

Comparing health outcomes in people living with chronic headache (questionnaire study) – substudy of CHESS

Submission date 22/07/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 03/09/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/11/2022	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Chronic headache is a major source of pain and disability worldwide. The focus of current research is on finding interventions that are clinically effective and cost-effective with the potential to alleviate pain and disability and improve the quality of life of sufferers. Conducting high-quality research into what works best for a given health condition requires an understanding of the impact of alternative strategies on health and health-related quality of life (HRQoL) outcomes. Assessment of health outcomes in general and HRQoL in particular can, however, be challenging in patients living with frequent chronic headaches. Patients may only be affected on some days, when their health state may be classed as very poor – perhaps for a few hours only. Standard measures of HRQoL, such as the EuroQoL 5-Dimensional (EQ-5D) questionnaire that assesses health status on the day of completion, may therefore not provide adequate data in this context. More headache-specific measures may be preferable as they are likely to be responsive to headache symptoms and their impact on patients' health and HRQoL. This study, therefore, aims to develop methods to predict the HRQoL of chronic headache patients based on responses to more responsive headache-specific questionnaires, such as the Headache Impact Test (HIT-6).

Who can participate?

Patients aged 18 or over attending an outpatient headache clinic for treatment and or management of headache symptoms

What does the study involve?

Participants are recruited from outpatient headache clinics and asked to complete a one-off questionnaire about their headache and its impact on their health and HRQoL. The data collected is used to develop methods for converting responses from headache-specific measures, such as HIT, to generic HRQoL life measures, such as the EQ-5D. Generic HRQoL measures permit outcomes to be expressed in terms of quality-adjusted life years, which provide a common scale for comparing the effectiveness of interventions across different health conditions.

What are the possible benefits and risks of participating?

There is no direct benefit to individual participants but the results should help researchers to better understand the health needs of people living with frequent headaches and may help to develop better interventions to meet the needs of patients. No risks are expected by taking part in this study. However, a participant may find a question distressing or upsetting whilst completing the questionnaire, and they are advised to speak to either a member of the clinical team for help and advice or contact the study team.

Where is the study run from?

1. University of Warwick
2. University Hospitals Coventry and Warwickshire NHS Trust
3. University College London Hospitals NHS Foundation Trust
4. Luton and Dunstable University Hospital NHS Foundation Trust
5. Royal Free London NHS Foundation Trust
6. St George's University Hospitals NHS Foundation Trust
7. University Hospitals Of North Midlands NHS Trust

When is the study starting and how long is it expected to run for?
February 2018 to August 2020

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

1. Chloe Norman
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2. Prof. Martin Underwood
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

40104

Study information

Scientific Title

Comparing health outcomes in people living with chronic headaches (questionnaire study)

Study objectives

Chronic headache is a major source of pain and disability worldwide. The focus of current research is on finding interventions that are clinically effective and cost-effective with the potential to alleviate pain and disability and improve the quality of life of sufferers. Conducting high-quality research into what works best for a given health condition requires an understanding of the impact of alternative strategies on health and health-related quality of life (HRQoL) outcomes. Assessment of health outcomes in general and HRQoL in particular can however be challenging in patients living with frequent chronic headaches. Patients may only be affected on some days, when their health state may be classed as very poor – perhaps for a few hours only. Standard measures of HRQoL, such as the EuroQoL 5-Dimensional (EQ-5D) questionnaire that assesses health status on the day of completion, may therefore not provide adequate data in this context. More headache-specific measures may be preferable as they are likely to be responsive to headache symptoms and their impact on patients' health and HRQoL. This study therefore aims to develop methods to predict the HRQoL of chronic headache patients based on responses to more responsive headache-specific questionnaires, such as the Headache Impact Test (HIT-6).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 29/05/2019, South Birmingham REC (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; Tel: +44 (0)2071048107;
Email: nrescommittee.westmidlands-southbirmingham@nhs.net), ref: 19/WM/0134

Study design

Observational; Design type: Cross-sectional

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Other

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

Chronic headache

Interventions

Participants will be recruited from outpatient headache clinics and asked to complete a one-off questionnaire about their headache and its impact on their health and HRQoL. The data collected will be used to develop methods for converting responses from headache-specific measures, such as HIT, to generic HRQoL life measures, such as the EQ-5D. Generic HRQoL measures permit outcomes to be expressed in terms of quality-adjusted life years, which provide a common scale for comparing the effectiveness of interventions across different health conditions. The study will contribute to the understanding of outcomes measurement in this population and help inform to select measures for future headache studies.

Intervention Type

Other

Primary outcome measure

Headache-specific quality of life measured using HIT-6 and CHQLQ at a single timepoint

Secondary outcome measures

Measured by a questionnaire at a single timepoint:

1. Generic quality of life measured using EQ-5D-5L and SF-12
2. Mental health assessed using HADS

Overall study start date

01/02/2018

Completion date

01/08/2020

Eligibility

Key inclusion criteria

1. Aged 18 or over attending an outpatient headache clinic for treatment and or management of headache symptoms. Patients have to have headache symptoms for 15 or more days of the month for at least 3 consecutive months to be classified as chronic headache
2. Able and willing to comply with the study procedures and give informed consent
3. Able to understand English and complete the questionnaire booklet

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 500; UK Sample Size: 500

Total final enrolment

349

Key exclusion criteria

1. Unable to understand or complete questionnaire booklet in English
2. Have an underlying serious mental illness that may impair their ability to understand and complete the study questionnaire

Date of first enrolment

09/09/2019

Date of final enrolment

03/04/2020

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Warwick

Warwick Clinical Trials Unit

Warwick Medical School

University of Warwick

Gibbet Hill Road

Coventry

United Kingdom

CV4 7AL

Study participating centre

University Hospitals Coventry and Warwickshire NHS Trust

Walsgrave General Hospital

Clifford Bridge Road

Coventry

United Kingdom

CV2 2DX

Study participating centre

University College London Hospitals NHS Foundation Trust

250 Euston Road

London

United Kingdom

NW1 2PG

Study participating centre

Luton and Dunstable University Hospital NHS Foundation Trust

Lewsey Road

Luton

United Kingdom

LU4 0DZ

Study participating centre

Royal Free London NHS Foundation Trust

Royal Free Hospital

Pond Street

London

United Kingdom

NW3 2QG

Study participating centre

St George's University Hospitals NHS Foundation Trust
St George's Hospital
Blackshaw Road
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SW17 0QT

Study participating centre

University Hospitals Of North Midlands NHS Trust
Newcastle Road
Stoke-on-Trent
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ST4 6QG

Sponsor information

Organisation

University of Warwick

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/01a77tt86>

Funder(s)

Funder type

Government

Funder Name

NIHR Central Commissioning Facility (CCF); Grant Codes: NF-SI-0616-10103 - Prof. Petrou

Results and Publications

Publication and dissemination plan

1. Peer-reviewed scientific journals
2. Conference presentation
3. Publication on website
4. Other publication
5. Submission to regulatory authorities
6. A summary of results will be provided to participants in the study, to the charity partners and via the University of Warwick Clinical Trials Unit webpage

Intention to publish date

01/03/2021

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V1.2	26/02/2019	03/09/2019	No	No
Results article		26/10/2022	02/11/2022	Yes	No
HRA research summary			26/07/2023	No	No