Published in final edited form as:

Arch Phys Med Rehabil. 2022 September ; 103(9): 1807–1826. doi:10.1016/j.apmr.2022.01.142.

A Systematic Review of Functional Outcomes in Cancer Rehabilitation Research

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Conflicts of Interest Statement:

Ann Marie Flores reports a consulting role with University of Pittsburg, LeaRRN. Lynn Gerber reports that she is on the scientific advisory board of the International Society of Physical Medicine & Rehabilitation, and she is on the board of the Foundation for Physical Medicine & Rehabilitation. Timothy Marshall reports that he is a paid consultant for Select Medical and is employed by Ivy Rehab Network.

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Abstract

Objective: To systematically review the evidence regarding rehabilitation interventions targeting optimal physical or cognitive function in adults with a history of cancer, and describe the breadth of evidence as well as strengths and limitations across a range of functional domains

Data Sources: PubMed, CINAHL Plus, Scopus, Web of Science, EMBASE. The time scope was January 2008 – April 2019.

Study Selection: Prospective, controlled trials including single- and multi-arm cohorts investigating rehabilitative interventions for cancer survivors at any point in the continuum of care were included, if studies included a primary functional outcome measure. Secondary data

analyses and pilot/feasibility studies were excluded. Full text review identified 362 studies for inclusion.

Data Extraction: Extraction was performed by co-author teams, and quality and bias assessed using the American Academy of Neurology (AAN) Classification of Evidence Scheme (Class I-IV).

Data Synthesis: Studies for which the functional primary endpoint achieved significance were categorized into 9 functional areas foundational to cancer rehabilitation: 1) quality of life (109 studies); 2) activities of daily living (61 studies); 3) fatigue (59 studies); 4) functional mobility (55 studies); 5) exercise behavior (37 studies); 6) cognition (20 studies); 7) communication (10 studies); 8) sexual function (6 studies); and 9) return to work (5 studies). Most studies were categorized as class III in quality/bias. Averaging results found within each of the functional domains, 71% of studies reported statistically significant results following cancer rehabilitation intervention(s) for at least one functional outcome.

Conclusions: These findings provide evidence supporting the efficacy of rehabilitative interventions for individuals with a cancer history. The findings should be balanced with the understanding that many studies had moderate risk of bias and/or limitations in study quality by AAN criteria. These results may provide a foundation for future work to establish clinical practice guidelines for rehabilitative interventions across cancer disease types.

Keywords

neoplasms; rehabilitation; functional status; systematic review

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The number of cancer survivors in the United States —defined as those from the point of cancer diagnosis through the balance of life—is rising steadily, with a projected increase to more than 26 million by 2040.[1,2] Functional limitations associated with cancer and its treatment are common and impact physical, cognitive, and psychosocial domains.[3–6] More than half (55%) of cancer survivors report challenges with instrumental activities of daily living[7] and 64% of older adult cancer survivors report functional limitations.[8]

Evidence broadly supports the benefits of rehabilitation interventions for cancer survivors[9], however, specific guidance for clinical decision-making based on high quality evidence regarding rehabilitative interventions is currently limited[10], particularly with regard to function—defined as the ability to perform the basic actions essential for maintaining independence and carrying out more complex activities.[11,12] The unique and expressed purpose of this review was thus to examine the literature through the lens of measurable and significant changes *in function*. This differs from other reviews that aggregate and report changes in clinical measures of body structure or physiologic measures (impairments) elicited by rehabilitation interventions. Physiologic measures such as VO_2 or blood gases and measures of body structure, such as joint range of motion, muscle strength, or limb volume, are critical for clinical assessment and decision-making regarding impairment; however, while these measures may correlate with and support function, they do not directly assess functional management of daily activities and engagement in life roles. Importantly, achieving statistical significance in physiological measures in clinical trials may not equate to meaningful changes to patients or improvements in desired and needed life activities.

We therefore identified the strengths, limitations, and breadth of evidence for rehabilitative interventions designed to promote *optimal function* for individuals living with and beyond cancer treatment. These findings may inform cancer rehabilitation practice guidelines and future research.

Methods

This systematic review was led by a core team (*AS, CA, LG, NS, TM*) and a biomedical informationist from the National Institutes of Health (NIH) Biomedical Library (*AL*). The core team developed the preliminary PICO (participants, intervention, comparisons, outcomes) question and search criteria with support from the NIH Informationist. For the purpose of this review, the term *cancer rehabilitation intervention* is defined based on Silver et al's definition[11] "…an intervention directed at managing patients' physical and/or cognitive impairments in an effort to maintain or restore function, maximize participation, and/or improve quality of life. These interventions can be provided at any time throughout the oncology care continuum." Rehabilitation professionals were defined to include physiatrists, physical therapists, occupational therapists, behavioral therapists, speech and language pathologists, recreational therapists, music therapists, vocational rehabilitation specialists, neurocognitive specialists, and rehabilitation nurses.

Search

Search terms were formulated using the *PICO* structure. *Participants* (P) were adults (>18 years old) with any type of cancer, including adult populations of childhood cancer survivors. *Intervention* (I) was any intervention within the scope of practice of a rehabilitation provider delivered to cancer survivors in any setting with therapeutic intent to impact physical or cognitive function (interventions designed to impact psychosocial function were excluded from this review). *Comparisons (C)* broadly addressed rehabilitative intervention versus none, supervised versus unsupervised, varied frequency and duration of interventions as well as comparison of different types of rehabilitative interventions. *Outcomes (O)* were determined a priori based on the International Classification of Functioning, Disability, and Health (ICF) framework and the multidisciplinary author team's clinical expertise about the top areas of concern in cancer rehabilitation. These included outcome measures of activities of daily living/instrumental activities of daily living, exercise behavior, fatigue, functional mobility, cognition, communication, health related quality of life (HRQOL), return to work, and sexual function.

The comprehensive search strategy is provided in Appendix 1. Five databases were searched: PubMed, CINAHL Plus, Web of Science, EMBASE, and Scopus with date range from January 1, 2000 through March 30, 2019.

Study Identification and Selection

Inclusion and exclusion criteria are outlined in detail in Table 1. Studies were included if they included a study population with a cancer diagnosis, a rehabilitation intervention focusing on physical, sexual, or cognitive abilities, participation, and/or health-related quality of life; and an interventional study design with a function-based outcome. The

initial search yielded 18,416 results. Fifty-seven duplicates were removed resulting in 18,359 studies for screening. The review team used the Covidence software program to facilitate reviewer screening and reviews. Two co-authors reviewed each article for relevance of title and abstract and for eligibility of full text review. In instances of disagreement between reviewers, two of the three core team authors (*AS, LG, and NS*) made the final determination on inclusion. Following full text review, the volume of articles exceeded what the core author team believed could be realistically managed for this review and, at this point, decided to further consolidate the inclusion criteria by 1) reducing the time scope of the project, including only articles from January 1, 2008 through March 30, 2019, and 2) excluding any article identified as a pilot or feasibility study. The rationale for this adjustment was to assure the most contemporary evidence was included for review and to reduce the bias from studies with low statistical power.

Data extraction and quality reviews were conducted by two co-authors using a standardized data collection form in Excel. Elements extracted from studies included country where the study was conducted, cancer disease type, disease stage, time period in the cancer continuum when the study was conducted, setting in which the intervention was conducted, study cohort(s) and control cohort interventions, between group and within group results, primary functional outcome reported, whether statistical significance was achieved, favorability of significance for the intervention, and additional functional outcomes and significance reported (if applicable). All co-authors contributed to data extraction and worked in teams to synthesize results.

Quality Assessment

Quality and risk of bias were assessed by authors during the extraction phase using the American Academy of Neurology (AAN) classification of evidence system.[12,13] The AAN system is used by the American Congress of Rehabilitation Medicine (ACRM) to inform guideline development and divides studies into four classes based on a succinct list of qualities such as randomization, blinding, and overarching study design, and are presented in detail in Table 2. The evidence rankings are noted, by citation, in Supplemental Table 1 and Supplemental Table 2.

Results

Articles (n=18,359) were initially screened for relevance through title and abstract reviews. 16,130 articles were excluded as irrelevant. The remaining 2,229 articles underwent full text review with 1,394 of those being excluded. The most commonly cited reasons for exclusion were studies that did not report a functional outcome (n=411), studies that did not conduct a rehabilitative intervention (n=340), studies that were not prospective, controlled trials (n=235), case studies or case series (120), and secondary analysis of a controlled trial (n=97). The PRISMA diagram in Figure 1 provides insight on the remaining exclusion categories and flow of article reviews. After full text reviews, 835 articles were included for extraction. Following refined exclusion criteria additional studies were excluded for being out of the revised timeline (n= 153), when the article explicitly defined its research as a

pilot or feasibility trial (n= 250), and because the article did not have a primary functional outcome listed (n= 70). This resulted in 362 studies remaining for full extraction.

A descriptive narrative synthesis of the 362 studies within each domain is presented in the text below for those studies with statistically significant interventions followed by those lacking significant functional intervention effects, though the latter with less detail. Supplemental Table 1 provides the study characteristics and intervention synopsis for studies that achieved statistical significance through rehabilitative interventions in each functional domain while Supplemental Table 2 provides the synopsis for studies that did not achieve statistical significance in their primary outcome. More detailed characteristics of all studies regardless of statistical significance can be found in Supplemental Table 3.

Functional Outcome Domain Findings

Figure 2 provides a breakdown by primary domain of interest and whether studies found intervention(s) were statistically significant vs nonsignificant. For those studies that found statistically significant outcomes for the intervention(s), summary data is provided in Figures 3–5, with cancer diagnoses studied by domain summarized in Figure 3, the participants' phase of cancer treatment during the study in Figure 4, and the study treatment setting in Figure 5.

Health-Related Quality of Life (HRQOL)—One hundred and eight studies examined the effects of rehabilitation interventions on the primary outcome of health-related quality of life and/or quality of life (HRQOL/QOL), HRQOL is defined as an individual's perceived physical and mental health over time, while QOL is a broader concept encapsulating an individual's general perception of their position in life within the context of their culture and value systems. Eighty studies (73%) had a statistically significant impact on HRQOL/QOL. Fifty-four of the statistically significant studies were RCTs and 26 were single arm trials. These studies were conducted across breast[1–38] (n=39), gynecologic[39–43] (n=5), colon and GI[44–50] (n=7), hematologic[51–53] (n=3), head and neck[54,55] (n=2), lung[56,57] (n=2), prostate[58,59] (n=2), and brain and CNS[60] (n=1) cancers, while 19 studies included various cancer diagnoses in their cohort[61–79]. A variety of cancer stages were represented across the studies, yet 34 studies did not specify stage of cancer for their cohort. Most studies were conducted in the active treatment phase (n=30) or the survivorship post-active treatment phase (n=39), and 3 studies included individuals in both phases. The majority of interventions were delivered in a clinic or hospital-based setting (n=51).

Rehabilitation interventions varied from exercise-based interventions to cognitive therapies, therapeutic exercises, aquatic therapy, and clinical interventions for specific impairments such as lymphedema. HRQOL/QOL was investigated as a primary outcome using patient-reported outcome measures encapsulating at least one domain of either quality of life or health-related quality of life, with the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ C30), the 36-Item Short Form Survey (SF-36), and the Functional Assessment of Cancer Therapy: General (FACT-G) being the most commonly used across studies. A majority of these studies (n=44) used the subscale of a HRQOL assessment as the only measure of physical or cognitive functional outcomes.

Although these studies also included clinical measures such as strength, range of motion (ROM), etc. there were no additional functional outcomes measures reported. Studies that did report secondary functional outcomes of statistical significance included measures of functional mobility[1,10,11,62,70], exercise behavior[36,53,58,63], sexual function[40,42], ADL/IADL function[25,73], and communication[55]. Twenty-eight studies (25%) of HRQOL/QOL reported non-significant findings. Interventions not achieving statistical significance varied and included psychoeducational interventions such as stress management training and variations of supervised exercise training.[51,80–106]

Activities of Daily Living & Instrumental Activities of Daily Living (ADL/IADL)—Sixty studies investigated rehabilitative interventions for their impact on the primary functional outcome of performing activities of daily living and/or instrumental activities of daily living (ADL/IADL). Forty-two of 61 studies (70%) reported significant improvement in ADL/IADL function, 35 randomized controlled trials (RCTs) and seven single arm trials[107–113]. Most interventions were conducted in clinic or hospital system-based settings, with three exceptions: an independent, self-directed internet-based intervention[114] and two community based: a Nordic walking intervention[107] and a goal-oriented rehabilitation program.[16] Hospital and clinic-based interventions focused less on IADL and more on basic ADLs (dressing, feeding, etc) ADL/IADL studies were conducted with individuals with head and neck[109,110,115–124] (n=12), prostate[125–134] (n=10), breast[107,113,114,135–143] (n= 12), gastrointestinal[144,145] (n=2), brain and central nervous system (CNS) tumors[112] (n=1), lung[146] (n=1), bladder[147] (n=1) and mixed cancer types[108,111,148,149] (n=4). The majority of studies were conducted following the completion of active treatment phase (n=23) in the survivorship phase and during active treatment (n= 15). Four studies tested prehabilitation interventions.

Interventions included various standard physical, occupational, or speech therapy techniques such as therapeutic exercise and activities for strengthening, kinesiotaping, or manual therapy, cognitive behavior therapy, electrical stimulation, biofeedback, swallowing exercises (e.g. shaker exercises, effortful swallows, tongue strengthening), pelvic floor exercises, and yoga.

One RCT (n=116)[25] providing a neuromuscular electrical stimulation (NMES) intervention reported significantly worse swallow function in head and neck cancer survivors compared to sham stimulation, suggesting a need for additional research to test outcomes using NMES in this population. Studies used a variety of outcome measurement approaches including performance-based measures of function and activity (e.g. the Functional Independence Measure [FIM]) and patient-reported measures of function and quality of life (e.g. Patient-Reported Outcomes Measurement Information System [PROMIS] Global-10). Secondary outcomes achieving significance with rehabilitation interventions predominantly included fatigue[114,140], health-related quality of life/quality of life (HRQOL/QOL)[107,111,113,116,118,124,125,127,132,134,135,139,146,149], functional mobility[112,146], and communication[112].

Eighteen ADL/IADL studies (31%) reported non-significant findings with interventions including resistance training, aerobic exercise, toileting behavior and biofeedback, pelvic

floor exercises, patient education, swallowing rehabilitation, dietary instruction and training, manual therapy and upper extremity exercise.[150–167].

Fatigue—Fifty-nine studies investigated rehabilitation interventions for their impact on cancer-related fatigue as a primary outcome and forty of these studies (67%) achieved statistical significance. Thirty-four of these trials were RCTs, 6 were single arm trials. The studies were conducted across breast[168–181] (n=14), hematologic[182–186] (n=5), lung[187,188] (n=2), head and neck[189,190] (n=2), prostate[191] (n=1), colon[192] (n=1), pancreatic[193] (n=1), and mixed cancer types[194–207] (n=14). Most studies occurred during active cancer treatment (n= 25) while 13 studies took place during post-treatment survivorship. The most common effective intervention for fatigue was aerobic or resistive exercise; however, five studies used movement-based interventions such as yoga[170], tai chi[173,188,190], and dance[204]. Several studies also included a cognitive-behavioral therapy (CBT) approach[175,176,192,196,198,205,207] (n=7) with or without exercise interventions. Most studies took place in clinical or hospital-based settings (n=25) with few either being community-based[173,188,195,203,208] (n=5) or independent, self-directed.[177,186,189,193,196] (n=5). Studies that demonstrated improvements in cancer-related fatigue also reported significant improvement in selected secondary functional outcomes including HRQOL[168,172,174,178,182,184,185,189,194,196,199,203,206] (n=13), functional mobility169,185,203,204 (n=4), exercise behavior171,172,193,199,203,206 (n=6), and return to work[206] (n=1).

Nineteen studies (32%) reported no statistically significant outcomes on fatigue. Interventions not reaching statistical significance included various home-based, group, or individual interdisciplinary exercise-based rehabilitation programs (e.g. walking, stretching, yoga).[209–227].

Functional Mobility—Fifty-five studies examined rehabilitation interventions on the primary outcome of functional mobility, defined as the means by which an individual moves within the environment to interact with society. Forty-three (78%) achieved improved statistically significant functional mobility. Thirty studies were RCTs, and 13 single arm trials. The studies were conducted across breast[228–234] (n=6), lung[235–244] (n=10), prostate[245–253] (n=9), colorectal[254,255] (n=2), head and neck[256–258] (n=3), hematologic[259–262] (n=4), brain and CNS[263,264] (n=2), esophagogastric[265] (n=1), and other various types of cancer[266–272] (n=6). Studies included a mix of localized and advanced stage-included populations. Intervention timing in cancer care delivery varied: survivorship post-active treatment phase in 22, during active treatment in 15, and prehabilitation in 4 studies; the remaining did not identifying the timing of the intervention. Both clinical or hospital system-based interventions were the most commonly reported settings. Studies that demonstrated improvements in functional mobility also reported significant improvement in secondary functional outcomes including HRQOL231,234,240,242,247,250,251,254,256,261,268,270–272 (n=14), ADL/IADL251,263,264,270 (n=4), cognition263 (n=1), exercise behavior254 (n=1), and fatigue 234,242,249,250,267,269,271,272 (n-8).

Twelve (22%) of functional mobility studies reported non-significant findings. Interventions included home exercise programs, supervised exercise programs, and patient education programs.[273–283].

Exercise Behavior—Thirty-seven studies investigated rehabilitation interventions for their impact on the primary functional outcome of exercise behavior, or the behaviors involving physical activity. Of the twentyeight (76%) reporting significant improvement in exercise behaviors, 23 were RCTs and five single arm trials. The interventions were conducted during prehabilitation (n=1), active treatment (n=6), and post-active treatment (n=21) and included physical activity education & behavior change interventions delivered through remote video or phone contact[58–60, 62–69 284–295,297–308](n=11), physical activity education & behavior change intervention with supervised exercise[296,297] (n=2), aerobic & resistance combined interventions[298–304] (n=7), aerobic only exercise interventions[305,306] (n=2), resistance only exercise interventions[307] (n=1), or therapeutic interventions[308–311] (n=4). Cancer populations studied included breast[286,288_290,295_297,305,306,311,312] (n=11), lung[301,308,309] (n=3), gynecologic[285] (n=1), GI/colorectal[293,294,298] (n=3), prostate[291,299,300] (n=3), hematologic[307] (n=1), and mixed cancer types[284,287,292,302–304,310] (n=6). While studies were mixed between early and advanced stage populations, most studies were administered during the survivorship post-treatment phase (n=21) however one study performed a prehabilitation intervention[298] and 6 took place during active cancer treatment[289,292,301,307–309]. Studies demonstrating improvements in exercise behaviors also reported significantly improved secondary functional outcomes including fatigue289,292,296,303,306,307,310,311, HRQOL285,287–289,297,299,302,303,305, ADL/IADL function[287,310], functional mobility[294,295,298,302,307,312], and cognition[311]. Intervention type, duration and length of follow-up varied substantially across trials and is outlined in Supplemental Table 1.

Nine (27%) exercise behavior studies reported non-significant results. Interventions included exercise training, patient education, and skills training programs.[313–321].

Cognition—Twenty studies examined the impact of rehabilitation interventions on the primary outcome of cognition. Thirteen of the studies (65%) reported a significantly improved primary cognitive outcome; all of these 13 studies were RCTs. Cancer types that were represented include breast[322–327] (n=6), brain and CNS[328] (n=1), and prostate[329] (n=1). Five studies included cohorts with various cancer types[330–334], representing both early and advanced stage-included populations. The majority of studies occurred during survivorship post-active treatment phase, with only one occurring during active treatment. Interventions were commonly delivered in a clinic or hospital system-based setting (n=6) or four provided independently in a self-directed manner. Cognitive and memory training, CBT, physical activity (e.g. walking, exercise bike), and psychoeducation were utilized. A few studies used mind/body therapies such as yoga and Qigong. Both neuropsychological tests as well as PRO measures assessed for changes in cognitive function. Additional secondary functional outcomes that reached statistical significance in these studies were HRQOL/QOL[327,330,331,334], ADL/IADL function[333], exercise behavior[322,326], and functional mobility[325].

Seven (35%) of cognition studies reported non-significant findings. Interventions included cognitive training, psychoeducational programming, memory and attention adaptation training, and relaxation training.[335–341]

Communication—Ten studies examined the impact of rehabilitation interventions on the primary outcome of communication. Six studies (60%)−-5 RCTs and 1 single arm trial--identified statistically significant improvements in communication and all were conducted in those with head and neck cancer[342–348] (n=6). All cancer stages were represented across the seven trials, and all were conducted in a clinic or hospital system-based settings in the survivorship post-active cancer treatment phase. Interventions across the trials included similar voice rehabilitation programs with therapeutic interventions including breathing, relaxation, posture, and vocal exercises. The studies primarily used PRO measures for participant voice perception and/or auditory analysis. The only other secondary functional outcome reported was HRQOL/QOL, which improved significantly in 3 studies.[55,347,348]

Four (40%) of studies, all performed in those with head and neck cancer, reported nonsignificant findings. Various voice rehabilitation programs including modalities such as breathing, relaxation, home voice exercises, and biofeedback were used as inteventions.[349–352].

Sexual Function—Six studies investigated the impact of rehabilitation interventions on the primary functional outcome of sexual function with five articles (83%) demonstrating statistically significant improvement. Of those, 4 were RCTs and 1 a single arm trial. Cancer types included were prostate[353,355 356,357] (n=3) and gynecologic (n=2). The timing of the rehabilitation intervention was either during active cancer treatment (n=2) or during survivorship post-active cancer treatment (n=3). Clinic or hospital system-based (n=3), research center (n=1), or one community-based (n=1) settings were utilized. The interventions included rehabilitation training (e.g. pelvic floor muscle training) delivered with the intent to improve sexual function, sexual health education, resistance and aerobic exercise, and CBT to address sexual symptoms. Sexual function-specific PRO measures were used across all studies. HRQOL/QOL was investigated as a secondary outcomes in two studies[353,357] and achieved statistical significance in both of these trials.

One study (17%) investigating patient education in various gynecological and anorectal cancers reported non-significant findings.[358].

Return to Work—Five studies examined the effects of rehabilitation interventions on the primary outcome of return to work with three studies (60%) demonstrating statistically significant improvements, 2 single arm studies[359,360] and 1 an RCT[361]. Two studies included various cancer types and one included individuals with brain and CNS cancer[360]. Stage of cancer was not reported for the studies with mixed cancer types. One study with individuals with brain and CNS cancer included tumor grades I-IV and was delivered in a community-based setting during survivorship post-active treatment. The remaining studies provided interventions in a clinic or hospital system-based setting while individuals were in active cancer treatment and in survivorship post-active treatment. Interventions included individualized counselling sessions on work-related issues and physical activity with PRO

measures used to track the outcome of interest. One study included secondary functional outcomes that achieved statistical significance in fatigue and HRQOL with rehabilitation interventions.[359]

Two return-to-work studies (40%) reported non-significant findings. The interventions involved patient skill building.[362,363].

Quality Assessment

No studies in this review met the criteria for AAN Class I, the highest tier of evidence with a requirement of being "triple masked" according to the classification system. Eighteen studies met the criteria for Class II. (See Table 2.) The majority of studies that met the Class II criteria used the 6minute walk test—an objective, performance-based measure—to assess functional mobility. The majority of studies in this review were categorized as Class III (n=321) primarily because they used PROs as primary functional outcome measures. Ninety-three were categorized as Class IV.

Discussion

This systematic review provides insight into the efficacy of rehabilitation interventions in improving functional outcomes for individuals with a history of cancer. While the volume of cancer rehabilitation literature has grown substantially over the last two decades,[364] only recently have measures of function been critically reviewed in oncology rehabilitation research trials.[365,366] Notably, in this review, the most cited reason for full text exclusion was "no functional outcomes reported." In other words, many studies that were reviewed fell within the scope of cancer rehabilitation and measured an intervention that impacted symptoms or impairments, but they addressed primary endpoints that were purely physiological measures (e.g. VO_2max, body mass index, lean mass etc.) or clinical measures (e.g. ROM, strength, limb volume, etc.). These measures are frequently divorced from an individual's capacity to function within the context of their everyday lives. The frequency with which primary physiological and/or impairment endpoints are selected for cancer rehabilitation studies is significant. We maintain that a major strength of the cancer rehabilitation field is its ability to address symptoms and impairments in a holistic manner, considering the person's goals, strengths, and contextual factors and addresses function and participation in everyday life. The fact that 362 unique cancer rehabilitation studies have specifically addressed function within the past decade indicate that the field is moving towards a more patientcentered framework. Accordingly, this review highlights an opportunity for the field to continue focusing on intervention trials that include function as a primary outcome alongs with objective measures of physiological health.

The studies in this review primarily took place during the post-treatment survivorship time frame. Studies of prehabilitation—during the time period after cancer diagnosis but prior to the initiation of treatment—were few and were mostly identified in the last five years of the timeline for this review. Prehabilitation is an emerging practice model in oncology, commonly associated with Enhanced Recovery After Surgery (ERAS) protocols. This review highlights an opportunity for the field to continue to innovate in the area of

prehabilitation in order to identify and intervene on functional impairments before they become amplified by cancer and its treatment.

There is a dearth of studies about impact of rehabilitation interventions on return to work and sexual function after cancer (6 studies in each category) and this is surprising considering the desire of many cancer survivors to resume pre-diagnosis life roles. Considering the long-term effects associated with cancer and its treatment, there is a need to design future studies with ample power with longer follow-up time to better understand the durability of rehabilitative impact on function over time. Additionally, few studies evaluated functional outcomes during palliative care. Likely, functional endpoints in this population is challenged by the inherent deterioration of function at end of life. Rehabilitation interventions may mitigate the *rate* of functional decline in palliative care and end-of-life settings; however, we argue that relevant endpoints in these palliative studies remain unique compared to other cancer treatment phases. This treatment phase may benefit from independent consideration.

An additional finding was that no studies achieved a level I AAN Classification (highest quality), reflecting the challenges inherent in conducting such rigorous trials in a cancer rehabilitation setting. Producing high quality evidence is made more challenging by hurdles such as attentional controls, blinding of outcome assessors, selection bias, sampling bias, missing data, response bias with PROs, and overestimation of treatment effects due to natural recovery. The need to develop evidencebased rehabilitation treatments with sophisticated methods to objectively verify and test their contents remains important.[367] However, the findings of this review also suggest that comparing cancer rehabilitation studies using traditional classification systems (e.g. AAN) may produce results that do not fully capture their strengths as many studies were graded Class III due to their use of patient-reported outcomes (PROs) to capture function. Paradoxically, these studies were included in this review based on the merit of their function-focused design, only to be designated as “lower quality” based on the subjective measures they justifiably used to measure function. Recent research has demonstrated that PROs carry significant prognostic value in oncology[285–287] and may hold more value than the label of “subjective” traditionally affords them in biomedical science. Conversations in the field are thus warranted to determine: 1) the value of PROs beyond the measurement of symptom burden in oncology, and 2) the utility of classification systems typically used for biomedical studies to classify studies of function in cancer rehabilitation.

This review also included 102 cancer rehabilitation studies out of 362 (28%) that did not report statistically significant results in their primary outcome. Across all nine functional domains, the proportion of studies with non-significant intervention(s) ranged from 17% (sexual function) to 40% (return to work and communication). While the examination of null versus negative findings is beyond this manuscript’s scope, there is a need to examine study design features in rehabilitation medicine to provide appropriate context to findings. The use of general labels for interventions and the lack of specificity about the important aspects of the intervention limit the synthesis and application of evidence.[368] While this report purposefully removed studies labeled ‘pilot’ or ‘feasibility’ in an effort to minimize the inclusion of underpowered studies, studies with small cohorts, those that implement

a previously studied intervention without fidelity, or studies with multiple confounding variables could contribute to the rate of null findings. Future research in rehabilitation oncology should seek to incorporate reporting guidelines such as the Template for Intervention Description and Replication (TIDieR), the Consolidated Standards of Reporting Trials of nonpharmacologic treatments, or the Consensus on Exercise Reporting Template so that relevant, detailed descriptions of rehabilitation and exercise trial interventions are provided.[369–371]

Due to the variety in cancer populations and the substantial heterogeneity in interventions across studies, a meta-analysis of these findings was not possible. The studies reported herein cross many cancer types and many different stages of cancer, suggesting rehabilitative interventions are relevant to a broad range of cancer treatment side effects and adverse consequences of cancer treatments. The high variability across the types of interventions used in these studies is a strength of the field. Rehabilitation interventions are contextual, and necessarily so, to achieve individualization in treatment. This tremendous variability within the field suggests that a broad, overarching cancer rehabilitation guideline encompassing all disciplines, cancer types, and treatment modalities may not be the most valuable outcome of this work. Rather, it may be that in order to move toward authoritative issuance of evidence-based practice guidelines, future efforts must systematically review the state of cancer rehabilitation in greater detail within specific cancer *populations* and/or among those with specific *functional limitations*.[365] The ultimate outcome of this type of work may therefore be a number of more detailed, tailored guidelines for specific subspecialties of cancer rehabilitation which—taken as a whole—may supersede a single, overarching guideline.

Limitations

This study represents a broad look at a vast field encompassing a variety of disciplines. The large volume of citations covered by this review presented methodological challenges and necessitated a large and diverse research team. Finding consensus around defining foundational terms such as “rehabilitation” and “function” required extensive team discussion during this review and continues to present philosophical challenges for the field. Due to the diverse disciplines and backgrounds reflected on the author team, variability in interpreting key terms during study exclusion and extraction may have occurred. We included fatigue as a functional outcome despite its definition as a symptom because it is seen as a multi-dimensional, comprising factors that are physiological, functional, and environmental, and it often correlates strongly with most functional outcome measures.

We acknowledge that publications in cancer rehabilitation with functional endpoints have been published since the conclusion of our literature search, and we recognize the need for future reviews to capture this more recent body of work. This review included cancers of all types and stages (I-IV), a methodological choice that introduced the potential for substantial variability in results between studies—for example, improved functional outcomes in people with stage I cancer may present considerably differently than improved functional outcomes in people with stage III or IV cancers. While it was beyond the scope of this manuscript, it would be warranted for future efforts to more deeply examine functional outcomes within

various cancer disease populations and stages and determine relationships between these and physiological measures. Some cancer treatment-related symptoms and side effects, like fatigue, neuropathy, and lymphedema, occur across different types of cancer. While elements of interventions may have similar benefit across populations, further detailed analysis is needed to specifically investigate interventions in context of disease types and treatment paradigms. In addition, psychosocial interventions were not included in this review. Future work may benefit from analyzing the results of function-based cancer rehabilitation studies with a focus specifically on psychosocial function. Finally, we focused on studies with a statistically significant improvement in a primary outcome of function. A limitation of this approach is that some changes in outcomes may have been clinically meaningful without reaching statistical significance. Clinically meaningful change lacks a clear definition in clinical rehabilitation research and remains contextually dependent. Further research is needed within individual practice areas to establish changes in outcomes that will be clinically meaningful for the specific population(s) in question.[288]

Future Directions

Future endeavors should consider comparing study characteristics for those studies that fail to achieve statistical functional outcomes versus studies where interventions are significant. This type of analysis may aid in determining whether some cancer rehabilitation interventions that are inadequate, or whether other aspects of study design help or hinder robust functional outcome measurement and provide a better guide for practitioners. Overall, this work is intended to be foundational to future efforts in research and clinical practice. Few clinical practice guidelines exist to inform multidisciplinary rehabilitative care for individuals with cancer, and the American Congress of Rehabilitation Medicine's (ACRM) Cancer Rehabilitation Networking Group Task force on Research and Outcomes is leading this effort. This work and the accompanying findings in supplemental tables can and should be leveraged by future guideline development groups within ACRM and in collaboration with other key professional organizations across rehabilitation specialties. This work should also help to guide consensus on optimal measures of function across cancer populations.

Conclusion

This systematic review outlines evidence supporting the use of a wide variety of rehabilitation interventions to improve functional outcomes across different cancer types and stages. The results presented here may serve as a foundation for continued movement towards function as an essential endpoint within cancer rehabilitation, while also highlighting the broad and necessary usage of PROs. Additionally, this review suggests that classifying evidence within cancer rehabilitation based on the objectivity of outcome measures does not fully capture the utility of context-dependent, patientcentered data gathered by PROs. Finally, this review should enable future work towards establishing practice guidelines for a variety of specialized cancer rehabilitation areas and catalyze further research into best practice for function-based, patient-centered medicine.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgements:

The ideas and opinions expressed herein are those of the authors. They do not necessarily represent the official views of the National Cancer Institute, the National Institutes of Health, or any other organization affiliated with the authors. [Additional acknowledgements forthcoming.]

Data Availability Statement:

The data that support the findings of this study are available on request from the corresponding author.

List of Abbreviations

ADL	Activities of Daily Living
AAN	American Academy of Neurology
ACRM	American Congress of Rehabilitation Medicine
CBT	Cognitive Behavioral Therapy
FIM	Functional Independence Measure
HRQOL	Health-Related Quality of Life
IADL	Instrumental Activities of Daily Living
NIH	National Institutes of Health
NMES	Neuromuscular electrical stimulation
PICO	Participants, intervention, comparisons, outcomes
PROs	Patient-Reported Outcomes
PROMIS	Patient-Reported Outcomes Measurement Information System
RCT	Randomized controlled trial
ROM	Range of motion

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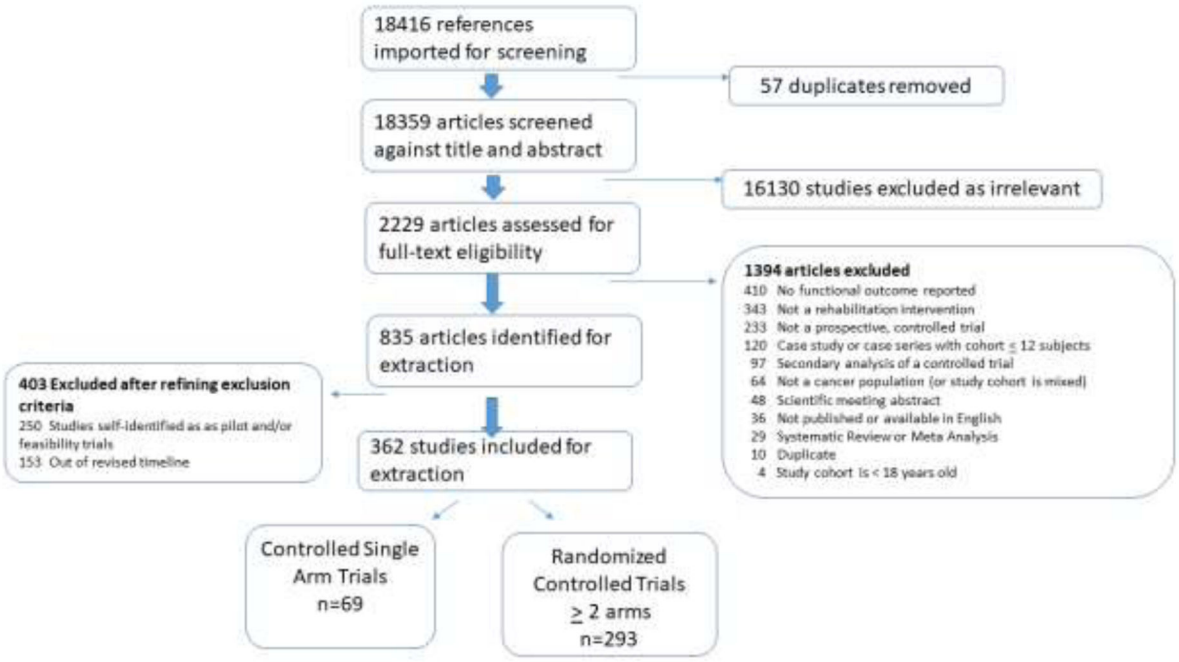

Figure 1.
PRISMA diagram

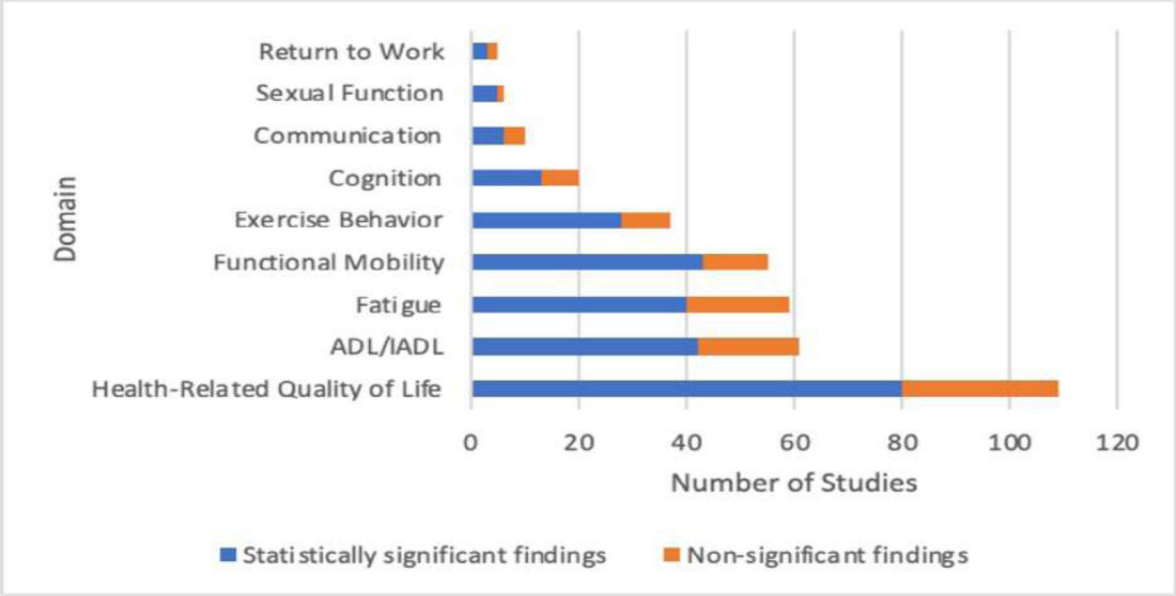

Figure 2.
Significance and number of studies by functional domain

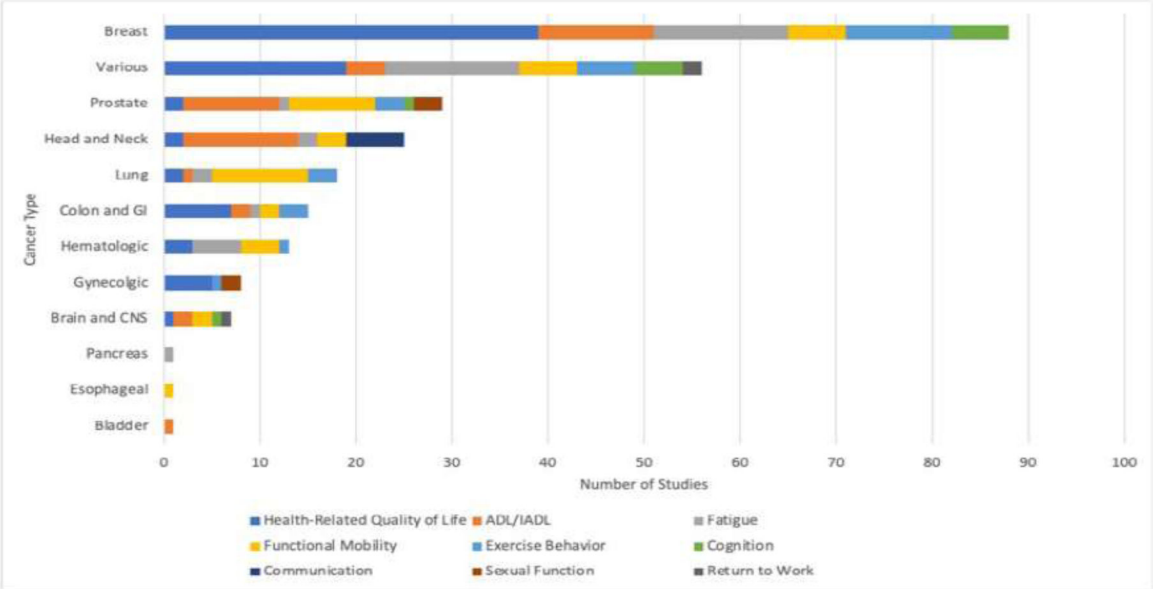

Figure 3.
Cancer types studied by functional domain for studies with interventions achieving statistical significance

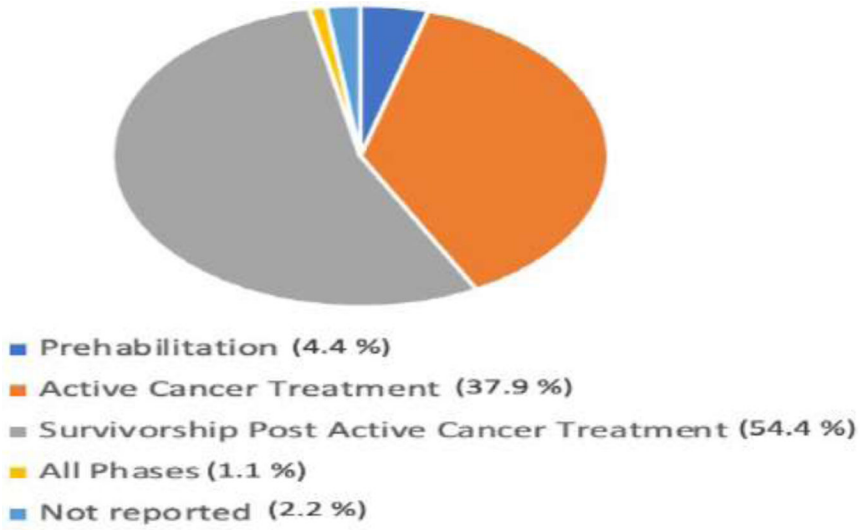

Figure 4.
Phases of treatment studied for studies with interventions achieving statistical significance

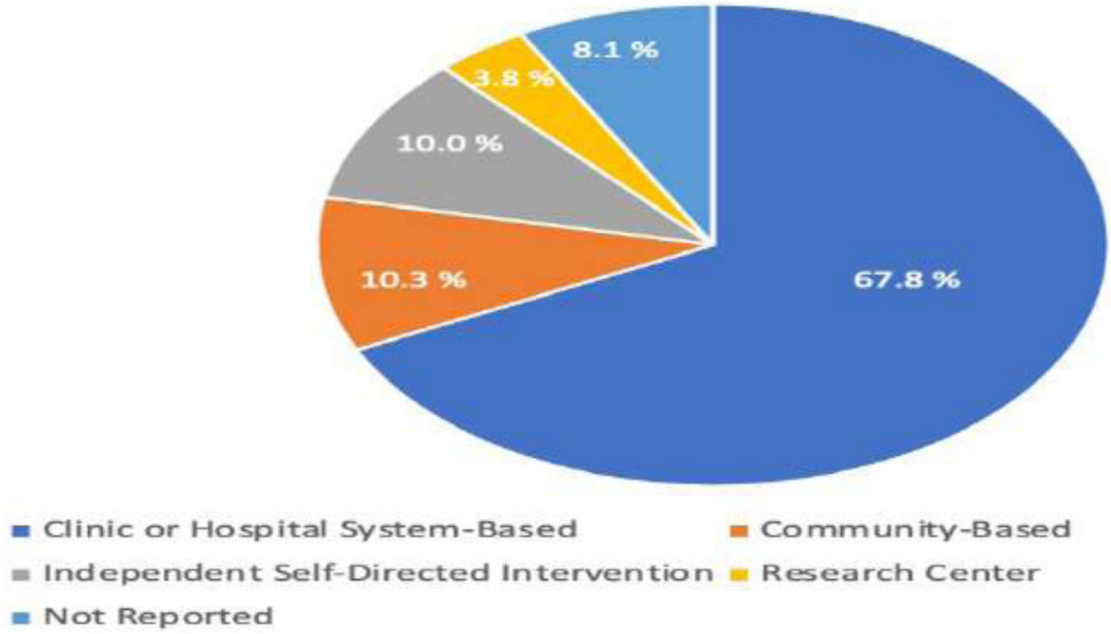

Figure 5.
Treatment settings for studies with interventions achieving statistical significance

Table 1.

Inclusion and Exclusion Criteria

Inclusion	Exclusion
• Publications from January 2008 to March 2019 • Study population with cancer diagnosis • Subjects ≥ 18 years of age • Rehabilitation intervention that focuses on physical, sexual, and cognitive abilities, participation, or health-related quality of life • Controlled intervention trials with one or multiple study arms that include a functional or participation-based outcome as a primary, secondary or exploratory aim • Healthcare delivery interventions that include a rehabilitation component	• Articles not available in English • Published protocols of ongoing or anticipated trials • Case studies or case series with < 12 patients • Pilot or feasibility studies (identified as such by authors of study) • Complementary and alternative medicine interventions that are not movement-based or not considered rehabilitation • Intervention studies that included non-cancer populations as controls or comparison groups • Studies on cancer prevention interventions • Studies that reported only physiological outcomes with no reported functional measures
	• Studies that examined interventions for psychological issues only, including anxiety, emotional distress, or depression
	• Studies investigating psychometric properties of measurement tools
	• Pharmacologic interventions that do not report functional outcomes or are out of the scope of rehabilitation provider practice
	• Cross-sectional and descriptive studies of function
	• Observational studies
	• Commentaries, narrative reviews, editorial reviews, published abstracts, systematic reviews, meta-analyses

Table 2.

AAN Classification of Evidence System

Class	Criteria
Class I	• Randomized controlled clinical trial (RCT) in a representative population • Triple-masked studies (i.e. the patient, treating provider, and outcome assessors are unaware of treatment assignment) • Relevant baseline characteristics of treatment groups (or treatment order groups for crossover trials) are presented and substantially equivalent between treatment groups, or there is appropriate statistical adjustment for differences • Additional Class I criteria: a. Concealed allocation b. No more than two primary outcomes specified c. Exclusion and inclusion criteria clearly defined d. Adequate accounting of dropouts (with at least 80 percent of participants completing the study) and crossovers
Class II	• RCT that lacks one or two Class I criteria a-d • Cohort studies employing methods that successfully match treatment groups on relevant baseline characteristics (e.g., propensity score matching) meeting Class I criteria b–d (see above) • Randomized crossover trial missing one of the following two criteria: a. Period and carryover effects described b. Baseline characteristics of treatment order groups presented • All relevant baseline characteristics are presented and substantially equivalent across treatment groups (or treatment order groups for crossover trials), or there is appropriate statistical adjustment for differences • Masked or objective outcome assessment
Class III	• Controlled studies (including studies with external controls such as welldefined natural history controls) • A description of major confounding differences between treatment groups that could affect outcome** • Outcome assessment performed by someone who is not a member of the treatment team • Crossover trial missing both of the following two criteria: a. Period and carryover effects b. Presentation of baseline characteristics
Class IV	• Studies not meeting Class I, II, or III criteria