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PROTOCOL FOR DEVELOPING A HEALTHCARE TRANSITION INTERVENTION FOR YOUNG PEOPLE WITH SPINAL CORD INJURIES USING A PARTICIPATORY ACTION RESEARCH APPROACH

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AUTHOR CONTRIBUTIONS

EAB, BE, AG, YS, LMR were responsible for the study conception and design. EAB, BE, AG, YS, LMR were responsible for drafting the manuscript and making critical revisions to the paper for important intellectual content.

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ABSTRACT

Introduction

While healthcare transition (HCT) interventions are recognised as an important area in paediatric rehabilitation, there has been limited research focusing on young people with spinal cord injuries (SCI). In this study, researchers will collaborate with young people with SCI and their parents/caregivers to develop, implement and evaluate the feasibility and acceptability of a HCT intervention aimed at supporting young people with SCI during their transition from paediatric to adult healthcare services.

Methods and analysis

A participatory action research (PAR) approach will be used to co-develop the HCT intervention with young people with SCI aged 14 to 25 years and their parents/caregivers. Three phases will be conducted to address the five objectives of this study. Phase 1 will use semi-structured interviews to explore young people and parent/caregivers' experiences of HCT. In Phase 2a, both young people and parent/caregivers will be co-researchers. They will be included in the analysis of the interviews and will be asked to participate in co-design workshops to inform the development of a prototype HCT intervention. In Phase 2b, using focus groups, feedback on the prototype HCT intervention will be collected. In Phase 3, the refined prototype HCT intervention will be implemented, and young people with SCI and their parent/caregivers will evaluate the feasibility and acceptability of the HCT intervention in semi-structured interviews. A reference group, including stakeholders and end-users, will be consulted at different time points.

Ethics and dissemination

Specific ethical concerns that will be considered include the young person's capacity to understand what the research involves, their ability to consent, possible coercion by parents, peers and researchers, and the conflicting values and interests of parents and children. The study has received ethics approval from Western Sydney University Human Research and Ethics Committee (H14029).

Trial registration number

Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12621000500853

Keywords

Healthcare transition, young people, spinal cord injury, qualitative research, participatory action research

ARTICLE SUMMARY

Strengths and limitations of this study

- This study is the first study to use a PAR approach and involve youth with SCI to co-create and evaluate a HCT support intervention.
- Using PAR methodology will give a voice to a group of young people whose voices have historically been ignored.
- Inclusion of PAR principles in the development of the HCT intervention increases the likelihood that the intervention will be acceptable to end-users.
- Clear articulation of the methods of the study will provide guidance on the use of PAR in the development of HCT interventions.
- PAR requires prolonged engagement with participants and is time intensive.

INTRODUCTION

Healthcare transition (HCT) is "the purposeful, planned movement of adolescents and young adults with chronic physical and medical conditions from child-centred to adult-oriented healthcare systems"(1). Transition from the paediatric to adult healthcare system is a complex process that requires care to be delivered in a coordinated and uninterrupted manner through the provision of developmentally appropriate and comprehensive services(1-4).

Challenges in the process of transition occur as a result of the procedural and cultural differences between paediatric and adult healthcare, and the crucial yet turbulent developmental phase of adolescence(4-6). Families speak about the difficulty of terminating the lifelong relationships that have developed with paediatric providers, the challenges of building working relationships in new healthcare settings, and the fears that adult professionals lack the knowledge and quality of care provided by their paediatric providers(6). Furthermore, the adult healthcare system is characterised by decreased family involvement where success managing your health requires skills such as self-advocacy and self-determination. Yet, there is evidence to suggest that developing these skills is not deemed a priority for young people with chronic conditions transitioning out of the paediatric sector(4, 7). Adolescence is also a complex phase, with biological maturity preceding psychosocial maturity. This may contribute to tension arising between adolescents, their families and healthcare providers as they attempt to find an identity for themselves outside of the family unit and push the boundaries of these relationships(4).

The aforementioned challenges associated with the move from paediatric to adult healthcare systems and inadequate transition preparations can alter the health

outcomes of young people with chronic conditions(2, 8). Research indicates that post transition some young people with chronic conditions often fail to adhere to treatments, are lost to follow up, experience deteriorating health, develop secondary complications, and face negative social and emotional outcomes(2, 7). Despite this, there is evidence to suggest that effective HCT interventions can improve health outcomes for young people with chronic conditions(8). However, little has been written on HCT interventions for young people with a paediatric onset spinal cord injury (SCI)(9, 10) and what does exist suggests that there is a lack of support for young people with SCI transitioning into adulthood and adult healthcare services(10). Therefore, this study aims to address the transition needs of young people with SCI and the current gap in services, contributing to the evidence while improving transition outcomes and quality of life for these individuals.

Aims

The overall aim of this study is to co-develop, implement, and evaluate a HCT intervention to support young people with SCI. The specific objectives will be to:

1. Identify current services and resources that aid in facilitating the transition of young people with SCI from paediatric to adult health services.
2. Understand the experience of transition for young people with SCI and their parents/caregivers.
3. Explore the current needs of young people with SCI to identify gaps within the transition process.
4. Co-design and develop a HCT intervention to support young people with SCI.

5. Implement the HCT intervention and evaluate its acceptability and feasibility in supporting the transition process.

Methodology

This study draws on Article 7 of the UNCRPD(11) and Article 12 of the UNCRC(12) to inform its research methodology. The UNCRC acknowledges that children have the right to express their opinions and to have those opinions heard and acted upon when appropriate, to be protected from abuse or exploitation, and have their privacy protected(12). Article 7 of the UNCRPD furthers this sentiment specifically stating that actions should be taken to "ensure that children with disabilities have the right to express their views freely on all matters affecting them, their views being given due weight in accordance with their age and maturity, on an equal basis with other children, and to be provided with disability and age-appropriate assistance to realize that right"(11). As a result of the increase in emphasis on children's rights, the academic community have responded by ensuring children's participation in research on issues that affect them(13). Participatory action research (PAR) offers an approach to research that engages individuals and communities in identifying problems relevant to their own lives, redistributing the power between researcher and participants, and giving them a chance to be part of social change(13, 14). The process champions the concept of "research with, rather than on, people"(15).

This study will be informed by PAR methodology as it seeks to understand the experience of young people with SCI, and focuses on equal and collaborative participation. Little has been written on the process of co-designing HCT interventions with young people with chronic conditions and disabilities (Authors own work, currently under review). However despite the lack of literature on the

development of HCT interventions using PAR and other co-design approaches, the authors reported that it was feasible to co-develop age-appropriate HCT interventions for young people with chronic conditions. Using a PAR framework to inform the methodology behind this study will ensure that the needs of young people with SCI are integral to the proposed interventional approach, and that their voice is heard and taken into consideration. The study will recognise and value the experiential knowledge of young people with SCI in understanding and addressing the key factors that impact on their successful transition from paediatric to adult healthcare services. Furthermore, it will integrate the input of young people in the design and implementation of the model, to secure their support of the HCT intervention.

Theoretical framework

This study will be informed in its thematic data analysis by the principles of critical disability theory (CDT). Critical theory is a multidisciplinary framework with a goal of explaining oppression and identifying achievable and practical ways to change it(16). CDT centres disability and challenges ableist assumptions. Adopting CDT in this study will serve as a lens to examine transition needs and ensure the rights of children with disabilities are recognised whilst also respecting their voice, which has too often been marginalised.

Contextual framework underpinning intervention development and evaluation

This study will use the Care Transitions Framework to inform the development of the HCT intervention for young people with SCI transitioning from paediatric to adult healthcare services. The framework provides a guide to implementation, organised into eight domains; Intervention Characteristics, External Context, Organisational Characteristics, Characteristics and Roles of Providers, Characteristics and Roles of

Patients and Caregivers, Process of Implementation, Measures of Implementation, and Outcomes(17).

A scoping review and ongoing consultations with services and stakeholders will generate knowledge on the external context, organisational characteristics and characteristics and roles of providers. The phases of this study will address the remaining domains as outlined in Figure 1.

METHODS AND ANALYSIS

There will be three phases to this study that will address the five objectives outlined in the Aims section of this paper. The phases and study objectives are depicted in Figure 1.

Phase 1 will include semi-structured individual interviews or paired interviews to explore current experiences and unmet needs. Phase 2a will use group co-design workshops to help analyse the interviews and inform the development of a prototype HCT intervention. Phase 2b will gather feedback on the prototype HCT intervention from the young people and parents/caregivers involved in the workshops as well as the reference group to allow refinement and revision and improved practical application. Phase 3 will implement the HCT intervention and evaluate its acceptability and feasibility.

All phases of the study will be informed by the principles of PAR and involve cycles of planning, acting, observing and reflecting as described by Kemmis and McTaggart(18). Three PAR cycles will be conducted throughout the study as per Figure 2.

This protocol paper has been guided by the SPIRIT 2013 statement(19).

Study setting

Due to the small population of paediatric-onset SCI(20), the study will cover both metropolitan and rural New South Wales. It is a goal of this study to recognise the importance of providing opportunities for participants from rural areas to be involved in the study as young people with disabilities can be particularly disadvantaged in rural areas(21). Often they experience a lack of services and continuity of care(21), as such their experiences transitioning from paediatric to adult healthcare services may vary greatly from young people residing in metropolitan areas.

Study population

Young people between the ages of 14 to 25 years who acquired a paediatric-onset SCI (before the age of 16) and parents/caregivers of young people with a paediatric-onset SCI will be eligible to participate. Young people will either be preparing to transition or will have transitioned. Individuals who are currently an inpatient in a children's hospital receiving rehabilitation treatment for a SCI acquired in the last 12 months will not be eligible for inclusion. The first year after injury can be overwhelming and requires tremendous adjustments for both the individual and their family. The researcher does not want to burden the individual or their family with the demands of participating in research, nor risk causing any additional emotional distress during this challenging time.

The study will also only include young people with SCI and parents/caregivers with sufficient English language proficiency to allow for engagement in discussions during the interviews and participation in the co-design workshop. Please note hereafter and unless otherwise specified, the term participants will be used to denote both young people with SCI and parents/caregivers.

Recruitment and sample size

The researcher will use purposive, convenience and snowball methods of recruitment for the study. An electronic flyer and video will be emailed to paediatric SCI support organisations for advertisement through their networks and on their social media pages and websites. The researchers will also recruit through word-of-mouth and social media (Twitter, LinkedIn, Facebook). Approximately six to eight young people with SCI and six to eight parents/caregivers of young people with SCI will be recruited for this study.

Patient and public involvement

Young people with SCI and their parents/caregivers were not involved in setting the research question or design of the study, but they will be heavily involved in the design, implementation and evaluation of the HCT intervention.

A reference group, consisting of paediatric SCI healthcare service providers and young people with SCI specifically chosen for their particular areas of expertise, will be consulted throughout the study and asked to provide expert advice on:

- recruitment;
- appropriateness of the interview schedule and co-design workshop activities;
- identification of issues or barriers that could impede the success of the study;
- identifying solutions to problems with implementation of the study;
- discussing the key outcomes of the study and;
- providing feedback on the final HCT intervention.

Phase 1: Exploring current experiences and unmet needs

Data collection

Semi-structured interviews will be used to collect qualitative data on the HCT experiences of young people with SCI from the perspectives of the young people themselves and parents/caregivers. Semi-structured interviews have been chosen to allow for the flexibility to explore ideas and responses that are important to participants but may not have been previously considered by the researchers(22). Semi-structured interviews will also allow for the researcher to adapt the interview techniques to the child or young person's developmental age.

In an attempt to reduce power imbalances, participants will be offered the opportunity to participate in a paired interview with another young person that is also eligible for the study. Paired interviews, where a pre-established relationship exists, can provide a more complete picture of the issues as the other interviewee supports the filling of gaps in the story(23).

Interview guides will be developed to explore the needs, gaps, weaknesses and opportunities relating to HCT for young people with SCI. The interviews will be conducted online via the use of video-conferencing software (Zoom) at a time that is convenient to the participant. The interviews are anticipated to take 60 minutes. Interviews will be audio-recorded and transcribed verbatim to assist with data analysis.

Analysis

An inductive thematic analysis approach, as described by Braun and Clarke(24, 25), will be undertaken to identify major themes and sub-themes arising from the participant responses. This style of analysis involves six phases: familiarisation, code

generation, searching for themes, review and theme naming and report production. These phases need not be treated linearly and thus movement between the six phases will occur as required. An inductive thematic analysis approach has been chosen as it allows for a 'bottom up' analysis of the data to occur, whereby analysis is not driven by the researchers' preconceptions or pre-existing coding frame but instead is driven by the participants' responses and strongly links the themes identified to the data(25).

PAR methodology requires collaboration at all stages of the research progress and Liebenberg et al. suggest that simply "being reflexive and conducting member checks of findings from the analysis is insufficient"(26). Instead participants should actively participate in the data analysis however, guidelines on how this can be successfully achieved is limited(26).

In this study, the principal researcher and another member of the research team will individually code the transcripts. Following this, a final list from each reviewer will be developed and a meeting hosted, where through consensus, a final list of themes and sub-themes will be determined. In addition to this, the co-design workshops will begin by asking the participants to review the codes and themes generated from the individual interviews. Researcher and participants (co-researchers) will compare and discuss the analysis decisions until consensus is achieved.

Phase 2a: Co-designing the HCT intervention (workshops)

Data collection

The co-design workshops will be facilitated by two researchers and are anticipated to take between 60 and 90 minutes. The workshops will either be held in person at the university campus or via video-conferencing (Zoom) at a time convenient for the

group. There will also be the option for rural and remote participants to dial into the workshops using Zoom. Two workshops will be held—one for young people with SCI and one for parents/caregivers.

The workshops will have two phases, the first being to analyse the data from the interviews and the second to co-design the HCT intervention.

The first phase of the workshop will require participants to review samples of unidentifiable excerpts of interviews and initial codes/categories generated by the researchers and decide on their authenticity. Once in agreement on codes/categories, working together researchers and participants (co-researchers) will group codes/categories into themes using post-it notes or the white-board function on Zoom. During this process, participants (co-researchers) will be asked to explain their analysis decisions to the researchers.

In the co-design phase young people's HCT needs and participants' recommendations for the development of the HCT intervention will be explored. The researcher will use the future workshop method(27, 28) to facilitate discussion and generation of ideas for the development of the HCT intervention and participants will then work together to brainstorm designs. The future workshop method guides participants through three phases: a critique phase, a fantasy phase and an implementation phase(27, 28). The aim of the critique phase will be to review the themes identified in the data analysis phase to identify deficits or challenges related to HCT experienced by young people with SCI. In the fantasy phase, the participants will be given creative freedom to generate utopian ideas about the best possible way to mitigate the issues. In the third phase, the participants will transform the utopian ideas into a design for a practical and realisable HCT intervention.

Analysis

The workshops will be audio-recorded. The design ideas developed in the workshops will be captured in creative forms such as drawings/writings or verbally. Participants will also be asked to describe their design ideas to the group so that the researchers can capture these in the audio-recordings.

Phase 2b: Co-designing the HCT intervention (focus groups)

Data collection

In this phase participants will be provided/shown the prototype intervention and invited to partake in a focus group conducted online using video conferencing software (Zoom). Qualitative data will be collected to identify whether the HCT needs of young people with SCI and participants' recommendations have been met by the prototype. The focus groups are anticipated to take approximately 60 minutes and will be facilitated by two researchers. The focus group will be audio recorded and transcribed to assist with data analysis.

Analysis

The transcripts from the focus groups will be analysed thematically in a similar process to Phase 1 in order to identify any adjustments required to the HCT intervention. The principal researcher and another member of the research team will individually code the transcripts. A final list from each reviewer will be developed and a meeting hosted, where through consensus, a final list of themes and sub-themes will be determined and the HCT intervention will be refined based on this feedback.

Phase 3: Implementing and evaluating the HCT intervention

Data collection

Due to the iterative nature of PAR, it is anticipated that the HCT intervention will evolve within the research process as participants' experiences and needs influence its development. As such, the nature of the final HCT intervention cannot be known prior to the commencement of the study. Nevertheless, following the completion of the focus groups the researcher will refine the prototype HCT intervention and send the final HCT intervention to participants. They will be asked to review or use the HCT intervention and will be invited to partake in a brief interview. Brief interviews will be conducted over the telephone or online using video-conferencing software (Zoom) at a time that is convenient to the participant. The interviews are anticipated to take between 15 and 20 minutes.

The interviews will evaluate the feasibility and acceptability of the HCT intervention. Bowen and colleagues'(29) framework will inform the evaluation of the HCT intervention (Supplementary file 1). This framework will support making judgments about the feasibility of the intervention and determine whether additional, more comprehensive evaluation is justified. As this study is part of a 3-year doctoral project, time constraints restrict the researchers on conducting a comprehensive pilot study of the HCT intervention to determine its efficacy and effectiveness. Using Bowen and colleagues' framework the researchers will be able to determine whether the HCT intervention is appropriate for further testing, and is relevant and sustainable.

Analysis

Data analysis of Phase 3 will mirror the analysis method in the earlier Phases.

RIGOUR

To ensure that the rigour of the study's qualitative data is maintained the researcher will address the following criteria: credibility, transferability, dependability and confirmability(30). In regard to credibility, the researchers will engage in frequent debriefing sessions to provide an opportunity for the researchers to identify and challenge any assumptions made as a result of their own biases and preferences. Furthermore, credibility will be achieved by including young people with SCI and their parents/caregivers as co-researchers in the analysis of the interviews and by providing opportunities for them to review, reflect on and refine the co-developed HCT intervention.

Transferability will be achieved through detailed reports, thick descriptions and analysis of contextual details, as described by Ponterotto(31). Such details include demographic information, the location and settings of the interviews, workshops and focus groups, and descriptions about non-verbal behaviour.

The researcher will maintain an audit trail and report in detail the processes that occurred within the study related to research design and implementation, operational details of data gathering and provide a reflective appraisal of the processes undertaken. This process will enhance dependability.

Lastly throughout the project, the researcher will keep a comprehensive reflective research journal, reflecting on and cataloguing the progress, obstacles and successes of the research process. This level of documentation will increase confirmability of the research by providing an audit trail for the study.

ETHICAL AND SAFETY ISSUES

This study has received ethics approval from the Western Sydney University Human Research and Ethics Committee (H14029).

Written consent will be required from all participants prior to their involvement in the study (Supplementary file 2). As the study includes young people under the age of 16 years, the study aims, objectives and requirements will be discussed with these individuals using age-appropriate language and written consent will also be required from their parent/caregiver. Verbal consent will also be obtained from all participants at the beginning of each interview, workshop or focus group prior to starting any recordings.

Given the small size of the paediatric onset SCI community in which this study will be undertaken, there are ethical considerations in relation to protecting the anonymity of participants and confidentiality of data, particularly regarding workshops and focus groups. Before starting any group activities, participants will be advised that all personal information shared in the discussion will be kept confidential and is not for discussion outside of the group. Participants will be asked to uphold the principle of respect regarding their own behaviour and the privacy of other participants. Additionally, the utmost care will be taken in analysis and presentation of data to ensure participant confidentiality and anonymity. Data that may overtly identify participants will be excluded.

It is possible that recalling experiences associated with acquiring a SCI or negative experiences with healthcare services may cause some discomfort to the young people or parents/caregivers. As such, the researchers will monitor and respond to participant's psychological wellbeing. Information on where to access emotional support will be made available to all participants.

DISSEMINATION

As this is a supervised doctoral research study the researcher will use the results as chapters of a thesis to obtain a Doctor of Philosophy degree. It is anticipated that the findings from this study will also be disseminated via publication in peer-reviewed journals and will be presented at local, national or international conferences and professional forums. Participants will also be invited to co-present with the researcher at a local conference or professional forum. The progress and findings of the study will be communicated to young people with SCI and parents/caregivers as well as professional stakeholders via reports and websites maintained by SCI organisations, as well as through social media.

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FIGURE LEGEND

Figure 1. Care Transition Framework domains and study objectives addressed in each study phase

This figure describes the domains of the Care Transition Framework and how the study objectives within each phase address the domains.

Figure 2. Participatory action research cycles and study phases

This figure depicts the cycles of the participatory action research methodology adopted in this study.

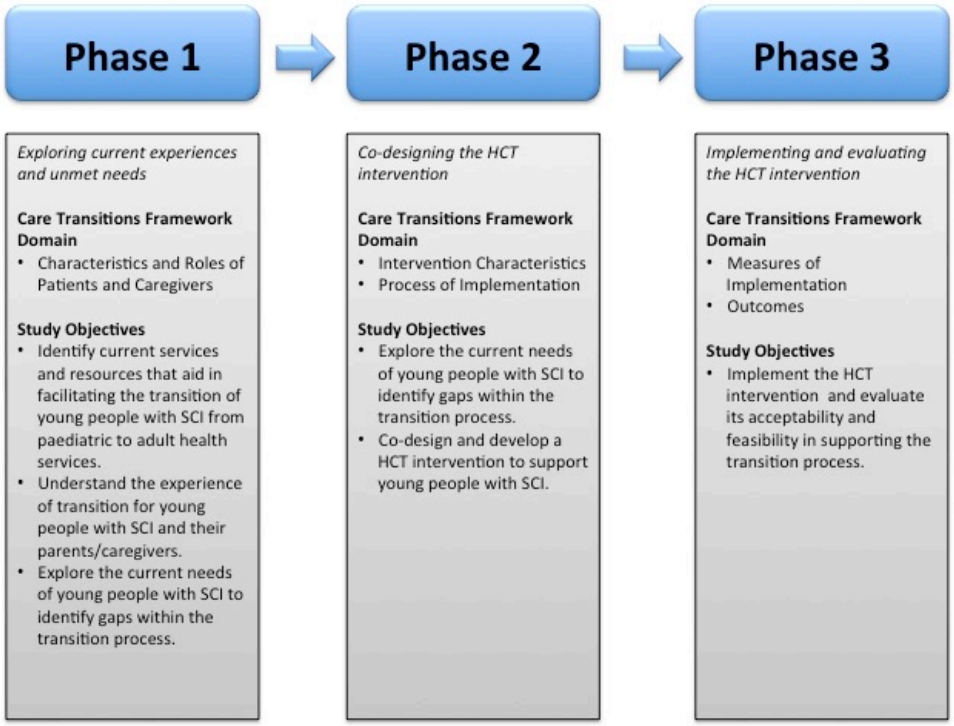

Figure 1. Care Transition Framework domains and study objectives addressed in each study phase

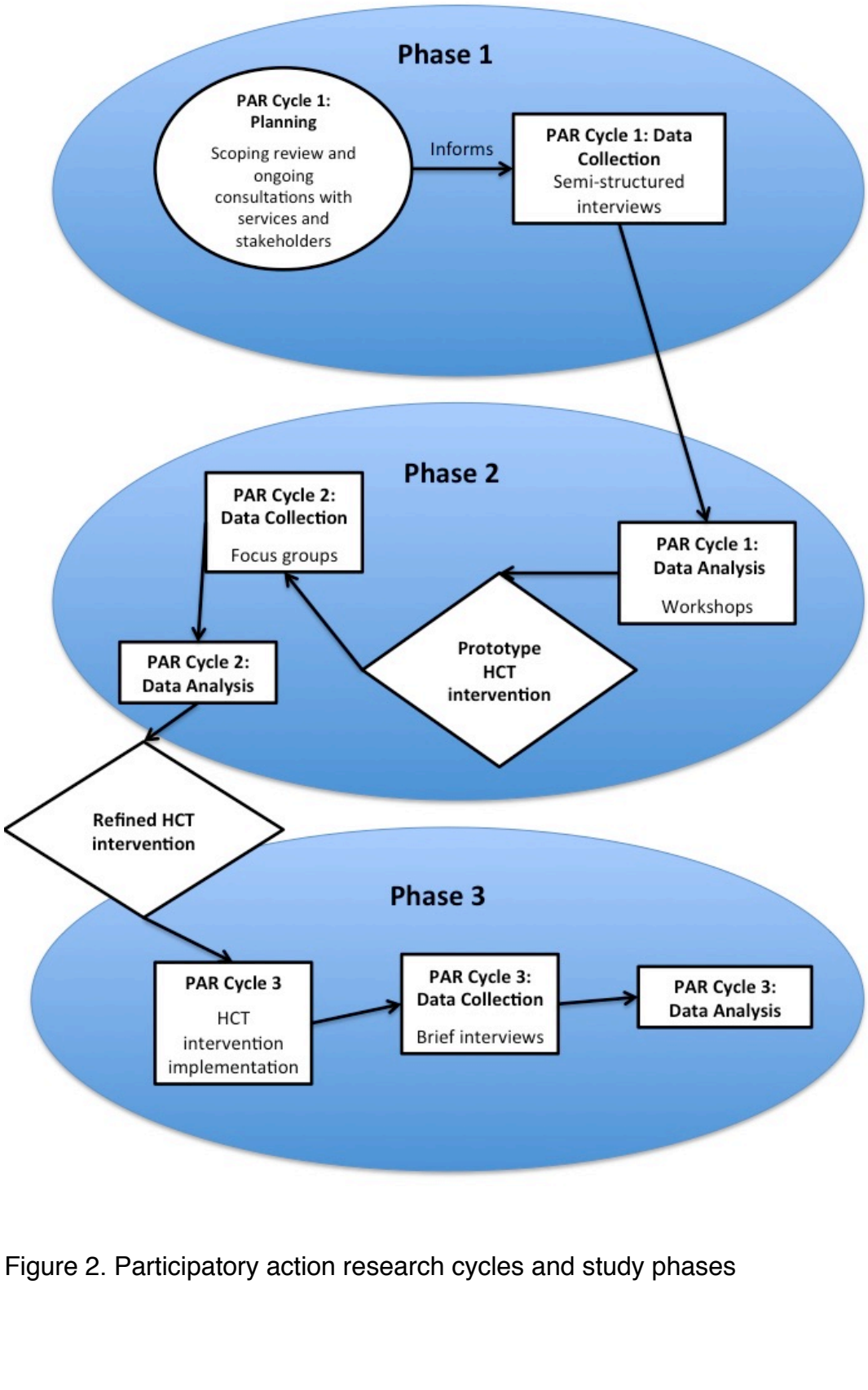

Figure 2. Participatory action research cycles and study phases

Supplementary file 1

Key areas of focus for assessing the feasibility and acceptability of the HCT intervention based on Bowen and Colleagues' framework(29)

