SEURO

Participant Information Leaflet

for

Persons with Multimorbidity

Study Title

Scaling EUROpean citizen driven transferable and transformative digital health (SEURO): An Effectiveness-Implementation Hybrid Trial

SEURO

Netwell CASALA

DUNDALK INSTITUTE OF TECHNOLOGY

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

SEURO

Dear Reader,

You are invited to take part in a research study being carried out by Dundalk Institute of Technology and Trinity College Dublin.

Before you decide whether you wish to take part, you should carefully read the information provided below, and if you wish, discuss it with your family, friends, or doctor. It is important that you do not feel rushed or under pressure to decide whether to take part. If you have any questions, you can contact a member of the research team using the details provided at the end of this leaflet.

You should clearly understand the risks (e.g., the time demands of participation in this study) and benefits (e.g., the potential opportunity to use technology to monitor your health) of taking part so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You do not have to participate in this study and a decision not to do so will have no impact on the healthcare treatments or services you receive now or in the future. You can also change your mind about taking part at any time. Even if the study has started, you can still choose to leave it. You do not have to provide a reason. If you do opt out, it will not affect the quality of the treatments or services you receive.

Why is this study being done?

People with more than one chronic health condition (e.g., heart-related, diabetes, chronic bronchitis, hypertension) sometimes find it difficult to keep

track of the different symptoms, medications, and tasks that are needed to manage their health and well-being. The aim of this study is to find out if a new technology system called ProACT can help them with these tasks and improve the support they receive.

The ProACT technology system is designed to help people to measure symptoms and activities related to their health and well-being (e.g., their blood pressure levels, physical activity, and sleep), to view all this information in an app on a tablet device (e.g., an iPad) or a smartphone, to help them to manage aspects of their health and well-being (e.g., to create medication lists and activity goals), and to receive educational material about their health conditions. It also allows people to share their health and well-being information with people in their care networks (e.g., a family member or doctor).

Who is organising and funding this study?

This study is being carried out by researchers at Dundalk Institute of Technology and Trinity College Dublin as part of a project called SEURO, which involves 12 partners across 4 European countries. A full list of partners involved in the wider project is provided at the end of this leaflet. The funding has been provided by the European Union, under a programme of research called Horizon 2020.

Why am I being asked to take part?

We are asking individuals who are aged 65 and older and who have two

or more of the following health conditions to participate in this study:

- Diabetes
- Chronic Respiratory Disease (e.g., Chronic Obstructive Pulmonary Disease (COPD), Chronic Bronchitis, Emphysema, or Chronic Asthma)
- Chronic/Congestive Heart Failure, Coronary Artery Disease, or Cardiovascular Disease (e.g., Hypertension, Atherosclerosis, Angina, or Arrhythmia)

Who cannot take part?

- People who are under 65 years of age
- People who do not have two or more of the health conditions listed above
- People with a current diagnosis of dementia or a problem with their memory or thinking that would prevent them from being able to provide informed consent (i.e., that would prevent them from being able to understand why this study is being carried out and what their participation would involve)

How will the study be carried out?

Participants will take part in this study for six months. The study aims to test the potential impact of the ProACT technology on a person's quality of life (e.g., their mobility, level of pain or discomfort, and level of anxiety or depression), use of healthcare services (e.g., how often they attend hospital), and ability to self-manage their conditions. Participants will be randomly

assigned to one of three groups. If you are assigned to group one or two, you will receive and use variations of the technology. If you are assigned to group three, you will continue to receive and use your existing healthcare (will not receive any technology).

We will provide participants in groups one and two with the following items of technology, as well as full training in how to use them:

- **Measuring Devices to monitor health conditions**: Depending on your health conditions, you will be provided with measuring devices relevant to you. You may be offered a smart watch (e.g., to measure your physical activity levels and sleeping patterns), a blood glucose monitor (e.g., to measure the level of sugar in your blood), a blood pressure monitor, a pulse oximeter (e.g., to measure the level of oxygen in your blood), a thermometer and/or a weight scale. You will be required to return the measuring devices at the end of your six-month study period; at which time we can offer you advice on purchasing your own replacement devices if you wish to do so. If you already own a relevant measuring device and wish to use it during the study, you can do so.

- **ProACT CareApp**: We will ask you to regularly use the ProACT CareApp. This is an online platform that works on a computer/laptop, tablet device (e.g., an iPad), or a smartphone. If you have your own device you can use this to access the ProACT CareApp, otherwise, we can provide you with an iPad for the duration of the study. You can use the

ProACT CareApp to view the health and well-being data that you measure through the devices (e.g., your blood pressure readings), create a medication list and schedule, receive feedback and educational material about your health conditions, set activity and weight goals, and answer questions about your health and well-being. If you receive an iPad from the team, you will have to return it at the end of your six-month study period; at which time we can offer you advice on purchasing your own if you wish to do so.

- **Internet:** If you do not have an Internet connection, we may be able to arrange and cover the costs of one throughout your six-month study period.

If you are assigned to group one, you will receive support from a clinical triage service, provided by nurses employed by the healthcare organisation Caredoc in County Carlow. The nurses will monitor your vital signs (e.g., your heart rate, blood pressure, and blood oxygen levels[1]) between 9am and 5pm Monday to Friday during your six-month study period only (i.e., they will not monitor your vital signs after this period ends). A nurse will phone you if your vital sign readings are unusual and will advise you on what to do. The nurse will only monitor and advise you on vital sign readings that could have an immediate negative impact on your health (e.g., unusual blood pressure readings); they will not monitor or advise you on non-vital sign readings (e.g., activity levels and sleep). The clinical triage service is not a replacement for your doctor; if you feel unwell or worried about any symptoms at any time during the study, you should still follow your usual healthcare plan, such as

[1] The vital signs that are monitored will be different for different people, and will depend on what conditions you are monitoring.

contacting your GP or the emergency services.

The objective of this study is not only to examine how the technology can help you to manage your own health and well-being, but to also examine whether the technology might help to improve the quality of support you receive. If you are assigned to group one, you will also have the option of including up to five people in your care network in this study (e.g., informal carers such as your family or friends, formal carers such as your paid care assistant, and/or healthcare professionals such as your GP or pharmacist), provided these individuals wish to participate. Care network individuals will be able to view your health and well-being data (i.e., your readings), or the aspects of this data that you wish them to see, during the study period via their own tablet device, smartphone, or computer. They will also receive access to educational material about your health conditions and how to provide support.

However, if you prefer not to include a care network member in this study, you are free to take part on your own. Even if you do not wish for your GP to take part, you will receive a letter and a copy of this information leaflet to give to them should you decide to let them know that you are taking part.

It is important to note that while you might add one of your healthcare professionals to your care network in this study (e.g., your GP or consultant), they are under no obligation to monitor your data. Furthermore, they will not use this data to make any decisions about the treatment you receive. Rather, it may be used as a prompt to further investigate any issues of concern.

Should you decide to take part in this study, full details on what we will ask you to do and information we require are provided in the next section. We

hope that 300 individuals will participate in this study, which will provide us with a lot of useful information about health and well-being management, the effectiveness of the technology, and how it might be improved.

What will happen to me if I agree to take part? What information about me will be used as part of this study?

1. Study Induction

If you wish to participate in this study, we will ask you to complete an informed consent form to indicate your agreement to participate, whilst fully understanding what participation involves. We can send this to you via post, with a stamped addressed envelope to return the form, or you can do this online if you are comfortable with that. Once we receive a signed informed consent form, you will be randomly assigned to one of the three study groups.

If you are in group one, you will receive the measuring devices and ProACT CareApp. You can also add people to your care network (e.g., family members, paid care assistants, or clinicians) and your vital signs will be monitored by the clinical triage nurses.

If you are in group two, you will receive the measuring devices and ProACT CareApp. You will not be able to add people to your care network or have access to the clinical triage service.

If you are in group three, you will not receive any technology or additional services beyond your usual care. While we would love for everyone to be able

to try the technology and to have access to the clinical triage service, the purpose of the study is to understand what impact both the technology system and associated support (from the clinical triage service and a care network) have on participants' health and well-being, and self-management. As such, group three participants are an essential part of the research. If you are assigned to group three, we will provide you with regular updates on the project, and at the end of the trial, we will provide you with information on the measuring devices used and where to access them should you be interested.

You will be free to withdraw from this study at any time, even after you have signed the informed consent form. A decision to not participate or to withdraw from this study further down the line will have no adverse impact on you or the healthcare services or treatments you receive. A researcher will call you to let you know which group you are in and to prepare you for starting the study.

2. Personal data

If you decide to take part in the study, we will ask you to provide the following personal information. We have also listed the main reasons why we will ask you for this information.

Name: to identify you so that we can apply an ID code to all information you provide throughout the study (i.e., so that your identity can remain confidential; only select members of the research team will be able to link your name with this code; more information about this process is provided later in this leaflet).

Home address: to facilitate home visits to provide and remove the technology at the beginning and end of the study, and to resolve any technology issues you may have during the study (if you are assigned to group one or two). To post informed consent forms to you (all groups). For those in group one, this information will also allow the clinical triage team to direct an emergency response service to you, if needed.

Phone number/email address: to organise home visits and to provide a way for the research team to contact you about the study.

3. Study Questionnaires and Interviews

At the start of the study, we will ask you to complete some questionnaires that capture demographic information (e.g., your gender and date of birth), health and well-being information, and your current healthcare service use. You can fill these out in different ways. If you are comfortable with technology, we will email you a link to the questionnaires and these can be completed online. Otherwise, if you are in group one or two, we can complete these with you when we call to your home to set up the technology or you can complete the questionnaires with the research team over the phone. For those in group three, questionnaires can be completed online or, if you prefer, the research team can assist you complete the questionnaires over the phone. You will be free not to answer any particular questions if you prefer not to.

If you are in group one or two, with your permission we may also ask you to participate in an interview during the initial visit to your home or by phone. During this interview, we will ask you about your experiences of managing

your health to date and how often you use healthcare services.

4. Technology Provision

For those in group one or two, a researcher will provide you with the technology during the initial visit to your home. You will be asked to use the technology for six months. You will be offered the use of all measuring devices that are relevant to your health conditions (e.g., you will be asked to use a blood glucose monitor if you have diabetes), and you will be free to choose which ones you want to use. Some of the measuring devices will require little or no interaction from you and will automatically record information (e.g., the smart watch will automatically count the number of steps you take during a day). Other measuring devices will require your active engagement (e.g., you will need to actively use the blood pressure monitor to take a reading). Your interactions with the technology system will be automatically collected throughout the study period (e.g., every time you use the ProACT CareApp to view your health and well-being readings, this will be automatically logged on our system).

You will receive full training from the researcher in using the technology and you will also receive a corresponding training manual. We will ensure that the training is quick, easy, and as convenient for you as possible. If necessary, we can visit you more than once to help. If you have any questions about the technology, you can phone the study helpdesk between 9.30am and 4.30pm Monday to Friday; the phone number is provided at the end of this leaflet.

5. Study Questionnaires, Interviews and Health and Well-being Data

During your six-month study period we will ask you to participate in some additional research activities. Each month, we will ask all groups to fill in a brief questionnaire about how often you have used healthcare services over the past month (e.g., how often you have attended hospital). At the mid-point of the study period (after three months), we will ask all groups to fill in a brief questionnaire about your quality of life (e.g., your mobility, experience of pain, and levels of anxiety or depression). We will ask you to complete these questionnaires online or over the phone.

At the end of your study period, we will ask all groups to complete many of the same questionnaires you completed at the start. We will ask you to complete these questionnaires online or over the phone. For group one or two, if needed, we can help you to complete the questionnaires when we pay a final visit to your home to withdraw the technology at the end of your study period. You will be free not to answer any particular questions if you prefer not to.

For those in group one or two, with your permission we may also ask you to participate in interviews during the same final visit to your home or by phone if more convenient. We will ask you questions about your experiences of using the technology system.

As part of the research, we will examine how often you engage with the ProACT technology system throughout the study period. We will also explore changes in your health and well-being data over time. For example, if you have diabetes, we can explore whether your blood glucose readings improve

over the course of the study or stay the same.

6. Technology Removal

For those in group one or two, we will remove the technology from your home during the final visit. If you are in group one, we will also remove your care network's access to your health and well-being data via the technology. If you wish to continue using a tablet or the measuring devices used in the study, we can offer you advice on purchasing you own replacement devices.

7. Should you wish to withdraw from the study

You will have the option to leave the study at any point. This includes the option to leave individual interviews. If you wish for any information you have given (e.g., in an interview or questionnaire, or the data recorded from the measuring devices) to be deleted, then the researchers can ensure this happens. Data from any participant who wishes to withdraw will be deleted and removed from analysis. However, there are certain circumstances that prevent the withdrawal of data from the study. For example, once data analysis is completed, withdrawal of your individual data from the study will not be possible. At this stage, we and our project partners will have pooled or collated the data for analysis, so we will not be able to identify your information in order to withdraw it from the data. If you wish to opt out before data analysis is completed, please contact a member of the research team who will arrange this for you. Data collected from this study may be published in a research report or journal. No information in publications will identify you individually.

What other treatments are available to me?

This study does not include any treatment for any health condition. You should continue to use and receive your existing treatment as prescribed by your doctor(s). Your doctor(s) will not use any of the data or information collected during this study to make decisions about your treatment. Your decision about whether to participate or not will have no impact on the treatments or services you receive now or in the future.

What are the benefits?

Your participation in this study will help us to determine whether the ProACT technology system is effective in helping people with more than one chronic condition to manage their health and well-being. It will also help us to determine whether the ProACT technology facilitates improved support for them. In addition, we will use the findings to further improve the technology, which should benefit you or others who use it in the future.

Group one and two will also receive the technology for six months. This technology should help you to monitor and manage your health and well-being (e.g., easily monitor your symptoms in one place at any time, create and track physical activity goals, view educational materials about your health conditions). All of this might mean that you are more knowledgeable about your health conditions and how to manage them, as well as more motivated and confident to do so. If you have never used a tablet device, you will also have a chance to learn how to do so. Furthermore, if you do not have an internet connection, you may receive one for six months.

For those in group one, with your permission people in your care network will also receive access to your chosen health and well-being readings for six months. In addition, your care network will receive access to educational material about your health conditions and how best to provide support. The benefits of this include their being able to view and discuss your readings with you and provide more informed support. Lastly, you will receive support from a clinical triage service for six months, who will monitor your vital signs between 9am and 5pm Monday to Friday. The triage team will contact and advise you about unusual readings as needed (e.g., if you have a high blood pressure reading).

What are the risks?

For those in group one and two, the technology does not pose a risk. The only demand on your time is in the use of measuring devices, the use of the ProACT CareApp, and taking part in research activities such as interviews and answering questionnaires. Through visits and phone calls we will be available to address any concerns or questions you may have.

It is possible that monitoring your health and well-being may cause you undue anxiety or stress. Should you have any concerns, the researchers are happy to talk to you at any time about the technology system and the study process. If you are concerned about your health, we encourage you to seek medical advice, as you usually would. You are also free to withdraw from the study at any time.

If during the study you disclose information to a researcher about unacceptable work practices in a healthcare setting or by a healthcare professional that have affected you, the researcher is obliged to report this to the relevant management personnel.

What if something goes wrong when I'm taking part in this study?

We do not expect that anything will go wrong during this study. However, if you have any questions or concerns about your participation and/or the ProACT technology system, you can phone the study helpdesk between 9:30am and 4:30pm Monday to Friday. The phone number is provided at the end of this leaflet. The helpdesk will be operated during these times by one of the researchers listed at the end of this leaflet. If there is no answer, you can leave a message and someone will get back to you as soon as possible. All the technology used for this study is insured, so if you receive it (groups one and two) you do not need to worry about anything happening to it.

If you receive the technology, you may use it to measure important health-related symptoms. For those in group one, a clinical triage service will monitor your vital signs between 9am and 5pm Monday to Friday. A nurse will phone you if they notice that any of your vital sign readings are unusual and will advise you on what to do. However, the clinical triage service is not a replacement for your doctor. If you feel unwell or worried about any symptoms at any time during the study, you should follow your usual healthcare plan, such as contacting your GP or the emergency service.

For those in groups two or three, if you have concerns about your health or

any symptoms, we advise that you follow your usual healthcare plan, such as contacting your GP or the emergency service.

If during your six-month study period you experience any health complications, or if for any other reason you are unable to participate for a period of time, you are welcome to withdraw temporarily or permanently from this study, without any adverse impact on you.

What will happen to the information I provide? Is the study confidential?

Your identity will always remain confidential. The information that we collect from you will be stored securely in password-protected and encrypted files. You will be assigned a unique study ID code which will be assigned to the information that you provide during the study. The researchers listed at the end of this leaflet, the project lead (Dr. Julie Doyle), and the team in DkIT who develop and maintain the ProACT technology (Shane Gavin and Gordon Boyle) are the only people who will be able to link your name with this code. Other partners in the SEURO project, including imec (Belgium), Umeå University (Sweden) and IBM (Ireland) will only be able to access the coded data for the purposes of analysis. This coded data may contain information such as your age but will not contain identifiable information such as your name, address, phone number, or email address.

Some of the measuring devices (e.g., smart watch, blood pressure monitor) are sourced from a French consumer electronics company, Withings. The research team will set you up with a Withings account. When doing so, we will not use any directly identifying information, such as your name or email

address.

If you are in group one or two and use the technology to monitor your health and well-being, data collected through your measuring devices or ProACT CareApp will only be available to members of the research team in DkIT and TCD (for groups one and two) and the clinical triage nurses (for group one). If you are in group one and choose to include someone from your care network in the study, they will only be able to view the data that you have granted them access to. However, please note, that your selected care network will also be able to see your name when using the technology to review your data. Given that your doctor may have more than one patient participating in this study, they must be able to see your name to accurately identify whose data they are reviewing at any given time.

