ISRCTN16572400 https://doi.org/10.1186/ISRCTN16572400

The COPING feasibility study

Submission date
17/11/2023

Recruitment status
Recruiting

Registration date
28/11/2023

Overall study status
Ongoing

Last Edited
28/10/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Self-harm, defined as intentional self-injury or poisoning regardless of intention, in young people is an international health concern. The number of young people presenting to general practitioners (GPs) after self-harm is increasing. Evidence shows that currently there are no effective treatments for GPs to use with young people who have harmed themselves and this impacts on GPs' confidence of managing these patients. To address this, researchers have developed the COPING (CO-produced Psychosocial INtervention delivered by GPs to young people after self-harm) treatment in partnership with young people aged 16-25 with experience of self-harm and GPs. The COPING treatment is a new coproduced treatment for GPs to use with young people aged 16-25 years to help them avoid future self-harm. The COPING treatment is to be delivered by GPs across two 10-minute GP appointments and is a talking treatment targeting psychosocial factors in the young person. The aim of this study is to deliver COPING to all participants across GP practices, to find out whether a clinical trial of COPING is doable in the NHS and to help inform a future larger study.

Who can participate?
Young people aged 16-25 years with a history of self-harm in the last 12 months

What does the study involve?
The researchers will recruit up to 12 GP practices across England and train practice GPs to deliver the COPING intervention. Participants will receive the COPING intervention and be asked to complete three follow-up questionnaires. They and GPs will be invited for an interview to hear their thoughts on COPING.

What are the possible benefits and risks of participating?
It is hoped that participants will find the COPING intervention useful and acceptable. There is the potential that COPING leads to reduced participant distress, repeat self-harm, and suicide and death risk. There is risk that participants may describe self-harm or suicidal intent when returning self-report questionnaires or while partaking in an interview. Two risk protocols have been developed: should likely risk to participants be identified, the relevant risk protocol will be activated, and the participant's GP notified. All participants will receive a Staying Safe Sheet which lists free support services for use when needed.

Where is the study run from?
Keele University (UK)

When is the study starting and how long is it expected to run for?
December 2019 to December 2025

Who is funding the study?
National Institute for Health and Care Research (UK)

Who is the main contact?
Dr Faraz Mughal, f.mughal@keele.ac.uk

Study website
https://www.keele.ac.uk/research/ourresearch/medicine/primarycareresearchthemes/mentalhealth/coping/

Contact information

Type(s)
Scientific

Contact name
Dr Faraz Mughal

ORCID ID
http://orcid.org/0000-0002-5437-5962

Contact details
School of Medicine
Keele University
Newcastle-under-Lyme
United Kingdom
ST5 5BG
+44 (0)1782 733991
f.mughal@keele.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327529

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 58957, IRAS 327529

Study information

Scientific Title
The CO-produced Psychosocial INtervention delivered by GPs for young people who self-harm (COPING) feasibility study

Study objectives
The main objective of this study is to examine aspects of the feasibility of a main randomised clinical trial of the COPING intervention within the areas of recruitment, delivery, and retention and follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/11/2023, East of England, Cambridge East Research Ethics Committee (2 Redman Place, London, EC20 1JQ, UK; +44 (0)2071048181; cambridgeeast.rec@hra.nhs.uk), ref: 23/EE/0238

Study design
Non-randomized study design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
https://www.keele.ac.uk/research/ourresearch/medicine/primarycareresearchthemes/mentalhealth/coping/

Health condition(s) or problem(s) studied
Self-harm

Interventions
The COPING intervention is GP-led and consists of eight behaviour change techniques (BCT) aimed at encouraging the young person to use new skills to avoid future self-harm and facilitate GPs to use COPING in daily NHS practice, across two COPING appointments. GPs will be instructed on how to use COPING with young people and will be offered a video demonstration of COPING in prior training. GPs will be recognised after the full delivery of COPING. COPING will be delivered across one face-to-face appointment and the format (face-to-face/remote) of the

second appointment will be decided in the first COPING consult. The time (between 2 and 4 weeks) between both COPING appointments will be agreed upon between the GP and the young person.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Participant consent and willingness of enrolled participants and GPs to be randomised in a future RCT, estimated using rates of consent, participant, and GP self-report from the start of recruitment to the end, including at the 2-month participant follow-up timepoint
2. GP fidelity to COPING delivery and participant adherence to COPING, assessed retrospectively using case report forms and examining the proportion of participants who attend for a second COPING appointment
3. Participant follow-up data collection examined by total completions of the suicidal behaviours questionnaire-revised questionnaire at 2, 4, and 6 months
4. Acceptability of COPING for both participants and GPs, and deliverability of COPING for GPs, assessed using semi-structured interviews and a GP online survey post COPING delivery to end recruitment date

Secondary outcome measures
Measured from the recruitment start date to the study end date (unless otherwise specified):
1. The response rate of invited general practices to participate, measured throughout the recruitment window
2. Whether GPs can be recruited, trained, and retained to deliver COPING
3. Identification of patients at GP site
4. Proportion of identified patients deemed eligible for inclusion
5. Participant recruitment uptake and baseline characteristics through each recruitment strategy
6. Participant attrition, follow-up, and withdrawal rates
7. Data collection procedures
8. Exploratory effectiveness data via participant-reported patient health questionnaire and suicidal behaviours questionnaire-revised at baseline, 2, 4, and 6 months

Overall study start date
01/12/2019

Completion date
01/12/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 25/07/2024:

General practices who are research active will be invited into the study and those who agree will become a study site.

Participant inclusion criteria:
1. Young people aged 16-25 years
2. History of self-harm (defined by NICE) in the last 12 months
3. Able to give informed consent

_____

Previous inclusion criteria:

General practices who are research active within the NIHR Local CRN West Midlands primary care will be invited into the study and those who agree will become a study site.

Participant inclusion criteria:
1. Young people aged 16-25 years
2. History of self-harm (defined by NICE) in the last 12 months
3. Able to give informed consent

Participant type(s)
Patient

Age group
Mixed

Lower age limit
16 Years

Upper age limit
25 Years

Sex
Both

Target number of participants
Planned Sample Size: 39; UK Sample Size: 39

Key exclusion criteria
Participant exclusion criteria:
1. Acute risk of suicide or harm to others needing urgent referral or admission
2. Moderate to severe learning disabilities
3. Current psychotic episode or organic mental illness
4. Receiving current psychological therapy including NHS talking therapies
5. Unable to provide informed consent

Date of first enrolment
01/12/2023

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NIHR CRN: West Midlands
James House
Newport Road
Albrighton
Wolverhampton
United Kingdom
WV7 3FA

Sponsor information

Organisation
Keele University

Sponsor details
Keele
Newcastle-under-Lyme
England
United Kingdom
ST5 5BG
+44 (0)1782 732980
research.governance@keele.ac.uk

Sponsor type
Hospital/treatment centre

Website
https://www.keele.ac.uk/

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/12/2026

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		15/10/2024	28/10/2024	Yes	No