BMJ Open Characteristics of activity-based therapy interventions for people living with spinal cord injury or disease across the continuum of care: a scoping review protocol

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ABSTRACT

Introduction Individuals living with spinal cord injury and disease (SCI/D) experience sensory and motor impairments below their neurological level of injury. Activity-based therapies (ABT) are interventions that provide activation of the neuromuscular system below the level of lesion with the goal of retraining the nervous system to recover a specific motor task. ABT can lead to increased function and improved quality of life; however, research and clinical settings currently lack tools to track participation in ABT. As a first step towards developing such a tool, a scoping review will be conducted with the objective of identifying the characteristics of ABT that individuals with SCI/D participate in across the continuum of care.

Methods and analysis The review will follow the Joanna Briggs Institute scoping review framework. Studies that involve at least two sessions of ABT for individuals with SCI/D aged ≥16 years will be included. Seven databases were searched from their inception to 4 March 2020: Medline, Embase, Emcare, Cumulative Index to Nursing and Allied Health Literature, APA PsycINFO, Physiotherapy Evidence Database, Cochrane Database of Systematic Reviews and the Cochrane Central Register of Controlled Trials. The search will be rerun in November 2020 prior to manuscript submission. Screening of titles and abstracts will be followed by a review of full texts to identify articles meeting inclusion criteria. Stakeholders will be consulted for the creation of the data extraction table. The Downs and Black Checklist or the Mixed Methods Appraisal Tool will be used to assess article quality. Results will be reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews checklist.

Ethics and dissemination Ethical approval is not required for this scoping review. Study findings will be shared with key stakeholder groups through academic, clinical and public venues.

INTRODUCTION

Spinal cord injuries and diseases (SCI/D) are devastating conditions affecting over 85 000 people in Canada of all demographics, with nearly 3700 new cases of SCI each year.¹ The aetiology of SCI/D may be classified

Strengths and limitations of this study

- The engagement of stakeholders in the development of the review objective, creation of the data extraction table and synthesis of the data is a strength.
- The inclusion of quality appraisal tools appropriate for quantitative, qualitative and mixed-methods studies is a strength.
- The exclusion of grey literature from the search strategy is a potential limitation.

as traumatic or non-traumatic. Traumatic injuries are often a result of motor vehicle collisions, sport-related incidences, falls or violence leading to crushing, shearing, bursting or penetration of the spinal cord. Non-traumatic injuries have a wide range of aetiologies including infections, cancer and vascular disorders.² The level and severity of the injury to the spinal cord determine the extent of paralysis. In addition to sensorimotor loss, the resulting damage leads to a multitude of sequelae including: bowel, bladder and sexual dysfunction; pressure ulcers; neuropathic pain; pulmonary and cardiovascular disease; and osteoporosis.^{3,4} The economic burden on the healthcare system of caring for individuals living with traumatic SCI is staggering at a cost of US\$2.67 billion annually.⁵ Hence, strategies to enhance neurorecovery are paramount to increase function and independence, reduce secondary complications, improve quality of life and reduce the strain on the healthcare system.

Activity-based therapies (ABT) are intensive approaches to rehabilitation that focus on restoring function through the principles of neuroplasticity.^{6,7} Behrman and Harkema defined ABT as ‘interventions that provide activation of the neuromuscular system below

the level of lesion with the goal of retraining the nervous system to recover a specific motor task.⁸ It is the promotion of neurorecovery that sets ABT apart from exercise, which is repetitive and structured physical activity completed with the intent of maintaining or improving fitness.⁹ A distinguishing feature of ABT is the high intensity and frequency of the sessions, which combine massed practice and task-specific training with sensory stimulation, technology and motivated mental effort. Although ABT often involve specialised equipment, such as functional electrical stimulation and body weight-supported treadmills,¹⁰ minimal and/or low level technology may be used, increasing the applicability of ABT across socioeconomic levels and clinical care settings.¹¹

In addition to promoting neurorecovery and/or increased function below the level of injury, there are numerous health benefits of ABT. Health benefits include reduced spasticity, decreased incidence of pressure injuries and urinary tract infections, and improved bowel motility, body composition and quality of life.^{6 12–16} Participation in ABT may prove beneficial across all degrees of severity and stages of injury (ie, acute, subacute and chronic stages), however, little is known about the characteristics and delivery of ABT across the continuum of care (ie, acute care, rehabilitation and community living).¹⁶ Although ABT are gaining in popularity, there remain a number of challenges to their implementation in clinical practice. A lack of consensus regarding programme delivery and standardised guidelines, as well as available tools to effectively document participation and performance in ABT, limit the use of ABT in acute care, neurorehabilitation and community settings.

The Canadian ABT Working Group was formed in 2019 by the Praxis Spinal Cord Institute in order to improve the availability of quality ABT for Canadians living with SCI/D.¹⁷ The multistakeholder Working Group was tasked with identifying research priorities for ABT in Canada. One of the five priorities identified by the Working Group was the development and implementation of tracking tools that can be used by individuals living with SCI/D, healthcare professionals and health systems to track the details of participation in ABT. Such tools will enable the collection of valuable data; data that will assist with individualised treatment planning and performance monitoring, enable people with lived experience to track their progress to inform individual-level, programme-level and health system-level decisions and contribute to the development of ABT practice guidelines concerning the optimal delivery and dosing of ABT.

In order to develop a useful ABT tracking tool, the tool must be comprehensive, meaning it must include all key characteristics of ABT. Key characteristics of an ABT session may include the type of ABT, duration of the activity, number of repetitions performed, technology used and assistance required. Identifying these key characteristics prior to the development of a tracking tool is crucial for ensuring the tool possesses content validity and clinical relevance. No literature reviews currently exist

that describe the characteristics of ABT available across the continuum of care. Presently, one systematic review and one scoping review protocol on ABT are published. The systematic review described the effects of ABT interventions on mobility, functional independence and quality of life for people living with SCI/D.¹⁸ It searched nine databases (ie, Medline, Embase, Cumulative Index to Nursing & Allied Health Literature (CINAHL), Allied and Complementary Medicine Database, Scopus, SPORT-Discuss, Web of Science, Cochrane Library, Physiotherapy Evidence Database (PEDro) from the earliest record to February 2016.¹⁸ The scoping review protocol describes an upcoming review that will evaluate the evidence of ABT interventions for individuals with neurologically impaired upper extremities.¹⁹ Five databases were searched in this scoping review (Medline, EBSCOhost, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL), OTseeker) from the year 2000.¹⁹

The absence of a review relevant to the characteristics of ABT and the overall paucity of information in this field warrant a scoping review to provide a comprehensive overview of the characteristics of ABT.^{20 21} A scoping review is ideally suited to identify the characteristics of ABT for several reasons. First, scoping reviews are appropriate for research questions that are broad in nature, particularly in areas lacking a comprehensive review.^{20 22} Second, scoping reviews are capable of synthesising research evidence in emerging fields of study where a paucity of information exists and there is lack of agreement among experts.²⁰ Finally, scoping reviews may also identify knowledge gaps to direct future research initiatives.^{20 21 23 24} Hence, here the authors describe the protocol for a systematic scoping review, the objective of which is to identify the characteristics of ABT that individuals with SCI/D participate in across the continuum of care. The results from this review will inform the content to include in an ABT tracking tool.

METHODS AND ANALYSIS

This review will follow the Joanna Briggs Institute (JBI) guidelines for scoping reviews.^{20 25} The scoping review protocol was registered with the Open Science Framework in March 2020 <https://osf.io/ac2qu/>.²⁶ Any significant revisions to the protocol will be noted on this webpage. Results of the scoping review will be reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist.²⁷

Search strategy process

The search strategy used the JBI recommended three-step process and was developed under the consultation and guidance of an information specialist (MP). First, a limited database search was undertaken in Medline and Embase using the terms SCI/D and ABT. This was followed by an analysis of the assigned subject headings in the extracted records and a careful examination of the

text terms used in the title and abstract fields. Second, based on all of the information gleaned from that initial search, a comprehensive Medline search strategy was designed based on an adapted Population, Concept, Context framework. The Population included SCI and non-hereditary spinal cord diseases. The Concept focused on finding materials where ABT was specifically noted as the intervention. A Context section was not used in order to keep the results broad to cover the entire continuum of care (ie, all settings in which ABT could occur), such as acute care, inpatient and outpatient rehabilitation, community-based clinics (both private and non-profit) and home programmes. The Medline search strategy (see online supplementary appendix 1) was reviewed by all team members and edited where appropriate. This search strategy was translated as necessary for use in each of the additional databases being searched. In the third step, team members will search the reference lists of all included studies and existing reviews identified through the search for additional relevant materials.

Information sources

The following eight databases were searched from their inception to 4 March 2020: Medline, Embase, Emcare, CINAHL, APA PsycINFO, PEDro, Cochrane Database of Systematic Reviews and the CENTRAL. No language or date limits were applied. The search will be run a second time in November 2020 prior to submitting the scoping review results for publication.

Scoping review questions

The primary scoping review question will be 'What are the characteristics of ABT (concept) that have been used across the continuum of care (context) with adults living with SCI/D (population)?' Characteristics may include the types, duration, intensity, and frequency of ABT documented in included studies. Secondary review questions will further explore the population and context. For example, the population will be further explored by comparing ABT that have been used with individuals living with paraplegia to individuals living with tetraplegia. We will also explore sex and gender differences in ABT participation and performance, if sex and gender data are available. As the prevalence of SCI/D is greater in males^{1 28} and females are underrepresented in human SCI/D research,²⁹ it is possible the data required for these analyses will not exist. The context will be further explored by comparing the characteristics of ABT used in acute care, rehabilitation and community settings.

Eligibility criteria

Inclusion criteria will be kept broad and inclusive to satisfy the review objective. Inclusion criteria are as follows:

- ▶ Study participants reported as having a diagnosis of SCI/D due to a traumatic or non-traumatic cause.
- ▶ All neurological levels of injury (ie, cervical, thoracic and lumbar segments).

- ▶ All degrees of injury severity (ie, American Spinal Injury Association Impairment Scale (AIS) classification of A, B, C or D)
- ▶ Individuals with SCI/D may be at any stage in their recovery; that is, acute, sub-acute or chronic stages.
- ▶ Intervention that meets the following definition of ABT: 'Interventions that provide activation of the neuromuscular system below the level of lesion with the goal of retraining the nervous system to recover a specific motor task.'⁸

Exclusion criteria are as follows:

- ▶ Animal studies.
- ▶ Literature reporting on individuals less than 16 years of age for who the approach to rehabilitation would likely be paediatric focused (eg, play based).
- ▶ Studies focused on congenital causes of spinal damage (eg, spina bifida).
- ▶ Studies reporting only one session of ABT.
- ▶ Studies reporting on exercises targeting muscles above the level of injury only.
- ▶ Conference proceedings, textbook chapters and systematic or scoping reviews.

Abstract and full-text screening

The literature search results will be uploaded to Mendeley V.1.19.3 (Elsevier, London UK) where duplicate records will be removed. Records will then be imported to Covidence V.1513 (Veritas Health Innovation, Melbourne, Australia) for article screening. Any additional duplicates will be automatically removed prior to screening. Two researchers (AK and KC) will independently screen a random sample of 10 records to assess eligibility for inclusion based on the criteria previously described. The researchers will discuss the records for which there was disagreement concerning inclusion. This process will be repeated until $\geq 75\%$ agreement between the two researchers is reached. The same two researchers (AK and KC) will then proceed to independently screen the remaining returned titles and abstracts according to the inclusion and exclusion criteria, which may be revised as needed.²⁰ Conflicts will be resolved by a third researcher (KEM).

Next, the full texts of all included abstracts will be screened. Two researchers (AK and KC) will independently screen a random sample of 10 full-text articles to assess eligibility for inclusion. The researchers will discuss the full-text articles for which there was disagreement concerning inclusion. This process will be repeated until $\geq 75\%$ agreement between the two researchers is reached. The same two researchers (AK and KC) will then proceed to independently screen the remaining full-text articles, documenting reasons for exclusion. Discrepancies will be discussed with a third researcher (KEM). The researchers may contact article authors for clarification regarding eligibility criteria.

Data extraction and charting

The researchers, along with two key stakeholders (ie, an individual living with SCI/D and a front-line physical therapist), will review a random sample of five included

articles to develop a charting table that aligns with the study objective and review questions.²⁵ Data extraction fields may include: title, author, year of publication, study aim, study design, participant demographics (eg, sex, gender), injury characteristics, type of ABT, intensity, frequency and duration of ABT, technology use, level of assistance, outcomes and outcome measures. The organisation of data extraction fields in the charting table will reflect key themes, such as study characteristics, participant characteristics, type of ABT, technology and training parameters to facilitate data synthesis.²⁰ Two researchers (AK and KC) will review the included articles, extract data from the articles and chart the data in the table. Weekly meetings will be held with a third author (KEM) to verify the extracted data, discuss discrepancies and further refine the charting table through an iterative process. The researchers will contact article authors to request missing data.

Quality appraisal

A quality appraisal of the included articles will be completed to aid in the evaluation of the evidence retrieved; the presence of bias may impact the validity of the ABT characteristics identified in the review. As we expect the included articles to be quantitative research studies (eg, randomised controlled trials, observational studies) we will use the Downs and Black checklist to appraise study quality.³⁰ The Downs and Black checklist has high internal consistency, test-retest reliability and good inter-rater reliability.^{31 32} The checklist has been used in other rehabilitation intervention reviews.^{33–36} The checklist consists of 27 questions divided into five domains: reliability, external validity, internal validity, confounding and selection bias and power. Studies are evaluated based on an overall score out of 28 and subscores in each domain; higher scores reflect higher methodological quality.³¹ The overall score will be interpreted as follows: <11 indicates poor methodological quality, 11–19 indicates moderate quality and >19 indicates good quality.³⁷ In the event that qualitative or mixed-methods research studies are included in the review, we will perform the quality appraisal for those studies using the Mixed Methods Appraisal Tool (MMAT).³⁸ The MMAT requires researchers to evaluate five methodological quality criteria customised for each type of research approach (eg, qualitative or mixed methods).³⁸ Two researchers (AK and KC) will independently score each included article using either the Downs and Black checklist or the MMAT and any discrepancies between the two researchers' scores will be discussed with a third researcher (KEM).

Synthesis of results

A narrative description of the search decision process will be produced and the results of the screening process will be summarised in a PRISMA-ScR flow diagram.^{20 27} The overall risk of bias of the included articles will be evaluated by descriptively synthesising the findings of the

Box 1 Review questions

Primary review question

What are the characteristics of activity-based therapies (ABT) (concept) that have been used across the continuum of care (context) with adults living with spinal cord injury and disease (population)?

Secondary review questions

To further explore the population:

- ▶ What ABT have been used with individuals living with paraplegia compared with individuals living with tetraplegia?
- ▶ Do ABT participation and performance differ between sexes and gender identities?

To further explore the context:

- ▶ How does the ABT in acute care, rehabilitation and community settings differ?

quality appraisals. A descriptive synthesis of the extracted data charted for each key theme will be produced (eg, study characteristics, participant characteristics, type of ABT, technology and training parameters). To address the primary review question (see box 1), descriptive statistics, such as frequency counts, will be used to identify commonly reported types and characteristics of ABT across the included articles. To address the secondary review questions, extracted data (ie, types and characteristics of ABT) will be descriptively compared between sexes, genders, level of injury (tetraplegia vs paraplegia) and healthcare setting.

Patient and public involvement

Patients and other stakeholders are involved in this scoping review. The scoping review questions were generated following a stakeholder meeting including 16 individuals who represented individuals living with SCI/D, clinicians, researchers, healthcare administrators and health policy experts. All of these individuals had knowledge of ABT; the individuals with SCI/D, clinicians and researchers had prior experience with ABT.

ETHICS AND DISSEMINATION

Approvals from the research ethics boards of the University Health Network and the University of Toronto will not be required to complete this scoping review.

The scoping review findings will be disseminated in academic, clinical and public venues. The researchers will present the review findings at conferences and publish the work in a peer-reviewed rehabilitation journal. The researchers will also share information about ABT and the characteristics of ABT through webinars targeting key stakeholder groups, including individuals with lived experience, clinicians, healthcare administrators, researchers and health policy experts. In addition to these end-of-project knowledge translation activities, the researchers will promote integrated knowledge translation by engaging key stakeholders (ie, an individual with SCI/D and front-line clinician) in the creation of the data

extraction table and synthesis of the findings for each key theme for this scoping review.

One potential limitation of this scoping review protocol is the exclusion of grey literature from the search strategy, which may limit the breadth and comprehensiveness of the search. Further, the inclusion of published articles only may introduce publication bias and the omission of some ABT. Since the purpose of this review is to identify the characteristics of ABT that individuals with SCI/D participate in across the continuum of care, it is not critical that we capture every piece of available evidence. Moreover, the researchers anticipate book sources to be scarce as the field of ABT is still relatively new. In the unexpected event that our literature search of primary data sources returns few articles on ABT, the researchers will expand the search to include grey literature sources. If few articles on ABT are returned, it is possible that relevant characteristics will be omitted from the results. Hence, the findings of this review should be combined with other methods of identifying the characteristics of ABT. For example, in parallel with this scoping review, our research team is conducting semi-structured interviews with a variety of stakeholders (eg, people with SCI/D, clinicians, healthcare administrators and researchers) to gain their perspectives concerning the parameters and characteristics to include in an ABT tracking tool. Through these efforts the characteristics of ABT will be identified, which will lay the foundation for the development of ABT-related measures, tools, interventions and guidelines by SCI communities, researchers and healthcare groups from across the globe.

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Contributors AK and KEM designed the scoping review. MP designed the search strategy in collaboration with AK and KEM. AK, KC, MP and KEM were involved with writing the scoping review protocol.

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Competing interests None declared.

Patient and public involvement Patients will be involved in the design, conduct, reporting, and dissemination of this research.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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