MELODIC

Mental Health Support for Young Adults with Cancer

Project Number: 101101253

WP2: Needs assessment

Deliverable 2.2: Survey report

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Version	Date	Comments	Modified by
V1.1	03.10.2025	The deliverable updated according to the comments from THCC.	WH Oldenmenger, S Morsink, L Kranenburg

Executive Summary

In the first phase of the MELODIC project, the mental health needs of young adults with a lived cancer experience and their family members are explored by using a qualitative research approach through conducting interviews. In addition, health care professionals working with people with lived experience of cancer will be interviewed to explore their perceptions on mental health needs of these young adults. In the same period, a survey study will be conducted to identify the educational needs of healthcare professionals working in cancer units and/or mental health services.

Deliverable 2.2. focuses on the survey report. Next to the study protocol, the approval from the Medical Ethical Committee of the Erasmus MC and the questionnaire, also the process of data collection is described in this document. Finally, an overview of the main outcomes is presented.

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1. MELODIC project

This project entitled 'Mental health support for young adults with cancer' (MELODIC) aims to promote mental health and wellbeing of young adults (YA) with lived experience of cancer and their family/caregivers by improving screening, early detection and efficient and person-centered management of mental health needs during the first year post-cancer diagnosis.

Specifically, MELODIC will:

1) examine mental health needs of YAs with lived experience of cancer and their family members /caregivers,
2) examine the training needs of Health Care Professionals (HCPs) and develop and implement an online training program for them,
3) implement an intervention which includes physical activity in natural surroundings (green/blue space), with information support for YAs with lived experience of cancer and their family members/caregivers, and
4) develop guidance and practical recommendations for HCPs on how to provide support for YA adults and their family/caregivers with mental health needs.

These objectives will be realized through in-depth information gathered via interviews (YAs with a lived cancer experience, their family/caregivers, and HCPs), and surveys (HCPs). An intervention inspired by social prescribing is developed and tested to support YAs and their families to maintain and improve their mental health and wellbeing. As part of the overall project, in WP3, training for health care professionals will be developed and implemented. In WP4 the natural spaces intervention will be implemented and evaluated. In WP 5 overall project evaluation is conducted.

2. Development study protocol for MELODIC I

The team from Erasmus MC, as the lead of workpackage 2 and consequently the MELODIC I study, created the first draft of the study protocol and discussed this with the co-lead of workpackage 2 and the project coordinator. Afterwards the draft protocol was shared via the project Teams, and all partners were encouraged to give their feedback.

Erasmus MC also led the suvey qustionnaire development. The survey questions focused on the educational needs of HCPs in assessing and managing the mental health needs in YAs with cancer. As there is no already existing validated questionnaire on this topic, the Erasmus MC together with the international research consortium developed the survey based on literature, and clinical expertise of the international consortium members. The initial questions were reviewed by a panel of experts in oncology, psychology, mental health and public health from the consortium, via the project Teams. The most appropriate questions were selected by consensus, based on their relevance to the research question and their clarity. The final questions were refined and simplified to a B2 English level, so that all potential participants were able to understand all the items. To increase the validity and reliability, a small purposive sample of HCPs from the different countries have tested the questionnaire. Feedback was sought on general impressions of the survey, clarity of wording, biased or problematic questions, logical structure and any potential concerns about navigation or physical completion of the questionnaire. The questionnaire was adapted as appropriate based on this feedback (Appendix 4).

After the online discussions and agreement from all partnerts, the final version of the protocol and questionnaire was approved by the Medical Ethical Committee of the Erasmus MC on February 6th 2025 (Appendix 1, 2, 3).

During the meeting in Rotterdam, the process of the dissemination of the survey was discussed and agreed (Appendix 5).

3. Dissemination strategy

During the meeting in Rotterdam the dissemination strategy was discussed.
The survey was conducted online and anonymously via the Castor platform. Participants were invited to participate in the survey through general emails and newsletters from our consortium partners, such as the European Cancer Organisation, through consortium members and promoted through professional social media networks, like LinkedIn. With this strategy we had the opportunity to reach many of the healthcare professionals working in cancer care in Europe.

A concept email and message were developed that all partners could use to disseminate the survey (Appendix 5). Potential participants were able to read further information about the study and a consent form to participate in the study. Participants were able to consent to participate after reading the participant information. The survey was anonymous, and participants were only asked general, non-identifiable demographic variables that are not identifiable, and questions about clinical practice in their region.

4. Main outcomes

The **main endpoint** of the survey was to get an insight into the educational needs of HCP involved in the management of young adults with cancer, with regard to:

- Mental health screening among young adults with cancer
- Support of mental health problems of young adults with cancer

The survey was open for inclusion from May until August 2025. In total 271 HCP completed the survey for at least 70% and 183 HCP completed all items of the survey. A typical respondent was >45 years old (46%), female (85%), nurse (40%) or medical doctor (26%), working in a public cancer center (31%) or public university hospital (31%) in Greece (21%), France (17%), Portugal (14%) or Ireland (10%), with >10 years of working experience (58%) (Tabel 1).

Table 1.Socio-demographic characteristics

		N=271 N (%)
Age*	<25 years	18 (6.6)
	25-34 years	47 (17.3)
	35-44 years	81 (29.9)
	45-54 years	84 (31.0)
	55-64 year	32 (11.8)
	>65 years	8 (3.0)
Gender	Male	37 (13.7)
	Female	230 (84.9)
	Non-binary	1 (0.4)
	Do not want to disclose	2 (0.7)
Country	Greece	56 (20.7)
	France	46 (17.0)
	Portugal	38 (14.0)
	Ireland	28 (10.3)
	Estonia	24 (8.9)
	Netherlands	23 (8.5)
	other	56 (20.7)
Work setting		
	Public cancer center	85 (31.4)
	Public University hospital	84 (31.0)
	General public hospital	54 (19.9)
	Private cancer center	21 (7.7)
	other	27 (10.0)
Profession	Nurse	109 (40.2)
	Medical Doctor	69 (25.5)
	Psychologist	23 (8.5)
	Health Visitor	21 (7.7)
	Social worker	9 (3.3)
	Community health scientist	4 (1.5)
	Spiritual/ religious counselor	2 (0.7)
	other	34 (12.5)
Experience*	<1 year	15 (5.5)
	1-5 years	56 (20.7)
	5-10 years	42 (15.5)
	10-20 years	87 (32.1)
	>20 years	70 (25.8)

Current practices

205 respondents completed this part of the questionnaire. Overall, 60% of the respondents believe that they are capable to screen for the presence of distress in YA, and 54% also do this regularly in daily practice. A quarter of the respondents think they are able to use brief screening tools, however, only 13% actually do this and around 38% does perform a comprehensive assessment whenever someone screens positive for distress (Table 2).

Around half of the respondents think they can screen for anxiety in YA, and 42% do this. Only 9% use validated questionnaires or tools for this. For depression around a third of the respondents think they can screen for depression in YA and do this also in daily practice. Twenty-three percent of the respondents think they can use validated questionnaires or tools for this, but 9% actually made use of validated questionnaires in daily practice (Tabel 2).

Half of the respondents do discuss mental health in YA in their practice, 46% think they can discuss health lifestyle. However 60% of the respondents reported to do this in their daily practice. Exercise and social activities are discussed by 60%. Around 45% of the respondents think they can discuss Green and Blue spaces, but 32% actually do this. Finally, sixty-four percent of the respondents think they can refer YA to mental health professionals and 58% of all respondents indicated they also do this (Table 2).

Table 2. Current practices

	I think I can do this					I do this				
	Not at all	Not sufficient	More or less	Sufficient	Good	Never	Rarely	Occasionally	Frequently	Always
1.Do you screen for the presence of distress in young adults with cancer?	7 (3.4)	19 (9.3)	56 (27.3)	76 (37.1)	47 (22.9)	16 (7.8)	23 (11.2)	45 (22.0)	79 (38.5)	42 (15.5)
2. When you screen for distress in young adults with cancer, do you use brief tools such as Distress Thermometer, ESASr etc.?	50 (24.4)	45 (22.0)	49 (23.9)	31 (15.1)	23 (11.2)	93 (45.4)	44 (21.5)	34 (16.6)	18 (8.8)	8 (4.0)
3. When young adults with cancer screen positive for distress, do you perform a comprehensive assessment to identify the sources, nature and extent of distress?	17 (8.3)	39 (19.0)	51 (24.9)	48 (23.4)	29 (14.1)	35 (17.1)	37 (18.0)	40 (19.5)	56 (27.3)	23 (11.2)
4. Do you screen for the presence of anxiety/fear of cancer recurrence in young adults with cancer?	11 (5.4)	24 (11.7)	42 (20.5)	65 (31.7)	34 (16.6)	20 (9.8)	29 (14.1)	46 (22.4)	60 (29.3)	26 (12.7
5. When you screen for anxiety in young adults with cancer, do you use a validated questionnaire or tool?	54 (26.3)	33 (16.1)	35 (17.1)	30 (14.6)	22 (10.7)	93 (45.4)	37 (18.0)	27 (13.2)	10 (4.9)	9 (4.4)
6. Do you screen for the presence of depression in young adults with cancer?	17 (8.3)	35 (17.1)	45 (22.0)	46 (22.4)	28 (13.7)	34 (16.6)	33 (16.1)	37 (18.0)	46 (22.4)	22 (10.7)
7. When you screen for depression in young adults with cancer, do you use a validated questionnaire or tool?	60 (29.3)	35 (17.1)	29 (14.1)	26 (12.7)	20 (9.8)	91 (44.4)	39 (19.0)	24 (11.7)	11 (5.4)	7 (3.4)
8. Do you discuss mental health in young adults with cancer in your practice?	5 (2.4)	18 (8.8)	41 (20)	49 (23.9)	54 (26.3)	3 (1.5)	20 (9.8)	48 (23.4)	60 (29.3)	44 (21.5)
9. Do you discuss healthy lifestyles with young adults with cancer?	2 (0.7)	9 (3.3)	31 (11.4)	65 (24.0)	60 (22.1)	2 (1.0)	11 (5.4)	38 (18.5)	74 (36.1)	48 (23.4)
10. Do you discuss physical activity /exercise with young adults with cancer?	6 (1.0)	6 (1.0)	29 (14.1)	63 (30.7)	61 (29.8)	6 (1.0)	15 (7.3)	30 (14.6)	67 (32.7)	56 (27.3)
11. Do you discuss social activities with young adults with cancer?	4 (2.0)	6 (2.9)	33 (16.1)	76 (37.1)	48 (23.4)	6 (3.0)	11 (5.4)	36 (17.6)	77 (37.6)	44 (21.5)
12. Do you discuss visiting nature (so-called green and blue spaces) with young adults with cancer?	13 (6.3)	17 (8.3)	44 (21.5)	58 (28.3)	34 (16.6)	14 (6.8)	34 (16.6)	56 (27.3)	51 (24.9)	16 (7.8)
13. Do you refer young adults with cancer to mental health professionals, such as psychologists?	4 (2.0)	8 (3.9)	22 (10.7)	59 (28.8)	72 (35.1)	6 (3.0)	10 (4.9)	39 (19.0)	72 (35.1)	47 (22.9)

Educational needs in addressing mental health with young adults with cancer

In total, 185 respondents answered this question. On all suggested topics to improve their skills in addressing mental health in YA with cancer, between 50% and 70% of the respondents reported that they need additional training. Most respondents expressed a need for training with regard to the use of screening tools for mental health problems (70%).

Table 3. What do you need to improve your skills in addressing mental health in young adults with cancer?

	Definitely not	Probably not	Maybe	Probably yes	Definitely yes
General theoretical information about mental health in young adults with cancer	6 (3.2)	16 (8.6)	39 (21.1)	70 (37.8)	54 (29.2)
Training in the use of screening tools for mental health problems	4 (2.2)	27 (14.6)	23 (12.4)	63 (34.0)	67 (36.2)
Training in addressing mental health during consultation/ counselling	7 (3.9)	25 (13.5)	35 (18.9)	61 (33.0)	54 (29.2)
Training in addressing social relationships	7 (3.9)	29 (15.7)	49 (26.5)	56 (30.3)	39 (21.1)
Training to learn which mental health problems are typical for patients with cancer	6 (3.2)	31 (16.8)	32 (17.3)	61 (33.0)	50 (27.0)
Training in recognizing early signs of mental health problems	6 (3.2)	23 (12.4)	31 (16.8)	65 (35.1)	55 (29.7)
Training in the use of green and blue spaces to improve mental wellbeing	8 (4.3)	28 (15.1)	47 (25.4)	56 (30.3)	42 (22.7)
Training in the use of physical activity to improve mental wellbeing	12 (6.5)	31 (16.8)	49 (26.5)	51 (27.6)	38 (20.5)
Training in the use of social prescribing	5 (2.7)	23 (12.4)	45 (24.3)	62 (33.5)	44 (23.8)

*not all participants answered these questions

Besides, we asked respondents to score a top 3 of the above-mentioned educational training that would be most helpful for them. The three mentioned topics are related to recognizing and screening. The top 3 is:

1. Using screening tools for mental health
2. Recognizing typical cancer-related mental health problems
3. Recognizing early signs of mental health problem

5. Future

The results of this survey study will be used as input for the development of the educational curriculum (WP3) and the pilot intervention study (WP4). In deliverable 2.4, we will describe this in more detail. At the moment a scientific paper is written. When we submit this paper (probably early 2026) we will also upload it in the EU system.

