

FIBROLINE: A MOBILE APP FOR IMPROVING THE QUALITY OF LIFE OF YOUNG PEOPLE WITH FIBROMYALGIA

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Abstract

Fibroline is a mobile application with a self-administered cognitive behavioral treatment (CBT) for young people with fibromyalgia or chronic widespread pain, designed to reduce pain and other common negative symptoms, and improve quality of life. Our aims are to report on the usability and feasibility protocols used to assess the app. Two usability cycles were implemented. A group of patients followed the CBT intervention to test its feasibility. Qualitative data was collected and content analyses were conducted. The results demonstrated that the app is error-free, easy to use, liked by the users and acceptable.

Key words. Cognitive behavioral treatment; mHealth; young people; fibromyalgia; chronic widespread pain.

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). 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, can 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 et al., 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 patients (and their families) to cope. Several studies have demonstrated the efficacy of Cognitive Behavioral Treatments (CBT) for JFS. For example, Degotardi et al. (2006) found a reduction in pain intensity, somatic symptoms, anxiety and fatigue; improvements in sleep quality and functional ability; and fewer school absences after an eight-week treatment focusing on pain management, sleep hygiene, and activities of daily living. Similarly, Kashikar-Zuck et al. (Kashikar-Zuck et al., 2013) found a significant reduction in catastrophizing and a

significant improvement in coping and coping efficacy after an eight-week treatment based on learning new and/or better coping strategies.

Internet CBT interventions have already demonstrated efficacy reducing pain, activity limitations, and costs associated with treatment, as shown in a systematic review of randomized controlled trials of Internet interventions for different kinds of chronic pain, including fibromyalgia (Bender et al., 2011). Most recently a meta-analysis of randomized controlled trials of distance psychological therapies for the management of chronic pain in children and adolescents, found reductions on pain intensity at post treatment (Fisher et al., 2015). 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). mHealth applications may save time and reduce cost burden (e.g., because patients will not be obliged to drive as much – or at all – 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 easily.

The objectives of this work are to describe: (1) what *Fibroline* is designed to do and how it works, (2) the usability protocol used to ensure that the app is easy to use, error-free, and liked by the user, (3) problems encountered when using the app, and the preferences of the participants.

Methods: Usability and acceptability testing

Participants

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 (XXX – **Masked information**), contacting a local school, and informing through Facebook and Twitter. Ethical approval was obtained from our University (XXX- **Masked information**) ethics committee.

The inclusion criteria for the usability testing were (1) being between 13 and 24 years old and (2) being able to speak and read Spanish. According to Nielsen (Nielsen, 2000), the minimum sample size needed to perform the usability testing is 5 for each cycle. 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 older. 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%). **A “community based” sample was selected for the initial usability steps and to look into potential usability issues that the general population of**

young people may encounter when using the app. This will enable us to generalize the findings and to use the app structure with a more representative population (not only young people with JFS). All other usability tests were conducted with patients to ensure that the app was suitable for them.

Participants in the feasibility testing were young people (with the same characteristics as described in the inclusion criteria for usability testing) with a diagnosis of JFS or CWP, as provided by a rheumatologist. Three fibromyalgia patients (15, 21 and 24 years old) completed the CBT treatment.

Procedures

A qualitative usability testing approach with a semi-structured interview was conducted. Two of the authors with clinical and usability testing experience conducted the usability test. 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, (de la Vega et al., 2014).

In order to determine the feasibility of *Fibroline* in everyday life for a period of time, and in different environments (home, school or work), we assessed the acceptability, and related technical issues, as suggested by Stinson et al. (2006).

Usability 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 informed that they should do the tasks on their own and that the researchers were not allowed to answer any questions or solve any problems. Particular emphasis was placed on the goal of usability testing: that is to say, to improve the app and not to assess the participants' abilities.

Participants were asked to use *Fibroline*, follow the instructions provided by the app and perform a series of tasks (e.g., log in the app, change settings, access certain resources –read a PDF file, listen to an audio and watch a video-, set an alarm for medication, go back to the main screen, etc.). Participants were not given any further instructions, as the app is intended to be self-explanatory and to guide users through the content. 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 individually interviewed. They were asked to (a) report on their acceptability (that is, the extent to which they would be willing to continue using *Fibroline* if they needed it); (b) respond to a series of open-ended questions about the ease of use, the problems found, their satisfaction using *Fibroline*, and suggestions for potential improvements; and (c) answer to a questionnaire about their previous use of

technology. After the results of cycle I had been analyzed, the app underwent the required changes. **On average, the full session took an hour.**

Usability 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 solving the previous 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. **On average the full session took an hour.**

Expert patient test and interview. A young woman (24 years old) with fibromyalgia or CWP 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). **The full session took an hour.**

Feasibility and acceptability. Three young women **with fibromyalgia** followed the CBT treatment included in the **app for nine weeks. They were instructed to log into the app and to follow the instructions given.** After they had completed the **treatment**, they completed an online survey with the same **usability** questions that all other participants were asked **(the instructions are described in the section usability cycle I).**

Materials

Fibroline. *Fibroline* is an app that was developed for iOS 4 and more recent versions (i.e. iOS 5, iOS 6, iOS 7 and iOS 8). It is designed mainly for iPhone and iPod, although it can also be used with iPad and iPad mini.

Fibroline was coded with Xcode (<https://developer.apple.com/xcode/>), an integrated development environment (IDE) containing a suite of tools for software development created by Apple for developing software for OS X and iOS. The programming language used was Objective C. The internal data of *Fibroline* used to represent the treatment has two logical components: static and dynamic. The static data refers to the model of treatment, which is the same for all users. The model has two main components: (1) the content of the treatment program (videos, notes, registers, etc.) and (2) the temporal rules that show the content. We designed a modeling language to represent the treatment, which is serialized in json language (www.json.org). The dynamic data is the information provided by the patients, which is specific to a particular user (e.g. the specific pain intensity score for the current day, the number of times a pdf has been read, etc.). All the data is saved in the device and it is communicated using a secure channel to an Internet database server.

Use of Technology Questionnaire (UTQ). This questionnaire was created 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 includes questions about the use of technology (e.g., for how long participants have had a Smartphone, what are the apps that they are using,

how often, etc.). It was administered in interview form after the usability protocol had been completed.

Semistructured individual 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?”). 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 to use and more attractive.

Online survey. The survey included the questions as described above. We used the online survey tool *Lime Survey* through a secure server at our University.

Data analysis

Demographic and other quantitative data from the interview were analyzed using SPSS Statistics 20 for Mac 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*. The constant comparative method (Miles et al., 2014) was followed to ensure the reliability of the data collected. Categories from a previous usability study (XXXX masked information) were selected. Two of the

researchers independently coded the usability sessions, and any discrepancy was resolved by a third researcher.

Results

Fibroline: contents and functionality

Fibroline (<https://www.fibrolineapp.com/>) includes a Smartphone-delivered CBT program designed to help improve the quality of life of young people with JFS or CWP. A team of clinical psychologists with many years of experience treating people with chronic pain and engineers with experience in developing health-related apps worked together on the design and implementation of *Fibroline* from the beginning. Once a first prototype was ready, the usability testing was conducted to refine the app.

The CBT treatment is condensed in nine weeks, and contains the following modules or units of treatment: life values and goal setting, sleep quality, anxiety management, pain education and coping, medication use, physical conditioning, mood regulation, thoughts management and relapse prevention. Psycho-education, goal setting, relaxation techniques, cognitive restructuring, stimuli control, sleep hygiene strategies, activity pacing, yoga exercises and feedback techniques were all used.

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., alarms). The treatment content (e.g., educational materials, tasks, self-report questionnaires) 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) to ensure that he or she follows the treatment at a right pace.

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.

[Please insert Figure 1 about here.]

With the patient's consent, a health professional can see the patient's performance data (e.g., results of the assessment, time spent using the app) in real time 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,) and any related activities that are requested are also explained before the resource is accessed.
2. **Assessment:** questions about the user's sleep quality, pain intensity, mood, anxiety and fatigue. 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 collect this information (Castarlenas et al., 2015).

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.

Another important feature of *Fibroline* is the "Progress" section, in which the user can see a chart with his or her accomplishments (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.

[Please insert Figure 2 about here.]

All users' data collected with the app are stored in a private cloud (only accessible by the researchers), which makes it accessible anytime and anywhere, and simplifies the transfer of data between different information systems. The app can be installed in an iPhone, iPod or iPad, and requires identification and authentication to access it (i.e., the user needs a username and a password to access the app).

Medical and personal user data are decoupled into two separate parts of the database. These two fragments are linked by a random generated field which associates a number with each user. With this approach, nobody can be identified through their medical data. All these data are saved in their personal

Smartphone, in a non-encrypted database called "Core Data" by iOS (<https://developer.apple.com/library/watchos/documentation/Cocoa/Conceptual/CoreData/index.html>). Users can choose to synchronize their data with the Internet Cloud. To save data on the Cloud, *Fibroline* uses an open-source NON-SQL database called "Parse" (<https://parse.com/docs/ios/guide>). From the technical point of view, all connections are made using HTTPS and SSL, and Parse will reject all non-HTTPS connections (which are less secure than HTTP connections). Access to the database is managed by security mechanisms, such as class-level permissions (<https://parse.com/docs/ios/guide#security-class-level-permissions>) and ACLs (Access Control Lists <https://parse.com/docs/ios/guide#security-object-level-access-control>).

Usability

Usability cycle I

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 daily for an average of 36 months.
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. Suggested changes. The users suggested: (1) adding some instructions about the alarm settings, (2) making the design more colorful, (3) explaining how to quit the first written presentation.

4. Most popular features. The users reported to like the most: (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%).
5. Ease of use. Most participants (85%) rated *Fibroline* as “Easy to use”.
6. Acceptance. Most participants (92%) would use *Fibroline* if they needed it.

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.

[Please insert Figure 3 about here.]

Usability cycle II

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 daily for an average of 34 months.
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. Suggested changes. The users 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.
 4. Most popular features. The users reported to like the most: (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%).
 5. Ease of use. All participants (100%) rated *Fibroline* as “Easy to use”.
 6. Acceptance. All participants (100%) would use *Fibroline* if they needed it.

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.

[Please insert Figure 4 about here.]

Expert patient test and interview

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 daily for 24 months.
2. Problems reported. No problems were reported.

3. Suggested changes. The participant suggested adding more images to the presentations.
4. Most popular features. The participant reported to like the most: (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”.
5. Ease of use. The participant rated *Fibroline* as “Easy to use”.
6. Acceptance. The participant would use *Fibroline* mainly to: (1) keep a record of her progress (i.e., having a graphical representation of the scores in her self-reports across time), (2) practice relaxation exercises, and (3) use the reminders (i.e., set the alarms in order to remember doing certain tasks).

Feasibility and acceptability

Problems that were reported. The evening assessment could not be completed if they had completed it the previous day after 12AM (midnight). This problem was fixed right after it was discovered and no new problems appeared.

Suggested changes. The users suggested: (1) changing the assessments setting so that they could complete the evening assessment after 12AM, and (2) developing an Android version.

Most popular features. The users reported to like the most: (1) that *Fibroline* included multimedia content, (2) the reminders to take medication, (3) the availability of the app at any time in any place, (4) the graphical feedback.

Ease of use. All participants (100%) rated *Fibroline* as “Easy to use”.

Acceptance. All participants (100%) completed the treatment. The mean satisfaction with the treatment was 7 out of 10.

Discussion

Fibroline, a mobile app with a self-administered CBT program created to help improve the quality of life of individuals with JFS or CWP has been described, and its usability, refinement process and acceptability reported.

The CBT treatment included in *Fibroline* was found to be a feasible intervention. Yet, some technical problems that otherwise could have been overlooked (i.e., completing assessments after 12AM) appeared at this stage, therefore testing mobile applications over a period of time in a natural environment is essential to ensure that the application is ready to be used by end users.

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). Moreover, some distance and Internet-delivered treatments have proved to be appropriate and efficient in the treatment of fibromyalgia and CWP (Kristjánisdóttir et al., 2013).

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, feasible and easy-to-use program.

This is a preliminary test of *Fibroline*, and our study is not exempt of certain limitations. First, participants in the first usability test were younger than our expert patient, and some age-related differences may have gone unnoticed. However, this is highly unlikely as the patients who tested the app for nine weeks were 15, 21 and 24 years old, and no usability problems were reported by anyone.

Second, in this study we used qualitative usability questionnaires only. Future research with quantitative usability questionnaires is required.

Finally, *Fibroline* was tested either in a single session or with patients with JFS or CWP using the program for the nine planned weeks. It remains to be seen if the CBT treatment is effective in reducing the pain intensity and associated symptoms and for how long the effects last. A pilot study will be conducted. *Fibroline* is only available for iOS devices, but an Android version is being developed so most users will be able to access it.

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. Informing health professionals 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.

In a recent systematic review (de la Vega and Miró, 2014), it was 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).

In conclusion, mobile health technology can make healthcare more accessible to those in need. This study showed that *Fibroline* is a mobile app that can help to provide the best available treatment for JFS or CWP. *Fibroline* has demonstrated good usability and feasibility characteristics and shown to be acceptable for end users. Due to its convenient accessibility and simplicity of use, this app might be an important support to professionals and patients in remote places where healthcare services are scarce. However, additional research is needed to assess and establish its effectiveness.

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Declaration of Conflicting Interests

The Authors declare that there is no conflict of interest.

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Figure legends

Fig.1 *Fibroline* main menu

Fig.2 Screenshots with an example of each of the five sections

Fig.3 Changes made after cycle I

Fig.4 Changes made after cycle II

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