Usability and Accuracy Comparison between Physical and Digital Pain Logging Device

Participant Information Sheet (Version 3.0, 18/08/2017)

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. We suggest that it may take about 5 minutes to read thoroughly. If, after reading this information sheet, you think you may be interested in taking part you will have the opportunity to ask any questions before you agree to anything.

Summary

Given that there is no medical test to directly measure pain, we mainly rely on patient self-reports either in a paper diary or by telling a nurse who writes the answer in a log. This method can result in missing data if patients are not asked regularly or cannot write down their pain level or they forget to fill in the diary. It also results in a slow response, as it may be a long time before someone is able to read the pain levels and act on

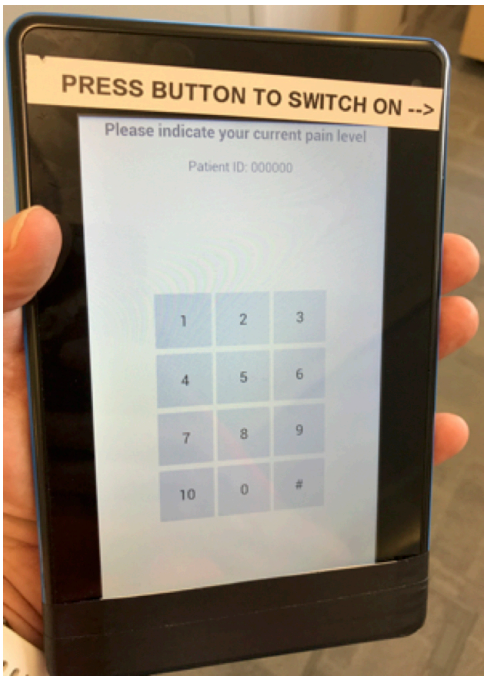
them. This study involves giving you a small device called a PainPad so you can record your pain levels on your own. You would be also asked to enter pain scores on 2 different applications on an android tablet. Application A (*Android Slider*) would be given on day 1 and Application B (*Virtual Painpad*) on day 2 or vice versa.

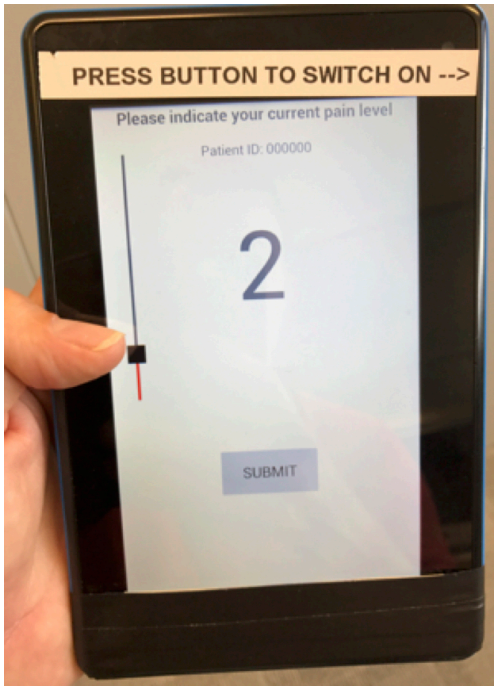
What's involved?

After reading this sheet and having any questions answered, you will be asked to provide your consent to participate in the study. If you agree we will give you one of two devices to use for the first two days you are in hospital. We ask that you use these devices to indicate how much pain you are in on a scale from 0 (no pain) to 10 (maximum pain). The devices will beep at most once an hour between the hours of 8 AM and 10 PM to prompt you to enter a pain value. You can also enter your pain score at any time. If you don't hear the beeping or don't enter a value for any reason don't worry, the device will still beep for you the next time and it does not matter if you miss entries.

One of the devices we call the *physical painpad*, it is a handheld box that looks like this:

The other device is a small tablet computer, like an iPad, which we call the *virtual painpad*. It has two types of screens and it looks like this:





You would get one of these devices on your first day in hospital and the other on the second day. We will give you a very short 1 page 3 question questionnaire about your experience of using the devices and ask that you fill it out before you leave the hospital. During your stay you may also be asked by nursing staff to give your pain level for their records.

What are the potential benefits and risks?

While the immediate benefits of this study to you are limited, the primary benefit of this study, however, is to improve the current process of pain management in hospitals.

There are no foreseeable risks arising from participation in this research and while you will not receive any payment, you will make a vital contribution to pain management research and possibly improving the experience for others.

What will happen if I don't want to carry on with the study?

Your participation in the study is entirely **voluntary**, and you can choose to withdraw at any time without giving a reason and this will not affect your care or treatment in any way. You may also ask to have your data deleted at any time, although if we have anonymised your data this may not be possible.

How will my information be kept confidential?

The data collected will only be accessible to the named researchers on this study. Personally identifying information will not be electronically stored with your data. Instead a unique ID will be generated to record your data and we will ensure that you can never be identified by any data we publish.

The data will be retained for up to 5 years after the study. The results of this study may be published in a scientific journal. If you would like to receive the results of the study you can indicate this on the consent form.

Who is organising and funding this study?

This research is in part being supported by a research grant from the Engineering and Physical Sciences Research Council and researchers from both the [REDACTED] University and [REDACTED] Hospital.

Who has reviewed this study?

This research has been reviewed by the [REDACTED] University's Human Research Ethics Committee (REDACTED) and the NHS [REDACTED] Research Ethics Committee has been given a favourable opinion by both.

Invitation to ask further questions

Please feel free to ask any member of the researcher team if you have any concerns or questions in relation to this study before agreeing to the Consent Form. You may also ask any questions throughout and after completion of the study.

You can contact the researchers as follows:

[REDACTED]

Thank you for taking the time to read this information sheet and considering taking part in this study