The COPING feasibility study

PARTICIPANT INFORMATION SHEET

Version 1.2, 05-Sep-2024, IRAS reference: 327529

- This information sheet explains in detail why this research is being carried out, what it involves and how you can take part. This information will help you decide whether you want to take part.

- If you choose to take part, you are free to withdraw at any time. If you choose not to take part, this will not affect the current or future health care you receive.

KEY THINGS TO KNOW

- You have recently been identified as aged between 16-25 years with a history of self-harm in the last 12 months. This means you can be invited to take part in the COPING feasibility research study.

- Everyone who takes part in the study will receive best NHS care.

- Everyone who takes part will receive a newly developed co-produced treatment for self-harm, called 'COPING', from a trained study GP across two GP appointments. We are looking to see if this new COPING approach may be helpful and can be tested in a larger study in the future.

- **The COPING treatment is not a new medicine.** It is a treatment approach targeting psychological and social factors which the GP will talk through with you.

If you decide to take part in this study, it will involve:

- Completing an online consent form and baseline questionnaire. If you are happy to take part, you will need to submit consent online and complete the e-questionnaire.

- Attending two COPING appointments

- Completing 3 further electronic questionnaires at approximately 8 weeks, 4 months, and 6 months after the baseline questionnaire

The questionnaires will ask about your health. Each questionnaire may take approximately 10-20 minutes to complete. Questionnaires will be completed online.

- We will also ask your agreement for
  - Researchers accessing your medical records
  - Being interviewed to hear your experiences of receiving COPING (optional)

- **Taking part in this COPING study will not affect your current or future NHS healthcare**

If you think you might be interested in taking part, please now read the rest of the information sheet carefully.

If there is anything unclear or if you would like more information, please contact the COPING study team by email on coping.study@keele.ac.uk

Your involvement is extremely valued.

Why is the COPING research study being carried out?

- This COPING feasibility study will help us to understand if a larger future study (a clinical trial) of the COPING intervention is doable in the NHS
- At the moment there are no effective treatments for GPs to use with young people aged 16-25 after self-harm, and so we have developed with patients, carers, and GPs, a new approach called 'COPING', which aims to help young people after self-harm
- The results from this research will tell us how practical and acceptable the COPING intervention is in the NHS and will also tell us if the COPING intervention can be evaluated in a larger future study.

Why have I been invited?

You have been invited to take part because you have been identified as a young person aged 16-25 years with a history of self-harm in the last 12 months and are registered as a patient at one of the participating study GP practices.

Who is funding and conducting this research?

This study is funded by a National Institute for Health and Care Research (NIHR) Doctoral Fellowship award: NIHR300957, awarded to Dr Faraz Mughal (Chief Investigator). Dr Mughal is leading this research study as part of his PhD with support from his supervisors and a wider study team. This study is hosted at Keele University.

What will happen if I take part?

If you agree to take part in this, we will ask you to:

A. Complete the consent form

- A consent form is where you give your permission to take part in the research. You only need to do this once and it will be online. When going through your responses we may contact you to complete any missing information

B. Complete 4 questionnaires

- You will be asked to complete 4 questionnaires, one to be completed now, one 8 weeks, 4 months, and 6 months, after the first one.

- If you would like to take part in this study, you will need to complete the first questionnaire **along with** the e-consent form. You will be able to do this online.

- The questionnaires will ask about you and your experiences of self-harm. We would like to hear your thoughts before and after the COPING intervention

- When going through your responses, if we find that key questions are unanswered or unclear, we may contact you by email or telephone, to see if we are able to help you complete the information. If we do not reach you the first time, we will not make any more than 2 more attempts to contact you

- You can stop completing the questionnaire at any time, but we would like to keep any answers you have given to that point as a partially completed questionnaire. If you would like to opt out of this please let us know on coping.study@keele.ac.uk – this will not change any of your future care

- If you do not return the questionnaires, we will send you a reminder and may try and contact you by telephone or email. If we do not reach you the first time, we will not make any more than 2 more attempts to call you.

- If you change your phone number, email or postal address during the study, please contact us by email coping.study@keele.ac.uk

C. Attend the two COPING appointments

- You will be invited to attend a first COPING appointment in person by your GP practice. The GP in discussion with yourself will book the second COPING appointment for a few weeks later. The second appointment can be in person or online

- You will be asked to use the COPING resource in-between appointments and the GP will ask to see this if you are happy to share it

D. General practice medical record review

- We will need to use information from your medical records for this study. On the consent form at the front of the questionnaire, we ask your permission to review your medical records.

E. Optional interview

- If you **do** decide to take part in this study, you may be contacted to ask if you would be willing to take part in an interview to hear about your experiences of receiving the COPING intervention. Not everyone who takes part in the COPING study will be asked to take part in an interview. If you are contacted about an interview, you can choose whether to take part or not. You will be offered a £75 payment for your time in partaking in an interview

- If you give consent to be interviewed, interviews will be audio-recorded, and typed up and anonymised by a professional company called The Transcription Company, **so you cannot be identified**

We have provided detail on how the data you provide to us on the questionnaires and consent form is kept safe in this Information Sheet. Information you provide on questionnaires or in interviews during the study will not be shared with your healthcare team.

Do I have to take part?

Your participation is **voluntary.** We can assure you that whatever you decide to do, your healthcare will not be affected in any way, now or in the future. However, please note, that if you are currently receiving psychological therapy including from an NHS Talking Therapies service, you are unfortunately unable to take part because this may interfere with the COPING approach.

What shall I do if I do not want to take part anymore?

We realise that people are busy, and do not always have the time to take part in a research study. For this reason, if we do not receive the questionnaire or have any contact from you after 2 weeks, we will assume you do not wish to take part, and we will not organise a COPING appointment for you.

Why should I take part?

If you choose to take part, you will be extremely important in helping us to understand the COPING intervention better and improve it, assess whether a larger study in the future is realistic, and increase the chances that COPING can help young people aged 16-25 avoid self-harm

What are the possible risks of taking part?

If we are concerned that you may be at significant risk of self-harm or suicide from your questionnaire responses or contact with the study team we will encourage you to notify your GP who will be able to support you. We will inform your GP or other agencies as appropriate if we identify risk of self-harm or suicide or a serious safeguarding concern. There are support services which are freely available and clearly outlined at the start of each questionnaire. You will need to spend some of your time completing the questionnaires.

In relation to taking part in an interview we recognise that talking about experiences of self-harm may be upsetting. **You can ask for the interview to be stopped at any point**, and you can change your mind about taking part. You will also be given a list of

support services. There is a risk protocol which may need to be activated if the researcher feels necessary.

In the unlikely event that something does go wrong, and you are harmed during the research study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Who has approved this study?

To protect your interests, all research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed and given favourable opinion by East of England - Cambridge East Research Ethics Committee (reference: 23/EE/0238). The study has also been reviewed by scientific experts on behalf of the NIHR before awarding funding.

DATA INFORMATION

What will happen to the information collected about me during the study?

Keele University is the sponsor for this study based in the United Kingdom. Keele University will be using information from you to undertake this research and will act as the data controller for the data collected during this study. Keele University will keep identifiable information about you for 10 years after the study has ended.

You have rights in relation to your personal information. To learn more please refer to :https://www.keele.ac.uk/informationgovernance/informationgovernanceforthepublic/

You can contact the University's Data Protection Officer about any concerns you have with how we deal with your personal data by emailing dpo@keele.ac.uk.

Your identifiable data and information you share from interviews will be securely held on Keele University servers. Consent forms will be stored separately to the other data that you provide. Data shared to other researchers will be anonymised.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. To safeguard your rights, we will use the minimum personally-identifiable information possible.

If you agree to an interview, **you can stop the interview at any time** without giving a reason. For up to one week after the interview you can change your mind and ask for your interview to be removed from the study. This time period of one week is so that you

have time to think about whether or not you still want your information to be used as part of the study.

We need to manage your records in specific ways for the research to be reliable. This means we won't be able to let you see or change the data we hold about you.

If you do decide to take part in this study a letter will be sent to your GP notifying them that you are taking part in this study.

How will we use information about you?

We will need to use information from you and your medical records for this research project.

This information about you will include your name, date of birth, NHS number and contact details. The information from your medical records will include your prescribed medications, past medical history, and other relevant aspects. Authorised individuals from Keele University and regulatory organisations will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. The data you provide will be anonymised which means your data will have a unique study ID number instead. If you agree to an interview, the audio from these recordings will be written up (called a 'transcript') which will be anonymised.

We will keep all information about you safe and secure.

The information you give in this study, including through questionnaires and interviews, will be included in my PhD thesis, in publications, presentations to clinicians, researchers, and the public, and in sharing findings digitally. Once the study has ended audio recordings of interviews will be destroyed but anonymised interview transcripts will be kept for 10 years and may be used in future research.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Our procedures for handling, processing, storage of and destruction of data

Our procedures for handling, processing, storage of and destruction of data are in line with relevant regulatory requirements. To ensure electronic data are stored securely, it will be held on networks approved by a government backed cyber security scheme.

In accordance with Keele University, the Government's, and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoid duplication

of research) and to understand the bigger picture in particular areas of research. Your anonymised data may be used in other research studies subject to appropriate approvals.

CONTACT DETAILS

If you have any questions or would like any further information, including seeing the study findings, please access the study website COPING - Keele University and contact the COPING study team on:

E-mail:

Coping.study@keele.ac.uk

If you have any concerns or complaints, you can contact Keele University's Head of Project Assurance on email: research.governance@keele.ac.uk, telephone: 01782 732980, or by post: Directorate of Research Innovation and Engagement, Keele University, Keele, Staffordshire, ST5 5BG.

Thank you for taking the time to read this information sheet and for considering taking part in this research study.

This study is funded by an NIHR Doctoral Fellowship awarded to Dr Faraz Mughal [NIHR300957].

FUNDED BY
NIHR | National Institute for Health and Care Research