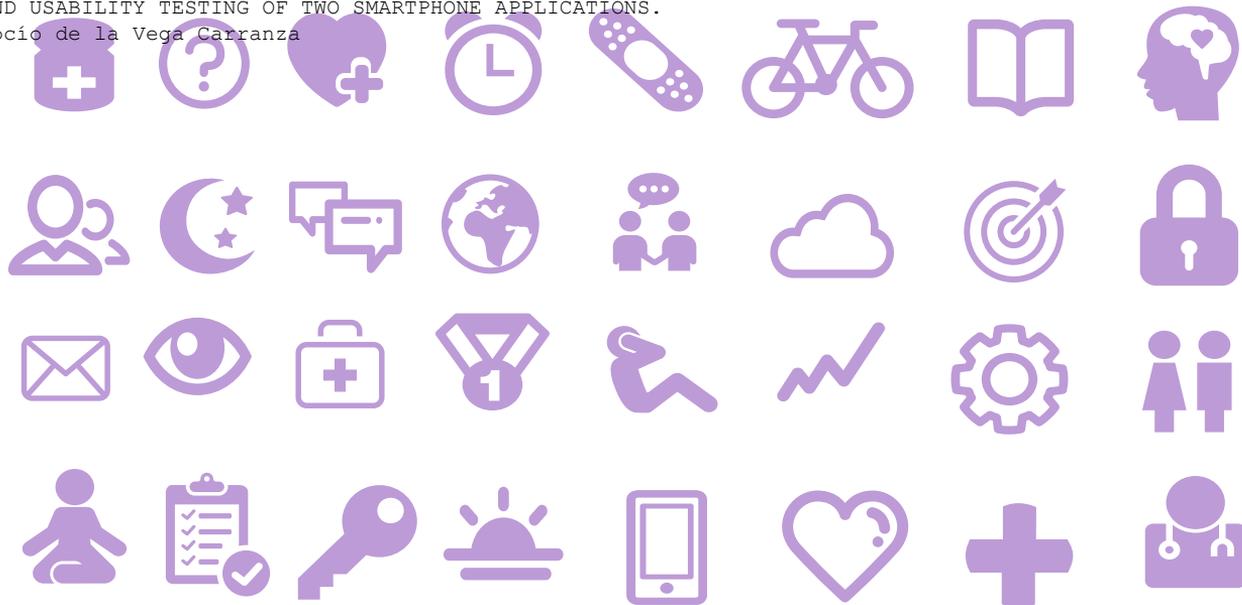# MHEALTH: A NEW AND COMPLEMENTARY WAY TO HELP YOUNG PEOPLE WITH PAIN. STATE OF THE ART, DEVELOPMENT, AND USABILITY TESTING OF TWO SMARTPHONE APPLICATIONS.

Rocío de la Vega Carranza

mHealth: a new and complementary way to help young people with pain

State of the art, development, and usability testing of two Smartphone applications

Rocío de la Vega de Carranza

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DOCTORAL THESIS

Supervised by Dr. Jordi Miró

Department of Psychology

UNIVERSITAT ROVIRA I VIRGILI

Tarragona, 2014

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This is to certify that:

The Present Dissertation: "mHealth: a new and complementary way to help young people with pain. *State of the art, development, and usability testing of two Smartphone applications.*", presented by Rocío de la Vega, has been supervised by Jordi Miró, Professor at the Department of Psychology of the Universitat Rovira i Virgili, in fulfillment of the requirements for the degree of Doctor of Philosophy.

30 October 2014, Tarragona

Jordi Miró, PhD

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A mi abuelo Pepe, el Coronel con alma de poeta, a quien me gustaría

preguntarle tantas cosas… gracias por aquellas palabras que me dijiste antes

de irte.

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Agradecimientos

Érase una vez, hace más de cuatro años comenzó una aventura. La que entonces era una niña decidió dejar Kansas y volar en medio de un tornado hacia la tierra de Oz para perseguir un sueño. No fue una decisión fácil pues, a diferencia de otros, no se sentía a disgusto en casa, al contrario, tenía mucho allí. Una familia pequeña pero unida, que le enseñó los valores del amor incondicional y del trabajo por aquello que se quiere, gracias a Mabel y Pedro aprendió a caminar por esta vida con una sonrisa en la cara, sin miedo a mostrar la creatividad y el entusiasmo siempre que le brotaran; aprendió que es posible mirar a otra persona como si te acabaras de enamorar pese a llevar casi 30 años casados, y que se puede combinar el éxito profesional con la vida en familia (y los viajes por Europa). Gracias a Marina y Paloma, aprendió lo que es el amor de una hermana mayor y la satisfacción de estar orgullosa de alguien a quien has ayudado a crecer pero también que una de las mejores cosas que te pueden pasar es compartir el 50% de tus genes con dos de tus mejores amigas. Gracias a sus abuelos: Maite, Pepe, Jose Luis, Casi, Juana, Nino, Teresa y Maribel comprendió cómo la ternura puede cambiar a las personas. Gracias a su hada madrina, la bruja buena que de pequeña le hacía varitas mágicas y coronas con el cartón de las cajas de galletas, aprendió que la magia existe. Gracias a Fernando y Coral aprendió cómo los opuestos se atraen y cómo se puede

seguir siendo "guay" por mucho que pasen los años (y traer al mundo cosas tan bonitas e inteligentes como Carmen e Isabel), Gracias a Jose aprendió que se puede volver a empezar, que se puede crecer en la adversidad y ver el mundo con ojos nuevos, y gracias a María, Jose Luis y Juan Carlos, que no importa el tiempo que pases sin ver a otra persona para volver a conectar y disfrutar con ella.

Muchos mentores y profesores le inculcaron el amor por las letras y las ciencias, quizá los que más la transformaron en su forma de ver el mundo fueron: Mery King, que la inició en el aprendizaje del inglés pero se fue demasiado pronto; Lola, quien la puso en contacto con la disciplina y confió en ella para ser el hada madrina en "La Cenicienta"; Pilar, quien le enseñó a improvisar y a subirse sin miedo a un escenario; Manolo, quien le animó a escribir; Héctor, quien la introdujo en el maravilloso mundo de la hipnosis; Rosa, quien la propuso como candidata para esta aventura y finalmente Margarita y Alicia, quienes le enseñaron que la excelencia profesional no está reñida con la accesibilidad, la humildad y una vida más allá de los muros de la Universidad.

Fueron muchos los amigos que dejó en su tierra, amigos que la habían visto crecer o que habían crecido con ella, compartiendo tropiezos y aprendizajes. Los había ido recogiendo en la escuela, en la carrera o en los sitios más insospechados, todos ellos forjaron recuerdos únicos e irrepetibles que necesitarían un tomo entero para ser mencionados: el descubrimiento de la amistad con Irene, las risas con Helena, Hermi y Anita;

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los años de facultad con Pat (y sus abrazos), Berta (y sus locuras), Elena (y su lógica aplastante ante los agobios), Fran (y su cámara), Juan (y su sabiduría), Chema (y las pelis extrañas en su casa), Juanma (siempre dispuesto a ayudar) y Mar (que le demostró que la distancia no es excusa y le hizo cuestionarse que quizás la bruja mala no lo fuese tanto... y con quien sigue de la mano, a pesar de los pesares); las conversaciones con Mamen, Coral, Ruth, Andrea o Mariana, los Km para ver a David P., los "cafelitos molones" con David M. y Jose; los "buriburiburi" de María, las notas de voz de Miguel, o las cenas con Araceli y Maite entre otros muchos momentos.

Gracias a todo ese equipaje que mis seres queridos habían puesto en mi mochila, me sentí preparada para volar hacia lo desconocido y acepté la llamada del Gran Mago de Oz, quien al llegar me propuso esta locura de viaje hacia Ciudad Esmeralda. Tuvo la visión de que nos embarcásemos en este proyecto de mHealth, me permitió ser creativa y escuchó mis ideas con entusiasmo, incluso cuando yo misma dudaba de ellas. Me presentó también a amigos poderosos que me enseñaron las habilidades necesarias para recorrer el camino y me guió en los procelosos mundos de la redacción de proyectos, propuestas y artículos, que gustaba de adornar con sus palabras mágicas como: guachumaku, yepali, jesuset, xup-xup, iabadabaduuuu y otras similares, que parece ser que han surtido efecto.

Al llegar a Oz me estaban esperando cuatro Munchkings para darme la bienvenida, explicarme cómo funcionaban las cosas en aquellas

tierras y ayudarme a sobrellevar el jetlag emocional que se experimenta cuando te mudas lejos de casa. Cada una tenía una especialidad: una era abogada, otra fotógrafa, otra cocinera y otra era la presidenta, más tarde se incorporó la experta en comunicación; lo que está claro es que nada habría sido igual sin ellas. En Oz, había también otras aldeas: había Munchkins masculinos a los que llamábamos los "chicos de al lado", de quienes nunca faltó una sonrisa, estaban las "chicas de los bebés", con quienes compartimos penas y alegrías, y también las "chicas de las matemáticas", quienes nos salvaron de más de un apuro.

En el camino de baldosas amarillas hubo unos cuantos monos alados y trampas de la bruja del Oeste, hubo situaciones en las que casi me puse a gritar: "¡Leones, panteras y tigres, Dios mío!". Por suerte, no tuve que enfrentarme a esos peligros sola, ya que por el camino encontré tres compañeros de viaje muy muy especiales. En primer lugar me encontré con el hombre de hojalata, él sabe que gracias a su inteligencia y su destreza he podido hacer cosas que yo sola no hubiera hecho, sin embargo, a veces se le olvida que tiene corazón, pese a tener uno gigante. Más adelante en el camino, nos cruzamos con alguien que parecía tímido y casi hasta cobarde, pero resultó ser un león capaz de protegernos (aunque sea a nivel de la seguridad de los datos). El último en unirse a nuestra aventura de mHealth fue el espantapájaros, él si es consciente de que tiene un corazón enorme pero en lo que aún no acaba de confiar es en su inteligencia, supongo que debe recorrer su propio camino para descubrir lo equivocado que está.

En este largo camino hubo momentos especialmente dulces, en los que viajar a Hamburgo, Halifax, Girona, Milán, Estocolmo, Vancouver o Buenos Aires. En mitad del camino viajé tres meses a la "meca helada del dolor infantil", donde moran los Munchkins más sabios de Oz, allí aprendí cosas necesarias para continuar mi viaje. Gracias a: Patrick, Anna, Allen, Jill, Bruce, Paula, Mike, Sharlene y el resto de habitantes de la aldea del IWK Health Center. Pude conocer a los maravillosos integrantes de PICH (Pain In Child Health), de los que tanto he aprendido y tanto apoyo he recibido. También vino a visitarnos Mark, cuya especialidad eran los malabares, que me dio valiosos consejos sobre cómo avanzar en el camino.

Este viaje no habría sido posible sin los que han conseguido que tenga agua y pan para el camino y un sitio donde refugiarme, por tanto, gracias al Ministerio de Ciencia e Innovación por concederme la beca FPI. Gracias a las ayudas del PICH, Departamento de Psicología de la URV y la IASP por su financiación para asistir a congresos. Gracias también a aquellos "pequeños Munchkins" que se prestaron voluntarios para participar en los estudios.

Como dice un aforismo que me gusta mucho: "para lograr algo que no hayas conseguido nunca deberás hacer algo que no hayas hecho nunca", así que aquí estoy, a las puertas de Ciudad Esmeralda, el lugar donde moran los doctores, preparada para decir las palabras mágicas y entrar.

Este es mi final feliz, y como los buenos finales felices es, en realidad, un principio feliz. Gracias de corazón a todos los que, de una u otra manera, formáis parte de mi historia.

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Abstract

Pain is an unpleasant experience that affects millions of people around the globe, overwhelming the healthcare systems and costing governments billions. The treatments available improve the quality of life for many people with pain, but the results are still modest. Even worse, treatments are not always readily available for all those in need. mHealth (healthcare using mobile devices) has great potential to help in the delivery of treatment, because it reaches more people and reduces costs.

To analyze the current state of the art on mHealth and pain, a systematic review was conducted of the mHealth literature (i.e. peer-reviewed papers in scientific databases) and the commercially available pain-related Smartphone applications (in the main shops).

Two applications have been developed for this dissertation: *Painometer* (an app that helps in the process of assessing pain intensity), and *Fibroline* (an app that aims to improve the quality of life of young people with fibromyalgia or chronic widespread pain). Both applications were developed using an iterative design; they underwent a usability testing protocol and an interview with end-users to refine the prototypes until they were understandable, error-free, easy to use, and liked by users.

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Three main conclusions can be drawn from this dissertation:

1. mHealth is still in its infancy. Of central importance is the need to build a better-defined regulatory environment, and to improve the translation process, bonding the academic and commercial sides of this technological milieu.

2. *Painometer* is an app that has good usability. Scales in the application provide valid and reliable pain intensity reports.

3. *Fibroline* is an app that has also proved to have good usability properties. A pilot study will be conducted to test its efficacy. If proven effective, *Fibroline* could be a great asset to help young people and their families, and improve their quality of life.

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1. Introduction

What you are about to read is part of the work that I have been undertaking for the past four years in close collaboration with my colleagues in the ALGOS group. I started to study pain quite by chance when an opportunity came along in 2010. I soon got very involved, and must admit that I see it as a great career opportunity. The dissertation has three parts. The current state of development of mHealth is discussed and exemplified with the case of pain-related apps. The development and testing of two Smartphone applications (i.e. a pain-intensity assessment app, and an app embedding a cognitive-behavioral treatment for young people with fibromyalgia) is also reported.

First, the central ideas and concepts – pain and mHealth – are stated and the objectives specified. To introduce the topic, some explanations about pain and its consequences in both adults and youths are given. Then the role of psychology in managing pain is explained. Emphasis is placed on fibromyalgia. Next, mHealth is introduced, its relationship with pain is described, and its advantages, risks, and solutions are discussed. The introduction ends with an explanation of usability tests and the procedures for testing Smartphone applications.

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The three main objectives of this dissertation are then presented, followed by an overview of the methodology of each study (i.e. participants, procedure, measures). In the Results section, the three studies are reported in full.

Finally, a general discussion integrates the results obtained and reflects on future lines of research. The dissertation ends with a brief conclusions section in which we summarize the findings.

1.1 Pain

1.1.1 On the concept of pain

Definition. Pain is defined by the International Association for the Study of Pain (IASP) as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (Merskey & Bogduk, 1994). It is a subjective experience resulting from the interaction of many factors (i.e., physical, cognitive, emotional, behavioral, cultural), among which are age, gender, previous experience, self-efficacy, anxiety and social support (Etherton, Lawson, & Graham, 2014; Kerns, Rosenberg & Otis, 2002). As a symptom, pain is present in a wide range of diseases but when it is chronic, it can be considered a disease in itself (Siddall & Cousins, 2004).

Acute versus chronic pain. Pain can be classified in many ways: for example, its location, its quality, its intensity, or the way in which it presents (see Miró, 2003). The most important feature of pain for this dissertation is its duration, which can be divided into acute and chronic. *Acute pain* is the response to a painful stimulus or procedure (e.g. vaccines, surgery, wounds), and it warns us of something that could be a danger to us. It is usually related to tissue damage, it is limited in time and disappears when it heals (Carr & Goudas, 1999). If pain persists after the normal period of healing, lasts more than three months or recurs (appearing at least once a month) it is known as *chronic pain* (Merskey & Bogduk, 1994). This kind of pain has no protective power, as it is not usually related to any underlying physical problem in the organism; furthermore, it has a number of negative biopsychosocial consequences. Chronic pain is a complex experience that is the result of the interaction of numerous factors and which encompasses multiple levels (thoughts, feelings, behaviors, physiology) and units of analysis (individual, dyad, group) (Miró, 2003).

Consequences. People with chronic pain report a worse quality of life and higher levels of disability than those who do not have this problem. It usually affects many areas of the person's life: health (e.g. sleep problems or fatigue (Moldofsky, 2001)), psychological wellbeing (e.g. anxiety (Pagé et al., 2011), depression (Miller & Cano, 2009), cognitive processes (Landrø et al.,

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2013)), social relationships (e.g. (Peat, Thomas, Handy & Croft, 2004), work and/or school (Neupane et al., 2013), and economy (Gaskin & Richard, 2012)).

Epidemiology. Pain is a very common experience for everybody, with the rare exception of those with congenital insensitivity to pain ("Congenital Insensitivity to Pain with Anhidrosis," 1993). It is considered a public health priority worldwide (Goldberg & McGee, 2011). Although it is a global phenomenon, its reported prevalence varies between countries. For example, in Europe 19% of adults report moderate to severe pain (Breivik, Collett, Ventafridda, Cohen & Gallacher, 2006); in a survey conducted in the USA, 28% presented some kind of pain (Krueger & Stone, 2008), and in Canada 19% of those surveyed reported having chronic pain (Schopflocher, Taenzer & Jovey, 2011).

1.1.2 Pain in adolescents and young adults

Importance of the problem. Chronic pain is also a common experience for young people (Eccleston, Jordan & Crombez, 2006; Huguet & Miró, 2008; Perquin et al., 2000). As is the case with adults, young people experience a range of negative consequences in their daily life due to pain. Their social functioning and peer relationships are affected (Forgeron et al., 2010, 2011), their school-related outcomes are poorer than their healthy counterparts'

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(Vervoort, Logan, Goubert, De Clercq & Hublet, 2014), their sleep quality is poor (de la Vega & Miró, 2013), and their mental health can also be affected (Ando et al., 2013).

The family context. When a child or an adolescent is in pain, the whole family is affected. The burden for caregivers can be very high, because it increases their stress and anxiety, or causes economic problems (Groenewald, Essner, Wright, Fesinmeyer & Palermo, 2014). When a family is dysfunctional, it has consequences for the young person's physical and psychological wellbeing (Lewandowski, Palermo, Stinson, Handley & Chambers, 2010).

The Juvenile Fibromyalgia Syndrome (JFS). One important problem is that of JFS or Chronic Widespread Pain (CWP). JFS is defined by Anthony and Schanberg (2001) as "A common musculoskeletal pain syndrome of unknown etiology characterized by widespread persistent pain, sleep disturbance, fatigue, and the presence of multiple discrete tender points on physical examination. Other associated symptoms include chronic anxiety or tension, chronic headaches, subjective soft tissue swelling, and pain modulated by physical activity, weather, and anxiety or stress." (p.165). Although no studies on its prevalence have been conducted in Spain, other studies conducted in Israel, Italy, and Mexico have shown that Juvenile

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Fibromyalgia Syndrome is present in between 1.2% and 6% of young people (Buskila, 2009).

1.1.3 The role of psychology in the treatment of pain

Efficacy of multidisciplinary treatments. Pain is a widespread problem that causes considerable biopsychosocial upheaval to those who have it, so treatments should be designed to cover all the affected areas. A review of randomized controlled trials (RCT) of multidisciplinary interventions (Scascighini, Toma, Dober-Spielmann & Sprott, 2008) found strong evidence that they were more effective than no treatment or standard medical treatment. Fibromyalgia and chronic back pain patients had the best outcomes. A meta-analysis of RCTs of fibromyalgia (Häuser, Bernardy, Arnold, Offenbächer & Schiltenwolf, 2009) supported these results by showing that multidisciplinary interventions reduce pain, fatigue, depressive symptoms, and limitations to health-related quality of life and improve pain self-efficacy and physical fitness. A meta-analysis of complementary and alternative exercise for fibromyalgia (Mist, Firestone & Jones, 2013) recommends adding this kind of exercise to regular treatment because it has few side effects and can moderately improve pain.

The importance of psychological components. Jensen and Turk (Jensen & Turk, 2014) recently wrote an overview of the main contributions made by

psychologists to the understanding and treatment of pain. These contributions range from some of the main pain models (i.e. the operant model, the peripheral physiological models, the cognitive and coping models, and the central neurophysiological models) to a number of successful intervention techniques (e.g. contingency management, relaxation training, biofeedback, cognitive-behavioral therapies, neurofeedback or hypnosis). The contribution of psychology and psychologists has been central to the development of treatment programs that work. Some studies have shown the efficacy and cost-effectiveness of psychological interventions in treating pain in both adults and children. A recent review of reviews summarizes the evidence of several psychological treatments for pain, and found the strongest evidence to be in favor of cognitive behavioral therapy: specifically, cognitive coping strategies and behavioral rehearsal (Eccleston, Morley & Williams, 2013). A Cochrane review of psychological therapies for the management of chronic and recurrent pain in children and adolescents (Eccleston et al., 2012) reports that pain improved at post-treatment, mood significantly improved only in those with headaches at follow-up, and disability significantly improved in those with non-headache pain at post-treatment. According to these data, multidisciplinary pain interventions should have psychological components.

Psychological interventions for fibromyalgia. Focusing on the effects of psychological interventions in fibromyalgia, a meta-analysis performed in

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2010 found significant but small effect sizes for short-term pain reduction, and small-to-medium effect sizes for long-term pain reduction for all psychological interventions. They were also effective at improving sleep, depression, functional status, and reducing catastrophizing. Cognitive-behavioral treatment (CBT) was significantly better at reducing pain than such other psychological treatments as relaxation or education (Glombiewski et al., 2010). Several studies have demonstrated the efficacy of CBT for JFS. For example, Degotardi et al. (Degotardi et al., 2006) found a reduction in pain, somatic symptoms, anxiety and fatigue; improvements in sleep quality and functional ability; and fewer school absences after treatment. Similarly, Kashikar-Zuck et al. found a significant reduction in catastrophizing and a significant improvement in coping and coping efficacy in a group of young people with fibromyalgia after successful completion of a CBT program (Kashikar-Zuck et al., 2013).

1.2 mHealth and pain

1.2.1 The concept of mHealth

Mobile health technology or mHealth refers to those health interventions delivered using mobile devices. The World Health Organization (WHO) Global Observatory for eHealth defines mHealth as "medical and public health practice supported by mobile devices, such as mobile phones, patient

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monitoring devices, personal digital assistants (PDAs), and other wireless devices" (Kay, 2011, p. 5). This kind of intervention has numerous advantages: for example, it relieves the load on the health system, reaches more people, and is faster than traditional interventions (TrustLaw Connect, 2013; West, 2012). The number of mHealth apps is rapidly growing, and at present there are about 100,000 (Jahns, 2013). Because of the improvement in wireless networks all around the world and the rapid progress of mobile technology, the number of healthcare professionals and patients using mHealth applications is increasing exponentially.

1.2.2 The efficacy of distance health interventions

Technology is widely used for the distance management of chronic illnesses (Rosser, Vowles, Keogh, Eccleston & Mountain, 2009). Williams (Williams, 2011) provides a thorough explanation on how the Internet can be of great help to improve the treatment of people with chronic pain. He alludes to the potential it has to extend treatment and reduce costs with such procedures as eHealth or mHealth, e-mail discussion groups, therapeutic interactive voice response, and therapist-monitored or automated websites.

Two meta-analyses, one of all ages (Macea, Gajos, Daglia Calil & Fregni, 2010) and the other of children and adolescents (Palermo, Eccleston, Lewandowski, Williams & Morley, 2010) focused on their efficacy and found that web or computer-based CBT programs show considerable promise at

reducing pain intensity and associated symptoms but they still need to be further investigated. In their systematic review of randomized controlled trials of internet interventions for chronic pain Bender et al. (Bender, Radhakrishnan, Diorio, Englesakis & Jadad, 2011) found similar results and also concluded that CBT Internet interventions can improve pain, activity limitation, and costs associated with treatment. However, more studies are needed to replicate the findings.

1.2.3 Risks and solutions of mHealth.

The use of this kind of distance intervention gives rise to some privacy, security and quality concerns (Krieger, 2013). It would seem to be necessary to create quality standards and certification processes to ensure that patients using mHealth can undergo interventions that are safe and high quality. In this regard, some initiatives are beginning to be implemented. For example, the European Commission has included mHealth on the Digital Agenda for Europe ("Digital Agenda for Europe - European Commission," 2012) and has dedicated an entire issue of the *European Journal of ePractice* (a digital publication created to promote the sharing of good practices in eGovernment, eHealth and eInclusion) to mHealth (Stylianou, McCormack & Kokmotou, 2013). In the USA, the Food and Drug Administration has laid down some guidelines for developing Smartphone apps that function as medical devices (Center for Devices and

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Radiological Health, 2013). Finally, the WHO and the United Nations specialized agency for information and communication technologies (ITU) have come together to create an interesting initiative: the ITU-WHO Mobile Health for Non-Communicable Diseases Initiative (International Telecommunication Union (ITU). The United Nations specialized agency for information and communication technologies, 2013).

1.2.4 Young people and mHealth

mHealth interventions are especially suitable for young people for a number of reasons. They are "digital natives" and usually feel comfortable using technology. Smartphones are part of their daily life (Madden, Lenhart, Duggan, Cortesi & Gasser, 2013), so it is easy for them to interact in this environment. When asked if they like mHealth apps, they usually say that they are "cool" and in studies that compare electronic and paper-and-pencil versions of self-report measures, they prefer apps to traditional paper-and-pencil questionnaires (e.g. (de la Vega et al., 2014; Stinson et al., 2013)). Another plus point is anonymity: teenagers are often embarrassed when talking about their health and tend to search for information on the internet (Gray & Klein, 2006), so they may feel more comfortable receiving treatment in the privacy of their Smartphone.

1.2.5 Pain assessment using mobile devices

Real time data capture is perhaps the major advantage of using mHealth. When a Smartphone is used to assess a patient's pain, the data go directly to the health expert (e.g., the doctor, nurse, psychologist, etc), so that they can know how the patient feels in real time (Stinson, 2009). Another benefit is that cheating is not possible because the time and the date of the data collection is recorded by the phone, preventing the patient from filling in the assessment *a posteriori* and, consequently, avoiding memory biases. Completing an electronic portable diary is less of a chore than completing a paper-based diary, and the fact that alarms can be set to remind them leads to higher completion rates (Junker et al., 2008; Morren, van Dulmen, Ouwerkerk & Bensing, 2009).

Although this is a relatively new research field, mHealth has already been satisfactorily used to assess adults and children with different kinds of pain (Vardeh, Edwards, Jamison & Eccleston, 2013): for example, cancer-related pain (Stinson et al., 2013), sickle cell disease (Jacob, Duran, Stinson, Lewis & Zeltzer, 2013) or headaches (Allena, Cuzzoni, Tassorelli, Nappi & Antonaci, 2012). For example, Stinson et al. (2013) developed a game-like diary for pain and cancer-related symptoms, medication intake, and other physical and psychological pain management strategies. Participants showed high

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compliance rates (mean 81%, SD 22%) and users rated the app as "likeable, easy to use, and not bothersome to complete".

1.2.6 Pain treatment using mobile devices

Although internet interventions for pain have proved to be promising (Bender et al., 2011), validated mHealth interventions aiming to change behaviors are still scarce (de la Vega & Miró, 2014). Some things suggest that developing this kind of intervention could improve the quality of life of those in pain. As mentioned above, patients could have such advantages as being able to contact a specialist without having to travel (saving time and money), improving treatment adherence, or making follow up and feedback easier. Moreover, those who have difficulty in accessing healthcare resources can find a way of receiving treatment (e.g. those with low incomes (TrustLaw Connect, 2013) and those living in remote places (West, 2012)). All this results in better treatment outcomes.

1.3 Usability

1.3.1 The concept of usability

Usability is defined as "the effectiveness, efficiency and satisfaction with which specific users can achieve a specific set of tasks in a particular environment" (Schoeffel, 2003, pp. 6–7). An essential first step before

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MHEALTH: A NEW AND COMPLEMENTARY WAY TO HELP YOUNG PEOPLE WITH PAIN. STATE OF THE ART, DEVELOPMENT,
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analyzing the efficacy of an mHealth intervention is to test its usability. By testing usability, it can be ensured that the targeted users of the application understand, like and use it easily.

1.3.2 Usability testing of Smartphone applications

Testing the usability of Smartphone applications is somewhat different from the classic usability testing tasks designed to test computer programs or Webpages. The different screen sizes, the possibilities that Smartphones offer (e.g. they can be taken from one place to another), the tactile function of the screen and other differences make it necessary to adapt the process.

Some studies have followed this process to test the usability of pain-related electronic diaries or applications: for example, arthritis (Stinson et al., 2006), pain in general (Johnson, Luckmann & Vidal, 2010), cancer (Stinson et al., 2013), and sickle cell disease (Jacob et al., 2012). They all needed two or three iterative cycles to refine their apps, demonstrating that the participation of the end-user in this process is necessary.

——————————————— Objectives ———————————————

2. Objectives

This doctoral dissertation explores how mHealth can help young people with pain. To do so, three main objectives were set.

2.1 Objective 1

To learn about the current state of development of mHealth in the area of pain, and in particular the number and quality of pain-related apps reported in scientific studies, and the ones available in commercial app shops. To do so, a systematic review was conducted and is presented in Study1.

2.2 Objective 2

To develop and test an app to help assess pain intensity. This app (*Painometer*) includes four widely used and validated scales. The process is described in Study II.

2.3 Objective 3

To develop and test a treatment app for Juvenile Fibromyalgia Syndrome or chronic widespread pain: *Fibroline*. The process is described in Study III.

3. Methods

Three studies were conducted and are presented in this dissertation: a systematic review of mHealth apps (Study I), and the development and testing of *Painometer* (Study II) and *Fibroline* (Study III), two pain-related apps. The methods of each of the studies are only briefly described in this section as they are reported in full in each of the articles in this dissertation.

3.1 Participants

The first study (de la Vega & Miró, 2014) is a systematic review of the literature and the application shops. A systematic review was conducted of the pain-related apps available in scientific databases (Medline, Web of Science, Gale, Psycinfo, etc.) and the main application shops (App Store, Blackberry App World, Google Play, Nokia Store, and Windows Phone Store). Only applications (designed for both patients and clinicians) focusing on pain education, assessment and treatment were included.

For the second study (de la Vega et al., 2014), participants tested *Painometer* in two usability cycles. For this kind of design, a minimum of five participants is needed for each user type and usability cycle (Nielsen, 2000). We recruited two samples of participants: a sample of healthcare

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professionals who could use the app to assess someone else's pain intensity, and a group of young people who could use the app to assess their own pain intensity. A sample of 24 health professionals (53% women) including nurses, doctors, and psychologists, and a sample of 30 children, adolescents, and young adults (62% women) participated in the study.

The same design was implemented in Study III (de la Vega, Roset, Galán & Miró, *under review*). That is, a usability testing protocol with iterative cycles was conducted. This time a sample of potential end users was recruited to test *Fibroline* in two cycles. A total of 25 adolescents, and young adults (68% women) participated in the study. Finally, a chronic pain female patient tested the app.

3.2 Procedure

For the systematic review (Study I) the PRISMA protocol (Moher, Liberati, Tetzlaff & Altman, 2009) was followed to report on papers that had been published about pain-related mHealth apps, and for the apps of this kind available in the main shops (i.e. App Store, Google Play, Windows Phone Store, Blackberry World and Nokia Store). A step-by-step sequential analysis was made to compare both results. A more detailed explanation of the procedure can be found in the paper (de la Vega & Miró, 2014).

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The procedure in Studies II and III was identical. A usability protocol with iterative cycles was implemented to test and refine the apps *Painometer* (Study II) and *Fibroline* (Study III). Standardized instructions on how to use the apps were given to the participants, and they were asked to use them and to perform a series of tasks while thinking aloud. Field notes were taken and transcribed into text format. The mistakes made by participants were recorded. Finally, they were interviewed about their experience. At the end of each cycle, the suggested modifications were implemented in the app. The process stopped when all the previous problems were solved and no new problems arose. The full procedure is described in the articles (de la Vega et al., 2014, *under review*).

3.3 Measures

In the systematic review (Study I) no measure was needed. Nevertheless, a series of features were reported for the apps. That is, for each app found in the scientific databases, we reported the author and year of the paper, the app name (when available), the domains covered (e.g. pain intensity, location, sleep quality, mood), the pain problem (e.g. headache, arthritis), the targeted population (e.g. healthcare professionals, adult patients, adolescents), the language/s of the app, the reported properties (e.g. compliance, usability, reliability of the scores obtained), and the device/s which the app was compatible with. For each app found in the stores we

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reported its name, its language/s and its developer. Of these, for the ones that showed some kind of support we reported the name, developer, country, kind of support (e.g. created by a licensed healthcare professional, recommended by a patient association), pain problem, features (e.g. information, social support, monitoring, diagnosis), platform (e.g. Android, iOS), price (in euros and dollars), language/s, user rating (when available), and the description as provided by the developers.

In Studies II and III we administered a series of open-ended questions that had been developed *ad hoc* using the procedure described by Stinson et al. (Stinson et al., 2006). After completing the requested activities with the apps, all participants were asked a number of open-ended questions about the ease of use, efficiency, and their satisfaction using the apps (i.e. *Painometer* in Study II, and *Fibroline* in Study III). They also responded to a use-of-technology questionnaire adapted from the one developed by the Society for Technical Communication "Usability and User Experience Resources" (Society for Technical Communication, n.d.).

4. Results

In this section, the three studies included in the dissertation are presented:

- **Study I.** de la Vega R, Miró J. mHealth: A Strategic Field without a Solid Scientific Soul. A Systematic Review of Pain-Related Apps. PLoS One; 2014 Jan;9(7):e101312.

- **Study II.** de la Vega R, Roset R, Castarlenas E, Sánchez-Rodríguez E, Solé E, Miró J. Development and testing of Painometer: a Smartphone app to assess pain intensity. J Pain; 2014, 15(10), 1001-1007.

- **Study III.** de la Vega R, Roset R, Galán S, Miró J. Fibroline: a smartphone delivered treatment for young people with fibromyalgia or chronic widespread pain. *Under review.*

———————————————— Results ————————————————

4.1 Study I

mHealth: A Strategic Field without a Solid Scientific Soul. A

Systematic Review of Pain-Related Apps

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PLOS ONE

mHealth: A Strategic Field without a Solid Scientific Soul. A Systematic Review of Pain-Related Apps

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Abstract

Background: Mobile health (mHealth) has undergone exponential growth in recent years. Patients and healthcare professionals are increasingly using health-related applications, at the same time as concerns about ethical issues, bias, conflicts of interest and privacy are emerging. The general aim of this paper is to provide an overview of the current state of development of mHealth.

Methods and Findings: To exemplify the issues, we made a systematic review of the pain-related apps available in scientific databases (Medline, Web of Science, Gale, Psycinfo, etc.) and the main application shops (App Store, Blackberry App World, Google Play, Nokia Store and Windows Phone Store). Only applications (designed for both patients and clinicians) focused on pain education, assessment and treatment were included. Of the 47 papers published on 34 apps in scientific databases, none were available in the app shops. A total of 283 pain-related apps were found in the five shops searched, but no articles have been published on these apps. The main limitation of this review is that we did not look at all stores in all countries.

Conclusions: There is a huge gap between the scientific and commercial faces of mHealth. Specific efforts are needed to facilitate knowledge translation and regulate commercial health-related apps.

Introduction

Healthcare systems worldwide are becoming exhausted; many demands are placed on them but resources are scarce. Healthcare costs are escalating and our public health systems seem to be incapable of satisfying the needs of a fast growing population [1]. In this scenario, what is known as mobile health technology or "mHealth" – that is, healthcare supported by mobile communication technologies – has undergone exponential growth in the last few years.

Mobile health technology can make healthcare more accessible and affordable for all. It has proven to be a good way of delivering high-quality healthcare services to a variety of patient populations, particularly those with low incomes [2] and in remote places (far from reference centers) [3]. mHealth technology has also proven to be highly suitable for young people (and also very popular) [4] as they spend more time using electronic media than doing any other activity besides sleeping [5].

It has been estimated that by the end of 2016, there will be ten billion mobile devices in use around the world [3]. Patients and healthcare professionals are increasingly using health-related applications [6]. To date, more than 97,000 of these applications have been developed and in the next few years more than three million free and 300,000 paid downloads are expected to be made of mHealth applications just in the USA [7]. A recent study

concluded that the Smartphone is the most popular technology among physicians since the stethoscope [1]. Furthermore, mobile phone use seems to be greater among those populations most in need of such interventions [8]. mHealth seems to be a logical, acceptable, and affordable way to extend and improve health care.

Although the progress of mHealth has many advantages, some of which have been summarized above, this extremely fast growth also has a negative side: namely, most of the procedures available have not been subject to a thorough assessment and validation [9,10]. Explicit and sensible concerns about ethical issues, bias, conflicts of interest [11], and security and privacy problems [2] have been raised in the specialized literature.

Some action protocols and strategies are being developed to deal with these as yet unsolved issues in Europe [12,13] and the USA [14,15]. For example, the World Health Organization in partnership with the United Nations specialized agency for information and communication technologies has developed an initiative regarding the management of Non-Communicable Diseases using mHealth [16]. Also, some charities, and not-for-profit or private organizations have launched initiatives to boost the potentialities of mHealth. This is the case, for example, of the mHealth Alliance, hosted by the United Nations Foundation [17]. Similarly, PatientView has recently released the web page "myhealthapps.net", recommended by the Directorate General for Communications Networks, Content and Technology of the

European Commission. This web page is an evolution of the previously published "European Directory of Health Apps" [18], in which patients' associations from all over the world used a zero-to-five Likert-type scale to rate 307 health-related apps on the extent to which they help control their condition, keep them healthy, are trustworthy, are easy to use, allow them to network with people like them/who understand them, and can be used regularly. In the context in which we find ourselves, then, commercial apps are developing exponentially, while mHealth-related scientific publications are also growing. However, it is not clear that both worlds interact and, if they do, how. That is to say, is the growth rampant, or is there fruitful interaction between the two worlds? Are research findings translated and used to improve the apps that are created or are knowledge transfer processes failing?

In this situation, it would be extremely useful if a review were to map out the terrain, identify problems and tentatively suggest avenues for improvement.

However, the field of mHealth is so wide that a complete review and analysis cannot be contemplated. Therefore, we decided to focus on pain-related apps as a way of managing an otherwise insurmountable amount of information. First, although mHealth uses various alternatives and technologies to educate patients, and to prevent and/or treat illness, apps are at the heart of the process. Two specific features of apps make it particularly important for their quality and scientific rigor to be studied: namely, (1) the app is available to consumers who do not have a professional to recommend, prescribe or even monitor how they use it, and (2) too often there is nobody "responsible" and available if the app is not working as expected or if something goes wrong. Second, we decided to concentrate on pain-related apps because pain is one of the most generalized symptoms of chronic health conditions [19]. It is a ubiquitous health problem, and well suited to be assessed and managed with these mHealth interventions [20–22]. So it can be readily used to explore and exemplify the issues when looking into the current state of development of mHealth.

The general aim of this paper is to provide an overview of the current state of development of mHealth. In order to do so, and to exemplify the issues, we conducted a systematic review of the pain-related apps available and reported on their characteristics; we looked both at the commercial and the scientific aspects of this development. The specific objectives of our review are to: (1) detect the number of pain-related apps reported in scientific databases, (2) find out which ones are available at the stores for general consumers, (3) identify which pain-related apps are available at the main apps shops, (4) find out which of these apps are scientifically supported, and (5) uncover any other additional support that the apps may have.

Our specific hypotheses were that (1) only a few of the apps reported in peer-reviewed publications are available to the consumer, and (2) of the apps available in the shops, very few have a scientific base.

Methods

Phase I: what can be found in scientific databases?

Search strategy and selection criteria. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [23] were followed. Data for this review were identified by searches of following scientific databases: Medline (National Library of Medicine), Science Citation Index Expanded (Web of Science), Health Reference Center Academic (Gale), Wiley Online Library, American Psychological Association (Psycinfo), SciVerse ScienceDirect (Elsevier), SpringerLink, Wolters Kluwer - Ovid -

Lippincott Williams & Wilkins (CrossRef), Directory of Open Access Journals (DOAJ), Social Sciences Citation Index (Web of Science), Taylor & Francis Online - Journals, Expert Reviews (Future Science), Informa - Informa Healthcare (CrossRef), SpringerLink Open Access, Wolters Kluwer - Ovid (CrossRef), BMJ Journals, DiVA - Academic Archive Online, Informa (CrossRef), and references from relevant articles using the search terms (Pain OR *ache) AND (Smartphone OR app OR application OR electronic OR "Personal Digital Assistant" OR PDA). Only peer-reviewed articles published in English or Spanish between 1996 (the release date of the first palmtop computer [24]) and December 2013 were included.

Phase II: what scientifically assessed pain-related apps are available in the stores?

The name of each app retrieved in phase I was searched for in each of the following shops: App Store (iPhone), Blackberry App World, Google Play (Android), Nokia Store and Windows Phone Store.

Phase III: what can be found in the stores?

In December 2013, the main Smartphone application shops were reviewed: App Store (iPhone), Blackberry App World, Google Play (Android), Nokia Store and Windows Phone Store. The review was conducted in the following countries: Canada, Spain, and USA. The search terms were: "Pain", "*ache" and "dolor". The applications (designed for both patients and clinicians) focused on pain education, assessment and treatment were included.

Phase IV: what support do the apps available in stores have?

A step-by-step sequential strategy was followed to assess the quality of the apps found in phase III. First, the name of each app was searched for in the same databases as in Phase I. Then, the web page "myhealthapps.net" was also reviewed. All the pain-related apps were recorded. Finally, the name of each app was Google searched for such information as whether the developers had a webpage, which research centers used the app, who its creators were and/or the results it had provided, etc. This information was compared with the information obtained in phase I to see if the authors of the apps were the same as the authors of the publications.

Results

Phase I: what can be found in scientific databases?

After reviewing the databases, we found 47 papers reporting on 34 pain-related apps. Figure 1 describes our study's selection process.

As can be seen in Table 1, all apps are related to assessment, and almost all are available in English (26, 76.5%) and address non-specific chronic pain problems (28, 82.4%). About two-thirds are designed for adults (22, 64.7%).

Phase II: are the scientifically assessed apps available in the stores?

No pain-related app reported in any paper found during Phase I was available in any of the five main shops for the general public.
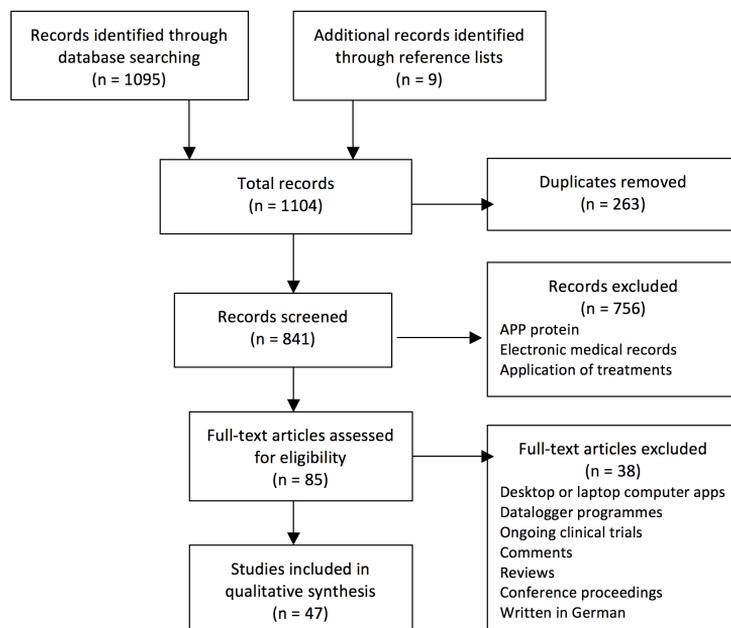
Figure 1. Flow chart of our systematic review selection process.
doi:10.1371/journal.pone.0101312.g001

Phase III: what can be found in the stores?

A total of 283 pain-related apps were found in the five shops searched. Because of word count and space limitations, the full list is provided as an annex to the article (see Table S1).

Phase IV: what type of support do the pain-related apps available in stores have?

When we searched for these 283 apps in the scientific databases, we did not find a single article that was related to them in any way. Therefore, this search found no evidence of scientific support for the 283 pain-related apps. Nevertheless, some apps do have other support types. Figure 2 describes our app selection process.

A full description of 40 apps – including name, developers, supports, pain problem it addresses, features, platform, price, language/s and user ratings – is provided as an annex to the article (see Table S2). Figure 3 summarizes the type of support that the pain-related apps have.

Most of the apps are available in English (36, 90%), and have been developed in the USA (16, 40%), the EU (15, 37.5%), or Canada (6, 15%). The App Store and Google Play are the most important platforms, hosting 39 (97.5%) of the supported apps. The most important sources of support to these apps are: having a licensed professional as a creator (24, 62.5%) or being recommended by a patient association (12, 30%). "Pain in general" (9, 22·5%), followed by back pain (8, 20%), headache (7, 17.5%) and arthritis (6, 15%), are the types of pain that these apps are most commonly designed for. As far as the targeted consumers are concerned, most of the apps are addressed to patients (28, 70%) and only a few have been developed for healthcare professionals

(5, 12.5%) or both audiences (7, 17.5%). Most patient-oriented apps provide information about the pain problem/illness and ways to check symptoms and track medication consumption. Only a few provide information about alternative ways of coping with the health problem either through videos or written instructions, for example, about exercising, massage, or even hypnosis. Professional-oriented apps provide support for diagnosis, medication dose calculation, or self-report questionnaires. All patient-oriented applications are classified as +4 years or "low maturity", while professional-oriented are classified as +17 years.

None of the authors/developers of the apps were found to be the authors of articles about them.

Discussion

Overall, this review indicates that the commercial and scientific sides of the mHealth coin do not interact properly. We found that pain-related apps that have been reported in scientific journals have not yet made their way into the shops and are therefore unavailable to clinicians and/or patients. Conversely, 283 pain-related apps were available in the main shops, but none of them had been scientifically validated or proven to be effective. These findings are in line with our hypotheses but the situation is even more extreme than we had imagined. However, it may be just a matter of time before this state of affairs changes because some apps are currently in the last stages of the knowledge translation process. For example, *Painometer V2*, an app developed to help with the assessment of pain intensity is already available in Google Play and has shown some evidence of usability [72,73] and of the psychometric properties of the scales contained [74]. Pain Squad is

Pain-Related Apps

Table 1. Apps reported on the scientific databases.

Author/s and year	App name	Domains	Pain problem	Targeted population	Language/s	App properties	Device
Aaron et al., 2005, 2006 [25,26] Turner et al., 2005 [27]	Not reported	Pain intensity, pain-related activity interference, jaw use limitation and pain-coping strategies (cognitive coping, relaxation, activity reduction, and emotional support).	Chronic temporo-mandibular pain	Adults	English	Reliability (Cronbach's α range, 0.64 to 0.88) and validity were demonstrated for all the scales.	PDA
Affleck et al., 1996 [28]	Not reported	Sleep quality, pain intensity, and attention to pain.	Fibromyalgia	Adults	English	Not reported	PDA
Allena et al, 2012 [29]	Not reported	Sleep time, presence of aura symptoms, Pain: time onset, intensity, side, type, presence of associated symptoms, medication use, and trigger factors.	Headaches	Adults	The study was conducted in Italy but a figure shows an English written diary	Easy to understand and to use. 98% completion rate.	PDA
Alfvén et al; 2010 [30]	SMS-pain-diary	Pain intensity, pain duration, and functional impairment.	Chronic pain	Children and adolescents (9–15 years old)	Norwegian	High construct validity (concordance of 0.77) High test-retest reliability (K=0.73) Compliance: 75–83% Acceptability: easy to understand and use.	SMS-delivered diary
Chen et al., 2004 [31]	Not reported	PDA-based data management system	Acute Pain	Staff of an Acute Pain Service	English	User satisfaction, ease of access to drug reference and clinical guidelines were similar between the PDA and paper systems.	PDA
Connelly et al., 2010 [32]	Not reported	Headaches: occurrence, duration, and intensity. Child negative affect (PANAS-C) Weather variables	Headaches	Children and adolescents	English	80% completion rate	PDA
Connelly et al., 2010[a], 2012 [33,34]	Not reported	Assessment of: pain characteristics, activity limitations (Activity Scale for Kids), intensity of positive and negative emotions (PANAS-C) and emotion management (Children's Emotion Management Scale).	Juvenile Idiopathic Arthritis	Adolescents (8–18 years old)	English	Rates of compliance: 41% to 100% Electronic version of the "Activity Scale for Kids" showed strong internal consistency (Cronbach's α=0.88–0.94)	Smartphone's screen optimized e-diary, not properly an app itself.
Evans et al., 2007 [35]	Not reported	Pain data: Gracely pain scale, study medication dosing, rescue medication use and sleep quality.	HIV-associated sensory neuropathies (HIV-SN)	Adults	English	90% completion rate.	PDA
Gaertner et al., 2004 [36]	Not reported	MIDOS for pain and symptom assessment.	Cancer and non-cancer chronic pain	Adults	English	No significant difference with paper diary on pain and symptom intensity. It was used more frequently. Good patient satisfaction.	PDA

Pain-Related Apps

Table 1. Cont.

Author/s and year	App name	Domains	Pain problem	Targeted population	Language/s	App properties	Device
Ghinea et al., 2008 [37]	Not reported	Pain location, type (numbness, pain, pins and needles, and ache) and intensity using a 3D mannequin, time of input.	Back pain	Adults	English	Good acceptability and usability results in clinicians and patients. Finer division of the body mannequin suggested.	PDA
Goldberg et al., 2007 [38]	Not reported	Presence of headache symptoms, pain intensity, localization and quality, related symptoms, interference and premenstrual symptoms.	Menstrually related headache	Adult females	English	Difficulties with the PDA were encountered. 35% of abnormal session endings.	PDA
Goldstein et al., 2003 [39]	Not reported	Postoperative pain measured by the number of pills taken and patient return to work.	Hernia	Adults	English	Not reported	PDA
Gulur et al., 2009 [40]	CFS	Pain intensity and mood state.	Acute pain	Children and adolescents (3–17 years old)	English	Good feasibility: children were able to use the CFS. Adequate test-retest reliability for both pain ($r_1 = 0.77$, $r_2 = 0.80$) and mood ($r_2 = 0.82$). High concurrent validity ($r_5 = -0.68$) Adequate discriminant validity ($r = 0.55$) 77% of children preferred the CFS to the WBFS.	PDA
Heiberg et al., 2007 [41]	Not reported	VAS for pain, fatigue, and global disease; the Rheumatoid Arthritis Disease Activity Index; the Short Form 36 and Modified Health Assessment Questionnaire	Rheumatoid arthritis	Adults	Norwegian	The average scores and measures of variation did not differ significantly between PDA and paper diaries. The completion was similar. 82.9% preferred using PDA.	PDA
Jacob et al., 2012, [42] 2013 [43]	Not reported	Assessment of symptoms, pain intensity, medication, non-pharmacological strategies, sleep, feelings/thoughts, fluids and healthcare use.	Sickle cell disease	Children and adolescents (10–17 years old)	English	Allows accurate symptom assessment. It is easy to use and efficient to complete.	Smartphone's screen optimized e-diary, not properly an app itself.
Jamison et al., 2002 [44]	Electronic VAS	Assessment of pain intensity (VAS).	Healthy volunteers	Adults	English	High correlations between electronic VAS and paper VAS scores for both cognitive (verbal intensity) and sensory (weight) stimuli ($r = 0.91$).	PDA
Jamison et al., 2001, [45] 2006 [46]	Not reported	Pain, mood, activity, medication, and side effects.	Chronic low-back pain	Adults	English	High degree of agreement between electronic diary and telephone-collected data.	PDA
Jibb et al., 2012 [47] Stinson et al., 2013 [48]	Pain Squad	Assessment of pain and cancer-related symptoms.	Cancer	Children and adolescents (8–18 years old)	English	Good usability and feasibility results High rates of compliance (81%)	iPhone

Pain-Related Apps

Table 1. Cont.

Author/s and year	App name	Domains	Pain problem	Targeted population	Language/s	App properties	Device
Johnson et al., 2010 [49]	EPTAD	Assessment of routine pain, acute pain episode, routine medication and non-medication treatment, sleep.	Non-cancer chronic pain	Adults	English	Poor usability results: screen and font size were found acceptable but navigation problems were found.	PDA
Junker et al., 2008 [50]	Electronic version of VAS and the pain DETECT questionnaire	Pain severity: average and worst over the last 2 weeks, present and symptoms of nociceptive pain (painDETECT).	Chronic pain	Adults	English	High correlations between electronic and paper measures.	PDA
Kristjánsdóttir et al., 2011, [51] 2013 [52,53]	Not reported	Diaries and daily situational feedback	Chronic widespread pain	Adults	Norwegian	Moderate improvements in catastrophizing and acceptance. Moderate rates of compliance (66.7%)	Smartphone's screen optimized website, and some audio files included in a Smartphone.
Lewandowski et al., 2009 [54]	Not reported	Pain intensity, pain location, activity restriction, and depression.	Chronic pain	Children and adolescents (8–16 years old)	English	Greater compliance (98%) with the electronic format (mean of 6.89 days completed) in contrast to the paper format (mean of 4.97 days completed)	PDA
Marceau et al., 2010 [55]	Electronic version of BPI, PCS, ODI, CES-D	Assessment of pain history, intensity, location, interference with daily activities, and mood (BPI); rumination, magnification, and helplessness (PCS); disability (ODI); depression (CES-D).	Non-cancer chronic pain	Adults	English	All the patients were able to complete the diaries. Good acceptance rates by both patients and doctors.	PDA
McClellan et al., 2009 [56]	Daily Pain and Activity Diary	Pain location and severity, sleep quality, functional activities, use of medication, and coping skills.	Chronic pain	Children and adolescents (8–20 years old)	English	Usability and feasibility: High daily diary completion (no incomplete data, 100% of items completed) Both parents and children rated the diaries as easy to use.	PDA
Palermo et al., 2004 [57]	Not reported	Pain and distress ratings (occurrence, location, intensity, duration, and emotional upset), somatic symptoms, and activity limitations.	Headaches and Juvenile Idiopathic Arthritis	Children and adolescents (8–16 years old)	English	Greater compliance compared with a paper diary (83.3% vs. 46.7%) Greater accuracy compared with a paper diary (100% vs. 51.3%) No differences in acceptability depending on the diary format.	PDA
Peters et al., 2000 [58]	Not reported	MPI (pain severity, interference of pain, affective distress, social support as well as punishing, solicitous and distracting responses to the pain problem by the spouse), the SF-36 (physical functioning, role functioning, vitality) and CSQ (catastrophizing, denying/ignoring pain, positive self-talk and diverting attention), sleep quality, sickness leave, medication and satisfaction with role functioning.	Unexplained pain	Adults	Dutch	88% completion rate. MPI scales with equivalent diary items (range: r=0.33–0.53). SF-36 and the diary correlated highly (r=0.73). CSQ and the diary: catastrophizing (r=0.66), diverting attention and ignoring/denying pain (r=0.41). No evidence of instrument reactivity was found.	PDA

Pain-Related Apps

Table 1. Cont.

Author/s and year	App name	Domains	Pain problem	Targeted population	Language/s	App properties	Device
Roelofs et al., 2004, [59] 2006 [60]	Not reported	Current pain intensity, attention to pain, passive attention to pain, additional questions (not specified).	Chronic low-back pain	Adults	English	72.7% completion rate.	PDA
Sorbi et al., 2006 [61,62]	Not reported	Pain intensity, fear-avoidance, cognitive and spousal solicitous, and punishing pain responses.	Chronic pain	Adults	Dutch	A pilot study in 4 patients: feasibility and patient acceptability. 86–93% completion rate.	PDA
Sorbi et al., 2007 [63] Kleiboer et al., 2009 [64]	Not reported	Migraine headache, medication use, attack precursors, self-relaxation and other preventive behavior, menstruation, and disturbed sleep.	Migraine headache	Adult females	Dutch	Feasibility: minimal technical problems, good compliance, and successful execution. Acceptability: positive participant responses concerning usefulness, supportiveness, and low burden.	PDA
Stinson et al., 2006, [65] 2008 [66,67]	e-Ouch electronic diary	Pain intensity, number of painful joints, number of word descriptors, pain unpleasantness, interference (e.g. activities, mood, sleep), stiffness and tiredness, control over pain.	Arthritis	Children and adolescents (8–18 years old)	English	Good usability, feasibility, validity and sensitivity to change properties.	PDA
Stone et al., 2003 [68]	Not reported	Pain: intensity (rated on a 100-point VAS), sensory characteristics, affective responses, and degree that activities were limited by pain. Additional questions about place, activity, and mood.	Chronic pain	Adults	English	94% completion rate. Little difficulty and burden with the diary was reported.	PDA
VanDenKerkhof et al., 2003 [69]	Not reported	Standard pain scoring systems vand an extensive list of drug-related side effects.	Acute Pain	Staff of an Acute Pain Management Service	English	PDA assessments were more likely to report pain and side effects. The median time of the assessment was 53 sec longer using the PDA but the median time of the full visit was 74 sec shorter.	PDA
Walker et al.; 2002 [70]	Not reported	Gastrointestinal symptoms: abdominal discomfort, bowel dysfunction, extent of discomfort, frequency of bowel movements, and stool consistency.	Gastrointestinal pain	Children (6–10 years old)	English	Usability Easy to learn, quick to use and understand. No interference with family activities. Children needed little assistance in answering the questions. Feasibility Accuracy: Responses were "very accurate" or "accurate". High level of satisfaction. Compliance: 100% (no missing data).	PDA

Table 1. Cont.

Author/s and year	App name	Domains	Pain problem	Targeted population	Language/s	App properties	Device
Wood et al., 2011 [71]	Electronic version of FPS-R	Assessment of pain intensity (FPS-R).	Postoperative disease-related pain	Children (4–12 years old)	Pictures	High agreement (K = 0.85) and high correlation (r = 0.91) between electronic and paper versions. No mean difference between the two versions (3.1±2.3 for paper and 3.2±2.3 for electronic version). The electronic version was preferred by 87.4% of the children.	PDA

^aIt is an earlier version, slightly different from the final version.
PDA: Personal Digital Assistant; SMS: Short message service; PANAS-C: Child version of the Positive and Negative Affective Schedule; MIDOS: minimal documentation system; CFS: Computer Faces Scale; WBFS: Won Baker Faces Scale. VAS: Visual Analogue Scale; EPTAD: Electronic pain treatment activity diary; BPI: Brief Pain Inventory; PCS: Pain Catastrophizing Scale; ODI: Oswestry Disability Index, CES-D: Center for Epidemiologic Studies-Depression Scale; MPI: Multidimensional Pain Inventory; CSQ: Coping Strategy Questionnaire; FPS-R: Faces Pain Scale – Revised.
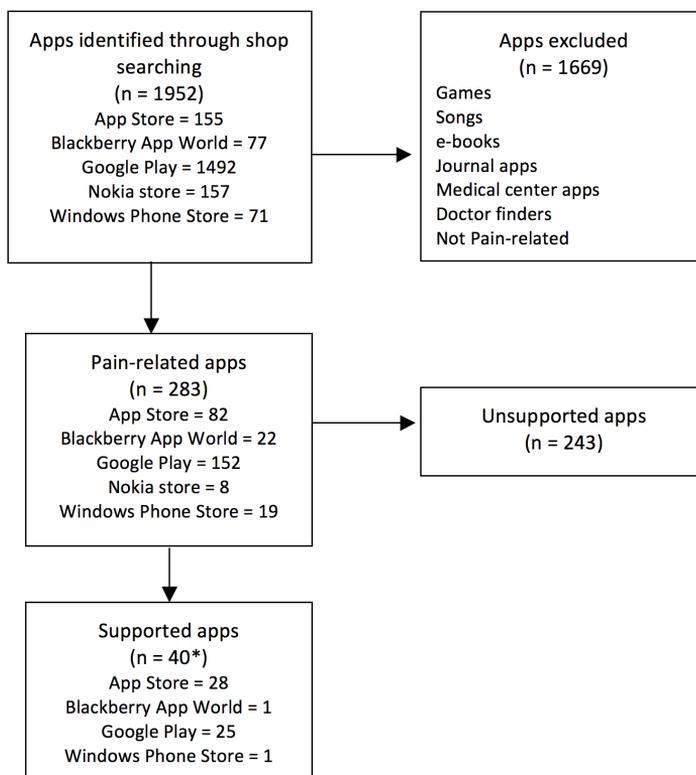doi:10.1371/journal.pone.0101312.t001

another app that has already reported information on usability, feasibility, and compliance [47,48]. It is currently available in four Canadian hospitals and may be available soon at the App Store [75].

mHealth technologies have numerous important advantages over other more traditional alternatives. For example, they capture time- and date-stamped information, and provide detailed and non-biased information on such fundamental health-related variables as physical activity or physiological responses, thus reducing memory bias. They can also be extremely useful in public health actions (for example, by providing routes to help patients who have to take medications on a specific schedule) and help us reach underserved populations, those that are most in need of health care support.

In the midst of this *huge*, positive development there are some fundamental concerns that require appropriate responses. For example, issues of confidentiality or the protection of patients' personal data still have to be dealt with. Furthermore, some apps occupy a "legal void". For example, electronic diaries or cognitive-behavioral treatments for health conditions are unregulated, a situation that needs to be remedied. Overall, the results of this review indicate that consumers run some risks above and beyond paying for a potentially useless app. For example, we found some apps that claimed they could heal the body by emitting vibrations, "brain waves", or accessing the subconscious to "tell the body to heal". These unproven claims may lead patients to a feeling of helplessness and lack of control about their illnesses.

As mentioned above, there is a gap between the scientific and the commercial sides of the mHealth coin. Significant developments have been made in both areas but they remain essentially disconnected, advancing in parallel with no significant interaction. None of the apps in the shops have proved to have scientific support and only a fifth (57, 40+17 versions for other platforms, 20.1%) of them have some type of support. Some scientifically developed apps look promising but there is an urgent need to promote actions for knowledge translation in this field. Other researchers have found similar results when looking into other mHealth areas: apps to manage diabetes [76] and the world deadliest diseases [77]. They both found that the commercial area was significantly more developed than the research field. Referring to cardiology apps [78], they found that most of the published papers reviewed monitoring apps, but similarly to our findings, the majority was not smartphone apps themselves but computers apps that could be also used by a mobile phone or a smartphone.

In the near future, perhaps, physicians will be prescribing specific applications to specific patients for specific problems [79] (very much like today when they electronically prescribe medications, or work with the patient's electronic clinical history system and health records). It does not make much sense for drugs to have to go through a long and complex process between the discovery of the active ingredient and being put on the market, while apps do not have to fulfill any requirements at all, not even show that they are effective and safe. There may be no need for health-related apps to go to the extremes of approved drugs, but a minimum level of quality should be compulsory. Health-related apps can also have negative effects. Therefore, we should be able to regulate what is available in stores, and prevent unregulated apps from being published in the field of health (health-related apps should inform about quality controls and prove they are efficacious before they can use the adjective health, in the same way that current laws prevent food from bearing the name "bio" if their real properties have not been subject to strict analysis). Furthermore, lists of approved health-related apps ought to be published and the general public informed, for example, through

Pain-Related Apps

* 16 of the 40 apps have an Android and iPhone version; one has a Blackberry and iPhone version.

Figure 2. Flow chart of pain-related apps selection process.
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an app-related vade-mecum, so that both health experts and patients can make informed decisions about whether to use certain apps. A promising avenue that would prove fruitful in the near future is the work done by Public Agencies in the field of quality distinctions, for example, the "AppSaludable Distinctive", reported in the last European Journal of e-practice [80] To date, and to the best of our knowledge, no pain-related app has been awarded this quality stamp and just one (*Painometer v2*) has applied for it [81].

Perhaps the most important limitation of this review is that we did not look at all stores in all countries. We selected three of the possibilities, not only because it was convenient, but also because it was what could be feasibly done. Our hypothesis is that if we had conducted specific reviews for the 97,000 health-related apps available worldwide, results would not have been much different, particularly considering that we explored the most important app stores and that other researchers [76–78] found similar results.

All the articles reviewed were related to pain assessment, with some dealing with educational issues. Future studies are needed in the area of pain management. We are aware that some research groups are working on this subject, so we can expect developments
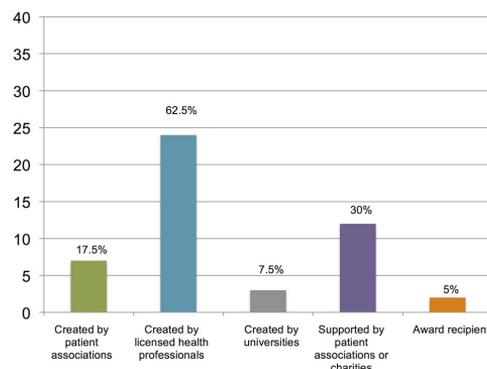

Figure 3. Type of support that the pain-related apps have.
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in the future. Most apps are designed for adults or adolescents, but there are very few for children. However, children are using these technologies at a very early age: 72% of children younger than eight years old use mobile devices and 50% of those use apps [82]. Therefore, additional research is greatly needed in this area if health-related apps are to be developed that are efficacious and developmentally appropriate.

Supporting Information

Table S1 Pain apps available in the main five shops.
(DOCX)

Table S2 Characteristics of the commercial apps that have some sort of support.
(DOCX)

Protocol S1 Protocol for the systematic review.
(DOCX)

Checklist S1 PRISMA Checklist.
(DOC)

Author Contributions

Conceived and designed the experiments: RdlV JM. Analyzed the data: RdlV JM. Wrote the paper: RdlV JM.

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MHEALTH: A NEW AND COMPLEMENTARY WAY TO HELP YOUNG PEOPLE WITH PAIN. STATE OF THE ART, DEVELOPMENT,
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Results

4.2 Study II

Development and testing of Painometer: a Smartphone app to

assess pain intensity

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Development and Testing of Painometer: A Smartphone App to Assess Pain Intensity

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Abstract: Electronic and information technologies are increasingly being used to assess pain. This study aims to 1) introduce Painometer, a smartphone app that helps users to assess pain intensity, and 2) report on its usability (ie, user performance and satisfaction) and acceptability (ie, the willingness to use it) when it is made available to health care professionals and nonprofessionals. Painometer includes 4 well-known pain intensity scales: the Faces Pain Scale–Revised, the numerical rating scale–11, the Coloured Analogue Scale, and the visual analog scale. Scores reported with these scales, when used in their traditional format, have shown to be valid and reliable. The app was tested in a sample of 24 health care professionals and 30 nonprofessionals. Two iterative usability cycles were conducted with a qualitative usability testing approach and a semistructured interview. The participants had an average of 10 years' experience in using computers. The domains measured were ease of use, errors in usage, most popular characteristics, suggested changes, and acceptability. Adding instructions and changing format and layout details solved the usability problems reported in cycle 1. No further problems were reported in cycle 2. Painometer has been found to be a useful, user-friendly app that may help to improve the accuracy of pain intensity assessment.

Perspective: Painometer, a smartphone app to assess pain intensity, shows good usability and acceptability properties when used by health care professionals and nonprofessionals.

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Key words: Pain intensity, assessment, mobile app, smartphone, usability testing.

Over the last 2 decades, significant advances have been made in the assessment of pediatric pain. One important development has been the integration of electronic and information technologies (EITs), particularly web-based systems and mobile handheld devices. EITs have a number of advantages when assessing pain in young people, such as greater accessibility,[8,9] improved compliance,[1,7] and minimization of

recall bias because data are collected in real time.[22] Children report greater satisfaction with[21-23] and preference for these EIT-based devices than the traditional paper-and-pencil format.[3,4,26] Generally speaking, available studies show that children learn easily[25] and have no difficulties using these EIT-based devices.[15]

Nowadays, an increasing number of smartphone apps claim to be of value in assessing different pain domains. Nevertheless, most of their properties have not undergone any validation or empirical analysis.[24] For example, although electronic pain diaries using real-time data capture might be able to improve compliance and ensure reliability and validity, their usability, feasibility, acceptability, and psychometric properties must be tested in patients and health care professionals before recommending widespread use. Of particular importance is the influence of age and developmental stage issues.

The aims of this study are to 1) describe the purpose and functionality of Painometer, a smartphone app that helps users assess self-reported momentary pain intensity, and 2) report its usability and acceptability properties when made available to health care professionals and nonprofessionals (children, adolescents, and young adults).

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Methods

A Brief Description of the App and Its Development

Painometer is a smartphone app that contains 4 pain intensity scales: the Faces Pain Scale–Revised (FPS-R),[5] the numerical rating scale–11 (NRS-11), the Coloured Analogue Scale (CAS),[10] and visual analog scale (VAS). Settings and instructions are available in Catalan, English, French, Portuguese, and Spanish. These scales have satisfactorily been used with children and adolescents,[19] adults,[2,12] and the elderly,[11] and thus it could also be implemented with these populations when appropriate.

Written permission for using 2 of the scales (CAS and FPS-R) was requested and obtained from the authors and copyright holders. The other 2 scales (NRS-11 and VAS) are not copyrighted or authored, so no permission was required. The resulting app is free for academic and research purposes.

There are 2 approaches to developing mobile apps: native technology and web technology. Painometer is powered by the latest web technology: html5, css3, and JavaScript. It uses a JavaScript framework called Sencha.[27] It should be pointed out that a desktop app written with web technology is not necessarily a web app. Painometer is not executed in a web server but in the device itself. The visual interface of the app is shown via a web browser, and the app can also be used without an Internet connection once it has been installed.

Any device with a web browser can use Painometer. It is compatible with iPhone, iPad, and Android-based devices. It can also be used in a web page as an embedded "gadget" (eg, YouTube videos). Painometer can be used in 3 different ways: 1) face-to-face: a health professional, such as a nurse, shows the scales to patients, provides explanations, and records their self-reported pain intensity; 2) self-administered: people with pain can keep a record by downloading the app to their device; and 3) programmatically: as an extension of another app, Painometer can be used as a web gadget and extended to third apps. For example, it can be used as a gadget in an electronic pain diary.

The identification of Painometer users is not possible through collected data; the data are only used to show a temporal chart of pain intensity records. Users may share the data by sending the information to an e-mail address of their choice. Painometer does not use the data in other terms (ie, neither accessing nor collecting data from other apps in the device is allowed; uploading or collecting data to an external server is not possible either).

The first version of the app is shown in Fig 1.

Usability and Acceptability Testing

As defined by Schoeffel,[16] "usability is the effectiveness, efficiency and satisfaction with which specific users can achieve a specific set of tasks in a particular environment" (pp. 6–7). The usability objectives for Painometer are that the app is 1) easy to learn, 2) error-free, and 3) liked by the user. Because it is fundamental that the testing be conducted with end users, health professionals and children, adolescents, and young adults, as potential patients, were recruited for the usability tests. The design was based on the concept of a "hermeneutical circle" as described by Snodgrass and Coyne,[17] which is an iterative process of implementing a design, learning and understanding from discussion and feedback, and making subsequent design refinements.

Professionals were also requested to report on their acceptability, that is to say, the extent to which they preferred the Painometer rather than the traditional paper-and-pencil way of assessing patients' pain intensity.
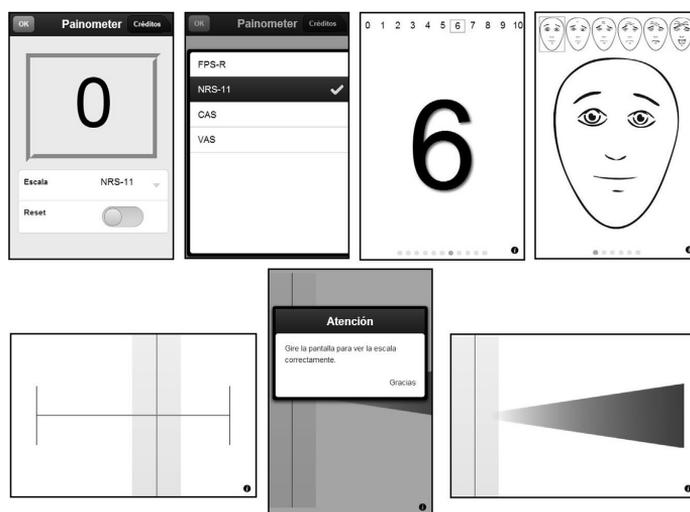

Figure 1. Screenshots of the different parts of the original Painometer.

Phase 1: First Usability Cycle

Participants

A convenience sample of 19 health care professionals (53% female) and 14 nonprofessionals (57% female) participated in this phase of the study. It has been found that testing with 5 users is enough to detect 85% of the usability problems, whereas testing with 15 users detects 100%. Therefore, it is suggested to have at least 3 participants in each group when different groups are tested.[14] Health care professionals (mean age = 31.2 years, standard deviation [SD] = 16.9) were eligible if they were able to speak and read Spanish or Catalan. Nonprofessionals (mean age = 17.9 years, SD = 4.9) were eligible for the study if they were between 6 and 24 years of age, had experienced pain over the last 3 months, and were able to speak and read Spanish or Catalan. The nonprofessional participants reported pain in the head (n = 4), the abdominal region (n = 6), the legs (n = 2), the cervical region (n = 1), and the pelvis (n = 1). Participants would have been excluded if they had any major cognitive or psychiatric disorders or severe hand deformities that would prevent them from using the app. None of those volunteering to participate had to be excluded. Additional details are shown in Table 1.

