Supporting Cancer Survivors in Making Healthful Lifestyle Changes

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I believe that people who actively participate in their own health do much better. After all, exercise is so connected to mental health, and paying attention to what you feed your body makes a big difference in overall health—it just makes sense.

> Susan Rossman, breast cancer survivor, Birmingham, Ala.

Harvest for Health is testing the effects of vegetable gardening in more than 300 cancer survivors aged 60 and older—an age group that is particularly vulnerable to declines in physical functioning.

S ince 1981 Alabama Master Gardeners have been important volunteers with the Alabama Cooperative Extension System, hosting displays and information booths at county fairs, offering educational programs, assisting at botanical gardens, working with historic properties, implementing civic beautification projects, partnering with local schools, donating fresh produce to charity, supporting scholarships in secondary education, and much more. Learn more at mg.aces.edu.

In 2010, when Susan Rossman was offered the opportunity to participate in a University of Alabama at Birmingham (UAB) pilot study of a vegetable gardening intervention that paired her with a local master gardener mentor from the Alabama Cooperative Extension Service and provided her with the necessary gardening supplies, she jumped at the chance. As Rossman predicted, the intervention produced significant improvements in several aspects of physical health among participants, which included four breast, four prostate, and four childhood cancer survivors (and their parents). Specifically, results indicated:

- Better hand grip strength (+4.5 [3.0 to 6.7] kg).
- Improved agility as assessed by the 8 foot Up and Go (-1.5 [-2.1 to -0.2] seconds).
- Improved leg strength as assessed by the 30-second chair stand (+1.5 [-1.0 to 5.0] stands).
- Improved endurance as assessed by the 6-minute walk (+38 [20 to 120] feet).

Half of the cancer survivors also increased their vegetable and fruit intake by at least one serving per day and two-thirds increased their physical activity by at least 30 minutes per week.¹ Results from this pilot study led to two larger feasibility studies that assessed the effects of the vegetable gardening intervention among a total of 128 additional cancer survivors. Findings from these two trials reinforced the positive changes observed in the first study^{2,3} and led to a large, National Cancer Institute (NCI)-funded (NCT02985411) randomized controlled trial. The trial, called Harvest for Health, will accrue a variety of cancer survivors across





(Top) Cancer survivor and Harvest for Health participant, Susan Rossman, in her vegetable garden. (Bottom) Cancer survivor and Harvest for Health participant, Sarah Harkless, enjoying the fruits of her labor.

Alabama and will complete enrollment in April 2020 in the northern part of the state (Harvest4Health@uab.edu).

Harvest for Health

The trial is a community-based partnership between UAB and Auburn University that began in 2010, when Wendy Demark-Wahnefried, PhD, RD, a cancer survivorship researcher, was recruited to UAB and reached out to Tony Glover, an Alabama Cooperative Extension System coordinator. Dr. Demark-Wahnefried had previous experience with the Master Gardener program when she was on faculty at Duke University and wondered whether the Alabama Cooperative Extension would be interested in collaborating on a pilot study that would be supported through some of her startup funds. The small pilot study eventually led to the large randomized controlled trial currently in the field. Harvest for Health is testing the effects of vegetable gardening in more than 300 cancer survivors aged 60 and older-an age group that is particularly vulnerable to declines in physical functioning. The study aims to improve vegetable intake, physical activity and function, health-related quality of life (QoL), and select biomarkers of healthy aging (e.g., interleukin-6 and telomerase). Harvest for Health participants are randomly assigned to either the one-year mentored, home-based vegetable gardening intervention immediately or another group that will receive the intervention after a one-year waiting period. Participants are paired with master gardeners, who provide guidance in planning, planting, and maintaining a spring, summer, and fall garden. Vegetables grown in these gardens include: lettuce, peppers, squash, and tomatoes, as well as any other vegetable the survivor wants.

Every six months, participants complete surveys on their diet, physical activity, and QoL either by mail or online. In-person assessments are conducted at baseline, one year, and two years at the participants' home or community center and consist of measuring weight and height and waist circumference, testing physical performance, and collecting biospecimens (i.e., saliva and toenail clippings to measure cortisol [stress hormone], fecal samples to assess potential changes in the microbiome, and blood to quantify changes in interleukin-6 and telomerase).

Though the study is still ongoing, participant feedback is positive. Sarah Harkless, a former schoolteacher and current research participant, has enjoyed playing an active role in her health by gardening and receiving all of the necessary tools and support needed to grow a successful garden. She feels that Harvest for Health has given her a "jump start" on healthier living. "I am eating new things and I am now back in the kitchen cooking. Gardening makes me want to do better. I am eating better and have even lost 10 pounds. It has given me something to look forward to every day. I love it; my family loves it!"

Patricia Saffles, Harkless's master gardener mentor, who recently lost her husband to cancer, signed up to volunteer for Harvest for Health to "give back and make a difference in someone's life." Saffles has always had a passion for growing flowers and was so inspired by Harkless and her veggies that she has started a vegetable garden of her own. Her new passion for growing vegetables has led her to make heathier eating choices. Saffles believes that Harvest for Health is mutually beneficial for cancer survivors and master gardeners: "We have had a great time, a lot of laughs, and are learning from each other. Sarah even inspires me to try new things in my garden."

