IMPLIO PPI Group

Intelligent Monitoring of Prosthesis Conditions in Lower Limb Amputees

What is the IMPILO Trial about?

The IMPILO Trial is testing out a sensor that will be placed in the prosthesis lining to detect early signs of skin damage. The sensor will pick up information such as skin temperature and humidity and this will be collected through a phone app and sent to a clinical team that can notify the user. The aim is to reduce skin breakdown before it happens. The IMPILO Trial will compare two groups: people using the sensor in their prosthesis and those monitoring their skin as they do typically.

What is Patient and Public Involvement?

Public and Patient Involvement (PPI) and public contribution are often used interchangeably. In this document we use public contribution to refer to all such activities. In this context a public contributor refers to:

Parents/carers/patients with experience of, or interest in clinical research, health conditions and/or health settings who are interested in helping researchers design and run clinical trials

What Patient and Public Involvement will be in the IMPILO Trail?

Project Proposal:

As we apply for funding for this project, we will have meetings to ask your opinions on the participants experience in the trial as part of a PPI group. For example, we will ask if you think the way we are asking participants to participate in the trial is appropriate or are there better ways. We will ask

your opinion on the goals of the study and our recruitment of people into the study. Our first meeting will be in **May 2022 the week of the 23rd**. The second meeting will be **June 2022 the week of the 13th**. There will be a break while we wait to hear the outcome of our funding proposals.

Clinical Trial:

Once funding is confirmed the team will start planning the clinical trial. At this point we will provide training to people wanted to be a public contributor in the project. The PPI group will be consulted to support the undertaking and management of the research. This will include assisting to write the patient information sheet and consent form, co-develop training for participants to participate in the project and support recruitment. In addition, project meetings, held predominantly through teleconference, will be held 2-3 times a year.

Dissemination:

The PPI group will support the research team interpret the findings and translate the findings into plain English summaries. They can also support the sharing of results with voluntary sector organisations and conferences if they wish.

What is my role as a public contributor?

As a public contributor we ask you to:

- Attend training at the beginning of the project to support your role
- Attend PPI 2-3 meetings (these are usually by teleconference) a year for the duration of the trial
- Provide a public perspective on discussions
- Respond to written or verbal communications about the trial between meetings providing a public perspective
- Maintain the confidentiality of discussions and information relating to the PPI meetings and activities in accordance with the PPI confidentiality agreement (This is part of the PPI Terms of Reference).
- Report to the trail coordinator any studies or information known to you which highlights patient related issues that may inform the work of the group.

What qualities do I need as public contributor?

Essential criteria	Desirable criteria
• Understanding of the issues relating to using a prosthesis following a lower limb amputation • Understanding of the issues relating to skin management of lower limbs • Be able to maintain confidentiality (keeping information about the trial confidential, not discussing any information about the trial outside of the meetings) • Ability to work effectively in a group situation • Good communication skills with an ability to listen to others and constructively express a lay view beyond their own personal experience • Have the time to attend meetings via teleconference. Have the time to comment on written information / emails between meetings	• Understanding of clinical trials or experience of taking part in a clinical trial • Access to a computer, email and telephone.

This template is adapted from Bagley et al. (2016) PPI Toolkit in Research Involvement and Engagement Journal

Confidentiality

All members of the PPI group must abide by the confidential agreement set out in the Terms of Reference of the group.

Will I receive any payment or expenses?

At this point in the project, we have no funding to pay public contributors as we have not yet secured a grant. We aim to have a set payment to attend virtual meetings if we are successful in our grant submission. When the clinical trial begins, we will pay £50 for attending a virtual meeting with related documents to read in advance. We do not plan to have an in person meeting however if it becomes necessary £75 will be paid for an in-person meeting that will equate to a half day of activity and travel expenses. Any additional commitments will be discussed and agreed in advance. Payment will be based on the NIHP recommended payment structure.

Who will I contact if I am interested?

The project is a team of people working in Ulster University, in UK based hospital settings and in company's developing these sensor technologies. The Chief Investigator of the project is Dr Jill Cundell and she will be overseeing the entire project. She is a podiatrist working in clinical practice and at Ulster University. She can be contact on 02890366307 or jh.cundell@ulster.ac.uk. Jean Daly-Lynn will be leading the PPI aspects in the project. She is a lecturer in psychology at Ulster University. You can contact Jean on 02895367422 or j.daly-lynn@ulster.ac.uk