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VALIDITY, RELIABILITY, FEASIBILITY, AND USEFULNESS OF PAIN MONITOR, A MULTIDIMENSIONAL SMARTPHONE APP FOR DAILY MONITORING OF ADULTS WITH HETEROGENEOUS CHRONIC PAIN

Running title: Pain Monitor, a multidimensional pain app

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1. Introduction

Ecological Momentary Assessment (EMA) is considered by some the gold standard assessment method in health settings,[1] including chronic pain.[2]EMA can reduce recall biases by collecting real-time, momentary data,[3,4] and improve the accuracy of health and pain variability and treatment effectiveness over time,[5,6] and further allows the possibility to perform prospective, naturalistic assessment at home or at work.[7]EMA in health and pain studies has been relatively rare, arguably because of its costs, the non-compliance problems of traditional procedures (i.e., paper diaries), and the need for technology assistance when using more modern tools to collect and save electronic assessments (i.e., Personal Digital Assistants, smartphones).[8,9]

The explosion of smartphone applications (apps) and increased availability of smartphones, which are estimated to be used by 70% of the population in 2020,[10]has renewed interest in EMA for the management of chronic illnesses.[11]The use of apps for EMA has shown to overcome the limitations of traditional paper-and-pencil diaries by eliminating manual data entry and increasing compliance because of their accessibility and allure.[7,12,13]As a result of this, the way health data are tracked is likely to change in the next years, and a shift towards EMA using electronic assessment is expected.[14]

The number of pain apps has boosted in the past few years. In only 3 years, reviews have indicated a 200% increase in published pain apps, from 111 in 2011 to 224 in 2014.[15,16]However, the same concerns raised 5 years ago still prevail, and reviews agree that there is little evidence to support the use of the majority of existent apps.[15–20]Specifically, (1) most of them do not report the validity of their content, (2) the majority (86%) fail to specify pain expert involvement in app development, and (3) almost all apps ignore psychological components of pain.

There have been some attempts to explore the psychometric properties and utility of pain apps. Pain Squad, a multidimensional app for children and adolescents with cancer pain, obtained adequate construct validity in the measurement of pain intensity, interference, and unpleasantness, as well as good test-retest reliability and feasibility.[21]Good construct validity and acceptability have also been revealed for Painometer, which evaluates pain intensity, in a sample of children, adolescents, and young adults.[22,23]Jamison et al. [24,2] have recently tested the acceptability and utility of a multidimensional app for adults with pain. The authors also reported good construct validity and reliability in the assessment of pain intensity.

Although these studies have addressed some of the issues raised in recent reviews of existent pain apps, there are additional issues that need to be addressed. Validated apps tend to assess pain intensity or a few pain-related variables only. Key psychological constructs and some outcomes recommended in clinical guidelines, such as adverse effects, use of rescue medication, and emotional functioning, tend to be ignored.[16] Also, very few investigations have comprehensively examined the validity, reliability, usability, compliance, and utility of a pain app in adults with chronic pain.[13,24,25]

A multidisciplinary team designed a new pain app, called Pain Monitor, following IMMPACT guidelines for pain measurement[26] and the recommendations from existent reviews on apps for pain.[15–17,19,20,27]The goal of the present investigation is to explore the validity, reliability, feasibility, and usefulness of Pain Monitor in adults with chronic pain.

2. Methods

2.1. Pain Monitor app

Pain Monitor evaluated 34 pain-related variables in less than 5 minutes, twice a day (once in the morning and once in the afternoon, at configurable hours), for 30 days. Also, it

allows patients to record their acute pain episodes (they can access the app at any time in addition to pre-established hours), so that patient monitoring becomes personalized and occurs in real-time.

Pain Monitor was developed and tested in Spanish, but it has been translated into English using a back-translation approach. An independent bilingual researcher translated the content. Then, a back translation was obtained by a different bilingual researcher and this back-translated version was compared against the original version. Pain Monitor can be downloaded for free at the Google Play store(https://play.google.com/store/apps/details?id=painmonitor.srccode). The app is currently only available for Android (version 2.3 or higher) because this is the operating system used by more than 90% of smartphones in Spain[28] and 85% of users in Europe.[29]Before downloading it, a description is given, including the name and contact information of the principal investigator (A. G. P.), the purpose of the app, the study design, a declaration guaranteeing data confidentiality, and a summary of how the content of the app was created.

Content included in Pain Monitor was developed via consensus with a panel of pain experts from the Labpsitec group of the Jaume I University (2 psychologists) and the Pain Clinic of the Vall d'Hebron Hospital (5 physicians, 2 nurses, and a psychologist). First, assessed variables were selected following IMMPACT[26] and Rosser and Eccleston's[16] recommendations. These included pain intensity, use of rescue analgesics, side effects of the medication, interference of pain in functioning (sleep, work, leisure, and social interactions), fatigue, mood (happiness, depression, anxiety, and anger), perceived health status, and activity level, as well as psychological and behavioral factors that influence the pain experience (catastrophizing, acceptance, fear/avoidance of pain, and coping).

Moreover, demographic and general illness characteristics were included in the assessment protocol (i.e., pain duration and localization).

Next, app items were developed. Because of the characteristics of the study (daily assessment using a mobile phone) and the number of variables selected, only 1 item was included for each assessed variable. However, when a variable was multidimensional (i.e., pain catastrophizing), an item was included for each subscale (i.e., helplessness, magnification, and rumination).

For several variables (pain intensity and interference, perceived health status, catastrophizing, acceptance, and fear/avoidance of pain), items were adapted from well-established paper-and-pencil measures. These were the Brief Pain Inventory (BPI) for pain intensity and pain interference;[30] the Short Form 12 for perceived health status;[31] the Pain Catastrophizing Scale (PCS) for pain catastrophizing;[32] the Fear-Avoidance Beliefs Questionnaire (FABQ) for fear/avoidance pain caused by work and physical activities;[33] and the Chronic Pain Acceptance Questionnaire (CPAQ) for pain acceptance.[34]The item adaption procedure was as follows: first, shorter and most representative items (highest factor loadings as shown in previous research) were selected from the aforementioned scales. Thereafter, the expert pain panel discussed whether wording of selected items needed modification for readability reasons. Finally, item instructions and response options were homogenized to facilitate the use of the app. Specifically, 2 types of response scales were used in item development. When the original questionnaires used a numerical scale of 11 points, this response scale was maintained (i.e., pain intensity and interference). When traditional measures used a Likert-type response scale, the response scale in the app was converted to a 5-point Likert scale with labels "strongly disagree", "disagree", "neither agree nor disagree", "agree", and" totally agree". The instruction

before each item was changed to "please indicate your degree of agreement with the following statement".

Mood items (depression, anxiety, anger, and positive mood) were adapted from a previous app created by the authors.[7]The coping item included several response options, each representing a coping strategy based on scales in the Chronic Pain Coping Inventory-42(CPCI-42)[35] and the Coping Strategies Questionnaire (CSQ).[36] Finally, the remaining items (demographic characteristics, daily activity level, use of rescue medication, and adverse effects of the medication) were created *ad hoc*. The latter was created after reviewing the most frequent or alarming adverse effects of medication for pain, including analgesics, non-sterioidal anti-inflammatory drugs, antidepressants, antiepileptics, opioids, and steroids, and invasive techniques, such as blocks and implanted devices.[37–46] The list of items in Pain Monitor can be found in Appendix I. supplemental Digital Content 1 (http://links.lww.com/CJP/A506).

Once the app items were created, they were assigned to an assessment time (see Table 1), considering item content (i.e., interference of pain on sleep was assessed in the morning as all the participants in the study slept during the night, while interference of pain on daily work was administered in the evening as all participants worked during the day) and burden of assessment (i.e., more stable constructs, like in pain acceptance and fear of pain, were either administered in the morning or evening to make both administration times comparable). Pain intensity, fatigue, and mood were collected at all times because they can vary during the day. We compared morning-to-evening compliance rates because validity and reliability estimates of study outcomes might be affected by low compliance rates.

Once the content was developed, the app was designed following the Technological Acceptance Model criteria to optimize its usability and acceptance of use in patients' daily

lives,[47] as well as data protection premises established by Spanish laws.[48]From a graphical point of view, the interface was reduced to 3 question formats: check-list with single response option (i.e., sex and pain catastrophizing), check-list with multiple response options (i.e., current pain treatment/s and pain localization/s), and an 11-point visual analogue scale using a slider (i.e., pain intensity, fatigue, and activity level). Examples of app items are provided in Figure 1. From a confidentiality perspective, the application collects data anonymously. To link user responses with the anonymous answers, a user code is automatically generated when installing the app. This is displayed in the app menu and is only known by the user and the healthcare professional/researcher.

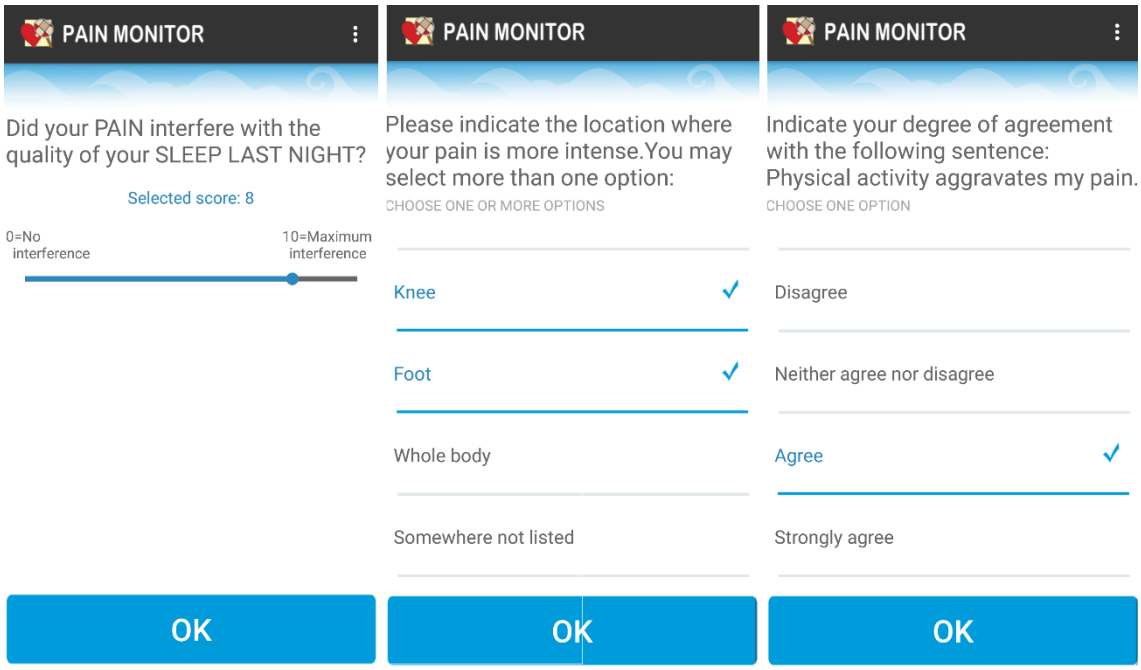

FIGURE 1. Examples of app items. The screens show a limited number of response options. In the app, there is a drop-down window to allow for multiple responses other than what is presented in the figure.

2.2. Procedures, sample, and measures

This is a repeated-measures, observational study. The study was approved by the Institutional Review Board at the Vall d'Hebron Hospital (approval number

PR(ATR)381/2015). We used a convenience sampling method for patient recruitment. Inclusion criteria were (1) having the first appointment at the Pain Clinic between January 2016 and June 2016; (2) having between 18 and 65 years of age; (3) experiencing chronic pain (> 6 months in duration) at the time of assessment; (4) understanding Spanish; and (5) having a mobile phone with internet connection that uses Android as the operating system. Older patients were excluded because, in Spain, the use of smartphones with internet connection is still infrequent in individuals aged over 65[49].

=n the basis of previous research, we expected a moderate correlation (0.48 to 0.68) between standard questionnaires and app content.[25]We calculated that, using a conservative correlation of 0.50 and an alpha of .05, 29 participants were needed to obtain 80% power when exploring construct validity of the app.[50]Because of the longitudinal nature of the investigation, we anticipated that some patients would withdraw from the study on the basis of previous research,[24] hence, we decided to increase the number of participants by 20% (*n*=38).

The study was conducted at the Pain Unit of Vall d'Hebron Hospital (Barcelona, Spain) from January 2016 to July 2017. First, patients whose first appointment at our Pain Clinic was scheduled for between February 2016 and July 2016 (inclusion criterion 1; *n*=57) were selected. Then, age was screened using the hospital clinical database (inclusion criterion 2). Phone calls were made to patients meeting the criterion of age to evaluate the remaining eligibility criteria. All patients had been experiencing pain for more than 6 months (inclusion criterion 2). However, 2 of them did not use Android as operating system (inclusion criterion 4) and 2 of them were not fluent in Spanish (inclusion criterion 3), hence, they were excluded from the study. Study goals and procedures were explained to the remaining 38 participants, who were cited for an assessment appointment at the

Pain Clinic approximately 1 week before their first medical consultation, to obtain a baseline measurement.

In this first assessment appointment before the medical consultation, all participants signed the informed consent. Next, they were asked to download the app on their smartphones and were then given a 5-minute demonstration by the lead researcher, C.S.R., which included answering to initial demographic and pain information. During the demonstration, patients were encouraged to ask questions about app content (i.e., meaning of words) and app use. The assessment with the app took about 5 minutes. To end this first assessment session, patients were asked to complete multiple well-established measures to determine the construct validity of the app. These included the BPI,[30] the Profile of Mood States (POMS),[51] the Hospital Anxiety and Depression Scale (HADS),[52] the Beck Depression Inventory-II (BDI-II),[53] the Short Form-12,[31] the Chronic Pain Acceptance Questionnaire,[34] the Fear Avoidance Beliefs Questionnaire,[33]the Pain Catastophizing Scale,[32] the CSQ,[36]the CPCI-42,[35] and the Roland Morris Disability Questionnaire (RMDQ).[54]The paper-and-pencil assessment took about one hour. All the questionnaires used in this study had been validated in Spanish.

During the study duration, participants were asked to respond to the app twice daily, in the morning and the evening. The app informed patients automatically when to respond (by default, at 11 AM. and 7 PM) using a push notification system, but patients could change the assessment times with a flexibility of 2 hours from given times. Furthermore, every week until the end of study (end of weeks 1, 2, and 3), a phone call was made to assess recalled pain intensity and interference (using the BPI) and mood and fatigue (using the POMS). After the first phone call, app usability and acceptability were evaluated by means of the System Usability Scale.[55]Exploring usability and acceptability in early use stages and before the end of the study is recommended as practice can mask

early usability problems and early assessment allows a prompt detection of problems.[56,57]The app interface was similar to a previous app created by our team that had obtained very good acceptability results[7] ; hence, no major issues were expected. Indeed, as reported in the results section, no usability problems were detected in Pain Monitor; therefore changes in the app were not required. Similarities between the current and the previous app include some interface features and the assessment of pain intensity, fatigue, and mood (yet, using different response scales and a single mood item). Also, the validity and reliability of these items were not tested.

At the end of the study (after 30 days of app use), a final appointment was set, and patients completed the same paper-and-pencil protocol described above for the baseline assessment. Both paper-and-pencil evaluations (baseline and follow-up) were completed in the clinic.

Data obtained with the app are stored on a secure server at the Jaume I University. To optimize security, the app and the data are stored on different servers with different domain names and connected locally only (the server containing the data does not have Internet access). The participants did not receive any compensation for their participation.

2.4. Data analysis

To evaluate the construct validity of the app, we explored correlations between (1) first-day paper-and-pencil and app assessments, (2) weekly average scores with the app and recalled ratings obtained by phone, and (3) last week average scores using the app and end-of-study assessment via paper-and-pencil. We conducted same-day and weekly average correlations to compare the validity of both types of ratings. Because recall bias is a frequent finding when comparing EMA and week recalls (e.g., overestimation of recalled pain and fatigue),[7,58]we calculated mean-differences between week average

scores using the app and recalled ratings obtained by phone by means of paired-samples *t* tests. Because mood items in the app and in the POMS have different response scales, scores will be standardized to have a mean of 0 and a standard deviation of 1 when exploring recall bias.

Paper-and-pencil scales were adapted to ensure the consistency of instructions in these assessments. Thus, patients were asked to report on their same-day experience in the baseline assessment, while they were encouraged to report on average past-week experience in the following measurements. The RMDQ was also adapted so that limitations in activities were not only related to back pain but to overall pain, regardless of its location (most patients reported pain on several localizations).

To investigate the reliability of the app, we examined correlations between average weekly scores in the app for all study period and hypothesized that they would be larger than 0.70.[21]

Feasibility was investigated via participants' evaluation of app usability and acceptability and compliance.

3. Results

3.1. Demographic and disease information

The 38 participants who met inclusion criteria for the study had between 21 and 59 years (mean age was 42.74 y, *SD* = 9.92). Males and females were similarly represented in the sample (52.6% females). Most participants were married (52.6%). The rest of them were either single (28.9%), divorced/separated (15.8%), or widowed (2.6%). Almost all patients were born in Spain (89.5%). Two of them were born in non-Spanish speaking countries (i.e., Moldavia and Morocco) but were fluent in Spanish. Two participants were born in Spanish-speaking countries other than Spain (Peru and Honduras). As regards

educational level, 39.4% of participants had > 12 years of education. With respect to job status, half of the participants were working at the time of assessment (50.0%). The rest of participants were either studying (5.3%), unemployed (15.8%), on sick leave (23.7%), or they had a permanent disability (5.3%). Three participants were in a legal process for a permanent disability. A large majority of participants claimed to have problems sleeping (76.3%) but most patients did not refer to have comorbidity of depression or anxiety (68.4%).

Duration of pain ranged from 1 year to 31 years (mean = 6.0 y, *SD* = 6.9 y, median = 2.5 y). Most frequent sites of pain were low back (71.1%) and neck (47.4%). A large percentage of patients with low back pain (85.2%) and neck pain (61.1%) presented radiculopathy. Pain characteristics and medication use are shown in Table 1.

Four patients had technical issues with the app between weeks 3 and 4 and stopped receiving app notifications. These problems could not be fixed due to their uncontrollability (smartphones were too old and could not receive operating system updates or had too little working memory).

3.2. Construct validity of app content and analysis of recall bias

Bivariate associations were calculated between app responses and scores obtained with traditional paper-and-pencil measures (Table 2). Overall pain interference was calculated as an average of all pain interference items (4 in the app and 7 in the BPI), as recommended in previous research.[59]Pearson correlations ranged from moderate (between 0.3 and 0.5) and strong (>0.5) for all variables, except for same-day activity level and RMDQ ratings. Post hoc power calculations considering sample size and observed correlations were satisfactory for most correlations (>80%), except for several coping items (inactivity, talk to someone, distract, and self-statements) and a few

correlations using one app item instead of weekly averages (i.e., activity level, magnification, fear of exercise).

In addition to Pearson correlations, we performed paired-samples *t* tests between aggregated app scores and the weekly averages obtained by phone (weeks 1 to 3) or by paper-and-pencil in the clinic (week 4). Differences were only revealed for pain interference at week 1 (M_{app} = 4.54, *SD* = 2.05, M_{phone} = 5.46, *SD* = 2.23, *t* = -3.79, *p* <.001), week 2 (M_{app} = 4.27, *SD* = 2.04, M_{phone} = 5.04, *SD* = 2.35, *t* = -2.79, *p* < .001), and week 4 (M_{app} = 4.41, *SD* = 2.01, M_{clinic} = 5.23, *SD* = 2.36, *t* = -2.59, *p* < .001). No recall bias was found for pain intensity and mood.

3.3. Reliability of app ratings

Weekly averages were calculated for all app items and intercorrelations were conducted (Table 3). Strong correlations were found for almost all constructs at all assessment times. Post hoc power calculations were satisfactory (>80%) for almost all correlations, with the only exception of relaxation during the second and the third week.

3.4. Feasibility of the app

In the present study, feasibility of the app was explored by means of compliance, usability, and acceptability.

3.4.1. Compliance

Compliance was calculated by dividing the number of completed assessments (whole sample, *n* = 38) by the number of possible assessments (30 dx 2 times a dayx38 patients = 2280 possible assessments). Overall compliance with app assessments was 75.7%. Compliance by week was 81.8%, 80.8%, 70.6%, and 71.3% for weeks 1, 2, 3, and 4,

respectively. Compliance was 75.4% in the morning and 75.7% in the evening. Differences in compliance between weeks and between times of day were not significant.

3.4.2. Usability and acceptability

Usability and acceptability were assessed in early stages (after 1 wk of use), before this would be masked by practice. Overall, no problems of usability were observed. As revealed by the System Usability Scale, all participants (100%) found the app extremely easy to use. Most of them (92.7%) found it extremely useful and the remaining participants indicated that they found it somewhat useful. A minority of patients (12.9%) experienced some burden due to daily use of the app. We further explored this finding and all patients experiencing some burden (*n*=5) reported difficulties in using the app in the morning, either because answering to the app at work was difficult or because they had limited time to do it before going to work.

As exposed earlier, patients were also encouraged to ask questions about app content (i.e., meaning of words) and app use during the 5-minute demonstration by the lead researcher. Patients did not report difficulties understanding medical terms used in the app (i.e., pharmacotherapy, infiltrations, tachycardia, gait instability).

3.5. Usefulness of the app

3.5.1. Physical symptoms (side effects of the medication)

Over the study period, 1874 physical symptoms were reported with the app. Most frequent symptoms were headache (median=20 d), urine retention (median=15.5 d), dry mouth (median=5 d), gait instability (median=2.3 d), and fever (median=1.5 d). The remaining symptoms were either so infrequent that median was 0 or they were never reported (i.e., facial redness and another symptom).

In general, symptoms were either tolerated or not attributed to pain medication (i.e., patients continued to use their medication), despite some patients reported long-term symptomatology (i.e., 3 patients experienced tachycardia for two wk, 3 patients reported feeling sedated for approximately 3 wk, and 3 patients indicated that they had experienced itch during >1 one wk, among others). However, 1 case of low treatment tolerance was detected with the app. A 45-year old female with neck pain started to feel sedated 4 days after the onset of an analgesic medication. After 1 week of experiencing this symptom, she decided to stop using the medication, as reported in the app.

As seen in Appendix I, Supplemental Digital Content 1 (http://links.lww.com/CJP/A506), patients could also select "A different symptom" option, which was created to detect the occurrence of side effects that were not included in the list. None of the patients selected this option.

3.5.2. Use of rescue medication

Daily use of rescue medication, that is, medication that is recommended in the presence of an exacerbation of pain, was assessed. The median of rescue medication use ranged from 1.3 (week 3) to 2 days per week (week 4). During weeks 1 and 2, the median use of rescue medication was 1.75 days per week. Indeed, weekly bivariate associations revealed that the use of rescue medication was more frequent when pain was more intense (week 1: r = .41, p = .012, n =37; week 2: r = .48, p = .003, n =37; week 3: r = .55, p = .001, n =32; week 4: r = .43, p = .012, n =33).

4. Discussion

This study aimed at exploring the validity, reliability, usefulness, and feasibility of a multidimensional smartphone app for daily monitoring of adults with chronic pain.

Evidence of construct validity was supported by moderate-to-strong correlations with well-established, paper-and-pencil measures, both when assessed during the same day and when using weekly averages. Also, morning and evening assessment with Pain Monitor was feasible, showing high adherence and acceptability.

Although large number of pain apps surely exist, a number of recent reviews have pointed to the lack of health care professional involvement, content validity, and reference to psychological components of pain as critical problems of existing pain apps.[15–20]A number of studies have addressed some of the aforementioned shortcomings in children and adolescents[21–23]and adults with pain.[24,25]However, a comprehensive study including validity, reliability, feasibility, and usability has been rare.[16] Besides, key psychological constructs and other pain-related outcomes recommended in existent clinical guidelines have been generally ignored, with some exceptions.[24,25]

Following existent recommendations on the development of pain apps, Pain Monitor was developed by a multidimensional team of healthcare professionals through a series of meetings following existent guidelines for pain measurement.[26] Key psychological constructs involved in the experience of pain, such as fear of pain, pain catastrophizing, pain acceptance and willingness, and coping, were also measured in the app. Construct validity was supported for all assessed variables, including the aforementioned psychological constructs, as well as pain intensity and interference, mood (depression, anxiety, anger, and happiness), perceived health status, and general activity level.

An important finding in the present study was that important pain-related constructs (i.e., pain intensity and interference, mood, pain catastrophizing, fear of pain, pain acceptance and willingness, and coping) can be evaluated via app with a reduced number of items, while acknowledging information loss. Specifically, with 20 items in the app assessed once, Pain Monitor explained approximately 35% of the variance of 237 paper-and-pencil

items from 11 well-established scales. This has important implications in times where ecological moment assessment are being advocated.[1,60,61]Thus, the present study evidenced that shorter assessment protocols can be created within an app context if, as in Pain Monitor, items are developed thoughtfully and validated against well-established measures.

Validity of Pain Monitor was supported for all assessed constructs, though not to the same extent. For example, bivariate associations between app and paper-and-pencil reports on average pain intensity and interference were strong (r> .50), in line with previous research.[62]Strong evidence for construct validity was also revealed for fatigue, mood (happiness, sadness, anxiety, and anger), perceived health status, fear of pain, pain catastrophizing, and pain acceptance and willingness. It is important to note that some of these variables did better when assessed weekly (i.e., magnification, fear of exercise, perceived health status, and activity level), which justifies the need for repeated assessment. Coping items showed the poorest evidence for construct validity (between moderate and strong, depending on the coping strategy). This result may not be surprising considering the difference in format between the app item (several strategies are presented in one item only) and the CPCI and the CSQ (each scale consists of several items).

In addition to construct validity, we evaluated recall bias based on previous research showing that pain and fatigue tend to be overestimated when recalled.[7,58]Consistent with these results, recalled pain interference in the present study was also overestimated when compared with EMA using an app. Contrary to past findings, this recall bias was not observed for pain intensity and fatigue. No bias was observed for mood either. At this stage, interpretation of these findings should be taken with caution as there are significant methodological differences between the present and previous studies which might have influenced the discrepancy in the findings. These include the devices used for momentary

assessment, the number of daily measurements, the time of evaluation, and the method used to obtain the weekly recalls, among others.[7,58]In addition, there are important differences in the items used in the app and during phone and on-site assessment which might have influenced the results (i.e., fatigue and mood in the app were measured using an 11-point numerical response scale and a single item each, while the POMS uses a 5-point categorical response scale and 5 items). These methodological issues should be addressed with before further conclusions can be drawn.

Pain Monitor also assessed physical symptoms and use of rescue medication on a daily basis. Our results revealed that, despite physical symptoms were frequent, these were generally well tolerated or not associated with the use of pain medication. However, the study supports the need to monitor symptoms daily as some patients (one in the present investigation) might experience a threat to safety and discontinue the medication. With regards to the use of rescue medication, an association was found with pain intensity ratings. In the light of these findings, daily assessment of rescue medication might help guide interventions in chronic pain (i.e., change regular treatment for pain when the use of rescue medication does not decrease with time).

The present study certainly has some limitations. Our results were tested in young and middle-aged adults with heterogeneous pain, so the applicability of findings to individuals aged over 65 and specific pain populations would need further research. Furthermore, the statistical power in the validation of coping strategies was low. Whether this is because of construct validity problems or insufficient sample size is unclear, hence, the use of items strategies as reported with the app should be interpreted with caution before a large sample size is collected. Another important limitation is that the app is currently only available for Android operating system. Despite this was not problematic for the purpose of the present study due to the reduced number of iPhone users in Spain, a next step will

be to adapt the app for iPhone operating system. It is also important to note that, despite Pain Monitor is a quite comprehensive app, there are surely important pain-related constructs that are not represented in the app. For example, neuropathic characteristics of pain and overall satisfaction with treatment were not included in the validated version of the app and have only been added recently after a discussion of study findings, so their validity stills needs to be tested. Moreover, all data in the present study was self-report. We are now working in the measurement of objective measures, such as number of steps for physical activity. Last but not least, this study did not report on the specificity and sensitivity of single app items to assess constructs originally assessed with multiple items. This is important to determine cut-offs that are clinically relevant when using the app, but requires a previous effort to establish robust cut-offs for all assessed constructs.

Despite the previous shortcomings, the present investigation has important strengths and clinical implications. Pain Monitor was developed by a multidimensional team specialized in the management of chronic pain. It is one of the most comprehensive multidimensional pain apps, as it evaluates the constructs recommended by IMMPACT guidelines,[26] together with key psychological variables in chronic pain. Also, the app is available in Spanish and English, which might be important in contexts where both languages coexist (i.e., United States). Note, though, that content has only been validated in Spanish, hence, validity and reliability testing should also be replicated for the English version. Another important feature of Pain Monitor is that it overcame the problem of participant non-compliance from paper diaries[8,9] and obtained excellent usability and acceptability results. Similar to other studies using apps,[24,63] compliance in the present investigation dropped off over time. Several factors have been argued to influence compliance, including the difficulty of the program, the burden of assessment, perceived utility of daily monitoring. In our study, the app was found easy to use and burden was

generally low. While this could explain why compliance in the present study was high, it should be pointed out that the participants were called once a week, which likely improved compliance.

With regards to app utility, we believe that important improvements can be made to suggest to the user that daily monitoring can help improve their care. In fact, a new feature has now been added to the app so that clinicians can receive an alarm in the presence of pre-established undesired events. We expect that the use of these alarms will improve the perceived utility of the app and, therefore, compliance rates. By contrast, the use of alarms can also increase the burden of clinicians and raise a number of legal concerns, for instance, if there was a delayed response in the presence of a crisis. To minimize these problems, alarms have been negotiated with the clinicians to ensure that they are clinically-relevant. In addition, patients will be reminded by the clinician and when installing the app that alarms are used at the discretion of the clinicians, so that they should perform as usual (i.e., go to the emergency services) in the presence of a serious undesired event.

Some possible clinical applications for the app are proposed. Pain Monitor might serve guide interventions, for instance, in the presence of undesired adverse effects of the medication, nonresponse to treatment, poor adherence to treatment, or excessive use of rescue medication. As argued in previous research, telemonitoring using apps is likely to be a solution to long-distance travel or regular clinic visits in the management of pain.[64–66]The inclusion of alarms is a step forward in this direction. Together with telemonitoring, ecological momentary intervention is another interesting feature that can be implemented in apps.[67–69] For instance, Jamison and his team implemented a 2-way messaging strategy in their self-management app for pain.[25] Further research is needed to reveal the contributions of using apps for the management of chronic pain.

The app has been patented and is owned by three public institutions (corresponding to the host institutions of the authors at the time of app development, that is, the Jaume I University, the University of Barcelona, and the Carlos III Research Institute). With regards to commercial use, the app has research purposes at the moment. However, contracts to use the app can be signed with private or public entities (for further information, contact the lead author, CSR).

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TABLE 1. Chronic Pain Characteristics of Study Participants

		inning of Study (n=38)			End of Study (n=35)	
	n (%)	M (SD)	Median	n (%)	M (SD)	Median
Average pain intensity	—	5.7 (2.1)	6.0	—	5.2 (2.5)	5.0
Medication used	—	1.5 (1.3)	1.0	—	1.6 (1.3)	1.0
Analgesics	12 (31.6)	—	—	16 (45.7)	—	—
NSAIDs	12 (31.6)	—	—	8 (22.9)	—	—
Anticonvulsants	12 (31.6)	—	—	11 (31.4)	—	—
Muscle relaxants	4 (10.5)	—	——	2 (5.7)	—	—
Antidepressants	2 (5.3)	—	—	5 (14.3)	—	—
Opioids	10 (26.3)	—	—	12 (34.3)	—	—
Steroid injections	0	—	—	3 (8.6)	—	—
No medication	8 (21.1)	—	—	5 (14.3)	—	—

NSAID indicates nonsteroidal anti-inflammatory drugs.

TABLE 2. Correlations Between Assessments With the App and Traditional Scales at Different Times

App Items	Traditional Scale	1st Day	1st Week	2nd Week	3rd Week	4th Week
Morning and evening		n=37	n=37	n=37	n=35	n=33
Current pain intensity	BPI (current pain intensity)	0.71***	0.73***	0.76***	0.68***	0.78***
	BPI (average pain intensity)	0.64***	0.81***	0.76***	0.72***	0.76***
Pain interference	BPI (average interference)	0.67***	0.77***	0.72***	0.60***	0.67***
Fatigue	POMS (fatigue)	0.66***	0.73***	0.79***	0.60***	0.55***
Happiness	POMS (vigor)	0.51**	0.56***	0.43**	0.46**	0.45**
	POMS (depressed mood)	−0.39*	−0.56***	−0.41*	−0.45**	−0.51**
	HADS (depressed mood)	−0.49**	—	—	—	−0.58***
	BDI (depressed mood)	−0.46**	—	—	—	−0.50**
Sadness	POMS (depressed mood)	0.65***	0.53***	0.72***	0.57***	0.60***
	HADS (depressed mood)	0.63***	—	—	—	0.47**
	BDI (depressed mood)	0.56***	—	—	—	0.40*
Anxiety	POMS (anxiety)	0.78***	0.74***	0.62***	0.48**	0.67***
	HADS (anxiety)	0.69***	—	—	—	0.62***
Anger	POMS (anger)	0.68***	0.55***	0.68***	0.54***	0.70***
Morning		n=33				n=32
General health	SF-12 (general health)	0.48**	—	—	—	0.70***
Fear of work	FABQ (fear of work)	0.55***	—	—	—	0.66***
Fear of physical exercise	FABQ (fear of exercise)	0.41*	—	—	—	0.73***
Acceptance	CPAQ (acceptance)	0.55***	—	—	—	0.46**
Willingness	CPAQ (willingness)	0.50**	—	—	—	0.47**
Helplessness	PCS (helplessness)	0.83***	—	—	—	0.79***
	CSQ (catastrophizing)	0.83***	—	—	—	0.77***
Evening		n=36				n=33
Rumination	PCS (rumination)	0.55***	—	—	—	0.73***
Magnification	PCS (magnification)	0.40*	—	—	—	0.64***
Inactivity	CPCI (persist)	NA	—	—	—	−0.44*
Relaxation	CPCI (relax)	NA	—	—	—	0.51**
Talk to someone	CPCI (social support)	NA	—	—	—	0.38*
Physical activity	CPCI (exercise)	NA	—	—	—	0.50**
Distraction & positive emotions	CSQ (cognitive distraction)	NA	—	—	—	0.32γ
Self-statements	CSQ (self-statements)	NA	—	—	—	0.37*
Ignore	CSQ (ignore)	NA	—	—	—	0.48**
Pray	CSQ (pray)	NA	—	—	—	0.47**
Activity level	RMDQ	−0.09	—	—	—	0.48**

App ratings correspond to weekly averages except for first day correlations, where 1-day responses were used. Because of the characteristics of the coping item in the app (8 strategies are available, but their use may vary across days), validity using same-day correlations could not be performed (some strategies were not selected during the first day of assessment). BDI-II indicates Beck Depression Inventory-II; BPI, Brief Pain Inventory; CPAQ, Chronic Pain Acceptance Questionnaire; CPCI-42, Chronic Pain Coping Inventory-42; CSQ, Coping Strategies Questionnaire; FABQ, Fear Avoidance Beliefs Questionnaire; HADS, Hospital Anxiety and Depression Scale; NA, not available; PCS, Pain Catastrophizing Scale; POMS, Profile of Mood States; RMDQ, Roland Morris Disability Questionnaire; SF-12, Short Form 12. *P<0.05. **P <0.01. ***P <0.001. γP =0.06.

TABLE 3. Reliability of Assessments With the App

	Weeks 1-2	Weeks 2-3	Weeks 3-4
Morning and evening	n=38	n=36	n=33
Current pain intensity	0.84	0.84	0.91
Pain interference	0.74	0.87	0.91
Fatigue	0.83	0.87	0.94
Happiness	0.84	0.78	0.89
Sadness	0.83	0.86	0.85
Anxiety	0.84	0.91	0.90
Anger	0.84	0.89	0.84
Morning	n=38	n=33	n=30
General health	0.72	0.87	0.97
Fear of work	0.83	0.84	0.91
Helplessness	0.85	0.89	0.96
Willingness	0.90	0.95	0.92
Fear of physical exercise	0.80	0.84	0.86
Acceptance	0.76	0.95	0.99
Evening	n=37	n=33	n=32
Magnification	0.83	0.83	0.92
Rumination	0.69	0.68	0.94
Inactivity/rest	0.75	0.85	0.86
Relaxation	0.65	0.38*	0.86
Talk to someone	0.80	0.85	0.50**
Physical activity/stretch	0.47**	0.85	0.73
Positive emotions	0.58	0.47**	0.89
Self-statements	0.95	0.87	0.94
Ignore/distract	0.70	0.85	0.83
Pray	NA	NA	NA
Activity level	0.77	0.83	0.92

The reliability of Pray could not be performed because of its low frequency across weeks.
NA indicates not available.
In all cases, P<0.001, except for *P<0.05 and **P<0.01.

Appendix I. Items in the Pain Monitor app

Items assessed once, the first day of app use:

1. Please indicate your date of birth (DD/MM/YYYY)

2. What type of user are you?
    a. I am a person with chronic pain
    b. I do not have chronic pain, but I want to see the app

3. Please indicate your gender:
    a. Male
    b. Female

4. Please indicate your type of pain. You may select more than one option:
    a. Fibromyalgia
    b. Low back pain
    c. Cervical pain
    d. Rheumatoid arthritis
    e. Osteoarthritis; Headache
    f. Neuropathic pain
    g. Cancer pain
    h. None of the above.

5. If you selected "None of the above" please indicate your type of pain. Otherwise, leave this question blank. Press OK to continue.

6. Please indicate the location where your pain is more intense:
    a. Head
    b. Shoulder
    c. Neck
    d. High back
    e. Lower back
    f. Arm
    g. Elbow
    h. Wrist
    i. Hand
    j. Abdomen
    k. Chest
    l. Buttock
    m. Hip
    n. Leg
    o. Knee
    p. Foot
    q. Whole body
    r. Somewhere not listed

7. Who is currently treating your pain? You may select more than one option:
    a. General practitioner
    b. Rheumatologist

c. Orthopedic specialist
d. Rehabilitation physician
e. Psychiatrist
f. Pain Unit
g. Neurosurgeon
h. Neurologist
i. Oncologist
j. Another professional.

8. When did your current pain start?
    a. Less than one year ago
    b. Between 1 and 5 years ago
    c. Between 5 and 10 years ago
    d. More than 10 years ago

9. What is your current treatment for pain? You may select more than one option:
    a. Physiotherapy
    b. Pharmacotherapy
    c. Infiltrations
    d. Psychological treatment
    e. Natural / alternative treatments
    f. My pain is not being treated

10. Did you start a new treatment for pain in the last month?
    a. Yes
    b. No

11. Please select the treatment/s you started in the last month. You may select more than one option:
    a. Physiotherapy
    b. Pharmacotherapy
    c. Infiltrations
    d. Psychological treatment
    e. Natural / alternative treatments
    f. I have not started a new treatment

12. What is your marital status?
    a. Single
    b. Married
    c. In a relationship
    d. Divorced
    e. Separated
    f. Widowed

13. What is your job status?
    a. Active worker
    b. Sick leave
    c. Permanent disability
    d. Unemployed
    e. Homemaker

f. Retired
g. Student

14. What is the highest level of education you have completed?
    a. No studies
    b. Less than high school
    c. High school graduate
    d. Technical training
    e. University degree

15. Do you currently have a diagnosis of depression by a physician or a psychologist?
    a. Yes
    b. No

16. Do you currently have a diagnosis of anxiety by a physician or a psychologist?
    a. Yes
    b. No

Items assessed twice a day and in the event of acute pain episodes

17. Please indicate the intensity of your CURRENT PAIN:
    0 No pain ---------10 Extreme pain

18. Please indicate the intensity of your CURRENT FATIGUE:
    0 No fatigue ---------10 Extreme fatigue

19. Please indicate the intensity of your CURRENT HAPPINESS:
    0 No happiness -------10 Extremely happy

20. Please indicate the intensity of your CURRENT SADNESS:
    0 No sadness -------- 10 Extremely sad

21. Please indicate the intensity of your CURRENT ANXIETY:
    0 No anxiety ------- 10 Extremely anxious

22. Please indicate the intensity of your CURRENT ANGER:
    0 No anger ------- 10 Extremely angry

Items assessed in the morning

23. In general, your HEALTH is:
    1) Very poor
    2) Poor

3) Average
4) Good
5) Very good

24. Did your PAIN interfere with the quality of your SLEEP LAST NIGHT?
    0 No interference ------- 10 Maximum interference

25. Indicate your degree of agreement with the following sentence: With my current pain, I should not do my usual job (it includes housework and work outside the home).
    1) Strongly disagree
    2) Disagree
    3) Neither agree nor disagree
    4) Agree
    5) Strongly agree

26. Indicate your degree of agreement with the following sentence: Experiencing pain is terrible and I feel that pain is stronger than me.
    1) Strongly disagree
    2) Disagree
    3) Neither agree nor disagree
    4) Agree
    5) Strongly agree

27. Indicate your degree of agreement with the following sentence: I need some control over pain before I can make serious plans.
    1) Strongly disagree
    2) Disagree
    3) Neither agree nor disagree
    4) Agree
    5) Strongly agree

28. Indicate your degree of agreement with the following sentence: Physical activity aggravates my pain.
    1) Strongly disagree
    2) Disagree
    3) Neither agree nor disagree
    4) Agree
    5) Strongly agree

29. Indicate your degree of agreement with the following sentence: I am living a rewarding life despite my pain.
    1) Strongly disagree
    2) Disagree

3) Neither agree nor disagree
4) Agree
5) Strongly agree

Items assessed in the evening

30. Did your PAIN interfere with your ability to perform your USUAL WORK or HOUSEWORK TODAY?
    0 No interference ------- 10 Maximum interference

31. Did your PAIN interfere with your LEISURE ACTIVITIES TODAY?
    0 No interference ------- 10 Maximum interference

32. Did your PAIN interfere with your SOCIAL INTERACTIONS TODAY?
    0 No interference ------- 10 Maximum interference

33. Which STRATEGY did you use to COPE WITH YOUR PAIN TODAY? You may select more than one option:
    a. Inactivity / rest
    b. Relaxation exercise
    c. Speak with someone
    d. Physical Activity / Stretching
    e. Self-statements to persist in a task
    f. Do something to feel positive emotions
    g. Ignore the pain/distract
    h. Pray for the pain to disappear

34. Indicate your degree of agreement with the following sentence: I fear that the pain will get worse.
    1) Strongly disagree
    2) Disagree
    3) Neither agree nor disagree
    4) Agree
    5) Strongly agree

35. Indicate your degree of agreement with the following sentence: Today I could not keep my pain out of my mind.
    1) Strongly disagree
    2) Disagree
    3) Neither agree nor disagree
    4) Agree
    5) Strongly agree

36. Please rate your degree of activity TODAY:
    0%= Completely inactive -100%= Completely active.

37. In which area have you been more active today? You may select more than one option:
    a. Work
    b. Family
    c. Couple
    d. Friends
    e. Leisure
    f. Physical activity
    g. Other.

38. Did you take a rescue medication TODAY (i.e., medication you only use in the event of acute pain)?
    a. Yes
    b. No

39. Did you experience any of these symptoms TODAY? You may select more than one option:
    a. Nausea
    b. Vomiting
    c. Tachycardia
    d. Constipation
    e. Drowsiness / sedation
    f. Blurred vision
    g. Dry mouth
    h. Headache
    i. None of the above

40. Did you experience any of these symptoms TODAY? You may select more than one option:
    a. Dizziness
    b. Itching
    c. Diarrhea
    d. Gait instability
    e. Excessive sweating
    f. Fever
    g. Urine retention
    h. Facial redness
    i. A different symptom
    j. None of the above

41. Did you take your prescribed medication TODAY?
    a. Yes
    b. No, but I will do it later

c. No and I do not plan to take it
d. I haven't been prescribed a pain medication

42. With respect to the beginning of treatment, how are you feeling NOW?
    1) Much worse
    2) Somewhat worse
    3) The same
    4) Somewhat better
    5) Much better

Items included in the updated version of Pain Monitor (not assessed in the present study)

43. Does your pain have any of these characteristics? You may select more than one option:
    a. Burning
    b. Painful cold
    c. Electric shocks
    d. Tingling
    e. Pins and needles
    f. Numbness
    g. Itching
    h. Reduced sensitivity to touch
    i. Pain when brushing against the skin
    j. None of the above

44. Have you experienced any negative life event in the PAST MONTH?
    a. No
    b. Yes, but it did not affect me at all
    c. Yes, but it did not affect me much
    d. Yes and it had quite an effect on me 5) Yes and it affected me a lot

45. If you experienced a major negative life event in the last month, please indicate its characteristics using the list below. You may select more than one option:
    a. Death of a close person
    b. Job problem
    c. Relationship problem
    d. Economic problem
    e. Health problem
    f. Family problem
    g. An event not listed above
    h. I have not experienced any major negative event this month.

46. In the past 30 days, how many days were you unable to perform your normal job due to your pain? Job includes housework or work outside the home.
    0 ------- 5------- 10 ------- 15 ------- 20 ------- 25 ------- 30

47. How many times did you take a rescue medication TODAY?
    a. 0
    b. 1
    c. 2
    d. 3
    e. 4
    f. 5
    g. 6
    h. 7
    i. 8
    j. 9
    k. 10
    l. More than 10