TEMPLATE RESEARCH PROTOCOL
for non-WMO-applicable research

16-12-2024, version 1

Full title of protocol	‘Identifying educational needs of health care providers related to mental health care for young adults with cancer’
Short title or Acronym	MELODIC-I
Protocol ID / Panama number	13238
Version	1.0
Date	16-12-2024
Coordinating investigator[1]/ Project leader	S. Morsink MD Erasmus MC Department of Psychiatry E: s.morsink@erasmusmc.nl M: 0031-6 24582736
Principal investigator[2] **(in Dutch: hoofdonderzoeker/ uitvoerder)** **<Multicenter research[3]: principal investigator per site>**	Wendy H. Oldenmenger. Erasmus MC Department of Medical Oncology. E: w.h.oldenmenger@erasmusmc.nl Mari Lahti, Turku University of Applied Sciences. Finland. E: mari.lahti@turkuamk.fi Martin Power, University of Galway, Ireland. E: martin.p.power@universityofgalway.ie Joaquim Oliveira-Lopes, Nursing School of Lisboa, Portugal, E: joaquimlopes@esel.pt. Evanthia Sakellari, University of West Attica. Greece. E: sakellari@uniwa.gr. Siret Kivistik, Tartu University Hospital. Estonia. E: siret.kivistik@kliinikum.ee.
Sponsor[4] (in Dutch: verrichter/opdrachtgever)	Erasmus MC
Subsidizing party[5]	HaDEA

Name	**Signature**	**Date**
Sponsor or legal representative: **Head of Department:** *Prof.dr. W.J.G. Hoogendijk,* *department of Psychiatry*		13-1-2025
Coordinating Investigator/Project leader/Principal Investigator: *S. Morsink MD* *Coordinating Investigator*		**16-12-2024**

1. *Coordinating investigator: Investigator who bears the responsibility for the coordination of investigators operating in the various centers participating in multicenter research. Not all multicenter research will have a coordinating investigator. There is no requirement to appoint one. A project leader has the responsibility to develop a research protocol and to complete the study within the predefined goals.*
2. *Principal investigator: Investigator who has the overall responsibility to comply and to complete the study within the predefined goals.*
3. *Multicenter research: as an alternative you can also state that these are specified in the list with participating centers including principal investigator. This separate document with version date must be uploaded under category I1.*
4. *Sponsor: The party that commissions the organization or performance of the research, for example a pharmaceutical company, academic hospital, scientific organization or the investigator's employee. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidizing party.*
5. *Subsidizing party: A party that provides funding for a study but does not commission it*

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List of abbreviations and relevant definitions*

CTA	Clinical Trial Agreement
De novo biobank	A new data, human material or imaging collection
DMP	Data Management Plan
DPIA	Data Protection Impact Assessment
DTA	Data Transfer Agreement
Exception consent	Form Care for data Template, in Dutch: Formulier uitzondering toestemming
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation in Dutch: Algemene Verordening Gegevensbescherming
IC	Informed Consent
IFU	Instruction For Use
MTA	Material Transfer Agreement
NWTC	Non-WMO Review Committee; in Dutch: Niet WMO Toetsingscommissie
UAVG	Dutch Act on Implementation of the General Data Protection Regulation; in Dutch: Uitvoeringswet Algemene Verordening Gegevensbescherming
WMO	Medical Research Involving Human Subjects Act, in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen

**Please add any new definitions that are used in the research protocol*

Summary

Rationale
Cancer is a life-altering event and often has a profound impact on the mental and emotional well-being of those who receive the diagnosis. It may have significant psychosocial consequences, for patients as well as their families. Young adult (YA) cancer survivors are at an increased risk for experiencing mental health issues after cancer treatments, yet many YA cancer survivors might not receive the mental health support they need during their survivorship care.

Objective(s)
The primary objective of this study is to identify educational needs of healthcare professionals (HCPs) related to mental health screening, detection and support of YAs with cancer.

Study type
International cross-sectional survey among HCPs.

Study population
HCPs who are working with YAs with cancer.

Methods
International cross-sectional survey among HCPs.

Burden and risks
No risks. Burden includes the time needed for filling out the survey (10 minutes).

Recruitment and consent
All participants provide written informed consent. All participants can decline the study at any time, without notification of reason(s) for doing so.

1. Introduction and rationale

Cancer is one of the most common diseases in developed societies globally. Cancer affects everyone regardless of age, gender or social status and represents a tremendous burden for people with cancer, families, and societies (EU Cancer Mission). In 2020, 19 million new cancer cases occurred worldwide (Sung et al. 2021) and every year around 3 million people living in the EU are diagnosed with cancer (Bray et al., 2018). The number of cancer survivors is growing every year, with a continuous increase in 5-year survival rates for the most common cancer types in all countries. However, cancer is not only a disease of the elderly as an increase of cancer diagnosis has been identified especially in people under 50 years (Zhao et al. 2023) and in adolescents and young people (AYA). According to De et al. (2021) survival rates among adolescents (A) and young adults (YA) with cancer are improving in the developed countries (Miller et al., 2020). Still, in Europe incidence and mortality vary widely between countries with the highest mortality observed in the Eastern EU countries.

Cancer is a life-altering event and often has a profound impact on the mental and emotional well-being of those who receive the diagnosis (Zebrack et al., 2015; Kaul et al., 2017; Chang & Lai, 2022). It may have significant psychosocial consequences, as well for their closest ones and families (Caruso et al., 2020). YA cancer survivors are at an increased risk for experiencing mental health issues after cancer treatments, yet many YA cancer survivors might not receive the mental health support they need during their survivorship care. Overall, childhood, adolescent, and young adult cancer survivors were in the Lee et al. (2020) study 57% more likely to develop depression, 29% more likely to develop anxiety, and 56% more likely to develop psychotic disorders in the years following treatment compared to their siblings or healthy members of a control group. Young adults are also at a unique stage in their emotional, cognitive, and social development, which cancer often disrupts (Nass et al. 2015). Furthermore, YAs with cancer and YA cancer survivors can face significant mental health challenges throughout their cancer journey that are different to those faced by children and older adults (Tanner et al. 2023).

