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Using qualitative and co-design methods to inform the development of an intervention to support and improve physical activity in childhood cancer survivors: a study protocol for BEing Active after ChildhOod caNcer (BEACON)

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ABSTRACT

Introduction Childhood cancer survivors (CCSs) treated with cardiotoxic cancer treatments are at increased risk of developing cardiometabolic complications. This risk is further exacerbated by poor health behaviours. In particular, CCSs are less active than non-cancer comparators. Existing interventions aiming to improve physical activity (PA) levels in CCSs are methodologically weak. The aim of this study is to rigorously and systematically develop an evidence-based and theoretically-informed intervention to promote, support, improve and sustain PA levels in CCSs, with the long-term goal of reducing CCSs' cardiovascular morbidity and mortality.

Methods and analysis The BEing Active after ChildhOod caNcer (BEACON) study involves two workpackages at two National Health Service sites in England, UK. Participants will be CCSs and their parents, and healthcare professionals (HCPs) involved in their care. Workpackage one (WP1) will use qualitative methods to explore and understand the barriers and facilitators to PA in CCSs. Two sets of semistructured interviews will be conducted with (1) CCSs (aged 10–24 years) and (2) parents of CCSs. WP2 will use co-design methods to bring together stakeholders (CCSs; their parents; HCPs; researchers) to develop a prototype intervention. Where possible, all data will be audio recorded and transcribed. Data from WP1 will be analysed using a thematic approach. Analysis of WP2 data will involve content analysis, and analysis of formative output and procedures.

Ethics and dissemination The study was approved by North East-Tyne & Wear South Research Ethics Committee (REC ref: 18/NE/0274). Research findings will be disseminated primarily via national and international conferences and publication in peer-reviewed journals. Patient and public involvement will inform further dissemination activities.

Strengths and limitations of this study

- The Being Active after Childhood Cancer study will provide in-depth knowledge on the barriers and facilitators to physical activity in childhood cancer survivors (CCSs).
- The use of recognised frameworks of intervention development and principles from behavioural science to systematically develop an evidence-based and theoretically-informed health behavioural change intervention is a significant strength.
- Intervention development will actively engage stakeholders (CCSs, parents and healthcare professionals), ensuring that the resulting intervention is co-produced with those it aims to support, and maximising likely acceptability and feasibility.
- Strategies will mitigate against potential sources of bias and challenges in recruitment. COVID-19 guidelines at the time of study, as well as participant preference, will dictate the modes of participation. As such we offer multiple ways in which individuals may contribute to the study and recognise the potential limitations of conducting co-design work remotely.
- The prototype intervention developed will be ready to be taken forward into production and testing.

INTRODUCTION

As a result of treatment advances, the population of childhood cancer survivors (CCSs) has rapidly grown. In the UK alone, there are more than 40 000 CCSs,[1] while across Europe there may be up to 500 000.[2] Two-thirds of CCSs may develop chronic health conditions by 15–25 years postdiagnosis.[3] In particular, those treated with cardiotoxic therapies

can experience persistent and cumulative damage to their cardiovascular, pulmonary and metabolic systems.[4] Cardiovascular complications are a leading cause of morbidity among CCSs, and British CCSs have a 3.4-fold excess risk of cardiac death.[5] Development of these chronic conditions impacts adversely not only on the survivors' physical health, but also on their psychological health and well-being and incurs costs for the healthcare system.

In the general population, it is well recognised that poor cardiovascular outcomes are strongly related to modifiable health behaviours, including a lack of physical activity (PA).[6] Similarly, low levels of PA in even young CCSs (<18 years), have been linked to a worse cardiovascular risk profile,[7] and CCSs are often less active than controls without a history of cancer.[8] However, among long-term survivors of childhood lymphoma, a higher level of vigorous PA is associated with a 50% lower risk of any cardiovascular event.[9] Moreover, a Cochrane review indicated that physical exercise training programmes may improve physical fitness, body composition and cardiorespiratory fitness in childhood cancer patients and survivors.[10] Considered together, this evidence provides a strong rationale for developing effective interventions to increase PA in CCSs.

