e-Prehabilitation System of Care for Teenagers and Young Adults diagnosed with Cancer: Study Protocol

Abstract

Background: A diagnosis of cancer in young adulthood can pose many different and unique challenges for individuals. Provision of adequate and appropriate information, care and support for teenagers and young adults around the time of diagnosis is central to their healthcare experience going forward. Appropriate and accessible information provision is critical to ensure young people with cancer feel equipped and empowered to make decisions about, and be involved in, their treatment and recovery throughout their experience; a concept known as prehabilitation. As digital interventions and resources to support TYA with cancer are an increasingly desirable part of healthcare provision, this study will focus on the development of an age and population appropriate (e) electronic-prehabilitation system of care.

Objective: An exploratory, co-design research project will inform the development of an e-Prehabilitation system of care to support Teenagers and Young Adults diagnosed with cancer. A collaborative approach to data collection and prototype design will ensure a patient-centred approach is embedded throughout.

Methods: Qualitative, co-design utilising surveys, interviews and focus groups with Teenagers and Young Adults, Health Care Professionals and Technologists.

Results: This research study is in progress; recruitment and data collection activities have commenced and findings are expected early 2019.

Conclusions: The findings from this study will have important implications for informing the future development and evaluation of an e-Prehabilitation system of care to support TYA diagnosed with cancer.

Keywords
Digital Health
Human Factors
Co-design
Prehabilitation
Teenagers and Young Adults
Cancer
Introduction

Although cancer is relatively rare in teenagers and young adults (TYA; people aged 15 - 24 years, inclusive)[1], incidence rates in the UK have increased by around a fifth over the last decade[1]. In the UK from 2009 - 2011, 2,234 new cases of cancer were diagnosed in TYA. The diagnostic profile of cancers in TYA differ to those in adults, with lymphoma the most common group of cancers diagnosed in people in the 15 - 24 years age group[1]. Collectively, lymphomas, carcinomas and germ cell tumours account for more than half of the total number of diagnoses of cancer in the 15-24 year old population[1].

A diagnosis of cancer presents a range of physical, financial and psychosocial challenges for young adults and their families[2,3,4], including disruptions to education / career[5], family life[6], self-esteem / identity[7], peer and sexual relationships and body image[8,9,10]. There is also a need to manage the side effects of treatment, both short and long term, and the possible impacts on future fertility[11,12,13]. These various challenges are often compounded by the developmental stages and changes that accompany young adulthood[14]. Thus, a diagnosis of cancer in young adulthood can pose many different and unique challenges for these individuals. As a consequence, there is a significant body of research that recognises the importance of providing adequate and appropriate information, care and support to teenagers, young adults and their families at the time of diagnosis[15,16,17]. Such information provision is critical in ensuring that young people feel equipped and empowered to make decisions about, and be involved in, their treatment and recovery, thereby enhancing a sense of mastery and control / self-efficacy[18].

There is an increasing interest and growing momentum within a cancer context of the concept of “positive psychology”[19]. Positive psychology includes building and strengthening the resilience of patients and their families following a diagnosis of cancer, the adoption of coping strategies and the utilisation of strengths based assessment and interventions[20]. A key component of the positive psychology process is the proactive anticipation of the challenges which are likely to be encountered following a diagnosis of cancer and associated treatments to ensure that young people and their families can be equipped with information and effective coping strategies prior to the commencement of treatment, rather than during or after treatment, in which case a deficit/reactive model may have to be implemented[21].

As such, the delivery of health-related interventions in the period between a patient’s diagnosis and treatment commencement is known as prehabilitation[22]. Typically delivered in the intervening period between a patient receiving a diagnosis and their treatment initiation, strategies tend to be implemented to maximise people’s fitness, adjustment and to ultimately have a positive impact on survival and associated patient reported outcomes and coping[23-30]. The application of prehabilitation strategies are becoming more evident within healthcare, with a growing evidence base for their benefits for patients receiving surgery[29,31] and coronary artery bypass surgery[32], as examples.

However, within a cancer care context, prehabilitation is a relatively new and emerging concept. Against this backdrop, following a review of non-cancer prehabilitation
literature, cancer prehabilitation has recently been defined as “a process on the continuum of care that occurs between the time of cancer diagnosis and the beginning of acute treatment, includes physical and psychological assessments that establish a baseline functional level, identifies impairments, and provides targeted interventions that improve a patient’s health to reduce the incidence and the severity of current and future impairments, and provides targeted interventions that improve a patient’s health to reduce the incidence and the severity of current and future impairments”[22].

It was concluded from this review[22] on cancer prehabilitation that opportunities exist for prehabilitation interventions to help support people with cancer. Such interventions may improve physical and psychological health outcomes, increase the number of potential treatment outcomes, and reduce direct and indirect health costs attributed to cancer. However, the paucity of prehabilitation research, developed interventions and associated packages of care within this context means there is a real need to identify the best interventions to use with various groups of people affected by cancer[22]. Developing tailored prehabilitation interventions and associated packages of care for particular patient groups is critical to ensure they are responsive to and meet the particular needs of these patient groups. Ultimately, doing so may help increase rates of compliance with treatments, consequently having a positive impact on treatment survival outcomes[22]. Despite the potential benefits of an established prehabilitation programme, there is, however, a notable paucity of information that focuses on teenage and young adults with cancer within this context.

New interventions should be designed and developed in collaboration with the target population to help ensure their success. Evidence-based co-design, in which people’s experiences are explored and collated to help develop service improvements[33] is one recognized way of ensuring a person-centered approach to care. In addition, young people are now digital natives[34] and so digital resources to support TYA with cancer are increasingly desirable. In a recent service evaluation survey with TYA with cancer in one clinical site in one area of the UK, TYA were responsive to potential provision and development of digital resources to support them during their cancer experiences[34]. In another service development initiative in the UK, a digital pathway, known as the Integrated Assessment Mapping (IAM) portal, was recently developed by the University Hospitals Bristol NHS Foundation Trust and the TYA South West Cancer service. The project aimed to provide TYA cancer patients with emotional and clinical support using a holistic, age-appropriate digital platform[35]. Via a co-creation approach, three interconnected services were developed following engagement sessions with the TYAs. The three services included a TYA website, the IAM website and mobile app and the SWIMMS patient database. Collectively the three services provide the patient with support based on their self-identified needs, additionally, the clinical care team and service provider and able to better identify the support needs of TYA cancer patients based on the information provided by the patients themselves[35]. The IAM project highlights that it is possible to co-design, develop and integrate an e-Health platform to provide support for TYA diagnosed with cancer.

Thus, collaborative engagement, the prioritisation of TYA’s experiences and needs and the development of a suitable, effective and appropriate digital health solution are the central tenants of this study. As the current evidence base for prehabilitation care
is limited, particularly for TYA with cancer, it is timely to develop an evidence-based and experientially informed system of care for use by this patient population.

**Study Objectives**

This exploratory research project will inform the development of an e-Prehabilitation system of care to support TYA diagnosed with cancer. To do this, there are four overarching research objectives: 1) Understand the needs of TYA with cancer at the time of diagnosis. 2) Understand the potential role of e-Health solutions to assist in the prehabilitation care offered to TYA with cancer by Health Care Professionals (HCP). 3) Identify appropriate technologies and technological platforms to support the delivery of an e-Prehabilitation system of care. 4) Generate the content of a prototype e-Prehabilitation system of care for use by HCP and TYA diagnosed with cancer.

**Study Design**

This study draws on two main conceptual frameworks to ensure the intervention is developed appropriately. First, the study draws on the Medical Research Council (MRC) Framework for the development, evaluation and implementation of complex interventions to improve health[36]. Drawing on Stage I of the MRC Framework, activities in this study will focus on engaging with TYA and Professionals working in Health Care or as Technologists working with Digital Health solutions and innovations in industry or the NHS and developing the theory to inform the development of the intervention. Theoretically, this study will draw on the Behaviour Change Wheel as this provides a framework for understanding behaviour as an enabler for behaviour change interventions[37].

**Ethics Approval**

The ethical aspects of this study were approved by the Yorkshire and The Humber – Bradford Leeds research ethics committee and was endorsed by the lead author’s University ethics committee (Research Ethics Committee Reference:17/YH/0352). The study has also received R&D approval from the relevant NHS Board in the UK.

