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Integrating contextual and online self-reported data for personalized healthcare: a tennis elbow case study

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Abstract

Advances in sensors and mobile technology have helped evolve the use of eHealth, especially in the field of chronic pain. Chronic pain is a widespread problem where self-management is important. Current studies tend to collect data at sparse intervals due to the cost involved in collecting data using traditional instruments. We demonstrate how technology enables richer data collection frequencies to analyse the influence of patients' context on their pain levels. In this paper, we present a case study as an add-on analysis to a clinical trial for lateral epicondylitis (tennis elbow). We explore the usefulness of on-line key data collected at higher frequencies in explaining or discovering changes in pain. This dataset allowed us to learn that there are no associations with temperature and humidity to this type of pain, that patients tend to have different pain experiences, and that pain at night tends to be higher than overall or activity-related pain.

Keywords eHealth, chronic pain, pain trajectory, context, tennis elbow

1 Introduction

In the last decade, eHealth has become an area that describes digital and technological solutions, that benefit and enhance the quality of healthcare. The adoption of sensors and mobile technology in eHealth has paved the way towards personalization of care, which is, care that is tailored or adjusted depending on the symptoms shown by the patient.

Chronic pain is defined as pain that persists beyond three months (Merskey 1986). As the definition suggests, patients typically do not get cured in a short period of time. In this area, one key component of their care is the self-management of pain. The majority of studies in this field are longitudinal studies, which collect repeated measures over an extended period of time. These studies tend to be expensive, and therefore limited in terms of data that can be collected, with the typical study using traditional data collection instruments such as paper questionnaires. These studies also tend to collect data at sparse intervals. With the use of sensors and mobile devices, we are able to evolve traditional data collection instruments and enable the collection of richer data from the patient, at higher frequencies.

In this study, our main purpose is to illustrate that the use of technology in data collection, at higher frequencies, can provide more informative results. We collected key data at increased frequencies to determine whether measurement of environmental factors such as the temperature and humidity influence symptoms. The analysis explored the usefulness of such data to explain changes in pain due to context, and whether increased data collection frequencies improve the depth of understanding on the trajectory of pain.

The study is an add-on data analysis component to an ongoing randomized controlled trial investigating the value of platelet rich plasma injection or glucocorticoid injection compared with placebo for lateral epicondylitis (LE) commonly known as (tennis elbow). Ethics approval for this study was granted by Monash University and Cabrini Health ethics committees.

The following section will provide some background to our research.

2 Background

2.1 eHealth

In the past, doctors have used sensors and handheld devices to collect data from patients, as is seen in studies such as Silva et al. (2015)'s work on creating a remote monitoring system using sensors and smartphones, Hayn et al. (2015)'s work on using accelerometer and pressure sensors for pressure ulcer risk assessment, or Fisher et al. (2015)'s work on wearable sensors for remote monitoring of symptoms in Parkinson's disease. More recently, technologies such as the Apple ResearchKit and CareKit (Apple Inc. 2016a; 2016b) have changed how doctors perceive the usefulness of technology in healthcare. Researchers are using these technologies as tools to provide better insight to patients about their condition, improving their own care management and health, and care providers about treatment and patient conditions (Apple Inc. 2016b). The move towards personalized care has introduced a need for more data on the patient's condition and context to be collected, in order to best provide accurate care for the patient. Traditionally, such data would have been collected during trips to the hospital or doctor, and in some cases, over the telephone check-ups on a patient's progress (Huang and Matricardi 2016; Raju et al. 2012). It was not too long ago when doctors scoffed at collecting this type of data on a frequent basis due to the problems faced with manpower and costs, but with the introduction of health monitoring devices that utilize sensors, mobile technology and the internet, this has become a reality.

The next section will briefly discuss existing issues in data collection for chronic pain.

2.2 Data Collection in Chronic Pain Studies

There are two main classes of chronic pain, the first being an identifiable class that can be attributed to a known cause; and the second being of a non-specific class, which is not attributed to a known cause (Krismer and van Tulder 2007). One of the main areas of non-specific chronic pain is low back pain, which is the leading cause of disability worldwide (Hoy et al. 2014).

Chronic pain studies typically focus on either identifying factors that contribute towards the pain, or on treatment methods and effectiveness. Regardless of their focus, these studies tend to be longitudinal in nature, that is - studies involving data collected with repeated measures over a period of time. Some of the more prominent studies in this area include Chaffin and Park (1973)'s longitudinal study of low back pain investigating associations with occupational weight lifting factors,

Dunn et al. (2006, 2013)'s work on a seven-year low back pain study on long term pain trajectories, Maul et al. (2003)'s eight-year study on low back pain among nurses, and Siddall et al. (2003)'s five-year study on pain following spinal cord injury.

In most of these studies involving identification of contributing factors, what is typically studied is the main measure of pain represented by a pain trajectory, which is the progress of pain over time. These studies typically attempt to generalize or categorize a population of participants into classes, or clusters (Axen et al. 2011; Dunn et al. 2006). Research shows that pain is typically a very individual experience (De Souza and Oliver Frank 2011; Olson 2014), meaning no two patients would experience the same pain, nor can one assume that pain ratings between patients are equal as patients have varying pain tolerance that cannot be objectively measured (Etherton et al. 2014; Reinhardt et al. 2013).

Similarly, such studies typically collect data from participants over a long period of time, which varies between months and a few years. The intervals of data collection observed also vary between weeks, months and years (Dunn et al. 2011; Henschke et al. 2008; Macedo et al. 2014; Bousema et al. 2007). This presents a problem, as any data collected that is of a sufficiently sparse interval will tend to miss the fluctuations and changes that take place between the intervals. To provide an example, this would be like taking a heart rate measure once every ten-minute interval for 15 seconds duration, which might sound reasonable, but be completely inaccurate for a patient requiring constant monitoring due to a heart condition. In context, this would mean that it would be ideal for a patient to be reporting changes to perceived pain, as soon as they experience it. Unfortunately, it is impossible to demonstrate this with existing data due to the intervals of data collection by current studies. Most studies would have either a sparse interval over an extended period of time, or closer intervals over a shorter period of time. The primary contributing reason to this decision is the cost of data collection – it is relatively expensive to conduct data collection using face to face, over the telephone, or mailed questionnaires, especially once the overhead cost in administering the study, manpower, time, postage costs, and printing costs of instruments required is factored in. This cost quickly scales up due to the population sample size required. As a result, an attempt to compromise by adjusting the intervals of data collection is made.

Traditionally, data collection in this field is done using survey instruments, either in person or via mail. With the emergence of eHealth, new methods of collecting data such as using a secure survey website, or a secure mobile application over the Internet is possible (Silva et al. 2015; Merolli et al. 2015; Stinson et al. 2013). Using such data collection methods can also reduce the manpower requirements in processing physical data collected. This also introduces a level of convenience to the participants, as they will be able to report or provide data while at home, or while mobile using the Internet. Platforms and tools such as ResearchKit or CareKit (Apple Inc. 2016a) bring value to the table by facilitating the environment necessary for researchers and doctors alike to develop applications that provide a two-way flow of information between science and patient care. Patients can provide data to researchers through the data collection application, and receive findings and information that is specific to their condition or context, which is a form of personalized care in itself. Applied in context to chronic pain, this would result in better understanding of pain and the conditions for both researchers and doctors, and a better ability to self-manage the patient's pain.

The following section will briefly describe the research context.

3 Research Context

LE is considered to be an overload injury. It is the overuse of specific muscles at the elbow, which leads to persistent elbow pain (Winston and Wolf 2015). Typically, two thirds of persistent elbow pain are attributed to LE. LE has a typical recovery period of 1-2 years for 80% to 90% of patients (Descatha et al. 2016).

The pain trajectory is used as the main measure of recovery for LE. The pain trajectory is a graph plotting the pain intensity over time. This pain trajectory is important in chronic pain as it is used as the primary measure of recovery and to monitor the patient's progress over time.

In personalized care, the intent is to improve and personalize healthcare for the individual patient. This requires an understanding of the unique context in which the patient is experiencing chronic pain, which can include the scenario or situation in which the experienced pain worsens, or is improved. We can do so by using sensors and online mobile-friendly questionnaires in collecting the relevant data. One issue that then rises is of the data required for the context to be understood. Currently, there are no context models in the specific space for our study on LE. We therefore build

upon the context model by Goh et al. (2015). Although the original model is formulated for low back pain, we believe that the model is generalizable to some extent for other chronic pain areas as they share similar context categories. In this study, we use the context categories provided by the model. One of these categories is the environment, which includes variables such as the weather. The weather has previously been identified to potentially have some influence on pain, which suggests that some symptoms of patients were individually affected by some weather conditions (Bossema et al. 2013).

We collected data online using a secure data collection site that was built for this purpose. We will consider these variables shown in Table 1, which includes the appropriate categories from the model. We have excluded some collected data from this study as they were not collected frequently enough, or the data returned was inaccurate. This is indicated in Table 1 under the 'Excluded' column.

Variable	Context Category	Excluded
Overall Pain	Pain Characteristics	
Pain at night	Pain Characteristics	
Activity pain	Pain Characteristics	
Min Temperature	Environment	
Max Temperature	Environment	
Humidity	Environment	
Independent Living	Disability	X
Exercise	Physical	X
Employment Effects	Employment	X

Table 1. Variables in Context Categories

4 Research Method

This study follows Peffers et al. (2007)'s Design Science Research Model (DSRM), that starts by identifying the problem, defining objectives, conducting design and development of an artifact, demonstration of suitable context to solve a problem, evaluating the artifact and communicating the result. The model is shown in Figure 1.

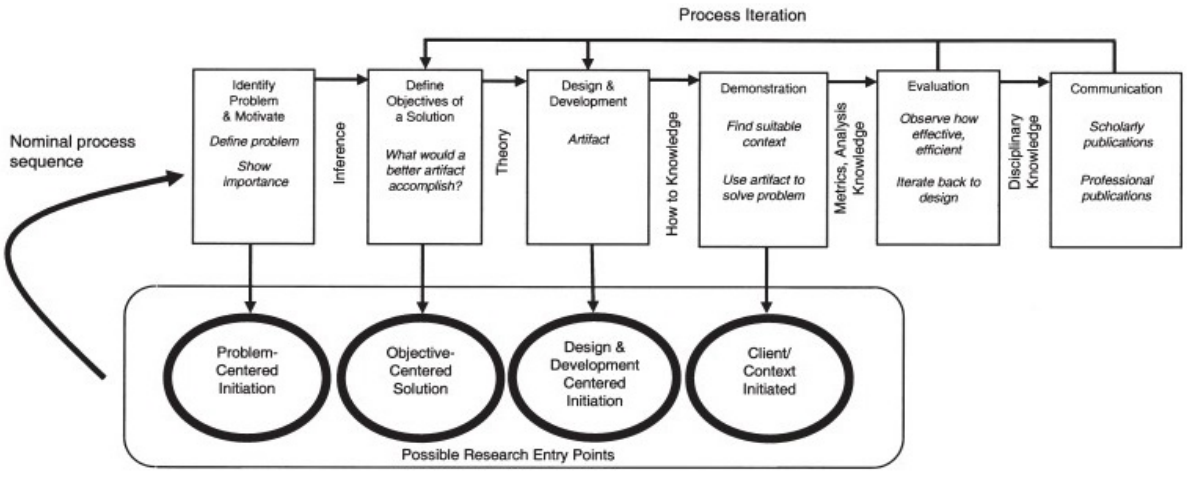

Figure 1. DSRM Process (Peffers et al. 2007, p.54)

Based on the DSRM Process, the problem identified was the issue of sparse intervals in longitudinal chronic pain studies. Our motivation was the emergence of eHealth technologies such as on-line surveys and various platforms such as ResearchKit. The objectives of our study was to then demonstrate how the use of technology can enable the collection of richer data at higher frequencies. This would enable increased explainability of data collected in longitudinal studies, and the ability to address the challenges faced by such studies using more traditional methods of data collection. As

mentioned previously, we designed and developed an on-line secure survey system with a mobile friendly interface for data collection, and then used it with a real world case study. In the section, we used the variables identified in Table 1 to demonstrate the difference with the increased frequency of data collection, when compared to sparser intervals.

