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# Chronic headache education and self-management study (CHESS)

**Submission date**
16/12/2015

**Recruitment status**
No longer recruiting

**Registration date**
16/12/2015

**Overall study status**
Completed

**Last Edited**
06/08/2024

**Condition category**
Signs and Symptoms

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

## Plain English summary of protocol

Background and study aims
Chronic headache is defined as a headache occurring on at least 15 days per month for more than 3 months. It is a very common problem, affecting around one in thirty of the population. There are three main types of chronic headache: migraine, tension type headache (TTH) and medication overuse headache (MOH). There is currently very little information about the use of non-drug treatments or the best ways to support people to manage their chronic headaches better (supported self-management). For many people living with long-term conditions it is thought that giving patients a better understanding of their condition can help them to live with their disorder and improve quality of life. Many people report that meeting with others with similar disorders helps them to manage the problems better. This study will design a programme, that consists of personalised advice and support from a specially trained nurse on how to manage chronic headache including information about choice of drugs, and group sessions to support people to manage their headaches more effectively. This study is in two parts. The aim of the first part of this study is to assess this programme and see if it is possible to recruit patients to take part. The aim of the second part of this study is to test the effectiveness and cost-effectiveness of the self-management support programme.

Who can participate?
Adults suffering from chronic headache.

What does the study involve?
In the first part of the study, all participants are asked to complete a smartphone App to record the frequency, severity and duration of their headaches. Those that consent to take part in the study are asked to take part in a short telephone headache classification interview with a specially trained nurse using an approach specifically developed for this study to classify their headache type. All participants are asked to complete a postal questionnaire at the start of the study, and then after two and 12 weeks.
In the second part of the study, participants are randomly allocated to one of two groups. Those in the first group receive usual GP care plus a group headache education and self-management support programme, a short course run over two days held in local community settings with groups of about 8-10 people who have chronic headaches. Those in the second group receive usual GP care plus a a relaxation CD. All participants are asked to complete a postal

questionnaire at baseline four, eight and 12 months. Some participants are also asked to take part in interviews to find out about their experience taking part in the study.

What are the possible benefits and risks of participating?
The findings of this study may help to develop better services for people with chronic headaches. The study team hope that the participants find taking part in the study beneficial to their headache management. The study team does not think there are any major risks with taking part in this study. Occasionally, participants may find some of the topics during the self-management programme challenging or upsetting, however the facilitators are fully trained and will provide appropriate support and assistance should this be the case.

Where is the study run from?
The study is run from Warwick Medical School Clinical Trials Unit and takes place in GP practices (UK)

When is the study starting and how long is it expected to run for?
January 2015 to January 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
chess@warwick.ac.uk; Ctuenquiries@warwick.ac.uk

### Study website
www.warwick.ac.uk/chess

# Contact information

### Type(s)
Public

### Contact name
Dr Trial Team

### Contact details
Warwick Clinical Trials Unit
Warwick Medical School
University of Warwick
Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL
-
Ctuenquiries@warwick.ac.uk

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
215304

# Study information

### Scientific Title
Chronic Headache Education and Self-management Study (CHESS) – a study of the clinical and cost effectiveness of an education and self-management intervention for people with chronic headache

### Acronym
CHESS

### Study objectives
Feasibility study:
The aim of this study is to investigate the feasibility of a self-management support programme for people living with chronic headache (the CHESS Intervention).

Randomised controlled trial:
In adult patients diagnosed with chronic headaches, the provision of a self-management support programme in addition to best usual care within the NHS is clinically and cost-effective.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Feasibility study: West Midlands – Black Country Research Ethics Committee, 11/06/2015, ref: 15/WM/0165
Randomised controlled trial: North-West Greater Manchester East Research Ethics Committee, ref: 16/NW/0890

### Study design
Feasibility study: Multi-centre non-randomised feasibility study
Randomised controlled trial: Multi-centre randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
GP practice

### Study type(s)
Treatment

## 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
Chronic headaches

## Interventions
Feasibility study:
An education and self-management support intervention for the management of chronic headaches, specifically, migraine, TTH and MOH will be designed and evaluated. The design of the intervention will be informed by systematic reviews on the lived experience of chronic headache, prognostic factors for people living with chronic headache, and style and content of intervention programmes.

Randomised controlled trial:
Participants will be randomised to either the relaxation group or self-management group and will receive written notification of the randomisation outcome. The same information will also be sent to the participant's GP to notify them of randomisation into the study and a copy of the information provided to the participant for the patient notes. The randomisation will be stratified by geographical locality (Midlands and North-east London) and headache type (six possible headache types; tension type headache, probable chronic migraine and definite chronic migraine with or without medication overuse headache) using randomly permuted blocks, and implemented using a remote, independent telephone randomisation service at Warwick Clinical Trials Unit. Warwick CTU will manage randomisation ensuring allocation concealment. Staff responsible for follow-up data collection will be blinded to randomisation.Groups of 4-5 geographically close practices will be clustered with the aim to launch recruitment at around the same time in the practices. Participants ware then randomised whensufficient participants to populate a group in batches of around 20 participants are enrolled. This will help reduce any delay between randomisation and start of the intervention.