People with cancer require mental health support throughout the different phases of their cancer journey (Brandenbarg et al., 2019). However, mental health issues of people with cancer are poorly recognized or even minimized by health care professionals (HCPs) (Fernando et al. 2023), as they often consider mental health symptoms as normal reactions to cancer diagnosis. In addition, HCPs lack skills and resources to recognize early signs of mental health problems and how to intervene (Granek 2019). This results in situations where people with cancer lack appropriate support and treatment for mental health issues, relating to poorer care outcomes and hampering engagement to care (Grassi 2017; Duggan 2021). HCPs need to have adequate skills to provide equal, accessible, high quality, effective yet person-centered cancer care (EU4Health programme 2021-2027, European Commission 2020, Cancer Mission; Eu Beating Cancer Plan 2021). Caring for people affected by cancer, including the family and caregivers, is not limited to specialist units. Therefore, all HCPs need basic competencies related to supportive cancer care with communication abilities to encounter people affected by cancer. Developing and sharing knowledge and skills in specific mental health needs of YAs with cancer would enable HCPs to detect problems earlier, intervene appropriately, liaise effectively with colleagues and provide holistic support to people affected by cancer and therefore lead potentially to overall better health outcomes (Nash, 2020). HCPs have a significant role: they are the gatekeepers who should be able to recognize mental health challenges at early stage (Lazenby, 2015). The under-recognition and associated undertreatment of mental health problems of people affected by cancer remains one of the pressing and urgent issues of relevance to young people with cancer and their caregivers/families. The health care professionals (HCPs) need to have adequate skills to provide equal, accessible, high quality, effective yet person-centered cancer care (EU4Health programme 2021-2027, European Commission 2020, Cancer Mission; EU Beating Cancer Plan 2021). There is body of evidence on the benefits of providing psychosocial cancer care as part of standard care in reducing distress and psychosocial morbidity associated with cancer and in fostering a better quality of life during and after treatment, and eventually in increasing survival (Caruso et al., 2020; Niu et al. 2021).

Counselling, psychoeducation, specific forms of psychotherapy, and pharmacological interventions (Mitchell et al., 2018), different combinations of physical activity and social interventions (Bikomeye et al., 2022; Milton et al., 2022) have been developed for people with cancer to alleviate the psychological maladjustment to cancer and treatment (Caruso et al., 2020). As there are evidence-based treatments available for this group, screening, identification and timely access to evidence-based psychosocial approaches for people with cancer must be provided, both in the hospital and in community settings (Lazenby, 2015; Grassi et al., 2018). Furthermore, it is important to identify patients who are most at risk, inform resource allocation, identify patient and institutional barriers to implementation and justify the delivery of a person-centered model of care (Chang & Lai, 2022).

2. Objective(s)

The overall aim of the MELODIC project is to promote mental health and well-being of young adults with cancer, and their family members by improving screening, early detection, and efficient and person-centered management of mental health needs during the first year after their cancer diagnosis.
As a first step in the development of the MELODIC intervention, in this study we will identify the educational needs of HCP in relation to the mental health of YA with cancer.

The primary objective of this study is to identify the educational needs of HCP in relation to mental health screening, detection and support for YA with cancer.

3. Study type

3.1. Study type

☐ Retrospective
☒ Prospective
☐ Combination Retrospective/Prospective

3.2. Single center / Multicenter

☐ Single center
☒ Multicenter

3.3 Check all the applicable boxes

☐ Medical records (re-use of data from healthcare, including AI)
☐ Case report
☐ Re-use data from research
☐ Evaluations of quality of healthcare (retrospective)

☐ Research with additional use of residual material from regular healthcare
☐ Research with re-use of human material from research or existing biobank
☐ De novo biobank
☐ Phase IV research
☐ Healthcare evaluation research (prospective)
☐ Research with medical devices
☐ Research with In Vitro Diagnostic Tests
☒ Other research, describe: survey among HCPs

4. Study population

4.1. Study population

☒ Adults (16 years and older)
☐ Minors (younger than 16 years)
☐ Incapacitated adults (16 years and older)
☐ Incapacitated minors (younger than 16 years)

4.2. Population (base)

The target population will include all HCPs (e.g. physicians, nurses, health visitors/community health scientists, psychologists etc.) working in cancer care who are involved in the management of young adults with cancer. The cohort will include a convenience sample of HCPs approached through European and national professional cancer organisations. The participation in the study is entirely voluntary. The focus of the survey are the HCPs in the participating countries of the MELODIC consortium, however, HCPs from other European countries may also participate. We anticipate that at least 200 HCPs will complete the survey.

4.3. Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- HCPs involved in the management of young adults with cancer
- Providing informed consent

4.4. Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Students involved in the management of young adults with cancer

4.5. Sample size calculation

We anticipate that at least 200 HCPs will complete the survey. This will be enough to get an insight in the educational needs of HCPs.

5. Methods

5.1. Research methods

Using a cross-sectional design, we will undertake an international online survey. This single assessment will take approximately 10 minutes. The survey is developed in the English language.

The survey questions focus on the educational needs of HCPs in assessing and managing the mental health needs in YAs with cancer. As there is no already existing validated questionnaire on this topic, the international research consortium developed the survey based on literature, and clinical expertise of the international consortium members.

Expert review & item selection

The initial questions are reviewed by a panel of experts in oncology, psychology, mental health and public health from the consortium. The number of questions should be as few as possible and as many as necessary. The most appropriate questions are selected by consensus, based on their relevance to the research question and their clarity.

Pretesting

The final questions will be refined and simplified to a B2 English level, so that all potential participants will be able to understand all the items. To increase the validity and reliability, a small purposive sample of HCPs from the different countries will test the questionnaire. Feedback will be sought on general impressions of the survey, clarity of wording, biased or problematic questions, logical structure and any potential concerns about navigation or physical completion of the questionnaire. The questionnaire will be adapted as appropriate based on this feedback.

We will enter the survey into Castor Electronic Data Capture (EDC) and distribute it to a small representative sample of HCPs. We will evaluate the usability of the platform (access, layout), and the content of the survey (interpretability of items and consent statement), and the time taken to complete the survey.

5.2. Standard clinical care versus extra for research

n/a

5.3. Burden and risks

The burden for HCPs consists of completing the questionnaire.

5.4. Medical device(s) / In vitro diagnostic tests

n/a.

6. Incidental findings

6.1. Chance of incidental findings

Is there a chance of incidental findings?

☐ Yes
☒ No

6.2. Procedures

n/a

7. Statistical analysis

7.1 Main study parameters/endpoints

The main study endpoint is to get an insight into the educational needs of HCP involved in the management of young adults with cancer, with regard to:

- Mental health screening among young adults with cancer
- Support of mental health problems of young adults with cancer

7.2 Secondary study parameters/endpoints

n/a

7.3 Other study parameters

n/a

7.4 Analysis

Data will be extracted from Castor EDC and analyzed in IBM SPSS Statistics for Windows (Version 29.0.2.0). Analysis will proceed using summary descriptive statistics, with exploration of between group differences (based on country, profession) analyzed and tested for statistical significance as appropriate by either Students t-tests and Wilcoxon rank-sum tests for continuous variables that are normally or not normally distributed, respectively, or Chi-square tests for categorical variables.

8. Ethical considerations

8.1 Regulation statement

The study will be conducted according to the principles of the Declaration of Helsinki as amended by 75th WMA General Assembly, Helsinki, Finland, Gedragscode Gezondheidsonderzoek 2022 and in accordance with other guidelines, regulations and Acts.

This is a voluntary survey that will collect anonymous data (not related to individual patient care). This study will be submitted for ethical approval by the Erasmus MC Ethics Committee. All data will be captured through Castor Electronic Data Capture Survey platform, which is compliant with European data management practices (GDPR), and all data will be securely stored in Europe.

8.2 Informed consent

Will the subjects be asked for informed consent?

☒ Yes *(Upload Participant Information Letter and Informed Consent)*

☐ No, consent already given in previous study *(Upload Participant Information Letter and Informed Consent previous study)*

☐ No, this research will be performed under the exception consent *(Upload form Care for data Template, in Dutch: Formulier uitzondering toestemming)*

☐ Other (e.g. partly, indirectly) *Please describe the situation.*

8.3 Recruitment and informed consent procedures

Participants will be invited to participate in the survey through general emails and newsletters from our consortium partners, such as the European Cancer Organisation, through consortium members and promoted through professional social media networks. Together this will reach almost all HCPs working in cancer care in Europe. The survey will be online and anonymous. The survey will be conducted through the Castor platform.

The emails will contain general information about the study, the background of the study and eligibility to participate, as well as a general anonymous link to the survey. Potential participants will be able to read further information about the study and a consent form to participate in the study. Participants will be able to consent to participate after reading the participant information. The survey will be anonymous and participants will only be asked general, non-identifiable demographic variables that are not identifiable, and questions about clinical practice in their region.

Exception consent

n/a

9. Handling and storage of data / images / sound recordings / photos / film recordings

9.1 Data / images / sound recordings / photos / film recordings

Data will be collected in Castor EDC and exported into the Erasmus MC research server for further data analysis. All data will be anonymous. All original data exports, analysis files, analysis script, and data dictionaries will be stored on the research server. A separate DMP describes the management of data for the MELODIC project.

9.2 Privacy protection

This is a voluntary survey that will collect anonymous data (not related to individual patient care). This study will be submitted for ethical approval by the Erasmus MC Ethics Committee. All data will be collected through the Castor Electronic Data Capture Survey platform, which is compliant with European General Data Protection Regulation (GDPR), and the Dutch Act on the Implementation of the General Data Protection Regulation, and all data will be securely stored in Europe.

9.3 Handling and storage of data

All data will be collected through Castor Electronic Data Capture Survey platform and exported into the Erasmus MC research portal for further data analysis. All data will be anonymous. In line with Erasmus MC guidelines, data will be kept 10 years after it is collected.

9.4 Handling and storage of images / sound recordings / photos / film recordings

n/a

9.5 Approval of access to data / images / sound recordings / photos / film recordings

n/a

10. Handling and storage of human material

10.1 Human material

No human material is used in this study.

10.2 Check all the boxes which are applicable to the human material origin:

☐ Residual material from regular healthcare

☐ Research (material acquired from a previous study).
Add the reference of the study i.e., MEC-number Erasmus MC.

☐ Re-use of human material from existing biobank
Describe whether the human material originates from research into the same disease.

☐ Other, *please specify*

10.3 Handling and storage of human material

☐ Anonymous, i.e. the material can never be traced back to an individual subject

☐ Pseudonymized/Coded

☐ Identifiable

10.4 Biobank

n/a

10.5 Approval of access to human material

n/a

11. Exchange, sharing or transfer of data and/or human material and/or images

n/a

12. Amendments

Amendments are changes made to the research after a favorable opinion by the NWTC has been given. All amendments must be submitted to the NWTC that gave the favorable opinion.

Substantial amendments must be approved by the Niet WMO Toetsingscommissie before they can be implemented.

13. End of study report

Within one year after the end of the study a final study report will be submitted with the results of the study, including any publications/abstracts of the study.

14. Publication

Do you have the intention to submit the study results in a manuscript for publication in a journal:

☒ Yes

☐ No, *please motivate*

The final study report with the results of the study will be submitted no later than three months after the end of the study.

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16. Attachments

☒ Participant information letter and Informed consent document

☐ Care for data Template – Formulier uitzondering toestemming

☒ Questionnaires

☐ Data Management Plan

☐ Data Transfer Agreement

☐ Material Transfer Agreement

☐ Clinical Trial (Site) Agreement

☐ Other, *please describe*

Information letter for research participants

Educational needs in health care providers related to mental health care for young adults with cancer (MELODIC I)

1. Introduction

Dear colleague,

In this information letter we ask you if you would like to participate in this research project. Participation is voluntary. You are receiving this information letter because you are a health care provider working with young adults with cancer.

This letter tells you what the study is about. You can also read what it means for you if you participate in the study. Are you interested? Then read this information letter carefully. When you agree to participate you can thick the box below.

2. General information

This survey study is part of the European MELODIC project involving six European countries: the Netherlands, Finland, Ireland, Portugal, Greece and Estonia. The Medical Ethics Research Committee of the Erasmus University Medical Centre in the Netherlands has reviewed and approved this protocol.

3. What is the purpose of the study?

Young adults with cancer are at increased risk of experiencing mental health symptoms after cancer treatment. However, young adults may not always receive the mental health services they need as part of the care they receive after cancer treatment.

The aim of this study is to identify the educational needs of healthcare providers in relation to the screening, identification and support of mental health symptoms in young adults with cancer.

4. How does the survey work and what does it mean for you?

This survey aims to identify the educational needs of healthcare professionals working with young adults with cancer. Your participation is not mandatory, but if you choose to participate, please complete this questionnaire. We estimate that this will take approximately 10 minutes.

5. What are the advantages and disadvantages of participating in the study?

There are no (direct) benefits to you from taking part in this study. However, your participation may contribute to a better understanding of the training needs of healthcare providers in the mental health care of young adults with cancer. This may help to improve the care of young adults with cancer in the future.

6. If you do not want to participate or want to quit the study

Participation in this study is completely voluntary. Only if you wish to participate will you sign the informed consent form (Appendix B). You can stop completing the questionnaire at any time.

7. What data do we collect?

As part of this survey, we will ask you to complete a one-time questionnaire which will include questions about:

- Some general demographic data (anonymous);
- To what extent you feel skilled in caring for young adults with cancer in the mental health field;
- What the educational needs are of healthcare professionals in addressing the mental health of young adults with cancer.

8. What do we do with your data?

Why do we collect, use and retain your data?

We collect, use and store your responses to the questions of this survey. We will use the results of this survey to develop a training module for healthcare professionals on managing the mental health of young adults with cancer. In addition, we also want to publish the results of the survey.

How do we protect your privacy?

This survey is anonymous, so we cannot trace any data back to an individual. We store the collected data in a secure location within the Erasmus MC to which only the research team has access.

How long do we keep your data?

We keep your research data for 10 years, as required to our national guidelines.

Can you withdraw your consent to the use of your data?

You can stop answering the questionnaire at any time without submission of the questionnaire.

Want to know more about your privacy?

Want to know more about your rights when processing personal data? See: General Data Protection Regulation (GDPR).

9. Will you receive compensation for participating?

We really appreciate your participation in this study. You will not receive any compensation for your participation.

10. Do you have any questions?

If you have any questions about this study, please contact the coordinating researcher, Sid Morsink, s.morsink@erasmusmc.nl.

Appendix A: Participant consent form

Educational needs in health care providers related to mental health care for young adults with cancer (MELODIC I)

I read the information letter. I was also able to ask questions. My questions were sufficiently answered. I had enough time to decide whether to participate.

- I know that participating is voluntary. I know I can stop answering the questionnaire at any time without submission of the questionnaire
- I consent to the collection and use of my anonymous responses to the questionnaire in the manner and for the purposes specified in the information letter.
- I give permission to keep the demographic data and questionnaire responses for 10 years after this study.

Please tick yes or no in the table below:

I want to participate in this study	Yes ☐	No ☐

Erasmus MC
Universitair Medisch Centrum Rotterdam

Medisch Ethische Toetsings Commissie
Erasmus MC

Niet WMO Toetsingscommissie Erasmus MC

Dr. W.H. Oldenmenger
Afdeling: Interne Oncologie
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Ons kenmerk MEC-2024-0812
Datum 6 februari 2025

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Contact & route
www.erasmusmc.nl

Voorzitter
Prof.dr. H.J. Metselaar

Het secretariaat is geopend
van maandag tot en met vrijdag
van 08.30 uur tot 17.00 uur

Niet WMO verklaring

METC nummer	MEC-2024-0812
Titel onderzoek	Identifying educational needs of health care providers related to mental health care for young adults with cancer (MELODIC I)

Geachte heer, mevrouw,

De Niet WMO Toetsingscommissie Erasmus MC heeft het ingediende onderzoek ontvangen op 20-01-2025.

De commissie heeft beoordeeld of dit onderzoek binnen de reikwijdte van de Wet medisch-wetenschappelijk onderzoek met mensen (WMO) valt.

De commissie heeft alleen de WMO-plichtigheid beoordeeld. Er heeft verder geen inhoudelijke toets van het onderzoek plaatsgevonden.

Omdat er geen medisch-wetenschappelijke vraagstelling is en de proefpersonen niet aan een handeling worden onderworpen of een gedragswijze krijgen opgelegd, is de commissie van mening dat het onderzoek niet WMO-plichtig is.

Dit onderzoek mag worden uitgevoerd in het Erasmus MC.

Dit oordeel is gebaseerd op de volgende documenten:

C01.-Non-WMO-Research-Protocol-MELODIC I 161224	16-12-2024
E1E2. non-WMO PIF MELODIC I 16122024	16-12-2024
F01. Melodic I survey questionnaire	16-12-2024
K6.-Risicoclassificatie 18-12-2024.pdf	18-12-2024

Als het onderzoek (ook) wordt uitgevoerd in een ander centrum dan het Erasmus MC dient u dit onderzoek daar aan te melden in overeenstemming met de lokale procedure.

Algemene aandachtspunten

De commissie attendeert u erop dat u er zelf voor verantwoordelijk bent dat uw onderzoek wordt uitgevoerd binnen de kaders van de geldende wet- en regelgeving en het beleid in de instelling waar u werkt. Wij wijzen u in ieder geval op het volgende:

- Voor het opslaan en gebruiken van persoonsgegevens moet gewerkt worden in overeenstemming met de Algemene Verordening Gegevensbescherming (AVG). Voor advies of vragen op het gebied van privacy kunt u terecht bij de PCP (Privacy Contact Persoon) van het Thema of het PKO (Privacy Kennis Organisatie).
- Voordat met de uitvoering van het onderzoek in het Erasmus MC gestart mag worden moet er een datamanagementplan zijn. Voor advies of vragen kunt u terecht bij de data stewards of het Research Support Office.
- Onderzoeksgegevens moeten worden vastgelegd in een gevalideerd data capture systeem. Voor Erasmus MC is dit bij voorkeur Castor en in sommige gevallen LimeSurvey/Gemstracker. Voor advies of vragen kunt u terecht bij het Data Capture Team.

Als de opzet van dit onderzoek inhoudelijk wijzigt, dient u dit als amendement in te dienen bij de Niet WMO Toetsingscommissie voor een nadere beoordeling.

De Niet WMO Toetsingscommissie verzoekt u haar betreffende dit onderzoek op de hoogte te brengen van:

- startdatum (datum inclusie eerste proefpersoon en/of start verzameling gegevens/lichaamsmateriaal/beelden)
- einddatum (laatste visite laatste proefpersoon of laatste verzameling van gegevens/lichaamsmateriaal/beelden)
- publicaties en/of eindrapport

Het besluit verliest zijn geldigheid als de start van de uitvoering niet binnen twee jaar na afgifte van dit besluit plaatsvindt.

Met vriendelijke groet,
namens de Niet WMO Toetsingscommissie Erasmus MC,

Spoelstra

Mw.dr. F.M. Spoelstra
Secretaris

To whom it may concern,

The Institutional research review board Erasmus MC (hereafter the Committee) of Rotterdam, The Netherlands, has reviewed the above mentioned research proposal. As a result of this review, the Committee confirms that the rules laid down in the Medical Research Involving Human Subjects Act (also known by its Dutch abbreviation WMO), do not apply to this research proposal.

Please indicate the above MEC-number in every correspondence on this study.

Yours sincerely,

Secretary of the Institutional research review board Erasmus MC

Educational needs in health care providers related to mental health care for young adults with cancer (MELODIC I)

Questionnaire survey

Section	Issue	#	Item	Responses
Demographics	Location	1	What country do you work in?	[scroll down list with all European countries]
	Profession	2	What is your main clinical professional role?	• Nurse Specialisation: [open] • Medical doctor specialisation:[open] • Health Visitor/Community Health Scientist • Psychologist • Social worker • Other
	Setting of work	4	Please indicate in which type of institution you work (if more than one sector please select all that apply) *:	1. Public cancer centre 2. General public hospital 3. Public university-hospital 4. Private cancer centre 5. General private hospital/medical centre 6. Hybrid public and private funding cancer centre/hospital/medical centre 7. Public Research center 8. Private Research center 9. Other:
	Experience		How many years have you been working in your field?*	• 20 years or more • 10 to 20 years • 5 to 10 years • 1 to 5 years • < 1 years
	Age		Can you please indicate to which age range you correspond to:	• <25 years • 25-34 years • 35-44 years • 45-54 years • 55-64 years • >65 years
	Gender		Can you please indicate to which gender you identify yourself*:	• Male • Female • Non-binary • Do not want to disclose

Section I: current practices

	I think I can do this						I do this				
	Not at all	Not sufficient	More or less	Sufficient	Good		Never	Rarely	Occasionally	Frequently	Always
1. Do you screen for the presence of distress in young adults with cancer?											
2. When you screen for distress in young adults with cancer, do you use brief tools such as Distress Thermometer, ESASr etc.?											
3. When young adults with cancer screen positive for distress, do you perform a comprehensive assessment to identify the sources, nature and extent of distress?											
4. Do you screen for the presence of anxiety/fear of cancer recurrence in young adults with cancer?											
5. When you screen for anxiety in young adults with cancer, do you use a validated questionnaire or tool?											
6. Do you screen for the presence of depression in young adults with cancer?											
7. When you screen for depression in young adults with cancer, do you use a validated questionnaire or tool?											
8. Do you discuss mental health in young adults with cancer in your practice?											
9. Do you discuss healthy lifestyles with young adults with cancer?											
10. Do you discuss physical activity /exercise with young adults with cancer?											
11. Do you discuss social activities with young adults with cancer?											
12. Do you discuss visiting nature (so-called green and blue spaces) with young adults with cancer?											
13. Do you refer young adults with cancer to mental health professionals, such as psychologists?											

Section II: educational needs in addressing mental health with young adults with cancer

What do you need to improve your skills in addressing mental health in young adults with cancer?

		Definitely not	probably not	maybe	Probably yes	Definitely yes
1.	**General theoretical information about mental health in young adults with cancer**					
2.	**Training in the use of screening tools for mental health problems**					
3.	**Training in addressing mental health during consultation/ counselling**					
4.	**Training in addressing social relationships**					
5.	**Training to learn which mental health problems are typical for patients with cancer**					
6.	**Training in recognizing early signs of mental health problems**					
7.	**Training in the use of green and blue spaces to improve mental wellbeing**					
8.	**Training in the use of physical activity to improve mental wellbeing**					
9.	**Training in the use of social prescribing**					

Could you rank a top 3 of the above-mentioned educational trainings you think would be the most helpful to you?

- General theoretical information about mental health in young adults with cancer
- Training in the use of screening tools for mental health problems
- Training in addressing mental health during consultation/ counselling
- Training in addressing social relationships
- Training to learn which mental health problems are typical for patients with cancer
- Training in recognizing of early signs of mental health problems
- Training in the use of green and blue spaces to improve mental wellbeing
- Training in the use of physical activity to improve mental wellbeing
- Training in the use of social prescribing

How many hours of training do you estimate you need to improve your skills in addressing mental health?

- None
- 1- 4 hours
- 4- 8 hours
- More than 8 hours

How do you prefer to be trained? (multiple answers possible)

- I prefer to be trained with theoretical information I can study
- I prefer to be trained with group discussions
- I prefer to be trained with reflective practice
- I prefer to be trained with problem solving/ problem-based learning
- I prefer to be trained with clinical cases
- I prefer to be trained with colleagues of the same profession
- I prefer to be trained in a multidisciplinary group

Co-funded by the European Union

MELODIC
MENTAL HEALTH SUPPORT FOR YOUNG ADULTS WITH CANCER

Subject: Request for Collaboration in distributing MELODIC Survey

Dear xxx,

I am writing to you on behalf of the MELODIC project, which aims to promote the mental health and wellbeing of young adults (YA) with cancer and their family members/caregivers.

The MELODIC project focuses on improving screening, early detection, and efficient, person-centered management of mental health needs during the first year post-cancer diagnosis.

Specifically, our project will:

1. Examine the mental health needs of YAs with cancer and their family members/ caregivers.
2. Assess the training needs of healthcare professionals (HCPs) and develop an online training program for them.
3. Implement an intervention that includes physical activity in natural surroundings (green/blue space) with informational support for YAs with cancer and their family members/caregivers.
4. Develop guidance and practical recommendations for HCPs on how to support YAs and their family members/caregivers with mental health needs.

As part of our initial steps, we are conducting a survey to gather valuable insights from HCPs. We believe that your society's involvement in distributing this survey would be instrumental in reaching a broader audience and ensuring the success of our project. We have an approval for the survey from the medical ethical research committee of the Erasmus MC, the Netherlands.

We kindly request your assistance in distributing our survey to your members and affiliates. Your support would greatly contribute to our efforts in enhancing the mental health and wellbeing of YAs with cancer and their families.

Thank you for considering our request. The survey is open from April till end of May 2025. Please feel free to contact me at [Your Email Address] or [Your Phone Number] if you have any questions or require further information.

Yours sincerely,

Possible message of social media:

🌟 **Calling all healthcare professionals working in cancer care!** 🌟

Young adults living with cancer are more likely to have mental health challenges during and after treatment. Unfortunately, they often don’t get the mental health support they need.

We need your help! Our study aims to uncover the educational needs of healthcare providers to better screen, identify, and support the mental health of young adults living with cancer.

To make a real difference, we're conducting a survey among healthcare professionals like you. Your insights will be invaluable in improving mental health care for these young adults.

Are you:

- A healthcare professional working in cancer care?
- Engaged in the treatment of young adults aged 18-39?
- Able to spare just 10 minutes?

If so, please take part in our survey and help us transform mental health support for young adults living with cancer. Your participation can make a world of difference! 🌍
Complete our survey here: Castor EDC

Dissemination Survey

- APRIL: awareness of AYA month

1. The above announcement will be sent to all partners of MELODIC project, with the question to disseminate
2. ECO:

Various networks: quality of life, survivorship;
Social media channels
IPOS, EONS,
Winette de Graaf – Strong AYA (whether they are interested to distribute the survey)

3. EONS: Ask them to make an announcement in their Newsletter and social media channels (@Virpi, is this possible?)
4. Announcement via MELODIC LinkedIn page
    a. Question to all partners to repost it

National strategies

1. Estonia

We can send the announcement to Estonian partners and they will send it further:

a. Estonian Oncology Nursing Society
b. Social media channels
c. Vähikeskused (Siret?)

2. Finland

We can send the announcement to Finnish partners and they will send it further

a. Finnish Oncology Nursing Society - Suomen Syöpäsairaanhoitajat
b. FICANWest – Western Finland Cancer Centre

3. Greece

We can send the announcement to Greek partners and they will send it further:

a. Kapa3
b. Hellenic Health Visitors Association
c. Social media channels

4. Ireland

We can send the announcement to Irish partners and they will send it further:

a. NCCP National Cancer Control Programme – monthly newsletter to all cancer support centres around Ireland
b. NCCP AYA Cancer Service Network
c. IPSON Irish Psycho-Social Oncology Network – monthly newsletter to members

5. Netherland

We can send the announcement to:

   a. Repost the MELODIC post
   b. Dutch Oncology Nursing Society
   c. Network of nurse practitioners oncology and palliative care
   d. Psychosocial oncology?? (Sid and Leonieke)
   e. Intranet (Agora) of Erasmus MC Cancer Institute

6. Portugal

The above announcement will be sent to all three major cancer hospitals in Portugal.

Cancer Care West The West of Ireland Cancer Charity
ESEL Escola Superior de Enfermagem de Lisboa
CIDNUR Centro de Investigação, Inovação e Desenvolvimento em Enfermagem de Lisboa
european cancer organisation
GUIDANCE CENTRE FOR CANCER PATIENTS
Erasmus MC University Medical Center Rotterdam
YOUTH CANCER EUROPE
UNIVERSITY OF WEST ATTICA
TARTU TERVISHOIU KÕRGKOOL TARTU HEALTH CARE COLLEGE
Tartu University Hospital A.D. 1804
TURKU AMK TURKU UNIVERSITY OF APPLIED SCIENCES
OLLSCOIL NA GAILLIMHE UNIVERSITY OF GALWAY
UNIVERSITY OF TURKU
varha The wellbeing services county of Southwest Finland

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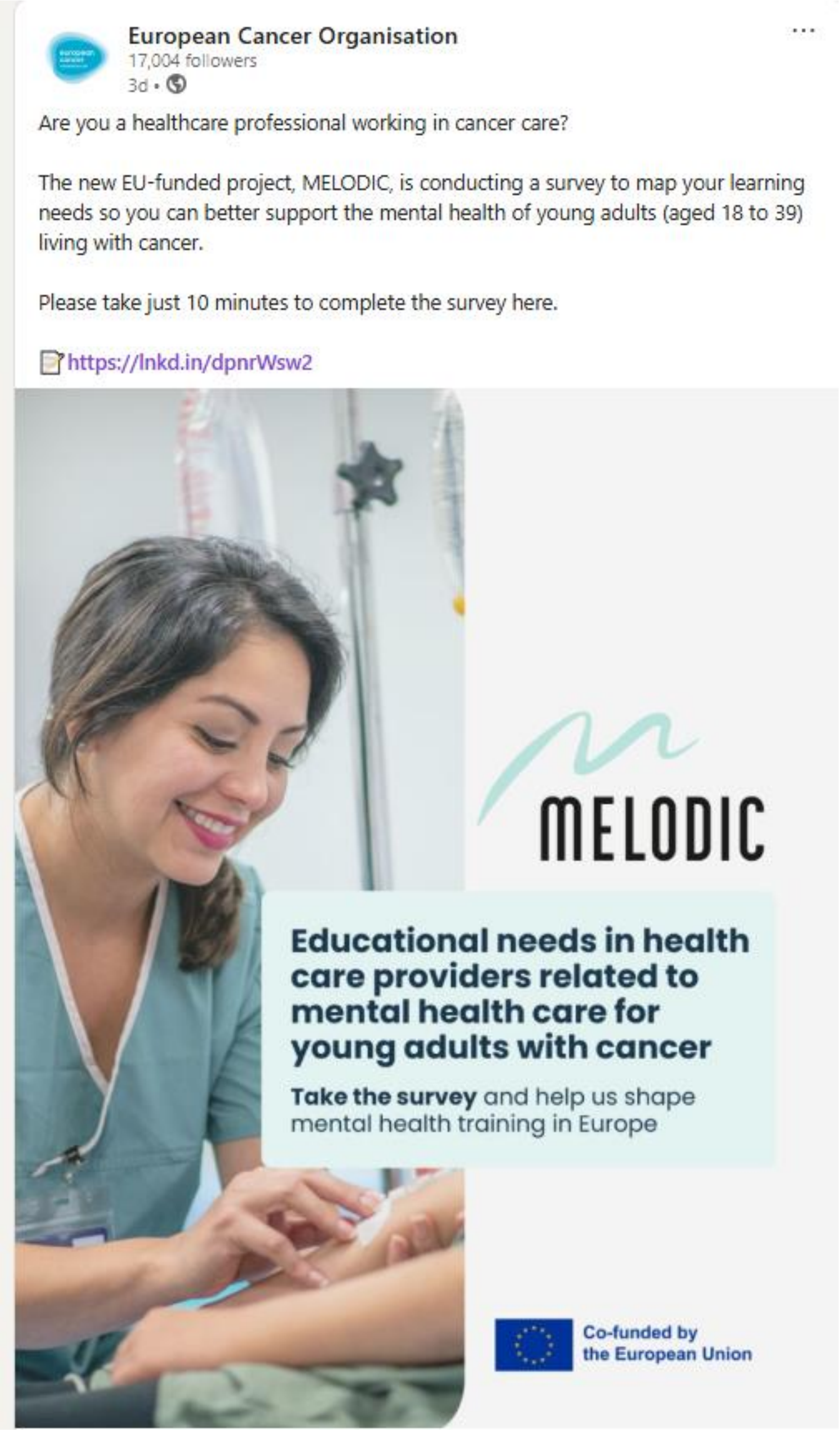

European Cancer Organisation
17,004 followers
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Are you a healthcare professional working in cancer care?

The new EU-funded project, MELODIC, is conducting a survey to map your learning needs so you can better support the mental health of young adults (aged 18 to 39) living with cancer.

Please take just 10 minutes to complete the survey here.

https://lnkd.in/dpnrWsw2

MELODIC

Educational needs in health care providers related to mental health care for young adults with cancer

Take the survey and help us shape mental health training in Europe

Co-funded by the European Union