MELODIC

Mental Health Support for Young Adults with Cancer

Project Number: 101101253

WP2: Needs assessment

Deliverable 2.3: Interview study report

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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 are interviewed to explore their perceptions on mental health needs of these young adults. In the same period, a survey study is conducted to identify the educational needs of healthcare professionals working in cancer units and/or mental health services.

Deliverable 2.3. focuses on the interview study report. Next to the study protocol, the approval from the Medical Ethical Committee of the Erasmus MC and other institutions, the questionnaires, and the process of this study 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 the following steps. First, in WP2 in-depth information is 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 II

Deliverable 2.3. focuses on the interview study report. During the interview study, 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 are interviewed to explore their perceptions on mental health needs of these young adults.

The two main objectives, as described in the protocol, for the interview study are:

a. To examine and identify mental health needs of young adults with cancer and their family members and the perspective of health care professionals on this.

b. To understand how young adults with cancer, their family members and health care professionals wish these needs for mental health support to be addressed.

The team from Erasmus MC, as the lead of workpackage 2 and consequently the MELODIC II 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.

After the online discussions, the face to face meeting in Rotterdam, and agreement from all partners, the final version of the protocol, patient information and interview guide was approved by the Medical Ethical Committee of the Erasmus MC on March 4th 2025 (Annex 1, 2, 3 and 4).

After this the patient information sheet, consent form and the interview guide was translated into the local language of the participating countries, Estonia, Finland, Greece, Ireland, and Portugal before they submitted the necessary documents to their local ethical committee. The approval letters from these ethical committees are included (Annex 5, 6, 7, 8 and 9).

3. Development interview guides

Erasmus MC led the development of the interview guide. As there is no already existing validated questionnaire on this topic, the Erasmus MC together with the international research consortium developed the interview guide based on literature, and the clinical expertise of the international consortium members. Initial questions were reviewed by a panel of experts in oncology, psychology, mental, and public health from the consortium via the project teams. All partners could prepare their feedback based on the content, as well as their local and/ or cultural background in time for the consortium meeting in Rotterdam, the Netherlands. During this meeting, we discussed the entire interview guide and reached a consensus that everyone found acceptable. We also shared a recorded interview (with permission of that person), and discussed this interview during the consortium meeting in Rotterdam. This was an important training exercise to ensure that everyone was on the same page.

The interview guide is based on the research questions:

- What are the experiences, perspectives and needs regarding mental health (support) of young adults with cancer?
    - What are their perceptions on social prescribing and green and blue spaces in relation to their mental health?
- What are the experiences, perspectives and needs of their relatives regarding their mental health (support)?
    - What are their perceptions on social prescribing and green and blue spaces in relation to their mental health?
- What are the experiences, perspectives and needs of health care professionals on this?
    - What are their perceptions on social prescribing and green and blue spaces?

- How do young adults with cancer wish their needs for mental health support to be addressed?
- How do their relatives wish their needs for mental health support to be addressed?
- How do health care professionals think that the needs for mental health support of YA and their relatives are best addressed?

Following the face-to-face meeting the interview guide was adapted and shared via the project teams for final feedback. Once everyone had agreed, we finalized the interview guide. To increase the validity and reliability, a small purposive sample of healthcare professionals from the different countries tested the questionnaire. Feedback was sought on general impressions of the interview guide, the clarity of the wording, any biased or problematic questions, the logical structure, and any potential concerns. The interview guide was adapted as appropriate based on this feedback (see Annex 3).

4. Quality assurance during study

The quality assurance process was initiated during the Rotterdam meeting, where Dr. L. Kranenburg delivered a presentation on qualitative interviewing and its various components. This was important for getting everyone on the same page and avoiding possible cultural bias. Another important aspect was the in-depth discussions about the interview guide during the Rotterdam meeting, as described in Chapter 3. We discussed the entire interview guide and reached a consensus that everyone found acceptable.

From May 2025 onwards, monthly meetings were held for researchers involved in the interview study. All countries were asked to send an anonymized summary of the initial interviews with young adults, family members, and healthcare professionals to the researchers from the Erasmus MC. The Erasmus MC researchers conducted an initial thematic analysis and developed a code tree. This code tree is used for the deductive analysis of the interviews in each country. A more detailed analysis will be conducted by the local teams in their native language.

Every month, the researchers discussed their progress and experiences, and advised each other on how to approach possible candidates.

5. Main outcomes

The (provisional) ethical approval has been obtained in all countries. However, in some countries, an additional data impact assessment is required before full ethical approval can be granted. There is a high degree of variation in how the EU regulations are interpreted in different countries. For example, in Ireland, the data protection officer has not yet given its approval. This means that the inclusion of respondents there has not yet been able to commence (Table 1).

Table 1. Included patients per country

	Young Adults	**Family Members**	**Healthcare professionals**
Estonia	5	2	5
Finland	2	1	5
Greece	5	5	5
Ireland	0	0	0
Portugal	4	0	0
The Netherlands	3	3	5

Per December 17th, we included 19 Young Adults, 11 family members, and 20 healthcare professionals in the interview study. Based on these interviews we have a preliminary overview of the results as shown in figure 1, 2 and 3.

Preliminary analyses showed the mental health impact on YA with cancer and their needs. Having cancer evokes feelings of shock and stress. YA patients feel overwhelmed by the diagnosis, which has a significant impact on their lives and gives them a sense of loss of independence. It also impacted their mental health, causing feelings of anxiety and depression, and diminishing their trust in their body (Figure 1).

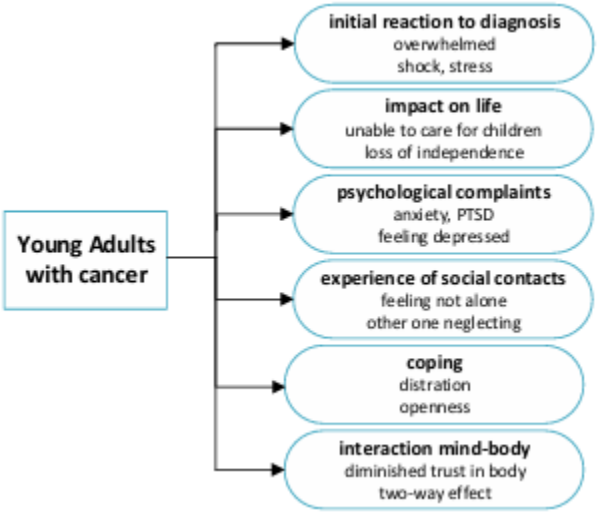

Figure 1. Mental Health Impact of Young Adults

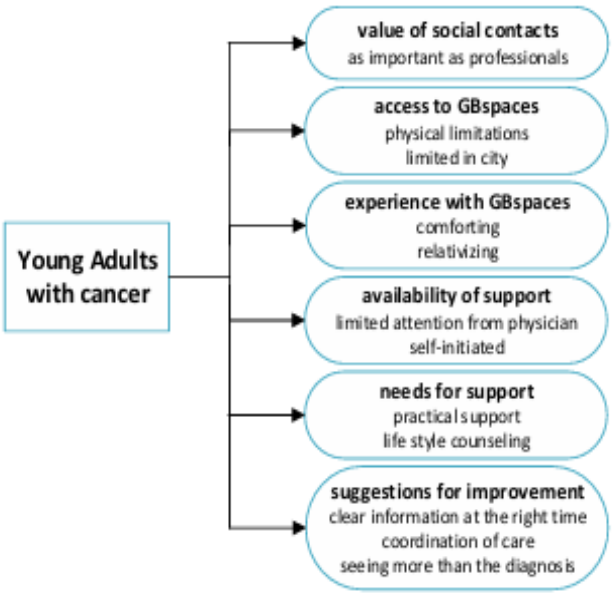

Figure 2. Needs of Young Adults

YA explained that social contacts are as important to them as professionals. They have a need for practical support and lifestyle counselling, which is usually self-initiated. Green and blue spaces are limited in cities and can be difficult to access due to physical limitations. However, when YA did use these spaces, they found them comforting. They suggested that healthcare professionals should provide clear information at the right time during the cancer journey and coordinate care, treating YA as individuals and not just as patients with a diagnosis (Figure 2).

The diagnosis of cancer had an effect on family members too, they said. They went into survival mode, they were very worried about life without their loved one and some were unable to work. They tried to stay strong for their loved one, but found that the support of their social contacts faded over time.

On the other hand, family members also explained that social contact and support from their employer are very important during cancer treatment. Family members had positive experiences of

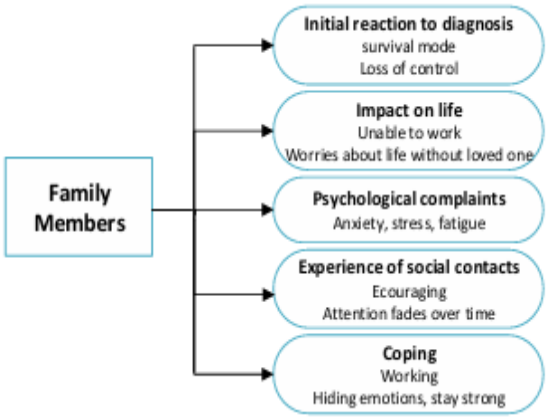

Figure 3. Mental Health Impact of Family Members

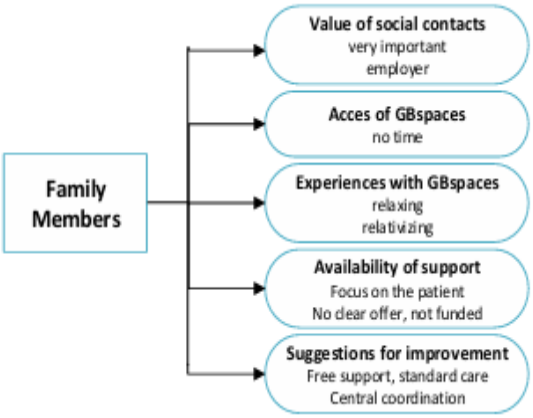

Figure 4. Needs of Family Members

green and blue spaces, finding them both relaxing and helpful for putting things into perspective, but since the diagnosis they have had no time to use them. Family members feel that all support is focused on the patient and that they receive little to no support. They have to organize and pay for it themselves. They suggested that free support should be available for them and that care should be centrally coordinated (Figure 3 and 4).

Healthcare professionals recognize reactions from YA, seeing fear, worry, disbelief, and anger. However, these reactions differ from person to person. Healthcare professionals indicate that prognosis, treatment, gender, and pre-existing psychopathology might influence YA reactions. According to the professionals, cancer diagnosis impacts not only YA patients, but also their family members. Family members are often overwhelmed with practical concerns and questions about fertility and sexuality. Some professionals provide advice and guidance, but most refer YA with mental health issues elsewhere. According to these professionals, the available mental health support for YAs is sufficient; however they acknowledge that mental health support for family members is limited, so they refer them to their general practitioner. Most health care professionals are unaware of social prescribing. They recognize the benefits of green and blue spaces and incorporate them into their daily practice by recommending outdoor activities (Figure 5).

In conclusion, these preliminary results clearly illustrate the mental health impact of a cancer diagnosis on YAs and their families. Healthcare professionals and YAs may perceive the availability of mental health support differently. Green and blue spaces are well-known and appreciated, but some hesitate to use them. Support from employers is very important for family members.

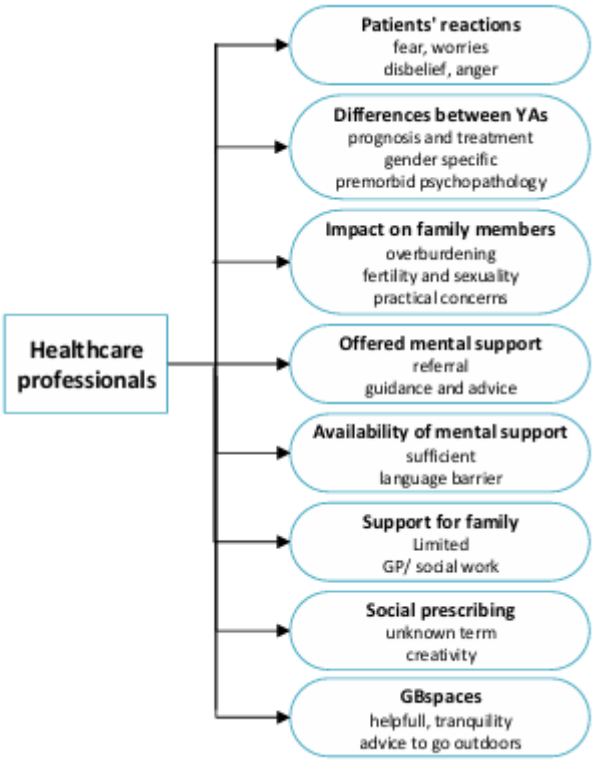

Figure 5. Healthcare professionals

6. Future

The results of this interview 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. When all interviews are conducted, checked and analyzed, a scientific paper will be written. When we submit this paper (2026) we will also upload it in the EU system.

TEMPLATE RESEARCH PROTOCOL

for non-WMO-applicable research

27-02-2025, version1.1

Full title of protocol	'Identifying mental health needs of young adults with cancer, their family members and health care providers'
Short title or Acronym	Melodic-II
Protocol ID / Panama number	13239
Version	1.1
Date	27-02-2025
Coordinating investigator[1]/ Project leader	S. Morsink MD Erasmus MC Department of Psychiatry E: s.morsink@erasmusmc.nl M: 0031-6 24582736
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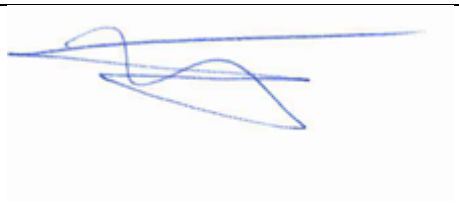
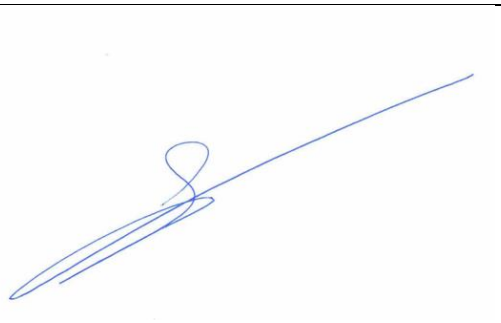
Sponsor[4] (in Dutch: verrichter/opdrachtgever)	Erasmus MC
Subsidizing party[5]	HaDEA

Name	Signature	Date
Head of Department: *Prof.dr. W.J.G. Hoogendijk,* *department of Psychiatry*		**03-03-2025**
Coordinating Investigator/Project leader/Principal Investigator: *S. Morsink MD* *Coordinating Investigator*		**27-02-2025**

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
With cancer incidence increasing over time worldwide, attention to the burden of psychosocial and psychiatric consequences of the disease is now needed from both cancer and mental health care professionals. Screening for mental health is important among cancer survivors; however, it needs to be better integrated into active cancer treatment and survivorship. Young adults have reported specific unmet needs during treatment and in their transition into survivorship.

Objective(s)
To examine and identify mental health needs of young adults with cancer and their family members and the perspective of health care professionals on this.

Study type
Multicenter interview study.

Study population
Young adults who are diagnosed or have been diagnosed with cancer, including cancer survivors, their relatives/family members and their health care providers.

Methods
Semi-structured interviews are applied and analyzed. A short summary of each interview, in English, will be delivered by each participating country, to enable comparison of interviews and supports the coding process in the international collaborative team. Based on these summaries, the Dutch research team will develop an initial coding tree in English. Using this initial coding tree, the researchers in the different countries will analyze their own interviews in the original language (to avoid loss of information). After that, the Dutch research team will systematically apply cross case/ country thematic analysis and integrate and describe the themes and categories into a meaningful structure, fitting the European perspective.

Burden and risks
There are no expected risks of participating in this study and the burden of participants should be minimal by performing one single interview (online when preferable by the participant).

Recruitment and consent
All participants provide written informed consent. Participants have the right to withdraw from the study at any time, without providing 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, HPCs 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 centred 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.

With cancer incidence increasing over time worldwide, attention to the burden of psychiatric and psychosocial consequences of the disease is now needed from both cancer and mental health care professionals (Caruso et al. 2020). Physical health and symptoms directly affect mental health, and vice versa. Screening for mental health is important among cancer survivors; however, it needs to be better integrated into active cancer treatment and survivorship. The mental health issues of people with cancer needs to be addressed not only at first diagnosis and during active treatment but also throughout the continuum of survivorship care (Naughton & Weaver, 2014). YAs have reported specific unmet needs during treatment and in their transition into survivorship. Most cited unmet needs are psychosocial, and information needs such as support from family and friends, psychological counselling receiving age-appropriate information from services and Internet sites and meeting peers and cancer survivors (Dyson et al., 2012).

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 to develop the intervention, insight into the mental health needs of young adults with cancer and to understand how to address these needs is needed.

The primary objective of this study is to gain insight into the mental health needs of young adults with cancer, their family members and health care professionals from six European countries: Estonia, Finland, Greece, Ireland, Netherlands, and Portugal.

a. To examine and identify mental health needs of young adults with cancer and their family members and the perspective of health care professionals on this.
b. To understand how young adults with cancer, their family members and health care professionals wish these needs for mental health support to be addressed.

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: qualitative interview study

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)

a. Young adults who are diagnosed or have been diagnosed with cancer
b. Family members or relatives of young adults with cancer
c. Health care professionals (e.g. physicians, nurses, health visitors/community health scientists, psychologists etc.) who are involved in the management of young adults with cancer.

4.3. Inclusion criteria

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

a. Young adults
   - Being diagnosed with cancer
   - Age between 18 and 35 years
   - In their first year after the diagnoses of cancer
b. Family member
   - A family member of a young adult who meets the above criteria
c. Health care professional
   - Health care professionals who are involved in the management of young adults with cancer

4.4. Exclusion criteria

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

Patients, family members or health care professionals who are 1) diagnosed with cognitive impairment, and/ or 2) unable to provide informed consent and/or 3) unable to communicate in the native language of the local research teams or sufficient English.

4.5. Sample size calculation

Purposive sampling will be used to recruit participants. This means that maximum variation of participants will be included to ensure broad and in-depth exploration of mental health needs. Interviews will be conducted to get an insight into mental needs and how these needs should be addressed. To get a comprehensive understanding of the phenomenon in question, often referred to as data saturation, in general 10-20 interviews are needed (Sandelowski 1995). For this study

we aim to include 5 young adults with cancer, 5 family members, and 5 health care professionals per county, resulting in a sample of 30 young adults with cancer, 30 family members and 30 health care professionals.

5. Methods

5.1. Research methods

Data will be conducted using semi-structured interviews.

The interviews will be performed with (a) young adults with cancer, (b) family members or partners of young adults with cancer, and (c) health care professionals.

The interviews will be performed in six European countries in the native language or, when preferred, in English. An interview guide will be used to ensure coherent and structured data collection. The interview guide is based on literature and the clinical expertise of project team members. The semi-structured form of interviewing also offers the possibility to ask participants to elaborate on their answers to allow for more detailed information (Greem & Thorogood, 2018).

The interview guide will be translated into five languages relative to the population per country to optimally support the interview process as well as providing clear and comparable meaning from the questions in all participating countries.

Researchers from the six participating countries will be trained by experts in qualitative research. During a face-to-face meeting in the Netherlands, the methods of qualitative data collection and analysis will be discussed, ensuring comparable data collection and methods for the participating countries (Whiting 1987; Dierckx de Casterle et al. 2012). Before this meeting, each research team will conduct one pilot interview to test the interview guide. If necessary, the interview guide will be adjusted.

Before the start of the interview, participants will be asked if they have questions concerning the information letters and informed consent forms. When participants have no questions and informed consent is signed, participants will be asked to complete the data collection form with demographic characteristics. When the participant has finished the form, the interview will start, and the interview guide will be followed. Data will be summarized during the interview by the researcher to check whether the information has been interpreted correctly. This form of member check will be used to correct errors in interpretations (Hoffart 1991). In addition, field notes will be used to document contextual information during the interviews, which can be helpful during further data analysis (LaDonna et al. 2021).

Interviews will be held in the participants' preferred setting, for example at the health care setting or online using MS Teams. The estimated duration of the interview is 30-60 minutes. Interviews will be digitally recorded and transcribed verbatim in the original language before data analysis.

5.2. Standard clinical care versus extra for research

n/a

5.3. **Burden and risks**

There are no expected risks of participating in this study and the burden of participants should be minimal by performing one single interview (online when preferable by the participant). Participants who might be at risk of mental problems during the interviews are encouraged to look for help with this and informed of the ways to do so.

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 mental health needs of the young adults and family members will be addressed with qualitative analysis (thematic content analysis).

7.2 **Secondary study parameters/endpoints**

Participants' wishes for addressing their mental health needs will be addressed with qualitative analysis (thematic content analysis).

7.3 **Other study parameters**

Basic characteristics (age, gender, type of cancer and cancer treatment; and in case of family members: relationship to the subject diagnosed with cancer; and in case of caregiver: profession/occupation, year of work experience) will be analyzed with descriptive statistics.

7.4 **Analysis**

The preparation of the coding process will be performed in the original language of the interviews by the country specific teams. A short summary of each interview, in English, will be delivered by each participating country, to enable comparison of interviews and supports the coding process in the international collaborative team. Based on these summaries, the Dutch research team will develop an initial coding tree in English. Using this initial coding tree, the researchers in the different countries will analyze their own interviews in the original language (to avoid loss of information). After that, the Dutch research team will systematically apply cross case/ country thematic analysis and integrate and describe the themes and categories into a meaningful structure, fitting the European perspective (Braun & Clarke, 2006). Adequate software such as NVivo12, will be used when necessary to support the data analysis.

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, October 2024, Gedragscode Gezondheidsonderzoek 2022 and in accordance with the EU GDPR (General Data Protection Regulation). This study will be submitted for an independent local quality review (non WMO) to ensure compliance with legislation and regulation requirements, including informed consent procedures, data management, and privacy and legal conditions and an ethical review from an accredited ethics committee in The Netherlands. Subsequently, this protocol will be submitted for ethical review in all participating countries.

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

To be able to include young adults with cancer, their family members, and health care professionals involved in the care for young adults with cancer, the following steps are followed:

A. As a first step in approaching eligible participants, clinicians will be informed about the study. Information about the aim, data collection, outcome measures and the way of including participants will be presented. For each partner, the optimal procedure for patient recruitment will be established.

B. When it is not possible to approach possible participants via HCPs, national/ local patient societies or trusts will be approached to ask for interesting young adults with cancer.

Potential participants, that is the young adults with cancer, will then receive information concerning the study's purpose, their role and the informed consent procedure. Furthermore, identification of the family member will be performed, by asking the young adult to identify their chosen person. This information will be provided verbally and, after the conversation, also in writing in the form of an information letter and informed consent form. When a young adult gives permission to share contact details with the researcher, the researcher will contact them by email or telephone within 7 days to answer their questions and to ask consent to participation. If the young adult is willing to participate, an appointment for the interview will be made. A letter of consent must be signed by the participant before the interview takes place.

