A co-produced qualitative exploration of young women's perspectives on psychological distress in their population and priority actions for responding

SHORT TITLE: INSIGHT (**I**nsight into **N**uanced **S**ources of Distress in **G**irls' Mental **H**ealth **T**oday)

PROTOCOL VERSION: Version 0.3; Date 12/03/2022

Funder Number: NIHR135295

SIGNATURES:

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: .... Date: ....../....../......

Name (please print): ....

Position: ....

Chief Investigator:

Signature: Date: 26/02/2022

Name: (please print):
Ola Demkowicz

Table of Contents

KEY STUDY CONTACTS

Chief Investigator:
Ola Demkowicz
Email: ola.demkowicz@manchester.ac.uk

Sponsor:
The University of Manchester
Gillian Whitworth gillian.whitworth@manchester.ac.uk

Funder:
This study/project is funded by the National Institute for Health Research (NIHR) Public Health Research Programme (project reference NIHR135295). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

NIHR Research Manager: Alan Marshall; alan.marshall@nihr.ac.uk

Key Contributors:
Chief Investigator (CI)
Dr Ola Demkowicz
Lecturer in Psychology of Education
Manchester Institute of Education
The University of Manchester

Co-Investigator (Co-I)
Dr Lucy Foulkes
Senior Research Fellow
Anna Freud National Centre for Children and Families

Project Researcher (RA)
Dr Rebecca Jefferson
Research Associate
Manchester Institute of Education
The University of Manchester

Young Co-Researchers:
Pratyasha Nanda
Common Room UK

Joanna Lam
Common Room UK

Collaborators:
Liz Neill
Director
Common Room UK

Professor Steven Pryjmachuk
Professor of Mental Health Nursing
Division of Nursing, Midwifery and Social Work
The University of Manchester

Dr Bernadka Dubicka
Consultant Psychiatrist

Greater Manchester Mental Health NHS Foundation Trust
and
Honorary Professor
The University of Manchester

Dr Laura Winter
Senior Lecturer in Education and Counselling Psychology
The University of Manchester

Dr Rhiannon Evans
Senior Lecturer in Social Science and Health
The DECIPHer Research Centre
Cardiff University

STUDY SUMMARY

Study Title:	A co-produced qualitative exploration of young women's perspectives on psychological distress in their population and priority actions for responding
Short Title:	INSIGHT
Study Design:	Qualitative
Study Participants:	Young women aged 16 to 18 across England
Planned Size of Sample:	40-45
Planned Study Period:	February to August 2022
Research Question/Aim:	**Aim:** to explore young women's perspectives of psychological distress in their population, including causal contributors and appropriate responses. **Research questions:** 1. What do young women perceive to be causing their population's high rates of psychological distress? 2. What do young women think could be helpful actions that could lessen psychological distress in their population? 3. What are priority actions to lessen psychological distress, and what approaches could be implemented to achieve these?

FUNDING

Funder: National Institute for Health Research (NIHR) Public Health Research Programme
Funder Project ID: NIHR135295

ROLE OF SPONSOR AND FUNDER

The University of Manchester acts as Sponsor in the research. Governance will be provided internally through existing support systems and the study will adhere to The University of Manchester's expectations and regulations.

NIHR funded the study through a commissioned call. The proposed research underwent review as part of the funding process, and suggested amendments to the design have been made through this process and approved by the funder. The views expressed in any expected outputs are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

ROLES & RESPONSIBILITIES OF STUDY STEERING GROUPS AND INDIVIDUALS

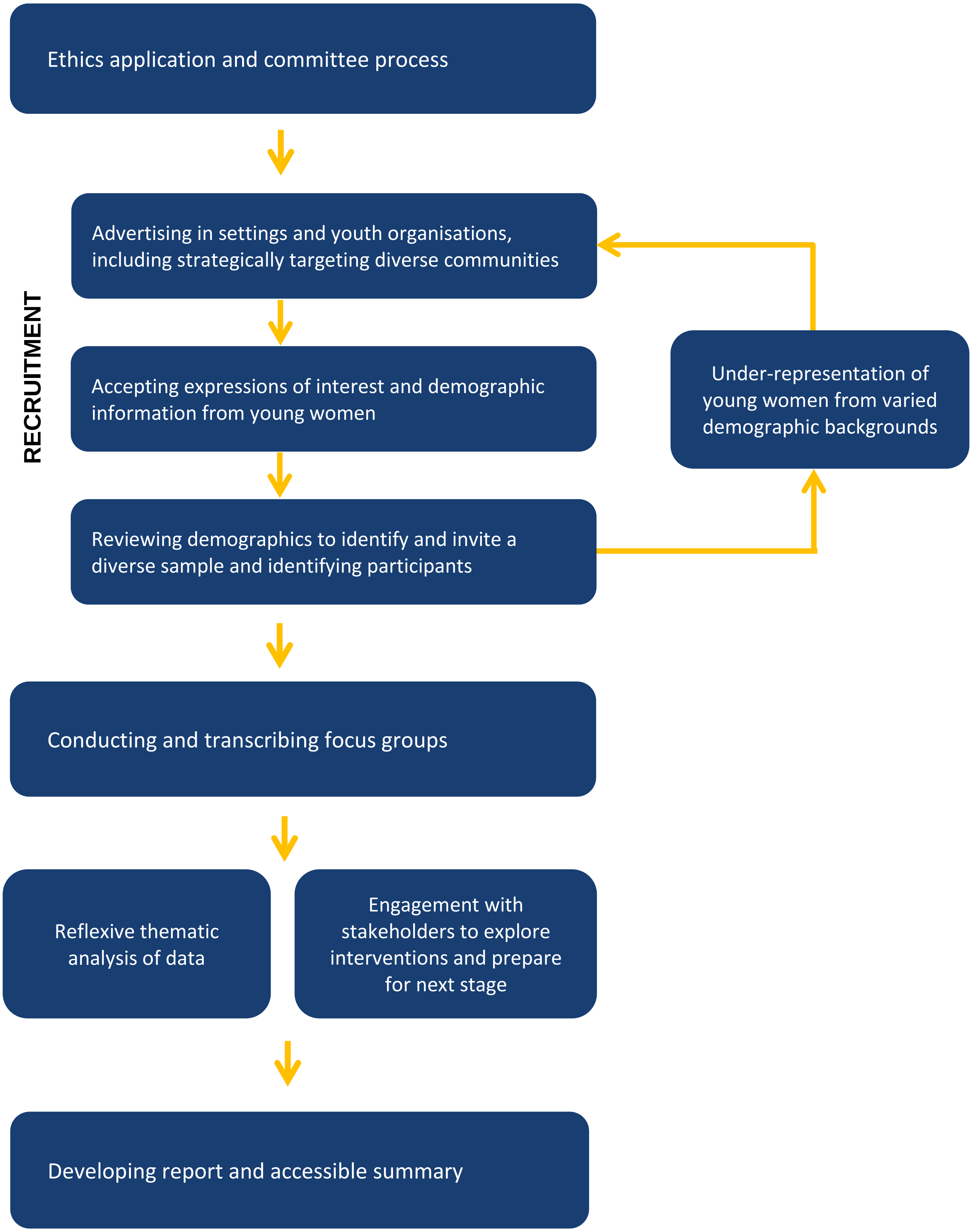
Project Management Group

Given the small scale and timeframe of the study and the many experienced collaborators involved with the project, it has been agreed with the funder that the project does not require a study steering group. Instead, our five collaborators (Neill, Pryjmachuk, Dubicka, Winter, and Evans) and two young co-researchers (Nanda and Lam) provide critical oversight for the project in the form of a Project Management Group. This group will advise on conceptual considerations, research methods, and interpretation and dissemination and will oversee timely completion. To aid this, we will hold a full team meeting each month across the span of the project to agree key study decisions by consensus, review progress and respond to any emergent considerations, and interpret study findings. We will engage in ongoing communication as needed between these meetings, including circulating drafts of procedural/ethical and dissemination documents for review and input as appropriate.

STUDY FLOW CHART

A GANNT chart and flow chart is shown below to provide a schematic overview of the study.

	02/22	03/22	04/22	05/22	06/22	07/22
Ethics application and committee process	🟥	🟥				
Recruitment and selection process		🟥	🟥	🟥		
Focus group training		🟥				
Conducting and transcribing focus groups			🟥	🟥		
Analysis training				🟥		
Data analysis and stakeholder engagement				🟥	🟥	
Developing report and accessible summary					🟥	🟥


Ethics application and committee process
RECRUITMENT
Advertising in settings and youth organisations, including strategically targeting diverse communities
Accepting expressions of interest and demographic information from young women
Reviewing demographics to identify and invite a diverse sample and identifying participants
Under-representation of young women from varied demographic backgrounds
Conducting and transcribing focus groups
Reflexive thematic analysis of data
Engagement with stakeholders to explore interventions and prepare for next stage
Developing report and accessible summary

STUDY PROTOCOL

1. BACKGROUND AND RATIONALE

Young women are reporting increasing rates of psychological distress (1–4), defined here as anxious and depressive symptoms. Such evidence is concerning and poses a growing public health concern (5,6), and indeed the COVID-19 pandemic appears to be contributing further to worsening distress among young women (7,8). Besides possible pandemic effects, the causes of this increased distress over the last decade remain unclear. Researchers have posited *possible* contributing factors across various life domains, including social media usage, increased sexualisation of young women from early adolescence, increased academic pressure, and lack of school emphasis on provision for psychological distress (1,2,9). There has also been a considerable societal shift in how mental health is discussed, which may have affected young people’s willingness to report their own distress (10,11).

However, such explanations are speculative and, critically, come from researchers without input from young women about possible contributors or responses that could be considered helpful. This limits the capacity of researchers and providers to respond effectively and with gender sensitivity. Research and policy has highlighted that there are unique drivers and patterns of mental health difficulties among women and that, accordingly, gender-sensitive preventative action and provision is required (12). Our study therefore seeks to understand the increase in psychological distress from the perspective of young women themselves. We will explore their perceptions of distress in their population, including possible causal explanations for this increase in distress. We will also explore their perspectives on helpful responses and actions that can be taken to lessen this distress, and engage with stakeholders (e.g. funders, public health policymakers and professionals, academics) to review how this could be targeted with intervention. This qualitative exploration with young women will allow a more comprehensive understanding of causal factors of psychological distress and will generate ideas and directions for appropriate responses, rather than relying on “top down” researcher hypotheses on a generational issue that adults cannot fully elucidate. In creating responses to women’s mental health issues it is critical that we engage with them to understand their needs, though this is frequently overlooked (12).

We focus on perceptions relating to adolescence, defined by the World Health Organization (13) as the period from 10 to 19 years, given that evidence of increased distress spans this stage, and will engage with young women in post-16 education (aged 16 to 18) in England. This older group will be able to reflect on their own and others’ experiences across their adolescent years, drawing on a fuller range of experience those in the earlier stages of adolescence could, and are likely to possess greater cognitive capacity for introspection and critical reflection, and greater understanding of complex societal issues (14). Notably rates of distress and related disorders are also highest in this older developmental stage (4). We will focus on perceptions among young women in England rather than across wider nations in the UK, as subtle national differences may play a role in experience around both gender and mental health (e.g. in education systems, relevant laws, cultural and religious influences).

To date, few peer-reviewed studies have explored young women’s broad understandings of how gendered experiences contribute to mental health difficulties (as opposed to asking them about pre-determined narrowed issues such as social media or relationship violence). These studies highlight several challenges for young women that appear linked to longstanding mental health disparities. This commonly includes considerable pressure and responsibility in daily life, sexual harassment and violence and related fear and restricted freedoms; and frustrating and limiting gender expectations and norms (15–19). Some also highlighted competing societal discourses of ‘femininity’, including traditional gendered norms, feminist ideals, and male-dominated ideals of femininity, that are difficult to assimilate (16,17). However, these studies have critical limitations that constrain the extent to which findings can be translated to understanding the current rates of psychological distress among young women in England. Data in all studies above were generated over ten years ago, and so cannot offer insights on the factors contributing to the increased rates of distress observed in the last decade. None occurred in an English context, and the majority were conducted in Sweden, which is the third most gender-equal country in the world according to the most recent Gender Inequality Index, while the UK ranks 31st (20). A small number of UK-based studies have produced *some* relevant insights, but these have lacked detail regarding women's perceptions of mental distress. For instance, The Children's Society's 2018 Good Childhood Report (21) explored gender differences in subjective wellbeing, and shared some young women's comments around expectations of attractiveness, but did not offer in-depth analysis or ask about specific mental health areas like distress.

Finally, studies to date have not explored young women's ideas on how we can respond to growing rates of psychological distress in their population. It is critical that we avoid "top down" speculation about what is helpful, and ask young women themselves what would be valuable. More closely focused, peer-reviewed investigation of young women's perspectives on current rates is needed, including exploration of what can be done to help lessen distress.

Thus, in the current study, we aim to explore young women's perspectives of psychological distress in their population, including causal contributors and appropriate responses. This will be undertaken through a co-produced qualitative design, engaging in online focus groups with diverse young women aged 16 to 18 years in England and engaging with key stakeholders to explore relevant public health intervention approaches that could be explored as a next step. The study is funded by NIHR as a development stage project, with the aim of progressing to develop a funding application to trial and evaluate a public health intervention. Thus, we will use findings to identify a public health intervention to trial and evaluate.

As well as building towards evaluation work exploring a public health intervention trial, we will also seek to be responsive to our findings more widely. We highlight that this is exploratory work on a current issue increasingly posing a national public health concern, and it is likely that our findings will raise further questions and thus directions for further investigation in a number of possible areas. For instance, our data will offer expansive insight into what young women would like to see from policymakers and services, and it may be valuable to undertake a scoping review of current policy and provision in specific areas and how this compares to young women's experiences and needs, given ongoing calls for gender-informed policy and provision (12). More widely, participants may raise considerations that go beyond direct mental health provision and tackle wider societal issues, such as issues around gendered inequality and gender-based violence, and this may open up wider avenues for further studies. As such, as well as working towards NIHR's subsequent evaluation call, we will be responsive to the nature of our data and pursue a range of next steps to build on this work, considering alternative funding schemes also such as the NIHR Health Services and Delivery Research Stream.

2. THEORETICAL FRAMEWORK

We define 'psychological distress' in the current study as anxious and depressive symptoms, wherein individual experience feelings of worry and low mood. Anxious and depressive symptoms are distinct but closely related, and often present comorbidly in adolescence (22), and so can be conceptualised as a shared construct in this way (also sometimes referred to as emotional distress/symptoms/problems/difficulties). We focus on symptomatic level experiences rather than disorder in recognition that these symptoms go beyond constricted diagnostic criteria (23) and given evidence of a general increase in distress among adolescent girls, rather than an increase only in narrow diagnoses based on such criteria (1–4).

We are guided by Bronfenbrenner's ecological systems theory (24), which recognises that health and development occurs in the context of multiple transactional environments and processes. Researchers' causal hypotheses for current rates of distress among young women span ecological domains, and use of ecological systems theory in qualitative research enables recognition of systematic processes in inequalities (25). We explored this with young women in designing the study, who felt that approaching the study in this way would help to frame and contextualise key issues.

3. AIM AND RESEARCH QUESTIONS

Aim: to explore young women’s perspectives of psychological distress in their population, including causal contributors and appropriate responses.

Research questions:

1. What do young women perceive to be causing their population’s high rates of psychological distress?
2. What do young women think could be helpful actions that could lessen psychological distress in their population?
3. What are priority actions to lessen psychological distress, and what approaches could be implemented to achieve these?

4. STUDY DESIGN AND METHODS

4.1. Study design

We adopt a co-produced qualitative design, generating data in online focus groups with diverse young women aged 16 to 18 years in England. For RQ 3, we will create a shortlist of actions identified by participants and engage with key stakeholders to identify related intervention approaches. This will form the basis of a bid for the NIHR intervention evaluation call. We will embed co-production in the study, to develop procedures that best meet participants’ needs and create more meaningful, applicable knowledge (26), drawing on NIHR guidance for co-production (27), wider recommendations, and worked examples (28,29). Thus far, we have engaged in a youth advisory discussion with seven young women from diverse backgrounds; this has influenced, for instance, our approach to conceptualising key constructs, plans for recruiting marginalised young women, and focus group methodology. We will create two young co-researcher roles for young women and engage them as active team members in all research stages including development of recruitment materials, the focus group approach and process, analysis, and interpretation, with training and support throughout. Engaging two young co-researchers will help to address team power imbalances, reduce burden on any one individual, and limit disruption if one young person becomes unable to continue. Note that we have engaged an experienced research assistant (Jefferson) at 0.5 FTE to undertake day-to-day project activity.

In focus groups, we will outline current rates of psychological distress in young women and directly explore perspectives on this topic. Note that here we will use the terms ‘low mood and anxiety’ rather than psychological distress and will clearly define this for participants, as this language is more familiar and less clinical sounding. By clearly introducing the current evidence of rates as the basis for our discussion, our design draws on principles of action and participatory research approaches, wherein population members contribute to unpicking issues affecting them and explore appropriate actions (30,31). We will be guided by Bronfenbrenner’s ecological systems theory (24), which recognises that health and development occurs in the context of multiple transactional environments and processes. Researchers’ causal hypotheses for current rates of distress among young women span ecological domains, and use of ecological systems theory in qualitative research enables recognition of systematic processes in inequalities (25). We explored this with young women in designing the study, who felt the approach would contextualise key issues.

4.2. Focus groups

Data will be generated using online focus groups. Focus groups offer additional, more nuanced insight compared to one-to-one interviews, as group interactions and discussions allow for contrast, challenge, and clarification (32). We will use a co-led approach, with a researcher *and* a young co-researcher leading sessions; having a young person leading as a peer can minimise power differentials and facilitate open, democratic discussion (33,34). The young women in our youth advisory discussion supported this approach, noting that a young co-researcher *slightly* older than participants would be most suitable; thus, we will engage young co-researchers aged 19 to 22. We will bring together participants not known to each other, rather than existing peer groups, as prior social dynamics and shared understanding can influence discussions, particularly with young people (35,36). We explored this with young women in our youth advisory discussion, who were enthusiastic about this approach and felt it could help to support diversity, and suggested steps to ensure a safe space.

Use of online focus groups allows us to draw together women who do not know each other, reduces burden on young co-researchers, and offers reductions in time, travel, and budget to suit the study's short turnaround and budget. Online focus groups show similar richness and depth to face-to-face focus groups (37), and studies have used this with young people to good effect (e., 36). We will use Zoom, with advantages for both participants and researchers in terms of cost-effectiveness, ease of use, and security (39). Zoom also allows flexibility to suit varied needs, such as having cameras on or off and allowing contributions via audio or chat, which was emphasised by young women in our youth advisory discussion to aid inclusivity. Focus groups are expected to last up to 90 minutes, consistent with guidance (35), and will run in the daytime on Saturdays, and weekdays in the late afternoon, to suit the needs of participants and co-researchers. When participants are invited to take part, they will be provided with selective dates and times from which they can choose based on their availability. At this stage we will also ask participants whether they have any needs that we may need to support to facilitate participation, and work flexibly to provide support as needed. Focus groups will be audio recorded and transcribed verbatim for analysis, using Zoom to provide foundational transcripts and then checking these for accuracy against the audio recording.

We will develop a semi-structured topic guide, covering key topics but with flexibility to follow the flow of discussion and explore unanticipated responses (35). As outlined, we draw on the collective problem-solving approach used in action and participatory approaches, directly exploring rates of psychological distress. Broad areas of discussion include: a) exploring perceptions of current reported rates of distress; b) possible causal contributors for distress among young women; and c) helpful actions that could be implemented to reduce distress, including what they would consider 'priority' actions, and their rationale on the underlying theory of change as to why they would expect this would create positive change, how we might measure success (i.e., outcome), and considerations around the context and implementation. We will draw on ecological systems theory to explore factors and possible actions across ecological domains. As above we note use of 'low mood and anxiety' here rather than the term psychological distress, to avoid confusion, and our young co-researchers have supported this terminology.

4.3. Analysis of focus group data

We will analyse data using coproduced reflexive thematic analysis, an approach wherein researchers create a thematic representation of the data, exploring patterns across participants' perceptions and experiences and identifying nuances and variation among individuals and groups. We will approach data inductively or "bottom-up" rather than applying a theoretical framework, given our aim of exploring young women's own perspectives. We follow Braun and Clarke's six-stage framework for thematic analysis (40): familiarisation with data, generating initial codes, searching for themes across codes, reviewing and refining themes, defining and naming themes, and presenting a written report of findings and implications. Coding and theme development will be undertaken in NVivo to facilitate an organised and systematic approach. Analysis will be coproduced, with each transcript being double coded by a researcher and a young co-researcher to allow expansion and development through shared interpretation. Next, the research assistant, co-researchers, and Demkowicz and Foulkes will meet via Zoom to refine coding and begin constructing themes. This will be reviewed and developed by the research assistant and Demkowicz and written up as a thematic report, checking in consistently with young co-researchers. We will then engage in a full team meeting, including collaborators Neill, Pryjmachuk, Dubicka, Winter, and Evans, to discuss findings and explore interpretations to feed into the final report.

4.4. Stakeholder workshop

Our data and approach will primarily provide a foundation for the subsequent NIHR call for the evaluation of a public health intervention. Our core next step will comprise a feasibility trial of a public health intervention, likely in community settings (e.g. schools, colleges, local neighbourhood services) to reduce levels of distress among young women. We will need to be responsive here to the specific interventions that are indicated throughout the focus group and stakeholder workshop, as the level of development or adaptation required in order to explore a given intervention will differ depending on existing work in this area. We hope to be able to undertake either initial development and adaptation work on a particular intervention approach if young women and stakeholders indicate a particularly novel approach, or should they indicate a more established approach we will undertake a feasibility randomised controlled trial (RCT) to explore feasibility, fidelity and acceptability, with the aim of eventually building toward an effectiveness RCT, with a cluster component if appropriate. This model of working through a feasibility trial is similar to approaches in recent protocols by Hayes and colleagues (41) and Willis and colleagues (42). RCTs of community-based mental health interventions are a key area of expertise in the Manchester Institute of Education, where Dr. Demkowicz (PI) is based and has collaborated on such work; Prof. Pryjmachuk, Prof. Dubicka, and Dr Evans also add expertise and considerable experience in the evaluation of mental health interventions across a range of public health and community contexts, and we note that Dr. Evans has critical expertise in the development, optimisation, and adaptation of public health interventions and in evaluation methodologies.

We will draw on the 'priority actions' and theories of change proposed by young women in their focus groups. First, we will hold a preparatory meeting with our full project team, including collaborators and young co-researchers. In this meeting, we will compile priority actions from all eight focus groups and use this to shortlist potential mechanisms of change in an intervention. To do this, we will use the nominal group activity (a structured group brainstorming approach). Mechanisms that could be reasonably targeted and where the theory of change proposed by young women appears logical and feasible based on our knowledge and wider evidence will be retained in a shortlist, along with indicative intervention approaches that offer this.

Next, we will host a half-day workshop presenting and exploring these shortlisted actions with key stakeholders including policymakers, academics, and funding bodies, to explore considerations on the theory of change and how such an intervention may be implemented in particular contexts, with the aim of identifying an intervention approach that we can seek funding to develop/adapt, and evaluate. We will include a range of stakeholders at this event, capitalising on existing contacts across key groups to engage approximately 15-20 people comprising:

a) Public health policymakers; we have a range of connections with such individuals including members of the Children, Young People and Families team at the Office for Health Promotion (formerly Public Health England);
b) Public health professionals; our team has a range of connections to this group at the local authority and national level;
c) Members of relevant funding bodies; team members have connections with relevant funding leads and evaluation teams at organisations including the National Lottery Community Fund and the Youth Endowment Foundation; and
d) Academics specialising in public health intervention in the context of youth mental health (we have connections with many such academics given our team's expertise, including in our own institutions and more widely across the UK).

The session will be chaired by Demkowicz, Jefferson, and young co-researchers Nanda and Lam will also co-chair with support from Demkowicz. Wider team members will also attend wherever possible to allow opportunities to ask questions and follow discussion. We have made the decision to involve young people in the event in this way only (rather than also inviting additional young people to take part as stakeholders) because our co-researchers will have considerable oversight of the focus group discussions and will be trained and fluent in the nature of the project by this time. In this way our young co-researchers will be well-equipped to engage in detailed discussion and ask questions of our attendees with support from Demkowicz and Jefferson, in order to represent the voices of our participants and young women in this process. We will draw on principles of the Delphi method in this workshop, which are techniques used to reach consensus between a panel of experts on a given decision through a structured workshop process, often with a goal of formulating clear recommendations for actions and resourcing (43,44).

At the workshop, we will present our shortlist of priority actions and theories of change, pointing to example interventions where available, and ask stakeholders to first independently reflect on these via a written survey, before coming together to discuss collectively. We will ask them to consider feasibility and expected efficacy but will also build in key values identified by young women in focus groups to help them consider appropriate responses. We will then return to Zoom together, to discuss and review these options drawing on participants' initial survey responses, and provide opportunities discussion of each option. Finally, we will ask attendees to subsequently endorse or reject each of the options, with the possibility of an additional follow-up to rank options should the majority of attendees endorse multiple options. The chair and co-chairs will raise any questions at this stage to help understand the options supported by attendees.

Following the workshop, our team will review those possible theories of change and associated intervention approaches with the greatest level of endorsement from stakeholders and consider this alongside available evidence to reach a decision on the intervention to focus on in subsequent funding bids. This workshop approach will also allow us to explore opportunities for collaboration with a funder to support next steps including delivery of an intervention to facilitate evaluation work, through establishing connections to the project with funders who we would engage to attend the workshop (as noted above, organisations such as the National Lottery Community Fund and the Youth Endowment Foundation are examples of funders for whom we would consider such delivery funding to be in remit, and thus we would seek to engage representatives from these organisations in this workshop process).

Taken together, these steps will enable us to identify an intervention approach, informed by young women themselves as well as a panel of experts, that could be developed/adapted as needed and evaluated through a feasibility trial in community settings.

5. STUDY SETTING

We will recruit participants via post-16 education settings and stakeholders will be contacted in their professional roles. Both focus groups and the stakeholder workshop will be undertaken remotely to allow us to effectively draw together participants and stakeholders, respectively, with minimal burden and budget. We will use Zoom given advantages in cost-effectiveness, ease of use, security, and flexibility to varied needs.

6. SAMPLE AND RECRUITMENT

6.1. Eligibility criteria

6.1.1. Inclusion criteria

Our target population for the main strand, the focus groups, is diverse young women aged 16 to 18 years across England. We focus on young women *generally,* rather than those with direct lived experience of mental health difficulties. The project focuses on their perspectives of contributing factors to psychological distress among their population as a wider group, rather than asking them to reflect on personal challenges they themselves have faced. We have three inclusion criteria:

a) **Women:** the study focuses on the perspectives of young women and so it is critical that our participants identify as such. We seek to be gender inclusive in our conceptualisation of “women”, viewing gender as a continuum and including those who consider themselves to be, for instance, fluid, non-conforming, or trans women, and recruitment materials have been designed to appeal to varied young women in this respect both in visual images used and the wording offered.
b) **Aged 16-18:** We focus on perceptions relating to adolescence, defined by the World Health Organization (13) as the period from 10 to 19 years, given that evidence of increased distress spans this stage, and will engage with young women in post-16 education (aged 16 to 18) in England. This older group will be able to reflect on their own and others’ experiences across their adolescent years, drawing on a fuller range of experience those in the earlier stages of adolescence could, and are likely to possess greater cognitive capacity for introspection and critical reflection, and greater understanding of complex societal issues (14). Notably rates of distress and related disorders are also highest in this older developmental stage (4).
c) **Currently based in England**: We will focus on perceptions among young women in England rather than across wider nations in the UK, as subtle national differences may play a role in experience around both gender and mental health (e.g. in education systems, relevant laws, cultural and religious influences).

No inclusion criteria are set for stakeholders, as this is more fluidly approached in identifying individuals who are able to provide professional expertise on this topic.

6.1.2. Exclusion criteria

In line with our inclusion criteria, our only exclusion criteria are a) not identifying as a woman; b) being outside of the age range specified; or c) not currently being based in England. There are no wider exclusion criteria set for focus groups or the stakeholder workshop.

6.2. Sampling

6.2.1. Size of sample

We aim to engage approximately 40-45 participants, spread across eight focus groups. We have opted for a moderately sized sample for focus group research (45), as our focus group approach offers breadth in topics covered via our ecological systems approach but is highly specific and explores an issue of personal importance, meaning we anticipate a reasonable level of depth *and* breadth in the data. We aim to have five to six participants at each focus group, but we will arrange for up to seven individuals in case of dropout/nonattendance, which is a common issue in focus group research (32). Thus, in the event that all individuals attend their focus group session we would expect a maximum possible sample of 56 participants.

6.2.2. Sampling technique

We will sample purposively for the study, in order to engage participants that meet the inclusion criteria and can thus effectively help to address the study research questions. We are engaging participants via post-16 education settings and youth organisations. Alongside this, in line with NIHR’s INCLUDE guidance (46), we are drawing on maximum variation sampling principles and techniques to ensure a diverse sample, with participants from varied backgrounds. This approach is implemented in recognition of the varied characteristics and experiences of young women in England, and in line with our use of ecological systems theory recognising that individuals each experience their own unique ecological system variant. This includes seeking to ensure that focus groups include participants from a range of regions and education settings, who vary in age across the 16-18 target age group, and individuals with varied backgrounds in terms of ethnic group, socioeconomic status, and sexual orientation.

For the stakeholder workshop, we will identify a range of stakeholders that we think may have particular interest and expertise in this area. We will initially identify 15 stakeholders with a general alignment with the topic as a whole (e.g. public health professionals, policymakers, funding bodies, academics) and once focus groups are complete and we have a fuller understanding of the points to explore, we may invite more specialist stakeholders in line with the actions put forth by participants (e.g. headteachers if some kind of school-based approach in a given area appears a commonly identified action in focus groups).

6.2. Recruitment

6.3.1. Sample identification

We will recruit through adverts, via post-16 education settings (e.g. sixth forms, further education colleges, vocational training centres) and youth organisations in England. Education/training is now compulsory for young people until age 18 in England, aiding us in reaching young women across varied contexts, and we have a range of connections across various English education networks. Given the relatively small sample size to be engaged, we will engage in this process through a select number of organisations, reaching out in the first instance via networks (e.g. Schools in Mind, National Association of Colleges) to ask interested settings to let us know if they would like to advertise the study to some of their students; we previously have had success engaging via networks, but if this does not prove fruitful in the first instance, we will put out a call for organisations via social media (Twitter and LinkedIn). We will select a range of varied setting types across different regions in England and share a recruitment advert with them, asking them to share the advert with a small number (5-10) of diverse young women aged 16 to 18 in their organisation.

Adverts will link to a Qualtrics website with a project summary, participant information, and introductory video with the lead researcher (Jefferson) and young co-researchers (Nanda and Lam). Individuals will express interest here, and we will ask them to provide brief demographic information, namely age, ethnic group, socioeconomic status (using free school meal eligibility as a brief proxy), and sexual orientation, given evidence that young women’s status across these demographics can influence day-to-day experiences and risk of mental health difficulties, including distress (47–50), and geographic region to ensure a spread of participants across England.

We will then identify and invite a diverse sample from this wider possible pool of participants, seeking representation of women from diverse backgrounds across and within our focus groups. We are seeking to recruit up to 150 interested individuals in this first stage, in order to allow us to identify a diverse sample and ensure representation of varied voices in focus groups. Those not invited to take part will be provided with a flyer noting alternative organisations that they could get involved with to contribute to discussions around mental health and similar youth issues (e.g. the iWill campaign). Should invited individuals *not* respond to our invitation or drop out of the study (common issues in focus group research) we can then draw on the wider set of interested individuals to avoid sample size issues.

Both to incentivise participation and to acknowledge the contribution participants offer to the project, all participants in focus groups will receive a £20 digital shopping voucher to thank them for their contribution to the project, as well as a digital “Active Citizenship” certificate, consistent with guidance (51).

For the stakeholder workshop, we will identify a range of stakeholders that we think may have particular interest and expertise in this area. We will initially identify 15 stakeholders with a general alignment with the topic as a whole (e.g. public health professionals, policymakers, funding bodies, academics) and once focus groups are complete and we have a fuller understanding of the points to explore, we may invite more specialist stakeholders in line with the actions put forth by participants (e.g. headteachers if some kind of school-based approach in a given area appears a commonly identified action in focus groups).

For stakeholders, our team will collectively identify and agree on a set of individuals that we think would be helpful to engage for the workshop. We will write to individuals we identify as, explaining key details about the study and providing a link to an information sheet.

6.3.2. Consent

Participants in focus groups will all be over the age of 16 years and thus able to consent for themselves. We note two consent stages relating to our focus group participants; first, individuals who initially express interest will all be asked to provide opt-in consent when they provide demographic information about themselves, regardless of whether they are then invited to take part in the main focus group stage. For those invited to take part, participants will be asked to complete a second online consent form via Qualtrics as part of confirmation they intend to attend the session they are invited to. We will then also ask for verbal confirmation of consent at the start of the focus group session. We will ensure that young women taking part are clearly informed at all stages and have opportunities for questions. This includes providing key information at various stages and in various means of communication, including participant information sheets, videos outlining key information, and reiterating key points at the start of focus groups., and we will take opt-in consent at the start of the focus group via a survey once any questions are addressed and researchers have reiterated key information and confirmed understanding. We will negotiate consent actively during the focus group, with researchers being attentive to indication of disengagement or discomfort during the focus group process, and we note that participants can stop taking part at any point without giving a reason. Individuals who begin taking part but change their mind will still be provided with a certificate and voucher.

For the stakeholder workshop, we will ask stakeholders to provide opt-in consent. When we identify and invite identified stakeholders, we will direct them to a participant information providing key information about taking part, and ask them to sign an online consent form confirming they understand what participation entails and are happy to take part. At the beginning of the workshop we will reiterate key information, provide opportunity for any final questions, and ask for final verbal confirmation of consent to proceed with the workshop.

7. ETHICAL AND REGULATORY CONSIDERATIONS

7.1. Assessment and management of risk

At the start of each focus group, we will collectively explore and agree on a set of ground rules to support a safe space within discussions, including to set expectations around confidentiality and reiterate that participants are not expected to share any experiences that are deeply personal or that may be upsetting.

We will signpost to relevant services at the end of the focus group and in a follow-up email check-in within one day after focus groups. Focus group training will involve clear discussion with researchers leading focus groups on monitoring engagement and reactions throughout discussion. We have developed a clear distress and safeguarding protocol, which outlines steps to follow should anyone become upset (going into a breakout room with the participant to check in and agree on next steps to either return to discussion when they are able or end their participation, and sharing signposting information at this stage) or indicate risk of serious harm (in which case we would contact their Emergency Contact provided during sign-up, the safeguarding lead at their education setting, or the police, depending on the nature of the disclosure).

Our focus group training for the research assistant and the co-researchers, who are leading the focus groups, will include detailed discussion and coverage of ethical procedures, and these members will also complete the University child protection training. Demkowicz will support and advise closely, with a debrief after each focus group to ensure ethical procedures are thoroughly followed and support responsiveness to any emergent considerations over the course of the project. Dr. Jefferson, the research assistant identified for the project, is experienced in ethical procedures and considerations, including in the context of online focus groups with young people on sensitive topics, having previously served as a postdoctoral researcher on a project with similar data generation methods. Dr. Jefferson and the co-researchers will all be DBS checked.

Regarding researcher safety, researchers will not be engaging in lone working at any point during data generation given the use of online focus groups. However, we have a policy for working outside of business hours which provides contact information for Demkowicz, Jefferson, and Neill in case of any issues. Demkowicz and Neill will be aware of the dates and times of focus groups and will engage in a debrief afterwards to check in and provide support as needed. The young co-researchers will be sensitively supported throughout the research process with regard to their emotional safety and wellbeing, particularly by Neill, Demkowicz, and Jefferson.

We anticipate less risk for the stakeholder workshop, however we note that we will ensure that discussion here stays focused on professional topics and guide stakeholders away from discussion of more personal elements of this area, and will similarly monitor engagement throughout in case of any difficulties.

7.2 Research Ethics Committee (REC) and other regulatory review and reports

Ethical approval will be sought via The University of Manchester before the commencement of the research, and we will follow all ethical guidance and policies set out by this institute. This relates to our study protocol, informed consent forms, and all other relevant documents (e.g. distress and safeguarding policy, adverts, data generation documents, etc.).

Should the team identify a need for any amendments, these will be communicated in writing to NIHR, the full team, and submitted via The University of Manchester's ethics committee system for approval before implementation. We will clearly label versions for version control on protocols and documents as required. This includes updating this protocol document.

As the study does not relate to NHS practices and does not ask individuals to engage in any engagement within an organisation, no other regulatory reviews are required.

7.3. Peer review

The study underwent expert review as part of the funding process, and suggested amendments to the design have been made through this process and approved by the funder. The current protocol is also subject to review by the funder.

7.4. Patient and public involvement

We held a youth advisory discussion with seven diverse young women aged 19-22 years in developing the design of the study at the application stage. We explored key concepts and design consideration and approaches, which has informed the shaping of the study in various ways (e.g. considerations around recruitment and maximum variation sampling, creating a safe space for discussion within focus groups, approaches to exploring key topics and language in focus groups).

The study is co-produced with two young people (Pratyasha Nanda and Joanna Lam), who will act as co-researchers across the project and were hired upon confirmation of funding as Project Workers at Common Room UK. Nanda and Lam will be closely involved in decisions and processes at each stage of the project, with training and support, including our ethics application, recruitment, data generation, analysis, and dissemination.

7.5. Protocol compliance

We will endeavour throughout to comply with this protocol and make any amendments in advance if needed. Any accidental deviation from the protocol will be documented and reported to the CI and Sponsor and this will be actively monitored to avoid persistent or excessive deviation that breaches our contract.

7.6. Data protection and confidentiality

Regarding data protection, we will keep all data confidential and securely stored on The University of Manchester's Secure Research Data Storage system, in line with current research governance and data protection regulations. Only members of the research team who require access to data will be able to access the storage system (e.g. for data management purposes, for reviewing information to aid recruitment and participation processes, and for analysis purposes), namely Demkowicz, Foulkes, Jefferson, Nanda, and Lam.We will anonymise data using a random code and pseudonym for each participant, using a participant key stored separately from data to be able to link this information to an individual if required (e.g. upon a data request by a participant or complaint). We will anonymise data in transcription, in line with good practice, including possible identifying information such as the names of people or places mentioned by our participants. In reporting on findings will be sensitive to ensuring any quotes shared cannot be linked back to an individual participant.

Audio data will be deleted at the end of the project in August 2022. All other data will be securely stored for five years, and then deleted. The Data Custodian is The University of Manchester.

7.7. Indemnity

The University of Manchester as Research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

7.8. Access to the final study dataset

Only members of the study team will have access to the full dataset, given the sensitivity of discussion.

8. DISSEMINATION POLICY

8.1. Dissemination policy

At the end of the study, we will produce a final project report for the funder, including anonymised quotes to support interpretations, which will be available as open access via NIHR' s website. We will also produce a short evidence briefing to share with our participants and to a wider audience to aid circulation of key findings among stakeholders and the public. NIHR will be acknowledged within any study publications. We will work with our policy engagement institute, Policy@Manchester, to create a briefing for policymakers and commissioners and seek Foulkes' considerable experience here. Finally, we will publish findings in high-impact academic journal articles and undertake presentations at professional and academic conferences (seeking open access and conference fees institutionally).

The full team will contribute to dissemination and outputs, and actively monitor impact work and if needed apply for additional light-touch impact funding beyond the project end. Any further plans within the research team to explore publishing from the data will be discussed and agreed with Demkowicz as CI.

8.2 Authorship eligibility guidelines

All project team members will be granted authorship on the final study report and will read and contribute to the development of drafts of this document. Wider dissemination (e.g. in academic articles) will then be negotiated actively through ongoing discussion and agreement, with all members of the team invited to be involved in any piece should they wish to and have capacity to offer a substantive contribution to each piece.

9. REFERENCES

1. Collishaw S, Maughan B, Natarajan L, Pickles A. Trends in adolescent emotional problems in England: A comparison of two national cohorts twenty years apart. J Child Psychol Psychiatry Allied Discip [Internet]. 2010;51:885–94. Available from: doi:10.1111/j.1469-7610.3010.02252.x

2. Fink E, Patalay P, Sharpe H, Holley S, Deighton J, Wolpert M. Mental health difficulties in early adolescence: A comparison of two cross-sectional studies in England from 2009 to 2014. J Adolesc Heal [Internet]. 2015;56:502–7. Available from: doi:10.1111/j.1469-7610.3010.02252.x
3. Lessof C, Ross A, Brind R, Bell E, Newton S. Longitudinal study of young people in England cohort 2: Health and wellbeing at wave 2 [Internet]. 2016. Available from: https://www.gov.uk/government/publications/longitudinal-study-of-young-people-in-england-cohort-2-wave-2
4. Sadler K, Vizard T, Ford T, Marcheselli F, Pearce N, Mandalia D, et al. Mental health of children and young people in England, 2017: Summary of key findings [Internet]. 2018. Available from: https://files.digital.nhs.uk/F6/A5706C/MHCYP 2017 Summary.pdf
5. Department for Education. State of the Nation 2019: Children and young people's wellbeing. 2019.
6. Ford T. Editorial Perspective: Why I am now convinced that emotional disorders are increasingly common among young people in many countries. J Child Psychol Psychiatry Allied Discip. 2020;61(11):1275–7.
7. Stroud I, Gutman LM. Longitudinal changes in the mental health of UK young male and female adults during the COVID-19 pandemic. Psychiatry Res [Internet]. 2021;114074. Available from: doi:10.1016/j.psychres.2021.114074
8. Magson NR, Freeman JYA, Rapee RM, Richardson CE, Oar EL, Fardouly J. Risk and protective factors for prospective changes in adolescent mental health during the COVID-19 pandemic. J Youth Adolesc [Internet]. 2021;50(1):44–57. Available from: http://dx.doi.org/10.1007/s10964-020-01332-9
9. Bor W, Dean AJ, Najman J, Hayatbakhsh R. Are child and adolescent mental health problems increasing in the 21st century? A systematic review. Aust N Z J Psychiatry [Internet]. 2014;48:606–16. Available from: doi:10.1177/0004867414533834
10. Dowrick C, Frances A. Medicalising unhappiness: New classification of depression risks more patients being put on a drug treatment from which they will not benefit. BMJ [Internet]. 2013;347:f7140. Available from: doi:10.1136/bmj.f7140
11. Collishaw S. Annual research review: Secular trends in child and adolescent mental health. J Child Psychol Psychiatry Allied Discip [Internet]. 2015;56:370–93. Available from: doi:10.1111/jcpp.12372
12. Mental Health Foundation. While your back was turned: How mental health policymakers stopped paying attention to the specific needs of women and girls. 2017;32. Available from: https://www.bl.uk/collection-items/while-your-back-was-turned-how-mental-health-policymakers-stopped-paying-attention-to-the-specific-needs-of-women-and-girls
13. World Health Organization. Adolescent health [Internet]. 2021 [cited 2021 Jul 26]. Available from: https://www.who.int/health-topics/adolescent-health#tab=tab_1
14. Smetana JG, Turiel E. Moral development during adolescence. In: Adams GR, Berzonsky MD, editors. Blackwell handbook of adolescence. Blackwell Publishing; 2006. p. 246–68.
15. Landstedt E, Asplund K, Gillander Gådin K. Understanding adolescent mental health: The influence of social processes, doing gender and gendered power relations. Sociol Heal Illn. 2009;31:962–78.
16. Wiklund M, Bengs C, Malmgren-Olsson EB, Öhman A. Young women facing multiple and intersecting stressors of modernity, gender orders and youth. Soc Sci Med [Internet]. 2010;71(9):1567–75. Available from: doi:10.1016/j.socscimed.2010.08.004
17. Einberg EL, Lidell E, Clausson EK. Awareness of demands and unfairness and the importance of connectedness and security: Teenage girls' lived experiences of their everyday lives. Int J Qual Stud Health Well-being [Internet]. 2015;10:27653. Available from: doi:10.3402/qhw.v10.37653
18. Strömbäck M, Formark B, Wiklund M, Malmgren-Olsson EB. The corporeality of living stressful femininity: A gender–theoretical analysis of young Swedish women's stress

experiences. Young [Internet]. 2014;22(3):271–89. Available from: doi:10.1177/0973174114533464
19. Banister E, Schreiber R. Young women's health concerns: Revealing paradox. Health Care Women Int [Internet]. 2001;22(7):633–47. Available from: doi:10.1080/07399330127170
20. United Nations Development Programme. Gender Inequality Index (GII) [Internet]. 2020 [cited 2021 Jul 14]. Available from: http://hdr.undp.org/en/content/gender-inequality-index-gii
21. The Children's Society. The Good Childhood Report 2018 [Internet]. 2018. Available from: https://www.basw.co.uk/system/files/resources/thegood_childhood_report_2018_0.pdf
22. Balázs J, Miklõsi M, Keresztény Á, Hoven CW, Carli V, Wasserman C, et al. Adolescent subthreshold-depression and anxiety: Psychopathology, functional impairment and increased suicide risk. J Child Psychol Psychiatry Allied Discip. 2013;54(6):670–7.
23. Fried EI, Epskamp S, Nesse RM, Tuerlinckx F, Borsboom D. What are "good" depression symptoms? Comparing the centrality of DSM and non-DSM symptoms of depression in a network analysis. J Affect Disord [Internet]. 2016;189:314–20. Available from: doi:10.1016/j.jad.2015.09.005
24. Bronfenbrenner U. The ecology of human development: Experiments by nature and design. Cambridge, MA: Harvard University Press; 1979.
25. Velez G, Spencer MB. Phenomenology and intersectionality: Using PVEST as a frame for adolescent identity formation amid intersecting ecological systems of inequality. New Dir Child Adolesc Dev. 2018;2018(161):75–90.
26. Staniszewska S, Denegri S, Matthews R, Minogue V. Reviewing progress in public involvement in NIHR research: Developing and implementing a new vision for the future. BMJ Open [Internet]. 2018;8(7). Available from: doi:10.1136/bmjopen-2017-017124
27. National Institute for Health Research. Centre for Engagement and Dissemination. Briefing notes for researchers: Public involvement in NHS, health and social care research. 2021;Accessed 08 May 2012. Available from: https://www.nihr.ac.uk/documents/briefing-notes-for-researchers-public-involvement-in-nhs-health-and-social-care-research/27371?pr=
28. Dewa LH, Lawrence-Jones A, Crandell C, Jaques J, Pickles K, Lavelle M, et al. Reflections, impact and recommendations of a co-produced qualitative study with young people who have experience of mental health difficulties. Heal Expect [Internet]. 2021;24(1):134–46. Available from: doi:10.1111/hex.13088
29. INVOLVE. Co-production in action: Number one [Internet]. 2021. Available from: https://www.learningforinvolvement.org.uk/?opportunity=nihr-co-production-in-action-number-one
30. Cornwall A, Jewkes R. What is participatory research? Soc Sci Med [Internet]. 1995;41(12):1667–76. Available from: doi:10.1016/0277-9536(95)00127-S
31. MacDonald C. Understanding PAR: A qualitative research methodology. Can J Action Res. 2012;13(2):34–50.
32. Wilkinson S. Focus groups. In: Smith JA, editor. Qualitative psychology: A practical guide to research methods. 3rd editio. London, United Kingdom: SAGE Publications Ltd; 2015. p. 199–221.
33. Djohari N, Higham R. Peer-led focus groups as 'dialogic spaces' for exploring young people's evolving values. Cambridge J Educ [Internet]. 2020;50(5):657–72. Available from: doi:10.1080/0305764X.2020.1754763
34. Murray C. Peer led focus groups and young people. Child Soc [Internet]. 2006;20(4):273–86. Available from: doi:10.1002/CHI.892
35. Krueger RA, Casey MA. Focus groups: A practical guide for applied research. 2nd ed. London, United Kingdom: SAGE Publications; 2015.
36. Robinson N. The use of focus group methodology - With selected examples from

sexual health research. J Adv Nurs [Internet]. 1999;29(4):905–13. Available from: doi:10.1046/j.1365-2648.1999.00966.x
37. Abrams KM, Wang Z, Song YJ, Galindo-Gonzalez S. Data richness trade-offs between face-to-face, online audiovisual, and online text-only focus groups. Soc Sci Comput Rev [Internet]. 2015;33(1):80–96. Available from: doi:10.1177/0894439313519733
38. Han J, Torok M, Gale N, Wong QJJ, Werner-Seidler A, Hetrick SE, et al. Use of web conferencing technology for conducting online focus groups among young people with lived experience of suicidal thoughts: Mixed methods research. JMIR Ment Heal [Internet]. 2019;6(10):1–10. Available from: doi:10.3196/14191
39. Archibald MM, Ambagtsheer RC, Casey MG, Lawless M. Using Zoom videoconferencing for qualitative data collection: Perceptions and experiences of researchers and participants. Int J Qual Methods [Internet]. 2019;18:1–8. Available from: doi:10.1177/1609406919874596
40. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol [Internet]. 2006;3:77–101. Available from: doi:10.1191/1478088706qp063oa
41. Hayes D, Moore A, Stapley E, Humphrey N, Mansfield R, Santos J, et al. School-based intervention study examining approaches for well-being and mental health literacy of pupils in Year 9 in England: study protocol for a multischool, parallel group cluster randomised controlled trial (AWARE). BMJ Open. 2019;9(8):e029044.
42. Willis K, Tibbitts B, Sebire SJ, Reid T, MacNeill SJ, Sanderson E, et al. Protocol for a cluster randomised controlled trial of a Peer-Led physical Activity iNtervention for Adolescent girls (PLAN-A). BMC Public Health. 2019;19(1):1–11.
43. Niederberger M, Spranger J. Delphi Technique in Health Sciences: A Map. Front Public Heal. 2020;8(September):1–10.
44. McMillan SS, King M, Tully MP. How to use the nominal group and Delphi techniques. Int J Clin Pharm. 2016;38(3):655–62.
45. O.Nyumba T, Wilson K, Derrick CJ, Mukherjee N. The use of focus group discussion methodology: Insights from two decades of application in conservation. Methods Ecol Evol [Internet]. 2018;9(1):20–32. Available from: doi:10.1111/2041-210X.12860
46. National Institute for Health Research. Improving inclusion of under-served groups in clinical research: Guidance from INCLUDE project. UK Natl Inst Heal Res [Internet]. 2020;1–10. Available from: https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435
47. Demkowicz O, Panayiotou M, Humphrey N. Risk factors and cumulative risk exposure for emotional symptoms among early adolescent girls. BMC Womens Health.
48. Patil PA, Porche M V., Shippen NA, Dallenbach NT, Fortuna LR. Which girls, which boys? The intersectional risk for depression by race and ethnicity, and gender in the U.S. Clin Psychol Rev [Internet]. 2018;66(August 2017):51–68. Available from: https://doi.org/10.1016/j.cpr.2017.12.003
49. Institute of Health Equity. Health equity in England: The Marmot Review 10 years on [Internet]. Available from: https://www.health.org.uk/publications/reports/the-marmot-review-10-years-on
50. Marcheselli F, Brodie E, Ning Yeoh S, Pearce N, McManus S, Vizard T, et al. Mental health of children and young people in England, 2017: Behaviours, lifestyles and identities [Internet]. 2018. Available from: https://files.digital.nhs.uk/81/542548/MHCYP 2017 Behaviours Lifestyles Identities.pdf
51. Shaw C, Brady LM, Davey C. Guidelines for research with children and young people [Internet]. 2011. Available from: http://www.ncb.org.uk/sites/default/files/uploads/files/NCB%2520guidelines%2520CYP.pdf