Area of focus	The feasibility study asks …	Sample outcomes of interest
Acceptability	The extent to which the HCT intervention is judged as suitable, satisfying, or attractive by young people with SCI and their parents/caregivers.	• Satisfaction • Intent to continue use • Perceived appropriateness
Demand	To what extend is the HCT intervention likely to be used?	• Expressed interest or intention to use • Perceived demand
Implementation	The extent, likelihood, and manner in which the HCT intervention can be fully implemented as proposed.	• Amount, type of resources needed to implement
Practicality	The extent to which the HCT intervention can be delivered by SCI healthcare service providers.	• Factors affecting implementation ease or difficulty
Adaption	Could you accommodate the HCT intervention context and requirements in a different format, media, or population?	• Perceived degree to which similar outcomes are obtained in new format or for a different population
Integration	Would SCI healthcare service providers be able to integrate the HCT intervention into the existing transition process?	• Perceived fit with infrastructure • Perceived sustainability
Expansion	Potential success of implementing the HCT intervention in a different setting (e.g. state).	• Perceived fit with organizational goals and culture
Limited efficacy	Testing of the HCT intervention in a limited way.	• Intended effects of program or process on key intermediate variables

Supplementary file 2

Example participant information sheet and consent form

Participant Information Sheet

Project Title: Supporting the Transition of Children and Young People with a Spinal Cord Injury from Paediatric to Adult Healthcare Services

Project Summary: You are invited to participate in a research study being conducted by Ms Emily Bray, PhD student at the School of Nursing and Midwifery, Western Sydney University under the supervision of Associate Professor Lucie Ramjan, School of Nursing and Midwifery, Western Sydney University.

The research aims to explore the experience and needs of children and young people with a Spinal Cord Injury (SCI) in their transition from paediatric to adult healthcare services. The PhD project also aims to co-develop a healthcare transition support tool or resource for children and young people with a SCI.

How is the study being paid for?

The SpineCare Foundation has funded this study.

What will I be asked to do?

You are being invited to participate in an interview (or upon request a paired interview with another young person with a SCI) that aims to explore your experiences, needs, and expectations regarding healthcare transition and the transfer to adult health services. The interview will be conducted via telephone or videoconference or face-to-face at a time most convenient for you. The interview will be audio-recorded.

Following this, you will participate in a co-design workshop to co-develop a healthcare transition support tool or resource. The workshop will be held in person at the Northcott offices/Western Sydney University or via videoconference. The workshop will be video-recorded and transcribed.

After the tool or resource has been developed you will be asked to provide feedback on the developed healthcare transition support tool or resource. To do this we will ask you to take part in an online videoconference focus group, this will be video-recorded.

Lastly following a period of use, we will ask you to evaluate the tool or resource. The evaluation will consist of an interview conducted via telephone or videoconference at a time most convenient for you. The interviews will be audio-recorded.

How much of my time will I need to give?

It is anticipated that after enrolling, the initial interview will take 30-45 minutes and the co-design workshop will run on a separate day for 60-90 minutes. After the development of a transition resource or tool, the feedback focus group will run for 60 minutes and following a period of resource use the evaluative telephone interview will take 15-20 minutes. In total, participation in this study will be expected to take 165-215 minutes over a staggered time-frame, approximately 12 months.

What benefits will I, and/or the broader community, receive for participating?

The findings of this study will help us provide better support to children and young people with SCI and their families in their transition from paediatric to adult healthcare services. The findings will provide insight into the development of an effective healthcare transition support resource or tool that complements current services and assists in providing children and young people with SCI with the necessary skills to better manage the current transition process.

As thanks for their time and effort, participants will receive three $20 Westfield vouchers ($60 total), one at the completion each of the three phases of the study; the initial interview, workshop and focus group, and the evaluative interview.

Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?

It is not anticipated that there will be any risk or discomfort to participants choosing to participate in this study. However, if you do experience any discomfort you are able to withdraw consent or choose not to answer particular questions without any consequence. If required, participants will be offered information on how to contact their local counsellor or be provided with information for accessing counselling via free counselling services including: KidsHelpline: 1800 551 800 Beyond blue: 1300 224 636, or Lifeline: on 13 11 14.

How do you intend to publish or disseminate the results?

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified, except with your permission. i.e. pseudonyms will be assigned to participants to ensure anonymity. Data will be stored securely on a password-protected computer and any physical data will be stored in a secure storage space at Western Sydney University.

Will the data and information that I have provided be disposed of?

All data files will be stored for a minimum period of 5 years from the date of publication. After this time, all paper files will be destroyed according to the requirements of Western Sydney University (i.e. destroyed using a shredder). All electronic files will be permanently deleted from the cloud drive and PhD student's computer.

Please be assured that only the researchers will have access to the raw data you provide. However, the same research team and/or another research student may use your data in other related projects for an extended period of time.

Can I withdraw from the study?

Participation is entirely voluntary and you are not obliged to be involved. If you do participate you can withdraw at any time without giving reason. You can withdraw via phone or email to Ms Emily Bray or Dr Lucie Ramjan.

If you do choose to withdraw, any information that you have supplied *will be destroyed.* Where participant's information cannot be withdrawn, for example the audio recording of a focus group, the information provided by the participant will not be used in this study or disseminated in any circumstance.

Can I tell other people about the study?

Yes, you can tell other people about the study by providing them with the PhD student's contact details. They can contact the PhD student to discuss their participation in the research project and obtain a copy of the information sheet.

What if I require further information?

Please contact Ms Emily Bray or Dr Lucie Ramjan should you wish to discuss the research further before deciding whether or not to participate.

PhD student:
Ms Emily Bray, School of Nursing and Midwifery, Western Sydney University
Building EB/LG, Parramatta South Campus
P: 0416 269 500 I E: 16251104@student.westernsydney.edu.au

Supervisor:
Dr Lucie Ramjan, Associate Professor, School of Nursing and Midwifery, Western Sydney University
Building EB/LG Room 35, Parramatta South Campus
P: 96859032 I E: l.ramjan@westernsydney.edu.au

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep and the consent form is retained by the researcher/s.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H14029.

Consent Form

Project Title: Supporting the Transition of Children and Young People with a Spinal Cord Injury from Paediatric to Adult Healthcare Services

This study has been approved by the Human Research Ethics Committee at Western Sydney University. The ethics reference number is: H14029

I hereby consent to participate in the above named research project.

I acknowledge that:

- I have read the participant information sheet (or where appropriate, have had it read to me) and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s
- The procedures required for the project and the time involved have been explained to me, and any questions I have about the project have been answered to my satisfaction.

I consent to:

□ *Participate in an interview/paired interview*

□ *Participate in a co-design workshop*

□ *Participate in a focus group*

□ *Participate in telephone interview*

□ *Having their information audio recorded*

□ *Having their photo/activities taken/video recorded*

I consent for my data and information provided to be used in this project and other related projects for an extended period of time.

I understand that the information gained during the study may be published and stored for other research use but no information about me will be used in any way that reveals my identity.

I understand that my participation in this study will have no effect on my relationship with the researcher/s, and any organisations involved, now or in the future. I understand that I will be unable to withdraw my data and information recorded in the focus group and/or workshop from this project but should I decide to withdraw (before data analysis), this information will not be used.

Signed:

Name:

Date:

Return address: *[please insert the land address]*

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	#3	Date and version identifier	N/A
Funding	#4	Sources and types of financial, material, and other support	3
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1-2

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	2
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	2
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	14
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	7-8
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	N/A – not an RCT
Objectives	#7	Specific objectives or hypotheses	8-9
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	9-10
Methods: Participants, interventions, and outcomes			

Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	12-13
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	13
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	17-19
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	18-19
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	N/A – reimbursement a strategy to improve adherence
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	19-20
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	N/A – not an RCT. Intervention trial with 3 phases illustrated in Figure 2.
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions	14

		supporting any sample size calculations	
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	14
Methods: Assignment of interventions (for controlled trials)		*This study is not a controlled trial*	
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related	15,17-22

		processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A - reimbursement a strategy to improve adherence
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	N/A – study has received ethics approval which included a data management plan
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Qualitative study. Thematic analysis see pg. 16, 18, 19, 20
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14-15 - Reference group and supervisory panel will monitor

Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	14-15 - Reference group and supervisory panel will monitor
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A – study has received ethics approval which included a risk assessment
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	21
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	N/A – study has received ethics approval and any amendments wil need to go through the IRB board and ANZCTR
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	21-22
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	22
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	3
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements	22-23 - No limitation on data access

		that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A - It is not expected that participants will suffer harm from participation in this study.
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	22
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Open access publishing
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary file 2
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

BMJ Open

PROTOCOL FOR DEVELOPING A HEALTHCARE TRANSITION INTERVENTION FOR YOUNG PEOPLE WITH SPINAL CORD INJURIES USING A PARTICIPATORY ACTION RESEARCH APPROACH

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Primary Subject Heading:	Qualitative research
Secondary Subject Heading:	Paediatrics, Research methods, Neurology
Keywords:	QUALITATIVE RESEARCH, Neurological injury < NEUROLOGY, Paediatric neurology < NEUROLOGY, Paediatric neurology < PAEDIATRICS, STATISTICS & RESEARCH METHODS

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PROTOCOL FOR DEVELOPING A HEALTHCARE TRANSITION INTERVENTION FOR YOUNG PEOPLE WITH SPINAL CORD INJURIES USING A PARTICIPATORY ACTION RESEARCH APPROACH

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AUTHOR CONTRIBUTIONS

EAB, BE, AG, YS, LMR were responsible for the study conception and design. EAB, BE, AG, YS, LMR were responsible for drafting the manuscript and making critical revisions to the paper for important intellectual content.

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This work was supported by the SpineCare Foundation, Sydney, Australia. Grant number: N/A

COMPETING INTERESTS STATEMENT

No conflict of interest has been declared by the authors.

TRIAL REGISTRATION NUMBER

Australian New Zealand Clinical Trials Registry (ANZCTR):

ACTRN12621000500853

WORD COUNT

3844 / 4000 words

ABSTRACT

Introduction

While healthcare transition (HCT) interventions are recognised as an important area in paediatric rehabilitation, there has been limited research focusing on young people with spinal cord injuries (SCI). In this study, researchers will collaborate with young people with SCI and their parents/caregivers to develop, implement and evaluate the feasibility and acceptability of a HCT intervention aimed at supporting young people with SCI during their transition from paediatric to adult healthcare services.

Methods and analysis

A participatory action research (PAR) approach will be used to co-develop the HCT intervention with young people with SCI aged 14 to 25 years and their parents/caregivers. Three phases will be conducted to address the five objectives of this study. Phase 1 will use semi-structured interviews to explore young people and parent/caregivers' experiences of HCT. In Phase 2a, both young people and parent/caregivers will be co-researchers. They will be included in the analysis of the interviews and will be asked to participate in co-design workshops to inform the development of a prototype HCT intervention. In Phase 2b, using focus groups, feedback on the prototype HCT intervention will be collected. In Phase 3, the refined prototype HCT intervention will be implemented, and young people with SCI and parent/caregivers will evaluate the feasibility and acceptability of the HCT intervention in semi-structured interviews. A reference group, including stakeholders and end-users, will be consulted at different time points.

Ethics and dissemination

The study has received ethics approval from Western Sydney University Human Research and Ethics Committee (H14029). The researcher will use the results of this study as chapters in a thesis to obtain a Doctor of Philosophy degree. The findings will be disseminated via publication in peer-reviewed journals and will be presented at local, national or international conferences.

Trial registration number

Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12621000500853

Keywords

Healthcare transition, young people, spinal cord injury, qualitative research, participatory action research

ARTICLE SUMMARY

Strengths and limitations of this study

- This study is the first study to use a PAR approach and involve youth with SCI to co-create and evaluate a HCT support intervention.
- Using PAR methodology will give a voice to a group of young people whose voices have historically been ignored.
- Inclusion of PAR principles in the development of the HCT intervention increases the likelihood that the intervention will be acceptable to end-users.
- Clear articulation of the methods of the study will provide guidance on the use of PAR in the development of HCT interventions.
- PAR requires prolonged engagement with participants and is time intensive.

INTRODUCTION

Healthcare transition (HCT) is "the purposeful, planned movement of adolescents and young adults with chronic physical and medical conditions from child-centred to adult-oriented healthcare systems"(1). Transition from the paediatric to adult healthcare system is a complex process that requires care to be delivered in a coordinated and uninterrupted manner through the provision of developmentally appropriate and comprehensive services(1-4).

Challenges in the process of transition occur as a result of the procedural and cultural differences between paediatric and adult healthcare, and the crucial yet turbulent developmental phase of adolescence(4-6). Families speak about the difficulty of terminating the lifelong relationships that have developed with paediatric providers, the challenges of building working relationships in new healthcare settings, and the fears that adult professionals lack the knowledge and quality of care provided by their paediatric providers(6). Furthermore, the adult healthcare system is characterised by decreased family involvement where success managing your health requires skills such as self-advocacy and self-determination. Yet, there is evidence to suggest that developing these skills is not deemed a priority for young people with chronic conditions transitioning out of the paediatric sector(4, 7). Adolescence is also a complex phase, with biological maturity preceding psychosocial maturity. This may contribute to tension arising between adolescents, their families and healthcare providers as they attempt to find an identity for themselves outside of the family unit and push the boundaries of these relationships(4).

The aforementioned challenges associated with the move from paediatric to adult healthcare systems and inadequate transition preparations can alter the health

outcomes of young people with chronic conditions(2, 8). Research indicates that post transition some young people with chronic conditions often fail to adhere to treatments, are lost to follow up, experience deteriorating health, develop secondary complications, and face negative social and emotional outcomes(2, 7). Despite this, there is evidence to suggest that effective HCT interventions can improve health outcomes for young people with chronic conditions(8).

This study aims to address the transition needs of young people with spinal cord injuries (SCI) and the current gap in services, contributing to the evidence while improving transition outcomes and quality of life for these individuals. SCI is a catastrophic event that impairs conduction of sensory and motor signals across the site(s) of lesion(s), as well as the autonomic nervous system, resulting in physical disability and impaired function of various organ systems(9). Paediatric onset SCI is relatively rare but carries significant psychological and physiological consequences. Impaired mobility and long-term risks for secondary complications including bowel and urinary complications, pressure injury, pain, and autonomic dysfunction, can lead to decreased independence, less community participation, and negative psychosocial outcomes(10, 11). Access to coordinated adult healthcare can facilitate the management of long-term risks during the transition to adulthood for young people with SCI. However, little has been written on HCT interventions for young people with a paediatric onset SCI(12, 13) and what does exist suggests that there is a lack of support for young people with SCI transitioning into adulthood and adult healthcare services(13).

Aims

The overall aim of this study is to co-develop, implement, and evaluate a HCT intervention to support young people with SCI. The specific objectives will be to:

1. Identify current services and resources that aid in facilitating the transition of young people with SCI from paediatric to adult health services.
2. Understand the experience of transition for young people with SCI and their parents/caregivers.
3. Explore the current needs of young people with SCI to identify gaps within the transition process.
4. Co-design and develop a HCT intervention to support young people with SCI.
5. Implement the HCT intervention and evaluate its acceptability and feasibility in supporting the transition process.

Methodology

This study draws on Article 7 of the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD)(14) and Article 12 of the United Nations Convention on the Rights of the Child (UNCRC)(15) to inform its research methodology. The UNCRC acknowledges that children have the right to express their opinions and to have those opinions heard and acted upon when appropriate, to be protected from abuse or exploitation, and have their privacy protected(15). Article 7 of the UNCRPD furthers this sentiment specifically stating that actions should be taken to "ensure that children with disabilities have the right to express their views freely on all matters affecting them, their views being given due weight in accordance with their age and maturity, on an equal basis with other children, and to be provided

with disability and age-appropriate assistance to realize that right"(14). As a result of the increase in emphasis on children's rights, the academic community have responded by ensuring children's participation in research on issues that affect them(16). Participatory action research (PAR) offers an approach to research that engages individuals and communities in identifying problems relevant to their own lives, redistributing the power between researcher and participants, and giving them a chance to be part of social change(16, 17). The process champions the concept of "research with, rather than on, people"(18).

This study will be informed by PAR methodology as it seeks to understand the experience of young people with SCI, and focuses on equal and collaborative participation. Little has been written on the process of co-designing HCT interventions with young people with chronic conditions and disabilities (Authors own work, currently under review). However despite the lack of literature on the development of HCT interventions using PAR and other co-design approaches, the authors reported that it was feasible to co-develop age-appropriate HCT interventions for young people with chronic conditions. Using a PAR framework to inform the methodology behind this study will ensure that the needs of young people with SCI are integral to the proposed interventional approach, and that their voice is heard and taken into consideration. The study will recognise and value the experiential knowledge of young people with SCI in understanding and addressing the key factors that impact on their successful transition from paediatric to adult healthcare services. Furthermore, it will integrate the input of young people in the design and implementation of the model, to secure their support of the HCT intervention.

Theoretical framework

This study will be informed in its thematic data analysis by the principles of critical disability theory (CDT). Critical theory is a multidisciplinary framework with a goal of explaining oppression and identifying achievable and practical ways to change it(19). CDT centres disability and challenges ableist assumptions. Adopting CDT in this study will serve as a lens to examine transition needs and ensure the rights of children with disabilities are recognised whilst also respecting their voice, which has too often been marginalised.

Contextual framework underpinning intervention development and evaluation

This study will use the Care Transitions Framework to inform the development of the HCT intervention for young people with SCI transitioning from paediatric to adult healthcare services. The framework provides a guide to implementation, organised into eight domains; Intervention Characteristics, External Context, Organisational Characteristics, Characteristics and Roles of Providers, Characteristics and Roles of Patients and Caregivers, Process of Implementation, Measures of Implementation, and Outcomes(20).

A scoping review and ongoing consultations with services and stakeholders will generate knowledge on the external context, organisational characteristics and characteristics and roles of providers. Early engagement with health professionals, service providers and key stakeholders will provide an opportunity to understand the range of services available, the current gaps and some of the limitations to providing care. The phases of this study will address the remaining domains as outlined in Figure 1.

METHODS AND ANALYSIS

There will be three phases to this study that will address the five objectives outlined in the Aims section of this paper. The phases and study objectives are depicted in Figure 1.

Phase 1 will include semi-structured individual interviews or paired interviews to explore current experiences and unmet needs. Phase 2a will use group co-design workshops to help analyse the interviews and inform the development of a prototype HCT intervention. Phase 2b will gather feedback on the prototype HCT intervention from the young people and parents/caregivers involved in the workshops as well as the reference group to allow refinement and revision and improved practical application. Phase 3 will implement the HCT intervention and evaluate its acceptability and feasibility.

All phases of the study will be informed by the principles of PAR and involve cycles of planning, acting, observing and reflecting as described by Kemmis and McTaggart(21). Three PAR cycles will be conducted throughout the study as per Figure 2.

Study setting

Due to the small population of paediatric-onset SCI(22), the study will cover both metropolitan and rural New South Wales, Australia. It is a goal of this study to recognise the importance of providing opportunities for participants from rural areas to be involved in the study as young people with disabilities can be particularly disadvantaged in rural areas(23). Often they experience a lack of services and continuity of care(23), as such their experiences transitioning from paediatric to adult healthcare services may vary greatly from young people residing in metropolitan areas.

Study population

Young people between the ages of 14 to 25 years who acquired a paediatric-onset SCI (before the age of 16) and parents/caregivers of young people with a paediatric-onset SCI will be eligible to participate. Young people will either be preparing to transition or will have transitioned. Individuals who are currently an inpatient in a children's hospital receiving rehabilitation treatment for a SCI acquired in the last 12 months will not be eligible for inclusion. The first year after injury can be overwhelming and requires tremendous adjustments for both the individual and their family. The researcher does not want to burden the individual or their family with the demands of participating in research, nor risk causing any additional emotional distress during this challenging time.

The study will also only include young people with SCI and parents/caregivers with sufficient English language proficiency to allow for engagement in discussions during the interviews and participation in the co-design workshop. Please note hereafter and unless otherwise specified, the term participants will be used to denote both young people with SCI and parents/caregivers.

Recruitment and sample size

The researcher will use purposive, convenience and snowball methods of recruitment for the study. An electronic flyer and video will be emailed to paediatric SCI support organisations for advertisement through their networks and on their social media pages and websites. The researchers will also recruit through word-of-mouth and social media (Twitter, LinkedIn, Facebook). Approximately six to eight young people with SCI and six to eight parents/caregivers of young people with SCI will be recruited for this study.

The researchers acknowledge that participants may drop-out between the different phases of the study. If this occurs, the researchers will attempt to recruit new participants as knowledge from previous phases, whilst helpful, is not required for inclusion in later phases.

Patient and public involvement

Young people with SCI and their parents/caregivers were not involved in setting the research question or design of the study, but they will be heavily involved in the design, implementation and evaluation of the HCT intervention.

A reference group, consisting of paediatric SCI healthcare service providers and young people with SCI specifically chosen for their particular areas of expertise, will be consulted throughout the study and asked to provide expert advice on:

- recruitment;
- appropriateness of the interview schedule and co-design workshop activities;
- identification of issues or barriers that could impede the success of the study;
- identifying solutions to problems with implementation of the study;
- discussing the key outcomes of the study and;
- providing feedback on the final HCT intervention.

Phase 1: Exploring current experiences and unmet needs

Data collection

Semi-structured interviews will be used to collect qualitative data on the HCT experiences of young people with SCI from the perspectives of the young people themselves and parents/caregivers. Semi-structured interviews have been chosen to

allow for the flexibility to explore ideas and responses that are important to participants but may not have been previously considered by the researchers(24). Semi-structured interviews will also allow for the researcher to adapt the interview techniques to the child or young person's developmental age.

In an attempt to reduce power imbalances, participants will be offered the opportunity to participate in a paired interview with another young person that is also eligible for the study. Paired interviews, where a pre-established relationship exists, can provide a more complete picture of the issues as the other interviewee supports the filling of gaps in the story(25).

Interview guides will be developed to explore the needs, gaps, weaknesses and opportunities relating to HCT for young people with SCI. The interviews will be conducted online via the use of video-conferencing software (Zoom) at a time that is convenient to the participant. The interviews are anticipated to take 60 minutes. Interviews will be audio-recorded and transcribed verbatim to assist with data analysis.

Analysis

An inductive thematic analysis approach, as described by Braun and Clarke(26, 27), will be undertaken to identify major themes and sub-themes arising from the participant responses. This style of analysis involves six phases: familiarisation, code generation, searching for themes, review and theme naming and report production. These phases need not be treated linearly and thus movement between the six phases will occur as required. An inductive thematic analysis approach has been chosen as it allows for a 'bottom up' analysis of the data to occur, whereby analysis is not driven

by the researchers' preconceptions or pre-existing coding frame but instead is driven by the participants' responses and strongly links the themes identified to the data(27).

PAR methodology requires collaboration at all stages of the research progress and Liebenberg et al. suggest that simply "being reflexive and conducting member checks of findings from the analysis is insufficient"(28). Instead participants should actively participate in the data analysis however, guidelines on how this can be successfully achieved is limited(28).

In this study, the principal researcher and another member of the research team will individually code the transcripts. Following this, a final list from each reviewer will be developed and a meeting hosted, where through consensus, a final list of themes and sub-themes will be determined. In addition to this, the co-design workshops will begin by asking the participants to review the codes and themes generated from the individual interviews. Researcher and participants (co-researchers) will compare and discuss the analysis decisions until consensus is achieved.

Phase 2a: Co-designing the HCT intervention (workshops)

Data collection

The co-design workshops will be facilitated by two researchers and are anticipated to take between 60 and 90 minutes. The workshops will either be held in person at the university campus or via video-conferencing (Zoom) at a time convenient for the group. There will also be the option for rural and remote participants to dial into the workshops using Zoom. Two workshops will be held—one for young people with SCI and one for parents/caregivers.

The workshops will have two phases, the first being to analyse the data from the interviews and the second to co-design the HCT intervention.

The first phase of the workshop will require participants to review samples of unidentifiable excerpts of interviews and initial codes/categories generated by the researchers and decide on their authenticity. Once in agreement on codes/categories, working together researchers and participants (co-researchers) will group codes/categories into themes using post-it notes or the white-board function on Zoom. During this process, participants (co-researchers) will be asked to explain their analysis decisions to the researchers.

In the co-design phase young people's HCT needs and participants' recommendations for the development of the HCT intervention will be explored. The researcher will use the future workshop method(29, 30) to facilitate discussion and generation of ideas for the development of the HCT intervention and participants will then work together to brainstorm designs. The future workshop method guides participants through three phases: a critique phase, a fantasy phase and an implementation phase(29, 30). The aim of the critique phase will be to review the themes identified in the data analysis phase to identify deficits or challenges related to HCT experienced by young people with SCI. In the fantasy phase, the participants will be given creative freedom to generate utopian ideas about the best possible way to mitigate the issues. In the third phase, the participants will transform the utopian ideas into a design for a practical and realisable HCT intervention.

Analysis

The workshops will be audio-recorded. The design ideas developed in the workshops will be captured in creative forms such as drawings/writings or verbally. Participants

will also be asked to describe their design ideas to the group so that the researchers can capture these in the audio-recordings.

Phase 2b: Co-designing the HCT intervention (focus groups)

Data collection

In this phase participants will be provided/shown the prototype intervention and invited to partake in a focus group conducted online using video conferencing software (Zoom). Qualitative data will be collected to identify whether the HCT needs of young people with SCI and participants' recommendations have been met by the prototype. The focus groups are anticipated to take approximately 60 minutes and will be facilitated by two researchers. The focus group will be audio recorded and transcribed to assist with data analysis.

Analysis

The transcripts from the focus groups will be analysed thematically in a similar process to Phase 1 in order to identify any adjustments required to the HCT intervention. The principal researcher and another member of the research team will individually code the transcripts. A final list from each reviewer will be developed and a meeting hosted, where through consensus, a final list of themes and sub-themes will be determined and the HCT intervention will be refined based on this feedback.

Phase 3: Implementing and evaluating the HCT intervention

Data collection

Due to the iterative nature of PAR, it is anticipated that the HCT intervention will evolve within the research process as participants' experiences and needs influence its

development. As such, the nature of the final HCT intervention cannot be known prior to the commencement of the study. Nevertheless, following the completion of the focus groups the researcher will refine the prototype HCT intervention and send the final HCT intervention to participants. They will be asked to review or use the HCT intervention and will be invited to partake in a brief interview. Brief interviews will be conducted over the telephone or online using video-conferencing software (Zoom) at a time that is convenient to the participant. The interviews are anticipated to take between 15 and 20 minutes.

The interviews will evaluate the feasibility and acceptability of the HCT intervention. Bowen and colleagues'(31) framework will inform the evaluation of the HCT intervention (Supplementary file 1). This framework will support making judgments about the feasibility of the intervention and determine whether additional, more comprehensive evaluation is justified. As this study is part of a 3-year doctoral project, time constraints restrict the researchers on conducting a comprehensive pilot study of the HCT intervention to determine its efficacy and effectiveness. Using Bowen and colleagues' framework the researchers will be able to determine whether the HCT intervention is appropriate for further testing, and is relevant and sustainable.

Analysis

Data analysis of Phase 3 will mirror the analysis method in the earlier Phases.

RIGOUR

To ensure that the rigour of the study's qualitative data is maintained the researcher will address the following criteria: credibility, transferability, dependability and confirmability(32). In regard to credibility, the researchers will engage in frequent

debriefing sessions to provide an opportunity for the researchers to identify and challenge any assumptions made as a result of their own biases and preferences. Furthermore, credibility will be achieved by including young people with SCI and their parents/caregivers as co-researchers in the analysis of the interviews and by providing opportunities for them to review, reflect on and refine the co-developed HCT intervention.

Transferability will be achieved through detailed reports, thick descriptions and analysis of contextual details, as described by Ponterotto(33). Such details include demographic information, the location and settings of the interviews, workshops and focus groups, and descriptions about non-verbal behaviour. The researchers acknowledge that the study findings and the tailored intervention may not be applicable to populations outside the study setting. Therefore, a comprehensive description of the process involved in co-designing a HCT intervention with young people with lived experience of SCI will be provided, as the co-design process may have transferability across contexts and medical conditions.

The researcher will maintain an audit trail and report in detail the processes that occurred within the study related to research design and implementation, operational details of data gathering and provide a reflective appraisal of the processes undertaken. This process will enhance dependability.

Lastly throughout the project, the researcher will keep a comprehensive reflective research journal, reflecting on and cataloguing the progress, obstacles and successes of the research process. This level of documentation will increase confirmability of the research by providing an audit trail for the study.

ETHICAL AND SAFETY ISSUES

This study has received ethics approval from the Western Sydney University Human Research and Ethics Committee (H14029).

Written consent will be required from all participants prior to their involvement in the study (Supplementary file 2). As the study includes young people under the age of 16 years, the study aims, objectives and requirements will be discussed with these individuals using age-appropriate language and written consent will also be required from their parent/caregiver. Verbal consent will also be obtained from all participants at the beginning of each interview, workshop or focus group prior to starting any recordings.

Given the small size of the paediatric onset SCI community in which this study will be undertaken, there are ethical considerations in relation to protecting the anonymity of participants and confidentiality of data, particularly regarding workshops and focus groups. Before starting any group activities, participants will be advised that all personal information shared in the discussion will be kept confidential and is not for discussion outside of the group. Participants will be asked to uphold the principle of respect regarding their own behaviour and the privacy of other participants. Additionally, the utmost care will be taken in analysis and presentation of data to ensure participant confidentiality and anonymity. Data that may overtly identify participants will be excluded.

It is possible that recalling experiences associated with acquiring a SCI or negative experiences with healthcare services may cause some discomfort to the young people or parents/caregivers. As such, the researchers will monitor and respond to participant's psychological wellbeing. Information on where to access emotional support will be made available to all participants.

DISSEMINATION

As this is a supervised doctoral research study the researcher will use the results as chapters of a thesis to obtain a Doctor of Philosophy degree. It is anticipated that the findings from this study will also be disseminated via publication in peer-reviewed journals and will be presented at local, national or international conferences and professional forums. Participants will also be invited to co-present with the researcher at a local conference or professional forum. The progress and findings of the study will be communicated to young people with SCI and parents/caregivers as well as professional stakeholders via reports and websites maintained by SCI organisations, as well as through social media.

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FIGURE LEGEND

Figure 1. Care Transition Framework domains and study objectives addressed in each study phase

This figure describes the domains of the Care Transition Framework and how the study objectives within each phase address the domains.

Figure 2. Participatory action research cycles and study phases

This figure depicts the cycles of the participatory action research methodology adopted in this study.

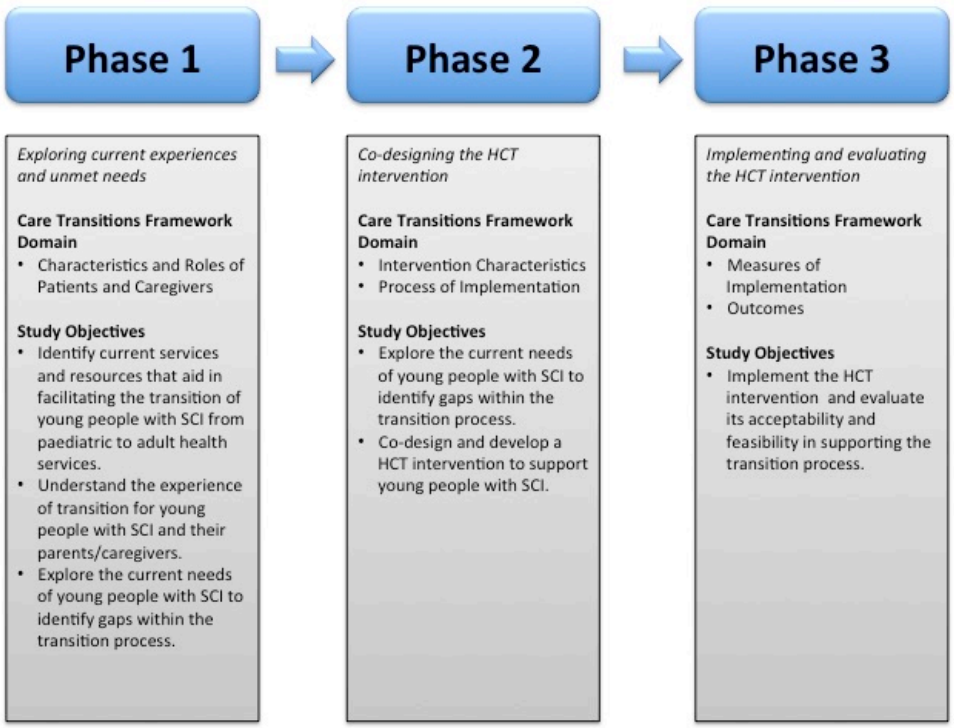

Figure 1. Care Transition Framework domains and study objectives addressed in each study phase

