

**Examining the Psychological Effects of Breathwork in Patients with Chronic Migraine -**

**A Pilot Randomised Control Trial**

**Information Sheet for the Participants**

*Ethical Clearance Reference Number:* HR/DP-23/24-42160

**You will be given a copy of this information sheet**

I would like to invite you to participate in this research project which forms part of my MSc Health Psychology programme dissertation research. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

**What is the purpose of the project?**

We understand that chronic migraine can be a debilitating condition. People living with chronic migraine often look for strategies to help manage the impact of their migraine. The purpose of this project is to explore whether a home-based breathwork intervention has potential to improve wellbeing and the way people feel about their migraines. We will ask people to practise a 5-minute breathing exercise every day for 28-days. We will also ask people to complete brief questionnaires and take body measurements (breathing rate and resting heart rate).

**Why have I been invited to take part?**

You are being invited to participate in this project because:

* You have been diagnosed for chronic migraine condition by a doctor
* You live in the United Kingdom (UK)
* You are above 18 years of age
* You have a device for video conferencing and receiving text messages

However, you may not be eligible to participate if:

* You are currently having psychological therapy for your migraine
* You are pregnant
* You have epilepsy
* You are unable to read or write in English to a level needed to complete questionnaires at home

**What will happen if I take part?**

You will first be sent an online link to a consent form and a short questionnaire to complete. You will then be assigned to either the intervention group or the control group by the lead researcher, which is decided randomly using a computer system. The information about which group you are in will be revealed to you end of the study.

You will then be invited for an online one-to-one training session, where you will learn the breathwork exercise and how to measure your breathing rate and resting heart rate. The study will involve you practicising breathwork for 5 minutes, at the same time, every day, for 28 days at your home. We will send you a reminder via text or every day to help you to remember.

You will be asked to fill out short questionnaires online a total of 4 times through the study (at the start, and 2, 4, and 6 weeks). The questions will ask about your demographic details, the impact of migraine on various areas of your life, your adherence to the breathwork routine, your mood, and your beliefs about migraine. For example, “When you have headaches, how often is the pain severe?”, “Over the past two weeks, how would you rate the frequency of your headaches”, and “How much do your migraines affect your life?”. Additionally, we will help you to measure your breathing rate and resting heart rate. At the end, you will be asked to fill out an additional short questionnaire about you satisfaction and acceptability of the breathwork exercise.

**Do I have to take part?**

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in any way. Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part. After being contacted about eligibility, you will have up to a week to make a decision on whether you wish to participate. You will be given a copy of this consent form to keep.

**Incentives**

You will receive a £20 shopping voucher at the end of the study as a token of gratitude for your time.

**What are the possible risks of taking part?**

We do not anticipate any significant risks of taking part. Some people might find answering questions about their mood and migraine stressful or uncomfortable. If you are concerned or distressed about this study or your mood in general, we encourage you to contact your GP. You can also contact MIND on 0300 123 3393 or reach out to The Migraine Trust on 0808 802 0066. Additionally, urgent risks requiring clinical attention such as risk of harm to yourself or others may be identified through the questions: “Over the last 2 weeks, how often have you been bothered by -Thoughts that you would be better off dead, or of hurting yourself” and “Are you currently making plans about how you would end your life?”. If you are identified to be at risk, we will contact you for a short risk assessment procedure. If you tell us that you are at urgent risk and unable to keep yourself safe, we may ask you to contact – or we may need to contact on your behalf - emergency health services.

**What are the possible benefits of taking part?**

You will get a chance to take a short amount of time out for yourself everyday. Breathwork is an age old practice for disciplining ones body and mind. 28 days of continuous practice may encourage you to make it a habit. You will receive £20 shopping voucher at the end of the study.

**Data handling and confidentiality**

Your data will be processed under the terms of UK data protection law (including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018).

Your phone number and email address will be the only identifiable details that will be collected. Only the research team will be able to contact you and none of your identifiable details will be shared with any third parties. Your contact details are only being collected for the purpose of sending reminders. All your survey responses will be anonymised with unique ID numbers, which will be provided to you at the start of the study. All your identifiable records will be securely deleted as soon as the incentives are shared. All your responses to the questionnaires will be recorded on Qualtrics (an online platform for data collection), after which it will be moved to the OneDrive institutional account. While presenting the study results anywhere, full anonymity and confidentiality will be maintained. The anonymised data will be stored with King’s College London for up to 10 years for future research use.

**Data Protection Statement**

If you would like more information about how your data will be processed under the terms of UK data protection laws please visit the link below:

<https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research>

**What if I change my mind about taking part?**

You are free withdraw at any point of the project, without having to give a reason. Withdrawing from the project will not affect you in any way. If you choose to withdraw from the study all the previously collected data from you will be deleted permanently.

**How is the project being funded?**

This project has not received any external funding. It is an internal project as part of a student Master’s degree through the KCL Department of Psychology.

**What will happen to the results of the project?**

The results of the project will be summarised in the lead researcher’s dissertation, being undertaken at the post graduate level in health psychology. The results may also be published in journals and presented at conferences. The participants will be provided a copy of published study if they chose so at the end of the study. The anonymised data would be publicly available through the King’s Open Research Data System (KORDS).

**Who should I contact for further information?**

* If you have any questions or require more information about this project, please email the Lead Researcher and MSc student Sajal Porwal at sajal.porwal@kcl.ac.uk

**What if I have further questions, or if something goes wrong?**

If this project has harmed you in any way or if you wish to make a complaint about the conduct of the project you can contact King's College London using the details below for further advice and information:

* Research Supervisors

Dr Emily McBride:

Health Psychology Section, 5th Floor Bermondsey Wing, Guy's Campus
London SE1 9RT

Email: emily.mcbride@kcl.ac.uk

Phone No.: 02071880189

Dr Sui Wong:

Dept of Ophthalmology, School of Life Course & Population Sciences,

Faculty of Life Sciences & Medicine, King's College London

Email: sui.wong@kcl.ac.uk

**Thank you for reading this information sheet and for considering taking part in this research.**