ISRCTN93856392 https://doi.org/10.1186/ISRCTN93856392

A study regarding rest, recreation and spending time outdoors as support for health and well-being of young cancer survivors

Submission date
23/01/2024

Recruitment status
Recruiting

Registration date
25/01/2024

Overall study status
Ongoing

Last Edited
09/01/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Childhood, adolescent and young adult (AYA) cancer survivors suffer from chronic health issues such as psychological distress, pain, fatigue and increased risk for secondary cancers. Given the multitude of these issues among them and given that few interventions have the potential to impact multiple factors, it is critical to investigate promising health promotion interventions. Exposure to nature may be an effective health promotion strategy. However, randomized controlled studies (RCTs), in which participants are randomly assigned to different groups to assess the effects of an intervention or treatment by comparing outcomes between the groups, on the effectiveness and safety of nature/wilderness for cancer survivors are lacking. A first pilot RCT (https://www.clinicaltrials.gov/study/NCT04761042) was performed which showed that it is feasible and safe to conduct such a study with childhood and AYA cancer survivors. A full-scale RCT is now proposed to investigate the effectiveness and safety of a wilderness program on the mental and physical health of young cancer survivors. Research questions are whether a wilderness program improves their psychological well-being, quality of life, nature connectedness, and physical fitness compared to a control activity.

Who can participate?
Childhood and AYAs cancer survivors aged 16-39 years old who have been diagnosed with any type of cancer during childhood, adolescence, or young adulthood.

What does the study involve?
Eligible participants will be randomly assigned to a wilderness or a holiday program. The wilderness program is an eight-day intervention including a six-day expedition. This is followed three months later by a four-day base camp. Activities include hiking, backpacking, kayaking, rock climbing, mindfulness, and bush-crafting. The comparison (control) group is an 8-day holiday program at a Spa-hotel followed by a 4-day holiday program at the same hotel after 3 months.

What are the possible benefits and risks of participating?
Possible benefits of participating in the study are that participants have a chance to meet, be

and talk with other young cancer survivors and that they may feel good during participation in the program because they are physically active and in nature or are relaxing at a Spa Hotel. As far as is known, participating in the study does not pose any extra risks for participants except for what can normally be expected when you are out in nature such as a forest and mountain. There is a possible risk of training soreness, chafing, sprain, sun exposure and other minor complaints. The outdoor team will assist in preventing any side effects where possible.

Where is the study run from?
This study will be performed in Sweden and Norway by a multidisciplinary team of researchers, wilderness experts and clinicians, in close collaboration with patient, public and stakeholder involvement.

When is the study starting and how long is it expected to run for?
March 2023 to December 2027

Who is funding the study?
Ekagastiftelsen and Sjöbergstiftelsen, Sweden
Stiftelsen DAM, Norway

Who is the main contact?
1. Professor Miek Jong, miek.jong@uit.no
2. Associate-professor Mats Jong, mats.jong@miun.se

Study website
https://www.miun.se/waya-anmalan

Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Nil known

Study information

Scientific Title
A randomized controlled multi-centre trial investigating the effectiveness and safety of a wilderness program on the mental and physical well-being of childhood, adolescent and young adult cancer survivors

Acronym
WAYA-2

Study objectives
A previous pilot RCT (Wilderness Program for Adolescent and Young Adult Cancer Survivors (WAYA); NCT04761042) demonstrated that the WAYA wilderness program was well-accepted by young cancer survivors. Furthermore, nature connectedness significantly increased over time among young cancer survivors in the wilderness program compared to those in a holiday program. Previous studies have reported on positive associations between nature connectedness and mental well-being and demonstrated that individuals with increased nature connectedness have a greater sense of psychological well-being. Therefore, it is hypothesized that the WAYA wilderness program is a highly appreciated health promotion intervention that substantially benefits the mental and physical well-being of adolescent and young adult cancer survivors.

It was also demonstrated in the pilot RCT that the occurrence of adverse effects was similar between the WAYA and holiday programs and that no serious adverse effects were reported. Therefore, it is hypothesized that the WAYA program is equally safe for childhood and AYA cancer survivors as a holiday program in a full-scale RCT.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 27/09/2023, Ethics Review Authority (Etikprövningsmyndigheten) (Box 2110, Uppsala, 75002, Sweden; +46 104750800; registrator@etikprovning.se), ref: Dnr 2023-05247-01

2. Approved 21/05/2024, Ethics Review Authority (Regional komité for medisinsk og helsefaglig forskningsetikk (REK) sør-øst B) (Postbox 1130 Blindern, Oslo, 0318, Norway; +47 22845501; rek-sorost@medisin.uio.no), ref: 694114

Study design
Multi-center mixed-methods randomized controlled trial with a two-armed parallel design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Fitness/sport facility, Medical and other records

Study type(s)
Quality of life, Safety

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
Mental and physical well-being of childhood, adolescent and young adult cancer survivors

Interventions
This is a multi-center mixed-method randomized controlled trial with a two-armed parallel design using individual randomization in which participants are allocated to a wilderness program or a holiday program. Participants will be randomized equally (1:1) to the wilderness or holiday program according to a randomization list as generated by a Random Allocation Software Program using a random block size of two to guarantee a balanced allocation. Randomization and assignment of participants to the two programs will be performed by a research member who is not involved in participant recruitment and intake so that allocation concealment is maintained. Participants will be stratified according to two age groups (16-30, 31-39 years), binary gender categorizations (male/female), and cancer survivorship (childhood cancer: age 0-14 years versus AYA cancer: age 15-39 years) to achieve equal distribution among the two programs. Per stratification and country (Norway, Sweden), separate randomization lists will be generated. Participants will be informed that the study compares two possible effective health promotion programs: a wilderness and a holiday program. To reduce expectation bias, it will not be revealed to participants whether one program is hypothesized to be better than the other (single-blinded). Quantitative analysis will be performed by researchers who are blind to program allocation.

Wilderness program:
The wilderness program intervention consists of three intervention parts: 1) An eight-day intervention that includes two days for traveling and physical testing and a six-day wilderness expedition; 2) A three-month in-between period where participants are contacted once every month online to coach them to engage in their outdoor activities; 3) A four-day intervention including a two-day base camp program. Both the expedition and basecamp program will take place in natural settings. The group size will be 10-12 participants. Activities in the program included, among others, hiking, sea-kayaking, backpacking, rock climbing, camping, mapping /compass/orienting, trail cooking, safety skills training, equipment planning, foraging, fishing, bush-craft skills and leave no trace. The program also includes (nature) reflective practices such as mindfulness, meditation, and forest bathing.

Holiday program:
The holiday program (control group) will be an eight-day summer holiday program at a Spa Hotel, including two days for traveling and physical testing, followed by a four-day stay at the same hotel three months later. During the three-month in-between period, participants will be contacted once every month to ask how they are doing. The rationale for choosing this holiday program is to control for factors typically present in a wilderness intervention that may benefit AYA cancer survivors: 1. Attention from facilitators, 2. Group support from other AYA cancer survivors, and 3. Getting out of their regular environment. The content of the holiday program includes the following activities: Spa facilities, museum visits, watching TV/movies, playing games/gaming, shopping, and fine dining. Participants will engage in organized group activities, but this does not include any nature activities. The group size is 10-12 participants.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 15/04/2024:
1. Psychological well-being measured using the Psychological Well-being Scale (PWS) at baseline, directly after the first 8-day intervention, at 3 months and 1 year after the first intervention
2. Nature connectedness measured using the Nature Relatedness Scale (NRS) at baseline, directly after the first 8-day intervention, at 3 months and 1 year after the first intervention.

Previous primary outcome measures:
1. Psychological well-being measured using the Psychological Well-being Scale (PWS) at baseline, directly after the first 8-day intervention, at 3 months and 1 year after the first intervention
2. Quality of life of childhood and adolescent and young adult (AYA) cancer survivors measured using the Minneapolis Manchester Quality of Life instrument (MMQL) at baseline, directly after the first 8-day intervention, at 3 months and 1 year after the first intervention
3. Nature connectedness measured using the Nature Relatedness Scale (NRS) at baseline, directly after the first 8-day intervention, at 3 months and 1 year after the first intervention.

Secondary outcome measures
Current secondary outcome measures as of 15/04/2024:
1. Quality of life of childhood and adolescent and young adult (AYA) cancer survivors measured using the Minneapolis Manchester Quality of Life instrument (MMQL) at baseline, directly after the first 8-day intervention, at 3 months and 1 year after the first intervention
And copy this under the section as secondary outcome measure.
2. Changes in physical activity measured using an ActiGraph at baseline, directly after the first 8-day intervention, at 3 months and 1 year after the first intervention

3. Changes in estimated maximal oxygen consumption (VO2max; ml/kg/min) measured using the Ekblom Bak cycle ergometer test at baseline and at 3 months after the first intervention
4. Blood Pressure and Heart Rate (BP/HR) measured using an electronic monitor in a seated position after a 5-min rest at baseline and at 3 months after the first intervention.
5. Body mass index (BMI) (kg/m2) will be calculated from body mass measured non-fasted and in light clothing to the nearest 0.1 kg using a digital scale and height measured to the nearest 1 mm using a stadiometer at baseline and at 3 months after the first intervention.
6. Occurrence of (serious) adverse effects during both programs measured using the number, seriousness, intensity, and types of adverse effects that are evaluated to be certain, probable /likely, or possibly related to the study programs in study records after the first 8-day intervention, at 1, 2 and 3 months and 1 year after the first intervention.

Previous secondary outcome measures:
1. Changes in physical activity measured using an ActiGraph at baseline, directly after the first 8-day intervention, at 3 months and 1 year after the first intervention
2. Changes in estimated maximal oxygen consumption (VO2max; ml/kg/min) measured using the Ekblom Bak cycle ergometer test at baseline and at 3 months after the first intervention
3. Blood Pressure and Heart Rate (BP/HR) measured using an electronic monitor in a seated position after a 5-min rest at baseline and at 3 months after the first intervention.
4. Body mass index (BMI) (kg/m2) will be calculated from body mass measured non-fasted and in light clothing to the nearest 0.1 kg using a digital scale and height measured to the nearest 1 mm using a stadiometer at baseline and at 3 months after the first intervention.
5. Occurrence of (serious) adverse effects during both programs measured using the number, seriousness, intensity, and types of adverse effects that are evaluated to be certain, probable /likely, or possibly related to the study programs in study records after the first 8-day intervention, at 1, 2 and 3 months and 1 year after the first intervention.

Overall study start date
01/03/2023

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/04/2024:
1. Adolescents and young adults (AYA) aged 16-39 years who have been diagnosed with any type of cancer during childhood, adolescence, or young adulthood
2. To be able to walk 2 km a day (walking aids or assistance from another person is permitted)
3. Participants with various disabilities and medical conditions can be included. This includes mobility impairments, amputations, vision and hearing impairments, balance problems and special treatment or dietary needs.
4. Prior experience with outdoor activities is not required for participation

Previous inclusion criteria:
1. Adolescents and young adults (AYA) aged 16-39 years who have been diagnosed with any type of cancer during childhood, adolescence, or young adulthood
2. To be able to walk 2 km without pausing (walking aids or assistance from another person is permitted)
3. Participants with various disabilities and medical conditions can be included. This includes

mobility impairments, amputations, vision and hearing impairments, balance problems and special treatment or dietary needs.
4. Prior experience with outdoor activities is not required for participation

Participant type(s)
Patient

Age group
Mixed

Lower age limit
16 Years

Upper age limit
39 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Active cancer treatment for which participation in the study can involve unwanted risks as evaluated by the treating physician/oncologist
2. A medical condition that prevents safe travel to, or participation in the program
3. Not willing to be randomly assigned
4. Previous participation in the WAYA 1 study

Date of first enrolment
19/02/2024

Date of final enrolment
01/06/2026

Locations

Countries of recruitment
Norway

Sweden

Study participating centre
Mid Sweden University
Holmgatan 10
SUNDSVALL
Sweden
851 70

Study participating centre
The University of Agder
Gimlemoen 25
Kristiansand
Norway
4630

Sponsor information

Organisation
Mid Sweden University

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Sponsor type
University/education

Website
https://www.miun.se/

ROR
https://ror.org/019k1pd13

Funder(s)

Funder type
Charity

Funder Name
Ekhagastiftelsen

Alternative Name(s)
Ekhaga foundation

Funding Body Type

Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Funder Name
Sjöbergstiftelsen

Alternative Name(s)
Sjöberg Foundation, The Sjöberg Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Funder Name
Stiftelsen DAM

Results and Publications

Publication and dissemination plan
We aim for a wide communication and dissemination of research results through close collaboration with national and international research partners and the wider communities in the respective countries. First and for all, results of the study will be presented to the participants. It is aimed to publish at least three scientific (peer-reviewed) articles and to present the results at (scientific) national and international conferences. Popular articles with study results will be disseminated in the form of interviews and chronicles. News items will also be spread via social media (Facebook, Twitter), websites and newsletter of collaborating partners and organizations and of the funding bodies.

Intention to publish date
01/06/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Mats Jong: mats.jong@miun.se.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/05/2024	22/05/2024	Yes	No