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Functioning and quality of life in pediatric cancer survivors, 5-10 years after diagnosis

Submission date
14/02/2025

Recruitment status
Recruiting

Registration date
24/02/2025

Overall study status
Ongoing

Last Edited
24/02/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Every year about 350 children and adolescents are diagnosed with cancer in Sweden. Tumors in the brain or central nervous system and leukemia account for almost 30% each of all pediatric cancer. The treatment includes surgery, chemotherapy, and radiation, often in combination. Improvements in treatment have led to higher survival rates and lower mortality.
Children with brain tumors are at high risk of developing complications from the central nervous system. The impairments can be a result of treatment or the location of the tumor itself. Pediatric brain tumor survivors exhibit reduced physical functioning, impaired fitness, poor functional mobility as well as lower health-related quality of life (HRQoL) compared to other cancer survivors and healthy peers.
Children treated for leukemia exhibit impaired motor functioning both during and after chemotherapy and these impairments can persevere into adulthood. Treatment has both short- and long-term consequences on the neuromuscular and musculoskeletal systems such as sensory and peripheral neuropathy. Impairments may negatively affect a child´s overall function, quality of life and ability to participate in age-appropriate activities including school and play.
Cancer-related fatigue is a distressing, persisting, subjective sense of physical, emotional and/or cognitive tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning. Fatigue has a negative impact on all areas of function including mood, physical function, work performance, social interaction, cognitive performance, schoolwork, community activities and sense of self. Fatigue and impairment of function may affect quality of life, especially in children, adolescents, and young adults, as they are no longer able to keep up their usual lifestyle and their participation in social interaction with peers is significantly affected. There is evidence that increased physical activity is associated with less fatigue.
There are many benefits to physical activity in pediatric cancer survivors; physical activity affects the endocrine system and endorphins which has a positive effect on mental health. Some cancer survivors are at risk of developing cardiovascular diseases and diabetes where physical activity can have a beneficial effect.
Children and adolescents surviving cancer have been reported to be less physically active than healthy siblings and several have treatment-related neurologic and/or musculoskeletal problems that affect their participation in regular physical activity.
According to the recommendations of the World Health Organization, children should at least

do 60 minutes/day of moderate to vigorous physical intensity, mostly aerobic physical activity, across the week and include vigorous-intensity aerobic activities as well as activities that strengthen muscle and bone at least 3 days a week. Also, children should limit time spent being sedentary, mainly the amount of recreational screen time.
Physical Activity on Prescription (PAP) is a medical treatment method with the purpose of helping individuals to gain a healthier and more active lifestyle and has been used within the Swedish healthcare system since early 2000. The method consists of three steps: 1) personalized consultative guidance, 2) personalized written prescription and 3) personalized follow-up. The method is recommended in the national guidelines for the prevention and treatment of unhealthy lifestyle habits and is considered effective for adults. PAP can be used as a treatment for children and adolescents who are at risk of developing illness due to an inactive lifestyle or who belong to a risk group developing illness because of a physically inactive lifestyle. PAP has been found feasible in children with cerebral palsy to increase physical activity and reduce sedentary behaviour and can be used in different clinical settings.
Research shows that cancer survivors may exhibit deficits in motor function and low levels of physical activity. Therefore there is a need to screen for and identify cancer survivors' challenges in incorporating physical activity to improve health and well-being.
The overall aim of this project is to explore functioning, levels of physical activity, HRQoL and fatigue among pediatric cancer survivors treated for brain tumor or leukemia 5-10 years after diagnosis.
A secondary aim is to study the feasibility of a PAP intervention on functioning, levels of physical activity, HRQoL and fatigue and the experience of PAP among inactive pediatric cancer survivors.

Who can participate?
Individuals 5-17 years of age who have been diagnosed and treated for a brain tumor or leukemia at the Children's Hospital at Skåne University Hospital, 5-10 years ago, and caregivers.

What does the study involve?
1. Focus group interviews with participants and caregivers' perception of functioning, levels of physical activity, health-related quality of life and fatigue in pediatric cancer survivors.
2. Screening with standardised tests of functioning, levels of physical activity, health-related quality of life and fatigue.
3. Participants who are found who are found not to reach the physical activity recommendations in the first phase of the project, will be recruited to a PAP intervention study, where the feasibility of PAP among pediatric cancer survivors will be explored.
4. Individual interviews on participants' and caregivers' perceptions and experiences of PAP.

What are the possible benefits and risks of participating?
There is strong evidence that increased physical activity has a positive influence on physical and mental health. Side effects such as soreness in muscles after physical exercise are harmless and will disappear after a few days. The PAP will be prescribed by a physiotherapist who will regularly follow up with each participant during the intervention for safety and motivational reasons.

Where is the study run from?
Department of Physiotherapy, Children's Hospital, Skåne University Hospital (Sweden)

When is the study started and how long is it expected to run for?
February 2023 to December 2031

Who is funding the study?
1. Foundation for the Memory of the Consul Thure Carlsson (Sweden)

2. Skåne University Hospital (Sweden)
3. Region Skåne (Sweden)

Who is the main contact?
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Additional identifiers

Protocol serial number
SUS 2024-1162

Study information

Scientific Title
FUNctioning, physical activity, health-related Quality of life and fatigue in PEDiatric cancer survivors and feasibility of a physical activity on prescription intervention

Acronym
FUNQ-PED

Study objectives
Many pediatric cancer survivors have reduced functioning and quality of life 5-10 years after diagnoses. Physical activity on prescription is a feasible and beneficial method for improving physical and mental health in this population.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/12/2023, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, Uppsala, 750 02, Sweden; +46 (0)10 475 08 00; registrator@etikprovning.se), ref: 2023-06785-01

Primary study design
Observational

Study design
Quantitative single-center cross-sectional observational cohort study in the first phase and an interventional feasibility study in the second phase of the project

Study type(s)
Other, Quality of life, Screening, Treatment, Efficacy

Health condition(s) or problem(s) studied
Brain tumor, leukemia

Interventions

In the first phase of the project, pediatric cancer survivors and caregivers will be interviewed about their experience of functioning and quality of life. Also, a consecutive cohort of pediatric cancer survivors will be invited to participate in a screening of functioning and quality of life, and those with low levels of physical activity will be identified and invited to participate in the intervention to increase physical activity and quality of life in the second phase of the project.

The initial screening study includes assessments of motor proficiency (Bruiniks Oseretsky test of motor proficiency, BOT-2), aerobic capacity and endurance (6-minute walk test), grip strength (Grippit), health-related quality of life using the Pediatric Quality of Life measure (PedsQL), fatigue using the Multi Fatigue Scale of the PedsQL (PedsQL-MFS), self-assessment of physical activity by a semistructured interview (International Physical Activity Questionnaire) and an objective measurement of levels of physical activity using an accelerometer for 7 days in the home environment.

In the second phase, participants with low levels (<60 min of moderate-vigorous levels of physical activity/ day) will be recruited to the Physical Activity on Prescription (PAP) intervention study within 1 month after the assessment in the initial screening of all eligible participants.

Upon agreement, the participant will be interviewed using the Canadian Occupational Participation Measure to identify the person's interests, preferences and self-assessed performance of the activities that may be suitable to prescribe for the intervention, in order to increase the person's motivation to be more physically active. Results from assessments in the screening (first phase), will form the baseline measurement for the intervention together with a second accelerometer measurement before the intervention starts.
The intervention consists of 12 weeks of prescribed physical activity to be performed at an individualized frequency and intensity. The researchers will have ongoing contact with the person and families during the intervention, to support implementation by face-to-face or in digital meetings.

At the end of the intervention and at the 12-month follow-up, all measurements will be repeated.

Participants will document the frequency and intensity of the prescribed activities as well as PAP-related side effects, discomfort or difficulties in an activity diary. Data from the assessments and accelerometer measurements will be analysed at an individual level to evaluate the feasibility of the PAP intervention along with reports in the activity diary as well as perceived experiences of the intervention.

Intervention Type
Mixed

Primary outcome(s)
1. Levels of physical activity objectively measured using an accelerometer (a wearable device). The amount of minutes registered over a consecutive week in the intensity moderate to vigorous physical activity per day will be analyzed.
2. Self-assessment of the level of physical activity, sedentary behaviour and estimation of the intensity of various physical activities in the last 7 days using the International Physical Activity Questionnaire in a structured interview

Assessments will be performed with both measures for all participants in the screening in the first phase of the project. For participants included in the PAP intervention the assessment will be repeated directly after the 12 weeks of intervention and at the 12 months follow-up in the second phase of the project.

Key secondary outcome(s)

In the first phase of the project, secondary outcome measures 1-6 will be used to assess functioning and health-related quality of life (HRQoL). In phase two of the project outcome measures 1-8 will be used to assess functioning and HRQoL.
1. The overall gross and fine motor function will be assessed for all participants by the short form of the standardized norm-referenced Bruiniks Oseretsky test (BOT-2- SF). Scores will be derived from the total score and results of the test will be presented with standard scores and percentiles. For participants included in the PAP intervention the assessement will be repeated directly after the 12 weeks of intervention and at the 12-month follow-up.
2. Aerobic capacity and endurance will be assessed by the 6 -minute walk test. The participant will be asked to walk during six consecutive minutes in a self-selected speed, the distance (m) walked during the 6 minutes will be measured. The test will be performed for all participants and for those included in the PAP intervention, the assessment will be repeated directly after the 12 weeks of intervention and at the 12-month follow-up.
3. The maximal grip strength of both hands will be measured by the Grippit measure for all participants. Participants will be asked to press a handle that measures the grip force (N) using a standardised routine. Results will be compared to results from a normal sample. For participants included in the PAP- intervention the assessment will be repeated directly after the 12 weeks of intervention and at the 12-month follow-up.
4. Health-related quality of life will be assessed using the questionnaire PedsQL in all participants and caregivers. PedsQL consists of 23 items categorised into four sub-scales; physical functioning, emotional functioning, social functioning and school functioning. A total score is determined by adding up all answered items and dividing the sum by the number of items answered. Higher scores demonstrate greater HRQoL.For participants included in the PAP intervention the assessment will be repeated directly after the 12 weeks of intervention and at the 12-month follow-up.
6. Level of fatigue will be assessed using the questionnaire PedsQL- multi fatigue scale (MFS) in all participants and caregivers. Eighteen items are distributed in three domains; general fatigue, sleep/rest fatigue and cognitive fatigue. A total score is determined by adding up all answered items and dividing the sum by the number of items answered. Higher scores demonstrate fewer fatigue symptoms. All participants included in the PAP intervention the assessment will be repeated directly after the 12 weeks of intervention and at the 12-month follow-up.
7. Self-perceived performance and satisfaction in the selected activities with the participants recruited to the PAP intervention, a structured interview using the Canadian Occupational Performance Measure is used. The participant estimates his/her ability and satisfaction with how the activity is performed. He/she will also rate the importance of being able to perform the activity. The rating scales range between 1-10, where 1 corresponds to low levels and 10 to high levels of ability/performance/importance. The measurement will be performed before the PAP intervention, directly after the 12-week intervention and at the 12-month follow-up.
8. Frequency and intensity of the performed activities as well as personal experiences and reflections during the intervention will be reported using an activity diary by all participants in the PAP intervention.

Completion date

31/12/2031

Eligibility

Key inclusion criteria
1. Aged 5-17 years
2. Diagnosed with brain tumor or leukemia before the age of 13 years
3. Treated at the Children’s Hospital, Skåne University Hospital
4. Followed 5-10 years after diagnosis at Children's Hospital, Skåne University Hospital
5. Caregiver

Participant type(s)
Patient, Carer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 Years

Upper age limit
17 Years

Sex
All

Key exclusion criteria
1. Participants unable to walk independently with/without walker
2. Participants who have had a relapse of their cancer
3. Participants who are having an ongoing medical cancer treatment

Date of first enrolment
01/10/2024

Date of final enrolment
31/12/2031

Locations

Countries of recruitment
Sweden

Study participating centre
Skåne University Hospital
Department of Paediatrics

Lund
Sweden
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Sponsor information

Organisation
Skåne University Hospital

ROR
https://ror.org/02z31g829

Funder(s)

Funder type
Charity

Funder Name
Stiftelsen Konsul Thure Carlssons Minne

Alternative Name(s)
Thure Carlsson Foundation, Foundation for the Memory of the Consul Thure Carlsson

Funding Body Type
Private sector organisation

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

Location
Sweden

Funder Name
Skånes universitetssjukhus

Alternative Name(s)
Skåne University Hospital, SUS

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
Sweden

Funder Name
Region Skåne

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made avaliable at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date