

Protocol v3

Version 3 of the protocol contains the adjustments made to the study because of Covid-19. These adjustments were instituted from 16th March 2020. The study is now collecting data exclusively online. This is a minor deviation from the study protocol because online data collection was a main component of the original stage 3 case study design. The Sponsor approved all 3 non-substantial changes to the ethics protocol. A summary of the revisions to the original protocol are below:

- Microsoft Teams online interviews with staff only
- WhatsApp text online interviews with young people only
- Microsoft Teams online carers and parent interviews only

Title of Project

Identifying and evaluating mental health early intervention services and self-care support for lesbian, gay, bisexual and transgender (LGBT) young people: A mixed methods study.

Summary of Research

RESEARCH DESIGN RATIONALE

Lesbian, gay, bisexual and transgender (LGBT) young people have a higher risk of poor mental health in comparison to heterosexual young people (1-7), and they underutilize mental health services and support (8-11). In addition, there is a paucity of UK research examining mental health early intervention and supported self-care provision for LGBT young people. The aim of the proposed study is to generate evidence to improve the delivery of mental health early intervention services and self-care support to LGBT young people in the UK.

The research project is a mixed methods study with 3 distinct stages: 1) Evidence synthesis; 2) Service mapping; 3) Case study evaluation. The study uses a theory-driven evaluation research strategy that is appropriate when there is little evidence on the effectiveness or acceptability of services and interventions (12, 13). We are in the early stages of developing mental health services/interventions that might support LGBT young people. This initial 'innovation stage' requires evaluation methods that can 'discover', 'describe' and provide a theoretical understanding of why, how and in what context a service or intervention might work (14).

Consequently, the study objectives are exploratory and theory-building to produce baseline data and understanding about acceptable and appropriate mental health early intervention services and self-care support to LGBT young people. We intend to review existing evidence, develop a programme theory, map services, and produce a theory-driven evaluation to not only understand why an intervention or service may work but also detail the underlying logic or theory of why it works (13, 15, 16). Our intention is then to produce commissioning guidance with key stakeholders to enable NHS mental health commissioners to make evidence-based decisions to improve local services to address the mental health of this disadvantaged group of young people. The project research questions are:

1. What evidence exists on mental health early intervention services and supported self-care for LGBT young people?
2. What type of service models for mental health early intervention and supported self-care to LGBT young people are currently provided?
3. How, why and in what context do mental health early intervention services and supported self-care work for LGBT young people?
4. In what ways do LGBT young people access and navigate formal and informal mental health early intervention services and self-care support?
5. How can LGBT young people be encouraged to access and engage with mental health early intervention services and self-care support?

The NIHR has asked that this study collaborates with a related study that they have also funded under the same call (HS&DR 17/09/08, PI Prymachuk, University of Manchester). While each study will retain its individual integrity, there are clear opportunities for collaboration and (non-confidential) data sharing. These opportunities are outlined in the detailed project plans of each study.

RESEARCH PLAN

The study design has 3 stages:

Stage 1 Evidence synthesis

Stage 1 will address research question 1 and involve a systematic review (17) of the literature on mental health early intervention services and self-care support for LGBT young people. The review questions are: a) what empirical studies have been undertaken on mental health early intervention services and self-care support for LGBT young people? b) what are the theoretical propositions for how and why these services may work?

We conducted a scoping review of the literature in preparation for the proposed project application and results suggested a small (n=55) but important evidence-base. As a result, we are using a configuring rather than aggregative approach to the systematic review (SR)(17). This SR methodology is appropriate for reviews with heterogenic literature and specifically aims to broaden understanding of particular interventions/services i.e. what happens? (18). The configuring systematic review methodology follows the same rigorous format as aggregative reviews but the synthesis of the research is focussed on theory generation rather than testing causal hypotheses (19). The included primary studies will be synthesized to develop a programme theory to provide a theoretical understanding of the mechanisms by which mental health early intervention services and self-care can support LGBT young people with common mental problems. This programme theory will be tested in stage 3 case study evaluation.

Stage 2 Service mapping

Stage 2 will address research question 2. This will involve the systematic online and offline search to identify *services* that provide current mental health early intervention and self-care support for LGBT young people in the UK. We will utilize the mapping methods used in Prymachuk's (co-applicant) previous NIHR HS&DR funded children and young people mental health self-care study (20). Data collection will be desk based and basic details (e.g. target population, mode of delivery, theoretical approach) of potential services obtained from any source will be extracted and entered into an Excel spreadsheet. The service mapping data will be organized using the dimensions in Prymachuk's (20) previous typology as well as other dimensions that may be identified during the proposed study. A full summary of the mapping data will then produce a typology of services and this will be used to inform the selection of the case study sites in stage 3.

Stage 3 Case study evaluation

Stage 3 will address research questions 3-5. A collective case study consisting of 12 case studies will be purposively (21) selected from services identified in Stage 2 (service mapping) to reflect the different dimensions of the service typology. We will collect data from key stakeholders in each of the case study *sites* (n=12) to examine factors such as service acceptability, gaps in provision, barrier/facilitators to access, views on service improvement and encouraging access/engagement. We will also collect data on service cost that will be used in the production of the commissioning guidance at the end of the study. At each case study *site* data will be collected via: i) online, telephone and face-to-face interviews with LGBT young people, family members and service staff (n=10); ii) focus groups with LGBT young people (n=2); iii) documentary review; iv) virtual non-participant observation (for online sites only). A purposive sampling strategy [14] will be used to select participants. Case study evaluation is a theory-driven evaluation methodology and therefore the data analysis strategy is theoretical using the 'explanation-building' analytical technique (12). The findings from each case study site will be used to gradually refine the theoretical model developed in stage 1 of the proposed study to produce an overarching theoretical understanding of how, why and in what context mental health early intervention services and self-care support work for LGBT young people. (22).

Working collaboratively with HS&DR study 17/09/08 (PI: Prymachuk), relevant literature from stage 1 and identified services from Stage 2 will be shared with Prymachuk's team. We will also ensure that our case study sites (Stage 3) do not overlap with those of the other study team. The case study evaluation findings will be shared with the other team so that their applicability can be tested in the model (or models) of effective, high quality service provision for CYP experiencing CMHPs they identify.

Background and Rationale

Lesbian, gay, bisexual and transgender (LGBT) young people report significantly higher rates of depression, self-harm, suicidality and poor mental health than heterosexual youth (1-7, 23). In a pooled analysis of 12 UK population surveys, those who were under 35 and identified as LGB were twice as likely to report symptoms of poor mental health compared to their heterosexual counterparts (6). A recent meta-analysis of studies comparing suicidality in young people found that 28% of LGBT youth reported a history of suicidality compared to 12% of heterosexual youth (5). Despite this mental health inequality, LGBT young people have significantly higher unmet mental health need than their heterosexual peers (24, 25). Recent evidence suggests that although there is a greater mental health burden in this population, LGBT youth underutilize mental health services, do not access them until crisis point and often find them unhelpful (9, 11).

Research suggests LGBT young people are reluctant to access mental health services because of homophobia and transphobia, difficulties disclosing their sexual and gender identity, and fears of being misunderstood or judged (8-10, 26). The lead applicant's previous study found only one fifth of participants had sought help from NHS services for their mental health problems (9). We know LGBT young people are hesitant to ask for help but we have minimal understanding of the barriers and facilitators to accessing mental health services (8, 9, 11, 27). In addition to the underutilisation of mental health services (28), studies suggest LGBT young people have poor overall experience of mental health services such as CAMHS, gender identity clinics and school-based support (9, 11, 24, 29). Problems highlighted are a lack of engagement with practitioners, staffs' limited understanding of LGBT issues, and exclusion from the decisions made about young people's care (9, 30). Importantly, studies show that LGBT youth will seek mental health help online and from peers (8-10, 26) and prefer accessing LGBT organisations for mental health support (9, 27, 31).

