PARTICIPANT INFORMATION SHEET – PART ONE

What is the comparative clinical and cost-effectiveness of pharmacological treatments for adults with chronic migraine?

Thank you for taking time to read this information. Before you decide if you want to take part, please talk to other people about the study if you wish, and feel free to ask any questions.

Why are having the consensus meeting?

We have been looking at all the available evidence about different medications used to prevent chronic migraine. We want to consider what we have found in our research and, with your help, decide what our recommendations should be for future research in this area. It is important that people who are most likely to be affected by future research such as people with migraine and health professionals are fully involved in the development of these recommendations. At the consensus meeting we will agree on what our research recommendations should be.

Who can take part?

We are looking for people who have received a diagnosis of chronic migraine either at the moment, or in the past. Chronic migraine is defined as: headaches on 15 more days per month for more than three months, with migraine on at least eight days of the month.

What does taking part in the meeting involve?

- We are inviting around 15 people with migraine and 10 health professionals to attend the meeting.
- The meeting will take place virtually using Microsoft Teams, and is expected to last no more than **4 hours.** There will be regular short breaks throughout the meeting.
- At the start of the meeting we will present evidence from our research looking at past studies about the effectiveness, cost-effectiveness, and side effects of medications used to prevent migraine. We will also send this information by email so that you have time to read it before the meeting if you would like to.
- Together we will decide what our recommendations should be for future research in this field. For example which medications should be prioritised for more research.
- The first discussions will be in small groups of about 5 people, so everyone feels comfortable to share their ideas and opinions. This will be a mix of people with migraine and health professionals. A member of the study team will facilitate the group to make sure that everyone gets a chance to speak and be fully involved.
- We will then bring everyone back together and share what each of the small groups decided. Together we will then agree on a set of research recommendations.
- With your consent we will audio record the meeting. After the meeting a member of the study team will listen back to the audio-records, write up notes, and then delete the recording.

What if I haven't used Microsoft Teams before?

Don’t worry if you have not used Microsoft Teams before, we will provide support. You are not required to download anything, and can access this meeting on a computer, tablet, or smartphone.

What will happen after the consensus meeting?

The study team will use the findings from the meeting to write up the agreed upon research recommendations. We will send a list of these recommendations to all the people who attended the meeting for any feedback. Later we will ensure these recommendations are available online.

Do I have to take part?

It is entirely up to you to decide if you want to take part. If you agree to take part, we will ask you to complete a consent form. Even after completing the consent form, you can withdraw from the study at any time without giving a reason, and without affecting you in any way.

What are the benefits or risks of taking part?

Although this research study may not offer you any direct benefit, the findings may help people with migraines in the future. You will be given a £25 Love2Shop voucher as a thank you for your participation. We do not think there is any risk to you taking part in this study. However, should you feel uncomfortable in any way, you can leave the meeting at any time. If you become distressed during the meeting we will help you to speak to a clinician. If you require further support, we encourage you to speak to your GP.

What will happen next?

If you are interested in taking part in the consensus meeting please complete the online consent form. Once we have received the completed consent form we will contact you with joining instructions for the meeting. If you would prefer to complete a paper version of the consent form, please contact us and we can arrange for this to be posted to you.

Contact for further information:

If you have any questions about the study, either now or in the future, do please contact us using the details below:

Dr Hema Mistry
Email: Hema.Mistry@warwick.ac.uk
Tel: 02476 151183

Thank you for taking the time to read this information and for considering taking part in this study.

PARTICIPANT INFORMATION SHEET -PART TWO

What is the comparative clinical and cost-effectiveness of pharmacological treatments for adults with chronic migraine?

Who is organising and paying for the study?

This study is managed by Warwick Clinical Trials Unit, University of Warwick. The study is funded by the National Institute for Health Research HTA (Health Technology Assessment).

Who has reviewed the study?

This study has been reviewed and been approved by University of Warwick Biomedical and Scientific Research Ethics Committee (BSREC) BSREC 49/22-23

Will my taking part in this study be kept confidential?

Yes. All information we collect about you during the study will be kept confidential at all times and held in compliance with the Data Protection Act 2018. For further information, please refer to the University of Warwick Research Privacy Notice which is available here: https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice or by contacting the Legal and Compliance Team at GDPR@warwick.ac.uk.

How will we use information about you?

We will need to collect your name and contact details, so that we can keep in touch over the duration of the study. We will keep all information about you safe and secure.

We will use Qualtrics to collect your expression of interest and later your consent. Qualtrics is a third-party company. Qualtrics has legal agreements in place with the University of Warwick and has been through strict information security assessment. For further information please see below the links to Qualtrics' privacy statement:

https://www.qualtrics.com/privacy-statement/

https://www.qualtrics.com/support/survey-platform/getting-started/data-protection-privacy/

What if there is a problem?

If you have any concerns about any aspect of this study, you should contact the study team who will do their best to answer your questions. If you are still not happy and want to make a complaint, you can do this through the University of Warwick complaints procedure. Please write to:

Head of Research Governance
Research & Impact Services
University House, University of Warwick

Coventry, CV4 8UW
Email: researchgovernance@Warwick.ac.uk
Tel: 02476 575733

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter: DPO@warwick.ac.uk.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO): casework@ico.org.uk

What will happen to the results of the study?

At the end of the study we will write up the list of recommendations and share them with all who attended. We will also make them available online. We will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications. If you would like a copy of the published results, please do let us know.

Contact for further information:

If you have any questions about the study, either now or in the future, do please contact us using the details below:

Dr Hema Mistry
Email: Hema.Mistry@warwick.ac.uk
Tel: 02476 151183

Thank you for taking the time to read this information and for considering taking part in this study.

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WARWICK CLINICAL TRIALS UNIT

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The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.