

BMJ Open 'Re-engage' pilot study protocol: a nurse-led eHealth intervention to re-engage, educate and empower childhood cancer survivors

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ABSTRACT

Introduction Many childhood cancer survivors are disengaged from cancer-related follow-up care despite being at high risk of treatment-related late effects. Innovative models of long-term follow-up (LTFU) care to manage ongoing treatment-related complications are needed. 'Re-engage' is a nurse-led eHealth intervention designed to improve survivors' health-related self-efficacy, targeted at survivors disengaged from follow-up. Re-engage aims to overcome survivor- and parent-reported barriers to care and ensure survivors receive the care most appropriate to their risk level.

Methods and analysis This study will recruit 30 Australian childhood cancer survivors who are not receiving any cancer-related care. Participation involves two online/telephone consultations with a survivorship nurse for medical assessment, a case review, risk stratification and creation of a care plan by a multidisciplinary team of specialists. We will assess the feasibility of implementing 'Re-engage' and its acceptability to participants and health professionals involved. The primary outcome will be survivors' health-related self-efficacy, measured at baseline and 1 and 6 months postintervention. Secondary outcomes will include the effect of 'Re-engage' on survivors' health behaviours and beliefs, engagement in healthcare, information needs and emotional well-being. We will also document the cost per patient to deliver 'Re-engage'. If Re-engage is acceptable, feasible and demonstrates early efficacy, it may have the potential to empower survivors in coordinating their complex care, improving survivors' long-term engagement and satisfaction with care. Ideally, it will be implemented into clinical practice to recall survivors lost to follow-up and reduce the ongoing burden of treatment for childhood cancer.

Ethics and dissemination The study protocol has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee (reference number: 16/366). The results will be disseminated in peer-reviewed journals and at scientific conferences. A lay summary will be published on the Behavioural Sciences Unit website.

Trial registration number ACTRN12618000194268.

Strengths and limitations of this study

- This is the first intervention of its kind, designed to recall survivors lost to care, while educating and empowering them to better ensure long-term cancer-focused engagement, which builds on a large mixed-methods study evaluating survivors' motivators and barriers to re-engaging in long-term follow-up care.
- As Re-engage is a distance-delivered intervention, participants will not be limited to those living in major cities and metropolitan areas, addressing a major barrier to accessing care: distance; however, this study may recruit a biased sample of disengaged survivors who are already interested in returning to follow-up care or may not represent non-English speaking or culturally diverse survivors.
- The intervention has been designed for translation into clinical practice and, depending on its success in the pilot, will have the potential to be implemented nationally with appropriate training.
- The success of the study will depend on the ability to trace long-term survivors, who may be disengaged for many years, in some cases using potentially out-of-date hospital data (addresses and contact details).
- While the pilot includes assessment of study outcomes in the short to medium term (1 and 6 months postintervention), the effect of the intervention in the long term will largely remain unknown.

INTRODUCTION

Many childhood cancer survivors are not receiving the follow-up care they need. Treatment for childhood malignancies can have serious and long-lasting impacts on survivors' physical and psychosocial health.^{1,2} Numerous guidelines have been devised worldwide which recommend regular and lifelong medical follow-up to reduce the burden of childhood cancer and its treatment.³⁻⁵ Despite the well-documented high risk of late arising



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complications in survivors, up to 77% do not access any regular cancer-specific follow-up care or adhere to their recommended follow-up programme.⁶ As a result, non-attendees fail to benefit from opportunities for health prevention and promotion, and ongoing surveillance for late effects, the risk of which increases as they age.⁷ The health outcomes of those who do not remain in care are largely unknown. However, the limited literature suggests improved physical and psychosocial outcomes among those who do engage in specialised long-term follow-up (LTFU) care, compared with non-attendees.⁸

This loss of up to 77% of survivors to follow-up suggests that there are numerous barriers to remaining engaged in follow-up. At a systems level, the healthcare of long-term survivors is characterised by highly varying practices globally and nationally. In Australia and New Zealand, insufficient funding, informal guidelines and inconsistent documentation limit coordinated care over time and across settings.⁹ These features suggest that current paediatric tertiary services are unsustainable for the long-term provision of care to the growing population of survivors. At the patient level, numerous barriers exist, including personal (reluctance to return to hospital) and logistical (too costly, long travel time) obstacles.¹⁰ In the greater than six decades on average that childhood cancer survivors live after completing treatment, they are a largely mobile group usually leaving parental care and moving from their local area to pursue their educational, career, travel and relationship aspirations. Up to 90% of young people aged under 35 without children have moved house in the last 5 years, and approximately 40% have moved three or more times, further adding to the challenge of delivering optimal and continuous follow-up care.¹¹

Optimal childhood cancer survivorship care is characterised by high-quality, safe, individualised and risk-based care that is economically feasible and accessible to patients.¹² Recently, the risk stratification of childhood cancer survivors has been proposed as necessary for the delivery of evidence-based survivorship care.¹³ Risk-based care involves stratifying survivors based on their cancer type and treatment(s) received to different levels of care ranging from low (supported self-management), medium (shared) to high (specialist-led) risk-based care.^{12 14} Once stratified, low- or medium-risk survivors are always able to re-enter specialist-led follow-up services if needed.

