Greater Manchester
Mental Health
NHS Foundation Trust

The Resilience Hubs evaluation

A multi-site, mixed-methods evaluation of an NHS Outreach, Screening and Support Navigation service model to address the mental health needs of key workers affected by the COVID-19 pandemic

RESEARCH PROTOCOL
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SIGNATURE PAGE

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

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

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

For and on behalf of the Study Sponsor:

Signature: Date:

..../...../.....
Name (please print):

.....
Position:

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Chief Investigator:

Signature: Date:

..../...../.....
Name: (please print):

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The Resilience Hubs evaluation: A multi-site, mixed-methods evaluation of an NHS Outreach, Screening and Support Navigation service model to address the mental health needs of key workers affected by the COVID-19 pandemic

Contents

Abbreviations

AE	Adverse Event
AUDIT	Alcohol Use Disorders Identification Test
BAME	Black, Asian and Minority Ethnic
CHEERS	Consolidated Health Economic Evaluation Reporting Standards
CRF	Case Report Form
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, 5th Edition
EQ-5D-5L	EuroQol Five Dimensions, Five Level Questionnaire
GAD-7	Generalized Anxiety Disorder 7 questionnaire
GCP	Good Clinical Practice
GMMH	Greater Manchester Mental Health NHS Foundation Trust
HRA	Health Research Authority
IP	Intellectual Property
IAPT	Improving Access to Psychological Therapy
ITQ	International Trauma Questionnaire
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
CTIMP	Clinical Trials of Investigational Medicinal Products
PCL-5	Post-Traumatic Stress Disorder Checklist for DSM-5
PCMIS	Patient Case Management Information System
PHQ-9	Patient Health Questionnaire 9
PI	Principal Investigator
PMG	Project Management Group
PPIE	Patient and Public Involvement and Engagement
PTSD	Post-Traumatic Stress Disorder
PSC	Project Steering Committee
QALY	Quality-adjusted life year
RA	Research Assistant
REC	Research Ethics Committee
REDCap	Research Electronic Data Capture
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
UoM	University of Manchester
UoS	University of Sheffield
WSAS	Work and Social Adjustment Scale
WTPT	Willingness To Pay Thresholds

Key study contacts

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Study summary

Study Title	The Resilience Hubs: A multi-site, mixed-methods evaluation of an NHS Outreach, Screening and Support Navigation service model to address the mental health needs of key workers affected by the COVID-19 pandemic
Internal ref. no. (or short title)	The Resilience Hubs evaluation
Study Design	Mixed methods case study, where the cases are the three Resilience Hubs considered in this project. The project comprises: 1) the analysis of mental health data routinely collected at Hub screening, 2) exploratory health economic evaluations based on service use and health economic data from key workers who completed Resilience Hub screening; 3) qualitative interviews with Hub providers (therapists; recovery workers; service managers; commissioners) as well as key workers who either accessed Hub support or did not register with the Hubs; 4) integration of the above through cross-case comparison, pattern-matching, explanation-building and logic modelling.
Study Participants	Key workers eligible for Hub support in three UK regions, and 'Hub providers' i.e. individuals involved in the Hubs' commissioning, setup and delivery of clinical offers (e.g. service managers, clinical team managers and other professional stakeholders including commissioners and project managers).
Planned Size of Sample (if applicable)	Not applicable for analyses of routinely collected data and subsequent service use and health economic data collection activities. Qualitative interviews will involve the recruitment of approx. 30-42 key workers who either accessed Hub support or did not register with the Hubs, and 18-24 Hub providers
Follow up duration (if applicable)	Not applicable
Planned Study Period	20 months (01/10/2020 to 31/05/2022)

Research Question/Aim(s)	There are four principal aims: 1) To conduct a quantitative analysis of routine demographic, occupational, and mental health screening data to model future service demand and guide adaptations to the Resilience Hub approach to suit contextual needs and inform evidence-based commissioning. 2) To conduct a health economic analysis, which will estimate the cost and health benefits associated with the set-up, use and management of Resilience Hubs, to understand whether they represent potentially cost-effective systems of care. 3) To conduct qualitative interviews with multiple stakeholder groups to identify the barriers and enablers to the repurposing of the Resilience Hub model to respond to novel crises and the implementation/scaling of the Resilience Hub model across various UK regions 4) To produce mixed method case studies integrating and triangulating findings from the above qualitative and quantitative components to produce recommendations for maximising outreach and mental health screening uptake and psychosocial support access and uptake following screening as well as resolving systemic and organisational barriers to accessing onward support.

Funding and support in kind

FUNDER(S)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
National Institute of Health Research (NIHR) netsmonitoring@nihr.ac.uk	All investigators, research support staff and project resources are funded through an NIHR COVID-19 "Recovery and Learning" Cross-programme grant (grant reference: NIHR132269) awarded to Greater Manchester Mental Health NHS Foundation Trust.

Role of study sponsor and funder

The proposed project has been reviewed by an NIHR funding panel as part of the COVID-19 "Recovery and Learning" Cross-programme call, and was recommended for funding in September 2020. The project's Sponsor is Greater Manchester Mental Health NHS Foundation Trust (GMMH). The GMMH R&I office will oversee study set up, delivery and close out to ensure research governance compliance. An individual from the study team will be identified and delegated by the Sponsor to act in a quality/compliance capacity on behalf of the sponsor in line with the sponsorship oversight framework.

The NIHR and the Sponsor have no direct involvement in the selection of the study design, conduct of the research, data analysis and interpretation or dissemination of results. The analysis, interpretation and preparation of outputs will be sole responsibility of the project team, and the views expressed will be those of the authors and not necessarily those of the NIHR, the Department of Health and Social Care or GMMH.

Roles and responsibilities of study management committees/groups & individuals

Project Steering Committee

In line with NIHR guidance, an independent Project Steering Committee (PSC) will be assembled to provide independent oversight of the project. The members of the PSC will be independent from the Sponsor and Investigators (i.e. they will not be involved other funded research collaborations with the Investigators and will not be affiliated with GMMH or any of the Investigators' substantial employers, in addition to other independence criteria outlined in relevant NIHR guidance). PSC membership will conform to NIHR guidance and will include: 1) an independent chair with experience of management of research projects in clinically applied areas; 2) an independent statistician; 3) an independent health economist; 4) an independent clinician; 5) an independent person able to provide relevant PPIE perspectives and 6) the project CI (Varese) and co-CI (French). Other members of the project team, as well as a representative of the Sponsor, will be able to attend PSC meetings in a non-voting capacity, on an ad-hoc basis when their contribution will be deemed necessary or beneficial by the members of the PSC.

Members of the PSC will be initially nominated by the project's CI and co-CI following consultations with other Investigators; these nominations will be communicated to NIHR in November 2020. PSC members will be then officially appointed by the NIHR after confirmation of independence of relevant PSC members, and subsequent variation in PSC membership will require formal approval from the NIHR. A minimum of three PSC meetings will be conveyed over the course of the project, timed around key project milestones (in January 2021, December 2021 and towards the end of the study), but additional ad-hoc meetings may be organised according to need.

The PSC will be responsible for the independent oversight of the project on behalf of the Sponsor and the NIHR and will ensure that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. To PSC will 1) provide advice on all appropriate aspects of the project; 2) review the progress of research against the project timeline, monitor adherence to the protocol and the consideration of new information of relevance to the research question; 3) review issues related to patient safety (e.g. any AE or SAE) and ensure that, throughout the project, the rights as well as safety and well-being of the participants will be prioritised over the interests of science and society; 4) agree proposals for substantial protocol amendments and provide advice to the Sponsor and NIHR regarding approvals of such amendments.

Patient & Public Involvement and Engagement (PPIE) Group

We will assemble a core PPIE advisory group, chaired by our PPIE Lead (McGuirk) and meeting every 2 months (10 meetings over the course of the project, with approx. 6-8 attending members per meeting). These will be crucial at 4 key time points: 1) Development and fine-tuning of participant-facing materials and design of service use questionnaire; 2) Recruitment strategies; 3) Refinement of interview topic guides; 4) Interpretation of findings. The core group will represent different occupational (e.g. care staff; medics; nursing etc.) and demographic groups (e.g. BAME; men). Members of the PPIE advisory groups will also advise on additional targeted consultations and community engagement activities that may be needed to gather wide-reaching feedback from other under-represented groups.