4.1 Data Collection and Analysis

As this study is a three-arm randomized placebo-controlled trial, we made as few modifications as possible to the primary protocol of the study. Table 2 shows the adjustments in interval for data collection made to the trial, primarily in the increase of frequency of data collection of pain data to a weekly interval for the first twelve weeks, then three-weekly for the remaining weeks up to 52.

Variable	Original Interval	Adjusted Interval
Overall Pain	Weeks 0, 3, 6, 12, 24, 52	Weekly from 0 - 12, 4-weekly from 12 - 52
Pain at night	Weeks 0, 3, 6, 12, 24, 52	Weekly from 0 - 12, 4-weekly from 12 - 52
Activity pain	Weeks 0, 3, 6, 12, 24, 52	Weekly from 0 - 12, 4-weekly from 12 - 52

Table 2. Adjustments in interval for data collection

Data was collected using a secure website, with a mobile friendly interface to allow for entering of data via a smart-phone's browser. Participants were sent reminders to complete the surveys twice weekly via email.

Patients were recruited into the randomized trial via print and online advertisements, and from medical practitioners (physiotherapists, sports physicians, orthopaedic surgeons, rheumatologists and general practitioners). Patients were considered for eligibility based on five criteria and fifteen exclusion criteria. The eligibility criteria are as follows: 1) lateral elbow pain ≥ six weeks' duration; 2) reproducibility of pain by two or more of the following tests: palpation of the lateral epicondyle and/or the common extensor origin of the elbow, gripping, resisted wrist or second or third finger extension (dorsiflexion); 3) ultrasound-confirmed lesion; 4) age 18 to 65 years; and, 5) ability to read and write in English.

The exclusion criteria are as follows: 1) bilateral symptoms of lateral elbow pain, any other elbow pathology; 2) generalised inflammatory arthritis such as rheumatoid arthritis; 3) concurrent shoulder and/or neck pain and/or pain proximal to the elbow on the affected side; 4) any wound or skin lesion on the lateral side of the affected elbow; 5) neurological symptoms or signs in the affected arm; 6) severe infection; 7) known malignancy; 8) bleeding disorder; 9) previous surgery to the elbow; 10) receiving local glucocorticoid injection in the previous six months; 11) receiving oral glucocorticoids in the previous three months; 12) large tear ≥ 15mm in the common extensor origin; 13) torn lateral collateral ligament; 14) lack of informed consent; and, 15) any other reason thought likely to result in inability to complete the trial.

All participants in the trial were initially screened using the pain reproducibility screening form and had their clinical eligibility criteria confirmed. These participants were then administered a diagnostic ultrasound by an expert ultrasonographer. The ultrasound was used to determine final eligibility and to randomise participants. For this study, we included participants from all arms of the randomized trial.

We originally had a sample size of 36 participants, which was reduced to a final set of 11 due to specific exclusion criteria, which are outlined as follows: 1) incomplete or missing data; 2) entered data late (i.e. week 3 reported in week 4); and, 3) provided data via the researchers directly (phone or in person). We utilized data collected from the first 13 intervals, which is from Week 0 to Week 12.

Participants were asked to report their worst pain level experienced in the past 24 hours for 'overall pain experienced', 'activity-related pain', and 'pain experienced at night', using a vertical eleven-point Visual Analogue Scale (VAS) from 0 to 10, where 0 represents no pain, and 10, the worst imaginable pain.

Weather data was provided by an external third party data source, and aggregated from multiple government weather meteorological services for accuracy, sourced from forecast.io (2016). This data was matched to the previous 24 hours from time of reporting, using the participant's home suburb and postal code.

Data analysis was conducted in two stages. The first stage was a comparison of the pain trajectory, which is pain plotted over intervals of time, for the original sparse intervals vs the adjusted weekly intervals. We plotted graphs for each participant case, for the three pain variables. We used SPSS 24 (IBM Corporation 2016) software for analysis in stage one. The second stage was an analysis using a linear mixed model with fixed and random effects. We used pain as the dependent variable, with minimum temperature, maximum temperature, humidity and type of pain as fixed effects, and the interval clustered within individual participants for random effects. We coded the type of pain as a categorical factor variable with overall pain coded as the comparison group (1), activity-related pain and pain at night coded as (2) and (3) respectively. We used Stata 13 (StataCorp LP 2016) for analysis in stage two.

5 Results and Discussion

This section will first address the pain trajectories generated from the data collected, and will include descriptions for each figure. The participants have been randomly numbered for the figures. Following that, we will discuss the findings of the analysis conducted using the weather and pain data.

The results from the first stage are shown as a set of pain trajectories below, to illustrate the difference in trajectories obtained with a higher frequency of data collection. The pain trajectories cover 3 variables, with overall pain in purple, pain at night pain in blue, and activity-related pain in green. As described earlier, the data was collected at weekly intervals (solid lines), but to allow for a view of what the data would have been should we have proceeded with the original intervals as selected by our medical colleagues, we have included the original interval in short dashed lines of the color of the variable.

The trajectory of the participant in Figure 2 shows an overall recovering trajectory. The participant's reported overall pain is observed to steadily spike up to a peak in Week 2, and again at Week 4, before showing an overall improvement down to Week 12. In comparison, the pain experienced at night seems to be the highest reported as compared to activity or overall pain. The sparse intervals at weeks 0, 3, 6 and 12 tell a completely different story. It seems that the participant is recovering well, with an overall spike at week 3. The pain spikes at weeks 2 and 4 are missed with the sparse interval.

The participant in Figure 3 shows an overall slight recovery, for both night pain and overall pain. The reported pain is erratic and just based on the overall pain, there are spikes in pain observed, peaking at weeks 1, 3, 9 and 12. The sparse interval data (dashed line) does not track any of these fluctuations observed, with a general curve showing improvement up to week 6 before rebounding in week 12.

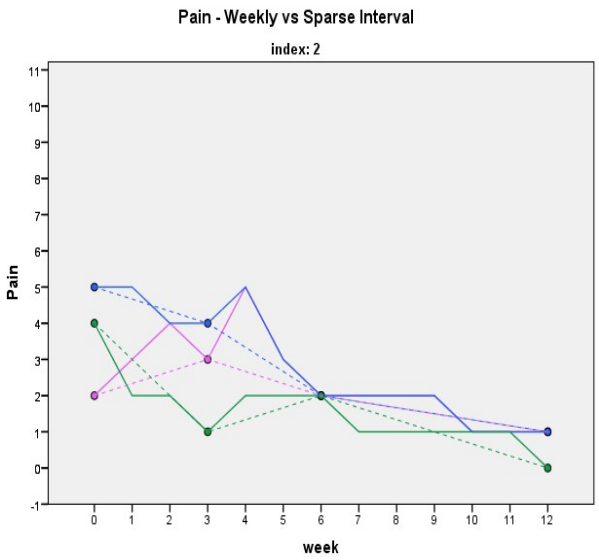

Figure 2. Pain Trajectory – 1

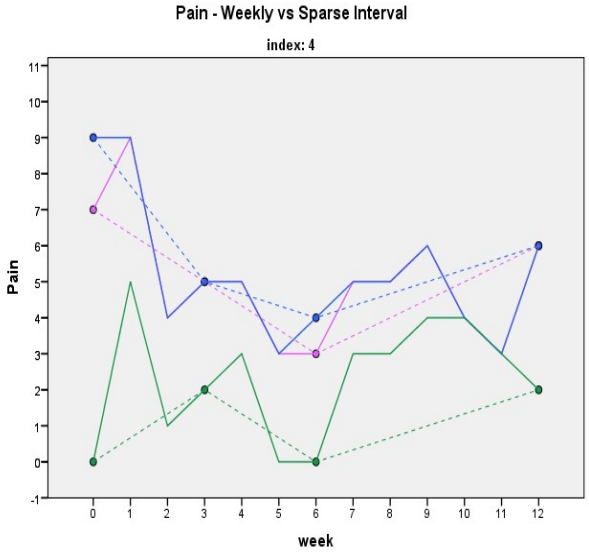

Figure 3. Pain Trajectory – 2

Figure 4 shows a participant with repeated rebounding pain events, where the pain level improves for a week before worsening again, as observed at weeks 2 and 7 at the negative drops in pain. The sparse intervals show an overall worsening trend, which is true of the full data collected for this participant. However, it is of interest to discover what caused the pain to rebound after minimum at weeks 2 and 7.

The participant in Figure 5 demonstrates an overall recovery trajectory, with one major rebound in pain at week 3. The sparse interval data at week 0, 3, 6 and 12 seems to capture the overall trajectory well, with the exception of the main rebound at week 3.

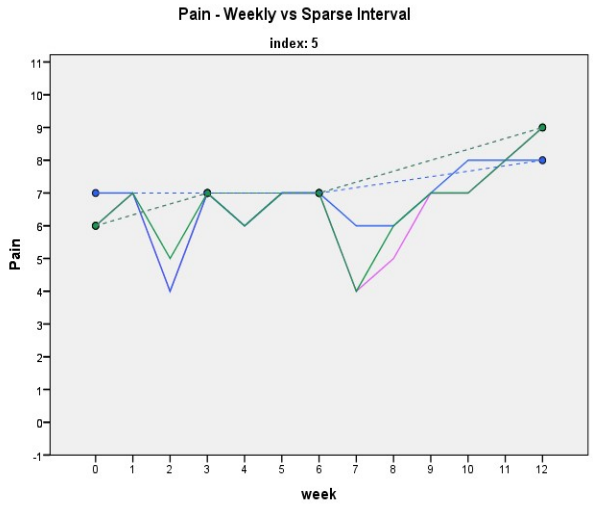

Figure 4. Pain Trajectory – 3

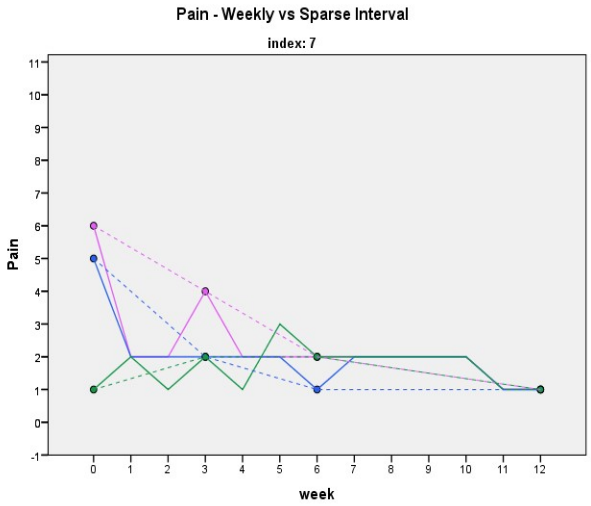

Figure 5. Pain Trajectory – 4

Figure 6 shows another relatively erratic pain trajectory. There are clear peaks in pain at weeks 2, 4, 8 and 12. The trajectory shows the patient improving in week 1 before an initial sharp rebound, although it did not reach the same level of pain as before. As before, the sparse interval fails to capture the bulk of the fluctuations detected, which is of interest.

The pain trajectory in Figure 7 illustrates an overall slight improvement in the condition, with pain peaking at week 3. There are periods of improvement with the rebound at week 3, over weeks 1 to 2. The second rebound in pain is at week 6, with recovery over 3 to 4, and finally a rebound at week 11 after recovery in week 9 to 10.

The sparse interval data fails to capture the three recovery phases in the participant's pain levels.

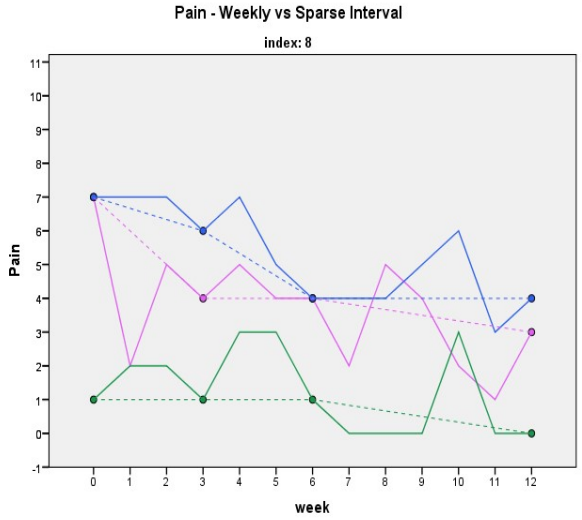

Figure 6. Pain Trajectory – 5

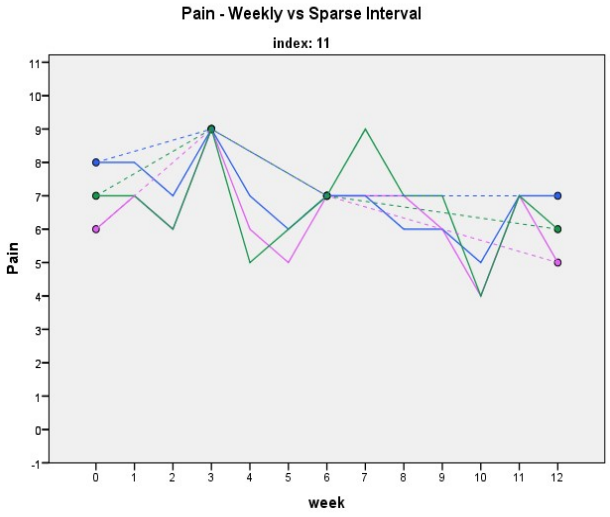

Figure 7. Pain Trajectory – 6

These pain trajectories demonstrate a clear difference in the pain experienced by each patient. It can be seen that the increased frequency of key data also enables the identification of fluctuations in pain that would have gone undetected at larger intervals. These fluctuations are of interest as it allows the identification and discovery of factors that affect or cause episodes of increased pain. Some other interesting points to note are also the differences between data reported for nightly pain vs overall pain. We believe that this introduces an opportunity to discover why such differences occur, which can lead to more effective treatment or interventions.

With regards to the second stage of analysis, we did not find any correlations between pain and temperature nor humidity. Table 3 illustrates the results of the model fitted.

Pain	Coefficient	Std. Err	z	P > |z|	Min 95% Conf.	Max 95% Conf.
minTemp	-0.0218	0.0257	-0.85	0.398	-0.0723	0.0287
maxTemp	0.0055	0.0148	0.37	0.710	-0.0235	0.0345
humidity	0.9893	0.5470	1.81	0.071	-0.0827	2.0615
Type - activity (2)	-0.9510	0.2981	-3.19	0.001	-1.5354	-0.3666
Type - night (3)	0.3706	0.1458	2.54	0.011	0.0847	0.6565
intercept	3.4534	0.7581	4.56	0.000	1.9674	4.9393

Table 3. Linear Mixed Model with fixed and random effects

Table 3 suggests that for the 11 included participants, pain level is not associated with minimum or maximum temperature or humidity. The average activity-related pain is 0.95 units lower than overall pain, and the average pain at night is 0.37 higher than overall pain.

We extended the model in Table 3 by including the interval as a fixed effect, and these results are shown in Table 4.

Pain	Coefficient	Std. Err	z	P > |z|	Min 95% Conf.	Max 95% Conf.
minTemp	-0.0498	0.0324	-1.54	0.124	-0.1134	0.0136
maxTemp	0.0086	0.0154	0.56	0.573	-0.0215	0.0388
humidity	1.0198	0.7770	1.31	0.189	-0.5031	2.5428
interval	-0.1403	0.0338	-4.15	0.000	-0.2066	-0.0739
Type - activity (2)	-0.9510	0.2981	-3.19	0.001	-1.5354	-0.3666
Type - night (3)	0.3706	0.1458	2.54	0.011	0.0847	0.6565
intercept	3.8145	0.8838	4.32	0.000	2.0822	5.5469

Table 4. Linear Mixed Model with fixed and random effects including interval as fixed effect

Similar to Table 3, none of the weather variables in the results shown in Table 4 are associated with pain. Pain is shown to decrease across the intervals as expected. Compared with overall pain, activity pain is lower, and pain at night is higher.

Based on the results of the model run for Table 3 and Table 4, there is no association with temperature or humidity with pain. As expected, the participants show a general recovery across intervals (time). Pain at night is shown to be higher than overall pain, and activity-related pain is lower than overall pain.

6 Conclusion

The introduction of sensors and mobile technologies in eHealth, and the advent of platforms such as ResearchKit and CareKit (Apple Inc. 2016a) has led to an increasing amount of chronic pain studies that utilize such technologies. However, we have yet to see other studies that address the critical problem of sparse data intervals, especially in chronic pain. We have illustrated in this study that increasing the data collection intervals will allow the detection of previously unknown fluctuations in the data, thereby possibly increasing the usefulness of the results and data. The increased frequency of data collection has identified interesting fluctuations in pain that are unexplained. This has been made possible with the use of eHealth technologies to overcome limitations of traditional data collection methods such as paper surveys. Such technologies can allow for participants to provide more accurate data in a convenient manner, enabling a path towards personalized healthcare.

There are some limitations to the data, the analysis, as well as our findings in this study.

First, the weather data collected was based on the previous 24 hours minimum and maximum temperature of the participant's home suburb. However, this may not have been the exact location of participants when they completed data collection. We did not differentiate between indoors or outdoors temperature as the participants were asked to provide a rating of the worst pain experienced in the past 24 hours, which probably includes time spent both indoors and outdoors. Similarly, the limitations to the study as a whole were our inability to collect and study other contextual factors such as physical activity, use of analgesia and emotional factors.

Secondly, the question provided to the participants was not about their current pain, but the worst pain experienced in the past 24 hours. Although unlikely there may have been recall bias. This is a two-pronged problem where both the data collected, and the questions asked have to be devised in a way that provides an accurate way to combine data from multiple sources. We believe that for the analysis to be accurate, the method of data collection has to be altered somewhat. We recommend that participants be asked to provide current ratings of pain rather than for a past period of time. The participants should also be asked to report any perceived changes as they occur. This will allow for the reported pain to be as accurate as possible.

Thirdly, there were incidents where the participant forgot to enter the data, and provided the information late (memory recall) to the system, or directly to the researchers. In these cases, we removed the participant from analysis as a result of an inability to map the data to the correct time period for the environmental context.

Fourthly, our sample number was small. While these data provided a useful insight into the fluctuation in pain seen over weekly intervals in people participating on a LE trial, whether or not more frequent data collection would alter the trial findings remains to be determined. On the other hand, further research trying to explain these fluctuations may provide useful insights into why these fluctuations occur and how these might best be managed.

Finally, in using Goh et al. (2015)'s context model categorizations in this study, we have utilized a minimal set of context factors. It is possible to include other contextual factors listed on the model, but we have not done so due to constraints of the clinical trial.

This paper has reported on findings from a case study conducted in conjunction with a clinical trial. We believe that this research has multiple implications in the information systems and medical domains of knowledge. First, although we have a small sample size, it is clear that the participants had different pain trajectories or experiences in pain. This supports the theory that pain is an individual experience (Olson 2014). Second, this study has been only made possible through eHealth - using technology for healthcare purposes. However, issues were met with participants not entering data in a timely manner. This remains an important issue, especially for longitudinal studies where data is typically collected over an extended period of time. Third, this study shows that collecting data at higher frequencies provides more informative results, and is possible with the use of technology. This allows traditional data collection instruments to evolve and surpass its limitations in the path towards personalized healthcare. Finally, as participants in this study are enrolled in an ongoing trial in which neither the participants nor outcome assessors know which treatment has been received we were unable to assess the pain data according to treatment group. We intend to follow up on this at the conclusion of trial to determine whether analysis by treatment group reveals any additional insights into the pain fluctuations that were observed.

7 Future Research

We will be extending this study into a larger scale data collection research. There is an opportunity to conduct a larger scale study with a larger set of context mapped variables with chronic pain patients. The work can potentially lead to better personalized healthcare, and to a deeper understanding of chronic pain conditions. There is also an opportunity to explore if the increase in the burden of response, or reporting requirements has had an impact on the motivation and willingness for participants to complete the study on time. We are looking to investigate this in a future study.

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