

# Healthy Habits: Teenage and Young Adult Cancer Survivors

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<b>Registration date</b> 20/08/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 24/04/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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**

Dr Gemma Pugh

**Contact details**

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## Additional identifiers

**Protocol serial number**

1

## 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

## Study type(s)

Other

## 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(s)

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.

### **Key secondary outcome(s)**

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.

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Sex**

All

### **Key exclusion criteria**

N/A

### **Date of first enrolment**

15/04/2019

### **Date of final enrolment**

31/07/2019

## **Locations**

### **Countries of recruitment**

United Kingdom

England

**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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SM2 5PT

## Sponsor information

**Organisation**  
UCL.UCLH Joint Research Office

**ROR**  
<https://ror.org/02jx3x895>

## Funder(s)

**Funder type**  
Not defined

**Funder Name**  
RM Partners and UCLH Cancer Collaborative

## Results and Publications

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