 3-items).

#### 2.2.6. Sample size

A formal sample size calculation was not performed for this study. With our targeted sample size of 30 participants (and allowing for 20% attrition), we will be able to estimate population parameters to within plus or minus 0.42 standard deviations of truth with 95% confidence in our analyses of secondary outcomes. The resulting estimated effect sizes will provide critical preliminary information that will enable the design

of a subsequent, larger study.

#### 2.2.7. Data analysis

Baseline descriptive characteristics (mean  $\pm$  SD, number (%)) are presented to characterize the enrolled study population (cancer survivors). Upon completion of the pilot study, we will evaluate pre-post intervention change for the health outcomes (vegetable servings per day, physical activity, QOL, etc.).

Preliminary evidence of the acceptability, appropriateness, and feasibility of the adapted vegetable gardening intervention among Master Gardeners will be assessed thorough the collection of detailed process data. Quantitative surveys will be distributed at the end of the intervention. Additionally, one-on-one interviews will be conducted with a sample of Master Gardeners. Additionally, we will assess the intervention outcomes of accrual, retention, adherence, and adverse events.

The digital audio files from the telephone or Zoom interviews will be transcribed verbatim. Transcripts will be uploaded into NVivo 10 Qualitative Data Management and Analysis software (QSR International) 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 inform the future trial. Illustrative quotes for each theme will be identified.

### 3. Results

#### 3.1. Adaptation

Table 3 describes the components of the original Harvest for Health intervention as well as the adaptations to the intervention, prior to and during implementation in New Mexico. A summary of how we applied the FRAME framework for documenting adaptations has been divided into two categories: pre- and during the COVID-19 pandemic. Prior to COVID-19, the adaptations: 1) occurred during the pre-implementation/planning stage; 2) were proactive/planned; 3) resulted from discussions and agreement between the Master Gardener Leadership Team and the UNM study team; 4) included content and contextual modifications; 5) were made primarily at the individual level (study participant); 6) were primarily tailoring, tweaking, or refining content; 7) were fidelity consistent; and 8) were made to improve feasibility, increase engagement, or to better fit the local context (e.g., climate, growing conditions).

Additional modifications were made due to COVID-19, which: 1) occurred during implementation; 2) were proactive/planned; 3) were jointly decided by the Master Gardener Leadership and UNM study teams; 4) included contextual modifications; 5) were made primarily at the individual level (both study participants and Master Gardeners); 6) N/A – adaptations are contextual; 7) were both fidelity consistent (pick-up vs. delivery of gardening tools and supplies) and inconsistent (suspension of monthly home visits); and 8) were made to allow us to start the intervention and keep it going, while maintaining everyone's safety during the COVID-19 pandemic.

#### 3.2. Pilot study

Enrollment opened on January 2, 2020 and was scheduled to close on March 2, 2020 in order to complete the baseline assessments prior to the Meet & Greet Event (scheduled for March 5th). The first study participant was enrolled on January 17th. A total of 42 individuals expressed interest in the study (Fig. 1). Of these, 10 did not meet eligibility criteria and two were unable to be screened before the enrollment period closed. Thus, 30 individuals were enrolled in the study. Enrollment was completed on February 25, 2020.

Table 3 provides the baseline characteristics of the enrolled study participants. The mean age at study enrollment was 68 years (range 50–83), 70% of participants are female, 73% are non-Hispanic White,

**Table 3**  
Baseline characteristics of cancer survivors in the Southwest Harvest for Health pilot study.<sup>a</sup>

Characteristics	Mean (SD) or Frequency (%)
<b>Sociodemographic Characteristics</b>	
Age	68.0 ± 7.2
Sex	
Female	21 (70%)
Male	9 (30%)
Race-ethnicity	
Non-Hispanic White	22 (73%)
Hispanic White	6 (20%)
Other <sup>b</sup>	2 (7%)
Living Arrangement	
Alone	13 (43%)
With Others	17 (57%)
College degree	
No	13 (43%)
Yes	17 (57%)
Income Group	
<\$50,000	12 (40%)
≥\$50,000	15 (50%)
Declined to answer	3 (10%)
<b>Health Characteristics</b>	
Number of comorbidities	3.2 ± 2.0
General Health	
Fair, poor	5 (17%)
Good,	18 (60%)
Very good, Excellent	7 (23%)
Cancer Type	
Breast	11 (37%)
Prostate	6 (20%)
Lung	4 (13%)
Other	9 (30%)
Time since cancer diagnosis	
<5 years	13 (43%)
≥5 years	17 (57%)
Treatment received <sup>c</sup>	
Surgery	23 (77%)
Chemotherapy	10 (33%)
Radiation	22 (73%)
Hormonal therapy	12 (40%)
Other	2 (7%)
<b>Lifestyle Behaviors</b>	
Smoking Status <sup>d</sup>	
Never	16 (53%)
Former or current	14 (47%)
BMI	29.4 ± 5.6
Fruit & Vegetable Servings per Day	4.4 ± 2.5
Moderate-intensity Physical Activity (minutes per week) <sup>e</sup>	24.7 ± 39.5
Light-intensity Physical Activity (minutes per week)	94.4 ± 99.0

<sup>a</sup> Table includes characteristics for the 30 cancer survivors enrolled in the study.

<sup>b</sup> Other racial groups not identified due to the small number of cases within the study catchment area.

<sup>c</sup> Percentages do not total 100%, since some participants may have had more than one type of treatment.

<sup>d</sup> Only one participant reported currently smoking.

<sup>e</sup> No vigorous-intensity physical activity was reported at baseline.

and 57% have graduated from college. The majority of participants reported three or more comorbidities (63%; mean of 3.2 ± 2.0) and reported their general health as good (60%). Over one-third are survivors of breast cancer, and the remainder have been diagnosed with prostate (20%), lung (13%), and a variety of other cancer types (30%). At baseline, participants reported an average of 1.8 ± 1.7, and 2.6 ± 1.5 servings per day of fruits and vegetables, respectively. Nearly four times as many minutes per week were spent in light-intensity compared to moderate-intensity self-reported physical activity.

## 4. Discussion

While many lifestyle interventions conducted among cancer survivors have demonstrated efficacy in improving diet quality, 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 interventions is limited. Harvest for Health represents an integrated strategy to increase both vegetable consumption and physical activity, and improve quality of life among cancer survivors. Designed with widespread dissemination in mind, the Harvest for Health intervention utilizes the infrastructure of the nationwide Extension Master Gardener Program [31,32].

The current study has adapted the Harvest for Health intervention to the drastically different climate and growing conditions of New Mexico using a recommended adaptation process and framework [40,41,47]. This process led to the development of a study protocol to pilot test the adapted intervention, Southwest Harvest for Health, which was successfully launched as the COVID-19 pandemic was emerging. Upon completion, the pilot study will provide important information on acceptability, appropriateness, and feasibility among Master Gardeners from the New Mexico Extension. Understanding the local implementation context is essential for identifying barriers, and implementation strategies to overcome these barriers, prior to scaling-out to and evaluating effectiveness in a new population using a new delivery system.

As previously mentioned, the majority of adaptations that we made to Harvest for Health were related to context, specifically the vastly different climate and growing conditions of the Southwest. However, New Mexico also includes a multi-cultural population that differs substantially from the original population in Alabama. Thus, further adaptations, especially cultural adaptations, may be needed given that our ongoing pilot study recruited a convenience sample that was primarily (73%) non-Hispanic White, and only 20% Hispanic White (the remaining 7% represent other racial groups that account for less than 5% of the New Mexico population). Based on cancer case counts by race-ethnicity for the two counties included in the study [83], approximately 62%, 34%, and 4% of the cases are non-Hispanic White, Hispanic, and American Indian (the three largest racial-ethnic groups in New Mexico). Therefore, in future studies, work will be needed to ensure that our recruitment efforts reach out and increase awareness of this intervention among Hispanic and American Indian populations. Ongoing cultural adaptations may be needed to improve the relevance, acceptability, or effectiveness of Harvest for Health in this population.

### 4.1. Challenges

As with numerous research studies, the COVID-19 pandemic has caused several unexpected challenges for the Southwest Harvest for Health intervention. In addition to the proactive adaptations made during the pre-implementation/planning stage, we had to make several additional adaptations during implementation to allow the intervention to continue. These additional adaptations, decided jointly by the research and intervention delivery teams, were still planned, proactive (e.g., replacing monthly home visits with an extra telephone call). The planned evaluation at the end of the intervention will determine whether unplanned, reactive adaptations were made by individual Master Gardeners delivering the intervention. When asked what type of impact COVID-19 was having on the study, 91% of Master Gardeners indicated a negative impact (9% no impact; 0% positive), with a unanimous explanation that their preference was to meet with their participant in person and to see their garden (i.e., the monthly home visit). In contrast, when asked the same question, 47% of the cancer survivors indicated a negative impact (with the same reason as Master Gardeners), with 37% indicating no impact. Despite these modifications, participants were excited to receive their gardening supplies, establish a vegetable garden, and to be receiving guidance, albeit remotely, from their Master Gardener mentor.

