MELODIC

Mental Health Support for Young Adults with Cancer

Project Number: 101101253

WP4: Improvement of mental health and well-being of YA with cancer Intervention study protocol, ethics, data management plan, quasi-experimental study (YA 10/country, family member/caregiver 5/country), evaluation data

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Executive Summary

Young adults (YAs) aged 18-35 with cancer represent a vulnerable and underserved group within the cancer care system. A cancer diagnosis disrupts their lives and complicates typical developmental milestones, such as establishing independence and forming relationships. Studies show that YAs require specific psychosocial and supportive care during treatment, including information, counselling, practical support, and opportunities for socializing and peer support. Integrating psychosocial care into standard treatment can reduce distress, enhance quality of life, and potentially increase survival rates. Additionally, nature-based interventions and physical activity can improve cancer-related quality of life and mental well-being. Since young adults make up a minority of the cancer patient population, most interventions tend to focus on older age groups. Therefore, despite the tremendous impact of cancer on YAs and evidence regarding their unmet psychosocial needs, there are few interventions specifically developed and evaluated for young adults with cancer. The overall aim of the MELODIC project is to enhance the mental health and wellbeing of YAs with cancer, as well as their family members and caregivers. This will be achieved by improving screening, early detection, and the management of mental health needs within the first 24 months following a cancer diagnosis. This study aims to test the feasibility and impact of a novel intervention inspired by social prescribing, which combines physical activity in natural surroundings with psychoeducation and information support for YA's and their family members/caregivers' mental health and quality of life. The study has a pre-post intervention study design, and study participants are young people aged 18-35 years old who have no medical contraindication to participate in the study.

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1. Background

Young adults (YAs), aged 18-35 years old, with a lived cancer experience represent a distinct, vulnerable, and underserved population within the cancer care system (Ferrari et al., 2021; Barr et al., 2016). YAs frequently fit into "no man's land" between the paediatric and adult oncology specialties and are at risk for receiving fragmented medical and psychosocial care (NCI, 2021). This age group experiences various physiological changes and social transitions, and a cancer diagnosis can significantly disrupt nearly all aspects of their lives (Coccia et al., 2018; Ferrari & Barr, 2017). Thus, the cancer treatment experience is particularly difficult for YAs because it interrupts and challenges normative developmental events, including efforts to establish independence, form strong peer and intimate relationships, and make plans for the future (Compas et al., 2012; Docherty et al., 2015; Richter et al., 2015; Warner et al., 2016). Due to their natural developmental stage, young people may not have fully developed coping skills that could help them to manage feelings of distress and navigate complex social situations (Docherty et al., 2015; Lang et al., 2018). Most young people with a lived cancer experience can be expected to experience some impact on their mental health due to their diagnosis (e.g., sadness, worrying), but some may develop more heightened psychological distress, anxiety, and depression (Osmani et al., 2023). Several studies have identified the psychosocial and supportive care needs of adolescents and YAs during acute cancer treatment (Haase et al., 2020; Zebrack et al., 2014; D'Agostino & Edelstein, 2013), including the need for information and education for young people and their families, counselling, practical support, opportunities for socialising with other YAs and peer support, and having health care providers proactively raise salient issues, particularly psychosocial wellbeing, and information about available resources.

Research indicates that integrating early psychosocial cancer care into standard treatment can reduce distress and enhance quality of life, both during and after cancer treatment, which may increase survival rates (Cheng et al., 2025; Caruso & Breitbart, 2020; Niu et al., 2021). Interventions such as counselling, psychotherapy, and psychoeducation have been created to assist cancer patients in adjusting psychologically (Caruso & Breitbart, 2020). Psychoeducation is a therapeutic approach that involves giving individuals with cancer, their families, and caregivers information about the impact of cancer on all aspects of an individual's life, normalising feelings and reactions, adjustments to cancer diagnosis and treatment, coping and self-care,_discussing concerns, problem-solving and coping skills training, supporting expressions of emotions, and social support (Barsevick et al., 2002; McFarland & Hlubocky, 2019; Mirhosseini et al., 2025). Psychoeducation is important for YAs with a lived cancer experience and their family carers, friends and other informal support persons (from now on they will be referred as "caregivers") because it increases understanding of the cancer diagnosis, improves treatment adherence and management of condition, helps them to recognise, normalise, and understand the feelings they may experience, improves coping skills, and enhances communication, which can lead to a greater sense of control during this difficult time (Gomez-de-Regil, 2021; Mirhosseini et al., 2025). At the same time, as caregivers devote a significant amount of time and effort to providing cancer patients with physical, psychological, informational, and social support, these demanding tasks can negatively impact their own health and wellbeing. Moreover, a range of social-ecological factors may influence the outcomes of cancer caregiving, while supportive interventions such as psychoeducation and skills training can help reduce the burden, meet information needs, enhance coping strategies, and improve physical functioning, psychological well-being, and quality of life for caregivers (Molassiotis & Wang, 2022). Therefore, it is crucial to recognise that enhancing the quality of life and alleviating caregiver burden among family caregivers of cancer patients plays a pivotal role in the patient's recovery journey (Mirhosseini et al., 2025). In short, psychoeducation helps the entire family navigate the psychological and social impacts of cancer and empowers them to make informed decisions and cope with challenges more effectively (Santiago, 2022). Extensive research in the field of oncology has consistently shown that following psychoeducational interventions, significant enhancements in quality of life, stress coping skills, and notable reductions in caregiver burden, symptoms of depression, and anxiety have been observed among patients and their family caregivers (Çetin & Nehir, 2020; Çalık et al., 2022; Kusi et al., 2023; Gabriel & Mayers, 2019). Furthermore, psychoeducation is scalable since it is more easily administered and potentially more accessible than conventional psychological interventions, that require delivery by trained mental health professionals (Donker et al., 2009). This is because it can be delivered by trained non-specialist health workers, or in a self-help format (e.g., printed materials, audio-visual materials, internet content) which requires fewer resources (Setyowibowo et al., 2022).

In addition, interventions for promoting physical activity in natural surroundings or nature-based interventions can improve cancer-related quality of life (Bikomeye et al., 2022), mental health, and psychosocial wellbeing (Britton et al., 2020; Ortega-Gómez et al., 2025). For example, psychosocial and biological outcomes improved after participation in immersive, mindfulness-based treks in nature by YAs with a lived cancer experience and their caregivers (Victorson et al., 2021). Similarly, previous research has supported the positive influence of human connection to nature and associated feelings of closeness to others (Capaldi et al., 2014), improved mood and sense of wellbeing (White et al., 2019), and increased self-efficacy (Whitburn et al., 2020). Social prescribing, a community-based service that connects individuals with non-medical support, benefits mental health by reducing depression and anxiety, combating social isolation, enhancing overall wellbeing, and helping patients find a sense of purpose and belonging through participation in various community activities. Moreover, it empowers individuals to take an active role in their health, boosting confidence and coping skills (Spanos et al., 2025). Social prescribing thus addresses a broad spectrum of psychosocial needs (e.g., social, emotional, and environmental) and promotes holistic approaches to mental health beyond the traditional biomedical model (Napierala et al., 2022). For instance, a study by Connolly et al. (2024) with older adults found that social prescribing was a feasible and acceptable intervention for cancer survivors, with improvements observed in participants' physical, mental, and social health following their meetings with a link worker and attending local community-based activities, indicating the potential benefit of social prescribing for cancer survivors. In a similar fashion, several reviews highlight the positive effects of social prescribing interventions on mental health, particularly for young people. These reviews found that such interventions significantly reduced young people's symptoms of depression and anxiety, largely due to increased access to community-based activities that provide supportive networks and meaningful engagement (Cooper et al, 2022; Mitchell et al., 2025; Muhl et al, 2025). Furthermore, social prescribing for children and young people offers a promising avenue for addressing the rising tide of mental health challenges (All-Ireland Social Prescribing Network, 2025).

Currently, healthcare systems tend to prioritise age groups with higher cancer prevalence, such as children and older adults. As a result, YAs frequently find themselves in a gap between paediatric and adult oncology care, neither of which are designed to address their specific developmental stages and unique challenges related to identity, independence, careers, and family planning (Barr et al., 2016).

While much research has focused on identifying the needs of YAs, including their physical and psychological issues and information gaps, there is limited research dedicated to developing and testing interventions to meet them (Gudenkauf et al., 2024). This has created a significant gap in the evidence base for effective support programmes (Lea et al., 2020). Consequently, even though cancer significantly impacts YAs and there is compelling evidence of their unmet psychosocial needs, few interventions have been specifically developed and evaluated for this age group (Richter et al., 2015; Thornton et al., 2020). This lack of intervention research means that healthcare professionals often do not have clear, specific guidelines on providing effective support, particularly at the end of active treatment (Lea et al., 2020). Therefore, there is a pressing need for more research into specific interventions, such as tailored psychological support, age-appropriate resources, and long-term surveillance strategies, to bridge this evidence gap (Lea et al., 2020). More efforts are needed to incorporate this population into evidence-based psychosocial support services, focusing on age-specific strategies to address the unique psychosocial challenges faced by YAs with cancer.

In order to improve the management of mental health needs among YAs with a lived cancer experience, an international consortium of 12 organisations (universities, cancer support services, hospitals, patient organisations, and NGOs) from eight countries joined together to implement the MELODIC project. The overall aim of the MELODIC project is to enhance the mental health and well-being of YAs with a lived cancer experience as well as their caregivers. In this study, caregivers are defined as informal caregivers of YAs with a lived cancer experience who may be their family members, relatives, friends, neighbours, and other persons who provide YAs with physical, psychological, informational, and social support. The overall aim of the MELODIC project will be achieved by improving screening, early detection, and the management of mental health needs within the first 24 months following a cancer diagnosis. To reach this goal, five Work Packages (WPs) will be implemented. The intervention study protocol outlined here pertains to WP4, where the project team will implement a novel intervention specifically designed for YAs with a lived cancer experience and caregivers.

The intervention is designed to provide a holistic approach that addresses the physical, psychological, and social well-being of participants. By employing a multidisciplinary strategy, it integrates a psychoeducation component—aimed at enhancing individuals' understanding of and improving their mental health—with engaging physical activity components, including walks in nature and online physical exercises. This multifaceted approach draws inspiration from the social prescribing model, which links individuals to community resources and activities, fostering a supportive environment that promotes overall health and wellbeing. The goal is to empower participants by addressing their diverse needs through a tailored and collaborative process. These components were chosen based on insights from existing literature and findings from WP2, a qualitative study conducted with YAs with a lived cancer experience and caregivers, as well as health care professionals, to better understand the mental health needs of YAs. WP4 aims to determine how various evidence-based elements of the innovative MELODIC intervention meet the support needs of YAs with a lived cancer experience and caregivers.

2. Study aim and objectives

This study aims to test a novel group-based_intervention, which combines social prescribing-inspired physical activity in natural surroundings with psychoeducation and online physical exercises for improving YAs' and caregivers' mental health and quality of life. The study objectives are:

1. To explore the feasibility of an intervention that combines physical activity in natural surroundings with psychoeducation and online physical exercises during the first 24 months after cancer diagnosis to support the mental health needs of YAs and caregivers. To examine the impact (preliminary effectiveness) of the intervention on the mental health and overall wellbeing of YAs and caregivers.

We intend to test the following hypotheses:

Hypothesis 1: An intervention combining physical activity in natural surroundings with psychoeducation and online physical exercises is feasible to implement with YAs with a lived cancer experience and their family members/caregivers.

Hypothesis 2: An intervention combining physical activity in natural surroundings with psychoeducation and online physical exercises will result in improvements in mental health and wellbeing of YAs with a lived cancer experience and caregivers. These improvements will be measured by pre-post intervention questionnaires and are operationalised as follows:

1. The intervention will result in improvement of the mental health status of YAs and caregivers as measured by the Warwick-Edinburgh Mental Health Wellbeing Scale (WEMWBS).
2. The psychological distress levels will be reduced as measured by the Distress Thermometer.
3. Coping skills will be improved as measured by the General Self-Efficacy (GSE) Scale.
4. Health-related quality of life of YAs and caregivers will be improved as measured by EQ-5D.
5. YAs' fatigue levels will be reduced as measured by the Brief Fatigue Inventory (BFI).

3. Methods

Design

This pre-post intervention study follows a quasi-experimental design. This design is chosen over a full RCT study as the preliminary impact and feasibility need to be explored before full-scale testing of effectiveness. The reporting of this study protocol is guided by the Template for Intervention Description and Replication (TIDieR) (The Equator Network, 2014) and Improving the Reporting Quality of Nonrandomized Evaluations of Behavioural and Public Health Interventions: the TREND statement (Des Jarlais et al., 2004).

Participants

Inclusion criteria for participants are:

1. Being a YA aged between 18-35 who received a diagnosis of cancer in the past 24 months, **or** being a family member/caregiver of a YA aged between 18-35 who received a diagnosis of cancer in the past 24 months.
2. Being able to give consent to take part in the study.
3. Agreeing to take part in the study.
4. Have no contraindications to participate in the intervention and are able to participate in the physical activity intervention, and able to participate in groups and outdoors

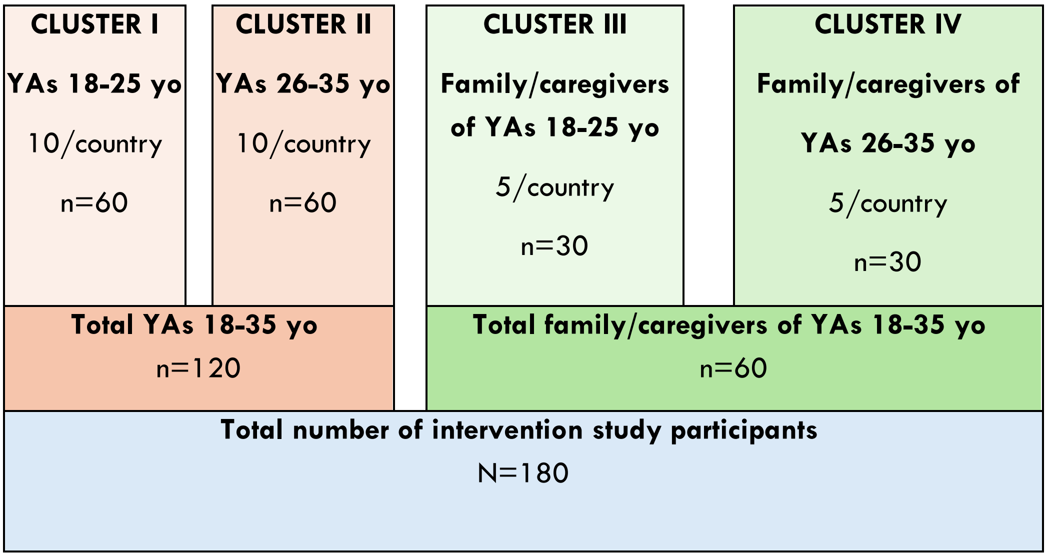
Inclusion criteria for participants are:

1. Being a YA aged between 18-35 years who received a diagnosis of cancer in the past 24 months, **or** being a caregiver of a YA aged between 18-35 years who received a diagnosis of cancer in the past 24 months.
2. Being able to give informed consent to take part in the study.
3. Having no contraindications to participate in the intervention and being able to participate in low to moderate intensity physical activity in groups, online, and outdoors. Prior to the intervention, the PAR-Q, Physical Activity Readiness Questionnaire, will be used as a screening tool for physical activity eligibility assessment and the presence of any contraindications, and if any issues are found, the participants will be advised to seek advice from a doctor.

Exclusion criteria are:

1. YAs and caregivers who are presenting with an acute state of mental health disorder, e.g., active psychosis, suicidal ideation, etc.
2. YAs and caregivers who have a health condition that prevents them from participating in low to moderate intensity physical activity or being in groups.

Four clusters of participants will be recruited: Cluster 1- YAs aged 18-25 years, Cluster 2- YAs aged 26-35 years, Cluster 3- caregivers of YAs aged 18-25, and Cluster 4- caregivers of YAs aged 26-35 (Figure 1). The number of participants in guided group walks will be defined locally.



CLUSTER I
YAs 18-25 yo
10/country
n=60

CLUSTER II
YAs 26-35 yo
10/country
n=60

CLUSTER III
Family/caregivers of YAs 18-25 yo
5/country
n=30

CLUSTER IV
Family/caregivers of YAs 26-35 yo
5/country
n=30

Total YAs 18-35 yo
n=120

Total family/caregivers of YAs 18-35 yo
n=60

Total number of intervention study participants
N=180

Figure 1. Diagram for sample size

Methods of recruitment consist of:

1. Displaying the study posters in outpatient clinics and community settings, such as sharing the study information in peer-support groups organised by volunteer organisations.
2. Inviting YAs with lived cancer experience and their family members/caregivers at any point of contact with their HCP in clinical settings.
3. Using social media posts, e.g., partners' social media channels and professional networks, providing the study information.

The recruitment will be conducted in six countries, including Estonia, Finland, Greece, Ireland, Portugal, and the Netherlands. The intervention will be coordinated locally to facilitate group activities.

Recruitment will be conducted in six countries, including Estonia, Finland, Greece, Ireland, Portugal, and the Netherlands. The intervention will be coordinated locally to facilitate group activities.

The sample size was calculated as 180 participants in total, of which 120 will be YAs (60 aged between 18-25 and 60 aged between 26-35 years, with 20 YAs from each country); and 60 will be caregivers of YAs aged between 18-25 (n=30) and 26-35 (n=30), with 10 caregivers from each country (Figure 1). No interim analyses will be conducted during participant recruitment.

Intervention

The intervention is designed to provide a comprehensive approach that addresses the physical, psychological, and social dimensions of well-being of YAs with a lived cancer experience and caregivers. By employing a multidisciplinary strategy, the programme draws on the expertise of various professionals, including mental health specialists, exercise physiologists, and other healthcare professionals, to deliver a well-rounded experience. Central to this intervention is the integration of psychoeducation with structured physical activity components. The psychoeducation component focuses on educating participants about their diagnosis, treatments, mental health concepts, coping strategies, the importance of emotional resilience, and the benefits of physical activity. This knowledge will support participants to understand their mental health better and to use effective tools for managing stress and emotional challenges. The structured physical activity components – guided group walks in natural surroundings and online physical exercises – aim to support patients and caregivers peer-support and social networks and encourage participants to engage in regular exercise, promoting not only physical fitness, but also enhancing mood and reducing symptoms of anxiety and depression. These activities are designed to be inclusive and adaptable to varying fitness levels, ensuring that everyone can participate. Inspired by the concept of social prescribing, this intervention also connects participants with support groups and social activities, fostering a sense of belonging and community engagement. This holistic approach aims to cultivate a supportive environment for YAs with a lived cancer experience and caregivers, ultimately improving their overall quality of life. The goal is to empower participants not only through psychoeducation and physical activity but also by strengthening their social networks and support systems.

A summary of the intervention is provided in Figure 2. The implementation of the intervention study will take nine months, excluding holidays. It will consist of three phases: three months for baseline data collection, three months for delivering the intervention, and three months for collecting post-intervention data. A diagram of the intervention study phases and components will be provided to participants to help them organise their time and participate regularly in the intervention (Figure 3).

INTERVENTION

Intervention components

Interactive psychoeducation session 1

At baseline

Duration: 90 minutes

Guided group walks with YAs and their family members/caregivers once a week for 12 weeks for each group, alternating green and blue spaces. HCPs will guide the walks. Duration up to 1 hour.

Online exercises

30-minute resistance exercises twice a week for 12 weeks (recording will be provided to participants at the beginning of the intervention) - total 3 videos with different workouts.

Interactive psychoeducation session 2

At 1.5 months

Duration: 90 minutes

Interactive psychoeducation session 3

At 3 months

Duration: 90 minutes

OUTCOMES

Effect and outcome measurement instruments

Pre-test: Month 0 (baseline)

Post-test: Month 3 (immediately post-intervention)

Primary outcome measurement (*mental health*):

For YAs and caregivers: Warwick-Edinburgh Mental Health Wellbeing Scale; The Distress Thermometer.

Secondary outcome measurement (general *wellbeing and quality of life*):

For YAs and caregivers:

EQ-5D-5L (improved health-related quality of life);

***Social connectedness* -** UCLA 3-Item Loneliness Scale; qualitative questions in pre- and post-tests.

For YAs:

Coping abilities - General Self-efficacy Scale (cancer-specific).

***Physical activity* -** Brief Fatigue Inventory (BFI); quantitative and qualitative questions in pre- and post-tests on the patterns of physical activity.

Post-test on study feasibility: Questionnaire completed by HCPs, YAs, and caregivers about the study's feasibility.

Figure 2. Summary of the intervention and targeted outcomes

Social prescribing-inspired physical activity in natural surroundings

Guided group walks

Local healthcare professionals (HCPs) will organise and facilitate group walks in green and blue spaces. Green and blue spaces are natural or semi-natural environments that include vegetated areas (green spaces) and bodies of water (blue spaces), such as parks, forests, lakes, rivers, canals, and coasts. Guided group walks will alternate between green and blue spaces, taking place in a green space every other week and a blue space on the alternate weeks. Each walk will be scheduled for 1 hour, which will include a warm-up and breaks as needed. The total duration of each individual's walking time during the hour will depend on the fitness levels of the participants.

Guided group walks will be organised once a week for 12 weeks (3 months) for each intervention group. Group compositions will be decided on a local level and in line with participants' preferences, with the following group compositions being possible: (1) YA and caregivers groups meet separately and at different times; (2) YA and caregiver groups meeting separately but at the same time; (3) mixed groups of YA and caregivers. This flexible approach aims to ensure that participants feel comfortable and supported during the walks.

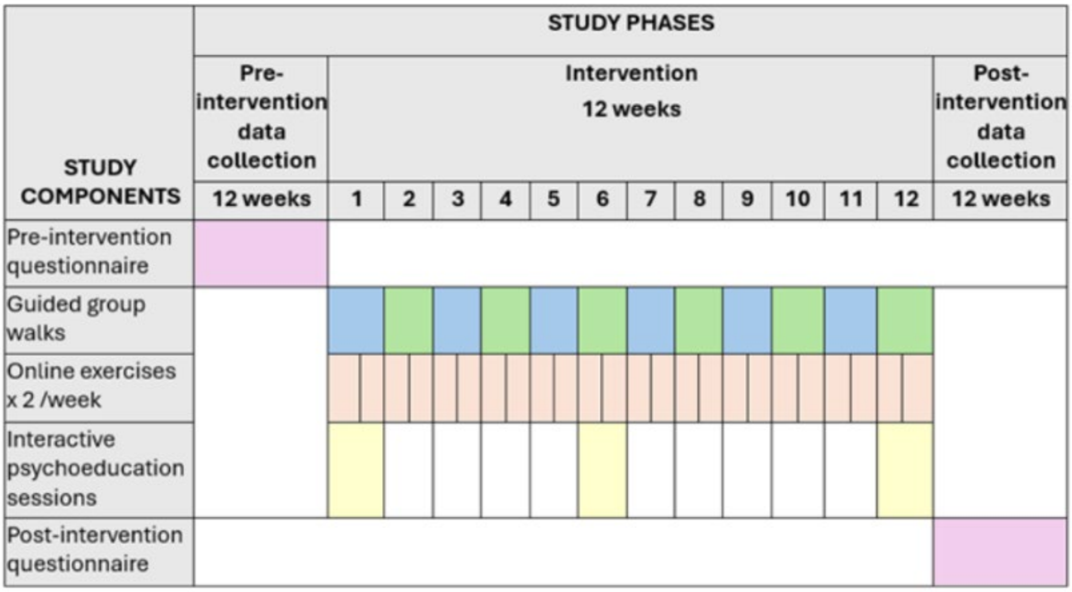
The psychoeducation and information support component will consist of three online group interactive sessions for YAs and caregivers facilitated by trained health care professionals at baseline, 1.5 months, and 3 months following the start of the intervention. If preferred and depending on local circumstances, in-person sessions can also be conducted. The interactive sessions will last approximately 90 minutes, and each will follow a pre-planned schedule that allows for discussion. Topics will include information and discussion around the topic of living with cancer, treatments, and life after cancer treatments, and discussion among the participants will be encouraged. In addition, time will be allocated to address participants' special interests and needs, which will be discussed with them prior to the sessions.

In the first interactive session, the participants will be introduced to each other and will get to know each other with the aim of encouraging them to form relationships, gain and provide peer support, and reduce social isolation. General information about psychosocial support and psychoeducation, as well as the intervention's objectives and components, will be presented. In addition, information about the online exercise sessions, the benefits of exercise, recommended dose, and types of exercises beneficial for YAs living with cancer will be introduced. The second interactive session will focus on topics for further development and discussion as identified by participants in the first session, and informed by the findings from WP2 needs assessment, such as mental and emotional challenges of a cancer diagnosis and how these might be addressed. The last session will be a summary of topics and a discussion on the long-term impact of cancer, information on survivorship and life after cancer, including return to work/studies, how to manage adverse effects of treatments, mood changes, sleeping, nutrition, relationships, sexuality, work, career, and education, starting a family, and financial support. The same HCP who facilitated the sessions will participate in the walks with the groups and will be available for further informational support. If some participants experience growing anxiety or distress due to the topics covered in the sessions, HCPs will guide them towards professional help for managing their distress.

Online physical exercises

Online 30-minute resistance exercise sessions will be held with young adults twice a week for 12 weeks. Caregivers may choose to participate in the exercises if they wish. Participants will receive recorded sessions at the beginning of the programme and will have the option to either join live group exercise sessions at a designated day and time or perform the exercises at their convenience by watching pre-recorded videos. Participants will be encouraged to repeat the exercises at home using these videos at least one more time each week. They will be asked to record the number and duration of exercise sessions they completed.

Follow-up discussions will be held during weekly walks or interactive sessions to address any challenges participants encounter while exercising and to promote consistent participation. A physiotherapist or exercise physiologist will design exercises specifically for cancer patients and create three pre-recorded videos, each featuring a different workout routine targeting specific muscle groups along with recommendations around the number of repetitions and how to increase these over time.



STUDY COMPONENTS	STUDY PHASES													
	Pre-intervention data collection	Intervention 12 weeks												Post-intervention data collection
	12 weeks	1	2	3	4	5	6	7	8	9	10	11	12	12 weeks
Pre-intervention questionnaire	🟪													
Guided group walks		🟦	🟩	🟦	🟩	🟦	🟩	🟦	🟩	🟦	🟩	🟦	🟩	
Online exercises x 2 /week		🟧🟧	🟧🟧	🟧🟧	🟧🟧	🟧🟧	🟧🟧	🟧🟧	🟧🟧	🟧🟧	🟧🟧	🟧🟧	🟧🟧	
Interactive psychoeducation sessions		🟨					🟨						🟨	
Post-intervention questionnaire														🟪

Figure 3. Diagram of the MELODIC intervention components and schedule

Tailoring of the intervention.

The intervention delivery sites will follow a standard intervention delivery guide. While this will support consistent delivery of the intervention in six sites, minor changes are expected in each site due to the nature of each intervention site and local context and circumstances. All tailoring, adaptations, and deviations will be recorded and reported transparently at the local level, describing the rationale for it, timing, and details of the changes.

Modifications to the intervention, adherence, and fidelity

Any changes to intervention during the course of the study, will be documented and described in detail (what, why, when, and how). Adherence to the intervention and fidelity assessments will be conducted by monitoring the tailoring, adaptations, and deviations reported by the local intervention delivery sites. Strategies to be used to maintain or improve fidelity include the intervention delivery guides (*Attachments XXX*) and ongoing reporting and monitoring of the intervention delivery at local and central levels.

Outcomes

The anticipated primary outcomes for young adults with a lived cancer experience and caregivers include improved mental health, specifically a reduction in symptoms of psychological distress, anxiety, and depression. The secondary outcomes will focus on enhanced general wellbeing and quality of life. These primary and secondary outcomes will be achieved through participation in the active ingredients of the intervention: psychoeducation, physical activity in natural surroundings, and online physical exercises. The active ingredients of the intervention are expected to lead to increased social connectedness, peer support, and reduced social isolation through interactive psychoeducation sessions, group walks, and participation in group online physical exercises. Furthermore, improvements in physical activity patterns and a reduction in fatigue are expected outcomes of the physical activity components, including guided group walks and online exercise sessions (Figure 2).

***Primary outcomes** – mental health status*

The mental health status of YAs and caregivers will be measured by the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS). The Distress Thermometer will be used to measure the distress levels of participants.

***Secondary outcomes** – general wellbeing and quality of life*

Coping abilities - the YAs' confidence in their ability to cope with the demands of cancer, including managing symptoms, treatment, and other related challenges will be measured by using a 'cancer-specific' version of the General Self-Efficacy (GSE) Scale.

Quality of life outcome will be measured by using EQ-5D-5L.

Social connectedness – this outcome will be measured using the UCLA 3-Item Loneliness Scale and qualitative questions in pre- and post-intervention questionnaires related to participants' perceptions of social isolation, loneliness, peer support, and other social health-related questions.

The physical outcome measures will assess changes in participants' physical activity patterns and fatigue levels. Physical activity will be seen as a mechanism of change for improving the mental health of participants as an active ingredient of the intervention, therefore quantitative (frequency and type of physical activity) and qualitative (perceptions of participants on physical activity and its impact on mental health and overall health, well-being, and quality of life) questions will be included in both pre- and post-intervention questionnaires. Evidence shows that cancer-related fatigue has been closely associated with depression (DSilva et al., 2023); therefore, participants' fatigue levels will be measured using the Brief Fatigue Inventory (BFI).

Study feasibility

To evaluate the study's feasibility, Case Report Forms (CRFs) (Appendix …) will be completed by each partner. The CRFs include sections on basic study details (title, protocol number, phase, indication), site-specific information (staffing, equipment, space), recruitment details (inclusion/exclusion criteria), and an assessment of operational and budget feasibility. This form will help gather specific data on the study's potential for success at a particular site, focusing on practical, site-level considerations. In addition, the post-intervention questionnaire will include open-ended questions on the study's feasibility (e.g., adherence of participants to the activities, challenges encountered, usefulness of psychoeducation component, etc.).

The MS Forms will be used for the study's online data collection platform, to be uniform across all partners' data. Quantitative and qualitative questionnaires and previously developed and validated instruments (detailed below) will be used for data collection. Translations, language adaptations, and validity and reliability assessments of these instruments will be performed by the project partners if the instruments are not readily available in their local language.

Data will be collected at two time points: baseline and immediately post intervention using the MS Forms platform and will be stored on a two-factor authentication SharePoint. The Irish partner (University of Galway) will create links for the local partners, who will complete any language adaptions or translations. The local partners will distribute the link in their national language to their local participants, who will have been provided with a unique identifier number that both the young adults with a lived experience of cancer and their caregivers will include on the forms. Participants' anonymous responses will be returned via MS Forms to the Irish partner only, and the Irish partner will give access to the collated anonymous data to the partners so that they can translate the responses to English for analysis by the University of Galway, who will conduct the analysis for all partners. This will allow for uniformity across the partners, while also supporting cultural/language nuances to be maintained to the greatest extent. A range of quantitative and qualitative questionnaires and previously developed and validated instruments (detailed below) will be used for data collection.

Warwick-Edinburgh Mental Health Wellbeing Scale (WEMWBS) will be used to measure the mental health status of YAs and caregivers. The WEMWBS is a 14-item scale of positively worded statements covering feeling and functioning aspects of mental well-being (Tennant et al., 2007). WEMWBS demonstrates good validity and reliability across diverse populations, as supported by studies showing strong internal consistency (Cronbach's alpha < 0.89), high test-retest reliability (0.83), and a single-factor structure confirmed by factor analysis (Stewart-Brown et al., 2011). The scale accurately reflects population groups, responds to change in various interventions and patient populations, and has a valid and reliable short version, the SWEMWBS, for populations where a shorter measure is needed (CORC, 2025).

The Distress Thermometer **(DT)** will be used to measure the distress levels of YA and caregivers. The Distress Thermometer is the most widely used rapid self-report screening tool for assessing psychological distress in people affected by cancer (Ownby, 2019). It works similarly to a pain scale, asking the individual to rate their distress on a scale of 0 to 10, where 0 is "no distress" and 10 is "extreme distress". An accompanying "Problem List" allows the user to check off specific issues that have been a source of worry, helping to identify causes and inform further support. The DT is an acceptable and useful tool for outcome measure and can be used for enhancing the delivery of structured psycho-oncology care. It may also provide evidence to support the effectiveness of specialist psycho-oncology interventions (Blenkiron et al, 2014). Its validity is supported by findings of good sensitivity and specificity compared to other measures, while reliability is generally supported by consistent test-retest results. The threshold of significance varies between 4/10 and 5/10 with a sensitivity ranging from 0.77 to 0.80 and a specificity from 0.59 to 0.70 (Van Lander et al., 2019).

A 'cancer-specific' version of the General Self-Efficacy (GSE) Scale will be used as a tool to measure YAs' confidence in their ability to cope with the demands of cancer, including managing symptoms, treatment, and other related challenges. While the original GSE measures general confidence in a wide range of life situations, a cancer-specific version tailors questions to the unique issues faced by cancer patients, such as "Coping with Treatment-Related Side Effects" or "Seeking and Understanding Medical Information" (Heitzmann et al., 2011). Cancer Self-Efficacy Scale's validity is supported by its ability to assess self-confidence in self-managing cancer-related problems and its strong correlation with other scales measuring self-efficacy and satisfactory internal consistency, with a reported Cronbach's alpha between 0.75 and 0.95 (Huang et al., 2018).

EQ-5D-5L will be used to measure quality of life of YAs and caregivers. EQ-5D-5L is a widely used, patient-reported outcome measure that assesses health-related quality of life across five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Users answer a short questionnaire by selecting the level of difficulty they experience in each dimension and also rate their overall health on a visual analogue scale. This information is used to inform healthcare decisions, compare health states, and track changes in health over time. The EQ-5D-5L shows good convergent validity, meaning it correlates well with other established health status measures like the SF-36, SF-6D, and the WHO-5 Well-Being Questionnaire. Cronbach's alpha for the EQ-5D-5L has been reported as excellent (e.g., 0.79) (Dams et al., 2021).

The UCLA 3-Item Loneliness Scale will be used to measure the social connectedness levels of YAs and caregivers. This brief instrument has been widely used in public health and psychosocial intervention studies, is validated across multiple European languages, and effectively captures perceived social connectedness in pre- and post-intervention assessments. shows good reliability and validity, particularly with high internal consistency and temporal stability. Its reliability is supported by Cronbach's alpha values 0.81-0.89, and test-retest reliability is good, with correlations around 0.71. For validity, this tool demonstrates concurrent validity through significant correlations with other loneliness measures (Alsubheen et al., 2023; Katsiroumpa et al., 2025).

The Brief Fatigue Inventory (BFI) will be used to measure YAs' physical activity patterns. The Brief Fatigue Inventory (BFI) is a short, self-administered questionnaire used to measure the severity of fatigue and its impact on daily life in cancer patients (MDAnderson Cancer Center, 2025). It consists of nine items; each rated on a 0–10 scale and is designed to be completed in under five minutes. The tool assesses both the patient's current level of fatigue and how much it has interfered with various activities over the past 24 hours, such as general activity, mood, walking, work, and relationships. The BFI has shown adequate values of internal consistency (α Cronbach = 0.94), substantial reliability [$ICC_{2,1}$ (95% CI) = 0.87 (0.81 to 0.91)] and very good agreement (standard error of measurement = 1% and MDC90% = −0.37) (Nunes et al., 2019).

Since the selected outcome measurement instruments (e.g., WEMWBS, EQ-5D-5L, GSE, BFI) are validated self-report measures suitable for use in adult populations, they will be self-administered. Local staff will be available to assist participants with any technical issues or clarifications during online questionnaire completion, while the participant responses should remain independent.

In order to address the potential lack of change in the outcome measures and to capture the qualitative aspects of participants' experiences, we will incorporate open-ended questions to the data collection materials. These questions will focus on participants' perceptions of the intervention's effectiveness and its components, assessing their usefulness or lack thereof. This approach will provide valuable insights alongside the quantitative data.

Assignment methods and blinding

Participants will be assigned individually to the intervention. No restrictions, such as blocking, stratification, minimisation, are planned regarding the assignment of units to study condition, i.e., YAs with cancer diagnosis. There will be no randomisation or matching of participants, and all eligible participants will be assigned to the intervention.

Data analysis

Unit of analysis will be based on assessing the impact of the intervention at the individual level. Statistical methods will be employed to provide a descriptive analysis of the baseline and follow-up data. If permitted by the data, regression analyses will be performed. Subgroup analyses and adjusted analyses will be performed as needed. Intention to treat (ITT) principle will be followed for inputting missing data for the two pre- and post-intervention data collection points, using their last available data (Sainani, 2010). The characteristics of the data of the participants who did not take part_in the post-intervention data collection will be analysed and presented. IBM SPSS 27 statistical analysis package programme will be used for data analysis.

Ethics

Ethics approvals will be obtained from the local research ethics committees in the participating six countries. All participants will be required to give informed consent before participating in the study. They will be provided with the study materials in advance before making any decisions regarding participation. They will have time to think about their participation for at least seven days. The participants will have the right to withdraw from the study without giving any reason and this will not lead to any consequences.

Data management plan

Principles of data collection: Personal data (age, gender, health-related data, address, phone number) will be collected locally in a way that limits the negative impact on the participants. The participants' addresses will be collected to identify suitable local green and blue spaces where the walks will take place. Microsoft Forms will be configured to ensure that responses are not associated with participants' email addresses. People with cancer and caregivers can be seen as a vulnerable patient group due to the severe health situation and thus, require a sensitive approach and the ability to emphatically recognise the situation at hand. Extra psychological harm must not be delivered to them, nor to their close family members. Data will be collected in a way that ensures fairness, transparency, and accountability of the data processing, data quality, and confidentiality. Personal data will be collected, analysed, stored, and shared in full compliance with European (i.e., GDPR

2016 requirements) and national legislation, conventions, declarations, and manuals relevant to the country of the data collection taking place. Data collection will be based on informed consent from the participants. Data collected will be used only for the purposes of the current project. No data that is not strictly necessary to complete the current study will be collected. All partners will be asked to work with their local Data Protection contact person responsible for overseeing all personal data processes on that research site.

Processing and storing of data: There will be two types of data for processing and storing. The pre-post online questionnaires (including the outcome measures, e.g., Distress Thermometer, etc.) will be collected anonymously using unique identifiers via Microsoft Forms and stored and processed in Ireland at University of Galway. The pre-post intervention questionnaire data will be stored in multi-factor authenticator password-protected SharePoint folders in the Irish study site, University of Galway. The project partner teams will be given access to their collated anonymous data for translation into English from their local languages so that the University of Galway team can perform the data analysis for the whole data collected from six countries. The consent forms to take part in the intervention and key/code list with participant personal and contact details will be obtained and stored locally by each partner country. No individual participants will be identifiable in the reports produced from the study. Ultimately, all non-personal data will be freely available as an open anonymised resource for further research.

Data storage and security: The consent forms to take part in the intervention and key/code list with participant details will be obtained and stored locally by each partner country in password-protected SharePoint folders. The pre-post questionnaire data will be stored in multi-factor authenticator password-protected SharePoint folders in the Irish study site, University of Galway. After data processing, partners will have access to their collated anonymous data for translation purposes, and they will be required to comply with EU and national data protection legislation and best practices for data security. University of Galway institutional policies will be followed for data storage, protection, retention, and destruction, in line with GDPR 2016 regulation. In line with the University of Galway data retention policy, the data will be retained securely for 7 years via multi-factor authenticator password-protected SharePoint folders of the Irish project team members. Details of local arrangements for protection will be supplied by each partner based on their institutional policies. Details of such arrangements will be presented by each partner when applying for ethical approval to the local ethics committee.

Confidentiality and privacy: When applying for ethical approval, partners will be required to supply detailed information on how privacy and confidentiality will be ensured for participants' data. Before consent is obtained from participants and before the data collection starts, project personnel must inform participants of the purpose for which personal information provided will be used, any potential risks related to confidentiality or anonymity of personal data, which individuals will have access to personal data, and under what circumstances such access will be granted.

Risks to participants

Although minimal, there is a risk of injury, discomfort or distress during the walks in green and blue spaces and online physical exercises. The participants will self-declare their fitness. Prior to the intervention, the PAR-Q, Physical Activity Readiness Questionnaire, will be used as a screening tool for physical activity eligibility assessment and presence of any contraindications, and if any issues are found, the participants will be advised to seek advice from a doctor. The exercise sessions will be developed by qualified physiotherapists or exercise physiologists who are trained to develop exercise programmes for cancer patients. Group walk facilitators will be provided by 'MELODIC WP4 - Guidelines for Group Walk Facilitators' (Appendix ....) to assist them with preparation and facilitation of the group walks safely. For example, a risk assessment using a standard tool will be conducted (e.g., Unit Risk Assessment Methodology https://www.universityofgalway.ie/media/healthsafety/Part-3---Unit-Risk-Assessment-Methodology-2022.pdf). In case some of the participants experience growing anxiety or distress during the group walks or the interactive lessons, HCPs can guide them to get professional help to manage distress. In addition, there will be a distress protocol in place to be used by the facilitators (if needed) during the group walks and interactive lessons.

Incentives

To support participants and increase compliance with the intervention activities, minor incentives such as refreshments, items with the MELODIC project logo (e.g., T-shirts), where applicable, entrance tickets to a national park or botanical garden, etc., will be budgeted and provided locally.

Benefits of the study

The expected benefits to YAs with a lived cancer experience and caregivers will include improved mental health, specifically a reduction in symptoms of psychological distress, which may lead to enhanced general wellbeing and quality of life. The social benefits may include increased social connectedness and peer support and reduced social isolation. Additionally, by taking part in the intervention, the participants may improve their physical activity patterns, and their fatigue levels may be reduced.

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