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Abstract

Design of mobile, personalised healthcare information systems facilitate a paradigm shift in management of chronic conditions. They provide an infrastructure for creating personalised treatment plans that are evidence based. This is especially important in chronic pain, which is a long-term condition and requires self-management by the patient. In this paper, we use a mobile accessible, web based system to collect daily reports on chronic low back pain. Based on this data a pain trajectory is generated to provide a report for patients to track their pain. We present an empirical study exploring the experiences of the participants, the usability, and issues that encompass frequent data collection using such systems in chronic low back pain.

Keywords Chronic Pain, Pain Trajectory, Empirical Study, Personalised Healthcare, Low Back Pain
1 Introduction

Personalised healthcare and medicine began from tailoring treatments and medication based on the biological profile of an individual using their DNA, and has driven a change in paradigm away from a ‘one size fits all’ healthcare approach, towards personalised treatments. One recent development of interest is the Quantified Self (QS), which describes "any individual engaged in the self-tracking of any kind of biological, physical, behavioural, or environmental information" (Swan 2013). The concept of QS is especially relevant in the field of Chronic Pain, where the self-management of pain is critical to the long-term treatment of most chronic pain conditions (Goh et al. 2016). Thus, the collection of such information in QS can be considered as the contextual data available around pain experiences. QS isn’t sufficient by itself to trace or track every factor possible, but is required in order to track specific factors that affect the individual patient.

QS is considered to be a specialised area of data collection. Doctors have specialist instruments that assist in viewing or studying specific incidents of pain, such as questionnaires or equipment that can scan or monitor various pointers that may trigger pain. The critical problem here is that - for self-management of pain, patients do not have such instruments available, as these specialised instruments are not and have not been translated into self-recordable instruments to study the burden of cLBP.

Personalised healthcare and QS combined have also enabled a second change in paradigm, away from episodic treatment of chronic pain, towards continuous healthcare. Continuous healthcare refers to the provision of healthcare that is ongoing and adjusted according to the symptoms of the patient, and is independent of the patients’ visits to their doctors (Fernandaz and Ong 2015). Instead, by collecting real-time information and data on the patient’s experience of pain, it is possible to provide real time advice and enable the understanding of how behaviours and actions affect the patient’s outcome and tailor therapy accordingly. Therefore, it becomes possible to have personalised, close to real-time monitoring, with feedback to the patient which has the potential to better target therapies including medication so that rather than a set prescription medications and other therapies can be better targeted to peak pain. This has the potential to significantly reduce the use of medications such as narcotics, whose use is currently at epidemic proportions with significant community wide harm.

Real-time information on the patient’s experience of pain is critical as recall of pain has been shown to be a potential affect with longer durations (Schneider et al. 2011; Turk and Melzack 2011). Ideally, pain should be measured as close to when the patient experiences it as possible. In research on Tennis Elbow, Goh et al. (2016) showed that it would be promising to collect data using a web based, mobile accessible data collection site with contextual factors. The use of mobile devices such as smartphones to collect data makes sense as many people carry around such a device on a regular basis, and has been done in other research studies (Boulos et al. 2011; Medhanyie et al. 2015; Torous et al. 2014).

This study focuses on exploring the mobile data collection method for chronic low back pain, and to study the strengths, limitations and impact that such methods would have on the participant. In answering this research question, we have conducted an empirical study that used mobile devices to collect data on daily changes in cLBP levels. The theoretical foundation supporting this study was based on a contextual model for low back pain that was discussed previously (Goh et al. 2015). In this paper, we report the study results on the usability of the web-based system empirically as a reflection from the process of setting it up, as well as the data collected. The results are discussed in the context of what participants found to like or dislike, which can be considered factors that drive the use or disuse of the system. This study builds on the generalised usability guidelines recommended by Nielsen (1995), which were widely referred by more recent studies of mobile technologies, including those applied for healthcare applications (Arnhold et al. 2014; Villarreal et al. 2015). The study received ethics approval from the university ethics committee, and was conducted in collaboration with colleagues from Victorian hospitals.

The following sections will briefly discuss chronic pain within personalised healthcare, data collection in terms of the use of some mobile technologies, outline our research methods and then present our findings and discussion of the results.

2 Chronic Pain in Personalised Healthcare

Chronic pain is pain that persists beyond three months (Merskey 1986). This means that the patients suffering from chronic pain typically do not recover after an extended period, and in many cases, not at all. Chronic Low Back Pain (cLBP) is a chronic, ongoing condition that can be classified into two classes: i) Specific, and ii) Non-Specific. Specific refers to cLBP that has an attributable cause or condition, whereas Non-specific refers to cLBP that can’t be resolved to a specific cause of the pain (Savigny et al. 2017, Hobart, Australia).
2009). Pain intensity is represented visually as a Pain Trajectory (PT), which presents an overview of the pain experienced over time using an eleven-point scale of 0 to 10. The pain trajectory is important as it visually shows the experience of pain over time. Non-specific cLBP typically doesn’t have an estimated recovery period and is expected to take years for improvement, therefore the emphasis in treatment is the self-management of pain over an extended period of time.

Pain is a very individual experience, with no two patients having the same pain experience (Kongsted et al. 2016; Olson 2014). This can be due to any combination of lifestyle patterns, occupation, living conditions, and not least of all - the type of chronic pain that the patient is suffering from. Currently, chronic Low Back Pain (cLBP) is the leading contributor to disability (Hoy et al. 2014). In studying such pain, existing studies typically collect data specific to one domain of interest, such as the patterns of cLBP in nurses (Maul et al. 2003), the effect of weather on cLBP (Steffens et al. 2014), or even depression symptoms as a factor in cLBP (Pinheiro et al. 2016).

Pain is a self-reported variable, and is typically collected using validated measures such as the Visual Analogy Scale (VAS) (Bijur et al. 2001), Numerical Pain Rating Scale (NPRS) (Farrar et al. 2001), or Categorical Rating Scale (CRS) (Hartrick et al. 2003). This data is commonly collected at intervals of monthly, and 3-monthly in the case of clinical randomized trials.

Research in chronic pain discussing personalised healthcare, or means towards more individualised measures and treatment have started to identify the need for more granular data (Kongsted et al. 2017), especially in the case of cLBP where the majority of the cases are non-specific. A recent review of non-specific low back pain by Maher et al. (2016) identified a major research priority in the field, which was to understand what causes low back pain. The same review also described the need to identify phenotypes with a pathoanatomical or clinical basis in order to find new approaches to self-management of cLBP.

The move towards personalised healthcare is also present in the use of medication. Schork (2015) put forward a case towards ‘one person trials’ for medication, by utilising mobile devices (i.e. apple watch, monitors) that can collect health data such as glucose or heart rate information. Zheng et al. (2008) proposed a self-management system for chronic pain that would enable monitoring of changes in chronic conditions that can be provided to the individual patient as feedback, in order to self-adjust their lifestyle and activity patterns to reduce pain.

The following sub-section will outline some studies that utilising dairy style or web based questionnaires in Chronic Pain.

2.1 Mobile Technologies in Data Collection for Chronic Pain

We reviewed recent studies utilising mobile accessible data collection methods over a period of time to collect data on Chronic Pain.

Stinson et al. (2006) evaluated the usability of an electronic chronic pain diary for adolescents suffering from arthritis. The diary collected pain ratings three times daily using the VAS measure, along with a picture of the body that allowed the patient to indicate where they were hurting, along with questions on how much it hurt, among other questions from the Brief Pain Inventory-Short Form. The researchers also reported that the use of such diaries require more consideration on the user interface design.

Macedo et al. (2014) used short messaging service (SMS) to poll participants of the study for their pain ratings every month for a year. They reported that there were participants that did not reply to the messages, and there were participants that did not own mobile phones, or know how to use SMS. Kristjansdottir et al. (2013) evaluated the efficacy of a smartphone based intervention for self-management of chronic pain. The device used 3-daily diary style entries over a period of four weeks. They report that such mobile interventions are beneficial, especially when personalised feedback is provided. Similarly, a systematic review by Cuijpers et al. (2008) shows that internet based interventions are comparable to face-to-face versions, and will be a major method in delivering such interventions in the future.

Although there were studies through history that utilised such data collection methods, we found none that focused on the use of mobile devices (i.e. smartphones) that enable the patient to self-monitor their pain using a pain trajectory. The following section will describe the research design of this study.

3 Research Design

This study used a participatory research approach, as the research project was collaborative in nature (Linger 2006). This was necessary for us to make use of the expertise that the medical researchers had,
in enabling the collaborative design of new questionnaires that collected contextual data about the pain experienced. The instruments used had to be adjusted in collaboration with the clinicians as the normal usability questions did not apply. The questionnaires formulated this way used both validated questions and instruments, as well as new questions to collect information about the context of pain from the participant.

There were four inclusion criteria for this study: i) Participant must be currently have chronic low back pain; ii) Participant must reside in Australia; iii) Participant must have access to the Internet regularly; iv) Participant must have an email address they check regularly.

We contacted 899 people in total via email, with 94 (10.5%) people signing up to the study. Of these 94, 5 participants dropped out during the study, giving a participation rate of (95%) of those who were recruited and a completion rate of 95%. The response rate for the exit questionnaire was 42.6% of the cohort.

Data was collected using an online, mobile-accessible secure data collection system that was custom built for this purpose. The system provided a view of the last seven days of pain reports as a pain trajectory that was featured on the user's dashboard upon logging into the system. The system sent daily reminders at a self-selected time of either 6am, 12pm or 6pm via email to the participant.

The study had four questionnaires, two of which collected daily and weekly pain data, over a period of 32 days. The other two questionnaires were administered at the completion of the study, and contained questions on usability, as well as the usefulness of the system and the pain trajectory display. These exit questionnaires were anonymized and were sent on the 34th day after beginning the study. The questionnaires used in this study were developed in collaboration with clinicians from Victorian hospitals.

The pain questionnaires collected data on pain intensity using the NPRS, as well as contextual variables that were identified by a contextual model of chronic pain (Buchbinder et al. 2011; Goh et al. 2015), as seen in Figure 1. The system provided the pain trajectory of the previous seven days’ worth of pain reports to the participant, as seen in Figure 1b.

![Figure 1. User Interface of (a) System Daily Questionnaire and (b) System Dashboard with Pain Trajectory](image-url)

The exit questionnaire was administered depending on the status of the participant. There was one for participants choosing to opt-out, or drop out of the study, as well as one for participants that completed the study. The exit questionnaires are described in Appendix 1.

From the viewpoint of setting up such a study, there are various considerations such as the security of the data, which typically is classified as ‘critical’ by data protection and privacy Acts. This means that the data stored must be encrypted and secured to some extent such that only the authorised researchers would be able to access it. Similarly, traffic to and from the data collection system must be secure and encrypted to prevent data leaks.
4 Data Analysis

The analysis will be primarily based around the exit questionnaire, as well as email and phone contact notes between the researchers and the participants over the course of the study.

We used NVivo to perform qualitative thematic analysis (Fereday and Muir-Cochrane 2006) to identify themes and code the data collected from the questionnaire, as well as the notes taken from the phone and email contacts between the participants and the researchers. The thematic analysis was aimed at understanding the impact that using such a system has on the participant. We intentionally made the questions open-ended in order to capture the user experience.

To better understand and represent the themes found throughout the data, we classified these into common themes. We found that there were four main themes that pertained to: i) self-management of pain; ii) user experience; iii) questionnaire design; and iv) compliance. Further sub-themes emerged from each main theme, as shown in Table 1.

<table>
<thead>
<tr>
<th>Main Theme</th>
<th>Sub-Themes</th>
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<tr>
<td>Self-Management of Pain</td>
<td>Monitoring of Pain over Time</td>
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<td></td>
<td>Awareness of cLBP</td>
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<td>Self-Reflecting Behaviour</td>
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<td>User Experience</td>
<td>Usability and Accessibility</td>
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<td>Questionnaire Design</td>
<td>Question Response Granularity</td>
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<td></td>
<td>Daily Diary Response Format</td>
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<td>Compliance</td>
<td>Issues with responding to questionnaires</td>
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<td></td>
<td>Missing Data</td>
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</table>

Table 1. Themes from Thematic Analysis

The following section will discuss our findings from the study.

5 Results and Discussion

We discuss the findings using the four main themes identified from the thematic analysis of the questionnaire data and notes taken during the study in this section.

5.1 Self-Management of Pain

The theme for self-management of pain relates to the ability of participants to self-manage or understand their own pain. This includes enabling the monitoring of their own pain, increased awareness and enabling self-reflecting behaviour with guided contextual questions.

Most participants described the ability to monitor their own pain levels useful, and one such participant mentioned liking the ability to “note(-ing) the status of my back pain systematically”. The pain trajectory graph shown on the dashboard allowed the monitoring of their own pain over time, and they could correlate and better remember what their pain was like at a previous reporting point. Another participant described it as “seeing the change over time” helped with their understanding on how their pain fluctuated and changed over time depending on what they did. It was also described as being “interesting to take note of my pain over the period and the changes...” that the participant experienced. The ability to monitor their pain has also increased the participants’ awareness of their own cLBP, as described in the next section.

The diary style where the participants “describe daily where the pain initiated from”, combined with the 7-day pain trajectory graph allowed them to be more aware of the days that they did not experience much pain, and “enabled me to appreciate the good days more than I would ordinarily”, or that it “helped ... realise my back pain isn’t as bad as some days”. There was also an increase in awareness of potential triggers of pain as participants identified some activities that they did that would cause an increase of pain, which was described as being “more aware of what activities aggravated or helped my back pain” and “… of what affects my pain”. As the participants become more aware of their own cLBP, we observed some self-reflecting behaviour, as described in the following section.
Some participants experienced self-reflecting behaviour, with reports that it “made me take more care in what I did”, and at the same time, “made me think about what I was doing to manage my back pain”. Some participants also reported that being able to “describe daily where the pain initiated from” was something they liked about the system. Some participants also communicated via email or phone that they liked how they could “… confirm the pain I had was as I thought”. Participants also commented that it was great as the system “drew my attention to the different levels of pain and gave me opportunities to do something proactive about them”, and that “I could see what my back pain was and relate it to what I had been doing”. On the other hand, there were participants with severe pain who commented that such systems were not so good as it made them “think about something I try very hard to ignore”. Some participants that mostly experienced constant pain reported that it was not as useful, and made them to think about the pain all the same.

5.2 User Experience

In discussing the user experience, we asked the participants to rate their experience on an 11-point scale from 0 to 10, with 0 representing ‘Worst’ and 10 representing ‘Best’. The average experience rating was 7.2, with a median score of 8, with 60% of respondents rating above the average score. We identified two themes within this area, the usability and accessibility of the system, which are discussed as follows.

We found that participants tended to describe the ‘usability’ of the system as a separate attribute or feature to the ‘accessibility’ of the system. Accessibility is not an attribute that has been used in usability studies, and is not discussed as a part of the ten usability heuristics in Nielsen (1995)’s work, nor the models described in Harrison et al. (2013) and Baharuddin et al. (2013). Participants described the system as being “easy to use”, “easy to complete” and “simple”, with some participants commenting that it was great as “the prompts where a good reminder”. The system was available over the Internet, and accessible using a modern web browser such as Google Chrome. It also had mobile views that allowed easy access on the go using smartphones or tablets, which was participants liked as it enabled “being able to log in anytime”. The data suggests that the accessibility of a system plays a part in the usability, or intention to use a system. The researchers also received email and phone calls after the study to thank them for the opportunity to “let me know more about my actual pain”, and in one case that “it didn't always hurt as much as I thought”.

5.3 Questionnaire Design

The questionnaires used in the system were designed using a participatory research approach in collaboration with clinicians. One of the objectives was to reduce the response load or burden of the participant when responding to these questionnaires. Therefore, we designed them to be short and guided diary styled using short questions that had specific selections, or short questions that would have open fields for answering.

During the first week of the study period, we had contact from participants regarding answering these questionnaires. There is a question that asks about ‘how long ago did you experience this pain’, and the answer field was for ‘about x hours’. The researchers discussed this and decided to use a whole number result (i.e. 1 hour) instead of decimals as we felt that no one would want to provide extremely accurate numbers (i.e. 0.33 hours). There were many participants that experienced errors as the system would not allow them to provide such accuracy, in the words of one participant that reported “couldn’t submit and there was an error on the hour question that i put 1.56 hours on”. We amended the question to read ‘in whole numbers’ instead to avoid confusion.

Participants also reported that the question responses did not offer enough granularity, such as “sometimes I couldn’t exactly explain my pain”, or “there was no way to describe the nature of the pain e.g. aching, stabbing, cramping, throbbing, … using yes or no as alternatives is frustrating too because I don’t know if I missed any”, and “the information I could provide to explain the variances in pain to be too limiting”. There needs to be further revision to the questionnaires used in expanding the way that we ask the participant on pain.

Some participants also reported that the questions were not very relevant or useful to their specific condition as there were “not enough expansive causes of back pain and associated pain”, and for some participants that did not exercise on a regular basis or at all, “the exercise question was not relevant”.

When asked about the use of the daily response format, participants were mostly positive and some reported “liking(d) that you had to do it every day”, with participants being more aware and “… take more care in what I did”, in terms of activities during the day. Concerns that we had on the burden of response regarding the time it would take to complete the questionnaire led us to designing the questionnaire in a way that would allow the participants to complete it in a short amount of time be
completed in a short manner, which seems like it was well appreciated by participants, who also reported that “it was very easy”, but would be better for the duration of the study to be shorter. The average daily response took about 48.18 seconds, or just under a minute.

5.4 Compliance

Compliance issues are broken down into two sub themes: i) issues to do with responding to the questionnaires; and ii) missing data from participants.

The most common issue we had were technical issues to do with the participant’s Internet connection, with 15% of participants reporting this problem. Some participants reported that they had “initial log on difficulties” in the first week of the study, which stemmed from them not remembering their password that was provided during the registration process. The system was amended to also include their password in their welcome email for the participants’ convenience. The other most common report from participants was that they could not remember if they did report on time or if they forgot to complete it as the system did not give them an overview of the reports that were missing, as summed up by a participant: “I’m not sure if I did, I just can’t be sure that I didn’t”.

In terms of missing data, we identified five main reasons that participants reported as the reason to them not completing surveys, which were that “I forgot to complete the survey although I received a reminder”, “was away on holiday”, “too busy at work”, “didn’t do it on the weekends” and “there was no change in pain”.

Participants that reported no change in pain found this style of daily reporting very tedious and of no benefit to them as they said that their pain does not fluctuate and that they are “not as sensitive to pain” after living with it for an extended period.

6 Conclusion and Future Research

We presented an empirical study that utilised a mobile-accessible, web based data collection system for chronic low back pain. It is expected that personalised healthcare will grow over the years in adoption and research that combine newer technologies that include sensors and mobile phones. This study has discussed some findings in terms of using daily questionnaires for the collection of data, as well as the use of a 7-day pain trajectory in helping memory recall and self-management of cLBP. This study also used Goh et al. (2016)’s recommendation that in collecting self-reports for pain intensity, that the question asks for current pain instead of pain for the past period of time. We have not seen many studies that address the integration of sources of contextual data into the routine data collection of cLBP in order to understand the patient’s pain experience.

There are some limitations to the findings in this study. The sample size in this study is not indicative of the population, but a small representation of the views from users of such a system. The system was built to be a web-based instead of native android or apple device application in order to have a single unified site that will also accommodate participants that want to make reports from desktop based devices.

We believe that the findings of this research have multiple implications in both the medical domain of knowledge, as well as the domain of information systems, especially for researchers that want to build onto the existing work.

The development of such data collection instruments such as the daily questionnaire has to be using validated outcomes, and where none exist for the measure to be collected, it is imperative that the work is done in a participatory, collaborative way that includes the medical experts such that the data collected can be analysed in a meaningful manner.

It may be useful to have a system that is capable of ‘learning’, that is; it allows participants to add options to questions as we found that participants actually wanted to be more descriptive in their answers where we were prescriptive in the options available.

Some participants that already have been living with chronic pain do not want to think of the pain, and try to distance themselves from the pain. This is true especially if the study protocol requires daily reporting as ours did. There needs to be a clear separation between self-reflection and simply making the patient think about how bad the pain was. One participant that contacted us via phone near the conclusion of the study described how the pain was so bad that they usually avoid thinking about the pain and immerse themselves in work or other activities.

