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Effectiveness of online platform Red Sinapsis monitoring in the quality of life of people with fibromyalgia

Submission date
06/01/2017

Recruitment status
No longer recruiting

Registration date
07/02/2017

Overall study status
Completed

Last Edited
07/02/2017

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Fibromyalgia (FM) is a common long-term condition, which causes widespread muscle and joint pain all over the body. The exact cause of FM is unknown, but it is thought that a variety of physical, mental and emotional factors are responsible. Many people diagnosed with FM are dissatisfied with treatments offered by health professionals and often seek out alternative treatments elsewhere. Previous studies have shown that more than half of patients seen in pain units look for information online. Therefore knowing how to advise on tools that help with data searches, using quality and safe sources, could help improve quality of life and well-being. The Red Sinapsis platform is an online platform managed by nurses that allows patients to access information about their condition and treatment. The aim of this study is to find out whether use of this online platform can improve the quality of life and mental wellbing of patients with FM.

Who can participate?
Adults who have been diagnosed with fibromyalgia and have access to a computer.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are given access to the Red Sinapsis platform. Through this platform they are able to access information about FM and send messages which will be answered by trained nurses 12 hours each day. If participants do not access the platform for 15 days, then they are sent a reminder email with a follow up reminder telephone call. Those in the second group continue as normal for the duration of the study. At the start of the study and then after six and 12 months, participants in both groups complete questionnaires to assess their emotional state and how they view their health status. The participants who use the platform are also asked to provide their opinions about it after 12 months.

What are the possible benefits and risks of participating?
Participants benefit from being able to have any questions they may have about their condition and treatment answered quickly. There are no direct risks involved with participating.

Where is the study run from?
Pain Clinic of Madrid (Spain)

When is the study starting and how long is it expected to run for?
May 2013 March 2016

Who is funding the study?
Universidad Autónoma de Madrid (UK)

Who is the main contact?
1. Dr Eva García-Perea (scientific)
2. Dr Azucena Pedraz-Marcos (scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
UAM-CEI-46-894

Study information

Scientific Title
Effectiveness of online platform Red Sinapsis monitoring in the quality of life of people with fibromyalgia: A randomized controlled 1-year follow-up study

Study objectives
The online consultation of nursing with people with fibromyalgia, through a computer platform, shared between patients and health professionals (Red Sinapsis), improves the quality of life with regards to perception of well-being, anxiety and depression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University Autonoma of Madrid (Spain) Research Ethics Committee, 27/06/2013, ref: 46-894
2. Hospital Clinico of Madrid (Spain) Ethical Committee for Clinical Research, 26/06/2013, ref: 13-208-E

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Fibromyalgia

Interventions
Participants are randomised to one of two groups.

Intervention group: Participants are telephoned and they are called in to the clinic to register them in the Red Sinapsis platform and assign them the access codes, giving them a few instructions for using the system. It is explained that the messages will be taken care of during consultation hours from Monday to Friday from 10 a.m. to 10 p.m., although the patient can use the messenger at the time he wants. To ensure that the patient has no doubts about the management of the platform, a message is sent to those patients who have not been connected to the platform within 15 days of being logged into the system. In these messages they are asked about their doubts or possible connection problems. If no response is received, then participants are contacted by telephone. Through the messages to the patient, information is provided based on the available scientific evidence, correctly documented related to their illness (FM) and the medication they habitually consume, providing data sheets containing the indications, side effects, contraindications and interactions from the same.

Control group: Participants are telephoned and told that they are in the control group and will not be using the Red Sinapsis platform. Participants then continue to receive usual care for the duration of the study.

At baseline, 6 and 12 months, participants in both groups complete a range of questionnaires.

Intervention Type
Device

Primary outcome(s)
1. Perception of health status is assessed using the FIQ and SF-36 questionnaires at baseline, 6 and 12 months
2. Emotional state (anxiety and depression) is assessed using the FIQ and SF-36 questionnaires at baseline, 6 and 12 months

Key secondary outcome(s))
Degree of satisfaction with the platform usage is assessed using a survey designed for the purpose of this study at 12 months (intervention group only).

Completion date
31/03/2016

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Diagnosed with Fibromyalgia following the American College of Rheumatology criteria
3. Have access to a computer

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Those who not have a computer or means to be followed up online
2. People with severe cognitive or mental disorders
3. Not providing informed consent to participate.

Date of first enrolment

03/07/2013

Date of final enrolment
27/03/2015

Locations

Countries of recruitment
Spain

Study participating centre
Clínica del Dolor de Madrid (Pain Clinic of Madrid)
Vallehermoso, 26. Madrid (Spain)
Madrid
Spain
28015

Sponsor information

Organisation
Universidad Autónoma de Madrid

ROR
https://ror.org/01cby8j38

Funder(s)

Funder type
University/education

Funder Name
Universidad Autónoma de Madrid

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Eva García-Perea (eva.garcia@uam.es)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes