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

Protocol for pilot RCT and Process Evaluation

PROJECT DETAILS

Research Project 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.

Project Start Date: 27th October 2025

Project End Date: 31st December 2026

Keywords: Adolescent Mental Health, Youth Mental Health, GP Education, Continuing Professional Development, Continuing Medical Education, Suicide Prevention.

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Sponsor name: Trinity College Dublin

Trial Registration: This study will be registered with the ISRCTN registry.

Project Summary (including background, objectives and project plan):

There has been an increase in mental health presentations among young people in Ireland over the past 10 years and recent reports suggest this has been exacerbated during and following the Covid-19 pandemic. GPs are often the first point of contact for Adolescent Mental Health (AMH) presentations and form a critical point in the care pathway. However, many GPs do not feel equipped to confidently deal with adolescents presenting with mental health issues.

An online educational intervention for GPs on the topic of Adolescent Mental Health is being developed by the research team. In order to ascertain the impact of the new training on key outcomes it is important to conduct an evaluation in the real-world setting. This study will be a pilot RCT to evaluate the feasibility of its implementation and its impact on participating GPs' awareness of AMH topics, reported practice, and self-perceived knowledge and confidence. The study will also involve a parallel process evaluation of the pilot trial.

BACKGROUND AND SIGNIFICANCE

This pilot randomised controlled trial (RCT) and parallel process evaluation will form Stage 3 of an existing overarching research project. The overarching project aims to improve GP knowledge and skills in managing Adolescent Mental Health presentations. Stage 1 and 2 of the project involved qualitative consultation with young people, parents and GPs, together with a systematic search of the literature on pedagogical strategies for use in Continuing Medical Education and a review of clinical guidelines on the management of Adolescent Mental Health in Primary Care. Ethical approval for both Stage 1 and 2 was already obtained from the ICGP REC. An online educational intervention on the topic of Adolescent Mental Health is being designed by the research team using findings from Stage 1 and Stage 2 of the study. This intervention is being developed in collaboration with Dr. Anna Beug, GP and subject matter expert, based on a previous AMH online module she had designed for GP trainees and informed by findings from Stage 1 and 2 of the project.

The first My World Survey published in 2012, concluded that "the number one health issue for [Irish] young people is their mental health" [1]. Worryingly, the follow-up study, My World Survey 2, published in 2019, has highlighted that there has since been a notable increase in mental health presentations among young people in Ireland[2]. In addition, there is great concern that the social control measures introduced during the Covid-19 pandemic are likely to have ongoing mental health impacts on our adolescent population, resulting in long lasting effects even post pandemic. Adolescent mental health is therefore a critical public health concern.

Given that GPs are often the first point of contact for adolescent mental health presentations, they are a critical point in the care pathway, playing a key role in evaluation, assessment, signposting, support, diagnosis and management for these patients including onward referral if indicated. GPs are experiencing long delays in accessing Child and Adolescent Mental Health Services (CAMHS). Often referrals to CAMHS are declined and redirected back to the referring GP. Therefore, it is a national priority that primary care is adequately prepared to respond to the increasing numbers of adolescent mental health presentations.

However, many GPs do not feel equipped to deal effectively and confidently with adolescents presenting with mental health issues. Previous work has shown that GP satisfaction rates are low in Ireland with regards to postgraduate training received in child and adolescent mental health[3]. Training that focuses on mental health and in working with adolescent populations would be extremely beneficial for GPs and patients.

Taken together, this evidence highlights the need for suitable training for GPs to facilitate them to effectively manage adolescents presenting with mental health concerns. It is important that training in this area is tailored to GPs working in the Irish context. Furthermore, existing interventions rarely incorporate youth participation or PPI in an effective way. In line with best practice in patient and public involvement (PPI), the development of this new training included consultations with young people and parents. As empowerment and user involvement are important tenets of contemporary health care,

young people's experiences and perspectives must play a central role in shaping best practice[4].

In order to ascertain the impact of the new training on key outcomes it is important to conduct an evaluation in the real-world setting. This pilot RCT will evaluate the impact of the educational intervention on participating GPs' awareness, practice, and self-perceived knowledge and confidence. The parallel process evaluation will help to determine the feasibility of delivering and implementing the online AMH educational intervention. This critical information is needed to evaluate the potential for wider implementation of the educational intervention.

STUDY OBJECTIVE(S); INCLUDING SPECIFIC AIMS AND/OR HYPOTHESES

Primary objectives

- To conduct a pilot RCT of an online educational intervention to evaluate the impact of the intervention on participating GPs' awareness, practice, and self-perceived knowledge and confidence.
- To evaluate the potential for wider implementation of the GP educational intervention using the Medical Research Council process evaluation components of recruitment, context, implementation and mechanism of impact[5].
- To produce and disseminate outputs of this study to the project's target audiences through national and international communications and dissemination to specific target audiences, using tailored messages and channels for each audience including: GPs, researchers, policy makers, the media and general public.

METHODS

Study Design

A pilot RCT will be conducted to evaluate the online educational intervention on the topic of adolescent mental health. The study will be conducted and reported using the appropriate CONSORT extension for pilot trials guidance[6]. Alongside the pilot RCT, we will conduct a process evaluation and fidelity assessment of intervention delivery and receipt, to explore the implementation of the intervention.

This protocol will first outline the pilot RCT after which the process evaluation will be described.

PILOT RANDOMISED CONTROLLED TRIAL

In the pilot RCT, 120 GPs will be randomly allocated to a control or intervention group, receiving either intervention: new online training on AMH; or control: no online training on AMH. An allocation ratio of 1:1 will be used. Intervention participants will complete a self-reported questionnaire before (Baseline) and immediately after (Time 2) receiving the CME training to assess their knowledge, perceived AMH practice, awareness of AMH issues and confidence on a range of issues relating to AMH presentations, with a three-month follow up questionnaire (Time 3). Control participants will receive the questionnaire at Baseline and

Time 3. Collection of data at Time 2 in the intervention group is to measure immediate intervention effect but the primary study end-point is at Time 3, three months following randomisation/intervention. Data will be collected from self-report surveys by participating GPs using the Qualtrics survey platform. Questionnaires will be based on an evaluation of an educational tool for Dementia in Australian GPs[7]. All baseline questionnaires will also collect demographic information.

The research team will apply for CPD recognition for study participants. It is anticipated that 5 CPD credits will be applied for. Once the intervention group research participants have completed their 3 month follow-up questionnaire they will be given the relevant CPDR code at the end of the questionnaire that they can use to gain CPD credits on their ePortfolio. As a form of wait list control, GP participants in the control group will be offered access to the intervention at Time 3. Control group GPs will be given their CPDR code on completion of the online educational module, which they will be invited to complete once they have completed their 3 month follow up questionnaire.

Study Population

Approximately 120 GP participants will be recruited to take part, through advertisements on social media, GPbuddy, Forum journal, ICGP Membership ezine email, and at the monthly ICGP Webinar meeting.

Inclusion criteria

- General Practitioner currently active in clinical practice
- The GP must be practicing within the Republic of Ireland
- ICGP member

Exclusion criteria

- Not active in clinical practice
- Not practicing in the Republic of Ireland
- Not an ICGP member
- GP trainee

The inclusion and exclusion criteria have been chosen as the study sample should include fully qualified GPs who are active in clinical practice in the Republic of Ireland, as this is the intended audience for the online educational module. Research participants need to be an ICGP member as the online educational module will be run through the ICGP's online learning platform and only ICGP members will have access to this.

Randomisation

GP participants will be randomised to either the intervention group or control group using the randomiser feature within Qualtrics.

Intervention and Intervention delivery

The AMH intervention itself will consist of an online educational tool for GPs on the subject of Adolescent Mental Health. Content will include core issues around AMH presentations,

communication with adolescents, primary care management of AMH presentations and best use of resources as they exist in Ireland currently. It will take approximately 60 minutes for GPs to undertake the training. This intervention has been designed in close consultation with subject matter expert, Dr. Anna Beug, and based on the research team's findings in the literature review and analysis of the focus group interviews. The intervention will be run through the ICGP Education Platform, the ICGP's online learning platform.

Sample Size Considerations

In this pilot RCT we primarily want to assess the feasibility of delivering and implementing the GP AMH online educational tool. While we do not seek to demonstrate the benefit of the intervention, we will consider its potential impact, which will be used to inform a formal sample size calculation for the main trial. The research team will aim to recruit 120 GP participants as based on similar work by Eldridge et al. and our prior experience, this would be a large enough sample to inform feasibility of delivering and implementing this intervention[8].

While there is no formal sample size required for a pilot study, based on data we have collected previously, we have estimated a sample size which we feel will be large enough to inform about the practicalities of delivering the intervention, recruitment and retention rates, in addition to exploring potential change in outcome measures for going forward to a definitive RCT.

Blinding

Blinding of participant GPs will not be possible due to the nature of the intervention. The trial statistician will not be blinded to GP participant group allocation for practical reasons.

Outcomes

Primary Outcomes

- Feasibility of delivering and implementing the GP AMH CME intervention[8] will be determined by questionnaires designed for this study which emcompass both outcome and process evaluation.

Secondary Outcomes

- The questionnaire will collect outcomes on:
    - GP knowledge
    - Perceived AMH practice
    - Awareness of AMH issues
    - Confidence on a range of issues relating to AMH

The outcome measures are modelled on a previous similar study evaluating an education tool for Dementia training in Australian general practice[7]. See supporting documents for the questionnaires.

Study Procedures

Recruitment

Approximately 120 GP participants will be recruited to take part, through advertisements on social media, GPbuddy, Forum journal, ICGP Membership ezine email, and at the monthly ICGP Webinar meeting. The advertisement will contain a link to Qualtrics. Within Qualtrics participants will be able to view the Participant Information Leaflet and then complete the consent form. We will aim to recruit 30 GP participants per month over a 4 month period.

Description of Study Procedures

Once the consent form is completed by GP participants within Qualtrics, they will be asked to complete a Baseline questionnaire which will also include demographic questions. After participants have completed the Baseline questionnaire, the randomiser feature within Qualtrics will be used to allocate participants to either the control or intervention group, and participants will be advised what group they have been assigned to.

The Intervention group will receive an email from the PI within 7 days containing the link to the online educational tool. Participants will be asked to complete the training within 3 weeks. If participants have not completed the training within 3 weeks, they will be emailed a maximum of up to 2 reminders by the PI. At the end of the online educational tool, there will be a link to Qualtrics where participants will complete the Time 2 questionnaire. In order for study participants to gain access to the online training module, the PI will email the names of participants to be granted access to the ICGP. Participants in the Intervention group will be given access to the online training within 1 week of completing their Baseline questionnaire. Following completion of the Baseline questionnaire the Control Group participants will be advised that they have been allocated to the Control group.

3 months post randomisation all participants in both the Control and Intervention groups will receive an automated email from Qualtrics with a link to the Time 3 questionnaire.

Participants in the control group will be given access to the online educational training once they have completed the Time 3 questionnaire. The PI will share the names of participants to be given access to the module with the ICGP, and will then email a link to the module with participants in the control group.

Continuation Criteria

We will use formal continuation criteria to determine if progressing this pilot RCT to a definitive pragmatic RCT is warranted based on data from the pilot RCT and process evaluation. The criteria for continuation (also referred to as progression criteria) will be based around pre-determined measures of feasibility, including participant recruitment, retention, data collection and the potential for intervention effectiveness. These continuation criteria will be monitored by the research team and will determine whether the ongoing trial is feasible to continue.

Proceed with RCT	Proceed with RCT following some changes to the protocol	Do not proceed with RCT unless problems can be overcome
Recruitment of 80 GP participants over 4 month period	Recruitment of 51-79 GP participants over 4 month period	Unable to recruit at least 50 GP participants over 4 month period
Retention of ≥ 80% GP participants	Retention of 51-79% GP participants	Retention of ≤ 50 %GP participants
GP AMH online educational intervention ranked as acceptable to majority of GPs (>50%) as per process evaluation quantitative and qualitative data	Some elements of the GP AMH online educational intervention acceptable to the majority of GPs (>50%) as per process evaluation quantitative and qualitative data	GP AMH online educational intervention reported to be unacceptable to majority of GPs (>50%) as per process evaluation quantitative and qualitative data
Delivery of GP AMH online educational intervention feasible (module delivered as intended)	Delivery of GP AMH online educational intervention partially feasible (module partially delivered as intended)	Delivery of GP AMH online educational intervention not feasible (module not delivered as intended)

Table 1 - Continuation criteria which indicate whether to proceed with a randomised controlled trial

PPI involvement

Aligned with best practice in patient and public involvement (PPI)[9-11], two youth and two parent advisors have been recruited to guide the project and they will be remunerated for their time. These advisors will give input into dissemination methods for phase 3 of the study. They will guide the choice of dissemination outlets and contribute to dissemination content, particularly for target adolescent, parent and public audiences. We hope to work with our parent and youth advisors to create video abstracts for all academic papers generated through the project, together with accompanying lay summaries. Furthermore, under the guidance of the parent and youth advisors, we hope to disseminate project outcomes to the public with a particular focus on communicating the findings to young people and parents. Ideas include an article on the SpunOut website, and a webinar for all interested parties.

PROCESS EVALUATION

Alongside the pilot RCT, we will conduct a process evaluation and fidelity assessment of intervention delivery and receipt, involving GPs who received the online educational training, to explore the implementation of the intervention from multiple perspectives in line with the MRC Framework for the Process Evaluation of Complex Interventions[12]. The following issues surrounding integration, context, fidelity, implementation and experiences of the intervention will be explored as part of the process evaluation.

For the process evaluation, the 60 GP participants who received the educational intervention will also complete questionnaires (in the same questionnaire as the one used for the pilot RCT) at Time 2 and Time 3 that assess ratings of acceptability and appropriateness and will be invited to provide free-text comments reflecting on their immediate experience of the intervention. Quantitative data will be summarised with descriptive statistics and thematic analysis will be conducted for the qualitative data. At

Time 3, all participants will be asked if they completed any other training on AMH in the preceding 3 months.

Both the quantitative and qualitative results will inform the Continuation Criteria outlined above. The PPI advisors will be involved in establishing what would be seen as indicators of acceptability and in interpretation of process evaluation findings.

DATA COLLECTION

Data will be collected from self-report surveys by participating GPs using the Qualtrics survey platform. These surveys will be completed at 2 or 3 timepoints as outlined above. These surveys are in the supporting documentation.

Data regarding the participant's engagement with the online educational module will also be collected using the ICGP Moodle online learning platform. Data collected will include date and time module started, date and time module last accessed, overall score in assessment section, status if complete/incomplete/browsed, total time spent on module, time at which question was answered and latency between questions. The identifiable data including participant names will be shared by the ICGP with the PI using a password protected file using Sharepoint.

DATA ANALYSIS

Statistical Methodology

Statistical analysis of all quantitative data gathered will be undertaken under the guidance of a statistician. Quantitative Data will be compiled from completed questionnaires which will be summarised using descriptive statistics, overall and for each study arm separately. For categorical measures, frequencies and percentages will be presented, and for continuous variables the mean and SD, or median and interquartile range (IQR) will be reported. The effect size will first be assessed in a univariate analysis comparing the difference between the intervention and control arms. For the qualitative data collected in questionnaires, thematic analysis will be undertaken.

ETHICAL CONSIDERATIONS

Research Ethics Approval

Research Ethics Committee approval will be sought from the ICGP REC for this research study.

Informed Consent

GPs will be recruited to take part, through advertisements on social media, GPbuddy, Forum journal, ICGP Membership ezine email, and at the monthly ICGP Webinar meeting. The advertisement will contain a link to Qualtrics. Within Qualtrics participants will be able to view the Participant Information Leaflet and then complete the consent form. Participant signatures will also be collected using the signature feature within Qualtrics.

All potential research participants will be given the opportunity to refuse to participate or withdraw from the study up until the data analysis is complete and the findings of this study have been published. Each study participant can email the PI if they wish to withdraw from the study. All study participants will be given a unique participant identifier which can be used to identify which person the responses are from. This is clearly explained in the participant information leaflet. Participants will also be informed that withdrawal of their study information will not be possible once the data analysis has been completed and published.

The Principal Investigator's contact details will be made available to all potential research participants should they have any questions about any aspect of the study.

Risks and Side Effects

There are no direct risks to taking part in this study. During the online educational intervention, some GPs may find the issues raised uncomfortable or upsetting. However, there is a low probability of this transient risk of harm occurring during the study given that all study participants are GPs who are very familiar with receiving training on challenging clinical situations and sensitive topics. 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.

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

Benefits to Subjects

By taking part in this research, it is hoped that study participants will improve their knowledge and confidence in dealing with Adolescent Mental Health presentations in General Practice. This in turn should help to improve the care that adolescents receive regarding their mental health in primary care.

Costs to Subject

There should be no financial costs incurred to subjects apart from the costs associated with using their laptop, desktop or mobile phone to access the training.

Compensation to Subject

There shall be no compensation to research study participants as part of this research study.

Subject Privacy and Data Confidentiality

The collected data from the study is confidential. There are certain circumstances under which confidentiality may be breached. If during the course of the study, the research team is made aware that a participant or any other person is at risk, the research team will need to inform appropriate services (e.g. Tusla, the Gardaí). Prior to this disclosure however, the participant will be notified.

If information is required as part of a legal process or Garda investigation, collected data from the study may be disclosed to appropriate third parties without permission being sought.

PLAN FOR RECORD RETENTION AND DISPOSAL

On completion of the project, TCD will remain in control of the data. The consent forms, pseudo-anonymised questionnaire responses (including pseudo-anonymised personal data), pseudo-anonymised engagement data with the module, participant emails and key to re-identifying participants will be kept for 7 years from date of consent in line with TCDs data protection responsibilities. This is to allow audit of study materials and address any queries subsequent to publication.

The consent forms, participant emails and key to re-identifying participants will be stored on a local drive on the PI's TCD desktop after the research study is complete. This desktop will be password protected, encrypted, located in a locked office in the IPH, and have up to date TCD recommended anti-virus software installed.

The key to re-identify participants, consent forms and email addresses that are stored on the TCD desktop of the PI will be backed up in a separate folder to the research participant survey data in Sharepoint. These files will be encrypted before uploading them to Sharepoint.

The pseudo-anonymised questionnaire responses (including pseudo-anonymised personal data) and pseudo-anonymised engagement data with the module will be stored in a limited access folder on the TCD SharePoint system.

After 7 years from the date of consent, the consent forms, pseudo-anonymised questionnaire responses (included pseudo-anonymised personal data), pseudo-anonymised engagement data with the module, participant emails and key to re-identifying participants will be deleted.

FUNDING, INDEMNITY AND INSURANCE

Funding

This 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.

Indemnity and Insurance

Dr. Dónal Wallace, Prof. Susan Smith, Dr. Sadhbh Byrne and Dr. Lina Zgaga are covered by TCD Insurance policies.

PLANS FOR DISSEMINATION OF FINDINGS

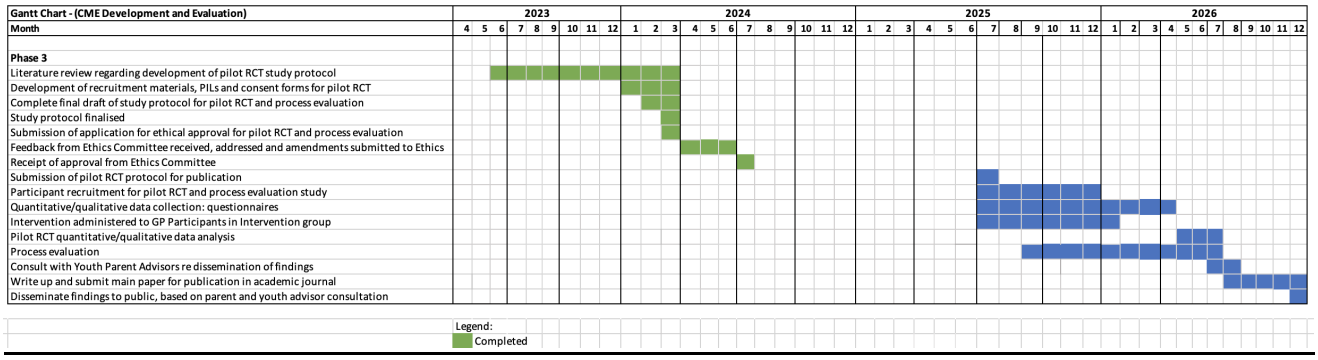
The aggregated study results will be published in a peer-reviewed academic journal. Video abstracts for the journal paper will be developed to coincide with the journal paper publication. The research team hopes to present the findings from the study as an oral or

poster presentation at national and international academic conferences. Meetings that will be considered include the AUDGPI Annual Scientific Meeting and the North American Primary Care Research Group Annual meeting.

These outputs will contribute towards the wider project outputs which include the GP educational intervention itself and will inform educational policy and practice in AMH for GPs and will have knock-on benefits for adolescents experiencing mental health problems and their parents presenting to GPs. It is expected that this training will impact on the future practice of GPs. The educational intervention has the potential to enhance GPs' confidence and skills to effectively manage this patient group at primary care level. The data gathered during the process evaluation can guide future training provided to Irish GPs throughout the country.

The aggregated study results may also be made available through articles for some media outlets e.g. blogs, websites.

TIMELINE



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