Reviews have concluded that interventions to increase PA levels among CCSs are feasible and safe. However, studies are heterogeneous and most are methodologically limited.[11 12] In addition, there is little evidence that interventions have been systematically developed using recognised frameworks of intervention development.[13] Critically, while an understanding of factors which may promote or inhibit the target health behaviour (here, PA) is an essential first step in intervention design,[14–17] most interventions appear to have been developed without having undertaken formative work to gain this understanding. Indeed, currently, little is known about determinants of PA behaviours in CCSs. Additionally, although the application of appropriate theory is recognised in behavioural science as an essential element of behaviour change interventions,[14–17] most interventions appear to have no robust theoretical underpinnings.

Leading authorities advocate active stakeholder involvement in the design and development of novel health interventions[14–17]; this is essential to understanding the perspectives and psychosocial context of users.[18] However, most interventions for CCSs have been developed without the involvement of CCSs, raising concerns about the relevance and acceptability of the interventions to survivors. Moreover, although parents are key agents in their children's PA behaviour,[19 20] there has been little attempt to understand either: (1) how the beliefs of parents of CCSs might influence their child's PA behaviours or (2) how parental support may be harnessed to encourage PA in CCSs.

A further consideration is wider implementation of interventions among CCSs. Those developed thus far were not designed to be deliverable within the context of the UK National Health Service (NHS). More generally, there is a lack of research exploring how support to modify health behaviours (including PA) among CCSs can be implemented effectively and feasibly in follow-up care. Involvement of healthcare professionals (HCPs) and other relevant stakeholders in the development process would increase the likelihood that an intervention will be feasible, acceptable and implementable in the current healthcare pathway for CCSs; this does not appear to have been widely done.

This project seeks to comprehensively investigate barriers and enablers to PA among CCSs—from the CCSs, parental and wider stakeholder perspective. Using the knowledge gained, and with the support of key stakeholders, we will develop a person-centred evidence-based and theory-based prototype intervention aimed at promoting and supporting sustainable PA behavioural change in CCSs.

AIMS AND OBJECTIVES

Aim

The ultimate goal of the BEing Active after ChildhOod caNcer (BEACON) project is to develop an intervention which can reduce cardiometabolic risk markers in the medium term, and reduce cardiovascular morbidity and mortality in the long-term, while also helping to prevent a deterioration in patient well-being and health-related quality of life due to poor cardiovascular health.

Objectives

The objectives of this phase of the BEACON project are to:

1. Explore CCSs' experiences of, and participation in, PA behaviours.
2. Identify and explore the barriers and enablers of PA behaviours in CCSs.
3. Explore CCSs' and parents' experiences of receiving advice on PA or exercise, and perceived need for this information.
4. Actively engage key stakeholders (CCSs, their parents, HCPs) in a co-design process to develop a prototype intervention.

METHODS AND ANALYSIS

Study design

The study will be informed by intervention development approaches—notably the Medical Research Council framework of intervention development[15] and the Person-Based Approach[18] to ensure that the resulting intervention is systematically developed from the bottom-up and: (1) is theory-informed and evidence-based[14 15 17 21–23]; (2) prioritises and incorporates the views of the people who will use the intervention[18 24] and (3) is likely to be implementable and scalable in the NHS.[25 26] The current phase of the project is focused on the intervention development. The planned research activities (which form

two sequential workpackages), and the other formative work previously undertaken by the study team which will feed into intervention development, are summarised in table 1 and figure 1. Workpackage 1 (WP1) will generate evidence on determinants of PA among CCSs. WP2 will involve a co-design process to produce a prototype intervention.

Participants

WP1 involves CCSs and parents/guardians of CCSs; eligibility criteria are shown in table 2. Participants will be recruited via two clinical sites which are both specialist centres in childhood cancer treatment.

WP2 will recruit CCSs, parents/guardians of CCSs and HCPs. The same inclusion and exclusion criteria as for WP1 will apply for CCSs and parents/guardians. HCPs will be eligible if they are involved in the follow-up care of CCSs. Academics and researchers with relevant expertise will also be eligible.

Sampling

WP1: generating evidence on determinants of PA among CCSs

Potential participants will be selected using purposive sampling with strata comprising of: age (for CCSs - current age of 10-15/16-24 years; for parents/guardians—age of child at diagnosis:≤10; 11–18 years); clinical site; and cancer site (haematological malignancy/solid tumour/central nervous system tumour). Diversity in other characteristics (eg, gender, treatment, time since diagnosis) will be sought to ensure sample heterogeneity and elicitation of a broad range of views and experiences.

Recruitment will continue until data saturation is reached in each interview set, defined as no new themes arising in the last three interviews.[27] We estimate that, interviews with 25–30 CCSs and 25–30 parents/guardians will provide adequate data. CCSs may participate without their parent/guardian taking part and vice versa.

WP2: co-design process

Up to 40 CCSs, parents/guardians of survivors, HCPs and academics/researchers will take part in the co-design process. At least 20 participants will be CCSs (due to the nature of the activities, participation is deemed only to be suitable for CCSs aged 16 and above) and 10 will be parents/guardians. As with the interviews, it will be important to seek diversity in the participants.

HCPs invited to take part in WP2 will include consultant oncologists and nurse specialists from paediatric and teenage and young adult services and other relevant HCPs (eg, occupational therapists, physiotherapists, psychologists, cardiologists). The aim is that at least six HCPs will participate in the co-design process. Academics/researchers with expertise in the following fields will also participate: behavioural science, health psychology, PA and exercise science, healthcare technologies, human-centred design and childhood cancer survivorship.

Identification, screening and recruitment of sample

Identification and screening of CCSs began in February 2019 with recruitment expected to end December 2020.

WP1: generating evidence on determinants of PA among CCSs

Employing multiple recruitment strategies can guard against recruitment problems,[28] therefore, we will use up to three methods for recruiting participants. The primary method will require consultant oncologists/nurse specialists to screen attendance lists of forthcoming CCSs follow-up clinics at collaborating sites. At the clinic, eligible CCSs and their parents/guardians will be informed of the study by their child's oncologist/nurse specialist and asked if they would like to meet the researcher (MB). If so, the researcher (MB) will provide further details, including the study information sheet, and will answer any questions. Potentially interested CCSs and parents/guardians will be asked whether the researcher can contact them in a few days to find out whether they would like to participate. Meeting the researcher at clinic will help potential participants feel more at ease and aid the establishment of rapport, which may be particularly important for younger patients.[29]

Approvals are in place for variants of this process in the event that the researcher cannot attend the clinic, or the clinic is too busy for collaborating clinical colleagues to approach eligible CCSs and parents/guardians individually. These include (1) clinical colleagues recording details of those potentially interested of behalf of the researcher, who will follow-up by phone and (2) provision of study packs (containing a reply slip) to eligible CCSs and parents/guardians at clinic check-in, with those interested returning the reply slip in a sealed envelope to the receptionist to forward to the researcher.

The second method will involve consultant oncologists/nurse specialists at the two sites screening patients in their care for eligibility and mailing a study information sheet; follow-up telephone calls by the clinical colleagues are permitted. Interested CCSs and parents/guardian may contact the researcher directly.

The third method, if required, will be identification of survivors via cancer registries in the study areas: the Northern Region Young Person's Malignant Disease Registry and the Yorkshire Specialist Register of Cancer in Children and Young People.

Information sheets for CCSs are developmentally appropriate and designed for ages 10–12, 13–15 and ≥16 years. CCSs aged 10–15 years will also receive a copy of the Charter of Rights for Children and Young People in Research.[30] Parents of CCSs aged 10–15 years will receive an information sheet explaining the study their child has been invited to participate in.

WP2: co-design process

WP1 participants will be asked if they wish to be notified of/invited to the co-design activities. New participants, without experience of the study, will also be recruited. Methods for recruiting CCSs and their parents/guardians

Table 1 Domains, actions and planned methods to develop physical activity (PA) intervention for childhood cancer survivors (CCSs)

Key actions to consider for intervention development[17]	Domain of intervention development and associated specific action(s)[16]	Methods utilised, or planned, in this research to develop the BEACON intervention
Planning the process Involving stakeholders Bringing together a team	**Conception**	
	1. Identifying the problem in need of a new intervention (including the health problem, the problematic behaviour and the target population)	Identification and evaluation of the literature on: ► Prevalence of cardiovascular late effects in CCSs ► Low PA in CCSs ► Benefit of PA to the health of CCSs Clinical experience/knowledge of low PA in CCSs
	Planning	
	2. Setting up a planning group/development team	Establishing a multidisciplinary steering group involving: ► Researchers and academics with expertise in health psychology, behavioural science/ intervention development, exercise physiology, PA interventions in clinical populations, digital health innovation ► HCPs and service providers (consultant oncologists, nurse specialists) ► Patient representatives
Reviewing published evidence Undertaking primary data collection Drawing on existing theories Articulate programme theory Understanding context Attending to future implementation	3. Understanding the problem to be addressed i. Understanding the views and experiences and psycho-social context of the potential target population	Use of PPI during initial stages of planning: ► Gaining young peoples' views of PA and the study concept via an NHS young persons' advisory group ► Consultation with CCSs on the need for PA interventions via focus group and survey methods Identification of literature reporting HCPs (who may be involved in the resulting intervention) views of PA in CCSs, and the provision of PA advice to CCSs.
	ii. Assessing the causes of the problems	Undertaking research to explore and understand CCS's views and experiences of PA: ► Literature review of the barriers and facilitators to PA in CCSs ► Undertaking in-depth interviews with CCSs and their parents regarding their views and experiences of PA, including perceived barriers and facilitators (informed by the Theoretical Domains Framework) ► Creating a logic model of the problem
	iii. Describing and understanding the wider context of the target population and the context in which the intervention will be implemented	Undertaking research to explore CCS's views of receiving PA advice in follow-up care: ► Survey and interviews with CCSs attending follow-up care Involving HCPs, service providers and patients in steering group and in co-production of intervention.
	iv. Identifying the effectiveness of interventions for PA in CCSs	Identification and evaluation of existing PA interventions in CCSs: ► Systematic reviews of PA interventions in CCSs ► Research evaluating PA interventions in CCSs
	v. Understanding wider stakeholders' perspectives of problems and issues	Actively engaging with stakeholders, service providers and CCSs throughout research and in co-production of intervention.

Continued

Table 1 Continued

Key actions to consider for intervention development[17]	Domain of intervention development and associated specific action(s)[16]	Methods utilised, or planned, in this research to develop the BEACON intervention
Drawing on existing theories Articulating programme theory Understanding context Attending to future implementation	4. Making decisions about aims and goals of intervention	Based on the evidence generated in WP1, the steering group and research team will make decisions on the specific aims and goals of intervention.
	5. Identifying what needs to change and how to bring about change	Following WP1, a logical model of change will be developed for PA in CCSs drawing on the evidence and constructs from relevant theories.
	6. Specify who will change, how and when	Following WP1, the steering group and research team will break down the behavioural outcomes to consider, prioritise and map who needs to change what, how changes will occur as a result of the intervention and when these changes are expected to take place.
	7. Considering the real-world issues about cost and delivery of any intervention to reduce risk of implementation failure	Involvement of HCPs/service providers in steering group. Co-design workshops with stakeholders (including HCPs). Use of Normalisation Theory Process to inform discussion with HCPs.
	8. Considering whether it is worthwhile continuing with development of intervention	Steering group and stakeholder input on feasibility of intervention.
Designing and refining intervention	**Designing**	
	9. Generating ideas about solutions and components and features of an intervention 10. Re-visit decisions about where to intervene	Mapping of behavioural determinants onto behaviour change techniques using Behaviour Change Wheel. Co-design workshops using creative methods and activities to enable idea generation. Input from stakeholders to make final decisions regarding the scope, the target population, key features and components of intervention which will be further refined during workshops.
	11. Make decisions about the content, format and delivery of the intervention	Findings of WP1 will be combined into a theoretical model of PA in CCSs and will inform initial ideas about content, format and delivery. Actively engaging with steering group and stakeholders via co-design workshops to obtain views on the potential content, format and delivery of intervention.
	12. Design an implementation plan, thinking about who will adopt the intervention and maintain it	Design of potential implementation plan will be informed by discussions with HCPs and other stakeholders regarding potential implementation barriers and previous research.
	Creating	
	13. Make prototypes/mock-ups of the intervention where relevant	Generation and discussion of mock-ups and paper-based prototypes during co-design workshops.

CCSs, childhood cancer survivors; HCPs, healthcare professionals; NHS, National Health Service; PA, physical activity; PPI, patient and public involvement.

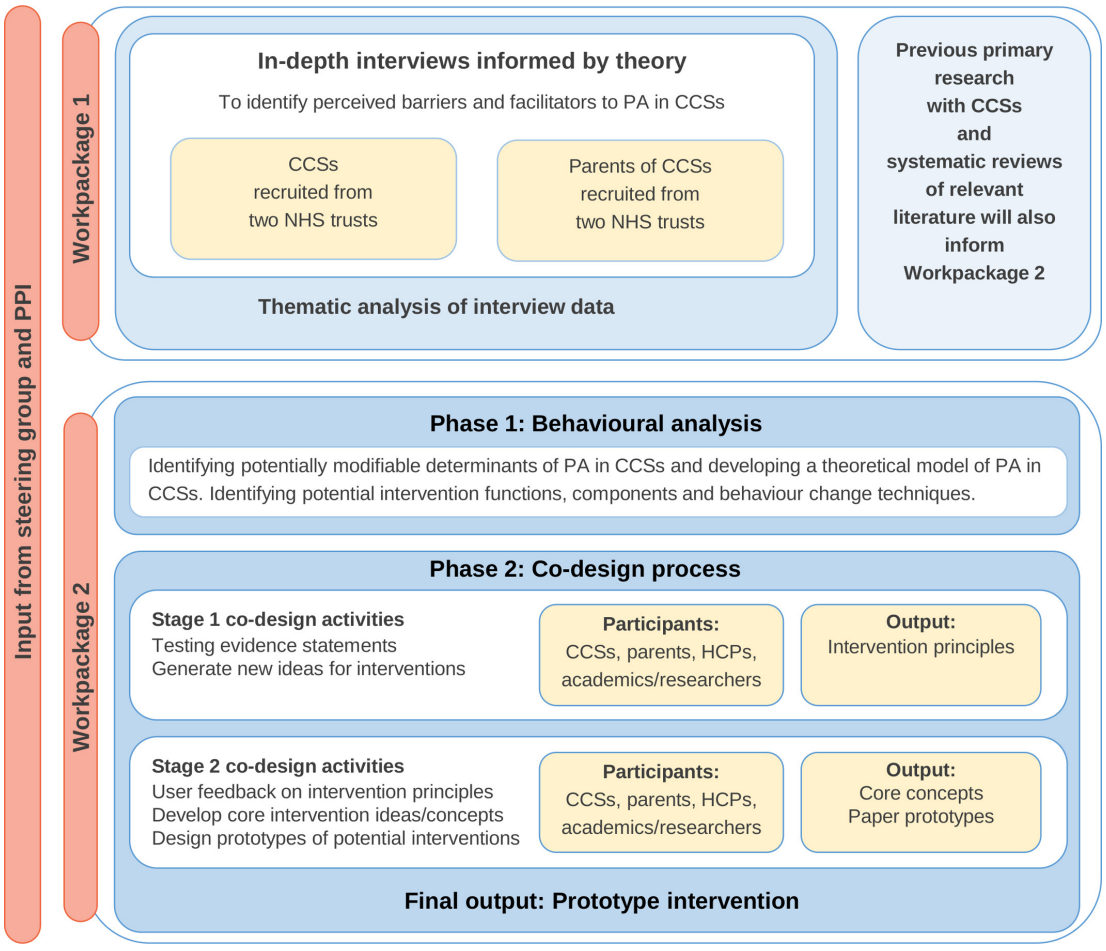

Figure 1 Overview of planned research for the BEACON project. CCSs, childhood cancer survivors; HCPs, healthcare professionals;NHS, National Health Service; PPI, patient and public involvement; PA, physical activity.

will mirror those of WP1. In addition, we will also seek to recruit via social media, support groups and charities. Posts advertising the study will ask for interested individuals to contact the researcher who will assess eligibility and provide further information.

Eligible HCPs working at the collaborating sites will be invited to take part. We will also promote the study via social media, and through networks of the Children's Cancer & Leukaemia Group, to encourage participation of HCPs from across UK. Academics and researchers experienced in relevant areas (also previously stated) will also be asked to participate.

Table 2 Childhood cancer survivors' inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Diagnosed with any haematological malignancy or solid or CNS tumour under the age of 19 years	Any cognitive or physical impairment of sufficient severity to limit their ability to understand, engage with or undertake PA
Currently aged 10–24 years	Any contraindications to exercise
Currently 2–15 years from the end of treatment	
No active disease	

CNS, central nervous system; PA, physical activity.

Data collection

WP1: generating evidence on determinants of PA among CCSs

Interviews with CCSs aged 10–15 years will take place face-to-face at the interviewee's and their parents preferred location (eg, university/home). A parent/guardian may be present if they or the child wishes. These interviews are expected to last 30–60 min, but length will be determined by the child.

Interviews with CCSs aged ≥16 years, and those with parents/guardians, will take place by telephone, an end-to-end encrypted web app which enables secure audio/video calls (eg, WhatsApp, Zoom), or face-to-face at a location of their choosing; providing choice on ways to participate can help maximise recruitment.[28] Experience suggests these interview will last 60–90 min,[31] but may be longer if the interviewee wishes.

Before the interview commences, the researcher will seek informed consent; for those aged 10–15 years, a parent/guardian will provide consent and the interviewee assent to ensure that the child feels involved in

the decision about their participation.[32] Participants (and parents on behalf of children aged 10–15 years) will be asked to complete a short demographic questionnaire. Time will be spent developing rapport and creating a secure, trusting environment,[28] particularly with younger children.[29]

The interviews will be guided by a topic guide, which will be informed by the Theoretical Domains Framework (TDF), an integrative framework of behavioural change theories,[21 22] and will cover: participant's views and attitudes towards their own/their child's PA; difficulties experienced with, and barriers to, PA; whether support/advice has been given regarding PA; and what helps or would help the survivor to be more active. Questions will be open and neutral. Topic guides will be used flexibly to allow interviewees to raise issues they consider important to the topic (PA); if this results in new areas, these will be explored in subsequent interviews to ensure sufficient depth is reached.

Interview content will be developmentally appropriate. Interviews with children aged 10–15 years will use cue cards and images to help engage and focus the participant and provide them with some control over the order of the questions.[29] With the interviewees' permission, interviews will be audio recorded; if permission for recording is not granted, the researcher will take detailed notes.

WP2: co-design process

We will follow the sequential and systematic co-design approach to integrate scientific evidence, expert knowledge and experience and stakeholder involvement to design a prototype intervention.[24] The two phases of WP2 are described below.

Phase 1: behavioural analysis

The researcher team will combine WP1 findings and other formative work previously conducted (eg, a systematic review) (figure 1), into a 'theoretical model' of PA engagement among CCSs. They will identify which influences on PA are potentially modifiable to determine what needs to be done to change behaviours. The Behaviour Change Wheel will be used to map the TDF domains, and organise these into a working theoretical model of PA in CCSs.[23] For each identified factor the team will identify which intervention functions might be effective in changing PA behaviours. For each of the relevant intervention functions, associated behavioural change techniques will be identified (ie, the techniques that can be used to overcome barriers to, and enhance enablers of, engagement with PA).[33]

Phase 2: co-design process

This process will involve a range of methods in order to engage and collaborate with stakeholders flexibly. Due to the current global COVID-19 pandemic, we will offer multiple modes of participation including workshops (face-to-face or online), interviews (one-to-one or small groups of 2/3 people; face-to-face or online); and online collaborative groups. The mode of participation will be guided by participant preference, as well as COVID-19 guidelines at the time of study.

Face-to-face workshops are expected to last 3–4 hours, while those online will be shorter (1–2 hours). Interviews are likely to also last 1–2 hours. Video conferencing is an acceptable method for discussion with young people and an optimal alternative to face-to-face groups; it also enables people from various geographical location to attend.[34]

Online collaborative groups allow stakeholders to engage with the development process, and one another, both in real time and asynchronously. Secure groups will be set up via WhatsApp, Facebook or an Ideaboard.co.uk website developed specifically for the study. WhatsApp and Facebook are widely used and familiar applications, and have successfully been used for co-design[35 36]; Ideaboard offers greater flexibility. Preferences of potential participants will inform the choice of platform. The team will post content to the groups (eg, videos, images, questions) and invite feedback.

Following patient and public involvement (PPI) input, CCSs will have the choice to participate in a survivor only or mixed (survivors plus parents/HCPs) workshop/small group interview/collaborative group.

Using these methods, a range of activities (eg, think aloud, mapping, brainstorming, storyboarding) will be used to engage participants, provide ways for them to share, envision and develop their ideas with others and to facilitate interaction. The specific activities will be dictated by the findings of WP1, and the findings of any preceding workshops.

Two steps in the co-design process are envisioned (figure 1). In the first step, evidence statements on PA among CCSs will be presented. Stakeholders' views on the relevance, importance and effectiveness will be sought. Activities will be used to generate insights into what is needed to improve PA levels in CCSs and novel intervention ideas which stakeholders think could be effective and acceptable in improving PA in CCSs. Ideas will also be sought for how an intervention should be designed, where and how it should be implemented, and the relevant components. Mapping activities will enable organisation and visualisation of resulting intervention ideas and their key components. The research team will analyse information collected to develop 'intervention principles', ensuring that the evidence and theory, which is central to the success of the intervention, remains intact.[37]

During the second stage, activities will focus on gaining user feedback on intervention principles. Content and mode of delivery will be further developed and refined. Intervention tailoring will also be considered. Participants will identify and discuss potential challenges around acceptability, usability and feasibility from different perspectives (eg, CCSs, parents, HCPs, commissioners, service providers). Based on participants discussion and decisions, designers/creative facilitators will begin to sketch paper based 'mock-ups' of the intervention.

Outputs will be critically evaluated and translated into a design brief which details the aims of the intervention, the design features it will include, and how these will be operationalised, taking care to ensure alignment with evidence and theory. A logic model will be developed,[14] providing a graphical/textual representation of how the intervention is intended to work, linking outcomes with processes, the underlying theoretical assumptions and active ingredients (or the behavioural change methods and techniques that will be used to target the identified processes/mechanism associated with behaviour and behaviour change).[33 38] The outcome will be a mock-up of the prototype which will represent the main features of the intervention. This prototype will be ready to take into production and undergo refinement and optimisation before going forward into further testing in a future study.

Prior to participation in co-design activities, informed consent will be sought and a ground rules for communication and engagement established. The researchers will ensure an atmosphere which is welcoming and non-judgemental and will be clear that all participants are treated as equals whether they are young people, parents, researchers or HCPs.

Where possible, co-design activities will be audio or video recorded and transcribed. Other data collected will include written data/notes, mapping activities and sketches resulting from the various activities (eg, group work, brainstorm) and written comments generated by the online collaborative groups.

Data analysis plan

WP1: generating evidence on determinants of PA among CCSs

Interview recordings will be transcribed verbatim. Analysis will occur in parallel with data collection to ensure that any new issues raised are explored in subsequent interviews. Interviews from CCSs and parents/guardians will be analysed separately. To identify views and experiences of, and barriers and facilitators to, PA in CCSs an inductive thematic analysis will be conducted.[39] Two team members will code data from preliminary interviews and discuss and agree the emerging codes and potential themes. Codes relating to the barriers and facilitators to PA will be mapped onto the TDF.[21 22] These codes will then be applied by the researcher to remaining interviews, incorporating any new codes and themes as they are identified. For analytical rigour, the classification of belief statements to the TDF domains will be discussed and agreed within the team. Coding and analysis will be facilitated by QSR International's NVivo software (V.12, 2018).

WP2: co-design activities

Analysis of co-design activities will be focused specifically on the aims of each activity, pragmatic and expeditious so findings can be fed into subsequent stages.[37] Qualitative content analysis will be performed using QSR International's NVivo software (V.12, 2018), supplemented by other forms of analysis as required.

ETHICS AND DISSEMINATION

A favourable opinion has been granted from the North East-Tyne & Wear South Research Ethics Committee (REC ref: 18/NE/0274).

Informed consent will be sought prior to participation. Participants will be informed that participation is entirely voluntary, and they may withdraw at any point, without giving a reason and without negative consequences. They will be asked for their agreement to audio/video record (where relevant) and informed that recordings are confidential, and transcriptions of audio recordings will be anonymised. Ethical considerations relating to the interviewing of children (aged under 16 years) are described above. Interview participants will be offered payment of any travel expenses and a £20 high-street shopping voucher. This amount is based on the need to provide some compensation for the participant's time, expertise and contribution to the research but without coercing individuals to take part when they would rather not.[40] Participants will be notified of the voucher in the study information sheet and will be offered the voucher at the beginning of the interview to convey to them that they are being rewarded for their attendance, and not for what they share during the interview.[41] Participants recruited to co-design activities will receive a high street voucher which reflects the time commitment and nature of the activity they choose to participate in, in accordance with INVOLVE guidance.[42]

Findings will be disseminated via our study website (https://research.ncl.ac.uk/beingactive/), conferences and journal publications. A summary of research findings will be available for participants. PPI will inform further dissemination activities (eg, via patient organisations, social media), appropriate formats (eg, infographics, video) and content to ensure lay summaries are understandable and engaging to survivors.

Patient and public involvement

Feedback on the study concept and methods were gained from two established PPI groups in Newcastle: the Young Person's Advisory Group-North England (YPAG-NE) whose members are young people aged 13–18 years old, and the Perspectives in Cancer Research group whose members are survivors of adult cancer. Views of young adult CCSs were gained via representatives of two European cancer organisations, PanCare (Pan-European Network for Care of Survivors after Childhood and Adolescent Cancer) and Youth Cancer Europe, and a survey posted to a closed Facebook group for survivors of cancer. YPAG-NE and two adult CCSs provided comments on patient information and interview topic guides/cue cards. Patient representatives (OB and JH) sit on the project steering group, and will be involved in

data interpretation, co-design activities and advising on dissemination.

DISCUSSION

A high proportion of adolescents and young adults do not meet recommended levels of PA,[43] and there are already many publicly available programmes and interventions to encourage PA, including government/health service initiatives and apps.[44–46] This raises the question of whether a specific PA intervention is needed for CCSs. While there is considerable overlap between determinants of PA in CCSs and young people without cancer, many influences are likely specific to CCSs (eg, cancer-related fatigue, frustration about impact of cancer).[13] There are also concerns about the quality and likely effectiveness of many of the publicly available PA programmes.[46] In addition, cancer survivors may question the relevance of general (ie, non-cancer specific) PA programmes to them,[47] and there is evidence that tailoring interventions to a specific target population is likely to increase effectiveness.[48] Taken together, this suggests that the route most likely to lead to changes in CCSs' PA levels is to develop an intervention specifically for this group.

The strength of our study lies in the adoption of an evidence-based, person-centred approach. However, we also recognise the need to mitigate potential study limitations. To minimise selection bias, the importance of giving all eligible patients the opportunity to hear about the study, and allowing them make their own choice as to whether they want to participate or not, will be highlighted to those involved in the screening process.[49] For example, participating in this research may appeal more to CCSs who are physically active, than to those who are not. Therefore, patients will also be made aware that a judgement will not be made on their current activity levels and that we are interested in their views regardless of whether they consider themselves to be active or not.

Although several determinants of PA may be common across CCSs as a group (eg, fatigue), survivors will experience barriers and limitations specific to the cancer they had, and the treatment they received.[50] Many CCSs have ongoing health conditions and impairments to the neurological, endocrine, musculoskeletal and cardiopulmonary systems which can influence physical performance, function and mobility in a variety of ways.[51] Therefore, it is essential that PA interventions should not only be targeted to the needs of CCSs as a group, but allow tailoring to the needs of individuals.[13] To enable this, recruitment will occur via follow-up clinics for survivors of haematological malignancies, solid tumour and central nervous system tumours, and sampling will ensure variation across key characteristics including diagnosis and treatment to ensure heterogeneity in the potential influences on the PA of CCSs.

CCSs can be challenging to recruit to research,[52] therefore, we propose several routes by which CCSs may be made aware of the study. This will help to safeguard against any potential recruitment issues and will also ensure that a wide range of individuals are offered the opportunity to participate. We also acknowledge the potential impact of the current COVID-19 pandemic on the study, including the possible need to conduct co-design activities remotely. The use of video conferencing could exclude those who have limited access to the required technology, or those who do not feel comfortable using it.[53] The use of remote methods may also hinder the interactive, creative and collaborative process essential to co-design. Therefore, we have proposed several ways that individuals can take part in co-design activities, including online synchronous and asynchronous methods. Careful and considered planning will be needed to adapt co-design activities to ensure participation and engagement, as well as an online environment in which individuals feel safe and able to contribute.

The final output from this phase of the BEACON study will be a prototype evidence-based and theoretically-informed intervention. The next step will be to fully operationalise the intervention and any supporting materials (eg, training manual). Efficient and systematic user pretesting studies will be conducted to provide insight into different aspects of the intervention and iteratively refine and optimise it.[37] Subsequently, as recommended in the area of PA research,[54] we plan to assess feasibility and acceptability to users and, following that, evaluate effectiveness and cost-effectiveness in a randomised controlled trial, with a parallel process evaluation.[55]

Various organisations, including the American Cancer Society[56] and Macmillan Cancer Support,[57] have produced PA recommendations for cancer survivors (of all ages). However, understanding remains limited on how best to support survivors to improve levels of PA and maintain changes.[58 59] The study described here—although it focuses on CCSs—provides an example of how to use a behavioural science approach to develop a person-centred, evidence-based and theoretically-informed PA intervention and, therefore, may be informative for those interested in systematically developing PA interventions for other survivor groups.

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specialist advice and expertise throughout the study. MB drafted the manuscript, and AG, JS, LS, RS, KM, NS, VA-S provided revisions and comments. All authors approved the final manuscript.

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