Participant Information Sheet

**Invitation**

You are being invited to take part in research being conducted at Ulster University (UU) and Letterkenny Institute of Technology, (LYIT). Before you decide whether or not to participate, please read the following information and do not hesitate to ask any questions about anything that is unclear to you.

**What is the purpose of the study?**

* ***To* *examine risk and protective factors for mental health problems and wellbeing in the student population*** (UU and LYIT) during their 3 years at university (Phase 1).
* This is being undertaken as part of the World Health Organisation World Mental Health International College Student Initiative (https://www.hcp.med.harvard.edu/wmh/college\_student\_survey.php).
* A subset of participants who are experiencing ***mild to moderate levels of depression and/or anxiety*** will be contacted to consider participating in a follow up randomised control trial to test if an online mental health intervention is effective in improving the symptoms of depression and/or anxiety compared to current usual care (Phase 2)

**Why have I been chosen?**

All first-year undergraduate students over the age of 18 who are starting university for the first time (not repeating first year), and who are residents of the UK or Ireland are invited to participate.

\*\*While we will invite you to participate following registration or during Welcome Week, **this study is not part of the registration process and it is completely voluntary**.

**What do I have to do?**

If you are interested in taking part in this study, you will be asked to complete a consent form and provide contact details prior to participation.

All participants will be asked to:

* **Give written consent to participate in this study**
* **Provide one saliva/DNA sample by spitting into a tube. Researchers will show you the self-collection kit in advance and how to use it to collect the sample. Privacy screens will be provided.**
* **Complete an online survey with questions on mental health and wellbeing at a time and place convenient to you. This survey takes approximately 30 minutes to complete. The survey will include personal questions related to your physical and mental health, along with background information, details on your lifestyle, and use of services.**
* **Complete a follow up survey at the beginning of your 2nd and 3rd year at university**

**Do I have to take part?**

**It is completely up to you to decide whether or not you take part.** If you decide to participate, you will be given this information sheet to keep and you will be asked to provide contact details and sign a consent form. You have the right to withdraw from the study at any time without giving a reason up until the point that the questionnaire is submitted. You can do so by contacting any of the research team on the email addresses provided. **A decision to withdraw, or a decision not to participate, will not have any implications whatsoever for you as a student at Ulster University.** If you withdraw from the study without completing the online survey, stored samples will be destroyed in accordance with the Human Tissue Act regulations.

We also ask you if you agree to be contacted by researchers from Ulster University and invited to take part in Phase 2 and other related studies. **You will only be agreeing to receive information and will not be under any obligation to take part in any future studies.** If you decide not to consent to being contacted in the future it will have no influence on your involvement in this research study

**Data Sharing**

This study is part of the World Mental Health International College Initiative. The study involves different collaborators and we will share survey data and saliva/DNA samples with other institutions. **All shared data will be anonymised and all linking information will be held at Ulster University only, accessible only by senior staff.** The saliva samples will be used to study biological factors associated with mental health. The information obtained from your saliva/DNA sample will not be used to diagnose any mental health conditions, and you will not be informed of results.

Ulster University are working together with genomic service providers such as Genomic Medicine Ireland (GMI; Dublin, Ireland) in this study. Ulster University approved genomic service providers will help to analyse the sequence of your DNA. It will be necessary to send your samples to genomic service providers for testing. **All samples and information sent to external service providers will carry a study code number only and your identity will remain protected**. Only with your agreement under specific conditions and rules to protect your identity, research organisations will be permitted access to anonymised clinical and biological data. These research organisations could be not-for-profit e.g. universities or for-profit commercial companies e.g. making drugs or diagnostic tests. Your name, address and personal details will not be made available to any organisation beyond the study team.

**Data Processing**

Ulster University is the sponsor for this study based at the Northern Ireland Centre for Stratified Medicine, Northern Ireland. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. **To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at: https://www.ulster.ac.uk/about/governance/compliance/gdpr**

Ulster University researchers involved in this study will use your name and contact details (telephone number and address/email address) to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Ulster University Governance and regulatory organisations may look at your research records to check the accuracy of the research study. Ulster University researchers will pass these details to Ulster University Governance staff, along with the information collected from you. The only people in Ulster University who will have access to information that identifies you will be people who need to contact you about your health and wellbeing, invite you to be involved in other research projects, if you have given your permission, or; auditors of the data collection process. The people (outside the immediate research team) who analyse the information will not be able to identify you and will not be able to find out your name or contact details. Ulster University will keep identifiable information about you from this study for 10 years after the study has finished, unless you have consented to being contacted about future studies.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

##### Risks and/or disadvantages of taking part?

There is minimal risk associated with taking part in this study. **It is important to note that the survey includes some questions that may be considered sensitive and there is the potential that it could lead to some distress.** However, support is available through University Student Wellbeing services and local charities and organisations (contact details provided below).

##### Are there any possible benefits in taking part?

There are no direct benefits from taking part in this study although the information gained will provide valuable information on student mental health and wellbeing. Participants who provide a saliva/DNA sample and who also fully complete the on-line survey will receive a university hoodie.

**What if new information becomes available?**

If new information becomes available during the course of the study, you will be kept informed and any options or requests/requirements fully explained. New information could result in termination of the study, the withdrawal of certain participants, or modifications/amendments to the study.

**What happens when the study ends?**

Participants may be contacted to consider participating in Phase 2 of the study. As the study will monitor students throughout their time at university, all participants will be contacted at the beginning of year 2 and year 3 to complete a follow-up on-line survey. Student Wellbeing will provide help and information to students if required.

**What if something goes wrong?**

It is very unlikely that something will go wrong during this research. However, the University take complaints and concerns seriously and has procedures in place for reporting, investigating, recording and handling them. The University is insured for its staff and students to carry out research involving people however this does not extend to non-negligent harm. The University knows about this research project and has approved it. Further details on insurance can be found in the University’s research indemnity statement. Ask us if you would like a copy.

**Will my taking part in this study be kept confidential?**

All information collected for the study will be kept strictly confidential, in accordance with Ulster University guidelines and will be kept for a minimum of 10 years. The data will be archived securely in a restricted access room. All identifiable information collected from you will be stored in a locked filing cabinet. All computerised data will be coded so that you cannot be identified, and the data will be held on password protected and encrypted computers. Your saliva/DNA sample will also be coded so that you cannot be identified from it, and it will be stored in a secure location until it is processed. Information will be safely destroyed once it is no longer required.

While all information provided will be treated in a secure and confidential manner if you endorse specific patterns of symptoms you will receive an email with advice to contact your GP and/or Student Wellbeing and a second email two weeks after the survey, to ask about whether you have done this. Participants who say that they have suicidal thoughts will receive the same email and will be contacted by Student Wellbeing by phone. If through the course of the research we believe that there has been illegal activity or someone is at risk or harm, confidentiality will be broken, and the appropriate authorities will be informed.

**What will happen to the results of the research study?**

It is intended that the findings from this study will be published in scientific or medical journals and presented at conferences. You will **not** be identified in any report or publication.

**Is there an independent contact that can give me advice?**

Should you have any concerns about the ethical procedures surrounding the research or if you have any complaints please contact Nick Curry, Head of Research Governance, n.curry@ulster.ac.uk. Full details of the UU research complaints procedure can be found here: <http://research.ulster.ac.uk/rg/02078ResearchVolunteerComplaintsProcedure.pdf>.

Copies are available upon request. If you have any queries or complaints relating to GDPR regulations please contact The University’s Data Protection Officer, Mr Eamon Mullan, University Secretary and Data Protection Officer, University of Ulster, Room J313, Coleraine, BT52 1SA. e.mullan@ulster.ac.uk

**Who is organising and funding the research?**

Funding for this study was obtained from Cross-border Healthcare Intervention Trials in Ireland Network (CHITIN).

**Who has reviewed this study?**

The study has received ethical approval from Ulster University Research Ethics Committee (REC/19/0072).

**Thank you for taking the time to read this information.**

**If you have any questions or would like more information, please contact:**

* Dr Elaine Murray; Chief Investigator; e.murray@ulster.ac.uk
* Professor Siobhan O’Neill, sm.o’neill@ulster.ac.uk
* Dr Margaret McLafferty, m.mclafferty@ulster.ac.uk

**If you feel that you are having difficulties coping, please find below some resources which may be of help to you:**

**Ulster University Student Wellbeing**

**Drop in on your own campus:**

Belfast: **Room:** BA02034

Coleraine **Room:** E023

Jordanstown **Room:** 15G20A

Magee **Room:** MG108G

**Telephone:** **+44 (0)28 9536 7000** **or**

**email:** **studentwellbeing@ulster.ac.uk**

**The Students Union at:** **info@uusu.org** [**https://www.uusu.org/advice/**](https://www.uusu.org/advice/)



**Lifeline: 0808 808 8000**

**Web:** [**www.lifelinehelpline.info**](http://www.lifelinehelpline.info/)

**Samaritans: 116 123 Web:**[**www.samaritans.org**](http://www.samaritans.org/)

**Email Samaritans:** **jo@samaritans.org**

 **Talk to Family, Friends, Studies Advisor, Year Tutor or Course Director**