Addressing survivors' complex follow-up needs requires the involvement of numerous healthcare providers, including paediatric oncologists, adult oncologists, and other subspecialists and their general practitioner (GP). However, recent research suggests that GPs are dissatisfied with the timing and level of communication provided by the survivors' treating hospital, specifically information regarding patients' records and recommended screening schedules.¹⁵ Hospital-based care usually takes place in a 'vacuum', with the responsibility of the communication of complex details falling on patients themselves.¹⁶ This has led to the need for patients to become their own 'care integrator', advocating for the management of their

own care. This is a considerable medical and emotional challenge, especially for young survivors who may have complex care needs and little knowledge, given their early age at treatment.¹⁷

Maintaining engagement in follow-up, and the success of risk-stratified follow-up care, depends on survivors' health-related self-efficacy and ability to self-manage treatment-related illnesses. While the risks of cancer and its treatment may be relayed to parents of young patients with cancer during treatment and in early survivorship, this information does not always translate to survivors themselves.¹⁸ This may explain survivors' often low perceived impact of cancer and their low perceived risk of late effects,¹⁹ which are key barriers to remaining engaged in follow-up care. Educating survivors is critical, particularly young adult survivors as they begin assuming greater responsibility for their own care.²⁰ Research suggests that survivors' primary motivation for attending follow-up services is to gain reassurance that they are well, and that they are less likely to attend unless worried or symptomatic.²¹ Educating survivors about their treatment history and personal risk of late effects may help maintain their motivation and engagement in follow-up.

Innovative interventions may offer feasible solutions to meet some of the above-mentioned challenges. Web and telehealth measures can alleviate the disadvantages of living rurally and minimise travel costs, particularly problematic in countries such as Australia and New Zealand where specialised clinics are limited to major cities.⁹ National eHealth policy highlights the need to encourage better consumer self-management and control over personal outcomes by offering electronic access to health services and information.²² This highlights the importance of investigating novel, web-based interventions in this setting to provide safe, high-quality and more accessible alternatives for patients.

Our team have harnessed technology to develop a new distance-delivered, nurse-led programme called 'Re-engage'. Re-engage aims to recall survivors disengaged from cancer-related care, with the aim of empowering them with the knowledge to take responsibility for their ongoing care. Re-engage offers 'disengaged' survivors a novel and low-burden intervention to identify their risk factors and improve their physical and emotional health. It uses nurse-led support to facilitate access to care for disengaged survivors. Re-engage is a synchronous, that is, 'live', intervention with the option of being delivered online via WebEx—similar to Skype—or alternatively through Skype or by telephone if requested. This study protocol describes the pilot project, aimed at evaluating the acceptability and feasibility of Re-engage. If successful, this intervention has the potential to minimise the long-term burden of treatment for childhood cancer through education and improved engagement, and ultimately improve survivors' physical health and quality of life.

Objectives

The pilot aims to assess the feasibility and acceptability of delivering an evidence-based intervention to survivors of childhood cancer who are not engaged in any cancer-related care. The primary outcome of Re-engage will be the effect of the intervention on survivors' health-related self-efficacy—or their sense of control over their environment and behaviour—which can be an influencing factor on their motivation to attend clinic, and navigate the health-care system. The secondary aims of the pilot intervention include evaluating their health behaviours and beliefs, engagement in follow-up care, well-being (quality of life and distress) and cancer-related information needs.

We hypothesise that survivors' health-related self-efficacy will improve with the intervention, through provision of a personalised treatment summary, care plan and other resources, as well as discussion about their personal risks and recommended future surveillance. We also anticipate that Re-engage will improve participants' health behaviours, health beliefs and emotional well-being, and reduce their unmet information needs. We expect that Re-engage will be low cost to deliver, with the majority of costs allocated to researcher and staff time in delivering the intervention.

METHODS AND ANALYSIS

Study design

The development of this pilot protocol was guided by the Standard Protocol Items: the STROBE statement (Strengthening The Reporting of Observational studies in Epidemiology),²³ and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist and procedures.²⁴ For this study, we will use a single group, pretest and post-test design to evaluate the acceptability, feasibility and efficacy of the Re-engage programme in improving survivors' health-related self-efficacy.

Setting

This pilot study involves a distance-delivered intervention, from Sydney Children's Hospital, Australia. Researchers at the Kids Cancer Centre, Sydney Children's Hospital, will lead the project administration, with the support of senior clinicians, senior researchers and research fellows, the Head of the Centre, as well as the Head of Clinical Oncology at the Hospital. The intervention will be delivered by a trained and experienced Clinical Nurse Consultant (CNC) and overseen by the Director of the Cancer Survivorship Program at the Hospital.

As an alternative to independent or self-directed online resources, Re-engage is a 'live' distance-delivered intervention, with synchronous participation by survivors and the nurse delivering the intervention. Evidence indicates that synchronous online interventions have a stronger effect than asynchronous (ie, self-directed) interventions, allowing the building of facilitator-patient rapport and patients' questions to be addressed in real time.²⁵ We will offer participants the opportunity to complete

consultations via telephone, or using a videoconferencing computer software for online meetings called WebEx. WebEx is a secure platform with similar functions to Skype. The consultation will be free of cost to all participants. For those who do not have access to the required technology, including a stable internet connection and a device which supports WebEx, we will lend participants the appropriate apparatus. If preferred, the programme will be delivered by phone instead at participants' request.

Participants

We will recruit long-term survivors of childhood cancer, and parents of survivors <16 years, who are not currently receiving any cancer-related care.

Eligibility criteria

We will recruit individuals who satisfy the following criteria: (1) is over the age of 16 years; (2) was diagnosed with a form of cancer prior to 16 years of age; (3) was diagnosed at least 5 years prior to study participation; (4) was treated for cancer at one of the participating hospitals; (5) has completed active cancer treatment; (6) is alive and in remission at the time of study participation; and (7) has not received cancer-related LTFU care in the past 2 years.

Parents of survivors less than 16 years who meet the above criteria will also be eligible to participate.

Survivors aged 16–17 years old, or their parent(s), may participate in the study based on the maturity of the young adult and family preferences. The family, together with the CNC, will be able to choose who is most appropriate to participate, based on the maturity of the young person and the family's preferences. All participants must be sufficiently proficient in the English language to successfully complete each phase of the study.

The study exclusion criteria are as follows: (1) individuals with insufficient English language skills to complete the study questionnaires; (2) individuals who, in the clinical opinion of the nurse or oncologist, would be unsuitable for the study (eg, if a survivor/parent is currently experiencing severe mental health difficulties, or would be unable to complete the questionnaire due to cognitive limitations); (3) individuals not capable of providing fully informed consent due to psychiatric or cognitive difficulties.

Individuals who are not eligible for the programme will be offered face-to-face consultations at the clinic instead.

Recruitment

We will identify eligible survivors/parents through Sydney Children's Hospital electronic medical database records. We will search records using the following terms: name, address, phone number, diagnosis, date of diagnosis, date of birth, vital status (eg, 'alive') and date of last visit to clinic. The head of clinic (treating oncologist or CNC) at participating hospitals may also identify potentially eligible participants who no longer attend the LTFU clinic, from their clinic lists and obtain permission

from the survivor (or their parent if they are less than 18 years old) to be approached regarding the research.

We will invite eligible participants via phone or post and send a package containing a personalised invitation letter, information sheet and opt-in/opt-out card, and consent form (online supplementary file 1). Participants will be able to opt in by returning the consent form and opt-in card via the reply paid envelope. If the consent form and opt-in/opt-out card have not been received within 2 weeks after the initial call or contact, we will contact participants by phone twice before they are classified as lost to contact. No further follow-up will be made at this point. Non-participants may opt out by returning the opt-out card, or informing the principal investigator over the phone during a follow-up call. The voluntary nature of the study and the option to opt out will be clearly stated in the information sheet, and by the principal investigator who makes the follow-up call.

Re-engage intervention

Design

Figure 1 outlines the stages of participation in the Re-engage intervention. This project will offer 'disengaged' survivors who currently access no cancer follow-up care a novel, free and low-burden intervention to identify their risk factors and improve their physical and emotional health. The intervention will involve the following:

1. *An online/telehealth consultation with a CNC specialising in child cancer survivorship.* The consultation will be distance-delivered and will collect the survivor's medical/lifestyle history and assess risk factors (eg, barriers to care, family history). The collection of this data will be facilitated by the use of a triage tool (see online supplementary file 2), developed by a team of adult and paediatric specialists and trialled in both populations of cancer survivors. The triage tool follows a 'top-to-toe' approach and assesses all domains of

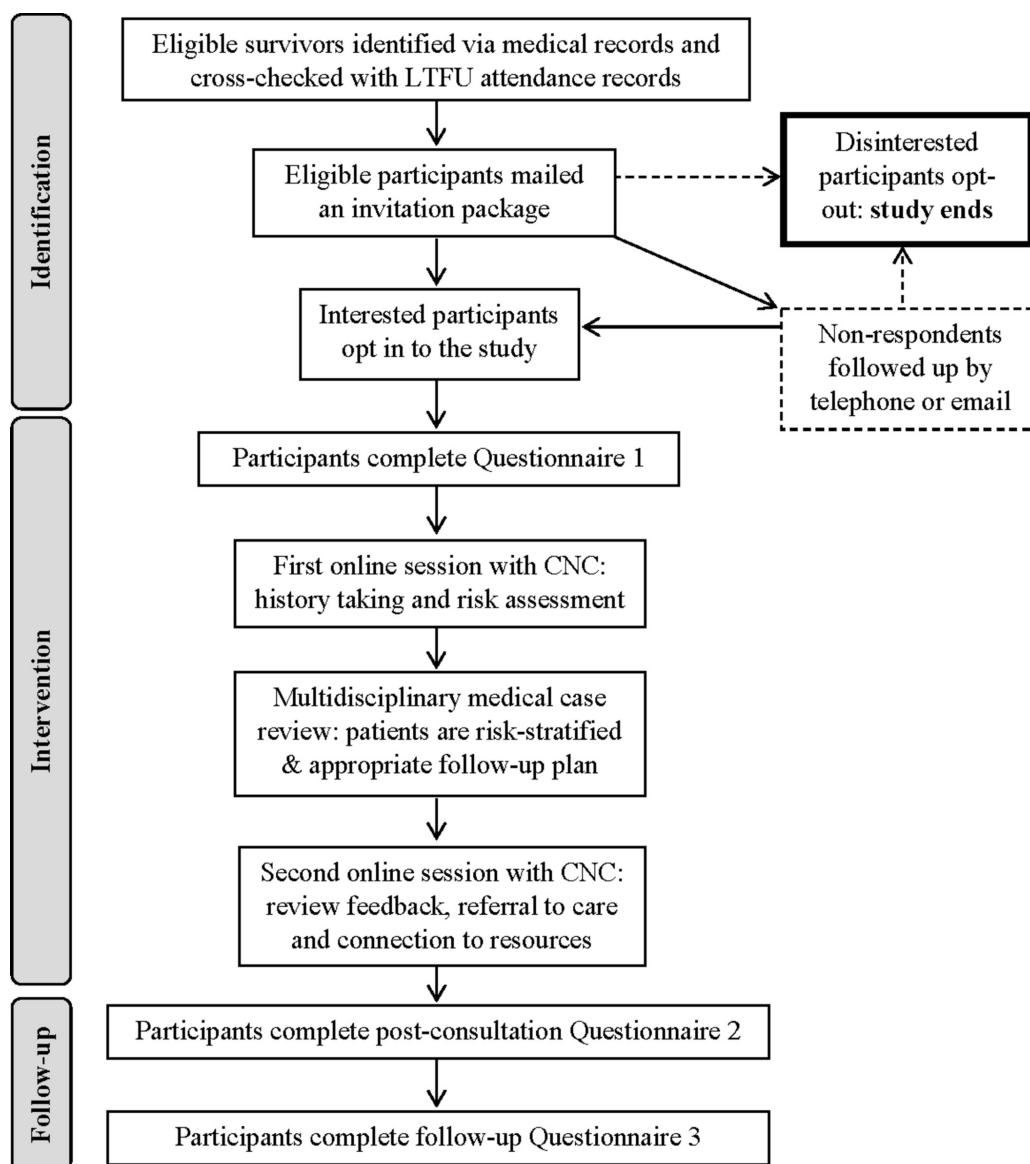


Figure 1 Stages of participation in the Re-engage pilot study. CNC, Clinical Nurse Consultant; LTFU, long-term follow-up.

Table 1 Potential risk-based referral pathways for survivors

Level of risk	Treatment type(s)	Examples of tumours	Other considerations	Frequency of follow-up	Recommended model of care
1 (low)	Treated with surgery alone or low-risk chemotherapy treatment.	Wilms' tumour stage I or II Langerhans cell histiocytosis (single-system disease) Germ cell tumours (treated with surgery alone).		Every 1–2 years	Supported self-management. Referred to primary services for primarily GP- led follow-up care.
2 (medium)	Treated with standard risk chemotherapy or low-dose cranial irradiation (<24 Gy).	Acute lymphoblastic leukaemia or lymphoma.	Considered to be at moderate risk of developing late effects, for example, anthracycline-induced cardiotoxicity, could be followed up by an appropriately trained individual, such as a late effects nurse specialist.	Every 1–2 years	Primarily shared care, with engagement from both the survivor's GP and oncologist.
3 (high)	Treated with radiotherapy (except low-dose cranial irradiation), bone marrow transplants or received intensive therapy.	Patients who have had a central nervous system tumour or stage 4 disease of any tumour type.	Require medically supervised follow-up within a multidisciplinary team of specialists.	Annually	Referred to specialist LTFU clinic, for primarily oncologist-led or survivorship specialist FU care.

GP, general practitioner; LTFU, long-term follow-up.

survivors' physical health (eg, cardiovascular, pulmonary, reproductive) and psychosocial well-being (eg, cognitive, vocational, psychiatric). The content of the consultations will mirror that of a face-to-face consultation at the LTFU clinic, and will generally last up to 60 min, depending on the individual.

2. *Medical case review by a multidisciplinary team (MDT)* including a paediatric and adult oncologist, nurse consultant, GP, psychologist and social worker. Using the information collected in the first consultation and triage tool, the MDT will determine the patient's level of risk and determine appropriate referral pathways for each patient as informed by evidence-based risk stratification. Survivors identified as high-risk will be referred to specialist LTFU clinics. Low-risk survivors will be referred to primary services. See [table 1](#) for potential referral pathways and risk criteria.
3. *A second distance-delivered consultation with the CNC*, including medical case review feedback, recommendations for referral to specialists and a review of foreseeable barriers to adherence. This step is critical, as it will ensure the programme is feasible and sustainable. Following the medical panel review, the second consultation will specifically focus on educating the survivor about their diagnosis, treatment and medical history, and potential future risks, recommended screening, and referral to specialists if necessary. The consultation is also used as a teachable moment regarding benefits of healthy lifestyle to prevent or ameliorate late effects. Survivors will be offered a summary of the MDT discussion, including suggestions for ongoing healthcare and appointment details for

a follow-up appointment (if appropriate or desired by the patient). The CNC will discuss shared care and the importance of a good GP, especially following transition from paediatric to adult services. At participants' request, the nurse will also send a letter with these details to the participant's GP and other health PCP added to their patient files on electronic hospital records for future reference, including a summary of the results of the triage tool, any referrals made as a result and the outcome of resulting visits. Finally, the CNC will introduce the survivor to an electronic survivorship care plan with access to additional resources (such as the Children's Oncology Group 'Health Links')²⁶ for further information and support to aid them with ongoing management of their survivorship care. This will improve survivors' understanding of late effects and further build on patient self-advocacy and self-care characteristics. This may also help survivors manage their health-related risks after cancer more independently and navigate the adult health-care system.

Data collection

We will invite participants to complete three questionnaires in total: one prior to the intervention and two questionnaires subsequent to the delivery of the intervention, at 1 and 6 months. We will offer participants the option to complete questionnaires online or on paper, according to their preference. Research suggests there is no difference in response rates in paper versus online questionnaires; however, offering alternative methods of participation, particularly for survey completion, may

encourage participation.²⁷ Figure 1 illustrates the stages of participation in the pilot study.

With the permission of participants, we will audio or video-record consultations for telephone and WebEx-delivered consultations. We may also obtain information from participants' medical records, for example, regarding their healthcare use to verify self-reported data about their visits to LTFU clinic, GP and other specialists recorded on database.

Outcomes

The primary outcome for the pilot is the acceptability and feasibility of the intervention. This will be assessed in the postconsultation questionnaire (questionnaire 2), with questions relating to the length, content and nature of the consultation, including open-ended questions. The primary aim for the pilot will be to improve survivors' self-reported health-related self-efficacy, assessed using a three-item General Self-Efficacy measure.²⁸ This measures survivors' belief in their sense of control over their environment and behaviour, specifically confidence in (1) asking doctors about concerns, (2) deciding when care is needed and making appointments and (3) getting the follow-up care needed. Response options are on a Likert-type scale ranging from (1) not confident, to (2) confident, to (3) very confident. These are summed to create a total score where a higher total score indicates greater self-efficacy. This measure has previously been used with young adult survivors of childhood cancer and demonstrates reasonable reliability (Cronbach's $\alpha=0.64$), good internal consistency (exceeding 0.77), test-retest reliability (exceeding 0.82), item convergence (exceeding 0.50). Items in the scale were also reasonably well distributed with no floor or ceiling effects observed.

We have also included five additional purpose-designed questions to capture self-efficacy and confidence in obtaining the healthcare survivors require. These questions assess confidence in (1) knowledge of cancer diagnosis, (2) knowledge of treatment-related information, (3) perceived risk of late effects, (4) ability to recognise the signs of cancer recurrence or a new cancer and (5) finding the right healthcare professionals. Response options are on a Likert-type scale ranging from (1) not confident, to (2) confident, to (3) very confident. These will be summed to create a total score where a higher total score will indicate greater self-efficacy. If the psychometric properties of this new measure (added to the original validated three-item General Self-efficacy measure) are good, we plan to use the overall new measure of Childhood Cancer Survivorship Self-Efficacy (eight items) as the primary outcome measure.

Re-engage is also designed to improve quality of life and decrease complication-related healthcare experiences and costs for paediatric cancer survivors by facilitating (1) standardised and enhanced follow-up care in the long term; (2) healthy lifestyle; and (3) self-monitoring of survivors' health status, focussing on early identification of late effects. We will therefore also assess survivors'

health-related quality of life, satisfaction with care, knowledge about late effects and health behaviours. We will also measure the cost consequence of the intervention, including the costs of delivering the intervention, and referrals and medical care received.

Measures

The study questionnaires use a variety of validated and purposely designed items. In some cases, despite an extensive search of the literature, validated measures were not available to specifically assess some of the domains this study aims to explore. In those cases, an expert panel including a behavioural scientist, psychologist, oncologist and specialist cancer nurse developed items which were then tested with two consumer representatives. We selected questionnaire measures based on their psychometric properties, brevity and ability to evaluate survivors' outcomes. Table 2 summarises the specific domains we will assess in questionnaires.

To evaluate the cost consequences of Re-engage, we will record details of the resources used to implement the intervention including time spent per patient, number of follow-up calls and time of each call, duration of consultations and MDTs, number of packages sent to participants and the associated printing and postage costs etc. We will consider each of these factors to produce a final cost per patient associated with the delivery of Re-engage.

Data analysis

We will conduct all statistical analyses using SPSS V.24.0.²⁹ We will classify results as statistically significant when $p<0.05$ (two-tailed). We will use descriptive statistics (proportions, means, SD) to report sample characteristics. We will use multilevel models (MIXED function) to evaluate the difference between baseline and postintervention. This analysis allows evaluation of longitudinal data in the case where missing data exist. We will investigate the psychometric properties of our additional self-efficacy questions in relation to the original three-item General Self Efficacy scale using correlations and factor analysis. Where factor analysis indicates an adequate single-factor structure, we will use multilevel models to evaluate the difference between baseline and postintervention on the overall measure of self-efficacy. We will use univariate analyses to identify various factors significantly associated with health-related self-efficacy, before conducting a multivariate regression analyses. We will summarise secondary outcomes, such as health-related self-efficacy, satisfaction with care, health behaviours, emotional well-being and need for information related to childhood cancer using descriptive statistics, correlations and t-tests.

Sample size

The target sample size for this project is 30 participants. This is based on sample size analyses assuming 80% power, an alpha of 0.05 and a minimally important improvement in self-efficacy scores (medium effect size of 0.5). For a pilot study, this sample size is considered sufficient for the

Table 2 Domains assessed in Re-engage questionnaires and the associated measures

Domain (assessed at all time points unless specified)	Description
Demographic items	<ul style="list-style-type: none"> ▶ Participants' age, postcode, sex, height and weight (for the calculation of BMI), marital status, education, religion, ethnic background, employment, health insurance status and income.
Clinical data	<ul style="list-style-type: none"> ▶ Primary cancer diagnosis and treatment(s) received. ▶ Relapse and recurrence status. ▶ Survivors' perceived risk of cancer recurrence and late effects (ranging from 1: 'Not at all' to 5: 'At high risk') and associated anxiety (ranging from 1: 'Not at all worried' to 5: 'A great deal worried'). ▶ An open-ended question on survivors' chronic health conditions or illnesses and their beliefs about the relation of these conditions to their primary cancer diagnosis. ▶ History of discussions about late effects with the survivors' doctor.
Healthcare use and satisfaction	<ul style="list-style-type: none"> ▶ General satisfaction with cancer-related care (ranging from 1: 'Poor' to 4: 'Excellent') (all surveys). ▶ History of consultations with various health professionals, including regularity of GP visits, and the reason for not seeing a regular GP. ▶ A 4-item cancer-related information needs scale, with an additional four items added (ranging from 1: 'Not needed' to 3: 'Needed and received enough').³⁴ Overall, the measure addresses the following information areas: cancer diagnosis, treatment(s) received, follow-up care needed, late effects risks, personal and familial cancer risks, fertility, Vitamin D and second cancer risks.
Adherence to recommended guidelines (postconsultation only, not assessed at baseline)	<ul style="list-style-type: none"> ▶ Participants will be invited in the postconsultation survey to report on the cancer-related recommendations they received, for example to visit a psychologist or to quit smoking. The Clinical Nurse Consultant will also document the physical and mental health recommendations made by the medical review board and during the second online consultation for each participating survivor. Survivor-listed recommendations will be compared with the Clinical Nurse Consultants recommendations, and assessed for compliance.
Health behaviours and lifestyle	<p>These are based on previously implemented questionnaires,³⁵ and selected as childhood cancer survivors are at increased risk of such problems.³⁶⁻³⁸ Their inclusion also enables comparison with Australian normative data, collected by the Australian Bureau of Statistics.</p> <ul style="list-style-type: none"> ▶ Sun protection behaviours (ranging from 1: 'Never' to 5 'Always'). ▶ History of sunburn and clinical skin examinations (ranging from 1: 'Never' to 5: 'five times or more'). ▶ Pap smear screenings (ranging from 1: 'Never' to 5: 'five times or more'). ▶ Eating habits including weekly intake of major food groups (ranging from 1: 'Not at all' to 4: 'Every day', exercise in hours over the last week). ▶ Alcohol consumption (ranging from 1: 'Never/given up' to 2: 'Current' to 3: 'Regularly'). ▶ Smoking (ranging from 1: 'Never' to 2: 'Ex-smoker', to 3: 'Current—less than 10 cigarettes per day', to 4: 'Current—more than 10 cigarettes per day') and recreational drug use and frequency (ranging from 1: 'Less often' to 4: 'Most days'). ▶ Dental hygiene and compliance with medication use (ranging from 1: 'Not at all' to 5: 'All the time').
Emotional well-being	<ul style="list-style-type: none"> ▶ Participant's belief on whether changes in their lifestyle can improve their physical health. ▶ A validated emotion thermometer,³² assessing participant's emotional well-being (depression, anxiety, anger and distress, ranging from 1: 'None' to 10: 'Extreme') and need for help (ranging from 1: 'Can manage by myself' to 10: 'Desperately need help') ▶ Participant's rating of their health 'today' (ranging from 0: 'The worst health I can imagine' to 100: 'The best health I can imagine').
Cost consequence and quality of life	<ul style="list-style-type: none"> ▶ A validated, six-item, quality of life measure, the EQ-5D-5L. These items assess mobility, self-care and ability to participate in usual activities (each ranging from 1: 'No problems' to 5: 'I am unable to'), as well as pain/discomfort, and anxiety/depression (each ranging from 1: 'None' to 5: 'Extreme'). Each item focuses on the participant's <i>current</i> feelings about these sub-scales. The EQ-5D-5L has good reliability and validity.³⁹ ▶ In the parent versions of the survey, the validated, nine-item Child Health Utility 9D measure will be used to assess children's health-related quality of life, outlining any problems with school work, sleep, daily routine (ranging from 1: 'No problems' to 5: 'Can't do') and ability to join activities (ranging from 1: 'Can join in with any' to 5: 'Can join in with no').⁴⁰ Parents will be asked to assess how worried, sad, tired, annoyed (ranging from 1: 'Doesn't feel' to 5 'Feels very') and in pain (ranging from 1: 'Doesn't have any pain' to 5: 'Has a lot of pain') their child is on that day.
Survey and consultation evaluation (questionnaire 2 only, immediately after the consultation)	<ul style="list-style-type: none"> ▶ Length of time taken to complete the survey (minutes) and satisfaction with length (ranging from 1: 'too long' to 2: 'just right', to 3: 'too short'). ▶ Length of time for consultations (minutes) and satisfaction with length (ranging from 1: 'too long' to 2: 'just right', to 3: 'too short'). ▶ Perceived benefit and burden of participation, ranging from 1: 'Not at all' to 5: 'Very much' and accompanied by an open-ended question (all surveys). ▶ Overall satisfaction with the programme, including help needed and received, services needed and received, online delivery and content (ranging from 1: 'Strongly disagree' to 5: 'Strongly agree') (postconsultation survey only). ▶ Open-ended questions regarding evaluation of the consultations and further suggestions for improvement (postconsultation survey only).

The survey to be sent to parents of younger survivors (aged <18 years) includes the same content (unless specified) and has been rephrased to read 'my child's...' wherever relevant.

BMI, body mass index; GP, general practitioner.

purpose of providing initial feedback data to improve the intervention, testing the planned recruitment method and assessing the acceptability/readability of the questionnaires from the perspective of participants.³⁰

Patient and public involvement

Re-engage is a purpose-designed programme, building on our team's large and ongoing mixed-methods study evaluating survivors' motivators and barriers to re-engaging

in LTFU care. The programme is designed to address patient-reported barriers to accessing follow-up care and encourage long-term engagement. The development of the Re-engage protocol was further informed by Scientific and Consumer Advisory Committees. The Scientific Advisory Committee consists of an MDT of oncology, fertility, allied health and other professionals independent of the study investigators and with an interest in paediatric oncology and survivorship care. The Consumer Advisory Committee consists of survivors of childhood cancer and parents of young survivors. Both committees will remain involved throughout the duration of the project to inform recruitment and the conduct of the study, through regular quarterly meetings.

ETHICS AND DISSEMINATION

Data management

All participant information and data will be stored securely on password-protected computers, including participant files, signed consent forms, questionnaires, correspondence, data and medical information collected, and other documents relating to the conduct of the study. Electronic data will be kept on computers at the Kids Cancer Centre, Sydney Children's Hospital, that are located on a secure server which is password protected and backed up daily. Any hard copy data that contains participant information will be filed in a lockable filing cabinet at the Kids Cancer Centre under the responsibility of the principal investigator, data custodian and other research staff. Documents containing participant identifiers will be kept separately to data collected, which will be identifiable by unique participants IDs instead. Only approved research team members can access the relevant file locations. Access to the database and passwords will be restricted to the principal investigator, study co-ordinator and study research assistants. We will not require a data monitoring committee as the proposed study poses minimal risk to participants.³¹ At the conclusion of the study, we will store study resources and participant information/data in a secure storage facility for 7 years (from publication) after the youngest child participant turns 18. Ethics applications for any future research activities during this time will be applied for as necessary. After this time, we will confidentially dispose of any reidentifiable information; paper-based documents will be shredded and all electronic files deleted.

Ethics

We will submit any amendments to the study, as necessary, for review by the Committee before their implementation. As required by South Eastern Sydney Local Health District Human Research Ethics Committee, we will report the study status annually. We will forward a final study notification at the completion of the study. We will remind participants in the information provided, and verbally, that participation is voluntary, and that anyone who wishes to revoke their consent can do so at any time before or during the study

without consequence to their care or relationship with hospital or research staff.

Adverse events

This study is of low risk, and we do not anticipate any serious adverse events to take place. However, our priority is to ensure participants' safety, and therefore the following risk-management measures will be implemented across the study. At recruitment, all participants will be informed both in writing (in the information sheet) and verbally of the steps they can take if they feel emotionally distressed during the intervention, including the contact details of the researchers. All participants will also be screened for distress when they complete the Emotion Thermometers tool in the questionnaires, which will occur preintervention and postintervention.³² Participants who report ≥ 8 out of 10 on either distress or need for help will be approached and offered additional support by the study psychologist. Appropriate referrals to local or hospital support will be provided. If participants are determined to be at risk of self-harm or suicide, the study psychologist will provide the contact details for numerous crisis services (eg, Lifeline 13 11 14 or the New South Wales Mental Health Line 1800 011 511) and will encourage participants to make an appointment with their GP for ongoing support. Finally, all adverse events will be recorded throughout the study and monitored at fortnightly team meetings. We will document progress-addressing adverse events until they are resolved.

End of study

We will end study recruitment when at least 30 survivors and parents are recruited and have attempted all three questionnaire assessments (baseline, and 1 and 6-month postintervention).

Study oversight

The Behavioural Sciences Unit research team at the Kids Cancer Centre, Sydney Children's Hospital, will be responsible for all components of the study. This includes the study design, project administration, ensuring ethical conduct, delivering the intervention, conducting statistical analysis and disseminating the results of the study.

Dissemination

We will ensure that all data collected from participants are deidentified and summarised (eg, reporting averages) in disseminating the findings. We will publish the results in high-quality peer-reviewed journals and at relevant scientific conferences. We will also publish a lay summary on the Behavioural Sciences Unit website (which can be accessed at <http://www.behaviouralsciencesunit.org/>).

Study status

We commenced study recruitment in March 2017. We expect recruitment to be completed in late 2018.

DISCUSSION

To our knowledge, no intervention of this kind has previously been trialled, and there is little consensus on how

best to provide this care.³³ Re-engage is a world-first distance-delivered, nurse-led intervention designed to recall survivors who are not receiving any cancer-related care, back into appropriate follow-up care matched to their personal level of risk. The intervention aims to improve survivors' health-related self-efficacy and to empower them through survivorship education to improve long-term engagement in follow-up care. The Re-engage intervention has been designed for translation into clinical practice. We anticipate that the careful design of the study, in light of existing research, will contribute to its success. For example, the study is designed to overcome commonly documented barriers to engaging in follow-up care, including time and financial burdens, accessibility and distance to specialised care, and eliminates survivor reluctance to return to their treating hospital due to negative memories of their cancer treatment during childhood. Methodologically, it is purposely designed to maximise participation rates to improve the reliability and validity of the findings, for example, by offering options for survey (paper vs online) and consultation (telephone vs WebEx) completion. Furthermore, it harnesses technology to deliver an intervention accessible to all survivors, regardless of their geographical location and incorporates eHealth measures to provide consumers with the information and resources they need to optimally self-manage their own care.

Data for the pilot study will be collected in the short to medium term (up to 6 months), which will shed some light on the efficacy of Re-engage longitudinally. If successful, Re-engage has the potential to educate and empower survivors to manage their own complex cancer-related care, and may reduce long-term disengagement from follow-up care. Depending on the success of the pilot study, Re-engage might be able to be implemented nationally in paediatric hospitals with appropriate training. Ultimately, we hope that Re-engage will also equip young survivors for a more positive survivorship experience in which they have the least burden of illness possible and are able to go on to live happy, healthy and productive adult lives.

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Competing interests None declared.

Patient consent Not required.

Ethics approval This study has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee (reference number: 16/366).

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