

# A trial of hope-focused mentoring to improve mental health and social outcomes for young women who are not in education, employment, or training in deprived coastal areas

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<b>Registration date</b> 10/09/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/09/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Evidence shows that young women who are not in education, employment, or training (NEET) can often have poor mental, physical, and sexual health. They tend to have more negative outcomes than NEET young men or young women who are working or studying. They also have a reduced sense of hope for the future. Increasing hope seems to be a good thing to target to try and help NEET young women. Higher hope is linked to being NEET for less time. Higher hope is also linked to positive mental health and social outcomes for young people. We worked with NEET young women and their supporters to create an intervention designed to increase hope for this group. It is called HOPEFUL. To learn if HOPEFUL is helpful, we need to conduct a kind of test that is called a randomised controlled trial. We aim to first test whether we can deliver the trial and the HOPEFUL intervention as planned, using a small version of the trial. We then aim to deliver a larger version of the trial to test the effects of HOPEFUL. We aim to identify if HOPEFUL enhances hope, mental health and social outcomes, and offers value for money.

### Who can participate?

Young women aged 16 to 25 years who are not in education, employment, or training. Mentors who participate in supporting the young women to use the intervention being tested are selected by the young women themselves.

### What does the study involve?

NEET young women will take part in an eligibility assessment and a baseline assessment, during which they will also identify one or more people that they would like to be their mentor from their existing social network. Following the baseline assessment, each young woman will be randomly assigned to one of two arms of the trial. In HOPEFUL TOGETHER, their identified mentor will be approached. The mentor will support the young women to use the HOPEFUL package of materials. These include videos, stories, and activities designed to improve positive sense of self and to learn and practice the skills needed to be more hopeful. The mentor will support the young women to use the intervention over 16 weeks. The young women will carry

on having any existing support they already get. Mentors will receive training and support for their role. The other arm of the trial is called HOPEFUL FUTURE. In this arm, young women will continue with any existing support they already get. After the end of their involvement in the trial, they will be sent the HOPEFUL package of materials for use as they like. After 16 weeks, and then again about 8 months later (12 months after being randomised), the young women will take part in follow-up assessments. The assessments will measure hope as the primary outcome. Secondary outcomes will also include mental health symptoms (for example, depression), wellbeing, time spent in structured activities including employment, social relationships, help-seeking, and support service use. Mentors will also be asked to complete brief assessments of their hope and wellbeing at baseline and 16-week follow-up. A smaller number of young women and mentors will be invited to individual interviews to speak in depth about their experiences of HOPEFUL and the trial.

What are the possible benefits and risks of participating?

HOPEFUL aims to improve the hope, mental health, and wellbeing of young women. HOPEFUL has been designed to be used with the support of a mentor. Finding and working with a mentor can be a very positive experience. We hope that those receiving HOPEFUL will find it helpful, but we cannot guarantee this. By taking part in this project, participants will help us to learn about whether HOPEFUL is helpful for young women who are NEET. This project will involve both young women and mentors answering questions about their mental health and wellbeing. Some people in similar projects have told us that they have found it interesting and helpful to answer such questions. However, some people can find it difficult or distressing. Some of the questions asked may be sensitive, for example, about low mood. Participants do not have to answer questions that they do not wish to answer. We also hope that mentors will find their role in the project to be a positive experience, but we cannot guarantee this. We will collect information about both young women's and mentors' experiences of the HOPEFUL intervention and the trial.

Where is the study run from?

Brighton and Sussex Medical School (UK)

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

April 2024 to January 2029

Who is funding the study?

NIHR Public Health Research (UK)

Who is the main contact?

Charlotte Rawlinson, [c.rawlinson2@bsms.ac.uk](mailto:c.rawlinson2@bsms.ac.uk)

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Clio Berry

**ORCID ID**

<https://orcid.org/0000-0003-1164-9836>

**Contact details**

Primary Care and Public Health  
Watson 104  
Brighton and Sussex Medical School  
University of Brighton  
Falmer  
United Kingdom  
BN1 9PH  
+44 (0)872 218 2296  
c.berry@bsms.ac.uk

### **Type(s)**

Public, Scientific

### **Contact name**

Dr Charlotte Rawlinson

### **Contact details**

Primary Care and Public Health  
Watson 104  
Brighton and Sussex Medical School  
University of Brighton  
Falmer  
United Kingdom  
BN1 9PH  
+44 (0)872 218 2296  
c.rawlinson2@bsms.ac.uk

## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

327723

### **ClinicalTrials.gov (NCT)**

Nil known

### **Protocol serial number**

CPMS 57552, IRAS 327723, NIHR158476

## **Study information**

### **Scientific Title**

A pragmatic adaptive trial of hope-focused mentoring to prevent mental ill-health and improve social outcomes for young women who are not in education, employment or training in deprived coastal areas: the Looking Forward Project

### **Study objectives**

The primary hypothesis (H1) is that HOPEFUL with mentoring plus usual support services (HOPEFUL TOGETHER) will be superior to usual support services plus HOPEFUL workbook waitlist (HOPEFUL FUTURE) in increasing the primary outcome of hope at 16 weeks post-randomisation. The secondary hypotheses are as follows:

H2: HOPEFUL TOGETHER significantly improves the secondary outcomes of mental health symptoms, wellbeing, life meaning, time use, loneliness, and help-seeking for NEET young women at 16 weeks' post-randomisation relative to compared to HOPEFUL FUTURE.

H3: HOPEFUL TOGETHER (HOPEFUL and mentoring plus standard support) will be cost-effective compared to the HOPEFUL FUTURE in terms of improvements in hope and wellbeing.

H4: HOPEFUL TOGETHER significantly improves mental health symptoms, wellbeing, life meaning, time use, loneliness, and help-seeking for NEET young women at 12 months' post-randomisation relative to compared to HOPEFUL FUTURE.

H5: The mentoring relationship (measured post-intervention HOPEFUL session three) and idiographic goal attainment score (measured HOPEFUL module 6 or last provided) will mediate the intervention effects on primary and secondary outcomes at 16 weeks and 12 months post-randomisation.

H7: Change in hope at 16 weeks post-randomisation will mediate change in secondary outcomes at 12 months post-randomisation.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 12/08/2024, London-Surrey Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8088, +44 (0)207 104 8131; surrey.rec@hra.nhs.uk), ref: 24/LO/0521

## **Study design**

Randomized; Interventional; Design type: Prevention, Psychological & Behavioural

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Public health

## **Interventions**

We propose an adaptive, assessor-blind, pragmatic, controlled superiority parallel groups randomised controlled trial with a mixed-methods process evaluation. The trial will have two stages: a feasibility stage followed by a definitive RCT stage. The trial has two arms with 1:1 randomisation, stratified by local authority area and age. The two arms are:

1. HOPEFUL with mentoring plus usual support (called HOPEFUL TOGETHER)
2. Waitlist access to the HOPEFUL workbook plus usual support alone (called HOPEFUL FUTURE)

HOPEFUL is a six-module psychosocial intervention comprising psychoeducation, cognitive, behavioural, and interpersonal activities. It aims to first raise a positive sense of self before helping young women to learn and practice the skills needed to enhance and maintain their

hope, for example, values identification and goal setting. The explicit primary focus of HOPEFUL is on hope, drawing primarily on cognitive hope theory. The intervention is delivered primarily 1:1 and in-person, supported by an online/paper workbook. Each module contains core psychoeducational material, lived experience stories, and a menu of selectable activities to put newly learned concepts and skills into practice. The intervention has been designed to be delivered over a flexible and collaboratively agreed session number and spacing within 16 weeks. Sessions can be delivered in person, online, and/or via telephone as preferred. Module activities can be completed flexibly using role play, discussions, creative arts, writing, outdoor activities, and/or in self-study. HOPEFUL is designed to be supported by a youth-initiated mentor, i.e., someone known to and trusted by the young woman. The mentor's role is to provide supportive accountability, i.e., to provide encouragement to the young woman to continue using the package and to offer assistance to understand the components when needed. The mentor does not need to have or use specialist knowledge or technical skills. The mentor is provided with brief, self-administered written and video-based training on hope, intervention model and components, and principles of providing supportive accountability, supervision (c. fortnightly) by an experienced youth worker, and a paper/digital intervention manual.

Young women randomised to the HOPEFUL TOGETHER arm of the trial will be offered a paper-based version of the workbook. They will additionally be sent a link to set up an account on the intervention website on which they can access these materials in a digital form. Mentors will be offered a paper-based version of the mentor manual and will also be sent a link to set up an intervention website account. They will be able to access training videos in addition to digital versions of the mentor manual. Young women randomised to the HOPEFUL FUTURE arm of the trial will be sent a copy of the intervention materials at the end of their trial involvement, to use as they like.

This trial design is adaptive because the feasibility phase will be subsumed into the definitive trial outcome analysis, unless feasibility results indicate this should not occur. Participants will consent to the adaptive nature of the trial. The design approach draws on the Medical Research Council guidance for the evaluation of complex interventions. We seek to understand whether the intervention works at the group level, but also what was actually implemented, what the effects were, how and why they arose, and what contextual factors may influence implementation and outcome. Our design is additionally influenced by the person-based approach to intervention development, with a focus on involving "end-users" in the evaluation (as we did in the development) of our intervention. We chose the "wait-list" style control on the advice of our public involvement colleagues.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Hope is measured using the 12-item self-report Trait Hope Scale (THS) at baseline, 16 weeks (the primary endpoint) and 12 months post-randomisation

## **Key secondary outcome(s)**

1. Wellbeing is measured using the 7-item Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS) at baseline, 16 weeks and 12 months post-randomisation.
2. Depression symptoms are measured using the 9-item self-report Patient Health Questionnaire (PHQ-9) at baseline, 16 weeks and 12 months post-randomisation.
3. Anxiety symptoms are measured using the 9-item self-report Generalised Anxiety Disorder

Scale (GAD-7) at baseline, 16-weeks and 12-months post-randomisation.

4. Social anxiety symptoms are measured using the 12-item self-report<sup>49</sup> that combines Social Interaction Anxiety Scale short form (SIAS-6) and Social Phobia Scale short form (SPS-6) at baseline, 16 weeks and 12 months post-randomisation.

5. Meaning in life is measured using the 10-item Meaning in Life self-report scale (MLQ) at baseline, 16 weeks and 12 months post-randomisation.

6. Social-occupational functioning is measured using three measures:

6.1. Time spent in Education, Employment, and Training (EET), plus other constructive economic (childcare, housework, and chores) and structured (sports and structured leisure) activities, are measured using the structured interview Time Use Survey (TUS) at baseline, 16 weeks and 12 months post-randomisation

6.2. Loneliness is measured using the short 8-item self-report UCLA Loneliness Scale (UCLA-8) at baseline, 16 weeks and 12 months post-randomisation

6.3. Observer-rated global social and occupational functioning is measured using the assessor-rated Social and Occupational Functioning Scale (SOFAS) at baseline, 16 weeks and 12 months post-randomisation.

7. Help-seeking is measured using the 10-item self-report General Help-Seeking Questionnaire (GHSQ) at baseline, 16-weeks and 12-months post-randomisation.

8. Adverse events are captured using a modified self-report Edinburgh Adverse Events of Psychological Therapy scale (EDAPT) at baseline, 16 weeks and 12 months post-randomisation.

9. Formal and informal support and service use is measured using a brief semi-structured Client Service Receipt Inventory (CSRI) questionnaire, adapted to measure statutory and broader support, at baseline, 16 weeks and 12 months post-randomisation.

## **Completion date**

31/01/2029

# **Eligibility**

## **Key inclusion criteria**

Young women:

1. Aged 16 to 25 years at the time of consent
2. Identifying as a woman
3. NEET, operationalised as no involvement in education, employment, or training (EET) activity in the past month as measured using the Time Use Survey – EET activity will not include informal activities such as casual babysitting, or one-off activities such as waiting tables at a single event
4. Able to give informed consent

Mentors:

1. Aged 18 years or more at time of consent
2. Able to give informed consent

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Adult

**Lower age limit**

16 years

**Upper age limit**

25 years

**Sex**

Female

**Key exclusion criteria**

Young women:

1. Current EET activity (including being on temporary leave from and with planned return to their place of employment/education/training)
2. Serious risk of suicide, operationalised as a score of non-zero on the suicidality item of the Patient Health Questionnaire plus a rating of four or more out of seven with respect to the severity of the suicidality

**Date of first enrolment**

01/08/2024

**Date of final enrolment**

31/10/2027

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****Brighton & Hove City Council**

Youth Employability Services

Hove Town Hall

Brighton

United Kingdom

BN3 4AH

**Study participating centre****East Sussex County Council**

Department name Early Help

Hailsham Hub

Vega Close

Hailsham

United Kingdom

BN27 2JZ

**Study participating centre**  
**Xtrax Young People's Centre**  
27-29 Cambridge Road  
Hastings  
United Kingdom  
TN34 1DJ

**Study participating centre**  
**Norfolk County Council**  
Children's Services  
Martineau Lane  
Norwich  
United Kingdom  
NR1 2DH

**Study participating centre**  
**Kent County Council**  
Children, Young People & Education  
Invicta House  
Maidstone  
United Kingdom  
ME14 1XQ

**Study participating centre**  
**Medway Council**  
Youth Service  
Gunwharf  
Dock Road  
Chatham  
United Kingdom  
ME4 4TR

**Study participating centre**  
**The Education People**  
NEET Support Service  
Sessions House  
Maidstone  
United Kingdom  
ME14 1XQ



**Study participating centre**  
**NIHR CRN: Kent, Surrey and Sussex**  
Bevendean House  
Room BE205  
University of Brighton  
Falmer  
United Kingdom  
BN1 9PH

**Study participating centre**  
**NIHR CRN: East of England**  
Floor 4  
Rouen Road  
Norwich  
United Kingdom  
NR1 1QQ

## **Sponsor information**

**Organisation**  
University of Sussex

**ROR**  
<https://ror.org/00ayhx656>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. Following outcome analysis, an anonymised derived version of the full trial dataset will be made available to the public in the sponsor's (or another if more suitable) repository. A data dictionary will be provided to aid in data use. Participants are asked

to provide explicit consent to this data sharing as part of the informed consent process. All care will be taken to anonymise these data before sharing.

**IPD sharing plan summary**

Stored in publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes