Participant Information Leaflet

Study Title	Sustain-WORK-ability: Perspectives on digital health interventions to support work ability in arthritis
Research Site(s)	Discipline of Occupational Therapy, Trinity College, Dublin
Principal Investigator(s) and Co-Investigator(s) (Study Team)	Susan Somerville (Lead investigator) Discipline of Occupational Therapy, School of Medicine, Trinity College, Dublin frys@tcd.ie Dr. Christine M.T. Madsen (Assistant Professor) Danish Hospital for Rheumatic Diseases cmadsen@danskgigthospital.dk Dr. Yvonne Codd (Assistant Professor) Discipline of Occupational Therapy, School of Medicine, Trinity College, Dublin coddy@tcd.ie
Study Organiser/ Sponsor	Ireland Taighde Éireann - Research
Data Controller	Trinity College Dublin (research data)
Data Protection Officer (Research Data)	Data Protection Officer Secretary's Office Trinity College Dublin Dublin 2

Introductory Statement

Invitation

We would like to invite you to take part in a research study that is being carried out by Susan Somerville, lead investigator and co-investigators Dr. Christina M.T. Madsen and Dr. Yvonne Codd at Trinity College Dublin. The purpose of this study is to describe the impact of arthritis on a person's work role and discover whether a digital health intervention could support people in their work roles.

Before you decide whether or not you wish to take part, please take time to read this information leaflet carefully.

If there is anything which is not clear, or if you would like more information, please ask the researchers. You should understand the benefits and any risks of taking part in this study so that you can make a decision that is right for you.

Do I have to take part?

You do not have to take part in this study. It is entirely voluntary and up to you. If you decide not to take part, it won't affect your employment. Don't feel rushed or under pressure to take part or to make a quick decision. You can change your mind and opt out at any time even if the study has started, without giving a reason, up until the point that your data has been analysed and reported.

This leaflet has five parts:

Part 1 - The Study

Part 2 - Data Protection

Part 3 - Approval, Organising and Funding

Part 4 - Further Information

Part 5 - Next steps

Part 1 - The Study

Why have I been invited to take part?

The purpose of this research study is to describe the impact of arthritis on a person's work participation from the perspectives of relevant stakeholders and explore whether a digital health intervention could support people in their work roles. A digital health intervention is defined as healthcare support that is provided remotely by technology such as a website or phone/device application.

The objectives of this study are:

1. What are the identified needs of people living with arthritis to support them in their work roles?

2. Could a digital health intervention be useful in supporting these needs?

3. What content should a digital health intervention include?

4. How should the intervention be delivered to align with users' work contexts?

5. What are the facilitators and barriers of digital health interventions for people living with arthritis?

You are being invited to participate in this study as you are a healthcare provider working with people with arthritis (any type of inflammatory arthritis or osteoarthritis).

We are hoping to recruit 15 healthcare providers for this study. They will attend a focus group of approximately 6 to 8 people. If you decide to take part, you will be assigned to one of these focus groups.

There will also be focus groups for people working with arthritis and employer representatives on the same content. These participants will be in different focus groups.

Why is this study being done?

We are doing this study to explore the impact of arthritis on a person's work role and discover whether a digital health intervention could support people in their work roles.

This study is part of a larger PhD research project at Trinity College, Dublin that is planning to develop a digital intervention to support people with arthritis in their work roles.

By taking part in this focus group, you will assist us to understand:

- The needs of people living with arthritis to support them in their work roles.
- Whether a digital health intervention could help support people with arthritis in their work roles.
- What would a digital health intervention include in terms of the topics that would be most relevant, how could it be accessed and structured to support people in their work roles.

We wish to learn from your insights and clinical experience with people living with arthritis regarding the challenges in their work roles and identify how this area could be supported.

What does taking part involve?

If you decide to take part, you have the option of requesting that the lead investigator (Susan Somerville frys@tcd.ie) phones you at a time that suits you to discuss this information leaflet and consent form with you.

If you wish to take part, you need to virtually sign and return the consent form. You will be given a copy of your signed consent form and this leaflet to keep. Each member of the focus group will also be asked to sign a confidentiality statement.

You will be invited to attend an online (Microsoft® teams) focus group meeting with other healthcare professionals. The meeting will be scheduled for a convenient time for all the participants and will last 60-90 minutes. With your permission, the focus group will be audio recorded and auto-transcribed.

The focus group meeting will be facilitated by the lead investigator (Susan Somerville), and the primary academic supervisor (Dr. Yvonne Codd) may be in attendance. During the focus group, you and the other participants will be asked questions as outlined in the focus group guide attached.

You will have an opportunity to check the transcript of your focus group session and review your contributions for accuracy if you wish.

What are the possible benefits of taking part?

Taking part in this study may not directly benefit you. However, your contributions are very helpful. We hope that this research, which includes your thoughts and opinions, may help us to better understand the needs of people living with arthritis in their work roles and may result in new programs that will support these needs better in the future.

Are there any possible disadvantages or risks from taking part?

There are no known risks involved in this study. At all times, the well-being of participants takes priority over research activities. We take many measures to ensure the confidentiality of all data and the risk to you of a breach of confidentiality is considered low.

We follow the guidelines of Trinity College Dublin's Good Research Practice Policy. All participants will sign a confidentiality statement. However, no study is completely without risk so we cannot guarantee that your personal data could never be compromised.

What will happen to the results of the study?

The results of this study will be used as part of a PhD research project being carried out by the lead investigator, Susan Somerville.

The results of the study will be reported in peer-reviewed healthcare research journals and disclosed at health/medical conferences. No information which reveals your identity will be disclosed. Participants will be provided with a copy of the report if they wish.

Some quotations from the focus groups may be used in reports. However, no information which reveals your identity will be disclosed.

Part 2 - Data Protection

What information about me (personal data) will be used for this study

We will collect the following information about you:

- Name
- Gender
- Profession
- Job title
- How long you have worked in rheumatology services
- Contact details to arrange the focus group interview.

This information will allow us to describe the people that took part in the study. This helps readers of the final paper to understand who is represented in the research and the background to their views and experiences. This information will be anonymised and will not be able to identify any individual participant.

We will collect an audio recording of your focus group interview. This recording will be used only for transcription and analysis. The audio recording will be stored securely and kept separate from any other information that could identify you. Once the recording has been transcribed and checked for accuracy, it will be permanently deleted. The transcript of the focus group will be fully anonymised, meaning that any names or identifying details well be removed. This anonymised transcript will be used for research analysis.

We will also collect and store the following research data:

- Audio recording of your focus group interview (temporary, deleted after transcription and checking)
- Anonymised transcript of your focus group interview (retained for analysis).

Your name and contact details will be stored separate from the research data. This helps to protect your privacy and reduces the risk of your identity being linked to the information you provide, even in the unlikely event of a data breach.

Who will access my personal data?

Only the lead investigator (Susan Somerville) and the primary academic supervisor (Dr. Yvonne Codd) will be able to identify you. They will keep the master file which links your identity to the research data. The secondary academic supervisor (Dr. Christina M.T. Madsen) may require access to the coded research data to ensure academic rigour.

The lead investigator will replace your name with a code on all research data. The key to link participants to their data will be kept separate to the rest of the research data in a private folder and will be deleted when the data is collected and checked. The coded information will be analysed and will used to develop study findings which will be shared at conferences and in an academic journal.

No other professional organisation or employer will be able to view or access your personal information.

How is the information kept confidential and secure?

Your privacy is important to us. We take many steps to make sure that we protect your confidentiality.

All research data is held securely on a private database in Trinity College Dublin, with password protection. The access is restricted to Susan Somerville (lead investigator) and Dr. Yvonne Codd (primary academic supervisor).

All researchers involved in this study are governed by a professional code of ethics to maintain your confidentiality. Training in data protection law and practice has been completed by the research team involved in carrying out and analysing the research.

A data protection impact assessment was carried out and the risk identified was low.

How long will my personal data be needed?

The audio recording of the focus group will be retained until it has been transcribed and the content verified after which it will be permanently deleted. This will be completed within seven days of the focus group event.

Your name and contact details will be kept until the next phase of the study takes place. We will be recruiting a smaller group to develop a consensus on what a digital health intervention to support people with arthritis in their work roles could look like. Once recruitment to the next phase of the study is completed, your name and contact details will be permanently deleted.

All other information collected relating to you (answers to initial questionnaire, focus group transcripts containing focus group discussion) will be pseudonymised. The link between you and your personal data will be securely deleted after the focus group recording has been written out and checked. At this point the data is anonymous. This information will be kept for a period of three years following the completion of the Sustain-WORK-ability project as is advised in Trinity College's data retention policy.

Your consent form will be retained for a period of three years after the completion of the Sustain-WORK-ability project and then securely deleted in line with Trintiy College's data retention policy.

What is the lawful (legal) basis to use my personal data?

We will only use your personal data for this research project, which we hope will assist in developing a digital health intervention to support people with arthritis in their work roles. We will also ask for your consent as a requirement of Irish law (Health Research Regulations), but we do not rely on this as our legal basis under GDPR (Article 6(1)(e) and Article 9(2)(i)).

What are my rights under Data Protection law?

You are entitled to:

- object to our use of your personal data or any further use;
- request access to your personal data and to receive a copy of it;
- request inaccurate personal data be corrected or deleted;
- request restriction of our use of your personal data;
- request deletion of your personal data.

By law you can exercise the above rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. For example, if the study is about to be published then we may not be able to delete data as it would impact on the results.

You can exercise these rights by contacting your study researcher: Susan Somerville, Lead Investigator, Discipline of Occupational Therapy, School of Medicine, Trinity College Dublin frys@tcd.ie or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: https://www.tcd.ie/dataprotection/

Part 3 - Approval, Organising and Funding

Has this study been approved by a research ethics committee?

Yes, this study has been approved by Trinity College Dublin Research Ethics Committee (REC). Approval was granted on 26 May 2026. An annual report will be provided to the REC and on completion of the study.

Who is organising and funding this study?

This study is being undertaken by Susan Somerville as part of her Ph.D. studies. It is being funded by Taighde Éireann - Research Ireland.

Will I be paid for taking part?

No, we are not paying you to take part. However, you will be reimbursed for travel expenses if you attend an in person focus group.

Part 4 - Further Information

What happens if I change my mind?

Your participation in this study is voluntary, and you can change your mind even if the study has started.

You do not have to give a reason for changing your mind. This will not affect your employment in any way.

If you would like to withdraw from the study, please contact Susan Somerville frys@tcd.ie who can organise this for you.

We will check if you are happy for us to continue to use information about you (personal data) which has already been collected. If you do not consent to your personal data being retained for this study, we will delete any information that could identify you.

Please note that we will not be able to remove personal data which has been pooled for use in analysis and publication before your request for deletion.

If you decide to withdraw from the study at any point, we will not contact you again.

Who should I contact for information or concerns?

If you have any concerns or questions, you can contact:

Susan Somerville (frys@tcd.ie) or Yvonne Codd (coddy@tcd.ie).

If you have any questions in relation to your rights under data protection law, you can contact the Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: https://www.tcd.ie/dataprotection/.

Under GDPR, if you are not satisfied with how your data is being processed, you have the right to raise a concern with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie

Part 5 - Next Steps

Will I be contacted again?

We will contact you in seven days’ time, to give you time to consider your participation in the study. If we do not hear back from you, we will contact you on one further occasion and if we do not hear from you after that, we will not contact you again.

Thanks

Thank you for taking the time to read this Participant Information Leaflet.

You will be given a copy of this Leaflet and the signed Consent Form to keep. Please retain these in case they are needed for future reference.