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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

Registration date
21/03/2022

Overall study status
Completed

Last Edited
30/03/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Quality of life

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

Key secondary outcome(s))
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

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-IIIA
5.2.1. Stages I-IIIB

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

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 Brasilia Centro De Investigacao Da Fundacao Champ Alimaud
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
European Commission

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, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes