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Internet-based self-help for adolescents and young adults diagnosed with cancer during adolescence

Submission date
15/08/2016

Recruitment status
No longer recruiting

Registration date
15/08/2016

Overall study status
Completed

Last Edited
01/02/2017

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Adolescents that have been diagnosed with cancer often suffer from psychological distress, but not all have access to psychological support. There are currently few psychological treatments developed specifically to fit the needs of young survivors of cancer. An internet-based self-help programme for treating symptoms of anxiety and depression in young people diagnosed with cancer has been developed. This study is looking at whether the programme and the study methods that will be used evaluating the programme seem doable and acceptable to those receiving it.

Who can participate?
Young people aged between 15-25 who have been diagnosed with cancer during adolescence, have completed successful cancer treatment and have been identified as needing psychological support.

What does the study involve?
All participants are given access to a 12 week internet-based self-help programme. This programme includes internet-based cognitive behavioral therapy, psychoeducation (education to help people deal with mental health issues) and interactive support. Each participant works independently and is given support by a therapy via internet based messages or by telephone on a weekly basis, or more if requested.

What are the possible benefits and risks of participating?
By enrolling in this study participants can receive psychological support. There are no anticipated adverse effects of the self-help programme. Potential negative effects will however be explored within the study by via interviews with participants following use of the self-help programme. Working with one's mental health problems can involve some distress. However, the programme teach skills to cope with such distress and includes weekly and at-need contact with a therapist who receives supervision from a clinical psychologist. Participants in need of immediate/more intensive psychological treatment than can be offered within this study will be guided to appropriate healthcare.

Where is the study run from?
Uppsala University, in Uppsala (Sweden)

When is study starting and how long is it expected to run for
September 2016 to May 2017

Who is funding the study?
The Swedish Childhood Cancer Foundation

Who is the main contact?
1. Mrs Malin Ander (public)
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Study website
www.u-care.se

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
U-CARE: YoungCan, BCF PR2013-0039

Study information

Scientific Title
Internet-based self-help to reduce symptoms of anxiety and depression among adolescents and young adults diagnosed with cancer during adolescence (U-CARE: YoungCan): a feasibility trial

Acronym
U-CARE: YoungCan

Study objectives
The primary aim of the planned study is to investigate the feasibility of an internet-based self-help programme (YoungCan) primarily targeting symptoms of anxiety and depression among young people diagnosed with cancer during adolescence, and of the planned study procedures for a future controlled trial to evaluate the programme’s clinical efficacy and cost-effectiveness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board in Uppsala, Sweden, 13/07/2016, ref: 2016/210

Study design
Interventional non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Internet/virtual

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Cancer-related psychological distress

Interventions
All participants will receive an internet-based self-help programme consisting of internet-based cognitive behavioral therapy (ICBT), psychoeducation and interactive peer support. Participants will work independently with the programme over 12 weeks and receive weekly and at-need support from a therapist via messages within the internet platform via which the programme is delivered or by telephone.

Intervention Type
Behavioural

Primary outcome measure
1. Feasibility of recruitment and eligibility criteria will be evaluated by examining:
1.1. Number of people identified via the Swedish Childhood Cancer Registry, invited via telephone, invited via letter, assessed for eligibility
1.2. Percentages of people interested in participation, assessed for eligibility, meeting the inclusion criteria, and included, of the total number identified
1.3. Ambiguities regarding eligibility criteria
1.4. Reasons for ineligibility and for non-participation
2. Feasibility of data collection will be evaluated by examining:
2.1. Percentage of participants completing the baseline assessment and the assessments three months and six months post baseline
2.2. Numbers of missing items in outcomes
2.3. Types and number of potential uncertainties in diagnostic interviews
3. Attrition, evaluated by calculating dropout rates.
4. Resources needed to complete the study and the programme will be evaluated by examining:
4.1. Length of time for participants to work through the programme and complete questionnaires and interviews
4.2. Length of time for therapists and study personnel to deliver the programme and administer the study
5. Participants' adherence to programme, evaluated by examining number of activities in the programme
6. Therapists' adherence to programme, examined by analysing the content of online written therapist-participant communication.
7. Participants' acceptability of programme and data collection and exploration of mechanisms of impact, via semi-structured interviews

Self-report data will be collected either by telephone or online at one or more of the following time points: the eligibility interview, baseline assessment, assessment three months post baseline (post-assessment) and assessment six months post baseline (follow-up assessment).

Secondary outcome measures

The feasibility of using the following psychological and health economics measurements will be examined to assess whether or not to include them in a controlled study:
1. The PHQ-9 to measure symptoms of depression
2. The GAD-7 to measure anxiety symptoms
3. Body Image Scale Body to measure body image
4. PCL-C to measure posttraumatic stress symptoms
5. SIAS to measure Reactions to social interaction situations
6. The EuroQol EQ-5D to calculate quality-adjusted life years
7. TiC-P to measure aspects regarding use of healthcare services, employment, absence and sick leave

Data will be collected at baseline, and three and six months post baseline

Overall study start date
01/09/2016

Completion date
01/05/2017

Eligibility

Key inclusion criteria
Eligible participants will:
1. be aged 15-25 years at study start
2. have been diagnosed with cancer when aged 13-18 years
3. have been treated at a paediatric oncology unit in Sweden
4. have completed successful cancer treatment
5. be able to read and write text in Swedish
6. have access to e-mail, the internet, and a mobile telephone
7. report a need for psychological support

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
30

Key exclusion criteria
Potential participants will be excluded if they:
1. currently receive psychotherapy
2. display symptoms of severe depression, active suicidality, psychosis, bipolar disorder and/or alcohol and/or substance abuse in immediate need of treatment

Date of first enrolment

03/10/2016

Date of final enrolment
30/11/2016

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala University
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75122

Sponsor information

Organisation
Uppsala University

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75105

Sponsor type
University/education

Website
www.uu.se

ROR
https://ror.org/048a87296

Funder(s)

Funder type
Charity

Funder Name
The Swedish Childhood Cancer Foundation

Results and Publications

Publication and dissemination plan

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/01/2017		Yes	No