Effects of Home-Based Diet and Exercise on Functional Outcomes Among Older, Overweight Long-term Cancer Survivors

RENEW: A Randomized Controlled Trial

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Context Five-year survival rates for early stage colorectal, breast, and prostate cancer currently exceed 90% and are increasing. Cancer survivors are at greater risk for second malignancies, other comorbidities, and accelerated functional decline. Lifestyle interventions may provide benefit, but it is unknown whether long-term cancer survivors can modify their lifestyle behaviors sufficiently to improve functional status.

Objective To determine whether a telephone counseling and mailed print material–based diet and exercise intervention is effective in reorienting functional decline in older, overweight cancer survivors.

Design, Setting, and Participants Randomized controlled trial of 641 overweight (body mass index ≥25 and <40), long-term (≥5 years) survivors (aged 65-91 years) of colorectal, breast, and prostate cancer, who were randomly assigned to an intervention group (n=319) or delayed intervention (control) group (n=322) in Canada, the United Kingdom, and 21 US states. Individuals were recruited for the Reach out to Enhance Wellness (RENEW) trial from July 1, 2005, through May 17, 2007.

Intervention A 12-month, home-based tailored program of telephone counseling and mailed materials promoting exercise, improved diet quality, and modest weight loss. The control group was wait-listed for 12 months.

Main Outcome Measures Change in self-reported physical function on the Short-Form 36 physical function subscale (score range, 0-100; a high score indicates better functioning) from baseline to 12 months was the primary end point. Secondary outcomes included changes in function on the basic and advanced lower extremity function subscales of the Late Life Function and Disability Index (score range, 0-100), physical activity, body mass index, and overall health-related quality of life.

Results The mean baseline Short-Form 36 physical function score was 75.7. At the 12-month follow-up, the mean function scores declined less rapidly in the intervention group (–2.15; 95% confidence interval [CI], –0.36 to –3.93) compared with the control group (–4.84; 95% CI, –3.04 to –6.63) (P=.03). The mean baseline basic lower extremity function score was 78.2. The mean changes in basic lower extremity function were 0.34 (95% CI, –0.84 to 1.52) in the intervention group compared with –1.89 (95% CI, –0.70 to –3.09) in the control group (P=.005). Physical activity, dietary behaviors, and overall quality of life increased significantly in the intervention group compared with the control group, and weight loss also was greater (2.06 kg [95% CI, 1.69 to 2.43 kg] vs 0.92 kg [95% CI, 0.51 to 1.33 kg], respectively; P<.001).

Conclusion Among older, long-term survivors of colorectal, breast, and prostate cancer, a diet and exercise intervention reduced the rate of self-reported functional decline compared with no intervention.

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In 2008, the Centers for Medicare & Medicaid Services declared mobility maintenance and functional independence among at-risk older individuals as the sole priority in aging research.[1] Older cancer survivors represent an important target because cancer and its treatment are associated with accelerated functional decline.[2] Furthermore, cancer survivors face increased risk for second malignancies, and other chronic diseases such as cardiovascular disease, osteoporosis, and diabetes, all of which are associated with increased functional limitations.[3-5]

The practice of healthy lifestyle behaviors may reduce risk for disease and functional decline. However, many older cancer survivors report poor lifestyle behaviors, and few meet recommended health promotion guidelines. While most older cancer survivors are nonsmokers, their dietary and physical activity behaviors are suboptimal.[6] Although cancer survivors report high interest in exercise-related and diet-related interventions, this is most pro-

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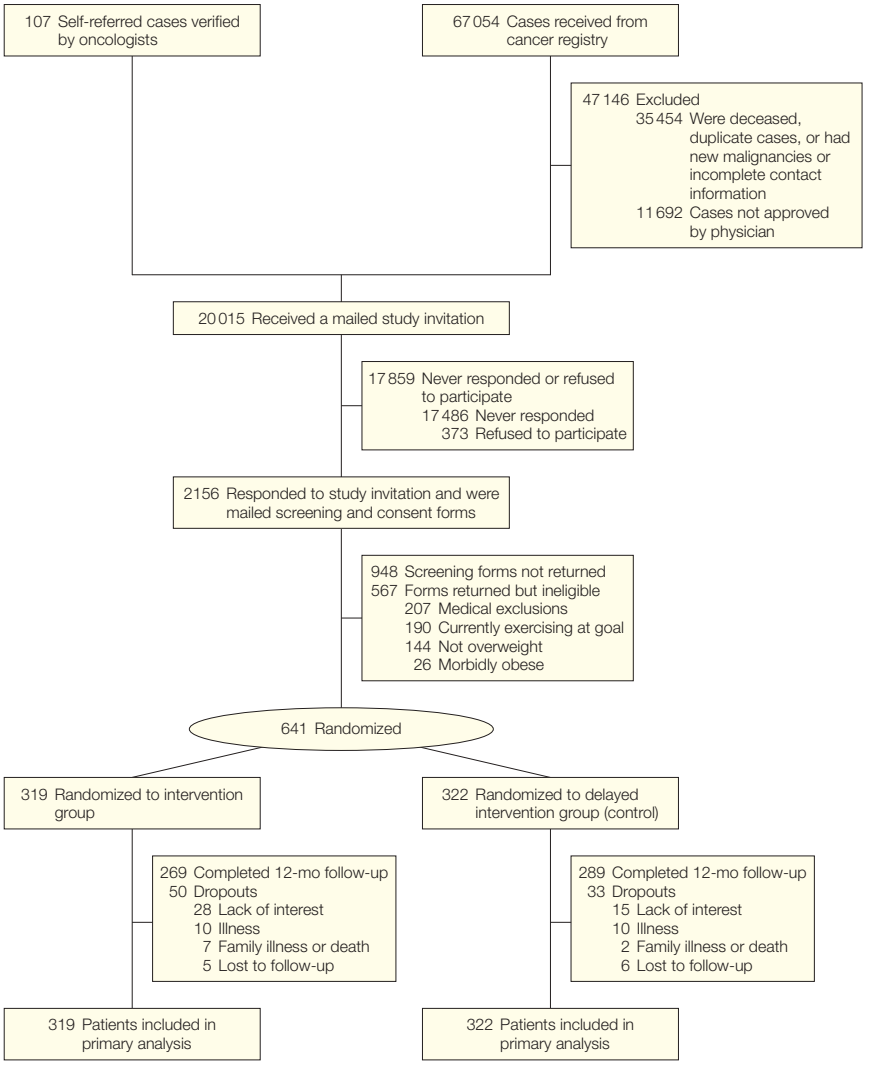
nounced among younger cancer survivors with a relatively recent cancer diagnosis.[7] We previously showed positive trends in reversing functional decline with a home-based physical activity and dietary intervention among 182 older adults with newly diagnosed cancers.[7] It is unknown whether long-term cancer survivors, whose cancer diagnoses are in the distant past, would partake and benefit from a similar intervention.

Reach out to Enhance Wellness (RENEW) is a randomized controlled trial that tested a home-based diet and exercise intervention on reorienting the functional trajectory of older, long-term survivors of breast, prostate, and colorectal cancer. Overweight and obese cancer survivors were targeted for this study because of the increase in obesity among older adults,[8] and the likelihood that obesity would further compromise functional status. Change in physical function over 12 months in the intervention group compared with the control group served as the primary end point. Secondary end points included measures of physical activity, body mass index (BMI; calculated as weight in kilograms divided by height in meters squared), and overall health-related quality of life.

Figure. Flow of Participants Through the Study



METHODS

Study Design

Methods of the RENEW trial have been published elsewhere.[9] In brief, this randomized controlled trial compared a 12-month diet and exercise intervention delivered via telephone counseling and tailored mailed materials with a delayed intervention control group. The research protocol was approved by the Duke University institutional review board and the North Carolina Central Cancer Registry, and written consent was obtained from all study participants.

Study Participants

The FIGURE depicts the multitiered screening and enrollment process. The trial relied on self-referred participants and those ascertained from the North Carolina Central Cancer Registry. A total of 67 161 individuals with breast, prostate, and colorectal cancer diagnosed at least 5 years ago and currently aged 65 years or older with no evidence of progressive disease or second cancers were identified. After comparing case lists to state mortality tapes and conducting further follow-up, duplicates were found and those deceased or with missing contact information were excluded for potential contact. Cases whose physicians denied permission to contact their patients also were excluded. Study letters of invitation were mailed to 20 015 individuals. Of these, 2156 expressed interest in participation and received a consent form and brief questionnaire to screen for eligibility. Responses were received from 1208 individuals of whom 567 individuals were deemed ineligible because they (1) were institutionalized; (2) had a BMI of less than 25 or greater than 40; (3) had a severe hearing or speaking impairment; (4) were non-English speaking or writing; (5) had contraindications to unsupervised exercise (angina, myocardial infarction ≤6 months, congestive heart failure, chronic obstructive pul-