Children and young people's mental health is a national priority (32) and LGBT young people have been recognized as a high-risk group (33-36) less likely to access mainstream mental health services (8-10). NHS England have identified the importance of providing access to high quality mental health services to those young people who have a greater vulnerability to mental health problems but who find it more difficult to access help (32). However, the UK evidence-base examining LGBT young people's mental health support needs and service preferences is very limited. Consequently, (and despite this manifest inequality and underutilization of mental health services), there is no UK research on how to develop appropriate mental health early intervention and supported self-care provision to this vulnerable group. Our application aims to deliver rigorous evidence to fill this gap, address this inequality and fulfil the requirements of NHS mental health strategic direction.

Evidence explaining why this research is needed now

Young people's mental health is a national priority because 75% of all mental health problems have been established by the age of 24 and 75% of diagnosable mental health disorders occur before age 21 (36). There are long term negative consequences of developing mental health problems in adolescence on education, employment, and physical health (34). LGBT youth constitute a group of young people who may encounter additional difficulties specific to their LGBT status which impact of their mental health. These include homophobic and transphobic bullying at school, family rejection, isolation and homelessness (8, 9, 37, 38). These experiences make them more vulnerable to poor mental health, and may be a barrier to accessing mental health services and support (9).

The purpose of the HS&DR commissioned call is to provide evidence to fulfil the requirements of national strategic initiatives, such as Future in Mind (32, 36), aimed at improving young people's mental health. The HS&DR commissioning brief identifies LGBT youth as a key group that are less likely to access and engage with early intervention and self-care mental health services. Despite LGBT young people having elevated rates of poor mental health (6) and under-utilizing mental health services (9, 10), there is no UK research on how to develop appropriate mental health early intervention and supported self-care provision to this vulnerable group. Our application aims to deliver rigorous evidence to fill this gap.

Aims and Objectives

AIM: To improve the provision of mental health early intervention services and self-care support to lesbian, gay, bisexual and transgender (LGBT) young people in the UK.

OBJECTIVES:

1. To produce a synthesis of the evidence on mental health early intervention services and self-care support to LGBT young people.
2. To identify service models for mental health early intervention and supported self-care which are accessible and acceptable to LGBT young people.
3. To develop a programme theory of how, why and in what context mental health early intervention services and self-care support work for LGBT young people.
4. To increase understanding of LGBT young people's access to and navigation of formal and informal mental health early intervention services and self-care support.
5. To generate commissioning guidance (including service costs) on mental health early intervention and supported self-care services for LGBT young people.

RESEARCH QUESTIONS:

1. What evidence exists on mental health early intervention services and supported self-care for LGBT young people?

2. What type of service models for mental health early intervention and supported self-care to LGBT young people are currently provided?
3. How, why and in what context do mental health early intervention services and supported self-care work for LGBT young people?
4. In what ways do LGBT young people access and navigate formal and informal mental health early intervention services and self-care support?
5. How can LGBT young people be encouraged to access and engage with mental health early intervention services and self-care support?

Research Plan / Methods

RESEARCH DESIGN OVERVIEW

Design Rationale

The research project is a mixed methods study with 3 distinct stages: 1) Evidence synthesis; 2) Service mapping; 3) Case study evaluation.

The study uses a theory-driven evaluation methodology that is appropriate when there is little evidence on the effectiveness or acceptability of services and interventions (12, 13). There is a paucity of UK research examining mental health early intervention services and supported self-care provision for LGBT young people. As a consequence, there is a need to design a study that recognises we are at the first stage of understanding the ways in which mental health services might support LGBT young people. This initial ‘innovation stage’ requires evaluation methods that can ‘discover’, ‘describe’ and provide a theoretical understanding of why, how and in what context a service might work (14).

Experimental designs are excellent to assess the effectiveness of services and interventions but they cannot assess how or why services achieve particular outcomes in a variety of contexts (39, 40). Theory-driven evaluation approaches seek to not only understand why a service may work but also detail the underlying logic or theory of why it may work (13, 15, 16). In order to develop health services which are likely to be effective, sustainable and scalable, evaluations need to understand not just whether, but how, why and in what contexts a service has a particular outcome (14, 41, 42). Theory-led evaluation methods acknowledge that health care delivery takes place in complex social systems with potentially multiple pathways to the provision of services that work (41, 43, 44).

It is now widely recognized that theory is important to health services research because it aids the development of generalizable and robust knowledge and builds a scientific understanding of health care quality (16, 44). Case study design has been criticized because of concerns regarding external validity i.e. that a single case study is poor basis for generalizing. However, the Medical Research Council, amongst others (12, 22, 45, 46), have argued it is possible to generate ‘cumulative knowledge’ about the factors that influence health care delivery by adopting a theoretically driven method. We will utilize Yin’s (12) ‘analytical generalization’ approach whereby the programme theory established before the case study is ‘tested’ during the case study data analysis. This means a case study evaluation research design does not generalise results to the population as a whole, but generalizes to theoretical propositions on how or why a service/intervention may work (12). We intend to use a case study evaluation to generate a theoretical understanding of the mechanisms by which mental health early intervention services and self-care provision can support LGBT young people with common mental health problems.

Theoretical/Conceptual Framework

The lack of research on LGBT young people and their use of mental health services has resulted in few theoretical explanations for why current services may be inappropriate. Both the lead applicant and Johnson (co-applicant) have been at the forefront of developing theories to explain why LGBT populations have elevated rates of mental health problems (11, 47). This work builds on Meyer’s (48) minority-stress model that explains LGBT individual mental health and wellbeing in terms of experiences of discrimination/victimization/stigma and is a plausible explanation for poor experiences of mental health service provision (11, 49).

McDermott (CI) and Johnson’s (CA) theoretical perspective uses the concept of heteronormativity (the social and cultural presumption that heterosexuality is the only ‘normal’ sexual orientation (50)) as a central lynchpin to understanding why LGBT young people may face additional burdens on their mental health. Young people, particularly in the early stages of non-normative gender and sexual identity development, can feel alienated from traditional forms of support (family, friends) (48) and at odds with normative expectations of heterosexuality (11, 51, 52). This isolation will often be underpinned by deep feelings of shame which are implicated in both poor mental health and a reluctance to access formal support services (27, 53, 54).

Theories and models that explain why LGBT young people are hesitant to ask for help for their mental health problems will be crucial to the development of early intervention mental health service models that are acceptable and accessible to LGBT youth. We will be utilizing models of young people's help-seeking for mental health problems that go beyond the barriers/facilitators model that is commonly used in research. Our approach will draw from Biddle et al.'s (55) 'cycle of avoidance' model that conceptualises help-seeking in relation to normalising and coping. The lead applicant's development of this model (8, 10, 11) posits that LGBT young people are hesitant to ask for help because they are afraid of being judged and humiliated in relation to normative expectations of adolescent development, heteronormativity and mental health, as a result they minimize their mental health problems and try to cope alone (8-11, 27). However, LGBT young people will look for support from places/people where they feel they are not judged such as peers, LGBT individuals/organizations and online (10), and this provides some initial evidence for the development of appropriate service models. Thus theories for understanding appropriate mental health early intervention services for LGBT young people need to be informed by models of youth help-seeking (8, 10, 11), youth psychology (51), theories of sexuality and gender (11, 47) and developmental approaches to identity (47), rather than narrowly defined sexual orientation labels (56).

Population

- Age

Sexual orientation and gender identity development occurs at a variety of ages most usually from the age of 12 onwards (51, 56) and the population will be defined as young people aged between 12-25 years of age.

- Sexual orientation and gender identity

Research indicates that there is a proliferation of terms that young people use to describe their gender identity and sexual orientation (57). In the lead applicant's previous study young people used 23 different terms for their sexuality and /or gender. Measuring young people's sexual orientation is notoriously difficult but it is generally agreed that questions for research can consider three dimensions of sexual orientation: sexual attraction, sexual behaviour, self-identification (58). The ONS recommends asking a sexual identity question with five possible responses- 'heterosexual or straight', 'gay or lesbian', 'bisexual', 'other', and 'prefer not to say' (59). More recent literature recommends additional sexual identity categories because the five category measure does not adequately capture young people's sexual identity diversity (57, 60). We will use the sexual identity measure used in the lead applicants last study that includes eight closed-option responses - 'lesbian', 'gay', 'bisexual', 'heterosexual', 'queer', 'pansexual', 'questioning', 'unsure', and one 'other'- open ended response.

The measurement of gender identity is in its infancy and the Equality and Human Rights Commission recommend a question which measures sex at birth (response options - male, female, intersex, I prefer not to say) and/or a gender identity question (response options - male, female, in another way) (61). We intend to use an adaptation of the EHRC question developed in the lead applicant's previous study following extensive pilot testing with LGBT youth (9)

Intervention

Early intervention and supported self-care will include any health, social care or educational intervention, service or technology provided by the public, private or third sectors that aims to facilitate LGBT young people (or carers) taking action to address their mental health problems (20). This will include services that specifically target LGBT young people and services that have adapted their delivery to meet the mental health needs of LGBT young people.

Outcomes

The main aim of this study is to generate a theoretical understanding of the mechanisms by which mental health early intervention services and self-care provision can support LGBT young people with common mental health problems. It is *not* a study that is measuring the effectiveness of those services/interventions. We are interested in how, why and in what contexts services facilitate positive change in young people's mental health, functioning, education or training, or service user experience. In the interviews and focus groups (stage 3 case study evaluation), qualitative data will be collected on the participants' experiences of services/interventions and their subjective viewpoint on whether the service is accessible, acceptable and has improved their mental health, functioning, education or training. Validated measures of mental health will be obtained at the end of interviews and focus groups with LGBT young people but this will be to provide demographic mental health status data on the *sample* rather than as a measure of service/intervention effectiveness.

In the interviews and focus groups, we will use the following validated measures of subjective mental wellbeing and mental health that are suitable for young people aged 12-25 years old:

- ONS Personal Wellbeing Domain for Children and Young People - ONS4 (62)

The ONS measures the personal mental wellbeing domain through four subjective measures asking about life satisfaction, happiness, worthwhileness and anxiety. The measure has been used on the Annual Population Survey (APS) and the Millennium Cohort Study (MCS56) and is suitable to ask children and young people aged 10 and above. The four questions are:

- a. Overall, how satisfied are you with your life nowadays?
- b. Overall, to what extent do you feel the things you do in life are worthwhile?
- c. Overall, how happy did you feel yesterday?
- d. Overall, how anxious did you feel yesterday?

- Hospital Anxiety and Depression scale (HADS)

This is a reliable and user-friendly 14-item scale for measuring anxiety and depression and has been validated for use with adolescents (63).

- Self-harm

Self-harm will be measured by asking participants whether ‘they had ever tried to harm themselves in some way’? (yes/no). If yes, they will be asked whether this has happened on more than one occasion, and the last time they carried out self-harm. Self-harm will be defined by using the following phrase: “This may include any behaviour that you purposely use to cause yourself physical or emotional discomfort, for example: using drugs, cutting, risky sexual practices, starving yourself or other behaviours” (9, 64).

STUDY METHODOLOGY

The proposed study has 3 distinct stages: 1) Evidence synthesis; 2) Service mapping; 3) Case study evaluation. These are detailed below.

Stage 1. Evidence synthesis

Stage 1 will address research question 1 and involve a systematic review (17) of the literature on mental health early intervention services and self-care support for LGBT young people (objectives 1 and 3).

Scoping review

We conducted a scoping review of the literature in preparation for the proposed project application. The primary aim of the scoping search was to assess the size of the available published literature on LGBT youth mental health early intervention services and self-care support research. We searched four main databases, from 2005, for research examining LGBT youth and mental health services, and research on mental health interventions aimed at LGBT youth. We located 55 relevant studies suggesting a small but significant evidence-base. To date, we have been unable to locate any systematic reviews on the topic.

Systematic review methodology

Research on LGBT youth mental health early intervention services and self-care support is an emerging field of investigation and the nascent nature of the literature has guided our view that a theory-led systematic review methodology may be more fruitful than the traditional Cochrane and Campbell collaborations approach. Our scoping review did not find any randomized control trials and very few large scale studies that could be used to test causal hypotheses and ask what works? (18). As a result, we are using a configuring rather than aggregative approach to the systematic review (17, 65). This SR methodology is appropriate for reviews with heterogenic literature and specifically aims to broaden understanding of particular services/interventions i.e. what happens? (18). The configuring systematic review methodology follows the same rigorous format as an aggregative review but the synthesis of the research is focussed on theory generation rather than testing hypotheses (19, 44, 66). In this first stage of the proposed study methodology, the included primary studies will be synthesized to develop a programme theory to produce a theoretical understanding of the mechanisms by which mental health early intervention services and self-care can support LGBT young people with common mental health problems.

Review questions

1. What empirical studies have been undertaken on mental health early intervention services and self-care support for LGBT young people?
2. What are the theoretical propositions for how and why these interventions/services may work?

Search strategy

The search strategy will use an electronic search of both discipline specific databases (Medline, CINAHL, PsychINFO, British Education Index) and multidisciplinary databases (Web of Science, Academic Search Complete and Scopus) because bibliographic or disciplinary databases rarely cover the scope of a systematic review (17). For thoroughness the electronic literature searching will be supplemented with expert consultation, forward citation tracking and hand-searching especially of relevant journals such as the Journal of Gay and Lesbian Mental Health and the Journal of LGBT Youth. The search terms will be divided into four main domain categories: sexual orientation and gender identity; age; mental health; and intervention/service. The timespan of included papers will be 1990 to date because research published before 1990 is unlikely to be relevant given substantial changes in attitudes, policies and laws towards LGBT populations. Research written in English, Spanish, Portuguese, Italian and French will be included because these languages are spoken within the research team. Any literature that we identify that is pertinent will be shared with Pryjmachuk's study team.

Review strategy

- Inclusion/exclusion criteria

Articles identified will be preliminary screened for relevance based on their titles and abstracts by using the following inclusion criteria: i) the focus of the study is mental health; ii) participants of the study are LGBT youth aged ≤ 25 years old; iii) the study investigated a mental health early intervention, service or self-care support. Studies meeting all three inclusion criteria will remain in the review and be subject to a detailed full-text screening and appraisal process. Full-text manuscripts will be assessed by two researchers independently and results will be compared and discussed (65).

- Quality and relevance appraisal

To assess the quality and relevance to addressing the review questions we will utilize the Eppi-Centre 'Weight of Evidence Framework' (17). This assessment determines how much weight is placed on the evidence of each study included in the final synthesis. There are three key components to the assessment: the study's relevance to the review question, the appropriateness of its methods in the context of the specific review, and the quality of the execution of these methods (67).

- Synthesis

Study findings will be synthesized using a configurative approach to develop a programme theory to produce a theoretical understanding of the mechanisms by which mental health early intervention services and self-care can support LGBT young people with common mental health problems. Configurative approaches to research reviews are concerned with meaning and interpretation across a heterogeneous range of study designs. They are used to develop ideas and theories and are 'inductive' rather than 'deductive' (17). There are many forms of configurative approaches in reviews and we intend to use a meta-narrative synthesis (68, 69). The programme theory will be tested in the stage 3 case study evaluation.

Stage 2. Service mapping

Stage 2 of the proposed study addresses research question 2. This will involve the systematic online and offline search to identify *services* that provide current mental health early intervention services and self-care support for LGBT young people in the UK (objective 2). We will utilize the successful mapping methods used in Pryjmachuk's (co-applicant) previous NIHR HS&DR funded children and young people mental health self-care study (20). We will also liaise with the HS&DR 17/09/08 project to ensure there is no duplication of the case study sites.

Setting/context

The lead applicant's preceding study (9) found that across the country specific mental health support services aimed at LGBT young people were being developed. These services include a variety of intervention types e.g. self-care, peer-support, digital, clinical; and a range of service setting e.g. health, local authority, third sector. We intend to map the full range of these emerging services and *examples* include:

- CAMHS services in third sector youth organisations e.g. self-harm support groups, individual counselling and gender identity support groups (Merseyside)
- Peer-support initiatives in LGBT youth provision (Bristol)
- Specialist LGBT youth mental health practitioners employed by CAMHS (Leeds)
- Online LGBT mental health support by third sector organisations such as MindOut (Brighton) and LGBT Foundation (Manchester).
- LGBT support groups in schools with mental health provision (Lincolnshire)
- CAMHS service development with LGBT youth (Herefordshire).

Inclusion criteria

Since the work undertaken in this stage will provide the sampling framework for the Stage 3 case study evaluation, we will limit the search to current services in the UK that will be operational during the 12-month data collection period. For consistency, we will use the same population and intervention definitions used for Stage 1.

Search strategy

We will utilize the search strategy used in Prymachuk’s (co-applicant) previous NIHR HS&DR funded children and young people mental health self-care study (20) as follows:

- Online search strategy

The lead applicant has extensive experience of online methodologies and effective ways of searching the internet for LGBT youth mental health data (8-11, 70-72). For the online search we will use a variety of standard and academic Internet search engines such as Google, Intute, Yahoo and Bing. The online search will aim to locate services in the UK where youth, sexuality, gender identity, and mental health are a focus, for example, LGBT youth websites, mental health support websites, forums, blogs, social networking sites. The search terms that we identify for Stage 1 will also be appropriate for this stage. To find such specific websites, we will search for two categories of relevant sites: (a) those tailored for LGBT youth and (b) those focusing on mental health.

- Offline search strategy

The offline search will be facilitated through the following key contacts and networks:

- LGBT third sector service providers e.g. MindOut, Viva LGBT youth (Wales), Gendered Intelligence
- LGBT third sector national umbrella organizations e.g. National LGB&T Partnership, Stonewall, Stonewall Cymru, LGBT Foundation, LGBT Consortium, LGBT Youth Scotland, Cara-friend (Northern Ireland).
- Key third sector youth organizations e.g. 42nd Street, Banardos,
- Key third sector mental health organizations e.g. Young Minds, selfharmUK
- Key expert informants i.e. professionals developing LGBT youth mental health services
- Professional groups such as the Royal Colleges of Nursing, General Practice and Psychiatrists, Schools & Students Health Education Unit, CAMHS Nurse Consultants network, British Psychological Society
- NIHR clinical research networks e.g. primary care, mental health
- All primary care trusts and mental health trusts
- All directors of children’s services in local authorities
- National third sector umbrella organizations e.g. NCVO, National Youth Agency

Data collection and selection of services

Data collection will be desk based and utilize previously successful mapping data collection methods used by Prymachuk (20) (co-applicant). Basic details of potential services obtained from any source will be extracted and entered into an Excel spreadsheet. This spreadsheet will contain the fields that are important in formally identifying the service as a mental health early intervention or self-care support service, and for us to be able to provide sufficient information for the service mapping to be meaningful. Table 1 lists the fields and those marked ‘inclusion criterion’ will be mandatory for a judgement of inclusion to be made. When sufficient information is gathered two members of the research team will decide if the service is to be included in the service map.

The service mapping data will be organized using the dimensions in Prymachuk’s (20) previous typology as well as other dimensions that may be identified during the proposed study. A full summary of the mapping data will then produce a typology of services and this will be used to inform the selection of the case study sites in stage 3.

Table 1. Fields for service mapping data collection (20)

Service name
Service provider including sector (statutory, private, voluntary)
Mental health condition*
Ages targeted*
Gender identity*
Sexual orientation*
Target group (who attends)
Theoretical approach
Mode of delivery
Aims of the service tools/techniques used

Self-care elements
Support element
Facilitator (agent)
Setting (community, home, etc.)
Geographical location (including whether urban/rural)*
Length of contact
Timing (frequency of contact).
Service current/dates of service operation*
*Inclusion criterion

Stage 3. Case study evaluation

Design

The third stage of the proposed study addresses research questions 3-5. This stage is a collective case study evaluation of mental health early intervention & self-care support services for LGBT youth comprising of 12 case studies (objectives 2-5). A case study is an empirical enquiry that focuses on a single phenomenon in its real-life context, especially useful (as in our circumstances) when description or explanation is required (73). Collective case studies are those in which multiple cases are studied simultaneously or sequentially in an attempt to generate a broad appreciation of a particular issue (22). Yin (12, 73) defines a 'case' as a 'bounded entity', a broad and flexible definition that allows the case to be as varied as an event, an individual, a service or a policy. In this project we have defined the case as 'mental health early intervention and self-care support service for LGBT young people in the UK'.

Setting/context

Statutory and non-statutory providers of mental health early intervention and self-care support services in the UK.

Sampling

The 12 case studies will be purposively (21) selected from services identified in Stage 2 (service mapping) to reflect the different dimensions of the Stage 2 service typology. We estimate that 12 will be an adequate number of cases to capture the range of services identified in stage 2. The sample selection criteria will be developed from the Stage 2 typology but it is likely to include: service setting (e.g. education, third sector, NHS); geography; intervention type (e.g. self-care, peer-support, digital, clinical); and other criteria to be determined. The specific case studies will be determined in consultation with the LGBT youth advisory group and the project advisory group.

Sampling within the case study sites will also be purposive in that we will ensure that a diverse range of appropriate stakeholders (LGBT youth, parents and carers, health, social care and education professionals, and volunteers) are invited to participate. Particular attention will focus on ensuring a diverse range of LGBT youth participants are recruited across:

- the age range i.e. 12-25 years old
- sexual orientation e.g. lesbian, gay, bisexual, pansexual, queer, questioning
- gender diversity e.g. transmale, transfemale, non-binary, genderqueer, gender fluid
- ethnicity
- socioeconomic status
- disability

The research team (McDermott, Johnson, Hughes, Pryjmachuk) have expertise developed over numerous studies of recruiting participants who are 'hard-to-reach' (LGBT, young people) and on sensitive topics (suicide, self-harm, mental health and sexuality).

Data collection

We will collect data from key stakeholders in each of the case study *sites* (n=12) to examine factors such as service acceptability, gaps in provision, barrier/facilitators to access, views on service improvement and encouraging access/engagement. We will also collect data on service cost that will be used in the production of the commissioning guidance at the end of the study. At each case study *site* data will be collected via: i) online, telephone and face-to-face interviews with LGBT young people, family members and service staff (n=10); ii) focus groups with LGBT young people (n=2); iii) documentary review; iv) virtual non-participant observation (for online sites only).

- Semi-structured interviews (online, telephone, face-to-face)

We will conduct 10 semi-structured qualitative interviews with the three groups of participants (LGBT youth, family/carers and staff) at each case study site. The aim of the interviews is to generate in-depth, exploratory data from the perspectives of the participants (74). The rationale for employing different modes of interviewing are the twin difficulties of researching a hard-to-reach group, and the sensitivity of the topic. There are difficulties recruiting samples because participants may be unwilling to be open about their LGB or T and/or mental health status. Previous studies, including the lead applicant's, have demonstrated that online interviews can be successfully used to examine LGBT youth mental health (9, 11, 71) because a virtual interface provides unique access to LGBT youth who may not otherwise participate in research (75), and the internet is an important vehicle by which LGBT youth seek information and support regarding their sexual orientation, gender identity and mental health (72, 76).

The three groups of participants (LGBT youth, family/carers and staff) will be given a choice of interview mode. Topic guides for the individual interviews will be informed by the evidence syntheses and piloted in consultation with our LGBT Youth advisory group. The costing study from the case study sites will collect data from individuals when interviewed. We will ask questions about use of health care, social care or any other services (primary care, hospital care, medicines, school nurses, online services, support groups, etc.) and mental health services in the last three months to calculate service cost (costs will be taken from published sources).

All of the interviews will be audio recorded (or downloaded in case of online interviews) and subsequently transcribed. Non-professional participants (e.g. young people and parents/carers) will be offered £20 in gift vouchers as a token of thanks for participation.

- Focus groups

A focus group is a research method using a group discussion where the researcher is actively encouraging of the group interaction to elicit a wide range of views, perspectives and ideas (74). Focus groups are particularly effective as a research method on under-researched, sensitive topics (77) and for accessing marginalised population groups because speaking with others 'like you' may be less intimidating or stigmatising than speaking to a researcher alone (78). The interactions between focus group participants often produces unexpected perspectives and this method can be used for collective problem-solving such as 'what should mental health services for LGBT youth look like?' The lead applicant has used focus groups with LGBT youth to investigate mental health and found them effective at eliciting unexpected and unknown knowledge that goes beyond interview data (11, 27).

We will conduct two focus groups with LGBT youth (one for LGB youth (n=6) and one for gender diverse youth (n=6)) at each case study site, these may be face-to-face in the service setting (e.g. school, LGBT youth group, CAMHS) or online (where the case study site is web-based). The topic guide will be informed by the stage 1 evidence synthesis and piloted in consultation with our LGBT Youth advisory group. All of the focus groups will be audio recorded (or downloaded in case of online) and subsequently transcribed. Participants will be offered £20 in gift vouchers as a token of thanks for participation.

- Virtual non-participation observation

We anticipate that some of the case study sites will be online and this is especially important because LGBT youth specify online support as their preferred route to getting mental health assistance (8, 10, 72). Data from these sites will be collected via 'netnographic' non-participation observation. Netnography is a form of ethnography that has been used in the study of online health behaviour (79), and similar to ethnography, it is concerned with everyday routine behaviours in a natural setting (80). The lead applicant and Pryjmachuk (co-applicant) have extensive experience of conducting studies examining young people's mental health using online methods and netnography (8, 10, 11, 20, 70-72) and this method is appropriate for the observation of a service that may operate entirely online. All postings over a 4-month time period during the data collection in year 2 of the study will be collected from appropriately identified discussion boards. These discussion threads with their individual messages will be screened for relevance, using 'age', 'sexual orientation', 'gender identity' and 'mental health' as an inclusion criteria. The postings will be copied from the website and pasted into Microsoft Word prior to analysis in Atlas.ti/7.

- Documentary review

Where available, relevant documentary evidence will be collected from each site such as operational manuals, service evaluations, administrative service datasets, strategic plans, intervention protocols, information leaflets. The documentary evidence will largely serve to provide a contextual background to, and additional understanding of, the 12 case studies.

Data analysis

Case study research requires data from a variety of sources and generates large volumes of data that need to be managed systematically (12, 73) with a clear analytical data strategy in place prior to data collection (22). Case study evaluation is a theory-driven evaluation methodology and therefore the data analysis strategy is theoretical using the ‘explanation-building’ analytical technique (12). Explanation-building in case study’s with multiple case sites (like ours) aims to build a general explanation that fits each individual case. Yin (12) (p.142) states this is ‘analogous to creating overall explanation, in science, for findings from multiple experiments’. The programme theory developed from Stage 1 evidence synthesis will provide the theoretical orientation for the case study data analysis. A clear theoretical proposition provides a coherent frame when combining data from multiple methods for a within case and cross-case analysis (22).

Firstly the four data sets – interview transcripts, focus transcripts, documentary evidence and the online group postings – from each individual case study site will be imported into Atlas.ti.7 computer software designed to assist in the organisation and analysis of qualitative and mixed-methods data. The data for each case study site will then be analysed thematically in 3 stages: i) descriptive and conceptual coding; ii) cross sectional analysis of clustered coded data; iii) interpretative analysis (81, 82). The findings from each case study site will be examined and compared to the programme theory, the theory will be revised, and the evidence examined again. This is an iterative process and it is important to ensure other plausible explanations are considered in the process (12, 22). In this way the findings from each case study site data analysis are used to gradually refine the theoretical model developed in stage 1 to produce an overarching theoretical understanding of the mechanisms by which mental health early intervention services and self-care can support LGBT young people with common mental problems.

Costs will be presented using a NHS and social care perspective, as suggested by NICE guidance. Total costs will be calculated by multiplying resource use with the accompanying unit costs collected from routine NHS sources (e.g. NHS reference costs and British National Formulary (BNF)) and from mental health services. For each case study site we will be able to provide a profile of services used and respective average costs at user lever. Information collected on services used within and outside the NHS will be used to inform the commissioning guidance that will be produced at the end of the study.

We will share our case study evaluation findings with Pryjmachuk’s team so they may test their identified models of high quality service provision for CYP for applicability for LGBT youth.

Dissemination and Projected Outputs

OUTPUTS

Service provider and user outputs:

- NIHR HS&DR journal report
- Third sector research summary
- LGBT young people ‘fact-sheet’

- NHS commissioning guidance and short (10) commissioning guidance slide show

The development of co-produced guidance for commissioners will be led by Wesson (co-applicant) who has direct experience of commissioning mental health services for LGBT youth. An expert reference group will be established drawing from both the Project Advisory Group and other individuals identified through the research. This group will work closely with the LGBT Youth Advisory Group and will comprise of the research team (including a service user), CYP mental health commissioners and clinicians, and representatives from those providing early intervention mental health and self-care support to LGBT youth. The expert reference group will begin work in month 31 when the case-study evaluation is complete in order to incorporate evidence from this last phase of the research.

The commissioning guidance will be compatible with available guidance for commissioners of CAMHS, and consistent with national mental health strategy, including Sustainability and Transformation planning and Local Transformation planning. This includes the planned guidance commissioned by NHS England from the National Institute for Health and Care Excellence and the National Collaborating Centre for Mental Health to develop generic and crisis CYP mental health ‘pathways’ to support commissioners and providers across health, social care, education and the voluntary sector (DH and Dept. of Education, 2017).

It is anticipated the guidance will concentrate on the following components: i) Key messages for commissioners; ii) what is currently known about LGBT youth early intervention mental health services; iii) what good looks like; iv) strategic planning; v) designing service specifications and contracts; vi) developing providers; vii) monitoring and evaluation. The draft guidance will be discussed at the Knowledge Mobilization Conference with nationwide service

users, providers and commissioners. A dissemination and communication plan will be formulated by the expert reference group which will guide the distribution of the final publication.

We will liaise with HS&DR 17/09/08 project to ensure outputs are complimentary across both projects.

- LGBT youth 'Can you help?' animation:

Cartoons have proven to be an effective form of health communication (83). This animation co-produced with the LGBT Youth Advisory Group will explain the type of mental health support LGBT young people need and want. We will work with Fruitfly Collective (<http://fruitflycollective.com>) a BMA award winning company that specializes in using creative practices for communication and understanding of health. The online resource will be aimed at YP and professionals working in health and education.

Professional journals: We will write articles reporting findings for health and social care professional publications such as Mental Health Practice and online media such as mentalhealthtoday.co.uk

Academic publications: We will produce 2 gold open access peer-reviewed academic journal papers: i) evidence synthesis paper; ii) a paper reporting the evaluation findings.

DISSEMINATION

Study website: This will be central to dissemination and provide electronic access to all research outputs. Links to the study website will be circulated through the study twitter and Facebook accounts.

Social media: McDermott @QueerFutures and Hughes @RESPECTstudy have both used social media successfully in previous research studies to disseminate outputs. The proposed study will have a twitter and Facebook account to disseminate findings.

Knowledge mobilization conference: We will organize a national event to present findings and seek expert opinion on the draft commissioning guidance. All key stakeholders will be invited.

Conferences: Findings will be presented at 3 conferences: i) Faculty of Public Health Conference; ii) RCN International Mental Health Nursing Research Conference; iii) European Conference on Mental Health.

Professional networks: We will disseminate via professional and third sector organizations e.g. NHS England, CCGs, NIHR regional clinical networks, Royal College of Nursing, Royal College of Psychiatrists, CLAHRCs, Stonewall, National LGB&T Partnership.

IMPACT

We will work with key stakeholders from the NHS, Public Health England, Local Authorities and third sector organisations to ensure the outputs will be adopted within the NHS. Key knowledge mobilization strategies include:

Knowledge mobilization conference: We intend to have an end of study conference aimed at key stakeholders i.e. mental health service commissioners, service providers, LGBT youth, third sector organizations and local authorities. The draft commissioning guidance will be discussed and finalized. The aim of the conference is to develop robust commissioning guidance through debate with service users, providers and commissioners.

Electronic outputs: The availability of resources that can be accessed free of charge from the project website has been used successfully in the past by McDermott (CI) and Hughes (CA) in studies (e.g. www.queerfutures.co.uk) and ensures a wide distribution and use.

LGBT Third sector organizations: Key to impact and knowledge mobilization will be the network of LGBT third sector organizations that work at a local and national level to address the inequalities in health service provision to LGBT people. Key organizations and initiatives include: LGBT youth groups, Stonewall, LGBT Foundation's Pride in Practice initiative, The National LGBT Partnership which is a national umbrella organization that aims to reduce health inequalities and improve access to health care for LGBT people. Both the lead applicant and Johnson (co-applicant) have well established networks with the sector.

NHS Networks: We intend to utilize our work with the following NHS networks to ensure knowledge mobilization:

- The North West Coast, Yorkshire & Humber and Greater Manchester Collaborations for Leadership in Applied Health Research and Care (CLAHRC)
- NIHR School for Public Health Research through the Liverpool and Lancaster Universities Collaboration for

- Public Health Research (LiLaC).
- NIHR Clinical Research Networks (Regional and Children, Mental Health and Public Health)

MCDERMOTT (CI) is a co-investigator in the North West Coast CLAHRC and NIHR School for Public Health. HUGHES (CA) is a co-investigator in the Yorkshire and Humber CLAHRC and is a member of the CLAHRC-YH research capacity building work stream (ACORN). PRYJMACHUK (CA) is a co-investigator in the Greater Manchester CLAHRC and the Manchester Academic Health Sciences Centre (MAHSC), (University of Manchester collaboration with six local NHS trusts). CLAHRC is an NIHR infrastructure that supports research that has direct impact for the NHS on topics related to clinical need. CLAHRC also supports dissemination of findings into service through Knowledge into Action. All CLAHRCs have a mental health theme and in the North West Coast CLAHRC, MCDERMOTT (CI) is a member of the 'Improving Mental Health' work stream and in addition is part of the CYP mental health work developing across CLAHRCs nationally. She is also involved in the NIHR School for Public Health Research 'Child Mental Health' work. HUGHES (CA) is part of the 'Mental Health and Comorbidities' stream in Yorkshire and Humber CLAHRC which aims to undertake research to address health inequalities in those who have mental health problems. PRYJMACHUK (CA) is part of the 'Mental Health' work programme of the Greater Manchester CLAHRC. Our research proposal fits well within these work streams and is likely to be informed by our on-going relationships within these networks. This will mean the evidence we produce will benefit from networks that are set-up to assist the translation of research into the organisation and delivery of mental health services.

Professional networks: All the research team members are involved in the improvement of young people's mental health and are in a position to ensure the outputs are recognized and utilized through their professional work. This includes the Dept. Health, the Government Equalities Office, Royal College of Nursing, Royal College of Psychiatrists, NIHR CLAHRCs, NIHR School for Public Health Research, CCGs, NIHR regional clinical networks, The British Psychological Society.

HS&DR 17/09/08 project: We will liaise with Pryjmachuk's team to maximize impact. Since the target audiences are likely to be similar for both studies we will, if possible, hold the two final stakeholder events jointly. We will share appropriate outputs (e.g. the commissioning guidance, third sector summary and social media outputs) with Pryjmachuk's team and publicise the launch, progress and findings of our respective studies on each other's study websites and social media channels.

Plan of Investigation and Timetable

TIMETABLE

This is a 36 month project and the timetable is in table 2 below:

Table 2. Project timetable

Pre-project start date: recruit Lancaster administrator (Lancaster and Leeds researcher currently in post).	
YEAR 1 EVIDENCE SYNTHESIS AND SERVICE MAPPING	
Month 1 Research set-up	Establish LGBT Youth Advisory Group, project advisory group, steering group; develop project website and social media, Research Team Management meeting. <i>Key milestones: LGBT Youth Advisory Group and project advisory group established; project website functioning; staff employed</i>
Month 2-12 Evidence synthesis Service mapping	Evidence synthesis (Lancaster); service mapping (Lancaster and Leeds); ethics application (Leeds); apply for research ethics approval (month 9); recruit researcher (Brighton month 9), PPI, share SR literature and liaise re: case study sites with HS&DR 17/09/08 project. <i>Key milestones: Production of evidence synthesis and programme theory, ethics approval received, service mapping complete, Brighton research staff in post</i>
YEAR 2 CASE STUDY DATA COLLECTION	
Month 13 pilot	LGBT Youth Advisory Group to pilot topic guides for interview and focus groups.
Month 14-15 Recruitment	Case study sampling and recruitment (Lancaster, Leeds, Brighton)
Month 15-24 Data collection	Data collection (Lancaster, Leeds, Brighton)

	<i>Key Milestones:</i> Completion of 12 case sites data collection
YEAR 3 CASE STUDY DATA ANALYSIS AND OUTPUTS	
Month 25-30 Data analysis	Case study data analysis, PPI.
Month 31-36 Outputs	Produce planned outputs and disseminate; LGBT Youth Advisory Group to develop animation; specific meeting on producing commissioning guidance, organise knowledge mobilization conference, liaise with HS&DR 17/09/08 project to maximize outputs and impact
	<i>Key Milestones:</i> Production of electronically available: commissioning guidance; slide show on commissioning guidance; LGBT youth ‘Can you help?’ animation; third sector research summary; LGBT YP ‘fact-sheet’, professional journal articles submitted; academic journal articles in process; conference papers submitted, Knowledge mobilization conference organised.

WORK RESPONSIBILITIES AND WORKLOAD ALLOCATION:

Table 3. outlines the distribution of the workload and responsibilities across the research team:

Table 3 Project responsibilities and workload

	<i>Year 1</i>		<i>Year 2</i>	<i>Year 3</i>
	Stage 1 Evidence synthesis	Stage 2 Service mapping	Stage 3 Case study	
Workload allocation and leads:				
Lancaster 0.3WTE McDermott 1WTE RA (Rachael Eastham) (36 months)	Stage 1 lead Project set-up Evidence synthesis	Stage 2 lead Fieldwork Data entry Typology	Stage 3 joint lead Case site recruitment 4 case sites fieldwork	Case study analysis Lead on report and academic publications
Leeds 0.1WTE Hughes 1WTE (Emily Patterson) (36 months)	Stage 3 Ethics (lead)	Fieldwork Data entry Typology Stage 3 ethics	Stage 3 joint lead Case site recruitment 4 case sites fieldwork	Case study analysis Lead on commissioning guidance
Brighton 0.1WTE Johnson 1 WTE RA (month 13-36)	PPI (lead)	PPI	Stage 3 joint lead Case site recruitment 4 case sites fieldwork PPI	Case study analysis Lead on youth/community outputs & animation PPI

Project Management

This programme of work will be hosted by and managed from Lancaster University (LU). Financial management will be in accordance with LU and our partner organizations’ requirements. The CI (McDermott) will have direct control of the NIHR funding and her leadership will be supported by the Research Management Group (RMG) arrangements. There will be 4 levels of project management to facilitate effective communication (electronic and face-to-face), to monitor progress and ensure the work is completed within budget and in the timeframe:

1. The Steering Group: We will set up independent oversight group comprising of expert academics, clinicians and people with lived experience – all of whom will be unconnected to the study team and their organisations. The purpose of this is to provide independent oversight of the study progress and provide critical feedback to the team at each stage. It is likely that this group will meet up face to face once per year and also use teleconference facilities for any other meetings that are required. We will provide a report prior to each independent advisory group meeting, as well as minutes of the meeting which we will upload to the HSDR via NETSCC-MIS. We will report any adverse events and protocol breaches to this group. The chair of the independent oversight group will be able to make recommendations to

the funder on the outcomes of any adverse events or failure to meet milestones including requesting a termination of the study or extension of deadlines. We have budgeted for travel and subsistence for this activity.

2. The Research Management Group: will comprise all the applicants including service user, research staff and project administrator, and will meet every four months (face to face and electronically) and be responsible for ensuring progress according to project milestones and deliverables within each of the 3 stages of the research. The project advisory group will be invited to attend these meetings, in addition to a 'commissioning guidance' working group meeting in year 3.

3. Project Leads Group: will comprise of the CI, the two co-applicants with specific workload responsibilities (Hughes – Leeds, Johnson – Brighton) and the research and administration staff. They will meet monthly to ensure cohesion and a smooth transition between different work stages. Meetings will also be timed at key project points e.g. development of programme theory, production of data collection tools, data analysis strategy.

4. Project Site Staff Group: at the 3 project sites (Lancaster, Leeds, Brighton) each lead (McDermott, Hughes, Johnson) will meet weekly with the researcher on site to discuss the day to day running of the project and ensure the allocated workload is being conducted satisfactorily.

There are some project management activities that will enhance our collaboration with Pryjmachuk's HS&DR study:

- We will exchange study protocols with Pryjmachuk's team.
- The studies' PIs will have regular telephone discussions regarding the progress of the two studies.
- Pryjmachuk is a co-applicant on McDermott's study; a team member from McDermott's study will be invited onto the advisory group of this study.
- The five researchers on the two projects (three based in Lancaster, Leeds and Brighton for this study; two based in Manchester and Cardiff for Pryjmachuk's) will meet face-to-face on a six-monthly basis throughout the lifetime of the studies and keep in touch via email and telephone at other times. This will provide an additional support network for the researchers and should also help capacity building for these researchers. It will also help ensure that different case study sites are used in the two studies.

Approval by ethics committee

ETHICAL ISSUES

There are ethical issues that arise from researching a marginalized population (LGBT) and a sensitive topic (mental health). Stage 1. evidence synthesis and stage 2. service mapping are desk-based and do not require the involvement of human participants. The stage 3 case study will involve LGBT young people, family members and service staff and there are consequently important ethical issues to address.

Ethical research is underpinned by three inter-related factors: (1) informed consent; (2) the safety of participants and researchers; and (3) the safeguarding of any data obtained during the course of the research. However, ethical research code of conducts rarely discuss the application of such standards to the problems which may arise when researching LGBT young people (84). A major ethical challenge is that by asking young people about their sexual orientation and gender diversity this may place young people at risk from discrimination (e.g. homophobic bullying) or harm (e.g. emotional distress). It may also be a sensitive question because they are undecided, confused and/or apprehensive about their LGBT status and/or their mental health. This proposed study will seek ethical approval via the NHS research ethics process and address the main ethical issues as follows:

Informed consent

For participants in interviews and focus groups, informed consent will be gained through a written signature (face-to-face) or an electronic signature (online). This has been successfully used in studies with other marginalized population groups including the lead applicant's (9). Informed consent is an ongoing process, with participants being reminded of their right to withdraw at intervals throughout the study. For those LGBT young people aged 12-15, they will be afforded the right to give consent. Parental consent is not always possible because it may place the young person at risk of hostility, abuse and rejection if their parents are unaware of their sexual orientation or gender diversity (84). It is increasingly recognized that young people are able, and should, give consent for taking part in research as long as they are judged as competent (85-88). In Medical Research Council ethics guidance on research with children, competency is considered not to depend primarily on age, but rather on the ability to understand and weigh up options (88). Competency can be influenced by the way information is presented and many young people will be competent if information is presented in an appropriate way and they are supported through the decision-making process (88). The

three main components of informed consent are: is the information presented in an understandable way; consent is voluntary; and the participant has capacity to provide consent (85).

Participant and researcher safety

LGBT youth who are potentially vulnerable will be recruited and a priority throughout the study will be to ensure young people are not harmed by contributing to the research. Although some participants may find it difficult to discuss or reveal personal issues, others are known to find it very useful and affirming (9, 89). All participants will have access to support (e.g. youth groups, mental health and LGBT-specific support) via telephone, internet or when appropriate on site (face-to-face interviews). A procedure for reporting risk and adverse events will be in place, and the research staff will receive training on recognising and responding to these. During data collection, the researchers will have the telephone number of a designated senior member of the research team who will be available for advice if any potential issues arise. In the event that a research participant involved in the study is assessed as at risk, it will be necessary to break confidentiality. This protocol was used in the lead applicant's previous study and no adverse incidents were reported.

Safeguarding of data

Confidentiality and anonymity are crucial to ensuring that LGBT young people are able to participate safely (90). Online methods, such as the proposed on-line interviews, have been highlighted as beneficial for helping to preserve the anonymity of vulnerable participants thus enabling them to be included in social research (78). All identifying features will be removed from the data. All anonymised data will be stored electronically on a password protected secure drive on a university server. Interviews and focus groups will be recorded using encrypted digital recorders. These and the downloaded online interviews/focus groups/posts will be deleted when the anonymised electronic transcripts have been created. Paper consent forms will be kept in a secure location.

ETHICAL APPROVAL TIMELINE

- Month 1-6 Development of programme theory required for ethics approval
- Month 7-8 Write ethics protocol
- Month 9 Submit Ethics application for review
- Month 12 NHS Ethics approval
- Month 13-24 Data collection
- Month 26-36 Data analysis and production of outputs.

Patient and Public Involvement

The aim of involving LGBT young people, the public and service users in the proposed study is to ensure that we generate research that will be useful to a wide range of stakeholders. In our experience it is not possible to produce high quality research without the involvement of those it impacts upon. Being young, LGBT and having mental health problems remains stigmatizing and isolating. As a consequence some LGBT youth do not use mental health services and are reluctant to talk to adults in their lives. In order to identify and understand mental health early intervention services and self-care support for LGBT young people, we need their active involvement to help us to ask the right questions, in the right way and gain an in-depth rigorous understanding of their mental health support needs.

Our study will involve service users and the public in three ways. A service user from OpenMinds, a LGBT mental health youth group, will be part of the research team and will attend research team management meetings. We will provide training, support and payment for the service user to participate in these meetings. They will have direct experience and knowledge of mental health services and the issues faced by LGBT young people.

The second way we will involve the public and patients is through a LGBT Youth Advisory Group that will consist of young people from 3 LGBT youth groups: The Proud Trust in Manchester, Leicester LGBT Centre and Allsorts in Brighton. This group will 'meet' virtually throughout the study using an online media format (e.g. twitter, Facebook) that will be determined by the young people at the initial study training day. This will be supplemented by two face-to-face meetings for each year of the study. The young people's advisory group will run the project blog from the study website to engage a range of LGBT young people. Young people use blogs widely and they offer an innovative interactive PPI tool that enables a broader range of public/service user involvement. The lead applicant has successfully used social media to involve LGBT young people in previous mental health research [11] and the young people who were involved stated that using online media made it easier to take-part.

The LGBT young people's advisory group will contribute to the development of study materials, participant recruitment, interpretation of findings and dissemination activities. In particular they will co-produce the commissioning guidance and the **LGBT youth 'Can you help?' animation**. Cartoons have proven to be an effective

form of health communication [48]. This animation made with the LGBT youth advisory group will explain the type of mental health support LGBT young people need and want. This online resource will be aimed at YP and professionals working in health and education and be freely available via the study website.

The third strand of our patient and public involvement is the study's Advisory Board which will include a range of LGBT third sector stakeholders who work with young people e.g. Gendered Intelligence, Albert Kennedy Trust.

Expertise and justification of support required

RESEARCH TEAM EXPERTISE

McDermott (chief investigator) is a Senior Lecturer in Health Research at Lancaster University. She is an expert in LGBT young people's mental health. She has over 15 years experience in leading studies funded by ESRC, British Academy, Equality and Human Rights Commission. Her last 29 month study, funded by the DH Policy Research Programme (330K) was completed on time and within budget. She has expertise in systematic reviews, qualitative methods, mixed methods and online methods. She specializes in theory-led methodologies. She will have overall responsibility for the management of the study, lead on all 3 stages, supervising the data collection, analysis and production of outputs.

Hughes (co-applicant) is a Professor of Applied Mental Health at the University of Leeds. She has a track record delivering on large and complex NHS research projects over multiple sites as lead investigator as well as local investigator for NIHR and the Department of Health. Hughes has worked in health services research since 1999 and has methodological expertise in randomized controlled trials, undertaking surveys and needs assessments, and mixed methods, as well as stakeholder engagement. She will supervise the NHS ethics application, data collection & analysis in the Yorkshire & Humber region and jointly lead the commissioning guidance output.

Johnson (co-applicant) is a Professor of Psychology at the University of Brighton. She has been researching the mental health of LGBT populations for over 15 years and was involved in the first national study of LGB mental health in the UK (King et al, 2003). She has expertise in theory-led methods, qualitative methods and community-participation methods. She will supervise PPI, the data collection and analysis in the London/South region and lead the production of the community/youth outputs.

Prymachuk (co-applicant) is a Professor of Mental Health Nursing at the University of Manchester. He has significant experience of health services research having been an investigator in 5 funded NIHR projects, including one as Principal Investigator. This latter project was a large scale project exploring self-care support in children and young people's mental health. It included evidence syntheses of the international literature, mapping of services and empirical case study research across several sites in the UK. He has large scale project management expertise in both research and healthcare education. He will advise.

Mateus (co-applicant) is a Senior Lecturer in Health Economics at Lancaster University and has expertise in health economics and the evaluation of mental health services. She will advise on the health economic requirements for data collection and analysis.

Open minds service user (co-applicant) has experience of mental health services and the needs of LGBT young people. They will advise on the design and conduct of the research, the production of all outputs and the dissemination strategy.

PROJECT ADVISORY GROUP COLLABORATORS:

Polly Blydes, Visible LGBT+ Leader and *Amulya Nadkarni*, Consultant Child and Adolescent Psychiatrist from Lincolnshire Partnership NHS Foundation Trust. Both have been involved in developing LGBT sensitive mental health services.

Andy Kerr, Mental Health Commissioner, Liverpool/Merseyside CCG, has experience of developing mental health services for LGBT people and commissioning mental health services for LGBT youth.

Jane Davies, Senior Mental Health Nurse Practitioner (CAMHS School Link Pilot), *Louise Theodosiou*, Consultant Psychiatrist CAMHS from Central Manchester NHS Foundation Trust and *Emily Edwards*, Senior Commissioning Manager, Children's Services, Salford City Council. All three are leading the development of LGBT youth specific mental health services in Greater Manchester

Ali Hanbury, The Proud Trust, Greater Manchester based LGBT youth organisation that provides a range of mental health support.

Anna Roscher, Allsorts, Brighton based LGBT youth organisation that provides a range of mental health support.

Jay Stewart, Gendered Intelligence, national charity supporting transgender young people, that provides a range of mental health support and involved in developing mental health staff training.

Harri Weeks, LGBT Partnership, national charity aiming to reduce LGBT Health Inequalities.

JUSTIFICATION OF SUPPORT

Staff

Ensuring the correct staff expertise and time is crucial to successfully meeting our objectives. We have costed staff only if they will make a clear contribution to the study. Co-applicants are costed at: 5% FTE if they are acting in an advisory capacity only; 10% if they have an additional supervisory role; 30% for the CI because the study relies on her expertise and she will have overall responsibility for managing the research.

Three research staff will have responsibility for data collection and analysis in their geographical regions (North West, Yorkshire & Humber, London & South). They are costed depending on their role, grade 6 for fieldwork and analysis, grade 7 for those roles that require more expertise (e.g. complex data analysis, NHS ethics, journal writing). Their workloads are allocated as:

- LANCASTER, 1FTE (grade 7) (Rachael Eastham) 36 months: Y1 project set-up, evidence synthesis and service mapping; Y2 data collection; Y3 data analysis and production of outputs.
- LEEDS, 1FTE@ 36 months (grade 7) (Emily Patterson): Y1 NHS ethics, PPI, service mapping; Y2 data collection; Y3 data analysis, and production of outputs.
- BRIGHTON, 1FTE 24months (grade 6): Y2 data collection, PPI; Y3 data analysis, PPI and production of outputs.

We have costed for a project administrator at Lancaster (0.5FTE grade 4) to perform the administration associated with co-ordinating a large-scale study. This ensures research staff are not burdened.

Technology and equipment

We have costed for a study website to be built that will be key to recruitment of participants and dissemination of outputs. We have included cost of a computer, digital recorder and headphone for each of the 3 researchers.

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