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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
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2. Prof. Martin Underwood
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Observational

Study design
Observational; Design type: Cross-sectional

Study type(s)
Other

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

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
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Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
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Study participating centre
Luton and Dunstable University Hospital NHS Foundation Trust
Lewsey Road
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Royal Free Hospital
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United Kingdom
NW3 2QG

Study participating centre
St George's University Hospitals NHS Foundation Trust
St George's Hospital
Blackshaw Road
Tooting
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United Kingdom
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Study participating centre
University Hospitals Of North Midlands NHS Trust
Newcastle Road
Stoke-on-Trent
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Sponsor information

Organisation
University of Warwick

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

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?
Results article		26/10/2022	02/11/2022	Yes	No
HRA research summary			26/07/2023	No	No
Protocol file	version V1.2	26/02/2019	03/09/2019	No	No