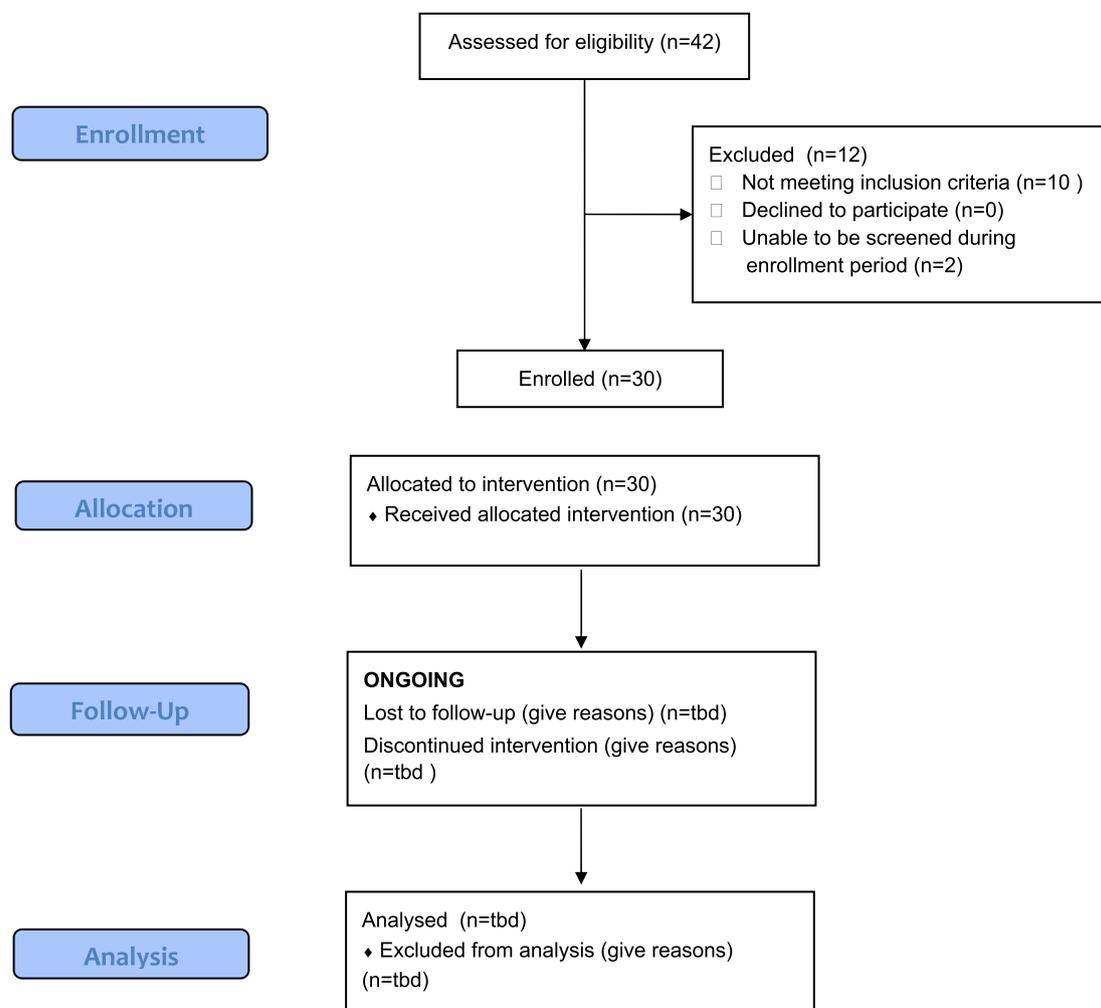


Fig. 1. Study design and CONSORT Diagram for the pilot study.

## 5. Conclusion

The current study represents a concerted and planful effort to grow the Harvest for Health intervention in order to 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 hybrid effectiveness-implementation study to identify implementation strategies to increase the adoption and successful implementation of this intervention throughout New Mexico, and perhaps even further beyond to states with comparable environments, populations, and services.

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## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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