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Behavioural change for cancer prevention: A pilot study protocol of a digital intervention

Submission date
28/08/2025

Recruitment status
No longer recruiting

Registration date
15/10/2025

Overall study status
Completed

Last Edited
01/06/2026

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Cancer remains a major global health challenge, with over 20 million new cases annually. Many cancer cases, especially lung, colorectal, and breast, are linked to modifiable risk factors such as smoking, poor diet, alcohol use, obesity, and inactivity. Psychosocial factors like stress and anxiety also contribute, making Behavioural Change (BC) and Emotional Management (EM) essential strategies for prevention.

To address these risks, the iBeChange pilot study aims to deliver a digital platform that promotes BC and EM through personalised, adaptive interventions. These are supported by AI-powered eHealth tools, which offer tailored feedback and guidance based on individual data. The platform uses a stepped-care model, providing automated support for most users and reserving professional help for those with greater needs.

A wearable sub-study is included to explore the feasibility and benefits of passive, non-intrusive health monitoring. Some participants will use the Oura smart ring, chosen for its discreet design, biometric accuracy, long battery life, and GDPR-compliant data security. These devices collect continuous data on health, emotions, and lifestyle, aiming to reduce participant burden and improve adherence. The sub-study will assess whether wearable users show greater behavioural and psychosocial improvements compared to non-users. By integrating wearable data with questionnaire responses, the sub-study seeks to enhance risk detection and support more effective, personalised interventions.

Ultimately, the project combines digital innovation, emotional support, and behavioural science to create a scalable, user-friendly solution for primary cancer prevention across Europe.

Who can participate?
Otherwise healthy individuals who are at age risk for breast cancer (women aged 45-70 years), colorectal cancer (individuals aged 50-70 years) or lung cancer (individuals aged 50-80 years) and have participated in a screening test for breast, colorectal or lung cancer

What does the study involve?
Individuals who agree to participate in this study will be randomly assigned to one of two

research groups:
A) to the control group, where they will receive a printed document with general lifestyle recommendations for cancer prevention;
or
B) to the experimental group, where they will receive access to the iBeChange mobile application that has a scaled and personalised digital behaviour change intervention for 12 weeks.

In addition, regardless of the group assigned to, participants will have to answer a series of online questionnaires (that will be received through a link on their personal email to access them) to determine their lifestyle habits in health areas at the beginning and at the end of the study, 12 weeks later. Those participants assigned to the experimental group will, at the end, also have to answer questions about their experience with the use of this application.

If randomly assigned to the experimental group, participants will be asked to download an application on their mobile phone, the iBeChange platform. At the start, the app will ask participants to answer questions to know about their habits (smoking, alcohol consumption, nutrition, physical exercise), their emotional state, and their context for achieving healthier lifestyle habits. The iBeChange app will guide participants every step of the way to achieve habit change through missions, and by providing personalised recommendations and resources. Periodically, the app will ask participants to answer questions to track their progress in changing their habits and their emotional state.

Within the application, and if deemed necessary and if participants meet the criteria for adherence to the intervention, they can write messages to a professional to resolve any doubts they may have, and even access pre-arranged video calls with a professional, to help them in the process of adopting healthier lifestyle habits and improving their wellbeing. Also, if they are randomly assigned to the experimental group, they may be invited to participate in a sub-study to integrate smart rings in the iBeChange digital solution under a separate informed consent form.

What are the possible benefits and risks of participating?
Those in the experimental group will benefit from closer monitoring of their health habits and psychosocial care, along with support from a health professional when needed during the study. If assigned to the control group, participants will be able to have detailed information about their health habits and emotional well-being.
This pilot study is of minimal risk due to its non-invasive nature. The administration of online questionnaires and the use of a mobile application to promote behaviour change have no risk of complications. The maximum number of questions to be answered is 156 with an estimated response time of 75 minutes.

Where is the study run from?
Catalan Oncology Institute (ICO) is leading the clinical studies of the iBeChange project on behalf of the iBeChange consortium, and coordinates and supervises the training and activity in all three recruitment centres (ICO, Barcelona, European Institute of Oncology (IEO), Italy, and Carol Davila University of Medicine and Pharmacy (UMFCD), Romania).

When is the study starting and how long is it expected to run for?
July 2025 to August 2026

Who is funding the study?
This pilot study is part of the European project iBeChange: ‘Addressing psychosocial and lifestyle

risk factors to promote primary cancer prevention: an integrated platform to promote behaviour change', funded by the European Commission under a Horizon Mission Cancer grant.

Who is the main contact?
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Additional identifiers

Protocol serial number
Horizon Mission Cancer grant no. 101136840

Study information

Scientific Title
Studying the feasibility of a 12-week stepped-care digital behavioural change intervention towards healthier lifestyle and emotional wellbeing habits for cancer prevention: A pilot study (iBeChange pilot study)

Acronym
iBeChange pilot study - iBC/PS

Study objectives
The primary objective of this pilot study is to assess the feasibility of iBeChange. This digital behavioural change platform aims to address lifestyle and psychosocial risk factors associated with cancer risk in a personalised way.
Additionally, preliminary data regarding the effectiveness and cost-effectiveness of iBeChange compared to general cancer prevention guidelines will be collected.
Additionally, exploratory data will be collected from Oura smart rings from the allocated participants.
Finally, usability and satisfaction will be assessed for the iBeChange platform and for the selected wearable devices.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/07/2025, Ethics Committee for Research with Medicines (CEIm) of Bellvitge University Hospital (C/Feixa Llarga, s/n, L'Hospitalet de Llobregat (Barcelona), 08907, Spain; 93 260 73 89; presidenciaceic@bellvitgehospital.cat), ref: PR101/25

Primary study design
Interventional

Study design

Multicenter interventional randomized pilot study

Study type(s)
Efficacy, Prevention, Other

Health condition(s) or problem(s) studied
Prevention of lung, breast, and colorrectal cancer disease in the healthy at-risk age population

Interventions
This pilot study includes two randomisations, both carried out centrally using the REDCap platform. The first randomisation assigns subjects in a 1:1 ratio to the control and experimental groups, stratifying by participating centre. The second randomisation will be carried out on subjects from the experimental group who express their willingness to participate in the wearable sub-study by signing the dedicated ICF, assigning them in a 1:1 ratio to the Oura and non-Oura groups, stratified by participating centre.

Participants will be randomly assigned to two different groups: the experimental group (EG), which will receive a digital stepped-care intervention (i.e., iBeChange; iBC), used as a smartphone application, and the control group (CG), which will receive the usual practice recommendations (UPR). The experimental intervention will last 12 weeks. Outcomes will be obtained at baseline and at the end of the intervention (12 weeks).

Intervention Type
Behavioural

Primary outcome(s)
The primary outcome measure of this pilot study is its feasibility, which will be assessed through the following variables:
1. Recruitment capability will be measured by collecting the recruitment numbers and rate per centre and in total for the pilot study duration. Potential difficulties in the recruitment process will be registered and analysed. Also, the resulting sample characteristics will be studied according to demographic variables.
2. The integrity of the data collection procedures and outcome measures will be measured using the completion of study questionnaires at baseline and after 12 weeks at the end of the intervention
3. The acceptability and suitability of intervention and study procedures will be measured by the System Usability scale and open-ended feedback at the end of the intervention from participants in the experimental group
4. The resources and ability to manage and implement the study and intervention will be measured using the feedback from study personnel on the workload and areas for improvement collected for further analysis and development of mitigation strategies to implement in the larger RCT.

Key secondary outcome(s)
The following secondary outcome measures are the preliminary effectiveness and cost-effectiveness of iBeChange in achieving a sustainable behavioural change in smoking, alcohol consumption, nutrition, physical activity habits, and emotional well-being symptoms at baseline, and the end of the intervention (12 weeks), unless stated:
1. Behavioural change in Smoking habits is measured using seven-day point prevalence abstinence, average of cigarettes smoked per day in the past seven days, and the Fagerström test for Nicotine Dependence (FTND) by all participants

2. Behavioural change in Alcohol consumption habits is measured using the Alcohol Use Disorders Identification Test by all participants
3. Behavioural change in Nutrition habits is measured using the Nutri S-Can scale by all participants
4. Behavioural change in Physical activity is measured using the Global Physical Activity Questionnaire (GPAQ) by all participants
5. Emotional distress is measured using the Emotional Distress Thermometer – 0-10 Visual Analogue Scale (VAS) by all participants
6. Perceived Stress is measured using the Perceived Stress Scale (PSS-4) by all participants
7 i 8. Anxiety and Depression are measured using the Patient Health Questionnaire (PHQ-4) by all participants
9. Social support is measured using one item from the Protocol for Responding to and Assessing Patient Assets, Risks, and Experiences (One item from PRAPARE) by all participants
10. Insomnia is measured using item #3 of the Patient Health Questionnaire (PHQ-9) by all participants
11. Usability of the iBeChange intervention (with or without the Oura ring) is measured using the System Usability Scale (SUS) at the end of the intervention (12 weeks) from participants in the experimental group.
12. Cost-effectiveness is measured using an ad-hoc questionnaire for this project, assessing household income, healthcare costs, behaviour-related costs, and working situation

Completion date
19/08/2026

Eligibility

Key inclusion criteria
1. Ability to understand and voluntarily provide signed written informed consent approved by the study site's Institutional Review Board (IRB).
2. Being at a high-risk age for breast (women between 45-70), colorectal (individuals between 50-70) or lung cancer (individuals aged 50-80 years).
3. Having participated in a test for early detection of cancer (i.e., mammography or ultrasound for breast cancer, faecal occult blood test (FOBT) or colonoscopy for colorectal cancer, and CT-scan for lung cancer)

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
45 Years

Upper age limit
80 Years

Sex

All

Total final enrolment
210

Key exclusion criteria
1. History of any prior or current personal cancer diagnosis. In the case of colorectal and breast cancer, this will be restricted to the pathology tested for screening.
2. Current severe disease that may significantly compromise the performance on the study according to the criteria of the investigator.
3. Not owning a smartphone.
4. For breast and colorectal cancer, participants undergoing screening for alert symptoms or family history of these cancer types (the latest are eligible for specific hereditary cancer programs).

Date of first enrolment
15/12/2025

Date of final enrolment
27/05/2026

Locations

Countries of recruitment
Italy

Romania

Spain

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Catalan Oncology Institute (ICO) [Institut Català d'Oncologia (ICO)]
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Sponsor information

Organisation
Institut Català d'Oncologia (ICO)

ROR
https://ror.org/01j1eb875

Organisation
European Institute of Oncology

ROR
https://ror.org/02vr0ne26

Organisation
Carol Davila University of Medicine and Pharmacy

ROR
https://ror.org/04fm87419

Funder(s)

Funder type
Government

Funder Name
European Health and Digital Executive Agency

Alternative Name(s)
Health and Digital Executive Agency, Agencia Ejecutiva Europea en el Ámbito Sanitario y Digital, Europäische Exekutivagentur für Gesundheit und Digitales, Agence exécutive européenne pour la santé et le numérique, Agenzia esecutiva europea per la salute e il digitale, HaDEA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The pseudonymised datasets generated during the current pilot study are planned to be stored in a non-publicly available repository (internal databases). The aggregated data results of the analysis of the current study will be published in a scientific, peer-reviewed publication. The data collected will be useful only for the development of the platform and its later validation through a larger randomized controlled trial. The Consortium will consider open availability based on utility and appropriate consents as the programme develops.

IPD sharing plan summary
Published as a supplement to the results publication, Stored in non-publicly available repository