

# Mobile application for rehabilitation from inner ear disorders causing dizziness

<b>Submission date</b> 20/01/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/02/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/02/2020	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 possible 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 Andalucía) (Spain)

Who is the main contact?

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**Protocol serial number**

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

### **Study type(s)**

Quality of life

### **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(s)**

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

**Key secondary outcome(s)**

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

**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 Smartphone or Tablet system android or ios
4. Sign informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

# Funder(s)

## Funder type

Government

## Funder Name

Council of Andalusian Health Services (Consejería de Salud, Junta de Andalucía) (Spain)

# Results and Publications

## 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