Psycho-Oncology
Psycho-Oncology **18**: 429–439 (2009)
Published online 31 December 2008 in Wiley InterScience (www.interscience.wiley.com). **DOI**: 10.1002/pon.1491

Reach out to ENhancE Wellness in Older Cancer Survivors (RENEW): design, methods and recruitment challenges of a home-based exercise and diet intervention to improve physical function among long-term survivors of breast, prostate, and colorectal cancer†

Denise Clutter Snyder[1]*, Miriam C. Morey[2,3,4], Richard Sloane[1,2], Valeda Stull[1], Harvey Jay Cohen[2,3,4], Bercedis Peterson[5], Carl Pieper[2], Terryl J. Hartman[6], Paige E. Miller[6], Diane C. Mitchell[6] and Wendy Demark-Wahnefried[1,7]

[1]*Duke University School of Nursing, Durham, NC, USA*
[2]*The Center for Aging and Human Development, Duke University Medical Center, Durham, NC, USA*
[3]*Durham Veterans Affairs Medical Center, Durham, NC, USA*
[4]*Department of Medicine, Duke University Medical Center, Durham, NC, USA*
[5]*Duke Comprehensive Cancer Center, Durham, NC, USA*
[6]*Penn State University, University Park, PA, USA*
[7]*M.D. Anderson Cancer Center, University of Texas, Houston, TX, USA*

**Correspondence to: Duke University School of Nursing, Box 3322, Durham, NC 27710, USA. E-mail: denise.snyder@duke.edu*
†*Results presented in a poster session at the 4th Biennial Cancer Survivorship Research Conference: Mapping the New Challenges, 18 June 2008, Atlanta, GA*

Received: 27 June 2008
Revised: 23 September 2008
Accepted: 26 September 2008

Abstract

***Objective*: Cure rates for cancer are increasing, especially for breast, prostate, and colorectal cancer. Despite positive trends in survivorship, a cancer diagnosis can trigger accelerated functional decline that can threaten independence, reduce quality-of-life and increase healthcare costs, especially among the elderly who comprise the majority of survivors. Lifestyle interventions may hold promise in reorienting functional decline in older cancer survivors, but few studies have been conducted.**

***Methods*: We describe the design and methods of a randomized controlled trial, RENEW (Reach out to ENhancE Wellness), that tests whether a home-based multi-behavior intervention focused on exercise, and including a low saturated fat, plant-based diet, would improve physical functioning among 641 older, long-term ($\geqslant$5 years post-diagnosis) survivors of breast, prostate, or colorectal cancer. Challenges to recruitment are examined.**

***Results*: Twenty thousand and fifteen cases were approached, and screened using a two-step screening process to assure eligibility. This population of long-term, elderly cancer survivors had lower rates of response ($\sim$11%) and higher rates of ineligibility ($\sim$70%) than our previous intervention studies conducted on adults with newly diagnosed cancer. Significantly higher response rates were noted among survivors who were White, younger, and more proximal to diagnosis and breast cancer survivors (p-values < 0.001).**

***Conclusion*: Older cancer survivors represent a vulnerable population for whom lifestyle interventions may hold promise. RENEW may provide guidance in allocating limited resources in order to maximize recruitment efforts aimed at this needy, but hard-to-reach population.**

Keywords: cancer; oncology; exercise; diet; randomized controlled trial

Introduction

There are over 10.5 million cancer survivors in the United States, and 61% are at least 65 years of age [1]. Survivors of colorectal, breast, and prostate cancer comprise the majority of survivors since these are the most common forms of invasive carcinoma, and if detected early, these cancers have excellent 5-year cure rates (cure rates for localized colorectal, breast, and prostate cancer are 90, 98, and nearly 100%, respectively) [2]. Given advances in early diagnosis and treatment, coupled with the aging population, the number of elderly cancer survivors is expected to double from 1.3 M currently to 2.6 M over the next 50 years [3].

Despite the growing rates of survivorship, cancer and/or its treatment sequelae are associated with significant morbidity that may impair function and

result in disability [4–7]. Functional decline is common among older adults, with an even greater risk of decline for those diagnosed with cancer [8–10]. Further, the presence of other medical conditions (common in older cancer survivors) may increase the odds of having functional limitations [10], thus when further functional decline occurs, independence is often lost, resulting in reduced quality-of-life and increased healthcare costs [9,11,12].

Physical activity (PA) can boost independence and reduce several chronic health conditions [13–16]. Exercise interventions have the potential to reorient the trajectory of functional decline among older cancer survivors and improve outcomes [17]. Evidence supports that such interventions may be even more powerful if combined with strategies to improve diet, since eating more vegetables and fruit (V&F) and less fat [18], and achieving a healthy weight [19] may have a positive and independent effect on physical function.

The RENEW (Reach out to ENhancE Wellness) study is a randomized controlled trial (RCT), utilizing a mixed modality approach of telephone prompts and counseling, and mailed print materials to deliver a multi-behavior intervention focused on exercise and dietary change (low saturated fat, plant-based diet) to 641 older, long-term ($\geqslant$5 years post-diagnosis) survivors of breast, prostate, or colorectal cancer. The trial has accrued its full sample and is currently in the field, collecting data to determine if this intervention is effective in reducing functional decline (primary endpoint), and if it has a positive influence on other health outcomes. The purpose of this paper is to report the design, methods, and recruitment challenges encountered during the implementation of this trial.

Trial design and methods

Overview

The RENEW trial aims to improve PA and dietary behaviors among overweight, older, long-term breast, prostate, and colorectal cancer survivors, and ultimately test if these lifestyle improvements will positively reorient trajectories of physical function. At 1-year follow-up, we hypothesize that the experimental intervention arm will report higher levels of physical function than the control (wait-listed) arm. At 2-year follow-up, assessment will occur to determine if these changes in function are sustained after the intervention concludes and if the control arm is able to improve functional status after being wait-listed for 1 year (i.e. if 'catch-up' is possible). Changes in secondary endpoints such as diet quality, PA, body mass index, quality-of-life, and perceived health, will be assessed during the 2-year study period and between the two arms. Potential effect modifiers such as social support, gender, comorbidity, and self-efficacy will be evaluated to determine whether the intervention is more effective among subsets of survivors.

Inclusion and exclusion criteria

Inclusion criteria include overweight or obese (body mass index: 25–39.9) elders (at least 65 years of age (no upper limit) 5 or more years post-diagnosis (no upper limit) for breast, prostate, or colorectal cancer and who were found to have no evidence of malignancy in the past 5 years, i.e. individuals who are considered 'cured' of their cancer. Breast, prostate, and colorectal cancers were selected because these are the most commonly diagnosed cancers with cure rates of 90% or higher) [1]. Further, all three cancers share similar health promotion guidelines post-diagnosis (i.e. healthy weight, moderate exercise and low saturated fat, plant-based diet) [20].

Individuals self-reporting exercise at a moderate intensity of 150 min per week or more were deemed ineligible based on specific exercise items (e.g. walking, aerobic training, etc.) from the Community Health Activities Model Program for Seniors (CHAMPS) questionnaire [21,22]. In addition, excluded were individuals for whom unsupervised exercise (i.e. angina, recent heart attack, congestive heart failure, plan to have a hip or knee replacement, walker or wheelchair use, recent stroke resulting in walking or speaking problems, or chronic obstructive pulmonary disease) is contraindicated. Additionally, individuals on warfarin or dialysis were excluded because of contraindications to eating a diet high in V&F. Individuals unlikely to comprehend or benefit from a telephone and mail-based intervention (i.e. hearing impaired, non-English speaking or writing, mentally incompetent, or residing in a skilled nursing facility) were excluded.

Randomization

Potentially eligible subjects completed two baseline telephone surveys and if eligible, were block randomized to either the experimental intervention (delivered in year 1) or delayed intervention (control wait-listed arm delivered intervention in year 2). Subjects were randomized according to the following strata: cancer type (breast, prostate, or colorectal); race (White or non-White); and gender (male or female for colorectal cancer only). Randomization was conducted by a statistician who had no subject contact.

DOI: 10.1002/pon

Sample size and power

Sample size calculations were based on the *t*-test for an arm difference in change in the Short Form (SF) physical function subscale from baseline to year 1. Only subjects with non-missing data at year 1 will be used in the primary analysis; the dropout rate is expected to be at most 15%. With 640 accrued patients, the *t*-test (two-sided alpha of 0.05) has at least 80% power to detect a standardized arm difference of 0.24. A difference of 0.23 was observed in an intervention development study entitled Project LEAD [23].

Sample identification and recruitment

Many researchers utilize cancer registries as a resource for identifying cancer survivors for research studies [24,25]. For RENEW, we ascertained cases from the North Carolina Central Cancer Registry (NCCCR) and Duke Cancer Registry. This trial complied with Health Insurance Portability and Accountability Act (HIPAA) guidelines and was approved by the institutional review boards at both Duke University Health System and NCCCR. The cancer registries identified breast (female), prostate, and colorectal cancer cases at least 5 years out from diagnosis (Figure 1) with no evidence of malignancy. Physician codes associated with each case were requested, and individual hospital registries were contacted to translate physician codes. Identified physicians were asked for written permission to contact their patients for participation in the trial.

Several self-referrals were directed from fliers posted to websites, physicians' offices, national meetings and NexCura, Inc (Thompson Company, Seattle, WA) an electronic mail posting to cancer registrants. Although self-referral networks were productive for use in previous studies targeting all ages of cancer survivors, more proximal to diagnosis [26], the self-referral process did not work as effectively in this population of older, long-term cancer survivors (8% of the sample was accrued via self-referrals).

Primary challenge to recruitment

Five months into study recruitment, we had approximately 50 subjects enrolled and had exhausted the contact of identifiable physicians listed for each case. Owing to a large number of missing or unidentifiable physician codes, we obtained a waiver to notify survivors about the study. Potential participants with unidentified physicians were sent a letter providing information about how their contact information was obtained and a flier listing study information. Interested individuals were encouraged to call a toll-free study telephone number to obtain further information. If the individual did not contact the study, no further contact was permitted. Survivors expressing interest were sent a consent form and enrollment mailing.

Consent and enrollment

Enrollment mailing included a (1) letter from the principal investigator; (2) study flier; (3) consent form; (4) screening survey; (5) felt-tipped marker to enhance survey completion; and (6) preaddressed, postage-paid return envelope. First class postage and return service from the US Postal Service were used to provide the study with address updates and forwarding for undelivered mailings. For undelivered mailings, local and national Internet-based public directory information sources (e.g. www.whitepages.com and the search engine Google™) were used in an attempt to obtain updated address and telephone information. Within 2 weeks, survivors were called to review the consent form and answer study-related questions. After 4 weeks, if no response was received, potential participants were mailed a reminder postcard. Returned paperwork was checked for completeness and scanned. If deemed ineligible, a thank you letter and a National Cancer Institute (NCI) 'Cancer Information Service' card (NCI Z575) were mailed. Potentially eligible subjects were mailed a letter informing them that they would be contacted for telephone surveys; response cards (survey scale anchors), and a poster depicting 2-dimensional representations of food portions (2D Food Portion Visual, Nutrition Counseling Enterprises, Framingham, MA) to facilitate baseline surveys.

Intervention materials

Materials developed for the intervention and the telephone scripts used to guide counseling, were based primarily on Social Cognitive Theory [27], where the key concepts of behavioral capacity, expectancies, self-control, reinforcement, and self-efficacy were operationalized (see Telephone Counseling). Print materials also drew on the theoretical framework offered by the Transtheoretical Model to develop introductory messages aimed at engaging the participant [28].

Participants assigned to the RENEW experimental intervention arm received a personalized workbook (their name is on the front cover and accompanying materials) of exercise and diet information. Their current exercise and dietary behaviors were compared with national guidelines [29–31] and feedback provided. Specifically, the first few pages of the book were tailored according to data collected from the baseline survey to show current status for the following: (1) strength exercise minutes (goal = at least 15 min, every other day); (2)

DOI: 10.1002/pon

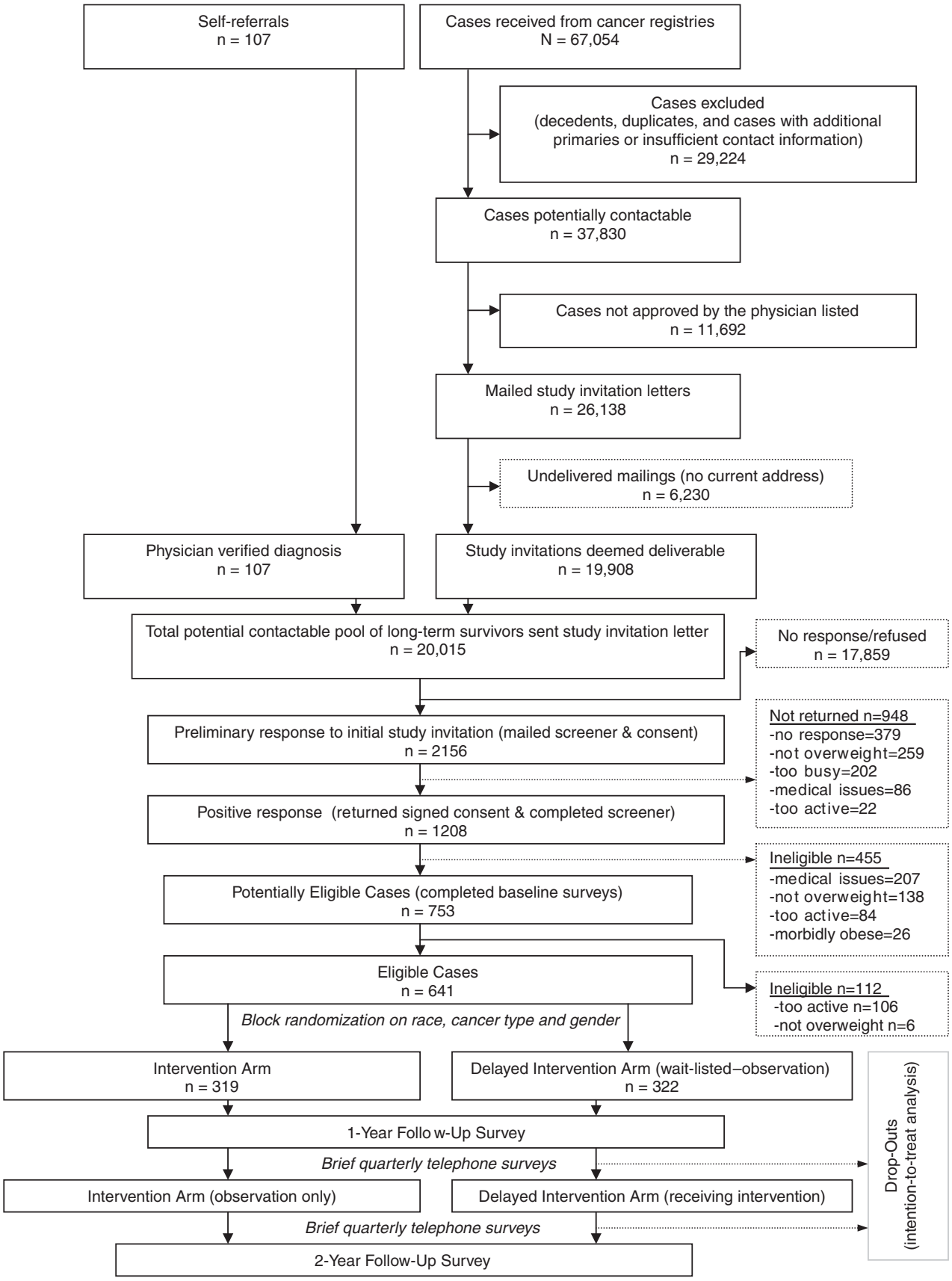

Figure 1. RENEW (Reach out to ENhancE Wellness in Older Cancer Survivors) study flow

endurance exercise minutes (goal = at least 30 min a day); (3) average daily V&F intake (goal = 7 servings for women and nine servings for men); (4) average daily saturated fat intake (goal = $<10\%$ total calories from saturated fat); and (5) weight (goal = BMI <25 with realistic goal set at 10%

DOI: 10.1002/pon

weight loss over 1 year). Given that RENEW was aimed at improving physical functioning and that expected improvements would be mediated primarily through increased aerobic and strength-training exercise, intervention participants received a pedometer (Accusplit®, Pleasanton, CA), and three levels (red, green, blue) of Thera-bands® (The Hygenic Corporation, Akron, OH). Participants also received an exercise poster depicting six lower extremity strength exercises including colored illustrations and instructions; the intervention was focused on improving strength in the lower body since these muscle groups largely drive physical functioning [32]. Additional equipment included Portion Doctor® tableware (to guide food portion sizes) (Portion Health Products, St. Augustine Beach, FL), the T-Factor 2000 Fat gram book (to assist with self-monitoring of fat intake) (W.W. Norton & Company, New York, NY), a pocket magnifier (to assist with reading any materials or devices using small print) (UltraOptix®, East Haven, CT), and personalized record logs (to guide daily exercise and diet self-monitoring).

Telephone counseling

To establish rapport and enhance social support, participants were assigned a counselor at the beginning of the intervention and remained with that counselor for the duration of the study. Weekly counseling sessions were scheduled during the first 3 weeks, followed by two semi-weekly sessions (interspersed with tailored telephone prompts), and then monthly sessions for the remainder of the intervention period (interspersed with telephone prompts or tailored progress reports) (Figure 2). Each telephone session was 15–30 min in duration. During each session, the counselor engaged the participant using SCT to develop strategies to overcome barriers and achieve incremental behavioral goals, monitor progress, provide reinforcement upon attainment of those goals, field questions, and direct participants to appropriate workbook pages [23,33,34]. In order to standardize the data collection and message delivery, the four counselors were provided computer-assisted templates with branching algorithms to guide counseling sessions.

Telephone prompts

Telephone prompts were used intermittently throughout the intervention as a means of providing additional reinforcement, e.g. 'Hello, I'm Dr. Demark, from Duke University Medical Center and I'm so happy that you're part of the RENEW study! We hope the materials and the counseling calls will motivate you to exercise more and eat healthier foods. Keep in mind—you don't need to achieve your exercise and diet goals overnight, but over time, as you work with your personal trainer, the work should really pay off! Good bye for now & welcome to RENEW'.

Tailored progress reports

To provide participants with visual reinforcement and printed motivational messages, participants were mailed a tailored progress report every 12 weeks. The progress report consisted of a two-page, fold-out newsletter with a motivational greeting (tailored on stage of readiness), a graph comparing participant's behavioral change over time in five distinct areas, i.e. strength exercise, endurance exercise, grams of saturated fat, servings of V&F, and use of portion size tableware. These were accompanied by a motivational sign-off message (tailored to stage of readiness). A RENEW magnet was provided for subjects to display progress reports on their refrigerator, providing reinforcement and an environmental cue.

Delayed intervention

In previous studies, we found that the use of an attention control arm served as a potential barrier to recruitment, a problem that has been reported by others who have conducted research in cancer survivor populations [35]. To minimize this effect, a delayed intervention (wait-list for 1 year) was the control arm.

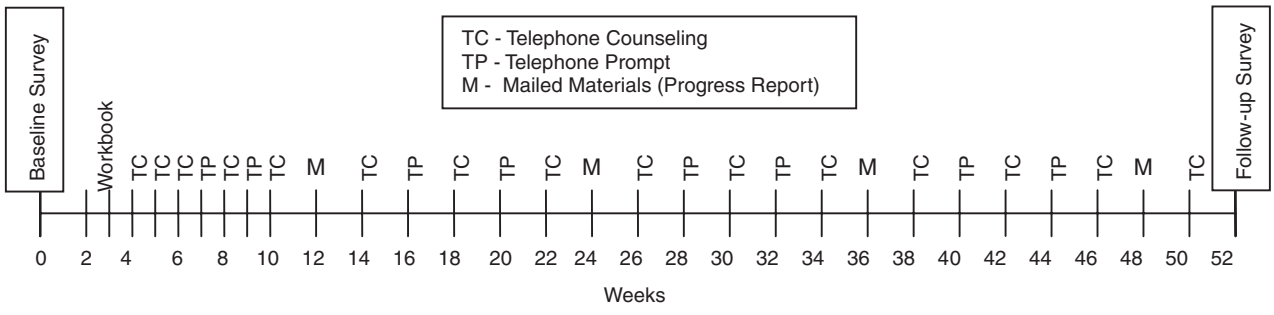

Figure 2. Specific intervention elements and their timing over the 50-week intervention period

DOI: 10.1002/pon

Study measures (baseline, quarterly, 1- and 2-year follow-up)

Two telephone surveys (45–60 min) were conducted at baseline, 1- and 2-year follow-up. Brief (5–10 min) surveys were conducted quarterly throughout the 2-year study.

Primary outcome: functional status

Functional status was our primary endpoint. The physical function subscale of the SF-36 served as our primary measure of functional status [36]. This 10-item self-report of functional status was selected because it is widely used, well tested, validated, and considered reliable in both healthy and chronically ill adults and is sensitive to change [36]. This subscale was administered at all time points, including quarterly surveys. At baseline, 1- and 2-year follow-up the SF-36 was administered in its entirety and included the following subscales: role limitations due to physical problems; bodily pain; social functioning; general mental health; role limitations due to emotional problems; vitality, energy or fatigue; and general health perceptions. In addition, two physical function subscales (basic and advanced lower extremity function) from the Late Life Function and Disability instrument were used to assess lower extremity function [37] at all time points.

Secondary outcomes

Physical activity

PA was measured using CHAMPS, a questionnaire developed for use in older adults and tested in home-based interventions [21,22]. This measure was selected because it has good construct validity and reliability, and is sensitive to change. There are two scores produced by the CHAMPS questionnaire: (1) frequency per week of all physical activities and (2) minutes of all PA per week, which can be used to calculate caloric expenditure. A subset of CHAMPS items was included as part of the quarterly surveys to assist in measuring the success of the intervention over time, e.g. walk or hike uphill; walk fast or briskly; and moderate strength training.

Dietary intake

Dietary intake data are averaged from two, random, 24-h recalls at baseline, 1- and 2-year follow-up; recalls were performed by trained interviewers at the Diet Assessment Center at Pennsylvania State University using the interactive Nutrition Data System-Revised software (NCC Food and Nutrient Database System Version 2006, Nutrition Coordinating Center, Minneapolis, MN). Overall diet quality was calculated using the revised Healthy Eating Index [38].

Weight status

Self-reported height was collected only at baseline. Self-reported body weight was collected at baseline, 1- and 2-year follow-up. Body mass index (kg/m^2) was calculated and change estimated over time.

Self-efficacy

Self-efficacy, measured at all time points, was assessed for exercise as confidence in the ability to do strength training for 15 min 3 or more days per week and to walk 30 min 5 or more days per week [39]. Self-efficacy also was assessed for diet as the confidence in the ability to eat a low saturated fat diet with at least seven or nine daily servings of V&F and to regularly limit calories by reducing portion size.

Co-morbidity

To assess both the effect of co-morbid conditions on function and the potential effect of the intervention on symptom severity, six medical conditions (arthritis or rheumatism, high blood pressure, heart trouble, circulation trouble in arms or legs including varicose veins, osteoporosis, and cataracts) and 22 symptoms were assessed using a survey previously developed by our research center [40]. Medical conditions were assessed only at baseline, but symptoms along with one open-ended item ('Do you currently have any other illnesses or conditions that interfere with your activities?') were collected at all time points.

Social support

Data on social support were captured at baseline using the Duke Social Support Index, a validated 11-item short form measure with excellent psychometric properties [41]. The short form was selected to capture the essential components of social support related to mental health outcomes and use of health services in elderly individuals. Support specifically for exercise and dietary change was assessed at all time points using two items: (1) 'To what extent would your friends and family support your efforts to increase your amount of exercise?' and (2) 'To what extent would your friends and family support your efforts to improve your diet?' (Responses included not at all, a little, somewhat, very much, and extremely, coded from 1–5, respectively.)

Additional items

Income, smoking status, alternative contact, cancer treatment history (yes or no responses for all cancers—radiation, hormonal, chemotherapy,

DOI: 10.1002/pon

surgery, other; prostate cancer only—brachiatherapy, active surveillance), adherence, and process questions (post-intervention delivery) were collected. To enhance study completion, small incentives were provided throughout the study; i.e. 30 min phone cards for quarterly surveys and $10 for annual surveys.

Health events

Changes in health status were monitored throughout the study. Participants receiving the intervention were asked for any health issues that kept them from exercising or eating a healthy diet. Participants not currently receiving the intervention were instructed to call a toll-free study number to report health problems. Clearance was sought from the participant's physician in cases where exercise was contraindicated (e.g. recent injury, surgery, heart condition, etc.) At both follow-up surveys, structured questions gathered information to ascertain if participants had any serious health event for which they sought medical attention. For each event, participants provided a date, event description, and if hospitalization occurred.

Data analysis

The general linear model will be used to test for arm differences in change in the primary and secondary endpoints from baseline to year 1. Effect modifiers will be tested in this model by including terms for their interaction with arm. In sensitivity analyses (intent-to-treat), the impact of missing values will be studied by using a range of imputed change scores for missing values, and by analyzing only those subjects who provide complete data. The mixed linear model will be used to estimate the trajectory of physical function across time, using measures collected quarterly from baseline to year 2.

Results

As indicated in Figure 1, NCCCR provided a total of 67 054 breast, prostate, and colorectal cancer cases. After excluding decedents, duplicates, second primaries, or insufficient contact information, 37 830 cases remained. Additional decedents (expired after recruitment commenced) and cases for which the physician denied contact were removed ($n = 11\,692$). The final number of registry cases deemed eligible for mailing was 26 138 (39% of those initially identified). Of these, 6230 cases were deemed undeliverable, i.e. the study invitation was returned with 'addressee unknown'. Additional study participants self-referred from other sources ($n = 107$).

Table 1 describes the total pool of potential participants contacted ($n = 20\,015$) and characterized according to a positive response to full study enrollment. From the initial study invitation letter and flier, we received a preliminary response from 2156 survivors who called-in for more information (11% response rate). Upon receiving more

Table 1. Non-respondent and respondent characteristics of older cancer survivors approached to participate in RENEW (Reach out to ENhancE Wellness in older cancer survivors)

	Non-respondents ($n = 18\,807$)	Respondents ($n = 1208$)	*p*
Age (years)			
Mean (sd)	76.2 (5.9)	73.4 (5.4)	<0.0001
Range	65–97	65–91	
Race			
White	82.8	87.5	<0.0001 (White vs others)
African American	15.3	11.3	
Other/unknown	1.9	1.2	
Sex % (*n*)			
Female	44.9%	50.1%	0.0004
Male	55.1%	49.9%	
Years post-diagnosis			
Mean (sd)	9.5 (2.4)	8.7 (2.8)	<0.0001
Distribution % (*n*)			
5–10 years	67.2%	77.0%	
>10 years	32.8%	23.0%	
Cancer type % (*n*)			
Breast	34.7%	40.1%	0.0003
Prostate	44.7%	42.5%	
Colorectal	20.6%	17.4%	
Cancer stage			
In situ	0.06%	0.6%	0.07 (localized vs others)
Localized	72.0%	69.5%	
Regional	23.9%	26.1%	
Unknown	4.1%	3.9%	

All data represent invitations deemed posted and received.

DOI: 10.1002/pon

comprehensive study enrollment information, a positive response was determined by a completed screener and signed consent form ($n = 1208$, 6% response rate). Compared to non-respondents, cancer survivors who responded with interest were significantly younger and more proximal to diagnosis, and greater proportions were White and female breast cancer survivors. Most survivors were diagnosed initially with localized disease. Subjects deemed initially eligible for participation according to the screener ($n = 753$) completed the two baseline surveys where additional screening on BMI and/or 150 min of moderate to vigorous exercise per week rendered an additional 112 subjects ineligible. Ultimately, 641 participants were enrolled into RENEW. At present, approximately half of participants are receiving the intervention and completing follow-up.

Discussion

To our knowledge, this is the first home-based exercise and diet trial among older, long-term cancer survivors, a population that has been specifically identified for study [7,20]. A recent analysis by Blanchard *et al*. examined the clustering of PA, V&F intake, and smoking across six cancer survivor groups and found that up to 12.5% of cancer survivors do not practice any lifestyle behavior recommendation, and less than 10% adhere to two or more recommendations [42]. In their conclusion, these researchers voice the need for multi-behavior interventions, noting that while this approach is more challenging, it may produce greater improvements in health outcomes. The RENEW trial should provide valuable information to begin to fill the current void in this area.

With RENEW in the field, our largest accomplishment to date relates to accrual of our targeted sample. In doing so, we identified and screened a large number of potential cancer survivors in order to identify a select group of elderly participants who may benefit most from a distance-based exercise and diet intervention that ultimately could improve functional status. Although a number of survivors were excluded from enrollment based on exclusionary criteria (i.e. medical or physical reasons, not overweight or obese, or practicing 150 min or more per week of exercise), this RCT demonstrates that conducting trials with older, long-term survivors is feasible, but requires a considerable amount of personnel time and study resources to recruit and enroll subjects. In this trial, over 26 000 letters were posted and more than 2000 initial telephone calls were made in order to reach our accrual target. This initial telephone time alone conservatively equated to nine full time equivalent working weeks. Similarly, Tercyak *et al*. reported that recruitment calls for a health promotion RCT among a potential pool of 244 adolescent childhood cancer survivors took two full working weeks of telephone time [43]. Thus, the resources needed to conduct such studies are substantial and should be considered in planning such trials. Furthermore, as suggested by the comparison of RENEW with previous studies in younger patients more proximal to diagnosis, the resource requirements to accrue older patients who are further out from diagnosis may be even larger. The lack of current contact information represents a key obstacle in identifying long-term survivors.

Although we used first class postage, which provided mail forwarding and address correction, this is only effective if the participant has a known address or has moved recently [44]. In RENEW, we employed search engines such as Google™ and the online white pages with reverse look-up features to locate addresses of survivors whose initial letters were posted to inactive addresses.

While the use of more than one recruitment method has been key in helping us achieve our accrual targets in previous studies [26,45] and has been endorsed by others [46,47], our attempts in trying to attract self-referred subjects to this trial via physician offices, advertisements, and the Internet was relatively non-productive. These results are similar to a study of 509 older long-term breast cancer survivors in which the majority of women were recruited using the cancer registry as compared with recruitment from community resources [48]. Given that long-term survivors are not likely to have continued contact with their oncologist, innovative recruitment strategies are needed that do not rely on oncology offices or networks [49]. Although recruiting via cancer registries requires sufficient manpower, we do encourage researchers to consider this as a potential recruitment avenue for long-term survivors both within and across state registries.

Various methods of recruitment to research studies have been studied, including the use of cancer registries in cancer survivorship [24]. State cancer registries have varying policies for contacting survivors [25]. While we were successful in identifying a number of physicians coded in the registry through the assistance of individual hospitals, much of this information was missing. In addition, these survivors were a minimum of 5 years out from diagnosis and the institution may or may not have been required to report physician information during that timeframe. Even so, in the instances where physicians were identified, approval was obtained for only about half of these long-term cases. Smith *et al*. report similar observations, noting that active physician consent is more difficult to obtain as survivors move beyond treatment and stop follow-up with the physician listed in the registry [50]. Thus, obtaining a waiver that enabled a

DOI: 10.1002/pon

direct mailing not only improved our ability to increase subject accrual; it also allowed us to cast a wider net across North Carolina, and allowed us to offer this intervention to a greater number of rural-dwelling and minority-group elders. Institutional constraints for the one-time contact kept us from following up with the participants who did not respond to the study invitation. One suggestion might be to provide two toll-free numbers for response—one number for survivors requesting more information and a separate number that allows participants to key their study ID number and a reason that they do not wish to participate. This information might be useful in understanding why a segment of this population is not participating in such trials.

Although 56% of elders returned a screener and consent form to participate, several survivors called in to the study number reporting that they were ineligible (17%) or too busy (9%) with about 18% never responding. Reminder cards did improve screener returns by 5%, but a follow-up call to assess interest/eligibility might be more productive. Since these elders have hit the '5 year' mark, they may have a false sense of security that they are 'cured', and hold the belief that follow-up and prevention are no longer helpful [49]. Other reasons that older adult survivors may elect not to participate could be similar to those reported in trials that target older populations in general, e.g. fear of injury with exercise; physician advice to limit exercise; attitudinal barriers, such as perceived lack of ability and beliefs about exercise; and illness and injury [51].

The lessons learned in implementing this RCT may be useful in the design of other lifestyle intervention studies. Certainly, there is a tremendous need to develop effective lifestyle interventions in cancer survivors and this need may be even further exacerbated among those who are elderly. Data from RENEW may assist other researchers who are dedicated to this goal and provide guidance for designing and implementing such studies, especially in a climate of limited resources.

Acknowledgements

RENEW is supported by the National Institutes of Health through the following grants CA106919 and P30AG028716, and a grant from the Veterans Affairs Research & Development E3386R. The authors dedicate this manuscript in memory of our esteemed and beloved colleague, Dr Elizabeth C. Clipp. We wish to thank Drs Marci Campbell and Bess Marcus for their guidance in areas of design and implementation. We are grateful for the contributions and professionalism demonstrated by the staff of People Designs, Inc. (David Farrell, MPH, Jetze Beers, Marley Beers, MFA, and Kay Michaels, MS) who helped craft the RENEW intervention materials. We thank Phil Page, PT at Thera-band Academy for donating products. The authors also wish to thank the following individuals who have and are continuing to contribute expertise and support: Teresa Baker, Jenni Grover, Emily Hill, Jenn Laheta, MEd, Avery Lutz, Heather MacDonald, Barbara Parker, Linda Phelps, Russell Ward, Pam Eberle Wiley, MS, RD, and Nanyamka Williams. We also are grateful to our participating institutions (Duke University Medical Center, Durham VA Medical Center, North Carolina Central Cancer Registry, and The University of Chicago), cancer registrars (Cheri Willard and Karen Knight), and participating oncology care providers Maureen Broderick, LCSW, Cheryl Landini, RN, Sue Wingate, NP, and physicians Oyewale Abidoye, Victor Abraham, Onyekwere Steven Akman, Akwari, Ron Allison, Mark Altschuler, Fabian Alzamora, E. Everett Anderson, Mitchell Anscher, William Anthony, Sasan Araghi, Birgit Arb, Lisa Banker, Thomas Bartholet, Robert Belt, Elizabeth Benson, Lee Berkowitz, Stephen Bernard, Andrew Billon, Sidney Blake, William Bobzien, Christine Bounous, Malcolm Branch, Geoffrey Burbridge, John Burnett, W. Woodrow Burns, William Caddick, Linda Calhoun, Benjamin Calvo, Elizabeth Campbell, William Cance, Lisa Carey, David Carr, Peter Carroll, Majd Chahin, Frances Collichio, David Cook, D. Scott Covington, John Crawford, Thomas Cruden, Richard Dales, Thomas D'Amico, John Daniel, Alonzo Davis, John Davis, Carlos De Castro, Denise Dechow, Margaret Deutsch, John Doster, Alfred Doyle, David Draughn, Maha Elkordy, Demosthenes Esporas, Jeffrey Scott Falk, Steve Flashner, William Folds, James Foxworthy, Laurie Frakes, Anna Gattani, Harcharan Gill, Aregai Girmay, Jon Gockerman, Ismael Goco, Paul Godley, Winston Godwin, Kathryn Greven, Michael Gribetz, O. Drew Grice, Andrew Griffin, Thomas Grote, Daniel Gup, Cynthia Guy, Craig Hall, Jan Halle, Douglas Harrison, James Hathorn, Carolyn Hendricks, Robert Henihan, Jose Hernandez, William Hicks, Leroy Hoffman, Frankie Holmes, Robert Holmes, Judith Hopkins, Russell Howerton, Frank Hubbard, Richard Ihnat, Gregory Jones, Richard Kane, James Keller, Booker Keyes, Alan Keys, William King, Joseph Kittinger, Matthew Klain, James Knost, Gordon Kruger, Eric Larsen, Catherine Lee, W. Robert Lee, Douglas Leet, George Leight, Jonathan Levine, Marian Llenado-Lee, Kirk Ludwig, Paul Lui, H. Kim Lyerly, Kenneth MacDonald, Janet Macheledt, Rajeev Malik, James Manley, P. Kelly Marcom, Lawrence Marks, David Martin, Richard Marx, Gordon Mathes, Alfred May, Daniel McClellan, Charles McMurchy, Charles Meakin, Mark Medley, Anthony Meluch, Alex Metzger, Anthony Meyer, Richard Michaelson, David Miles, James Mohler, Gustavo Montana, Joseph Moore, Dawn Moose, Richard Morgan, John Morrison, Michael Morse, H. Curtis Mostellar, Judd Moul, Joseph Moylan, George Mozingo, Ziyad Mugharbil, Magaral Murali, Thomas Mutton, Charles Myers, Richard Mynatt, Manuel Neto, Larry Norton, Michelle Ong, Michael O'Neill, Joyce O'Shaughnessy, C. Lawrence Parker, Peter Parker, Eugene Paschold, Anthony Patterson, David Paulson, David Pearsall, Charles Penley, John Petersen, Randall Pierce, Walter Pories, Leonard Prosnitz, Debra Prow, Robert Purdon, Henry Purvis, Robert Raju, Michael Rees, Charles F. Reid, Donald Ribeiro, Cary Robertson, Howard Robertson, Thurman Ross Jr., Michael Rowland, Andrea Ruskin, William Russell, John Ryan, Scott Sailer, Romulo Sanchez, Charles Scarantino, Robert Schellenberg, Gary Schenk, Tim Schneidau, Stanley Schwartz, Ronald Schwarz, Daniel Scott, Charles Scott, Victoria Seewaldt, Hilliard F. Seigler, Stephen Shaban, Heather Shaw, Ronnie Sheena, Craig Shriver, Carlos Sicilia, Judy Siegel, Dennis Sinar, Bijai Singh, Chirapa Sinthusek, Patrick Sitorius, Nancy Sklarin, Susan Slovin, Rodney Stalheim, Davey Stallings, Jerry Stirman, Lewis Stocks, Hal Stoneking, Erika Struble, Patrick Stuart, Allston J. Stubbs, Linda Sutton, Thomas M. Swantkowski,

Julia Symon, A. Darrell Tackett, Sharon Taylor, Debra Tegeler, Chris Teigland, Hugo Tettamanti, Judith Thompson, Stuart Todd, Lisa Tolnitch, Frank Torti, Donald Trump, Douglas Tyler, T. Reed Underhill, Henry Unger, Barry Usow, Linga Vijaya, Mark Vrana, Patrick Walsh, Philip Walther, Leo Warshauer, Gregory Waters, Bradley Weisner, Douglas White, Geoffrey White, Edward Whitesides, Max Wicha, Ellen Willard, Joanne Wilson, Richard Worf, Mark Yoffe, and Patricia Zekan. The authors indicated no potential conflicts of interest.

References

1. American Cancer Society. *Cancer Facts and Figures—2008*, American Cancer Society, 2008. (Available from: http://www.cancer.org/docroot/STT/stt_0.asp [cited 9 June 2008].)
2. National Cancer Institute Office of Cancer Survivorship. *Cancer Control and Population Sciences*: *Research Findings*. (Available from: http://dccps.nci.nih.gov/ocs/prevalence/index.html [cited 9 June 2008].)
3. Yancik R, Riles LA. Aging and cancer in America. Demographic and epidemiologic percepectives. *Hematol Oncol Clin North Am* 2000;**14**(1):17–23.
4. Aziz NM. Cancer survivorship research: challenge and opportunity. *J Nutr* 2002;**132**(11S):3494S–3503S.
5. Meadows AT, Varricchio C, Crosson K *et al*. Research issues in cancer survivorship. *Cancer Epidemiol Biomarkers Prev* 1998;**7**(12):1145–1151.
6. Rowland JH, Aziz N, Tesauro G, Feuer EJ. The changing face of cancer survivorship. *Semin Oncol Nurs* 2001;**17**(4):236–240.
7. Deimling GT, Sterns S, Bowman KF, Kahana B. Functioning and activity participation restrictions among older adult, long-term cancer survivors. *Cancer Invest* 2007;**25**(2):106–116.
8. Baker F, Haffer S, Denniston M. Health-related quality of life of cancer and noncancer patients in Medicare managed care. *Cancer* 2003;**97**(3):674–681.
9. Chirikos TN, Russell-Jacobs A, Jacobsen PB. Functional impairment and the economic consequences of female breast cancer. *Women Health* 2002;**36**(1):1–20.
10. Hewitt M, Rowland JH, Yancik R. Cancer survivors in the United States: age, health, and disability. *J Gerontol A Biol Sci Med Sci* 2003;**58**(1):82–91.
11. Yabroff KR, Lamont EB, Mariotto A *et al*. Cost of care for elderly cancer patients in the United States. *J Natl Cancer Inst* 2008;**100**(9):630–641.
12. Mandelblatt JS, Edge SB, Meropol NJ *et al*. Predictors of long-term outcomes in older breast cancer survivors: perceptions versus patterns of care. *J Clin Oncol* 2003;**21**(5):255–263.
13. Brach JS, FitzGerald S, Newman AB *et al*. Physical activity and functional status in community-dwelling older womens: a 14-year prospective study. *Arch Intern Med* 2003;**163**(21):2565–2571.
14. Brach JS, Simonsick EM, Kritchevsky S, Yaffe K, Newman AB. The association between physical function and lifestyle activity and exercise in the health, again and body composition study. *J Am Geriatr Soc* 2001;**52**(4):502–509.
15. Fiatarone S. Exercise comes of age: rationale and recommendations for a geriatric exercise prescription. *J Gerontol Med Sci* 2002;**57**(5):262–282.
16. Heath JM, Stuart MR. Prescribing exercise for frail elders. *J Am Board Fam Pract* 2001;**15**(3):218–228.
17. Edwards BK, Howe HL, Ries LA *et al*. Annual report to the nation on the status of cancer, 1973–1999, featuring implications of age and aging on US cancer burden. *Cancer* 2002;**94**(10):2766–2792.
18. Demark-Wahnefried W, Clipp EC, Morey MC *et al*. Physical function and associations with diet and exercise: results of a cross-sectional survey among elders with breast or prostate cancer. *Int J Behav Nutr Phys Act* 2004;**1**(16):1–6.
19. Fine JT, Colditz GA, Coakley EH *et al*. A prospective study of weight change and health-related quality of life in women. *J Am Med Assoc* 1999;**282**(22):2136–2142.
20. Doyle C, Kushi LH, Byers T *et al*. Nutrition and physical activity during and after cancer treatment: an American cancer society guide for informed choices. *Can J Clin* 2006;**56**(6):323–353.
21. Stewart Al, Mills KM, Sepsis PG *et al*. Evaluation of CHAMPS, a physical activity promotion program for older adults. *Ann Behav Med* 1997;**19**(4):353–361.
22. Stewart AL, Mills KM, King AC, Haskell WL, Gillis D, Ritter PL. CHAMPS physical activity questionnaire for older adults: outcomes for interventions. *Med Sci Sports Exerc* 2001;**33**(7):1126–1141.
23. Demark-Wahnefried W, Clipp EC, Morey MC *et al*. Lifestyle intervention development study to improve physical function in older adults with cancer: outcomes from project LEAD. *J Clin Oncol* 2006;**24**(21):3465–3473.
24. Pakilit AT, Kahn BA, Petersen L, Abraham LS, Greendale GA, Ganz PA. Making effective use of tumor registries for cancer survivorship research. *Cancer* 2001;**9**(5):1305–1314.
25. Beskow LM, Sandler RS, Weinberger M. Research recruitment through US central cancer registries: balancing privacy and scientific issues. *Am J Public Health* 2006;**96**(11):1920–1926.
26. Snyder DC, Sloane R, Lobach D *et al*. Differences in baseline characteristics and performance at one-and two-year follow-up of cancer survivors accrued via self-referral versus cancer registry in the FRESH START diet and exercise trial. *Cancer Epidemiol Biomarkers Prev* 2008;**17**(5):1288–1294.
27. Bandura A. *Social Foundations of Thought and Action*: *A Social Cognitive Theory*. Prentice-Hall: New Jersey, 1986.
28. Prochaska JO, Velicer WF, Rossi JS *et al*. Stages of change and decisional balance for 12 problem behaviors. *Health Psychol* 1994;**13**(1):39–46.
29. Mazzeo RS, Cavanagh P, Evans WJ *et al*. ACSM position stand: exercise and physical activity for older adults. *Med Sci Sports Exerc* 1998;**30**(6):992–1008.
30. American College of Sports Medicine. *Guidelines for Healthy Aerobic Activity*. (Available from: http://www.acsm.org/AM/Template.cfm?Section = Home_Page&TEMPLATE = /CM/HTMLDisplay.cfm&CONTENTID = 7764 [cited 9 June 2008].)
31. Department of Health and Human Services. *Dietary Guidelines for Americans*, 2005. (Available from: http://fnic.nal.usda.gov/nal_display/index.php?info_center = 4&tax_level = 2&tax_subject = 256&topic_id = 1332 [cited 16 June 2008].)
32. Morey MC, Peterson MJ, Pieper CF *et al*. Project Life—learning to improve fitness and function in elders: methods, design, and baseline characteristics of randomized trial. *J Rehabil Res Dev* 2008;**45**(1):31–42.
33. Clark NM, Dodge JA. Exploring efficacy as a predictor of disease management. *Health Educ Behav* 1999;**26**(1):72–89.
34. Campbell AJ, Robertson MC, Gardner MM, Norton RN, Buchner DM. Falls prevention over 2 years: a randomized controlled trial in women 80 years and older. *Age Aging* 1999;**28**(6):513–518.

35. Madsen SM, Mirza MR, Holm S, Hilsted KL, Kampmann K, Riis P. Attitudes towards clinical research amongst participants and nonparticipants. *J Intern Med* 2002;**251**(2):156–168.
36. Ware JE, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36). *Med Care* 1992;**30**(6): 473–483.
37. Jette AM, Haley SM, Coster WJ *et al*. Late life function and disability instrument: I. Development and evaluation of the disability component. *J Gerontol A Biol Sci Med Sci* 2002;**57**(4):M209–M216.
38. Guenther PM, Reedy J, Krebs-Smith SM, Reeve BB, Basiotis PP. Development and evaluation of the Healthy Eating Index—2005. *Technical Report*, Center for Nutrition Policy and Promotion, US Department of Agriculture, 2007. (Available from: http://www.cnpp.usda.gov/Publications/HEI/HEI-2005/HEI-2005TechnicalReport.pdf [cited 9 June 2008].)
39. McAuley E, Elavsky S, Motl RW, Konopack JF, Hu L, Marquez DX. Physical activity, self-efficacy, and self-esteem: longitudinal relationships in older adults. *J Gerontol Psychol Sci Soc Sci* 2005;**60**(5):P268–P275.
40. Morey MC, Schenkman M, Studenski S *et al*. Spinal-flexibility-plus-aerobic versus aerobic-only training: effects of a randomized clinical trial on function in at risk older adults. *J Gerontol A Biol Sci Med Sci* 1999;**54**:M335–M342.
41. Koenig HG, Westlund RE, George LK, Hughes DC, Blazer DG, Hybels C. Abbreviating the Duke Social Support Index for use in chronically ill elderly individuals. *Psychosomatics* 1993;**34**(1):61–69.
42. Blanchard CM, Courneya KS, Stein K. American Cancer Society's SCS-II. Cancer survivors' adherence to lifestyle behavior recommendations and associations with health-related quality of life: results from the American Cancer Society's SCS-II. *J Clin Oncol* 2008;**26**(13):2198–2204.
43. Tercyak KP, Donze JR, Prahlad S, Mosher RB, Shad AT. Identifying, recruiting, and enrolling adolescent survivors of childhood cancer into a randomized controlled trial of health promotion: preliminary experiences in the Survivor Health and Resilience Education (SHARE) Program. *J Pediatr Psychol* 2006;**31**(3):252–261.
44. Mertens AC, Walls RS, Taylor L *et al*. Characteristics of childhood cancer survivors predicted their successful tracing. *J Clin Epidemiol* 2004;**57**(9):933–944.
45. Demark-Wahnefried W, Clipp EC, Lipkus IM *et al*. Main outcomes of the FRESH START trial: a sequentially tailored, diet and exercise mailed print intervention among breast and prostate cancer survivors. *J Clin Oncol* 2007;**25**(19):2709–2718.
46. Swanson GM, Ward AJ. Recruiting minorities into clinical trials: toward a participant-friendly system. *J Natl Cancer Inst* 1995;**87**(23):1747–1759.
47. Cabral DN, Nápoles-Springer AM, Miike R *et al*. San Francisco Bay Area Lung Cancer Study. Population- and community-based recruitment of African Americans and Latinos: the San Francisco Bay Area Lung Cancer Study. *Am J Epidemiol* 2003;**158**(3):272–279.
48. Mishel MH, Germino BB, Gil GM *et al*. Benefits from an uncertainty management intervention for African-American and Caucasian older long-term breast cancer survivors. *Psycho-Oncology* 2005;**14**:962–978.
49. Mertens AC, Cotter KL, Foster BM *et al*. Improving health care for adult survivors of childhood cancer: recommendations from a delphi panel of health policy experts. *Health Policy* 2004;**69**(2):169–178.
50. Smith T, Stein KD, Mehta CC *et al*. The rationale, design, and implementation of the American Cancer Society's studies of cancer survivors. *Cancer* 2007;**109**(1):1–12.
51. King AC, Rejeski WJ, Buchner DM. Physical activity interventions targeting older adults. A critical review and recommendations. *Am J Prev Med* 1998;**15**(4): 316–333.

DOI: 10.1002/pon