



HeadFlex Study
Personalised process-based psychological intervention for paediatric headaches
Participant Consent Form

The purpose of this form is to gain your written permission for you to take part in this study. It is important to remember that this does not commit you to taking part for the whole duration of the study. If you change your mind at any point, you are free to withdraw from the study without giving a reason.

You can contact the researchers at any point using the below contact details:

Researcher	Research Supervisor and chief investigator
Anastasiia Calladine, Trainee Clinical Psychologist Email: anastasiia.calladine.2022@live.rhul.ac.uk	Dr. Vasilis S. Vasiliou, Clinical and Health Psychologist Email: vasilis.vasiliou@rhul.ac.uk

Please carefully read each statement below, and place a “tick” if you have understood and agree with each statement. If you consent to take part in the study, please complete all sections and sign below.

I confirm that:	Tick
I have read and understood the study information sheet.	
I have been given the opportunity to ask any questions regarding the study, and any questions I have asked, have been appropriately answered.	
I understand that participation in this research study is entirely voluntary, and I can withdraw from the study without giving a reason and without consequence.	
I understand that if I decide to withdraw from the study, data already collected from me will be fully anonymised and kept for analysis.	
I understand that I am free to ask questions or discuss my concerns with the research team at any time.	

HeadFlex study

Participant Consent Form V3

Version and date: V3, September 2024

IRAS project number: 340890

PI: Dr. Vasilis S. Vasiliou, C.Psychol (Clinical & Health) Royal Holloway, University of London

I understand that my data will be anonymised fully. I understand that the research team will only report on demographic data such as gender, age-range and primary diagnosis, which cannot be used to identify any one specific individual.	
I understand that my referring clinic will be aware of when I start and end the study participation, and they might make a brief note of this in my medical record-	
I understand that the researchers will tell my GP that I am taking part in the study.	
I understand that the researchers have a duty of care to report any significant risk concerns to the referring NHS clinic and my GP.	
I understand that the intervention offered during the study is not part of my NHS standard care which I would receive in the referring clinic.	
I understand that I will be unable to partake in any other additional therapy or treatment to address headaches <i>during</i> my participation in the study.	
I understand that I will be offered up to 5 online 30 minute 1-to-1 on-line intervention sessions with the researcher, to work specifically on improving how I manage my headaches.	
I understand that the research team will contact me via mobile number and my email.	
I understand that I will be asked to complete frequent daily questionnaires for a period of up to 12 weeks, via the mPath app and Qualtrics.	
I understand that the personal data will be processed in accordance with GDPR regulations (see privacy statement).	
I give my consent to participate in this study.	
Optional: when the study is finished, I would like to be provided with a summary of the results.	

My full name: _____

My contact email: _____

My contact number: _____

My GP practice and address: _____

Named GP (if known): _____

Signature: _____

Date: _____

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Researcher name: _____

Researcher signature: _____

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