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Evaluation of the effectiveness and transferability of the digital health platform (ProACT) to support home-based multimorbidity self-management in Europe

Submission date	**Recruitment status**	[X] Prospectively registered
05/01/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/01/2023	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/01/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Older persons with multimorbidity (PwMs) face considerable challenges in managing their conditions. They must monitor symptoms, take medications, and coordinate with care providers, to name just a few tasks. They must also manage their conditions despite the limitations of healthcare systems; systems traditionally designed to support those with single conditions, faced with an ageing population amongst whom multimorbidity is increasingly prevalent. One potential solution is to empower PwMs, using digital health, to self-manage their conditions with support. However, research examining digital solutions in this context is limited. The SEURO trial, upon which this study builds, is one of the few studies to test and demonstrate at a proof-of-concept level the potential utility of a digital health solution, ProACT, in facilitating multimorbidity management in older persons. The aim of this study is to examine the effectiveness and implementation of the updated personalised ProACT platform, combined with the ProACT-service care network and clinical triage service support, in comparison to the updated standardised ProACT platform, absent ProACT-service care network and clinical triage service support, and in comparison to standard care. The completion of this study will also facilitate the realisation of wider project aims: to evaluate the key factors necessary to prepare any EU region to implement and scale innovative, people-centric, digitally integrated health and social care solutions for multiple disease management.

Who can participate?
Persons aged 65 years old and over with two or more of the following conditions: diabetes; chronic respiratory disease (i.e., COPD, chronic bronchitis, emphysema, or chronic asthma); chronic heart disease, coronary artery disease, or cardiovascular disease (i.e., hypertension, atherosclerosis, angina, or arrhythmia); and chronic heart failure.
Care Network members (CNs; i.e., informal carers, formal carers and formal care quality assistants, and healthcare professionals).

What does this study involve?
PwMs will be randomly assigned to one of three trial arms. Those assigned to Trial Arm 1 will receive measuring devices relevant to their conditions (e.g., a pulse oximeter), the personalised ProACT CareApp, and a tablet device upon which they can view the CareApp. They will also receive a ProACT-service care network and clinical triage service support. Those assigned to Trial Arm 2 will receive measuring devices relevant to their conditions, the standardised ProACT CareApp, and a tablet device. Those assigned to Trial Arm 3 will continue to manage their healthcare as usual.

All PwMs will complete questionnaires at the beginning, once per month during, and at the end of their trials. A selection of Trial Arm 1 and 2 PwMs will participate in interviews at the beginning and end of their trials. Trial Arm 1 and 2 PwMs' system use data (e.g., how often they use the CareApp) and system data (e.g., symptom measurements) will be collected throughout their trials.

CNs will receive access to a customised ProACT CareApp, through which they can view their PwM's health and well-being data and educational material. They will also complete questionnaires at the beginning and end of their trials, a selection will participate in interviews at the end of their trials, and their system-use data will be collected throughout their trials.

Healthcare organisation management who oversee the delivery of ProACT will complete questionnaires several months prior to, immediately prior to, and after the trial; a selection will also participate in interviews after the trial. A selection of healthcare organisation staff who facilitate the delivery of ProACT during the trial will participate in interviews after it, as will clinical triage service nurses.

What are the possible benefits and risks of participating?
ProACT may help Trial Arm 1 and 2 PwMs to manage their conditions; ProACT-service care network and clinical triage service support may also facilitate improved support for Trial Arm 1 PwMs, and enhanced well-being amongst informal carers (e.g., due to reduced carer burden).

If Trial Arm 1 and 2 PwMs have never used a tablet device, they will have the opportunity to learn how, and if they do not have an internet connection, they will receive one for six months.

Trial Arm 1 and 2 PwMs may find it inconvenient to use the measuring devices. However, the harm of such inconvenience is transient, and they will be free not to use particular devices.

Monitoring their health and well-being may cause undue anxiety. However, to minimise this risk, the role of ProACT will be clearly explained: it is to be used as a self-management tool, as part of which PwMs can learn to better understand their baseline symptoms and what is 'normal' for them. This may facilitate a reduction in their anxiety. Should they have any concerns, the researchers will be happy to talk at any time. If they are concerned about their health, they will be encouraged to seek medical advice, as they usually would. They will also be free to withdraw from the study at any time.

For Trial Arm 1 PwMs, a clinical triage service will view their vital signs. However, they will be informed that they should follow their usual response procedures if they observe changes in their vital signs or feel unwell (e.g., they should contact their GP). In addition, they will be informed that the clinical triage service will operate during normal working hours only and will no longer be available after the conclusion of their trials. Trial Arm 2 PwMs will also be informed that they should follow their usual response procedures if they observe changes in their vital signs or feel unwell.

Participants will be asked to complete questionnaires and take part in interviews. Some may find it upsetting to answer questions about issues related to living with chronic conditions or caregiving. They will be informed that they can decline to answer any question and that they can withdraw from the study at any time without giving a reason. The researchers will be available to discuss any concerns.

Where is the study run from?
The study will be implemented across Ireland, Belgium and Sweden

When is the study starting and how long is it expected to run for?
May 2021 to November 2025

Who is funding the study?
SEURO received funding from the European Union's Horizon 2020 (H2020) research and innovation programme under Grant Agreement No. 945449

Who is the main contact?
Dr John Dinsmore (Project Coordinator/Lead Principal Investigator), dinsmorj@tcd.ie (Ireland)
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Study website
https://www.seuro2020.eu

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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
Scaling European citizen-driven transferable and transformative digital health: a multi-site effectiveness-implementation hybrid trial of the Digital Health Platform ProACT to support older adults managing multiple chronic health conditions (multimorbidity) in Europe

Acronym
SEURO

Study objectives
1. To evaluate the impact of the ProACT platform on people with multimorbidities QoL and HCU (i.e., the trial primary outcomes). Participants in each trial arm will be compared with these outcome variables
2. To evaluate the cost-effectiveness of the personalised ProACT CareApp with the care network and triage support in comparison to the non-personalised ProACT CareApp and control group
3. To explore via a mixed methods approach (analysis of system and questionnaire data and interviews with participants) the potential impact of ProACT on multimorbidity self-management
4. To evaluate the impact of the ProACT platform on informal carers' caring burden
5. To evaluate participants' (people with multimorbidity and care networks) overall experiences with the ProACT platform in managing multimorbidity. Data collected from participants in Trial Arms 1 and 2 will also be compared. Furthermore, to explore the impact of contextual factors (e. g., participants' conditions, age, and socioeconomic status; care network participants' motivation to take part in the trial) on the fidelity of use and use outcomes (e.g., reach, uptake, and acceptability)
6. To understand how ProACT is implemented and delivered in healthcare settings, and to

identify systematic differences and variations in delivery
7. To evaluate via the process evaluation organisational readiness to transfer and optimise a digital health solution as part of the care delivery
8. To evaluate whether trial outcomes can inform future analysis of the impact of digital solution implementation in practice

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 23/12/2021, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; +46 0104750800; registrator@etikprovning.se), ref: 2021-05368-01
2. Approved 01/07/2022, Trent College Dublin Faculty of Health Sciences Research Ethics Committee (Faculty of Health Sciences, Chemistry Building, Trinity College Dublin, The University of Dublin, Dublin 2, Ireland, UK; +35318964255; ldohert@tcd.ie), ref: 220504
3. Approved 07/07/2022, DkIT School of Health and Science Research Ethics Committee (Dundalk Institute of Technology, Dublin Road, Dundalk, County Louth, A91 K584, Ireland; +353429370200; dolores.mcgill@dkit.ie), ref: none available
4. Approved 20/07/2022, HSE NorthEast Research Ethics Committee (Bective Street, Kells, County Meath, A82 NX32, Ireland; +353494377343; consumeraffairs.hsedne@hse.ie), ref: REC/22/026
5. Approved 22/07/2022, Caredoc Ethics Committee; Caredoc, St. Dympna's Hospital, Athy Road, Carlow, County Carlow, R93 DE62, Ireland; +353599138199; info@caredoc.ie), ref: none available
6. Approved 26/09/2022, Blackrock Clinic Ethics Committee; Blackrock Clinic, Rock Road, Blackrock, Co. Dublin, A94 E4X7, Ireland; +35312832222; info@blackrock-clinic.com), ref: none available
7. Approved 28/09/2022, Universitair Ziekenhuis Brussel Ethics Committee; Commissie Medische Ethiek, Laarbeeklaan 101, 1090 Brussel, Belgium; +3224775584; commissie.ethiek@uzbrussel.be), ref: EC-2022-246

Study design
12-month multi-site mixed-methods study comprising a pragmatic-randomized controlled trial and process evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied

Multimorbidity consisting of two or more of any of the following:
1. Diabetes
2. Chronic Respiratory Disease (i.e., COPD, Chronic Bronchitis, Emphysema, and Chronic Asthma)
3. Chronic Heart Disease, Coronary Artery Disease, and Cardiovascular Disease (i.e., Hypertension, Atherosclerosis, Angina, and Arrhythmia)
4. Chronic Heart Failure

Interventions

This 12-month multi-site trial will adopt a Type 1 Effectiveness-Implementation Hybrid design, which will comprise a pragmatic-Randomised Controlled Trial and process evaluation to assess the effectiveness and implementation of ProACT in real-world conditions respectively, with the person with multimorbidity (PwM), recruited on an ongoing basis during the first six months of the trial, randomly assigned to one of three unblinded trial arms for six months:
1.0. Trial Arm 1 participant receives:
1.1. Tablet device and suite of sensors devices. These include 'off-the-shelf' devices that are used to collect health and wellbeing data from PwM in their homes (e.g., blood glucose, blood pressure, pulse oximetry, heart rate, weight, sleep, and/or activity measures).
1.2. Personalised ProACT CareApp
1.3. Ability to link in with their Care Network (informal carer, formal carer and healthcare professional) via customised ProACT CareApp user interfaces tailored to each key stakeholder group
1.4. Clinical triage service and technical Helpdesk support (Mon to Fri 9am to 5pm)

Details on personalised ProACT CareApp: Accessed via an interactive device (e.g., a tablet or smartphone), this app displays users' health and wellbeing data as derived from the different measuring devices. To support PwM self-managing their health and wellbeing, the CareApp provides feedback (e.g., feedback on health status including exacerbations), tools (e.g., medication management tools and goal-setting features), and personalised educational content (e.g., written, audio, and visual content sourced from relevant, reliable, and trusted organisations localised by region) that is contextualised to the person's current health and wellbeing status. It also provides participants with the option to self-report through a series of questions about their health and wellbeing (e.g., for those parameters not easily measured by a sensing device, such as breathlessness, mood etc.) Trial Arm 1 will receive: Tablet device and suite of sensors, Personalised ProACT CareApp, have the ability to include their Care Network via, be in receipt of clinical triage service and technical Helpdesk support (Mon to Fri 9am to 5pm).

2.0. Trial Arm 2 participant receives:
2.1. Tablet device and suite of sensors devices. These include 'off-the-shelf' devices that are used to collect health and wellbeing data from PwM in their homes (e.g., blood glucose, blood pressure, pulse oximetry, heart rate, weight, sleep, and/or activity measures).
2.2. Standard ProACT CareApp with no personalisation. The primary differences in the CareApp for those in trial arm 2 are that exacerbations are not highlighted and educational content is not contextualised to current status, therefore representing a more standard application that might be downloaded from an app store.
2.3. Technical Helpdesk support (Mon to Fri 9am to 5pm).

3.0. Trial Arm 3 participant receives:
Usual care (no technology)

Intervention Type

Behavioural

Primary outcome measure

1. Quality of Life measured using the EuroQol EQ-5D-5L questionnaire and Control, Autonomy, Self-realisation and Pleasure Scale (CASP-19) at T1 (baseline) and T7 (at the end of a PwM's 6-month trial period)
2. Healthcare Utilisation measured using a SEURO trial-designed Healthcare Utilisation questionnaire at the beginning of the trial period, once per month during, and at the end of a PwM's 6-month trial period (at T1, T2, T3, T4, T5, T6, and T7)

Focus is on exploring cost effectiveness using these outcomes.

Secondary outcome measures

Persons with multimorbidity (PwMs):
1. Type, number, and perceived burden of comorbidities measured, measured using the Comorbidity Index, baseline and 6 months post-baseline
2. Self-care, the belief in one's ability to self-care, and the self-care of chronic illness, measured using the Self-Care Chronic Illness Inventory, baseline and 6 months post-baseline
3. Medication adherence, measured using the MARS-5, baseline and 6 months post-baseline
4. Health literacy, measured using the HLS-EU-Q16, baseline and 6 months post-baseline
5. Digital health literacy, measured using the eHealth Literacy Scale, baseline and 6 months post-baseline
6. Digital literacy, measured using the MDPQ-16, baseline and 6 months post-baseline
7. Technology acceptance, measured using the UTAUT2, at 6 months
8. The usability of the ProACT technology, measured using the User Burden Scale, at 6 months
9. The utility of and experiences with ProACT, measured using a SEURO-trial-designed ProACT Impact Evaluation questionnaire, at 6 months
10. The health support system of PwMs (e.g., the individuals in PwMs' care networks and the role they play), measured using a SEURO-trial designed Health Support System questionnaire, baseline and 6 months post-baseline
11. Expectations about ageing (e.g., expectations about physical health, mental health, and cognitive function), measured using the ERA-12, at baseline and 6 months post-baseline
12. Self-management effectiveness (e.g., setting and meeting activity goals and controlling symptoms), measured daily using system data throughout the participants' trial period (baseline to 6 months post-baseline) and by interview at 6 months
13. Engagement with ProACT, measured daily using system data throughout the participants' trial period (baseline to 6 months post-baseline) and by interview, at 6 months
14. Experiences with ProACT (e.g., the usability, accessibility, and acceptability of, and engagement, satisfaction, and overall experiences with ProACT) measured daily using system data throughout the participants' trial periods (baseline to 6 months post-baseline) and by interview at 6 months
15. The care network of PwMs (e.g., the quality of support), measured using interviews, at baseline and 6 months post-baseline
16. Demographic data (e.g., gender, date of birth, and marital status), which will be used to perform inferential statistics and to include as covariates during the analysis of primary and secondary outcomes etc., measured using a SEURO-trial designed Demographics questionnaire, at baseline.

Care Network Members:
1. Carer burden, measured using the Zarit Burden Interview, at baseline and 6 months post-baseline. This measure completed by informal carers only.

2. The usability of the ProACT technology, measured using the User Burden Scale at 6 months.
3. The utility of and experiences with ProACT, measured using a SEURO trial-designed questionnaire at 6 months.
4. Daily engagement with ProACT measured using system data throughout the participants' trial periods (baseline to 6 months post-baseline)
5. Experiences with ProACT (e.g., the usability, accessibility, and acceptability of, and engagement, satisfaction, and overall experiences with ProACT), explored by interview, at 6 months.
6. Demographic data, collected using a SEURO-trial designed Demographics questionnaire, at baseline.

Healthcare Organisations:
1. Healthcare organisations' administrative data, which will be used to explore, for instance, the factors that differentiate between organisations that do and do not implement and deliver ProACT with fidelity, measured using a SEURO-trial designed questionnaire prior to the commencement of the trial, at baseline and 12 months post-baseline.
2. Healthcare organisations' preparedness for digital health solution transfer, measured using the ProTransfer questionnaire, measured at least 4-6 months pre-baseline, baseline and 12 months post-baseline
3. Experiences of ProACT (e.g., the reach, uptake, and fidelity of implementation of, the usability, accessibility, and acceptability of, and engagement, satisfaction, and overall experiences with ProACT), measured using an interview, at 12 months post-baseline

Clinical Triage Service Nurses:
1. Daily engagement with ProACT (e.g., the number of calls made by nurses to PwMs in response to alerts) measured using system data throughout the trial (baseline to 12 months post-baseline). This data may also be indicative of PwMs' self-management efforts and outcomes
2. Experiences with ProACT (e.g., the usability, accessibility, and acceptability of, and engagement, satisfaction, and overall experiences with ProACT), measured using an interview, at 12 months post-baseline

Overall study start date
03/05/2021

Completion date
02/11/2025

Eligibility

Key inclusion criteria
Participants with multimorbidity must:
1. Be aged 65 years old and over
2. Possess sufficient cognitive capacity to provide written informed consent
3. Have at least 2 of the following conditions: diabetes, chronic respiratory disease (e.g. chronic obstructive pulmonary disease (COPD), chronic asthma), chronic heart failure, chronic heart disease (e.g., coronary artery disease, cardiovascular disease (including hypertension, atherosclerosis, angina or arrhythmia))

For care network participants to be included, the person with multimorbidity must provide consent for their participation. Care network participants must:
1. Be aged 18-90 years old and over

2. Be providing support to a consented participant with multimorbidity in trial arm 1 (if they are an informal carer, they must be providing support to a participant with multimorbidity for at least six months; and if they are a formal carer, formal care Quality Assistant, or healthcare professional, they must be formally recognised as such and possess at least two years' experience of professionally working in a relevant health or primary care setting with people with multimorbidity with the same health conditions as those involved in the current trial)
3. Have access to a tablet, smartphone, or computer with an internet connection
4. Possess the skills to use an internet-based application or website
5. Possess sufficient cognitive capacity to provide written informed consent

Partner organisation management and staff must:
1. Be aged 18 or older
2. Be overseeing and/or implementing the delivery of ProACT to their clients with multimorbidity
3. Have access to a tablet, smartphone, or computer with an internet connection
4. Possess the skills to use an internet-based application or website

Participant type(s)
Mixed

Age group
Mixed

Lower age limit
65 Years

Sex
Both

Target number of participants
720 participants with multimorbidity; a maximum of 1500 care network participants

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
23/01/2023

Date of final enrolment
02/05/2025

Locations

Countries of recruitment
Belgium

Ireland

Sweden

Study participating centre
Caredoc
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St. Dympna’s Hospital
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Study participating centre
Home Instead Senior Care
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Sponsor type
Government

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ROR
https://ror.org/04xvhsp09

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

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

Intention to publish date
02/05/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. No trial data will be made openly available. Due to the personal nature of the data collected, data will not be available outside of the trial site partners within the consortium. In addition, although data will be pseudonymised, there is risk that individuals could be identified from their data. Hence, even pseudonymised data cannot be made openly available. While these datasets will not be made openly available, the possibility of making them discoverable for transparency will be investigated throughout the SEURO project. If any changes are made this will be updated with outcomes later in the project timeline.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	20/01/2023	No	Yes
Participant information sheet	20/01/2023	No	Yes