

Can a digital self-help tool, created together with autistic people, support them in managing headaches?

Submission date 30/06/2026	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 01/07/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 30/06/2026	Condition category Nervous System Diseases	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Headaches are very common and can make everyday life difficult. Research suggests autistic people get headaches more often than other people, but they are rarely included in headache research. Apps that help people manage their own headaches already exist, but they are designed for the general population and may not suit autistic people without changes. This study works with autistic people to adapt an existing headache self-management app so that it suits autistic users better. The aim is to find out whether the app and the study itself are practical and acceptable. This is an early study to help plan a larger one in the future.

Who can participate?

Autistic people aged 16 and over who have frequent or long-lasting headaches (headaches at least once a month, for three months or more). A formal autism diagnosis is not needed, and people who identify as autistic are welcome. For the app part of the study, people need a smartphone or tablet they can use regularly.

What does the study involve?

There are two parts, and people can take part in one or both.

In Phase 1, participants take part in one interview lasting 45 to 90 minutes, online or in person at Ulster University. They share their experiences of headaches and what they would want from an app. A group that includes autistic members then helps design the app.

In Phase 2, participants use the app for 12 weeks on their own phone or tablet. For the first two weeks they only track their headaches. After that they can use short lessons on topics like sleep, pacing, relaxation and managing headache attacks. Participants fill in a short survey at the start and end, and may be invited to a short interview at the end. We offer vouchers as a thank-you.

What are the possible benefits and risks of participating?

There is no promised personal benefit, but what participants share will shape the app. Talking about pain or health, or tracking headaches closely, can sometimes feel upsetting, and some

people notice their headaches more while tracking them. Breaks, support information and a paper alternative to the app are available. The app does not give medical advice and does not replace care from a GP.

Where is the study run from?
Ulster University (UK).

When is the study starting and how long is it expected to run for?
The study is expected to start recruiting in autumn 2026, once ethical approval is in place, and to run until March 2028.

Who is funding the study?
A Physiotherapy Research Foundation (PRF) award, managed by the Chartered Society of Physiotherapy Charitable Trust (UK).

Who is the main contact?
Dr Joanne Marley, j.marley@ulster.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Physiotherapy Research Foundation (PRF) award
PRF/25/POD11

Study information

Scientific Title
Feasibility of a co-designed digital self-management intervention for autistic individuals with headache: a mixed methods study.

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

Submitted 30/06/2026, Ulster University Research Ethics Committee (York Street, Belfast, BT15 1ED, United Kingdom; +44 28 9536 5028; researchgovernance@ulster.ac.uk), ref: FCNUR-26-048

Primary study design

Interventional

Allocation

N/A: single arm study

Masking

Open (masking not used)

Control

Uncontrolled

Assignment

Single

Purpose

Device feasibility

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

Self reported persistent or chronic headache in autistic individuals

Interventions

This is a two-phase, single-arm mixed-methods feasibility study. There is no control group and no randomisation.

Phase 1 (qualitative and co-design): participants take part in one semi-structured interview lasting 45 to 90 minutes, held online via Microsoft Teams or in person. Interviews cover lived experience of headache, communication of pain, and preferences for digital self-management.

Based on the findings of phase 1, the study steering group will adapt an existing self management app prior to phase 2.

Phase 2 (single-arm feasibility): participants use the autism-adapted self-management app for 12 weeks. For the first two weeks (familiarisation) only the symptom-tracking feature is available. From Week 0 to Week 10 participants have full access to 8 to 10 short self-management modules of about 5 minutes each, covering sleep, pacing, hydration, relaxation, stress management, exercise and managing headache attacks. Participants are encouraged to use the app around three times a week, may complete modules in any order, and can turn reminders on or off.

Outcome measures are administered by a researcher via Jisc Online Surveys: HIT-6 and GAD-7 at Week 0 and Week 10, and the System Usability Scale at Week 10. App engagement and symptom-diary data are collected automatically across the 12 weeks. Up to 10 Phase 2 participants take part in an optional online exit interview at around Week 12.

Intervention Type

Behavioural

Primary outcome(s)

1. Recruitment over 6 month recruitment window measured using the number of participants enrolled as a proportion of the Phase 2 target of 20, collected at one time point at the end of the study
2. Retention measured using the proportion of enrolled participants completing the Week 10 outcome measures at Week 10
3. App engagement measured using the mean logins per week and proportion of available modules completed between Weeks 0 - 10, collected at one time point at the end of the study
4. Outcome-measure completeness measured using data on the item-level completeness of the Headache Impact Test (HIT-6) questionnaire, Generalized Anxiety Disorder 7-item (GAD-7) and the System Usability Scale (SUS) between Week 0 and Week 10, collected at one time point at the end of the study

Key secondary outcome(s)

Completion date

31/03/2028

Eligibility

Key inclusion criteria

1. Age 16 or older
2. Formal autism diagnosis or self-identification as autistic
3. Persistent primary headache disorder or cervicogenic headaches
4. Persistent defined as:
 - 4.1. Episodic (1 to 14 days per month)
 - 4.2. Chronic (15 or more days per month) headache for 3 months or more

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

16 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Currently enrolled in another headache or pain intervention trial
2. New headache, or symptoms suggestive of serious pathology (red flags, or secondary headaches other than cervicogenic)
3. Acute mental health (for example, very recent hospital admission or active care from a crisis team)
4. Photosensitive epilepsy, or epilepsy where the participant has been advised against the use of mobile screen-based apps

Date of first enrolment

01/09/2026

Date of final enrolment

31/03/2027

Locations**Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

Ireland

Isle of Man

Study participating centre

Ulster University

York Street

Belfast

Northern Ireland

BT15 1ED

Sponsor information

Organisation

University of Ulster

ROR

<https://ror.org/01yp9g959>

Funder(s)**Funder type****Funder Name**

Chartered Society of Physiotherapy Charitable Trust

Alternative Name(s)

CSP Charitable Trust, The Chartered Society of Physiotherapy Charitable Trust, The CSP Charitable Trust, Chartered Society of Physiotherapy, The Chartered Society of Physiotherapy, CSPCT

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available