Harvest for Health offers a holistic means to improve both diet and exercise behaviors to improve the overall health of cancer survivors. However, not all cancer survivors are interested in sowing seeds in order to "shovel-up" better health.⁴ Thus, the research team, which was originally based just at UAB, has expanded to the University of Tennessee Health Science Center (with the subsequent moves of some members) and is exploring other ways to improve dietary and physical activity behaviors, as well as promote safe weight loss among cancer survivors who struggle with making changes in their diet, exercising, and managing their weight, particularly if they carried a few extra pounds before their diagnosis and gained even more weight with treatment—as many cancer survivors do.

Web-Based Clinical Trials

The UAB/University of Tennessee Health Science Center team is now recruiting cancer survivors across the southeastern United States (Alabama, Mississippi, North Carolina, and Tennessee) for two new web-based healthy lifestyle trials. See Table 1, page 28, for eligibility criteria, contact information, and other study details.

The Aim, Plan, and Act on Lifestyles (AMPLIFY) Survivor Health (NCT04000880) is NCI funded and builds on two previous NCI-funded research clinical trials that tested diet and exercise interventions that were found to be effective.

The Better Exercise Adherence after Treatment for Cancer (BEAT Cancer) research clinical trial (NCT00929617) tested an in-person exercise intervention that gradually tapered to a homebased program among 222 breast cancer survivors. The BEAT Cancer intervention significantly improved levels of physical activity, as well as fitness and quality of life—effects that were maintained at a six-month follow-up.⁵

Likewise, the Reach-out to Enhance Wellness (RENEW) in Older Cancer Survivors research clinical trial (NCT00303875) tested the efficacy of a one-year program of tailored mailed print materials plus telephone counseling among 641 older, overweight and obese survivors of breast, prostate, and colorectal cancer who resided in 21 U.S. states, as well as Canada and the United Kingdom. The RENEW intervention significantly improved diet quality, physical activity, and body weight status—effects that were durable at a two-year follow-up.^{6,7} Most important, the intervention reduced the rate of physical function decline among these cancer survivors.

In the words of participant, Paul Finegan, "RENEW was, and is, so very good for me! The in-home program provided helpful information and was very convenient. I lost 15 pounds and kept it off. Ten years later, I still watch my portions and eat very little red meat. As a former teacher, I give the program an A+." Like other RENEW participants, Finegan's physical function improved on the program. Now, at age 87, Finegan says, "I have no trouble



Harvest for Health participant, Sarah Harkless, and her master gardener mentor, Patricia Saffles, posing by Sarah's garden.

walking a mile or climbing 10 flights of stairs. In fact, I am busy building houses for Habitat for Humanity several days a week."

Over the past year, the AMPLIFY study team has worked to adapt both BEAT Cancer and RENEW to a web-based platform that can be delivered via computers, tablets, and smartphones to enhance dissemination potential. In addition, AMPLIFY provides diet and exercise guidance according to the most recent recommendations issued by the American Institute of Cancer Research and the National Comprehensive Cancer Network.8,9 The goals of AMPLIFY are to test the impact of the diet and exercise interventions on change in health behaviors, physical performance, body weight, muscle mass, overall health, and QoL. Plus, AMPLIFY will determine whether the diet and exercise components are more effective if delivered one at a time (first diet then exercise or vice versa) or combined over a 12-month period. The enrollment target is 652 cancer survivors across the states of Alabama, Mississippi, North Carolina, and Tennessee and kicked off in January 2020 to coincide with the new year-a perfect time to begin healthful resolutions.

The Daughters, Dudes, Mothers, and Others Together (DUET) research clinical trial is funded by the American Institute of Cancer Research and is similar to the AMPLIFY clinical research trial. The primary difference between the two is that the DUET research clinical trial will intervene upon the lifestyle behaviors of cancer

Table 1. Study Descriptions for AMPLIFY and DUET

	AMPLIFY	DUET
Purpose and specific aims	To improve diet and exercise health behaviors of cancer survivors with suboptimal diet and physical activity and overweight/obesity by (1) adapting efficacious interventions through technology; (2) optimizing acceptability and use of interventions among older, rural, minority survivors; (3) testing the efficacy of the adapted interventions delivered alone, in sequence, or combined; and (4) determining factors that improve the dissemination and implementation of distance-delivered health behavior change interventions.	To test the acceptability and efficacy of an online diet and exercise intervention for partnered cancer survivors with overweight/obesity by (1) deter- mining whether the intervention significantly improves weight status; (2) assessing the impact of the intervention on self-reported, objective, and select biomarkers associated with cancer risk and progression; for example, TNF- α , insulin, and IGF-1; and (3) identifying predictor variables associated with program efficacy.
Measures, assessors, and time points	Outcomes assessed via telephone and online surveys for patient-reported dietary intake, physical activity, health conditions and health care utilization, and quality of life. Visiting staff will perform anthropometric measures and physical function and blood pressure testing and collect blood and urine samples for assessment of inflammatory markers, immune status, and muscle mass. These assessments will be performed in community or home-based settings at baseline, 6, 12, 18, and 24 months.	Outcomes assessed via online surveys for patient-reported dietary intake, physical activity, health conditions, and quality of life. Visiting staff will perform anthropometric measures, conduct physical function and blood pressure testing, and collect blood samples for assessment of inflam- matory and metabolic markers at baseline and six months. These assessments will be performed in community or home-based settings at baseline and six months.
Size, reach, and randomization	Six hundred fifty-two cancer survivors from Alabama, Tennessee, Mississippi, and North Carolina; 326 participants will be randomized to sequenced diet and exercise intervention group and 326 participants to the combined diet and exercise intervention group.	Fifty-six dyads consisting of cancer survivors and partners of their choice. Each dyad will be ran- domized evenly to receive the intervention either immediately or after a six-month delay.
Duration	Up to 24 months.	Six months.
Incentives, materials, and supplies	Participants will receive up to a total of \$100 and ~\$125 worth of supplies (digital scale, portion plate, exercise bands, pedometer).	Participants will receive up to a total of \$30 and ~\$125 worth of supplies (digital scale, portion plate, Fitbit).

survivors and their chosen partners. Fifty-six cancer survivors will enroll in this six-month diet and exercise weight management program with a partner of their choosing; for example, a friend, neighbor, spouse, or other relative. This trial banks on a previous research clinical trial, Daughters and Mothers (DAMES) Against Breast Cancer (NCT00630591), which was limited to mothers with breast cancer and their biological daughters. Significant weight loss and changes in diet and exercise were noted with this

trial of 68 mother-daughter dyads.¹⁰ In fact, success in one DAMES family was particularly remarkable. Over the course of the oneyear study, the breast cancer survivor lost 23 pounds and her daughter lost 10, but pound for pound, the biggest loser was the family dog ("Rocky"), who lost 11 pounds as he served as the walking companion for the two DAMES participants. By expanding the number of eligible cancer types for survivors and the relationships between survivors and their chosen partners in the

Table 1. Study Descriptions for AMPLIFY and DUET (continued)			
	AMPLIFY	DUET	
Eligibility criteria	 Adult male or female aged 50+ Residents of Alabama, Mississippi, North Carolina, or Tennessee Completed primary treatment for the following cancers: multiple myeloma; localized (stage I) kidney, ovary; localized through regional (stage I-III) breast, colorectum, endometrium, or prostate cancer No evidence of progressive cancer (metastasis) or recurrence (except for multiple myeloma and prostate [if just biochemically detected]) or other cancers (except for cancers listed above and non-melanoma skin cancer) BMI 25 to <50 kg/m2 <2.5 cups of vegetables and fruits/day <150 minutes of moderate-to-vigorous exercise/week High risk for functional decline English speaking and writing; have completed at least eighth grade No medical conditions that require dietary or physical activity limitations Not residing in a skilled nursing or assisted living center Have wireless coverage and an active email address or willing to have us create one Not participating in another diet and/or exercise program. 	 Adult male or female aged 18+ Residents of Alabama, Mississippi, North Carolina, or Tennessee Live within a 15-minute drive of qualified partner At least one team member has been diagnosed with localized renal or loco-regional ovarian, colorectal, endometrial, prostate, or breast cancer AND completed treatment No evidence of progressive cancer (metastasis) or recurrence (except for multiple myeloma and prostate [if just biochemically detected]) or other cancers (except for cancers listed above and non-melanoma skin cancer) BMI >25 kg/m2 <2.5 cups of vegetables and fruits/day <150 minutes of moderate-to-vigorous exercise/ week English speaking and writing; have completed at least eighth grade No medical conditions that require dietary or physical activity limitations Not residing in a skilled nursing or assisted living center Use the Internet and have a computer, iPad, or smart phone Not participating in another diet and/or exercise program. 	
Contact information	Telephone: 1-833-535-7934 Email: amplify@uabmc.edu	Telephone: 1-866-435-7938 Email: duet@uabmc.edu	

TNF- α = tumor necrosis factor-alpha; IGF-1 = insulin-like growth factor-1; BMI = body mass index.

current study, Demark-Wahnefried and her research team hope to improve the generalizability and the reach of this partner-based intervention.

The UAB/University of Tennessee Health Science Center team is eager to take cancer survivorship research to the next level by extending the reach of evidence-based interventions and programs designed to promote the health and well-being of cancer survivors. Research interventions like Harvest for Health, AMPLIFY, and DUET offer potential cost-effective, viable solutions for community cancer programs to help their patients achieve optimal health outcomes. These research programs—at no cost to community cancer programs—provide a much-needed resource for survivors and address patient goals to live a full and healthy life. Research programs are value-added to patient care. Cancer centers who are interested in learning more about the programs are encouraged to refer cancer survivors to either the AMPLIFY or DUET programs (see Table 1).

In closing and in the words of Harvest for Health participant Susan Rossman: "Cancer can be the worst thing that can happen to you, or it can be a life changing event that you do something with. If every cancer survivor could do something like this, it could change the way they look at everything."

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