

Study Information

Please read the following information carefully to make an informed choice about participating in this study.

Title of Study:

A cognitive-behavioural approach to Migraine as a cyclical disorder.

Purpose of Study:

I am a doctoral student in the Department of Psychology, Maynooth University. As part of the requirements for my PhD, I am undertaking a research study under the supervision of Dr Unai Diaz-Orueta and Professor Andrew Coogan.

Until recent years Migraine has commonly been perceived as just another headache. Migraine is a neurological disorder that causes severe headaches and physical and mental symptoms that can last for up to 6 days. These symptoms can include changes in the how you feel and how your body and mind function. Until recently researchers have ignored these nonpainful migraine symptoms which can impair wellbeing. It is hoped through this study we will learn more about nonpainful migraine experiences to provide better prediction and treatment of migraine.

This study has three goals:

- To see if there are any changes in the body or behaviour that happen before a migraine starts, and if these changes can be used to predict when a migraine will happen.
- To measure how people's thinking and mental processes are affected after a migraine attack has ended, during a period called the "postdrome phase."
- To raise awareness among researchers and medical professionals about the complexity of migraines and the need for more research into this condition.

Who Can Take Part:

Adults over the age of 18 years living in Ireland that have been diagnosed with primary migraine (not caused by another health difficulty) by a licenced medical practitioner. Need to have access to a mobile phone daily.

PLEASE NOTE: Due to the nature of the study individuals who with coexisting secondary physiological conditions which could be causing their migraine including but not limited to respiratory illnesses such as asthma and sleep apnoea cannot participate in this study. Similarly, individuals who are or have ever received treatment for psychiatric conditions are also excluded from participating in this study. Individuals who are allergic to silicone are further excluded due to materials present in the active watches.

Do you have to take part?

No, you are under no obligation to take part in this research. It is entirely up to you to decide whether or not you would like to take part. If you decide to do so, you will be asked to sign a consent form and given a copy and the information sheet for your own records. If you decide to take part, you are still free to withdraw at any time without giving a reason and/or to withdraw your information up until data is irreversibly anonymised and compiled for analysis. A decision to withdraw at any time, or a decision not to take part, will not affect your relationships with Maynooth University or Migraine Association of Ireland.

Study Procedures:

This study will take measurements using Fitbit trackers, neuropsychological tests and a daily migraine and sleep diary. The Fitbit trackers will take measures of heart rate, activity (distance, calories burned) and sleep measures including time of sleep onset, time of sleep offset, sleep efficiency and total sleep count. Heart rate variability may also be computed from heart rate data. The neuropsychological tests will measure mental processes such as attention and memory.

Study Instructions:

At the beginning of the study you will complete the online neuropsychological assessment once. This will take approximately 20 minutes to complete.

The study will last for a duration of three months to try capture functioning leading up to and after migraine. For the duration of the study (90 days), it is required that:

- You wear the Fitbit on the wrist of your non-dominant hand every day and night, *except where the watch may be submerged in water or needs to be recharged.*
- You sync the Fitbit to the Fitbit application on your mobile phone and synchronise your devices daily using Bluetooth.
- You complete a paper booklet diary that includes brief questions to track your migraines and sleep

Warning: You do not have to complete the diary and questionnaires if you are experiencing pain as a result of migraine. When you are no longer in pain, please continue to complete the daily questionnaire and mark in “yes” for the days you were experiencing migraine pain.

- If you have experienced a migraine, please click on the link sent to your email address provided. You will be redirected to an online platform which will include some cognitive tests that will take 20 minutes to complete. You will be asked to complete the test again following a period of 2 days. Repeat this for up to three migraine attacks (six times).
- Please use the addressed envelope to post the migraine and sleep diary back to us at the Department of Psychology, Maynooth University

- Data from the paper and migraine sleep diary will be digitised. Following this all paper records will be destroyed. Digitised data will be stored on MU's server following the study (see below).

Follow Up Study:

This a two-part study, you may be invited to participate in part two of the research. As such, we request for your email to contact you about participating (**this is separate from part one and is voluntary**)

- Part two of the study involves an online semi-structured interview, which will last approximately 45 minutes.
- Invitation to part two in no way denotes any clinical or diagnostic significance.
- All email addresses will be kept confidential and destroyed following the study completion. If you are interested in participating and sharing your experience, please provide your email address below.
- Data from the interview will be used to understand the lived experience of migraine and used in a postgraduate research thesis and for publication in academic journals. No personally identifiable data will be used
- Please see below for information on your rights as a participant and data usage

Email: _____

How long will it take?

