Qualitative Protocol Development Tool

The research protocol forms an essential part of a research project. It is a full description of the research study and will act as a ‘manual’ for members of the research team to ensure adherence to the methods outlined. As the study gets underway, it can then be used to monitor the study’s progress and evaluate its outcomes.

The protocol should go into as much detail about the research project as possible, to enable the review bodies to fully understand your study.

The use of this collated consensus guidance and template is not mandatory. The guidance and template are published as standards to encourage and enable responsible research.

The document will:
- Support researchers developing protocols where the sponsor does not already use a template
- Support sponsors wishing to develop template protocols in line with national guidance
- Support sponsors to review their existing protocol template to ensure that it is in line with national guidance.

A protocol which contains all the elements that review bodies consider is less likely to be delayed during the review process because there will be less likelihood that the review body will require clarification from the applicant.

We would appreciate self-declaration of how you’ve used this template so we are able to measure its uptake.

Please indicate the compatibility of this template with any existing templates you already use by stating one of the following on the front of each submitted protocol:

- **This protocol has regard for the HRA guidance and order of content**

FULL TITLE OF THE STUDY

Developing a hopeful intervention to improve mental health and social outcomes among young women who are not in education, employment or training (NEET) and living in coastal communities

SHORT STUDY TITLE / ACRONYM

HOPEFUL

COMBINED PROTOCOL VERSION NUMBER AND DATE

Note: this protocol covers all research activities related to the NIHR PHR-funded HOPEFUL project. Research activities involving NHS and social care staff were approved by the Health Research Authority. Complementary research activities involving community participants recruited from outside statutory services were approved by the University of Sussex, Sciences & Technology C-REC.

Protocol V2, 5th May 2022. Changes were made to the community-focused research activities and approved by the Sussex C-REC. (1) The geographical focus was widened to include parts of coastal Kent and Sussex beyond the originally specified localities of Margate and Hastings. (2) The upper limit of the participant age range was increased to 26 years, so that 24- and 25-year-olds could be engaged in the study and reflect on prior experiences of being NEET. (3) Lived experience of mental health problems was removed as an eligibility criterion for participants in the NEET group, recognising that NEET young women have a wide variety of mental health experiences and these are all relevant to the intervention development process.

RESEARCH REFERENCE NUMBERS

U of Sussex C-REC Number:	ER/DMM55/2
IRAS Number:	310439
Sponsor’s Number:	099 MIC
Funder’s Number:	NIHR135316

LIST of CONTENTS

KEY STUDY CONTACTS

Chief Investigators	Dr Daniel Michelson, School of Psychology, University of Sussex. Email: d.michelson@sussex.ac.uk Dr Clio Berry, Brighton and Sussex Medical School, University of Sussex. Email: c.berry@bsms.ac.uk
Study Co-ordinator	Dr Leanne Bogen-Johnston. Email: l.r.bogen-johnston@sussex.ac.uk
Sponsor	Dr Antony Walsh, Research Governance Officer, University of Sussex
Joint-sponsor(s)/co-sponsor(s)	Not applicable
Funder(s)	NIHR Public Health Research
Committees	Not applicable

STUDY SUMMARY

Study Title	Developing a hopeful intervention to improve mental health and social outcomes among young women who are not in education, employment or training (NEET) and living in coastal communities
Internal ref. no. (or short title)	HOPEFUL
Study Design	Phased qualitative design involving interviews and participatory workshops
Study Participants	Key informants will be sampled from four stakeholder groups i) 16–26-year-old women with lived experience of being NEET (not in employment, education, and training)* ii) Family members of the target group of NEET young women iii) Representatives from voluntary and community sector organisations (e.g., arts- and sports-based youth clubs, faith groups) and neighbourhood associations working with the target group iv) Statutory service providers (including professionals from NHS primary care, mental health services and local authority social services) working with the target group Research activities with participants from stakeholder groups i-iii are governed by ethics approval from the University of Sussex Sciences & Technology C-REC (ref: ER/DMM55/2). Research activities with participants from stakeholder group iv are governed by ethics approval from HRA (IRAS 310439). *The specific demographic group of interest for intervention development is NEET young women aged 16-24 years. However, the upper age limit for participants in group i has been set as 26 years, so that 25-26-year-olds can be engaged in the study and reflect on prior experiences that are relevant to the project's aims. We have not imposed any

	specific mental health case-related or service criteria for the target group, recognising that NEET young women have a wide variety of mental health experiences and these are all relevant to our intervention development process.
Planned Size of Sample	Phase 1: up to 40 interviews with individuals from stakeholder groups (i-iv) from coastal areas in Sussex and Kent. Phase: 2: up to 12 NEET young women to participate in co-design activities. Phase 3: up to 12 statutory service providers/voluntary and community sector representatives to take part in a theory of change workshop.
Follow up duration (if applicable)	Not applicable
Planned Study Period	6 months: 1.2.22 to 31.7.22.
Research Question/Aim(s)	i. What settings are viable for delivering a brief, low-cost, hope-focused intervention to NEET young women aged 16-24 years in deprived coastal communities? ii. What are the most meaningful short- and long-term outcomes related to hopefulness and its theorised effects on mental health and social functioning, and how can these be measured? iii. Who are possible non-specialists that could credibly deliver the intervention? iv. What is the theory of change for the intervention? v. What should be included in a manual that can be used by intervention providers, trainers and supervisors to support optimal delivery in line with the theory of change?

FUNDING AND SUPPORT IN KIND

Funder	National Institute for Health Research, Public Health Research, Application Development Award
Amount awarded	£50,942
Investigators	Co-PI: Dr Daniel Michelson, School of Psychology, University of Sussex Co-PI: Dr Clio Berry, Brighton and Sussex Medical School, University of Sussex Co-I: Ms Julia Fountain, PPI co-ordinator, Sussex Partnership NHS Foundation Trust Co-I: Prof. Lindsay Forbes, Clinical Professor of Public Health, University of Kent
Study Steering Committee	Independent chair: Prof. Elizabeth Barley, University of Surrey.

ROLE OF STUDY SPONSOR AND FUNDER

Neither the sponsor nor the funder will have any responsibility for study design, conduct, data analysis or interpretation, manuscript writing, or dissemination of the results.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Michelson and Berry will share overall leadership of the project and will form a Project Management Group (PMG) along with the other applicants (Fountain and Forbes). The purpose of the PMG is to implement the programmed activities, with responsibilities for all day-to-day operational aspects of the project including research governance, data collection/analysis and dissemination. Research staff (to be appointed) will support the PMG. A fortnightly meeting schedule (increasing to weekly where required) will use a mix of videoconferencing and face-to-face meetings (the latter as appropriate considering any pandemic-related restrictions in force). Research staff (to be appointed) will support the PMG.

The Study Steering Committee (SSC) will meet at least twice during the project lifetime (and more frequently if needed) to provide independent expert advice to the PMG on all aspects of the research, including the design of future studies. The SSC will comprise the applicant team and other members to include the following:

- Prof. Elizabeth Barley (Chair; University of Surrey)
- Nicola Blake (East Sussex County Council, Public Health)
- Prof. Carrie Llewellyn (BSMS)
- Dawn Maddison (Dover Smart)
- Nel Margerison (Lived Experience Research Advisor)
- Prof. Paul McCrone (University of Greenwich)
- Dr Jon Wilson (Norfolk and Sussex NHS Foundation Trust/University of East Anglia)

PROTOCOL CONTRIBUTORS

Neither the sponsor nor the funder had any input in study design or protocol development. Protocol development was jointly led by Co-PIs Michelson and Berry, with inputs from Fountain and Forbes.

STUDY PROTOCOL

1 BACKGROUND

The proportion of 16-24-year-olds who are NEET peaked at 16.9% in 2011 and has stabilised at around 10% nationally (Powell 2018). Young people who are NEET experience significantly worse mental health and life chances than older economically active and socially engaged peers (Knapp et al. 2016). Research using the UK E-Risk birth cohort study found a prevalence of 35.4% for major depressive episode and 13.5% for generalised anxiety in NEET young people aged 18 years, compared to 18.1% and 6.4% respectively among non-NEET young people (Goldman-Mellor et al. 2016). NEET young people are also more likely to engage in self-harm, antisocial and other risky behaviour, and to require psychiatric hospitalisation (Sellström et al. 2011; Gutiérrez-García et al. 2017). ‘Scarring’ effects are a particular concern, such that time spent NEET is associated with chronic mental ill-health, unemployment and low wages later on in life (Bell and Blanchflower 2011; Ralston et al. 2016).

NEET young women outnumber their male counterparts and suffer from worse long-term mental health and social outcomes (Office for National Statistics 2017; Jongbloed and Giret 2021). Additional structural and contextual risks affecting NEET young women include gendered bullying, harassment and discrimination restricting work and educational opportunities; social isolation and unemployment related to unpaid caring responsibilities; and domestic violence and abuse (Escott 2012; Maguire 2019; Tanton et al. 2021). The effects of these multiple disadvantages are compounded in deprived areas (UCL Institute for Health Equity 2012). Some of the most intense neighbourhood deprivation occurs in seaside towns across South East England, where young people face transient job opportunities, under-performing schools and long-term decline in infrastructure, all of which contribute to low levels of aspiration (House of Lords Select Committee on Regenerating Seaside Towns 2019).

2 RATIONALE

The Chief Medical Officer’s annual report from 2021 (Whitty 2021) highlights that public health policy and research in England have been slow to address inequalities in coastal communities, where intersecting challenges around economic deprivation, gender and mental ill-health necessitate a broad lens for community-based interventions. In this project, we aim to complete the groundwork for an intervention that is directly relevant to a constellation of mental health and social inequalities affecting young women in these neglected areas, with wider applications nationally. We anticipate long-term dividends for the young people themselves, their families, local communities and society.

The last Public Health England-commissioned review of the evidence on NEETs was published in 2014 (Akinwale et al. 2014). Its focus was on the need for early interventions across NEET populations and did not consider public health approaches specifically for young women. Mental ill-health was identified as a general priority based on evidence that symptoms can pre-empt and increase likelihood of disengagement from education and work. The review also highlighted the reciprocal relationship between NEET status and mental health, where the perception (from oneself and others) of failing to ‘keep up’ can be harmful to mental health and discourage service use and social re-engagement. Subjective perceptions related to self-worth and personal goals therefore represent important intermediate outcomes among young people for whom immediate re-entry into education, training or work may be unrealistic.

In a new Wellcome Trust-commissioned systematic review of ‘active ingredients’ for youth mental health interventions, we found that a key feature of effective help – particularly for disadvantaged young people with anxiety and depression – is the potential to increase hopefulness (Berry et al. 2021). The latter can be defined as a mindset that is directed towards a meaningful goal, and comprises self-agency (motivation and self-belief) and pathways (identifying the instrumental routes needed to achieve goals) (Snyder 2000). The most effective interventions incorporated cognitive, behavioural and interpersonal elements that (i) promoted hopeful thinking; (ii) identified meaningful goals and activities; and (iii) were delivered in a timely, hopeful and inspiring way. The constituent practice elements were often brief (i.e., involving 6 or fewer sessions) and included (but were not limited to) structured goal-setting, teaching problem-solving skills, and supporting young people to create artwork based on their hoped-for future self-image. Our review additionally found that hope-building interventions can be flexibly deployed, with evidence of effectiveness across health, social services, education and community settings.

Hopefulness interventions thus provide a promising theory-driven and evidence-based framework through which to address mental health and social outcomes among NEET young women. The target group commonly lacks self-belief and optimism about changing their circumstances, even when they are motivated to seek out work or education (Goldman-Mellor et al. 2016). A recent study using data from the UK Understanding Society survey found that NEET young people exhibited less hopeful self-agency compared with other groups, while greater self-agency reduced the longitudinal risk of being NEET (Murphy et al. 2020). There is also evidence for relatively lower hopefulness among young women compared with men, particularly in smaller, rural and remote communities (Venning et al. 2009).

Moreover, a hopeful intervention stance is directly relevant to managing service engagement challenges associated with NEET groups (Berry et al. 2021). Engagement may be strengthened further by using other best practices identified from NEET-focused case studies (Akinwale et al. 2014). These include (i) offering flexible support with a high degree of personalisation; (ii) delivering programmes in ‘neutral’ community settings, without the stigma or other negative connotations of statutory services; (iii) encouraging non-hierarchical relationships between participants and providers; (iv) delivering programmes in small groups where possible, and providing individual support for young people who experience multiple barriers to re-engagement and/or have been NEET long-term; and (v) involving community representatives and NEET young people in the design and possible delivery of programmes.

From these conceptual and practice-based starting points, we will develop a low-cost, scalable psychosocial intervention for NEET young women aged 16-24 years. The goal of the intervention is to reduce mental ill-health and improve social outcomes through the theorised mechanisms of increased hopeful thinking and engagement in personally meaningful activities, with content delivered in a timely, hopeful and inspiring way. Practice materials will be adapted from existing intervention elements that we identified in our earlier systematic review (Berry et al. 2021). Moreover, the intervention should be deliverable by non-specialists in community settings to maximise population health impacts. This is important because specialist services are accessible to just a small proportion of those with mental health problems. We will also follow best-practice approaches for engaging NEET young people in supportive interventions. We will carry out the research in coastal communities across Sussex and Kent, which contain large NEET populations and where we have pre-existing statutory service and community links.

3. Research questions

i. What settings are viable for delivering a brief, low-cost, hope-focused intervention to NEET young women aged 16-24 years in coastal communities?
ii. What are the most meaningful short- and long-term outcomes related to hopefulness and its theorised effects on mental health and social functioning, and how can these be measured?
iii. Who are possible non-specialists that could credibly deliver the intervention?
iv. What is the theory of change for the intervention?
v. What should be included in a manual that can be used by intervention providers, trainers and supervisors to support optimal delivery in line with the theory of change?

3 THEORETICAL FRAMEWORK

We will apply a phased, qualitative design that draws on principles and practices of person-based intervention development (Yardley et al. 2015). An iterative process of reflection and action will entail capturing local needs and priorities in formative stakeholder interviews, followed by smaller co-design groups that pool community, practice-based and academic knowledge with lived experience insights. We will apply an intersectoral lens to understanding the population-level effects of multiple disadvantages experienced young women who are NEET. Our approach will also be informed by evidence for intrinsic behavioural, cognitive and interpersonal mechanisms implicated in social causation of mental ill-health. We are specifically interested in hopefulness and will be guided by an evidence-based process model developed through our previous work (Berry et al. 2021). This process model of hopefulness is reproduced in Appendix 1.

4 AIMS, OBJECTIVES & OUTCOMES

4.1 Aims & objectives

The aim of this project is to co-design a low-cost, scalable psychosocial intervention for NEET young women aged 16-24 years, drawing on evidence and theory for hopefulness as an active ingredient in reducing mental ill-health improving social outcomes. The specific objectives are:

i. to obtain formative qualitative evidence for use in selecting from and adapting evidence-based hope-focused intervention elements so that they can be delivered by non-specialists
ii. to produce an intervention manual and other outputs following from this evidence

4.2 Outcomes

An intervention blueprint will be shaped by formative qualitative interviews, and then elaborated through co-design workshops with NEET young women and other key stakeholders in both sites. Ultimately, we aim to be ready at the end of six months to seek funding for feasibility work, pilot testing and subsequently a full trial of the effectiveness and cost-effectiveness of the intervention.

5 STUDY DESIGN & METHODS

5.1 Study design and data collection

We will apply a phased qualitative design.

Phase 1: We will complete formative qualitative interviews with each of the following groups: (i) young women with lived experience of being NEET; (ii) family members of NEET young women; (iii) representatives from local voluntary and community sector organisations currently working with NEET young women; and (iv) professionals from statutory health and social care providers in and around coastal areas in Sussex and Kent.

Precise participant numbers will be guided by the principle of information power (Malterud et al. 2015). Where possible stakeholders will be sampled in similar proportions from Sussex and Kent.

Topic guides will explore: (i) types of mental health and social problems experienced by young NEET women; (ii) links between contextual risk factors, hopefulness and trajectories of mental ill-health and social disability; (iii) overview of local service provision; and (iv) practical ways to integrate hopefulness into a community-based intervention. Participants will additionally be asked for basic demographic data at the beginning of the interview.

Phase 2: Up to 12 NEET young women (reprised where possible from Phase 1 with initial consent forms including an opt-in for Phase 2 participation) will be invited to take part in co-design activities. Flexibility will be deployed in format and hosting, for example through hybrid in-person and online activities, and by enabling young people to contribute individually as well as in group workshops. Co-design activities will be co-facilitated by members of the research team with relevant training and experience. The workshops will allow us to identify and narrow down the approaches that are most relevant to NEET young women.

Phase 3: A theory of change workshop will involve up to 12 practitioners representing statutory, voluntary and community sector organisations. Where possible, these will reprise Phase 1 participants with initial consent forms including an opt-in for participation in the workshop. An external facilitator will be used for this workshop, with the study co-ordinator or another member of the research team co-facilitating. Intervention components will be linked within an organising theory of change. This will delineate the mediating pathways implicated in mental health and social outcomes and specify intervention elements that can address these mediators. The workshop will additionally identify strategies to embed the intervention model in relevant policy, practice and legal frameworks, and describe the political and institutional processes that may hamper or facilitate scaling up. Suitable workforce development strategies will be considered with an emphasis on scalable approaches and potential use of digital platforms. Workshop materials will be adapted from a variety of sources, including *Using Theory of Change in the development, implementation and evaluation of complex health interventions: A practical guide*, created by the Mental Health Innovation Network at the London School of Hygiene and Tropical Medicine (De Silva, Lee, & Ryan, 2015; see Appendix 2). Summaries from Phase 1 interviews and Phase 2 workshops will be shared with participants by email prior to the workshop, as well as being reviewed at the start of the workshop itself.

5.2 Data analysis

Phase 1 qualitative interviews will be transcribed verbatim. All identifying information (e.g., names and identifiable locations) will be redacted during transcription and each participant will be assigned a study alias. Thematic analysis will be used to analyse the data, seeking to identify shared patterns of meaning within and across transcripts relevant to the study research questions.

Phases 2 & 3: Transcripts of the recorded workshop will be elaborated using field notes and post-workshop reflections from facilitators. Findings will be triangulated with themes from Phase 1 qualitative interviews and combined in a matrix using a constant comparative method. The matrix will address an evolving number and variety of questions related to intervention requirements and parameters (e.g., essential and optional intervention elements, and their sequencing). Information from the matrix will be distilled into an illustrated theory of change model.

6 STUDY SETTING

We will carry out the research in and around coastal areas of Sussex and Kent, which contain large NEET populations and where we have pre-existing professional and community links. We will aim to be as flexible and accessible as possible with respect to the locations of research activities (i.e., in-person or online), subject to pandemic-related social restrictions which may be in force.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility criteria

Inclusion criteria for NEET young women (involved in Phases 1 and 2):

- Women aged 16-26 years
- Living in coastal areas of Sussex or Kent or surrounding areas

- Self-identify as NEET (not in employment, education, or training)*
- Able to speak English (with or without the support of an interpreter)
- Able to access a computer or device with access to the internet and/or able to access a telephone and/or able to attend in-person interviews and workshops

* a working definition of 'NEET' will be formulated with input from local public health consultants to ensure consistency with existing service and policy frameworks.

Inclusion criteria for family members (involved in Phase 1):

- Lived experience as a parent or family carer of a NEET young woman aged 16-24 years (who may be currently aged up to 26 years)
- Able to speak English (with or without the support of an interpreter)
- Able to access a computer or device with access to the internet and/or able to access a telephone and/or able to attend in-person interviews and workshops

Inclusion criteria for statutory, voluntary and community sector representatives (involved in Phases 1 and 3):

- Holds a substantive or voluntary role in health, social care, youth work, education, employability, and/or community development sectors
- Experience of working with NEET young women in coastal Kent, Sussex and/or surrounding areas

7.2 Sampling

7.2.1 Size of sample

Phase 1: up to 40 interviews with participants from groups i-iv. The precise number will be determined by information power.

Phase 2: up to 12 NEET young women; may be organised as one or two group workshops supplemented by individual contributions, depending on participants' availability and preferences.

Phase 3: up to 12 statutory, voluntary and community sector representatives to take part in a theory of change workshop.

7.2.2 Sampling technique

Purposive and snowball methods will be used to achieve a broad representation across stakeholder groups and localities.

7.3 Recruitment

We have secured early expressions of interest in supporting recruitment of young people and their family members from Xtrax (xtrax.org), YMCA (www.hastingsymca.net) and the Youth Employability Service (www.cxk.org/services/youth-employability-service-yes). We will further promote the project in other community spaces that the target group and/or their family members may visit (e.g., food banks and hairdressers), and community venues with notice boards (e.g., libraries, nurseries, town halls and supermarkets). Community and voluntary sector representatives will be recruited using existing contacts gained through previous research by our team; suggestions from our Study Steering Committee; and a mapping exercise to identify additional relevant services across Kent and Sussex. Statutory service professionals will be recruited through networks associated with the NIHR Applied Research Collaboration in Kent, Surrey and Sussex, including contacts in local NHS adult mental health service providers (e.g., Sussex Partnership NHS Foundation Trust), community CAMHS, primary care and local authority social care services.

7.3.1 Sample identification

Eligible young people and their family members will be identified with reference to written descriptions of NEET characteristics, which will be formulated with input from local public health consultants to ensure consistency with existing service frameworks. These consultants will also be involved in approaching statutory, voluntary and community sector stakeholders in their respective localities. We will approach a range of services in the relevant geographical areas to advertise the study and disseminate recruitment materials.

7.3.2 Consent

Informed consent will be obtained by the study co-ordinator and research staff. These staff will be trained in taking informed consent according to the ethically approved protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki. The informed consent process will include a discussion with the potential participant about the objectives of the study, what he or she will be asked to do if they choose to participate, and the possible risks and benefits of participation. Potential participants will be provided with a written information sheet and will be given at least 24 hours to read and consider the information before being asked to provide consent. Participants will be given the opportunity to ask questions and have these answered to their satisfaction. If the individual wishes to participate following this process, they will be asked to complete a consent form to document the informed consent process and their willingness to participate. The consent form will include an option to opt-in to participate in the workshop.

We will not include individuals who do not have capacity to give their consent to participation. During the consent process, it will be made completely and unambiguously clear that the participant is free to refuse to participate in all or any aspect of the study, at any time, without giving a reason and without incurring any penalty. The participant’s continued willingness to participate will be confirmed at each study contact before commencing any research procedures. Participants will be free to withdraw from the study at any time up until the time of data analysis without giving a reason. Data collected up to the point of withdrawal will be used if the participant. Every effort will be made to ensure that vulnerable individuals are protected and participate voluntarily in an environment free from coercion or undue influence.

8 ETHICAL AND REGULATORY COMPLIANCE

Informed consent: Informed consent will be required to take part in the study. Prior to providing informed consent, participants will be provided with an information sheet which will outline the rationale for the study, what participation will involve, and all data security processes. The information sheet will contain contact details for member/s of the study team so that participants will have the opportunity to ask questions about the study before deciding whether to participate. If the participant is completing any aspect of the study with a member of the research team, they will have an opportunity to ask questions about the study with the researcher before providing consent. Participants will not be able to take part in the study if they do not agree to all mandatory consent items.

Right to withdraw: Participants will be informed of their right to withdraw from the study in the participant information sheet and during the informed consent process.

Confidentiality: Data will be stored electronically on secure computer systems at University sites. Qualitative interviews will be conducted using a secure video conferencing platform on university computers and/or an encrypted audio recording device. These data will only be accessible to members of the research team. Informed consent will be collected and stored online via Qualtrics, using a University of Sussex institutional licence and a survey form only accessible by members of the research team, using their own respective individual university IT log-in username and password. Data will be transferred between sites securely to ensure no-one outside the research team is able to access it. Fully anonymised data may be shared outside of the research team for research purposes. Participants will be informed of this within the participant information sheet and during the consent process. Only members of the research team will have access to this information, which will be stored confidentially in accordance with GDPR (2018).

<u>Anonymity:</u> Data will have identifiable information removed and thereafter be identified only using a pseudo-anonymous study identifier. There will be a master log that is accessible only to the research team. This information will be used if any participants request withdrawal of their data, and to share findings from the research study where requested.

8.1 Assessment and management of risk

Semi-structured topic guides for interviews with NEET young women and family members have been jointly developed by an experienced Patient and Public Involvement Coordinator from Sussex Partnership NHS Foundation Trust (Julia Fountain) who also has lived experience as a family carer and in consultation with representatives from the Sussex Partnership NHS Foundation Trust Youth Research Café. Other members of the core research team comprise a clinically qualified psychologist (Dr Daniel Michelson) and another experienced senior academic (Dr Clio Berry) who are both highly experienced in applied mental health research involving disadvantaged young people. Our team has given particular attention to ensuring that data collection activities are not overly time-consuming and will not involve intrusive lines of questioning. Nevertheless, it is possible that some NEET young women and family member participants may encounter potentially upsetting or distressing topics during interviews and/or workshops. All participants will be advised during the consent process and during participation that they do not have to discuss or answer questions they may find difficult or upsetting. They can also request breaks if required and withdraw without giving a reason, and this will be reiterated both in writing (in the participant information sheet) and verbally at the time of data collection. Following interviews/workshops participants will be provided with a copy of a debrief sheet (printed if present in person or emailed if a session takes place remotely). The debrief sheet will provide contact details for support to access if taking part has contributed to any significant distress. It will also suggest that participants get in touch with their care team and/or GP if they need to. Additionally, participants will be informed during the consent process that disclosures relating to risk of harm to themselves or others will need to be shared with a relevant professional.

We do not anticipate that interviews with statutory service staff and voluntary/community sector representatives will address areas of personal sensitivity or risk. Nonetheless, all members of the research team involved in recruitment and data collection have been trained to conduct workshops/interviews in a sensitive and flexible manner. At the start of the interview/workshop participants will be reminded of what taking part will involve and the themes that will be covered. They will be reminded of their right to take breaks, to skip questions they would prefer not to answer, and to withdraw at any point without needing to give a reason. Standard risk reporting measures will be in place and outlined within the participant information sheet.

8.2 Research Ethics Committee (REC) and other regulatory review & reports

HRA approval for research involving statutory professionals has been granted.

A parallel ethical application has been approved by the University of Sussex Sciences & Technology Cross-Schools Research Ethics Committee (C-REC) for the recruitment of participants via non-statutory organisations and networks.

The responsibility for decisions to amend the protocol and for deciding whether an amendment is substantial or non-substantial will be held by the joint Chief Investigators. Amendments will be approved by the relevant ethics committee prior to implementation. Once approved, amendments will be communicated to all study personnel via email correspondence and/or team meetings. A version tracking document will be used to track amendment history.

8.3 Peer review

This study has been independently assessed by NIHR peer reviewers as part of the funding award. In addition, the study will be subject to two phases of peer review by the Sponsor, through a Pre-sponsorship Review Panel and Sponsorship Panel.

8.4 Patient & Public Involvement (PPI)

Co-applicant Julia Fountain is a PPI Co-ordinator in Sussex Partnership NHS Foundation Trust (SPFT), with direct lived experience as the parent of a young woman who is not engaged in employment, education or training (i.e., meeting NEET criteria). We sought feedback on the study proposal from four service providers and one NEET young woman in the Sussex area. All respondents agreed that more research is needed to understand and better support the mental health and social outcomes of NEET young women. Issues around authenticity and credibility of expertise were highlighted and it was suggested that many young people perceive professionals as ‘experts by textbook, not by lived experience.’ We consulted with the Sussex Partnership NHS Foundation Trust’s Youth Research Café, a lived experience expert panel, during development of study materials. We anticipate one further consultation during delivery of the study.

In addition, the rationale for the current proposal was developed through a Wellcome Trust-commissioned systematic review and participatory evidence synthesis led by co-Chief Investigator Berry with Michelson. Fifteen youth advisors participated in reviewing the existing literature on hopefulness in youth mental health interventions, developing a mechanistic process model and setting future research priorities. The Youth Advisory Group’s top priority was to improve understanding of how social marginalisation interacts with hopefulness and youth mental health. The current project will directly address this topic.

8.5 Protocol compliance

Every effort will be made to ensure protocol compliance. Accidental protocol deviations will be fully documented on the relevant forms and reported to the Chief Investigators and sponsor immediately. Deviations from the protocol which are found to frequently recur will be acted on immediately and could potentially be classified as a serious breach.

A ‘serious breach’ is a breach which is likely to effect to a significant degree:

i) the safety or physical or mental integrity of the participants of the trial; or
ii) the scientific value of the trial

The sponsor will be notified immediately of any case where the above definition applies during study conduct phase.

8.6 Data protection and patient confidentiality

Personal data will be stored electronically on secure University computer systems. These data will only be accessible to members of the research team. Informed consent will be collected and stored online via Qualtrics, using a University of Sussex institutional licence and a survey form only accessible by members of the research team, using their own respective individual university IT log-in username and password. Qualitative interviews will be conducted using a secure video conferencing platform on university computers or an encrypted audio recording device.

Data will be transferred between sites securely to ensure no-one outside the research team is able to access it. Fully anonymised data may be shared outside of the research team for research purposes.

Participants will be informed of this within the participant information sheet and during the consent process. Only members of the research team will have access to this information, which will be stored confidentially in accordance with GDPR (2018).

8.7 Indemnity

The University of Sussex (Sponsor) has insurance in place to cover its legal liabilities in respect of this study.

9 DISSEMINATION POLICY

9.1 Dissemination policy

Our research will produce an intervention manual containing details about delivery, content and organisation of the hope-focused intervention. This will include information about how, where and by whom it will be delivered; specific content areas and procedures; structure (number and spacing of sessions); selection criteria and intended outcomes (and ways of assessing these); and quality assurance methods. An associated theory of change will describe how intervention components bring about short- and long-term outcomes. The intervention development process will be written up for a final report and as an open-access publication in a peer-reviewed journal.

We will communicate non-academic outputs to participants from the statutory, voluntary and community sectors in Kent and Sussex and through their/our extended networks. This includes the NIHR Applied Research Collaboration in Kent, Surrey and Sussex, focusing on public health, primary care and social care sectors in particular. We will widely circulate a project infographic and invite an expanded group of local, regional and national stakeholders to a webinar at the end of the project. The theory of change will be discussed and potential adaptations in other contexts will be explored. We will also mobilise interest in a future multi-site research bid and initiate a community of practice around the mental health and social needs of NEET young women. Reports will be sent to the Department of Health and Social Care, and to national charities such as The Children's Society and UK Youth. A parallel summary of outputs will be developed for NEET young women, and other members of the public, in the form of a short video. This will be disseminated through youth-focused and public-facing channels such as YouTube and Twitter accounts for relevant community organisations.

Most importantly, the research will enable us to develop a proposal for piloting and testing the intervention. Ultimately, we intend for the intervention to impact positively on the long-term mental health of NEET young women, and to improve their chances of leading more socially connected, economically active and personally fulfilling lives.

9.2 Authorship eligibility guidelines and any intended use of professional writers

In line with International Committee of Medical Journal Editors and NSFT guidelines, only individuals who meet all of the following criteria will be named as authors on publications resulting from the study: conception and design, or acquisition of data, or analysis and interpretation of data, drafting the article or revising it critically for important intellectual content, final approval of the version to be published

The agreed primary author of each manuscript is responsible for ensuring:

- timely circulation of all drafts to all co-authors during manuscript development.
- timely circulation of reviewers' comments to all co-authors
- incorporation of comments by authors and reviewers into subsequent drafts

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11. APPENDICIES

11.1 Appendix 1- Process model of hopefulness in youth mental health

11.2 Appendix 2- Using Theory of Change in the development, implementation and evaluation of complex health interventions: A practical guide