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Effectivity of virtual reality physical exercise program in brain and motor aging in fibromyalgia

Submission date
22/11/2017

Recruitment status
No longer recruiting

Registration date
07/12/2017

Overall study status
Completed

Last Edited
18/01/2023

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Physical activity can help cope with brain and motor aging, both in healthy people and those with pathologies. This is the case of people with fibromyalgia, characterized by chronic pain, which because of the impact that the disease has on the physical, cognitive and cerebral functions, are a good study model. The effects of a physical activity program on cerebral, electrical and volumetric brain function, such as the pineal gland, in this population and its relation to well-being, sleep, heart rate variability and cognition, are unknown. Taking advantage of the development of new technologies, the use of video games to implement physical activity programs could offer us the advantage of working both physical and cognitive aspects, creating tasks where these two aspects occur simultaneously (dual tasks), resembling more to the conditions that we find in our day to day. The aim of this study is to develop and verify the effectiveness of a physical activity program based on virtual reality (VirtualEx-FM) on cognitive, cerebral, motor and cardiac function, as well as to study the relationships and mechanisms between cerebral aging In daily tasks related to quality of life in people with fibromyalgia.

Who can participate?
Women aged between 30 and 75 years old who have fibromyalgia

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the standard level of care. Those in the second group receive six months of twice weekly virtual reality physical activity. Participants are assessed before and after for their symptoms of fibromyalgia and effectiveness of the physical activity programme.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in their symptoms. There are no risks associated with participation.

Where is the study run from?
University of Extremadura (Spain)

When is the study starting and how long is it expected to run for?
July 2017 to June 2018

Who is funding the study?
1. Ministry of Economy and Competitiveness, MINECO (Spain)
2. Government of Extremadura (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
DEP2015-70356-R

Study information

Scientific Title
Cost-effectiveness of a virtual reality physical exercise program in brain and motor aging in fibromyalgia

Study objectives
1.Expermiental group will improve the quality of life and impact of fibromyalgia
2. Physical fitness tests, body composition and daily life activities will enhance with the intervention program
3. Brain dynamics and structures will be remodeled with the intervention
4. Cognitive impairments, psychophysiological response to daily life activities autonomic

function, cortisol and melatonin samples will improve with the exercise program
5. Impact of pain, depression and quality sleep index will enhance with the intervention
6. Fear of falling and kinesiophobia will be reduced after the intervention program

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethics and biosafety committee of the University of Extremadura, 07/07/2017, ref: 62/2017

Study design
Blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

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

Interventions
Participants are randomly allocated to one of two groups.

Those in the first group are the control group.

Those in the second group perform physical activity within the VirtualEx-FM program. The program consists of two weekly 1-hour sessions for 24 weeks. It will be based on a Motion-Controlled Video Game on Microsoft Xbox Kinect and it will be carried out indoors in a room of the local fibromyalgia association's building.

Participants are evaluated before and after the program in a non-invasive way:
1. Sociodemography, quality of life, life habits and impact of fibromyalgia
2. Brain aspects - magnetic resonance without contrast, cognitive, mental and cardiac (heart rate variability)
3. Electroencephalographic pattern and motor in daily activities by means of standardized tests of physical condition

Intervention Type
Mixed

Primary outcome(s)
1. Health related quality of life is measured using EQ-5D-5L and Whoqol – Brief questionnaires at baseline and 24 weeks
2. Impact of fibromyalgia is measured using Fibromyalgia Impact Questionnaire (FIQ) and its revised version, the FIQ-R at baseline and 24 weeks
3. Cost-effectiveness is measured using EQ-5D-5L and Whoqol – Brief questionnaires at baseline and 24 weeks
4. Activities of daily living and physical fitness (with and without dual-task) are measured at baseline and 24 weeks by:

4.1. Lower limb strength using 30s chair stand test and the 10-step stair climbing test with and without carrying a load
4.2. Hand-grip strength using a grip-strength dynamometer (TKK 5401 Model)
4.3. Aerobic endurance using the Canadian Aerobic Fitness Test and 6 min walking
4.4. Upper body strength using the “Arm Curl Test”
4.5. Balance using Biodex Balance System. This device measures, in degrees, the tilt about each axis during static and dynamic conditions and calculates a mediolateral stability index, an anteroposterior stability index, and an overall stability index
4.6. Chair sit-and-reach and Back scratch to evaluate upper and lower body flexibility
4.7. Cognitive tasks tested using a wireless motion capture device "Functional Assessment of Biomechanics (FAB)" and a wireless electroencephalography (EEG) system (Enobio, Neuroelectrics) in order to assess the motor and brain pattern of the activities of daily living
5. Electrical activity and volumes of important structures of the brain measured at baseline and 24 weeks by:
5.1. Electrical activity at rest using Enobio (Neuroelectrics, Cambridge, MA, USA)
5.2. Volumes of structures such as hippocampus or pineal gland using Magnetic Resonance Imaging (MRI)

Key secondary outcome(s))

1. Cognitive impairment is measured using the Mini-Mental State Examination (MMSE) and executive function with the Stroop test at baseline and 24 weeks
2. Psychophysiological response to daily life activities is measured using EEG register while they are watching a video where people are doing different daily activities with and without pain at baseline and 24 weeks
3. Pain-related fear measured using the Tampa Scale for Kinesiophobia (TSK- 11SV) at baseline and 24 weeks
4. Cortisol and melatonin levels are measured using saliva samples at baseline and 24 weeks
5. Pain is measured using the Visual Analog Scale (VAS) and with an algometer on the fibromyalgia-specific tender points at baseline and 24 weeks
6. Depression is assessed using the Geriatric Depression Scale (GDS) at baseline and 24 weeks
7. Body composition is measured using a bioelectrical impedance analysis (Tanita BC-415) and waist to hip ratio at baseline and 24 weeks
8. Perceived effort using a Borg Scale is measured at each session (after finishing each session)
9. Drug treatment is measured using questionnaires at baseline and 24 weeks
10. Cost-effectiveness analysis is measured using the number of visits to the health care system in the last six months at baseline and 24 weeks
11. Self-reported work absence is assessed by a single question asking the number of days that participants had to miss work in the last 6 months at baseline and 24 weeks
12. Fear of falling will be assessed with a VAS from 0 (no fear) to 100 (extreme fear) and using the FES-I questionnaire at baseline and 24 weeks
13. Number of falls are recorded as the self-reported number of falls in the last year and in the last six months at baseline and 24 weeks
14. Volume of physical activity in their free time is measured using the international physical activity questionnaire (IPAQ) at baseline and 24 weeks
15. Covariables are measured at baseline and 24 weeks using:
15.1. Sociodemographic variables: gender, age, education level, profession, income level, religiosity, postal code and familiar situation.
15.2. Other diseases
15.3. Current treatment and therapies, years since diagnosis of FM and years since the first symptoms
15.4. Current pain “at today”

16. Sleep quality, latency, duration, efficiency, disturbances, use of sleep medication is measured using the Pittsburgh Sleep Quality Index at baseline and 24 weeks
17. Health habits are assessed using the EUROPALIQ questionnaire at baseline and 24 weeks

Completion date
29/06/2018

Eligibility

Key inclusion criteria
1. Women
2. Aged between 30 and 75 years
3. Diagnosed with fibromyalgia by a rheumatologist
4. Able to communicate effectively with the study staff
5. Read and signed the written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
Female

Total final enrolment
55

Key exclusion criteria
1. Pregnancy
2. Changes in usual care therapies during the 8 weeks of treatment
3. Contraindications for physical exercise

Date of first enrolment
18/12/2017

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Spain

Study participating centre

Faculty of Sport Science (University of Extremadura)
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Sponsor information

Organisation
University of Extremadura

ROR
https://ror.org/0174shg90

Funder(s)

Funder type
Government

Funder Name
Ministerio de Economía y Competitividad

Alternative Name(s)
Ministry of Economy and Competitiveness, MINECO, MEC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Funder Name
Government of Extremadura

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 Narcis Gusi (ngusi@unex.es).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/12/2019	18/01/2023	Yes	No
Results article		11/07/2019	18/01/2023	Yes	No
Results article		30/07/2020	18/01/2023	Yes	No
Results article		20/03/2020	18/01/2023	Yes	No