



## **HS&DR STUDY PROTOCOL**

<b>Project title:</b>	Developing a model for high quality service design for children and young people with common mental health problems
<b>Short project title:</b>	Blueprint: Service design for children and young people's mental health
<b>HS&amp;DR Project reference:</b>	17/09/08
<b>Version:</b>	1.2
<b>Date:</b>	22 <sup>nd</sup> June 2021
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<b>Sponsor:</b>	University of Manchester (from 15 <sup>th</sup> January 2020), delegated from Greater Manchester Mental Health NHS Foundation Trust (Sponsor from 1 <sup>st</sup> October 2018 – 14 <sup>th</sup> January 2020)
<b>Funder:</b>	National Institute for Health Research, Health Services & Delivery (HS&DR) programme
<b>PROSPERO Registration</b>	CRD42018106219
<b>IRAS Project ID</b>	272762
<b>NIHR CRN portfolio number:</b>	272762/1412852/20/389
<b>Research ethics approval:</b>	(For Workstream 3) South Central - Berkshire Research Ethics Committee reference 20/SC/0174
<b>Start date:</b>	1 October 2018
<b>End date:</b>	30 April 2022

## Protocol version control

Version	Date	Author(s)	Details
0.1	04-09-17	Applicant team	Original detailed project description (DPD) submitted as part of the stage 2 (full) application
0.2	28-03-18	Applicant team	DPD revised following feedback from the HS&DR panel after provisional funding awarded. NIHR approved version of the DPD.
1.0	30-08-18	Steven Prymachuk	Approved DPD renamed project protocol; NIHR logo, cover sheet and version control box added.
1.1	04-03-20	Claire Fraser; Steven Prymachuk; Sue Kirk	Updates to research sponsor; additions to research team; co-applicant changes; addition of third sector partner for co-researcher recruitment. Division of Responsibilities section added.
1.2	22-06-21	Steven Prymachuk	Research ethics approval reference added. Change to end date and project timetable (section 7) following of seven-month costed extension agreed by the NIHR as a result of the coronavirus pandemic

## 1. Summary of research

The mental health of children and young people (CYP) is a national and international priority, with around 1 in 10 UK CYP having a mental health difficulty. Most of the need lies with CYP experiencing 'common' mental health problems (CMHPs). CMHPs are a range of psychological, emotional and behavioural problems that includes anxiety, depression, obsessive-compulsive disorder (OCD), self-harm, post-traumatic stress disorder (PTSD), gender identity issues and emerging personality disorders. While health needs for this population group are rising, services across the UK tend to be fragmented, uncoordinated and variable, and most struggle to meet demand.

This study aims to develop a model (or models) of effective, high quality service design for this population group by examining the factors that facilitate access to, and navigation of, services for CYP experiencing CMHPs and the effectiveness and acceptability of those services. CYP with CMHPs typically do not require hospitalisation so the services investigated will be out-of-hospital services providing primarily assessment/triage, early intervention and supported self-care. This evidence-based model will help inform the NHS and assist commissioners and providers in the design and transformation of out-of-hospital services for this population group.

The study has four work streams. In Work Stream 1, a series of systematic reviews of the international literature will be conducted, specifically:

- (a) a *scoping* review identifying the range of service models available internationally for CYP experiencing CMHPs;
- (b) an *effectiveness* review that identifies and evaluates those service models where comparative effectiveness data are available;
- (c) an *acceptability* review that identifies and evaluates those service models where acceptability data are available; and
- (d) an *economic* review that considers provider and user costs/benefits associated with specific service models.

The reviews will be synthesised using EPPI-Centre meta-synthesis principles.

In Work Stream 2, a survey and the literature obtained in Work Stream 1 will be used to map current services in England & Wales across a range of different service dimensions (referral/access arrangements, theoretical underpinnings, location, staffing, provider, delivery platform, etc.). A typology of service provision for CYP experiencing CMHPs will be derived from Work Streams 1 and 2.

In Work Stream 3 (a collective case study), 8-10 services will be purposively sampled from Work Stream 2's service map to reflect the various dimensions of the typology. At each site, in line with the principles of case study research, we will: (a) conduct interviews with key stakeholders, i.e. providers, managers and users (including those who could not or did not access services); (b) obtain relevant documents; and (c) observe, where possible, key interactions. These three case study datasets will be analysed using Framework. We will also collect economic data in Stream 3 for which bottom-up estimates of costs associated with services will be calculated.

In Work Stream 4, data from all three work streams will be synthesised to elicit a model (or models) of effective and acceptable, high quality service design for CYP experiencing CMHPs that integrates all of the factors associated with accessing, navigating and receiving help from services for this population group.

Service user and provider perspectives will permeate the entire study via an independent advisory group (that will include NHS commissioners, CYP, parents, child (mental) health professionals and service managers), through having an NHS manager and service user group as co-investigators, and through employing young service users as co-researchers. The advisory group will have an independent chair and we anticipate having a young service user co-chair this group with an independent chair.

*The NIHR has asked that this study collaborates with a related study that they have also funded under the same call (HS&DR 17/09/04, PI McDermott, Lancaster University: 'Identifying and evaluating mental health early intervention services and self-care support for lesbian, gay, bisexual and transgender young people: A mixed methods study'). Prymachuk is a co-application on this study. 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.

## 2. Background and rationale

For over a decade there have been consistent reports of fragmented, uncoordinated, variable and inaccessible services that often lack an evidence-base<sup>1-10</sup>. Moreover, to date, the disparate factors associated with accessing and navigating high quality healthcare services for CYP experiencing CMHPs have not been synthesised into a coherent model of effective and acceptable high quality service provision: we propose to address this.

Many factors influence how access to health care is navigated<sup>11-12</sup>. First, a population or individual health care need has to be identified. This need requires matching to an available service, usually via a 'first contact' agency (e.g. GP, school counsellor, helpline), and a desire by individuals to use that service. Several access barriers can emerge at this point. Barriers identified in CYP's mental health in our prior NIHR research<sup>6,13-14</sup> include: **individual** barriers (e.g. cultural inappropriateness, previous experiences); **social** barriers (e.g. fear of stigma or dislocation from peers); **organisational** barriers (e.g. service unavailability); and **financial** barriers (e.g. costs of travel to services/taking time out of work).

Where services are available, access and navigation is affected by elements such as theoretical stance, location, staffing, provider and delivery platform. A variety of service models in CYP's mental health are available across the UK with varying claims about their effectiveness, e.g. CYP IAPT, THRIVE/iTHRIVE, and the Choice & Partnership Approach (CAPA). Our previous NIHR work on self-care support in CYP's MH<sup>6</sup> found factors like choice, child-centeredness and staff flexibility may be more important than a service's theoretical stance. The degree to which the outcomes expected of a service are concordant with those obtained is another factor. Service delivery is thus subject to translational complexities: a service predicated on seemingly effective, evidence-based *interventions* may not necessarily be effective in itself, i.e. services may emphasise specific interventions at the expense of important secondary service characteristics such as accessibility, child-centredness and the 'fit' with the individual child or young person.

## 3. Why this research is needed now

This proposal has been designed in response to a specific NIHR research call that reflects general concerns about CYP's mental health and the services provided for this population group. The mental health of CYP is a national<sup>4-10</sup> and international<sup>15</sup> priority, with 1 in 10 children aged 5-16 having a mental health difficulty<sup>16</sup>. Healthcare need in this area is rising and services across the UK are fragmented, uncoordinated, variable and struggling to meet demand<sup>7-10</sup>. Moreover, there is an acknowledged link between CYP's health and well-being and their educational attainment<sup>17-18</sup>. We also know that half of all adult mental health problems begin in childhood, so there is a clear benefit in early intervention, i.e. addressing mental health needs when they first present<sup>16,19</sup>. Yet CYP's mental health is under-researched and under-resourced, receiving only 0.6% of the total NHS budget<sup>20</sup>. While there has been some additional investment in services for CYP experiencing CMHPs, there appears to be a lack of understanding and evidence about what works in what context and investment has not necessarily produced the anticipated outcomes.

The recent introduction of Sustainability and Transformation Plans (STP) in England provides further impetus for conducting this research. The majority of the research team are based in Greater Manchester which has had a year's advantage over other STPs via the so-called 'Devo Manc' initiative. Its STP – *Taking Charge of our Health and Social Care*<sup>21</sup> – explicitly emphasises the importance of transforming out-of-hospital care in both physical and mental health. We also have a team member based in Wales, another geographic area with a devolved administration. Our links with these devolved administrations provides opportunities to both influence service transformation in CYP's mental health in devolved areas and be influenced (via the case study sites) by any existing novel or innovative services in these areas.

Specific reasons for conducting this research include:

- **A discrete health need:** CYP's mental health is a national and international priority, with 1 in 10 children aged 5-16 having a mental health difficulty. In addition, half of all adult mental health problems begin in childhood so there is a clear benefit in addressing mental health needs when they first present. Across the lifespan, early intervention can improve educational and employment

opportunities, reduce the levels of substance misuse, self-harm and suicide, and increase life expectancy, economic productivity, social functioning and quality of life<sup>17</sup>.

- **An expressed need:** While there are increasing health needs among CYP experiencing CMHPs, services appear to be fragmented, uncoordinated and variable and many struggle to meet demand. Providing more money for existing services is not necessarily the answer given that the financial responses to crises in CYP's mental health identified in 1999<sup>1</sup> and 2008<sup>2</sup> did not result in any wholesale improvements in quality or access to services some 10-15 years later. In these times of financial prudence, evidence-based service redesign within the same or only modestly increased (or indeed reduced) budgets may be more apt and our proposed study can make a significant contribution to the NHS transformation agenda.
- **Sustained interest:** CYP's mental health is under-researched and under-resourced, receiving only 0.6% of the total NHS budget<sup>20</sup>. General societal concerns about CYP's mental health (reflected in recent, and likely to be continued, media focus on this issue) together with a continuing political drive for integrated care and parity of esteem between physical and mental health means that there is likely to be significant sustained interest in this topic in the future.
- **New knowledge generation:** We have generated new knowledge via previous NIHR and other studies<sup>6,13-14,22-23</sup> and anticipate that we will do so with this study. For CYP experiencing CMHPs, there is currently no model of effective service design that incorporates all of the factors and dimensions associated with accessing and navigating high quality health care services: this will be a principal output of our proposed study.
- **Organisational focus:** The primary focus of this study is the organisation and delivery of services for CYP experiencing CMHPs which is consistent with the HS&DR's remit.
- **Generalisable findings and prospects for change:** The principal output of the study will be the production of an evidence-based model (or models) of high quality service provision for CYP experiencing CMHPs. This should help commissioners and managers design, transform and deliver services that are tailored to the needs of the local population and which can be easily accessed and navigated by CYP and their families/carers.
- **Building on existing research:** The majority of team members (Kirk; Pryjmachuk; Evans; Bee; Bower) have already worked together on research relevant to this study, some of which was NIHR funded. In particular, team members have been involved in research on self-care support<sup>6,13,23-24</sup> and assessment and triage<sup>22</sup> in CYP's mental health. Our previous research contributes to this research in two ways. Firstly, the findings from our previous research projects provide a foundation for this research in that we already have background knowledge around service provision, self-care support, assessment and triage in CYP's mental health. Secondly, since our proposed research methods have been 'tried-and-tested' in our previous research projects, we know that they are capable of producing research that is rigorous and robust. Regarding building on our previous study on self-care support in CYP's MH<sup>6</sup> in particular, self-care is merely one approach to be considered within out-of-hospital services for CYP with CMHPs alongside others that we and the brief have specified (eg triage and early intervention). It is likely that other approaches will be identified during the project. Our previous self-care study was published in 2014 but conducted in 2011-13. Since then, there has been growing interest in self-care/self-management in MH (e.g. it features within the Five Year Forward View for Mental Health<sup>25</sup>) and, some 5 years later, it is worth re-exploring this aspect within the broader context of out-of-hospital care for CYP with CMHPs to see how much services have (or have not) changed.

#### 4. Study aims and objectives

*Aim:* to develop a model (or models) of effective, high quality service design for children and young people (CYP) experiencing common mental health problems (CMHPs) by identifying services available to this population group, barriers and enablers to access, and the effectiveness and acceptability of those services.

*Specific objectives:*

1. To systematically search, appraise and synthesise the international literature on services for this population group in order to (i) build evidence of the effectiveness and acceptability of current service provision and (ii) assist with the development of the descriptive typology described in Objective 2

2. To develop a descriptive typology of services for this population group in England & Wales through a survey of service provision and reference to the literature referred to in Objective 1
3. Through primary research, to explore the barriers and enablers that CYP and their families/carers experience in accessing and navigating these services
4. To identify the key factors influencing effectiveness and acceptability in order to build an evidence-based model of high quality service provision for this population group
5. To estimate provider and user costs/benefits associated with different service models
6. To make evidence-based recommendations to the NHS about future service provision

Our study addresses aspects 1 (evidence syntheses), 2.1 (effective service models), 2.2 (CYP and parents' navigation) and 2.3 (engagement of service users) of the commissioning brief. It may partially inform aspect 2.4 (parenting programmes).

## 5. Research plan and methods

### *Design*

The study consists of an evidence synthesis combined with primary research, using a sequential mixed-methods design that we have used in previous NIHR studies<sup>6,13-14</sup>. This design is useful for contrasting systematic syntheses of research/policy data with directly obtained service user/provider data to provide insights into help-seeking behaviour, access barriers and facilitators and why services underpinned by notionally effective interventions do not always have their intended outcomes.

There are four work streams in our study. Table 1 below and the attached flowchart outline how the four work streams map onto the study's aims and objectives and the specific research questions that will drive each work stream.

**Table 1:** Cross-referencing of objectives, research questions and work streams.

<b>Work Stream</b>	<b>Supports objectives</b>	<b>Specific research questions</b>
Work Stream 1: Literature reviews	1, 2, 4, 5, 6	What does the international literature say about the types of services available for CYP experiencing CMHPs? What is the international evidence for the effectiveness, cost-effectiveness and acceptability of these services?
Work Stream 2: Mapping/typology	2, 4, 6	What out-of-hospital services are available in England & Wales for CYP experiencing CMHPs? What are the characteristics of these services?
Work Stream 3: Case study	3, 4, 5, 6	What are the barriers and enablers that CYP and their families and carers experience in accessing and navigating services for CYP experiencing CMHPs in England & Wales? What factors determine whether a service is viable, accessible, appropriate and cost-effective?
Work Stream 4: Model development	4, 6	In what ways might the key factors associated with access to, navigating, and receiving help from these services be synthesised into a model (or models) of effective and acceptable, high quality service design for CYP experiencing CMHPs?

The first two work streams (Stream 1/Stream 2) will help us identify the types of services available in England & Wales for CYP experiencing CMHPs. In Stream 1, we will carry out systematic reviews of the international literature in order to evaluate the effectiveness, cost-effectiveness and acceptability of services for CYP experiencing CMHPs. In Stream 2, we will use an online survey (augmented by internet searches and our extensive networks of contacts in CYP's mental health) to map service provision in England & Wales for this population group. From the data obtained in Streams 1 and 2, we will derive a typology similar to the typologies derived in our previous research on healthcare services for CYP with physical health<sup>13</sup> and mental health<sup>6</sup> problems. In Stream 3, we will identify 8-10 cases that are representative of this typology and collect

quantitative and qualitative data from key stakeholders in each case study site in order to further explore issues such as acceptability, barriers to implementation, and the appropriateness of available services.

We will consider key factors associated with navigating services (identification of need, help-seeking behaviour, access, service effectiveness and acceptability) in all of these work streams. Streams 1 to 3 underpin Stream 4 and the study's main output: the development of an evidence-based model (or models) of effective, high quality service provision for CYP experiencing CMHPs.

*Working collaboratively with HS&DR study 17/09/04 (PI: McDermott), relevant literature from Work Stream 1 and identified services from Stream 2 will be shared with McDermott's team. We will also ensure that our case study sites (Stream 3) do not overlap with those of the other study team. The model (or models) of effective, high quality service provision for CYP experiencing CMHPs we identify (Stream 4) will be shared with other team so that they can test its applicability to services for LGBT youth.*

#### *Theoretical/conceptual framework*

In the course of our study, we will encounter a variety of theoretical and conceptual frameworks that underpin CYP's mental health provision which means that it is important that we are not constrained by any particular theoretical framework. Indeed, part of our study will focus on disentangling *interventions* (that may have a specific theoretical or conceptual basis) from the organisational and systemic factors that characterise a *service*. Nonetheless, 'services' in this study can, to some extent, be seen as 'complex' interventions<sup>26</sup> or complex adaptive systems<sup>27,28</sup> and as such there are a number of models and frameworks which are likely to influence our work, e.g. those relating to **empowerment**, such as 'recovery' in mental health<sup>29</sup>, self-efficacy<sup>30</sup> and co-production<sup>31</sup>; those relating to **access**<sup>11-12</sup> (including the NIHR-funded<sup>32</sup> work on 'candidacy'); and model and frameworks underpinning **public mental health**<sup>17</sup>, e.g. behaviour change theories such as the behaviour change wheel<sup>33</sup> and the theory of planned action<sup>34</sup>.

Importantly, our stance on the 'effectiveness' of service models is broader than simply looking for measurable changes in quantitative outcomes. To a large extent it is shorthand for the 'effectiveness, cost-effectiveness, acceptability, viability and appropriateness of service models' with 'acceptability, viability and appropriateness' being concerned with outcomes that reflect service user views and perceptions on the relative success of a particular service. The syntheses we have employed in previous studies<sup>6,13</sup> involve comparing and contrasting these broader views/perceptions with 'standard' effectiveness syntheses (including meta-analyses) in order to determine both the common (what works?) and specific (for whom and in what circumstances?) factors that underpin high quality service provision.

#### **Work stream 1: Systematic searches and appraisal of the international literature on services for CYP with CMHPs (~18m)**

In this work stream, we will use standard systematic review techniques<sup>35-36</sup> to conduct systematic searches and appraisal of the international literature relating to services for CYP experiencing CMHPs.

We will conduct four parallel literature reviews: (a) a **scoping** review identifying the range of service models; (b) an **effectiveness** review of service models for which comparative (trial) data are available; (c) an **acceptability** review of user and provider views and perceptions of services; and (d) an **economic** review considering provider and user cost/benefits associated with specific service models.

With stakeholder guidance, we will meta-synthesise these four reviews using EPPI-Centre principles<sup>37</sup>. EPPI-Centre syntheses are especially suitable for policymakers, managers and decision makers<sup>38</sup>. Where appropriate, the Stream 1 reviews will be registered with PROSPERO, the international prospective register of systematic reviews.

*Literature that we identify that is pertinent to MH services for LGBT youth will be shared with McDermott's study team.*

#### *a. Team member contributions*

- Stream lead: Pryjmachuk
- Advising on search strategy: all research team members, especially Bee, Bower and Pryjmachuk

- Conducting searches: Manchester Research Associate; Prymachuk
- Paper/study selection and review: Prymachuk, Kirk, Evans, Fraser and Lane
- Analyses: Prymachuk, Bee, Bower, Kirk, Fraser and Lane; Camacho (economic elements)
- Writing up: Fraser, Lane, Prymachuk and Kirk; Camacho (economic elements)

*b. Research questions*

- What does the international literature say about the types of services available for CYP experiencing CMHPs?
- What is the international evidence for the effectiveness, cost-effectiveness and acceptability of these services?

*c. Setting:* ‘Desk’ research examining services for CYP experiencing CMHPs worldwide.

*d. Design:* Evidence synthesis using standard systematic review techniques.

*e. Data collection*

Inclusion criteria and definitions: Using an adaptation of the ‘PICOS’ framework<sup>35</sup> our inclusion criteria are listed in Table 2.

Search strategy: We will search research, professional, policy and grey literature using systematic search strategies in appropriate databases. Published searches (e.g. those in the Cochrane Library) and our knowledge of the background literature will be the starting place for the identification of the search terms we will employ, augmented by reference to thesauri (e.g. the Medical Subject Headings (MeSH) thesaurus) and consultation with our advisory group. We will search the electronic health (e.g. Cochrane Library, MEDLINE, CINAHL PsycINFO), social care (e.g. Campbell Collaboration, ASSIA, Social Care Online) and educational (e.g. ERIC) databases. In addition, we will search the reference lists and bibliographies of retrieved articles for relevant materials that our search may have missed, and we will contact authors of any recent or ongoing studies we are aware of to see if publications are available. While no limiters will be applied to our search, the relevance of any international material will be determined following consultation with our advisory group.

**Table 2:** Inclusion criteria

PICOS element	Definitions and notes
<b>Population</b> children and young people experiencing common mental health problems	<p>‘Children and young people’ is defined as those <b>under the age of 18</b>. This reflects the definition in the UN Convention on the Rights of the Child<sup>39</sup>, of which the UK is a signatory. Given there are culturally and socially accepted age demarcations within this population, where appropriate we may divide the population into natural subgroups, e.g. pre-school (0-4), primary school (5-11), secondary school (12-16), young people (17+).</p> <p>As defined in the commissioning brief, the term ‘common mental health problems’ encompasses a range of psychological, emotional and behavioural problems such as anxiety, depression, obsessive-compulsive disorder (OCD), self-harm, post-traumatic stress disorder (PTSD), gender identity issues and emerging personality disorders. The commissioning brief excludes eating disorders and psychosis though those at risk of developing psychosis are included. The commissioning brief also includes substance misuse within the definition of CMHPs. While addiction is considered a mental disorder, substance misuse in itself is generally not seen as a mental health problem. However, since substance misuse does have the capacity to exacerbate some mental health problems and may be a risk factor in psychosis in young people<sup>40</sup> we will seek advice from our independent advisory group whether we should include substance misuse as a CMHP or not.</p> <p>By referring to CYP ‘experiencing’ rather than <i>diagnosed with</i> such problems, CYP exhibiting signs and symptoms of CMHPs that cause them or their friends, peers, family, teachers, etc. significant distress can also be considered within the study.</p>
<b>Intervention</b> any services for the population group outlined	<p>There is often ambiguity at the top of the childhood range (17+) because of differing international views of the age range for a ‘young person’. Some services also provide for those over 18. Thus, we will include <b>services for young people up to the age of 25 so long as there is core provision for under 18s</b>.</p>

above	<p>Unlike services for CYP with severe mental health problems (such as psychosis, suicidality or eating disorders), services for CYP experiencing CMHPs typically do not require hospitalisation. Thus, in line with the commissioning brief, the services investigated will be <b>out-of-hospital services</b> providing primarily <b>assessment and triage, early intervention</b> and <b>supported self-care</b>. We have been deliberately broad in our inclusion criteria regarding service models because our experiences in our self-care support research<sup>6,13</sup> was that services adopting these approaches do not necessarily define themselves as such. In our previous research in MH<sup>6</sup>, had we only searched for 'self-care' models, we would have missed many that were actually underpinned by self-care, and we suspect the same may apply to 'early intervention' and 'out-of-hospital' models. In addition to searching for these generic service models, we will also search for the specific service models identified in the commissioning brief and supporting information (i.e. THRIVE/i-THRIVE, CYP-IAPT, CAPA and Brief Consultation and Advisory Group).</p> <p>Since the population is 'children and young people <i>experiencing</i> common mental health problems', we will include only <i>targeted</i> services, i.e. we will exclude services designed to promote mental health or prevent common mental health problems in the general (universal) population of CYP.</p>
<b>Comparisons</b>	<p>Not relevant to the descriptive review.</p> <p>For the effectiveness review, we are unsure whether we will find sufficient studies with a control or other such comparison group (see 'Study design' below) so we have not set a comparator at the outset. If robust data are available for the cost-effectiveness review, we will compare the relative cost-effectiveness of different service models.</p> <p>This element is not relevant to the acceptability review which is concerned with absolute, rather than relative, service user views of specific services.</p>
<b>Outcomes</b>	<p>Not relevant to the descriptive review.</p> <p>For the effectiveness review, we are interested in whether there is a demonstrable positive change in the CYP's mental health, psychological, social and emotional wellbeing (including educational attainment), family functioning or quality of life, evidenced through formal, validated measures of these outcomes. For the economic review, we are interested in the costs (service provision and additional health service utilisation) and benefits (outcomes listed) associated with CYP's mental health services.</p> <p>For the perceptions review, we are not interested in outcomes per se, but in qualitative and quantitative data that captures service user or service provider views.</p>
<b>Study design</b>	<p>Not relevant to the descriptive review.</p> <p>For the effectiveness review, we will initially consider all quantitative studies in which there is, at minimum, a relevant pre- and post-test outcome measure. Final decisions about study design will be based on the scope and quality of the evidence, in consultation with the advisory group. For the economic review, we will include studies in which costs and benefits have been synthesised as an incremental cost-effectiveness ratio or equivalent.</p> <p>For the acceptability review, we will include qualitative or quantitative designs in which either participants' views are expressed or in which participation data (e.g. uptake and attendance data) are available.</p>

A scope of the literature suggests that the reviews are feasible in the time allocated. A rapid search of the literature in Medline and PsycINFO, using relevant keywords to identify material pertaining to engagement with, and the effectiveness of, service models in CYP's mental health elicited ≈4,200 hits. A title scan suggested that ≈15% may be relevant to the reviews above indicating a potential pool of around 650 articles. With regard to the economic review, 'costs' added as a search term resulted in ≈350 hits, with a title scan suggesting that roughly 18% (≈60 articles) would be relevant.

**Review strategy:** For all four reviews, two members of the research team will independently screen titles and abstracts for relevance. Disagreements will subsequently be resolved through discussion with other members of the team. Relevant articles will then be allocated to one or more of the four reviews as appropriate and full copies of the articles obtained.

#### f. Data analysis

Data extraction and quality assessment: Each of the full articles selected for inclusion will be delivered to two members of the team for review, data extraction and, where appropriate, quality assessment. Data extraction and quality assessment will be performed by two reviewers independently. Discrepancies will be resolved by referral to the original studies and if necessary through arbitration by a third reviewer. For studies selected for the effectiveness and cost-effectiveness reviews, we will categorise the studies as RCT, controlled trial (non-randomised), time series design, cross sectional study, case control study or cohort study according to standard criteria. Data will be extracted and quality assessed using an appropriate combined data extraction/quality assessment sheet for each study design category. Where quality appraisal is required, we will use a suitable quality appraisal tool, e.g. the Cochrane Collaboration Risk of Bias tool<sup>41</sup> for RCTs or the tools, based on criteria from Dixon-Woods et al<sup>32</sup> and the EPPI-Centre<sup>42</sup>, that we have used to assess 'views and perceptions' papers in our previous NIHR studies<sup>6,13</sup>.

Data synthesis: If sufficient effectiveness data are available which can be meaningfully compared, we will undertake a meta-analysis on the data. Relevant outcome data will be translated to a standardized effect size using conventional methods<sup>36</sup>. Initial meta-analyses will use a fixed or random effects model depending on considerations of clinical and statistical heterogeneity, the latter assessed with the  $I^2$  statistic. We will conduct assessments of publication bias using funnel plots, and assess the impact of study quality, population and intervention characteristics using sensitivity analysis and meta-regression where indicated. If insufficient data are available for meta-analysis, we will undertake a structured narrative review. For the cost-effectiveness review, we will construct an economic decision model comparing the relative cost-effectiveness of different service models if robust data are available; if not we will conduct a narrative synthesis. For the acceptability review, we suspect we will find a mix of qualitative and quantitative evidence which we will narratively synthesise, comparing and contrasting the two datasets as appropriate.

In line with EPPI-Centre principles for mixed-methods synthesis<sup>6,42</sup> we will then compare and contrast the effectiveness, cost-effectiveness and acceptability reviews to produce a meta-synthesis of the international literature on services for CYP experiencing CMHPs.

## ***Work Stream 2: Identifying the range and type of services provided in England & Wales for CYP with CMHPs (≈12m)***

In this work stream, we will map out-of-hospital services in England & Wales (NHS or otherwise) for CYP experiencing CMHPs. The map will be derived from a survey, facilitated via the academic, clinical and professional networks research team members have in each English and Welsh health region. A typology of service provision for CYP experiencing CMHPs will be developed from this work stream and the literature underpinning Work Stream 1. The service map derived from Work Streams 1 and 2 will provide the sampling frame for Work Stream 3.

*Services that we identify that are pertinent to McDermott's HS&DR study will be shared with that study's team.*

### *a. Team member contributions*

- Stream lead: Pryjmachuk
- Advising on search strategy: all research team members
- Devising survey: all research team members
- Conducting searches: Manchester Research Associate
- Data extraction (questionnaire completion): individual service provider respondents; Manchester and Cardiff Research Associates
- Analyses/typology development: all team members
- Writing up: Manchester and Cardiff Research Associates; Pryjmachuk

### *b. Research questions*

- What out-of-hospital services are available in England & Wales for CYP experiencing CMHPs?
- What are the characteristics of these services?

### *c. Setting: 'Desk' research examining services for CYP with CMHPs in England & Wales*

#### d. Design: Survey

#### e. Sampling and data collection

Inclusion criteria: The inclusion criteria are the same as for Work Stream 1 (see Table 2). Since the work undertaken in this work stream will provide the sampling framework for Work Stream 3, an additional inclusion criterion for the PICOS 'intervention' element will be services that are available in England or Wales during the data collection period (months 4-15 of the study).

Search strategy: Services will be identified via online and offline searches. The offline searches will be facilitated primarily through NHS commissioning offices in each English and Welsh health and/or local authority district (we have commissioners from both England and Wales as advisors who will help here). We will also use the contacts and networks we already have (our advisory group; key third sector organisations such as YoungMinds and 42nd Street; professional groups such as the Royal Colleges of Nursing, General Practice and Psychiatrists, CAMHS Nurse Consultants network; electronic networks such as the CAMHS jiscmail group and relevant CHAIN mailing groups; relevant NIHR clinical research networks). We will also search for services online using standard internet search engines such as Google, Yahoo and Bing. We will also search appropriate social media sites.

Survey questionnaire: Data will be collected from the services identified through the search strategy using a questionnaire. The data fields for the questionnaire will be based on our previous work<sup>6,13</sup> and determined in collaboration with our advisory group. Fields likely to be included are those evident in our previous typologies: access/referral mechanism; target (age range, gender, ethnicity, condition type, etc.); locality/setting (urban-rural, home-clinic-other, etc.); provider (NHS or otherwise); theoretical perspective; mode of delivery (face-to-face, online, telephone); staffing skill mix; evaluation processes; length of contact. To ensure clarity, that it is not onerous and easy to complete, the questionnaire will be piloted (in months 4 and 5) with a small number of identified services and amended as necessary.

To increase response rates, a number of options for completing the questionnaire will be available. A self-completed online version will be available as will a paper version and a telephone option whereby a researcher can complete the questionnaire on behalf of the provider. Data may also be extracted by a researcher from information provided directly from a service's website (with researcher follow-up directly with the service where appropriate). In addition, we will use snowballing techniques in the survey to ensure that there are opportunities for respondents to identify other relevant services.

#### f. Data analysis – Service map and typology

The survey data will be analysed using simple descriptive statistics. We will produce a descriptive service map outlining the features of each health district's population (e.g. size, demographics, urban-rural) together with key features of the services provided within that district.

Together with data from the literature reviews we will identify the common (and uncommon) features of service provision for CYP with CMHPs and derive a typology of services for this population group, similar to the typologies we derived in our previous NIHR studies<sup>6,13</sup>. This typology will be presented to our independent advisory group for validation or, indeed, further amendment. The typology we will derive necessarily assumes there will be heterogeneity in services; purposive sampling for the case study sites (see below) will also ensure that a variety of service dimensions will be considered, e.g. access arrangements, rural-urban, theoretical perspective, NHS vs. other provider, delivery platform.

### **Work Stream 3: Collective case study (≈18m + extra 6m from costed extension)**

In this work stream, we will conduct a collective case study<sup>44</sup>, the case being *services for CYP experiencing CMHPs*. With advisory group input, we will purposively sample 8-10 services across England & Wales to reflect the various typology dimensions. We will seek to recruit and employ (via a third sector partner: The McPin Foundation) young person co-researchers with lived experience of mental health issues to work with the Manchester and Cardiff Research Associates at case study sites.

#### a. Team member contributions

- Stream leads: Kirk (England); Evans (Wales)

- Advising on sampling: all research team members
- Training of young person co-researchers: Bee and Neill and Manchester and Cardiff Research Associates
- Data collection: Manchester and Cardiff Research Associates; Young Person Co-Researchers (employed by McPin Foundation)
- Data analysis: Kirk, Evans, Manchester and Cardiff Research Associates, Young Person co-researchers (with other research team members advising); Camacho (analysis of economic data)
- Writing up: Cardiff and Manchester Research Associates, Kirk and Evans; Camacho (economic elements)

#### *b. Research questions*

- What are the barriers and enablers that CYP and their families and carers experience in accessing and navigating services for CYP experiencing CMHPs in England & Wales?
- What factors determine whether a service is viable, accessible, appropriate and cost-effective?

#### *c. Setting: Services for CYP experiencing CMHPs in England & Wales*

#### *d. Design and sampling*

Design: A qualitative, case study design, using data elicited from focus groups, individual interviews, documentation and, where possible, observation.

Sampling: The service map from Workstream2 will provide the sampling framework with the typology derived from Workstreams 1 and 2 being used to ensure that there is heterogeneity in services. Thus 8-10 services for CYP experiencing CMHPs will be purposively selected so that they reflect the different dimensions of the typology. Our past research suggests that these dimensions might include: age range; locality/setting (urban-rural, home-clinic-other, etc.); provider (NHS or otherwise); theoretical perspective and mode of delivery (face-to-face, online, telephone). The specific case study sites (services) selected will be determined in consultation with our advisory group. As in our previous research, we will include novel, innovative or specialist services e.g. digitally provided services, services provided specifically for a minority group, or a unique/unusual ('outlier') service as case study sites. We will also ensure that sites using one or more of the service models specified in the commissioning brief and supporting information are included.

*Given that the focus of McDermott's HS&DR study is LGBT youth mental health, we will not include services targeted specifically at this client group in our case study sites though, importantly, any LGBT service users accessing services at the case study sites we do select will not be excluded from participating.*

Sampling *within* the study sites will also be purposive in that we will ensure that a range of appropriate stakeholders are invited to participate (e.g. both younger and older children; parents and carers; a variety of staff to reflect the service skill mix, including unpaid/volunteer staff).

#### *e. Data collection*

We will use a range of methods to collect data from our case sites including individual interviews (in person or by telephone), focus groups, individual user journey accounts (access stories), documentary review (of operational manuals, internet forum postings, service evaluations, etc.) and, where possible, observational data (e.g. referral meetings, initial assessment reviews, team meetings).

Qualitative interview data will be collected from providers, managers and current and previous service users (primarily CYP but also parents and/or carers). Where possible, we will also collect data from those who refuse/do not attend offered services since their exclusion from research distorts the full picture. We acknowledge that collecting data from refusers or non-attenders of services will be difficult. In our previous NIHR studies, key informants connected to case study sites were able put us in touch with some CYP and families who chose not to engage with the services they were referred to. We will visit the majority of sites in person unless they are virtual or online services. At the sites we visit in person, we aim to interview 6-8 CYP (either individually or in groups), 2-3 parents and/or carers, and 2-3 staff members. Our past experience of studying virtual/online services<sup>6,45</sup> suggests that the numbers of

interviews will be smaller than face-to-face services (though this may be countered by including observational and documentary evidence). We also know from past case study research<sup>6,13</sup> that the numbers recruited will vary across sites and within participant subgroups; we do, however, expect to complete around 100 interviews in total. To ensure data saturation, we will also bear in mind the recommendation<sup>46</sup> that a minimum of 12 interviews be conducted per participant subset.

Topic guides for the individual and focus group interviews will be informed by the Work Stream 1 evidence syntheses and in consultation with our advisory group. Non-professional participants (e.g. CYP and parents) will be offered a £10 gift voucher each as a token of thanks.

We will also examine the costs associated with the delivery of services for CYP experiencing CMHPs by asking staff and managers at the case study sites to complete questionnaires providing details of the different staff roles and average time spent delivering the service, as well as other key resources (e.g. equipment) that might be involved. Data on costs borne by CYP and parents (e.g. transport and equipment) will also be collected where possible.

#### *f. Data analysis*

The data obtained from the case study sites will be managed and stored according to standard data protection and research governance regulations. The data obtained from the focus groups and individual interviews will be audio recorded and subsequently transcribed. The data will be analysed using *Framework*<sup>47,48</sup>, a matrix based analytic method widely used in qualitative research where there are pre-determined objectives for analysis and which has the advantage of allowing parallel inductive and deductive coding. Framework has five stages and how these stages apply to this study is as follows:

- i. *data familiarisation* – the raw data (transcripts, audio recordings, documents, observational data, etc.) will be read/listened to several times to ensure that we are familiar with the data;
- ii. *identification of a thematic framework* – the study's aims and objectives, literature review and topic guides will be used to draw out issues, concepts and themes;
- iii. *indexing* – the thematic framework will be organised according to a number of themes and subthemes;
- iv. *charting* – the data will be 'charted' into a matrix (using qualitative data management software such as Nvivo) according to its themes and subthemes; and
- v. *mapping and interpretation* – the charts from stage (iv) will be employed to map and interpret the data; in particular that data will need to be interpreted in relation to the acceptability, accessibility and appropriateness of services and the barriers and enablers to their implementation.

Regarding costs, for each resource identified, the cost will be estimated as the quantity of that resource multiplied by the resource's unit cost (using national average unit cost data from the most recently published versions of the NHS Reference Costs Database<sup>49</sup> and PSSRU Unit Costs of Health/Social Care report<sup>50</sup>). Total cost of a service from an NHS perspective will be estimated by totalling the costs of the component resources required to deliver the service. A broader societal perspective will also be explored by adding any out-of-pocket expenses borne by service users and their families.

#### ***Work Stream 4: Meta-synthesis of the work stream data and model development (~4m + 1m from the costed extension)***

In line with EPPI-Centre principles<sup>37</sup>, the discrete datasets from work streams 1 to 3 will be analysed separately in the first instance.

In Work Stream 4, as a next step in the EPPI-Centre approach, we will simultaneously explore, compare and contrast the three data sets (evidence from literature, service map/typology and case study data) in order to build a model (or models) of effective and acceptable high quality service provision for CYP experiencing CMHPs.

##### *a. Team member contributions*

- Stream leads: Prymachuk and Kirk
- Data synthesis: all team members, including Young Person co-researchers

- Writing up: Manchester and Cardiff Research Associates; Prymachuk, Kirk and Evans

#### b. Research question

- In what ways might the key factors associated with access to, navigating and receiving help from these services be synthesised into a model (or models) of effective and acceptable, high quality service design for CYP experiencing CMHPs?

#### c. Data synthesis

We will follow the approach to data synthesis that we took in our previous work on self-care support in CYP's mental health<sup>6</sup>. Team members Kirk, Prymachuk and Evans with the support of the Manchester and Cardiff Research Associates, will simultaneously explore, compare and contrast the analyses from the three data sets (evidence from literature, service map/typology and case study data) in order to build a preliminary model of effective and acceptable high quality service provision for CYP experiencing CMHPs that integrates all of the factors associated with access to, navigating and receiving help from such services.

To produce this preliminary model Kirk, Prymachuk, Evans and the two research associates will take an 'integration through narrative' approach which involves describing and interpreting findings from each workstream separately around specific themes or concepts<sup>51</sup>. The findings from each workstream will then be brought together using a mixed-method matrix to display the data visually (and transparently) which we will examine in order to consider the 'fit' of the data. This involves assessing whether the findings from each stage agree (confirmation), provide complementary information that expands insight (complementarity) or appear to contradict each other (discrepancy)<sup>52</sup>. Examining discrepancies between findings from different workstreams and seeking explanations for them is an important part of the process. In our previous NIHR research<sup>6,13</sup> we have found this leads to greater understanding of the research area.

As with our previous work on self-care support in CYP's mental health, we will use the principle of 'scientific parsimony' to develop the model. Using this principle, we will aim to devise as simple a model as possible which will help in both the understanding and application of the model. Thus, as a starting point, we will aim to produce a *single* model of effective and acceptable high quality service provision though the parsimonious principle might lead to more than one model. Importantly, our goal here is to provide an explanatory model of service provision not merely a descriptive one. Whether a single model or several models are developed will also depend, to a large extent, on consultation with, and feedback from, our advisory group.

The preliminary model (or models) will then be put to the whole research team, including the Young Person co-researchers, for refinement.

The research team will then present the refined preliminary model (or models) to our advisory group at a co-production workshop (which will be integrated into the final advisory group meeting). We are confident that we will be able to call our final model or models 'co-produced' because our advisory group will include NHS commissioners, CYP, parents, child (mental) health professionals and service managers and our research team includes young people service users and PPI and NHS manager co-investigators.

*We will share our model (or models) of effective, high quality service provision for CYP experiencing CMHPs with McDermott's team so that they can test its applicability to services specifically for LGBT youth and amend if necessary.*

## 6. Dissemination and projected outputs

We will work with our stakeholders to ensure the maximum impact of our study findings. Our PPI co-applicant (Common Room North Ltd) and NHS manager (McDougall) co-investigators will play a significant role in ensuring that the proposed study has an impact for both service users and service providers.

Other stakeholders we will engage in our dissemination plans include the mental health, child care, commissioning and education professionals who are not represented within the research team, e.g. child psychiatrists, psychologists, paediatricians, GPs, education staff (teachers, school nurses), social care staff (youth, justice and third sector workers), commissioners and parent/carer organisations. All members of the research team have access to these stakeholders via extensive and well-established networks and we will use our contacts within these networks to facilitate dissemination and to populate our advisory group.

The research team also have contacts in the devolved administrations in Greater Manchester and Wales. We are aware that these and other devolved administrations (London & the West Midlands and Liverpool City Regions, for example) are eager to explore models to support service redesign in mental health that are both effective and economical and so we will ensure the devolved administrations are included in our dissemination plans.

The key outputs of the study will be:

1. **A series of evidence syntheses and an EPPI-Centre guided meta-synthesis of the evidence.** This output will consolidate the evidence-base at service, rather than intervention, level and will be of particular importance to the academic community, commissioners and policy makers.
2. **A map of service provision across England & Wales for CYP experiencing CMHPs.** This output will clarify the range and variety of services available and will be of value to commissioners, service providers and service users.
3. **A typology of the factors involved in service design and delivery.** This output will identify the factors that need to be taken into account when designing and delivering services and will be of value to the academic community, commissioners and service providers.
4. **A model (or models) of effective, cost-effective and acceptable high quality service provision for CYP experiencing CMHPs that integrates all of the factors associated with access to, navigating and receiving help from such services.** As the core output of the study, this output will be of value to all stakeholders: policy makers, the academic community, commissioners, service users (including parents), service providers and managers. In particular, it will assist commissioners and providers in service design and transformation.

Publications (in the broadest sense) embracing these four key outputs will include:

- a final report/monograph for the NIHR journal series
- a set of interactive PowerPoint slides that distil the key research findings and augment the final report
- a commissioning toolkit, co-designed, co-produced and co-evaluated by the Young Person Co-Researchers, together with Neill and McDougall and the commissioners on our advisory group; this toolkit will translate our model (or models) of effective, cost-effective and acceptable high quality service provision for CYP experiencing CMHPs into practical guidance for commissioners (e.g. it will outline what elements are likely to improve access, help service users navigate systems, produce the most cost-effective outcomes); though the toolkit will be designed specifically for England & Wales, it is likely to have utility across the whole of the UK and we will share the toolkit with the contacts we have in Scotland & NI, some of whom may be members of our independent advisory committee
- oral presentations at local, national and international conferences or meetings relevant to CYP's mental health
- at least two open access papers in relevant peer-reviewed/professional journals to complement the HS&DR monograph
- short summary reports for professional and lay (including CYP) audiences co-produced with Common Room North Ltd.
- a project website
- a briefing paper for policy makers co-produced with young people

Dissemination of outputs will be tailored to specific audiences and will include:

- oral presentations at local, national and international conferences or meetings relevant to CYP's mental health (e.g. the national CAMHS conference in Northampton); one or more of these could be a webinar

- two final stakeholder events/workshops (one in England and one in Wales) focussing on how co-produced service design might improve navigation through, and access to, services for CYP experiencing CMHPs
- at least two open access papers in relevant peer-reviewed/professional journals (e.g. *BMC Child and Adolescent Psychiatry and Mental Health*) to complement the HS&DR monograph
- depending on the advice we get from Common Room North Ltd. and the Young Person co-researchers the short summary lay/professional reports may be in print, visual (e.g. an infographic), video or some other format; we will distribute these summaries to service provider leads and other relevant professionals, e.g. child health practitioners and health care educators
- social media (e.g. podcasts, YouTube videos, blogs, Twitter) and the project website in order to engage audiences and communicate project progress, disseminate findings and provide access to specific outputs (e.g. downloadable reports and guidance); again, Common Room North Ltd and the Young Person Co-Researchers will help us co-produce and disseminate material here

*Since the target audiences are likely to be similar for both studies we will, if possible, hold the two final stakeholder events jointly with McDermott's study team. We will share appropriate outputs (e.g. the commissioning toolkit, co-produced briefing paper and social media outputs) with McDermott's team and publicise the launch, progress and findings of our respective studies on each other's study websites and social media channels.*

## 7. Plan of investigation and timetable

See also the attached Gantt chart (Project Timetable)

### Project management (36m)

- *Months 1-6*: pre-study liaison with HS&DR; deal with ethics/governance issues; appointment of the advisory group; appointment of Manchester full-time researcher; first advisory group meeting; develop study website; PPI training.
- *Months 7-12*: second advisory group meeting; interim report.
- *Months 13-18*: appointment of Cardiff full-time researcher; training of Young Person co-researchers; ethical review for Stream 3; third advisory group meeting.
- *Months 19-24*: fourth advisory group meeting; interim report; national conference presentation.
- *Months 25-30*: fifth advisory group meeting.
- *Months 31-36*: sixth advisory group meeting and co-production workshop; final report; end of study workshops.
- *Months 36+*: continued dissemination of study; national/international conference presentations.
- *Months 1-36*: bi-monthly team meetings; website/social media dissemination.

### Project extension management (7m)

- additional advisory group added
- core research team (Prymachuk, Kirk, Fraser, Evans, Lane) to meet fortnightly
- full team meetings continue to be bi-monthly

### Work Stream 1 (≈18m)

- *Months 1-3*: develop search/review protocol; review/modify data extraction sheets.
- *Months 4-6*: conduct searches.
- *Months 5-8*: screening of papers/studies.
- *Months 8-13*: data extraction and quality assessment.
- *Months 13-16*: data syntheses.
- *Months 16-18*: write up literature reviews.

### Work Stream 2 (≈12m)

- *Months 4-5*: develop and pilot survey.
- *Months 4-7*: online/offline search for services.
- *Months 7-13*: data analysis/development of the typology.
- *Months 14-15*: write up of mapping exercise.

Work Stream 3 (≈24m; originally ≈18m)

- *Months 16-18*: using typology, identify and recruit case study sites.
- *Months 18-36*: data collection at case study sites.
- *Months 27-39*: transcribing and analysis of case study data.
- *Months 38-41*: write up case study.

Work Stream 4 (≈5m; originally ≈4m)

- *Months 39-40*: develop preliminary model of effective service models for CYP with CMHPs.
- *Months 40-42*: refine preliminary model/co-produce model (or models) of effective services for CYP with CMHPs.

## 8. Project management

The study will be managed by Pryjmachuk and Kirk as Co-Principal Investigators, though Pryjmachuk will be the nominal Principal Investigator (PI) for NIHR correspondence and reporting. Pryjmachuk and Kirk are both experienced project managers and both have been PIs on NIHR studies. The study will be conducted via the Manchester Academic Health Science Centre (MAHSC), a University of Manchester collaboration with six local NHS trusts including Greater Manchester Mental Health NHS Foundation Trust (GMMHFT). The contracting organisation will be GMMHFT and the work contracted to the University of Manchester. Pryjmachuk has had an honorary contract with the contracting organisation in the past; arrangements will be put in place for this to be re-established.

The entire research team will meet on a regular basis, no less than quarterly during the lifetime of the study. Specific work stream members will meet on a more regular basis during the lifetime of the work stream.

The study will be guided and supported through ongoing consultation with an advisory group, drawn from our extensive networks of contacts within the statutory (e.g. health, social care and education) and non-statutory sectors. Health representatives will include CYP's mental health professionals such as psychiatrists, nurses and occupational therapists (a psychiatrist and senior nurse from an NHS Trust have already agreed to be advisory group members); social care representatives will include professionals such as social workers; and education will be represented by teachers and pastoral care and welfare professionals. We have two commissioners of services (one for England and one for Wales) who have also agreed to be advisors on the project. The advisory group will also include parents, carers and CYP. Our previous experience of working with CYP advisors is they prefer not to have a separate CYP's advisory group though, where appropriate (e.g. in co-designing materials), we may well consult with our CYP advisors separately. We will appoint one member of the advisory group as an independent chair. There is nothing to prevent a young person from having this role; if this proves to be the best option for this study, we will use our independent contacts (e.g. in 42nd Street and YoungMinds) to ensure that the young person is fully supported in this role.

The advisory group will meet face-to-face six times during the lifetime of the study; ongoing communication with the advisory group will occur through secure email, telephone contact or videoconferencing.

Our past experiences suggest that there are advantages to employing an administrative assistant to support the team. Administrative support for the project will thus be provided by a 0.2 WTE administrative assistant.

*There are some project management aspects that will enhance our collaboration with McDermott's HS&DR study:*

- *We will exchange study protocols with McDermott'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 (two based in Manchester and Cardiff for this study; three based in Lancaster, Leeds and Brighton for McDermott'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.*

## 9. Ethics committee approval

### *Potential ethical issues*

Ethical issues pertain largely to the empirical aspects of the project, i.e. the Work Stream 3 case study. The primary ethical issues here (as in most research) are **consent, data protection and the safety of participants and researchers**. Of importance to this study is the involvement of CYP both as research participants and co-researchers.

Regarding consent, we will follow standard ethical procedures for gaining informed consent from participants which will include CYP, their parents/carers and other family members, service managers and service provider staff. This may require us to obtain 'assent' from those who are not old enough to consent for themselves. We have ample experience of obtaining informed assent/consent for all participant groups, including CYP.

Regarding data protection, any data we collect will be confidential to the project and stored securely in line with current research governance and data protection regulations. Any identifiable data will be anonymised prior to analysis in line with good research practice.

Regarding **participant safety**, we do not expect there to be any significant risks in taking part in Work Stream 3 but we will ensure that the researchers and Young Advisor co-researchers are trained in good interview practice and the use of distress protocols (immediately ceasing the interview if participants become upset, providing avenues for support, etc.). All researchers will be DBS checked; this includes the Young Person co-researchers. Co-investigator Bee has extensive experience in employing service users in a research capacity. Regarding **researcher safety**, we will provide the researchers/co-researchers with a mobile phone and, if necessary, lone worker devices. During data collection, the Young person co-researchers will always be accompanied by one of the researchers or a member of the research team (who will necessarily have undergone standard DBS checks). The Young Person co-researchers will also be sensitively supported by research team members (especially Prymachuk, Kirk, Evans and the Manchester and Cardiff researchers) during fieldwork. However, primary responsibility for emotional support for the Young Person Co-Researchers will remain with their employer, the McPin Foundation.

### *Ethical review details*

Ethical review is not required for the 'desk' research in Work Streams 1, 2 and 4 (literature review, service mapping and model development) but will be required for Work Stream 3.

We have had success in previous studies in obtaining proportionate review because the ethical review body (the NHS REC) determined that there were no 'material ethical issues' in collecting data on service users' opinions of the services they use. However, some of the data we wish to collect may fall into the NHS Health Research Authority's definition of 'highly sensitive' (because it is about mental health). Our intention is to try for proportionate review in the first instance, on the understanding that the determination from proportionate review may be that the study requires full ethical review. In any case, we will seek advice from our local NHS REC managers.

## 10. Service users/patient and public involvement (PPI)

PPI has influenced our proposed study in 3 ways:

1. Co-investigator Liz Neill is Director of Common Room North Ltd, a Young People's consultancy led by lived experience. Common Room North Ltd have reviewed and provided constructive advice on the proposed study, including this detailed project plan.
2. In 2014, in disseminating our previous HS&DR study on self-care support in CYP's mental health<sup>6</sup>, we conducted a priority-setting stakeholder event using James Lind Alliance principles. This event, which included CYP, parents/carers and service user groups, identified several research questions that are relevant to this proposal including:
  - What characteristics facilitate engagement in young people's MH services?
  - How can the NHS develop and commission accessible, flexible, child-centred MH services?
  - What makes a good therapist from a young person's perspective?

3. At a research planning meeting held in Manchester in May 2015, young service users and parents provided critical comments on, and endorsed, the mixed methods design we plan to use in this study.

Common Room North Ltd via its network of Young Advisors have expertise in leading PPI and engaging with local service user groups to ensure wider involvement in research. They can thus help with the recruitment of CYP and parent members to our independent advisory group.

We will also work collaboratively with The McPin Foundation to recruit and employ young person co-researchers with lived experience of mental health issues to work with the Manchester and Cardiff Research Associates at case study sites.

A summary of PPI involvement via Common Room North Ltd and the McPin Foundation across the study can be found in Table 3.

**Table 3:** PPI involvement across the study

<b>Stage</b>	<b>Common Room North Ltd/Young Advisor involvement</b>	<b>McPin Foundation involvement</b>
Proposal drafting	Have reviewed, and commented on, the outline and full proposals	
Work Stream 1: Literature reviews	Will advise on the search terms and critically comment on emerging synthesis themes to provide ecological validity	
Work Stream 2: Mapping	Will advise on the search strategy, particularly in relation to the contacts and networks they may have	
Typology emerging from Streams 1 & 2	Will advise on the 'fit' of our data to the typology, confirming the typology or recommending modification	
Work Stream 3: Case study	Will advise on: case study site selection; strategies for recruiting participants; methodology (e.g. viability of e-methods such as email discussions or webcam interviews) Will co-design: the information sheets, and consent/assent forms; the topic guides for focus groups/ interviews Will contribute to the training of the Young Person Co-Researchers employed by McPin	Will recruit 6 – 8 Young Person Co-Researchers (aged 18 – 24 years) with lived experience of mental health issues  The Young person co-researchers will assist the Research Associates with data collection at case study sites and where appropriate critically read transcripts and comment on the data analyses
Work Stream 4: Model development	Other CYP service users (and parents) will contribute to the co-production of the model via the advisory group	Young person co-researchers will contribute to the model development as part of the research team
Final report	Will give feedback on any initial findings; will critically review the final report	
Dissemination	Will advise on the dissemination strategy especially in relation to the	

	media channels used; will co-produce materials for commissioners, lay audiences and CYP	
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Common Room North Ltd and its Young Advisors will assist with strategic decision-making in Stream 1 (evidence syntheses) and in identifying and mapping services in Stream 2. Ethics permitting, we will fund The McPin Foundation to employ 6 – 8 young people (aged 18 – 24 years) with lived experience of mental health issues as co-researchers in Stream 3 so that the case study is truly co-produced. We will provide research methods and governance training to the Co-Researchers to equip them to undertake the role. We will engage with our Advisory Group to co-write the interview schedules we will use in this work stream so that any data obtained fully reflects the priorities of CYP, their families/carers and professionals working in the sector. Common Room North Ltd also has significant experience in helping disseminate research findings to service users, parents/carers and other relevant stakeholders such as policymakers and commissioners. Young Person co-researchers, CYP service users and parents will help with the co-production of the model in Stream 4.

The Young person co-researchers (employed by McPin) and the Common Room North Young Advisors will be sensitively supported throughout the study. ‘Sensitive’ support means that we are sensitive to the needs of the Young Advisors/Co-Researchers as both advisors/co-researchers and as young people. Regarding supporting them as co-researchers, co-investigator Bee has extensive experience of training young people in research methods (via NIHR programme grant RP-PG-1210-12007 and via Mental Health Research Network & CRN awards) and co-investigator Neill has extensive experience in supporting and training young people in advocacy, co-production and consultation. The McPin Foundation (who will recruit and employ the Co-Researchers) have extensive experience of working with young people with lived experience of mental health problems to facilitate their involvement in research methods and the research agenda. Regarding providing general support, most of the team (Prymachuk; Kirk; Evans; McDougall; Neill) have direct experience of working clinically and professionally with young people with a variety of physical and mental health needs and thus understand the sensitivities involved and are able to provide this support.

As outlined in the Project management section, we will ensure that parents and other family members (who may well be service users by proxy) are represented in our advisory group.

### *Reflexivity*

There will be inherent power issues in working with young service users as co-researchers. Though the young co-researchers will have equal status to the study’s full-time researchers, we are cognisant that they will need supporting both in terms of research training and pastorally and we have plans in place for both of these as outlined previously. Co-applicant Neill is a Director of Common Room North Ltd, a CYP’s MH consultancy led by lived experience. She (and indeed Common Room’s Young Advisors) are experienced in advocacy and co-production in CYP’s MH and have the expertise to ensure that power is balanced between professionals/academics and service users. In addition, two team members (Evans, Prymachuk) have published a paper<sup>53</sup> from another NIHR-funded project that focuses on promoting YP’s equality of decision making in research. Support for the Young person co-researchers will also be provided by the Senior Public Involvement & Research Officer at The McPin Foundation.

Both the study researchers and the young co-researchers will be expected to keep reflective diaries during data collection and analysis. Since it is important to devote time to reflect on the relationships between the young co-researchers and the study researchers, we plan to dedicate reflection time during our regular team meetings where we can discuss expectations, roles and positions (e.g. gender, age, class, ethnicity, academic, service user) and relationships. Indeed, the meetings themselves will need to create an environment where inter-researcher relationships can be openly discussed. A project reflective diary will be kept to record these discussions which will complement the co-researchers’ and study researchers’ own reflective diaries. At the outset, study researchers and co-researchers will receive joint training and induction to promote openness in their relationships and an awareness of power dynamics. We would aim to recruit study researchers with experience of working with service user co-researchers and/or young people.

We will discuss the relationships between the young co-researchers and study researchers in study outputs so that it is clear how their relationships may have impacted on the study. Indeed how co-researchers and researchers may have influenced data collection and data analysis is an important issue to discuss in project outputs. The GRIPP2 guidance<sup>54</sup> will be used to ensure that PPI is clearly and fully reported.

## 11. Expertise, division of responsibilities and justification of support required

### *Expertise and division of responsibilities*

Although Pryjmachuk is nominally the PI, we will deliver the study with Pryjmachuk and Kirk operating as co-PIs. Pryjmachuk and Kirk have successfully worked together on previous research projects. Both have CYP's health services research expertise: Pryjmachuk in mental health, Kirk in physical health. This strengthens the project given current health policy's growing focus on integrated care and 'parity of esteem'<sup>55</sup>.

- **Steven Pryjmachuk** (10% WTE) is Professor of Mental Health Nursing at the University of Manchester. He has been involved in five previous NIHR studies involving CYP's mental health including a self-care support study as PI. He has project management, systematic review and mixed methods expertise. As Co-PI, he will oversee the entire study, lead on Work Streams 1 and 2 and co-lead on Stream 4.
- **Sue Kirk** (10% WTE) is Professor of Child & Family Health at the University of Manchester. She has held NIHR grants as PI. She has expertise in CYP's physical health service provision and qualitative methods. As Co-PI, she will oversee the entire study, co-lead on Stream 3 with Evans and co-lead on Stream 4 with Pryjmachuk, and will contribute to Work Streams 1 and 2.
- **Nicola Evans** (10% WTE) is Reader in Mental Health, Learning Disabilities and Psychosocial Care at Cardiff University. She is experienced in systematic review and qualitative methods. She has particular expertise in triage in CYP's mental health, having completed her PhD in this area. Her background in CYP's mental health in a Welsh context will support Work Stream 2. She will co-lead Work Stream 3 with Kirk and help with Work Streams 1 and 4.
- **Penny Bee** (5% WTE) is Professor of Mental Health Services Research at the University of Manchester. She has systematic review and PPI expertise. She will contribute to Work Streams 1 and 4 and support Neill with the PPI aspects of the study, especially in training the Young Person co-researchers.
- **Pete Bower** (2.5% WTE) is Professor of Health Services Research at the University of Manchester and an NIHR Senior Investigator. He is a national expert in health services research and has specific expertise in review methods especially meta-analysis. He will contribute to Work Stream 1, leading on any meta-analyses. He will also contribute to Work Stream 4.
- **Liz Neill/Common Room North Ltd** (5% WTE). Liz Neill is a Director of Common Room North Ltd. She and her Young Advisors will provide PPI advice/guidance throughout with specific contributions in Work Streams 2 and 4. Neill will contribute to the training of the co-researchers in Work Stream 3.
- **Tim McDougall** (5% WTE) is a senior NHS manager at Greater Manchester Mental Health NHS Foundation Trust and former nurse consultant in CYP's mental health. He has written extensively about service delivery in CYP's mental health. He will contribute to all study work streams, but Stream 2 in particular.
- **Elizabeth Camacho** (5% WTE) is a Research Fellow in Health Economics at the University of Manchester. She is an experienced researcher, with expertise in mental health. She will lead on Stream 1/Stream 3 economic analyses, advised and supported by Professor Linda Davies if necessary. She will also contribute to Work Stream 4.

In addition to the research team co-applicants cited above, **the McPin Foundation** will be contracted (via a collaborative agreement) to recruit, employ and provide emotional support to up to 8 young person co-researchers.

### *Justification*

Intervening early and supporting CYP experiencing CMHPs in community settings (in school or at home) can have significant cost savings for the NHS in that, if implemented successfully, there is less need for expensive (and stigmatising) inpatient facilities. There can also be long- and short-term cost savings for CYP

and their families/carers in that school (for CYP) or employment (for families/carers and young adults) are less likely to be disrupted. This is important because the economic and social cost of mental health problems to the UK is estimated to be £70 billion a year<sup>56</sup>. Within this context, any research that contributes to a lower economic burden on services or service users is value-for-money.

Regarding specific value-for-money in the costs associated with our study, while the costs have been calculated using full economic costing (FEC) procedures, we have tried to minimise costs wherever possible. Where travel and accommodation are required, we will take advantage of university procurement networks to access low-cost travel and accommodation. Conference fees and long distance travel costs will be minimised by taking advantage of 'early bird' or advanced booking offers. To further minimise travel costs and offer choice to stakeholder group members, we will offer tele- or videoconference options for our advisory group meetings.

Posts and salaries have been calculated so that the proportion of WTE allocated accurately reflects the total contribution of each applicant during the study's three year duration. Posts and salaries are the study's greatest costs since the necessary expertise the study requires is also reflected in the senior positions that several team members (Prymachuk, Kirk, Bower, Bee, Evans, McDougall) have in their respective employing organisations. We also need the study's researchers to be able to work independently and with the necessary expertise to work with CYP experiencing CMHPs, their families/carers and young co-researchers. Hence we have costed for research associates rather than research assistants. Our past experiences suggest that there are advantages to employing an administrative assistant to support the team. Thus, we have also costed for a Manchester-based part-time administrative assistant.

Costs associated with Work Stream 1 include the costs of accessing literature not available through standard university library means, translation costs and specialist evidence-synthesis and meta-analysis software. Specialist survey software has also been costed for Work Stream 2.

Our Work Stream 3 (case study) fieldwork necessitates significant travel for one or more researchers. We have costed two full-time researchers, one each in Manchester and Cardiff, though the Cardiff researcher will not be required until Year 2 of the study. This has advantages in that the fieldwork can be spread across the geographical regions of England & Wales according to the researcher's location. Where appropriate, we will also offer participants in our Work Stream 3 fieldwork the option of telephone or remote video interviews. Other costs associated with Work Stream 3 include equipment (digital audio recorders, lone worker safety devices), transcription costs and any necessary translations to and from the Welsh language.

General costs include the costs of supporting PPI (including paying the co-researchers) and the advisory groups, equipment for the full-time researchers (laptops and mobile phones) and study website costs.

Dissemination costs include the costs for two end of project meetings (one in England; one in Wales), printing of a short/executive summary, two national and one international conference, digital media (e.g. a video summary) and two open access publications.

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