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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

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

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

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?
Results article		28/03/2023	05/09/2023	Yes	No
Protocol article	main trial protocol	12/04/2020	15/02/2021	Yes	No
Protocol article	process evaluation protocol	04/06/2019	31/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No
Interim results article	feasibility results	11/02/2019		Yes	No
Interim results article	Process evaluation results	07/01/2023	09/01/2023	Yes	No
Other publications	intervention development	18/03/2019	20/03/2019	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
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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes