ISRCTN41907183 https://doi.org/10.1186/ISRCTN41907183

Mobile application for rehabilitation from inner ear disorders causing dizziness

Submission date
20/01/2020

Recruitment status
No longer recruiting

Registration date
03/02/2020

Overall study status
Completed

Last Edited
03/02/2020

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
Vestibular rehabilitation is an important therapeutic option for the treatment of instability and imbalance. Dizziness or instability and imbalance in gait carry a risk of falls.
The prevention of them is an important consideration since they represent an important source of sequelae and therefore influence the patient's quality of life. Different studies have shown that older patients at risk of falling, regardless of gender or age or diagnosis, (whether central, peripheral or gait abnormalities) show a benefit with vestibular rehabilitation.
Vestibular Rehabilitation is developed at home by the patient through exercises with eye, head and body movements, following a prescribed guideline in consultation and delivered in paper format.
The objective of this research is to assess whether a vestibular rehabilitation based on the same exercises but offered through a mobile application with explanations and videos increases adherence to therapy and improves the expected results in the balance and stability of patients. This study does not imply any extraordinary or different measures than those usually performed.

Who can participate?
Patients with a diagnosis of vestibular dysfunction confirmed and have access to the smartphone or tablet will be recruited to take part in the study

What does the study involve?
The study will have two arms; patients in the treatment arm have access to the mobile application, while patients in the control arm will have access to usual care only (booklet).

What are the posible benefits and risks participants?
Vestibular rehabilitation based on the same exercises but offered through a mobile application with explanations and videos can increase adherence to therapy and improves the expected results in the balance and stability of patients.

In all vestibular rehabilitation, adverse events are rare, however, there is a possibility that they may experience any of the following symptoms: acute or prolonged pain in the neck, head or ear, feeling of fullness in the ear, deafness or noise in the ear, syncope, double vision and weakness or tingling in the arms or legs. In this case, you are advised to stop the intervention

and not continue until you have consulted with the research team. Most of the problems that occur when patients perform the exercises can be remedied by making the exercises more smoothly and slowly.

Where is the study run from?
Otorhinolaryngology Unit, Puerta del Mar University Hospital, Cádiz, Spain.

When is the study starting and how long is it expected to run for?
Recruitment into this study runs from October 2018 until February 2020

Who is funding the study?
Council of Andalusian Health Services (Consejería de Salud, Junta de Andalucia) (Spain)

Who is the main contact?
Antonio Martín
antoniomartinmateos@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Antonio Jesús Martín Mateos

ORCID ID
https://orcid.org/0000-0002-5639-1595

Contact details
Puerta del Mar University Hospital
Ana de Viya, 21
Cádiz
Spain
11009
+34 671568420
antonioj.martin.sspa@juntadeandalucia.es

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PIN-0357-2016

Study information

Scientific Title
Effectiveness of a mobile application for vestibular rehabilitation in patients with vestibular disorders: a randomized clinical trial compares mobile application versus booklet based vestibular rehabilitation

Acronym
MhVR

Study objectives
1. Vestibular rehabilitation at home through a mobile application is more effective than a home based exercise booklet in reducing symptoms in dizzy patients
2. Mobile application home based vestibular rehabilitation is better than a home based exercise booklet
3. Vestibular rehabilitation at home through a mobile application is more effective than a home based exercise booklet

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/10/2016, Research Ethics Committee of Cádiz. (Comité de Ética de la Investigación de Cádiz, Office 817. 8ª Floor, Hospital Universitario Puerta del Mar, Ana de Viya, 21,Cádiz, Spain , 11009; +34 956002005; ceic.hpm.sspa@juntadeandalucia.es), ref: n/a

Study design
Single-centre single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Disorders of vestibular function

Interventions

This study compares mobile application versus booklet based vestibular rehabilitation for vestibulopathy.

Control group: receive a booklet that explains Cawthorne-Cooksey (CC) exercises.

Experimental group: receive a mobile application that explains Cawthorne-Cooksey (CC) exercises with videos, with database to register the exercises make by patient. The patient can visualize the database with the exercises performed.

For each study arms: The exercises are classified into 4 progressive levels and each exercise should be performed at least twice a day.

Follow-up for each study arms: Six months.

Randomisation: The randomisation sequence is generated automatically by the Win Epi software . The randomisation algorithm is stratify patients by dizziness severity (> 60 DHI). Sample randomization and allocation is performed by a researcher who is not involved in the clinical trial. The sequencing remain concealed to the trial team.

Intervention Type
Behavioural

Primary outcome measure
Effect of dizziness on daily life measured by the Dizziness Handicap Inventory (DHI) at baseline, after 3 months and after 6 months

Secondary outcome measures
1. Dizziness measured using a single item measure of subjective improvement. This asks patients to indicate whether they had felt better, same or worse with regard to their dizziness symptoms than at baseline
2. Demographic characteristics, including age, sex ,clinical and topographic diagnosis

Overall study start date
01/01/2018

Completion date
01/03/2020

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Diagnosis of vestibular disease according to revised Society Barany criteria
3. Availability of Smarthphone or Tablet system android or ios
4. Sign informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
At least 84 patients, 42 in each study group.

Key exclusion criteria
1. Non-vestibular causes of dizziness
2. Medical contraindication for performing head movement exercises (such as diseases severe cervical)
3. Severe comorbidity (such as disabling neurological diseases)

Date of first enrolment
01/10/2018

Date of final enrolment
01/09/2019

Locations

Countries of recruitment
Spain

Study participating centre
Puerta del Mar University Hospital
Otorhinolaryngology Unit
Ana de Viya, 21
Cádiz
Spain
11012

Sponsor information

Organisation
Fundación para la Gestión de la Investigación Biomedica de Cádiz

Sponsor details
Ana de Viya, 21
Cádiz
Spain
11012

+34 956 245 018 / +34 956 245 019
fundacion.cadiz@juntadeandalucia.es

Sponsor type
Research organisation

Website
http://www.juntadeandalucia.es/index.html

Funder(s)

Funder type
Government

Funder Name
Council of Andalusian Health Services (Consejería de Salud, Junta de Andalucia) (Spain)

Results and Publications

Publication and dissemination plan
Dissemination of the research results within the clinical and scientific community, through papers published in clinical journals and presentations at conferences.

Intention to publish date
31/10/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
Will individual participant data be available (including data dictionaries)? Yes
What data in particular will be shared? All of the individual participant data collected during the trial, after deidentification.
What other documents will be available? Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code
When will data be available (start and end dates)? Immediately following publication. No end date.
With whom? Investigators whose proposed use of the data has been approved by an independent review committee (“learned intermediary”) identified for this purpose.
For what types of analyses? Any purpose
By what mechanism will data be made available? Data are available indefinitely (Link to be provided).

IPD sharing plan summary
Available on request