A SYSTEMATIC REVIEW OF RECRUITMENT AND RETENTION STRATEGIES USED IN DIETARY RANDOMIZED CONTROLLED INTERVENTIONS IN CANCER SURVIVORS

By

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Abstract

Interpretation of results of dietary intervention trials in cancer survivors may be limited by insufficient recruitment or retention of study participants. This systematic review describes recruitment strategies, accrual of participants, and attrition (withdrawal) rates for dietary interventions conducted in breast, prostate, and colorectal cancer survivors.

PubMed, CINAHL, Cochrane Central Register of Controlled Trials, Embase, PsychINFO, and Web of Science databases were searched. Eligible studies included national and international dietary randomized controlled trials (RCTs), with at least 12 weeks of intervention and 6 months of follow-up. Trials were required to include a CONSORT (CONsolidated Standards of Reporting Trials) diagram.

Twenty cohorts were included: breast cancer (BC) survivors (n=11), prostate cancer (PC) (n=3), colorectal cancer (CRC) (n=1), and combined (n=5). Primary recruitment methods included health care providers (n=13) or cancer registries (n=9). Of studies that set *a priori* sample sizes, 12 met accrual targets and five did not. Attrition rates averaged 18.6% at 6 months, 16.3% at 12-13 months, and 20.3% at 2 years. Among completed studies (n=18), seven trials met *a priori* retention targets, three trials did not, one assessed feasibility, and seven trials did not provide a clearly defined retention goal. There were few trials in PC and CRC survivors. Missing CONSORT diagrams reduced the eligible studies.

The majority of studies met recruitment goals (n=12). Overall, attrition rates averaged approximately 17.4%. Improved understanding of effective recruitment and retention strategies requires more diligent reporting. Qualitative research may allow for more systematic and detailed evaluation of challenges that contribute to insufficient recruitment and retention of cancer survivors in dietary intervention trials. Registration can be found at PROSPERO ref: CRD42018070396.

Chapter 1: Introduction

Background

The World Cancer Research Fund (WCRF) and American Institute for Cancer Research (AICR) define cancer survivors as, "all people who have been diagnosed with cancer, including before, during and after treatment".[1] Most recent data from 2016, reports more than 15.5 million people in the United States are cancer survivors.[2] Since the mid-1970s, improvements in detection and treatment of cancer have resulted in a large population of cancer survivors, a population which is expected to grow, with an estimated 1,735,350 new cancer cases diagnosed in 2018 alone.[3]

Dietary Recommendations for Cancer Survivors

Owing to the expanding population of survivors, leading organizations have proposed guidelines for dietary behaviors to promote survival, reduce co-morbidity and increase quality of life. The WCRF and AICR recommend maintaining a healthy weight during adulthood as well as consuming a diet high in daily intake of whole grains, vegetables, fruit, and legumes, and restricting consumption of sugar-sweetened beverages and alcohol.[1] The American Cancer Society (ACS) and American Society of Clinical Oncology (ASCO) provide similar recommendations for cancer survivors with additional advice to limit saturated fat intake.[4] Cancer survivors are at an increased risk for second primary cancers along with other diet-related chronic illnesses such as diabetes, osteoporosis and cardiovascular disease.[5] Incorporating healthy eating behaviors along with weight control, plays a key role in reducing comorbidities, improving overall health, promoting a longer lifespan, and supporting higher quality of life of cancer survivors.[5]

Adherence to Dietary Guidelines Among Cancer Survivors

Despite widespread dissemination of dietary guidelines among cancer survivors, observational research shows there is poor adherence.[6-8] Only 15% of prostate cancer (PC) survivors met the 5-A-Day fruit and vegetable goal from the ACS, while 17.6% of breast cancer (BC) survivors and 15.4% of colorectal cancer (CRC) survivors meet these guidelines.[6] Winkels et al., investigated adherence to the WCRF and AICR dietary guidelines in a cross-sectional analysis of 1,196 CRC survivors.[7] Adherence scores were divided into three categories: 0 to 4 points (lowest adherence), > 4 to ≤ 6 points, > 6 points to 8 points (highest adherence).[7] The mean adherence score to the dietary guidelines was 4.8, moderate adherence.[7] Only 12% (n=147) of participants had an adherence score greater than 6, indicating high adherence. The majority (65%; n=774) of participants had a score between 4 and 6 (moderate adherence), 22% (n=267) had a score between 2 and 4 (low adherence), and 1% (n=8) had a score between 0 and 2 (indicating the lowest adherence).[7] These data show that 88% of CRC survivors are not meeting the WCRF and AICR dietary recommendations.[7] Inoue-Choi et. al. studied adherence to WCRF and AICR dietary guidelines among 2,017 older female cancer survivors in the Iowa Women's Health Study.[8] There were a total of 938 breast cancer survivors and 380 colorectal cancer survivors.[8] Survivors were on average 8.6 years since cancer diagnosis, with an average age of 78.9 years.[8] For the WCRF and AICR healthy weight status recommendation, 37.5% of women were normal weight, 36.7% overweight, and 25.8% obese.[8] Fruit and vegetable intake recommendations were not met by 38.6% of the older female cancer survivors; while 55% did not meet the daily fiber intake recommendations from whole grains and legumes.[8] Data suggest a need for dietary interventions targeting older female cancer survivors. More broadly, these data support the need for research to increase adherence to dietary guidelines among cancer survivors.

Importantly, adherence to cancer survivorship lifestyle guidelines has been associated with decreased incidence of cancer and cancer-specific mortality.[9,10] For example, 73,784 incident cancer cases identified over a mean 12.6-years of cohort follow-

up in the NIH-AARP Diet and Health Study reported that high adherence compared to low adherence to ACS dietary guidelines was associated with a 17% lower risk of cancer mortality in men (HR=0.83, 95% CI 0.78 to 0.87, *P*-trend <0.0001) and a 12% lower risk of cancer mortality in women (HR= 0.88, 95% CI 0.82 to 0.94, *P*-trend = 0.0003).[9] Further support comes from the Third National Health and Nutrition Examination Survey (NHANES III) of 1,191 cancer cases diagnosed during a median follow up of 17.2 years.[10] Data suggest that high-quality diet [highest-quartile of the Healthy Eating Index (HEI) score] was associated with a 41% lower risk of overall mortality (HR=0.59, 95% CI 0.45 to 0.77) and a 65% lower risk of cancer-specific mortality (HR=0.35, 95% CI 0.19 to 0.63) compared to poor-quality diet (lowest-quartile HEI score).[10] Since diet appears to be a factor in mortality outcomes among cancer survivors, programs have been developed to enhance adherence to dietary guidelines.

Dietary Intervention Trials

Cancer survivors have indicated unmet needs for information and support for dietary improvement.[11] This led to the development of diet interventions to promote healthy eating to support the health and longevity of cancer survivors. There have been numerous dietary intervention trials conducted among cancer survivors to promote improved outcomes after cancer treatment.[12-14] These trials have employed various intervention delivery modes, with different duration and follow-up periods. Several published reviews have acknowledged the effect of these dietary interventions, largely from randomized controlled trials, on health outcomes in cancer survivors.[12-14] However, in order to assure the rigor of these trials, adequate recruitment and retention of participants is essential.

Challenges of Recruitment and Retention

In fact, concerns related to the appropriate interpretation of the findings from randomized controlled trials arises when recruitment (accrual) falls below statistically-powered estimates and/or drop-out rates (attrition) exceed *a priori* (pre-trial) estimates.

Differential recruitment or drop-out rates by study randomization assignment is an additional concern that reduces trial integrity and rigor. Reporting of *a priori* sample size is a necessary step for other researchers to determine if the study reached recruitment and retention goals and thus amply tested the proposed hypothesis.

It is not uncommon for trials to face challenges in relation to recruitment and retention. Recruiting adequate participants to randomized controlled trials requires coordinated efforts often involving outpatient oncology clinic providers, nurses, and staff to invite eligible cancer survivors to participate in ongoing trials. Research teams must engage willing clinics and often oversee data collection at multiple sites to recruit adequate numbers of participants in the timeframe set forth by the study. Other methods of recruitment include searching cancer registries for potential participants and sending letters, along with a wide variety of advertising through media outlets, including traditional television, radio, and print as well as online networks.

Beyond recruitment, retention of participants in trials, particularly those beyond 6-months, can be challenging. One factor that may influence retention is participant burden. This burden is not always well described in current literature, but potentially plays an instrumental role in the ability and likelihood of participation in research studies. Sources of burden to consider: frequency of measurements, travel and cost to attend intervention or clinic check-ins, time to adhere to intervention and change lifestyle, time to prepare food and measure for self-reported data, time to perform self-assessment (tracking food intake or steps), family time commitments, and family/friends not adhering to intervention (social burden). It is crucial that researchers report the reasons participants exit the study, thus providing key information to inform on balancing participant burden with research rigor in future research trials. Randomization to a perceived less favorable study assignment may also change a participant's interest and long-term engagement in a trial. Among the more common factors influencing study attrition are participant concerns such as the type of intervention (in-person or home-based), access to food resources, time constraints, family responsibilities, cost, and transport concerns.[13,15-17]

Finally, recruitment and retention may be influenced by reduced funding for study recruitment, retention and/or delivery of the intervention and follow-up measurements. Participant feedback plays an important role in helping advance methods of recruitment and retention into dietary interventions and yet, participant perspectives may be under studied in this regard.

Rationale and Objectives

Robust evaluations of dietary interventions to influence health after cancer are best tested using a randomized controlled trial design. In order to accurately test hypotheses, researchers must be able to recruit, enroll, and retain subjects' participation through completion of the trial. Importantly, interpretation of study findings requires that the details of recruitment and retention efforts be well-characterized in publications. To evaluate the quality of such reporting and to synthesize these data relative to future study design and methodology, we sought to examine the scientific literature for information on the recruitment and retention of cancer survivors into dietary intervention randomized controlled trials.

Specifically, the purpose of this systematic review is to describe recruitment and retention methods previously reported in published randomized controlled dietary intervention trials among four cancer survivor populations: breast, prostate, colorectal, and lung/ bronchus. Due to limited availability of lung and bronchus diet intervention trials and none meeting eligibility criteria, only breast, prostate, and colorectal cancer survivors were included in this systematic review. This review focused on accrual, attrition, and retention outcomes and the barriers that may affect recruitment and retention rates, and offers insight into approaches to enhance reporting and to promote optimal recruitment and retention in dietary trials among cancer survivors.

Aims

The aims of this systematic review were to 1) describe recruitment strategies and accrual of cancer survivors into dietary intervention randomized controlled trials and 2)

describe variable retention and attrition rates of cancer survivors enrolled in dietary intervention randomized controlled trials.

Chapter 2: Methods

Search Strategies

Data reported in this systematic review followed the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement guidelines.[18] The protocol was registered with PROSPERO International Prospective Register of systematic reviews Ref: CRD42018070396. PubMed, CINAHL, Cochrane Central Register of Controlled Trials, Embase, PsychINFO, and Web of Science databases were searched for relevant studies on June 17 and June 18, 2017. Search strategies were developed with assistance from a librarian and adapted for each database using standardized terminology. Key words or Medical Subject Heading (MeSH) terms used were "diet" or "nutrition" or "diet therapy" or "nutrition therapy" or "diet intervention" or "nutrition counseling" or "vegetarian" or "Mediterranean" AND "breast cancer" or "breast neoplasm" or "prostate cancer" or "prostate neoplasm" or "colorectal cancer" or "colorectal neoplasm" AND "human" or "patient" or "survivor" or "cancer survivor" or "participant" AND "recruit" or "recruitment" or "screen" or "eligible" or "ineligible" or "retain" or "retention" or "attrition" or "dropout" or "withdraw" AND "randomized controlled trial" or "randomized" or "controlled trial" or "controlled clinical trial" or "clinical controlled trial". Filters included human adults and peer-reviewed articles published 2002-2017 in English.

Eligibility Criteria

Eligible studies included adult (18+ years old) breast, prostate, colorectal, lung and bronchus cancer survivors. Other cancer types were allowed if one of the primary cancer types was included in the study. This systematic review includes dietary behavior change and weight loss intervention randomized controlled trials, pilot, and feasibility studies with at least 50 participants at time of randomization, at least 8 weeks of intervention, and at least 6 months of total expected participation. Outcomes investigated in this review include recruitment and retention methods and rates, which required the presence of a CONSORT

(CONsolidated Standards of Reporting Trials) flow diagram of participant engagement numbers. Trials still in active recruitment were ineligible.[19] The recruitment and retention methods were further analyzed by: study design, *a priori* sample size, cancer type, sex, age, methods of recruitment, number screened/eligible, time necessary for recruitment, intervention type and duration, mode of delivery, number of participants randomized, length of follow-up, number of participants retained, retention rate, and attrition rate.

Study Selection and Data Collection

Sarah Lavelle (SL) individually assessed title and abstracts of all identified studies. Articles that did not meet the inclusion criteria were excluded. Full-text articles were screened independently by two reviewers, SL and Tracy Crane (TC), the conflicting votes were resolved by a third reviewer Cynthia Thomson (CT). Data were extracted independently by SL and TC using a data extraction form developed by SL, TC and CT. SL screened the full-text articles and reference lists for protocol or design articles for the selected studies. Data collected from each study and/or protocol article included first author, corresponding author, title, publication year, country where study was conducted, study name, study design, cancer type and stage, *a priori* sample size, intervention type, mode of delivery, length of intervention and follow-up, methods of recruitment and retention, time necessary for recruitment, number recruited, number screened, number eligible, number randomized, and number retained. Retention rate was calculated as the percent of the number of participants who completed study follow-up divided by the number randomized. Attrition rate was calculated as the percent of the number of participant withdrawals divided by the number randomized.

Details not provided in the published manuscripts were requested from the corresponding authors. A standardized set of questions were developed and SL sent emails requesting select information. Questions were individually tailored to ask specifics regarding missing details of the recruitment and retention methodology utilized in the trial. Authors were given a timeline of two weeks to respond for inclusion in analysis.

Chapter 3: Results

Study Selection Results

Articles were identified through database searches (n=3,941) on June 17, 2017. References were imported into EndNote X8.2 and deduplication procedures were followed resulting in a total of 2,942 articles for title and abstract screening.[20] One hundred eighty-two full-text articles were screened, and after exclusion of articles based on *a priori* criteria, 22 studies were included for data analysis (Fig. 1). Three of the articles described the same study, and one article described two trials, resulting in a total of 20 study cohorts (Table 1). Protocol and design methodology publications found in the reference sections of included articles were evaluated for recruitment and retention detail lacking in study outcome papers. The 20 cohorts included Lifestyle changes for sedentary men with advanced PC on Long-term androgen deprivation therapy (ADT), Feasibility of lifestyle intervention in men with advanced PC on androgen suppression therapy (AST), North Carolina Strategies for Improving Diet, Exercise, and Screening (NC STRIDES), Harvest for Health (with two cohorts): Birmingham Breast Cancer Survivors (BBCS) study and Alabama Senior Cancer Survivors study (ASCS), Women's Intervention Nutrition Study (WINS), Survivor Training for Enhancing Total Health (STRENGTH), FRESH START, Exercise and Nutrition to Enhance Recovery and Good Health for You (ENERGY), Reach out to ENhancE Wellness in Older Cancer Survivors (RENEW), Lifestyle Intervention in Adjuvant Treatment of Early Breast Cancer (LISA), ¡Cocinar Para Su Salud! (¡CPSS!) – (Cook For Your Health!), Lifestyle, Exercise, and Nutrition (LEAN) Study, Kanker Nazorg Wijzer (Cancer Aftercare Guide), 6-mo Diet and Physical Activity Intervention for PC patients on ADT, Women's Healthy Eating and Living (WHEL) Study, Living Well after Breast Cancer™ Pilot Trial, Breast Cancer Recovery Project (BCRP), exercise and hypocaloric healthy eating program in early-stage BC, and Leading the way in exercise and diet (Project LEAD).[21-42]

Study and Participant Characteristics

All studies were randomized controlled trials with two employing a cross-over design at one year. One cohort included four study groups (arms), three cohorts included three study groups, and 16 cohorts included two study groups.[21-42] The majority of trials were conducted in breast cancer only (n=11; 55%), following with prostate cancer only (n=3; 15%), breast and prostate cancer only (n=2; 10%), all cancers including breast, prostate and colorectal (n=2; 10%), breast, prostate and colorectal only (n=1; 5%), and colorectal cancer cases and non-colorectal cancer controls (n=1; 5%).[21-42] Ten studies had between 46 and 100 participants randomized, 4 trials 101 to 500 participants, 4 trials between 501 and 1,000 participants, one trial with 2,437 participants and another with 3,088 participants.[21-42] Trials included adult participants with a mean age ranging from 41.8 years old to 73 years old.[21-42] Most trials combined diet and physical activity interventions (n=14; 70%), three trials focused on diet behaviors alone (15%), two trials conducted a gardening intervention to improve dietary behaviors (10%), and one trial included 3 arms comparing a diet intervention to a psychological education arm (5%).[21-42] Eleven of the studies involved only female cancer survivors (55%), with six having female and male participants (30%), and three trials including only men (15%).[21-42] Intervention length ranged from 12 weeks to 5 years.[21-42] Three trials conducted 12 week interventions, eight trials conducted interventions between 4 and 6 months, five trials conducted interventions between 10 and 12 months, and four trials conducted interventions between 2 and 5 years.[21-42] The length of follow-up ranged from 6 months to 7.3 years.[21-42] Eight trials conducted follow-up at 6 months, five trials at 12 months, and seven trials greater than 12 months.[21-42]

Nine studies used home-based intervention methods including tailored print materials, telephone calls, and tailored web-based counseling.[23,26,27,30-32,36,37,39,42] Eight studies used a combination of in-person and home-based interventions such as group sessions supplemented with telephone calls or individualized home gardening mentors supplemented with email or telephone contact.[21,22,24,25,28,29,35,38] Three trials focused

primarily on in-person counseling strategies and provided supervised exercise, dietary advice in group seminars, and cooking classes. [33,40,41]

Recruitment Results

All studies used at least one of the following recruitment methods: referring oncologists and nurses at outpatient clinics or cancer centers, or participants ascertained from cancer registries.[21-42] Eight studies used a variety of self-referral methods including media advertisements (radio, television, newspaper, electronic mail, flyers/brochures), community support programs, community events and organizations, or word of mouth.[22,24,27-31,35,41,43] Further detail on the number of trials using various methods of recruitment are shown in Figure 2.

This systematic review defined recruitment success as a trial that reached randomization of the *a priori* sample size accrual targets (Table 1). Twelve studies met accrual targets, five studies did not appear to meet accrual targets, one randomized, controlled feasibility study explored recruitment rates for future research, and recruitment goals were not identified in two studies.[21-42]

Of the trials that exceeded recruitment goals (n=4), multiple hospital or clinical center sites were employed to recruit participants.[27,35,36,38] The trial by Kanera et al., recruited 30.85% over accrual target of 376 participants.[36] Methods of recruitment in this study included medical staff of 21 participating hospitals assessing eligibility of patients during medical consultations or during review of patient files.[36] The largest trial, the WHEL study, recruited from seven cancer centers and research hospitals, and resulted in accrual above the target of 3,000 participants (n=3,088 randomized).[38] For the LEAN trial, Harrigan et al., was 11% over accrual target of 90 participants, and used a variety of methods of recruitment: five hospitals, cancer registry, and brochures at cancer clinics.[35]

However, recruitment methods were not successful in achieving accrual goals in other trials. In Project LEAD, recruitment by cancer registry resulted in 43.3% accrual of a

target of 420 participants.[42] The trial recruited older breast (57%) and prostate (43%) cancer survivors with an average age of 71.7 years-old, and used cancer registries with physician/oncologist permission.[42] Of 3,290 potential cases identified 2,431 had complete physician contact information, and 2,037 cancer cases were approved for contact by oncologists.[42] Those with a usable address (n=2,010) received a study invitation, consent and screening forms, and a prepaid envelope to return, with a follow-up reminder if forms were not received back within 4 weeks.[42] There were 1,232 non-responders, 90 declined to participate, and 688 consented to participate.[42] Five hundred and six respondents were found to be ineligible, with the remaining 182 eligible respondents enrolled and randomized to the intervention or attention control arm, well under the goal of 420 participants.[42]

Accrual attempts in other trials were halted due to loss of funding, with one trial at 15.7% of an accrual target set at 2,150 participants.[32] In this study, which consisted of long-term in-person dietitian counseling combined with an optional telephone counseling intervention in breast cancer patients, funding was lost for clinical centers and active dietary intervention at 97.4% of their accrual target (2,502 participants).[25] Of the 68,325 breast cancer cases assessed for eligibility, 3,029 declined participation, 62,859 did not meet inclusion criteria, and 2,437 were randomized.[25]

All three 12-week interventions were delivered in-person and met recruitment goals.[21,22,33] Among the seven trials of approximately 6-month intervention duration focused on diet and physical activity, six met recruitment goals.[26,35-37,39,41,42] Five trials had interventions of approximately 12 months, with three home-based telephone and print diet and exercise interventions, and two with a gardening intervention.[23,24,27,30,31] Of interventions approximately 12 months in length, three met recruitment goals, one did not meet their goal, and one trial did not appear to report an *a priori* sample size. [23,24,27,30,31] Both 2-year diet and physical activity interventions did not meet recruitment goals, one due to loss of funding.[28,29,32] The 4-year and 5-year duration trials focused on diet alone and used a combined intervention approach that included in-person and home-based delivery,

with accrual targets above 2,500 participants.[25,38] The WHEL study exceeded recruitment goals and WINS nearly reached its goal at 97.4% of the accrual target.[25,38]

The time necessary for recruitment ranged from 3 months with recruitment of the fewest participants (n=46) to approximately 7 years for one of the largest trials (n=2,437).[21-42] Trial recruitment time frames were as follows: three trials took between 3 and 12 months, six trials took between 1 and 2 years, three trials took between 2 and 3 years, two trials took between 3 and 4 years, three trials took between 5 and 7 years, and three trials did not identify the recruitment time frame.[21-42]

Retention Results

Eighteen studies were included in the retention analysis.[21-23,25-42] Ten studies focused on breast cancer; three studies were in prostate cancer survivors with 6-month follow-up; two studies combined breast and prostate cancer survivors with 12-month follow-up; two studies combined breast cancer, prostate cancer, and colorectal cancer survivors; and one study with colorectal cancer survivors and non-colorectal cancer controls.[21-23,25-42] Cumulative attrition (drop-out/withdrawal) rates among 8 trials averaged 18.6% at 6 months follow-up [range: 4.3% to 44%], 16.3% at 12-13 months [range: 4.4% to 44%, n=5], 20.3% at 2 years [range: 15.2% to 23.9%, n=3], 16.4% at 5 years [n=1], and 4.4% at 7 years [n=1](Figure 3). [21-23,25-42]

Eight studies provided retention data at 6-month follow-up. [21,22,26,33,34,36,37,39,41] Half of the studies investigated breast cancer survivors exclusively, with an average attrition rate of 13.0% % at 6 months [range: 8.9% to 17.8%].[26,33,34,39,41] The lowest attrition for breast cancer survivors at 6 months (8.9%) was found in the study with the youngest sample (mean age 41.8-years-old) included in this systematic review.[26] Participants were newly diagnosed early-stage patients scheduled for adjuvant chemotherapy.[26] The study employed telephone counseling and written instruction to promote dietary behavior change.[26] The higher attrition rate at 6-month follow-up (17.8%) was found among breast cancer survivors post-treatment, and approximately 16 months post-diagnosis in a

telephone delivered diet and physical activity weight loss trial.[39] All three prostate cancer survivor exclusive trials had follow-up periods of 6 months and attrition rates averaged 26.8% with a range of 4.3% to 44%.[21,22,37] O'Neill et al., provided a home-based telephone and individually tailored notebook intervention with an attrition rate of 4.3%.[37] Attrition of 32% and 44% resulted from two combined diet and physical activity programs with in-person supervised exercise, group nutrition seminars, and home-based dietary advice materials.[21,22] An individualized web-based counseling diet, exercise, and optional smoking cessation program delivered to all cancer types had an attrition rate of 16.9% at 6 months.[36]

Four studies completed follow-up through 12 months and one at 13 months.[23,27,35,40,42] Two of these trials combined breast and prostate cancer survivors with attrition rates of 4.4% to 12.1%.[27,42] FRESH START used home-based tailored print materials to promote eating behavior change in a sample of 543 cancer survivors with an attrition rate of 4.4%.[27] Project LEAD used a home-based tailored print and telephone counseling intervention among a sample of 65-86-year-old participants, with an attrition rate of 12.1%.[42] NC STRIDES investigated home-based tailored print communication (TPC), telephone motivational interviewing (TMI), or a combination TPC/TMI among colorectal cancer survivors and non-colorectal cancer survivors, with 10% attrition.[23] Scheier et al., studied in-person group sessions for early-stage breast cancer survivors who were on average 44.2-years-old and within 2 months post-treatment, and observed an 11.1% attrition rate.[40] A 3-arm 6-month intervention with a 12-month follow-up in breast cancer survivors tested in-person counseling versus home-based telephone counseling, and resulted in 15% attrition at 6 months and 44% attrition at 12 months.[35]

Three studies completed follow-up at 2 years with attrition rates ranging from 15.2% to 23.9%.[28-32] Despite not meeting expected attrition of 10%, breast cancer survivors in the ENERGY trial had the lowest attrition rate at 2 years follow-up (15.2%); during the in-person group-based diet and exercise weight loss trial, supplemented with telephone counseling and tailored newsletters.[28,29] Breast cancer survivors in a multi-center home-based telephone and print intervention trial demonstrated 21.9% attrition.[32]

RENEW had the oldest population (avg. 73-years-old) included in this systematic review with an attrition rate of 13.0% at 1 year, thus meeting expected target of 15% attrition at 1-year.[31] Following the 1-year telephone counseling and print material intervention, a cross-over was initiated and the delayed intervention arm received counseling. [30] Attrition at 2-year follow-up was 23.9%, with 26 participants randomized to the intervention group (9.7% of 1-year completers), and 44 participants from the delayed intervention (15.2% of 1-year completers) lost to follow-up.[30,31]

Both long-term trials met retention goals and studied combined in-person and home-based interventions in breast cancer survivors with follow-up at 5 years and 7.3 years, and attrition rates ranged from 4.4% to 16.4%.[25,38] A multicenter study of tapered in-person counseling with dietitian visits (option for home-based telephone calls every 3 months until trial completion) and optional monthly dietary group sessions, had 16.4% attrition at 5 years (anticipated up to 30% attrition).[25] The largest and longest trial included in this systematic review, the WHEL study, had 4.4% attrition at 7.3 years of follow-up, and used clinic-based cooking classes with home-based telephone calls and newsletters to promote behavior change.[38]

Trials that focused primarily on home-based telephone counseling and tailored print materials had attrition totals which ranged from 4.3% to 8.9% at 6 months, 12.1% to 13.0% at 12 months, and 21.9% to 23.9% at 24 months (Figure 4).[26,30-32,37,42] In trials with approximately 1 year or shorter follow-up periods, exclusively home-based trials had an average attrition rate of 10.6% [range: 4.3%-17.8%], exclusively in-person trials had an average attrition rate of 12.1% [range: 11.1%-13%], and combined in-person and home-based trials had a 40% average attrition rate [range: 32%-44%].[21-23,26,27,33,35-37,39-42] However, in trials with follow-up periods of 2 years or greater, average attrition rates were 12.0% in combined in-person and home-based interventions [range: 4.4%-16.4%].[25,28,29,38] Home-based calls with print materials reported average attrition rates of 22.9% for follow-up periods 2-years or greater [range: 21.9%-23.9%].[30-32]

Seven trials retained participants at an attrition rate that met *a priori* attrition goals, with an average attrition rate of 10.9% [range: 4.3% to 16.9%] over 6 months to 7.3 years of follow-up.[25,26,30,31,33,34,36-38] Three trials did not meet expected attrition targets set between 10% and 25% during 6- to 24-month follow-up; average attrition was 21.7% with a range of 15.2% to 32%.[21,28,29,39] One feasibility study investigated prostate cancer attrition at 6 months following a 12-week in-person and home-based intervention and demonstrated a 44% attrition at 6 months.[22] Attrition rates averaged 16.5% and ranged from 4.4% to 44% among the seven studies where no clearly defined attrition or retention goals were described.[23,27,32,35,40-42] No attrition goals were identified in any of the included trials with an estimated 12 months of follow-up; the average attrition rate was 16.3% [range from 4.4% to 44%].[23,27,35,40,42]

Chapter 4: Discussion and Conclusion

Summary of Evidence

This systematic review identified 22 publications representing 20 study cohorts that delivered dietary interventions in a randomized, controlled study design to cancer survivors. Overall, based on the available descriptions published or shared by authors through email survey, the majority of studies met recruitment goals and the majority reported attrition rates below 20%. Presented here are several factors that influenced recruitment and retention and thus inform upon the data interpretation for this systematic review. Noteworthy is the lack of detail in reporting recruitment and retention methodology across published studies, making it difficult to ascertain specific challenges, barriers or facilitators of recruitment and retention into cancer survival dietary interventions.

Reporting on the details of recruitment and retention was limited. Despite setting an eligibility criteria that required the inclusion of a study flow diagram, trials reviewed had inconsistencies in recruitment and retention enumeration. The CONSORT flow diagram was designed to address the inconsistencies across reported trials by providing a flow process detailing study participant numbers at each phase of randomized controlled trials.[19] The standardized figure includes four major sections: enrollment, allocation, follow-up, and analysis, with specific detail on reasons for exclusion/attrition at each phase of the trial.[19] However, 72% of completed trials in this review seemed to modify reporting in flow diagrams, either by not reporting reasons for withdrawal by study arm or not specifying the number analyzed in their results.[21-23,25,26,29,32,35,37,38,40-42] Continued efforts to standardize what is reported in flow diagrams is warranted, along with standardized data collection to assure that the necessary details to complete the CONSORT are available at study end, as these data are integral in relation to interpretation of research findings.

Recruitment Discussion

The results of this review demonstrated that 12 of 20 cohorts of cancer survivors met recruitment goals, with 5 not meeting their goal, 2 not specifying a target accrual, and 1 assessing recruitment feasibility.[21-42]

All trials used recruitment by provider referral from hospitals and clinics, and/or cancer registries.[21-42] Some trials combined self-referral methods such as media advertisements or flyers. Due to the combination of self-referral with one of the two primary methods of recruitment, the effectiveness of self-referral methods compared to hospitals and clinics and/or cancer registries remains unclear. The majority of trials that recruited through hospitals or clinics met their accrual goals. This indicates physician and nurse referrals may be effective in identifying eligible participants.

Five studies did not meet their recruitment goals with the majority running out of time for accrual or funding. Studies may unknowingly set unrealistic goals to achieve their recruitment targets. For large trials an extended recruitment timeline and funding may be necessary. Studies should also monitor recruitment progress, as this rate-limiting step in RCTs can result in an inadequate sample size to test hypotheses. If accrual rates are low changes can be made early on, such as incorporating additional self-referral methods.

Factors such as the mode of recruitment or the characteristics of the population may present unique challenges that reduce recruitment. Cancer registry recruitment of older or long-term cancer patients may require more protocol driven details to enhance recruitment successes and determine ways to address barriers. Demark-Wahnefried et al., describe the many steps and barriers to patient recruitment using cancer registries for older BC and PC survivors in Project LEAD (average age 71.7-years-old).[44] Tumor registries at medical centers in North Carolina were used to identify cancer survivors in one study.[44] North Carolina, like many other states, requires that physician permission is requested prior to contacting patients for research studies.[44] Physicians were given the option to give blanket approval for patient contact, approve on a case by case basis, or deny approval to

contact patients.[44] Depending on the provider, access to patients may be limited.[44] Further, a total of 3,290 potential participants were identified by tumor registries, but 26% (n=859) did not have complete contact information, thus making recruitment an impossibility.[42] Of the 2,431 cases with complete contact information, 16.2% (n=394) of cases were unapproved for contact by physician.[42] Cases received a mailed letter of invitation, consent and screening forms, preaddressed paid return envelope with a reminder postcard mailed after 4-weeks if no reply (n=2,037).[42] Of letters sent, 61% (n=1,232) were non-responders, 4% (n=90) refused, 1% (n=27) had an unusable address, and 34% (n=688) cases consented to participate.[42] Of the 688 cases consenting to participation, 74% (n=506) were ineligible, and 26% (n=182) eligible enrolled participants for randomization.[42] Expected enrollment of consenting participants was 35%, but only 26% were eligible.[42] Many participants were excluded for physical conditions that would interfere with intervention uptake, incompatible health conditions, and adherence to diet and physical activity recommendations.[42,44] This level of detail provides insight into the rate-limiting factors of recruiting by cancer registry in this population. As described, barriers to recruiting older cancer survivors by cancer registry include: lacking contact information, lacking physician consent to contact patients, non-responders to mailed invitations, and ineligible participants. Thus, cancer registries, while a viable option for recruitment, present unique challenges in identifying eligible participants and are not always as cost efficient as expected.

An additional trial notes challenges recruiting older cancer survivors to dietary interventions using cancer registries (average age 73-years-old).[30] The design and methodology publication for the RENEW trial describes the feasibility of accruing long-term cancer survivors and states that it "requires a considerable amount of personnel time and study resources".[45] In the trial, cancer registry ascertained cases totaled 67,054 individuals. Over 26,000 letters were sent to cancer registry ascertained cases, more than 2,100 provided a preliminary response, and more than 2,000 cases received an introductory telephone call.[45] Initial contact by telephone was estimated at "nine full time equivalent work weeks".[45] With the addition of 107 self-referred participants, 1,208 provided returned consent and screening forms, and 567 were deemed ineligible due to

medical issues or not meeting eligibility criteria.[45] This resulted in a final sample size of 641, with 56 from self-referral and 585 from the cancer registry.[30] Despite a large number of cancer registry ascertained cases, only a small percentage were able to be contacted, were eligible, and consented to participate. Key factors that influenced cancer registry recruitment were the lack of up-to-date contact information for physicians and cancer survivors.[45] For trials primarily recruiting older or long-term cancer survivors from tumor registries, provider and participant feedback may help researchers understand areas for improvement. Additional research into recruitment by cancer registries to standardize procedures and provide adequate contact information of participants and physicians is warranted.

Reports on participant engagement through trial completion by recruitment method used to enroll participants were limited. Snyder et al., published an article which describes baseline characteristics, adherence, outcomes and attrition of participants in the FRESH START trial.[46] Self-referred participants compared to those identified through the cancer registry were significantly younger, more likely to report a "fighting spirit" coping style, and had lower adherence to 5-A-Day fruit and vegetable recommendations at baseline.[46] No significant associations were found between the source of recruitment in terms of attrition or adherence to the intervention.[46] Studies that provide comparisons between methods of recruitment and outcomes also provide important information about the potential bias that may be introduced when participants self-refer and are willing to engage in programs to modify lifestyle behaviors. Future trials should consider publishing reports such as differential recruitment methods on participant outcomes among the FRESH START participants in order to inform on optimal recruitment strategies for lifestyle cancer survivor research in a broader context.[46] The accumulation of further research in this area can improve the collective understanding of successful recruitment methodologies among cancer survivors in dietary interventions.

Retention Discussion

Expected attrition (drop/withdrawal) targets were met by 7 studies, 3 studies did not meet their goal, and 7 studies did not provide a target attrition rate.[21-23,25-42] This systematic review provides average retention and attrition rates for dietary intervention trials among BC, PC, and CRC survivors for quantification of study retention success. Most importantly, attrition rates should not exceed *a priori* estimates as this would likely reduce the statistical power to test the proposed study hypotheses.

These data suggest that attrition rates varied widely across trials. One factor that may promote attrition in trials is the perceived participant burden in relation to length of follow-up and mode of intervention delivery. Among trials with 1 year or shorter follow-up, home-based only trials and in-person only trials had lower average attrition as compared to combined in-person and home-based trials, (10.6%, 12.1% vs. 40% respectively).[21-23,26,27,33,35-37,39-42] However, for trials with longer than 1 year follow-up, average attrition rates were lower in combined in-person and home-based interventions as compared to home-based alone, (12% vs. 22.9% respectively).[25,28-32,38] Home-based only or in-person only intervention delivery may benefit from shorter duration as trials of this nature have a "wear-out" quality. The potential flexibility of a combined intervention may be more congruent with longer term, sustained dietary behavior change. Longer trials also may benefit from engagement of in-person interaction to foster social support and accountability, thus keeping cancer survivors engaged long-term. Researchers need to take into consideration factors affecting perceived burden and benefit among study participants.

For retention and attrition rates, one of the key factors seems to be frequency of contact. Trials tend to have more contact in the beginning, and taper off or cease intervention contact before the final follow-up. Without contact after intervention delivery, trials appear to have higher attrition rates as compared to trials that maintain intervention contact until trial completion.[21,22,37] Among three prostate cancer survivor trials, studies that maintained contact until trial completion at 6 months had lower attrition rates of 4.3%

compared to trials that ended intervention contact at 12 weeks with 6 months of follow-up (attrition rates: 32% and 44%).[21,22,37] A trial in BC survivors with a 6-month intervention and 12-month follow-up, had 15% attrition at 6 months and 44% attrition at 12 months.[35] These data suggest that less frequent contact over time may increase attrition rates. Engaging participants until trial completion can pose a challenge, as resources and time available to deliver a dietary intervention are often limited. Data indicate that efforts to improve contact for retention purposes is relevant to reaching retention targets.

Cumulative attrition rates for BC survivors at 5 and 7 years were relatively low (16.4% and 4.4%, respectively).[25,38] However, these data represent single studies and therefore would require additional data from other studies in order to have a viable sample size to estimate average attrition rates.[25,38] Long-term dietary interventions should focus on including other cancer types such as prostate and colorectal cancer survivors.

Strengths and Limitations

Strengths of this systematic review include the rigor of the investigation focused on randomized controlled trials with at least 12 weeks of intervention delivery and 6 months of follow-up. The research has greater application having focused on commonly diagnosed cancers. The variance in study sample size, intervention length, mode of delivery, and length of follow-up provides evidence for recruitment and retention across multiple trial methods.

A number of limitations in the primary data for extraction and interpretation were identified through the systematic review process. For example, limited data were reported regarding specific retention strategies and expected retention rates across studies. Twelve studies were excluded for lacking a CONSORT diagram. Among trials that included CONSORT diagrams, many inconsistencies in reporting were identified. Six of eight trials that included self-referred participants, reported "self-referral" without further description as to how the individual was informed of the opportunity to participate in the study.[22,24,27,30,35,41] Media advertisements and other self-referral methods were combined

with other recruitment strategies, thus making it challenging to determine independent effects of these methods of recruitment.[35,41,43] More detail is necessary on self-referral strategies and their success. The authors of published articles with missing information on recruitment and retention methods, were sent standardized questions to gather additional detail. Twelve authors responded with information about their trials, but the level of overall detail was inadequate to analyze.

The majority of trials had approximately 12 months of follow-up or less, therefore evidence presented for trials longer than this timeframe is limited. The majority of trials included breast cancer survivors alone (n=10), and breast cancer survivors were included in 14 trials total. Breast cancer survivors were studied across all follow-up time points reviewed and had the two longest trials of 5 and 7 years in duration. Only three trials focused on prostate cancer survivors alone (although seven included PC), and three included colorectal cancer survivors. Prostate and colorectal cancer survivor interventions lasted 1-year maximum, with one trial conducting a cross-over intervention at 1 year with 24-month follow-up. Dietary trials among lung and bronchus cancer survivors were limited and none met the inclusion criteria for this review. More trials, with long-term interventions and follow-up are necessary, especially in prostate, colorectal, and lung/bronchus cancer survivors to provide robust evidence regarding recruitment and retention outcomes.

Recruitment and Retention Guidelines

Recruitment and retention in clinical trials has been studied broadly to improve the understanding of effective methods which can be used to influence subject participation. Organizations and published reviews provide general guidance for application across randomized controlled trials. The Cochrane Library has published two reviews which provide guidance on recruitment and retention methodology in randomized clinical trials.[47,48] The Cochrane Library review on recruitment identified 68 trials in the health care setting.[47] Trials with low recruitment using telephone reminders to participants not responding to mailed invitations as compared to no telephone reminder, had an estimated

6% absolute improvement in recruitment (Risk Difference: 6%, 95% CI 3% to 9%).[47] An open trial, where participants knew their group condition, as compared to a blinded placebo design had an absolute improvement of 10% recruitment (95% CI 7% to 13%).[47] This review suggested trials consider evaluating existing recruitment strategies to provide robust evidence for known methodologies, as opposed to developing new recruitment strategies.[47] As indicated in this systematic review, more detail on the strategies used to recruit subjects and the number accrued from these methods would allow for determining the effectiveness of various recruitment efforts.

The Cochrane Collaboration also reviewed the effects of retention strategies on the number of participants retained in 38 randomized trials.[48] For the return of mailed questionnaires, monetary incentives compared to no incentive improved retention (Risk ratio: 1.18, 95% CI 1.09 to 1.28, P-value <0.0001).[48] This review indicated a need for further research to determine the effects of various methods to enhance retention such as shorter questionnaires, prize drawings, or communication strategies.[48] The cost of monetary incentives may be a limiting factor, especially for trials with a large number of participants. Communication strategies for retention such as telephone calls, short message service (SMS) texts, electronic mail (e-mail) messages, social media posts, postcards, and newsletters may be more cost effective, while still engaging participants.

The Clinical Research Handbook, developed by the University of Washington's School of Medicine can be accessed through The Institute of Translational Health Sciences, and provides guidance for investigator-initiated clinical trials.[49] The handbook suggests documenting the effectiveness of recruitment strategies, in order to identify effective or ineffective methods throughout the recruitment process.[49] Overall, guidance provides evidence that records must be maintained throughout the research process to allow for adequate reporting of recruitment and retention efforts and success rates.

Strategies to Improve Recruitment and Retention

Qualitative work during study development and prior to study implementation can advance the knowledge of driving factors for recruitment and retention success. Participant feedback plays an important role in advancing methods to meet the needs of the cancer survivor population from a patient-centered approach. Details obtained through participant feedback could help inform on patterns of successful and unsuccessful recruitment and retention depending on different factors such as age, time since diagnosis and cancer type. Participant feedback can be gathered in the form of exit surveys or focus groups to investigate reasons participants remain involved and what aspects of study participation were found to be valuable or, alternately, disliked. It is possible that trials have collected participant data, but not reported it in their outcome papers. However, this information could help establish advanced understanding and data-driven protocols for trial recruitment and retention among the growing cancer survivor population.

Bourke and colleagues conducted focus groups after their feasibility study was completed to gather further insight into the experiences of PC survivors in their tapered exercise, nutrition education seminars, and print material intervention which lasted 12-weeks with 6-months of follow-up.[22,50] Focus group sessions were audio-taped, transcribed, and a thematic framework analysis was used to code for issues such as reason for participation, burden of assessments, and perceived benefits/problems.[50] Participants reported feeling motivated to participate in order to contribute to improved treatment for PC survivors.[50] This demonstrates that recruiting efforts might benefit from highlighting the relevance of the research study to the benefits of overall health for future patients with the disease. Participants reported that the group exercise sessions with people living with the same disease were helpful, and they would have liked to continue past the 12-week intervention.[50] While information provided for exercise and dietary changes at home were helpful, these goals were challenging for participants to adhere to.[50] Many men reported improved physical and psychological well-being after the study.[50]

Conclusion

This systematic review aimed to address the variable recruitment strategies and attrition rates among cancer survivors in randomized controlled dietary intervention trials. Based on present evidence, there is a need for published qualitative research to address gaps in recruitment and retention methodology reported in studies' primary outcome reports. Further efforts to improve standardization of CONSORT diagram reporting are warranted as many trials lack detail in reasons for withdrawal, which can provide insight into pitfalls of retention. Cancer registry recruitment of older long-term cancer survivors poses challenges in terms of up-to-date physician and participant contact information. Reporting and standardization of cancer registry procedures, along with updated contact information is necessary to improve outcomes for this recruitment method in this population. The data show that long term trials had better retention with combined in-person and home-based interactions to keep participants engaged. Short-term trials had better engagement with in-person only or home-based only interventions, which may provide more time to adapt dietary choices. Recruitment and retention strategies in dietary interventions among cancer survivors may be improved through the reporting of qualitative research that examines participant and health care provider feedback through focus groups or surveys. Future research should focus on standardization of what is required for published reports of dietary trials, particularly in relation to interpretation of findings for randomized controlled trials.

Table 1. Recruitment Strategies, Timeframe, and Effectiveness Across Dietary RCT in Cancer Survivors (n=20)

Study Lead, Year, Study Name, Country	Study Design, a priori sample size at randomization	Cancer type(s), Status	Mean age (SD), Age range, Sex	Methods of recruitment	Recruitment detail: screened to eligible	Time for accrual	Number randomized	Did Study Meet Recruitment (accrual) goal?
Bourke, 2014, Lifestyle changes for sedentary men with advanced PC on Long-term ADT, United Kingdom (England)	RCT, 2-arm, target accrual: randomize 100 men	PC, advanced locally advanced (n = 80) or metastatic (n = 20) prostate cancer	71-years old, range 53 to 87-years old, all male	Outpatient clinics	Unknown # screened, n=136 eligible	2008 to 2012 (5-years)	n=100 total: [n=50/group]	Yes: goal n=100, randomized n=100
Bourke, 2011, Feasibility of lifestyle intervention in men with advanced PC on AST, United Kingdom (England)	Pilot/feasibility study RCT, target accrual: assess for feasibility study	PC, Stage III-Stage IV (advanced), receiving androgen suppression therapy (AST), in treatment	72-years old, range 60 to 87-years old, all male	Nurse-led outpatient clinics (52%), requesting medical notes from medical folders (24%), other patients unknown method of recruitment	n=78 eligible and invited to study, n=58 responded and screened, n=50 eligible (recruitment rate of 64%)	Unknown	n=50 total: [n=25/group]	Goal to assess feasibility, result n=50
Campbell, 2009, NC STRIDES, United States (North Carolina)	RCT, 4-arm, case-control, 2x2 design, no goal identified	CRC and non-CRC, cancer survivors were about 2.5 years post-diagnosis of CRC, out of treatment	66.5-years old (9.95), 49% female and 51% male	Recruited from the North Carolina Colon Cancer Study (NCCCS) participants medical notes. Cases-North Carolina Central Cancer Registry. Controls-North Carolina Department of Motor Vehicles roster and those over age 65 came from the Health Care Financing Administration register	n=1,850 (38% cases, 62% controls) profiles assessed for eligibility, n=1,741 screened, n=922 respondents randomized (n=97 attrition post-randomization), n=825 eligible and completed baseline surveys	2001 to 2004 (4-years)	n=825 total: [n=207 TPC Only] vs. [n=208 TMI Only] vs. [n=204 TPC/MI] vs. [n=206 Control]	Goal unidentified, result n=825 completed baseline surveys
Cases, 2016, Harvest for Health, Birmingham Breast Cancer Survivors (BBCS), United States (Alabama)	BBCS: feasibility RCT, trial in progress, 2-arm, cross-over at 1-year, target accrual n=100 to build capacity of master gardeners in community setting to maintain long-term intervention	BBCS: female BC survivors, out of treatment	BBCS: 60.2-years old (11.1), 100% female	Self-referrals, UAB Cancer registry, consent forms were mailed to interested participants	BBCS: self-referred n=118, UAB Cancer registry of n=1,532 identified (n=1161 letters sent to cancer registry), n=194 positive respondents, n=82 eligible.	BBCS: August 2013 to May 2014 (10-months)	BBCS: n=82 total: [n=44 intervention] vs. [n=38 delayed intervention arm]	BBCS did not reach accrual target: goal n=100, result n=82, 82% of accrual target, reason: lack of time to recruit equal number of participants from surrounding 5 counties, many rural county participants were already gardening and ineligible
Cases, 2016, Harvest for Health, Alabama Senior Cancer Survivors study (ASCS), United States (Alabama)	ASCS: feasibility RCTs, trial in progress, 2-arm, target accrual n=46	ASCS: all cancers: BC (58.7%, n=27), PC (8.7%, n=4), CRC (4.3%, n=2) (28.3% various cancer types), out of treatment	ASCS: 70.3-years old (8.0), 70% female (n=32) and 30% male (n=14)	Self-referrals, UAB Cancer registry, consent forms were mailed to interested participants	ASCS: self-referred n=53, BBCS waitlist n=26, UAB Cancer registry n=710, referrals from other institutions' physicians n=82. Total letters mailed n=694 (of n=694 only n=620 total survivors to potentially contact with viable information), n= 117 positive respondents, n=46 enrolled and consented	ASCS: June 2014 to August 2014 (3-months)	ASCS: n=46 total: [n=24 intervention] vs. [n=22 delayed intervention arm]	ASCS yes: goal n=46, result n=46

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Study Lead, Year, Study Name, Country	Study Design, a priori sample size	Cancer type(s), Status	Mean age (SD), Age range, Sex	Methods of recruitment	Recruitment detail: screened to eligible	Time for accrual	Number randomized	Did Study Meet Recruitment (accrual) goal?
Chlebowski, 2006, WINS, United States	RCT, 2-arm, multicenter, target accrual of 2502 assuming 6 years accrual, and 3 years of follow-up after completion of accrual	BC, stage I-IIIA, resected breast cancer, in-treatment with conventional cancer management	Approximately 58.5-years old, range 43 to 73-years old, all female	39 clinical centers	Assessed for eligibility (n=68325) at 39 clinical centers, Excluded (n=65888): Not meeting inclusion criteria (n=62859), Declined participation (n=3029)	February 1994 to January 2001 (6-years and 11-months, approx. 7-years)	n=2,437 total: 40:60 intervention:control [n=975 intervention] vs. [n=1,462 control]. N=34 found to be ineligible, but included in analysis [n=12 intervention] vs. [n=22 control]	Did not reach accrual target: goal n=2,502 with 6-years of accrual, result n=2,437, 97.4% of accrual target, Reason: funding for active intervention an clinics ceased in May 2004, protocol-define follow-up period not finished
Demark-Wahnefried, 2008, STRENGTH, United States	Pilot/Feasibility study, RCT, 3-arm, target accrual n=30 per study arm	BC, stage I-IIIA, newly diagnosed BC, scheduled for adjuvant chemotherapy	41.8-years old (5.6), range 25 to 53-years old, all female	Identified through the Breast Oncology Clinic at Duke University Medical Center and sites affiliated with the Comprehensive Cancer Center of Wake Forest Community Clinical Oncology Program	60% recruited from Duke University Medical Center, 111 estimated eligible cancer cases	August 2001 to January 2004 (2-years and 6-months)	n=90 total: [n=29 Calcium-rich diet + exercise (CA + EX)] vs. [n=32 Calcium-rich diet + exercise + high FV, low-fat diet (CA + EX + FVLF)] vs. [n=29 Control group: Calcium-rich diet (CA)]	Yes for total participants, did not reach goal per study arm: goal n=30/study arm, result n=29, n=32, n=29 per study arm
Demark-Wahnefried, 2007, FRESH START, North America (United States and Canada)	RCT, 2-arm, target accrual n=530 total (n=265 per arm)	BC and PC, majority had had stage I or II cancers, out of treatment	57-years old (10.8), 56% female and 44% male	Self-referral, cancer registries, and large oncology practices throughout North America	2,155 breast and prostate cancer cases ascertained (343 self-referred + 1,812 cancer registry ascertained cases). Physicians approved contact of 1460 cases from cancer registry + 343 self-referred = 1,803 subjects approved for contact with mailed invitation and screening form. n=762 respondents (n=275 self-referred vs. n=487 registry). n=678 eligible after screening forms reviewed (n=265 self-referred vs. n=413 registry).	July 2002 to October 2005 (3-years and 4-months)	n=543 completed baseline surveys: [n=271 intervention] vs. [n=272 attention control	Yes: goal n=265/study arm, result n=271, n=272 per study arm
Demark-Wahnefried, 2012/ Morey, 2009, RENEW, United States (21 states), Canada, and the United Kingdom (2 year outcomes)	RCT, 2-arm, with cross-over design at 1-year, target accrual n=640	BC (n=221; 45%), PC (n=193; 40%), CRC (n=74; 15%), 8.6-years since diagnosis, out of treatment	73-years old, range 65 to 87-years old, 55% female (n=270) and 45% male (n=218)	Self-referred participants and those ascertained from the North Carolina Central Cancer Registry	Self-referred patients verified by oncology care physician (n=107) + Patients received from cancer registries (n=67,054), cancer registry excluded total: (n=47,146), Patients receiving a mailed study invitation (n=20,015 n=2,529 responded (12.64% response rate), n=641 eligible	Unknown	n=641 total: [n=319 immediate intervention arm] vs. [n=322 delayed intervention control arm] (n=56 self-referred vs. n=585 cancer registries)	Yes: goal n=640, result n=641

Table 1. Recruitment Strategies, Timeframe, and Effectiveness Across Dietary RCT in Cancer Survivors (n=20)

Study Lead, Year, Study Name, Country	Study Design	Cancer type(s)/Status	Mean age (SD), Age range, Sex	Methods of recruitment	Recruitment detail: screened tp eligible	Time for accrual	Number randomized	Did Study Meet Recruitment (accrual) goal?
Goodwin, 2014, LISA, Canada and United States	RCT, 2-arm, multicenter, target accrual n= 2,150	BC, stage I-III, approximately 9-months since diagnosis, approximately 30% received mastectomy, 57% received adjuvant chemotherapy, 78% received radiation therapy	60.9-years old, all female	Cancer institutes, medical centers, hospitals in America and Canada	Identified patients with potential contact (n=682) [not approached (n=15) + did not consent (n=121)] consented (n=546), met exclusion criteria (n = 208)	May 2007 to January 2010 (2-years and 9-months)	n=338 randomized: [n=171 received intervention - (n=2 never received call)] vs. [n=167 mail-based control - (n=1 accidentall received intervention)]	Did not meet accrual target: goal n=2,150, result n=338, 15.72% of target accrual, reason: loss of funding
Greenlee, 2015/Bernard Davila ,2015, Cocinar Para Su Salud, United States	RCT, 2-arm, target accrual n=70	BC, stage 0-III, average time since diagnosis was 3.4 years (range: 0.3–15.6 years), at least 3-months post-treatmen	56.6-years old (9.7), all female	Clinical centers, Columbia University Medical Center (CUMC) Breast Oncology Clinic	n=405 identified as potentially eligible [n=142 refused to participate, n=37 unable to contact], n=111 consented, n=102 eligible after screening	January 2011 to March 2012 (1-year and 3-months)	n=70 total randomized: [n=34 intervention] vs. [n=36 control]	Yes: goal n=70, result n=70
Harrigan, 2016, LEAN, United States	RCT, 3-arm, target accrual: n=30 per study arm	BC, stage 0-III (51% stage I), diagnosed in 5 years before enrollment, completed chemo and/or radiatio at least 3 months before enrollment, out of treatment	59-years old (7.5), all female	Cancer Registry at 5 hospital sites in Connecticut through Yale Cancer Center, self-referred from study brochures posted at Breast Center at Smilow Cancer Hospital at Yale-New Haven and the Yale Cancer Center Survivorship Clinic	n=825 screened via telephone (with n=744 recruited via the tumor registry, n=44 self-referred and n=37 recruited via physician referrals), n=396 eligible (25% of eligible women were randomized n=100)	June 1, 2011 to December 30, 2012 (1 year and 7-months)	n=100 were randomized: [n=33 in-person weight loss counseling] vs. [n=34 telephone weight loss counseling] vs. [n=33 usual care group]	Yes: goal n=30/study arm, result n=33, n=34, n=33 per study arm
Kanera, 2016, Cancer Aftercare Guide, Netherlands	RCT, 2-arm, target accrual n= 376 (n=188 per study condition)	Any cancer type including BC, PC, and CRC, completed primary treatment (surgery, chemotherapy, or radiation therapy) between 4-weeks to 56 weeks prior to enrollment	55.9-years old (11.4), 80% female (n=369) and 20% male (n=93)	Medical staff of 21 Dutch hospitals and various outpatient clinics assessed eligibility by reviewing patient files or during medical consultations. 45 hospitals approached with 22 agreeing to participate	n=1,303 assessed for eligibility, n=518 randomized before screening [control n=253 vs intervention n=265], n=26 did not complete baseline assessments	November 2013 to June 2014 (8-months)	n=492 total completed baseline measures: [n=252 intervention] vs. [n=240 control]	Yes: goal n=376 (n=188/study arm), result n=492 (n=240, n=252 per study arm) 30.85% over accrual target

Table 1. Recruitment Strategies, Timeframe, and Effectiveness Across Dietary RCT in Cancer Survivors (n=20)

Study Lead, Year, Study Name, Country	Study Design	Cancer type(s)/Status	Mean age (SD), Age range, Sex	Methods of recruitment	Recruitment detail: screened tp eligible	Time for accrual	Number randomized	Did Study Meet Recruitment (accrual) goal?
O'Neill, 2015, 6-mo Diet/PA Intervention for PC patients on ADT, United Kingdom (Northern Ireland)	RCT, 2-arm, target accrual n=47 per study arm	PC, 15.5-months since diagnosis, range 7 to 57-months since diagnosis, patients on ADT treatment	69.8-years old (6.9), all male	Northern Ireland Cancer Centre	n=158 patients met the inclusion criteria and were invited to participate. Declined (n=64): not interested (50%), feeling unwell (18.8%), distance/no transport (15.6%), healthy enough already (7.8%), no time (7.8%)	August 20, 2009 to March 15, 2011 (1-year and 7-months)	n=94 total: [n=47/group]	Yes: goal n=47/study arm, result n=47/stud arm
Pierce, 2007, WHEL, United States	RCT, 2-arm, multi-institutional, target accrual n=3000	BC, stage II or stage IIIA, complete with initial local treatment, diagnosed within the past 4 years	53.2-years old (9), all female	7 clinical sites, university cancer centers or research hospitals	n=7,572 potential participants screened by telephone: (n=3,664, 48% community outreach) + (n=2,805, 37% response to letters from cancer registry) + (n=1,103, 15% physician referral), n=3,479 eligible, n=3,107 were randomize	1995 to 2000 (6-years)	n=3,088 received intervention/control condition: [n=1,537 intervention] vs [n=1,551 comparison group]	Yes: goal n=3,000, result n=3,088, 2.9% over accrual target (n=88)
Reeves, 2017, Living Well after Breast CancerTM, Australia	Pilot/feasibility study, RCT, 2-arm, target accrual n=45 per study arm	BC, stage I–III, 15.9 (SD 2.9) months post diagnosis, 86.7% >6 months post-treatmen 73.3% taking endocrine therapy	55.3-years old (8.7), All female	State-based cancer registry, with oncologist permission to contact	n=927 identified from Queensland Cancer Registry & Oncologists sent letters for consent, n=743 oncologist consent & letter sent to patient, n=248 patient consent to contact, n=213 patients telephoned to assess eligibility and gain consent	October 2010 to February 2012 (1-year and 5-months)	n=90 total: [n=45 intervention] vs. [n=45 control]	Yes: goal n=45/study arm, result n=45/ study arm
Rock/Demark-Wahnefried, 2015, ENERGY, United States	RCT, 2-arm, target accrual n=800 with approx. 400 participants per arm	BC, stage I-III, approximately 2.5-years since primary treatment, out of treatment	56-years old (9), all female	Local or regional cancer registries at 4 university study sites "clinics, television and radio media coverage, local prin media, and community support groups, events and organizations, such as local chapters of the Susan G. Komen Foundation. Electronic announcements of the study were sent to the subscribers to the Army of Women (www.armyofwomen.org), a no profit breast cancer organizatio which serves as a recruitment source to researchers"	Tumor registry or oncology refer letters sent (n=11,311) + Flyers distributed (n=2,740), Telephone contacts or record review (n=7,501), Breast cancer cases screened (n=5,027), Baseline visits completed (n=714), Randomly allocated (n=697): [Intervention group (n = 348): Excluded post-randomization (n = 4), Received allocated interventio (n = 344)] vs. [Control group (n = 349): Excluded post-randomization (n = 1), Received allocated control (n = 348)]	Fall 2010 to May 2012 (approx. 1-year and 6-months)	n=692 received allocated condition: [n=344 intervention] vs. [n=348 control]	Did not reach accrual target: goal n=800 approximately n=400/study arm, result n= 692 received allocated intervention (n=344, n=348 per study arm), 86.5% of accrual target for number who received allocated condition, reason: time and budget

Table 1. Recruitment Strategies, Timeframe, and Effectiveness Across Dietary RCT in Cancer Survivors (n=20)								
Study Lead, Year, Study Name, Country	Study Design	Cancer type(s)/Status	Mean age (SD), Age range, Sex	Methods of recruitment	Recruitment detail: screened to eligible	Time for accrual	Number randomized	Did Study Meet Recruitment (accrual) goal?
Scheier, 2007, Breast Cancer Recovery Project (BCRP), United States	RCT 3-arm, no specific recruitment goal identified	BC, early stage 0-II, within 2 months of having completed active non-hormonal adjuvant therapy	44.2-years old, all aged younger than 51 years old, all female	Nurse referrals from hospital medical oncology clinics and physician offices	n=463 nurse referrals from hospital medical oncology clinics and physician offices, n=463 contacted by telephone, screened for eligibility, n=325 eligible women, n=272 (78%) of eligible participants agreed to participate	Unknown	n=252 total: [n=85 nutrition arm] vs. [n=83 education/information arm] vs. [n=84 control]	Goal unidentified, result n=252, authors report sample size retained 99% power to identify a moderate effect size with alpha 0.05
Scott, 2013, exercise and hypocaloric healthy eating program in early-stage BC, United Kingdom (England)	RCT, 2-arm, target accrual n=90 total (n=45 in each study arm)	BC, early stage I-III, treated 3-18 months before randomization	55.7-years old (9.5), range 36 to 77-years old, all female	Cancer Clinical Trials Centre at Weston Park Hospital, local cancer support services, local media press coverage, flyers in hospitals, or word of mouth	Sent recruitment letter (n=523) + enquiries from other sources (n=86): local press coverage (n=32), local cancer support services (n=23), flyers in hospitals (n=19), word of mouth (n=12); n=152 responded to recruitment letter	Trial registry website: October 1, 2005 to September 30, 2007 (2-years)	n=90 randomized total: [n=47 intervention] vs. [n=43 control group]	Yes for total participants, did not meet goal per study arm: goal n=90 (n=45/study arm), result n=90 (n=47, n=43 per study arm)
Snyder, 2007, LEAD, United States (North Carolina)	RCT, 2-arm, target accrual of n=420	BC (57% n=104) and PC (43% n=78), within 18 months of diagnosis with loco-regional prostate or female breast cancer	71.7-years old (5), range 65 to 91-years old, 57% female (n=104) and 43% male (n=78)	Cancer registries in 5 North Carolina medical centers, requiring permission from oncologist	n=3,290 prostate and breast cancer patients were identified by cancer registries, n=2,037 cases approved for contact by oncology care physicians, n=688 consenting to participate after screening by mail, n=182 enrolled eligible study participants	August 2000 through May 2003 (2-years and 10-months)	n=182 total: [n=89 intervention] vs. [n=93 attention control]	Did not meet accrual target: goal n=420, result n=182, reason: overestimated response rate, and percent eligible (only 26% of 688 cases consenting to participate were eligible for this trial), time and funding constraints

Table 2. Retention Rates, Attrition Rates, and Intervention Characteristics in Dietary RCT in Cancer Survivors (n=20)

Study Lead, Year, Study N Country	Cancer type(s), Status	Mean age (SD), A range, Sex	Intervention typ and duration	Mode of delivery	Number randomized	Length of foll up	Number retained	Retention and attrition (drop-o rates by time poi	Did study meet retention goal, b on attrition rate?
Bourke, 2014, Lifestyle c for sedentary men with advanced PC on Long-ter United Kingdom (Englan	PC, advanced locally advanced (n = 80) or metastatic (n = 20) pro cancer	71-years old, ran 53 to 87-years o male	Diet and physica activity (PA), 12 weeks	In-person: tapered supervised exercise, i person community-ba dietary advice given th small group seminars, home-based: nutrition packets	n=100 total: [n=50/group]	12-weeks, 6-months	12-weeks n=85 total: [n=43 intervention] vs. [n=42 control]. 6-months n=68 total: [n=35 intervention] vs. [n=33 control]	12-weeks: 85% retained, 15% attrition. 6-months: 68% retained, 32% attrition	Did not meet retention goal: expected 25% attrition at 6-mo
Bourke, 2011, Feasibility lifestyle intervention in n with advanced PC on AST United Kingdom (Englan	PC, Stage III-Stage IV (advanced), receiving androgen suppression therapy (AST), in treat	72-years old, ran 60 to 87-years o male	Diet and PA, 12-weeks	In-person: tapered supervised exercise, i person community-ba group nutrition semin and home-based: individualized dietary pack and self-directed exercise	n=50 total: [n=25/group]	12-weeks, 6-months	12-weeks n=43 total: [n=21 intervention] vs. [n=22 control]. 6-months n=28 total: [n=15 intervention] vs. [n=13 control]	12-weeks: 86% retained, 14% attrition. 6-months: 56% retained, 44% attrition	Goal: assess feasibility at 6-months
Campbell, 2009, NC STRI United States (North Car	CRC and non-CRC, canc survivors were about 2 years post-diagnosis o out of treatment	66.5-years old (9 49% female and male	Diet and PA, 1-y	3 interventions, Home based: mail and/or telephone: tailored pri communication (TPC), telephone-based motivational interview (TMI), or combination TMI/TPC	n=825 total: [n=207 TPC Only] vs. [n=208 TMI Only] vs. [n=204 TPC/MI] vs. [n=206 Control]	1-year	1-year n=735 total: [n=181 TPC Only] vs. [n=185 TMI Only] vs. [n=181 TPC/MI] vs. [n=188 control]	1-year: 89.09% retained, 10.91% attrition	No specific goal identified
Cases, 2016, Harvest for Birmingham Breast Canc Survivors (BBCS), United (Alabama)	BBCS: female BC surviv out of treatment	BBCS: 60.2-years (11.1), 100% fem	Other: gardenin promote diet an , 1 year interven with cross-over delayed interven during year two	Home-based and in-pe visits by Master Garde and home-based: telephone/email cont	BBCS: n=82 total: [n=44 intervention] vs. [n=38 delayed interventi	BBCS: cross-over at 1-yea years follow-	N/A In progress	N/A trial in progress	N/A trial in prog
Cases, 2016, Harvest for Alabama Senior Cancer Survivors study (ASCS), U States (Alabama)	ASCS: all cancers: BC (n=27), PC (8.7%, n=4), (4.3%, n=2) (28.3% va cancer types), out of treatment	ASCS: 70.3-years (8.0), 70% femal (n=32) and 30% (n=14)	Other: gardenin promote diet an , 1 year interven with control gro receiving intervention at year with no foll up	Home-based and in-pe visits by Master Garde and home-based: telephone/email cont	ASCS: n=46 total: [n=24 intervention] vs. [n=22 delayed interventi	ASCS: 1-year	N/A In progress	N/A trial in progress	N/A trial in prog

Table 2. Retention Rates, Attrition Rates, and Intervention Characteristics in Dietary RCT in Cancer Survivors (n=20)

Study Lead, Year, Study Name, Country	Cancer type(s), Status	Mean age (SD), Age range, Sex	Intervention type and duration	Mode of delivery	Number randomized	Length of follow-up	Number retained	Retention and attrition (drop-out) rates by time point	Did study meet retention goal, based on attrition rate?
Chlebowski, 2006, WINS, United States	BC, stage I-IIIA, resected breast cancer, in-treatment with conventional cancer management	Approximately 58.5-years old, range 43 to 73-years old, all female	Diet, median of 60-months (5-years)	In-person: counseling sessions (8 visits, bi-weekly up to 4-months), optional visits in-person or home-based (calls): dietician counseling (every 3-months, 5-months through 5-years), and optional in-person community-based: monthly dietary group sessions	n=2,437 total: 40:60 intervention:control [n=975 intervention] vs. [n=1,462 control]. N=34 found to be ineligible, but included in analysis [n=12 intervention] vs. [n=22 control]	Median follow-up of 60-months (5-years)	5-years (60-months) n=2,038 total: [n=753 intervention] vs. [n=1,285 control]	5-years: 83.63% retained, 16.37% attrition (approx 7-years of accrual)	Yes: expected 30% attrition with 6-years of accrual and 3-years of follow-up after accrual completion
Demark-Wahnefried, 2008, STRENGTH, United States	BC, stage I-IIIA, newly diagnosed BC, scheduled for adjuvant chemotherapy	41.8-years old (5.6), range 25 to 53-years old, all female	Diet and PA, 5-months	Home-based: telephone counseling and print materials	n=90 total: [n=29 Calcium-rich diet + exercise (CA + EX)] vs. [n=32 Calcium-rich diet + exercise + high FV, low-fat diet (CA + EX + FVLF)] vs. [n=29 Control group: Calcium-rich diet (CA)]	6-months	6-months n=82 total: [n=26 CA+EX] vs. [n=29 CA + EX + FVLF] vs. [n=27 control: CA]	6-months: 91.11% retained, 8.89% attrition	Yes: expected <20% attrition a 6-months
Demark-Wahnefried, 2007, FRESH START, North America (United States and Canada)	BC and PC, majority had had stage I or II cancers, out of treatment	57-years old (10.8), 56% female and 44% male	Diet and PA, 10-months	Home-based: tailored mailed print materials	n=543 completed baseline surveys: [n=271 intervention] vs. [n=272 attention control	1-year	1-year n=519 total: [n=253 intervention] vs. [n=266 control] Retention by recruitment method: [self-referred n=199: (98 invention, 101 control)] vs. [registry ascertained n=320: (155 intervention, 165 control)]	1-year: 95.58% retained, 4.42% attrition	No specific goal identified, intention to trea analysis
Demark-Wahnefried, 2012/ Morey, 2009, RENEW, United States (21 states), Canada, and the United Kingdom (2 year outcomes)	BC (n=221; 45%), PC (n=193; 40%), CRC (n=74; 15%), 8.6-years since diagnosis, out of treatment	73-years old, range 65 to 87-years old, 55% female (n=270) and 45% male (n=218)	Diet and PA, 1-year and then switch for cross-over	Home-based: telephone counseling and mailed-print materials	n=641 total: [n=319 immediate intervention arm] vs. [n=322 delayed intervention control arm] (n=56 self-referred vs. n=585 cancer registries)	1-year, 2-years	1-year n=558 total: [n=269 intervention] vs. [n=289 delayed intervention]. 2-years n=488 total: [n=243 intervention (observation period)] vs. [n=245 delayed interventio	1-year: 87.05% retained, 12.95% attrition. 2-years: 76.13% retained, 23.87% attrition	Yes: expected 15% attrition at year

Table 2. Retention Rates, Attrition Rates, and Intervention Characteristics in Dietary RCT in Cancer Survivors (n=20)

Study Lead, Year, Study Name, Country	Cancer type(s)/Status	Mean age (SD), Age range, Sex	Intervention type and duration	Mode of delivery	Number randomized	Length of follow-up	Retention: completed	Retention and attrition (drop-out) rates by time point	Did study meet retention goal, based on attrition rate?
Goodwin, 2014, LISA, Canada and United States	BC, stage I-III, approximately 9-months since diagnosis, approximately 30% received mastectomy, 57% received adjuvant chemotherapy, 78% received radiation therapy	60.9-years old, all female	Diet and PA, 2-years	Home-based: intervention-telephone calls, both study arms received mail-based materials	n=338 randomized: [n=171 received intervention - (n=2 never received call)] vs. [n=167 mail-based control - (n=1 accidentally received intervention)]	6-months, 1-year, 18-months, 2-years	6-months n=316 total: [n=161 intervention] vs. [n=155 control]. 1-year n=289 total: [n=142 intervention] vs. [n=147 control]. 18-months n=279 total: [n=135 intervention] vs. [n=144 control]. 2-years n=264 total: [n=133 intervention] vs. [n=131 control]	6-months: 93.49% retained, 6.51% attrition. 1-year: 85.5% retained, 14.5% attrition. 18-months: 82.54% retained, 17.46% attrition. 24-months: 78.11% retained, 21.89% attrition	No specific goal identified
Greenlee, 2015/Bernard-Davila ,2015, Cocinar Para Su Salud, United States	BC, stage 0-III, average time since diagnosis was 3.4 years (range: 0.3–15.6 years), at least 3-months post-treatmen	56.6-years old (9.7), all female	Culturally-based Diet only intervention (no PA or weight loss), 12-weeks	In-person community based: culturally-based group cooking classes, grocery shopping field trip, nutrition education	n=70 total randomized: [n=34 intervention] vs. [n=36 control]	6-months data described here, 1-year analysis to follow	3-months n=67 total: [n=31 intervention] vs. [n=36 control]. 6-months n=61 total: [n=30 intervention] vs. [n=31 control]	3-months: 95.71% retained, 4.29% attrition. 6-months: 87.14% retained, 12.86% attrition	Yes: expected 15% attrition at months
Harrigan, 2016, LEAN, United States	BC, stage 0-III (51% stage I), diagnosed in 5 years before enrollment, completed chemo and/or radiatio at least 3 months before enrollment, out of treatment	59-years old (7.5), all female	Diet and PA, 6-months	2 interventions, in-person: counseling vs. home-based: telephone counseling	n=100 were randomized: [n=33 in-person weight loss counseling] vs. [n=34 telephone weight loss counseling] vs. [n=33 usual care group]	Primary outcome at 6-months, 1-year follow-up	6-months n=85 total: [n=30 in-person] vs. [n=24 telephone] vs. [n=31 usual care]. 12-months n=56 total: [n=22 in-person] vs. [n=15 telephone] vs. [n=19 usual care]	6-months: 85% retained, 15% attrition. 12-months: 56% retained, 44% attrition	No specific goal identified, intention to trea analysis
Kanera, 2016, Cancer Aftercare Guide, Netherlands	Any cancer type including BC, PC, and CRC, completed primary treatment (surgery, chemotherapy, or radiation therapy) between 4-weeks to 56 weeks prior to enrollment	55.9-years old (11.4), 80% female (n=369) and 20% male (n=93)	Diet, PA, and smoking cessation, 6-months	Home-based: tailored web-based counseling	n=492 total completed baseline measures: [n=252 intervention] vs. [n=240 control]	6-months	6-months n=409 total: [n=188 intervention] vs. [n=221 control]	6-months: 83.13% retained, 16.87% attrition	Yes: expected 20-23% attrition at 6-months

Table 2. Retention Rates, Attrition Rates, and Intervention Characteristics in Dietary RCT in Cancer Survivors (n=20)

Study Lead, Year, Study Name, Country	Cancer type(s)/Status	Mean age (SD), Age range, Sex	Intervention type and duration	Mode of delivery	Number randomized	Length of follow-up	Retention: completed	Retention and attrition (drop-out) rates by time point	Did study meet retention goal, based on attrition rate?
O'Neill, 2015, 6-mo Diet/PA Intervention for PC patients on ADT, United Kingdom (Northern Ireland)	PC, 15.5-months since diagnosis, range 7 to 57-months since diagnosis, patients on ADT treatment	69.8-years old (6.9), all male	Diet and PA, 6-months	Home-based: telephone counseling, with individually tailored diet notebook self-directed walking with self-monitoring b pedometer, involved partner or caregiver if possible	n=94 total: [n=47/group]	6-months	3-months n=91 total: [n=45 intervention] vs. [n=46 control]. 6-months n=90 total: [n=45 intervention] vs. [n=45 control]	3-months: 96.81% retained, 3.19% attrition. 6-months: 95.74% retained, 4.26% attrition	Yes: expected 30% attrition at months
Pierce, 2007, WHEL, United States	BC, stage II or stage IIIA, complete with initial local treatment, diagnosed within the past 4 years	53.2-years old (9), all female	Diet, 4-years	Intervention: in-perso community-based: cooking classes and home-based: telephone calls and newsletters vs. control: in-person: limited cooking classes and home-based: general newsletters	n=3,088 received intervention/control condition: [n=1,537 intervention] vs [n=1,551 comparison group]	7.3-years, status at end of study (June 1, 2006)	7.3-years n=2,953 vital status confirmed total: [n=1,465 vital status confirmed in intervention (n=1,471 breast cancer status confirmed)] vs. [n=1,488 vital status confirmed in control (n=1,500 breast cancer status confirmed)]	7.3-years vital status: 95.63% retained, 4.37% attrition	Yes: expected 30% recurrence over 6-years with up to 3% attrition per yea
Reeves, 2017, Living Well after Breast CancerTM, Australia	BC, stage I–III, 15.9 (SD 2.9) months post diagnosis, 86.7% >6 months post-treatment 73.3% taking endocrine therapy	55.3-years old (8.7), All female	Diet and PA (weight loss), 6-months	Home-based: telephone counseling	n=90 total: [n=45 intervention] vs. [n=45 control]	6-months	6-months n=74 total: [n=40 intervention] vs. [n=34 control]	6-months: 82.22% retention, 17.78% attrition	Did not meet retention goal: expected 10% attrition at 6-months
Rock/Demark-Wahnefried, 2015, ENERGY, United States	BC, stage I-III, approximately 2.5-years since primary treatment, out of treatment	56-years old (9), all female	Diet and PA (weight loss), 2-years	In-person community-based: group sessions and home-based: telephone counseling and tailored newsletters	n=692 received allocated condition: [n=344 intervention] vs. [n=348 control]	2-years	2-years n=587 total: [n=300 intervention] vs. [n=287 control]	2-years: 84.83% retained, 15.17% attrition	Did not meet retention goal: expected 10% attrition at 2-years

Table 2. Retention Rates, Attrition Rates, and Intervention Characteristics in Dietary RCT in Cancer Survivors (n=20)

Study Lead, Year, Study Name, Country	Cancer type(s)/Status	Mean age (SD), Age range, Sex	Intervention type and duration	Mode of delivery	Number randomized	Length of follow-up	Retention: completed	Retention and attrition (drop-out) rates by time point	Did study meet retention goal, based on attrition rate?
Scheier, 2007, Breast Cancer Recovery Project (BCRP), United States	BC, early stage 0-II, within 2 months of having completed active non-hormonal adjuvant therapy	44.2-years old, all aged younger than 51 years old, all female	Diet vs. psychological education arm, 4-months	In-person community-based: group sessions for intervention and education arms	n=252 total: [n=85 nutrition arm] vs. [n=83 education arm] vs. [n=84 control]	13-months	13-months n=224 total: [n=78 nutrition arm] vs. [n=70 education arm] vs. [n=76 control]	13-months: 88.89% retained, 11.11% attrition	No specific goal identified
Scott, 2013, exercise and hypocaloric healthy eating program in early-stage BC, United Kingdom (England)	BC, early stage I-III, treated 3-18 months before randomization	55.7-years old (9.5), range 36 to 77-years old, all female	Diet and PA, 6-months	In-person: supervised exercise, individualized dietary advice and weekly group nutrition seminars	n=90 randomized total: [n=47 intervention] vs. [n=43 control group]	6-months	6-months n=79 total: [n=41 intervention] vs. [n=38 control]	6-months: 87.78% retained, 12.22% attrition	No specific goal identified, intention to treat analysis
Snyder, 2007, LEAD, United States (North Carolina)	BC (57% n=104) and PC (43% n=78), within 18 months of diagnosis with loco-regional prostate or female breast cancer	71.7-years old (5), range 65 to 91-years old, 57% female (n=104) and 43% male (n=78)	Diet and PA, 6-months	Home-based: telephone counseling and tailored print materials	n=182 total: [n=89 intervention] vs. [n=93 attention control]	6-months, 1-year	6-months n=168 total. 12-month n=160 total. No further detail by study group	6-months: 92.3% retained, 7.7% attrition. 1-year: 87.9% retained, 12.1% attrition	No specific goal identified, intention to treat analysis

Figure 1. PRISMA Flow Diagram

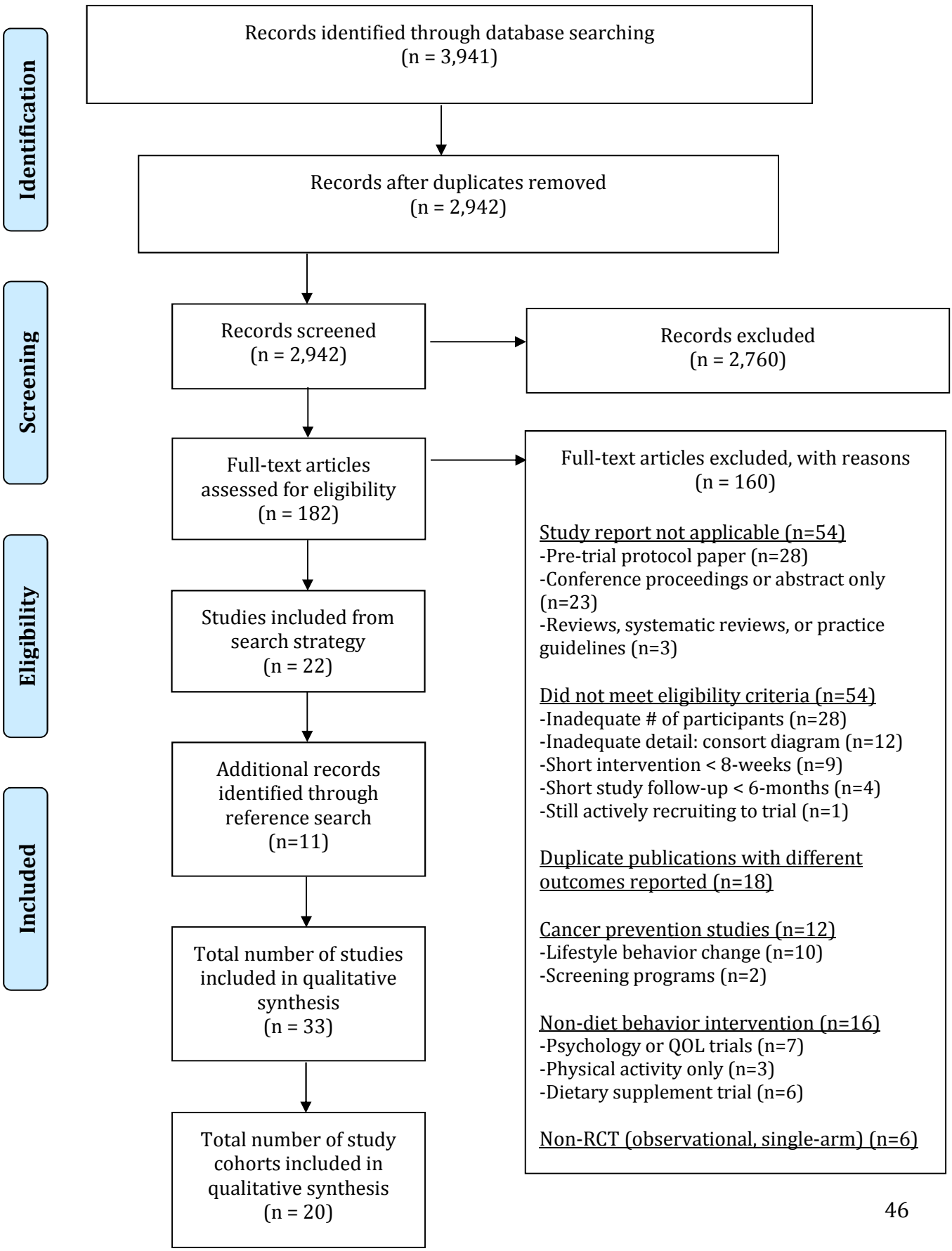


Figure 2.
Methods of Recruitment for Cancer Survivors into Dietary Intervention Trials

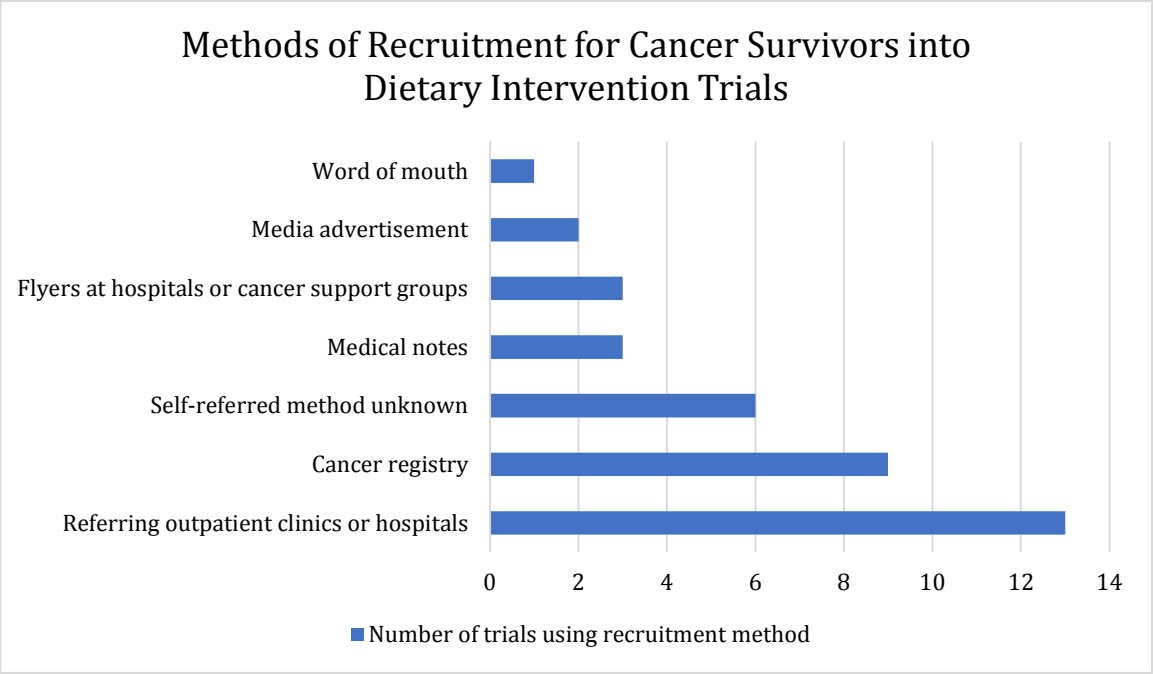


Figure 3.
Average Attrition Rates in RCT Dietary Intervention Trials Among Cancer Survivors by Length of Follow-up

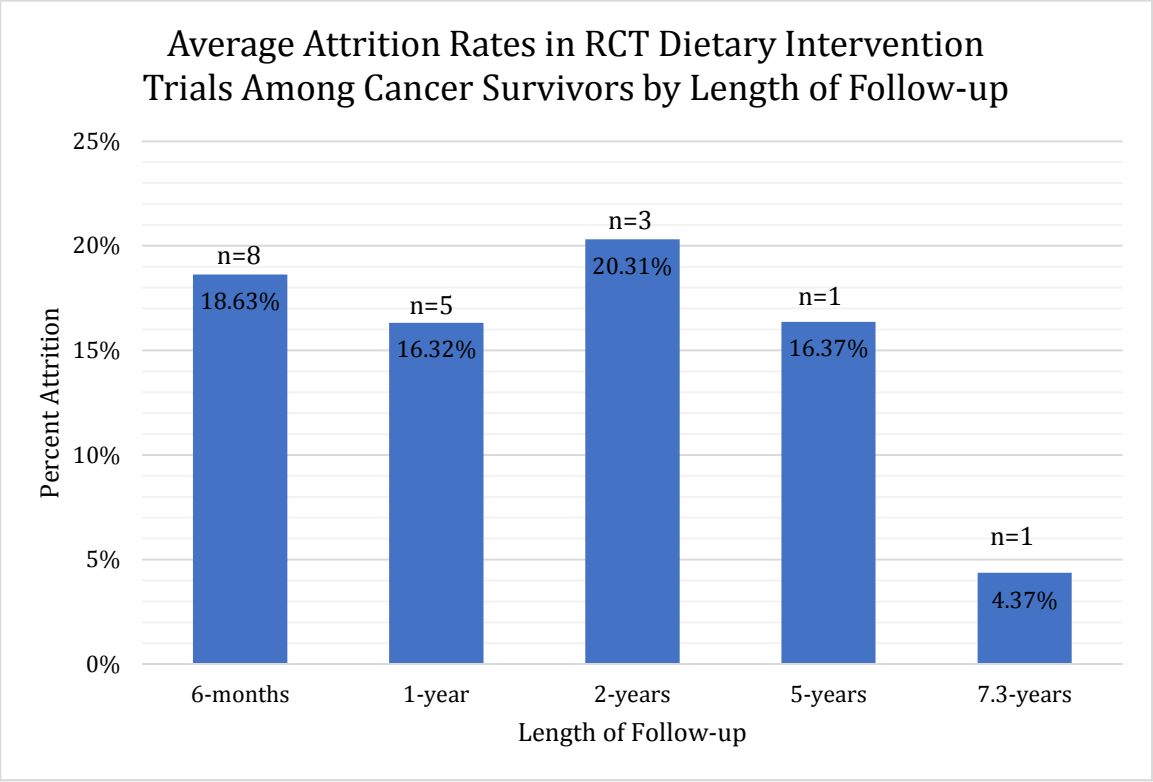
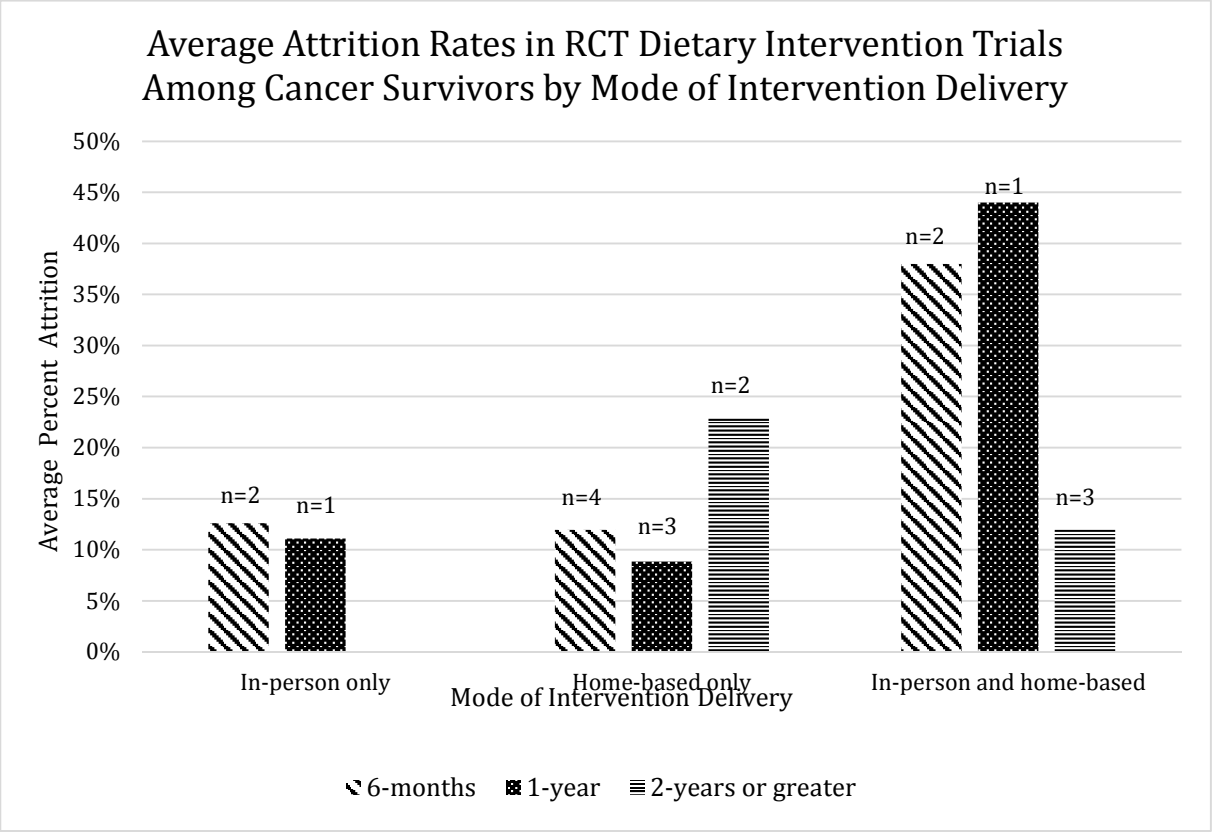


Figure 4.
Average Attrition Rates in RCT Dietary Intervention Trials Among Cancer Survivors by Mode of Intervention Delivery



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