**Methods**

**Eligibility Criteria**

The eligibility criteria for participation in the study are provided in Table 1. Although teenage and young adulthood is defined as 15-24 years, 16-26 years is the age range for referrals for TYA to access services at the partnering clinical site. TYAs and HCPs who fit the inclusion criteria and provide informed consent will be eligible to participate in the study.
<table>
<thead>
<tr>
<th>Participant Group</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
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<tbody>
<tr>
<td>Teenagers and Young Adults</td>
<td>• Young people aged 16 to 26 years</td>
<td>• Teenagers younger than 16 years</td>
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<td>• TYA who were diagnosed with cancer up to 3 years, but no less than 4 weeks, prior to participation in the study. TYA may be on acute anti-cancer treatments and therapies, on maintenance treatments or be considered to have completed all treatments in the period up to 3 years’ post-diagnosis.</td>
<td>• Young adults older than 26 years</td>
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<td>• Receiving/ received services by relevant NHS Board and/or partner Cancer Principal Treatment Centre.</td>
<td>• To avoid any additional potential stressors for TYA newly diagnosed with cancer, we will not recruit TYA in the first 4 weeks post-diagnosis</td>
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<td>• Sufficiently proficient in English to be able to participate in data collection activities</td>
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<td>• Able to provide informed consent</td>
<td>• TYA without a cancer diagnosis</td>
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<td>• Able to communicate sufficiently well in English</td>
<td>• TYA newly diagnosed with cancer (in last 4 weeks)</td>
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<td>• TYA who received a diagnosis of cancer more than 3 years ago</td>
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<tr>
<td>Health Care Professionals</td>
<td>• Members of the TYA Cancer Team / multidisciplinary team involved in the provision of care or services to TYA with cancer via NHS Board / partner cancer Principal Treatment Centre</td>
<td>• Unable to provide informed consent</td>
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<td>Have experience of working with TYA who have / have had a diagnosis of cancer</td>
<td>Able to provide informed consent</td>
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<tr>
<td>Technologists / Digital Health Professionals</td>
<td>Professionals with experience of working within the digital health space within the NHS/ Industry/ Academia</td>
<td>Able to provide informed consent</td>
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<td>Able to communicate sufficiently well in English</td>
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Recruitment

Teenagers and Young Adults
Direct Recruitment (NHS)

Patient databases will be screened for TYA that meet our inclusion criteria by members of the TYA Cancer Team at the recruiting site (Figure 1). The member of staff will approach potential participants in the first instance in person or by email to introduce the possibility of participation in the study and to pass on the study information material. Potential participants will be asked to complete / provide permission for proxy completion of a Consent-to-be-Contacted form (Figure 1) to indicate their agreement for their contact details to be passed to the research team. Only then will the research team contact TYA to further discuss participation in the study.

If possible, we will capture top level details of ineligibility for invitations to participate from the databases in partnership with the TYA Cancer Team.

Self-Referral
We will adopt a variety of self-referral strategies to provide TYA with opportunities to participate in the study. We will circulate study invitations in the form of recruitment adverts/posters/postcards and display these in the recruiting site and various other environment-appropriate locations throughout Scotland. Social media will be utilised to further increase the opportunities to recruit TYA to the study; where appropriate, we will post digital versions of the recruitment advert too. Study specific Twitter, Facebook and e-mail accounts have been created. We will also circulate information to other relevant support organisations working directly with TYA with cancer. If necessary, paid advertisements on social media and in the local press will be used to aid recruitment.

Potential TYA participants will be directed to an online screening questionnaire to establish their eligibility for taking part. The online screening questionnaire will also gather information which eligibility criterion was not met so the research team can track reasons for non-participation at the screening stage.

**Health Care Professionals**

Researchers will directly invite HCPs such as Consultant Oncologists, Psychologists, Allied Health Professions, Social Workers, Specialist Nurses, Ward Nurses, Youth Support to participate in the study. This will help ensure appropriate multidisciplinary participation in the study.

**Technologists / Digital Health Professionals**

Key individuals with a responsibility for digital health within the NHS, Industry and Academia will be directly approached by members of the research team to participate in the study.
Figure 1: Flow diagram of recruitment. TYA: Teenagers and Young Adults.
Participant Information and Informed Consent

TYA and Professionals will receive information about the study before consenting to participate in any data collection activities (Figure 1). TYA participants will receive a written information sheet in age-appropriate language and a link to a video and audio information sheet created specifically for this project. The video clip will be made available via the project website. Professionals will receive a written participant information sheet distributed by email or hard copy. Potential participants (TYA and Professionals) will have at least 24 hours to familiarise themselves with the study information and to decide whether or not they wish to participate. TYA and Professionals will have the opportunity to ask questions prior to signing the consent form / recording verbal consent. In instances where it is not possible to obtain written consent from participants (when conducting telephone interviews as an example), verbal consent will be obtained instead at the start of the audio recording.

Incentives

Indirect benefits of taking part in this research study for TYA and Professionals are sharing experiences and contributing to developing the design of a new digital health intervention. TYA will receive a study-specific certificate of participation from the research team which may benefit their portfolio of evidence for further education and/or job applications. TYA will be reimbursed for their travel expenses to attend any data collection activities away from their home and refreshments will be provided during any group data collection activities.

Data Collection

Throughout the data collection activities, we will utilise the TYA’s position of being an expert on general knowledge of experiences of young TYA at the time of cancer diagnosis, based on their own experiences. By doing so we will empower TYA to participate as expert representative of others too. There are four distinct streams to data collection in this study, as outlined in Figure 2.
Figure 2: Flow chart of the different stages of the data collection activities and outputs. TYA: Teenagers and young adults; HCP: Health care professionals

Stream 1: Focus Group/Individual Interviews with TYAs

We will conduct focus groups or individual interviews with TYA with a history of a cancer diagnosis to develop an understanding of the issues they faced upon a diagnosis of cancer. The focus groups will take place if at least three participants are available to meet.

If we are able to run focus groups, we aim to recruit up to 20 TYA who meet the inclusion criteria to participate in this first stage of data collection. We will conduct up to 4 separate focus groups with 3-7 participants each. However, if engagement levels for focus groups are low and we are unable to meet the minimum number of required participants (n=3 as a minimum to run a group), we will conduct a series of 1-1 interviews instead of alongside focus groups for this first stage of data collection. In this case, we will recruit up to 10 TYA who meet the inclusion criteria. Individual interviews will last up to 60 minutes and focus on the topics outlined above.

Stream 2: Interviews/Online Survey with Health Care and Digital Health Professionals

Stream 2 will run concurrently with Stream 1. In stream 2, Professionals will be invited to participate in one-off individual interviews to explore their preferences for the content and delivery of the e-Prehabilitation system of care, including the technology platform to be used and their requirements for the prehabilitation care resources and materials to be included within the intervention. Interviews will last approximately 30 minutes, be conducted face-to-face or by telephone based on participants’ preference and audio recorded. To enhance opportunities for participation, we will also provide
Professionals with the opportunity to complete a short online survey. The link to the online survey will be distributed by email.

Table 2: Participatory design activities for stream 3

<table>
<thead>
<tr>
<th>Topics</th>
<th>Purpose</th>
<th>Toolkit of Methods (will be selected/adapted as appropriate)</th>
<th>Data Output</th>
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</table>
| Content - Nature and focus    | To gather some ideas about the type of information displayed and collected | Researchers present a “Tree of ideas” made up of tag-clouds of themes generated from the focus group/interview responses from Streams 1 & 2  
Participants rate ideas as “keep”, “lose” or “change” using colour-coded post-it notes  
Verbal discussions and/or blank paper sheet for items labelled as “change”, participants suggest how the item needs to change for being rated as “keep”  
Participants rank ideas labelled as “keep” by priority using sequential numbers | Voice recording, text (annotations), photographs of post-it notes |
| Content - Visual designs      | To capture some ideas about how information might look                   | Researchers provide A4 paper sheets with blank smart phone mock-up  
Warm-up activity on paper prototyping  
Researchers provide examples of existing electronic cancer information tools via iPad (e.g. ‘IAM’ website, websites and materials from cancer charities, Video Game: Re-Mission)  
Participants draw ideas / write descriptions of how the information could be visually presented on a smart phone app/web site | Drawings, text (annotations), voice recording |
| Functions & features | To get a view of what the technology looks like and some of its properties | Researchers provide A4 paper sheets with blank smart phone mock-up  
Participants draw functions and features / write descriptions (What functions/features and how they work) | Drawings, (text annotations), voice recording |
|----------------------|--------------------------------------------------------------------------------|--------------------------------------------------------------------------------|--------------------------------------|
| Contextual enquiry of technology use | To capture ideas and preferences on the type of digital health technology and how and when it would be used | Research team provide 3 printed maps of a fictional town with images of typical locations and buildings where TYA might find themselves. Each map will represent a point in time of the cancer journey (Diagnosis, Treatment, Survivorship). Colour-coded stickers, pens and post-it notes will also be provided.  
Participants indicate on the map which type of information they would access/seek and where they would use a digital health intervention to do so. | Maps, text (annotations), photographs of post-it notes, voice recording |

**Stream 3: Design Workshops**

Drawing on data gathered in Streams 1 and 2, the research team will explore with TYA the technology platform to be used, the type, nature and focus of content of the material contained in the system and their requirements for this system. Design workshops will emphasise the need for technology that is not just designed for illness and medical activities. This requirement has been expressed by teenagers with a chronic medical diagnosis previously[37]. Participatory design activities for participants during Stream 3 are shown in Table 2.

