**Patient and Public Involvement in the SOFFT Trial: An update**

**July 2021**

SOFFT stands for the ‘Simple Olecranon Fracture Fixation Trial’ and the Chief Investigator is Professor Adam Watts who works at Wrightington Wigan Leigh Teaching Hospitals NHS Trust (WWL). Several years ago, Professor Watts met the WWL Patient and Public Involvement in Research group (PPI) to explain his idea that one type of repairing fractures (breaks) of the elbow joint may be better than another method. This is called a feasibility discussion and Professor Watts explained that one technique may prevent people having to have a second operation as some patients can experience pain if they lean on their elbow, as they have wires lying just under the skin. Preventing a second operation to remove the wires could mean less risks for patients and make important savings for the NHS.

However, nobody knew if this was a valid question to ask or if a study could be designed to prove this. As a group we were asked for our thoughts about whether this was a good idea to test, if people would find it acceptable to be ‘randomised’ to one or other method, if they would find it acceptable to complete questionnaires and have measurements of their elbow joint at different time points over the following 2 years. The group felt strongly that this was an important idea and one member also volunteered to be a Patient Partner for the Trial team.

To make a long story shorter, our PPI group were able to help with an application for a grant by working alongside academics from universities, with York Trials Unit and a sponsorship team from WWL. We were successful and awarded £1.75m in research funding from the National Institute for Health Research (NIHR). We were involved in the design of the trial stage, the application process and helped to give the ‘lay summaries’ (summaries which demystify the technical research and medical language to make it understandable for everyone) at the application stage and for the submission for ethical approval. Due to COVID-19 restrictions our group also helped in the review of the participant photograph instructions document for participants who would not be able to go back to be seen at their hospital. We have found that our participants are sending excellent images of how their elbow can move and this is because of being able to follow these instructions.

To be able to have an answer for our question we need to recruit 280 participants to have 140 participants who have had each operation. To reach this target it means that 35 sites (Hospital Trusts throughout the country) to help the study team by recruiting for us and following what happens to everyone who takes part in the study.

The way that we will be able to see if there is a difference is by using ‘outcome measures’ which we ask participants to complete such as questionnaires which ask about how well people can use their elbow, if they have pain and how severe it is, we measure the movement of the elbow , check to see that the fracture has healed well, if there have been any complications and if there has had to be a second operation to remove the metal work.

Because this is such a large study, the organisation that funds the study (NIHR) need to be able to check that we will be able to deliver what we have said that we could. Under the leadership of Professor Watts, there are several management groups of experts one of which is the Trial Management Group (TMG). We had a ‘pilot study’ to complete and this group have overseen the progress. All the clinicians and academics have a tremendous insight into the study requirements and have persevered with professional integrity during the COVID-19 pandemic to advance the study.  The PPI's involvement had been represented by our Patient Partner and this support has been encouraged and valued by the TMG.

It is amazing to be able to say that despite challenging circumstances our first site opened on 13th October 2020, by the end of June, 27 sites had opened to recruitment with more sites ready to open and 60 more sites had expressed that they would be interested in helping with the trial. This was amazing as our target has been 24 sites to have opened and we also were on target to have 50 participants recruited by the end of the pilot phase.

With research it is also important to check if people are finding it acceptance to participate in the trial, and we had aimed to have a rate of 70% and had achieved 88.4%. We also wanted to check if our participants had returned their questionnaires which are essential for our statisticians to work out if there are any differences. We required an 80% return rate and have achieved an 81% return rate. The study team would like to thank all our participants who have returned their questionnaires and we intend to share this report with everyone involved.

The SOFFT trial has now been given approval to continue which is an amazing achievement and it is thanks to a fantastic team effort. Our involvement from a PPI perspective is not yet over and will be essential when the results of the study are known to share the outcome with as many people as possible in language which is easily understandable from everyone. We look forward to the challenge.