

# The continuous ambulatory vestibular assessment (CAVA) multicentre dizziness trial

<b>Submission date</b> 27/01/2023	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 31/01/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/06/2025	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Dizziness is common and identifying the condition causing it is challenging. This can lead to patients experiencing significant delays in diagnosis. The aim of this study is to test the CAVA system's ability to use eye movement data collected by the device to diagnose dizziness conditions. This could greatly reduce the time to diagnosis saving the NHS money by reducing multiple visits to GP clinics, referrals to specialists and the number of treatments required.

### Who can participate?

Adults who have been diagnosed with Meniere's disease, vestibular migraine or benign paroxysmal positional vertigo (BPPV) and currently experiencing episodes of vertigo/dizziness.

### What does the study involve?

The study involves wearing a device that goes over the ear and attaches to the face for 30 consecutive days whilst logging dizziness symptoms in a diary. There will be up to five in-person hospital visits to learn how to use the device and complete questionnaires.

### What are the possible benefits and risks of participating?

Benefits include helping conduct the research around identifying dizziness conditions using the CAVA device. Risks include some redness caused by the electrode pads attaching to the skin.

### Where is the study run from?

The study is run from the Norfolk and Norwich University Hospital and the University of East Anglia (UK)

### When is the study starting and how long is it expected to run for?

July 2022 to October 2025

### Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK)

### Who is the main contact?

Dr Gregory M Howard, [Gregory.howard@uea.ac.uk](mailto:Gregory.howard@uea.ac.uk)

**Study website**

<https://www.cava-project.org>

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Gregory Howard

**ORCID ID**

<https://orcid.org/0000-0001-5749-0782>

**Contact details**

Norwich Clinical Trials Unit  
Norwich Medical School  
University of East Anglia  
Norwich  
United Kingdom  
NR4 7TJ

-

[gregory.howard@uea.ac.uk](mailto:gregory.howard@uea.ac.uk)

**Type(s)**

Principal Investigator

**Contact name**

Mr John Phillips

**ORCID ID**

<https://orcid.org/0000-0001-7886-6283>

**Contact details**

Norfolk & Norwich University Hospital NHS Trust  
Colney Lane  
Norwich  
United Kingdom  
NR4 7UY

-

[john.phillips@nnuh.nhs.uk](mailto:john.phillips@nnuh.nhs.uk)

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

317899

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CPMS 54262, IRAS 317899

## **Study information**

**Scientific Title**

Continuous ambulatory vestibular assessment (CAVA) - development of a system to provide an automatic diagnosis for vestibular conditions

**Acronym**

CAVA

**Study objectives**

The CAVA System will identify and differentiate nystagmus using the algorithm.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 24/10/2022, West Midlands – South Birmingham REC (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8345, +44 (0)207 104 8068, +44 (0)207 104 8143; southbirmingham.rec@hra.nhs.uk), ref: 22/WM/0229

**Study design**

Non-randomized; Both; Design type: Diagnosis, Device, Validation of outcome measures

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

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

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

Vestibular conditions

**Interventions**

All participants fulfilling the eligibility criteria and providing consent will wear the CAVA device for 30 days in a real-world context. Then the CAVA algorithm will diagnose each patient based only on the data recorded from the device. The accuracy of the system will be tested by comparing the CAVA system's diagnosis with each patient's known diagnosis.

All participants will be provided with the PIS after confirmation of eligibility at Visit 1. They will receive training on how to wear the monitoring device and how to use and care for it at the hospital at Visit 2 (Day 0). Once competency in the use of the CAVA system is demonstrated participants will be asked to wear the device for 30 consecutive days, 23 hours each day. At Visit 3 (Day 5) participants will return to the hospital to assess adherence and adverse reactions. The battery will need to be replaced around halfway through the 30 days so participants will return to the hospital for Visit 4 (Day 15) to have the battery changed, assess adherence and adverse events. Also at Visit 4 any participants with benign paroxysmal positional vertigo (BPPV) will receive treatment whilst wearing the device. The participants will return to the hospital for Visit 5 (Day 33) to return the device and all accessories as well as complete a questionnaire.

Participants will replace the electrode pads on a daily basis during their participation. The device has an 'event marker' button to be used when a patient experiences dizziness. The patient would press this button to effectively mark the data denoting an episode of dizziness. Support and advice will be provided by the research team to deal with any concerns which arise from using the CAVA system.

### **Intervention Type**

Device

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

CAVA device

### **Primary outcome measure**

Identification of nystagmus data from the device using a computer algorithm; data is collected during the 30 days wearing the device

### **Secondary outcome measures**

1. Safety events assessed using adverse event (AE) reporting on Day 5, Day 15, Day 33
2. Health economics measured using a bespoke health economic questionnaire, Social life & Work Impact of Dizziness (SWID) questionnaire and EQ5D3L on Day 0, Day 5, Day 15, Day 33
3. Average time to first dizzy attack determined using device and diary data collected during the 30 days
4. Device compliance measured using device data collected during the 30 days
5. Patient acceptability measured using a tailored user experience questionnaire on Day 33 or at end of participation if earlier
6. Device malfunctions assessed using device data collected during the 30 days
7. Commercialisation informed using the health economics data (post data collection analysis)

### **Overall study start date**

01/07/2022

### **Completion date**

31/10/2025

## Eligibility

### Key inclusion criteria

1. Age 18 years and over
2. Must have relevant index medical condition: Ménière's disease, vestibular migraine, posterior canal benign paroxysmal positional vertigo
3. Experiencing episodes of true vertigo with at least two episodes within the preceding 4 weeks at time of consent
4. The duration and nature of the vertigo is of a duration and a nature supportive of the relevant index medical condition
5. Owns and is able to use a telephone
6. Willing to provide informed consent
7. Willing to comply with the study protocol for using the CAVA device
8. Willing to complete all study materials
9. Adequate grasp of the English language or language used within an existing translated version of the informed consent form and patient information sheet and where hospital translators are available to provide support

### Participant type(s)

Patient

### Age group

Adult

### Lower age limit

18 Years

### Sex

Both

### Target number of participants

255

### Key exclusion criteria

1. Has an allergy to plasters and/or medical adhesives
2. Evidence of dermatitis, fragile skin, or any other condition that could be aggravated by the repeated application of skin surface adhesives
3. Pregnant or breastfeeding mothers
4. Bilateral or second side Ménière's disease
5. Active bilateral or second side posterior canal benign paroxysmal positional vertigo
6. Currently enrolled on an intervention trial (not including questionnaire-based or observational trial)
7. Patients who meet diagnostic criteria for more than one eligible condition at time of recruitment

### Date of first enrolment

21/02/2023

**Date of final enrolment**

31/08/2025

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****Norfolk and Norwich University Hospital**

Colney Lane

Colney

Norwich

United Kingdom

NR4 7UY

**Study participating centre****Worthing Hospital**

Lyndhurst Road

Worthing

United Kingdom

BN11 2DH

**Study participating centre****St Georges Hospital**

Blackshaw Road

Tooting

London

United Kingdom

SW17 0QT

**Study participating centre****St Thomas' Hospital**

Westminster Bridge Road

London

United Kingdom

SE1 7EH

**Study participating centre**

**Norfolk and Norwich University Hospital**  
Colney Lane  
Colney  
Norwich  
United Kingdom  
NR4 7UY

**Study participating centre**  
**Leicester Royal Infirmary**  
Infirmary Square  
Leicester  
United Kingdom  
LE1 5WW

**Study participating centre**  
**University Hospital Birmingham**  
Queen Elizabeth Hospital  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TH

**Study participating centre**  
**Addenbrookes**  
Addenbrookes Hospital  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

**Study participating centre**  
**Gloucester Royal Hospital**  
Great Western Road  
Gloucester  
United Kingdom  
GL1 3NN

**Study participating centre**  
**Southend University Hospital**  
Prittlewell Chase  
Westcliff-on-sea

United Kingdom  
SS0 0RY

## Sponsor information

### Organisation

Norfolk and Norwich University Hospitals NHS Foundation Trust

### Sponsor details

Colney Lane  
Colney  
Norwich  
England  
United Kingdom  
NR4 7UY  
+44 (0)1603647882  
julie.dawson@nnuh.nhs.uk

### Sponsor type

Hospital/treatment centre

### Website

<http://www.nnuh.nhs.uk/>

### ROR

<https://ror.org/01wspv808>

## Funder(s)

### Funder type

Government

### Funder Name

NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR202870

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

### Intention to publish date

30/06/2026



**Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol article</a>		07/11/2024	20/11/2024	Yes	No