

Early evaluation of the Children and Young People's Mental Health Trailblazer Programme – study protocol

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Protocol summary

Introduction¹

In 2017, the Department of Health and Department for Education (DfE) published the *Transforming Children and Young People's Mental Health* Green Paper. Building on previous initiatives and commitments, the Green Paper set out proposals for improving the services and support available to children and young people with mental health problems, with a particular focus on enhancing provision for those with low-moderate needs. The proposals had three main elements:

1. Incentivising schools and colleges to identify a senior mental health lead to oversee the approach to mental health.
2. The creation of Mental Health Support Teams (MHSTs) providing specific extra capacity for early intervention and ongoing help, and supporting the promotion of good mental health and wellbeing within education settings.
3. Piloting a four week waiting time for access to specialist NHS children and young people's mental health services.

The proposals will be tested in a national programme of 'trailblazer' sites, with the aim that the new approach and services will be implemented in 20-25% of areas in England by 2023-24.

The first wave of the programme involves 25 trailblazers and will see the creation of 59 MHSTs which will support children and young people in more than 1,000 education settings (including primary and secondary schools, special schools, colleges and other settings such as pupil referral units). MHSTs will have three core functions: i) delivering evidence-based interventions to children and young people with mild to moderate mental health issues; ii) supporting the senior mental health lead in each education setting to introduce or develop their whole school or college approach to mental health and wellbeing; and iii) giving timely advice to education setting staff, and liaising with external specialist services, to help children and young people to get the right support and stay in education. Areas will have flexibility to tailor their approach to local needs and circumstances and therefore some variation in service models and how they are implemented is expected.

MHSTs will be made up of around eight members, about half of whom will be Educational Mental Health Practitioners (EMHPs) – a new role in the NHS mental health workforce. Training of the first cohort of EMHPs commenced in January 2019 and it is expected that the first teams will be operational from January 2020. The programme is also funding training for the senior mental health leads to support them in their role, which will be available from June 2020 to July 2024 (subject to contract award).

The programme will be supported by a robust evaluation to increase understanding about the nature and effectiveness of the approach proposed in the Green Paper. A two-phase evaluation is planned. Phase 1 will provide an early evaluation of the trailblazer programme, focusing in particular on the first wave of areas participating in the programme (henceforth the 2018-19 trailblazers) and activities related to two of the programme's main components: the senior mental health leads and MHSTs. It is expected that this will be followed by a summative assessment of the programme's longer-term outcomes and impacts, including – if feasible – an economic evaluation (Phase 2).

This protocol outlines the proposed design and methods for the Phase 1 early evaluation.

¹ All language and terminology used in this protocol to describe the trailblazer programme is correct at the time of writing.

Aims

The overall aim of the early evaluation is to examine the development, implementation and early progress of the trailblazer programme. The early evaluation will explore how service delivery models and implementation strategies differ across trailblazer areas, highlighting the factors (e.g. local contexts) that are inhibiting or promoting progress towards programme goals and drawing out the practical implications of the findings for the development of the programme and the design of the longer term summative and potential economic evaluation.

The specific objectives are to:

1. Understand the baseline position and contextual features of the 2018-19 trailblazer areas, including the accessibility, quality and effectiveness of existing mental health services and support in education settings and perceived gaps in provision prior to the programme commencing.
2. Describe and understand the emerging delivery models, their leadership and governance, and explore how these vary across the trailblazer areas and the potential implications of this variation for future effectiveness of the programme. This includes examining how new roles and services are working in practice, what is working well and what is not, and barriers and facilitators to successful implementation.
3. Describe the experience of MHSTs, education settings, clinical commissioning groups (CCGs) and local authority commissioners, children and young people's mental health services (CYPMHS) and others of taking part in the delivery of the programme.
4. Capture views about the progress being made by trailblazers towards the goals of the programme, early impacts (e.g. the extent to which senior mental health leads judge that they are being better supported in their day-to-day work) and any unanticipated consequences in the initial phases of the programme.
5. Identify measures and data sources of relevance to assessing programme outcomes and costs as well as appropriate comparator areas and education settings in order to assess the feasibility and develop the design of a long-term outcome and economic evaluation.
6. Conduct formative and learning-oriented research, producing timely findings and highlighting their practical implications to inform ongoing implementation and support roll-out to trailblazer areas in later waves of the programme.

In October 2020, in light of the Covid-19 pandemic, a further objective was added:

7. Understand how mental health support teams adapted their services and ways of working in response to the COVID-19 pandemic, and explore experiences of and learning from these changes, as well as their legacy.

The four-week waiting time pilots, EMHP training and DfE commissioned training for senior mental health leads are outside the formal scope of the evaluation. Also outside of the scope of the evaluation is the Education for Wellbeing Return project, which was launched in August 2020 in response to the Covid-19 pandemic, and has been integrated into the trailblazer programme. However, it is likely that some interviewees may comment on these elements of the programme at interview.

While the Phase 1 early evaluation is not a summative evaluation, for it will be too soon in the timescale available to make a formal assessment of impact, it will explore with key groups their views and experiences of the programme and what they think it is achieving in its early stages.

Design and methods

This is a mixed-methods evaluation that combines quantitative and qualitative data collection from all 25 trailblazers with in-depth qualitative insights from five purposively selected case study trailblazers (focusing on one MHST within each case study area). This design will enable an analysis of starting points and development across the programme as a whole and provide the kind of information which is essential not just for assessing whether progress is being made, but also for teasing out the *underlying mechanisms*: where there is solid progress, how is this being achieved; where there is not, why is this so? Particular attention will be paid to the influence of contextual factors on the processes by which the new service models are implemented and any early impacts seen.

The programme operates at multiple levels and so too will the evaluation. It will capture developments, progress and experiences for children and young people; MHSTs; staff in education settings; and the wider local mental health and education systems. Given the complexity of the programme and of the local environments in which it is being implemented, the early evaluation has been designed to be flexible and iterative. Close working with the national programme team will enable the research team to adapt the approach or revise timescales, should circumstances change. This will also support timely sharing of findings to ensure that the research informs and supports implementation and wider roll-out as the programme progresses.

The study comprises three work packages (WPs):

Work Package 1: Establishing the baseline and understanding the development and early impacts of the trailblazers

- *Analysis of routine programme monitoring and other data*: the team will analyse the data which trailblazers will be reporting to NHS England (NHSE) on a quarterly basis during 2019/20 (from 2020 onwards some of the information, particularly on interventions, will flow through the Mental Health Services Data Set). These data will include service metrics (e.g. referral rates, number of children and young people seen, interventions delivered) as well as qualitative information on a range of topics including progress to date, workforce monitoring, issues and challenges, working towards a whole school/college approach to mental health and governance processes. DfE has already carried out a baseline survey of education settings in the 25 trailblazers, exploring current provision of mental health services; it is expected that data from this survey will be made available to the evaluation team for analysis. We will also review information on the budgets and expenditure of each trailblazer.

We will compare the profile and performance of education settings and NHS CYPMH services in trailblazer and non-trailblazer areas, using nationally available data. This analysis will assess the extent to which education settings and CYPMH services in trailblazer areas are representative of England as a whole, and help us to identify suitable comparison areas for the Phase 2 outcome and economic evaluation.

- *Surveys and telephone interviews with key trailblazer contacts*: we will conduct online surveys of trailblazer project leads, senior responsible officers, education leads, managers in the organisation(s) employing MHST staff, MHST managers and the participating education settings in each trailblazer area at two points in time: November/December 2020 and October/November 2021. The surveys will capture information from trailblazer areas that will not be collected through routine monitoring by NHSE and DfE. Follow-up telephone interviews will be carried out with a sub-sample of trailblazer project leads to probe issues, experiences and concerns in greater depth.

- *Interviews with regional leads and members of the national programme team:* we will conduct interviews with the DfE and NHSE regional leads, and members of the national team, supporting implementation of the programme. DfE and NHSE leads for the same region will be invited to be interviewed as a pair, to encourage a joint view of the programme across health and education. National programme team members will also be invited to participate in a group interview, bringing together individuals with similar or connected roles in relation to programme design and delivery. These interviews will explore the development and early progress of the trailblazers, as well as offering formative insights into the different models and approaches emerging across the different areas involved. They will also help us to understand the regional and national contexts for the programme, as well as the nature and extent of support being provided to trailblazer areas by regional and national teams.

Work Package 2: In-depth comparative case studies

- *Sampling and selection of case study trailblazers and MHSTs:* using early findings from WP1, we will develop a typology of trailblazers, identifying the characteristics that are most likely to influence implementation and success. Five case study areas will be selected to ensure diversity across these characteristics, providing a solid basis for comparison between areas. In each case study area, we will focus on one Mental Health Support Team, selected after initial familiarisation with the case study site and in consultation with local stakeholders.
- *Set up and familiarisation with case study sites:* there will be a single lead researcher for each case study site to ensure consistency and ease of contact. At the start of the case study process, research leads will meet with key people, gather relevant documentation and build a deeper understanding of the delivery model, local context, work to date and aspirations for the programme.
- *Qualitative interviews with key stakeholders:* in each case study area, we will conduct 10-15 interviews with a range of stakeholders. Interview samples will be selected to ensure we capture different experiences and perspectives, and will be drawn purposively (therefore the composition of samples may differ from area to area). The combined sample – across the five case study areas – is likely to include Mental Health Support Team staff, senior mental health leads and education setting MHST coordinators, staff from NHS CYPMHS and other local providers of child and adolescent mental health services, local commissioners, local authority children's services, voluntary sector organisations, EMHP training providers and any children and young people or parents/carers involved in the governance of the programme locally. Interviews will be semi-structured and carried out face-to-face, by telephone or via an online platform, guided by an interview topic guide which is tailored to the participant's role. With consent, they will be digitally recorded and transcribed verbatim for analysis.
- *Focus groups with children and young people:* we will carry out up to six focus groups with children and young people attending education settings, preferably those that have a relationship with the MHST chosen for detailed investigation within the case study area. The focus groups will explore children's views about the current environment and practices within the education setting in relation to mental health and wellbeing; awareness of and views about mental health provision within the setting, including the MHST; and whether children and young people have seen any early changes in whether/how their education setting promotes and supports mental health since the start of the programme. With consent, focus groups will be digitally recorded and transcribed verbatim for analysis. The focus groups will be undertaken in two of the five case study areas (purposively selected) and in a range of education settings, with research tools and approaches designed in consultation with a group of young people who have

lived experience of mental health issues acting as advisors to the study. Members of this group will also co-facilitate the focus groups alongside the evaluation team.

Work Package 3: Scoping and developing an evaluation protocol for Phase 2

One of the purposes of the early evaluation is to inform the design and development of a potential Phase 2 impact and economic evaluation. Using the data gathered in Phase 1, we will prepare a draft specification for Phase 2 by:

- reviewing previous, recent evaluations of similar programmes and initiatives to understand their strengths and weaknesses, and practical implications for any future outcome and economic evaluation
- assessing the quality, completeness, relevance and likely future availability of the routine data, including financial and resource use information for costing and educational outcome data. For example, the data available on Public Health England's Fingertips portal (www.fingertips.phe.org.uk) on the expenditure on Local Authority children and young people's services (excluding education), and the data on admissions of children and young people in CAMHS Tier 4 wards.
- developing the research questions for the longer-term study and identify the most practical design options for an evaluation comparing trailblazer and non-trailblazer areas, including ways to collect data that will not be available routinely and potential area comparators (for example, CCG, county and unitary authority), mental health services and education settings so that the added value of the trailblazer investment can be robustly assessed.

Our work will include development of a theory of change for the programme, specifying the programme's desired outcomes, and describing the activities and mechanisms by which these outcomes are expected to be achieved and the contextual conditions which may be integral to success.

Outputs and dissemination

The study findings will be formally reported in an interim (April 2021) and final (March 2022) report, which will be accompanied by short non-technical summaries. In addition to these formal outputs, we will seek regular and timely opportunities to share emerging findings to inform ongoing implementation at a national programme and trailblazer level. Regular meetings of an evaluation Stakeholder Group – which includes representation from the Department of Health and Social Care (DHSC), DfE, NHSE and Health Education England – are planned, and will provide a valuable route for presenting formative findings. We will work with this group to understand the key decision points for the programme, so that we can (as far as is possible) time formative feedback to align with and support these. A draft specification for the Phase 2 evaluation will be developed by February-March 2021. Dissemination activities will also include:

- Publication of findings in academic journals
- Presentations at conferences, seminars, workshops and meetings
- Tailored outputs addressing key findings and/or for particular audiences. This will include an output for children and young people, which we will be designed in collaboration with our child and youth advisors
- Blogs on the BRACE and PIRU websites
- Creating or identifying opportunities to disseminate through existing networks

- Use of social media such as Twitter.

Timescale

The study commenced in October 2019, but was subsequently paused due to Covid-19. Data collection resumed in October 2020, with a new study end date of March 2022. Data collection can only commence once necessary approvals (i.e. university research ethics and Health Research Authority approval) and access to trailblazer sites and data have been secured, therefore timescales may need to be adjusted depending on how long these processes take.

Funding

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Full project protocol

Background and rationale

Introduction²

Recent years have witnessed a growing recognition that mental health services have for too long been marginalised. The principle of parity of esteem as established in the 2012 Health and Social Care Act has important implications for both policy and practice. There is an awareness amongst policy makers and the wider public that children and young people's mental health (CYPMH) services are not consistently available, and in many cases the CYPMH services that do exist are experiencing sustained high demand and consequent delays in access for distressed and often vulnerable children and young people.

Alongside action to improve access to specialist services for children and young people with serious needs and acute problems, there is a growing focus on prevention and early intervention (see, in particular, *Future in Mind*, NHS England 2015). A key aim is to ensure that children with low to moderate needs get early support – to reduce distress more quickly and prevent further exacerbation and more serious need later. There is a recognition that all services that children and young people come into contact with can play a more active role in the identification of their mental health needs and mobilisation of appropriate support, above all, schools and colleges.

The 2017 publication of *Transforming Children and Young People's Mental Health Provision: a Green Paper* set out a joint strategic approach from the then Department of Health and the Department for Education (DfE) to act upon the issues highlighted above and develop a new shared approach to improving CYPMH services. It builds on previous commitments in this area such as *Future in Mind* (2015) and the *Five Year Forward View for Mental Health* (2016). It also builds on other similar work already being pursued in this area such as the *Mental Health Services and Schools Link Pilots*, *Improving Access to Psychological Therapy (IAPT)* and *Targeted Mental Health in Schools (TaMHS)* programme.

The Green Paper outlined a new collaborative approach to provide children and young people with increased support to tackle early signs of mental health problems and a commitment to extend the approach to 20-25% of the country by the end of 2022-23. The key ambitions set out by the government in relation to transforming CYPMH services were:

- Reducing variation in services between geographical areas
- Improving 'joined-up' working between schools, colleges and the NHS
- Reducing out of area placements by increasing the availability of specialist services and local services
- Improving early identification and early intervention
- Promoting resilience and good mental well-being
- Improving timely access for all, but particularly for high-risk and vulnerable groups.

(Department of Health and Department for Education, 2017).

The approach proposed in the Green Paper had three main elements:

1. Incentivising schools and colleges to identify a senior mental health lead to oversee the approach to mental health.

² All language and terminology used in this protocol to describe the trailblazer programme is correct at the time of writing.

2. The creation of Mental Health Support Teams (MHSTs), supervised by NHS CYPMH service staff. The teams will provide specific extra capacity for early intervention and ongoing help, and support the promotion of good mental health and wellbeing. They will be managed jointly by schools, colleges and the NHS.
3. Piloting a four week waiting time for access to specialist NHS CYPMH services.

As part of this new collaborative approach, a national programme of trailblazer areas across the country is leading the roll out of services. The programme will be supported by a robust evaluation to increase understanding about the nature and effectiveness of the approach proposed in the Green Paper. The next section provides a summary of the trailblazer programme.

The trailblazer programme

The first wave of the programme (henceforth the 2018-19 trailblazers) involves 25 trailblazers in 41 Clinical Commissioning Group (CCG) areas covering five regions of England: the North, Midlands and East, South East, South West and London (Figure 1). Key trailblazer selection criteria for 2018/19 included: demonstrable levels of investment in CYPMH services, knowledge of the mental health needs of CYP in the area, demonstrable progress to date in meeting targets for increasing access to mental health services for CYP, and strong leadership in mental health to ensure further improvements. The rationale given for these qualifying criteria was to ensure selected areas had the capacity and capability for implementation at sufficient pace to inform learning and testing. The Department of Health and Social Care (DHSC) and DfE also selected to ensure some geographical³ and demographic (e.g. deprivation, social mobility) diversity, and the first 25 trailblazers include areas involved in other national programmes and initiatives including the Troubled Families programme and Schools Link pilots.

Twelve of the 25 trailblazers will also incorporate pilots focusing on delivering the four week waiting time target. The local implementation of the programme will be supported by NHS England (NHSE) regional teams and newly created DfE mental health regional implementation teams (aligned to NHSE's regional structure).

³ Seven higher education institutions (HEIs) were appointed to provide accredited programmes to train Educational Mental Health Practitioners (a new role, core to the MHSTs). Proximity to one of these HEIs also guided trailblazer selection, which did place some limits on the geographical spread of the programme.

2018 Children & Young People Trailblazer Sites

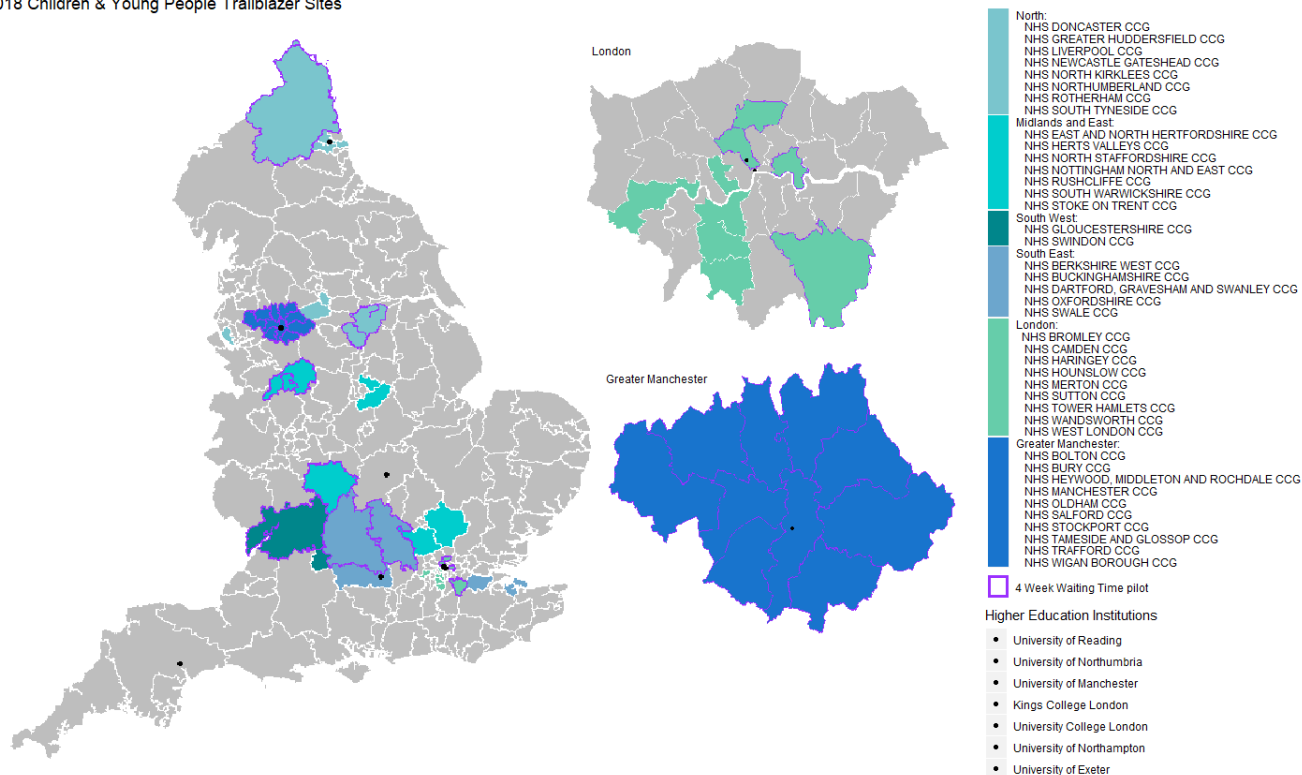


Figure 1: Trailblazer sites (Department of Health and Social Care, 2018)

The education settings recruited to take part in the programme are encouraged to identify a senior mental health lead to oversee the whole school/college approach to mental health. This is not a mandated role and schools and colleges may choose whether and how to embed it. Training will be provided for senior leads – commissioned by the DfE – to help equip them with the knowledge to implement effective processes for ensuring children and young people with mental health problems receive appropriate support, and to promote positive mental health within their education setting so that it becomes a key part of how schools and colleges operate.

The trailblazer programme will also provide funding for the new MHSTs to provide specific and extra capacity for early intervention and ongoing help. MHSTs will be linked to groups of schools and colleges that have opted to join the programme, to promote joined up working between schools, colleges and the NHS. Education settings will identify a Mental Health Support Team Co-ordinator to work closely with the MHST in agreeing the support that will be provided to the education setting. This is primarily a logistical and administrative role, and may or may not be performed by the senior mental health lead.

Trailblazer sites include a mixture of primary, secondary and other schools (e.g. independent and special schools, pupil referral units) and colleges, with a range of population and geographic characteristics including rural and urban mix, deprivation level, CCG rating (according to NHS England's CCG Assessment Framework) and waiting times for NHS CYPMH services.

Each Mental Health Support Team is expected to have three core functions (Box 1), with areas having flexibility to tailor their delivery model to fit local circumstances and needs. So different models of working will be expected to emerge in each area.

Box 1. Mental Health Support Teams' core functions

1. Delivering evidence-based interventions to children and young people with mild to moderate mental health issues
2. Supporting the senior mental health lead in each education setting to introduce or develop their whole school or college approach to mental health and wellbeing
3. Giving timely advice to education setting staff, and liaising with external specialist services, to help children and young people to get the right support and stay in education.

MHSTs will be supervised by more senior NHS specialists. Specifically, it is envisaged that each MHST will be made up of eight members. The indicative team composition is four Educational Mental Health Practitioners (EMHPs), a new NHS Band 5 (Band 4 during training) role which is based on the Children's Wellbeing Practitioner role developed in the CYP Improving Access to Psychological Therapies (IAPT) programme. A further three posts (NHS Band 6-7) will be allocated to more experienced senior clinicians, who will fulfil a more supervisory role or act as senior therapists, some of whom will undertake one year (two years in London) additional postgraduate training in a specific evidence-based psychological intervention. The remaining post will be split into one 0.5 full time equivalent senior manager (NHS Band 8a) and a 0.5 full time equivalent administrator role. In the first wave of the programme areas have been given greater flexibility in the composition of teams, although there is likely to be more standardisation in subsequent waves. Some teams in 2018-19 areas include roles such as family support workers, counsellors, wellbeing practitioners, clinical or educational psychologists, family therapists and youth workers.

MHSTs are expected to form a link between CYPMH services to improve timely access, building on support already available for children and young people with mild to moderate mental health issues. The first (2018/19) wave of the programme will see the creation of 59 teams across the 25 trailblazer areas, with each team providing support to around 8,000 pupils in approximately 20 education settings in their area. It is anticipated that MHSTs will link with a number of services, including:

- professionals providing mental health services in education settings, including educational psychologists, school nurses and counsellors
- special educational needs and disability (SEND) support professionals
- specialist NHS children and young people's mental health services
- inpatient NHS mental health services for children and young people
- specialist NHS eating disorder services
- NHS early intervention in psychosis services
- NHS forensic services
- NHS primary care
- urgent and emergency NHS mental health care
- local authority teams and services
- social workers
- voluntary and community services
- universities
- early years and childcare settings

Integrated services for children and young people with mental health problems will be implemented through the core functions of MHSTs and by linking with the services described above. A series of operating principles has been developed to underpin and guide the work of MHSTs (Box 2).

Box 2. Mental Health Support Team operating principles

1. There should be clear and appropriate local governance including health and education

2. MHSTs should be additional to and integrated with existing support
3. The approach to allocating MHST time and resources to education settings should be transparent and agreed by the local governance board
4. MHST support should be responsive to individual education settings needs, not 'one size fits all'
5. Children and young people should be able to access appropriate support all year (not just during term time)
6. MHSTs should co-produce their approach and service offer with users
7. MHSTs should be delivered in a way to take account of disadvantage and seek to reduce health inequalities.

As they develop their project plans, trailblazers are encouraged to consider the needs of vulnerable children and young people and those who face additional barriers accessing the right support. The Operating Manual for MHSTs notes that, *"MHSTs should work to consider ways in which health needs and inequalities are addressed and that take account of disadvantage. They may need to develop specific protocols for working with particular groups to achieve this."*

The trailblazer approach is intended to be innovative in a number of ways. Firstly, the EMHP role is new. Seven universities across the country are currently training the first cohort of EMHPs – these trainees are following a new curriculum and will be awarded new qualifications. Secondly, the MHSTs and their role reaching out into schools, colleges and other education settings is also new and these teams will need to foster good relationships across multiple organisational boundaries. Thirdly, while some education settings already have a named lead for mental health, the programme will encourage education settings to have a strategic 'senior mental health lead' role, and is funding training for all schools and colleges to support them in implementing this role.

Implementation of MHSTs began in 2018. The NHS Long Term Plan committed to funding increasing coverage of MHSTs to reach 20-25% of England by 2023. This is a key part of the ambition to provide access to support for an additional 345,000 children and young people aged 0-25 by 2023/24. The four week waiting time pilots being delivered by twelve of the 25 trailblazers are due to run for three years, until 2020/21. The current planned phasing of the waves is shown in Table 1.

Table 1. Timetable for programme implementation

	Expressions of interest for trailblazer areas launched	EMHP training commences	MHST delivery commences
2018/19 Wave 1	July 2018	January 2019	January 2020
2019/20 Wave 1	February 2019	September 2019	September 2020
2019/20 Wave 2	February 2019	January 2020	January 2021
2020/21 Wave 1	February 2020	September 2020	September 2021
2020/21 Wave 2	February 2020	January 2021	January 2022

EMHP supervisor training will take place between January and December 2019 for the MHSTs in the 2018-19 trailblazers.

Preliminary scoping research

As part of the orientation and planning process for the early stage evaluation of the trailblazers, we have undertaken preliminary scoping research. This has consisted of a review of policy documentation provided by DfE, DHSC and NHSE with useful detail on the make-up of individual trailblazer sites and the selection process used to decide which areas would be chosen as trailblazers. We also reviewed wider policy documentation of relevance to CYPMH and conducted interviews with more than 30 key informants, many of whom have been directly involved in the design and early implementation of the programme. These interviews added a further dimension of understanding beyond the policy documentation and enabled us to develop a deeper understanding of the aims, objectives and potential strengths and weaknesses of the programme. The key informants were drawn from the DfE, DHSC, NHSE, academia, professional associations and the third sector.

Whilst part of the scoping research was necessarily descriptive in order to sensitise and orient the research team to the topic, this work also identified themes which have implications for the proposed early evaluation of the trailblazer programme. A key emergent theme is the tension between standardisation and variation in the ways in which the different trailblazers develop. Informants spoke of an aspiration to see services tailored to local needs and contextual differences, but also emphasised the importance of areas ensuring that MHSTs deliver all three core functions as defined by the programme. A second theme was the desire expressed by many that the trailblazers are seen to bring something extra in terms of provision – informants were keen that the programme builds on and increases the support already in place and does not displace existing provision. We were told about many parallel programmes and initiatives that have similar or shared aims (such as the Schools Link Pilots). Likewise, we are interested in how the four week waiting time element of the programme will impact on what is delivered and how in the twelve trailblazer areas involved. These concurrent initiatives offer the research team natural experiments locally which we may wish to explore.

Two further important issues that emerged from the interviews related to the whole school/college approach and how we might identify and compare perceptions of this across sites. Also, perhaps most crucially, we will need to consider in the early evaluation how individuals from different sectors and organisations do or do not work together to deliver the aims of the programme. A likely important theme for both these issues will be the role of local NHS and education sector leadership.

The scoping interviews also identified a number of pragmatic concerns with respect to the proposed research – for instance about the best ways to access schools/colleges and involve children and young people in the research. We also need to consider what forms of routine data we can likely access, when and how. Reflecting on these issues has been important in the development of this document and will continue to be discussed further during the project.

Why is this research important/needed now?

Research into the trailblazer programme and wider CYPMH service developments is needed for a number of reasons. Firstly, these developments represent a significant financial investment by the government. There is an additional £1.4 billion available for CYPMH over five years following *Future in Mind* and *Five Year Forward View for Mental Health* commitments. The funding for the Trailblazer Programme is over and above that and is within the funding of the five year settlement for the NHS contained within the Long Term Plan. It is hoped that this investment will have a significant impact on the lives of the children and young people at whom it is targeted. It is important that we learn as much as possible about the processes through which impacts do or do not occur, what those impacts are, and also the extent to which changes in process and impact represent value for money for the taxpayer.

Secondly, the trailblazer programme promises a number of significant innovations in CYPMH, in particular with reference to workforce and professional development. The new EMHP roles and the MHSTs are relatively novel, posing interesting questions related to training, professional status and interactions with existing NHS CYPMH service professionals and teams. Beyond this, it is also crucial that existing and new teams interact positively with schools, colleges and other education settings, as well as others such as local authorities. It is important that the processes through which these organisational innovations develop and their impacts are properly understood.

Linked to this, because the programme will be rolled out in successive waves, timely early research on the experiences of the first year areas offers a valuable opportunity to inform subsequent waves of implementation. In this way, through a close, collaborative and developmental approach between researchers and policy makers, the evaluation can inform the growth of the programme over the coming years. We hope this study can build on other research in this area, such as the Schools Link Pilots evaluation (Day et al 2017), which has demonstrated that a more integrated approach between the NHS and educational establishments and investment in upstream activity is worthy of further focus. Cognisant of the findings of previous evaluations, the proposed research will explore in detail which approaches are most likely to be successful and also how and why this is likely to be so. It will then follow this (in a second phase of the study) with a greater focus on measuring impact and costs.

Finally, a key reason why this research is needed now lies in the fact that there remains a significant degree of unmet need amongst children and young people with respect to mental health service provision. A review of CYPMH services conducted by the Care Quality Commission (2017) concluded that *“too many children and young people have a poor experience of care and some are simply unable to access timely and appropriate support.”* Beyond the investment, workforce and programme effectiveness issues, it is hoped that the proposed research can aid the overall goal of informing policy to reduce the problem of unmet need.

Plan for the early evaluation

The research described in this protocol is for an early evaluation of the trailblazer programme. It is intended that this initial study will be followed by a summative assessment of the programme's longer-term outcomes and impacts, including an economic evaluation, if feasible.

Aim and objectives

The overall aim of the early evaluation is to examine the development, implementation and early progress of the trailblazer programme, with a specific focus on two of the programme's main components: senior mental health leads and MHSTs. The evaluation will explore how service delivery models and implementation strategies differ across trailblazer areas, highlighting the factors (e.g. local contexts) that are inhibiting or promoting success and drawing out the practical implications of the findings for the development of the programme and the longer-term evaluation.

The specific objectives are to:

1. Understand the baseline position and contextual features of the 2018-19 trailblazer areas, including the accessibility, quality and effectiveness of existing mental health services and support in education settings and perceived gaps in provision prior to the programme commencing.
2. Describe and understand the emerging delivery models, their leadership and governance, and explore how these vary across the trailblazer areas and the potential implications of this

variation for future effectiveness of the programme. This includes examining how new roles and services are working in practice, what is working well and what is not, and barriers and facilitators to successful implementation.

3. Describe the experience of MHSTs, education settings, clinical commissioning groups (CCGs) and local authority commissioners, children and young people's mental health services (CYPMHS) and others of taking part in the delivery of the programme.
4. Capture views about the progress being made by trailblazers towards the goals of the programme, early impacts (e.g. the extent to which senior mental health leads judge that they are being better supported in their day-to-day work) and any unanticipated consequences in the initial phases of the programme.
5. Identify measures and data sources of relevance to assessing programme outcomes and costs as well as appropriate comparator areas and education settings in order to assess the feasibility and develop the design of a long-term outcome and economic evaluation.
6. Conduct formative and learning-oriented research, producing timely findings and highlighting their practical implications to inform ongoing implementation and support roll-out to trailblazer areas in later waves of the programme.

In October 2020, in light of the Covid-19 pandemic, a further objective was added:

7. Understand how mental health support teams adapted their services and ways of working in response to the COVID-19 pandemic, and explore experiences of and learning from these changes, as well as their legacy.

The four-week waiting time pilots, EMHP training and DfE commissioned training for senior mental health leads are outside the formal scope of the evaluation. Also outside of the scope of the evaluation is the Education for Wellbeing Return project, which was launched in August 2020 in response to the Covid-19 pandemic, and has been integrated into the trailblazer programme. However, it is likely that some interviewees may comment on these elements of the programme at interview.

While the Phase 1 early evaluation is not a summative evaluation, for it will be too soon in the timescale available to make a formal assessment of impact, it will explore with key groups their views and experiences of the programme and what they think it is achieving in its early stages.

Research design

The key purpose of the early evaluation is to understand what is being implemented in the trailblazer areas, how it is being implemented and how successfully from the perspective of those tasked with implementation, and the factors that influence this. This calls for a research approach which is strongly formative and learning-oriented, with regular and timely feedback of findings to research funders, policy officials, programme leads, local participants (e.g. education settings, CYPMH service providers, CCGs) and wider national stakeholders. This study will produce substantive findings and learning for the programme in its early stages of development, as well as informing the design of the longer-term impact evaluation.

The design of the evaluation has been influenced by several important considerations, which are summarised below.

The study will describe *and* analyse local delivery in context and how this varies

The design of the trailblazer programme has sought to strike a balance between a centrally mandated and locally tailored approach. As the Delivery Support Pack states, “*MHSTs will provide a ‘core offer’ of evidence based mental health support, but localities will have flexibility to design teams according to local need and existing provision.*” Therefore, there will be some degree of variation in the service models and how they are implemented across the 25 areas, and an important task for the early evaluation will be to describe the main features of these service models and implementation strategies and how they differ from one another. As well as variation in the models themselves, there will also be diversity in the local contexts into which these models and the new workforce are being introduced. This could include, for example, differences in:

- the configuration and capacity of local mental health services, including current waiting times
- the composition and skills of the existing mental health workforce
- prior experiences of, and structures for, joint working – within the education and health sectors and between them
- the mix of education settings, and the extent and nature of prior investment in school/college-based mental health services
- previous or ongoing work targeting mental health within schools on which the programme will build
- the profile of mental health need and demography of the local population.

Such contextual factors are likely to have a significant influence on the processes by which the new service models are implemented and outcomes achieved (Bate et al 2014).

A key aim of this early study will be to identify the factors (e.g. particular implementation strategies, features of the local context) which are most likely to influence progress and long-term success. To this end, our approach includes the collection of contextual data: both high level data for all 25 trailblazers (Work Package 1) and more detailed information for a sub-set of case study sites (Work Package 2). Bringing these data together with other sources of evidence – such as routine monitoring data gathered by the programme team and qualitative research to explore the perceptions of key groups involved in trailblazer delivery – will enable us to examine the relationship between contexts, processes and early progress/achievements. This will support the identification of both generalisable and context-specific learning.

The study has been designed to combine breadth and depth in data collection

The overall design is a mixed-methods study, combining quantitative and qualitative data from all 25 trailblazers with in-depth qualitative insights from five purposively selected case study sites and five MHSTs, one in each case study area. This design will enable an analysis of starting points and development across the programme as a whole and provide the kind of information which is essential not just for assessing whether progress is being made, but also for teasing out the *underlying mechanisms*: where there is solid progress, how is this being achieved; where there is not, why is this so?

At the overall programme level, we will conduct online surveys and telephone interviews at two time points, as well as conducting preliminary analysis of routine and monitoring data being gathered by the programme team. A key output of this research will be a typology of the 2018-19 trailblazer sites and their main characteristics; an understanding of local aspirations and success measures; and the identification of emerging barriers and enablers to success. Analysis of routine data will provide a high-level understanding across the 25 trailblazer areas of factors such as MHST composition, activities, student contacts, referrals and spending.

In-depth data collection will be guided by a comparative case study approach. Comparative case studies are particularly useful for studying complex programmes of change where contextual conditions are evolving and interact, and are likely to have a significant impact on success (Yin 2014). Where this is the case, multiple perspectives are required to build a picture of what is happening, why and how. Our qualitative case study sample for interview will therefore include MHST staff, senior mental health leads, Mental Health Support Team Co-ordinators, CYPMH services and other local mental health providers, and wider organisations involved in governance and delivery, amongst others. We will also conduct focus groups with children and young people to explore what they think about their school or college's approach to promoting and supporting good mental health, and whether this is changing with the programme.

The new services will operate at multiple levels and so too must the evaluation

The three key functions of the MHSTs will see them operating at micro, meso and macro levels in the trailblazer areas:

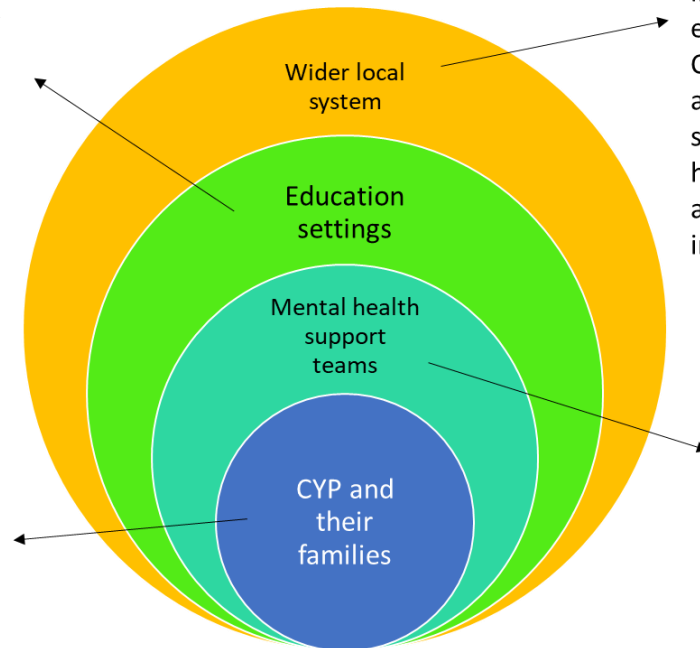
1. Delivering evidence-based interventions to children and young people with mild to moderate mental health issues (micro)
2. Supporting the senior mental health lead in each education setting to introduce or develop their whole school or college approach to mental health and wellbeing (meso)
3. Giving timely advice to education setting staff, and liaising with external specialist services, to help children and young people to get the right support and stay in education (macro).

As Figure 2 (below) shows, the evaluation will attend to the work of the MHSTs at each of these levels, as well as describing how the teams themselves are established, composed, operating and evolving. We will also seek to explore how teams interpret their three core functions and what proportion of their time and resources is invested in each. The goal here is not to determine whether there is an optimum balance across the three functions; indeed it is unrealistic to expect that teams will operate in the same way across diverse education settings. Rather we are interested in exploring how decisions about prioritisation of work and trade-offs between different functions/activities are made, and what the implications of these decisions may be. Understanding the extent to which education settings have been involved in developing the local delivery model for MHSTs will be another important area of focus.

Figure 2. Levels of investigation

e.g. to what extent, and in what ways, are senior mental health leads and MHSTs working in collaboration; how integrated are support teams into education settings and with existing sources of school/college-based mental health support; are, and how are, senior leads and MHSTs facilitating (further) progress towards whole-school approaches; are support teams enhancing, or displacing, current sources of mental health support within education settings; what are the resource implications of implementation for schools and colleges?

e.g. how accessible and effective were school/college-based mental health services prior to the introduction of MHSTs; what kind of services and support are children and young people receiving from MHSTs; who is being targeted and reached; how is equality of access for vulnerable and under-served groups being addressed?



e.g. which organisations are involved in designing and leading delivery; to what extent, and how, are MHSTs improving links and joint working between education settings and NHS CAMHS/other local providers of children and young people's mental health services; what impact is the programme having on patterns and the appropriateness and quality of referrals into CAMHS?

e.g. how are the teams composed and operating; what functions are they delivering; have they got the right balance of skills/is the MHST training programme appropriately equipping the new workforce; are they adequately supervised and supported; what is the staff experience?

The study will focus on the 2018-19 trailblazers and therefore the generalisability of the findings must be considered

The trailblazers will be rolled out in waves, with the 2018/19 MHSTs becoming fully operational in January 2020. It is likely to take some time for the teams to become established (as a team, within education settings and in the wider local system) and for their working practices to stabilise. Given the timescale for the evaluation (originally October 2019 – May 2021; end date subsequently revised to March 2022), the research will therefore focus only on the 2018-19 trailblazer areas, charting their progress as they move from set up to early delivery. In our scoping research, we have sought to understand how the 2018-19 trailblazers were selected and the extent to which they will be typical (both as areas and in the service delivery models being implemented) of the programme as a whole. We understand that there are some features that are particular to the first wave of trailblazers. For example, 2018-19 areas received different levels of funding depending on what was bid for, whereas in subsequent waves all areas will receive the same amount. There has also been more flexibility in the composition of the MHSTs in 2018-19, while future waves will receive a stronger steer from the national programme team, particularly in terms of how many EMHPs each team should include. We will continue to explore and understand the implications of these differences between the 2018-19 trailblazers and subsequent years in the Phase 2 evaluation.

Notwithstanding the above, research with the 2018-19 trailblazers will allow the identification of factors which have shaped the operation and potential effectiveness of MHSTs and senior mental health leads across a variety of settings. While not all the findings will be directly transferable to other areas, they will nonetheless contain practical learning which can inform planning and delivery in the trailblazers that follow. Moreover, the longer-term evaluation will widen the focus to assess experiences, processes and outcomes in sites across multiple waves, building on the insights from this early study.

Our approach to assessing progress towards a whole school or college approach will be informed by existing frameworks and data collection tools

A key feature of the trailblazer programme is the focus on prevention and early intervention, in particular by supporting progress towards a whole school/college approach, where mental health is woven into all aspects of school/college life and seen as everybody's business. The ultimate goal of this approach is to improve the mental health of all children within the setting, not just those with identified mental health needs. Achieving a whole school/college approach is fundamentally about cultural change and this is a long-term process. In the early evaluation, the goal will be to describe what education settings are planning or doing to foster a whole school/college approach and, where possible, identify the learning from these. We will do this through both quantitative and qualitative data collection, and our research will be designed to capture the eight principles which underpin an effective whole school/college approach as identified by Public Health England (see Figure 3). We are aware that there are existing audit and assessment tools based on Public Health England's framework, such as the Sandwell Wellbeing Charter Mark (which is used by more than 30 local authorities in England). We will explore the possibility of including items from these tools in our own data collection processes and of accessing data previously gathered using the tools, which could be used for benchmarking purposes.



Figure 3. Eight principles to promote emotional health and wellbeing in schools and colleges
(Public Health England 2015)

Evaluating a programme of this scale and complexity calls for a flexible and iterative approach

The design of this evaluation has been informed by careful scoping research, including consultation with children and young people, programme leads, wider stakeholders and our specialist advisors (see 'Team' section below for more details of our specialist advisors). The result is a clearly defined method and study timetable, described in the following section. However, change programmes and their contexts are dynamic and evolving and, especially where there is a high degree of innovation as is the case with the trailblazer programme, implementation can take longer than initially expected. In our experience, evaluation of such programmes is most successful when a flexible approach is taken with methodology and timings reviewed and, if needed, adapted in light of changed circumstances. This will be a key function of the quarterly meetings between the evaluation team and programme leads (see 'Project management, governance and delivery' below).

Methods

In order to address the objectives of the early evaluation, the research has been organised into three distinct, but complementary, work packages (WPs):

- **Work Package 1:** establishing the baseline for both the early evaluation and the subsequent longer term summative evaluation and understanding the development and early impacts of the trailblazers
- **Work Package 2:** in-depth comparative case studies of purposively selected trailblazer areas
- **Work Package 3:** scoping and developing the protocol for the Phase 2 summative outcome and economic evaluation.

Work Package 1: Establishing the baseline and understanding the development and early impacts of the trailblazers

Analysis of routine programme monitoring data

Trailblazers are required to report two types of data to NHSE: service metrics and programme monitoring information (see Box 3). Until the MHSTs are included in the routine NHS Mental Health Services Data Set (MHSDS), following the 2020 update of the MHSDS, it is planned that both types of data will be submitted from each MHST via the local CCG to regional teams and then to the national team at NHSE. After 2020, service metrics will be routinely reported through MHSDS; but we do not envisage that data will be available from MHSDS during most of the early evaluation period.

Box 3. Routine management information being reported by trailblazers

Service metrics

- Total number of referrals received and accepted
- Referrals by age, gender and ethnicity
- Number of people being support by MHST
- Primary reason for referral
- Intervention/clinical activity
- Outcomes (number of closed referrals with two or more contacts that i) have a paired outcome score recorded and ii) an intervention recorded)
- Whole school approach (number of i) hours and ii) sessions spent providing training to staff across educational settings).

Programme monitoring information

- Progress to date on providing monitoring data, learning and innovation, co-production, reducing inequalities and improving health outcomes
- Workforce monitoring (e.g. staff in post, vacancies)
- Issues and challenges
- Risks and steps taken in mitigation
- Working towards a whole school or college approach (e.g. details of any work with education settings to monitor wellbeing)
- Governance processes (e.g. evidence that a multi-disciplinary, multi-agency governance group is in existence and is overseeing set up and delivery of MHSTs; evidence that education as well as the NHS is involved in governance and decision making).
- Progress made towards being in a position to flow data to the MHSDS from December 2019, when MHSTs become fully operational.

Eventually, the data submitted by MHSTs will cover all three core MHST functions 1) delivering evidence-based interventions to children and young people with mild to moderate mental health issues; 2) supporting the senior mental health lead in each education setting to introduce or develop their whole school or college approach to mental health and wellbeing; and 3) giving timely advice to education setting staff, and liaising with external specialist services, to help children and young people to get the right support and stay in education. Currently, the information flows focus on the first of these functions. Management information relevant to functions 2 and 3 is still being defined but we know that there will be quantitative indicators on the number of hours MHSTs spend training education staff and the number of sessions delivered. The first quarterly submission from sites to

NHSE was in April 2019 (Q4) with a subsequent submission in July 2019 (Q1), and planned submissions in October 2019 (Q2) and January 2020 (Q3).

DfE has also conducted a baseline survey of education settings in the 2018-19 trailblazers, largely focused on the type and level of mental health support currently being provided within education settings.

As routine data become available for the three functions of the MHSTs, we will request from NHSE the raw data at MHST level used to prepare the quarterly reports (plus the dataset from the DfE baseline survey), and failing those use the reports from these sources alongside the data from our own surveys and interviews to produce an overall characterisation of the first wave of trailblazers at inception and over the first twelve months, at both trailblazer and MHST levels. Descriptive statistics will be produced on topics including staffing, the range of activities recorded, referral rates, the profile of children and young people receiving support from the teams and treatments delivered, etc. Preliminary work will be needed to understand the extent to which the populations covered by the trailblazers align with the populations and boundaries used in education and health routine data.

Analysis of other routine data

The ability to compare the trailblazer areas (e.g. their mental health services, their education settings and student populations) with non-trailblazers is an important consideration in the design of the early evaluation if it is to contribute fully to the design of the summative impact evaluation that is proposed. It would be unfortunate if the opportunity was missed to establish a clear picture during the early evaluation of whether and, if so, in which respects the 2018-19 trailblazers differ from other parts of the country.

We will compare the characteristics of 2018-19 trailblazer education settings with non-trailblazer settings nationally and within local authority areas using data from <https://www.compare-school-performance.service.gov.uk>. This is not to look at the impacts of the trailblazer programme, since it will be too soon to do so, but rather to assess the degree to which 2018-19 sites are representative of education settings in England in terms of variables such as size, qualifications attained by students, destination of students, absence rates, staffing, student-teacher ratio and spending per student. This analysis will also help in identifying suitable comparison areas and education settings for the outcome and economic evaluation (see below for a discussion of potential surveys of mental health provision and support to non-trailblazer education settings). Some data on levels of spending are available from the Children's Commissioner (2019) which could also be used for baseline and comparative purposes.

We will also assemble a comparative dataset on the performance of mental health services in each trailblazer area compared with non-trailblazer services at local and national level using data from the Care Quality Commission (CQC). For example, the CQC (2018) report *The state of care in mental health services 2014 to 2017* includes the ratings for each NHS mental health trust in terms of the degree to which services are safe, effective, caring, responsive and well led, and specific ratings for inpatient and specialist community services for children and young people. Our analysis will include comparing the proportion of services in trailblazer and non-trailblazer areas that are rated as 'outstanding', 'good', 'adequate', 'requires improvement' and 'inadequate'. We will use routine data on the financial position of NHS mental health service trusts (e.g. NHS Improvement 2019) to compare trailblazer area trusts with non-trailblazer area trusts, looking in particular at statistics such as variation between planned and actual expenditure and underlying deficits. Our analysis will also include comparison between trailblazer and non-trailblazer areas in terms of spend per head of population on NHS CYPMH services (using data drawn from NHS England's Mental Health Five Year Forward View Dashboard). Additionally, we will explore the data collated from a number of sources under the "Children and Young People's Mental Health and Wellbeing" profiling tool in Public Health

England's Fingertips portal (<https://fingertips.phe.org.uk/profile-group/mental-health/profile/cypmh>).

We will also review information on the budgets and expenditure of each trailblazer, primarily to help with the design of the economic evaluation but also to add to the description of variation in programme implementation across the trailblazers in the early evaluation.

Surveys and telephone interviews with key trailblazer contacts

We will conduct online surveys of key contacts within each of the trailblazer sites at two points in time: November/December 2020 and October/November 2021. In each trailblazer area the surveys will be sent to: trailblazer project leads, senior responsible officers, education leads, managers in the organisation(s) employing MHST staff, MHST managers and the participating education settings. The survey of education settings will be sent to the senior mental health lead or, if the setting has not appointed a senior lead, to the MHST coordinator to complete. Different groups of respondents will answer different questions depending on their role in the trailblazer and likely knowledge.

The main purposes of the surveys will be:

- **Survey 1:** to gather essential descriptive information from trailblazer areas that will not be collected through routine monitoring by NHSE and DfE. This will include their expectations for the programme, details about the local context including other local programmes of work to improve mental health in education settings, preparation for implementation, governance and stakeholder involvement, and the delivery model. The survey will also capture information about the resources required to set up the trailblazer (both the funding received from the programme and in-kind contributions from local partners to support set up), including some understanding of the opportunity costs.
- **Survey 2:** to understand activities, experiences, achievements and learning over the first year, including identifying barriers and enablers to success, early impacts and plans for future development and ongoing implementation. This survey will also capture information about the costs of ongoing implementation that may not be captured in routine financial information – e.g. how the funding received from the programme is being allocated, to whom and for what purpose, and what in-kind contributions local partners have made to support delivery.

Based on the responses to the online survey, we will probe issues, experiences and any concerns in greater depth in telephone interviews with a sub-sample of trailblazer project leads. The survey of education settings will be designed to complement and build on DfE's baseline survey.

We will work with DfE and NHSE to plan how the two rounds of trailblazer surveys will be distributed. The two options for surveying senior mental health leads, for example, are cascading the survey through regional teams and CCGs to education settings (the approach used in the DfE baseline survey) or administering directly to respondents. Our strong preference is to be able to contact senior mental health leads (or equivalent) and other groups of respondents directly.

Sample frames will be assembled with the help of NHSE and DfE nationally and NHSE/DfE regional support teams. Potential respondents will be emailed a link to the web-based survey plus at least two email reminders to improve response rates. The Key Contacts survey will be administered via SmartSurvey, the educational settings survey will be administered via Qualtrics. The surveys will be sent out with a short covering email explaining the purpose of the research, how the findings will be used and how long the survey will take to complete (no more than 10-15 minutes). For the senior mental health lead/MHST coordinator survey, the research team will gather some basic details about the education setting (e.g. OFSTED rating, performance and workforce information) from publicly available sources to minimise the completion burden on respondents.

Interviews with regional leads and members of the national programme team

Regional support and oversight of the trailblazer programme is provided by a network of NHSE and DfE regional leads. We will conduct interviews with these regional leads (there are 14 in total, seven NHSE and seven DfE), either in person, by telephone or via an online platform. DfE and NHSE leads for the same region will be invited to be interviewed as a pair, to encourage a joint view of the programme across health and education. Where this is not suitable or feasible, leads will be interviewed separately. Interviews will also be carried out with members of the national programme team, with interviewees selected to ensure representation from across the four main programme partners (Department of Health and Social Care, Department for Education, NHS England and Health Education England). These interviews will explore the development and early progress of the trailblazers, as well as offering formative insights into the different models and approaches emerging across the different areas involved (which will inform, for example, the development of a typology of trailblazers – see ‘Sampling and selection of case study trailblazers’ below for more details). They will also help us to understand the regional and national contexts for the programme, as well as the nature and extent of support being provided to trailblazer areas by regional and national teams.

Work Package 2: In-depth comparative case studies

Sampling and selection of case study trailblazers and Mental Health Support Teams

Five trailblazer areas will be selected for detailed investigation, with documentary analysis and qualitative research undertaken in each to provide in-depth insights into trailblazer set up, development, delivery models and progress. From analysis of key documents from the 25 areas (e.g. expressions of interest to join the programme, project plans, quarterly monitoring returns), it should be possible to identify a number of different types of trailblazer based on population size and characteristics, the balance of education settings involved, governance, team composition, etc. Drawing also on insights from published literature and previous evaluations (e.g. of the Schools Link Pilots and Targeted Mental Health in Schools programme), this typology will set out the variables that are most likely to influence trailblazer implementation and success.

Case study sites will be selected to ensure a diversity of different types of trailblazer as identified in the typology, thus providing a solid basis for comparison between areas. At this stage, we would expect such variables to include:

- **Geography:** urban and rural areas; a mix of trailblazers from different regions across England
- **Local provision:** differences in how local mental health services are configured, their quality, financial situation and waiting times, etc.
- **Demography:** a mix of more and less affluent areas, ethnic diversity, etc.
- **Education settings:** selection of sites to ensure inclusion of the full range of education settings, including primary and secondary schools, colleges and other settings
- **Delivery model:** a mix in terms of team composition and size of population covered by teams.

Given that we are unlikely to be able to study more than five sites in any depth, it will not be possible to include all possible combinations of the above variables. In addition, it is likely that we will include at least one case study site which is also implementing the four-week waiting time target. We will discuss the most appropriate approach to sampling with DfE, DHSC and NHSE.

In each case study area, we will select and focus on one of the MHSTs. We understand that teams within each trailblazer area will be operating largely to the same delivery model, team composition, and management and governance arrangements. Therefore, we would expect there to be consistency of approach among teams within the same trailblazer area. Focusing on a single team

will enhance the depth of description and explanatory power of the case study research. The selection of the MHST will be undertaken after initial familiarisation with the trailblazer (see 'Set up and familiarisation with case study sites' below for more details), and in consultation with project leads and other local stakeholders.

Set up and familiarisation with case study sites

There will be a single lead researcher for each case study site to ensure consistency, build relationships with the site and for ease of contact. Researchers will make contact with trailblazer project leads and set up times to meet the lead and other key people involved in design, set up and implementation. The purpose of these meetings will be to:

- Explain the research process, timings and what input/support will be required from the local project team (e.g. brokering access to informants for the qualitative research)
- Build a deeper understanding of the local context, aspirations, project plans and implementation so far, and of the process for selecting and working with education settings
- In sites which are also trialling the four week wait, understand any interdependencies between the different elements of the programme
- Identify key documents for the evaluation team to review as part of the familiarisation process
- Discuss which MHST to select for the research and begin to identify people to approach for an interview
- Develop good working relationships with the case study areas, clarifying expectations and agreeing lines of communication.

Qualitative interviews with key stakeholders

In each case study area, we will conduct 10-15 interviews with a range of stakeholders involved in the trailblazer programme. An iterative approach to sampling will be used whereby, in each area, a small number (e.g. 3 or 4) of initial interviews will be carried out with key respondents, on the basis of which we will identify issues for further exploration and generate a list of additional people to approach. Therefore, the range of interviewees may differ from area to area, but we would expect (across all five case study sites) that interviewees will include:

- Mental Health Support Team staff – a balance of different roles, including the service manager
- A sample of senior mental health leads and MHST coordinators in the education settings served by the Mental Health Support Team – selected to ensure a range of different education settings
- Staff from NHS CYPMH services and other local mental health services
- Relevant CCG and local authority commissioners
- Local authority children's services and education leaders
- Voluntary sector organisations
- EMHP training providers
- Any children and young people or parents/carers involved in the local governance group overseeing the set up and delivery of the programme.

For some groups – such as MHST staff, senior mental health leads and MHST coordinators – we will offer the option of a group interview, potentially 'piggy backing' onto existing meetings or events to maximise convenience. Interviews will be carried out face-to-face, by telephone or via an online

platform. Potential participants will be approached by email or telephone and provided with an information sheet which includes general information about the evaluation, the purpose of the research and what participation would entail. All interviews, with participants' content, will be digitally recorded and transcribed verbatim for analysis.

Tailored interview topic guides will be developed. For example, topic areas for interviews with senior mental health leads and MHST coordinators will include:

- How they were selected for the role
- What activities they are undertaking in the role
- Barriers and enablers to fulfilling the role effectively
- What training they have undertaken and how beneficial this has been
- How they are working with MHSTs and wider mental health services in their area
- Whether and how senior mental health leads in the area are working together and supporting one another
- What their education setting understands by, and how it is seeking to develop, a whole school or college approach
- Gaps in current mental health provision within the setting, including any barriers to access for certain groups of children and young people
- The extent and visibility of senior leadership within their setting for mental health and wellbeing
- What investment their education settings are making (in terms of staff time, use of school resources or direct funding) to support implementation
- Views about whether and how progress is being made, and what long-term success would look like.

Data will be analysed thematically and comparatively, using a team-based approach and guided by the principles of the framework method (see Gale et al 2013). Framework method involves the initial identification of themes from the research questions, to which additional themes are added as new insights emerge from the data. The value of this approach is that it is particularly well suited to the problem-oriented nature of applied policy research, whilst also allowing for an analytical process which remains grounded in and driven by participants' accounts. Comparative analysis will examine similarities, differences and patterns across the five areas, focusing in particular on the identification of explanatory factors – i.e. which factors account for observed differences between trailblazers/teams in their early experiences of implementation and progress made?

Focus groups with children and young people

We will carry out up to six focus groups with children and young people in the case study areas to understand their views about the current environment and practices within education settings in relation to mental health and wellbeing. The focus groups will be undertaken in late 2021, when MHSTs have been operational for some months.

Specifically, this research will explore:

- *Awareness and help seeking behaviours* – where children and young people would go for help if they had any worries about their mental health. We will ask about awareness of MHSTs and explore views about the teams, what they are/will be doing, and how their services are accessed.
- *Whole school or college approach* – what education settings are doing to promote and support mental health, and the extent to which mental health and wellbeing are embedded into the curriculum and across the whole school or college, as seen by children and young people.

- *Perceptions of early change* – whether children and young people have seen any changes in how their education settings are promoting and supporting mental health and wellbeing since the MHSTs came into operation, and their views about any observed changes.

The focus groups will be nested within the larger case study research, with the triangulation of different sources of data enabling an in-depth and multi-perspective examination of the new roles and services and their introduction/integration into education settings. They will be undertaken in two of the five case study areas, purposively selected to ensure diversity in terms of local area characteristics and early experiences of being a trailblazer (as assessed through the initial surveys and early findings from the qualitative interviews). In each area, we will work with trailblazer project leads and other local stakeholders to select and approach three different education settings (e.g. different school types, locations, pupil populations, etc.). The focus groups will bring together children and young people of a similar age, as is widely recommended in the literature (Gibson 2007). In primary schools, groups will include children aged 7 years and above.

Our approach will draw on and be informed by Macdonald and O'Hara's Ten Element Map (1998), an ecological framework for understanding how mental health is promoted and demoted, which draws attention to social conditions and processes at the micro, meso and macro levels. The framework highlights the systemic and structural aspects of mental health promotion. It is therefore particularly well-suited to examining whole school/college practices and has been used in previous studies with children and young people in education settings (e.g. Baker 2013; Hall 2010).

Our approach to recruiting schools and children and young people to participate in the groups will be based on the method developed by the Research Psychology Team at Sandwell Borough Council, and is outlined in Box 4 below.

Box 4. Approaching education settings and children and young people to take part in the research

- An initial approach will be made to the head teacher, explaining the purpose of the research and what taking part would mean for the education setting. An opportunity for the head teacher and/or any other key staff (e.g. the senior mental health lead or MHST coordinator) to speak to a member of the evaluation team before deciding whether to take part in the research will be offered.
- If agreement is given to take part, a member of the evaluation team will meet the head teacher and other key staff to agree how the research will be undertaken. Schools and colleges will be responsible for approaching children and young people to take part. At the set up meeting, the evaluation team representative will explain the importance of selecting a cross-section of pupils and confirm the process for securing *informed* and *voluntary* participation.
- The education setting will be provided with links to a secure website that includes an information video and electronic consent forms (which will have been developed in consultation with, and reviewed by, our child and youth advisors) to use when approaching pupils to take part. Information sheets will include the contact details of a member of the research team should a child or their parent/carer want more information about the purpose of the study or what taking part would involve, before they make a decision about whether to participate.
- The focus groups will take place within the education setting, during the school day. Their length and timing will be tailored to the setting and group concerned – we expect groups with primary age children to be no more than 45 minutes long, and in secondary schools/further

education colleges to be no more than an hour. With consent they will be digitally recorded and transcribed verbatim for analysis.

As is recognised good practice (Gibson 2007; Greene and Hogan 2005), the research process will be tailored and age appropriate:

- Group sizes will vary. With younger children, we will aim for no more than six participants, with older age groups we will increase the maximum number of participants to eight.
- Groups will be co-facilitated by a member of the evaluation team and young person with lived experience of mental health issues, with a second member of the evaluation team present to provide support and deal with any practical issues.
- While the topics to be discussed will be the same across all groups, the way in which these topics are explored will vary so that activities are developmentally and age appropriate. In all the focus groups, we will seek to use creative approaches so that the experience is engaging and enjoyable, ensuring that the process is led by and with the children and young people themselves so that they feel safe and in control. For example, participants might be asked to show researchers and take photos of places within the school environment that make them feel good/less good. Research tools and recruitment materials will be developed in consultation with children and young people who are acting as advisors to the study (see 'Involving children and young people' below).

Further details about the design of the focus group research are provided in the section 'Ethical issues and approvals required' below.

Work Package 3: Scoping and developing an evaluation protocol for Phase 2

One of the purposes of the early evaluation is to identify the main research questions, appropriate design, methods of data collection and data that will be needed for the outcome and economic evaluation, including the feasible balance between reliance on routinely collected data (e.g. from the quarterly returns/MHSDS) and primary data (e.g. longitudinal surveys of students looking at their quality of life and wellbeing). This will be in the form of a draft specification for a potential Phase 2 evaluation. A key element of this work will be the development of a theory of change for the programme, specifying the programme's desired outcomes, and describing the activities and mechanisms by which these outcomes are expected to be achieved and the contextual conditions which may be integral to success.

From the analysis of routine data, we will assess the quality, completeness, relevance and likely future availability of the routine data, including budgetary and financial information required for estimating the costs of the programme over time. From the surveys, interviews and case studies, we will refine the research questions and identify the most practical ways to collect data that will not be available routinely (e.g. the unbudgeted costs incurred by local education settings and other local agencies) and to link, for example, survey data with other datasets at the level of trailblazers, MHSTs, education settings and individual students. From the analysis of routine data, we will identify a range of appropriate potential comparators at the level of geographic areas, mental health services and education settings so that the added value of the trailblazer investment can be robustly assessed.

Project timetable

The project timetable below covers the research to be undertaken post the resumption of the study in October 2020. Primary data collection can only commence once necessary approvals (e.g. university research ethics committee and Health Research Authority (HRA) approvals), and permissions to access trailblazer sites and data have been secured. Therefore, timescales and the content of work packages may need to be adjusted depending on how long these processes take.

Please note, the timing of all data collection activities is provisional, and may need to be adjusted to ensure feasibility for local circumstances (for example, the research based in education settings will be scheduled to avoid particularly busy periods in the school/college calendar). We have proposed relatively large windows of time for key research activities, such as the qualitative interviews, to give us leeway to approach different groups of people at the times of the year that are most suitable to each.

Project timetable

	Oct 20	Nov 20	Dec 20	Jan 21	Feb 21	Mar 21	Apr 21	May 21	Jun 21	Jul 21	Aug 21	Sep 21	Oct 21	Nov 21	Dec 21	Jan 22	Feb 22	Mar 22
National and local approvals for resuming research with NHS staff																		
Regional lead interviews (first round)																		
Select and approach case study areas																		
Educational settings survey																		
Survey of other key informants																		
Initial meetings with case study areas and documentary analysis																		
Qualitative interviews with key stakeholders																		
Preliminary analysis of qualitative interview data																		
Telephone interviews with a sample of trailblazer project leads																		
Analysis of online survey and telephone interview data																		
Discussion paper and research brief for Phase 2 evaluation																		
Prepare and submit interim findings report																		
Set up focus groups with children and young people																		
Analysis of interview data																		
Regional lead interviews (second round) and interviews with national programme team																		
Undertake focus groups																		
Analyse focus group data																		
Undertake second educational settings and other key informants surveys																		
Telephone interviews with a sample of trailblazer project leads (second round)																		
Analysis of online survey and telephone interview data (second round)																		
Draft and submit final report																		
Analysis of programme monitoring data	Ongoing																	

Outputs and dissemination

We envisage that there will be a large audience for the findings of this evaluation including policy makers and programme leads, the managers and staff in trailblazer areas involved in local implementation, NHS CYPMH services, local authorities, schools and colleges (including teacher associations), commissioners of children and young people's mental health and wellbeing services, voluntary sector organisations, academics and researchers working in this field, children and young people, their families and carers, and the wider general public. The team will work closely with topic and communications specialists, including our specialist advisors (see 'Research team' below) and members of the BRACE Health and Care Panel,⁴ to tailor outputs to different audiences in order to maximise reach and impact. Through our scoping research we have already started to foster links with key national bodies, including leading voluntary sector and professional associations in both education and health. We will continue to build these networks and explore opportunities to disseminate through them as the project progresses.

We will produce interim and final reports, in April 2021 and March 2022 respectively. These will be accompanied by short non-technical summaries and – following review by NIHR HS&DR and PRP – will be published in the NIHR Journals Library and on the BRACE and PIRU websites. A draft specification for the Phase 2 evaluation will be prepared – for discussion with our funders and DHSC/DfE/NHSE – most likely in February-March 2021. In addition to these formal outputs, we will seek opportunities to share and discuss emerging findings to inform ongoing implementation at a national programme and trailblazer level. An evaluation Stakeholder Group – which includes representation from DHSC, DfE, NHSE and Health Education England (HEE) – will meet on a quarterly basis for the duration of the project (see 'Project Management, Governance and Quality Assurance' below for more details), and will provide a valuable route for presenting and discussing formative findings. We will work with this Group to understand the key decision points for the programme, so that we can (as far as is possible) time formative feedback to align with and support these.

Our dissemination work will also include:

- Publication of findings in academic journals
- Presentations at conferences, seminars, workshops and meetings
- Tailored outputs addressing key findings and/or for particular audiences. This will include an output for children and young people, which we will be designed in collaboration with our child and youth advisors (see 'Involving Children and Young People' below)
- Blogs on the BRACE and PIRU websites
- Creating or identifying opportunities to disseminate through existing networks, including the National Voices member network (National Voices are a partner in BRACE)
- Use of social media such as Twitter (e.g. tweet chats)

⁴ The BRACE Health and Care Panel provides advice and support for the design and delivery of BRACE projects. Its 49 members include services users and members of the public, senior and operational managers, frontline professionals, voluntary sector organisations, national bodies and researchers. The panel includes members who have lived experience of mental health services and people involved in mental health policy and provision.

Project management, governance and quality assurance

This protocol has been reviewed by two members of the BRACE Health and Care Panel, one of whom is a service user member. It has also been reviewed by representatives from NIHR HS&DR and PRP, DHSC, DfE and NHSE.

Jo Ellins will be responsible for the overall delivery of the evaluation, supported by Kelly Singh who – as project manager – will oversee day-to-day coordination of the research activities and project team. We will apply the following project management principles and processes: ensuring clarity of team members' roles and the delegation of tasks and reporting duties; development and use of project plans; and regular team meetings. Throughout the duration of the evaluation there will be fortnightly team teleconferences in order to update progress and promptly address any arising issues. Face-to-face meetings will be held every 2-3 months to review and discuss progress, share emerging findings and plan future work. The project will formally report to the BRACE Centre executive team – including regular progress reports and prompt sharing of any concerns or identified risks for resolution. Senior supervision and support will be provided by Professor Judith Smith, BRACE Centre Director, who also has overall accountability for all projects delivered by BRACE.

The involvement of the trailblazer programme's main policy stakeholders – DHSC, DfE, NHSE and Health Education England – will be secured through a Stakeholder Group. The group will chaired by representatives from HS&DR (responsible for BRACE) and PRP (responsible for PIRU) on a rotating basis and meet every three months. Formal sign off of all outputs – including this protocol – is by Programme Directors for HS&DR and PRP.

To assure the content of the evaluation (as opposed to its relationship to policy), standard programme requirements will apply and are the responsibility of the research team. The BRACE Centre Steering Group – comprised of members nominated by the BRACE research team and formally appointed by the NIHR HS&DR Programme Director – will also act as the steering group for this study, with responsibility for monitoring study progress and advising on scientific credibility.

Specialist advisors

The team is supported by a group of advisors offering specialist expertise and advice to support study design and delivery, analysis and interpretation of findings, and the production of outputs. Further advisors with specific expertise in different education sectors will be identified and approached as the study progresses to provide support on emerging topics of importance, including the design of the outcome and economic evaluation. Our advisors are:

Chris Bonell

Professor Chris Bonell is a social scientist researching how the school environment influences mental and physical health, and evaluating complex public health interventions. His most recent randomized trial, which was published in the Lancet in 2018, found that the 'Learning Together' whole school intervention, combining restorative practice and student participation, improved student mental health and reduced bullying and substance use.

Karen Newbigging

Dr Karen Newbigging is a Senior Lecturer in Healthcare Policy and Management at the Health Services Management Centre and University of Birmingham's Institute for Mental Health. She is a Chartered Psychologist, Associate Fellow of the British Psychological Society, Fellow of the Royal Society for Public Health, and Senior Fellow of the National Institute for Health Research's School for Social Care. Originally qualifying as a clinical psychologist, Karen has over thirty years' experience in mental health, including direct service provision and commissioning roles within the NHS. For the

past fifteen years, Karen has been involved in mental health research, service evaluations and system development for various health and social care organisations including government.

Colette Soan

Dr Colette Soan is a Specialist Senior Educational and Child Psychologist with a specialism in mental health. She has worked as an Educational Psychologist for 20 years and prior to that as a primary school teacher. Colette has contributed to developing whole school approaches to preventing and supporting mental health in schools. Colette is interested in how psychology can support people in changing things in their lives. She utilises consultative and collaborative principles in her work, in particular, person-centred approaches. Colette is enthusiastic about working systemically with organisations and thinking about how organisations develop. Colette is also an Academic and Professional Tutor with the Educational Psychology training course at The University of Birmingham and a regional tutor with the distance learning course for social, emotional and behavioural difficulties.

Alex Sutherland

Dr Alex Sutherland is Chief Scientist and Director of Research and Evaluation at the Behavioural Insights Team. For most of his near 20 years as a researcher, he has worked on evaluations with the mix of practice, theoretical and policy/political engagement that entails. Alex has extensive experience of research in educational settings, including designing and collaborating on numerous large-scale randomised controlled trials in education.

Florentina Taylor

Dr Florentina Taylor is a Senior Evaluation Manager at the Education Endowment Foundation (EEF), where she currently manages 20 large randomised controlled trials and other evaluations of educational interventions. She has produced several guidance documents on evaluation best practice for the EEF, in addition to academic and practitioner-oriented publications. She has 12 years' research experience in education and social justice, as well as over 20 years' teaching and curriculum development experience, including six years as a university academic.

Involving children and young people

The scoping work undertaken to inform the design of the study and development of the protocol included rapid consultation with two groups of young adults (16-25 year olds) who have lived experience of mental health issues: the University of Birmingham's Institute for Mental Health Youth Advisory Group and the Think4Brum group (the participation group for Birmingham's NHS Child and Adolescent Mental Health Services). The groups shared their views about the Green Paper proposals and what they would like the evaluation to focus on, as well as making practical suggestions about the design of the focus group research with children and young people. The draft protocol has been reviewed by a young person who is a member of the BRACE Health and Care Panel.

We will continue to work closely with members of the University of Birmingham Youth Advisory Group as the evaluation progresses. Our ongoing consultation with this group will fulfil the following aims:

- Co-designing the recruitment and consent process for the focus groups with children and young people, and the content/format of the groups themselves. Members of the Youth Advisory Group will also co-facilitate the focus groups, working with and supported by a member of the research team who has substantial experience of working in partnership with young people who have experience of mental health issues and services.

- Sharing and asking for comment on emerging findings – for example, about whether the focus, activities and early progress being made in trailblazers is addressing the priority issues and concerns for children and young people with mental health issues.
- Discussing which outcomes valued by children and young people should be measured in the longer-term study and how, including views about existing outcome measures and the feasibility and appropriateness of using these for impact evaluation.
- Seeking advice about the best ways to frame and disseminate the research findings to children and young people.

The children and young people consulted about the study will be paid for their time and have their expenses reimbursed, consistent with best practice guidelines (INVOLVE 2015).

Ethical issues and approvals required

Standards of good practice for research will be followed (Social Research Association 2003) and the project will be undertaken in compliance with the Data Protection Act and University of Birmingham policies relating to the conduct of research. The study will require approval by the University of Birmingham and London School of Hygiene and Tropical Medicine research ethics committees, and Health Research Authority approval (HRA) for the research with NHS employees. Applications for ethical and HRA review will be sought at the earliest possible opportunity. The team has significant experience of securing ethical and research governance approval including for projects on sensitive topics and/or involving service users and vulnerable groups.

Research processes will be designed to ensure that participation is informed and voluntary. All potential participants will receive information about the study (purpose, design, timescales, what involvement would entail, how data will be managed, etc.) before deciding whether to take part. This will make clear that they can withdraw from the study, without giving a reason, at any time up until a specified cut-off date. Should they withdraw, their data will be destroyed. Written consent will be taken prior to participation; in the case of telephone interviews, this will involve participants returning a signed electronic consent form either in advance or straight after the interview (no data will be processed until consent has been received). If the written consent form isn't returned, the researcher will go through the consent process verbally prior to the interview commencing, and will then ask the interviewee to re-confirm that they give their consent once the digital recorder has been turned on (so that consent is formally recorded on the interview transcript). Anonymity in reporting will be guaranteed.

Research with children and young people raises specific ethical and safeguarding issues (Einarsdóttir 2007; Greene and Hogan 2005; Parsons, Sherwood and Abbot 2016) which have been carefully considered in the design of the study. In particular we would emphasise that our approach includes:

- An information video and online consent form – for children and young people, and (for under 16s) their parents and carers - that was co-designed with young people, making use of clear, accessible and age-appropriate language. The information video will include contact details for the research team, should the child or young person (or their parent/carer) wish to find out more about the study and/or what taking part would involve.
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- The information video will emphasise that participation is voluntary and that the child can withdraw from the study at any time (up until a specified cut-off date). It will be made clear that

withdrawing from the study will have no consequences for the child and that their data will be immediately destroyed.

- Working closely with education settings to recruit participants to the focus groups. We will meet with key staff at all schools/colleges involved to talk through recruitment, emphasising the importance of voluntary participation and the practices which support this. Education settings will be encouraged to approach children from a mix of backgrounds to achieve a balance of different views and experiences.
- Before the focus group commences, a member of the research team will verbally re-iterate key information in clear and simple terms and check for understanding. Particular attention will be paid to the issue of confidentiality: what is it, why is it important, under what conditions would the research team break confidentiality and what would this involve? Every effort will be made to ensure that participants understand the basis on which consent is being given.
- Developing a 'breaking confidentiality' policy which all team members involved in the focus groups will be trained in. This policy will state the circumstances under which a researcher can or should disclose to a third party information which has been shared by a child/young person in a focus group, to whom that information would be disclosed and what support should be provided to the child/young person concerned.
- Researchers and co-researchers will participate in a debrief with a senior team member after each focus group, so that any potential concerns or emotional distress experienced as a result of the research can be discussed and appropriate support provided. A senior member of the team will be available by telephone after each focus group so that any immediate concerns can be discussed (and, if necessary, acted on) on the day.
- Research methods tailored to age groups to ensure they are appropriate and engaging. Our child and youth advisors will be involved in the focus group design, and will review all tools/materials to be used in them prior to use.
- Working with education settings to ensure that appropriate support is on hand in the event that a child becomes distressed or upset during or after the focus group. We will share and discuss the focus group guide in advance with the senior mental health lead, designated safeguarding lead and any other staff that the education setting wishes to be informed, so that they are aware of the topics that will be discussed.
- Two members of the research team being present at all focus groups, both of whom will be experienced qualitative researchers with appropriate Disclosure and Barring Service (DBS) checks.
- Producing short, age-appropriate summaries of the findings across the six focus groups to be shared with the children and young people, their parents and carers, and staff in the education setting.

Data security and data sharing

All data will be stored in accordance with the University of Birmingham's Data Protection and Research Data Management policies, and in compliance with GDPR and the UK Data Protection Act 2018. All electronic data will be stored on the University of Birmingham research data store (RDS), in a folder accessible only to members of the study team. Interviews with participants will be recorded on encrypted voice recorders or directly to encrypted laptops and data stored on research team laptops will be password protected. They will be transcribed by Clayton Research Support, with whom a confidentiality agreement will be signed.

Personal information will only be kept for as long as necessary practically and for no longer than seven years. Any paper-based data will be stored in locked filing cabinets in locked offices at the University of Birmingham, RAND Europe and London School of Hygiene and Tropical Medicine. Research data will be held for a period of 10 years in line with University of Birmingham's Research Data Management Policy.

If it is decided that survey data collected by the evaluation team can and should be shared with DHSC/DfE/NHSE for further analysis, we will develop a suitable process for secure data transfer and maintenance of respondent anonymity. These arrangements will be incorporated in a revised version of this protocol once they have been approved by the HRA.

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