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Healthy Habits: Teenage and Young Adult Cancer Survivors

Submission date	**Recruitment status**	[X] Prospectively registered
24/07/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/08/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/04/2019	Cancer	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Teenage and young adult cancer survivors (TYACS) are at an increased risk of health problems as a result of their diagnosis and treatment. There is growing evidence a healthy lifestyle could reduce the impact a cancer has upon TYACS growth, development, and long-term health. However, there are no lifestyle interventions available in the UK to support TYACS to change their health behaviour after a cancer diagnosis. To meet this need a multi-format, habit- theory-based, health behaviour intervention containing behaviour change support tools and age-appropriate information on physical activity, diet, smoking, and alcohol consumption has been developed following three years of background research. The aim of this project is to conduct a two-arm pilot randomised controlled trial, exploring the feasibility of delivering the intervention to young people with cancer. The outcomes of this pilot trial will include i) acceptability of the main trial components (e.g. recruitment procedures, randomization procedures) to TYACS ii) TYACS engagement with the intervention materials and iii) the feasibility of collecting data high quality data on proposed trial outcomes measures (including measures of health behaviour and well-being) among TYACS post-cancer treatment.

Who can participate?
Teenage and young adults between 13 and 24 years of age who have had a cancer diagnosis at any point their lifetime.

What does the study involve?
The study will run for 12 weeks in total. Participants will be randomly allocated to either the intervention group or control group.
The intervention group will receive a booklet containing information and support on physical activity, diet, smoking, alcohol consumption and sun safety. This information will also be available online. The booklet and website will also contain information about making lifestyle changes and forming healthy habits. When they receive the booklet, participants in the intervention group receive a 'coaching' phone-call with a member of the research team to help explain the contents of the booklet and website. Both groups will be given a health and lifestyle questionnaire to complete and an accelerometer (a small device worn to capture physical

activity) to wear at the beginning (week 0), in the middle (week 6) and at the end (week 12) of the programme.
The control group will carry on receiving normal care and support as usual.

What are the possible benefits and risks of participating?
The results of this study will help is to design better lifestyle interventions for young people who have had a cancer diagnosis. A possible disadvantage is having to take time to fill in the questionnaires and wear the accelerometer. However the questionnaires have been designed to completed in approximately 10 minutes and the pedometer is a lightweight device which can be worn unnoticed clipped into the waistband of participants clothes.

Where is the study run from?
The Department of Behavioural Science and Health at University College London (UK)

When is the study starting and how long is it expected to run for?
January 2018 to December 2019

Who is funding the study?
RM Partners, Accountable Cancer Network (UK)

Who is the main contact?
Dr Gemma Pugh
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
Feasibility Pilot of a Health Behaviour Change Intervention for Teenage and Young Adult Cancer Survivors

Study objectives
The primary aim of this project is to assess the feasibility and acceptability of a health behaviour change intervention designed specifically for teenage and young adult cancer survivors (TYACS). Specifically this project will:
1. Determine the proportion and demographic characteristics of TYACS interested in participating in a health behaviour intervention and 2. Assess TYACS engagement with and adherence to the health behaviour change intervention materials. The feasibility trial will also allow insight into the viability of collecting high quality data on proposed trial outcomes measures (including measures of health behaviour and well-being) among TYACS post-cancer treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Teenage and young adult cancer

Interventions
A pilot randomized controlled trial (RCT) of a multi-format, theory-based, health behaviour intervention containing formal behaviour change support tools and age-appropriate information

on physical activity, diet, smoking, and alcohol consumption will be carried out. 20 participants will be randomised into the intervention group and 20 participants will be randomised into the control group. Participants in the intervention group will receive a leaflet, a website and a coaching telephone call containing the behaviour change information and support tools. Participants in the control group will receive usual care. The intervention will last 6 weeks (T1) with follow-up occurring at 12 weeks (T2). Participants will be asked to complete questionnaires at three time-points enrolment (T0), post-intervention (T1) and at follow-up (T2). Participants will also be asked to wear pedometers at each timepoint.

Intervention Type
Behavioural

Primary outcome measure
Intervention feasibility, assessed by recording participant recruitment (% uptake) and compliance (% drop out) with the intervention materials across the study period. At T1 (6 weeks after the start of the intervention), the intervention group will be asked to complete a questionnaire which will include questions on how useful the intervention contents were, reasons for not complying with the intervention, if participants engaged with the intervention tools (the action plans, goal setting logs, and healthy habits tips) if they set goals, things that prevented them from setting goals and their overall satisfaction with the intervention.

Secondary outcome measures
Change in health behaviour (physical activity, diet, smoking, alcohol consumption and sun safety) and well-being (HRQoL, sleep and fatigue). Data on health behaviour and well-being will be gathered using a health and lifestyle questionnaire containing valid measures of physical activity, diet, smoking, alcohol consumption and sun safety. Measures of psychosocial health (general quality of life, fatigue and sleep quality) will also be included in the questionnaire booklet. Participants will be invited to complete the questionnaire at T0 (baseline), T1 (6 weeks) and T2 (12 weeks). Physical activity will also be assessed using accelerometers at each timepoint.

Overall study start date
01/01/2018

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Aged between 13 and 24 years
2. Had a cancer diagnosis at any point within their lifetime
3. Stable disease
4. Not receiving any cancer treatment (excluding maintenance therapy)
5. Willing and able to provide written informed consent

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
40

Key exclusion criteria
N/A

Date of first enrolment
15/04/2019

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospital
235 Euston Rd
Fitzrovia
London
United Kingdom
NW1 2BU

Study participating centre
The Royal Marsden
Downs Rd
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Sponsor information

Organisation
UCL.UCLH Joint Research Office

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Sponsor type
Other

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Not defined

Funder Name
RM Partners and UCLH Cancer Collaborative

Results and Publications

Publication and dissemination plan
The results of the trial will be disseminated in relevant scientific conferences and meetings. The results will also be written up as paper publications and submitted to scientific, peer reviewed journals. This is planned for the end of 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
We will not be sharing participant level data as participants have not consented to this, and it would therefore be against data protection legislation. The data will be held at UCL on a data safehaven which uses a walled garden approach to secure data storage. We may share anonymised data after our primary data are published, but only if formally requested so we can control the nature of the analyses.

IPD sharing plan summary
Not expected to be made available