HeadFlex Study

Personalised process-based psychological intervention for paediatric headache cases: An idiographic ecological momentary study with weekly feedback provision

Chief investigator: Dr. Vasilis S. Vasiliou (PI), Lecturer in Clinical Psychology
Local investigator: Anastasiia Calladine, Trainee Clinical Psychologist

Hi, I am Anastasiia (Anna) and I am a Clinical Psychology trainee. Thank you for your interest to our research. In our study we hope to help individuals like you who have headaches to learn ways to cope with headaches more effectively.

This research is an educational project, forming part of my doctorate in Clinical Psychology at Royal Holloway, University of London. I am conducting a study to examine a new way to personalise talking therapies for adolescents who have headaches. To help you decide whether to take part, it is important that you understand why we are conducting the research and what it would involve for you. Please take time to read this information carefully. If you have any questions or would like more information, we are here to help and respond to any questions.

Why am I conducting this study?

Frequent headaches are a relatively common problem for adolescents. Headaches can cause a lot of problems for people, and can impact daily life in school, going out with family and friends, as well as doing sports and other fun activities. Headaches can also make people feel unmotivated to do the things that they enjoy, such as listening to music, watching their favourite TV shows, and spending time with friends. This tells us that there is a need to do something to lessen the impact of headaches on people's lives.

There already are some known effective talking therapies which can help individuals cope better with their headaches, such as Cognitive Behavioural Therapy. However, standardised therapy packages are often generalised and can ignore individual differences and personalised needs. In our study, we would like to examine whether personalising talking therapies to people's individual needs can lead to improvements in how they manage their headaches.

Why have I been invited?

You have been invited to take part in this study as you are an adolescent who suffers with frequent headaches. Your clinical team at your referring NHS clinic has identified that you may benefit from taking part in our study, using our pre-determined study criteria. This would likely mean that you are somebody who might find be bothered by the impact of headaches on your daily life, and you may benefit from a treatment to help you cope better with your headaches.

Do I have to take part?

No. It is up to you to decide whether to take part. You are free to withdraw at any time and without giving a reason. Your clinical care will not be affected by deciding whether or not to take part in the study.

What will happen to me if I decide to take part?

If you decide to take part, you will participate in a brief talking therapies which includes several activities. To make this simple, we present these activities below in "phases".

All the activities below will occur online. We will ask you to engage in some daily questionnaires which we will send to you via an app called mPath, which is free to install on your mobile phone. These will take 2-3 minutes to complete each time. We will also ask you to attend five weekly online 1-to-1 talking therapy sessions, lasting 30 minutes each time.

The overall time from initial contact to finish will take up to 12 weeks.

If you do decide to take part in the study, you will ***not*** be able to begin any other talking therapies for headaches for the duration of the study, as this could interfere with the study.

If you are taking any medication for headaches, or seeing a GP or a Consultant, you can continue doing so. Following the completion of the study, you will be able to ask about any further support from the referring clinic if you wish to do this.

Initial screening/Enrolment

We will first ask for your consent to take part in the study, after reading this information sheet. If you agree to take part, we will invite you for an initial introductory meeting and online intake assessment lasting 1 hour. In this meeting, we will discuss your headaches and how you cope. Prior to this meeting, we will ask you to complete a short demographic questionnaire using the mPath app.

- **Phase 1: Problem understanding.** We will meet online again for up to 1 hour to create a shared understanding of how you cope with your headaches, based on the information gathered previously. This will help us understand how you cope with headaches and to develop a personalised treatment plan. We will also create some brief goals you want to achieve from the treatment

- **Phase 2: Initial information gathering.** We will ask you to complete questionnaires for a period of 1 to 2 weeks. On 3 to 4 days per week, we will ask you to complete a questionnaire up to 3 times per day using the mPath app, which will take 2-3 minutes each time The prompts will be sent at random points in the day.

- **Phase 3: Treatment.** You will be invited to attend up to 5 online brief talking therapy sessions to work on the specific goals and needs identified at Phase 2, each session lasting 30 minutes. The personalised treatment plan will be drawn from talking therapies which have been tested in research. In-between the sessions, you will continue to fill out questionnaires on 3 to 4 days per week, sent 2-3 times per day, which will take 2-3 minutes to complete each time This will help us to track your progress and tailor the treatment plan. The sessions will usually be on a weekday, on the same day and time each week. Alternatively, we might agree together to see each other twice per week (e.g. Monday and Friday). The sessions will usually be offered between 9AM to 5PM, but we will try our best to accommodate when you are free.

- **Phase 4**: **Follow-up**. We will ask you to continue completing the same questionnaires for a further 2 weeks. At the end of the study, you will be provided with a debrief form and we will offer you an opportunity to have a further meeting with us. You will also be able to approach your NHS referring clinic for any further support.

Are there any possible disadvantages or risks from taking part?

You may experience some disruption to your daily routine due to completing lot's questionnaires. We hope to minimise the inconvenience of completing frequent questionnaires by: having the questionnaires easily accessible via an app; not sending questionnaire completion prompts more than 3 times per day maximum; and finally, introducing breaks in data collection.

What are the possible benefits of taking part?

You will receive a personalised treatment which may help to reduce the impact of your headaches. You might gain psychological insight into factors which contribute to headaches, as well as techniques and strategies which could help you to manage your headaches more effectively. This overall may help to improve your quality of life and wellbeing.

Confidentiality

Who will be informed about my participation?

Your referring NHS clinic will be aware of your participation in the study, but have no further involvement with the research. We will not share any information with them while you take part in our study, unless we have significant worries about yours or someone else's safety. When you finish the study, we will let the clinic know so that they can offer you care.

If you chose to take part in this study, we will ask you for your GP practice and named GP (if known)- we will then let them know that you are taking part in our research. Any further contact with your GP will only happen if we have worries about your safety.

Your clinical team at *NHS* may choose to note that you are partaking in the study within your electronic clinical records, which your GP may have access to. The research team will **not** access or update your NHS clinical records during the study.

Will my taking part in the study be kept confidential?

If you agree to take part in the study, you will be assigned a unique participant ID known only to the researcher. All personal identifiable information (e.g. name, contact details) will be kept strictly confidential and known only to the researchers. All of your information will be stored on password protected cloud storage, which will only be accessible to the study team. Any information linked to you will be labelled with the participant ID code and will not contain any identifiable information.

When the results of the study are reported, data will be fully anonymised and individuals will not be identifiable. The research team will maintain the link between your personal details and your unique ID number for up to 3 months to allow the study to be reviewed, after which we will destroy all records containing your personal information. This excludes consent forms, that will be held securely at Royal Holloway, University of London, for 10 years after the end of the study.

Information and data

How will you collect information from me?

This study will use Qualtrics and M-path app to collect data from you. We will anonymously record data using only your participant ID to identify you, to ensure that the information cannot be traced back to you. Data gathered using Qualtrics and mPath may be permanently retained by these companies and their business associates, however this will be fully anonymous. This means that nobody can identify you as none of your personal information will be included.

The data that we collect will be extracted from mPath and Qualtrics, to be stored electronically in a secure password-protected location. The data will be made fully anonymous when we analyse it. Upon study completion, data is usually securely retained for up to 10 years.

How will we use information about you?

We will need to use information about you provided by your referring clinic for this research project. This information will include:

- Your name
- Your contact details (email, telephone number)
- Eligibility screening information (headache diagnosis and recent engagement with psychological treatment)
- Your GP

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at **www.hra.nhs.uk/information-about-patients/**
- using the NHS research leaflet available from: **www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team on 01784 911679 or by email: **Vasilis.vasiliou@rhul.ac.uk**
- by speaking to Royal Holloway's data protection officer at **dataprotection@royalholloway.ac.uk**

Other information

What if there is a safety concern?

Occasionally,-a research participant might tell us something that makes us worried about their safety. If this happened to you, we would need to tell your referring clinic and GP. We would also be able to provide you with emergency contact numbers where you would be able to access further support.

Will I be reimbursed for taking part?
Yes. If you decide to take part in the study, you will be reimbursed in the form of £10 e-vouchers at the end of the study, as a thank you for taking part.

What happens if I don't want to carry on with the study?
Your participation in the study is voluntary, and you are free to withdraw at any time and without giving a reason. Your clinical care will not be affected by deciding whether or not to take part in the study.

If you decide to withdraw from the study, this will immediately stop your participation in the research. In line with guidance from the Health Research Authority (HRA), in order to protect the validity of our research, data already gathered at the point of withdrawal will be retained. This will be fully anonymised.

If at any point you would like to withdraw, you may contact the researchers on 01784 911679 or via email:
Vasilis.vasiliou@rhul.ac.uk
Anastasiia.calladine.2022@live.rhul.ac.uk

What will happen to the results of the study?

After making your data completely non-identifiable, we will conduct statistical analysis to determine whether the talking therapies led to significant improvement in headache-related outcomes. We hope that our research will further advance our knowledge about psychological treatments in chronic headache management.

The findings of the study will be written up in a formal report, which we will aim to submit to an academic journal for publication. We will do this to inform other researchers about the study, but no personal information will be revealed. We may also present the findings at research conferences. Should you wish to, you will be welcome to request a summary of the results of the study.
What if there is a problem?
If any issues arise during the study, you will always be welcome to speak to the researcher, or the Principal investigator Dr. Vasilis Vasiliou, C.Psychol. (Clinical), C.Psychol. (Health), HCPC Registered Practitioner in Clinical & Health Psychology (#PYL043565) on 01784 911679 or via email at

vasilis.vasiliou@rhul.ac.uk. If you don't feel comfortable speaking to the research team directly, you may wish to contact the Royal Holloway Ethics Committee at **ethics@rhul.ac.uk.**

Please bear in mind that, while we aim to resolve any issues, you can always decide to withdraw from the study at any point, without giving a reason.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. You can find the contact details of your local PALS team using this website: https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/.

Royal Holloway University of London, as a sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. Please bear that Royal Holloway does not have provision for a no-fault compensation. In a case where negligence on our part cannot be demonstrated, you may be required to fund any legal action which you decide to take.

Who is organising the study?
This research is being conducted as part of the researcher's completion of the Doctorate in Clinical Psychological programme (Anastasiia Calladine, trainee Clinical Psychologist), at Royal Holloway University of London. The programme is being funded by the NHS, and the researcher's employer is Camden and Islington NHS Foundation Trust. The study sponsor is Royal Holloway, University of London.

Who has reviewed the study?
All research in the NHS is reviewed by an independent group of people, the Research Ethics Committee (REC), to protect participants' interests. This study has been reviewed by the South East Scotland REC 2. This study has also been reviewed and approved by the Research Ethics Committee at Royal Holloway, University of London (ID 517).

Further information and contact details: Thank you for reading this information sheet. If you have any questions or would like any more information, please contact Anastasiia Calladine (trainee Clinical Psychologist) via email: anastasiia.calladine.2022@live.rhul.ac.uk

Please retain this information sheet for your records.

Privacy Notice:

Royal Holloway University of London is the Data Controller and is committed to respecting and protecting your personal data in accordance with your expectations and Data Protection legislation. The University has a Data Protection Officer who can be contacted at ***dataprotection@royalholloway.ac.uk****. Further information about Data Protection, including your rights and details about how to contact the Information Commissioner's Office should you wish to complain, can be found at the following: https://www.royalholloway.ac.uk/about-us/more/governance-and-strategy/data-protection/*