Time needed daily: (5 minutes)

Time needed after a migraine has occurred: (25 minutes)

Interview: (30 to 45 minutes)

What benefits do I get from participating?

Participation in this study does not lead to any form of medical or psychological diagnosis, and treatment. Information collected from this study is for research purposes only and will not be of any direct clinical use to the individual. It is hoped this study however will provide valuable insight and contribute to existing research on migraine in understanding and treating the disorder. It is anticipated that the results of the study will be published and be available to the public and to participants on request. Participants will also get to keep the Fitbit Inspire 2 supplied by the Department of Psychology at Maynooth University as a thank you gesture for participating in the study.

What are the risks?

It is possible that you may feel distress when participating due to the studies duration or completing cognitive tasks which are designed to test individuals. If you experience distress, please contact the researcher and avail of the supports provided below.

Data usage:

Data collected from this study will be used for research purposes and academic publication. All data will be stored fully anonymised and unidentifiable for a maximum of 10 years on the MU server as per Maynooth University's Research Integrity guidelines and the European General Data Protection Regulation (GDPR) that came into force since 25th May 2018. Following this 10-year period all data will be destroyed, As Fitbit active watches and mobile app will be used to measure participant actigraphy, participants will have to refer to Fitbit's data usage policy.

Confidentiality:

All data collected will be treated as confidential, in compliance with both University regulations and current statutory provisions, or as required by law. **All data will e held in a fully anonymized format. You will not be personally identified with the data obtained. Only non-identifiable, anonymized data will be held for the 10-year period following completion of the research project as required by the University.** Data will be electronically stored on encrypted PCs and backed up to university secure cloud-based services, accessible only to the researcher and supervisor. It must be recognized that, in some circumstances, confidentiality of research data and records may be overridden by courts in the event of litigation or during investigation by lawful authority. In such circumstances the University will take all reasonable steps within law to ensure that confidentiality is maintained to the greatest possible extent. If during your participation in this study you feel the information and guidelines that you were given have been neglected or disregarded in any way, or if you are unhappy about the process, please contact the Secretary of the Maynooth University Ethics Committee at research.ethics@mu.ie or +353 (0)1 708 6019. Please be assured that your concerns will be dealt with in a sensitive manner.

For your information the Data Controller for this research project is Maynooth University, Maynooth, Co. Kildare. The Data Protection office is located in Room 27, Rye Building, North Campus, Maynooth University, which can be contacted at dataprotection@mu.ie. Maynooth University Data Privacy policies can be found at <https://www.maynoothuniversity.ie/data-protection>.

Research Standards and Rights of Participation:

Participation in this study is voluntary and you may decide not to participate. If you consent

to participate now, you may withdraw your data at any time up until the study is completed. Following this all data will be compiled and anonymised for analysis. **This study has been reviewed and received ethical approval by Maynooth University Research Ethics Committee.**

Results from this study:

The research will be written up and presented as part of the researchers doctoral thesis and presented at national and international conferences and published in scientific journals. A copy of the research findings will be made available to the participant on request.

Contact Information:

If you have any questions about participation in this study, please contact the researcher directly.

Researcher Information and Contact: Shannon Richardson/
shannon.richardson.2017@mumail.ie

Supervisor Information and Contact: Dr Unai Diaz Orueta/
unai.diazorueta@mu.ie

Additional Information

Please note if you are experiencing extreme distress, please contact your general practitioner who can provide you with medical assistance.

Migraine Association of Ireland

For more information on migraine and support please visit [Migraine Association of Ireland: Not Just Another Headache \(https://Migraine.ie/\)](https://Migraine.ie/)

Phone: 01 894 1280/1281

Mobile: 087 149 9798

Information Line: 01 906 1012 (all Ireland)

Phone lines are operated from 10am – 12pm and 2pm – 4pm Tuesday to Friday.

Samaritans

If you are experiencing psychological distress and cannot attend your GP please contact Samaritans

Phone: 116 123

Phone lines are operated 24 hours a day and it is free to call from both landlines and mobiles

Email: jo@samaritans.org