University of Sao Paulo

DEVELOPMENT OF A MOBILE APPLICATION TO PROMOTE SELF-CARE IN PATIENTS WITH FIBROMYALGIA

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The study protocol was registered at ClinicalTrials.gov.

Registration No.: NCT0300491

Sao Paulo

July 14th 2014

Objectives

The purpose of this work was to develop a mobile application software for the promotion of self-care and assess the effectiveness of its use during six weeks on health-related quality of life, symptoms and self-care agency of patients with FMS, and to compare the results to the use of a paper book of similar content. Secondarily, patients' adherence to ProFibro app was evaluated.

Methods

A randomized, single-blind, controlled trial was conducted in the Physical Therapy Clinical Research and Electromyography Laboratory at the Physical Therapy, Speech Therapy and Occupational Therapy Department of the School of Medicine of the University of Sao Paulo (USP), in the city of Sao Paulo, Brazil. The project was approved by the Research Ethics Committee of the School of Medicine, University of Sao Paulo (No. 274/14).

Participants (eligibility criteria)

Volunteers were identified using the USP Newspaper and related social media. After answering a screening questionnaire sent by email, potential participants were invited to a face-to-face assessment to confirm eligibility. All participants signed a written informed consent prior to entering the study.

The study included adults and middle-aged individuals (19-59 years) diagnosed with FMS, according to the 2010 American College of Rheumatology (ACR) diagnostic criteria[1], who were smartphone users and completed elementary education. Exclusion criteria were: individuals undergoing physical therapy or treated in the last three months; diagnosis of other conditions causing chronic pain (neuropathies, rheumatoid arthritis, osteoarthritis, spinal stenosis or cancer); severe mental disorders (schizophrenia, psychosis, bipolar affective disorder, severe depression); hearing or visual impairment.

Sample Size

The sample size was calculated to detect the minimal clinically important difference (MCID) of 14% between two groups in health-related quality of life, measured by the FIQR, with a standard

deviation of 24.3.[2, 3] Calculations indicated that a sample size of 30 participants would provide a power of 80% at a level of significance of 5%. Five participants were added to each group to compensate for possible dropouts, resulting in a total of 40 participants.

Randomization

Participants were randomly allocated into Experimental and Control Groups. A physical therapist who was not involved in the trial concealed a computer-generated random sequence in sequentially numbered, opaque, sealed envelopes.

Outcomes

An outcome assessor blinded to the interventions enrolled participants in the trial and evaluated them at baseline and after six weeks of intervention.

At baseline, the following demographic and clinical data were collected: age, sex, marital status, level of education, family income, duration of the syndrome and use of medication.

The primary outcome was health-related quality of life measured by the Brazilian Portuguese version of the FIQR.[3, 4] The FIQR has 21 questions based on an 11-point numeric rating scale of 0 to 10, with 10 being 'worst'. All questions are framed in the context of the past seven days. The FIQR is divided into three domains: (a) Function (contains nine questions), Overall Impact (contains two questions), and (c) Symptoms (contains ten questions regarding pain, stiffness, lack of restorative sleep, poor energy, anxiety, depression, tenderness, memory, balance and environmental sensitivity). The Function score is the sum of the nine questions divided by 3 (range 0 to 30), the Overall Impact score is the sum of two questions (range 0 to 20), and the Symptoms score is the sum of the ten questions divided by 2 (range 0 to 50). The total FIQR is the sum of the three domain scores (range 0 to 100).

Secondary outcomes were: pain measured by the Widespread Pain Index (WPI)[1] and the Visual Analog Scale (VAS)[5]; severity of symptoms measured by the Symptom Severity (SS) Scale[1]; agency of self-care measured by the Brazilian Portuguese version of the Appraisal of Self-Care Agency Scale – Revised (ASAS-R)[6, 7].

The WPI is one of the diagnostic variables of the 2010 ACR diagnostic criteria for FMS. It is a measure of the number of painful body regions (range 0 to 19) in the context of the past week.

The VAS for pain was used to measure the pain intensity (range 0 to 10) at the moment of the examination. It is a continuous scale comprised of a 10-cm horizontal line, anchored by two verbal descriptors: no pain (score of 0) and worst imaginable pain (score of 10).

The SS Scale is another diagnostic variable of the 2010 ACR diagnostic criteria. It is a 4-component scale (range 0 to 12) composed of assessor-rated cognitive problems, unrefreshed sleep, fatigue and somatic symptom count. The timeframe for the assessment of the SS Scale is one week.

The ASAS-R is a multidimensional measure that evaluates the level of self-care agency regarding having, developing and lacking the power for self-care (range 15 to 75). It comprises 15 items responded in a five-point Likert scale ranging from 1 (totally disagree) to 5 (totally agree).

ProFibro app was programmed to register the date and time of each access to the app functions. Patients' adherence to the use of ProFibro app was assessed according to the number of accesses to the app functions after six weeks.

Interventions

A physical therapist researcher who was not involved in the outcome assessment opened the sealed envelopes and assigned participants to each group.

At their first individual session, the researcher gave the participants of the Experimental Group a smartphone with the ProFibro app installed, and the participants of the Control Group a paper book of similar content to that of the mobile app. The book was made after the development of the mobile app was completed.

Both groups received a 20-min introductory tutorial leading the participants through the main functions of the mobile app or book chapters. For further instructions, the information icon of the app functions and tutorial video in the menu were presented to the participants of the Experimental Group. Finally, the participants were instructed to explore and use the tools for six weeks with a view to self-care.

Statistical methods

Primary and secondary outcomes were compared to baseline in each group and between groups. Change scores (the difference between the final and the baseline score) were used for comparison between groups. Analysis was performed on an intention-to-treat basis, with data carried forward from the baseline assessment in case of dropouts. Kolmogorov-Smirnov and Levene tests were used to verify normality and equality of variance of the data, respectively. Independent t tests were used with variables that were normally distributed, and Mann-Whitney rank sum tests were used with variables that were not normally distributed. A p-value <0.05 was considered statistically significant. These statistical tests were performed using software SigmaStat 3.5 (Systat Software, Inc, Erkrath, Germany).

In the analysis of clinical important changes, participants were classified as respondents if they scored higher than the MCID for an outcome, and non-respondents otherwise. The MCID for the FIQR total score was considered a change score of 8.1, and for VAS pain a change score of 2.[2, 8, 9] For the other variables, no MCID was yet identified, and a change score of 15% was used.[10]

Funding

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