Original Paper

Jaime Boceta¹, MD; Daniel Samper², MD; Alejandro De la Torre³, MD; Rainel Sánchez-de la Rosa⁴, MD, PhD; Gloria González⁵, MSc

Usability, acceptability and usefulness of a real-time mobile health app to assist in the diagnosis and monitoring of patients with breakthrough cancer pain

Affiliations and addresses of the authors

¹ Unidad de Hospitalización Domiciliaria y Cuidados Paliativos, Servicio de Medicina Interna, Hospital Universitario Virgen de la Macarena, Sevilla; ² Servicio de Anestesiología, Clínica del Dolor, Hospital Germans Trias i Pujol, Barcelona; ³ Servicio de Oncología Radioterápica, Hospital Universitario Puerta del Hierro, Madrid; ⁴ Teva Pharmaceutical, Medical Department; ⁵ Adelphi Spain

ORCID

¹ 0000-0003-4408-4376
² 0000-0001-7013-3712
³ 0000-0002-3277-7207
⁴ 0000-0002-7134-1203
⁵ 0000-0002-3670-0311

E-mail address, telephone and fax number of the corresponding author

Dr. Jaime Boceta Osuna

Unidad del Dolor

Hospital Universitario Virgen de la Macarena

Avd. Doctor Fedriani, 3

41071 Sevilla

T: 955 00 80 00

E-Mail: bocetajaime@gmail.com
Usability, acceptability and usefulness of a real-time mobile health app to assist in the diagnosis and monitoring of patients with breakthrough cancer pain

Abstract

Background: Breakthrough pain is a major problem and a source of high distress in patients with cancer. We hypothesized that healthcare professionals may benefit from a real-time mobile application to assist in the diagnosis and monitoring of breakthrough cancer pain (BTcP).

Objective: This study aimed to test the usability, acceptability and usefulness in real world practice of the mobile App INES·DIO developed for the management of patients with BTcP.

Methods: The study consisted of a survey research among a multidisciplinary sample of 175 physicians who evaluated the mobile App after testing it with 4 patients with BTcP each (total of 700 patients). Digital profile of the physicians, use of the different resources contained in the app, usefulness of the resources, usability, potential improvements, intention to use, and additional resources to add were recorded.

Results: 96% of physicians were working in public hospitals. They had an average of 12 (SD: 7) years of experience in BTcP and almost all (99.43%) had an active digital profile. The functional scales ECOG and Karnofsky, the Visual Analogue Scale (VAS) and Davis algorithm to diagnose BTcP were the most frequent used tools with patient’s sample and were assessed as very useful by more than 80% of the physicians. 90% answered that App INES·DIO was well designed and 94% would probably or very probably recommended it to other colleagues. 68% indicated that the report provided by the app was worth to be included into the patient’s clinical records. Most valued resource in the app was the recording of the number, duration and intensity of flares/day and baseline pain control to enhance diagnosis of BTcP. Additional patient-oriented cancer pain-educational contents were suggested to be implemented in future versions of App INES·DIO.

Conclusions: App INES·DIO is easy to use and useful for physicians to assist in the diagnosis and monitoring of breakthrough pain in patients with cancer. Participants suggested the implementation of new education material about breakthrough pain. They
agreed on the importance of adding new clinical guidelines/protocols for the management of BTcP, improving their communication skills with the patient, and introducing an evidence-based medicine video platform which gathers new education material on BTcP.

**Keywords**: breakthrough cancer pain; mHealth; mobile app; App INES-DIO.
**Introduction**

Pain is one of the most prevalent health-related concern and is one of the commonest clinical conditions for seeking medical help [1]. In cancer patients, pain is a frequent and distressing symptom, which occurs in up to 40% of patients in the early stages of the disease and rises up to 70–90% in its most advanced stages [2-4]. Despite adequately controlled background pain, many patients experience transient exacerbations of severe pain, known as breakthrough cancer pain (BTcP), a complex pain state that negatively impacts on patients’ quality of life and provokes intense suffering. Indeed, BTcP episodes are associated with increased levels of depression and emotional disorders, interfering with other features of the disease, and result in higher health care expenditures both for patients and society [5, 6].

With the aim of improving the BTcP management, the Spanish Society of Medical Oncology (SEOM) published, in 2013, a consensus recommendations for the diagnosis and treatment of BTcP and launched a program for the diffusion and implementation of these recommendations [7]. However, even today there is no unanimous consensus among specialists on the clinical features to define BTcP.

Factors enclosed in the definition of BTcP as well as the procedures for its diagnosis, assessment and monitoring may influence the choice of a treatment and, consequently, the patient outcomes. Hence, the importance of obtaining a consensus on these issues from a broad group of experts in cancer pain.

Recently, Boceta et al. published the results of a two-round Spanish multicenter exploratory Delphi study which investigated the opinion of an expert panel in cancer pain to conclude how to define, diagnose, assess, treat and monitor BTcP [8]. This study was intended to seek consensus in the definition of BTcP and identify the controversies regarding a set of recommendations for the complete management of BTcP in clinical practice. Regarding the clinical features to diagnose BTcP, it was generally agreed that background pain should be controlled, but not necessarily with opioids; there must be exacerbations (no matter whether the number of flares per day are ≥4 or not); the duration of an episode should be ≤ 1 hour; the intensity of pain greater than 7 out of 10; and it is not considered the same as an end-of-dose effect. Davies algorithm should be
used for the diagnosis of BTcP. All these recommendations should be followed along the
day-to-day clinical practice to enhance the management and control of BTcP patients.

The results of the previously mentioned Delphi study were used for the development of
a real-time mobile health (mHealth) cancer pain-related app named App INES·DIO (by
its abbreviation in Spanish, Instrument for the Assessment and Monitoring the
Breakthrough Cancer Pain).

Internet-based and mHealth apps are transforming how people monitor, manage, and
communicate health-related information [9]. mHealth is the practice in, and support of,
public health interests, which is reinforced and sustained by mobile devices [10,11].
Mobile applications (apps) to improve health are proliferating, but before healthcare
providers or healthcare organizations can recommend an app, strategies for evaluating
them will be necessary. More primary research is needed to identify apps that are
effective, provide accurate information, and are user-friendly [12].

**The App INES·DIO**

App INES·DIO was technically developed by an international information technology
expert company (Virtualware, Madrid, UK, Mexico) which was licensed by the Spanish
Agency of Medicinal Products and Medical Devices (AEMPS, by its abbreviation in
Spanish) in 2014 for the manufacturing of medical products. Likewise, the contents of
App INES·DIO as well as the test phase of the application were responsibility of
Adelphi Spain. Of note, the usability testing will be removed from the mHealth app as
this phase is completed, and the name of the app, when commercially launched, will be
different.

With the rise of smartphone usage in the medical space, in 2013, the FDA issued to
regulate mobile medical applications and protect users from their unintended use, soon
followed by European and other regulatory agencies [13]. App INES·DIO is certified as
a CE-mark Class-1 medical device used to produce and/or change data of an individual
cancer patient with the aim of a better management and control of the irruptive pain.

It has been reported that native apps are better accepted by end users than Web pages
and provide better support for customization to device characteristics [14,15]. The idea
was then creating a mobile application able to run in as a native app on various mobile
platforms and operating systems (such as Android, iOS). App INES·DIO contents
gathered the most significant results of a Spanish Delphi study about the consensus and controversies in the definition, assessment, treatment and monitoring of BTcP [8]. This application allows the physician to generate an individual patient register to be finally included (via email) in the clinical history.

The app development process was conducted following three steps: 1) enter a new register (use the app with a new patient) with a complete information of the breakthrough pain; 2) a new report will be created with all input data of the cancer patient; and 3) complete an assessment test related to the usability of the app (Figure 1). This last step will be no longer available upon the completion of this study and therefore not present in the future version of the App INES·DIO. This mHealth app was performed in Spanish language.

In detail, when initiating the app, user is requested to open a new registry of each patient to go through four sequential items (Figs. 1a, b). The workflow of a new register was summarized in Figure 2. Briefly, after reading two different definitions of BTcP (Davies et al. [6] and Escobar et al. [17]; Fig. 1c), some more information related to the Davies diagnosis algorithm of BTcP (frequency and control of baseline pain, and the occurrence of transient pain episodes) is introduced (Fig. 1d). Davies et al. [6] defined BTcP as a transitory exacerbation of pain that occurs, either spontaneously or associated with predictable factors or not, even though the baseline pain is relatively stable and well controlled. In line with Davies’ definition, Escobar et al. [17] adopted the term “breakthrough pain” to describe a sudden and transient exacerbation of pain of high intensity and short duration (< 20–30 min), which appears over the baseline of a stable persistent pain, when this has been reduced to a tolerable level by the fundamental use of strong opioids. In somehow, both definitions allow us to distinguish BTcP from end-dose pain flares and those flares that occurred during the drug analgesics titration of the background pain.

The clinician will be then asked to fill other considerations for a better diagnosis of BTcP (Figs. 1e and 2). As long as this last item is completed, the app will immediately remote clinicians to assess each patient’s baseline pain (Fig. 1f). Consequently, they are asked to evaluate the neuropathic component of cancer pain using the DN4 questionnaire (Fig. 1 g) and the last revised Edmonton’s Classification of cancer pain (Fig. 1h).
Additionally, right below the general information compiled to diagnose BTcP as registering a new patient, there is a toolbar incorporated into the app in order to help physicians to assist in the diagnosis and monitoring of patients with BTcP (Fig. 1b). Tools included were as follows: i) Opioid rotation refers to a switch from one opioid to another in an effort to improve the response to analgesic therapy or reduce adverse effects; ii) Functional scales to assess the quality of life of cancer patients: the Karnofsky index -an attempt to quantify cancer patients' general well-being and activities of daily life- and the ECOG Scale of Performance Status -standard criteria for measuring how the disease impacts a cancer patient’s daily living abilities in terms of their ability to care for themselves, daily activity, and physical ability such as walking, working, etc.; iii) Pain rating scales: Visual Numeric Scale (VNS)- a segmented numeric version of the visual analog scale in which a respondent selects a whole number (0, no pain–10, worst pain) that best reflects the intensity of pain- and the Categorical scale (CS: none/mild/moderate/severe), only used when the patient is not capable to self-assess pain with any of the former scales) iv) the Charlson Comorbidity Index, which predicts 10-year survival in patients with multiple comorbidities (age, acute myocardial infarction, congestive heart failure, peripheral arterial disease, cerebral-vascular disease, dementia, chronic pulmonary disease, connective-tissue disease, peptic ulcer, liver disease, diabetes mellitus, hemiplegia, renal failure, solid tumors and blood malignancies and AIDS); and v) PQRST pain assessment questions (P: provocative and palliative factors; Q: qualitative description of pain, “What does it feel like?”; R: region and radiation of pain; S: severity or intensity of pain after being scored by means of VNS and CS; T: timing or pain changes over time).

The primary objective of this study was to undergo a first-of-a-kind testing of the App INES-DIO to obtain results of the usability, acceptability and usefulness in real world practice as well as the need to include new information and recommendations for a better care of cancer patients suffering from BTcP.

**Methods**

**Study Design**

To evaluate App INES-DIO, we performed a survey research study of both the mobile phone and tablet computer versions of the app. This research consisted of testing the
usability of a first-of-a-kind prototype to validate the acceptability and usefulness of the mobile app tools on the daily clinical practice of patients with BTcP.

Usability testing study was conducted using a structured questionnaire to collect the response to 33 questions divided into three different blocks: (i) demographic and professional profile of participants, including the gender, age, professional background, experience in treating BTcP patients; (ii) their digital profile, being focused on previous experiences with mobile phone and tablet devices, and previous use of mHealth apps; and (iii) a patient-related questionnaire based on those clinical features that could help the doctor upon diagnosing and monitoring BTcP in cancer patients. At the end of testing period, participants were asked to answer few follow-up questions about the app design and its features, its overall usefulness, their intention to use it in other type of patients (not only those BTcP-related), the acceptability of the mobile app and its features in everyday health management, and new contents of interest to be included to the use of the mobile app in the future.

Participants

Our study sample consisted of 175 medical doctors homogenously distributed all over Spain from different health care units: medical oncology (n = 66), radiation oncology (n = 48), palliative care (n = 42), pain units (n = 18) and others (n = 1) . Participants were working in public hospitals (96%), and were highly experienced in breakthrough cancer pain (>12 years with more than 412 patients attended the last year).

Every participant was asked to test the usability and the value in the clinical setting of App INES-DIO in four cancer patients each (this makes a total of 700 patients), with a different clinical profile of BTcP: newly diagnosed or in follow-up.

Data Analysis

A descriptive study of the variables was carried out according to their type: for numeric variables, measures of central tendency and dispersion (sample size, mean, median, minimum, maximum, standard deviation, 95 % CI, Q1 and Q3) were applied. For the categorical variables, frequency distribution tables and percentages (n, %) were provided.
For the evaluation of some of the answers, a 7-point ordinal rating scale of the Likert type (where 1 = strongly disagree/never/never recommend, and 7 = strongly agree/always/always recommend) was used.

**Results**

**Professional and Digital Profile of Participants**

48.6% participants were females and 51.4% were males. By age, 37.6% participants referred to be between 36-45 y.o. Almost 77% of the sample were physician assistant and all BTcP-related medical specialties were represented among participants. Panelists are mostly working at public health care centers (96%) and half of them (49.7%) do it in large hospitals (≥ 500-beds). The experience in the management of patients with BTcP was shown to be >12 ± 7 years, with an average of > 400 patients attended during the last year. 36 (20.5%) out of the physicians recruited for the present study had also participated in the previous Delphi consensus study [8], and most of the sample (88.9%) was aware of the recommendations and (85.5%) considered them to be useful for their clinical daily practice. Table 1 shows the digital profile of the sample. All participants owned a private cell phone (56.6%, iOS; 43.4%, Android) and had access to different types of applications for private (i.e. maps, email, press news, instantaneous communication platforms) and professional use (20% of downloaded apps are for clinical use; n =144). The most commonly used function on the Web is related to their filiation for at least one social network (i.e. Facebook, Linkedin).
Table 1. Digital profile of participants.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician is user of a social network</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>174 (99.43)</td>
</tr>
<tr>
<td>No</td>
<td>1 (0.57)</td>
</tr>
<tr>
<td>Operative system of your private mobile</td>
<td></td>
</tr>
<tr>
<td>iOS</td>
<td>99 (56.57)</td>
</tr>
<tr>
<td>Android</td>
<td>76 (43.43)</td>
</tr>
<tr>
<td>Apps already downloaded in your mobile</td>
<td></td>
</tr>
<tr>
<td>Number (n = 123)</td>
<td>24</td>
</tr>
<tr>
<td>Clinical use only (n = 144)</td>
<td>5 (20)</td>
</tr>
<tr>
<td>Use of mobile services</td>
<td></td>
</tr>
<tr>
<td>News/Press/Online journals</td>
<td></td>
</tr>
<tr>
<td>Social networks (Facebook, Linkedin, Twitter, et.)</td>
<td>146 (83.43)</td>
</tr>
<tr>
<td>Instant messaging (WhatsApp, Snapchat, etc.)</td>
<td>119 (68)</td>
</tr>
<tr>
<td>eMail</td>
<td>154 (88)</td>
</tr>
<tr>
<td>Online banking</td>
<td></td>
</tr>
<tr>
<td>Information of interest</td>
<td></td>
</tr>
<tr>
<td>Never used</td>
<td></td>
</tr>
<tr>
<td>Mobile Application Intervention in Patients</td>
<td></td>
</tr>
</tbody>
</table>

The mHealth App INES-DIO has been tested by the 175 panelists clinicians after using it with 700 patients (4 patients per participant). Patients had been diagnosed of BTcP at an averaged time of 3.77 months before this study. The app was mainly used to help physicians during the visit of the cancer patient (45.1%), followed by the course of BTcP flares (27.6%), diagnosis of BTcP (24.3%), and drug titration/change of treatment to control BTcP (22.3%).
As described above, when initiating the app, every clinician was requested to open a new registry of each patient, going through four sequential steps to collect clinical information of relevance for an enhanced diagnosis procedure of BTcP. After testing the different level of usage of this diagnostic workflow, BTcP definition by Davies et al. [6] and Escobar et al. [17] along with the Davies algorithm were shown to be mostly used (Fig. 3). At time to define each patient’s baseline pain, DN4 neuropathic scale and the last reviewed classification of Edmonton scale were used by 69.5% and 63.4% of participants, respectively.

The usability of the tools incorporated into the app in order to help physicians to monitoring pain, functional performance and comorbidity of BTcP patients was also rated by the panel (Fig. 4). Both pain-rating and functional assessment scales were the most frequent tools used by clinicians, with a peak of 93.3% for the visual numeric scale followed by the use of ECOG scale (84.1%) and the Karnofsky Performance Scale index (81.3%).

Participants responded to the question about the utility of each corresponding app tool. The utility of all app tools was considered as highly important (5-7 scored) on a Likert scale (71-87% of panelists). Whenever these tools were considered of little use, this fact was highly attributable (80-90% of panelists) to the no-need of being used during the patient’s examination, although these might be used in further visits.

**Acceptability and Usefulness Testing of the Application**

The level of acceptability for App INES·DIO was tested among the sample. By the end of testing, all participants (n = 175) had gained some experience with the system and the mobile app features. Most clinicians (90%) concluded that the mobile app is well designed and easy to use, and 95% of participants would likely/most likely recommend the use of App INES·DIO.

A report including all the information collected by physicians from each patient was provided by the app. This report was always/almost always indicated to be worth to be included it into the patient’s clinical records by 68% of panelists (Fig. 5a). This mobile application was used as much as two-or three times a week by 42% of clinicians, and it
would even be worth using it in another patient's profile -not exclusively in cancer- to assess the diagnosis and control of pain (Figs. 5b,c).

Clinicians were questioned to state the usefulness of each app tool for the diagnosis and monitoring of patients with BTcP. Both most and least useful app resources are shown in Figure 6. Davies and Escobar definitions of BTcP (53%), the use of Davies Diagnostic Algorithm (55%) and other considerations for a better diagnosis of BTcP, such as the number of flares per day, their duration and intensity as well as the control of baseline pain (57%), were understood as the most useful tools of App INES·DIO. Conversely, the least useful tools valued by professionals were the ECOG Scale (30%), the use of a categorical scale (34%), and the Charlson Comorbidity Index (39%).

The feedback about future contents -five different proposals- to be included in the application given by participants who used the App INES·DIO takes the format of a statement based on a fully anchored 3-point Likert type response, with options being "Disagree" (score, 1-3) "Undecided" (score, 4) and “Agree” (score, 5-7). The sample vastly suggested the implementation of new education material for patients about the pathology and treatment of breakthrough pain (Fig. 7). They strongly agreed on the importance (mostly 5-7 scored) of adding new clinical guidelines/protocols for the management of BTcP, improving their communication skills with the patient, and introducing an evidence-based medicine video platform which gathers new education material on BTcP.

**Discussion**

**Principal Findings**

Mobile devices are continuously present in people’s everyday lives [18], and many individuals have a deeply personal relationship with their mobile phones, which are typically customized to their specific needs [19,20]. Evolving technical capabilities of mobile devices enable delivery of various services independent of the user’s time and place, and their dynamic adaptation to current context of use and users’ personal preferences [21]. These features make mobile devices well-suited terminals to develop apps for easier monitoring and managing of pre-existing health conditions, the delivery
of more efficient, individually tailored care at the point-of-need, and promotion of a better collaborative work between patients and health care providers [22,23].

To our knowledge, this was the first study to report on the development, usability, usefulness and acceptability testing of a mobile app to be used as an adjunct to breakthrough cancer pain intervention. Given the popularity of mobile apps within our participants (see the digital profile of the recruited sample in Table 2) and the difficulties related to the management of BTcP, we anticipated that a mobile app would be a useful tool to assist the diagnosis and monitoring of patients with breakthrough cancer pain and the results of this study support this. Strengths of the App INES·DIO study included the participation in the iterative development process of a group of medical experts, who were selected to achieve a fair distribution across the four professional profiles involved in the management of BTcP: medical oncology, radiation oncology, palliatives and pain units.

Most sample recruited was aware about the consensus and controversies driven by the original Delphi study [8] that set the ground for the development of App INES·DIO and the subsequent usability testing described along this study. Moreover, conclusions reported by the Delphi study were perceived to have a positive impact on clinical daily practice on attendance of BTcP patients.

Ultimately, there has been a rapid proliferation of mHealth apps, and for pain in particular. As of 2015, around 280 pain-related apps are commercially available to monitor and track pain [22,23]. In our study, App INES·DIO was tested by 175 professionals in 700 cancer patients with a mean historical diagnosis of BTcP of 2 years. This result is particularly important, mainly because only 8.2% of reported apps included a health care professional in their development, not a single app provided a theoretical rationale, and only 1 app underwent scientific evaluation [23].

In the literature, the treatment of BTcP involves strategies such as the treatment of cancer disease, modification of the baseline analgesic treatment, non-pharmacological interventions, and an appropriate rescue medication [24]. In line with this, our app was mostly used to help physicians during the examination of patients, but also the diagnosis, course and treatment of BTcP flares.

Some authors support the fact that pain history should include key elements that characterize the salient clinical features of breakthrough pain, in addition to standardly
described approaches to the cancer pain history [25]. Clinicians were requested to make
a new registry with each patient (4 per clinician), going stepwise through the different
validated tools incorporated into App INES·DIO to complement patient’s pain history.
Testing the usability of these tools revealed that definitions of Davies [6] and Escobar et
al. [17] along with the Davies algorithm were the most used. One of the difficulties
attributed to assess the prevalence of BTcP in the cancer population lies in the variety of
definitions that exist and are used for BTcP.

Furthermore, both pain-rating and functional assessment scales were highly used by
clinicians, with a peak of 93.3% for the visual numeric scale followed by the use of
ECOG scale (84.1%) and the Karnofsky Performance Scale index (81.3%). These
results are in line with the considerations about the use of such scales to test the control
of baseline pain [25]. To consider that baseline pain is adequately controlled, some
authors assume that the average intensity of pain must be less than four on a categorical
scale (CS) or somewhere at a visual numerical scale (VNS) from 0 to 10, where `0´
usually represents ‘no pain at all’ whereas the upper limit represents ‘the worst pain ever
possible’. Numerical Rating Scales have shown high correlations with other pain-
assessment tools in several studies [26, 27], and the feasibility of its use and good
compliance have also been proven [28].

During our study, the sample stated the usefulness of each app tool. Interestingly, the
tool `Other considerations for the diagnosis of BTcP´ was contemplated as the most
useful, even above the use of the Davies diagnosis algorithm. In other words, the
diagnosis of BTcP was interpreted by the sample to be highly sustained into those
features that complete the information related to the definition of an episode: number,
duration and intensity of flares per day and the management of baseline cancer.

Considering our study against the background of other studies [22,23], it is clear that
acceptability and usefulness testing done in physicians might be paramount for the
optimal design and development of mobile apps used in clinical cohorts. With regard to
user satisfaction, clinicians completed a questionnaire and 90% reported that they liked
using this pain app and found it user-friendly and well-designed while 95% reported
that they would likely/most likely recommend its use to other colleagues, even to be use
with other patient profiles. The generation of a report that physician could attach to the
clinical record of each patient was stressed to be of much value.
Participants were tested to give the feedback about five different contents to be included in future versions of App INES-DIO in order to promote a better interpretation of breakthrough pain in cancer patients. Interestingly, testing revealed the need of the future implementation of new education materials about the pathology and treatment of breakthrough pain. Thus, the sample agreed on adding some new app educational tools, such as consensus documents and clinical guidelines for the management of BTcP, improving their communication skills with the patient and evidenced-based medicine platforms. Refreshing the knowledge and communication skills of health-care providers may yield more favorable patient outcomes.

**Limitations and Future Work**

The most significant limitation of this study was the use of a one-group design to pilot pain App INES-DIO. This design precluded assessment of the feasibility of randomization procedures, as well as recruitment, attrition, outcome measure completion, and acceptability in a control arm. However, although we can learn a lot about the usability of a mobile app in a controlled setting, it is important to test it in real-world situations, which are highly variable [29].

Previously, we noted that there was a limited related research on how mobile devices could be used in the context of health care information systems for cancer patients. Further work is needed to identify the primary factors and design issues influencing acceptability and usefulness of different system features of mHealth care information services. In our future research, we are planning to continue work on the development of a new version of App INES-DIO and investigate how this app should be designed and adjusted to best fit clinicians’ needs in the care of BTcP patients. Some of the potential new app features were already identified throughout this survey study and these will be considered for next version of the app, as well as the need for further exploration of how we can add rich media to this BTcP mobile app.

**Conclusions**

In summary, all these results suggest that App INES-DIO could be shortly used as a tool to assist physicians in making decisions around breakthrough cancer pain management.
Indeed, this app can be a reference medical device to assess the diagnosis and monitoring of BTcP. Clinical use of those diagnosis tools going beyond the Davies Algorithm should be outlined in any patient with a history of cancer pain. Interestingly, the value of the app will be enhanced with the inclusion of new educational material on BTcP not only for medical professionals but also for patients. This study provided promising evidence for the success of a future mobile breakthrough cancer pain application.

Acknowledgements

We would like to express our gratitude to all the participants in the study. The authors received editorial help from Maite Artés and Gloria González of Adelphi Spain which was supported by TEVA Pharmaceutical Industries.

Conflict of interest

Dr. Jaime Boceta has received personal fees from Grunental, Esteve and Teva Pharma, and non-financial support from Grunental.

Dr. Daniel Samper has received personal fees from Teva.

Dr. Alejandro de la Torre has no conflict of interest to declare.

Dr. Rainel Sanchez-de la Rosa reports to work in the medical department of TEVA.

Mrs. Gloria González has no conflict of interest to declare.

Abbreviations

App INES·DIO: by its abbreviation in Spanish, Instrument for the Assessment and Monitoring the Breakthrough Cancer Pain

BTcP: breakthrough cancer pain

CS: Categorical Scale

ECOG: Eastern Cooperative Oncology Group

mHealth: mobile health

rESS: reviewed Edmonton Symptom Scale


**References**


11. O'Leary DP, Zaheer A, Redmond HP, Corrigan MA. Integration of advances in social media and mHealth technology are pivotal to successful cancer prevention and control. Mhealth 2016;2:38 [FREE Full text] [doi: 10.21037/mhealth.2016.09.02] [Medline: 28293611]