**Stream 4: Consensus Activities**

The data generated from Streams 1 – 3, in combination with the findings from the literature, will be considered collectively to develop a low-fidelity prototype. In Stream 4, we will endeavour to seek feedback from participants on this low-fidelity prototype. To do this, we will provide environments, physical (as in face-face group or individual discussions) and/or electronic (as in an online discussion forum/survey), for participants (TYA and Professionals) to access and comment on the low-fidelity prototype. If interest from participants warrants a further face-face meeting, a session will be arranged to present the low-fidelity prototype to TYA and Professionals together. However, if it will prove difficult to bring people to together physically, we will distribute an electronic version of the low-fidelity prototype (via PDF files of wireframes of suggested content, for example) by email/secured transfer and ask for comments.
and feedback. Participation in Stream 4 will be optional for both TYA and Professional participants.

**Demographic and Clinical Questionnaire**

We will ask participants to complete a questionnaire to obtain demographic and clinical (TYA only) characteristics on the day of the focus groups/interviews/online survey prior to participating in data collection activities. All data entries will remain anonymous.

**Data Analysis**

*Focus Groups, Interviews, Online Survey*

Focus groups/interviews with TYA with cancer and Professionals will be audio recorded and transcribed verbatim. Transcripts will be merged with field notes and outputs of brainstorming activities. During the analysis, two researchers will draw upon the research objectives and identify and develop themed categories to guide the data analysis. We will use NVivo, a qualitative data analysis software package to support these activities.

Thematic analysis is a useful approach for answering questions about the salient issues for a particular group of respondents or for identifying typical responses[39]. For reliability and validity purposes, two researchers will code a sub-sample of transcripts and field notes separately and then cross-check them together.

*Design Workshops*

Design activities will be audio recorded to capture discussions and reflections about design processes and products. It is less likely that audio recordings from design workshops will be transcribed due to expected levels of background noise but they will be listened to by members of the research team as an aide-memoire. We will take photographs of design sheets and maps that include post-it notes and stickers to avoid losing the sticky pads when transporting for analysis. With participants’ permission, we will take photographs of group work interactions during Streams 3 and 4.

As summarised in Table 2, the data output of the design workshop will comprise a number of different data types (text, maps, drawings). Two researchers will independently code the design ideas, based on a pre-defined and piloted coding template, using all data sources available. The coding of design ideas will be cross-checked between the researchers and disagreement will be resolved involving a third researcher. Independently, the two researchers will select the ‘single best’ design idea from each group or individual work that will be considered for prototyping the e-prehabilitation system.
Data Management
Participant Confidentiality

Personal data recorded on all documentation will be regarded as confidential and participants will be allocated a unique study number by the research team for reporting purposes. Participant’s personal details will not be recorded on any interview transcripts or surveys; only their designated unique study number will be included on these documents. Any identifiable information captured during the interviews will be anonymised during the transcription process. The participant identification key, which links the unique study number with the participants’ name, will be stored in a separate location to participant's personal data.

Data Storage and Disposal
During the Study

All data will be stored in locked filing cabinets at the lead authors institution. Personal data will be stored in a separate filing cabinet from anonymised hard copy data. Focus groups/interviews will be digitally audiorecorded on a password protected recording device which stores the recordings in encrypted form. All transcripts will be anonymised. Anonymised transcripts will be stored within the secure shared network of the lead author’s institution on password protected computers. Only authorised members of the research team will have access to the network drive and locked filing cabinets.

After the Study has ended

Personal data will be stored 6-12 months after the study has ended to allow dissemination of research findings to study participants. Anonymous research data will be stored for 10 years after this study has ended. After 10 years, the data will undergo a review process by the University's Research Data Management and Sharing Team in which will be decided whether the data remain in long term storage or not and thus will be deleted.

Results

Recruitment and data collection for this study commenced in February 2018 and results will be submitted for peer-review upon completion of data collection and analysis. Project expected end date is early 2019.

Conclusions

The current protocol describes a collaborative co-design study designed to focus on the development of an e-Prehabilitation system of care for TYA with cancer and its future use within current service delivery models. The study design is appropriate for the development of an intervention, utilising multiple perspectives and data collection methods. The findings from this study will have important implications for informing the
future development of an e-Prehabilitation system of care to support TYA diagnosed with cancer.

Acknowledgements

LM and CH are Co-Principal Investigators for this study and provided the intellectual background to the study aims, study design, funding award and will lead the study throughout. LM, KM & CH wrote the manuscript and all approved the final version of the submitted manuscript.

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Conflicts of Interest

None.

References


