

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

<b>Submission date</b> 12/03/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/03/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/08/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> 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?  
Dr Izidor Mlakar  
izidor.mlakar@um.si  
Mrs Urska Smrke  
urska.smrke@um.si

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Izidor Mlakar

**ORCID ID**  
<https://orcid.org/0000-0002-4910-1879>

**Contact details**  
Koroška cesta 46  
Maribor  
Slovenia  
2000  
+386 (0)2 220 7267  
izidor.mlakar@um.si

**Type(s)**  
Scientific

**Contact name**  
Mrs Urska Smrke

**ORCID ID**  
<https://orcid.org/0000-0003-3516-0429>

**Contact details**  
Koroška cesta 46  
Maribor  
Slovenia  
2000  
+386 (0)2 220 7267  
urska.smrke@um.si

# 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](mailto: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](mailto: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](mailto: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](mailto: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  $\geq 18$  and  $\leq 75$  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?
<a href="#">Protocol article</a>	protocol	14/08/2021	16/08/2021	Yes	No
<a href="#">Other unpublished results</a>		10/08/2023	16/08/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes