Improving chronic pain management with eHealth and mHealth: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Chronic pain has become a matter of public health concern due to its high prevalence and because public costs associated with treatment and disability increase each year. Research suggests that limitations in the traditional assessment of chronic pain patients limit the effectiveness of current medical treatments. The use of technology might serve change patient traditional monitoring into ecological momentary assessments, which might be visualised by physicians live. This study describes a randomised control trial designed to test the utility of a technology-based solution for pain telemonitoring consisting of a smartphone app for patients and a web application for physicians. The goal of this study will be to explore whether this combination of eHealth and mHealth improves the effectiveness of existing pain treatments.

Methods and analysis Participants will be 250 patients randomly assigned to one of these two conditions: treatment-as-usual (TAU) and TAU +app+. All participants will receive the usual treatment for their pain. Only the TAU +app+ group use Pain Monitor app, which generates alarms that are sent to the physicians in the face of previously established undesired events. Physicians will be able to monitor app reports using a web application, which might result in an adjustment of treatment. We anticipate that the use of Pain Monitor plus the therapist web will result in a reduction of pain intensity and side effects of the medication. Improvements on secondary outcomes, namely fatigue, mood, pain interference, rescue medication use and quality of life, are also expected. Mixed repeated-measure multivariate analyses of variances will be conducted to investigate whether there are differences between preassessment and postassessment scores as a function of the experimental condition.

Ethics and dissemination Ethical approval from the Hospital General Universitari de Castellon was obtained. The findings will be published in peer-reviewed journals.

Trial registration number NCT03606265

INTRODUCTION Pain can be defined as ‘an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage’ and can only be understood as an interplay between ‘sensory, emotional, cognitive and social components’. Although pain often is acute and disappears as tissues heal, sometimes pain persists for long periods of time and becomes chronic. For instance, it has been reported that 15% of individuals admitted to trauma hospitals due to a severe injury and 15%–60% of patients after surgery will continue to experience chronic pain months and years later. In general, a cut-off of 3–6 months is used to define the transition from acute/subacute to chronic pain.

The aforementioned chronification of pain is becoming a major public health problem across the globe. We refer here to primary chronic pain, a pain associated with important interference on functioning and/or emotional distress, which cannot be better accounted for by any other condition. Specifically, epidemiological studies indicate that the prevalence of this disease in the adult population ranges from 19% to 38% worldwide. Furthermore, the increase in life expectancy and the ageing of the population is likely to have an important impact on the
number of individuals experiencing chronic pain, since the prevalence of this syndrome boosts dramatically with age. For instance, it is expected that the population of chronic pain individuals will be doubled in 2050 for people older than 65 years and tripled for people over 80 years of age. Thus, chronic pain is a major public health challenge due to its high prevalence in the population and high direct and indirect costs for the institutions and the individual.

Indeed, chronic primary pain (eg, fibromyalgia or non-specific low back or neck pain, to name some examples) is imposing a huge burden in our societies as this disease has become one of the leading causes of years lived with disability globally. Not surprisingly, as a result of the growing concern about this disease, there have been numerous attempts to improve treatments for pain in the past decades. However, recent reviews on the effectiveness of numerous interventions, including medical treatments, psychological therapy, physical rehabilitation or a combination of these, indicate that the effectiveness of existing treatments is, on average, only modest. While there might be numerous factors explaining the limited effectiveness of current interventions for pain, including unexplored biomechanical mechanisms or genetic factors, patient characteristics or therapists’ training, some authors have pointed to methodological shortcomings as key elements explaining the modest effectiveness of pain interventions. Specifically, the way assessment is currently performed (ie, a single measure of pain intensity performed episodically during the onsite appointments) has been argued to impact negatively in the ability of existing interventions to achieve more reliable and powerful changes in patient outcomes. For instance, a single rate of pain intensity has been shown to be an unreliable measure of pain as this experience can vary dramatically within the same day and across days.

In addition, pain is frequently assessed retrospectively, which is known to lead to recall bias and to decrease the accuracy of pain ratings, and does not allow for timely responses to undesired events, so these often take place after the problem occurred.

As a consequence of the above, ecological momentary assessment (EMA), which refers to the assessment of pain repeatedly and in real life, has received renewed interest in the past years in the pain literature and is now considered by many as the gold standard method to assess the pain experience. Traditionally, EMA has been difficult due to the limitations and costs of repeated measurement procedures (ie, paper diaries or phone calls). However, with the explosion and availability of smartphones, EMA has become easier than ever and immediate communication between the patient and the physician is now a more feasible practice.

It has been argued that this change in the assessment paradigm towards ecological daily telemonitoring using apps will improve treatment effectiveness and reduce costs if used to respond to patient reports quickly. Indeed, there is evidence to suggest that smartphones are useful tools to be used for the assessment of pain core outcome measures in chronic pain settings. The extent to which this EMA of pain patients can effectively lead to better practices in pain medicine is still unknown. For this purpose, we developed a technology-based solution that integrated a pain and symptom tracking app for patients and a web for physicians where app-generated alarms are received daily and patient app responses can be monitored in real time.

With the previous goal in mind, in the present parallel group, superiority trial we will use the Pain Monitor app (https://play.google.com/store/apps/details?id=pain-monitor.srccode), which was developed by a team of psychologists and an engineer with the collaboration of physicians and nurses and has been recently validated in clinical settings, together with a web for the physicians where app responses and alarms can be tracked in real time to facilitate the professional’s decision-making process. As we will explain in more detail in the Methods section, Pain Monitor assesses a number of pain-related outcomes (ie, pain intensity, pain interference, anxiety and depression and use of pain-related health resources) and the most frequent side effects of medical treatments for pain. In the study, patients will be randomly assigned to a treatment-as-usual condition (TAU) or to a TAU with the support of the patients’ app and the physician’s web. We anticipate that the use of the web application linked with the smartphone app (TAU +app+ web condition) will improve the effectiveness of usual treatments resulting in reduced pain intensity and less frequent side effects of the medication after 1 month of medical treatment. Additionally, we expect that this group of patients will present additional improvements on secondary outcomes, including mood (depression and anxiety), pain interference, pain catastrophising and use of pain-related health resources in the past month as secondary gains of reducing pain levels, as suggested in the literature. We also expect that the rapid detection of treatment undesired events will rapidly minimise threats to the patient’s quality of life and mood.

**METHOD**

**Study design**

The current investigation is a randomised superiority clinical trial composed of two parallel groups (1:1 allocation ratio): (1) TAU and (2) TAU +app+ web. In the study, participants in the TAU condition receive the usual pain treatment by the physicians working at the pain unit (ie, pharmacological treatment or infiltration). Participants included in TAU +app+ web group receive the usual treatment for their pain plus daily monitoring of their symptoms and pain experience with the Pain Monitor app during 1 month. In the TAU +app+ web condition, alarms are generated in the presence of previously established undesired events, which have been previously determined by the physicians at the pain clinic (eg, pain intensity is higher than 7 in an 11-point numerical scale during three
Figure 1  Study schedule of enrolment, interventions and assessments.

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<tr>
<th>TIMEPOINT</th>
<th>STUDY PERIOD</th>
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<td>Physical symptoms</td>
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<td>Secondary outcomes</td>
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<td>Pain interference</td>
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<td>Mood</td>
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<td>Fatigue</td>
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<td>Rescue medication</td>
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<td>Quality of life</td>
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Box 1  Inclusion criteria

- The patient is over 18 years of age.
- The patient has a mobile phone with Android operating system (the app is currently only available for Android, which is the operating system used by more than 80% of users in Spain).46
- The patient has the physical ability to use the application.
- A new treatment plan is started during the first week after study onset.
- The patient does not present psychological and/or cognitive alterations or problems with language that make his/her participation difficult.
- The patient voluntarily wants to participate and signs the informed consent form.
supplementary file 2). Patients, who do not agree with the assigned condition, are given the opportunity to be allocated to the preferred condition, but are not used in the analyses. Any changes to modify the assigned condition are accepted at any time during the study, again resulting in an exclusion from the study. Changes in the medication or improvement of disease do not result in study discontinuation. Disease worsening is not expected to be associated with the inclusion of the app but, if existent, will result in the discontinuation of app use.

**Procedure**

The study is conducted at the pain clinic of the Hospital General Universitari de Castelló. The study is advertised by the physicians to all consecutive patients attending the pain clinic for the first time. To ensure enrolment, physicians will emphasise the importance of active patient participation in research in general and in self-monitoring in particular. Patients interested in participating are directed to another office where the lead author, IJ, explains the study procedures in more detail and ensures their eligibility. IJ is in charge of increasing adherence to the treatment (ie, app) by explaining the utility of the study and by contacting patients when an alarm informing of low app adherence (ie, more than three consecutive days without response) is received. All participants are provided with an information sheet and sign the informed consent. After participation acceptance, participants are assigned to one of the experimental conditions (TAU or TAU +app+web), which had been previously randomised by an external researcher. All participants then complete a paper-and-pencil assessment protocol in order to control for differences between the two assessment formats (app vs pen and pencil) and to compare both conditions using the same assessment approach. In addition to this paper-and-pencil evaluation, patients in the TAU +app+web condition download and install the Pain Monitor app into their phones. Once they install the app, they answer to an initial assessment and then complete two measures daily (10:00 and 19:00 hours) during 1-month (study duration). Finally, an end of study appointment is set (1 month later) to conduct the postassessment evaluation. Due to difficulties in transportation or availability, the postassessment intervention can either be completed onsite or via an online survey.

**Pain monitor**

The Pain Monitor app (figure 2) has been developed by a group of pain psychologists and an engineer, with the collaboration of physicians and nurses specialised in pain care. Pain Monitor is composed of several pain-related items which are to be answered twice a day at preset times (10:00 am and 19:00 hours, with a 2-hour flexibility) during 30 days. The app content has been previously validated with chronic pain patients at the pain unit of the Vall d’Hebron Hospital.

![Figure 2](http://bmjopen.bmj.com/) (A) Pain monitor instructions; (B) pain monitor assessment of pain intensity; (C) pain monitor assessment of fatigue.
and coping, among others, are measured with a single item to reduce the burden of daily assessment, each of which was adapted and validated against well-established paper-and-pencil measures.\(^2\) Additionally, the assessment protocol includes a list of side effects created ad hoc based on the literature findings on the most frequent adverse effects of pain treatments,\(^41\)\(^42\) as well as measures of treatment adherence, use of rescue medication, neuropathic characteristics of pain and use of medical services in the past month. All app items can be found in online supplementary file 3.

The app generates alarms in the presence of predefined events (see online supplementary file 4 for the alarms set in the present study in collaboration with the participating physicians). These alarms are sent to the physicians early in the morning on working days so that they can decide whether an action from their side is required (eg, calling the patient and setting an earlier appointment or suggesting a change in the medication). For this study, a website linked to the app was created for the physicians to observe patient alarms and evolution live. Examples of the physician web are presented in figure 3. Physicians are only asked to check the website when an alarm happens, but they are allowed to check any patient status at any time.

**Interventions**

Five physicians at the pain clinic of the Hospital General Universitari de Castelló participate in this study. All patients in the study receive the usual treatment for their pain irrespective of their assigned condition. However, a change in treatment might occur in the TAU +app+web condition at the discretion of the physicians in charge of treatment after receiving an alarm and consulting the web page with the graphical representation of patient app responses. As usual, patients in the TAU condition without the app are not contacted by the physicians between appointments. It is important to note that both patients in the TAU only and patients in the TAU +app+web condition are allowed to attend to the emergency services or the family physician in the event of an emergency at any stage of the study due to ethical reasons. At the end of the study, this practice is investigated for each participant in the final assessment.

**Assessment plan**

All participants in the study fill in a number of questionnaires in a paper-and-pencil format at the beginning and at the end of the study. This assessment protocol includes sociodemographic information, sickness work absence during the past month, use of pain-related health resources in the past month (ie, emergency services, family physician or pain clinic), pain-related physical symptoms experienced in the past week (ie, side medication effects), the Brief Pain Inventory (pain severity and interference),\(^43\) the Pain Catastrophising Scale,\(^44\) and the Hospital Anxiety and Depression Scale.\(^45\) In addition to this paper-and-pencil evaluation, participants in the TAU +app+web condition also inst a Pain Monitor app and complete a preintervention assessment in the app after the paper-and-pencil evaluation. Both baseline assessments include the same content and are duplicated to provide further evidence for the validity of app content. After this pretreatment evaluation, participants in the TAU +app+web group are asked to answer to the app assessments twice a day during 1-month (study duration). A push-up system notifies the patient about the need to respond to the app evaluation at 10:00 and 19:00 hours. These times can be adjusted by the patient with a 2-hour flexibility from the preset times.

Daily morning and evening assessments differ in a number of items. Some items are asked twice a day (ie, pain intensity, sadness, anxiety), while others are only administered in the morning (eg, interference of pain on sleep) or in the evening (eg, activity level during the day, interference of pain on daily activities, or physical symptoms experienced during the day).

Finally, 30 days after the treatment onset (ie, first evaluation), both groups complete a postassessment protocol. The measures included in this final evaluation are similar to the ones included in the baseline assessment, with the inclusion of a measure of negative events experienced during the study period and the evaluation of perceived change due to treatment.

In the study, primary outcomes are pain intensity and the number of side effects of the medication reported in the app, while secondary outcomes include mood (depression and anxiety), pain interference, pain catastrophising and use of pain-related health resources in the past month.

Note that app reports in the TAU +app+web condition are not used to determine treatment effectiveness compared with the TAU only condition because in the latter condition participants do not use the app. Therefore, app responses are only used for telemonitoring and early detection of treatment problems that result in an alarm to the physicians. The comparison of both conditions will be made using the traditional paper-and-pencil evaluations, which will be available for both groups. Additionally, the number of alarms and the physician’s responses to such alarms (eg, change in treatment strategies) will be registered. This information will be used to get better insight into the utility of the integrated technology to improve treatment efficacy.

**Patient and public involvement**

In the current study, patients or the public will not be involved in the design, or conduct, or dissemination of the research.

**Data analysis**

The aim of the present study is to explore the effect of an integrated technology-based solution for chronic pain monitoring (an app that monitors pain patients daily and sends clinical alarms to physicians and a web for physicians that graphically represents patient evolution as reported
in the app) compared with the usual treatment where monitoring is made using a paper-and-pencil, episodic, onsite evaluation. With this aim in mind and completer analyses will be performed following the recommendations of the Consolidated Standards of Reporting Trials guidelines (http://www.consort-statement.org/). First, the two conditions will be compared at baseline in the different continuous measures with a between-group analysis via a t-test to ensure that randomisation indeed resulted in comparable groups prior to intervention. $X^2$ tests will be used for all the categorical variables. To evaluate our hypothesis, mixed repeated-measure multivariate analyses of variances (MANOVAs) will be conducted to investigate whether there are differences between preassessment and postassessment scores as a function of the experimental condition (TAU or TAU +app+web).
Alternative to these traditional assessment methods, the use of smartphone apps appears to be an innovative and promising approach, as a result of telemonitoring. This technology allows for the personalisation of medical interventions by rapidly adjusting treatments to every individual patient, thus facilitating telemonitoring and reducing the need for face-to-face visits.

In the present study protocol, we describe a randomised controlled trial designed to test an integrative technology consisting of a web application for the healthcare professional, which serves as a basis for the implementation of telemonitoring. The app is designed to assess pain intensity and related variables from the patient's home, thus facilitating the personalisation of medical interventions by rapidly adjusting treatments to every individual patient.

The app is based on self-report, smartphone apps which are based on recall. The assessment methods used in this study are validated and have been shown to be accurate and reliable in previous studies. The app is designed to assess pain intensity and related variables from the patient's home, thus facilitating the personalisation of medical interventions by rapidly adjusting treatments to every individual patient.

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