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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

Submission date
09/09/2024

Recruitment status
Recruiting

Registration date
10/09/2024

Overall study status
Ongoing

Last Edited
10/09/2024

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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

Study website
http://www.behopeful.co.uk/

Contact information

Type(s)
Scientific

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Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327723

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures
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-report49 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.

Overall study start date
01/04/2024

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

Age group
Adult

Lower age limit
16 Years

Upper age limit
25 Years

Sex
Female

Target number of participants
Planned Sample Size: 318; UK Sample Size: 318

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
England

United Kingdom

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
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ME14 1XQ

Study participating centre
NIHR CRN: Kent, Surrey and Sussex
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Sponsor type
University/education

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ROR
https://ror.org/00ayhx656

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
We have produced a public website and will use this, at the end of the trial, to disseminate finalised paper and digital versions of the HOPEFUL package of materials (including young person's workbook and mentor and mentor supervisor manuals), and the intervention theory of change with an implementation toolkit. We plan to disseminate effectiveness data on HOPEFUL in a publicly accessible dataset. We plan to publish the trial protocol and make several other publications in high-impact journals; feasibility stage outcomes, definitive trial stage outcomes, trial process evaluation and mechanisms of effects. We will also disseminate non-academic outputs, including videos and infographics describing each stage of the study and its outcomes. We aim to submit outputs relating to the feasibility stage shortly after the end of year one and outputs relating to the definitive stage within three months of completing the trial. We will produce and disseminate non-academic outputs in the same timeframes.

Intention to publish date
31/01/2030

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