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Clinical study to assess the outcomes of a patient-centred survivorship care plan enhanced with big data and artificial intelligence technologies

Submission date
12/03/2021

Recruitment status
No longer recruiting

Registration date
26/03/2021

Overall study status
Completed

Last Edited
16/08/2023

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
In the last decades, evidence has emerged that the lifestyle of cancer survivors, such as exercise, increased fruit and vegetable consumption, healthy body weight and body composition, smoking cessation, and cognitive behavioral therapy, can positively influence their prognosis. However, few survivors are able to meet all of these recommendations. Many cancer survivors have unmet needs, especially when it comes to improving their quality of life, in addition to extending their life. It is estimated that about one in four people living after cancer treatment face moderate to severe physical or psychological issues after their cancer treatment has ended.
This study is designed to improve health outcomes and quality of life and reduce stress in breast and colorectal cancer survivors who have gone beyond curative cancer treatment. These cancer types have been chosen because of their relatively high incidence and survival rates, making up a relatively large survivor population whose follow-up can be improved. The study will evaluate the impact of the use of big data analytics and artificial intelligence on the self-efficacy of participants following an intervention supported by digital tools.

Who can participate?
Survivors of breast and colon cancer aged 18 to 75 in Belgium, Latvia, Slovenia and Spain

What does the study involve?
The intervention will be carried out through an mHealth app for collecting objective (vital signs) and subjective measurements (e.g. symptoms of depression) with the support of a chatbot. Additionally, the Clinical Decision Support System (CDSS) will enable oncologists to personalize treatment and care plans/follow-up for efficient management of patients.

What are the possible benefits and risks of participating?
No specific risks are expected for the participants.

Where is the study run from?
University of Maribor (Slovenia)

When is the study starting and how long is it expected to run for?
February 2020 to December 2022

Who is funding the study?
European Union Horizon 2020

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Grant No. 875406

Study information

Scientific Title
Patient-centered survivorship care plan after cancer treatments based on big data and artificial intelligence technologies: a multicenter clinical study

Acronym
PERSIST

Study objectives
Performing a comparison at the beginning and at the end of the intervention, participants will significantly increase their self-efficacy following the personalized intervention supported by the mHealth App.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Belgium: Approved 25/08/2020, Institutional Ethics Committee of CHU de Liege (Comité d'éthique Hospitalo-Facultaire Universitaire de Liège, domaine universitaire du Sart-Tilman B35 4000 liège 1; +32 (0)4/366 83 10; ethique@chuliege.be), ref: 2020/248
2. Latvia: Approved 06/08/2020, Riga Eastern Clinical University Hospital Support Foundation Medical and Biomedical Research Ethics Committee (Hipokrata iela 2, Riga, Latvia, LV – 1038; +371 (0)20281174; etika@aslimnica), ref: 8-A/20
3. Slovenia: Approved 18/08/2020, National Ethics Board, Ministry of Health Slovenia (National Medical Ethics Committee, Štefanova 5, 1000 Ljubljana, Slovenia; +386 (0)1 478 69 13; kme.mz@gov.si), ref: 0120-352/2020/5
4. Spain: Approved 21/10/2020, Pontevedra-Vigo-Ourense Research Ethics Committee (Consellería de Sanidade de Galicia, Complexo administrativo de San Lázaro, s/n 15703 Santiago de Compostela; +34 (0)881 542 734 / +34 (0)881 542 747; ceic@sergas.es), ref: 2020/394

Study design
Single-case experimental prospective study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Breast cancer and colorectal cancer survivors

Interventions
The intervention will be implemented via an mHealth App for collecting objective biomarkers (vital signs) and subjective biomarkers (PREMs/PROMs and symptoms of depression) with the support of (embodied) conversational agents. The CDSS (with cohorts and trajectories) will enable the oncologist to deliver personalized recommendations in well-being, personalized treatment and care plans/follow-up for efficient management of patients.

The study is designed as a single-case experimental prospective study with each individual serving as their own control group with the first measurement prior to intervention during recruitment and subsequent measurements every 6 months during follow up. The measurement will involve questionnaires (e.g. CASE-cancer, SSES, Patient Activation Measure; PAM, System Usability Scale; SUS). The study will involve 160 patients (80 survivors of breast cancer and 80 survivors of colon cancer) from four countries (40 each): Belgium, Latvia, Slovenia and Spain. The intervention will be implemented via a digital tool (mHealth Application), for collecting objective biomarkers (vital signs) and subjective biomarkers (PROs and experiences) with the support of (embodied) conversational agent (chatbot). Additionally, the Clinical Decision Support System (CDSS), which will include visualization of cohorts and trajectories, will enable the oncologist to personalize treatment and care plans/follow-up for the efficient management of patients.

Intervention Type
Other

Primary outcome(s)
Perceived self-efficacy measured using the Communication and Attitudinal Self-Efficacy scale for cancer (CASE-cancer) and Strengths Self-Efficacy Scale (SSES) measured prior to the intervention (during recruitment), twice during the intervention (July 2021 and June 2022) and a final measurement at the end of the intervention (December 2022)

Key secondary outcome(s))
1. Patient activation measured using the Patient Activation Measure (PAM) measured prior to the intervention (during recruitment), twice during the intervention (July 2021 and June 2022) and a final measurement at the end of the intervention (December 2022)
2. User acceptance measured using System Usability Scale (SUS) measured three times in July 2021(or August), June 2022 and December 2022
3. User experience measured with User Experience Questionnaire (UEQ) measured three times in July 2021(or August), June 2022 and December 2022
4. Inattentive and careless responding measured with Attentive Responding Scale (ASR) and the Directed Questions Scale (DQS) delivered randomly, since the researchers need to classify those participants that might fall into the Inattentive group and indicate why they are inattentive and try to remotivate them

Completion date
31/12/2022

Eligibility

Key inclusion criteria

1. Age ≥18 and ≤75 years at the moment of recruitment
2. Stable clinical situation, with a life expectancy of more than 2 years according to researcher opinion
3. Ability to understand study instructions, fulfil follow-up visits and sign an informed consent
4. Enough technology literacy that enables the patient to manage with mobile terminals (smartphones, smartphone apps, tablets)
5. Good internet connection in his/her place of residence

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
166

Key exclusion criteria
1. Life expectancy, in the physician opinion's, of less than 1 year
2. Diagnosis of dementia or cognitive decline that makes him/her unable to understand study information and/or sign the informed consent
3. Unable for self-management due to dependence on another person for medication compliance, or measuring blood pressure and daily weigh
4. Lacking decision capacity in relation to diet or preparing meals
5. Current participation in another clinical study
6. Patient has no further follow-up possibilities with enrolling investigation during the planned study period (such as anticipated relocation)
7. Patients with major depression or psychiatric medication that hinders their daily activity

Date of first enrolment
01/04/2021

Date of final enrolment
01/06/2021

Locations

Countries of recruitment
Belgium

Latvia

Slovenia

Spain

Study participating centre
CHU de Liege
Liege
Belgium
4000

Study participating centre
UKC Maribor
Maribor
Slovenia
2000

Study participating centre
Servicio Galego de Saúde
Vigo
Spain
36201

Study participating centre
University of Latvia
Riga
Latvia
1586

Sponsor information

Organisation
University of Maribor

ROR
https://ror.org/01d5jce07

Funder(s)

Funder type
Government

Funder Name
Horizon 2020 Framework Programme (Grant Agreement No. 875406)

Alternative Name(s)
EU Framework Programme for Research and Innovation H2020, Horizon 2020, Horizon 2020 Framework Programme (H2020), Rahmenprogramm Horizont 2020, Horizont 2020, Programa Marco Horizonte 2020, Horizonte 2020, Programme-cadre Horizon 2020, Orizzonte 2020, Programma quadro Orizzonte 2020, H2020

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
Subjects in the study are prospective patients who are in the clinical workflow. In order to ensure their anonymity, no specific dataset will be created to be used outside project PERSIST. The statistical analyses and specific results will be made public, however, through a process of generalization designed to accommodate the specific primary/secondary endpoint.

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	protocol	14/08/2021	16/08/2021	Yes	No
Other unpublished results		10/08/2023	16/08/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes