

An observational study for monitoring mental health predictors, such as activity, sleep, nutrition and voice, in cancer survivors

Submission date 21/09/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/03/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/03/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Depression is a common condition among cancer patients but is often not reported or goes unnoticed. It becomes more challenging to track patients' psychological changes in the period after treatment where the connection with the healthcare environment becomes sporadic. This study is part of a project sponsored by the European Community and the main goal is to identify and predict depressive symptoms in breast and lung cancer patients through a mobile App. The clinical centres involved are Euro Care Healthcare Limited (UPMC, Ireland), Hospital General Universitario Gregorio Marañón, (HGUGM, Spain) and Champalimaud Foundation (CF, Portugal).

Who can participate?

Lung or breast cancer patients from Portugal, Spain and Ireland, aged 18 to 70 years

What does the study involve?

Participants will be asked to directly or indirectly provide information on quality of life, depression and anxiety symptoms, nutrition, voice, sleep and activity that can be assessed either through questionnaires or an app. The questionnaires evaluate different aspects of quality of life, depressive and anxiety symptoms and nutrition, and some of these will need completion on an app every month, for a total of 12 months. About 15 to 60 minutes of time will be required at each timepoint to complete these self-rated questionnaires. Every 3 months, a clinical member of the research team will contact participants by telephone for the completion of a structured interview about mood status. This interview lasts about 45 minutes. Participants will be asked to respond to a question and read a small text through the app every month. This action has a duration of about 5 minutes. For the collection of sleep information, participants will be asked to wear a smart band on their wrist, smaller than a watch, that gathers relevant information automatically. Furthermore, participants will be asked to provide some sleep-related information monthly and to fill in a questionnaire every 3 months regarding their sleep habits. For the collection of activity information, all data will be extracted automatically through the app. Any time an action is required (questionnaires, voice recording or any other information), participants will receive a notification on their mobile phone.

What are the possible benefits and risks of participating?

There are no direct benefits related to participation in the study. However, participation will help the researchers to understand how to provide better support to cancer patients after treatment, as well as guidance for health professionals in monitoring mental health. Therefore, the results will benefit future patients and could lead to the development of patient support tools. As the study is a monitoring exercise and will not involve any test or procedure on the participants there will be no risk to the health or well-being of any person.

Where is the study run from?

Waterford Institute of Technology (Ireland)

When is the study starting and how long is it expected to run for?

January 2020 to May 2023

Who is funding the study?

European Commission

Who is the main contact?

Mr Gary McManus

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Contact information

Type(s)

Public

Contact name

Mr Gary McManus

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

A Federated Artificial Intelligence solution for moniToring mental Health status after cancer treatment

Acronym

FAITH

Study objectives

The primary objective of the FAITH project is to remotely identify and predict the risk or negative trends of depression in cancer survivor patients. FAITH models will significantly detect depressive symptoms in cancer survivors.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 07/12/2021, Champalimaud Foundation's Ethics Committee (Champalimaud Foundation Administration, Avenida Brasília, 1400-038 Lisboa, Portugal; +351 (0)210 480 200; andre.valente@research.fchampalimaud.org), ref: Albino.Maia_9_20211207

Study design

Longitudinal prospective observational cohort study

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

<https://cordis.europa.eu/project/id/875358>

Health condition(s) or problem(s) studied

Depression symptoms and quality of life of cancer survivors

Interventions

The study is designed as a 12-month longitudinal prospective observational cohort, with monthly (± 1 week) assessments after the end of primary cancer treatments ([1-5] years after), to evaluate depression symptoms and quality of life of cancer survivors.

As the study is not interventional, change in behaviours regarding markers will be traced but not used as alarms for potential depression, as this could not be ensured until all data analysis is performed with the complete set of data.

Participants will be asked to directly or indirectly provide information on quality of life, depression and anxiety symptoms, nutrition, voice, sleep and activity that can be assessed either through questionnaires or an app. The questionnaires evaluate different aspects of quality of life, depressive and anxiety symptoms and nutrition, and some of these will need completion on an app every month, for a total of 12 months. About 15 to 60 minutes of time will be required at each timepoint to complete these self-rated questionnaires. Every 3 months, a clinical member of the research team will contact participants by telephone for the completion of a structured interview about mood status. This interview lasts about 45 minutes. Participants will be asked to respond to a question and read a small text through the app every month. This action has a duration of about 5 minutes. For the collection of sleep information, participants will be asked to wear a smart band on their wrist, smaller than a watch, that gathers relevant information automatically. Furthermore, participants will be asked to provide some sleep-related information monthly and to fill in a questionnaire every 3 months regarding their sleep habits. For the collection of activity information, all data will be extracted automatically through the app. Any time an action is required (questionnaires, voice recording or any other information), participants will receive a notification on their mobile phone.

Intervention Type

Other

Primary outcome measure

The severity of depressive symptoms measured by the Hamilton Depression Rating Scale (Ham-D) at months 3, 6, 9 and 12 post-baseline

Secondary outcome measures

1. Anxiety and distress measured using the Hospital Anxiety and Depression Scale (HADS) at baseline and monthly until 12-months post-baseline
2. Perceived quality of life measured using European Organisation for Research and Treatment of Cancer (EORTC) questionnaires at baseline and monthly until 12-months post-baseline

Overall study start date

01/01/2020

Completion date

30/05/2023

Eligibility

Key inclusion criteria

Eligible participants include both breast and lung cancer patients who will be recruited after the end of primary cancer treatments (1-5 years after), and should meet the following criteria:

1. Signed informed consent
2. Age between 18-70 years
3. Native or fluent English/Spanish/Portuguese speakers
4. If Apple iPhone users: have iOS 14+/ If Android device users: have Android 7+ and Google Fit installed on the device
5. Cancer survivors complying patients after chemotherapy, radiotherapy or surgery with curative purposes treatment, divided as follows:
 - 5.1. Early breast cancer, stages I-III, of the subtypes:
 - 5.1.1. Luminal A-like
 - 5.1.2. Luminal B-like
 - 5.1.3. Luminal B HER2+ (HR+/-)
- Or
- 5.2. Lung cancer patients, with non-small cells lung carcinoma, of subtypes:
 - 5.2.1. Stages I-III A
 - 5.2.1. Stages I-III B
6. Performance status (ECOG): 0-2
7. Disease-specific treatments, to reduce the minimal risk of recurrence or relapse, are accepted according to each cancer subtype

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

300

Key exclusion criteria

Clinical exclusion criteria include:

1. The presence of distant metastases
2. A previous invasive malignancy whose treatment was completed within 5 years before the diagnosis of the current neoplastic disease (exceptions: patients with adequately treated, basal or squamous cell skin carcinoma or curatively resected cervical cancer in situ are eligible)
3. Any acute medical illness or other diagnosed concomitant disease clinically significant (i.e. active), such as cardiac disease (e.g. congestive heart failure, symptomatic coronary artery disease or cardiac arrhythmia not well controlled with medication) or myocardial infarction within the last 12 months
4. A major surgery for a severe disease or trauma which could affect a patient's psychosocial wellbeing (for example, major heart or abdominal surgery) within 4 weeks prior to study entry or lack of complete recovery from the effects of surgery
5. Treatment for any major illness in the last half year

6. Pregnancy or breastfeeding at time of recruitment
7. A diagnosis of a moderate to severe major depressive episode at baseline according to the MINI (diagnosis) and/or Ham-D17 (severity)
8. A current or previous hypomanic or manic episode, current or previous psychotic disorder or current mood disorder with psychotic symptoms, as well as substance abuse or dependence in the last 12 months, as screened by the MINI
9. Presence of any psychiatric disorder requiring urgent care or hospitalization at the time of recruitment
10. Cognitive impairment, such as dementia or other active neurodegenerative disease
11. Previously known structural lesion of the central nervous system (e.g., stroke)
12. Developmental disorders with low intelligence quotient or any other form of cognitive impairment
13. Illiteracy or otherwise not understanding instructions for the study

Date of first enrolment

01/04/2022

Date of final enrolment

01/07/2022

Locations

Countries of recruitment

Ireland

Portugal

Spain

Study participating centre

Fundação D. Anna de Sommer Champalimaud e Dr. Carlos Montez Champalimaud

Avenida Brasília Centro De Investigacao Da Fundacao Champ Alimaud

Lisbon

Portugal

1400 038

Study participating centre

Hospital General Universitario Gregorio Marañón. Servicio Madrileño de Salud

Plaza Carlos Trias, Bertran 7

Madrid

Spain

28020

Study participating centre

Care Healthcare Ltd (UPMC Whitfield)
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Sponsor information

Organisation

European Commission

Sponsor details

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Sponsor type

Government

Website

http://ec.europa.eu/index_en.htm

ROR

<https://ror.org/00k4n6c32>

Funder(s)

Funder type

Government

Funder Name

European Commission

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκή Επιτροπή, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságrol, Europese Commissie,

Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. The study protocol is in the final stages of updates based on feedback from the ethics board and can be submitted on completion.

Intention to publish date

31/12/2023

Individual participant data (IPD) sharing plan

Participant level data is private health data to be held within the hospitals and so is not suitable for public consumption. As part of the Informed Consent the researchers will be asking for permission for use of this data in future research and can change this record if there are sufficient approvals to make a difference.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/12/2022	30/03/2023	Yes	No