The use of the pain trajectory as a representation of the experienced pain in the last seven days helped with patient recall of their previous reports, and in turn made the data reporting more accurate. It also...
played a part in allowing participants to better understand their historical pain, with some participants reporting that they now realise that their pain was not as bad as they originally thought. This has implications for the data collection frequency as such a display simply is not useful at larger intervals. The usefulness here stems from having daily reports, as well as ad-hoc reports that are provided when the patient experiences changes in pain.

This work reinforces the finding made by Goh et al. (2016) that participants do not always enter pain reports in a timely manner. As discussed previously, there was missing data as participants forgot to provide the pain report due to various factors, despite reminders being sent daily. There needs to be further work into studying how this can be best alleviated.

The participation rate of 94 sign ups from the cohort contacted doesn’t reflect the likely utility of such a device as it was expected to get a modest participation rate from recruitment. Having 95% of the signed up cohort complete the study means that once the study started, people seemed to like it, which is important. The participants that were signed up to the study did not miss many reports, with more than half of the participants having 29 days of reports on average. The completion rate of the exit questionnaire indicates that the results are not unbiased, in that either people that liked or disliked the system have responded. There needs to be further work to look into this further in a systematic manner.

When designing such systems that are primarily used via mobile devices, the usability of the system on a mobile device must be considered separately to its counterpart on a desktop device. Our study used the following design rules: i) simple and consistent layout and design; ii) larger nodes and elements for ease of pressing; iii) distinct and clear use of colours to differentiate components; and iv) the interaction required of the interface is clear and visible through using visual affordances that requires no explanation (Norman 2013). These compliment the standard user design guidelines provided by Nielsen (1995), as well as these current studies (Joyce et al. 2016; Nayebi et al. 2012).

In considering usability testing attributes or variables, there have been studies that reviewed or elicited such measures. We find that most studies revolve around the standard Nielsen (1995) guidelines, and tend to use a similar set of usability attributes or variables in their model. The PACMAD model proposed by Harrison et al. (2013) describes an extension of Nielsen (1995)’s work, and identifies seven usability attributes for mobile applications, and considers the use factors of the user, task and context that impact the final design of an interface. Baharuddin et al. (2013) identified ten usability ‘dimensions’ that are based on the contextual factors of the user, environment, technology and task. This study took the approach of considering usability and other factors that impact the user’s experience by eliciting likes and dislikes of the system from participants by coding themes from the responses by the participants. Our results agree with the usability models discussed, but align closer to Baharuddin et al. (2013)’s work where the user experience or ‘usability’ was affected by the context in which the system was used for a specific task, or set of tasks. We found that the user experience was impacted by the environment, and the technology (e.g. iPad, android device, desktop computer, laptop) where the system was being used.

In future work, we intend to develop the questionnaires designed through participatory research further to encompass more contextual factors, including the use of sensors to detect and learn the patients’ regular movement and activity patterns. There are opportunities to extend this study to improve the use of such a system by participants, to understand what times are best for reminders to be sent and to explore the patient’s mood in relation to their experienced pain. We are also interested in the potential to link this to other data collection methods in order to make it a more integrated system. There will also be further work on how such systems could impact the participant’s daily routine and potentially their self-management or understanding of their own chronic pain. We also intend to build upon the themes coded in the analysis of this work to identify factors that affect the user’s intention to use such a system. Another potential area to explore is on how technology can best help alleviate the non-compliance of participants in terms of reporting their pain. This work would potentially lead to a deeper understanding of non-specific cLBP and a formal methodology of contextual data collection for cLBP.

7 References


Appendix 1

The following are the two exit questionnaires used in the study.

Exit Questionnaire A: For participants opting out mid study (dropping out)

1. Why are you opting out of this study?
   a. Not Interested
   b. Time constraints
   c. Technical Difficulties
   d. Other (please describe)

Exit Questionnaire B: For participants that have completed the study

1. What did you like about the study?
   1.1. Did you find the graph on the user dashboard page showing you the last seven days of pain reported useful?
       Yes / No
   1.2. Why?

2. What didn't you like about the study?

3. Is there anything that we can do to improve the study?

4. Did you miss any daily reports?
   Yes / No
   4.1. (If yes) Why?
       a) There was no change in pain
       b) I forgot
       c) There were technical issues
       d) Other (please describe)

5. Please rate your experience using this system from 0 – 10
   [Sliding scale from 0-10, where 0 represents worst and 10 represents best]

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