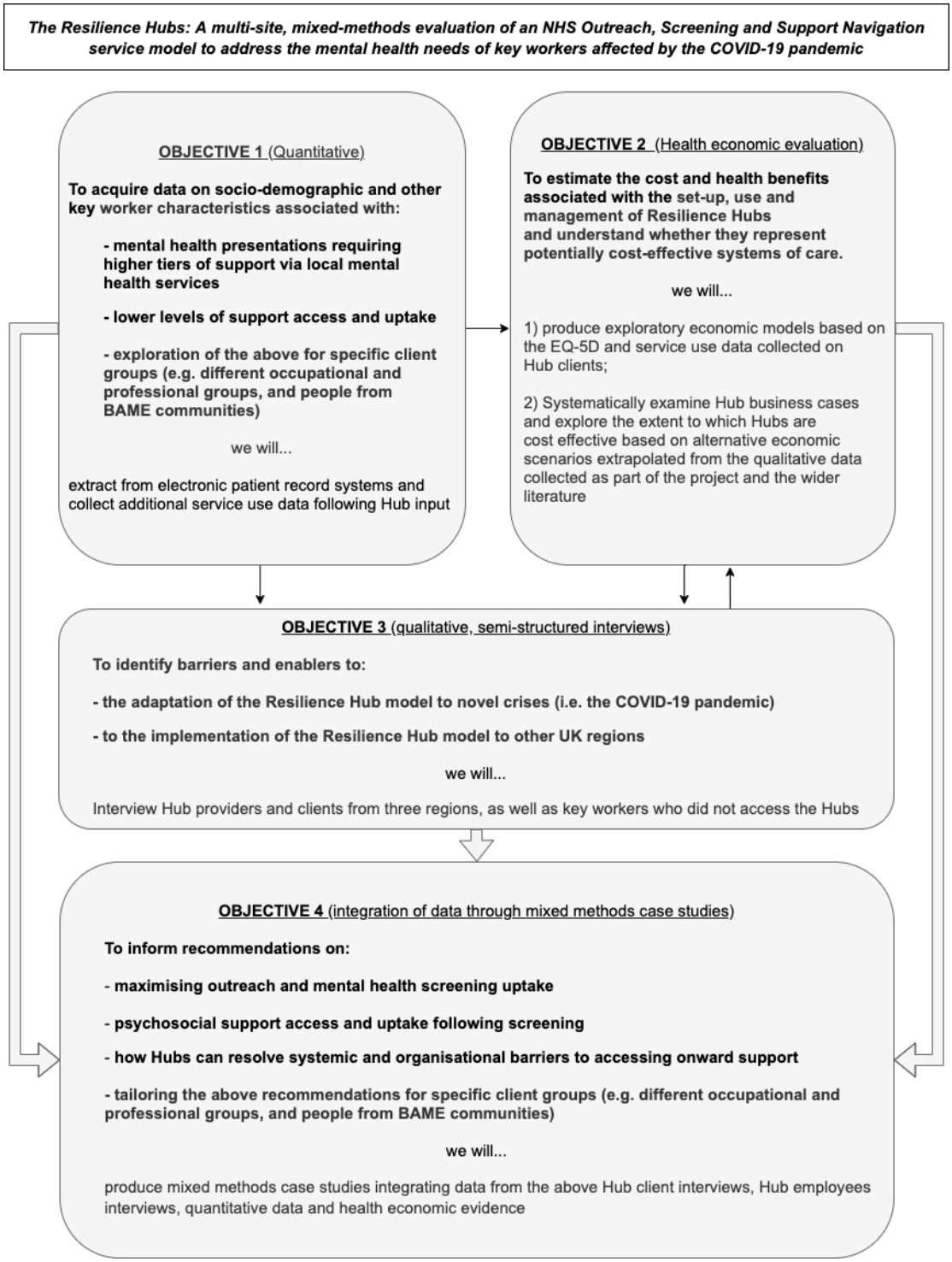
Protocol contributors

Drs Allsopp (project manager), Varese (CI) and French (co-CI) were responsible for the drafting of the protocol on the basis of the Detailed Project Plan of the grant application submitted to NIHR as part of the COVID-19 "Recovery and Learning" Cross-programme. Other co-Investigator provided specific contribution and oversight of specific sections of the protocol consistent with their methodological and clinical expertise, including statistics (Dr Carter), health economics (Prof Davies and Ms Shields), qualitative and mixed-method research (Prof Lind), clinical and service delivery aspects of the Resilience Hub model (Drs Barrett and Bhutani) and PPIE (Ms McGuirk). The NIHR and the Sponsor had no direct involvement in the preparation of the study protocol.

Key words

COVID-19, mental health, key workers, resilience, health service research

Study flow chart



1. Background

A healthy and resilient workforce is needed across the NHS and social care services to ensure optimal response to both the current pandemic and future large-scale incidents. Extensive research in post-disaster mental health and emerging evidence on the impacts of the COVID-19 pandemic has established that mental health issues are widespread, particularly within vulnerable groups including healthcare, social care and emergency response key workers. The personal and professional adversities that key workers are facing have a dramatic impact on their mental health. In addition to the personal distress experienced by individual workers, the mental health impact of the pandemic could further erode the ability of services to provide an ongoing optimal response to both COVID-19 and usual care, at potentially huge financial cost and loss of life. There is an urgent need to evaluate systems enabling i) the timely identification of key workers who experience mental distress as a result of the COVID-19 pandemic, and ii) the facilitation of access to evidence-based support most appropriate for their specific needs.

The 'Resilience Hub' approach is an innovative service model, originally developed in response to the 2017 Manchester Arena bombing, that could address the urgent mental health needs of key workers affected by the COVID-19 pandemic. This system of care was designed not only to respond to the immediate needs of young people, adults and emergency response workers affected by the bombing, but also as an adaptive system of response that could be redeployed when the situation demanded, ensuring that expertise in large-scale mental health screening and trauma management could be sustained and repurposed for responding to future crises. Therefore, when the COVID-19 pandemic arose, local expertise and infrastructure were already available to provide large-scale mental health screening and support, and the Hub was adapted in Greater Manchester to support NHS, social care and emergency service key workers throughout the COVID-19 crisis. This model is being replicated in other UK regions to support the mental health needs of key workers affected by the pandemic.

Our research will evaluate this model in order to maximise and inform the setup and implementation of new Hubs. Crucially, not only will these Hubs provide immediate support for the current pandemic, but also the legacy of an adaptable system of mental health response that can be flexed as necessary to manage mental health needs associated with large-scale crises.

2. Rationale

Meta-analyses and literature reviews on the mental health impacts of past epidemics (e.g. SARS, H1N1, MERS) have highlighted that key workers are at high risk for both acute and long-term mental health issues as a result of the personal and professional adversities faced during urgent public health crises. Key workers involved in varied forms of care provision during these outbreaks suffered from high levels of burnout, psychological distress (e.g. anxiety and depression) and

posttraumatic stress, with studies indicating that these adverse mental health consequences can endure for over 3 years [1, 2].

Mental health complaints are also a common response to the COVID-19 pandemic, both within the general public and especially among health and social care key workers. Observational studies from the countries most affected in the early stages of the pandemic (e.g. Italy, China) have highlighted that key workers are at significant risk of adverse mental health outcomes due to a range of distinctive risk factors, including long working hours, risk of infection and fear of infecting family members, shortages of personal protective equipment (PPE), loneliness, physical fatigue, and separation from families [3]. A meta-analysis of 13 studies [4] found that at least 20% of key workers report symptoms of depression and anxiety. Certain professional and demographic groups are disproportionately affected, e.g. female key workers and nursing staff [3]. There are growing concerns that key workers who belong to Black, Asian and other ethnic minorities (BAME) may be particularly affected [5], as well as key workers exposed to work circumstances conducive to 'moral injury', i.e. psychological distress that results from actions, or lack of, that violate a person's moral or ethical code; for example having to make difficult decisions about which patients can access life-saving equipment in times of critical shortage [6].

UK-specific evidence on the mental health impacts of the COVID-19 pandemic is mounting, with alarming findings. A recent community cross-sectional study (N = 3097), predominantly comprising key workers, observed levels of anxiety, depression and stress considerably higher than usual population norms [7]. A survey conducted on a nationally representative sample found that, in the first two months in the lockdown, health and social care key workers were more likely to report clinically significant levels of anxiety (approx. 25% of the key workers), depression (approx. 28%) and PTSD (approx. 37%) than non-frontline workers [8]. An ongoing longitudinal survey by our research team (with over 2500 NHS clinical and ambulance staff across 70 NHS organisations; www.manchester.ac.uk/covid19-resilience-project) suggests that 46% of NHS key workers report clinically significant levels of either anxiety, depression or post-traumatic stress, with approximately 10% of the sample having comorbid difficulties across all these domains. Many key workers also report signs of 'compassion fatigue' and burnout (36%), recent excessive/problematic alcohol use (17%) and suicidal ideation (3%). Our data further confirm that these difficulties are particularly pronounced in certain demographic groups (e.g. female staff; BAME staff; individuals who care for high-risk family members; pre-pandemic mental health problems), certain professional groups (e.g. staff whose workload comprises predominantly COVID-19 patients) and staff exposed to specific COVID-related stressors (e.g. potentially morally injurious work conditions). In a proportion of key workers, the above difficulties may represent an acute response to the current crisis. However, evidence from both past pandemics and large scale crises/disasters suggests that, if unsupported, a considerable number may develop enduring and debilitating mental health issues [9].

UK mental health services offer evidence-based psychological therapies, but what is missing is a way to identify key workers who most need support from these services,

and help them to access these therapies in a timely manner [10]. Consequently, both nationally and internationally, there have been numerous recommendations to establish, scale-up and evaluate effective and timely systems for monitoring the mental health impacts of the COVID-19 outbreak among key workers, and facilitate access to appropriate psychosocial support for those who most need it. These calls, informed by extensive research in disaster mental health [11], have particularly highlighted that response efforts should include: 1) proactive outreach approaches to encourage open communication about and disclosure of the mental health difficulties, therefore addressing possible reluctance amongst certain professional groups about disclosing vulnerability even when experiencing significant distress; 2) timely early detection and screening for mental health problems; 3) the importance of identifying and effectively treating milder mental health presentations before they evolve into more complex and enduring mental health issues; 4) the provision of tailored support according to individual needs, including 'lower intensity' support (e.g. psychoeducation; access to support hotlines and remote advice/support) as well as direct provision of psychological support to any healthcare workers who might need higher intensity interventions [1, 4, 11–13]. In the specific context of the UK stepped care mental health service structure, recommendations have included implementing mental health screening to determine the tier of support required, and subsequently ensuring the availability of systems for appropriate referral to the most appropriate higher tier of support, e.g. telephone counselling; IAPT low intensity and high intensity interventions; specialist mental health services [1].

The Resilience Hub approach is an existing model of outreach, mental health screening, and facilitation of key worker access to psychosocial support that addresses the above recommendations and is currently being implemented in several UK regions to address the mental health impacts of the COVID-19 pandemic. Developed in response to the 2017 Manchester Arena bombing, the original Greater Manchester Resilience Hub operated a version of other evidence-based 'screen and treat' approaches [14, 15] used in response to previous disasters/terrorist events, but adapted to include further outreach efforts to address the need of reaching the geographically dispersed population affected by the Arena attack [10]. Furthermore, the service was designed as an adaptive system of response that could be flexed and repurposed to respond to additional large-scale incidents. To date, in addition to the Arena attack, the Greater Manchester Hub has supported people affected by other potentially traumatic incidents in the Greater Manchester region, including the Bolton student accommodation fire (2019), the Reynhard Sinaga serial rape case (2019) and the Manchester Victoria stabbing (2018), as well as local victims of other large-scale incidents outside of Greater Manchester, including Grenfell (2017) and the Sri Lanka terror attack (2019). Research evaluations have attested the effectiveness of the Resilience Hub approach when responding to mass casualty events. Analysis of follow-up screening data from 3150 Hub clients suggests early registration was associated with greater improvement on mental health outcomes [16], demonstrating the value of proactive outreach and early intervention. Furthermore, process evaluation research conducted by our team [17] and practice-based learning from the application of the Hub approach [10] identified crucial areas of improvement relevant to the adaptation of the Hub approach to future crises.

First, Hub staff encountered considerable barriers in referring clients to mental health services, especially in non-urban areas where the availability of certain forms of recommended support (e.g. trauma-focused therapies) was inconsistent. Second, cultural factors are likely to hamper professionals' reporting of mental health symptoms and engagement with mental health services. Third, data sharing barriers can considerably delay outreach efforts.

In response to the above challenges, the current Resilience Hub model has been adapted to provide 1) an outreach and large-scale mental health screening offer supported by early negotiation with partner organisations around necessary data sharing (email/telephone contacts) to facilitate direct offer of Hub support to key workers, as well as 2) an additional 'support navigation' offer with a focus on negotiating and facilitating access to timely support and specialist interventions according to clinical need (see p.5). Due to the vast numbers of key workers affected by the pandemic and the likelihood of further COVID-19 waves, the Resilience Hub model is already being replicated across multiple regions (8 Hubs are currently at different stages of set-up), and there are advanced discussions within NHS England in rolling out the approach across the UK. The feasibility and effectiveness of using the Resilience Hub model for its current intended purpose across multiple regions is yet to be demonstrated. It is therefore vital that this knowledge gap is addressed and that we provide the NHS with the necessary knowledge to maximise the effectiveness of the Resilience Hub model and guide future implementation efforts.

3. Research question and objectives

This research will evaluate the 'Resilience Hub' model in three different UK sites. The project will involve a mixed-methods case study, integrating the findings from qualitative, quantitative and exploratory economic evaluation work that we will conduct across three Resilience Hubs. The mixed methods case study will be a multiple-case design, where the cases are the three Resilience Hubs, with four embedded units of analyses within each case (key worker interviews, hub worker interviews, routine quantitative data and health economic evidence collected as part of the project) and cross-case analysis.

Aims:
The overall aim is to provide crucial evidence-based recommendations for the refinement and improvement of an existing model of outreach, mental health screening, and facilitation of key worker access to psychosocial support; as well as best principles for ensuring the 'transactability' of the Hub approach (i.e. how can it be scaled up, replicated in other sites in the UK, and adapted and mobilised in response to future crises).

Objectives:
Specific objectives include:

OBJECTIVE 1: To conduct a quantitative analysis of routine demographic, occupational, and mental health screening data, which will provide findings to model service demand and guide future adaptations to the Resilience Hub approach to suit contextual needs and inform evidence-based commissioning. This will include:

a) socio-demographic and other key worker characteristics associated with mental health presentations requiring higher tiers of support via local mental health services;

b) socio-demographic and other key worker characteristics associated with lower levels of support access and uptake;

c) specific exploration of points *a* and *b* for different key worker groups, for example, different occupational and professional groups, and people from Black, Asian and Minority Ethnic (BAME) groups.

OBJECTIVE 2: Conduct a health economic analysis, which will estimate cost and health benefits associated with the set-up, use and management of Resilience Hubs, to understand whether they represent potentially cost-effective systems of care.

OBJECTIVE 3: Conduct a qualitative interview study, providing contextually rich data from multiple stakeholder groups to identify the barriers and enablers to:

a) the repurposing of the Resilience Hub model to respond to novel crises (i.e. the COVID-19 pandemic);

b) the implementation/scaling of the Resilience Hub model across various UK regions presenting significant contextual differences (e.g. levels of social deprivation; urban vs. rural regions; variations in service configuration according to local provision).

OBJECTIVE 4: Produce mixed method case studies integrating and triangulating findings from the above qualitative and quantitative components to produce recommendations for:

a) maximising outreach and mental health screening uptake;

b) maximising psychosocial support access and uptake following screening;

c) resolving systemic and organisational barriers to accessing onward support;

d) specific recommendations for points *a-c* for different key worker groups, for example, different occupational and professional groups, and BAME groups.

4. Study design

The project will use a multi-case mixed-methods case study design, where the cases are the three Resilience Hubs considered in this project. The project will comprise: 1) the analysis of mental health data routinely collected at Hub screening, exploratory health economic evaluation using routinely collected data, as well as service use and health status data from key workers who completed screening at 3 Resilience Hubs; 3) qualitative interviews with Hub providers (e.g. therapists; recovery workers; service managers; commissioners) as well as key workers who either accessed Hub support or did not register with the Hubs; 4) integration of the above through cross-case comparison, pattern-matching, explanation-building and logic modelling.

5. Setting

The research will consider three Resilience Hubs which support key workers from the NHS, social care services and 'blue light' services in their respective regions. The Resilience Hubs' offer is open to staff (including those regarded as having 'non-professionals' or non-clinical roles e.g. porters, receptionists) from NHS organisations, social care providers and 'blue light' services in their respective regions. These include acute non-specialist NHS Trusts, acute specialist NHS Trusts, mental health NHS Trusts, NHS community care providers, GP practices, social care providers (in particular nursing and care homes), fire services, ambulance services and police services. Nursing students, agency and locum staff are also eligible for Hub support.

6. Outline of the Resilience Hub model

Although local variation is expected in the exact configuration of each Hub, the model underpinning the above Hubs is delivered by a multidisciplinary team (e.g. mental health nurses; psychologists) comprising senior clinicians (Band 6 and above) and degree-level recovery workers (Bands 4-5), typically seconded from local NHS mental health Trusts. The model operates on two primary offers: *Outreach & Screening* and subsequent *Triaging & Support Navigation*:

Outreach & Screening: A proactive outreach approach is taken to offer mental health screening to key workers (e.g. via liaison with the HR and Comms department of NHS, social care and emergency response organisations in the region). A battery of self-report measures (completed online by individual key workers or over the phone with Resilience Hub staff) is used to facilitate screening and triage via the collection of demographic and work environment information (age; gender; ethnicity; sexual orientation; faith; job role; organisation; work environment) alongside standardised mental health questionnaires with robust clinical cut-off points that aid subsequent triage. These include screening tools for depression, anxiety, PTSD, impaired functioning, and alcohol abuse.

Triaging & Support Navigation: Following screening, the required level of support is identified using a scoring algorithm considering the clinical cut-offs of the above screening tools, which categorises key workers according to three potential levels of

support need (a ‘green’ category, which corresponds to mild difficulties across all clinical screening tools; an ‘amber’ category, assigned to key workers who meet cut-off scores for moderate difficulties in at least one of the clinical screening tools; a ‘red’ category, assigned to key workers who meet cut-off scores for severe difficulties in at least one of the clinical screening tools) . A stepped-care approach (universal support, targeted and specialist support) guided by the screening results is utilised. To account for potential issues around under-reporting of difficulties in professionals accessing the Hub and/or difficulties that might not fall within the domains assessed by the initial screening battery, this stepped-care approach is not fully determined by the level of support need identified at screening, but takes into account clinical judgement by Hub practitioners (e.g. based on additional information provided at screening or additional information provided by key workers during follow-up email correspondence or telephone conversations with Hub staff). This allows for a flexible response to meet the differing needs of groups and individuals, and adapt personal treatment pathways accordingly. Usually, all those who complete the online screening receive ‘universal support’ in the form of psychoeducation information and the Hub’s contact details if further support is needed. Those with mild difficulties (i.e. ‘green’ cases) who have self-referred to one of the Hubs receive information via phone or email around the normalisation of mild distress; this includes information on strategies that the person could implement to prevent escalation of need over time, such as the use of personal resources for the promotion of resilience as well as symptom management strategies that the person can use without additional specialist professional input. In addition to the above, those with mild-to-moderate (i.e. ‘amber’ cases) distress also receive self-referral information for low intensity interventions (e.g. via IAPT services). Hub clinical staff attempt to contact all individuals reporting moderate and severe mental distress (‘amber’ and ‘red’ cases), offering phone/email support, tailored psychoeducation and signposting to the most appropriate specialist service. Where clinically appropriate, the Hubs facilitate key workers’ referral to local services to access evidence-based psychological interventions. This 'support navigator' role involves liaison with services to ensure that clients receive timely and appropriate support, including negotiation of waiting times, suitability, and interventions offered. Hub staff continues to monitor and support clients (e.g. via ‘touch base’ phone calls) throughout the waitlist period, until appropriate support is accessed.

7. OBJECTIVE 1: Quantitative analyses of mental health screening and service use relevant to the Hubs’ Outreach & Screening and Triaging & Support Navigation offers

To achieve Objective 1, we will analyse demographic, occupational, and mental health screening data collected as part of routine practice at the three Hubs considered in the proposed project, alongside additional service use data we will collect as part of this project.

7.1 Sampling

Inclusion criteria

1. Over 18 years of age
2. Completed the mental health screening of one of the Resilience Hubs
3. Has given consent for screening data to be used for research purposes
4. Has given consent to be contacted for research purposes (applicable to participants contributing to analyses focusing on service use data only)

Exclusion criteria

1. Under 18 years of age
2. Has not given consent for screening data to be used for research purposes

7.2 Procedures

Routinely collected data:

Although a level of local variation in the exact information collected as part of the initial screening with the Hubs is expected, the three Hubs plan to routinely collect data on the following domains:

1) Mental health and functioning data:

- *Symptoms of depression*, e.g. using the Patient Health Questionnaire 9 (PHQ-9), a widely used measure of depression, commonly used in NHS mental health services, including IAPT;
- *Symptoms of anxiety,* e.g. using the Generalized Anxiety Disorder 7 (GAD-7), an anxiety questionnaire commonly used in NHS mental health services, including IAPT;
- *Symptoms of post-traumatic stress*, e.g. using widely employed measures such as the PTSD Checklist for the DSM-5 (PCL-5) or the International Trauma Questionnaire (ITQ);
- *Social and occupational functioning* e.g. using the Work and Social Adjustment Scale (WSAS), a brief measure of impaired functioning across multiple day-to-day tasks/domains;
- *Problematic alcohol use*, e.g. using the Alcohol Use Disorders Identification Test (AUDIT).

2) Demographic data:

- *Age;*

- *Ethnicity;*
- *Religion;*
- *Sexual orientation.*

3) Occupational and work environment characteristics:

- *Work setting and role*, i.e. whether the person works in a hospital setting (ICU/Critical care, Nightingale, A&E, Other Ward/Service, Across Hospital Site) or other setting (Primary care including GP Practices, Education, Emergency Services, Residential Care, Community Care, Local Authority, Voluntary/Charitable Sector, Other), and in what role (clinical or non-clinical role);
- *Usual employment status*, i.e. whether the person is Employed full time, Employer part-time, Bank/Agency worker, Self-employed, In Education, Not working or has other employment status;

4) Home environment and impact of COVID-19

- *Current home arrangements,* i.e. whether the person is living in a single occupant household, living with a partner, living with dependable children, living with elderly or disables relatives, living in a shared house/flat and/or away from home due to Covid-19;
- *Pre-pandemic mental health concerns,* i.e. whether the person was concerned about their emotional wellbeing / mental health before COVID-19;
- *Impact of COVID-19,* i.e. whether the person has been impacted by COVID-19 in any of the following ways: 1) seconded to a different post; 2) moved to work in a different location; 3) undertaking new tasks within usual role; 4) been ill with confirmed COVID-19 (recovered at home); 5) been ill with confirmed COVID-19 (including being in hospital); 6) family member been ill with confirmed COVID-19 (recovered at home); 7) family member been ill with confirmed COVID-19 (included being in hospital); 8) experienced family/close friend bereavement from COVID-19; 9) suffered financial loss within the household

In addition to the above information (collected either using online screening platforms or during initial phone screening assessment with Hub staff), all individuals screened by the Hubs are routinely asked by the service to provide consent for their anonymised data to be used for research purposes, and whether they would like to be contacted regarding opportunities to take part in further follow-up research.

The above data domains for all key workers at each Hub who consented for their data to be used for research purposes upon screening will be extracted from the Hubs' electronic patient records systems (PCMIS or IAPTUS). The data will be cleaned and anonymised by research assistants (RAs) based at each Hub, and subsequently the anonymised data will be entered onto a project-specific electronic database managed by GMMH and University of Manchester (UoM) researchers (Varese and Allsopp) using REDCap software (a secure web application for building and managing online surveys and databases, commonly used for database management activities by many UK Higher Education Institutions and Clinical Trials Unit). Access to the database will be restricted to members of the project team involved in data analysis, using an in-built secure system to grant access and data management privileges that can be authorised only by the project manager (Allsopp) and/or the CI (Varese). The Hub-specific data entered in REDCap will undergo quality checking and (if necessary) further re-coding/cleaning at UoM. These data management activities will be undertaken by an RA within the UoM Biostatistics Collaboration Unit, under the supervision of the project statistician (Carter).

Follow-up service use and health status survey

Key workers who completed Hub screening will be invited to complete a follow-up battery of measures. Participants at each Hub will be invited to complete these measures after the Hub in their region has been operational for a minimum of 6-8 months. The timing of these invitations may be amended according to the progression of the pandemic and the process of setup of individual Hubs, in order to maximise participation and uptake. These measures will include:

- *The EQ-5D-5L* [18], a brief measure of general health status commonly used in health economic evaluations,

- *A Service Use Questionnaire* adapted from our previous health economic research [19]. The questionnaire will collect information on: 1) what level of support participants have received directly from the Resilience Hub with which they are registered (e.g. screening; phone support; team consultation; referral for psychological intervention); 2) data on which mental health or psychosocial support services (if any) key workers have accessed (or are currently on waiting-list for); 3) wider data on physical health service use (including inpatient stays, outpatient visits, A&E visits, primary and social care use), and 4) for each of the above, whether key workers accessed these services as a result of Hub support.

The administration of the above measures will be via a bespoke research survey conducted by the project team. All key workers who, upon completing the initial Hub screening, consented to be contacted regarding opportunities to take part in further research will be sent an email invitation to complete the measures online, and up to four reminders, until they decline involvement or complete the survey. To minimise the impact of digital inequality, consenting key workers who reported not having reliable access to an email at Hub screening, or completed the Hub screening

measures over the phone with support of Hub staff will be contacted by their respective Hub's Research Assistant using an alternative contact method (e.g. mobile phone) and given the opportunity to complete survey using alternative means (e.g. receive a link to the survey via text if they have access to a smartphone; complete the measures over the phone with support of the Hub RA, who will be able to directly enter the data on the REDCap database on the participant's behalf).

Researchers based at the UoM Biostatistics Collaboration Unit and in the Manchester Centre for Health Economics will conduct data quality checks and (if necessary) resolve any data queries (e.g. around missing data) with RAs based within the Hubs. These data will then be merged with the routinely collected data above, in preparation for statistical analysis.

7.3 Statistical analysis:

Based on data from the support provided by the Greater Manchester Hub in the aftermath of the Arena attack, approx. 5-10% of in scope professionals are expected to complete Hub screening

Descriptive analyses of the screening data collected by the Hubs in their respective initial 6 months of operation will be used to estimate parameters relevant to the modelling of future service need (potential vs. actual coverage of Hub offers and Hub utilisation at each site [20]), including: 1) the uptake of the Hub's screening offer, via the proportion of key workers who were actively approached by the Hubs who went on to complete the screening assessments; and 2) the proportion of those completing screening who fall into different levels of potential support need ('green', 'amber' and 'red' cases), as determined by the standard scoring algorithms for the Hubs' clinical screening tools. The service use data will be used to estimate what proportion of key workers 3) had direct contact with the Hubs following screening; 4) accessed support services following screening (and which services were accessed); and 5) accessed these support services as a direct consequence of the Hubs' support.

The relationships between key demographic and professional groups (e.g. BAME groups) and the above outcomes will be investigated, controlling for confounders such as age and gender, where appropriate. All analyses will be stratified by Hub site. Furthermore, for each Hub, a series of regression models will be used to identify demographic and work environment characteristics associated with 1) mental health support needs amongst Hub users at initial screening (i.e. focusing on categorical and domain-specific 'caseness' outcome variables defined using standardised threshold for clinical significance of specific clinical assessment tools, as well as analyses focusing on continuous symptoms severity scores, where possible) , and 2) levels of support up-take following screening (i.e. categorically defined outcome variables accessed or did not access mental health support as a result of Hub support) .

Analyses will be pre-specified in a statistical analysis plan which will detail the particulars for analysis models and assumptions, and describe methods for handling missing data. These quantitative analyses will provide initial evidence of successful (or unsuccessful) provision of support and facilitation of access to services for Hub users, which will be contextualised further in the subsequent qualitative work.

7.3.1 Integration of additional data

Forty Resilience Hubs are being set up around the UK [34]. To maximise learning, should additional Resilience Hubs deploy a similar screening model to the three main study sites involved in the research, and ask relevant questions at registration around consent for use of anonymised data and research contact, we will explore the possibility of incorporating routinely collected quantitative mental health screening and/or service use data from these other Hubs.

8. OBJECTIVE 2: Health economic analysis of service use and health economic data relevant to the Hubs' Outreach & Screening and Triaging & Support Navigation offers:

The health economic analysis will explore the cost and health benefits associated with the set-up, use and management of Resilience Hubs, to understand whether they represent a potentially cost-effective use of resources.

8.1 Sampling

See Section 7.1, above.

8.2 Procedures

The economic evaluation will use the screening measures, health status and service use data described above (Section 7, Objective 2).

The Hub intervention will be costed from a review of each of the Hubs' business cases. Recognising that Hubs will develop and adjust over time, consultation meetings will be held with the Hub multidisciplinary teams and business leads to identify how the hub has evolved from the business case and how any changes may influence the costs of implementing, managing, and maintaining the Hubs services. This will cover the costs of healthcare, management/leadership, and administrative staff, overheads, promotion/advertisement and other costs (e.g. equipment and training).

The economic evaluation will also use the data from the qualitative interview with key workers (Section 9, Objective 3 below) to help identify what service use might have occurred without the Hubs (to act as a control arm). This will be supplemented

by expert opinion from the wider research team to define model scenarios and parameters.

Targeted literature reviews will be used to supplement the service use data collected, to inform the structure of an economic modulate and populate the model with data.

8.3 Economic Evaluation

Service use data will be costed using published standard national unit costs (e.g. national reference costs published by the Department of Health; Personal Social Services Research Unit Costs of Health and Social Care) will be used to estimate the total costs of health and social care services used by participants [21, 22].

The EQ-5D-5L will be collected at follow-up and converted to utility values using the published utility tariffs and methods recommended by NICE at the time of analysis. The generated utility weights will be compared to population norms to assess how the utility of people accessing Hub support compares to the norms for their age group.

The fixed and variable costs of implementing and providing the Hub intervention will be estimated by Hub design and whether Hubs are set-up as new services or repurposed from existing provision, at the actual levels observed in the study and the potential population level. The marginal cost per healthcare worker accessing Hub support will be estimated.

Tied to objective 1, the utility weighted health status measure and service use/total health and social care costs will be summarised (mean, standard deviation, 95% confidence interval) for the full sample and for different key worker groups, for example, different occupational and professional groups, and BAME groups. If there is sufficient data, statistical regression models will be used to assess differences in costs and health utility across groups.

If there are sufficient data, an economic decision model will be used to estimate the net cost and health benefits associated with the use of the Resilience Hubs, and whether they are a potentially cost-effective approach, from the perspective of NHS and social care. The model care pathways will be identified from targeted literature reviews and iterative, structured discussion with the wider team (which includes clinical advisors). The draft model structure will also be presented to the external Health Economics Adviser (part of the Steering Committee) and the PPIE group to assess its face validity and check it captures key events and outcomes. Model scenarios and parameters for the Hub intervention and hypothetical comparator (no Hub) will be generated from the data described in Sections 7, 8.2 and 9.

Cost effectiveness acceptability analysis will estimate the probability the intervention is cost-effective and the net benefit statistic. This will use a range of

cost per QALY willingness to pay thresholds (WTPT) to reflect uncertainty about the amount decision makers are potentially willing to pay to gain one unit of health benefit [23]. Threshold analysis will be used to explore how the incremental cost effectiveness ratio (ICER) changes with changes in the potential effectiveness of the Hub intervention. Sensitivity analysis will explore how sensitive the model results are to changes in the Hub design (e.g. by site) and subsequent intervention costs. Subgroups (e.g. by key worker group) may be explored in the economic evaluation if ethically acceptable and with sufficient data to inform these. These exploratory analyses, along with the detailed costs associated with implementation of the Hub intervention will help provide a baseline for further analysis and the design of research going forwards.

The economic evaluation will be reported using the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) [24].

9. OBJECTIVE 3: Semi-structured interviews with key workers and Hub providers

This qualitative interview study will identify the barriers and enablers to the repurposing of the Resilience Hub model to respond to the COVID-19 pandemic and its implementation across three UK regions.

9.1 Theoretical frameworks

Key workers: Interviews with key workers will be based on Sekhon's service acceptability framework [25], a multi-component framework that will be applied to examine the extent to which Hub clients consider the Hub model to be effective, based on their experience and perceptions of the support they have received. Sekhon's theoretical framework of acceptability consists of seven constructs: attitude towards the intervention, burden (e.g. reasons for dropout/ discontinuation/ non-engagement), perceived effectiveness, ethicality (extent to which the model fits with participants' value system), intervention coherence (extent to which the participants understands the Hub model and how it works), opportunity costs (extent to which benefits or values must be given up to the engage with the Hub), and self-efficacy (participants' confidence that they can do what is required in order to engage with the Hub offer). Additional questions will be drawn from two theoretical frameworks relating to behaviour change, the Theoretical Domains Framework [35] and the Behaviour Change Wheel [36]. These frameworks provide a method for theoretically assessing implementation problems within a health context, addressing constructs such as: beliefs about consequences; social influences; social/professional role and identity; capability; motivation; and opportunity. Both frameworks have been used to understand barriers and facilitators of uptake of health-related interventions [e.g. 37].

Hub providers: Interviews with Hub providers will be based on Normalization Process Theory (NPT), a widely used theory to explain the processes by which an intervention becomes, or fails to become, embedded into routine practice; NPT offers a framework for assessing the conditions under which interventions become practically workable in healthcare [26, 27]. NPT comprises four constructs (coherence, cognitive participation, collective action, reflexive monitoring), which we will use to explore Hub providers' perceptions, expectations, attitudes, challenges and unintended consequences of using the Resilience Hub model.

9.2 Sampling

Each of the following groups of participants will be purposively sampled for maximum variation from each Hub/Hub region, with consideration of a range of key characteristics (e.g. professional background, age and ethnicity etc.). The recruitment targets below should be sufficient given our focused aims, use of established theoretical frameworks and sample specificity [28].

Key workers who completed Hub screening:

Inclusion criteria

1. Over 18 years of age
2. Completed the mental health screening of one of the Resilience Hubs
3. Has given consent for screening data to be used for research purposes
4. Has given consent to be contacted for research purposes

Exclusion criteria

1. Under 18 years of age
2. Has not given consent for screening data to be used for research purposes

All key workers who completed Hub screening and who upon screening gave consent to be approached for research purposes will be eligible. Hub clients (6 to 8 per site; N=18-24 in total) who have given consent to be contacted for further research follow-up will be approached by email or by telephone if email is unavailable. Hub clients will be sampled according to demographic and occupational groups (e.g. ethnicity; gender; professional/non-professional groups), and severity of mental health symptoms and risk indicators identified from the quantitative data as well as on other relevant characteristics that might influence offer uptake and service access.

Key workers who did not complete Hub screening or otherwise engage with a Resilience Hub:

Inclusion criteria

1. Over 18 years of age
2. Within scope of the Resilience Hub client group in their region
3. Has sought mental health or wellbeing support since the start of the COVID-19 pandemic

Exclusion criteria

1. Under 18 years of age
2. Unwilling to give consent to take part

In order to provide a dissonant view, interviews will also be conducted with key workers who did not register with the Hubs, despite being eligible (4 to 6 per site region; N=12-18 in total). These participants may be identified through i) emails to key workers via organisations through which the Hub advertised their screening offer; ii) emails to participants in the relevant Hub regions who took part in a study led by members of the research team (The COVID-19 Resilience Project, IRAS ID 282827), who gave consent to be contacted about other research opportunities; iii) emails to key workers who completed Hub screening but did not self-refer to a Hub; iv) social media. Groups who appear to be underrepresented in the Hubs' client groups will be specifically targeted for recruitment to understand why they may be underrepresented.

Hub providers / wider stakeholders:

Inclusion criteria

1. Over 18 years of age
2. Has been directly employed by one of the 3 Resilience Hubs in the study, or has been a wider stakeholder involved in work relating to the setup of the Resilience Hubs or staff wellbeing initiatives in the region of one of the 3 Resilience Hub sites.

Exclusion criteria

1. Under 18 years of age
2. Unwilling to give consent to take part

Hub providers (6-8 Hub providers per region, N=18-24 in total) will be sampled according to different aspects of the Hubs' commissioning, setup and delivery of clinical offers, e.g. service managers, clinical team managers and wider professional stakeholders. Wider stakeholders may include, for example, commissioners, representatives from partner organisations and provider Trusts, HR directors or organisation wellbeing/occupational health leads.

9.3 Procedures

We will conduct semi-structured interviews according to the draft topic guides included with the NHS ethics/HRA application. These topic guides are based on the above theoretical frameworks. They will be open documents, updated according to preliminary findings of the previous objectives described above, and in light of new published literature in this area. Topic guides will also be shaped by feedback from our PPI group and activities. Interviews will be conducted by telephone or video call (e.g. Microsoft Teams). Where participants are unable to participate in digital interviews, it may be possible to arrange a small number of face-to-face interviews (to maximise accessibility to certain key worker groups, as highlighted by our PPI consultations). Interviews may take up to 90 minutes; they will be recorded using encrypted dictaphones and transcribed verbatim.

Key workers who completed Hub screening:

Semi-structured interviews will explore in-depth the acceptability, enablers, and barriers of the Hub's outreach approach (e.g. whether the Hub made direct contact with individual vs. information sent out by the participant's employer); the acceptability of the screening medium and questionnaires (e.g. whether the measures were fit for purpose and addressed relevant support needs); and reasons for engaging. The interviews will also explore i) the barriers and facilitators on the pathway from outreach to mental health access via the Hub's support navigator offer and ii) whether Hub clients were considering or would have considered accessing other services in the absence of the Hub, what these may have been (e.g. self-referral to IAPT services) and when they would have done this (e.g. if symptoms worsened). This will help to consider how key workers' service use and health may have varied had the Hub intervention not been available (information that will be used to populate hypothetical control scenarios for the health economic analyses).

Key workers who did not complete Hub screening or otherwise engage with a Resilience Hub:

Semi-structured interviews will explore whether participants had heard of the Resilience Hub in their region, and if so, reasons for choosing not to engage with the service. Participants will be asked about whether they received any support from other services (e.g. GP, other NHS support services or non-NHS services), and the types of difficulties for which they were seeking support. Participants will be asked to complete a version of the service use questionnaire used in Objectives 1 and 2 data collection activities, but modified to be avoid explicit reference to the Hubs' role/involvement in the processes of accessing services (as this would not be applicable to these key workers). The responses to the questionnaire will be used to elicit further qualitative information on how participants negotiated access to these services, whether they met their needs, and whether they considered them to be helpful.

Hub providers / wider stakeholders:

Semi-structured interviews will explore Hub clinicians' perceptions and experiences of working at the Hubs, the feasibility and appropriateness of the model for supporting key workers, and how the Hub model has come to be embedded into normal practice. Interviews will explore clinicians' perceptions of the enablers and barriers to outreach, supporting key workers, and helping them to access onward care via the support navigator model. Contextual factors and implementation aspects will also be explored, including clinicians' experiences of the setup and structure of the Hubs, such as staffing (e.g. recruitment and retention; skill mix) and integration with other services.

9.4 Qualitative analysis

The National Centre for Social Research 'Framework' analysis approach [29] will be used to analyse the interview data. Members of the research team will independently code a sample of the transcripts, before conferring with each other and the PPI panel to confirm the working coding tree. Themes of a priori interest relate to Normalization Process Theory and acceptability framework constructs. Additional themes of importance will be derived inductively. Analysis will take place in the latest version of NVivo. For Hub client interviews we will use cross-case comparison and joint displays [30] to explore convergence between quantitative screening data (demographics and clinical questionnaires information) with qualitative constructs.

10. OBJECTIVE 4: Produce mixed method case studies integrating and triangulating findings from the above qualitative and quantitative components

To integrate data from the different work packages and increase confidence in the study's findings, we will conduct multi-site mixed methods case studies (30) with the site as the level of analysis. The case studies will distil how it is possible to implement the model . There will be four embedded units of analysis: (1) framework analyses of client interviews within the acceptability framework; (2) framework analyses of Hub worker interviews within Normalization Process Theory; (3) routine quantitative data, and (4) Cost data summarised by Objective 2 (health economics). For key workers who have completed screening, the quantitative data will include: demographics (including ethnicity), professional category, depression, anxiety, trauma, functioning, alcohol use. For hub workers the quantitative data will include hub-level descriptive statistics related to: Hub worker professional background, potential vs actual Hub coverage, Hub caseload and case-mix. Hub-level, within-case analyses, will be used to merge and triangulate data from the four embedded units of analysis to identify barriers to repurposing and implementing/scaling up Resilience Hubs. Initially, triangulation will take place within the constructs of NPT

(against summary statistics derived from Objective 1, and cost data derived from Objective 2) and Sekhon's service acceptability framework (against quantitative outcome data at the individual level). Cross-case analysis will allow us to identify similarities and differences among the three cases as we merge the data to find convergent and divergent findings. We will use cross-case comparison joint displays [30] to look for convergence between routine data with experiences, views and values. Case descriptions will be developed using pattern-matching against the claims of Normalisation Process Theory, explanation-building and logic modelling [31–33]. This approach will help us to understand the complexity behind, while permitting theoretical generalisation about, the acceptability, enablers, and barriers of the use of the Resilience Hub model for supporting key workers and helping them to access onward care, alongside causal mechanisms and contextual factors associated with variations in observed quantitative screening and service use data.

We will invite feedback from interviewees via telephone / video call on a lay summary of triangulated results (member checking). The final report will highlight the interpretations of our PPI panel, and the Project Management Group. This will inform recommendations on the tailoring of future Hub provision.

11. Project management

Overall responsibility and project management will be with the CI (Varese), with support from the project co-Lead (French) and project manager (Allsopp). KA will be responsible for the day-to-day running of the project under the supervision of the CI. Specific team members will lead the methodological components of the project and the supervision of specialised research support staff (e.g. part-time post-doctoral research associates) contributing to the delivery of these components: Carter will lead the statistical analyses of Hubs screening data; Shields will lead the health economic analyses, with senior oversight by Davies; Hind will lead the qualitative analyses and delivery of the final mixed-method case studies, with support from Allsopp. The CI and project manager will hold ***weekly supervision meetings with all RAs*** (via Microsoft Teams) focusing on data management and processing; recruitment; adherence to research procedures and sharing best practice. Fortnightly RA line management/supervision meetings by local Hub leads (including Barrett, Greater Manchester; and Bhutani, L&SC) will supplement the above arrangements and aid local problem solving. There will be ***monthly digitally-mediated Project Management Group (PMG) meetings***, chaired by the CI and attended by all Co-Is; these will focus on operational management and governance; monitoring progress towards planned milestones and outputs; identifying risks to achieving milestones, plus solutions to ensuring the project will be delivered in the timeframe and within budget. Independent oversight will be provided by a ***Project Steering Committee (PSC);*** the PSC will be established at the outset of the project following NIHR Research Governance guidelines pertaining to PSC membership, and will be conveyed at least three times over the project's lifetime. The project will also be guided by ongoing consultations with key workers who would be eligible for Hub

support, via bi-monthly meetings of a ***PPI Advisory Group*** **and additional PPI engagement activities, supported and overseen by our PPIE Lead (KM)**

12. Ethical and regulatory considerations

All components of the research involving data collection from research participants will commence following satisfactory NHS Ethics and HRA approval, as well as local Capacity and Capability approval from NHS Trusts hosting the Resilience Hubs considered in this research.

12.1 Assessment and management of risk

All digital and face-to-face contact with research participants will be conducted following bespoke SOPs to manage any risk uncovered as part of the planned research assessments. Furthermore, any adverse event observed over the course of the research will be documented and reported according to bespoke SOPs that will fully comply with appropriate HRA safety reporting procedures for non-CTIMP studies, Sponsor's requirements and local R&D policies of participating NHS organisations.

All participants taking part in either the follow-up survey and/or a qualitative interview will be provided with debriefing information that will include the contact details of relevant local support services that participants could access in the event of a crisis, national support helplines and an invitation to contact the Resilience Hubs should they require additional mental health support. This debriefing document will be updated in collaboration with site leads at each Resilience Hub, to ensure that information and resources are as up to date as possible throughout the study.

No direct contact with participants is expected for research activities conducted as part of Objectives 1 and 2, so the chances of uncovering significant risks not disclosed as part of the routine screening procedures employed at the participating Resilience Hubs is minimal. The measures included in the follow-up service use and health economic survey do not enable the direct assessment of significant risks to self and/or others (e.g. suicidality), but only of general health status for health economic analytic purposes.

Interviewers contributing to Objective 3 research activities will be sensitive to participants' emotional state and will offer to truncate the interview and signpost to study-specific support from trained personnel at the appropriate Resilience Hub if distress is evident, or should participants report any significant risk. This would be followed up with the Hub locally if this issue should arise. Specific arrangements will be agreed at the study initiation visit with each Hub and cases overseen in regular meetings with site leads.

The interviewers will receive weekly supervision from a senior researcher with extensive expertise in qualitative inquiry with distressed individuals (Allsopp) as well

as access to Hub-specific supervision via their respective Hub Leads, who are clinically qualified NHS professionals and will be able to advise on specific local support provision and safeguarding systems, where appropriate. All interviews will take place at pre-specified times agreed by the project manager (Allsopp), and according to a 'clinical cover rota' that will guarantee that RAs have prompt access to clinically qualified members of the research team for initial risk management advice (Varese, French, the Hub Leads and/or suitable Hub clinicians with delegated responsibility).

Due to the ongoing COVID-19 pandemic, it is expected that most qualitative interviews will be conducted using remote means (e.g. telephone or digital platforms/software approved by the participating NHS organisations, e.g. MS Teams). Risks to the physical safety of the investigator are therefore minimal. Any necessary face-to-face interviews will be conducted in full compliance with the lone working policies of the participating NHS organisations where the RAs will be based, which will include locally adapted safety checking for lone workers SOPs implemented by local Hub services and/or NHS R&D departments. Furthermore, any face-to-face contact will be in full-compliance with all relevant COVID-19 risk mitigation policies and procedures of participating NHS organisations, and will only be conducted following approval by the CI, co-CI and/or project manager following the completion of any recommended local COVID-19 risk assessment.

12.2 Research Ethics Committee (REC) and other Regulatory review & reports

This research project, including the study protocol and all associated study documents, has been reviewed and given a favourable opinion by North West - Preston Research Ethics Committee (ref 20/NW/0462) and the NHS Health Research Authority.

12.2.1 Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body (REC, HRA, Sponsor and participating sites) in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

All correspondence with the REC and HRA will be saved in the Study Master File. The CI or designee will be responsible for the submission of annual reports and safety reports to the REC, the final REC project report / end of study notification and the prompt notification of the premature interruption of the study, should this be warranted.

12.2.2 Amendments

Amendments will be discussed with the research team at the study's Project Management Meeting (which meets monthly). Relevant members of the research team will then prepare updated study documents accordingly, and an HRA amendment tool document will be completed. These documents will then be reviewed and ratified by the Chair of the Project Steering Committee. The proposal of substantial amendments that will significantly impact the scientific value of the study will be also discussed with the project's funder (the NIHR) ahead to submission to Sponsor and regulatory bodies.

A member of the research team will submit updated study documents and the amendment tool to the study sponsor (GMMH), who will review and authorise the documents and lock the amendment tool for submission. The final decision regarding whether the amendment is substantial or non-substantial will be made in collaboration between the study CI or project manager and the Sponsor. The amendment will then be submitted to the HRA (and REC, when applicable) via the IRAS system, and once approved all relevant documents will be emailed to study sites by a member of the research team.

Amendment history, updated and superseded versions of study documents will be saved in the Study Master File.

12.2.3 Peer review

The study has been peer reviewed as part of the NIHR funding applications process for the Cross Programme COVID-19 Recovery and Learning funding call.

12.2.4 Patient and Public Involvement and Engagement (PPIE)

In developing this project, we consulted frontline staff and Hub clinicians from two Hubs about our proposed research and PPIE strategy. Embedded involvement of PPIE advisors from a wide range of occupational backgrounds will be essential throughout this research, and our PPIE strategy will ensure that our onward consultations are representative of the populations served by the Hubs.

To enable continued access to PPIE expertise throughout the lifetime of the project, we will assemble a core PPIE advisory group, chaired by our PPIE Lead (McGuirk) and meeting every 2 months (10 meetings over the course of the project, with approx. 6-8 attending members per meeting). The core group will represent different occupational groups (e.g. care staff; medics; nursing etc.) and demographic groups (e.g. BAME; men).

Input from our PPIE group will be crucial for the following co-production activities:

1) Ongoing fine-tuning of participant-facing materials, building on general templates approved by the REC, to enable the rapid adjustment of our recruitment material and therefore improving our ability to reach potentially underrepresented groups;

2) Piloting and fine-tuning of the format and content of the service use questionnaires approved by the REC used in research activities to meet Objectives 1, 2 and 3. PPIE expertise will be used to ensure that the final deployed measures will be as burdenless as possible and will be able to capture the varied sources of support that our diverse participant groups might access over the course of the study;

3) Adjustments to our recruitment and comms strategies, to improve our ability to reach under-represented groups;

4) Ongoing development and refinement of the qualitative interview topic guides, to better reflect the views and perspectives of all relevant stakeholders;

4) Interpretation of findings, with a particular emphasis on qualitative data that might guide further revisions of our topic guides and study materials.

Members of the PPIE advisory groups will also advise on additional targeted consultations and community engagement activities that may be needed to gather wide-reaching feedback from other under-represented groups.

12.2.5 Protocol compliance

Thorough training of all research workers at the study onset and subsequent weekly supervision of all RAs throughout their involvement in the study will minimise risk of deviations from protocol. However, accidental deviations from protocol can happen at any time; these will be documented and recorded in a protocol deviations log, which will be saved in the Study Master File. All deviations from protocol will be brought to the attention of the project CI and co-CI, and promptly communicated to the study Sponsor (GMMH), so that corrective actions could be promptly implemented. The protocol deviations log will also be reviewed at regular meetings with the PSC for additional scrutiny and suggestions of corrective actions.

12.2.6 Data protection and patient confidentiality

The processing of all personal and research data will be in full compliance with the Data Protection Act 2018 and the European Union's General Data Protection Regulation (GDPR). Any personal information will be retained up to three months following the completion of the study, and will be then deleted and/or safely destroyed e.g. through confidential waste management services available at our HEIs and NHS organisation. All research data will be kept in anonymised format and retained for a minimum of 5 years following the end of the study. All final locked datasets will be kept in encrypted files on robust and automatically backed up UoM and GMMH servers. The project's CI (Varese) will act as data custodian.

The processing of personal data and clinical data collected at Hub registration will only take place when participants provide consent to this. Upon mental health screening with each Resilience Hub, key workers are routinely invited by the service to give their consent to a) use of their mental health screening data for research purposes, and b) contact for follow-up research. Only data from participants that provided relevant consent will be considered in the planned analyses of routinely collected screening data. Similarly, only key workers who give the relevant consent will be invited to complete the follow-up service use and health economic survey and take part in a follow-up interview. Hub clinicians and health and social care key workers who did not engage with the Hub will be invited to take part in an interview on an opt-in basis, and informed consent for processing any relevant information collected from them will be sought.

Robust data security measures will be implemented throughout the study, in full compliance with national policies and relevant data management and information governance policies and procedures of the participating HEIs and NHS organisations. Following extraction from electronic patient health records, all mental health outcome data will be anonymised within each Resilience Hub using unique study IDs. Research data collected via follow-up questionnaire will not request identifiable information, and will be matched up with routinely collected data using the unique study IDs. Whenever possible, interviews will be conducted using recording devices enabling data encryption at the point of data collection, to provide additional data security. All interviews will be anonymised at the point of transcription, and all identifying details removed. Telephone consent (including participants' names) will be recorded on a separate audio file so that this information is not shared with the company transcribing the interview. Additional data security and confidentiality protection procedures relevant to specific component of the project are clarified below:

<u>Quantitative and health economic data:</u>

Hub-based Research Assistants will download aggregated data reports from the Hubs' electronic patient records systems in order to extract the routinely collected screening data. Personal identifying data will be stored securely on NHS servers in each Resilience Hub, and given a unique study ID. Research data will be identified

using this unique study ID. Personal identifying data and research data will be stored in separate locations using password-protected files.

Anonymised routinely collected data will be securely transferred from each Resilience Hub to the central research team at GMMH, using secure, encrypted methods, such as the nhs.net email system.

Participants completing follow-up questionnaires will complete the measures on a secure web-based database system, REDCap, hosted on University of Manchester servers. Access to the database will be restricted to members of the project team involved in data analysis, using an in-built secure system to grant access and data management privileges that can be authorised only by the project manager (Allsopp) and/or the CI (Varese).

Qualitative interview data

Interviews will be conducted by NHS members of the research team, and will be recorded using encrypted Dictaphones. Digitally encrypted audio recordings of the interviews (but not identifying consent data, see above) will be transferred to an external company for transcription. Anonymised transcripts will be returned to the central research team using digitally encrypted files.

Storage and destruction of data: Anonymised data will be kept for 5 years. Personal contact details will be destroyed after the end of the study. Information about data storage and destruction will be included on Participant Information Sheets.

12.2.7 Study End Date

The study end date is planned for 31st May 2022, which will include completion of all study activities, including data collection and analysis.

12.2.8 Archiving

At the end of the study, all study data, the Project Master File, and all site files will be forwarded for archiving with the study Sponsor (GMMH). Data will be retained for 5 years, in line with the Sponsor's current Standard Operating Procedures.

12.2.9 Indemnity

As the study is sponsored by an NHS organisation (GMMH), involving NHS sites, the NHS indemnity scheme will apply, covering potential legal liability of the sponsor/investigators for harm to participants arising from the: management; design; and conduct of the research.

As the study was designed in collaboration with researchers based at the University of Manchester, the university's Professional Indemnity policy will apply to potential legal liability for harms arising from the design of the research.

12.2.10 Access to the final study dataset

Future requests to access our data will be via the project's CI (Varese), co-CI (French) and project manager, and will be only approved on a case-by-case basis when sharing of data will not incur in any risk of participant identification, and only when secondary users will be from a bona fide research organisation and have been granted suitable regulatory approval to further interrogate our data. The exact procedures for accessing the final datasets, as well as relevant meta-data and statistical code used in all quantitative analyses, will be approved by the Project Steering Committee and made available to prospective future users upon request addressed to the CI, co-CI and/or project manager.

13. Dissemination

The study protocol will be publicly available on the NIHR Funding and Awards database. Foreground IP, including the anonymised datasets that will be produced as part of the study, will vest with the Sponsor. On completion of the study, a Final Study Report will be written up, submitted to the Funder and published in open-access format in the NIHR Journals Library following satisfactory review from the NIHR. The participating investigators will have the right to publish data collected as part of the study as a series of peer-reviewed publications, and use the study findings for educational, training and public awareness/dissemination purposes.

All publications and outputs arising from the project will comply with the NIHR's publication requirements, including advance output notifications to NIHR, standard NIHR funding statements and NIHR / disclaimers.

To ensure maximum benefit and timely impact on practice throughout and beyond the lifetime of the project, in addition to usual dissemination routes (national and international conferences; open-access publications in peer-reviewed journals; publication of the final report in the NIHR Library), we will employ a flexible strategy to disseminate emerging findings ahead of the project end date and as soon as outputs are available. This will involve: 1) creating a project website and using social media (e.g. Twitter) in collaboration with Comms divisions of our NHS and social care partners to increase the visibility of the project and emerging outputs; 2) delivering a series of free webinars on the progress and emerging findings of the project; 3) produce interim research briefings circulated to stakeholders with the support of the 'Resilience Hubs community of learning and practice' managed by NHS England; 4) With NIHR's permission, making all pre-print copies of our journal submissions available ahead of publication in suitable depositories (e.g. MedRxiv); 5) Holding an end-of-study digitally-mediated conference allowing dissemination to a broad stakeholder audience. All our study outputs will be accessible via our project website and the NIHR Funding and Awards database, and will be therefore accessible to all interested study participants and stakeholders.

13.1 Authorship eligibility guidelines and any intended use of professional writers

No professional writers will be involved in the production of the final project report and other peer-reviewed publications that will result from the research activities conducted as part of the project. Authorship of various project outputs will be informed by authorship criteria proposed by The International Committee of Medical Journal Editors or equivalent criteria endorsed by specific peer-reviewed journals where manuscripts will be submitted. Exact authorship decisions, including any time limits and review requirements by the broader investigators team, will be agreed by the project team during Project Management Meetings held over the course of the project.

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