



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Information Leaflet for General Practitioners

(Version: 3.0; Date: 14/3/2025)

Study title: Promoting Adolescent Mental Health through GP training (PACE-GP): A pilot RCT and process evaluation of an online educational intervention designed to support GPs in Ireland to manage adolescent mental health presentations.

Principal investigator's name: Dr. Dónal Wallace

Principal investigator's title: Assistant Professor in General Practice, Trinity College Dublin (TCD)

Contact Details of principal investigator: Phone: 01 896 3737
Email: wallacd1@tcd.ie

Co-investigators' names and titles:

Prof. Susan Smith (Professor of General Practice, TCD)
Dr. Sadhbh Byrne (Visiting Research Fellow, Institute of Population Health, TCD)
Prof. Lina Zgaga (Associate Professor of Epidemiology, TCD)

Data Controller's Identity: Trinity College Dublin

Data Protection Officer's Identity: Data Protection Officer, TCD

Data Protection Officer's Contact Details: Email: dataprotection@tcd.ie

You are being invited to take part in a research study which is being led by Dr Dónal Wallace, who is a GP based in the Discipline of Public Health and Primary Care in the School of Medicine, Trinity College Dublin.

Before you decide whether or not you wish to take part, you should read the information provided below carefully. Feel free to email Dónal to ask questions if you have any. Don't feel rushed and don't feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'. There is no obligation for you to take part in this study and you have the right to refuse to participate.

We understand that you might change your mind in the future. You can stop taking part in the project at any time. Even if you start taking part, you can still stop any time if you like. Just let Dónal know – his contact details are listed below. You do not need to provide any explanation. However, it will not be possible to withdraw your study information from this research study once the analysis of the data is complete and published.

This information leaflet contains the following sections:

- Part 1 - The Study
- Part 2 - Data Protection
- Part 3 – Costs, Funding and Approval
- Part 4 - Further Information
- Part 5 - Next Steps

Part 1 – The Study

Why is this study being done?

This research study is taking place to evaluate an online educational intervention exploring the impact of an educational intervention on GPs' awareness, practice, and self-perceived knowledge and confidence in relation to Adolescent Mental Health presentations. The study is being carried out to determine the feasibility of delivering and implementing this new online educational intervention and to explore its impact.

Why am I being asked to take part?

You are being asked to take part because you are a GP working in the Republic of Ireland.

Do I have to take part?

No, you do not have to take part. Your participation is entirely voluntary. If you decide not to take part, there will be no negative impact on you.

Can I withdraw from the study?

If you change your mind, you can stop taking part in the research study at any time and you do not have to give a reason. If you change your mind about taking part, just let Dónal know by emailing wallacd1@tcd.ie. Once the data analysis is complete and published, it will not be possible to withdraw your study or demographic information.

How will the study be carried out?

This study is a pilot randomised controlled trial that will last 3 months for participants. This means that you will be randomly allocated to either an intervention group (which will receive the training on Adolescent Mental Health during the study) or a control group (which will receive the training on Adolescent Mental Health after the study is complete). This study involves you completing online questionnaires on the topic of Adolescent Mental Health. These questionnaires will be administered using a TCD Licenced Qualtrics platform.

What will happen if I agree to take part?

If you agree to take part in this study, we will ask you to complete and sign the consent form below. Once the consent form has been completed you will be asked to complete a baseline questionnaire which will include questions on your knowledge of Adolescent Mental Health issues, perceived Adolescent Mental Health practice, awareness of Adolescent Mental Health issues and confidence in dealing with Adolescent Mental Health presentations. This questionnaire will also include background questions such as you age, gender, ethnic background, years practicing as a GP, questions regarding your training to date, number of sessions worked per week in clinical practice and if you work in an urban or rural setting. We are asking these questions so that we can compare participating GPs' backgrounds with those of GPs across Ireland. You do not have to answer any questions that you are not comfortable answering. You will then be randomly allocated to either the control group or the intervention group automatically by Qualtrics.

It is anticipated that each questionnaire should take 10 minutes to complete.

If you are allocated to the intervention group: you will receive an email from Dónal within 7 days containing the link to the online educational training on the ICGP Education Platform website. You will be asked to complete the online training within a three week window. The training will take about 1 hour to complete. Once you reach the end of the online training you will be provided with a link to a 2nd questionnaire for you to complete. This questionnaire will contain the same questions from the 1st questionnaire and will give us information on the immediate impact of the training. If you do not complete the training within the three week window you will be emailed up to two reminders by Dónal.

If you are allocated to the control group: you will receive a follow up email in 3 months to complete the same questionnaire.

All participants in both the control and intervention groups: will receive an email from Qualtrics three months after you have completed your initial questionnaire, asking you to complete your final questionnaire. This will contain the same questions as the first questionnaire that you completed. Participants in the control group will then receive an email from Dónal with the link to the online training.

We will aim to recruit 120 GPs for the study. All participants who consent will be recruited to the study.

Participants will be given a short list of contacts at the end of the online module and encouraged to make contact with them if they have been affected by any of the topics raised during the training.

In order for you to be given access to the online training, Dónal will email the ICGP with your name requesting that you are given access. The ICGP already holds your personal details as you are an ICGP member. You will be able to use this training towards your annual CPD requirements.

What are the benefits?

While taking part in this study may not directly benefit you, your participation will help us to understand more about how GPs can support young people who are concerned about their mental health. It will inform educational policy and practice for GPs to effectively manage Adolescent Mental Health at primary care level. You will be able to use this training towards your annual CPD requirements.

What are the risks?

There are no direct risks to taking part in this study. Some GPs may find the issues raised in the online training uncomfortable or upsetting. However, there is a low probability of this transient

risk of harm occurring given that GPs are very familiar with receiving training on challenging clinical situations and sensitive topics. You will be given a short list of contacts at the end of the online module and encouraged to make contact with them if you have been affected by any of the topics raised during the training.

There is a risk that a connection to your identity could be made from a data breach. Great care will be taken to ensure the confidentiality of all information and the risk to you of a breach of confidentiality is considered very low.

Please make sure that you do not identify yourself or anyone else in the comment boxes in the questionnaires you are asked to complete. You will be reminded of this when asked to complete the questionnaires.

Part 2 - Data Protection

What personal information are you collecting from me?

- We will ask for your email address, so that we can send you a copy of this information leaflet for you to save, along with your completed consent form and the link to online training. We will also need your email address so that Qualtrics can send you an automated email to complete the 3 month follow up questionnaire.
- We will ask for your age, gender and ethnic or cultural background, to determine if we are getting a broad representation of participants.
- We will collect your name and signature on the consent form.

Who will have access my personal data as part of this study?

The research team will have access to all information collected.

The Irish College of General Practitioners will be emailed with your name and email address so you can be given access to the online training on Adolescent Mental Health. The ICGP will have this information already as you are a current member. The ICGP will not have access to any information that directly identifies your individual questionnaire responses.

How long will the data be stored?

Your consent form, questionnaire responses and engagement data from the online training will be stored securely in TCD for seven years from the date you sign the consent form to maintain compliance with ethical requirements. All research data is identified by a code to replace your name.

The ICGP will store your name and whether or not you completed the module in line with their usual data storage policy and standard retention periods. Engagement data from the online educational module will be deleted by the ICGP once it has been shared with the research team.

Your contact information will be retained for seven years by the research team to invite you to take part in potential future related research but this will require additional consent for engagement.

How will my data be kept safe?

Your privacy is very important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe.

- Any information we collect from you is entirely confidential and is used only for the purpose of this research.
- A unique study ID code will be assigned to you (which is generated from the first three questions at the beginning of each questionnaire) and your study information will be gathered, stored, and accessed using this ID code only.
- Personal data (name, email address, age, gender, ethnic or cultural background, place of work) will be stored securely separately in a password-protected and encrypted database by Trinity College Dublin. Only researchers who are part of this study team will have access to these data.
- We need your name for the first questionnaire to be able to identify you. However, your questionnaire responses will then be stored using a Study ID only.
- All subsequent questionnaires that we ask you to complete will be saved using your study ID code.
- Analyses will be conducted on research data only identified by Study ID. No information that could directly identify you will be included in any reports or presentations.
- Electronic files containing research data will be password protected and stored on SharePoint licensed to Trinity College Dublin. Access is restricted to the research team by two step sign in.
- Consent forms and participant contact details will be stored on the TCD desktop computer of Dónal Wallace, which is password protected in a locked office in the Institute of Population Health. Your consent form and contact details will also be backed up and saved on Sharepoint licenced to Trinity College Dublin.
- Training in data protection law and practice has been undertaken by all TCD members of the research team.

Will the confidentiality of my data ever be breached or shared with a third party?

There are certain circumstances under which confidentiality may be breached. First, if you tell us something that indicates you or any other person is at risk, we will need to let the appropriate services know (e.g. Tusla, the Gardaí). This is required by law. We will not do this without informing you first.

Another circumstance is where disclosure is required as part of a legal process or Garda investigation. In such instances, information may be disclosed to appropriate third parties without permission being sought. Where possible, a full explanation will be given to you regarding the necessary procedures and the actions that may need to be taken.

What will happen to the findings of this study?

At the end of the research study, we will write up a report on what we found out and we hope to publish this in an academic journal. In the reports and publications from this study, we may use anonymous quotes from participants. Quotes can help to give examples of points that were raised in the questionnaire responses.

We also hope to present the findings of the study at academic conferences. We may also write up an article for Forum: Journal of the ICGP or some other media outlets that cater for GPs in Ireland, so that they can learn about the findings.

Any reports on the project will only talk about what the overall group of GPs think – it will not include any information specific to any one GP.

We will use the information gathered through this study to further develop this training module for GPs on adolescent mental health.

The findings of the research study will be communicated to you if you consent to this.

What is the lawful basis to use my personal data?

We will only use your personal information for this research project¹, which we hope will improve GP care of young people's mental health². We will also ask for your consent as a requirement of the Irish Health Research Regulations.

What are my rights?

Under Data Protection legislation, you have the following rights in relation to any use of your personal data:

- The right to request access to your personal data and to receive a copy of it
- The right to request deletion of your data
- The right to request inaccurate information about you is corrected or deleted
- The right to restrict or object to processing of your personal data or any future use of that information.

¹ Article 9(2) (j)

² Article 6(1)(e)

By law you can make these requests to us, unless the request would make it impossible or very difficult to conduct the research (for example if the information were about to be published).

You can make these requests by contacting Dónal at wallacd1@tcd.ie or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

Part 3 - Costs, Funding and Approval

Has the study been approved by a research ethics committee?

Yes, this study has been approved by the Irish College of General Practitioners Research Ethics Committee on 8th July 2024.

Who is organising and funding this study?

This study is being led by Dr. Dónal Wallace, who works as an academic GP in the School of Medicine, Trinity College Dublin. The research team involved with the project also includes Prof. Susan Smith (Professor of General Practice, TCD), Dr. Sadhbh Byrne (Visiting Research Fellow, Institute of Population Health, TCD) and Dr. Lina Zgaga (Associate Professor of Epidemiology).

The research study is funded by:

- The Irish College of General Practitioners through their Research and Education Grant Scheme. The HSE National Office of Suicide Prevention and the Irish College of General Practitioners are also funding the development of the online educational intervention.
- The Irish Network of Healthcare Educators and the Irish Medical Council, through their Research in Medical Education Award Scheme.
- The TCD School of Medicine and TCD Office of the Dean of Research through their TCD MED Research Impact Award Scheme.

Will it cost me anything to take part?

No, It will not cost you anything to take part in this study.

Part 4 – Further Information

Where can I get further information?

If you need any further information now or at any time in the future, please contact:

Name: Dr Dónal Wallace
Address: Public Health & Primary Care, Institution of Population Health, School of Medicine, Trinity College Dublin, Russell Centre, Tallaght Cross, D24 DH74, Ireland.

Phone: 01 896 3737 (This phone number is attended between 9am and 5pm on Mondays, Tuesdays and Thursdays only)
Email: wallacd1@tcd.ie

OR

If you wish to discuss any of your data protection rights, please contact:

Data Protection Officer, Trinity College Dublin:

Address: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland.

Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

Under GDPR, if you are not satisfied with how your data is being used, you have the right to raise a concern with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie.

Part 5 - Next Steps

After you have read this participant information leaflet, if you have decided that you would like to take part in this research study, please complete the consent form in the next screen. Once you have completed the consent form, you will then be directed to a baseline questionnaire to complete. If you do not wish to partake in this study you do not need to complete the consent form and you can leave this page.

You will be emailed copy of this participant information leaflet and your completed consent form for your records. Please retain this in case it is needed for future reference.