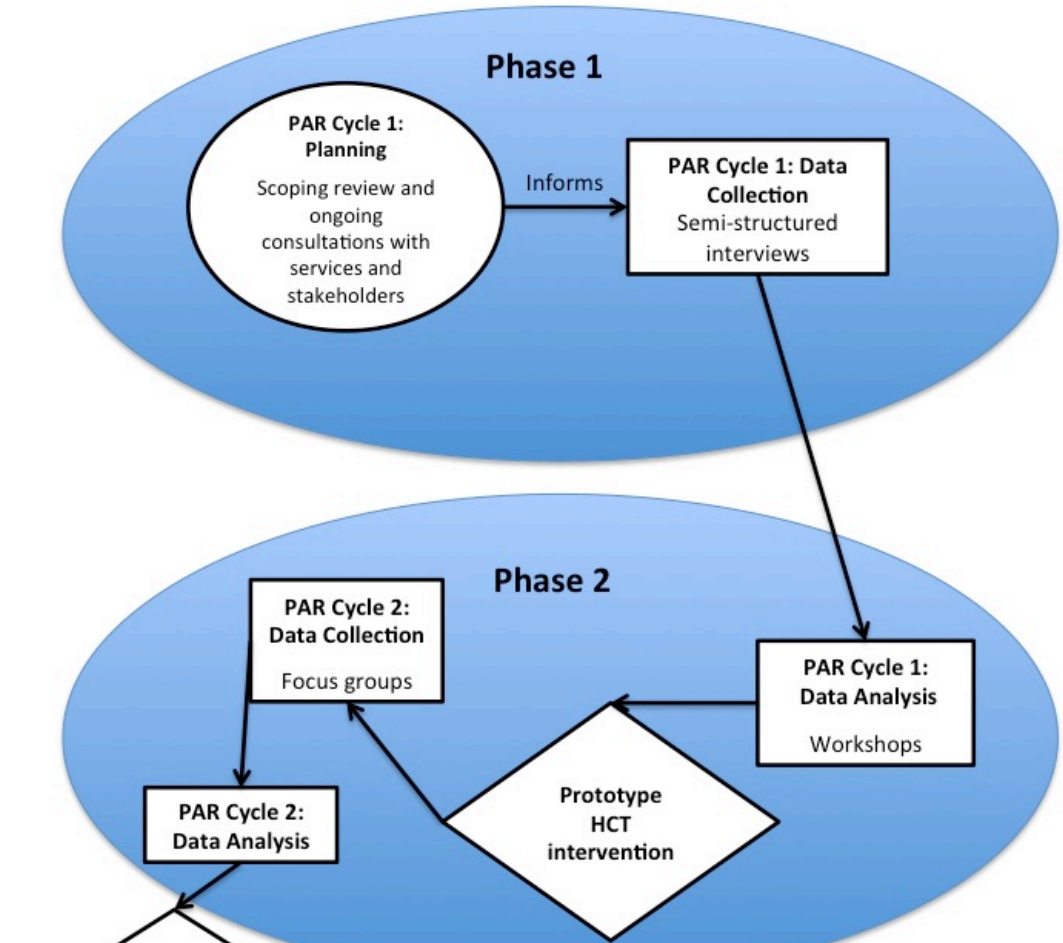

Figure 2. Participatory action research cycles and study phases

Supplementary file 1

Key areas of focus for assessing the feasibility and acceptability of the HCT intervention based on Bowen and Colleagues' framework(31)

Area of focus	The feasibility study asks …	Sample outcomes of interest
Acceptability	The extent to which the HCT intervention is judged as suitable, satisfying, or attractive by young people with SCI and their parents/caregivers.	• Satisfaction • Intent to continue use • Perceived appropriateness
Demand	To what extend is the HCT intervention likely to be used?	• Expressed interest or intention to use • Perceived demand
Implementation	The extent, likelihood, and manner in which the HCT intervention can be fully implemented as proposed.	• Amount, type of resources needed to implement
Practicality	The extent to which the HCT intervention can be delivered by SCI healthcare service providers.	• Factors affecting implementation ease or difficulty
Adaption	Could you accommodate the HCT intervention context and requirements in a different format, media, or population?	• Perceived degree to which similar outcomes are obtained in new format or for a different population
Integration	Would SCI healthcare service providers be able to integrate the HCT intervention into the existing transition process?	• Perceived fit with infrastructure • Perceived sustainability
Expansion	Potential success of implementing the HCT intervention in a different setting (e.g. state).	• Perceived fit with organizational goals and culture
Limited efficacy	Testing of the HCT intervention in a limited way.	• Intended effects of program or process on key intermediate variables

Supplementary file 2

Example participant information sheet and consent form

Participant Information Sheet

Project Title: Supporting the Transition of Children and Young People with a Spinal Cord Injury from Paediatric to Adult Healthcare Services

Project Summary: You are invited to participate in a research study being conducted by Ms Emily Bray, PhD student at the School of Nursing and Midwifery, Western Sydney University under the supervision of Associate Professor Lucie Ramjan, School of Nursing and Midwifery, Western Sydney University.

The research aims to explore the experience and needs of children and young people with a Spinal Cord Injury (SCI) in their transition from paediatric to adult healthcare services. The PhD project also aims to co-develop a healthcare transition support tool or resource for children and young people with a SCI.

How is the study being paid for?

The SpineCare Foundation has funded this study.

What will I be asked to do?

You are being invited to participate in an interview (or upon request a paired interview with another young person with a SCI) that aims to explore your experiences, needs, and expectations regarding healthcare transition and the transfer to adult health services. The interview will be conducted via telephone or videoconference or face-to-face at a time most convenient for you. The interview will be audio-recorded.

Following this, you will participate in a co-design workshop to co-develop a healthcare transition support tool or resource. The workshop will be held in person at the Northcott offices/Western Sydney University or via videoconference. The workshop will be video-recorded and transcribed.

After the tool or resource has been developed you will be asked to provide feedback on the developed healthcare transition support tool or resource. To do this we will ask you to take part in an online videoconference focus group, this will be video-recorded.

Lastly following a period of use, we will ask you to evaluate the tool or resource. The evaluation will consist of an interview conducted via telephone or videoconference at a time most convenient for you. The interviews will be audio-recorded.

How much of my time will I need to give?

It is anticipated that after enrolling, the initial interview will take 30-45 minutes and the co-design workshop will run on a separate day for 60-90 minutes. After the development of a transition resource or tool, the feedback focus group will run for 60 minutes and following a period of resource use the evaluative telephone interview will take 15-20 minutes. In total, participation in this study will be expected to take 165-215 minutes over a staggered time-frame, approximately 12 months.

What benefits will I, and/or the broader community, receive for participating?

The findings of this study will help us provide better support to children and young people with SCI and their families in their transition from paediatric to adult healthcare services. The findings will provide insight into the development of an effective healthcare transition support resource or tool that complements current services and assists in providing children and young people with SCI with the necessary skills to better manage the current transition process.

As thanks for their time and effort, participants will receive three $20 Westfield vouchers ($60 total), one at the completion each of the three phases of the study; the initial interview, workshop and focus group, and the evaluative interview.

Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?

It is not anticipated that there will be any risk or discomfort to participants choosing to participate in this study. However, if you do experience any discomfort you are able to withdraw consent or choose not to answer particular questions without any consequence. If required, participants will be offered information on how to contact their local counsellor or be provided with information for accessing counselling via free counselling services including: KidsHelpline: 1800 551 800 Beyond blue: 1300 224 636, or Lifeline: on 13 11 14.

How do you intend to publish or disseminate the results?

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified, except with your permission. i.e. pseudonyms will be assigned to participants to ensure anonymity. Data will be stored securely on a password-protected computer and any physical data will be stored in a secure storage space at Western Sydney University.

Will the data and information that I have provided be disposed of?

All data files will be stored for a minimum period of 5 years from the date of publication. After this time, all paper files will be destroyed according to the requirements of Western Sydney University (i.e. destroyed using a shredder). All electronic files will be permanently deleted from the cloud drive and PhD student's computer.

Please be assured that only the researchers will have access to the raw data you provide. However, the same research team and/or another research student may use your data in other related projects for an extended period of time.

Can I withdraw from the study?

Participation is entirely voluntary and you are not obliged to be involved. If you do participate you can withdraw at any time without giving reason. You can withdraw via phone or email to Ms Emily Bray or Dr Lucie Ramjan.

If you do choose to withdraw, any information that you have supplied *will be destroyed.* Where participant's information cannot be withdrawn, for example the audio recording of a focus group, the information provided by the participant will not be used in this study or disseminated in any circumstance.

Can I tell other people about the study?

Yes, you can tell other people about the study by providing them with the PhD student's contact details. They can contact the PhD student to discuss their participation in the research project and obtain a copy of the information sheet.

What if I require further information?

Please contact Ms Emily Bray or Dr Lucie Ramjan should you wish to discuss the research further before deciding whether or not to participate.

PhD student:
Ms Emily Bray, School of Nursing and Midwifery, Western Sydney University
Building EB/LG, Parramatta South Campus
P: 0416 269 500 I E: 16251104@student.westernsydney.edu.au

Supervisor:
Dr Lucie Ramjan, Associate Professor, School of Nursing and Midwifery, Western Sydney University
Building EB/LG Room 35, Parramatta South Campus
P: 96859032 I E: l.ramjan@westernsydney.edu.au

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep and the consent form is retained by the researcher/s.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H14029.

Consent Form

Project Title: Supporting the Transition of Children and Young People with a Spinal Cord Injury from Paediatric to Adult Healthcare Services

This study has been approved by the Human Research Ethics Committee at Western Sydney University. The ethics reference number is: H14029

I hereby consent to participate in the above named research project.

I acknowledge that:

- I have read the participant information sheet (or where appropriate, have had it read to me) and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s
- The procedures required for the project and the time involved have been explained to me, and any questions I have about the project have been answered to my satisfaction.

I consent to:

□ *Participate in an interview/paired interview*

□ *Participate in a co-design workshop*

□ *Participate in a focus group*

□ *Participate in telephone interview*

□ *Having their information audio recorded*

□ *Having their photo/activities taken/video recorded*

I consent for my data and information provided to be used in this project and other related projects for an extended period of time.

I understand that the information gained during the study may be published and stored for other research use but no information about me will be used in any way that reveals my identity.

I understand that my participation in this study will have no effect on my relationship with the researcher/s, and any organisations involved, now or in the future. I understand that I will be unable to withdraw my data and information recorded in the focus group and/or workshop from this project but should I decide to withdraw (before data analysis), this information will not be used.

Western Sydney University
ABN 53 014 069 881
Locked Bag 1797 Penrith NSW 2751
Australia

Signed:

Name:

Date:

Return address: *[please insert the land address]*

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.