

BMJ Open Protocol of a mixed-method randomised controlled pilot study evaluating a wilderness programme for adolescent and young adult cancer survivors: the WAYA study

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ABSTRACT

Introduction The majority of childhood, adolescent and young adult (AYA) cancer survivors suffer from long-term and late effects such as fatigue, psychological distress or comorbid diseases. Effective health promotion strategies are needed to support the health of this vulnerable group. This protocol provides a methodological description of a study that aims to examine the feasibility and safety of performing a randomised clinical trial (RCT) on a wilderness programme that is developed to support the health of AYA cancer survivors.

Methods and analysis The pilot RCT study has a mixed-method design, including quantitative and qualitative evaluations. Participants are AYAs, aged 16–39 years, that have been diagnosed with cancer during childhood, adolescence or young adulthood. A total of 40 participants will be randomly assigned to a wilderness programme (n=20) or a holiday programme (n=20). Both arms include participation in an 8-day summer programme, followed by a 4-day programme 3 months later. Primary outcomes are feasibility and safety parameters such as time to recruitment, willingness to be randomised, programme adherence and adverse effects. Secondary outcomes include self-reported health such as self-esteem, quality of life, self-efficacy and lived experiences. Descriptive statistics will be used to analyse outcomes and explore indications of differences between the programmes. Interviews are analysed by directed content analysis and hermeneutic phenomenology. A convergent parallel mixed-method analysis design will be applied to integrate quantitative and qualitative data. Results of this feasibility study will inform the preparation for a larger RCT with AYA cancer survivors.

Ethics and dissemination The study protocol is approved by the Swedish Ethical Review Authority (reference: 2020-00239). This study will be performed between January 2021 and December 2023. Results will be published in international peer-reviewed journals, presented at conferences and disseminated to participants, cancer societies, healthcare professionals and outdoor instructors.

Trial registration number NCT04761042.

Strengths and limitations of this study

- ⇒ To the best of our knowledge, this mixed-methods study includes the first randomised controlled trial (RCT) that will be carried out on a wilderness programme versus a control holiday programme for adolescent and young adult (AYA) cancer survivors.
- ⇒ Both quantitative and qualitative analyses will be applied to thoroughly assess the feasibility and safety of the study.
- ⇒ This study will provide valuable insights on the challenges and risks of a wilderness programme in this medically vulnerable population and will inform the preparation for a larger RCT.
- ⇒ The acceptability of a potential third arm in the RCT, consisting of no programme participation or a wait-list control, will not be investigated.
- ⇒ An obvious limitation of the feasibility design is that no conclusions can be drawn on the effectiveness of a wilderness programme for the health of AYA cancer survivors.

In loving memory of our highly respected research team member Leiv Einar Gabrielsen (06.04.1966 – 31.03.2021).

‘Contemplating the lace-like fabric of streams outspread over the mountains, we are reminded that everything is flowing - going somewhere...’ (John Muir, *My First Summer in the Sierra*, Houghton Mifflin, 1911)

INTRODUCTION

Due to advances in diagnoses and multimodal cancer treatments, cancer survival of children, adolescents and young adults has substantially increased in the last 50 years. In high-income countries, 5-year survival rates for childhood cancer were approximately



56% during the 1970s and currently exceed 80%.^{1 2} Five-year relative survival of adolescent and young adult (AYA) cancer survivors has also increased to >80% in the past decades.^{3 4} Unfortunately, surviving from cancer often comes with adverse health effects. Up to 70% of childhood and AYA cancer survivors suffer from long-term and late effects either from cancer itself or from cancer-related treatment.^{5 6} Fatigue, pain and fertility problems are examples of long-term treatment-related adverse effects that can last for years after the treatment has ended.⁷⁻⁹ Childhood and AYA cancer survivors also experience greater psychological distress compared with their siblings or those without cancer.¹⁰⁻¹² This can be very well understood from the perspective that they are diagnosed with cancer in a key period of their physical, mental/emotional and social development. Coping with a large variety of stressors, such as trying to keep up with school, friends, family, the start of an academic or working career, building their own family and managing their economic status, is reported to be particularly challenging for childhood and AYA cancer survivors.¹³⁻¹⁵ Late effects can appear many years after cancer treatment, and may include comorbidities such as cardiovascular disease, endocrine and neurological disorders, diabetes, osteoporosis and the development of secondary cancers.¹⁰ The consequences of not addressing these long-term and late effects of childhood and AYA cancer survivors extend far into adulthood, impairing their health and limiting opportunities to live fulfilling lives as adults. Therefore, it is critical that effective health promotion strategies are explored tailored to their specific needs.

In the last decade, there has been an increased interest in interacting with nature as an effective health promotion strategy.^{16 17} Two reviews have previously reported that nature-based programmes may be of benefit and support to the health of cancer survivors.^{18 19} These positive health effects were reported for a wide range of programme activities, including gardening programmes, therapeutic landscapes, dragon boat racing and other outdoor programmes.^{18 19} The majority of nature-based programmes that specifically address the needs of childhood and AYA cancer survivors can be categorised under the umbrella term of adventure programmes.²⁰ A previous observational study involving a 6-day outdoor adventure programme demonstrated improved body image, self-compassion, self-esteem and decreased depression and alienation in young adult cancer survivors compared with a wait-list control.²¹ Another observational study reported that a 1-week outdoor adventure camp significantly enhanced physical activity and reduced sedentary behaviour of young adult cancer survivors compared with wait-list controls up to 3 months after camp.²² A 1-week adventure programme has also been shown to significantly improve self-efficacy at post-trip and 1 month later when compared with pretrip.²³ These previously published studies did not apply randomised designs and can therefore not exclude the possibility that the observed beneficial health effects in young adult cancer

survivors are caused by factors other than the adventure programme. A recently published systematic scoping review that mapped the concept, content and outcome of wilderness programmes for childhood cancer survivors concluded that high-quality studies with appropriate comparison groups are needed to further build the evidence base for these programmes.²⁰ Therefore, the present study is initiated to examine the feasibility of performing a randomised clinical trial (RCT) of a wilderness programme that is specifically developed to benefit the health of AYAs that are diagnosed with cancer during childhood, adolescence or young adulthood. A holiday programme is chosen as a comparison to control for other possible effective factors such as attention, group support and getting out of their regular environment. This study design allows for the testing of active aspects of wilderness programmes including physical activity, physical challenges, experiential activities, being in nature and other reflective practices. Results of this feasibility study will inform the preparation for a larger RCT with AYA cancer survivors.

The primary objectives of the study are:

To investigate the feasibility and safety of conducting an RCT on a wilderness programme versus a holiday programme in AYA cancer survivors.

The secondary objectives are:

To explore the impact of a wilderness programme on the health of AYA cancer survivors, and to describe participants' experiences of the wilderness and the holiday programme.

METHODS AND ANALYSIS

Study guidance and design

This protocol is written in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 guidance for protocols of clinical trials and the SPIRIT 33-item checklist.²⁴ Results of this study will be reported according to the Consolidated Standards of Reporting Trials and 25-item checklist and flow diagram.²⁵ The study has a mixed-method design, including a pilot RCT and quantitative and qualitative evaluation.

Participants and eligibility criteria

Eligibility criteria for participation in the study are listed in [table 1](#). Participants are AYAs, aged 16–39 years that have been diagnosed with cancer during childhood, adolescence or young adulthood. Participants with various medical conditions, including mobility impairments, amputations, vision impairments and special treatment or dietary needs can be included. Prior experience with outdoor activities is not required for participation.

Intervention group: wilderness programme

The wilderness programme for adolescent and young adults (WAYA) cancer survivors is developed based on the results of a previous study.²⁰ It aims to increase

Table 1 Eligibility criteria

| Inclusion criteria | Exclusion criteria |
|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Any sex | Active cancer treatment for which participation in the study can involve unwanted risks (as evaluated by the treating physician/oncologist) |
| Aged 16–39 | Medical condition that prevents safe travel to, or participation in the programme |
| Diagnosed with any type of cancer at some point in their life | Inadequate understanding of the Swedish language |
| Ability to walk 2 km without pausing (walking aids permitted) | Cannot be reached by telephone |

physical activity, self-esteem, self-efficacy, self-care, personal growth and supportive relationships of participants. Nature has a central role in the WAYA, grounded in the ecosophy theory of Naess,²⁶ wherein the health and well-being of the natural world is intrinsically interwoven in a bi-directional fashion with the health and well-being of humans. The content of the WAYA is divided over five activity categories (table 2). Participants will first join in an 8-day expedition during summer, followed by a 4-day base-camp programme in the fall, both in nature areas around the High Coast of Sweden.²⁷ In the 3-month period between the expedition and base camp, participants are coached to develop their own practice of being physically active outdoors and connecting with nature. Each study arm aims to enrol two groups of 10 participants and each group will be supervised in a facilitator/participant ratio of at least 1:2, depending on the specific needs of participants.

Table 2 Content of the wilderness programme for adolescent and young adults

| Category | Activities |
|---------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Physical movement | Hiking, backpacking |
| 2. Challenge/risk activities | Sea-kayaking, rock climbing |
| 3. Experiential activities | Camping, outdoor skills, mapping/compass/orienting, trail cooking, safety skills training, equipment planning, foraging, ‘Allemansrätten’, leave no trace |
| 4. (Nature) reflective practice | Mindfulness, meditation, forest bathing, journaling |
| 5. Free time/leisure activities | Singing, swim/bath, fishing, campfire, reading, taking pictures, phone, playing games |

*The Swedish Right of Public Access allows people the right to walk, cycle, ride, ski and camp on any land with the exception of private gardens, near a dwelling house or land under cultivation.

Control group: holiday programme

Participants in the control group will join an 8-day summer holiday programme at a Spa Hotel in the County Västernorrland, Sweden, followed by a 4-day stay at the same hotel 3 months later. The rationale for choosing this holiday programme is to control for factors typically present in a wilderness intervention that may possibly 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 programme is developed in close collaboration with the Swedish organisation Ung Cancer, based on their previous experience with AYA cancer survivor programme planning. The content of the holiday programme includes the following activities: spa facilities, bowling, mini-golf, museum visits, watching tv/movies, playing games, shopping and fine dining. Participants will engage in organised group activities, but this does not include any nature activities. The group size is aimed for 10 participants and each group will be supervised in a facilitator/participant ratio of 1:5, depending on the specific needs of participants.

Medication, therapies, dietary and lifestyle measures

Participants can continue all their current medication, therapies and/or dietary and lifestyle measures during the study. Concomitant medication, therapies, dietary and lifestyle measures will be monitored during the study and documented in the case report form of each participant.

Programme facilitators

Programme facilitators of the WAYA will have competence in one or more of the following areas: outdoor life, survival, nature/wilderness guiding, kayaking, climbing, nursing, first aid, (youth/group) counselling/supervising, mindfulness, mind-body techniques and research methodology. Facilitators will undergo a 3-day preparation event for the WAYA prior to the start of the study. They will be instructed about safety/study protocols, their tasks/responsibilities and how to keep the WAYA field diary during the intervention period. For the holiday programme, facilitators will have competence in at least guiding/supervising of groups, first aid and research methodology.

Outcomes

The primary objective of this study is to investigate the feasibility and safety of conducting an RCT on a wilderness programme for AYA cancer survivors. The following feasibility and safety parameters will be monitored: (1) participants’ preferences and expectations of the two programmes, (2) willingness of participants to be randomised, (3) the time needed to recruit the proposed number of participants, (4) the adherence of the participants to the study programme, (5) logistics and burden (for participants) to perform physical performance/fitness tests, (6) willingness and logistics to complete all planned study-related questionnaires, (7) the adherence

of the participants to the 3-month at-home programme and transference of activities in this period, (8) occurrence of adverse effects during the programme interventions. Adverse effects will be coded according to the Medical Dictionary for Regulatory Activities²⁸ and analysed using preferred terms and allocation to system organ class. Safety of the programmes will be evaluated by analysing the number, seriousness, intensity and types of adverse effects that are evaluated to be certain, probable/likely or possibly related to the study programmes.

A secondary objective is to explore the impact of a wilderness programme on the health of AYA cancer survivors, and to describe participants' experiences with the wilderness and the holiday programme in the study. The health status of the cancer survivors will be monitored by means of self-reported validated questionnaires and physical tests that were selected based on the results of a previous study.²⁰

Minneapolis Manchester Quality of Life instrument (MMQL): the MMQL-Adolescent form is a quality-of-life questionnaire specifically designed for young cancer survivors (age 13–20 years old) and consists of seven quality of life domains.²⁹ The instrument is translated and validated in the Swedish context.³⁰

Rosenberg Self-Esteem Scale (RSES): the RSES is a validated 10-item scale that measures global self-worth by measuring both positive and negative feelings about the self.³¹ The RSES is translated and validated in the Swedish language and context.³²

Generalised Self-Efficacy scale (GSE): the GSE is a widely used 10-item measurement assessing general belief in oneself to solve problems and reach goals.³³ The GSE is translated and validated in the Swedish context.³⁴

Nature Relatedness Scale (NRS): the NRS is a 21-item scale that measures the 'affective, cognitive and physical relationship individuals' have with the natural world.³⁵ The NRS is not yet available in the Swedish language. Adequate translation, retranslation and validation procedures will be performed.

International Physical Activity Questionnaire (IPAQ): IPAQ measures average weekly physical activity, work, sedentary behaviour and leisure time,³⁶ and is available in the Swedish language.³⁷

The following physical performance/fitness tests will be performed:

Blood pressure and heart rate (BP/HR): BP/HR will be assessed as safety measures for performing physical performance/fitness activities. Relative contraindications for making tests for physical performance include resting tachycardia (HR>120 beats/min) or uncontrolled hypertension.³⁸

Six-minute walk test (6MWT): the 6MWT has been used in many different populations to measure functional exercise capacity before and after interventions.³⁹ The test is easy to administer, tolerated and reflects activities of daily living in a good manner.³⁸

Step counter: the step counter will be used to monitor the number of steps in a regular week. Technically, step

counter does not monitor the intensity of the activity, but there are equations that can be used in order to estimate moderate/intense activity.⁴⁰

Estimated maximal oxygen consumption: maximal oxygen consumption (VO_{2max} ; mL/kg/min) will be measured according to the single-stage Tecumseh submaximal step test protocol⁴¹ using the equation as developed by Hong *et al.*⁴²

Recruitment

Participants for the study will be recruited via Ung Cancer and Maxa livet, two national organisations for childhood and AYA cancer survivors in Sweden. The organisations will send information on the study via social media and email newsletters.

Sample size

Based on the recommendations of Whitehead *et al.*⁴³ and an expected small to medium effect size for changes in quality of life, a sample size of 40 participants (n=20 per group) is chosen for this pilot study. A sample size of 20 participants in each group is also thought to generate sufficient interviews for the qualitative evaluation in the study.

Randomisation and concealment

Participants will be randomised equally (1:1) to the wilderness or holiday programme according to a randomisation list as generated by a Random Allocation Software Program using a random block size of two to guarantee a balanced allocation. Randomisation and assignment of participants to the two programmes 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 three age groups (16–19, 20–30, 31–39 years) and according to gender (male/female) to achieve equal distribution among the two programmes. Per stratification, separate randomisation lists will be generated.

Blinding

Participants will be informed that the study compares two possible effective health promotion programmes: a wilderness and a holiday programme. To reduce expectation bias, it will not be revealed to participants whether one programme is hypothesised to be better than the other (single-blinded). Programme facilitators and researchers performing the qualitative analysis will not be blinded. Quantitative analysis will be performed by researchers that are blind to programme allocation.

Data collection

Table 3 gives an overview of data collection in the study. To avoid possible effects of program-related expectation-anxiety and return-euphoria, self-reported questionnaires will be completed by participants 2–3 weeks before the start of the 8-day programme (T=0), 2–3 weeks after the 8-day programme (T=1), 2–3 weeks after the 4-day follow-up programme (T=2) and 1 year following

Table 3 Data collection in the study

| Measurement | Intake | Randomisation | 8-day programme | | 3 months at home | | 4-day programme | 1 year |
|--------------------|-----------|---------------|-----------------|-----------|------------------|-----------|-----------------|--------|
| | Contact 1 | Contact 2 | Day 1 T=0 | Day 8 T=1 | Contact 3 | Contact 4 | T=2 | T=3 |
| P-pref | X | | | | | | | |
| P-exp | X | | | X | | | X | |
| P-willingness | X | | | | | | | |
| DD/MH/MU | | X | | | | | | |
| M/T/D/LM | | X | X | X | X | X | X | X |
| P-adherence | | | | X | X | X | X | X |
| MMQL | | | X | X | | | X | X |
| GSE | | | X | X | | | X | X |
| RSES | | | X | X | | | X | X |
| NRS | | | X | X | | | X | X |
| IPAQ | | | X | X | | | X | X |
| Step counter | | | X | | X | | X | X |
| 6MWT | | | X | | | | X | |
| VO _{2max} | | | X | | | | X | |
| BP/HR | | | X | | | | X | |
| AE | | | | X | X | X | X | |
| Interviews | | | | | | | X | |

AE, adverse effects; BP/HR, blood pressure/heart rate; DD, demographic data; GSE, Generalised Self-Efficacy Scale; IPAQ, International Physical Activity Questionnaire; MH, medical history; MMQL, Minneapolis Manchester Quality of Life instrument; M/T/D/LM, Other Medication/Therapies/Dietary or Lifestyle measures; MU, medication use; 6MWT, 6-minute walking test; NRS, Nature Relatedness Scale; P-adherence, participants' adherence; P-exp, participants' expectations; P-pref, participants' preference; P-willingness, participants' willingness to be randomised; RSES, Rosenberg Self-Esteem Scale; VO_{2max}, maximal oxygen consumption.

participation (T=3). The step counter will be performed in a regular week prior to and after the intervention and after 1 year. Participants will be interviewed about their experiences with the programmes approximately 2–3 weeks after the 4-day follow-up programme by means of a semi-structured interview guide. Participants are asked to describe their experiences of participating in the wilderness or holiday programme in relation to the programme activities, feasibility and safety of the programme, other participants and facilitators. They are also asked to reflect in more depth on their lived experiences regarding the nature context/holiday context of the programme and what the programme has meant for their health. Interviews will be performed online by researchers that have not been facilitating programme interventions, and interviews are expected to last between 30 and 60 min.

Data management and confidentiality

Study data of each participant will be documented in a case report form. Data for analysis will be anonymised by assigning each participant an unidentifiable screening number at the time of enrolment and additional study number on randomisation. The study numbers are sequentially allocated to the participants in the order of inclusion in the randomised intervention period. Paper data forms for the physical measurements, self-reported

online questionnaires and the SPSS dataset will only link data to participant's study number to maintain their anonymity. The case report forms, SPSS dataset and other participant-related documentation will be stored on a secure server at Mid Sweden University, will be password-protected, and can only be accessed by research team members that are authorised. To guarantee data quality, independent checks for data values will be performed by another researcher than the one entering the data in the database. The audio recordings will be stored on a secure server and the original recordings will be deleted from the recording device after transfer. All audio recordings will be transcribed verbatim by transcriptionists, who will delete all files after transfer to the storage on the secure server of Mid Sweden University. The collected data will be saved for at least 10 years after the end of the study.

Data analysis plan

Quantitative analysis

Descriptive statistics will be used to describe demographic and categorical data, recruitment time, willingness to be randomised, programme adherence, questionnaire completion rates and other outcome measures. Percentage, proportion, mean/median SD and 95% CI; range, where appropriate, will be reported for baseline values (T=0), follow-up values (T=1–3) and changes

from baseline to explore possible differences between, and within groups (over time changes). Additionally, the Aickin separation test⁴⁴ will be applied to determine whether there are indications of differences between the two arms.

Qualitative analysis

Verbatim transcripts of the audio-recorded interviews will be analysed by means of directed content analysis regarding study feasibility and safety⁴⁵ and a thematic analysis that follows the tradition of hermeneutic phenomenology regarding their lived experiences.⁴⁶ The NVivo qualitative software programme will be used for coding and as a tool for data analysis. It is aimed to interview at least 15 participants in each group.

Integration of quantitative and qualitative data

A convergent parallel mixed-method analysis design will be applied as described by Creswell and Plano Clark.⁴⁷ In the first step, quantitative and qualitative data are collected in parallel. In a second step, both datasets are analysed separately according to their own methodologies. In a third step, results will be merged through identification of content areas, comparing, contrasting and/or synthesising the results in tables. In a fourth step, merged results will be summarised and interpreted.

Study risk and safety plan

The study will be performed according to a risk and safety plan that is approved by the responsible body at Mid Sweden University prior to the study start. The risk and safety plan assesses the potential risks that can be predicted according to the risk exposure/consequence matrix of the Swedish Mountain Society.⁴⁸ The plan also describes the necessary precautions and preparations to perform the WAYA with acceptable risks, including COVID-19 measures, communication practices in case of an emergency, and scenarios for safe evacuation if needed.

Protocol amendments

All changes to the protocol will be documented, submitted to the Swedish Ethical Review Authority for approval where needed, and documented in the trial registry at clinicaltrials.gov. The study protocol in clinicaltrials.gov (version 2 of 8 June 2021) includes all items on the minimum standard list of items of the WHO checklist.²⁴

Ethics and dissemination

When entering the study, participants (and parents aged 16–17 years) will be informed about the study purpose, that participation is voluntary, and guaranteed confidentiality as findings will be presented at group level only. Participants will be informed that they, whenever they want, can abort participation without explaining cause, and that it will not have any influence on their treatment. Written informed consent will be obtained by the principal investigator from all participants prior to study inclusion. The study will provide adequate insurance for

all participants to cover any possible injury that may be experienced during or because of study participation. This study protocol has been approved by the Swedish Ethical Review Authority on 24 April 2020 (Study no: 2020-00239). Results of the study will be published in peer-reviewed journals, presented at conferences, and disseminated to participants and through the networks of cancer societies, healthcare professionals and wilderness/outdoor instructors. Consent forms, information letters and deidentified data sets will be made available on request.

Patient and public involvement

Patient and public involvement is an integrative part of all study phases, including dissemination of results. Patients'/participants' interests are represented by the national organisations Ung Cancer and Maxa livet. They will be involved in study protocol development, development of the wilderness/holiday programme, risk and safety plan, recruitment of participants, preparation for the train-the-trainer programme, interpretation, and dissemination of results. Wilderness/outdoor instructor interests are represented by members of the Swedish Survival Guild (Svenska Överlevnadssällskapet). They advise on the development of the WAYA, advise and assist in the train-the-trainer programme, advise how to motivate participants to move from more urbanisation to going out in nature, and advise on dissemination of study results. Public health actors are represented by employees from the County Council of Västernorrland. They will advise how to involve participants from different multi-cultural backgrounds, how to motivate participants to move from more urbanisation to going out in nature, advise on interpretation and dissemination of study results, and how to guarantee sustainability of the wilderness programme. Healthcare professionals will be represented by an oncologist and a medical doctor from the County Council of Västernorrland. They will prescribe the necessary study rescue medication, advise regarding the (medical) condition of participants, advise on monitoring of medical safety of participants during the study, and on interpretation and dissemination of study results.

DISCUSSION

To the best of our knowledge, this is the first RCT that will be carried out on a wilderness programme for AYA cancer survivors. Therefore, it is of great importance to first examine the feasibility of such a study design. The proposed WAYA wilderness programme, with an expedition as well as a base-camp component, is a complex and multi-faceted intervention. Performing RCTs on such complex programmes has proven to be challenging. A previous attempt in Norway involving adolescents with mental health problems did not succeed.⁴⁹ A major reason for failure was that participants felt deceived when randomised to the control group which was treatment as usual and not the wilderness programme. Subsequently

they were not motivated to engage in usual treatment and the planned randomised design was aborted.⁴⁹ The choice for an appropriate control arm in the present study was extensively discussed within the research team and with relevant stakeholders such as the national cancer organisations. Learning from the Norwegian study it became apparent that the control arm should also offer something 'attractive' for such a vulnerable group as AYA cancer survivors. Furthermore, in a larger RCT it is aimed to specifically investigate the effectiveness of the role of nature in the wilderness programme. Therefore, we plan to control for other effective components in the programme such as group support, getting out of their own home, and attention from facilitators. Based on these reasons, the current proposed holiday programme was designed as a control arm. It can be argued that a holiday programme may also promote participant's health, by offering pleasant experiences and the chance to recharge. Although this cannot be excluded, it is hypothesised that such possible beneficial effects are short-term. In addition, self-reported health outcomes are carefully selected in the present study and directly related to the specific theory and aims of the wilderness programme as to improve body image, self-efficacy, self-esteem, connectedness to nature and physical activity. Such aims are not targeted in the holiday programme. From a methodological perspective it would be interesting to examine the feasibility of a third arm in the study design, consisting of no programme participation or a wait-list control. However, based on previous experiences from the planned RCT in Norway,⁴⁹ it was decided not to be feasible.

Since this study is planned during the COVID-19 pandemic and related restrictions, it is of extreme importance to closely monitor and report how the COVID-19 pandemic has affected the performance of the study and might have influenced experiences and health outcomes of participants during the follow-up period.

Results of this feasibility study are of primary interest to plan the performance of a larger RCT on the effectiveness of a wilderness programme for the health of AYA cancer survivors. However, results of this study will also provide more understanding on the role of nature in supporting the health of young cancer survivors. This is of high interest to AYA cancer survivors, their families, outdoor instructors, clinicians, and other researchers.

This study will be performed by an international research team with members from the Netherlands, Norway, Sweden and the USA. They have expertise in epidemiology, paediatric psycho-oncology, wilderness therapy, complementary and complementary medicine, sport science, nursing, public health and scientific information services. Several members have previously been collaborating in performing a systematic review on the subject.^{20 50}

Study status

The study began in January 2021. Data collection started in June 2021 and is estimated to be completed in

October 2022. The estimated study end date is planned in December 2023.

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Contributors MCJ is a principal investigator of the WAYA study, coconceived the idea for the feasibility study, cowrote the study protocol, wrote the first draft of the protocol and manuscript, is responsible for randomisation and group allocation, and will be the logistic/research coordinator of the study. EM will be a facilitator of the wilderness programme and perform/analyse physical measurements. AEK will perform the statistical analyses of the quantitative data. TS will interview participants in the wilderness programme and perform qualitative analyses. HD and EV will interview participants in the holiday programme and perform qualitative analyses. EAL and WS will analyse feasibility and safety-related data. MJ is the other principal investigator of the WAYA study, coconceived the idea for the feasibility study, cowrote the study protocol, is responsible for study intake and contacts with participants, and will be leading all programme-related activities. All authors contributed to, and approved the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

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