Feasibility and Utility of Pain Monitor: A Smartphone Application for Daily Monitoring Chronic Pain

Irene Jaén[1(✉)], Carlos Suso-Ribera[1], Diana Castilla[2,3], Irene Zaragoza[3], and Azucena García-Palacios[1,3]

[1] Jaume I University, 12007 Castelló, Spain
{ijaen, susor, azucena}@uji.es
[2] University of Zaragoza, 44003 Teruel, Spain
castilla@uji.es
[3] CIBER of Physiopathology of Obesity and Nutrition CIBERobn, CB06/03 Instituto de Salud Carlos III (Spain), Madrid, Spain
irenezaragoza@gmail.com

Abstract. The way monitoring is performed in health settings in general and chronic pain in particular is mostly based on traditional, episodic, onsite evaluation. This assessment method has important limitations and might be negatively impacting the effectiveness of treatments by providing non-ecological, delayed, and retrospective information about the patients' course over treatment. This pilot study explores the feasibility and discusses the utility of using technology (i.e., a smartphone app) for daily ecological momentary assessment of chronic pain patients. Twelve individuals attending a specialized pain clinic used the app twice daily for a month. Alarms were sent to the physicians in the presence of unwanted events (i.e., side effects). Feasibility was evidenced by excellent response rates in the patients (>80%) and the physicians (>93% of alarms were responded to). Utility of daily monitoring was evidenced when graphically representing patients' responses, in which the fluctuation of pain within and across days evidences the need for daily assessment. The utility of alarms will also be discussed, considering the number of alarms received (i.e., 96), which would have remained undetected or belatedly detected with traditional assessment. The study evidences the utility and feasibility of EMA using apps both from the patients' and the physicians' perspective. We believe these findings are not only important for pain settings, but also relevant for other health conditions.

Keywords: Ecological momentary assessment · Smartphone app · Feasibility · Utility

1 Introduction

Chronic pain is defined as pain that persists over a normal healing period, in contrast with acute pain. Specifically, pain was considered chronic when it persists more than 3–6 months [1]. Chronic pain affects approximately 20 to 30% of the population

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worldwide, so this disease has become a matter of social concern globally [2]. There is a wide range of interventions addressed to treat chronic pain, with medical treatments being the mainstream and psychological and physical therapy increasingly being used in multicomponent interventions [3, 4]. Despite the advances made in the treatment of this disease, many reviews have evidenced an only modest effectiveness of current interventions for patients with chronic pain [4, 5].

Some authors have suggested that the limited effectiveness showed in research could be partly explained by deficits in the assessment of pain [5]. For instance, the evaluation of treatment effectiveness is frequently made on a discrete basis, with a reduced number of measurement points frequently during onsite consultations only. This is problematic as pain intensity can vary naturally between and within days even when no treatment is proposed. Additionally, the assessment of pain course is usually performed retrospectively (i.e., "How intense was your pain during the past week"), which has been shown to be an unreliable measure of average daily pain because of recall bias [6, 7].

Ecological Momentary Assessment (EMA) is an excellent alternative to traditional, episodic evaluation due to several factors. First, with EMA pain can be measured in the moment it occurs, which attenuates the memory effects derived from recalled past pain experiences. Second, EMA allows assessing pain in a natural environment (i.e., not only during onsite consultations). Third, obtaining a measure of pain in a real time allows giving feedback to the patient (i.e., suggest to call the pain clinic if pain is not being reduced), which might, in turn, be used to improve the treatment. Last but not least, momentary data collection allows capturing the real course of pain trajectories, so that the conclusions about the effectiveness of treatments become a result of several measurement points and, thus, they become more reliable [8–10].

To date, EMA has been rare due to the use of ineffective or unreliable data collection methods, including paper diaries or telephone calls [11]. In the last years, however, the use of smartphone apps for research has increased drastically, which has renewed the interest in EMA. This is also the case of chronic pain, a field in which the use of smartphones for EMA is attracting the interest of researchers and clinicians [11–13]. Hundreds of pain apps currently exist. However, to date very few studies have reported the feasibility and utility of such devices for EMA in chronic pain.

Our team recently developed and tested the validity, reliability, and feasibility of Pain Monitor, a smartphone app used for EMA of pain severity and pain-related biopsychosocial factors [14]. The results obtained are very promising and suggest that the content assessed in traditional paper and pencil methods can be reliably measured with an app. However, the incorporation of smartphones to pain research is still on an early stage and there is a need to further investigate the applicability of this new monitoring procedure in health settings to be able to generalize the existent findings and to integrate their use in daily routine practice. Additionally, feasibility was only calculated from the patients' perspective, but not from the physicians' point of view (i.e., number of alarms sent by the app to the physicians in the presence of unwanted clinical events and number of alarms attended by the physicians). With the aforementioned purpose in mind, the aim of this study was to evaluate the utility and feasibility of the Pain Monitor app in a different setting (i.e., different hospital, patients, and region) and including the physicians' perspective.

App feasibility from the patients' perspective was calculated by dividing the number of completed measurements by the number of possible assessment points (i.e., sixty, twice a day for thirty days). Completion rates were also calculated separately for morning and evening assessments to explore whether time of day was an important variable explaining feasibility. App feasibility from the physicians' perspective will be computed by calculating the number of alarms responded by the number of alarms sent. Utility was explored by observing pain trajectories graphically and discussing how EMA could affect the conclusions regarding pain course and treatment effectiveness. Additionally, the utility of daily monitoring will be discussed when considering the alarms received in the presence of unwanted events. We expect to obtain good feasibility results, that is, with similar completion rates compared with the previous study with the same app (70–80%), as well as to observe graphical representations of pain trajectories that justify the utility of EMA in chronic pain [14].

2 Method

2.1 Pain Monitor App

Pain Monitor was originally developed and tested by a multidisciplinary team of psychologists, physicians, and nurses from the Vall d'Hebron Hospital and the Labpsitec group at the Jaume I University [14]. There are four groups of items in the app. The first one is administered the first day of use and includes sociodmographic and patient health and pain status information. Next, on a daily basis, patients are asked to respond to two different sets of questions: one in the morning and another in the evening. Both assessment points have some items in common (i.e., pain severity and mood), while other variables are assessed in the morning (i.e., interference of pain on sleep) or in the evening (i.e., interference of pain on daily activities). Specifically, daily assessment was predefined at 10:00 a.m. and 7:00 p.m. with a two-hour range in which patients can respond to each measurement. At the end of the study (after 30 days of daily evaluation), an end-of-study measurement is made with additional items (i.e., perceived change after treatment).

App content includes pain-related variables selected by experts following IMMPACT and recent review's recommendations on outcome and app assessment in chronic pain settings [15, 16], which has been adapted from traditional, well-established paper-and-pencil measures for their use in an app context. These include sociodemographic information, pain intensity (Brief Pain Inventory) [17], fatigue and mood (Profile Mood States) [18], anxiety and depression (Hospital Anxiety and Depression scale) [19], perceived heath status (Short Form-12) [20], catastrophizing (Pain Catastrophizing Scale) [21], acceptance (Chronic Pain Acceptance Questionnaire) [22], fear/avoidance of pain (Fear-Avoidance Beliefs Questionnaire) [23], activity level (Roland Morris Disability Questionnaire) [24], and coping strategies (Chronic Pain Coping Inventory-42 and Coping Strategies Questionnaire for coping) [25, 26].

The app has an alarm system which sends the participating physicians an e-mail in the presence of a predetermined undesired event (i.e., pain intensity is above 7 for more

than 5 consecutive days, the patient is reporting nausea for more than 2 consecutive days, or the patient has stopped taking the medication for more than 2 consecutive days, to name some examples). The response to these alarms (i.e., call the patient and make a change in treatment or not taking any action) is determined by the participating physicians. The alarms are only notified to the physicians, but not the patients to reduce the risk of response expectation. However, all patients are informed at the beginning of the study that their responses might generate alarms and that physicians might call them.

The app is available for Android System (version 2.3 or higher) and can be downloaded for free at Play store (https://play.google.com/store/apps/details?id=painmonitor.srccode).

2.2 Sample and Procedure

This study was conducted with 12 participants with musculoskeletal pain who were being treated at the pain unit of *Hospital General Universitari de Castello* for the first time. Patients were over 18 years of age (mean= 49.83, *SD* = 8.47) with a mobile phone with Android operating system. Physical and psychological limitations or language problems which could prevent the use of the application were checked and resulted in study exclusion (n = 3). All participants had a chronic pain diagnosis (i.e., mostly back and neck pain over 3 months of duration) and began a medical treatment after this first consultation (see the results section for a more detailed description of clinical characteristics of the sample).

With respect to sociodemographic characteristics, the 25% of the sample was temporary on time off work, the 16.66% were active workers, the 16.66% were unemployed, the 16.66% had the incapacity to work, 16.66% were homemakers, and 16.66% were retired. Regarding the educational profile, 41.7% had primary studies, 23% had secondary studies, and 33% had coursed technical studies. Additionally, 66% of participants were married, 8.3% had a relationship, 8.3% were single, and 16.7% were widowed people.

All participants were identified by means of an alphanumeric code automatically generated by the app to ensure anonymity and confidentiality of data. This code was associated to the medical registry number so that the physicians could identify the patient. This file and the app data were saved following the Spanish law and data protection rules ("Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de carácter personal", "RD 1720/2007, de 21 de diciembre, por el que se aprueba el reglamento de desarrollo de LOPD (RLOPD)", and "Ley 34/2002, de 11 de Julio de Servicios de la Sociedad de la Información y de comercio electrónico"). In addition, all patients signing the informed consent were indicated that their participation was voluntary and would not affect the prospective treatment at the pain clinic.

2.3 Data Analysis

To evaluate the usability of Pain Monitor, the overall response rate will be calculated by dividing the number of completed assessments (both morning and evening responses) by the number of possible assessments (i.e., sixty). Additionally, morning

and evening responses rates will be computed separately. A similar procedure was used for the physicians' responses to the alarms (i.e., alarms responded divided by alarms sent). Finally, pain intensity responses of a number of patients will be graphically displayed to observe different pain trajectories and to discuss the utility of EMA as opposed to episodic assessment.

3 Results

3.1 Clinical Characteristics of the Sample

Patients had a mean pain intensity of 7.67 (*SD* = 1.72; possible range = 0 to 10). The majority of patients had been experiencing pain for more than 5 years (*n* = 9). Only one patient had experienced pain for less than one year. Pain diagnoses, including comorbidities, were low back pain (*n* = 11), neck pain (*n* = 6), fibromyalgia (*n* = 3), and migraine (*n* = 3). None of the patients had pain due to arthritis or cancer.

3.2 Feasibility

Patient perspective. The results showed an overall response rate of 82% after 30 days of daily use of Pain monitor twice a day. In addition to this, results showed that morning assessment was answered 80% of times, while evening evaluations were completed 84% of times.

Physician perspective. In total, 96 alarms were sent. Of these, the physicians responded to 90 alarms, so 93.9% of them were responded to.

3.3 Utility

A graphical representation of the pain course over the study period is shown for three patients to discuss the utility of EMA using a smartphone. As seen in Fig. 1, morning-to-evening pain reports for this patient differed notably, so that pain levels were repeatedly higher in the evening. Additionally, as reported in Fig. 2, a patient reported unstable pain reports with some days experiencing very severe pain (i.e., on day 3) and weaker pain levels on the other days. Finally, in Fig. 3, a trend recovery trajectory is observed, with a decrease in pain reports starting with pain treatment onset, especially for evening pain intensity.

Regarding the utility of daily telemonitornig and alarms, the majority of the alarms (i.e., 75) included taking action (i.e., calling the patient) and only in 15 alarms that were responded to no further action was considered (i.e., recurrent symptom already known and treated for or symptom presumably not related to the pain treatment).

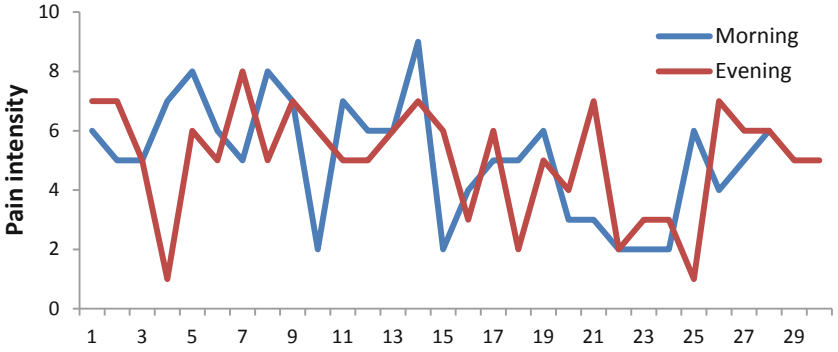

Fig. 1. Pain intensity responses of Patient A twice a day during 30 days of Pain Monitor app use.

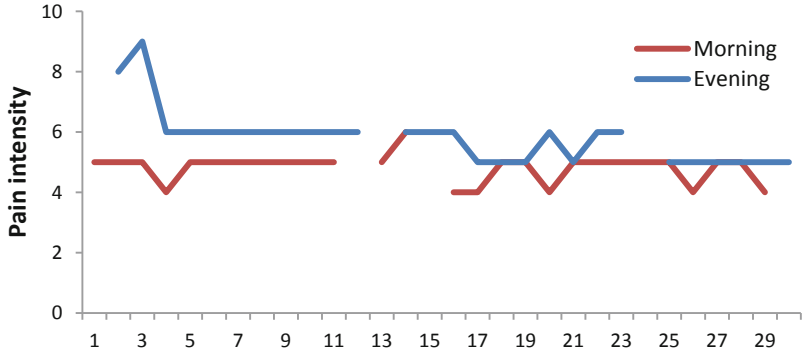

Fig. 2. Pain intensity responses of Patient B twice a day during 30 days of Pain Monitor app use.

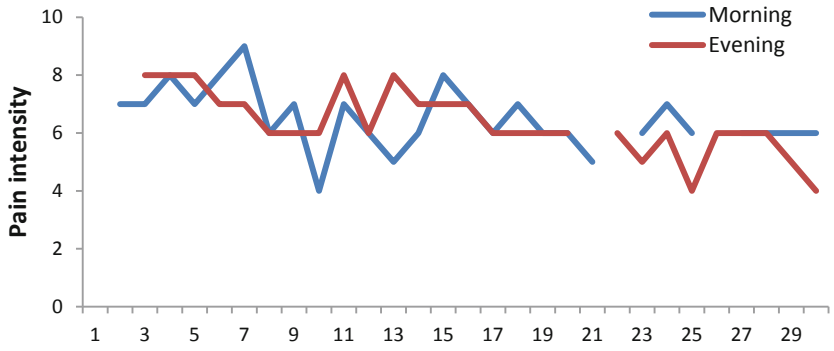

Fig. 3. Pain intensity responses of Patient C twice a day during 30 days of Pain Monitor app use.

4 Discussion

Assessment is a complex, but essential process for research and clinical practice. To date, however, traditional, episodic, and onsite evaluation is still the mainstream. As we have previously discussed, this might be impacting negatively in the quality of our studies and daily practice [27]. Thus, the present study goal was to test the feasibility and utility of Pain Monitor, an app developed by our team, in chronic pain settings.

Similarly to Suso-Ribera et al. (2018), we have obtained excellent feasibility results, that is, competition rates over 80% for both morning and evening assessments. Thus, diary assessment using EMA appears to be feasible since patients responded to the majority of the daily assessments (on average, 48 evaluations during a month). As a result of this, researchers and physicians obtained a large amount of data that would be very costly (or impossible) to collect by any traditional onsite assessments or other forms of EMA (i.e., paper diaries or phone calls).

An important finding in the present investigation is that feasibility was investigated not only form the patients' perspective, but also considering the responses obtained by the physicians to daily alarms sent by the app. To the best of our knowledge, this is the first study to explore this in pain settings. In this regard, our results indicate excellent feasibility findings, with physicians responding to more than 93% of alarms during their daily practice. Adding up to this, it is important to note that the fact that alarms were triggered suggests that the traditional assessment is not sufficient to reduce the patient symptomatology and provides further evidence for a paradigm change in the way monitoring is being performed. As revealed in the present study, the use of smartphone apps might solve this problem and help improve the detection of symptoms which might otherwise remain undetected with an evaluation based on a single assessment in a specific moment. While acknowledging this utility of alarms and EMA, we have also observed some difficulties in the physicians' response to alarms in days were there was a high workload, which suggests that there is a need to allocate a specific time during daily practice (i.e., 15 min daily outside the consultation hours as formally indicated by the physicians) to respond to the alarms.

In this study, we presented a graphical representation of patient pain trajectories over the study course (i.e., 30 days course) as indicated in the app to discuss the utility of EMA using technology. In line with previous research [14, 28, 29], the utility of EMA using apps seems clear. For instance, pain reports were shown to change within the same day (i.e., morning to evening differences) and across days. Consequently, taking a single measure of pain might lead to biased or imprecise conclusions. While this was evidenced for pain levels, the same discussion applies to other variables that can fluctuate, such as mood. Thus, conclusions extracted via episodic assessments might not show the reality of the pain experience for a number of patients. In addition to the previous, the utility of EMA was evidenced graphically by displaying the pain trajectories easily over time, including a large amount of data. Although the methodology used in this study prevents us from drawing causal inferences (a single case experimental design would be needed), the graphical representations presented in the study suggest that a more reliable conclusion about treatment effectiveness could be reached with EMA using technology.

The present study has certainly limitations. Because this is a pilot study to explore the feasibility and utility of using the app in clinical settings, before a larger implementation study is performed, the sample size is rather small. However, we consider the size to be sufficient to reach preliminary conclusions about feasibility and utility of the Pain Monitor app. It is also important to note that this is not a single case experimental study, so no conclusions about treatment effectiveness should be made. This was not a study goal at this stage and the step taken in the present investigation (i.e., ensuring that the use of the app for EMA is feasible and useful) was believed to be a necessary first step before the implementation of an experimental study.

The use of EMA with the support of smartphone apps in the health care system seems to be necessary to assess pain symptomatology. We believe, however, that this applies to other symptoms (i.e., mood) and a wide range of patients other than chronic pain individuals. The Pain Monitor app has demonstrated to be a useful and feasible tool to this purpose. In addition, Pain Monitor has not only demonstrated to be a feasible measure to assess pain from a patients' perspective, in the form of excellent completion rates, but also it demonstrated to be feasible when considering their daily use by physicians, as revealed by over 93% response rates to alarms. We believe that future research and health policies have to be directed towards the implementation of EMA using technology in routine medical practice.

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