

PanCareFollowUp: Feasibility of a person-centred eHealth intervention for survivors of childhood, adolescence, and young adult cancer

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28694

Source

Nationaal Trial Register

Brief title

PCFU-Lifestyle Intervention

Health condition

Late effects in survivors of childhood cancer

Sponsors and support

Primary sponsor: Radboud University Medical Center, Nijmegen, The Netherlands

Source(s) of monetary or material Support: European Union, Horizon 2020

Intervention

Outcome measures

Primary outcome

The main study endpoint of the PanCareFollowUp Lifestyle intervention will be the percentage

of survivors that improve their lifestyle on the behaviour(s) that they desire to change, i.e. the goals that were set with the coach.

Secondary outcome

Secondary endpoints are changes in physical activity level, dietary intake, BMI, motivation level, self-reported empowerment and costs.

Secondary endpoints regarding feasibility outcomes evaluation of the PanCareFollowUp Lifestyle intervention will be determined through a number of indices assessed with questionnaires and with nurses' reports: (i) adherence CAYA survivors with intervention (compliance); (ii) acceptability (satisfaction with content, delivery and time load); (iii) practicality satisfaction mode of delivery); (iv) integration/implementation of the interventions (facilitators/barriers, success/failure goals).

The secondary endpoint regarding to cost benefit evaluation will be the cost benefit ratio of the PanCareFollowUp Lifestyle intervention.

Study description

Background summary

The presence of lifestyle risk factors, including physical inactivity and unhealthy dietary habits, increases the already heightened risk for chronic health conditions in childhood, adolescent and young adult (CAYA) cancer survivors. To reduce these risks, cancer organisations and guidelines recommend that cancer survivors participate in regular physical activity and eat a healthy diet. Recently, the PanCareSurFup consortium has developed evidence-based health promotion guidelines with specific recommendations on lifestyle behaviours most effective for survivors. However, these guidelines are more general and not-tailor made to the individual survivor. In order to make interventions fit into the daily lives of CAYA cancer survivors, lifestyle interventions should be delivered in a way with limited time and travel burden. Therefore, electronic health (eHealth) is an attractive mode of delivery for lifestyle interventions in this population.

Within the PanCareFollowUp project, a person-centred lifestyle intervention has been developed that aims to support CAYA survivors to adapt and sustain healthy lifestyle behaviours with the support of a coach.

Study objective

We hypothesize that the PCFU Lifestyle intervention is effective and feasible.

Study design

The study will consist of three measurement points for CAYA survivors; prior to the intake session (T0), after completion of the last session (T1) and half a year after the last session (T2). At each of the measurement points, the CAYA survivors are asked to fill in an online questionnaire and to wear an accelerometer for 7 consecutive days (24 h/day).

Intervention

The PanCareFollowUp Lifestyle intervention consists of an intake session and 3 to 6 screen-to-screen video-coaching sessions via a secure internet connection within a period of 3-4 months. Four months after the last session, a reflection session will be planned to reflect with the survivor on the last period and to investigate the sustainability of the intervention's goal. The amount and duration of the sessions are personalised to the survivor's preferences. The average duration of a session will be approximately 30-45 minutes. Planning of the sessions will also be conducted according to the preferences of the survivors and the sessions will be held in the survivors' home situations.

Contacts

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Eligibility criteria

Inclusion criteria

To be eligible for the PanCareFollowUp Lifestyle intervention, a survivor must:

1. be a survivor of childhood, adolescent or young-adult cancer survivor (diagnosed with any type of cancer under the age of 25);
2. be at least 5 years from end of treatment;
3. be cancer free;
4. be aged 16-55 years at time of intervention;
5. have at least one of the following unhealthy lifestyle behaviours defined as;

- not meeting the World Health Organization norm for physical activity (exercising at least 150 minutes of moderate-intensity aerobic physical activity throughout the week or do at least 75 minutes of vigorous-intensity aerobic physical activity throughout the week or an equivalent combination of moderate- and vigorous-intensity activity);
 - unhealthy dietary intake manifested by overweight ($\text{BMI} \geq 25 \text{ kg/m}^2$).
6. be motivated to change their unhealthy lifestyle behaviour(s).

Exclusion criteria

1. diagnosed with Down syndrome;
2. diagnosed with cognitive disorders;
3. has depressive symptoms (H.A.D.S. total score ≥ 11 and anxiety and depression subscore ≥ 8);
4. currently receiving treatment for secondary malignancies;
5. diagnosed with endocrine disorders (with the exception of Type II Diabetes and/or hyperthyroid for which the survivor is treated) or other conditions that limit the survivor's ability to engage in health promotion discussions and activities
6. Has underweight ($\text{BMI} \leq 20 \text{ kg/m}^2$), as survivors with underweight need a different and multidisciplinary intervention.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2020
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date: 29-09-2020

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8932
Other	European Union : 824982

Study results

Summary results

Results of the lifestyle intervention study will be published in peer-reviewed journals.