If the family member is present when the information is provided, the information about the interview will be provided. The family member will be requested to give contact information, if it diverges from the young adult's contact information. If the family member is not present, their contact information is requested from the young adult participant. Within 7 days, the family member will be contacted and invited for participation, any final clarifications addressed, and

consent will be sought. If the family member is willing to participate, an appointment for the interview will be made. A letter of consent must be signed by the family member before the interview. The interviews of young adults and family members can be performed in dyads or separately, based on their preferences.

HCPs will be recruited via the local hospital, cancer centre or institution, depending on the local and national situation.

Subjects can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a subject from the study for urgent medical reasons.

8.4 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

Interviews will be recorded (audio). Through the participant's answers on interview questions, basic demographic data and data regarding the oncological diagnosis and treatment will be collected. See also the interview guide. No medical patient files will be used.

9.2 Privacy protection

Participants will be assigned a code, which is not traceable to the person. The key file and data file will be stored separately from each other.

Handling of personal data complies with the EU General Data Protection Regulation and the Dutch Act on Implementation of the General Data Protection Regulation (in Dutch: Algemene Verordening Gegevensbescherming en Uitvoeringswet Algemene Verordening Gegevensbescherming).

9.3 Handling and storage of data

In line with Erasmus MC guidelines, data will be kept 10 years after it is collected. Each partner/national research team will store their own data according to national and EU regulations. Within Erasmus MC, basic demographic data and data regarding oncological diagnosis and treatment extracted from the interview, will be stored in Castor. Anonymized transcripts of the interviews will be stored in protected Erasmus MC SharePoint.

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

In line with Erasmus MC guidelines, sound recordings will be kept 10 years after it is collected. In this study only sound recordings will be used.

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

Access to the data for members of the research team will be approved by the principal investigator.

10. Handling and storage of human material

N/A

10.1 **Human material**
N/A

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

Data sharing policies will be in line with the Data Transfer Agreement.

12. Amendments

All amendments will be submitted to the NWTC that gave the favorable opinion. Substantial amendments will need to 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 after all data has been collected, analyzed and written, this will expectedly be between 1 and 2 years after the start 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

Mental health needs in young adults with cancer, their relatives and health care providers (MELODIC II)

1. Introduction

Dear participant,

In this information letter we ask you if you would like to participate in (medical) scientific research. Participation is voluntary. You receive this information letter because either 1. You have been diagnosed with cancer and are in the age range 18-35 years, or 2. You are the relative of a young adult with cancer, or 3. You work as a health care provider in cancer care.

You will read in this letter what the study is about. You will also read what it means for you if you participate in the study. Are you interested? Then read this information letter carefully. Ask questions to the researcher/researcher who will give you this information.

Would you like to participate? Then fill out the consent form (Appendix B), sign and date it.

2. General information

This interview 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 have an increased risk of experiencing mental health symptoms after cancer treatment. However, young adults may not always receive the mental health services they need within the care they receive after cancer treatment.

The purpose of this study is to identify the mental health needs of young adults with cancer, their family members and their caregivers.

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

Within this study, we aim to identify mental health needs by interviewing young adults with cancer, family members and caregivers. Participation in the interview with one of the researchers will take approximately 30 minutes. The interview can take place in the health care setting or online, depending on your preference. Participating in this study will not affect the care you or your relative will receive.

When you participate in the study it means that we collect and use your data. You can find detailed information about the data to be collected, along with how it is collected, used, and protected, in

Sections 7 and 8. During the study we will make an audio recording of you. You can read in section 8 what we want to do with these recordings.

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

You will not benefit (directly) from participating in this study. However, your participation may contribute to more knowledge about how to optimize care for young adults with cancer.

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

Participation in the study is completely voluntary. Only if you wish to participate will you sign the consent form (Appendix B).

You can quit the study at any time. Please inform the investigator as soon as possible. You do not have to say why you are stopping.

7. What data do we collect?

In this study we collect the following data through the interview:

- Some anonymized general demographic data;
- If you are a patient yourself your diagnosis and treatment, or that of your family member (we will not use your (electronic) patient files, but by asking questions during the interview);
- Your role in caring for young adults with cancer, if you are a caregiver.

We will make audio recordings of the interview. These recordings will be transcribed and then deleted.

8. What do we do with your data?

Why do we collect, use and retain your data?

We collect, use and store your data, in order to answer the questions of this survey. We want to publish the results of the survey.

How do we protect your privacy?

To protect your privacy, we anonymize your data. On all your data we put only this code. We cannot trace this data back to you as an individual. When we process or share your data, we always use only this code. In reports and publications about the research, no one can trace back that it was about you.

How long do we keep your data?

We will keep your research data for 10 years.

What do we do with audio recordings?

During the interview, we will make audio recordings of you. You may be recognizable on these recordings. We will type out the sound recordings. After this, the sound recording will be destroyed.

May we use your data for other research?

Your data may also be of interest for other scientific research in the field of fear of cancer recurrence after this study has ended. To this end, your data will be stored for 10 years after the study ends. On the consent form you can indicate whether you approve of this. Do you not give consent? Then you can still participate in this study.

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

You can withdraw your consent to the use of your data at any time. This applies to use in this study and to use in other research. If you withdraw your consent, the researchers may still use the data already collected.

Want to know more about your privacy?

Want to know more about your rights when processing personal data? See: [national website about data protection].

9. Will you receive compensation for participating?

We really appreciate that you will participate in this study. You will not receive compensation for participating.

10. Do you have any questions?

If you have any questions about this study, please contact the coordinating researcher.

The contact information can be found in Appendix A.

Appendix A: Contact details

List here the details of the principal investigator, other investigators, the Complaints Officer and the Data Protection Officer with contact information such as email address and phone number.

Appendix B: Participant consent form

Mental health needs in young adults with cancer, their relatives and health care providers (MELODIC II)

- 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 also know that I can decide at any time not to participate or to stop the study. I do not have to give a reason for doing so.
- I consent to the collection and use of my data in the manner and for the purposes specified in the information letter.

Please tick yes or no in the table below:

I give permission to make and use voice recordings. These will be destroyed after transcription	Yes ☐	No ☐
I give permission to store my data for usage in other research, as described in the information letter	Yes ☐	No ☐

- I want to participate in this study.

Name (participant):

Signature: Date:

I certify that I have fully informed this participant about the said study.

If information becomes known during the study that could affect the participant's consent, I will inform him/her in a timely manner.

Name (researcher):

Signature: Date:

Identifying mental health needs of young adults with cancer, their family members and health care providers (MELODIC II)

Interview guide patients

General instructions

Interview questions indicated with [open] are first asked in an open way/manner. Then, depending on the participant's responses the interviewer can ask further questions, for instance "Can you name an example of…?", or "What do you mean by that…?", or "Can you tell a little bit more about that?", or any other question that is logical and/or relevant to ask as a follow-up question. The aim is to get a good insight in the participant's experiences and needs.

General questions

Instruction: please write down the participant's answer and/or circle the given answer

a. Age:
b. Gender (male/female/non-binary/prefer not to say)
c. Country of birth:
d. Country of residence:
e. Education level (primary education/secondary education/tertiary education, specify:)
f. Living situation / composition (alone; partner; children; with parents; other)
g. Living situation / area (city; rural; other)
h. Is there a possibility of accessing natural places such as parks, beaches or forests? (yes, easily; yes, with some effort; yes, with a lot of effort; not at all)
i. Employment in the previous 12 months (full-time/part-time/self employed/retired/studying/not working because of illness/other, specify:)
j. Age of the participant at first oncological diagnosis:
k. Oncological diagnosis:
l. Kind of oncological treatment received:
m. Current oncological treatment:

Interview questions

1. Some people who are recently diagnosed with cancer might also notice the impact on mental health.
   - How does your oncological diagnosis affect your mental health? [open]
   - What kind of mental health impact have you experienced since cancer was diagnosed? *(multiple options possible, ask all the prompts, circle when yes, and elaborate when yes)*
      - general stress;
      - feeling overwhelmed;
      - difficulty in managing roles and responsibilities;
      - worrying;
      - worry about others;
      - mood issues;
      - depression;
      - sleeping problems;
      - (general)anxiety;
      - fear of recurrence / fear of progression;
      - fear of dying;
      - memories that bother you / nightmares;
      - other, please specify:

Coping

2. What has helped you to manage your mental health during the time since your diagnosis? [open]

3. Do you engage in social activities? [yes, no, other]
   Please explain [open]:
   -Do you think that this affects your ability to cope with cancer? [yes, no, other]
   Please explain [open]:

4. Do you engage in leisure or physical activities? [yes, no, other]
   Please explain [open]:
   - Do you think that this affects your ability to cope with cancer? [yes, no, other]
   Please explain [open]:

5. Do you engage in sports/ physical exercise? [yes, no, other]
   Please explain [open]:
   -Do you think that this affects your ability to cope with cancer? [yes, no, other]
   Please explain:

6. Do you visit natural places such as parks, beaches or forests? [yes, no, other]
   Please explain [open]:

   What draws you to these places? [open]

   Do you think that this affects your ability to cope with cancer? [yes, no, other]
   Please explain [open]:

7. What do you think about the interaction between your mental and physical health? [open]

Psychosocial support received from others

8. Have you received psychosocial support (support with a focus on how you feel, think and relate to others) after you were diagnosed with cancer? [open]

   - Of whom did you receive support?

   (multiple options possible, ask all the prompts, circle when yes, and elaborate when yes)

   - GP;
   - MD;
   - Nurse;
   - Social worker;
   - Psychologist;
   - Partner;
   - Parent;
   - Sibling;
   - Children;
   - Friend;
   - Peer support / buddy;
   - Religious / spiritual counselor
   - Other, please specify:

- What did this support look like?

(multiple options possible, ask all the prompts, circle when yes, and elaborate when yes)

- Information /education;
- Practical support;
- Supportive conversations/counselling;
- Pharmacotherapy;
- Other (for example drama, art- or music therapy), please specify:

9. What did this support mean to you? [open]
   – What could supporters do better or differently? [open]

10. Are you able to access the support you need at this moment? [yes, no, other]
    Please explain [open]:

11. Reflecting on your experiences, what suggestions would you offer to improve care for young adults with cancer? [open]

Identifying mental health needs of young adults with cancer, their family members and health care providers (MELODIC II)

Interview guide relative

General instructions

Interview questions indicated with [open] are first asked in an open way/manner. Then, depending on the participant's responses the interviewer can ask further questions, for instance "Can you name an example of…?", or "What do you mean by that…?", or "Can you tell a little bit more about that?", or any other questions that are logical and/or relevant to ask as a follow-up question. The aim is to get a good insight in the participant's experiences and needs.

Use the same wording 'loved ones' or 'relatives' - when you find out in the beginning of the interview what the type of relation is (for example "your partner") you can adapt this during the interview

General questions

Instruction: please write down the participant's answer and/or circle the given answer

a. Age:
b. Gender: (male/female/non-binary/prefer not to say)
c. Country of birth:
d. Country of residence:
e. Education level: (primary education/secondary education/tertiary education, specify:)
f. Relation with person with cancer:
g. Living situation / composition (alone; partner; children; with parents; other)
h. Living situation / area (city; rural; other)
i. Is there a possibility of accessing natural places such as parks, beaches or forests? (yes, easily; yes, with some effort; yes, with a lot of effort; not at all)
j. Employment in the previous 12 months (full-time/part-time/self-employed/retired/studying/not working/other, specify)
k. Current oncological treatment of relative:

Interview questions

1. Some relatives of people who are recently diagnosed with cancer might also notice the impact on mental health.

   - In what ways is the medical situation of your relative affecting your mental health? [open]

   - What kind of mental health impact have you experienced since your relative's oncological diagnose?

   (multiple options possible, ask all the prompts, circle when yes, and elaborate when yes)

   - general stress;
   - feeling overwhelmed;
   - difficulty in managing roles and responsibilities;
   - worrying;
   - worry about others;
   - mood issues;
   - depression;
   - sleeping problems;
   - (general)anxiety;
   - fear of recurrence / fear of progression;
   - fear of dying of your relative;
   - memories that bother you / nightmares;
   - other, please specify:

Coping

2. What has helped you to manage your mental health during the time since the diagnosis? [open]

3. Do you engage in social activities? [yes, no, other]
   Please explain [open]:

   Do you think that this affects your ability to cope with the diagnosis of your relative? [yes, no, other]
   Please explain [open]:

4. Do you engage in leisure or physical activities? [yes, no, other]
   Please explain [open]:
   Do you think that this affects your ability to cope with the diagnosis of your relative? [yes, no, other]
   Please explain [open]:

5. Do you engage in sports/ physical exercise? [yes, no, other]
   Please explain [open]:
   Do you think that this affects your ability to cope with the diagnosis of your relative? [yes, no, other]
   Please explain [open]:

6. Do you visit natural places such as parks, beaches or forests? [yes, no, other]
   Please explain [open]:
   What draws you to these places? [open]
   Do you think that this affects your ability to cope with the diagnosis of your relative? [yes, no, other]
   Please explain [open]:

Psychosocial support received from others

7. Have you received psychosocial support (support with a focus on how you feel, think and relate to others) after your relative was diagnosed with cancer? [open]
   - Of whom did you receive support?
   (multiple options possible, ask all the prompts, circle when yes and elaborate when yes)

   - GP;
   - MD;
   - Nurse;
   - Social worker;
   - Psychologist;
   - Partner;
   - Parent;
   - Sibling;
   - Children;
   - Friend;

- Peer support / buddy;
- Religious / spiritual counselor
- Other, please specify:

- What did this support look like?

(multiple options possible, ask all the prompts, circle when yes, and elaborate when yes)

- Information /education;
- Practical support;
- Supportive conversations/counselling;
- Pharmacotherapy;
- Other (for example drama, art- or music therapy), please specify:

8. What did this support mean to you? [open]
   - What could supporters do better or differently? [open]

9. Are you able to access the support you need at this moment? [yes, no, other]
   Please explain: [open]

10. Reflecting on your experiences as a relative of a young adult with an oncological diagnosis, what suggestions would you offer to improve care for relatives? [open]

Identifying mental health needs of young adults with cancer, their family members and health care providers (MELODIC II)

Interview guide HCP

General instructions

Interview questions indicated with [open] are first asked in an open way/manner. Then, depending on the participant's responses the interviewer can ask further questions, for instance "Can you name an example of…?", or "What do you mean by that…?", or "Can you tell a little bit more about that?", or any other questions that are logical and/or relevant to ask as a follow-up question. The aim is to get a good insight in the participant's experiences and needs.

General questions

Instruction: please write down the participant's answer and/or circle the given answer

a. Age:
b. Gender: (male/female/non-binary/prefer not to say)
b. Country of birth
c. Country of residence
d. Profession:

    Nurse
    Specialisation: [open]
    Medical doctor
    specialisation: [open]
    Health Visitor/Community Health Scientist
    Psychologist
    Social worker
    Other, specify:

e. Work setting:
f. Years of working experience (with YA with cancer):

Interview questions

1. Some young adults who are recently diagnosed with cancer might also notice the impact on mental health.

   - In your opinion, what is the impact on mental health in your young cancer patients? [open]

2. What kind of psychosocial support (support with a focus on how you feel, think and relate to others) have **you** provided after they were diagnosed with cancer? [open]

   - What did this support look like?

   (multiple options possible, ask all the prompts, circle when yes, and elaborate when yes)

   - Information /education;
   - Practical support;
   - Supportive conversations/counselling;
   - Pharmacotherapy;
   - Lifestyle counseling (exercise/nutrition);
   - Referral to peer support platform;
   - Other, please specify:

3. Do you usually involve others in supporting YA's regarding their mental health? [open]

   -If yes, who?

   (multiple options possible, ask all the prompts, circle when yes and elaborate when yes)

   - GP;
   - MD;
   - Nurse;
   - Social worker;
   - Psychologist;
   - Rehabilitation
   - Partner;
   - Parent;
   - Sibling;
   - Children;
   - Friend;
   - Peer support / buddy;

- Religious / spiritual counselor;
- Other, please specify:

4. Would you say that this kind of support for your patients is generally accessible? [yes, no, partly]
   Please explain [open]:

5. Would you say that this kind of support for your patients is generally sufficient? [yes, no, partly]
   Please explain [open]:

6. Some **family members of young adults** who are recently diagnosed with cancer might also have mental health needs.
   - In your opinion, what is the impact on mental health in family members of your young cancer patients? [open]

7. What kind of psychosocial support (support with a focus on how you feel, think and relate to others) have **you** provided to family members after their relatives were diagnosed with cancer? [open]
   - What did this support look like?
   (multiple options possible, ask all the prompts, circle when yes and elaborate when yes)
   - Information /education;
   - Practical support;
   - Supportive conversations/counselling;
   - Pharmacotherapy;
   - Lifestyle counseling (exercise/nutrition);
   - Referral to peer support platform;
   - Other, please specify:

8. Of **whom else** do family members generally receive support? [open]
   - If yes, who?
   (multiple options possible, ask all the prompts, circle when yes and elaborate when yes)
   - GP;
   - MD;
   - Nurse;
   - Social worker;
   - Psychologist;
   - Partner;
   - Parent;
   - Sibling;
   - Children;
   - Friend;
   - Peer support / buddy;

- Religious / spiritual counselor;
- Other, please specify:

9. Would you say that this kind of support for the family members of your patients is generally accessible? [yes, no, partly]
   Please explain [open]:

10. Would you say that this kind of support for the family members of your patients is generally sufficient? [yes, no, partly]
    Please explain [open]:

11. What are your experiences with social prescribing (referring people to a range of local, non-clinical services that affect their health and wellbeing)? [open]
    - Do you use this in your clinical practice in working with young adults with cancer? [yes/ more or less/ no]

    Please explain [open]:

12. What are your experiences with recommending making use of green and blue spaces (forests, parks, beaches etc.)? [open]
    - Do you use this in your clinical practice in working with young adults with cancer? [yes/ more or less/ no]

    Please explain [open]:

13. What stands out for you / is most important for you in addressing the mental health needs of young adults with cancer?
    Please explain [open]:

14. What would help you in addressing mental health needs of YA with cancer and their family members?

    Please explain [open]:

Erasmus MC
Universitair Medisch Centrum Rotterdam

Medisch Ethische Toetsings Commissie
Erasmus MC

Niet WMO Toetsingscommissie Erasmus MC

dr. W.H.Oldenmenger
Afdeling: Interne Oncologie
Erasmus MC

Telefoon +31 107033625
Kamernummer Ae-337
E-mail metc@erasmusmc.nl
Ons kenmerk MEC-2025-0081
Datum 4 maart 2025

Postadres
Postbus 2040
3000 CA Rotterdam

Bezoekadres
Dr. Molewaterplein 40
3015 GD Rotterdam

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

Positief besluit Niet WMO	
METC nummer	MEC-2025-0081
Titel onderzoek	Identifying mental health needs of young adults with cancer, their family members and health care providers (MELODIC II)

Geachte heer, mevrouw,

De Niet WMO Toetsingscommissie Erasmus MC heeft het ingediende onderzoek ontvangen op 03-02-2025.

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

De commissie is van oordeel dat het onderzoek niet WMO-plichtig is.

Het Dagelijks Bestuur van de Niet WMO Toetsingscommissie heeft dit onderzoek ook inhoudelijk getoetst op:

- De inhoud en rationale
- De wijze van verzamelen van data
- De wijze van informeren en toestemming vragen aan de deelnemers

Dit onderzoek mag worden uitgevoerd in het Erasmus MC.

Dit oordeel is gebaseerd op de volgende documenten:

C01. Non WMO Melodic II protocol v1.1 270225	1.1 27-02-2025
C01. Non WMO Melodic II protocol v1.1 track changes	1.1 27-02-2025
E1E2. non-WMO PIF MELODIC II v1.1 03032025	1.1 03-03-2025
E1E2. non-WMO PIF MELODIC II v1.1 track changes	1.1 03-03-2025
F01. Melodic II interview guides	v1 d.d. 23-01-2025
K6.-Risicoclassificatie 23-01-2025	

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 van het Erasmus MC. 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,

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

Asia: ihmistieteellisen tutkimuksen eettinen ennakkoarviointi

Tutkimuksen nimi

MELODIC-projekti, haastattelututkimusosuus

Tutkimuksen yhteyshenkilöt

Mari Lahti, Johanna Berg ja Sonja Sahla

Tutkimuksesta vastaava henkilö

Mari Lahti

Käsittely Turun AMK:n ihmistieteiden tutkimuseettisessä toimikunnassa

Vastuullinen tutkija on pyytänyt ennakkoarviointilausuntoa ko. projektin tutkimussuunnitelman eettisyydestä ja muista tutkimukseen liittyvistä mahdollisista riskeistä.

Turun AMK:n ihmistieteiden tutkimuseettinen toimikunta on 10.3.2025 kokouksessaan käsitellyt hakijan lausuntopyynnön, tutkimussuunnitelman ja siihen liittyvät asiakirjat. Toimikunta on pyytänyt täydentämään hakemusta. Hakija on toimittanut pyydetyt täydennykset 16.4.2025 ja henkilötietojen käsittelyn vaikutustenarvioinnin (DPIA) 22.4.2025.

Asian käsittelyyn ovat osallistuneet Katja Heikkinen toimikunnan puheenjohtajana sekä Ursula Hyrkkänen, Harri Kilpiö, Hannele Kuusisto, Katariina Pajuranta, Samuel Raunio, Anne-Marie Tuikka ja Elina Vuorio toimikunnan jäseninä. Toiminnan sihteerinä on toiminut valmistelija Elina Vuorio.

Lausunto

Kun otetaan huomioon tutkijan lausuntopyyntö, mainitusta tutkimuksen asiakirjoista saatava selvitys sekä Tutkimuseettisen neuvottelukunnan (TENK) ohjeet ihmiseen kohdistuvan tutkimuksen eettisistä periaatteista sekä ihmistieteiden eettisestä ennakkoarvioinnista Suomessa (2019), toimikunta antaa puoltavan lausunnon. Toimikunnan käsityksen mukaan ennakkoarvioitavana oleva suunniteltu tutkimus on eettisesti hyväksyttävä.

Turussa 25.4.2025

Puheenjohtaja Katja Heikkinen

Valmistelija, sihteeri Elina Vuorio

Lisätietoja

Toimikunnan valmistelija, sihteeri Elina Vuorio

tutkimusetiikka@turkuamk.fi tai p. 040 3550 526

Muutoksenhaku

Jos ennakkoarviointilausunnon hakija ei hyväksy Turun AMK:n ihmistieteiden tutkimuseettisen toimikunnan päätöstä tai lausunnon sisältämiä muutosehdotuksia, hän voi pyytää asiasta lausuntoa Tutkimuseettiseltä neuvottelukunnalta (TENK). Perusteltu lausuntopyyntö liitteineen tulee jättää kahden kuukauden kuluessa Turun AMK:n eettisen toimikunnan päätöksestä.

MATTER: Ethical review of human sciences

Title of the research project

MELODIC project, interview part of the research

Contact persons for the research

Mari Lahti, Johanna Berg and Sonja Sahla

Principal investigator of the research project

Mari Lahti

Handling the matter at the Research Ethics Committee of Turku UAS

The researcher has requested an ethical review statement on the ethicality of the research plan and on other risks related to the research.

The Research Ethics Committee of Turku UAS has in its meeting on 10th March 2025 processed the applicant's request, the research plan, and the related documents. The Research Ethics Committee of Turku UAS has asked the researcher to supplement the application. The researcher has submitted the requested amendments 16th April 2025 and data processing impact assessment document 22th April 2025.

The matter has been handled by Katja Heikkinen as the chair of the Committee and Ursula Hyrkkänen, Harri Kilpiö, Hannele Kuusisto, Katariina Pajuranta, Samuel Raunio, Anne-Marie Tuikka and Elina Vuorio as the members of the Committee. Elina Vuorio was the secretary of the Committee.

Statement

When considering the researcher's request, information about the research obtained from the delivered documents, and the national guidelines for the ethical principles of research with human participants and ethical review in human sciences, the Research Ethics Committee of Turku UAS gives assent to the research. According to the Research Ethics Committee of Turku UAS, the planned research project under the ethical review can be ethically approved.

In Turku, 25th April 2025

Chair Katja Heikkinen

Secretary Elina Vuorio

More information

Ethics Committee rapporteur, secretary Elina Vuorio

tutkimusetiikka@turkuamk.fi of tel. +358 40 3350 526

Appeals

If the applicant for the statement does not accept the decision of the Research Ethics Committee of Turku UAS or the proposed changes in the statement, the researcher may request a statement from the Finnish Advisory Board on Research Integrity (TENK). The request for statement with justifications and appendices has to be submitted within two months of the decision of the Research Ethics Committee of Turku UAS.

ΕΠΙΤΡΟΠΗ ΗΘΙΚΗΣ ΚΑΙ ΔΕΟΝΤΟΛΟΓΙΑΣ ΤΗΣ ΕΡΕΥΝΑΣ

ΠΑΝΕΠΙΣΤΗΜΙΟ ΔΥΤΙΚΗΣ ΑΤΤΙΚΗΣ

ΠΑΝΕΠΙΣΤΗΜΙΟΥΠΟΛΗ ΑΛΣΟΥΣ ΑΙΓΑΛΕΩ
Ταχ. Δ/νση: Αγ. Σπυρίδωνος, Αιγάλεω ΤΚ 12243
Τηλέφωνο: 2105387294
e-mail: ethics@uniwa.gr
Πληροφορίες: Ευαγγελία Καπουτσή

Αιγάλεω: 19/05/2025

ΘΕΜΑ: Απάντηση σε αίτησή σας

ΠΡΟΣ : κ. Σακελλάρη Ευανθία

Έγκριση της πρότασης

Σας γνωρίζουμε ότι η Επιτροπή Ηθικής και Δεοντολογίας της Έρευνας (Ε.Η.Δ.Ε.) του Πανεπιστημίου Δυτικής Αττικής (ΠΑ.Δ.Α.), στην 13η/09-05-2025 συνεδρίασή της, μέσω τηλεδιάσκεψης, εξέτασε το περιεχόμενο του ερευνητικού πρωτοκόλλου με τίτλο **«Identifying mental health needs of young adults with cancer, their family members and health care providers»** και αριθμό πρωτοκόλλου 40914/05-05-2025 με Επιστημονικά Υπεύθυνη την κ. Σακελλάρη Ευανθία και συν-ερευνήτρια την κ. Λάγιου Αρετή.

Λαμβάνοντας υπόψη:

1. Το έντυπο υποβολής της αίτησης
2. Το ερευνητικό πρωτόκολλο
3. Το έντυπο συγκατάθεσης των συμμετεχόντων στην έρευνα
4. Όλα τα συμπληρωματικά στοιχεία και έγγραφα που ζητήθηκαν

Η Επιτροπή έκρινε ότι η προτεινόμενη έρευνα συνάδει με τους γενικά παραδεδεγμένους κανόνες ηθικής και δεοντολογίας της έρευνας και ερευνητικής ακεραιότητας ως προς το περιεχόμενο και τον τρόπο διεξαγωγής του ερευνητικού έργου.

Επισημαίνεται ότι οι Επιστημονικά Υπεύθυνοι ή/και οι Επιβλέποντες Καθηγητές και οι ερευνητές παραμένουν υπεύθυνοι για τη λήψη των κατάλληλων τεχνικών και οργανωτικών μέτρων για την ασφαλή επεξεργασία των προσωπικών δεδομένων των συμμετεχόντων ατόμων σύμφωνα με την ισχύουσα νομοθεσία, καθ' όλη τη διάρκεια της έρευνας καθώς και κατά την δημοσιοποίηση αυτής.

Η απόφαση αυτή δεν υποκαθιστά έγκριση ή αδειοδότηση που απαιτείται για τη διενέργεια της έρευνας από άλλο αρμόδιο φορέα ή υπηρεσία.

Εφόσον προκύψει οποιαδήποτε τροποποίηση στο πρωτόκολλο της μελέτης θα πρέπει να επανυποβληθεί στην ΕΗΔΕ για επικαιροποίηση της έγκρισης.

Η Πρόεδρος

Τ. Γκαράνη-Παπαδάτου

Tartu Ülikooli inimuuringute eetika komitee

Protokolli number: 400/T-25 **koosolek: 21.04.2025**

Komitee koosseis:

Esimees

Aime Keis	Tartu Ülikool, eetikakomitee esimees

Aseesimees

Kristi Lõuk	Tartu Ülikool, humanitaarteaduste ja kunstide valdkond, projektijuht / doktorant

Liikmed

Diva Eensoo	Tervise Arengu Instituut, teadur
Katrin Kaarna	Tartu Ülikool, meditsiiniteaduste valdkond, kliiniliste uuringute keskuse juhataja
Kalle Kisand	Tartu Ülikool, meditsiiniteaduste valdkond, laborimeditsiini professor
Piret Koosa	Eesti Rahva Muuseum, teadur
Malle Kuum	Tartu Ülikool, meditsiiniteaduste valdkond, farmakoloogia lektor / farmakoloogia teadur
Marje Oona	Tartu Ülikool, meditsiiniteaduste valdkond, peremeditsiini kaasprofessor
Maire Peters	Tartu Ülikool, meditsiiniteaduste valdkond, geneetika kaasprofessor
Raivo Puhke	Tartu Ülikool, meditsiinteaduste valdkond, funktsionaalse morfoloogia lektor
Atko-Sulhan Remmel	Tartu Ülikool, humanitaarteaduste ja kunstide valdkond, religiooniuuringute kaasprofessor
Anna-Liisa Tamm	Tartu Tervishoiu Kõrgkool, füsioteraapia ja tervisekaitse osakonna juhataja
Anni Tamm	Tartu Ülikool, sotsiaalteaduste valdkond, arengu- ja koolipsühholoogia lektor / arengupsühholoogia teadur
Maarja Torga	Riigikohus, tsiviilkolleegiumi nõunik

Otsus: Kooskõlastada uurimistöö

Uurimistöö nimetus: Vähktõvega noorte täiskasvanute (18-35a), nende pereliikmete ja tervishoiuteenuste osutajate kogemused vaimse tervise ja heaolu toetamisel

Vastutav uurija (asutus):
Siret Kivistik (SA Tartu Ülikooli Kliinikum, L. Puusepa 8, Tartu)

Komitee poolt läbivaadatud dokumendid:

1. Uurimistöö avalduse kooskõlastuse saamiseks Tartu Ülikooli inimuuringute eetika komiteelt, 08.05.2025
2. SA Tartu Ülikooli Kliinikum kooskõlastus uurimistöö läbiviimiseks
3. Lisa 1. Uuritava informeerimise ja teadliku nõusoleku vorm patsiendile, 14.05.2025
4. Lisa 2. Uuritava informeerimise ja teadliku nõusoleku vorm patsiendi lähedasele, 08.05.2025
5. Lisa 3. Uuritava informeerimise ja teadliku nõusoleku vorm tervishoiutöötajale, 08.05.2025
6. Lisa 4. Intervjuu kava, 08.05.2025

7. Lisa 5. Eetikakomitee luba projektile MELODIC (Erasmus MC)
8. Lisa 6. CV Kaire Jugar
9. Lisa 7. TÜK kooskõlastus uuringu algatamiseks
10. Lisa 8. Kogutavate andmete koosseis
11. Uuringu läbiviijate CVd (S. Kivistik, L.-T. Kõrgvee, M. Varik)

Uurimistöö lõpp: 31.12.2025

Komitee esimees: Aime Keis */allkirjastatud digitaalselt/*

Komitee sekretär: Kaire Kallak */allkirjastatud digitaalselt/*

Väljastatud: */viimase digitaalallkirja kuupäev/*

Selgitus:

- Tartu Ülikooli inimuuringute eetika komitee otsus uuringu taotluse osas ei kohusta isikuandmete või andmekogu vastutavat või volitatud töötlejat andmeid uurijale väljastama. Isikuandmete või andmekogu vastutav või volitatud töötleja on kohustatud hindama, kas isikuandmete väljastamine uuringu tegemise eesmärgil ja uurija poolt taotletud viisil on tehniliselt võimalik, lubatud ja vastab õigusaktidele.
- Tartu Ülikooli inimuuringute eetika komitee annab hinnangu planeeritavas uuringus isikuandmete töötlemise suhtes taotluses esitatud kirjelduse ja dokumentide alusel. Uuringus kasutatavate isikuandmete vastutav või volitatud töötleja (vastutav uurija ning uuringumeeskond) vastutab isikuandmete töötlemise nõuetekohasuse ja õigusaktidele vastavuse eest ka siis, kui eetikakomitee on uuringu kooskõlastanud.

University of Galway, REC Review and Decision Form

REC Application Reference Number: 2025.05.018
Title: Mental Health Supports for Young Adults with Cancer
Principal Applicant: Dr. Martin Power
Supervisor: n/a
School: School of Health Sciences
Application Type: New
Meeting Date: 6 May 2024
Decision: Approval with Notes

23 May 2025

Dear Dr Power,

I write to you regarding the above proposal, which was submitted for Ethical review. Your proposal was:

APPROVED with NOTES

Please consider the feedback provided, and aim to address the numbered points:

SECTION 2: STUDY DESIGN

- A qualitative study involving semi-structured interviews. A survey of health professionals will also be conducted. However, the 'Survey/Questionnaire' option was not ticked under the Study Design section of the application. Given that a questionnaire will be used, this should be highlighted.

2.4 Multi-centre studies:

- We note that while this is part of a larger EU study, this application only deals with Irish participants.

3.3 Children & Vulnerable Participants:

- Young adults with cancer and their carers can be considered a vulnerable population given the impact that a diagnosis with cancer can have. Appropriate steps appear to have been taken to protect and safeguard all participants.

3.5 Participant Identity & Confidentiality*:*

- Appropriate steps appear to have been taken to protect Participant Identity and Confidentiality

SECTION 6: PERSONAL DATA inc DPIA:

1. There is some inconsistency regarding the options selected in the Personal Data section and the subsequent DPIA screening section. Personal, identifiable data and information will be collected via the data gathering/interviewing phase of the study. However, in the DPIA Screening Checklist, the option "Data concerning vulnerable people (including children)" is ticked as 'No'.

   We highly recommend consulting with the GDPR Compliance Manager, OVPRI, Mr Aindrias Cullen (aindrias.a.cullen@universityofgalway.ie) to clarify your obligations with regard to the HRR and GDPR.

Ollscoil na Gaillimhe
University of Galway

University of Galway, REC Review and Decision Form

See below for an explanation of, and your obligations regarding each decision.
Any questions or concerns can be directed to ethics@universityofgalway.ie.

Yours sincerely,

Dr Maureen O'Sullivan, REC Chair

University of Galway, REC Review and Decision Form

DECISIONS EXPLAINED

FULL APPROVAL: Please note the following regarding REC approval:

1. This submission has been reviewed primarily from an ethical perspective. It is the responsibility of the Principal Applicant to ensure and monitor compliance with any relevant legislation/public health guidelines in the country where the study is due to take place or any local policy at the site where the study is due to take place.
2. REC approval does not constitute permission to proceed with the data collection prior to addressing all GDPR matters, including DPIA requirements; all members of the team have undertaken Data Protection training; finalising any/all necessary Data Processing/Sharing agreements.
3. Any significant alterations to an approved proposal must receive prior approval from the REC prior to implementation. Please request an Amendment Form.
4. You are responsible for notifying the REC in the event of serious or unexpected adverse effects, unforeseen circumstances, the termination of the study, and any significant decisions by other Ethics Committees. Section 7 of the REC's Standard Operating Procedures gives further details on instances requiring follow-up reviews and reporting obligations.
5. Principal Applicants given University of Galway REC approval must, upon completion of the approved research, submit an End-of Study report. Failure to submit such a report may impact upon future ethics review.

APPROVED WITH NOTES:

1. You are invited to consider the issues raised by REC review. However, you are not required to submit further information to the REC.
2. All aspects of approval are contingent on points 1-5 above.
3. If you confirm all issues have been addressed, you may request a letter of full approval.

APPROVED WITH TERMS:

4. Full approval is contingent upon you providing requested material and / or updating the application as required. Your updated application and related material will be kept on file.
5. All aspects of approval will be contingent on points 1-5 above.
6. Please request a letter of full approval if required.

PROVISIONAL APPROVAL: When provisional approval is granted, requested revisions or answers to the questions posed must be supplied.

When submitting your response, **please adhere carefully** to the following:

a. Provide a cover letter outlining your response(s), in turn, to each of the **numbered** conditions and refer the reviewer to the relevant page number(s) of the application document where the revisions have been incorporated.
b. Submit an amended application and associated documentation (with any changes to the document highlighted for ease of recognition) **no later than 30 days** from the date of this letter. Please email your response to ethics@universityofgalway.ie.
c. No data collection may commence until all conditions have been met and final approval has been granted.
d. Provisional Approval is valid for six months only, after which time the application may need to be resubmitted for full review.

DEFERRAL: A deferred research proposal can be re-submitted to the REC, where it will be reviewed as a new proposal. Check REC submission deadlines for the next submission deadline.

DECLINE TO REVIEW: Proposals may be rejected by the Committee if the project is outside the remit of this REC, it has been deferred several times and/or the Committee feels that the proposed research is not justified and/or poses severe or unnecessary risk to the subjects. A rejection will be supported by clearly defined reasons. The Committee may or may not, as it feels appropriate, invite resubmission of a substantially altered proposal for reconsideration.

Ollscoil na Gaillimhe
University of Galway

University of Galway, REC Review and Decision Form

Melodic II

Mail with the IPO study authorization

Conceição Costa

De: Direção Clínica
Enviado: 3 de novembro de 2025 10:14
Para: Conceição Costa
Assunto: FW: MELODIC II - submissão de autorização para realização de projeto de investigação - UIC/1787
Anexos: ACORDO TRATAMENTO DE DADOS_MELODIC_ESEL e IPO_08.10.2025_signed.pdf

Exmos. Senhores

No âmbito do assunto acima identificado, encarrega-me o Sr. Diretor Clinico de informar que o presente pedido está autorizado .

Com os melhores cumprimentos

Sandra Cristina Calca
O Secretariado | Direção Clínica
Ext. 1158 | Bip. 4292