

Participant Information Sheet

Student Psychological Intervention Trial (SPIT)

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, it is important that you fully understand what the research is for and what you will be asked to do. Please read the following information and do not hesitate to ask any questions about anything that is unclear to you. Take time to consider whether or not you want to take part.

What is the purpose of the study?

Ulster University (UU), in conjunction with Letterkenny Institute of Technology (LYIT) is conducting a research study. In the study we will carry out a **randomized controlled trial (RCT)** to determine if a guided **web-based intervention** is useful in improving emotional wellbeing. To do this, we will randomly assign participants to two separate groups: one group will have access to the online intervention and the second group will be directed towards current usual care through student support services at your institution (UU/LYIT). The effect of the intervention on wellbeing will be compared in each group following a 7-week intervention.

If you agree to participate, you will be sent a link to a short screening questionnaire to see if you meet the initial inclusion criteria (have low mood, lack motivation, are stressed or anxious and not currently receiving nor within last 12 months received treatment for anxiety and/or depression). Then a telephone interview will be conducted by a trained guide asking you to answer questions about your mental health. **If you meet the criteria you will then be randomly assigned to one of the two groups.**

Following the intervention or treatment as usual (TAU), all participants will be sent an email with a link to the online post-treatment questionnaires. You will also be asked to complete follow-up questionnaires at 6 and 12 months after beginning the study. At 12 months you will be asked to take part in a follow-up phone interview. Students who complete both the posttreatment and follow-up assessments will be offered a smart watch activity tracker. You may also be asked to consider taking part in a focus group to establish the factors that influenced uptake, adherence and the success of the intervention in targeting depression and anxiety. Alternatively, you may be asked to partake in an interview or a short survey if the status of the COVID-19 pandemic at the time does not permit focus groups.

Prior to participating in the study, you will be asked to provide a saliva sample (5ml) and/or a blood sample (20ml). Samples will also be taken during post-treatment assessments. If it is not safe to collect samples on campus due to the COVID-19 pandemic, we may post a self-collection saliva or dried blood spot collection kit to you with a stamped addressed envelope for you to return it to us or if this is deemed to be a risk, we may not collect samples at this time.

Why have I been chosen?

You have been chosen because you are a student at Ulster University or Letterkenny Institute of Technology and we believe you may be interested in an intervention aimed at improving emotional wellbeing. If you have noticed that you have been feeling low or sad, stressed, on edge or less motivated over the past few weeks or months, you may wish to consider participating in the current study.

What do I have to do?

All participants will be asked to:

- Give written consent to participate in this study
- Complete a short online questionnaire at the beginning of the study
- Participate in a telephone interview
- Participate in treatment (TAU/intervention) – 7 weeks
- Complete an online post-treatment questionnaire
- Complete follow-up assessments at 6 and 12 months
- At 12 months you will also repeat an interview by phone
- Provide a saliva and blood sample at pre and post-treatment assessments if it is safe to do so, in relation to the COVID-19 pandemic status at the time.

Some students will be asked to participate in a **focus group** which will take approx. 1 hour. Alternatively, according to COVID-19 guidelines at the time, you may be asked to participate in a short interview or complete a short survey at the end of the study.

Pre-intervention	Intervention	Post-intervention – 1 week	Post-intervention – 6 months	Post-intervention – 12 months
Sign consent	7 weekly sessions (45-60 minutes) Or Treatment as usual	Online questionnaires	Online questionnaires	Online questionnaires
Online depression, anxiety & health questionnaire (6 minutes)		-Depression (2.5 minutes)	-Depression (2.5 minutes)	-Depression (2.5 minutes)
Telephone Interview on mental health (MINI) (15 minutes)		-Anxiety (1-2 minutes) -Health (2 minutes) -Treatment satisfaction questionnaire (5-8 minutes)	-Anxiety (1-2 minutes) -Health (2 minutes)	-Anxiety (1-2 minutes) Health (2 minutes) -Telephone interview on mental health MINI (15 minutes)
Saliva/blood sample		Saliva/blood sample	Saliva/blood sample	Saliva/blood sample Collect incentive

Flowchart for Phase 2 of the SPIT project

Do I have to take part?

It is completely up to you to decide whether or not you would like to take part. If you decide to participate, you will be given this information sheet to keep. You have the right to withdraw from the study at any time without giving a reason. However, the data collected up until the point of withdrawal will still be included in the analysis. 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 or LYIT.

Data Sharing

This study is part of the World Mental Health International College Initiative. The study involves a number of collaborators and we will share some of the data collected 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. All information sent to external service providers will carry a study code number only and your identity will remain protected. 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.

What about side effects?

There will be no side effects to participating in the study.

Risks and/or disadvantages of taking part?

There is minimal risk associated with taking part in this study. There is a very small risk that you could become distressed during the study. There is a very small risk of bruising when giving a blood sample, but a fully trained phlebotomist will take your blood sample to ensure that any discomfort is kept to a minimum. If any aspect of the study causes your distress or you become upset or anxious, this will be communicated to Student Wellbeing.

Are there any possible benefits in taking part?

It is hoped that students will benefit from the intervention, with the symptoms of depression and/or anxiety reduced. Furthermore, the information gained will provide valuable information on the effectiveness of online interventions for treating depression and anxiety.

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?

Your direct involvement in the study finishes after the final follow up questionnaire. Student Wellbeing will provide help and information to students if required. At the end of the study we will analyse the data from all the participants and write scientific reports. Your data will be kept anonymous for any form of data analysis or report writing.

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. If through the course of the research we believe that there has been illegal activity or someone is at risk of 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. Findings of the study will be disseminated directly to students through the student's union and engagement events. We will register the study with the INVOLVE open access database which registers health care research projects involving members of the public as partners. We will use INVOLVE for posting information resources to the participants and dissemination of the study outcomes. At the end of the study, we will organise an Open Day event, where members of the public as well as the student body will be invited to find out about the study findings.

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?

This study has been reviewed by the University Research Ethics Committee.

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
- Natasha Brown, Natasha.Brown@lyit.ie



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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/>



Lifeline: 0808 808 8000

Web: www.lifelinehelpline.info



Samaritans: 116 123

Web: www.samaritans.org

Email Samaritans: jo@samaritans.org



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