For those in group one or two, with your permission, we may also ask you to participate in interviews about your experiences of using the technology. We will use an audio recording device (e.g., a Dictaphone) to record these interviews. All recordings will be stored securely under your unique study ID code and will be destroyed once a written copy of the audio recording has been made and analysed. We will send audio files to a transcription service, who will transcribe the interview and produce a document to make it easy for the research team to analyse your responses. We have a data sharing agreement in place with the transcription service that ensures your confidentiality is protected. We will also avoid using your name where possible during the interview recording.

For group one and two, we may ask for your permission to take photos of you using the technology to include in reports or publications. We will only

do this if you are comfortable and if you consent. We will show you what the image(s) look like beforehand to ensure you are satisfied. You do not need to agree to this to participate in the study.

We will use the study findings in research reports and publications. However, we will not include your name or any other identifying information in these. We will be happy to share these reports or publications with you once the study has ended and the information collected has been analysed.

We will not store the information collected during this study for more than seven years. After this time, we will ensure that all information is destroyed in accordance with data protection legislation. The information you provide will only be used in future health/technology-related research studies if they are approved by a Research Ethics Committee and you provide your consent for this.

What are my rights?

As a research participant, you have the following rights in relation to information about you (personal data) which is used for this project:

- You can access and request a copy of your data (e.g., questionnaire data, interview transcripts and ProACT CareApp system-use data) from a member of the research team and this request will be issued within one month. You can also object to any use of your information by us, and you can request deletion of your data at any stage, unless it has already been pooled for analysis.
- You can contact the Data Protection Officer of Trinity College Dublin or

DkIT if you have any questions about your personal data (see their contact details on the following pages). Trinity College Dublin and DkIT are the Data Controllers for this study. Your information will only be used for this research project, which we hope will help people to measure symptoms and activities related to their health and well-being.

Where can I get further information?

If you need any further information now or at any time in the future, please contact the **Study Helpdesk** at: 042 937 0296

DKIT Researchers:

Dr Julie Doyle

Dr Séamus Harvey

Dr Sarah Tighe

Dr Orla Moran

Ms Suzanne Smith

Ms Patricia Mc Aleer

Address: NetwellCASALA**,** PJ Carroll's Building, Dundalk Institute of Technology, Dublin Rd., Dundalk, Co. Louth, A91 K584

Email: seuro@dkit.ie

TCD Researchers:

Dr Jane Murphy

Address: Trinity Centre for Practice and Healthcare Innovation, School of Nursing and Midwifery, Trinity College Dublin, Room 1.8c, 1st Floor Chemistry Building Ext., Lincoln Place, Trinity College Dublin, Dublin 2

Email: seuro@tcd.ie

If you are not happy with how we have used information about you, you can raise a concern with the Data Protection Office in Trinity College Dublin or Dundalk Institute of Technology or the Data Protection Commission.

Data Protection Office Secretary's Office Trinity College Dublin Dublin 2 Email: dataprotection@tcd.ie Website: www.tcd.ie/privacy Data Protection Office Dundalk Institute of Technology Dublin Rd. Dundalk Co. Louth A91 K584 Email: Gerald.odriscoll@dkit.ie Website: https://www.dkit.ie/about-dkit/legal/data-protection.html	Data Protection Commission 21 Fitzwilliam Square South Dublin 2 D02 RD28 Website: https://www.dataprotection.ie/

Site	Dundalk Insitiute of Technology (DkIT) & Trinity College Dublin (TCD)
Co-Principal Investigator(s) and Co-Investigator(s)	**Co-Prinicipal Investigators:** Associate Professor John Dinsmore (TCD), dinsmorj@tcd.ie Dr Julie Doyle (DkIT), julie.doyle@dkit.ie **Co-Investigators:** Dr Séamus Harvey, Dr Sarah Tighe, Ms Suzanne Smith, Dr Orla Moran, Ms Patricia Mc Aleer, Dr Jane Murphy, Prof Anne-Marie Brady, Dr Marta Marques
Study Organiser/ Sponsor (if applicable)	European Union's Horizon 2020 research and innovation programme, grant agreement no. 945449
Data Controllers	DkIT & TCD
Data Protection Officers	Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2 Email: dataprotection@tcd.ie Data Protection Officer, Dundalk Institute of Technology, Dublin Rd., Dundalk, Co. Louth, A91 K584 Email: Gerald.odriscoll@dkit.ie

My Notes/Questions:

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SEURO Consortium

This study is being conducted as part of the wider SEURO Project, which has received funding from the European Commission.

The SEURO Consortium is made up of 12 partner organisations across Europe

Further information about SEURO is available on
www.seuro2020.eu