monary disease, plan to have a hip or knee replacement, walker or wheelchair use, recent stroke with hemiparesis); or (6) were already performing more than 150 minutes of moderate to vigorous exercise per week (already meeting recommended physical activity guidelines). A total of 641 individuals were deemed eligible and randomized with the block randomization method (by a statistician with no participant contact) by race, cancer type, and sex with even distribution into an intervention (n=319) or delayed intervention control group (n=322). Participants were recruited from July 1, 2005, through May 17, 2007. Race or ethnicity was defined and provided by the cancer registry. For the few participants who self-referred to the study, race or ethnicity was provided by either the approving clinicians or self-report using the following categories: white (not of Hispanic origin), black (not of Hispanic origin), Hispanic, or other. Race/ethnicity was assessed to determine the generalizability of the study and other factors such as participation and adherence.

RENEW Intervention

The RENEW intervention consisted of a personally tailored workbook and series of quarterly newsletters, along with a program of telephone counseling and automated prompts (ie, 15 sessions and 8 prompts over the 12-month period).[9] Costs for materials (including development), telephone counseling, and postage were $1000 per person. The intervention was theoretically based using the social cognitive theory and transtheoretical models.[10]

After assignment to the RENEW intervention, participants received a personalized workbook. The introductory pages featured bar graphs comparing participants' current lifestyle behaviors and weight status with recommended levels. These pages also recommended 15 minutes of strength training exercise every other day; 30 minutes of endurance exercise each day; consumption of at least 7 servings (for women) or 9 servings (for men) of fruits and vegetables per day[11]; restriction of saturated fat to less than 10% of energy intake; and a 10% weight loss goal during the 12-month study period. Workbook chapters provided standardized content on exercise and a healthy calorie-restricted diet. Participants also received a pedometer, exercise bands (3 levels of resistance), an exercise poster depicting 6 lower extremity strength exercises, a table guide to food portioning (Portion Doctor, Portion Health Products, St Augustine Beach, Florida), and personalized record logs to self-monitor daily exercise and dietary intake (including a fat gram booklet to assist with self-monitoring).

Each participant was assigned a health counselor for the 12-month period. Counseling sessions were conducted weekly during the first 3 weeks, every other week for 1 month, and then monthly. Each telephone session was 15 to 30 minutes in duration and served to enhance social support and self-efficacy. During each telephone call the counselor worked with the participant to monitor progress, provide reinforcement, explore strategies in overcoming barriers, field questions, direct participants to appropriate resources, and establish future goals. Automated telephone messages by the study principal investigator (W.D-W.) provided additional, intermittent reinforcement.

Every 12 weeks, participants received a tailored 2-page progress-report newsletter with a motivational greeting, a graph depicting behavioral change in the target behaviors related to the RENEW goals, and a sign-off message that was tailored to the participant's readiness to change behavior. Like many studies with lifestyle interventions,[12] a delayed intervention, wait-list control was used in this study.

Outcomes

The primary outcome, change in functional status between baseline and 12 months, was assessed using the physical function subscale of the Medical Outcomes Study Short-Form 36 (SF-36) questionnaire as an indicator of overall physical function.[13] The physical function subscale assesses the effect of health on the performance of activities ranging from basic self-care to vigorous physical activity and has been widely used with good construct validity and sensitivity to change.[14] Given that lower extremity function is central to the maintenance of independence,[15,16] function also was assessed using the basic and advanced lower extremity function subscales of the Late Life Function and Disability Index.[17,18] In addition, the entire SF-36 questionnaire was administered at each wave of data collection, thus providing health-related quality-of-life outcomes on general health, pain, vitality, social functioning, physical and emotional roles, and mental health. Raw data from all of these scales are normalized and range from 0 to 100 with higher scores indicating better function.

Secondary outcomes related to target behaviors of physical activity, diet, and weight loss. Physical activity was assessed using the Community Health Activities Model Program for Seniors questionnaire,[19] which was developed for use in older adults, has been tested with home-based interventions, and is sensitive to change.[20] For this study, strength and endurance items were scored separately as indicators of the physical activity target behaviors. Dietary intake data were averaged from 2 unannounced 24-hour recalls at baseline and at 12 months using the interactive Nutrition Data System for Research software, version 2006 (Nutrition Coordinating Center, Minneapolis, Minnesota). Self-reported height and weight were collected for estimation of BMI and weight loss.

Other items collected on the surveys included a count of the 6 most prevalent medical conditions (arthritis, hypertension, heart problems, circulatory problems, osteoporosis, and cataracts), a checklist of 22 symptoms, social support, income, smoking status, and cancer treatment. All surveys were conducted at baseline and at 12 months by interviewers at the Diet

Table 1. Baseline Characteristics of Participants

	No. (%) of Participants[a]	
	Intervention (n = 319)	Control (n = 322)
Age, mean (SD), y	73.0 (5.0)	73.1 (5.1)
White race	284 (89.0)	285 (88.5)
Male sex	147 (46.1)	145 (45.0)
Some college education	201 (63.0)	194 (60.2)
No. of comorbidities, mean (SD)	2.0 (1.3)	2.0 (1.2)
Current smokers	17 (5.3)	20 (6.2)
Cancer type		
Breast	143 (44.8)	146 (45.3)
Prostate	131 (41.1)	130 (40.4)
Colorectal	45 (14.1)	46 (14.3)
Years since cancer diagnosis, mean (SD)	8.5 (2.7)	8.7 (2.7)
Body mass index, mean (SD)[b]	29.1 (3.3)	29.2 (3.6)
Short-Form 36 physical function subscale score, mean (SD)[c]	75.9 (18.7)	75.6 (19.1)

[a] Unless otherwise indicated.
[b] Calculated as weight in kilograms divided by height in meters squared.
[c] The range of possible scores is 0 to 100; a high score indicates better functioning.

Assessment Center of Pennsylvania State University, who had no knowledge of the study's design or outcomes. Additional short quarterly surveys were conducted for self-reported physical function.

All study participants were provided with a telephone number to report any significant changes in health status. Changes in health also were assessed during each counseling call and during each of the outcome assessments and surveys. When appropriate, medical clearance was obtained for continuation or cessation of the intervention. Health events were classified by the investigative team who were blinded to group assignment, and who classified events as serious vs not serious, and either not attributable, possibly attributable, or attributable to the intervention.

Statistical Analyses

The sample size was set at 544 to give the *t* test (2-tailed α level of .05) at least 80% power to detect a group difference of 3.9 in change in the physical function subscale from baseline to 1 year. An SD of 16.2 was assumed. Data from the intervention development study helped to determine these calculations.[21] Under the assumption that at most 15% of the participants would drop out by 1 year, the sample size was inflated to 640. While physical function was the primary outcome, group differences in 17 secondary outcomes also were tested. The α level for these 17 tests was controlled at an overall 2-sided level of .05 using the procedure by Holm.[22] Finally, whether the groups differed on the percentage of participants who met study goals for the behavioral outcomes was examined. These analyses, using logistic regression models, were considered exploratory and *P* values are presented without reference to an α level.

Covariate-adjusted group effects for 17 of the 18 continuous outcomes were tested with the general linear model after verifying the approximate normality of the residuals. Duration of endurance exercise had a skewed distribution and the group effect on this outcome was tested with the proportional odds logistic regression model[23] by transforming number of minutes into a 10-level ordinal variable. The following covariates were included in all models regardless of their *P* values: baseline value of the outcome, age, race, number of comorbidities, number of symptoms, education, cancer type, BMI, and physical function (SF-36 subscale score). These covariates were selected a priori based on their clinical significance. Dropouts were included in all analyses by imputing change across time to be zero. Sensitivity analyses also were conducted by testing the group effect in only those who did not drop out. Group means are presented with standard errors (SEs); differences between group means are presented with 95% confidence intervals (CIs). Covariate-adjusted and unadjusted *P* values for the group effect are presented. All analyses were performed using SAS statistical software, version 9.1 (SAS Institute Inc, Cary, North Carolina).

RESULTS

Study participants largely resided in 21 US states, although a small number of participants were from Canada and the United Kingdom. Characteristics of the study sample are presented in TABLE 1. Despite efforts to attract an ethnically diverse sample, like most lifestyle intervention studies our sample was largely white and a majority reported some college education.[24] Furthermore, participants differed from nonrespondents in age (younger), sex (more females), cancer type (fewer colorectal cancer cases), and time elapsed since diagnosis (more proximal).

The 3 most prevalent medical conditions reported were arthritis, hypertension, and circulatory problems, and the most frequently cited symptoms were shortness of breath with exertion, muscle cramps, and sleep problems. The mean baseline physical function score of 75.7 is comparable with the median score for men and women aged 65 years or older.[14] The mean baseline score of 78.2 on the basic lower extremity scale indicated that study participants had relatively few difficulties in performing basic tasks (ie, going up and down a flight of stairs, stepping up and down from a curb, or using a step stool). But the mean score of 53 on the advanced lower extremity scale indicated more difficulties in the performance of advanced tasks such as walking a mile, going up and down stairs without a handrail, and running a short distance to catch a bus or train.

Of 641 individuals randomized, 558 (87%) completed the 12-month follow-up. Attrition was within the projected rate (15%) used for power calculations and reasons for withdrawal are listed in the Figure. Differences between dropouts and individuals completing the 12-month intervention were examined by age, race, education, number of comorbidities and symptoms, BMI, cancer type, physical function, and study group. There were more dropouts in the intervention group com-

pared with the control group (50 vs 33; $P = .04$) and dropouts had a higher BMI (mean [SD], 29.1 [0.14] vs 29.9 [0.40]; $P = .05$) than individuals completing the 12-month intervention.

Change in Physical Function

For the SF-36 physical function subscale, the control group experienced a mean score change of –4.84 (95% CI, –3.04 to –6.63), which was more than double that of the intervention group (–2.15 [95% CI, –0.36 to –3.93]; TABLE 2). There was a statistically significant difference between study groups in basic lower extremity func-

Table 2. Group Means and Differences Between Group Means for All Outcomes[a]

Outcomes	Mean (SE)				Mean Group Difference (95% CI)	*P* Value of Group Effect		Holm Procedure α Level[c]
	Intervention (n = 319)		Control (n = 322)					
	Baseline	Change at 12 mo	Baseline	Change at 12 mo		Unadjusted	Adjusted[b]	
Primary outcome								
SF-36 physical function (range, 0-100)	75.9 (1.1)	–2.15 (0.9)	75.6 (1.1)	–4.84 (0.9)	2.69 (0.17 to 5.21)	.03	.03	
Secondary outcomes								
LLF basic lower extremity function (range, 45.6-100)	78.4 (0.8)	0.34 (0.6)	78.1 (0.9)	–1.89 (0.6)	2.24 (0.56 to 3.91)	.005	.005	.005
LLF advanced lower extremity function (range, 0-100)	52.8 (0.8)	–0.37 (0.5)	52.9 (0.8)	–2.30 (0.6)	1.92 (0.45 to 3.39)	.01	.02	.006
Behavioral targets								
Duration of strength training exercise, min/wk (range, 0-600)[d]	7.0 (2.1)	18.7 (2.4)	11.5 (2.5)	0.5 (2.7)	18.21 (11.21 to 25.21)	<.001	<.001	.003
Duration of endurance exercise, min/wk (range, 0-149)	24.6 (2.1)	36.3 (4.9)	28.7 (2.3)	23.4 (5.6)	12.89 (1.89 to 27.58)	.003	.004	.004
Strength training exercise frequency, sessions/wk (range, 0-7)	0.5 (0.1)	1.4 (0.2)	0.5 (0.1)	0.2 (0.1)	1.12 (0.70 to 1.54)	<.001	<.001	.003
Endurance exercise frequency, sessions/wk (range, 0-15)	1.6 (0.1)	1.6 (0.2)	1.8 (0.2)	0.5 (0.2)	1.05 (0.39 to 1.72)		.005	.005
Daily servings of fruits and vegetables (range, 0-15.80)	3.72 (0.1)	1.24 (0.14)	3.54 (0.1)	0.13 (0.11)	1.11 (0.76 to 1.47)	<.001	<.001	.003
Saturated fat intake, g/d (range, 2-57 g)	19.6 (0.5)	–3.06 (0.51)	19.32 (0.5)	–1.07 (0.49)	–1.99 (–0.58 to –3.40)	<.001	.002	.004
Weight, kg (range, 59.1-125.5 kg)	85.7 (0.7)	–2.06 (0.19)	84.7 (0.7)	–0.92 (0.2)	–1.14 (–0.59 to –1.69)		<.001	.004
Body mass index (range, 25-47)[e]	29.1 (0.2)	–0.69 (0.07)	29.2 (0.2)	–0.31 (0.08)	–0.38 (–0.19 to 0.57)		<.001	.004
Health-related quality of life on SF-36								
General health (range, 15-100)	71.8 (0.9)	0.77 (0.72)	72.6 (0.9)	–1.94 (0.80)	2.71 (0.58 to 4.84)	.02	.03	.007
Pain (range, 10-100)	72.2 (1.2)	–0.78 (1.07)	72.6 (1.2)	–3.19 (1.22)	2.40 (–0.79 to 5.59)	.13	.16	.02
Vitality (range, 0-100)	61.9 (0.9)	–0.47 (0.89)	61.5 (1.0)	–2.42 (0.98)	1.95 (–0.64 to 4.55)	.09	.10	.01
Social functioning (range, 12.5-100)	90.2 (1.0)	–1.29 (1.05)	90.8 (0.9)	–5.05 (1.22)	3.75 (0.58 to 6.92)	.02	.03	.008
Mental health (range, 32-100)	85.6 (0.7)	0.50 (0.53)	86.3 (0.7)	–2.04 (0.74)	2.54 (0.75 to 4.33)	.08	.01	.006
Physical role (range, 0-100)	75.7 (1.9)	–2.43 (2.02)	78.6 (1.9)	–4.68 (2.14)	2.25 (–3.54 to 8.05)	.30	.32	.03
Emotional role (range, 0-100)	92.1 (1.2)	–0.73 (1.32)	92.0 (1.2)	–0.62 (1.38)	–0.11 (–3.86 to 3.64)	.98	.93	.05

Abbreviations: CI, confidence interval; LLF, Late Life Function and Disability Index; SF-36, Short-Form 36.

[a] Because the observed means and covariate-adjusted means were almost identical, only the observed means are shown. Both covariate-adjusted and unadjusted *P* values for the test of the group effects are given. Missing 1-year outcomes were imputed to the baseline value.

[b] All models were adjusted for baseline value of the outcome, age, race, number of comorbidities, number of symptoms, education, cancer type, body mass index, and SF-36 physical function subscale score.

[c] The Holm procedure first ranks the 17 *P* values from lowest to highest. The first (lowest) *P* value has to be less than .003 (.05/17) to be statistically significant and to permit continuation to the other *t* tests. The Holm procedure continues sequentially in this fashion using α levels of .003 (.05/16), .003 (.05/15), . . . , and .05 (.05/1) for the remaining 16 tests, respectively.

[d] Light strength training for 600 minutes is an outlier (next highest value is 210 minutes). Because we were unable to validate the accuracy of this data point, it was included in the analysis. Inclusion or exclusion of this data point made no difference on the estimates of the *P* value.

[e] Calculated as weight in kilograms divided by height in meters squared.

tion as function changed negligibly in the intervention group (mean, 0.34 [95% CI, –0.84 to 1.52]), whereas the control group showed a decrease (–1.89 [95% CI, –0.70 to –3.09]; $P=.005$). Advanced lower extremity function followed a similar pattern but did not achieve statistical significance. Sensitivity analyses were performed by testing the group effect in only those who did not drop out. *P* values from these sensitivity analyses were similar to those from analyses using imputed data.

Change in Targeted Behaviors

There were significant differences between the intervention and control groups for all targeted behaviors except endurance exercise frequency, indicating successful uptake of the intervention (Table 2). Duration of strength training exercise increased in the intervention group (mean [SE], 18.7 [2.4] minutes per week) and remained stable in the control group (mean [SE], 0.5 [2.7] minutes per week). Likewise, duration of endurance exercise minutes increased in the intervention group (mean [SE], 36.3 [4.9] minutes per week) and was stable in the control group (mean [SE], 23.4 [5.6] minutes per week). The mean (SE) intake of fruits and vegetables increased by 1.24 (0.14) daily servings in the intervention group and by 0.13 (0.11) daily servings in the control group. The mean (SE) consumption of saturated fat decreased by 3.06 (0.51) g per day in the intervention group and by only 1.07 (0.49) g per day in the control group. Furthermore, participants in the intervention group reported a mean weight loss of 2.06 kg (95% CI, 1.69-2.43 kg), which was more than twice that reported by the control group (0.92 kg; 95% CI, 0.51-1.33 kg).

In exploratory analyses, the groups were compared by percentage of participants meeting study goals at 12 months. At baseline, only 8% of the sample was doing strength training exercise at the recommended number of minutes. At 12 months, the mean (SE) percentage of participants performing recommended strength training was 28% (0.03%) in the intervention group and 11% (0.02%) in the control group ($P<.001$). The screening criteria excluded individuals performing more than 150 minutes per week of endurance exercise at baseline, but at the 12-month follow-up, a mean (SE) of 15% (0.02%) of participants in the intervention group and 11% (0.02%) in the control group were meeting weekly national guidelines for endurance exercise ($P=.07$). At baseline, 6% of participants met fruit and vegetable guidelines but at 12 months, a mean (SE) of 16% (0.02%) of the intervention group and 4% (0.01%) of the control group met the guidelines ($P<.001$). At baseline, 36% of participants consumed fewer than 10% of total calories from saturated fat; at 12 months, the mean (SE) percentage of participants meeting this guideline was 49% (0.03%) in the intervention group and 38% (0.03%) in the control group ($P=.001$).

Change in Health-Related Quality of Life

Overall health-related quality of life decreased in every subscale in the control group throughout the 12-month period. In the intervention group, decreases in subscale scores were of lower magnitude and were sustained for overall health and mental health (Table 2).

Adverse Events

Changes in health status were identified at each telephone contact (survey or counseling) or by self-report. A total of 201 events were reported, reviewed, and classified, with the majority coded as not serious. Because any cardiac, musculoskeletal, or digestive concerns were considered possibly attributable to the diet and exercise intervention, 106 of the 201 events were classified as such. Of these, 32 involved hospitalization and were thus considered serious. Only 5 events were considered directly attributable to the study. One participant experienced increased blood pressure with exercise (physician clearance was obtained for continued participation in the study). The 4 other participants experienced (1) hip pain with exercise, (2) pulled hamstring while walking, (3) fall during hiking, or (4) calf pain and stiffness while using exercise bands. After analysis of these events, there were no differences between the intervention and control groups in the total number of events, or in events in any subcategory.

COMMENT

The major finding of this trial is that older, overweight long-term cancer survivors successfully engaged in a behavioral lifestyle intervention that resulted in an amelioration of functional decline. To our knowledge, this is the first report of a long-term (ie, 12-month) intervention directed at maintaining function in long-term cancer survivors. The majority of physical activity or dietary interventions for cancer patients have targeted younger patients, those undergoing treatment, or those with recent diagnoses.[25]

This intervention was ambitious in that older, long-term cancer survivors were asked to change both diet and exercise behaviors. Even with modest change, they experienced clinically meaningful improvements in both physical function and other health-related quality-of-life domains. The functional benefits were clinically meaningful in that global physical function (as assessed by the SF-36 physical function subscale) declined by 4.8 points in as little as 12 months in the control group, but only by half as much in the intervention group. A decline of 6.5 points over a 4-year period is associated with a 10% higher mortality risk within a subsequent 3-year window.[26] A decline of 2 points is considered too small to be clinically detectable.[26]

To our knowledge, no other telephone counseling studies with functional outcomes directed at older adults have advocated changes in both physical activity and diet simultaneously. These findings are in contrast to those of Kolt et al,[27] who found no signifi-

cant differences in SF-36 physical function subscale scores among older adults in a primary care setting using a telephone counseling intervention of similar duration; however, it is unknown whether differences in study findings are due to differences in sample size and characteristics or that our intervention also promoted dietary change and weight loss.

Further evidence of functional benefit is indicated by the measures of lower extremity functioning, which were targeted for strength training by the intervention. Although the changes observed within the 2 study groups were modest, participants in the intervention group maintained their lower extremity function whereas participants in the control group experienced a decline. A parallel pattern of similar magnitude was observed in these 2 measures in a group of stroke patients following a 12-week progressive resistance training program in comparison with a control group.[28]

Although the samples in these 2 studies differ, it is important to note that our home-based strength training intervention provided only moderate-to-low doses, and yet was still able to preserve lower extremity functioning. The intervention in total not only enhanced physical functioning, but overall health and quality of life. Previous cross-sectional studies have found that quality of life is significantly higher among cancer survivors who meet public health physical activity guidelines, and results from this study provide cause-and-effect evidence that supports this association.[29]

Maintenance of function is particularly important for older adults. The results of this study are timely because the Centers for Medicare & Medicaid Services declared in 2008 that research aimed at maintaining mobility and function in at-risk older individuals was the only aging priority.[1] A comparison of older cancer survivors with age-matched individuals with no cancer history found significantly more functional limitations among those having had cancer.[30] The 12-month decline in physical function experienced by the control group in this study would be comparable with the added burden of ischemic heart disease.[31] Attenuation or reversal of functional decline in this population is therefore clinically relevant. Furthermore, the type of intervention (home-based with no requirement for travel or clinic visits) is likely to appeal to many older adults, with potential to reach even those in rural settings.

As noted, improved physical function was dependent on our ability to successfully modify unhealthy behaviors. This may be particularly relevant because adherence to physical activity and dietary guidelines tends to be low in cancer survivors. Data from the RAND-36 Health Status Inventory indicate that 39% to 47% of cancer survivors meet physical activity recommendations, 15% to 19% meet recommendations for fruit and vegetable consumption, and only 5% meet recommendations for all behaviors.[6] Data from the National Health Interview Survey suggest that adherence to physical activity is even lower, about 25%, for cancer survivors who are older.[30]

Our results are remarkable in that our intervention participants made improvements in all of the targeted behaviors. Yet, careful examination of the data indicates that there is still much to be done. For example, while minutes of endurance physical activity increased significantly in the intervention group compared with the control group, the mean number of minutes of endurance physical activity at 12 months within the intervention group was still low (70 minutes/week) and only 15% of the sample achieved the recommended level of 150 or more minutes of endurance exercise per week. Newly released physical activity guidelines acknowledge the challenges posed by meeting the recommended amounts of physical activity among individuals with chronic conditions and advise adults with chronic conditions to be as physically active as their condition allows.[32]

Our design had multiple features worthy of mention. First, we targeted overweight cancer survivors because being overweight or obese places individuals at higher risk for functional decline. Data from a recently completed trial of physical activity and dietary fat intake indicate that overweight and obese individuals were more likely to successfully change behavior than individuals of normal weight, which perhaps contributed to the success of our intervention.[33] Second, our pilot study provided foundational experience and in designing this trial we added a lower extremity strengthening component to enhance physical function, given the known association between lower extremity function and maintenance of independence.[15] Of note, newly published physical activity guidelines for older adults now include recommendations for strength training.[34] We believe successful implementation of strength training in this study played an important role in the observed reorientation of functional trajectory.

This study, however, has some limitations to consider, which may affect generalizability. First, all of the outcomes are based on self-report, and it is possible that some of the behavioral outcomes are subject to overestimation or underestimation of desired behaviors. On the other hand, the fact that there were no clinical or research visits in this trial enhanced our ability to deliver the intervention anywhere in the United States and other English-speaking countries. Second, our demographics indicate that this intervention was most likely delivered to highly motivated individuals.

Recruitment for this study was extremely difficult and has been detailed previously.[9] It should be noted, however, that long-term cancer survivors present a particular challenge to recruitment for the following reasons: (1) their follow-up with oncologists (who usually serve as points of entry to oncology-based trials) is frequently discontinued; (2) their contact information may no longer be accurate; (3) they

may have died; and (4) the teachable moment that often accompanies a cancer diagnosis wanes over time and diminishes interest in participating in clinical trials.[35] Despite these challenges, we were able to overcome obstacles in reaching this population, which has been previously understudied in survivorship research.[36]

In conclusion, this study provides data on a long overlooked, yet important faction in older long-term cancer survivors. Long-term survivors of colorectal, breast, and prostate cancer participating in a diet and exercise intervention reduced the rate of self-reported physical function decline in comparison with a group receiving no intervention. Future efforts should be directed toward health promotion programs among older cancer survivors, not only in those who are well beyond their diagnosis, but also in those who are more newly diagnosed and perhaps more motivated to participate in clinical trials targeting lifestyle change. Studies also should address whether overweight older adults with other conditions might benefit from similar interventions, especially given the current paradoxical controversy over weight loss as beneficial or detrimental in overweight older adults.[37,38] Future studies should not only assess the effect on health and well-being, but also should address cost-related outcomes, especially given that the economic burden associated with functional decline and loss of independence is exceedingly high.[39]

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Compassion is the desire that moves the individual self to widen the scope of its self-concern to embrace the whole of the universal self.
—Arnold J. Toynbee (1889-1975)