Intervention arm:
The intervention is a group education and self-management programme (around 10 participants per group) facilitated by a trained CHESS nurse and allied health professional. Those randomised to the intervention arm are asked to complete a paper headache diary for a period of up to eight weeks to help the nurse understand their headache pattern during the one to one session. Participants are booked in to attend the structured group sessions which run over two days, over two weeks followed by a nurse one to one consultation. The sessions will take place on weekdays and where possible, these sessions will run during school hours to accommodate those with children. The group sessions will be held in easily accessible venues in the community. Following the second group session each participant will be booked in to attend a one to one appointment lasting up to two hours with the CHESS trained nurse to classify their headache type, discuss medication and lifestyle factors and finally to explore goal setting. This discussion will be backed up by written information (for patient and GP). All participants will be offered telephone follow-up for up to eight weeks. The frequency of these follow-up calls will be individually negotiated and agreed with participants. This will be discussed and agreed during the one to one session. The group intervention comprises of self-management and education topics including acceptance, mood and headache, recognising unhelpful thought patterns and behaviours, stress management, sleep management, medication management, communication and mindfulness.

Control arm: Participants randomised to the control intervention will be provided with a relaxation CD to use. The CD comprises of progressive muscle relaxation and has been developed for the study. It will be available in both CD format as well as an MP3 download. Additionally those in the control arm of the study, and their GPs, will be provided with the final outcome of the classification interview/s. Participants will also receive a brief advice sheet on treatment options that is consistent with NICE guidance. The study team are seeking to make broad classifications and not aiming to produce a final diagnosis and that the suggestions are purely advisory.

Participants will be asked to complete follow up questionnaires at 4, 8 and 12 months post randomisation in both arms. Participants will be asked to complete the study smartphone app for 12 months from the date of consent.

## Intervention Type
Other

## Primary outcome measure
Primary outcome measures as of 04/05/2017:
Feasibility study:
Headache impact measured using the Headache Impact Test (HIT-6) as a self-complete postal questionnaire at baseline, 2 weeks and 12 weeks.

Randomised controlled trial:
Headache impact measured using the Headache Impact Test (HIT-6) as a self-complete postal questionnaire at baseline, 4, 8 and 12 months

Original Primary outcome measure:
Headache specific outcome measure collected by self-completed postal questionnaire.

## Secondary outcome measures
Feasibility study:
1. Migraine Disability measured using the Migraine Disability Assessment (MIDAS) as a self-complete questionnaire at baseline, 2 weeks and 12 weeks
2. Health related quality of life measured using the 12-Item Short Form Health Survey (SF-12) - at baseline, 2 weeks and 12 weeks
3. Mood measured using the Hospital Anxiety and Depression Scale at as a self-complete questionnaire at baseline, 2 weeks and 12 weeks
4. Self –efficacy measured using the Self-efficacy and Pain Self –Efficacy Questionnaire as a self-complete questionnaire at baseline, 2 weeks and 12 weeks
5. Headache quality of life measured using Chronic Headache Quality of Life Questionnaire (CHQLQ) a headache-specific modification of the Migraine Specific Quality of Life Questionnaire (MSQ) completed as a self-complete questionnaire at baseline, 2 weeks and 12 weeks
6. Health utility measured using EQ-5D as a self-complete questionnaire at baseline, 2 weeks and 12 weeks
7. Social activity measured using the Health Education Impact Questionnaire (Social Integration sub-scale) as a self-complete questionnaire at baseline, 2 weeks and 12 weeks
8. Health service activity measured as self-complete questionnaire: GP consultations, secondary care consultations, imaging, non-NHS treatments (e.g. acupuncture), over-the-counter medication for headaches, days lost from normal activities (e.g. work, study), loss of income and out of pocket expenses completed at baseline, 2 weeks and 12 weeks
9. Headache frequency, duration and severity measured via a smartphone App weekly for 12

weeks
10. Health service activity; consultations, outpatient appointments, imaging and medication use of acute and prophylactic headache treatments collected from GP records at 3 months

Randomised controlled trial:
1. Participant demographic data completed as a self-complete questionnaire at baseline
2. General Health including fatigue, sleep quality and bodily pain measured by the troublesomeness grid as a self-complete questionnaire at baseline, 4 months, 8 months and 12 months
3. Health related quality of life using the Short Form 12-item Health Survey (SF-12) as a self-complete questionnaire at baseline, 4 months, 8 months and 12 months.
4. Healthy Utility (EQ-5D-5L) as a self-complete questionnaire at baseline, 4 months, 8 months and 12 months
5. Headache specific quality of life measure using the Chronic Headache Quality of Life Questionnaire (CHQLQ) adapted with permission from the Migraine Specific Quality of Life (MSQ v2.1) as a self-complete questionnaire at baseline, 4 months, 8 months and 12 months
6. Hospital Anxiety and Depression Scale (HADS) as a self-complete questionnaire at baseline, 4 months, 8 months and 12 months
7. Pain self-efficacy questionnaire (PSEQ) as a self-complete questionnaire at baseline, 4 months, 8 months and 12 months
8. Social activity measured using the Social Integration Subscale (HEIQ) as a self-complete questionnaire at baseline, 4 months, 8 months and 12 months
9. Headache frequency, duration and severity completed as a smartphone app developed for the study collected weekly for up to six months, and monthly thereafter for 6 months
10. Health service activity collected from GP records at 12 months
11. Medication use measured as daily doses of acute and prophylactic headache treatment data collected from GP record at 12 months

### Overall study start date
04/01/2015

### Completion date
04/01/2020

## Eligibility

### Key inclusion criteria
1. Able and willing to comply with the study procedures and provision of written informed consent
2. Aged 18 years or above
3. Living with chronic headache; defined as headache for 15 or more days per month for at least three months.
4. Result of nurse classification interview confirms headache type to be definite or probable chronic migraine, or chronic tension type headache, and/or medication overuse headache
5. Fluent in written and spoken English

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Feasibility study planned sample size: 170; Main randomised controlled trial planned sample size: 689

### Total final enrolment
689

### Key exclusion criteria
1. Unable to attend treatment programme
2. No access to a telephone
3. Has an underlying serious psychiatric or psychological disorder that precludes participation in the group intervention
4. Known secondary cause of headache other than medication overuse headache; e.g. primary or secondary brain tumour
5. Is currently participating in another clinical trial (with an unregistered medicinal product), or less than 90 days have passed since completing participation in such a trial

### Date of first enrolment
01/04/2017

### Date of final enrolment
29/03/2019

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Warwick Medical School Clinical Trials Unit**
University Hospitals Coventry & Warwick
Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL

### Study participating centre

**Broad Street Health Centre**
Broad Street
Coventry
United Kingdom
CV6 5BG

**Study participating centre**
**Westside Medical Centre**
Hilton House
Corporation Street
Rugby
United Kingdom
CV21 2DN

**Study participating centre**
**Castle Medical Centre**
22 Bertie Road
Kenilworth
United Kingdom
CV8 1JP

**Study participating centre**
**Rother House Medical Centre**
Alcester Road
Stratford-upon-avon
United Kingdom
CV37 6PP

**Study participating centre**
**Holbrooks Health Team**
71 Wheelwright Lane
Coventry
United Kingdom
CV6 4HN

**Study participating centre**
**Bennfield Surgery**
Hilton House
Corporation Street

Rugby
United Kingdom
CV21 2DN

**Study participating centre**
**Alcester Health Centre**
Fields Park Drive
Alcester
United Kingdom
B49 6QR

**Study participating centre**
**Trinity Court Surgery**
Stratford Healthcare
Arden Street
Stratford-upon-avon
United Kingdom
CV37 6HJ

**Study participating centre**
**Sherbourne Medical Centre**
Oxford Street
Leamington Spa
United Kingdom
CV32 4RA

**Study participating centre**
**Chase Meadow Health Centre**
The New Dispensary
2 Alder Meadow
Warwick
United Kingdom
CV34 6JY

**Study participating centre**
**Lisle Court Medical Ctre**
Lisle Court
Brunswick Street
Leamington Spa
United Kingdom
CV31 2ES

### Study participating centre
**Walsgrave Health Centre**
50 Hall Lane
Walsgrave on Sowe
Coventry
United Kingdom
CV2 2SW

### Study participating centre
**Health Centre**
High Street
Bedworth
United Kingdom
CV12 8NQ

### Study participating centre
**Bulkington Surgery**
School Road
Bulkington
Bedworth
United Kingdom
CV12 9JB

## Sponsor information

### Organisation
University of Warwick

### Sponsor details
University House
Kirby Corner Road
Warwickshire
England
United Kingdom
CV4 7AL

### Sponsor type
University/education

### ROR
https://ror.org/01a77tt86

# Funder(s)

### Funder type
Government

### Funder Name
National Institute for Health Research

### Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Publication and dissemination plan
Planned publication of a number of papers in peer reviewed journals, as well as dissemination of study results at national and international conferences.

### Intention to publish date
31/12/2020

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Martin Underwood (CHESS@warwick.ac.uk; Ctuenquiries@warwick.ac.uk)

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Interim results article | feasibility results | 11/02/2019 | | Yes | No |
| Other publications | intervention development | 18/03/2019 | 20/03/2019 | Yes | No |

| | | | | | |
|---|---|---|---|---|---|
| Protocol article | main trial protocol | 12/04/2020 | 15/02/2021 | Yes | No |
| Other publications | comparative evaluation | 04/05/2021 | 05/05/2021 | Yes | No |
| Other publications | experiences of patient and public involvement | 19/11/2021 | 31/10/2022 | Yes | No |
| Protocol article | process evaluation protocol | 04/06/2019 | 31/10/2022 | Yes | No |
| Interim results article | Process evaluation results | 07/01/2023 | 09/01/2023 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Results article | | 28/03/2023 | 05/09/2023 | Yes | No |
| Other publications | post-hoc secondary analyses not specified in the original statistical analysis plan | 15/05/2024 | 20/05/2024 | Yes | No |
| Other publications | Qualitative interviews conducted during the CHESS study | 02/08/2024 | 06/08/2024 | Yes | No |