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

Submission date
22/07/2019

Recruitment status
No longer recruiting

Registration date
03/09/2019

Overall study status
Completed

Last Edited
02/11/2022

Condition category
Nervous System Diseases

[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 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
Chloe.norman@warwick.ac.uk
2. Prof. Martin Underwood
m.underwood@warwick.ac.uk

Contact information

Type(s)
Scientific

Contact name
Ms Chloe Norman

Contact details
Warwick Clinical Trials Unit
Warwick Medical School
University of Warwick
Coventry
United Kingdom
CV4 7AL
+44 (0)24 76573243
Chloe.norman@warwick.ac.uk

Type(s)
Scientific

Contact name

Prof Martin Underwood

ORCID ID
http://orcid.org/0000-0002-0309-1708

Contact details
University of Warwick
Warwick Medical School
Coventry
United Kingdom
CV4 7AL
+44 (0)2476574664
m.underwood@warwick.ac.uk

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 of 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
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
University Hospitals Of North Midlands NHS Trust
Newcastle Road
Stoke-on-Trent
United Kingdom
ST4 6QG

Sponsor information

Organisation
University of Warwick

Sponsor details
c/o Mrs Jane Prewett
Address Research Support Services
University of Warwick
Kirby Corner Road
Coventry
England
United Kingdom
CV4 8UW
+44 (0)2476522746
wmssponsorship@warwick.ac.uk

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