Procedure

Participants were first informed of the purpose, risks, and procedures of the test, and they (or their parents if they were minors) were requested to sign an informed consent document to participate. A qualitative usability testing approach with a semistructured interview, adapted from the study by Stinson et al,[20] was conducted.

Standardized instructions on the use of Painometer were given to the participants. Health care professionals were asked to use Painometer as if they were using it with a patient. If they did not have any experience in using pain intensity scales, they were taught to do so with paper-and-pencil versions of all the scales before using the app. To assess acceptability, they were also asked whether they preferred to use Painometer or traditional paper-and-pencil scales.

Nonprofessionals were requested to report the maximum pain intensity they experienced in the last 3 months. All participants were asked to "think aloud" while using the app (ie, changing between screens, assessing pain intensity with the 4 scales, reading the main menu, etc). Field notes were taken and the mistakes made by both groups were recorded. "Major usage

errors" were recorded when participants got stuck in any screen of the app or were unable to do the requested tasks, whereas "minor usage errors" were registered if they hesitated in doubt or touched the wrong buttons but were finally able to do the tasks successfully.

After completing the requested activities, all participants were asked 7 open-ended questions about ease of use, efficiency, and their satisfaction using Painometer. They also filled in a questionnaire about their previous use of technology; the questionnaire was adapted from the one developed by the Society for Technical Communication "Usability and User Experience Resources" webpage[18] and is available on request from the authors.

Analysis

The quantitative data from the interview were analyzed using SPSS Statistics 20 for Mac (http://www-01.ibm.com/software/analytics/spss/; IBM Corp, Armonk, NY) to determine measures of central tendency and the distribution of values. Field notes were taken and transcribed in text format. Simple content analyses were conducted to determine the users' satisfaction and problems with the categories emerging from the usability research questions.

Results

The professionals had an average of 12 years' experience in using computers, whereas the nonprofessionals had 8 years' experience. The professionals had been using smartphones for an average of 1 year and the nonprofessionals for 1.5 years.

Painometer was defined as easy, simple, intuitive, attractive, convenient, and useful when participants were requested to identify the characteristics that they liked the most. Most health care professionals (n = 18, 95%) preferred Painometer to the traditional versions of the scales; they stated that they would use the app as their first choice to assess patients' pain intensity. What nonprofessionals liked the most was that they could interact with the app by touching the screen. They had no major problems but did have some minor difficulties of usage related to the navigation menu and the orientation of the screen (see Fig 2 for details).

Figure 2. Main usability results of cycle 1.

Table 1. Sample Composition of Cycle 1

PROFESSIONALS		NONPROFESSIONALS	
SPECIALTY	N	AGE GROUP	N
Nurses	3	Children (8–12 y)	2
Physicians	3	Adolescents (13–18 y)	6
Physicians in training	8	Young adults (19–24 y)	6
Dental hygienists	1		
Psychologists	1		
Psychologists in training	2		

Table 2. Sample Composition of Cycle 2

PROFESSIONALS		NONPROFESSIONALS	
SPECIALTY	N	AGE GROUP	N
Nurses	3	Children (8–12 y)	4
Physicians	5	Adolescents (13–18 y)	4
Psychologists	3	Young adults (19–24 y)	8
Psychologists in training	4		

Changes to the App After Cycle 1

After analyzing the results of cycle 1, the following changes were made to the app: 1) A "guided tour" of the app was added: a short description of each element in the main menu emerges when the "?" button is pressed; 2) written instructions were provided for the scales: when a scale is selected, the usage instructions appear before the scale is displayed; 3) the configuration was simplified by a new screen navigation; 4) some device orientation issues were fixed.

Painometer was first developed in Spanish; then, the option to switch to the other 4 languages (ie, Catalan, English, French, and Portuguese) was added.

Phase 2: Second Usability Cycle

Participants

The inclusion-exclusion criteria were the same as in cycle 1; once again, none of those volunteering to participate had to be excluded. This time, the convenience sample of participants consisted of 15 health care professionals (mean age = 36.8 years, SD = 12.8;

53% female) and 16 nonprofessionals (mean age = 16.6 years, SD = 4.9; 67% female), none of whom had participated in phase 1. The nonprofessional participants reported pain in the head (n = 7), the abdominal region (n = 4), the legs (n = 3), and the shoulders and arms (n = 2). Sample composition is shown in Table 2.

Procedure and Analysis

All participants were instructed to use the app as in cycle 1 (see Fig 3 for details). The same kinds of analysis were conducted.

Results

The professionals had an average of 16 years' experience in using computers whereas the nonprofessionals had 6.5 years' experience. The professionals had been using smartphones for an average of almost 2 years and the nonprofessionals for 14 months. The most popular characteristics of Painometer were its ease of use and that it was practical, attractive, useful, tactile, funny, and mobile-integrated.

Participants had no major problems using the app, although 3 of them (2 professionals and 1 nonprofessional) did have some minor difficulties of usage because of the size of the buttons and the space between them. Fourteen (94%) health professionals stated that they would use Painometer as their first choice to assess pain intensity (see Fig 4 for details).

When they were asked about possible improvements or changes, participants suggested 1) keeping a record of the data collected and 2) adding a graphic representation of pain intensity records.
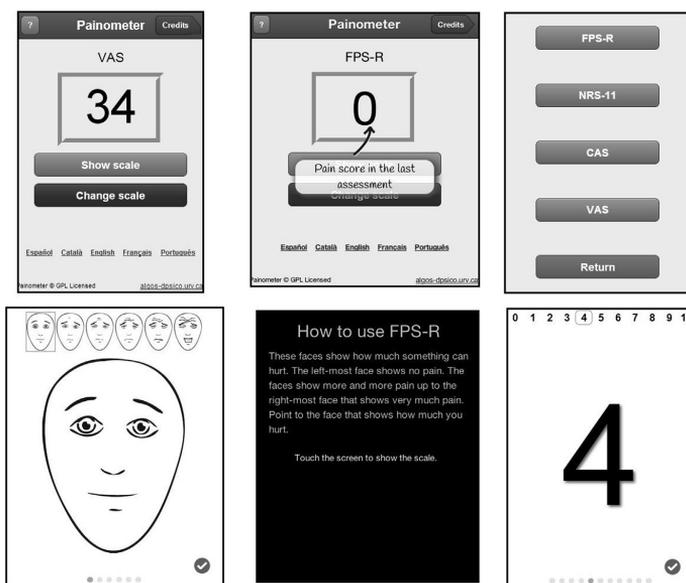
Figure 3. Screenshots of the improved Painometer.

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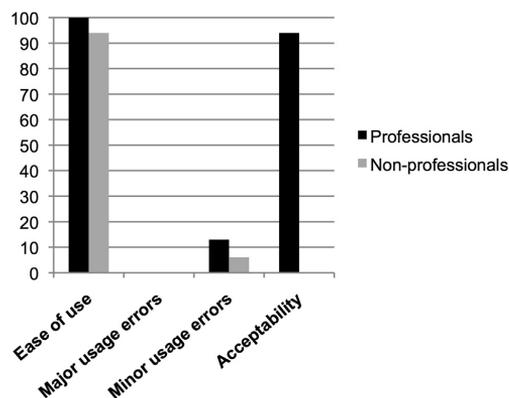
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Figure 4. Main usability results of cycle 2.

Discussion

Painometer is an app that integrates 4 pain intensity scales. These scales have been tested in a wide number of studies with different pain samples and patients' ages, and the reported pain intensity scores, when using the paper-and-pencil version of the scales, have demonstrated to be valid and reliable. It is compatible with most smartphones and has been demonstrated to be a functional, usable, and acceptable smartphone app for assessing pain intensity levels.

The app had to undergo some changes after the first cycle; namely, a "guided tour" of the app was added, written instructions were provided for the scales, the configuration was simplified, and some device orientation issues were fixed. As shown by other studies,[20,21]

2 iterative cycles were enough to assess the app and to develop it to the satisfaction of potential consumers.

At this point, the suggestions about adding graphics and saving data were taken into account and new functionalities were included. Painometer enables the pain intensity records to be saved and sent by e-mail. It also shows a graph with the pain intensity data. Although the changes to the app (resizing the buttons) or additions (the function of sending pain intensity records by e-mail) made after the second usability cycle had not been tested, they are not complex and would rarely interfere with the app's use. They are also explained in the "guided tour" and in a "user's manual" that has been developed. Some screenshots of the final version of Painometer are provided in Fig 5.

The agreement between a verbal version of the NRS-11 and its electronic version as provided by Painometer has been recently tested in a sample of adolescents. We found that pain intensity ratings on the verbal and electronic versions are comparable.[1] Similarly, a study with adult chronic pain patients found that the scores obtained with an electronic version of the VAS are comparable with those obtained with the paper-and-pencil version of the NRS-11.[6]

Although e-diaries are starting to be popular among researchers, most of the existing measures for assessing pain intensity rely on recall and do not allow for prospective longitudinal assessment in naturalistic environments.[13] Painometer solves these problems because it is portable and makes momentary assessment possible, thus helping to avoid the memory errors of retrospectives measures.

Most professionals found Painometer easy to use and preferred it to paper-and-pencil scales, so it might
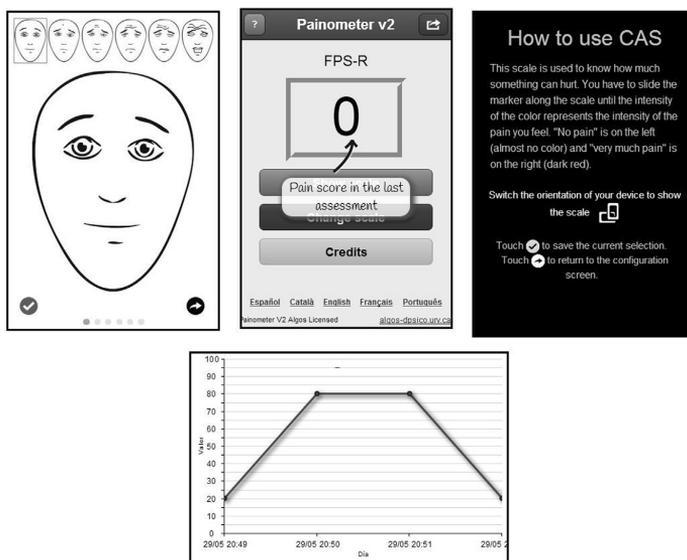

Figure 5. Screenshots of the final version of Painometer.

encourage health care professionals to use psychometrically sound scales to assess pain intensity. Because of its simplicity and versatility, Painometer can help to better control acute and procedural pain and also to keep an accurate record of pain intensity.

A potential limitation of the study is that the usability of Painometer was tested in a single session. Some problems might arise when the app is used for a period of time; to address this potential issue, an e-mail address is provided within the app description, so users can contact the developers if a problem appears. Another limitation is that the English, French, and Portuguese versions had not been assessed during usability testing because the app content, instructions, screens, and layout were similar in all languages. However, there have been several downloads from English-, French-, and Portuguese-speaking countries (ie, Canada, n = 12;

United States, n = 10; France, n = 6; Brazil, n = 5; and United Kingdom, n = 1), and we have not received any reports on usability problems, which might be considered as an indirect suggestion of proper functioning.

Painometer is available, for free, for research purposes and for clinical and/or educational uses. A user manual and the instructions to download the app for Android-based, iPhone, iPod, and other devices can be accessed following the link: http://algos-dpsico.urv.cat/en/painometer/.

Acknowledgments

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_____ Results _____

4.3 Study III

Fibroline: a smartphone delivered treatment for young people

with fibromyalgia or chronic widespread pain.

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Fibroline: a smartphone delivered treatment for young people

with fibromyalgia or chronic widespread pain

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ABSTRACT

Objectives: This paper provides the description and usability testing report of a new smartphone delivered treatment developed for treating young people with fibromyalgia or chronic widespread pain: Fibroline. **Methods:** Usability (i.e., the effectiveness, efficiency and satisfaction with which specific users can achieve a specific set of tasks in a particular environment) was tested in a group of end-users (i.e., adolescents and young adults). The design was iterative so that the prototype could be refined. A chronic pain patient who tested Fibroline was also interviewed. **Results:** Two usability cycles were needed to solve the difficulties (e.g., setting an alarm or accessing some of the contents) and respond to the suggestions (e.g., making the interface more colorful) that participants encountered and reported when using Fibroline. **Discussion:** Fibroline is a self-administered CBT program that is generally liked and easily used. It is designed to reduce pain and other common negative symptoms of fibromyalgia or chronic widespread pain in adolescents and young adults.

Key words. Fibromyalgia, chronic widespread pain, mHealth, usability testing, young people.

1. Introduction

Juvenile Fibromyalgia Syndrome (JFS) was first defined by Yunus and Masi (Yunus and Masi, 1985). The main feature of JFS is chronic widespread pain (CWP), a diffuse ache that is experienced in the right and left sides of the body, above and below the waist, and in the skeleton, which lasts more than three months (Wolfe et al., 2010, 1990). The pain is often accompanied by sleep problems, fatigue, stiffness, headaches, irritable bowel syndrome, cognitive problems, depression and anxiety (Shipley, 2010). There is some controversy about the reliability of diagnosing JFS (Zernikow et al., 2012) so for the purposes of this study we will use both terms (JFS and CWP) as synonyms.

A number of studies show that JFS, like other chronic pain conditions, may have an enormous negative impact on a person's daily life (Buskila, 2009; Kashikar-zuck et al., 2000). Emotional problems (Kashikar-Zuck et al., 2002), poor social relationships (Kashikar-Zuck and Lynch, 2007) and physical functioning (Kashikar-Zuck et al., 2010) are commonly reported. An added problematic issue when looking for treatment and support for people with JFS is that very few health professionals have been specifically trained to help them (and their families) to cope.

In recent years, what is known as mobile health or mHealth (i.e., health interventions supported by mobile devices) has been promoted as an alternative for addressing those health problems that like fibromyalgia cannot be addressed by the usual management circuits, either because of lack of resources or difficulty of access (Goyal and Cafazzo, 2013; Martínez-Pérez et al., 2014, 2013; Zheng et al., 2010). mHealth applications may save time and money (e.g., because patients will not be obliged to drive as much – or at all –

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to the health center to meet with the health expert, or to miss work), improve and reinforce patient's autonomy, increase the availability of empirically supported treatments wherever the patient is and whenever the patient needs it, and facilitate the anonymity of the patient and real-time data capture (Klasnja and Pratt, 2012).

It is in this context of lack of resources and the positive alternatives offered by mHealth that we decided to develop Fibroline, a smartphone app to help in the management of JFS. A fundamental first step before an mHealth app is given or recommended to consumers (health experts and/or end users) is to conduct usability testing (Stinson et al., 2006). This is essential if users are to understand, like and know how to use the app.

The objectives of this study are to describe: (1) what Fibroline is designed to do and how it works, and (2) the usability protocol used to ensure that the app is easy to use, error-free, and liked by the user.

1.1 Fibroline: contents and functionality

Fibroline (http://algos-dpsico.urv.cat/welltech/#concepto/1) includes a smartphone-delivered CBT program designed to improve the quality of life of young people with JFS or CWP. The treatment is condensed in nine weeks, and contains the following modules or units of treatment: sleep quality, anxiety management, pain coping, medication use, physical conditioning, mood regulation, problem solving, decision-making and relationships with others. All the content and settings are written in Spanish.

The treatment is administered in full through a smartphone, without any face-to-face contact. At the beginning, the user is requested to set his or her

preferences (e.g., some alarms). The treatment content (e.g., educational material, tasks, self-report questionnaires, etc.) is unlocked as the user advances through the treatment (i.e., new activities or information will not be available until the previous ones have been fully finished/attended to by the user).

Fibroline itself guides the user through the process. The number of pending tasks can be seen at the bottom of the screen if the app is on and alerts are displayed if the app is off. Figure 1 shows a screenshot of the main menu.
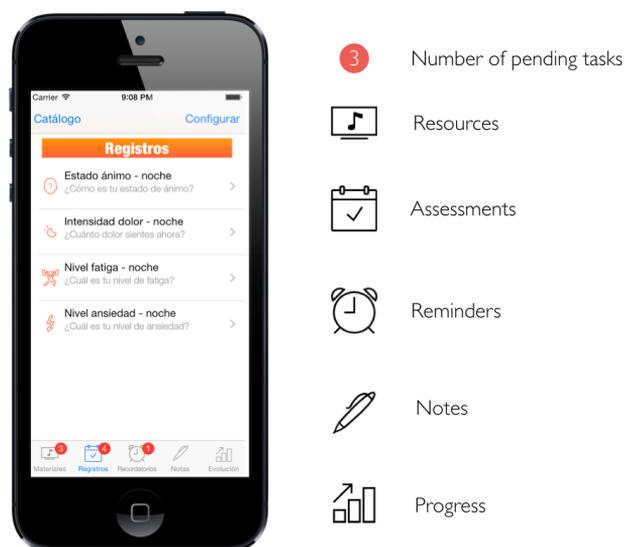

Fig.1 Fibroline main menu

With the patient's consent, a health professional can see the patient's performance data by accessing a related website.

Four types of tasks are activated when the treatment modules are accessed:

1. *Resources***:** written presentations, videos, and audios. The estimated time needed to read, watch or listen to them is displayed before the resource is accessed, so the user can decide when it is better to do so. Information about the topic (e.g., sleep, anxiety, medication, etc) and any related activities that are requested by the user are also explained before the resource is accessed.

2. *Assessment***:** questions about the user's sleep quality, pain intensity, mood, etc. These assignments are easy and quick to complete. They will pop-up in the morning and evening, at the time set by the user. An alarm and a text on the screen will indicate that it is the time to fill in the questionnaire. Digitalized self-report scales, which have proved to have good psychometric properties, are used to report this information (Castarlenas et al., 2014).

3. *Notes***:** user's annotations about treatment objectives (editable). The user will be able to write his or her own notes (e.g., "I have to tell the doctor that the new medication makes me feel dizzy").

4. *Reminders***:** a list of pending or "to do" tasks. These are exercises or activities that must be completed by the user (e.g., "Remember to practice the relaxation exercise"). The user can add his or her own reminders (for example, to take medication or to go to an appointment) and set an alarm at a convenient time.

5. Another important feature of Fibroline is the "*Progress*" section, in which the user can see a chart with his or her accomplishments in the different domains covered in the treatment package (e.g., pain, sleep, anxiety, physical activity, etc). This section is designed to allow the

user to relate his or her improvements with the performance on the treatment tasks. Figure 2 shows some screenshots with an example of each of the five sections.
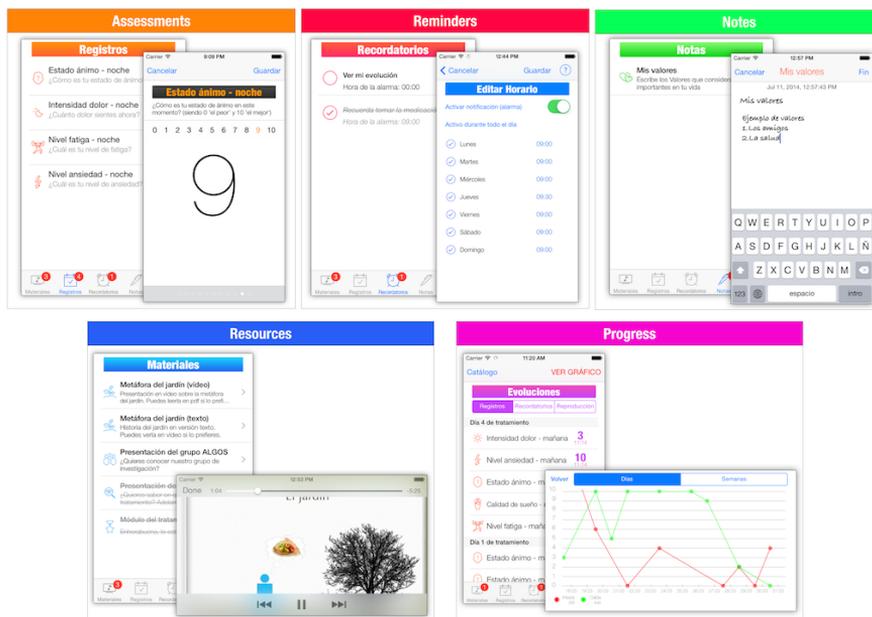
Fig.2 Screenshots with an example of each of the five sections

Fibroline is included in a Treatment Management System platform called WellTech (http://algos-dpsico.urv.cat/welltech). This platform has been developed by our research group. All users' data collected with the app are stored in the cloud, which makes it accessible any time anywhere and simplifies the transfer of data between different information systems. The app can be installed in an iPhone, iPod or iPad mini, and requires identification and authentication to access it.

2. Methods: Usability and acceptability testing

2.1 Procedure and participants

A qualitative usability testing approach with a semi-structured interview was conducted. The design was based on the concept of a ''hermeneutical circle'', which is an iterative process of implementing a design, learning and understanding from discussion and feedback, and making subsequent design refinements (Snodgrass and Coyne, 1996). Schoeffel defined usability as "the effectiveness, efficiency and satisfaction with which specific users can achieve a specific set of tasks in a particular environment (pp. 6-7)" (Schoeffel, 2003). This procedure has already been successfully used in previous studies. Of particular interest is the testing of *Painometer*, a pain related app that helps assess people with pain (de la Vega et al., 2014).

Participants were recruited by various strategies: placing poster advertisements on two university campuses, advertising the study on our university intranet, writing a post on our research group webpage (http://algos-dpsico.urv.cat/en), contacting a local school, and informing through Facebook and Twitter.

The inclusion criteria were (1) being between 13 and 24 years old and (2) being able to speak and read Spanish. The minimum sample size needed to perform the usability testing was N = 5 for each cycle (Nielsen, 2000). Nevertheless, as our targeted age range is wide, we decided to test the app with at least five users who were 18 years old or younger and at least five more who were 18 years old or more. The final sample consisted of 25 young people aged 13-24 years (mean age = 18.24; SD = 4.02) of whom 8 were boys or young men (32%) and 17 were girls or young women (68%).

Participants would have been excluded if they had any major cognitive or psychiatric disorders or severe hand deformities that prevented them from using the app. None of those volunteering to participate had to be excluded.

2.1.1 Usability cycles

2.1.1.1 Cycle I

A sample of 13 young people (77% female) participated in this phase of the study. Participants were first informed of the purpose, risks and procedures of the test and they (or their parents if they were minors) were requested to sign an informed consent document.

Standardized instructions on the use of Fibroline were given to the participants. They were asked to use Fibroline and to perform a series of tasks (e.g., change settings, access certain resources, set an alarm for medication, etc). A protocol of "concurrent thinking" (Jääskeläinen, 2010) was followed (that is to say, participants were asked to use the app and to verbalize their thoughts during the process). Field notes were taken and transcribed into text format; the mistakes made by participants were recorded.

After completing the requested activities, all participants were asked to report on their acceptability (that is, the extent to which they would be willing to continue using Fibroline if they needed it). They were also interviewed with a series of open-ended questions about the ease of use, problems found, suggestions and satisfaction using Fibroline and a questionnaire about their previous use of technology was administered. After the results of Cycle I had been analyzed, the app underwent the required changes.

2.1.1.2 Cycle II

A sample of 12 young people (58% female) participated in this phase of the study. They were all instructed to use the app as in Cycle I, and the same procedure was followed. This step was required in order to find out whether the problems in Cycle I had been solved and to ensure that no new problems had been created when fixing the old ones. After the results of Cycle II had been analyzed, minor changes were made to the app in response to the suggestions of the users.

2.1.2 *Expert patient test and interview*

A young woman (24 years old) with a two-year history of chronic pain tested the final version of Fibroline using the same procedure described above. This additional test was conducted to ensure that the app content is suitable for young people with chronic pain (i.e., that we did not miss any potentially relevant characteristic of young people with chronic pain that could make them use the app differently than young people without chronic pain – as was the case of the participants in our usability cycles).

2.2 Materials

To collect relevant information we used the following tools:

2.2.1 *Use of Technology Questionnaire (UTQ)*

This questionnaire was created (de la Vega et al., 2014) on the basis of the one developed by the Society for Technical Communication "Usability and User Experience resources" (Society for Technical Communication, n.d.), and is

available on request from the authors. The questionnaire was administered in interview form after the usability protocol had been completed.

2.2.2 *Semistructured interview*

After completing the requested activities, all participants were asked 29 open-ended questions (e.g. "What did you like the most?", "How would you improve the app?") and 12 yes/no questions about ease of use, efficiency and their satisfaction using Fibroline (e.g., "Was the font large enough?"; "Were the instructions about how to set the alarm useful?", "Was the treatment explanation easy to understand?"). The interview questions are available on request from the authors. To avoid social desirability related issues, particular emphasis was given to the importance of being sincere and making suggestions for improvement, pointing out negative aspects and telling the interviewers how to make the app easier and more attractive.

2.3 Data analysis

Demographic and other quantitative data from the interview were analyzed using SPSS Statistics 20 for Mac (http://www-01.ibm.com/software/analytics/spss/) to determine measures of central tendency and the distribution of values. Simple content analyses were conducted to determine the main problems, suggested changes and user's satisfaction with Fibroline.

3. Results

3.1 Usability Cycle I

3.1.1 Use of technology. Participants in this cycle spent, on average, nine hours per week at their computer for work- or class-related tasks and five hours for entertainment. All the participants had a smartphone and they had been using it for an average of 36 months.

3.1.2 Problems that were reported. The users did not know how to: (1) set the alarm, (2) go to the "notes" section, (3) view the contents on full screen, (4) choose to see some of the content in text or video format.

3.1.3 Suggested changes. They suggested: (1) adding some instructions about the alarm settings, (2) making the design more colorful, (3) explaining how to quit the first written presentation.

3.1.4 Most popular features. What users liked the most were: (1) that Fibroline included multimedia content (46%; i.e., audio recordings, videos, etc.), and (2) that the process and the tasks they had to do were explained and exemplified (38%).

3.1.5 Ease of use. Most participants (85%) rated Fibroline as "Easy to use".

3.1.6 Acceptance. Most participants (92%) would use Fibroline if they needed it.

3.2 Changes made after Cycle I

After the results of Cycle I had been analyzed, the following changes were made to Fibroline: (1) a guided tour about how to set the alarm was added; (2) graphic explanations about how to go to the "notes" section, quit the first written presentation, and view the content on full screen were added; (3) the layout was made more colorful; and (4) a clearer indication about the type of presentation that could be used (e.g., video *vs*. text) was added. A summary of the changes is presented in Figure 3.
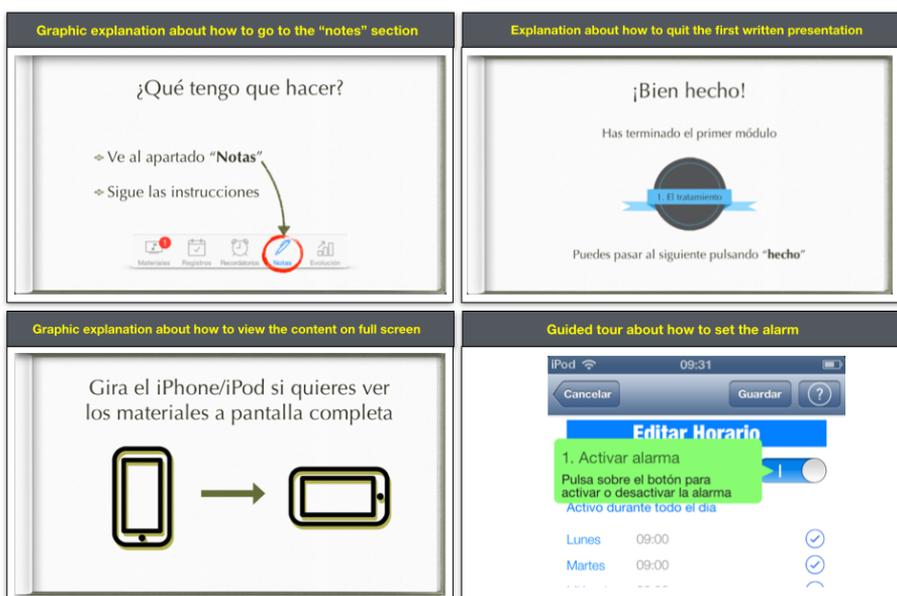

Fig.3 Changes made after Cycle I

3.3 Usability Cycle II

3.3.1 Use of technology. Participants in this cycle reported spending an average of 12 hours per week at their computer for work- or class-related tasks and 10 hours for entertainment. All the participants had a smartphone and they had been using it for an average of 34 months.

3.3.2 Problems that were reported. The users reported the following problems: (1) finding the button to access the chart showing their progress (this took them longer than expected), (2) setting the alarm (they did it correctly only after reading the guided tour instructions), (3) not noticing that they could choose to see some content in text or video formats.

3.3.3 Suggested changes. They suggested: (1) presenting the alarm instructions in a different way (participants wanted to set the alarm in the same way as they do on their smartphone), (2) explaining more clearly that, for some content, they could choose to watch a video or read a text, (3) making the "chart" button easier to find.

3.3.4 Most popular features. What users liked the most were: (1) the relaxation audios (50%); (2) the multimedia content (33%), and (3) the explanations and examples of the process and the tasks they had to do (25%).

3.3.5 Ease of use. All participants (100%) rated Fibroline as "Easy to use".

3.3.6 Acceptance. All participants (100%) would use Fibroline if they needed it.

3.4 Changes made after Cycle II

After the analysis of the results of Cycle II, the following changes were made to Fibroline: (1) a new screen to set the alarm was created; (2) the button to access the graph was colored red; and (3) the format of the content was written in capitals. A summary of the changes is presented in Figure 4.

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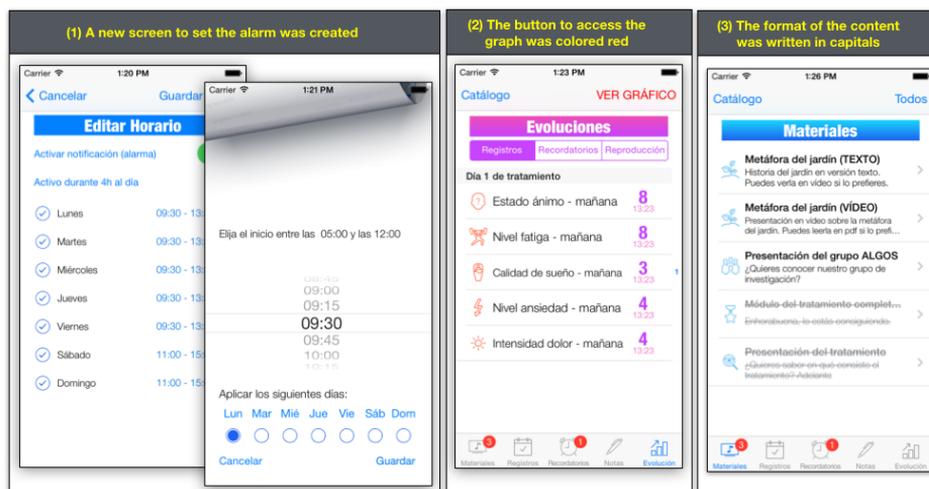
Fig.4 Changes made after Cycle II

3.5 Expert patient test and interview

3.5.1 Use of technology. The participant reported spending about 50 hours per week at her computer for work tasks and 4 hours for entertainment. She had a smartphone and had been using it for 24 months.

3.5.2 Problems reported. No problems were reported.

3.5.3 Suggested changes. The participant suggested adding more images to the presentations.

3.5.4 Most popular features. What the participant liked the most were: (1) being able to track her progress, (2) the graphics on her progress, and (3) that "Fibroline is very complete, it has a lot of options and content".

3.5.5 Ease of use. She rated Fibroline as "Easy to use".

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3.5.6 Acceptance. The participant would use Fibroline mainly to: (1) keep a record of her progress, (2) practice relaxation exercises, and (3) use the reminders.

4. Discussion

Fibroline, a smartphone delivered CBT program for the treatment of patients with JFS and CWP has been described, and its usability, refinement process and acceptability reported. Some changes were made to Fibroline after each usability cycle. In Cycle I we added a guided tour about how to set the alarm and new visual explanations, as well as graphic design changes. After Cycle II, a new screen was created for the alarm settings and the "Graphics" button was highlighted. As has been the case in previous studies (Stinson et al., 2010, 2006), two iterative cycles were enough to refine Fibroline. Finally, a chronic-pain patient tested Fibroline. She found no new problems and provided some positive comments and feedback.

The treatment content for Fibroline was designed on the basis of a CBT orientation because this therapeutic alternative has proved to be effective in the management of fibromyalgia (Bennett and Nelson, 2006; Thieme and Gracely, 2009) and JFS (Degotardi et al., 2006; Kashikar-zuck et al., 2012, 2005). Moreover, some distance and internet-delivered treatments have proved to be appropriate and efficient in the treatment of fibromyalgia and CWP (Kristjánsdóttir et al., 2011; Williams et al., 2010).

This study shows that: (1) a usability testing protocol is necessary to reveal the problems that may arise when an mHealth application is used and before it can be promoted to professionals and patients, (2) the preferred

content in Fibroline were the multimedia options, (3) even though users may have ample experience with smartphones, they still need some guidance to perform certain tasks (like accessing some resources or navigating through the different sections), and (4) Fibroline is an acceptable and easy-to-use program.

This is a preliminary test of Fibroline, and our study is not exempt of certain limitations that must be acknowledged. Fibroline was tested in a single session and just one patient with chronic pain participated in the process. It remains to be seen what happens when patients with JFS or CWP use the program for the nine planned weeks. A pilot study will be conducted.

The high acceptance by our participants reinforces the idea that an mHealth intervention, like the one in Fibroline, would help to improve patient's accessibility to the treatment. Letting health professionals know that these kind of apps are being validated and are available for patients is a key element in the process of knowledge transfer, critical if end users are to benefit from scientific findings.

Nevertheless, there is a long way to go. In a recent systematic review (de la Vega and Miró, 2014), we reported that some smartphone applications have been used to measure and assess people with pain, but that there is still a long way ahead if these research findings are to be brought to the application markets. Most of the pain-related apps that can be found in the stores (Google Play, App Store, etc) have not been validated and therefore have no warranties for those that might be interested in using them. Fortunately, the number of studies reporting on these issues is increasing (de la Vega et al., 2014; Stinson et al., 2013).

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UNIVERSITAT ROVIRA I VIRGILI
MHEALTH: A NEW AND COMPLEMENTARY WAY TO HELP YOUNG PEOPLE WITH PAIN. STATE OF THE ART, DEVELOPMENT,
AND USABILITY TESTING OF TWO SMARTPHONE APPLICATIONS.
Rocío de la Vega Carranza

Discussion

5. Discussion

This dissertation has focused on exploring an emerging area of potential interested for the study, assessment and treatment of young people with (chronic) pain.

The *first objective* was "to learn about the current state of development of mHealth in the area of pain, and in particular the number and quality of pain-related apps reported in scientific studies, and the ones available in commercial app shops." As has been shown, mHealth has grown rapidly in the last few years. A recent report (Jahns, 2014) estimates that the number of mHealth apps has more than doubled in two and a half years. Focusing on pain related apps, a review paper of the main app stores showed that 111 apps were available in 2010 (Rosser & Eccleston, 2011). Study I shows that this figure had risen to 283 by 2013: that is, nearly three times as many. Nevertheless, as shown in our study (de la Vega & Miró, 2014) none of these apps had been produced on the basis of any published scientific papers, so concerns about the quality of the commercial apps have to be discussed.

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Four years ago, Keogh et al. (Keogh, Rosser & Eccleston, 2010) made a list of concerns to must be taken in account in the field of eHealth. Below, we shall discuss each of these in the light of new developments and publications. Four main points have arisen:

1) *"Many products claiming to be therapeutic have been developed in response to a technological innovation rather than being driven by a user need. We suggest that user-centered design and user-centered solutions should be the starting points."* (Keogh et al., 2010, p. 20). As mentioned above, user-centered designs beginning with usability testing are crucial if the helpfulness and efficacy of apps are to be ensured. Fortunately, scientists are moving towards the development and validation of patient-centered apps. For example, Stinson et al. (2014) are developing an online platform for managing chronic pain in adolescents and their first step has been to perform a study of the health-care needs of the adolescents by asking the subjects themselves and a group of healthcare professionals. However, these are just the first steps on the long journey to a patient-centered mHealth world.

2) *"There is currently little guidance on how to develop or translate therapy from a traditional human-mediated delivery system to an electronic delivery system. The extent to which solutions can be independent of any face to face therapy involvement is unknown, although less human involvement is associated with*

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greater patient drop out from therapy." (Keogh et al., 2010, p. 20). As far as the first sentence of the paragraph is concerned, a number of studies have been published on the development and testing of mHealth applications. These studies include some information about the "lessons learned", in order to give future developers some guidance when creating their apps. Examples of this are Studies II and III in this dissertation or the study conducted by Huguet et al. about a headache management app (Huguet et al., 2014). Moreover, some papers have tried to provide a framework for conducting and reporting online interventions (e.g. (Eysenbach, 2011; Proudfoot, Klein & Barak, 2011)). And with reference to the second sentence, scientists are using more robust methodologies to test the efficacy of their interventions (e.g. a RCT of an Internet intervention for pain (Dear et al., 2013) or for fibromyalgia (Williams et al., 2010)). Despite the efforts that have been made, however, more research is still needed to consolidate the efficacy of this kind of intervention. Fortunately, scientific journals are taking greater interest in mHealth: for example, an entire journal (*JMIR mHealth*) is dedicated to it, and *The Clinical Journal of Pain* is preparing a special issue on mHealth interventions for pain.

3) *"Many new technologies enable the hidden monitoring and recording of behavior, leading to concerns surrounding privacy, monitoring and storage. Further investigation, policy and guidance are needed on how to ensure privacy and control access."* (Keogh et al., 2010, p. 20). As mentioned above, some

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public agencies (for example, the FDA or the European Commission) are taking steps in this direction. Also some articles have been published about ethical and social issues. For example, the paper by Henderson et al. about ethical guidance for pediatric e-health research (Henderson, Law, Palermo & Eccleston, 2012) or the paper by Krieger about the public and academic perspectives of medical apps (Krieger, 2013). A framework for addressing privacy law issues in mobile health has also been created (TrustLaw Connect, 2013). Consequently, it seems that we are on the way to building an ethical and safe environment for treating patients through eHealth and mHealth interventions.

4) "*Unchecked, e-health innovations may introduce as many new inequalities in health care provision as they solve. Particular attention should be paid to age-related differences in technology confidence, skill, and use, and to the unequal provision of costly infrastructure (e.g., broadband computing) in different economies.*" (Keogh et al., 2010, p. 20). Nowadays, the use of mobile phones is widespread, even in developing countries (TrustLaw Connect, 2013). WHO issued a report (Kay, 2011) that analyzed the mHealth initiatives adopted around the world. They found differences in number, the extent to which they had become established (e.g. established, pilot, informal), and type (e.g. health surveillance, doctor appointment reminder) of the initiatives depending on the income level of the country. All countries reported at least one initiative. They found that America (75%), Europe

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(64%) and South-East Asia (62%) reported high rates of mobile telemedicine initiatives, though a large proportion of these initiatives were informal or in the pilot phase. Nevertheless some barriers still have to be overcome: all the countries surveyed reported having competing priorities, cost-effectiveness issues, and a lack of knowledge about mHealth initiatives. mHealth is suitable for all ages. Certainly for young people, but also for the elderly (e.g. sensors connected to home alert systems improve safety and prevent needless deaths through accidents or falls (The Boston Consulting Group, 2012)) but user interfaces have to be age-adapted.

Since we performed the review in Study I (December 2013), to our knowledge none of the validated apps (i.e. those with peer-reviewed articles reporting them) have made their way into the stores yet. A search on PubMed (http://www.ncbi.nlm.nih.gov/pubmed) using the name and authors of the 40 apps that showed some kind of support in Study I (de la Vega & Miró, 2014) revealed that the only app that has an article published about it is our app: *Painometer* (i.e. Study II).

The *second objective* was "To develop and test an app to help assess pain intensity. This app (*Painometer)* includes four widely used and validated scales." Besides the study included in this dissertation, a number of studies have investigated the reliability of the scores obtained with the scales included in *Painometer* and their agreement. In the work by Castarlenas et

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al. (Castarlenas, Sánchez-Rodríguez, de la Vega, Roset & Miró, 2014) pain intensity ratings provided with the verbal Numerical Rating Scale-11 and its electronic version seemed to be comparable, at least for the 80% confidence interval of agreement, as suggested for children by von Baeyer (von Baeyer, 2012). Another study, which is now under review (Sánchez-Rodríguez, de la Vega, Castarlenas, Roset & Miró, 2014), has been conducted to test the validity of the four digital scales included in *Painometer*. The results showed that the scales provide valid scores when used to measure pain intensity in young people (i.e moderate to high convergent validity, adequate discriminant validity with fatigue ratings, and adequate concurrent validity with fatigue and pain catastrophizing ratings). Another article that is now in preparation (Sánchez-Rodríguez, Castarlenas, de la Vega, Roset & Miró, *in preparation*.) will report on the agreement of the paper-and-pencil and the electronic versions of the four scales. The results of the study show that all the electronic versions of the four scales are comparable with their paper-and-pencil versions (confidence interval of 80%).

As far as the acceptance of *Painometer* is concerned, to date it has had over one thousand downloads (363 for iOS and 716 for Android devices). The app has been downloaded in 17 countries: Spain, Canada, USA, Chile, Sweden, Argentina, Brazil, Mexico, Colombia, UK, Denmark, France, New Zealand, Bangladesh, Japan, Poland and South Africa.

———————————————— Discussion ————————————————

Painometer has obtained the quality seal "Appsaludable", provided by the Andalusian Quality Agency (Andalusian Quality Agency, 2014), and is the first pain-related app to have done so. Moreover, it was awarded the "mHealth prize" by the Mobile World Capital Barcelona ("Mobile World Capital," n.d.).

The *third and last objective* was "To develop and test a treatment app for Juvenile Fibromyalgia Syndrome or chronic widespread pain: *Fibroline*". Although the tests conducted in Study III have shown good usability and acceptability, *Fibroline* has still to be tested in terms of efficacy. A pilot study will begin in January 2015. Young people with JFS or CWP between 14 and 24 years old will follow the CBT treatment contained in the app. Before and after the treatment, they will answer an online battery of questionnaires about their socio-demographic information, health status, personality and mood. A follow-up assessment is planned at one, three and six months after the treatment. The app will be refined in response to users' feedback.

Furthermore, considering that JFS is a relatively unexplored disease and healthcare specialists often work far from the hometown of the patients and their families, this treatment could help them to receive specialized care and reduce the number of visits to the reference center, thus saving time and money, and helping to relieve the burden on the healthcare system.

———————————————— Discussion ————————————————

Fibroline has already been recognized by two private foundations: the *Fundación FF* which awarded a prize in 2013 to support the development and implementation of the application, and the *Fundació Príncep de Girona* which awarded its "Young talent award 2014" to the app. Moreover, *WellTech*, a project in which *Fibroline* is included, has received an award from the board of trustees of the *Universitat Rovira i Virgili* as one of the "best entrepreneurial ideas" of 2014. It has been provided with funding to help in the creation of a spin-off enterprise, which can help develop the apps and take the necessary steps to make the app available to more patients (e.g. programming the app also for Android systems).

6. Conclusions

The main conclusions of this dissertation are the following:

1. Pain is a global and unpleasant experience. Improved treatments and ways of delivering treatment need to be created and tested.

2. mHealth has considerable potential for improving healthcare and reducing costs. Nevertheless, it is still taking its first, faltering steps and requires more research, and a better-defined regulatory environment. Greater efforts are needed to bond the academic and commercial sides of mHealth.

3. *Painometer* is an mHealth app with good usability, which is valid and reliable. Its widespread use can lead to more rigorous and easier pain intensity assessment.

4. *Fibroline* has also proved to have good usability. If it is shown to be effective at helping those with JFS, it will be able to help improve the quality of life of a considerable number of people.

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