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Research Protocol

Characterising Pragmatic Exercise Interventions to Reduce Cognitive Impairment in Cancer Survivors: A Scoping Review Protocol

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Abstract

Objective: The objective of this scoping review is to identify the characteristics of pragmatic exercise interventions aimed at reducing cognitive impairment in cancer survivors, and their effectiveness in reducing this impairment and maintaining high adherence. **Introduction:** Cognitive impairment (CI) is a particularly troublesome side effect of cancer treatment that has been suggested to decrease following exercise interventions. Most existing research consists of randomized control trials, which often lack external validity. Pragmatic interventions fill this gap. However, some pragmatic trials that provide real-world evidence struggle to maintain strong participant adherence. Thus, examining characteristics of pragmatic interventions with high levels of adherence may be beneficial in improving overall adherence in future pragmatic trials on this topic. **Inclusion criteria:** This review will examine literature with cancer survivors who are partaking in pragmatic exercise programs. Specifically, literature exploring the effects of pragmatic exercise interventions in decreasing cancer survivors' CI will be examined, with no limits to intervention frequency, intensity, time, or type. "Cancer survivor" will be defined as any individual with a cancer diagnosis, at any point along the survivorship continuum. **Methods:** A comprehensive search strategy was developed in accordance with JBI methodology to retrieve relevant sources. Databases to be reviewed from inception to present will include CINAHL, MEDLINE, Embase, SPORTDiscus, Scopus, and PsycInfo. Two independent screeners will examine titles and abstracts as well as full texts of relevant sources. The results of the search and the study inclusion process will be reported in full in a Preferred Reporting

Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) flow diagram. The results will be presented narratively, using appropriate tables and figures.

Keywords: physical activity, chemobrain, cognitive dysfunction, community-based

Introduction

Cancer is a malignant disease in which mutated cells proliferate independently, invade surrounding tissues, and metastasize throughout the body, and it is the leading cause of death in Canadians (Statistics Canada, 2018). Largely due to a growing aging population, the number of individuals diagnosed with cancer is on the rise. Responsible for 30% of all deaths nationwide, 45% and 43% of Canadian men and women, respectively, will be diagnosed with cancer at one point over their lifetime (Canadian Cancer Statistics Advisory Committee, 2019). However, due to progress in detection and treatment technology, survival rates are increasing. Since 1988, survival rates for men and women with cancer have increased by 35% and 20%, respectively (Canadian Cancer Statistics Advisory Committee, 2019). With parallel increases in both diagnoses and survival, more survivors are facing the long-term side effects associated with cancer and its treatments than ever before—effects that have been found to significantly hinder their quality of life (Boykoff et al., 2009; Frost et al., 2000; Holzner et al., 2001; Mitchell & Turton, 2011; Schmidt et al., 2016; Selamat et al., 2014). Of these side effects, cognitive impairment (CI), colloquially referred to as "chemobrain" or "brain fog," is particularly troublesome.

CI refers to any declines in perceived or objectively measured cognitive functioning including, but not limited to, deficits in attention, executive function, concentration, memory, processing, spatial and task processing speeds, and cognitive fatigue (Joly et al., 2015; Mitchell & Turton, 2011; Schmidt et al., 2016; Selamat et al., 2014). Empirically, it has been suggested that chemotherapy directly induces CI in survivors, citing cases in testicular, colorectal, prostate, and breast cancers (Buffart et al., 2015; Joly et al., 2015). In addition to cognitive deficits, CI also impacts survivors' psychosocial well-being and is often reported as a survivor's most troublesome symptom, resulting in declines in quality of life and daily functioning, as well as social and professional drawbacks (Boykoff et al., 2009; Frost et al., 2000; Holzner et al., 2001; Saarto et al., 2012; Schmidt et al., 2015). In those living with CI, there is often a perceived inability to perform tasks that had been appraised as simple prior to receiving chemotherapy, such as those related to survivors' occupations, contributing to a lost sense of identity (Henderson et al., 2019). This detrimental undermining of identity has been linked to reduced confidence, doubts regarding returning to work, and difficulties with social interaction (Henderson et al., 2019).

In managing and reducing CI symptoms, research has found considerable success in developing exercise as a promising intervention (Campbell et al., 2020; Myers et al., 2018). Aerobic, resistance, and mixed modal exercise interventions have each demonstrated positive effects on CI in survivors, when examining both cognitive functioning as a whole as well as cognitive fatigue specifically (Campbell et al., 2020; Hacker et al., 2011; Schneider et al., 2007). This variety in effective intervention style provides survivors with flexibility in terms of program design that can lead to the attainment of personal fitness goals as well as CI symptom improvements. Interestingly, exercise interventions have been suggested to reduce CI acutely as well, diminishing time commitments required by survivors to draw benefits (Salerno et al., 2019).

While some survivors will require acute psychosocial support, supportive lifestyle interventions such as exercise may be viewed by survivors as less stigmatizing than discussing mental health issues, while still offering substantial mental health benefits. Moreover, resources allocated to psychosocial programs are frequently not adequate to provide services

beyond the needs of patients currently receiving therapy or who have acute mental health needs (Recklitis & Syrjala, 2017). Similarly, access to psychosocial oncology care providers may be limited to those survivors living in close proximity to major cancer centres. Community group-based exercise programming can increase access to complementary mental health care and may offer benefits beyond those of psychotherapy alone. Literature also suggests that there are benefits to conjunctive exercise and psychotherapy interventions (Courneya et al., 2003). Breast and prostate cancer survivors have credited these forms of interventions with creating mutual aid and trust while helping with self-identity and returning to normalcy (Martin et al., 2015).

While there is encouraging research evaluating exercise interventions' effectiveness in diminishing survivors' CI, it has been found that adherence levels are critical limitations to these studies. In a recent systematic review conducted by Campbell et al. (2020), over 25% of randomized control trials examined had low intervention adherence, taking away from the review's promising finding that exercise had beneficial effects on survivors' CI. Low adherence levels hinder the ability to draw practical and accurate interpretations from these studies. Thus, achieving high adherence levels is critical in determining the efficacy of exercise interventions, making it advantageous to determine the qualities of interventions that maintained high subject participation. Recognizing trends emerging from this body of interventional research could provide researchers with valuable intervention designs to improve adherence and decrease attrition.

Most studies examining exercise's effect on survivors' CI follow randomized control trial designs in which participants and programs are extensively controlled. While randomized control trials are deemed the gold standard for determining causal relationships, the addition of real-world evidence in this field would be beneficial in developing knowledge regarding applications of exercise interventions to a broader and more diverse population of cancer survivors. Real-world evidence is often gathered from pragmatic trials—studies designed to assess interventions in environments that mimic real-world routine clinical practice conditions (Patsopoulos, 2011). Pragmatic exercise trials may feature loose inclusion criteria, individualized interventions, or self-directed programming (Cuesta-Vargas et al., 2011; Treweek & Zwarenstein, 2009).

The objective of this scoping review is to identify the characteristics of effective pragmatic trials that have examined the impact of exercise interventions on cancer survivors' CI. Specifically, the frequencies, intensities, times, and types of these exercise interventions that maintained consistently high participant involvement will be analyzed for any similarities and trends. Attention will also be given to those specific studies that found positive effects of exercise on decreasing symptoms of CI. A scoping review method was chosen to capture studies that incorporated a variety of designs, which will allow reviewers to investigate this topic using a heterogeneous data set of previously published literature. A preliminary search of MEDLINE, the Cochrane Database of Systematic Reviews, and *JBI Evidence Synthesis* was conducted, and no current or underway systematic reviews or scoping reviews on the topic were identified. Findings from this review will provide researchers, health care professionals, and allied health care providers with practical guidance on improving intervention adherence and effectiveness in reducing CI.

Review Questions

The questions to be addressed in this review are the following:

1. What were the frequencies, intensities, times, and types of pragmatic exercise interventions that led to a positive effect on CI in survivors? How do they compare to those interventions that did not show such effects?

2. What are the frequencies, intensities, times, and types of pragmatic trials that had high adherence levels?

Inclusion Criteria

Participants

This review will examine literature with adult cancer survivors as participants. Cancer survivorship involves the well-being and health of those living with cancer, beginning at the time of diagnosis through to the end of life (National Cancer Institute, n.d.). For the purposes of this review, the term "adult cancer survivor" will apply to any adult (over 18 years of age) having received a cancer diagnosis, at any point along the cancer continuum (diagnosis through to palliation).

Concept

This review will consider literature exploring the effects of pragmatic exercise interventions in decreasing cancer survivors' CI. Exercise will be defined as structured, planned, and purposeful physical activity (Caspersen et al., 1985). All types of exercise interventions, including aerobic, resistance, meditative movement (e.g., yoga, tai chi), and multimodal interventions of any frequency and duration will be examined. Adherence will be defined as the degree to which participants follow agreed-upon exercise plans.

Context

This review will examine studies with no limits related to geographic location or care setting. Studies must include an element of "real world" to be considered, and this includes pragmatic trials or studies run in communities by qualified health care professionals and/or trained fitness professionals.

Types of Sources

This scoping review will consider various study designs including non-randomized controlled trials, pre-post studies, and interrupted time-series studies. In addition, analytical observational studies including prospective and retrospective cohort studies, case-control studies, and analytical cross-sectional studies will be considered for inclusion. This review will also consider descriptive observational study designs including case series, individual case reports, and descriptive cross-sectional studies for inclusion.

Methods

The proposed scoping review will be conducted in accordance with the JBI methodology for scoping reviews (Peters et al., 2020). There was no patient or public involvement in the design, conduct, reporting, or dissemination plans of this research.

Search Strategy

The search strategy will aim to locate both published and unpublished studies. An initial limited search of MEDLINE and CINAHL will identify articles on the topic. The words contained in the titles and abstracts of relevant articles and the index terms used to describe the articles will be used to develop a full search strategy for CINAHL, MEDLINE, Embase, Scopus, SPORTDiscus, and PsycInfo (see Appendix A). The search strategy, including all identified keywords and index terms, will be adapted for each included database and/or information source. The reference list of all included sources of evidence will be screened for additional studies. Only studies published in English will be included. There will be no date range for this review, in order to explore trends across time.

Information Sources

The databases to be searched include MEDLINE, CINAHL, Embase, Scopus, SPORTDiscus, and PsycInfo. Sources of unpublished studies and grey literature to be searched include ProQuest Dissertations and Theses Global and the first 10 pages of Google Scholar. We will also search for grey literature using the Canadian Agency for Drugs and Technologies in Health (CADTH) grey literature checklist *Grey Matters: A Practical Tool for Searching Health-Related Grey Literature* (CADTH, 2019).

Study/Source of Evidence Selection

Following the search, all identified citations will be collated and uploaded into Covidence (a citation management platform) and duplicates removed. Following a pilot test of 50 included articles, titles and

abstracts will then be screened by two or more independent reviewers for assessment against the inclusion criteria for the review. Potentially relevant sources will be retrieved in full, and their citation details imported into the JBI System for the Unified Management, Assessment, and Review of Information (Piper, 2019). The full text of selected citations will be assessed in detail against the inclusion criteria by two or more independent reviewers. Reasons for exclusion of sources of evidence at full text that do not meet the inclusion criteria will be recorded and reported in the scoping review. Any disagreements that arise between the reviewers at each stage of the selection process will be resolved through discussion, or with review performed by a third reviewer. The results of the search and the study inclusion process will be reported in full in the final scoping review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) flow diagram (Tricco et al., 2018).

Data Extraction

Data will be extracted from papers included in the scoping review by two or more independent reviewers using a data extraction tool developed by the reviewers. The data extracted will include specific details about the participants (age, diagnosis, stage, and treatment), concept, context, study methods, and key findings relevant to the review questions. CI outcomes, measured both objectively and subjectively, will be extracted, including—but not limited to—working and spatial memory, verbal fluency, task switching, cognitive fatigue, and cognitive functioning pertaining to quality of life. There will be no constraints regarding which CI outcomes will be included. Before data extraction begins, two independent reviewers will pilot the data extraction tool for five of the same articles, and they will discuss any additional information needed to be extracted.

A draft extraction form is provided (see Appendix B). The draft data extraction tool will be modified and revised as necessary during the process of extracting data from each included evidence source. Modifications will be detailed in the scoping review. Any disagreements that arise between the reviewers will be resolved through discussion, or with the input of a third reviewer. If appropriate, authors of papers will be contacted to request missing or additional data, where required.

Data Analysis and Presentation

Data regarding frequency, intensity, time, and type of physical activity will be extracted for the relevant studies' exercise interventions. When evaluating adherence, a graded approach will be used. Studies will be categorized as having either low (≤33%), mediocre (34-66%), or high (≥67%) adherence levels when comparing the number of participants who started the intervention to the number of those who completed it. Any discrepancies will be resolved by consensus or with a third reviewer. Final categorizations will be reviewed and discussed with the entire research team.

Given the focus of this scoping review on mapping existing literature, Tomlin and Borgetto's (2011) classification of research pyramid will be used to assess the level of evidence. This pyramid breaks down articles into four separate categories (descriptive, experimental, outcomes, and qualitative research) to evaluate the level of evidence of studies included from different study designs. Each category describes four levels of evidence from most to least rigorous. Descriptive research is divided into Level 1: Systematic reviews of related descriptive studies; Level 2: Association, correlational studies; Level 3: Multiple-case studies (series), normative studies, descriptive surveys; and Level 4: Individual case studies. Experimental research is divided into Level 1: Meta-analyses of related experimental studies, Level 2: Individual (blinded) randomized controlled trials, Level 3: Controlled clinical trials, and Level 4: Single-subject studies. Outcome research is divided into Level 1: Meta-analyses of related outcomes studies; Level 2: Pre-existing group comparisons with covariate analysis; Level 3: Case-control studies, pre-existing group comparisons; and

Level 4: One-group pre-post studies. Finally qualitative research is divided into Level 1: Meta-synthesis of related qualitative studies; Level 2: Group qualitative studies with more rigor ([a] Prolonged engagement with participants, [b] Triangulation of data [multiple sources], [c] Confirmation of data analysis and interpretation [peer and member checking]); Level 3: Group qualitative studies with less rigor (a, b, c); and Level 4: Qualitative studies with a single informant.

The PRISMA-ScR reporting guideline will be followed for this scoping review (Tricco et al., 2018). The extracted data will be presented in tabular form that aligns with the review objectives and questions. In addition to the tables, a graphic image will be created of the frequency, intensity, time, and type of exercise interventions found in the included studies. A narrative summary will accompany these presentations and will describe how the findings relate to the review's objectives and sub-questions. Results will be classified under main conceptual categories: study characteristics (including country or origin, study population, study setting, design), outcome measures, key findings, and implications.

Funding

No funding was provided for this project.

Conflicts of Interest

There is no conflict of interest in this project.

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Appendix A
Search Strategy

Database	Search Terms	Results
MEDLINE (Ovid)	#1 exp Cognition/ #2 exp cognition disorders/ or exp cognitive dysfunction/ #3 exp Memory/ #4 (cognitive* adj2 (function* or dysfunction* or impair*)).ti,ab. #5 (memor* or remember*).ti,ab. #6 ("chemo brain" or "chemo fog" or chemobrain).ti,ab. #7 Executive Function/ #8 Prefrontal Cortex/ #9 Hippocampus/ #10 Brain/ #11 Attention/ #12 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 #13 exp Antineoplastic Agents/ #14 Cancer Survivors/ #15 exp Neoplasms/ #16 exp Antibiotics, Antineoplastic/ #17 exp Doxorubicin/ #18 exp Fluorouracil/ #19 exp antineoplastic protocols/ or exp chemotherapy, adjuvant/ or exp consolidation chemotherapy/ or exp induction chemotherapy/ or exp maintenance chemotherapy/ #20 Neoadjuvant Therapy/ #21 (chemotherapy or cancer* or neoplas* or leukemia* or leukaemia* or lymphoma* or metasta*).ti,ab. #22 #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 #23 exp Exercise/ or exp Exercise Therapy/ #24 exp Yoga/ #25 Qigong/ #26 exp Exercise Movement Techniques/ #27 (pilates or "tai chi" or "tai ji" or qigong or yoga or aerobic* or exercise or "resistance training" or "weight training" or workout* or swim*).ti,ab. #28 #23 or #24 or #25 or #26 or #27 #29 #12 and #22 and #28	979

Appendix B
Data Extraction Instrument

Author		Cancer treatment(s)	
Title		Pragmatic Elements	
Country		Intervention Frequency	
Year		Intervention Intensity	
Study Aim		Intervention Time	
Study Design		Intervention Type	
Inclusion Criteria		CI Measure	
Exclusion Criteria		Adherence	
Number of Participants		Key Findings	
Cancer type		Implications	
Cancer stage		Limitations	